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● Letter to the Editor

WORLD FEDERATION FOR ULTRASOUND IN MEDICINE AND BIOLOGY POSITION STATEMENT: HOW TO PERFORM A SAFE ULTRASOUND EXAMINATION AND CLEAN EQUIPMENT IN THE CONTEXT OF COVID-19

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INTRODUCTION

On March 11, 2020, the World Health Organization formally declared the outbreak of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (also known as COVID-19) a pandemic. This has impacted the way health care facilities operate globally to ensure patient and practitioner safety and to minimize all risks associated with infection transmission.

Ultrasound is a safe and essential tool for the diagnosis of a variety of medical conditions and for patient care. Bedside lung ultrasound has been invaluable in the treatment of the critically ill (Lichtenstein 2014; Soldati et al. 2020) and, specifically, for diagnosis of pneumonia in COVID-19 patients (Gorbalenya et al. 2020). Ultrasound is increasingly used within the point of care setting, as chest computed tomography is often not available in emergency departments (Poggiali et al. 2020). Ultrasound may also be used for longitudinal monitoring of affected patients (Peng et al. 2020). However, the ultrasound unit can be a potential vector in the transmission of an infection (Skowronek et al. 2016; Westerway and Basseal 2017), and previous surveys have indicated a gap in knowledge of basic infection prevention measures in ultrasound (Westerway et al. 2019). Because of the highly contagious nature of COVID-19 and given the proximity necessary to perform an ultrasound examination, it is essential to take all safety precautions when undertaking routine clinical activity.

Several national and international guidelines for general precautions in ultrasound infection prevention have been published (Kanagala et al. 2011; Hoyer et al. 2016; Abramowicz et al. 2017; Basseal et al. 2017; Nyhsen et al. 2017; Liu et al. 2018; Muller et al. 2018), and some societies have developed and published cleaning guidelines on their websites, but not in peer reviewed journals (e.g., American College of Emergency Physicians, American College of Radiology, International Society of Ultrasound in Obstetrics and Gynecology [ISUOG] and the American Institute of Ultrasound in Medicine). More recently, specific guidance documents for COVID-19 have also been published on various websites (e.g., ISUOG). There are also national and international guidelines for the performance of routine or targeted ultrasound investigation (American College of Emergency Physicians 2009; Dietrich et al. 2017; American Institute of Ultrasound in Medicine 2018; Aakjær Andersen et al. 2019; Society and College of Radiographers/British Medical Ultrasound Society 2019). The decision as to what constitutes an

elective or an emergency examination is to be made locally and is not the goal of this document; rather, it is intended to serve as guidance on infection control when performing ultrasound examinations in the context of the current COVID-19 pandemic.

This statement has been written on behalf of the World Federation for Ultrasound in Medicine and Biology (WFUMB) Safety Committee as official guidance with the collaboration of experts from various affiliated federations. While this statement ensures that a consistent approach to infection prevention and safe ultrasound practices are implemented during the COVID-19 pandemic, there may be some operational and organizational differences at the local level.

PURPOSE

This statement provides guidance on equipment cleaning and safe performance of ultrasound examination within the context of COVID-19. It is relevant to all practitioners (sonographers, physicians and allied health professionals) using ultrasound for diagnostic imaging during the COVID-19 pandemic (e.g., obstetrics, gynecology, point-of-care ultrasound, accident and emergency medicine, pediatrics, critical care and cardiology). This statement has been written to protect both patients and health care workers, particularly when scanning suspected or confirmed COVID-19 patients.

As the evidence base for COVID-19 is rapidly evolving, this document is current at time of publication, and further updates may be provided as new evidence emerges.

PROPERTIES AND SPREAD OF SARS-COV-2 (COVID-19)

SARS-CoV-2 (Gorbalenya et al. 2020), a small lipid-based enveloped virus belonging to the coronavirus family, is least resistant to inactivation by common disinfectants used in low-level disinfection (LLD) (see guidelines on Centers for Disease Control and Prevention [CDC] and Environmental Protection Agency [EPA] websites). The structure of these viruses includes a lipid envelope, which is easily disrupted by most disinfectants such as 62%–71% ethanol, 0.5% hydrogen peroxide or 0.1% sodium hypochlorite within 1 min. Other biocidal agents such as 0.05%–0.2% benzalkonium chloride or 0.02% chlorhexidine digluconate are less effective. The virus is involved in human-to-human transmission of the COVID-19 pandemic (Chan et al. 2020; Yuen et al. 2020), and

there are increasing reports of asymptomatic carriers of the disease (Bai et al. 2020; Holshue et al. 2020). As such, ultrasound practitioners need to implement appropriate infection prevention measures not only with confirmed but also suspected COVID-19 patients.

The transmission of COVID-19 is thought to occur mainly through respiratory droplets that are generated by coughing and sneezing and *via* contact with contaminated surfaces. Once infected droplets have landed on surfaces, their viability depends on the type of surface and temperature (Kampf et al. 2020). Survival on dry inanimate surfaces such as metal, glass and plastic (and ultrasound systems) is, as far as is known, between 48 and 96 h (Nyhsen et al. 2017; Kampf et al. 2020). However, SARS coronavirus, Middle East respiratory syndrome coronavirus or endemic human coronaviruses have been shown to persist on fomites for up to 9 d (Kampf et al. 2020), and this is an important consideration for ultrasound equipment used in all clinical settings.

Furthermore, viral ribonucleic acid has been found in stool samples from infected patients (Holshue et al. 2020), and this is a vital aspect to consider for any ultrasound practitioners involved in trans-rectal ultrasound or scanning infants within the pediatric setting.

SCHEDULING OF PATIENTS (GENERAL RECOMMENDATIONS)

Non-essential examinations should be deferred or cancelled to minimize exposure of an at-risk group of patients to potential COVID-19 contact in the hospital environment. Acute situations may require immediate point-of-care or other ultrasound examinations (*e.g.*, acute abdomen, motor vehicle accident etc.). All patients and visitors should be screened using standardized checklists for symptoms of acute respiratory infection, significant travel history, occupation, contacts, *etc.*, consistent with recommendations of local authorities. Ideally, triage should be undertaken before the patient arrives to the ultrasound unit.

STANDARD AND TRANSMISSION-BASED PRECAUTIONS FOR COVID-19

Aspects that should be considered when planning to perform an ultrasound in a clinical care setting in the context of COVID-19 are:

- Triage of patients to routine (delay is possible) or emergent examination
- How to protect the patient and ultrasound providers (physicians, sonographers and allied professions)
- How to prepare and clean the ultrasound room and equipment

Note: It is evident that some of these recommendations may not be applicable to all practices. Furthermore, it is understandable that some may not be achievable in some locations⁴.

Triage of patients

Generally, how to prioritize patients into emergency or urgent examination versus examination that can be postponed must be determined by local facilities/authorities (see above). Some scientific societies may already have such recommendations published or in press at the time of this document preparation (Boelig et al. 2020).

Protecting the patient and ultrasound practitioner

Preventing transmission of infection requires all health care practitioners to implement both standard and transmission-based precautions, regardless of suspected or confirmed COVID-19. Standard precautions for COVID-19 as outlined by the CDC in 2020 include:

1. Ultrasound practitioners with specific health problems that place them at greater risk (as detailed by local occupational health guidelines) are to be excluded from performing ultrasound.
2. Ensure the ultrasound practitioners have undergone infection control training and fit testing for respirators, if required (for example N95 and FFP3).
3. To reduce the risk of transmission, it is important to (i) respect the time of scheduled visits, (ii) widen the appointment intervals to prevent crowding in the waiting room and (iii) space the seats in the waiting room to at least 6 feet (2 meters) apart.
4. Limit the number of visitors in the examination room to a maximum of 1, preferably with no children. During the pandemic, it is reasonable not to allow trainees or students to participate. Encourage use of alternative mechanisms for patient and visitor interactions such as video-call applications on cell phones or tablets.
5. If the status of a patient is confirmed as COVID-19 infected, it would be preferable to scan the patient at the end of the clinic list so that the equipment and room will undergo vigorous cleaning and disinfection (see below, Preparing and cleaning the ultrasound room)).
6. Hand hygiene: All ultrasound practitioners should perform hand hygiene before and after all patient contact, contact with potentially infectious material (*e.g.*, linen from patient room) and before and after removing personal protective equipment (PPE), including gloves. Hand hygiene should be performed using an alcohol-based hand rub (60%–95% alcohol) or washing hands with soap and water for at least 20 seconds. If hands are visibly soiled, use soap and water before the alcohol-based hand rub. Latex-free disposable gloves should be used during the ultrasound examination and changed after each patient.
7. Scanning should, as much as possible, be performed with one (clean) hand and transducer while having the other hand semi-clean but in contact with the keyboard. Gel application should occur with the semi-clean hand dispensing clean gel (see below), with post-procedure thorough cleaning of the gel bottle using an LLD. See details on gel use below (Specific recommendations regarding ultrasound gel).
8. If required to scan the patient in an isolation room, ultrasound practitioners, as all attending medical staff, should don PPE (respirator, goggles, face protective

shield, surgical gown and gloves) before entry of isolation room, where the level of PPE is set by institutional guidelines.

9. PPE: Any reusable PPE (*e.g.*, gowns) must be properly cleaned and decontaminated. Specific PPE recommendations when caring for a patient with suspected or confirmed COVID-19 infection include:
 - a. Respirator or face mask: As ultrasound practitioners are in close contact with patients, surgical face masks are essential to offer protection. These must be put on before entry into the patient room or care area. N95 respirators or respirators that offer a higher level of protection should be used instead of a face mask when performing or present for an aerosol-generating procedure, particularly for use in the intensive care unit. It is important to perform hand hygiene after removal of the respirator or face mask.
 - b. Eye protection (for ultrasound practitioners in the critical care setting): This includes goggles or a disposable face shield that must be put on when entering the patient room or care area. Reusable eye protection (*e.g.*, goggles) must be cleaned and disinfected according to the manufacturer's reprocessing instructions before re-use. Disposable eye protection should be discarded after use. An individual risk assessment should be carried out before or at the time of providing care to the patient.
 - c. Gloves: Wearing clean, non-sterile gloves upon entry into the patient room or care area is essential for all ultrasound practitioners. Once the ultrasound examination is complete, remove and discard gloves when leaving the patient room or care area and immediately perform hand hygiene.
 - d. Gowns: Wearing a clean isolation gown upon entry into the patient room or care area is essential. Reusable gowns should be discarded in a dedicated container for linen and laundered. Disposable gowns should be discarded after use. If there are shortages of gowns, they need to be prioritized for aerosol-generating procedures and high-contact patient care activities that provide opportunities for transfer of pathogens to the hands and clothing.
 - e. Donning and doffing training: Workers who need to use protective clothing and equipment must be trained on how to put it on, use and wear it and how to take it off correctly, including in the context of their current and potential duties. Training material should be easy to understand and available in the appropriate language and literacy level for all workers. Information may be found on the European Centre for Disease Prevention and Control and the Occupational Safety and Health Administration websites.

Preparing and cleaning the ultrasound room

Note: Protective eyewear and gloves should be used when cleaning and disinfecting any equipment, and hand hygiene is essential after removing protective wear.

- The ultrasound room should be cleaned thoroughly each morning, and all content should be wiped with a compatible LLD recommended by the CDC and EPA, such as quaternary ammonium compounds (see Preparing and cleaning of ultrasound equipment). Items for disinfection include monitors, computer keyboard and mouse, stretcher rails, gel container, door handles, cabinet knobs, light switches, chairs and counter tops. Extra attention should be given to high touch surfaces which should be cleaned vigilantly.
- Unnecessary accessories in the room should be removed and, where possible, individually stored in the cabinets.
- Fabric-covered chairs should be replaced with hard-surface chairs that can be wiped.
- The patient bed or couch should be wiped by an LLD before replacing the disposable paper cover.
- The disposable paper cover should be removed with gloved hands and folded and disposed of immediately at the end of each examination.
- At the end of the day, soiled linen should be handled double-gloved and disposed of in the appropriate container. The room and equipment should undergo terminal cleaning using an LLD. Hands are to be washed for 20 seconds afterward.

Preparing and cleaning of ultrasound equipment

Note: Protective eyewear and gloves should be used when cleaning, disinfecting or sterilizing any equipment, and hand hygiene is essential after removing protective wear.

- If feasible, it is recommended to have one (or more) dedicated machine(s) for patients with suspected or confirmed COVID-19.
- Equipment should be cleaned using an LLD with agents recommended by the CDC and EPA (see websites); this includes the ultrasound equipment monitor and user interface (*e.g.*, keyboard, knobs, track ball and touch screen). In emergency medicine, primary care and critical care, handheld ultrasound instruments are often used for COVID-19 infected (and other) patients because of ease of transport and seemingly easier cleaning methods, secondary to a simpler user interface. If possible, keep the whole device and phone in a sterile transducer cover sleeve, which is available commercially. An example of how to place the transducer and ultrasound instrument in a sheath can be found on the Butterfly website (See below table of various ultrasound manufacturers). The

hardware should be cleaned with an LLD, and transducers should be cleaned and disinfected as detailed below.

- If available, equipment covers, such as for the ultrasound scanner console, will enhance the workflow, as LLD of mechanical keyboards and console controls is time-consuming. It is important to note that if the cover is contaminated, it must be cleaned, and the presence of a cover does not preclude the need for cleaning the equipment at regular intervals.
- Reduce the number of transducers connected to the ultrasound machine to a minimum. All other transducers should be individually stored safely in a clean, closed cabinet and brought out as needed.
- Ultrasound transducers and cables should be cleaned (see Transducer cleaning and disinfection), and this should also be performed after each scan.

Transducer cleaning and disinfection

Reusable medical devices are classified into three categories based on the Spaulding classification system depending on the procedure and risk, which includes non-critical, semi-critical and critical (also referred to as low risk, medium risk and high risk).

- a. Non-critical devices are ultrasound transducers that come into contact with intact skin; examples include transducers used for trans-abdominal, musculo-skeletal (MSK), vascular and lung ultrasound, *etc.* As the risk of infection transmission is low, ultrasound transducers can be cleaned and disinfected using an LLD or intermediate-level disinfection, which will denature most bacteria, some fungi and some viruses, such as COVID-19, influenza A and human immunodeficiency virus.
- b. Semi-critical devices are ultrasound transducers that come into contact with non-intact skin, blood, body fluids and mucous membranes; examples include vaginal, esophageal and rectal ultrasound transducers and those used in interventional procedures that are at risk of contact with body fluids. As the risk is higher for infection transmission, ultrasound transducers must be cleaned and disinfected using a high-level disinfection (HLD) method. A single-use transducer cover is mandatory.
- c. Critical devices are ultrasound transducers that are used for invasive procedures (*e.g.*, needle guidance during biopsies, aspirations and drainages) and where there is a risk of blood or body fluid exposure. These transducers must undergo sterilization if compatible or, if not, must undergo HLD, as per medical facility guidelines. Use of sterile transducer covers is mandatory.

Reprocessing ultrasound transducers requires 2 steps: cleaning followed immediately by disinfection. Any product used for cleaning or disinfection must be compatible with the ultrasound

equipment as determined by the ultrasound equipment manufacturer. Certain products may damage ultrasound equipment or transducers and invalidate warranties. It is also essential to follow the instructions for use to ensure the entire process has been successful (*e.g.*, maintaining “wet” contact time for chemical disinfection and accurate time for a soak solution). Furthermore, it is important to wear gloves for cleaning and disinfection of ultrasound transducers and to perform hand hygiene upon removal of gloves.

In the context of COVID-19, the normal practices of HLD are not changed (*i.e.*, endocavitary transducers still require cleaning followed by HLD). The only change in the context of COVID-19 is that all external probes must undergo cleaning followed by LLD to denature any presence of SARS-CoV-2 (*e.g.*, transducers used for trans-abdominal scanning, lung ultrasound or in the pediatric or emergency department setting). It is important to note that the LLD for COVID-19 is approved for use on ultrasound transducers and has proven viricidal efficacy.

Cleaning. Cleaning is an important first step because any remaining gel can act as a barrier to the disinfectant, thus diminishing its efficacy. The CDC defines cleaning as “the removal of foreign material (*e.g.*, soil and organic material) from objects and is normally accomplished using water with detergents or enzymatic products.” Ineffective cleaning before disinfection can limit the effectiveness of the chemical disinfection.

Current recommendations for cleaning transducers are as follows (steps to be performed with disposable gloves):

- a. Disconnect the transducer.
- b. Remove the transducer cover (where applied) and dispose of in clinical waste.
- c. Rinse the end of the transducer with tap water to remove any residual gel or debris.
- d. Clean the transducer with a damp gauze pad or other soft cloth and a small amount of mild nonabrasive liquid soap (approved for use on medical instruments) to thoroughly cleanse the transducer. Consider the use of a small brush especially for the crevices and areas of angulation depending on the design of your particular transducer.
- e. Rinse with tap water.
- f. Clean all other parts of the transducer (including handle, connector and electrical cord) that cannot be immersed with a low-level disinfectant wipe.
- g. Dry with cloth/towel (residual water can dilute chemical disinfectant, if this is the preferred method)

Disinfection. Always refer to your facility’s infection control policies and protocols as well as the transducer manufacturer’s instruction for use and labels for use. As disinfection technology is rapidly evolving, it is essential to check with the manufacturer about what level the technology offers (low, intermediate or high). This document contains the most current recommendations. As mentioned above, HLD is recommended for endocavitary but not abdominal transducers on intact skin. Specific product instructions must be consulted. Disinfection methods include manual and automated systems that can be either chemical or light based.

1. Chemical “wet” disinfection:

- 2.4%–3.2% glutaraldehyde products (such as Cidex [ASP, Advanced Sterilization Products, Zug, Switzerland], Metricide [Metrex, Orange, CA, USA] or Procide [Metrex])
- Non-glutaraldehyde agents (such as Cidex OPA (o-phthalaldehyde), Cidex PA (hydrogen peroxide and peroxyacetic acid))
- Approved multi-step disinfectant wipes containing chlorine dioxide, used extensively in the United Kingdom and Australia (Tristel Duo [Tristel, Snailwell, Cambridgeshire, UK])
- 7.5% hydrogen peroxide solution works by producing destructive hydroxyl free radicals.
- Sodium hypochlorite 0.21% (Antisapril Blu 2% [Monteroni d’Arbia, Italy])

A very large number of disinfectants are available throughout the world. Various ultrasound manufacturers have clear instructions. See examples in the following table.

Butterfly	https://www.butterflynetwork.com/covid19/cleaning-and-disinfection
Canon/Toshiba	https://global.medical.canon/products/ultrasound/more_information/guideforcleaning
GE Healthcare	https://www.gehealthcare.com/products/ultrasound/ultrasound-transducers
Mindray	https://www.mindraynorthamerica.com/wp-content/uploads/2019/03/Mindray_M-transducers_disinfection-guide_40369A.pdf
Philips	https://www.usa.philips.com/c-dam/b2bhc/master/whitepapers/ultrasound-care-and-cleaning/disinfectant-tables-manuals/dt-us.pdf
Samsung	https://samsunghealthcare.com/en/products/uss/RS80A-with-Prestige/Radiology/transducers
Siemens Medical Solutions	https://www.siemens-healthineers.com/en-us/ultrasound/ultrasound-transducer-catalog#Care
Zonare/Mindray	https://www.mindraynorthamerica.com/wp-content/uploads/2019/03/Mindray_Zonare-transducers_-disinfection-guide_40368A.pdf

2. Automated HLD:

- Antigermix (Germitec, Ivry-sur-Seine, France): The transducer is placed in a closed cabinet and exposed to high-intensity ultraviolet type C radiation. Vaginal, rectal and esophageal transducers
- Astra VR (CIVCO Medical Solutions, Orange City, CA, USA): Automated disinfection with Cidex OPA and Metricide solutions. Vaginal, rectal and esophageal transducers
- Trophon (Nanosonics, New South Wales, Australia): Sonicated hydrogen peroxide mist. Vaginal, rectal and esophageal transducers
- ADVANTAGE PLUS Pass-Thru Automated Endoscope Reprocessor (Cantel, Little Falls, NJ, USA): Automated disinfection with hydrogen peroxide or ortho-phthalaldehyde. Endoscope

- TD100 (CS Medical, Creedmoor, NC, USA): Automated disinfection with 0.59% Ortho-phthalaldehyde (OPA) or 2.65% glutaraldehyde. Transesophageal transducer
- Series TEE (Soluscope, Aubagne, France): automated disinfection with paracetic acid. Transesophageal transducer

After cleaning, store transducer in a clean closet or its case with foam inset to prevent damage and protect from contamination with dirt, if not immediately re-used.

Specific recommendations regarding ultrasound gel

Ultrasound gel has been associated with numerous outbreaks and, in the context of the COVID-19 pandemic, it is recommended that single-use, non-sterile gel packets are used for any external ultrasound examination with a probable or confirmed COVID-19 patients. Any unused portion should be discarded. If these are not available, use gel bottles for external scans only. It is essential that gel bottles are not topped off, refilled or heated. The lid must remain closed, and the external gel bottle must be disinfected with an LLD as per all other ultrasound machine components.

For any interventional, internal or critical procedures, as per normal safe scanning recommendation, only single-use sterile gel packets are to be used.

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