

## [High Priority ] - H0592 : [COVID-19] Recommendations for Reprocessing Ultrasound Devices Used on COVID-19 Patients [ECRI Exclusive Hazard Report] Medical Device Hazard Report

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### UMDNS Terms:

- Scanning Systems, Ultrasonic, Abdominal [16241]
- Scanning Systems, Ultrasonic, Cardiac [17422]
- Scanning Systems, Ultrasonic, General-Purpose [15976]
- Scanning Systems, Ultrasonic, Obstetric/Gynecologic [15657]

**Geographic Regions:** Worldwide

**Suggested Distribution:** Anesthesia, Clinical/Biomedical Engineering, Critical Care, CSR/Materials Management (inactive), Dialysis/Nephrology, Emergency/Outpatient Services, Infection Control, Nursery, Nursing, Oncology, OR/Surgery, Orthopedics, Pulmonology/Respiratory Therapy, Diagnostic Imaging, Risk Management/Continuous Quality Improvement, Home Care, Urology, Dentistry/Oral Surgery, Phlebotomy, Physical Therapy/Rehabilitation, Internal Medicine, Dermatology, Endocrinology, Point-of-Care Coordination, Vascular Laboratory, Pain Clinic, Staff Education, NICU, EMS/Transport, IV Therapy, Materials Management

### Problem:

Inadequate cleaning and disinfecting of ultrasound devices after use on COVID-19 patients can lead to cross-contamination of patients or staff.

### ECRI Recommendations:

Listed below are our recommendations for measures that can minimize exposure of staff and patients to the SARS-CoV-2 virus and reduce the likelihood of COVID-19 transmission.

*Administrators, Risk Managers, and Infection Preventionists*

1. Review existing policies and procedures regarding reprocessing of ultrasound devices to ensure compliance with current [Centers for Disease Control \(CDC\) guidelines](#) .
2. Determine whether the cleaning and disinfection products used in your facility:
  1. Meet the Environmental Protection Agency (EPA) criteria for use against SARS-CoV-2, the virus that causes COVID-19, and are on the [EPA List N](#) .
  2. Are approved for use by the ultrasound device vendor. Refer to the device Instructions for Use (IFU) or consult with the vendor to identify approved cleaning and disinfectant products and procedures.
3. Procure an ultrasound vendor-approved product that is on the [EPA List N](#) \_if necessary.
4. Ensure that all users and relevant support staff are trained in, and comply with policies and procedures regarding reprocessing of ultrasound devices.
  1. Maintain updated policies and procedures and make them available to staff.
5. Ensure that the required personal protective equipment (PPE), including gloves, gowns, face and eye protection are available where clinical ultrasound assessments, and device reprocessing are performed.

*Clinicians and Support Staff*

1. Follow facility policies and procedures regarding the use of PPE when assessing patients with suspected or known COVID-19, and while reprocessing potentially contaminated devices.
2. ECRI's recommendations for cleaning and disinfecting ultrasound probes are described in [Cleaning and Disinfecting Diagnostic Ultrasound Transducers: Our Recommendations](#) .
  1. Cleaning and disinfection must be performed using a disinfectant that is included on the [EPA List N](#) .
  2. Adhere to the product's contact time (also referred to as the "wet time") and other recommendations as indicated on the disinfectant's label to ensure effective disinfection. See the ECRI resource [Disinfectant Concentrations and Contact Times for EPA's List of Products Effective against Novel Coronavirus SARS-CoV-2, the Cause of COVID-19](#) .
3. Specific recommendations for ultrasound probes used to assess patients who have or may have COVID-19 include the following:
  1. Use a disposable probe sheath to add an additional level of protection and make the probe easier to clean by not having gel directly on it.
    1. Use of a sheath does not obviate the need for cleaning and disinfecting the device as described below.
  2. Clean the probe, and follow with low-level disinfection (LLD) after transcutaneous scanning areas with intact skin. If LLD agents are not available, soap and water should be used in accordance with CDC guidance.
  3. Clean the probe, and follow with high-level disinfection (HLD) after endocavity scanning and use on non-intact skin.
  4. Probes used for transcutaneous interventional guidance procedures should be covered with a disposable sheath during use, as per institutional policies.
    1. After the procedure, the probe should be cleaned and followed by LLD.
    2. If the sheath integrity is compromised or the probe may otherwise be contaminated, cleaning followed by HLD should be performed.

3. If probe sheaths are not available, medical gloves or other physical barriers should be used.
4. The ultrasound console, including the user interface, display, probe cables, and accessories such as gel bottles, should be cleaned and LLD after use. Aerosolization may occur from patients coughing, or if they are on mechanical ventilation.
  1. Minimize contamination of the console by using one "semi-clean" gloved hand that has not touched the patient to operate the scanner, and one "dirty" gloved hand to hold the probe and perform the scan.
  2. Disposable drapes can be used to cover ultrasound consoles to reduce the likelihood of contamination.
  3. Use of a drape does not obviate the need for cleaning and disinfecting the device.
5. If possible, use a dedicated ultrasound scanner for assessments of patients who have or may have COVID-19. When selecting a scanner, consider the following:
  1. Small, portable units are easier to reprocess than cart-based scanners.
  2. Remove all non-essential components and accessories, such as transducers, that are not required for the exam.
6. Consult with your Infection Preventionists for institutional policies and procedures.

#### Background:

1. The transmission of COVID-19 is thought to occur mainly through respiratory droplets, which are produced by coughing and sneezing and by contacting contaminated surfaces.
  - Recent reports from the CDC and EPA indicate that the SARS-CoV-2 virus, which is responsible for the COVID-19 pandemic, can be effectively inactivated using LLD products (CDC 2020, EPA, 2020).
2. Point-of-care ultrasound (POCUS) is a valuable means to identify pulmonary, cardiac, and other abnormalities related to COVID-19. These devices can also be used to monitor changes over time, which enhances patient management.
3. Routine cleaning and disinfecting of ultrasound devices after use on suspected or known COVID-19 patients is essential to prevent cross-contamination and to reduce the spread of disease.
4. Reports indicate that ultrasound devices may not be properly reprocessed between patients (Westerway, Basseal. 2017).
5. The Spaulding classification is used to determine the required cleaning, disinfecting, and sterilization processes of ultrasound devices.
  1. Probes that come into contact only with intact skin, sometimes referred to as external probes, are considered non-critical devices, and should be cleaned and then low-level disinfected using manufacturer-recommended products and processes.
  2. Probes that come into contact with mucous membranes, such as endorectal or endovaginal probes (sometimes referred to as internal probes) and probes used to scan areas of non-intact skin, are considered semi-critical devices, and should be covered with an appropriate sheath during use. The probes should then be cleaned and high-level disinfected using manufacturer-recommended products and processes.
    - As ECRI has [previously reported](#) , the use of disposable probe sheaths does not obviate the need to use HLD on these probes.

#### ECRI Resources

1. [Adoption of Point-of-Care Ultrasound Is Outpacing Safeguards](#)
2. [Cleaning and Disinfecting Diagnostic Ultrasound Transducers: Our Recommendations](#)
3. [H0573: Point-of-Care Ultrasound Is Beneficial to Triage Patients for Suspected COVID-19; Safeguards Are Required \[ECRI Exclusive Hazard Report\]](#)
4. [Disinfectant Concentrations and Contact Times for EPA's List of Products Effective against Novel Coronavirus SARS-CoV-2, the Cause of COVID-19](#)

#### References & Source Documents:

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2. Agency USEP. List N: *Disinfectants for Use Against SARS-CoV-2*. Published 2020. Updated March 20, 2020 March 23, 2020.10. Available: <https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2> Accessed 4/16/2020.
3. American Institute of Ultrasound in Medicine. *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*. Updated 3/27/2020. Available at: <https://www.aium.org/officialStatements/57> Accessed 4/16/2020.
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10. Westerway SC, Basseal JM. The ultrasound unit and infection control – Are we on the right track? *Ultrasound* 2017;25(1):53-57.

**Comments:**

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

**Source(s):**

- 2020 Apr 22. ECRI researched report