

Guidelines for Cleaning and Preparing External- and Internal-Use Ultrasound Transducers Between Patients, Safe Handling, and Use of Ultrasound Coupling Gel

Summary

Adequate transducer preparation is mandatory. The level of preparation depends on the type of examination performed. Routine high-level disinfection (HLD) of internal transducers between patients is mandatory, plus the use of a high-quality single-use transducer cover during each examination is required to properly protect patients from infection. It would be reassuring for the user to be able to consult manufacturer's instructions, particularly those that have been validated by the manufacturer, for sterilizing devices. Barriers used for internal and interventional percutaneous procedures must be single-use transducer covers that meet the sterility requirements of the procedure. Preparation of external transducers between patients is less critical and reduced to a low-level disinfection (LLD) process. For all chemical disinfectants, precautions must be taken to protect workers and patients from the toxicity of the disinfectant.

The AIUM does not endorse or promote any specific commercial products. It is the responsibility of each entity to follow transducer manufacturer guidelines and applicable infection control recommendations.

Section I: New Literature and Other Relevant Guidelines

Kac et al¹ examined endocavitary transducers and found them persistently contaminated despite the use of transducer covers. They concluded that transducers may carry pathogens, including human papillomavirus (HPV), unless properly disinfected between examination sessions. For disinfection, they recommend an antiseptic-impregnated towel as well as a type C ultraviolet light.

Adhikari et al² compared infection rates between ultrasound-guided and traditionally placed peripheral intravenous lines. A nonsterile glove was used as a barrier between

the ultrasound transducer and the patient, and coupling was achieved using a bacteriostatic lubricant. Transducers were cleaned between patients using LLD. They concluded that both showed low infection rates (0.52% ultrasound, 0.78% traditional; $n = 402$ each; $P = .68$), and that there was no increased infection rate with ultrasound guidance. The Spaulding classification³ is inconsistent with the results of this study.

Casalegno et al⁴ stated that a considerable number of endocavitary transducers are infected with high-risk HPV despite LLD and recommend that endocavitary transducers should be high-level disinfected (2.5% of transducers showed high-risk HPV after use, 1.8% before use; $n = 198$).

Westerway et al⁵ examined 171 swabs of transabdominal and transvaginal transducers. Sixty percent and 14% of these were found to show evidence of bacterial contamination, respectively. After LLD, both showed approximately a 4% likelihood of contamination.

Westerway and Basseal⁶ also investigated if appropriate training was received and if cleaning procedures were followed. They found that 60% of respondents ($n = 188$ total) failed to receive adequate training before using any cleaning product. In addition, 33% had no access to written infection control policies for either transducers or ultrasound scanners (keyboard, connectors, cables, etc). Westerway and Basseal⁷ also investigated specifically the Australasian medical ultrasound practice. They found that only 10% of 392 users cleaned their keyboards after each patient. Fifty-six percent cleaned it once a day and 21% once per week.⁷ The machine cord was cleaned after each patient by 35% of all users ($n = 393$ total) and once a day by 32%. Fifteen percent cleaned it once a week. They naturally concluded that education and updated guidelines may remedy this situation.

In the same year, Sartoretti et al⁸ compared the bacterial load on ultrasound transducers ($n = 36$), bus poles ($n = 11$), and toilets ($n = 10$). Before training, 53 colony-forming units (CFU) were found in cultures from transducers, 0 afterward. Bus poles and toilets showed 28 CFU ($P = .772$) and 4 CFU ($P = .055$), respectively. Thus, training was a key point to improve healthcare-associated infections.

Gottlieb et al⁹ acknowledged that the use of ultrasound for intravenous line placement adds a potential source for infection. However, they concurrently highlighted studies concluding that ultrasound-guided peripheral intravenous line placement reduces the need for central venous catheter placement in up to 80% of patients.¹⁰⁻¹³

Abramowicz et al¹⁴ provided cleaning guidelines for transvaginal transducers on behalf of the World Federation for Ultrasound in Medicine and Biology Safety Committee. They listed several HLD methods. Of these methods, only chlorine dioxide and a vaporized hydrogen peroxide system have been reported to effectively remove HPV. However, the supporting evidence for the latter method was based on several studies paid for by grants from its manufacturer.

The Ultrasound Working Group of the European Society of Radiology released best practice recommendations for infection prevention and control in ultrasound.¹⁵ They stated that for ultrasound transducers with protective covers and in contact with mucous membranes or any body fluids (including interventional procedures, injections, tissue sampling, use in the theater, etc) require HLD.

Protective barriers such as medical gloves, etc, are regulated by an acceptable quality level (AQL). The AQL is the maximum percentage of defective items permitted in a regulated product. Hence, the AQL may also mean the acceptable quality limit. The Center for Devices and Radiological Health in the Office of Device Evaluation at the Food and Drug Administration (FDA) uses the AQL to define the acceptance level for medical gloves (21CFR800.20).¹⁶ Similarly, condoms, also mechanical protective barriers, are regulated by the AQL, and the World Health Organization (WHO) provides an AQL to set limits for their quality.¹⁷ Practitioners should be aware that condoms have a 10-fold stricter (lower value) AQL (0.25%, WHO) compared to standard examination gloves (2.5%, FDA). They even exceed the AQL of surgical gloves (1.5%, FDA). Users should be aware of latex sensitivity issues and have non-latex-containing barriers available. In addition, transducer covers with pore sizes of less than 30 nm are now available. They effectively block most viruses, including HPV of 50 nm.

Conclusions

The current literature points to the need for education on the proper use of transducer cleaning agents and procedures. It also points to the need of HLD for internal transducers (endocavitary) due to the risk of infection with HPV, for example. Contrary, external use, ie, on intact skin, does not show an increased infection risk in conjunction with LLD. Prudent use of ultrasound includes guidance for interventional percutaneous procedures. In this case, the use of sterile gel and single-use protective covers (level of sterility dictated by the procedure sterility classification) justifies subsequent LLD, analogous to institutional health care guidelines for the use of gloves and LLD hand disinfection for medical personnel.

Section II: Ultrasound Transducer Cleaning and Preparation

The purpose of the second section of this document is to provide guidance regarding the cleaning and preparation of ultrasound transducers. Some manufacturers use the term “probes” or “imaging arrays.”

Medical instruments fall into different categories with respect to their potential for pathogen transmission. The most critical instruments are those that are intended to penetrate skin or mucous membranes. These require sterilization. Less critical instruments (often called “semicritical” instruments) that simply come into contact with mucous membranes, such as fiber-optic endoscopes, require HLD rather than

sterilization. “Noncritical” devices come into contact with intact skin but not mucous membranes.

- **External transducers** that only come into contact with clean, intact skin are considered noncritical devices and require cleaning after every use as described below.
- **Interventional percutaneous procedure transducers** that are used for percutaneous needle or catheter placement, such as vascular access, thoracentesis, paracentesis, arthrocentesis, pericardiocentesis, lumbar puncture, ultrasound-guided regional/local anesthesia, and other percutaneous procedures, should be cleaned using low-level disinfectants and be used in conjunction with a single-use transducer cover. Such a cover must warrant protection against human viruses, including human immunodeficiency virus, HPV, hepatitis B, and others of clinical significance. The level of transducer cover sterility is dictated by the level of procedure sterility. As examples, clean procedures requiring nonsterile transducer covers include peripheral vascular intravenous line placement, whereas full sterility procedures requiring full sterile transducer covers include percutaneous biopsies. Transducer covers can be condoms or commercial transducer covers as long as they fulfill institutionally set infection control guidelines and procedure sterility requirements. If there is reason to believe that the transducer cover may have become compromised, the transducer must be high-level disinfected before the procedure.
- **Internal transducers** should be covered with a single-use transducer cover as described above, when feasible. If a transducer cover is used, the level of transducer cover sterility is dictated by the level of procedure sterility. These transducers are therefore classified as semicritical devices.

One should perform HLD of the internal transducer between each use and employ an adequate transducer cover as a protective barrier. *For the purpose of this document, “internal transducers” refers to all vaginal, rectal, and transesophageal transducers, as well as intraoperative transducers.*

Definitions

All cleaning, disinfection, and sterilization represent a statistical reduction in the number of microbes present on a surface rather than their complete elimination. Meticulous cleaning of the instrument is the key to an initial reduction of the microbial/organic load by at least 99%. This cleaning is followed by a disinfecting procedure to ensure a high degree of protection from infectious disease transmission, even if a disposable barrier covers the instrument during use.

According to the Centers for Disease Control and Prevention (CDC) Guideline for Disinfection and Sterilization in Healthcare Facilities¹⁸:

“*Cleaning* is the removal of visible soil (eg, organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products. Thorough cleaning is essential before high-level

disinfection and sterilization because inorganic and organic material that remains on the surfaces of instruments interfere with the effectiveness of these processes.”

“*Disinfection* describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores.”

Low-Level Disinfection—Destruction of most bacteria, some viruses, and some fungi. Low-level disinfection will not necessarily inactivate *Mycobacterium tuberculosis* or bacterial spores.

Mid-Level Disinfection—Inactivation of *M Tuberculosis*, bacteria, most viruses, most fungi, and some bacterial spores.

High-Level Disinfection—Destruction/removal of all microorganisms except bacterial spores.

“*Sterilization* describes a process that destroys or eliminates all forms of microbial life and is carried out in healthcare facilities by physical or chemical methods. Steam under pressure, dry heat, ethylene oxide (EtO) gas, hydrogen peroxide gas plasma, and liquid chemicals are the principal sterilizing agents used in health care facilities When chemicals are used to destroy all forms of microbiologic life, they can be called chemical sterilants. These same germicides used for shorter exposure periods also can be part of the disinfection process (ie, high-level disinfection).”

The following specific recommendations are made for the cleaning and preparation of all ultrasound transducers. Users should also review the CDC document on sterilization and disinfection of medical devices to be certain that their procedures conform to the CDC principles for disinfection of patient care equipment.

1. **Cleaning**—Transducers should be cleaned after each examination with soap and water or quaternary ammonium (a low-level disinfectant) sprays or wipes. The transducers must be disconnected from the ultrasound scanner for anything more than wiping or spray cleaning. After removal of the transducer cover (when applicable), use running water to remove any residual gel or debris from the transducer. Use a damp gauze pad or other soft cloth and a small amount of mild nonabrasive liquid soap (household dishwashing liquid is ideal) to thoroughly cleanse the transducer. Consider the use of a small brush, especially for crevices and areas of angulation, depending on the design of the particular transducer. Rinse the transducer thoroughly with running water, and then dry the transducer with a soft cloth or paper towel.

2. **Disinfection**—As noted above, all internal transducers (eg, vaginal, rectal, and transesophageal transducers) as well as intraoperative transducers require HLD before they can be used on another patient.

For the protection of the patient and the health care worker, all internal examinations should be performed with the operator properly gloved throughout the procedure. As the

transducer cover is removed, care should be taken not to contaminate the transducer with secretions from the patient. At the completion of the procedure, hands should be thoroughly washed with soap and water. Gloves should be used to remove the transducer cover and to clean the transducer as described above.

Note: An obvious disruption in condom integrity does not require modification of this protocol. Because of the potential disruption of the barrier sheath, HLD with chemical agents is necessary. The following guidelines take into account possible transducer contamination due to a disruption in the barrier sheath.

After removal of the transducer cover, clean the transducer as described above. Cleaning with a detergent/water solution as described above is important as the first step in proper disinfection, since chemical disinfectants act more rapidly on clean and dry surfaces. Wet surfaces dilute the disinfectant.

High-level liquid disinfection is required to ensure further statistical reduction in the microbial load. Examples of such high-level disinfectants are listed in Table 1. A complete list of US FDA-cleared liquid sterilants and high-level disinfectants is available at <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm194429.htm>, and other agents are under investigation.

To achieve HLD, the practice must meet or exceed the listed “High-Level Disinfectant Contact Conditions” specified for each product. Users should be aware that not all approved disinfectants on this list are safe for all ultrasound transducers.

The CDC recommends environmental infection control in the case of *Clostridium difficile*, consisting of “meticulous cleaning followed by disinfection using hypochlorite-based germicides as appropriate.”¹⁸ A hydrogen peroxide nanodroplet emulsion might provide an effective high-level disinfectant without toxicity.

The principal steps can be summarized as: remove, clean, disinfect, cover, where disinfection should be discussed with local infection control authorities, as proposed by Abramowicz et al.¹⁴

Table 1. Sterilants and High-Level Disinfectants Listed by the FDA

Name	Composition/Action
Glutaraldehyde	Organic compound (CH ₂ (CH ₂ CHO) ₂) Induces cell death by cross-linking cellular proteins; usually used alone or mixed with formaldehyde

Hydrogen peroxide	Inorganic compound (H ₂ O ₂) Antiseptic and antibacterial; a very strong oxidizer with oxidation potential of 1.8 V
Peracetic acid	Organic compound (CH ₃ CO ₃ H) Antimicrobial agent (high oxidation potential)
Ortho-phthalaldehyde	Organic compound (C ₆ H ₄ (CHO) ₂) Strong binding to outer cell wall of contaminant organisms
Hypochlorite/hypochlorous acid	Inorganic compound (HClO) Myeloperoxidase-mediated peroxidation of chloride ions
Phenol/phenolate	Organic compound (C ₆ H ₅ OH) Antiseptic
Hibidil	Chlorhexidine gluconate (C ₂₂ H ₃₀ Cl ₂ N ₁₀) Chemical antiseptic

The Occupational Safety and Health Administration as well as the Joint Commission (Environment of Care Standard IC 02.02.01 EP 9) have issued guidelines for exposure to chemical agents, which might be used for ultrasound transducer cleaning. Before selecting a high-level disinfectant, users should request the Material Safety Data Sheet for the product and make sure that their facility is able to meet the necessary conditions to minimize exposure (via inhalation, ingestion, or contact through skin/eyes) to potentially dangerous substances. Proper ventilation, a positive-pressure local environment, and the use of personal protective devices (eg, gloves and face/eye protection) may be required.

Immersion of transducers in fluids requires attention to the individual device's ability to be submerged. Although some scan heads as well as large portions of the cable may safely be immersed up to the connector to the ultrasound scanner, only the scan heads of others may be submerged. Some manufacturers also note that the crystals of the array may be damaged if, instead of suspending the transducer in the disinfectant, it rests on the bottom of the container. Before selecting a method of disinfection, consult the instrument manufacturer regarding the compatibility of the to-be-used agent with the transducers. Relevant information is available online and in device manuals. Additionally, not all transducers can be cleaned with the same cleaning agents.

Although some agents are compatible with all transducers of a given manufacturer, others must be limited to a subset of transducers.

After soaking the transducer in an approved disinfectant for the specified time, the transducer should be thoroughly rinsed (especially to remove traces of toxic disinfectants in the case of ortho-phthalaldehyde) and dried.

Summary

Adequate transducer preparation is mandatory. The level of preparation depends on the type of examination performed. Routine HLD of internal transducers between patients is mandatory, plus the use of a high-quality single-use transducer cover during each examination is required to properly protect patients from infection. It would be reassuring for the user to be able to consult manufacturer's instructions, particularly those that have been validated by the manufacturer, for sterilizing devices. The transducer cover sterility requirements for use in internal and interventional percutaneous procedures are governed by the level of sterility of the given procedure. Preparation of external transducers between patients is less critical and reduced to an LLD process. For all chemical disinfectants, precautions must be taken to protect workers and patients from the toxicity of the disinfectant.

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Section III: Safe Handling and Use of Ultrasound Coupling Gel

Background

Infection control is an integral part of the safe and effective use of ultrasound in medicine. For example, guidelines are in place for transducer disinfection to reduce the risk of iatrogenic and nosocomial infections. Although aspects of ultrasound coupling gel management, and administration have been implicated in outbreaks of nosocomial infections with a variety of pathogenic organisms, recommendations for reducing gel-related infections vary (see Clinician Outreach and Communication Activity safety communication and Health Canada alert in the "Related Websites" section).¹⁹

The purpose of this document is to provide guidance regarding ultrasound coupling gel use to minimize risks of iatrogenic or nosocomial infections.²⁰

Recommendations

Practices and institutions should adopt an infection control policy regarding the use of ultrasound coupling gel and ensure that appropriate staff are educated regarding this policy.

Sterile Gel

Sterile single-use gel packets are preferable to nonsterile gel when possible infection is a concern. Such situations include but are not limited to:

- All invasive procedures that pass a device through a tissue (eg, needle aspiration, needle localization, and tissue biopsy);
- All ultrasound examinations performed on neonates; and
- All ultrasound examinations or procedures performed on nonintact skin or near fresh surgical sites.

Sterile or bacteriostatic gel should be considered for endocavitary examinations performed on intact mucous membranes (eg, esophageal, gastric, rectal, and vaginal).

Nonsterile Gel

Single-use gel packets or multidose containers may be used.

If multidose containers are used, care should be taken to:

- Discard and replace multidose containers when empty; these should not be refilled;
- Appropriately seal the container when not in use; and
- Avoid direct contact between the gel container dispensing tip and any persons or instrumentation, including the ultrasound transducer.

If gel is to be used on a patient who is under droplet or contact precautions, discard the multidose container after use, or use a single-use gel packet.

Gel Warming

Dry heat should be the only method used to warm gel. Gel warmers should be cleaned and disinfected regularly according to the manufacturers' and infection control policy's requirements.

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