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### [High Priority] - H0573: [COVID-19] Point-of-Care Ultrasound Is Beneficial to Triage Patients for Suspected COVID-19; Safeguards Are Required [ECRI Exclusive Hazard Report] Medical Device Hazard Report

Published: Monday, March 30, 2020

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# **UMDNS Terms:**

- Scanning Systems, Ultrasonic, General-Purpose [15976]
- Scanning Systems, Ultrasonic, Portable [18143]

### Geographic Regions: Worldwide

Suggested Distribution: Anesthesia, Clinical/Biomedical Engineering, Critical Care, Emergency/Outpatient Services, Infection Control, Nursing, OR/Surgery, Diagnostic Imaging, Risk Management/Continuous Quality Improvement, Internal Medicine, Point-of-Care Coordination, Staff Education, EMS/Transport, Central Sterilization Reprocessing

### Problem:

- 1. Inappropriate use of point-of-care ultrasound (POCUS) to triage patients with suspected COVID-19 can lead to the following:
  - 1. Cross-contamination of patients or staff if devices are not properly cleaned and disinfected
  - 2. Misdiagnoses if clinicians are not qualified to perform POCUS for lung application

## **ECRI Recommendations:**

5.

- 1. Facility administrators should determine if their emergency department (ED) staff have the skills and technology to perform lung POCUS.
  - 1. If the skills and technology are available, the use of POCUS should be considered for assessment of patients suspected of having COVID-19.
- 2. The use of POCUS by qualified clinicians may serve as an initial imaging modality for assessment of patients presenting in the ED suspected of having COVID-19. The potential clinical benefits of POCUS for this application include:
  - 1. POCUS can be performed in an isolation setting and does not require transport of the patient into the hospital or computed tomography (CT) suite.
  - 2. POCUS has the potential to improve the ability to determine the patient's risk of having COVID-19.
- 3. Healthcare professionals who are qualified to perform POCUS for lung assessments should review imaging findings associated with COVID-19 virus (see references below). Early reports indicate that COVID-19 affects the peripheral lung fields more than central pulmonary areas and have described a wide variety of findings including the following:
  - 1. Thickening and irregularity of the pleural line
  - 2. A variety of B-line patterns, including focal, multifocal, and confluent
  - 3. A variety of lung consolidation patterns, including small multifocal, translobar, and non-translobar
  - 4. The appearance of A-lines when patients are recovering
  - 5. Pleural effusions are uncommon.
- 4. A lung exam protocol for assessment of suspected or known COVID-19 patients was recently published online (Soldati, et al. 2020). In general, lung POCUS is most commonly performed using:
  - 1. 3 MHz to 6 MHz convex linear array (CLA) or sector transducers to obtain the necessary penetration. A higher frequency flat linear array transducer should be used for a detailed assessment of the pleura and peripheral lungs.
  - 2. A "Lung" exam preset (if available) to reduce the need to manually adjust parameters and accelerate image acquisition and assessment
  - 3. A deep (>15 cm) field of view to identify B-lines if present
  - 4. A single focal point, which should be positioned to optimize image quality in the region of interest
  - Ultrasound scanners must be properly cleaned and disinfected after each patient.
    - 1. Clinicians and support staff should be familiar with the required cleaning and disinfecting methods to use, which are described in ECRI's report "<u>Cleaning and Disinfecting Diagnostic Ultrasound Transducers: Our Recommendations</u>."
    - 2. After scanning areas with intact skin on patients who have, or may have COVID-19, the entire ultrasound system, including the console, probe cable, and probe, must be cleaned and low-level disinfected using products and processes that are:
      - 1. Approved by the ultrasound device manufacturer; and
      - 2. Are on the Environmental Protection Agency's List N; products that meet the criteria for use against SARS-CoV-2, the virus that causes COVID-19, on hard surfaces.
- 6. Use disposable probe sheaths 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 low-level disinfection (LLD) of the device (see Hazard Report

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<u>H0572</u>).

7. Consult with your infection preventionists for institutional policies and procedures.

#### **Background:**

- 1. The COVID-19 pandemic has placed unprecedented stress on healthcare systems globally.
  - Emergency departments are receiving many patients who may or may not have COVID-19, and there is a need to enhance
    patient triage and management of affected patients.
- 2. A real-time reverse transcriptase-polymerase chain reaction (RT-PCR) test is the only means to confirm a diagnosis of COVID-19, but this test requires several hours, or even days, to obtain results, and false-negative results are not uncommon.
- 3. CT may be used to identify changes in the lungs that may be related to COVID-19. However:
  - a. CT should be used sparingly and reserved for hospitalized, symptomatic patients with specific clinical indications for CT.
  - b. CT uses ionizing radiation, may not be readily available, and requires transport of the patient to the imaging suite.
  - c. When used for this application, the CT scanner and suite must undergo deep cleaning and HLD between patients, which is labor intensive, time consuming, and takes the scanner out of service
- 4. POCUS is recognized as a highly sensitive and specific imaging method for early diagnosis of pneumonia and other lung abnormalities, and it is used as an alternative to chest radiography or CT for many indications. Early reports indicate that POCUS is a viable alternative to CT to identify lung abnormalities related to COVID-19. The benefits of POCUS include:
  - a. POCUS can be performed in isolation settings outside of the hospital, such as in COVID-19 screening areas.
  - b. Use of POCUS provides immediate results that can help clinicians manage the patient.
  - c. POCUS devices can be cleaned and disinfected more easily and in less time than CT scanners.
  - d. POCUS does not use ionizing radiation.
- 5. Safe and effective use of POCUS requires qualified operators, proper interpretation of results, and other safeguards, which are described in our report Adoption of Point-of-Care Ultrasound Is Outpacing Safeguards.

### **ECRI Resources:**

- 1. Adoption of Point-of-Care Ultrasound Is Outpacing Safeguards (published September 26, 2019)
- 2. Cleaning and Disinfecting Diagnostic Ultrasound Transducers: Our Recommendations
- 3. Hazard Report H0572.

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# Comments:

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

# Source(s):

• 2020 Mar 27. ECRI researched report.