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AMERICAN INSTITUTE OF ULTRASOUND IN MEDICINE

Official Statements

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

SUMMARY

Adequate transducer preparation is mandatory to protect patients from potential infection. The level of preparation depends on the type of examination performed. Preparation of **external** transducers between patients requires a low-level disinfection (LLD) process. Preparation of **internal** transducers between patients requires routine mandatory high-level disinfection (HLD), and the use of a high-quality single-use transducer cover during each examination. Users should consult transducer manufacturer's instructions for disinfecting devices. Barriers used for internal and interventional percutaneous procedures must be single-use transducer covers that meet the sterility requirements of the procedure. For all chemical disinfectants, precautions must be taken to protect workers and patients from the toxicity of the disinfectant. Sterile single-use gel packets should be used when infection is a concern. If cross-contamination is a concern, non-sterile single-use gel packets should be used. For all other situations, multidose containers may be used. Dry heat should be used to heat gel where medically needed. LLD cleaning of equipment is a significant part of interrupting the cross-contamination chain. The cleaning frequency is dictated by operator and patient exposure to microbial activity.

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.

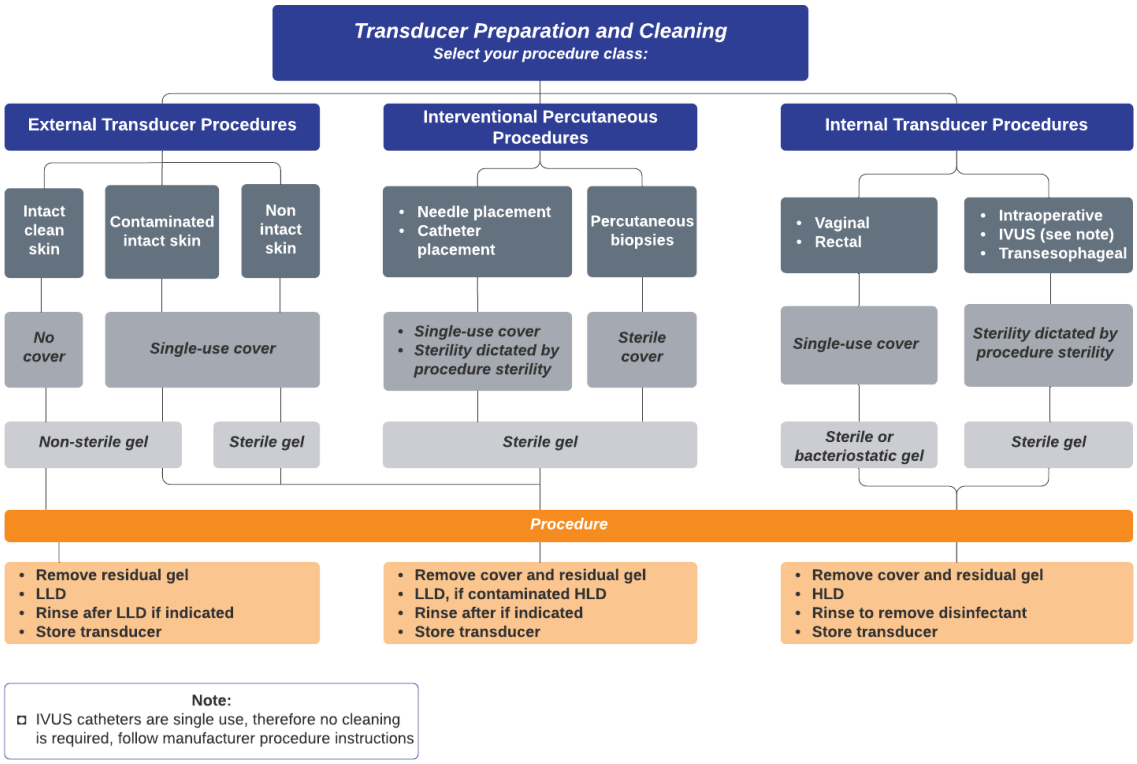
CHANGES DUE TO COVID-19 OUTBREAK

- **Level of disinfection:** For external and interventional procedures low-level disinfection is effective per CDC guidelines.[1] Currently, EPA approved disinfectants for use against COVID-19 (SARS-CoV-2) can be found online.[2] If LLD agents are depleted soap and water should be used per CDC guidelines. If indicated but no transducer covers are available, medical gloves or other physical barriers (e.g. compatible medical dressings) should be used.
- **Education and execution:** Dissemination of cleaning guidelines is essential and so is their proper execution. [10]
- **Equipment:** Cleaning involves all ancillary equipment involved in the procedure at hand. A cover sheet may be used as a physical barrier between the keyboard/console and the operator, in addition to LLD cleaning. If possible, use a dedicated system (scanner and transducers) for COVID-19, positive or suspected, patients. COVID-19 is viable on plastic surfaces for up to 72 hours [25]
- Special attention needs to be paid to COVID-19 and other respiratory infection cases requiring aerosolization procedures, i.e. mechanical ventilation, aerosolization application, etc. Here a transducer cover should be used and the entire equipment requires full LLD (top to bottom) as pathogens are likely to become airborne.
- Always follow manufacturer guidance and institutional guidelines.

SECTIONS

SECTION I: PROCEDURAL GUIDELINES FOR TRANSDUCER CLEANING AND PREPARATION

Procedural Graphics (see detached page)



Introduction

The purpose of the first 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. Therefore, different types of medical instruments require different cleaning method. The most critical instruments are those that are intended to penetrate skin or mucous membranes such as scissors, forceps, tweezer, hemostats, etc. These require sterilization. Less critical instruments (often called "semicritical" instruments) that simply come into contact with mucous membranes, such as endocavitary transducers, require high-level disinfection (HLD) rather than sterilization. "Noncritical" devices come into contact with intact skin but not mucous membranes, such as blood pressure cuff, stethoscope, external transducers, etc., require low-level disinfection (LLD).

- External transducers that only come into contact with clean, intact skin are considered noncritical devices and should be cleaned after every use as described below in number 1.
- External transducers that come into contact with contaminated skin (such as skin infections) should be covered with a single-use transducer cover.
- 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 commercial transducer sheaths or condoms as long as they fulfill institutionally defined infection control guidelines and procedure sterility requirements. If the transducer cover becomes compromised, the transducer must undergo high-level disinfection.
- Internal transducers should be covered with a single-use transducer cover as described below, when feasible. The level of transducer cover sterility is dictated by the level of procedure sterility. These transducers are therefore classified as semicritical devices.

Ultrasound Transducer Cleaning and Preparation

The following specific recommendations are made for the cleaning and preparation of all ultrasound transducers. 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.Transducers need to be cleaned after each exam, by using all of the following steps as proposed by Abramowicz et al. [4]:

1. Cleaning of all transducers — Disconnect the transducer from the ultrasound scanner as appropriate. After removal of the transducer cover (when applicable), remove bulk gel or debris from the transducer. Consider the use of a small brush, especially for crevices and areas of angulation, depending on the design of the particular transducer. Use a damp gauze pad or other soft cloth and a small amount of mild nonabrasive liquid soap, e.g. household dishwashing liquid or use a wipe to remove any remaining gel (film).

2. Disinfection can be (a) low-level or (b) high-level:
    a. Disinfection of all transducers in external procedures as well as interventional percutaneous procedures should undergo LLD. If the transducer came in contact with mucous membranes or any body fluids then HLD is required (see step 2.b). If a transducer cover was required and becomes compromised, the transducer must undergo high-level disinfection (step 2.b).
    b. Disinfection of all internal transducers (e.g., transvaginal, transrectal, and transesophageal transducers) as well as intraoperative transducers require HLD before they can be used on another patient. HLD chemical disinfectants rely on clean and dry surfaces, as wet surfaces dilute the disinfectant, therefore dry the transducer before performing HLD.

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

3. Rinsing — Depending on the employed disinfection agent, the transducer should be thoroughly rinsed and dried after disinfection, following manufacturer guidelines.

4. Storing — Transducers need to be stored in accordance to their disinfection level.

5. Remove gloves, dispose and wash hands.

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 online,[2] 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.

Immersion of transducers in fluids requires attention to the individual device's ability to be submerged. Although some transducers as well as large portions of the cable may safely be immersed up to the connector to the ultrasound scanner, only the transducers of others may be submerged. Some manufacturers also note that the crystals of the array may be damaged if the transducer rests or impacts the bottom of the container, instead of being suspended in the disinfectant. Before selecting a method of disinfection, consult the instrument manufacturer regarding the compatibility of the to be used agent with the specific 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.

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."[3] A hydrogen peroxide nanodroplet emulsion might provide an effective high-level disinfectant without toxicity.

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 (e.g., gloves and face/eye protection) may be required.

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

Name	Composition/Action

Glutaraldehyde	Organic compound ($CH_2(CH_2CHO)_2$) Induces cell death by cross-linking cellular proteins; usually used alone or mixed with formaldehyde
Hydrogen peroxide	Inorganic compound (H_2O_2) Antiseptic and antibacterial; a very strong oxidizer with oxidation potential of 1.8 V
Peracetic acid	Organic compound (CH_3CO_3H) Antimicrobial agent (high oxidation potential)
Ortho-phthalaldehyde	Organic compound ($C_6H_4(CHO)_2$) 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_6H_5OH) Antiseptic
Hibidil	Chlorhexidine gluconate ($C_{22}H_{30}Cl_2N_{10}$) Chemical antiseptic

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, i.e., 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: NEW LITERATURE AND OTHER RELEVANT GUIDELINES

Background

Kac et al.[5] 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 al.[6] 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 classification[7] is inconsistent with the results of this study.

Casalegno et al.[8] 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 al.[9] 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 Basseal [10] 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 Basseal [11] 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.[11] 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.

Seki et al. (2013) [12] traced an institutional nosocomial outbreak of multidrug-resistant pseudomonas aeruginosa to a transesophageal echocardiogram transducer, specifically a 5 mm large defect on the insertion tube, 15 cm from the end of the device. While the transducer was cleaned at centralized sterilization, the mechanical defect retained bacterial contamination. No transducer sheath was used.

In the same year, Sartoretti et al. [13] 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 al. [14] 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. [15-18]

Abramowicz et al. [4] 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.[19] 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). [20] 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.[21] 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. One should perform HLD of the internal transducer between each use and employ an adequate transducer cover as a protective barrier.

CDC Definitions

According to the Centers for Disease Control and Prevention (CDC) Guideline for Disinfection and Sterilization in Healthcare Facilities: [3]

"**Cleaning** is the removal of visible soil (e.g., organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with soap 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 (i.e., high-level disinfection)."

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).[22]

The purpose of this document is to provide guidance regarding ultrasound coupling gel use to minimize risks of iatrogenic or nosocomial infections.[23]

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 infection is a concern. Such situations include but are not limited to:

- All invasive procedures that pass a device through a tissue (e.g., 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 (e.g., 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 (such as COVID-19), 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.

SECTION IV: SAFE HANDLING OF SCANNER AND OTHER EQUIPMENT
Users should follow institutionally defined infection control guidelines for cleaning of ultrasound scanners, cables, connectors, and other equipment. The extent to which equipment needs to be cleaned is dictated by its exposure to the operator and the patient. Typically, this involves the ultrasound scanner console, its handles, the transducer cable and connector, gel containers, the patient bed, among others. Institutional infection control guidelines may also require a full scanner wipe down, e.g. for scanning in operating rooms. CDC guidelines for healthcare facilities (2017) address microbicidal activity of quaternary ammonium compounds (low-level disinfectant) specifically for keyboards. [24, 25]
Equally important to creating cleaning guidelines is their dissemination to and subsequent execution by the operators. Westerway and Basseal[10] highlighted the lack of appropriate training for a significant number of their survey responders. Approximately half of them did not undergo training for either purchased ultrasound equipment or cleaning products. Similarly, were the responses regarding actual equipment cleaning. Approximately 50% cleaned the transducer cord after each patient but only 15% cleaned the keyboard. Most operators (57%) cleaned the keyboard daily but 7.6% never did. Even in a non-critical setting, i.e. external transducers, not cleaning a keyboard is concerning. The cleaning frequency and level of sterility of ancillary equipment should follow institutional infection control guidelines for the procedure at hand and are dictated by operator and patient exposure to microbial activity. For example, for surgical procedures equipment should be disinfected prior to the procedure (to prevent infection), for COVID-19 patients after the procedure (to prevent cross-contamination).

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