

WFUMB Position Paper:

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

1	WFUMB Position Statement: How to perform a safe ultrasound examination and clean equipment in
2	the context of COVID-19
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13	Table of contents
14	Introduction
15	Scope and background
16	Purpose
17	Properties and spread of SARS-CoV-2 (COVID-19)
18	Scheduling of patients
19	Standard and transmission- based precautions for COVID-19

20	Triage of patients
21	Protecting the Patient and Ultrasound Providers
22	Preparing and Cleaning the Ultrasound Room
23	Ultrasound equipment disinfection
24	Transducer cleaning
25	Specific recommendations regarding ultrasound gel
26	Recommendations for safe scanning
27	References
28	
29	Scope and background
30	On 11 March 2020, the World Health Organization (WHO) formally declared the SARS-CoV-2 also known
31	as COVID-19 outbreak, a pandemic. This has impacted the way that healthcare facilities operate globally
32	to ensure patient and practitioner safety and to minimize all risks associated with infection transmission.
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35 36 37	care. Bedside lung ultrasound has been invaluable in 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 CT is not often available in the emergency departments (Poggiali, et al. 2020). Ultrasound may also be used for longitudinal monitoring

al. 2019). 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.

44 There have been several national and international guidelines for general precautions in infection 45 prevention in ultrasound. Several have been published (Kanagala, et al. 2011, Hoyer, et al. 2016, 46 Abramowicz, et al. 2017, Basseal, et al. 2017, Nyhsen, et al. 2017, Liu, et al. 2018, Muller, et al. 2018) but 47 some societies have developed and published cleaning guidelines on their websites, but not in peer 48 reviewed journals (for example, American College of Emergency Physicians(Acep 2018) [ASEP], American College of Radiology [ACR], International Society of Ultrasound in Obstetrics & Gynecology [ISUOG] 49 50 https://www.isuog.org/resource/isuog-safety-committee-position-statement-safe-performance-of-51 obstetric-and-gynecological-scans-and-equipment-cleaning-in-the-context-of-covid-19.html, and the 52 American Institute of Ultrasound in Medicine [AIUM], 53 https://www.aium.org/accreditation/Guidelines Cleaning Preparing.pdf) . More recently, specific 54 guidance documents for COVID-19 have also been published on various websites (for instance ISUOG, 55 see above and AIUM https://aium.s3.amazonaws.com/covid19/Covid19 Quick Guide PUPP.pdf and 56 https://aium.s3.amazonaws.com/covid19/Covid19 Quick Guide UTEG.pdf). There are also national 57 and international guidelines for the performance of routine or targeted ultrasound investigation (Acep 58 2009, Asum 2014-2020, Dietrich, et al. 2017, Aium 2018, Aakjær Andersen, et al. 2019, Scor/Bmus 2019). The decision as to what constitutes an elective or an emergency examination is to be made 59 60 locally and is not the goal of this document, rather it is intended to serve as guidance on infection 61 control when performing ultrasound examinations in the context of the current COVID-19 pandemic. 62 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 63

64 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. 65 66 Purpose 67 This statement provides guidance on equipment cleaning and safe performance of ultrasound 68 examination within the context of COVID-19. It is relevant to all practitioners (sonographers, physicians 69 and allied health professionals) utilizing ultrasound for diagnostic imaging during the COVID-19 70 pandemic (such as obstetrics, gynecology, point of care ultrasound, accident and emergency medicine, 71 pediatrics, critical care and cardiology). It has been written to protect both patients and healthcare 72 workers, particularly when scanning suspected or confirmed COVID-19 patients. 73 As the evidence base for COVID-19 is rapidly evolving, this document is current at time of publication 74 and further updates may be provided as new evidence emerges. 75 Properties and spread of SARS-CoV-2 (COVID19) 76 Severe acute respiratory syndrome coronavirus 2, SARS-CoV-2 (Gorbalenya, et al. 2020), a small lipid 77 based enveloped virus belonging to the coronavirus family is least resistant to inactivation by common 78 disinfectants used in low level disinfection (see guidelines on Center for Disease Control,CDC (Cdc 2015) 79 and Environmental Protection Agency, EPA websites). The structure of these viruses includes a lipid 80 envelope, which is easily disrupted by most disinfectants such as 62–71% ethanol, 0.5% hydrogen 81 peroxide or 0.1% sodium hypochlorite within 1 minute. Other biocidal agents such as 0.05–0.2% 82 benzalkonium chloride or 0.02% chlorhexidine digluconate are less effective. The virus is involved in 83 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. 84 85 2020). As such, ultrasound practitioners need to implement appropriate infection prevention measures 86 not only with confirmed but also suspected COVID-19 patients.

87 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 88 89 droplets have landed on surfaces, their viability depends on the type of surface and temperature 90 (Kampf, et al. 2020). Survival on dry inanimate surfaces such as metal, glass, plastic (and ultrasound 91 systems) is, as far as is known, between 48 and 96 hours (Nyhsen, et al. 2017, Kampf, et al. 2020). 92 However, SARS coronavirus, Middle East Respiratory Syndrome (MERS) coronavirus or endemic human 93 coronaviruses (HCoV) have been shown to persist on fomites for up to 9 days (Kampf, et al. 2020) and 94 this is an important consideration for ultrasound equipment used in all clinical settings. 95 Furthermore, viral RNA has been found in stool samples from infected patients (Holshue, et al. 2020) 96 and this is a vital aspect to consider for any ultrasound practitioners involved in transrectal ultrasound 97 or scanning infants within the pediatric setting. 98 Scheduling of patients (general recommendations) 99 Non-essential examinations should be deferred or cancelled to minimize exposure of an at-risk group of 100 patients to potential COVID-19 contact in the hospital environment. Acute situations may require 101 immediate point-of-care or other ultrasound examinations, for example, acute abdomen or motor 102 vehicle accident, or for obstetrics and gynecology, pregnancy of unknown location/bleeding in early 103 pregnancy. All patients and visitors should be screened using standardized checklists for symptoms of 104 acute respiratory infection, significant travel history, occupation, contacts, etc., consistent with 105 recommendations of local authorities. Ideally, triage should have been undertaken before the patient 106 arrives to the ultrasound unit.

107

108 Standard and transmission-based precautions for COVID-19

109 Aspects that should be considered when planning to perform an ultrasound in a clinical care setting in

110 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

113 professions).

- How to prepare and clean the ultrasound room and equipment.
- 115 NOTE: It is evident that some of these recommendations may not be applicable to all practices.
- 116 Furthermore, it is understandable that some may not be achievable in some locations.

117 Triage of patients

118 Generally, this must be determined by local facilities/authorities (see above). Some scientific societies

119 may already have such recommendations, published or in press at the time of this document

120 preparation(Boelig, et al. 2020).

121 Protecting the patient and ultrasound practitioner

- 122 Preventing transmission of infection requires all healthcare practitioners to implement both standard
- and transmission-based precautions, regardless of suspected or confirmed COVID-19. Standard
- 124 precautions for COVID-19 as outlined by the Centers for Disease Control and Prevention in 2020 include:
- 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.
- Ensure the ultrasound practitioners has undergone infection control training and fit testing
 for respirators, if required (for example N95 and FFP3)

- 130 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.
- 133 4) Limit the number of visitors in the examination room to a maximum of 1, preferably with no
- 134 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.
- 137 5) If the status of a patient is confirmed as COVID-19 infected, it would be preferable to scan at
 138 the end of the clinic list so that the equipment and room will undergo vigorous cleaning and
 139 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.
- 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). See details on gel use below.
 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 levelof 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 infection* 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.

168 c) Gloves: Wearing clean, non-sterile gloves upon entry into the patient room or care area is
 169 essential for all ultrasound practitioners. Once the ultrasound examination is complete, remove and
 170 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

178 and potential duties. Training material should be easy to understand and available in the appropriate

- 179 language and literacy level for all workers. Information may be found on the European Centre for
- 180 Disease Prevention and Control (ECDC) and the Occupational Safety and Health Administration (OSHA)
- 181 websites (https://www.ecdc.europa.eu/en/publications-data/disinfection-environments-covid-19 and
- 182 <u>https://www.osha.gov/SLTC/covid-19/controlprevention.html#health</u>).
- 183 Preparing and Cleaning the Ultrasound Room

184 Note: protective eyewear and gloves should be used when cleaning and disinfecting any equipment
 185 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, 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.

202 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.

207 Equipment should be cleaned using LLD with agents recommended by the CDC and EPA (see ٠ 208 websites). This includes the ultrasound equipment monitor and user interface (e.g. keyboard, knobs, 209 track ball, touch screen, etc.). In emergency medicine, primary care and critical care, handheld 210 ultrasound instruments are often used for COVID-19 infected (and other) patients due to ease of 211 transport and seemingly easier methods to keep clean, secondary to simpler user interface. If possible, 212 keep the whole device and phone in a sterile transducer cover sleeve, available commercially. An 213 example of how to place the transducer and ultrasound instrument in a sheath can be found on the 214 Butterfly website. The hardware should be cleaned with LLD and transducers should be cleaned and 215 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

218	note that if the cover is contaminated, it must be cleaned, and the presence of a cover does not
219	preclude the need for cleaning the equipment at regular intervals.
220	• Reduce the number of transducers connected to the ultrasound machine to a minimum. All
221	other transducers should be individually stored safely in a clean closed cabinet and brought out as
222	needed.
223	• Ultrasound transducers and cables should be cleaned (see "Transducer cleaning") and this
224	should also be performed after each scan.
225	Transducer cleaning and disinfection
226	Reusable medical devices are classified into 3 categories based on the Spaulding Classification system
227	depending on the procedure and risk. They include non-critical, semi-critical and critical (also referred to
228	as low-risk, medium-risk and high-risk).
229	a) Non-critical devices are ultrasound transducers that come into contact with intact skin.
230	Examples include transducers used for transabdominal, MSK, vascular, lung ultrasound etc. As the risk of
231	infection transmission is low, ultrasound transducers can be cleaned and disinfected using a low- or
232	intermediate level disinfection, which will denature most bacteria, some fungi and some viruses, such as
233	COVID-19, influenza A and human immunodeficiency virus (HIV).
234	b) Semi-critical devices are ultrasound transducers that come into contact with non-intact skin,
235	blood, body fluids and mucous membranes. Examples include vaginal, esophageal, rectal ultrasound
236	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.

243 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

245 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

248 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.

251 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

253 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

255 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 viricidalefficacy.

258 **1.** Cleaning

259 This is an important first step since any remaining gel can act as a barrier to the disinfectant thus

260 diminishing its efficacy. The US Center for Disease Control and Prevention (CDC) defines cleaning as:

261 "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
- 263 disinfection can limit the effectiveness of the chemical disinfection.
- 264 Current recommendations for cleaning transducers are as follows (steps to be performed with
- 265 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)

267

268 2. Disinfection

269 Always be sure to refer to your facility's infection control policies and protocols, as well as the

270 transducer manufacturer's Instruction for Use and Labels for Use. As disinfection technology is rapidly

- 271 evolving, it is essential to check with the manufacturer what level the technology offers (low,
- 272 intermediate or high). This document recommendations are the most current. As mentioned above,
- 273 high-level disinfection is recommended for endocavitary but not abdominal transducers on intact skin.
- 274 Specific product instructions must be consulted. Disinfection methods include manual and automated
- systems which can be either chemical or light based.

276 a. Chemical "wet" disinfection:

277

- 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.

278

- 279 A very large number of disinfectants are available throughout the world. Various ultrasound
- 280 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

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291 Specific recommendations regarding ultrasound gel

- 292 Ultrasound gel has been associated with numerous outbreaks and in the context of the COVID-19
- 293 pandemic, it is recommended that single-use, non-sterile gel packets are used for any external
- 294 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
- 297 must be low level disinfected as per all other ultrasound machine components.
- 298 For any interventional, internal or critical procedures, as per normal safe scanning recommendation,
- 299 only single use, sterile gel packets are to be used.
- 300

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379 **Acknowledgements:** Thank you to Oliver Kripfgans, PhD and Sue Westerway, PhD for their input.