

[High Priority] - H0572 : Ultrasound Probes Used on Non-Intact Skin Require High-Level Disinfection, Even When a Probe Cover Is Used [ECRI Exclusive Hazard Report] Medical Device Hazard Report

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UMDNS Terms:

- Scanning Systems, Ultrasonic, Cardiac [17422]
- Scanning Systems, Ultrasonic, General-Purpose [15976]
- Scanning Systems, Ultrasonic, Obstetric/Gynecologic [15657]
- Scanning Systems, Ultrasonic, Portable [18143]
- Scanning Systems, Ultrasonic, Vascular [15957]

Geographic Regions: Worldwide

Suggested Distribution: Cardiology/Cardiac Catheterization Laboratory, Clinical/Biomedical Engineering, Emergency/Outpatient Services, Infection Control, Obstetrics/Gynecology/Labor and Delivery, OR/Surgery, Diagnostic Imaging, Risk Management/Continuous Quality Improvement, Point-of-Care Coordination, Central Sterilization Reprocessing

Summary:

Please [CLICK HERE](#) for a brief Micro e-learning Video related to this Hazard Report. For more information, please contact hda@ecri.org.

Problem:

1. Ultrasound is commonly used as a means to assess patients who have open wounds or non-intact skin. Often, a sheath or probe cover is used to prevent cross-contamination between patients and caregivers.
2. Clinicians may mistakenly believe that the use of a sheath or a low-level disinfecting wipe obviates the need for high-level disinfection (HLD) of ultrasound probes after they are used to scan patients who have open wounds, or other areas of non-intact skin.
3. This problem could lead to serious infection or death.

Manufacturer's Corrective Action/Recommendations:

1. Ultrasound manufacturers provide recommended products and procedures that should be followed when reprocessing ultrasound probes.

ECRI Recommendations:

Risk Managers and Department Managers

1. Inventory all probes and ultrasound units within the organization to determine the ultrasound probe manufacturers' approved cleaning, low-level disinfection, HLD, and sterilization products and processes.
2. Alert clinicians and support staff that when an ultrasound probe is used to scan over open wounds or non-intact skin, the probe is considered a semi-critical device.

Clinicians

1. Always clean and perform HLD after each use of a probe as a semi-critical device, even in cases when a probe cover is used.
2. Understand and comply with accepted probe reprocessing requirements and processes. A complete description is available in ECRI's 2018 publication [Cleaning and Disinfecting Diagnostic Ultrasound Transducers: Our Recommendations](#).

Background:

1. Point-of-care ultrasound (POCUS) is widely used throughout hospitals, physician offices, and clinics. Because they are not imaging specialists, POCUS users, especially new ones, may have little experience with the requirements of reprocessing ultrasound transducers (also referred to as probes).
2. It is essential that all ultrasound users follow the appropriate methods to clean and reprocess probes to comply with clinical guidelines and to avoid placing patients and users at risk for cross-contamination.
3. As part of the regulatory FDA 510(k) submission process, manufacturers must provide validation of the labeled cleaning, disinfection, and sterilization processes.
4. Ultrasound probes are classified as noncritical, semi-critical, or critical, based on the Spaulding system and the clinical applications and potential for cross-contamination.
 1. Noncritical transducers, such as models used for abdominal, obstetric, and other exams on intact skin, must be cleaned after each use.
 2. Semi-critical transducers, such as models used for endovaginal, endorectal applications, and exams on open wounds or areas of

non-intact skin, require HLD after each use. The use of a sheath or probe cover does not obviate the need for HLD.

3. Critical transducers, such as transesophageal echocardiography and laparoscopic transducers, require sterilization.

References & Source Documents:

1. Centers for Disease Control and Prevention (CDC), U.S. Guideline for disinfection and sterilization in healthcare facilities, 2008 [online]. Updated 2017 Feb 15. Available from: <https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html> .
2. American Institute of Ultrasound in Medicine. Guidelines for cleaning and preparing external- and internal-use ultrasound probes between patients, safe handling, and use of ultrasound coupling gel [official statement]. 2018 Mar 25. Available from: <http://www.aium.org/officialStatements/57> .

Comments:

- This alert is a living document and may be updated when ECRI receives additional information.

Source(s):

- 2020 Mar 30. ECRI researched report