

WFUMB Position Statement: How to perform a safe ultrasound examination and clean equipment in the context of COVID-19

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Scope and background

On 11 March 2020, the World Health Organization (WHO) formally declared the SARS-CoV-2 also known as COVID-19 outbreak, a pandemic. This has impacted the way that healthcare 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 critically ill^{1,2} and, specifically, for diagnosis of pneumonia in COVID-19 patients.³ Ultrasound is increasingly used within the point of care setting, as chest CT is not often available in the emergency departments.⁴ However, the ultrasound unit can be a potential vector in the transmission of an infection⁵ and previous surveys have indicated a gap in knowledge of basic infection prevention measures in ultrasound.⁶ Due to 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.

There have been several national and international guidelines for general precautions in infection prevention in ultrasound⁷⁻¹² and, more recently, specific guidance for COVID-19.¹³ There are also national and international guidelines for the performance of routine or targeted ultrasound investigations.¹⁴⁻²¹ 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 WFUMB Safety Committee as official guidance with collaboration of experts from various affiliated Federations. Whilst 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) utilizing ultrasound for diagnostic imaging during the COVID-19 pandemic (such as obstetrics, gynecology, point of care ultrasound, accident and emergency medicine, pediatrics, critical care and cardiology). It has been written to protect both patients and healthcare 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 (COVID19)

Severe acute respiratory syndrome coronavirus 2, SARS-CoV-2²², a small lipid based enveloped virus belonging to the coronavirus family is least resistant to inactivation by common disinfectants used in low level disinfection.^{23, 24} 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 minute. 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^{25, 26} and there are increasing reports of asymptomatic carriers of the disease.^{27, 28} 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 which 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.²⁹ Survival on dry inanimate surfaces such as metal, glass, plastic (and ultrasound systems) is, as far as is known, between 48 and 96 hours.^{9, 29} However, SARS coronavirus, Middle East Respiratory Syndrome (MERS) coronavirus or endemic human coronaviruses (HCoV) have been shown to persist on fomites for up to 9 days²⁹ and this is an important consideration for ultrasound equipment used in all clinical settings.

Furthermore, viral RNA has been found in stool samples from infected patients³⁰ and this is a vital aspect to consider for any ultrasound practitioners involved in transrectal 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, for example, acute abdomen or motor vehicle accident, or for obstetrics and gynecology, pregnancy of unknown location/bleeding in early pregnancy. 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 have been 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, 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 locations.

Triage of patients

Generally, this 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.³¹

Protecting the patient and ultrasound practitioner

Preventing transmission of infection requires all healthcare 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 Centers for Disease Control and Prevention²³ 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 practitioner has undergone infection control training and fit testing for respirators, if required (for example N95 and FFP3)
- 3) In order to reduce the risk of transmission, it is important to (i) respect the time of scheduled visits, (ii) widen the appointment intervals in order to prevent crowding in the waiting room and (iii) space the seats 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 at the end of the clinic list so that the equipment and room will undergo vigorous cleaning and disinfection (see below).
- 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 and having the other hand semi-clean but in contact with the keyboard. Applying gel would be with the semi-clean hand dispensing clean gel (see below) with post procedure thorough cleaning of the gel bottle using a low-level disinfectant (LLD).
- 8) If required to scan patient in an isolation room, ultrasound practitioners, as all attending medical staff, should don personal protective equipment (PPE, respirator, goggle, face protective shield, surgical gown and gloves) prior to entry of isolation room, where the level of PPE is set by institutional guidelines.
- 9) Personal protective equipment (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* include:
 - a) Respirator or facemask: As ultrasound practitioners are in close contact with patients, surgical facemasks 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 facemask 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 facemask.
 - 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 manufacturer's reprocessing instructions prior to re-use. Disposable eye protection should be discarded after use. An individual risk assessment should be carried out prior to/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 protecting clothing and equipment must be trained on how to put it on, use/wear it, and 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.^{32, 33}

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 low-level disinfectant, LLD, recommended by the CDC and EPA^{23, 24}, such as quaternary ammonium compounds (see below). 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 prior to 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 exam.
- 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 afterwards.

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 patients.
- Equipment should be cleaned using agents recommended by the CDC and EPA^{23, 24} (LLD).
- 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 this should also be performed after each scan.

Transducer cleaning and disinfection

Reusable medical devices are classified into 3 categories based on the Spaulding Classification system depending on the procedure and risk. They include 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 transabdominal, MSK, vascular, lung ultrasound etc. As the risk of infection transmission is low, ultrasound transducers can be cleaned and disinfected using a low- or intermediate level disinfection, which will denature most bacteria, some fungi and some viruses, such as COVID-19, influenza A and human immunodeficiency virus (HIV).
- 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, 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 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, drainages) and where there is a risk of blood or body fluid exposure. These transducers must undergo sterilization, if compatible, or, if not, 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 eg: maintaining ‘wet’ contact time for chemical disinfection, accurate time for a soak solution etc.

Furthermore, is important to wear gloves for cleaning and disinfection of ultrasound transducers and hand hygiene upon removal of gloves.

In the context of COVID-19, the normal practices of high-level disinfection 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 low level disinfection to denature any presence of SARS-CoV-2 e.g. transducers used for transabdominal scanning, lung ultrasound or in the pediatric or emergency department setting. It is important to note that the low level disinfectant for COVID-19 is approved for use on ultrasound transducers and has proven viricidal efficacy.

1. Cleaning

This is an important first step since any remaining gel can act as a barrier to the disinfectant thus diminishing its efficacy. The US Center for Disease Control and Prevention (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 prior to 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)

2. Disinfection

Always be sure to 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 what level the technology offers (low, intermediate or high). This document recommendations are the most current. As mentioned above, high-level disinfection is recommended for endocavitary but not abdominal transducers on intact skin.

Specific product instructions must be consulted. Disinfection methods include manual and automated systems which can be either chemical or light based.

a. Chemical “wet” disinfection:

- 2.4-3.2% glutaraldehyde products (such as "Cidex," "Metricide," or "Procide").
- Non-glutaraldehyde agents (such as Cidex OPA (o-phthalaldehyde), Cidex PA (hydrogen peroxide & peroxyacetic acid).
- Approved multistep disinfectant wipes containing chlorine dioxide, used extensively in the UK and Australia (Tristel Duo®)
- 7.5% Hydrogen Peroxide solution works by producing destructive hydroxyl free radicals.

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

Canon/Toshiba	https://global.medical.canon/products/ultrasound/more_information/guideforcleaning
GE	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	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

b. Automated high-level disinfection:

- Antigermix (Germitex, France): the transducer is placed in a closed cabinet and exposed to high-intensity ultraviolet type C radiation. Vaginal, rectal, esophageal transducers
- Astra VR (CIVCO medical, USA): automated disinfection with Cidex OPA and Metricide solutions. Vaginal, rectal, esophageal transducers
- Trophon (Nanosonics, Australia): sonicated hydrogen peroxide mist. Vaginal, rectal, esophageal transducers
- ADVANTAGE PLUS™ Pass-Thru Automated Endoscope Reprocessor (Cantel, USA): automated disinfection with hydrogen peroxide or ortho-phthalaldehyde . Endoscope
- TD100 (CS Medical, USA): automated disinfection with 0.59% Ortho-phthalaldehyde (OPA) or 2.65% glutaraldehyde. Trans-esophageal 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 case. Any unused portion should be discarded. If these are not available, for external scans only, use gel bottles. 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 low level disinfected 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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