Prevention of pathogen transmission during ultrasound use in the Intensive Care Unit: Recommendations from the College of Intensive Care Medicine Ultrasound Special Interest Group (USIG)

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Abstract

ICU ultrasonography constitutes important part of modern car patient care. Current standards and practice of infection control and prevention are inadequate. This purpose of this document is to adapt and expand the 2017 Australasian Society for Ultrasound in Medicine (ASUM) and the Australasian College for Infection Prevention Control (ACIPC) guidelines on minimum standards for reprocessing/cleaning of ultrasound transducers to the specifics of intensive care medicine and provide advice to the ICU practitioners and health care administrators. It considers the medical, administrative, financial and practical controversies surrounding implementation, and addresses emerging issues of care for patients with confirmed or suspected Corona Virus Disease 2019 (COVID-19).

Keywords: disinfection, guidelines, ICU, infection prevention, intensive care, patient safety, recommendations, ultrasound.

Background

The Australasian Society for Ultrasound in Medicine (ASUM) and the Australasian College for Infection Prevention Control (ACIPC) published guidelines on minimum standards for reprocessing/cleaning of ultrasound transducers in 2017 to further regulate the framework relevant to the practice of ultrasonography for all medical specialities in Australia and New Zealand.[1]

This purpose of this document was to adapt and expand the 2017 ASUM/ACIPC guidelines to the specifics of intensive care medicine and provide advice to the ICU practitioners and healthcare administrators. It considers the medical, administrative, financial and practical controversies surrounding implementation and addresses emerging issues of care for patients with confirmed or suspected Corona Virus Disease 2019 (COVID-19).

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Overview of the ASUM/ACIPC 2017 Guidelines for Reprocessing Ultrasound Transducers

- Failure to adhere to minimum infection control standards, including the proper cleaning and disinfection of the ultrasound equipment, increases the risk of pathogen transmission to patients and staff and has led to infection arising from ultrasound examinations.[2–6]
- The requirements in these guidelines have been based on the standards of AS/NZS4187:2014 and AS/NZS4185:2006

- Low-level instrument grade disinfection (LLD): disinfectant that kills vegetative bacteria, some fungi and few viruses.
- High-level instrument grade disinfection (HLD): disinfectant that kills all microorganisms except for high numbers of bacterial endospores.
- Low-level instrument grade disinfection (LLD): disinfectant that kills vegetative bacteria, some fungi and few viruses.
- The ASUM/ACIPC guidelines do not mention intermediate-level disinfection (ILD) as it was unavailable at the time of publication. It is used for intermediate level disinfection of non-critical ultrasound probes and equipment. While the ILD technology offers higher levels of disinfection than LLD, this should not be confused as being HLD in the context of ICU patient management.
- The Spaulding classification system is used to sub-categorise ultrasound devices as non- critical, semi-critical or critical based on the risk of infection transmission.
  - Non-critical: ultrasound probes that encounter unbroken and uninfected. They require LLD following clinical use.
  - Semi-critical: ultrasound probes that come into contact with non-intact skin and / or mucous membranes and transducers that have had likely contact with blood / body fluids are considered as semi-critical medical devices due to the high risk of potential contamination. They require HLD following clinical use.
  - Critical: ultrasound probes that come into contact or proximity to broken skin, blood, bodily fluids, infected tissue or mucus membranes. They require HLD following clinical use.
- Cleaning and removal of organic debris is an essential first step before any disinfection.
- Following ultrasound-guided insertion of vascular devices or body cavity drainage, the guidelines allow for either LLD or HLD. LLD may be considered adequate if the study was conducted over clean intact skin using a sterile probe cover that had not been damaged during the procedure. The decision between the two levels remains at the discretion of a clinician and/or local policy, based on clinical judgement of the probe's 'close proximity' to the broken or infected skin.
- Successful cleaning and disinfection require the correct use of products and appropriate levels of training by all staff involved.
- Ultrasound gels have been the source of past outbreaks of infection. The use of sterile gel is recommended for all invasive procedures.
- Documentation following HLD should include the date, time, transducer probe, the person performing disinfection and cleaning agent used (including batch numbers).
- Specific reference tables for cleaning ultrasound transducers relevant for different clinical specialities are provided but not ICU.

Current specifics of ultrasound practice within intensive care relevant to infection control

- Most ICU ultrasound studies are performed as a point of care investigations (POCUS), ranging from basic to highly advanced.[7–22]
- The use of ultrasound and echocardiography within intensive care medicine has expanded rapidly. While the majority of ICUs now possess modern ultrasound machines, the quantity and quality of scanners do not often match clinical needs. Funding models remain mostly ad-hoc. In particular, there has been underinvestment in the wider logistical components needed to support the safe use of ultrasound within ICU. As a result, infection control is often grossly inadequate.[23–27]
- Demand for ultrasound use is high. Scanners must be available at all times for immediate use. This requires either the availability of multiple machines or rapid disinfection turnaround to avoid compromise of either clinical service or infection control measures.
- Demand for POCUS greatly accelerates during mass admissions of patients with highly transmissible infections, such as severe acute respiratory syndrome coronavirus 2 (SARS CoV-2).[28–32]
- In contrast with radiology and cardiology, ICU practitioners rather than sonographers perform the majority of studies as a component of complex clinical management, while simultaneously providing care to other critically ill patients. The pressure of prioritising other immediate tasks frequently competes with the time required to perform scanning and follow adequate infection control measures.[7] This issue is particularly relevant in times of mass casualties and pandemics.
- In contrast with radiology and cardiology, intensive care doctors are traditionally responsible for cleaning and disinfection of ultrasound equipment. A survey of ICU and ED departments found that 50% of probes retained traces of blood despite current cleaning/disinfection regimes.[24] Contaminated equipment presents a clear danger to other patients, staff and visitors.
- In contrast with radiology and cardiology, ICU has a large cohort of doctors with variable seniority, backgrounds and rotation terms who are performing POCUS. This precludes adequate training in disinfection and results in significant variability of skills in infection control standards.
- There is a high prevalence of patients with multidrug-resistant organisms, immunocompromise and airborne pathogens in ICU. This predisposes to a greater danger of cross-contamination and demands frequent high-level disinfection (HLD) of ultrasound equipment compared with other clinical settings.[2–4]
- Ultrasound equipment in ICU has a large exposure to the extracorporeal biohazards, especially due to the high rate of invasive and semi-invasive procedures. This is especially

relevant for patients with droplet and airborne transmissible pathogens (e.g. SARS-CoV-2).[32]

Current methods of disinfection

Ultrasound probes and scanners cannot be sterilised. A table outlining different methods of disinfection is provided below Table 1.

Different manufacturers produce an array of different products, each with advantages and disadvantages that are best assessed according to local needs. Options exist for all disinfection methodology with and without need for the purchase of upfront capital equipment. A complete list of all TGA045 approved ultrasound cleaning agents is available at: https://tga-earch.clients.funnelback.com/s/search.html?query=&collection=tga-artg

Table 1: Current methods of disinfection.

Disinfection	Type	Methodology	Upfront Capital Expenditure
Low level disinfection (LLD)	Chemical	Wipes	No
Intermediate level disinfection (ILD)	Chemical	Wipes	No
High level disinfection (HLD)	Chemical	Wipes	No
		Soaks	Yes
		Sonicated Hydrogen Peroxide mist	Yes
	Ultraviolet light	UV-C	Yes

Objective costs and practicality

Our current review of available options (at time of publication) for one LLD of probe and high-frequency touch area of machine suggests that the costs can be limited to AUD$2-5 for LLD and AUD$3-23 for HLD, depending on the chosen option and the manufacturer. The time required for one cycle of LLD can be as short as 2 minutes, while HLD ranges from 3 to 30 min. Therefore, time and cost should not be barriers to the wide adoption of appropriate infection control measures. The necessary expense is justifiable, given the potential for iatrogenic harm.

Recommendations from the USIG

The CICM USIG welcomes the ASUM/ACIPC guidelines[1] as offering clear advice on infection control to a wide group of practitioners involved in ultrasound medicine. The specifics of practice within intensive care settings require further clarifications and expansion of these guidelines.

Correctly followed infection control policies and procedures represent the best opportunity to mitigate risks and optimise benefits that ultrasound brings to critical care patients.[25–27]

Provision of safe medical care and minimisation of iatrogenic risks is a joint responsibility between healthcare organisations and healthcare practitioners.

Ultrasound-guided procedures

Most ultrasound-guided procedures in intensive care are urgent and are performed with live guidance involving sharp objects, such as needles, trocars and scalpels. The setting presents an elevated risk of unintended micro or macro perforation of the sterile plastic probe cover resulting in exposure of the patient and the equipment. In response to the absence of clear evidence of harm as well concerns as to the practicality of HLD after ultrasound-guided procedures, the ASUM/ACIPC 2017 guidelines[1] permit LLD if the clinician judges that the transducer has remained at 'some distance' from potential contamination. The term 'some distance' offers excessive ambiguity. Considering all risks, the specifics of ICU practice as well as the minimal time and cost difference between options, HLD is preferred and recommended over LLD as the standard of care following ultrasound-guided procedures within ICU.

Ultrasound machine and probe

Immediately cleaning following use, prevents drying and adherence of biological debris which may interfere with disinfection later. Disinfection immediately before the use minimises the risk of probe contamination. Individual policies must consider these factors in designing workflows reflecting local specifics.

Cleaning and disinfection of the ultrasound probe alone will not adequately control the transmission of pathogens. Disinfection must apply to the entire ultrasound scanning equipment. High-frequency touch areas such as the keyboard, screen and probe holder are at risk of exposure to the same pathogens and require the same level of disinfection as the probe, frequently requiring HLD.

Following disinfection, it is important that the probe remains uncontaminated prior to subsequent use. The use of clean or sterile covers may avoid contamination of probes following disinfection.

Use of sterile probe covers

Qualitative standards for probe covers are absent. Breakages are rare in high-quality commercial products.[33–36] Sterile sheaths are mandatory for semi-critical procedures such as ultrasound-guided vascular access and critical procedures such as intra-operative ultrasound as well as during trans-rectal and trans-vaginal studies.

Probe covers of correct size and shape minimise image degradation. Home-made solutions such as plastic bags, cling film, surgical gloves or transparent film dressing should not substitute sterile probe covers as these do not offer a consistent barrier. Any detected breach of the sheath surface must immediately prompt the change of the damaged sterile cover.

Performance of transoesophageal echocardiography does not mandate the use of probe cover but is recommended when practical. Progressive image degradation often happens over time as a result of dissipation and drying of the gel inside the plastic sleeve, making long procedures and monitoring applications difficult.

Use of ultrasound gel

Transmission of infection with ultrasound gel has been well reflected in the medical literature.[39–42]

Reusable containers present high-risk to patients due to potential for contamination of gel and bottle surface. While their use may be acceptable in low-risk situations, disinfection of container surfaces before use is necessary, rendering it impractical.

Single-use sachets of sterile ultrasound gel are relatively cheap and present the best option to minimise potential contamination and cross-infection between patients.

Routine warming of the gel is not recommended due to the increased risk of bacterial proliferation.

Documentation and traceability

Documentation of HLD must include the date and time, scanner and transducers identifiers, the name of the person performing disinfection and chemical agents with batch numbers. This documentation must be stored for a period prescribed by the local policy.

Documentation following LLD while preferable is not mandated by these guidelines.[1]

COVID-19

Australian ICUs are facing unprecedented demands with COVID-19 pandemic. There is emerging evidence that point of care ultrasound (POCUS) may be beneficial for assessing pneumonia, adult respiratory distress syndrome and haemodynamic

Table 2: Summary of recommendations from the USIG for Intensive Care Unit settings

Transducer	Procedure	Use of probe cover[b]	Recommendation for minimum standard
External	Intact skin (i.e. transthoracic echocardiography, lung and abdominal ultrasound, soft tissue ultrasound) = non-critical	No	LLD or ILD
	Non intact skin or contaminated with bodily fluid (i.e. transcranial Doppler with leaking CSF) = semi-critical	Yes/No	HLD[a]
	Broken skin, visible skin lesions, ulcers, infected skin = semi-critical	Yes/No	HLD[a]
	Ultrasound-guided invasive procedure (vascular cannulation, pleural, abdominal and pericardial drainage, abscess drainage) = critical	Yes	HLD[a] (due to use of sharp objects and elevated risk of perforation of cover)
Internal	TOE = critical	No	HLD[a]
		Yes	HLD[a]
	Intracardiac = critical	No	Not-reusable, discard after use
Intraoperative	Epicardial, vascular, intra-abdominal = critical	Yes	HLD[a]

Colour codes:
Blue = Low or intermediate level disinfection (LLD or ILD).
Yellow = High level disinfection (HLD).

[a] HLD to be performed only by specially trained personnel. Separate trays for dirty and clean TOE probes must always be used.

[b] Probe covers must be of commercial nature and intended for use on a medical device.

impairment in patients with COVID-19. In addition, all patients admitted to ICU will require ultrasound-guided procedures.[28–32,43]

The availability of cardiopulmonary ultrasound equipment in ICUs must be scaled to the institutional level, clinical requirements and available expertise and should be regarded as an essential critical care equipment.

The two pillars of ICU care of COVID-19 patients are supportive management and impeccable infection control measures. Medical practitioners and organisations have an obligation to resolve this immediately.

The USIG has sought an advice from specialist's infectious disease experts regarding the levels of disinfection for ultrasound equipment used for surface scanning without obvious biocontamination from COVID-19 patients. The advice states that LLD is sufficient for patients with suspected or confirmed COVID-19, assuming no criteria for HLD are present.

Infection control related to ultrasound equipment is part of a broader safety environment. The American Society of Echocardiography (ASE) has produced a helpful statement on protection of patients and providers during the COVID-19 pandemic that offers wide-ranging advice regarding reviewed indications for echocardiography and infection control measures including handwashing, use of PPE and provision of special care for ultrasound equipment.[3]

Provision of dedicated ICU sonographers is appropriate during mass surge in ICU capacity to assist both clinical service provision and performance of infection control tasks.[32] They will need education and supervision by suitably qualified intensive care specialists, particularly those inexperienced in assessment of hemodynamic state. It is strongly recommended that additional trained non-medical staff specifically tasked with disinfection of ultrasound equipment in ICU must be provided at all times.

Summary of USIG recommendations

The following aspects should be considered for all clinicians and hospital administrators when providing clinical ultrasound services for critically ill. Table 2 below summaries all procedural recommendations.

General principles

- Ultrasound medicine is an integral part of diagnostic, monitoring and interventional practice of modern critical care medicine, including POCUS in mass casualties and pandemics.
- Policies for cleaning and disinfection of the ultrasound equipment should be standardised and form a part of the overall strategy of infection control across ICUs.
- Optimisation of infection control policies and procedures should reflect local specifics and should be done under the guidance of intensive care specialists involved in the provision of ultrasound services.
- Clinicians carry joint responsibility with the organisations for minimising the risks of iatrogenic infection associated with practising ultrasound medicine.
- Healthcare organisations are responsible for providing sufficient resources to ensure adequate implementation and ongoing maintenance of infection control and prevention, including periods of mass casualties and pandemics.
- Physicians should not be required to consider prioritising patient care duties against ultrasound equipment disinfection tasks.
- All clinicians using ultrasound equipment must be familiar with these policies and procedures.
- If available, the use of touch screen machine interfaces over difficult to clean controls that use knobs, dials and sliders is recommended when they offer similar or superior user control.
- Research should be conducted on infection control associated with ultrasound practice in intensive care.

Specific recommendations

- Single-use sachets of sterile ultrasound gel should be used within ICUs. Reusable gel containers are not recommended.
- Appropriate high-quality sterile covers should be used for ultrasound probes during invasive procedures.
- All cleaning and disinfection procedures should follow manufacturer guidelines.
- Cleaning and removal of debris must always precede disinfection.
- Detailed recommendations for levels of probe disinfection are summarised in Table 2.
- Detailed workflow process descriptions are available in 2017 ASUM/ACPC guidelines.[1]
- High touch areas of the ultrasound machine should be disinfected to the same level as probes after each patient.
- Low touch frequency areas of the ultrasound machine should be cleaned in accordance with the local policy adopted for mobile ICU equipment and disinfected following exposure to contaminants.
- HLD is recommended over LLD following all ultrasound-guided invasive procedures.
- LLD and ILD is acceptable for ultrasound probes used over intact and non-infected skin.
- Where appropriate, probes should be stored in clean disposable covers to minimise risk of environmental contamination.
- Cleaning and disinfection of ultrasound equipment should be the responsibility of adequately trained non-medical staff such as dedicated ICU sonographers, Central Sterile Service Department staff, ICU equipment officers and cleaning staff.
- Medical proceduralists can be reasonably expected to perform cleaning of the equipment from biological debris immediately following use, subject to clinical priorities.
- Dedicated adequately trained non-medical personnel within intensive care departments must be available during and out-

of-hours periods to conduct disinfection of the ultrasound equipment.
- Documentation following HLD should be standardised as per ASUM/ACIPC guidelines[1] and regularly audited.
- Documentation following LLD is preferable but not mandatory.
- Hospital's administration is fully responsible for the provision of human and material resources to ensure adequate compliance with these recommendations commensurate with local unit requirements and available ultrasound expertise.
- Infection prevention and control should be included in future CICM curriculum revisions of ultrasound modules and accreditation of intensive care units for training.
- Infection prevention and control in ultrasound practice within intensive care units should be included in future Australian Council on Healthcare Standards' hospital accreditation standards.

COVID-19 recommendations

- LLD is sufficient for patients with suspected or confirmed COVID-19 who do not meet standard criteria for HLD.
- Provision of additional cardiopulmonary ultrasound equipment scaled to clinical need and available expertise.
- Provision of dedicated ICU sonographers and additional non-medical staff tasked with disinfection of equipment is recommended to meet surge demand and improve infection control.
- The writing group agrees with and recommends implementation of advice provided by ASE advisory statement.[32]

Conclusions

ICU ultrasonography constitutes important part of modern standards of care, but infection control and prevention remain inadequate. Immediate wide implementation of 2017 ASUM/ACIPC recommendations and these specific ICU guidelines is necessary to support critical care services and prevent avoidable iatrogenic risk, especially during current SARS-CoV2 pandemic.

Authorship statement

The authors declare that this manuscript confirms with authorship policy and that all authors are in agreement with the content of this manuscript.

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Conflict of Interest

The authors of this article have no conflicts of interest to disclose.

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Appendices

Definitions/Abbreviations

- *Cleaning* describes the physical removal of debris from a surface typically using detergent and water. This process may reduce but does not eliminate microorganisms.
- *Disinfection* describes a process that kills a large proportion but not necessarily all microorganisms from a surface.
- *Sterilisation* destroys microorganisms, rendering devices free from viable microorganisms. The heat required for sterilisation damages ultrasound transducers making this impossible. Ultrasound probes can be covered with sterile sheaths.
- *Non-critical medical device* only comes into contact with intact skin and not mucus membranes.
- *Semi-critical medical device* is a medical device that comes into contact with mucus membranes or non-intact skin.
- *Critical medical device* is a medical device that comes into contact with sterile tissues.

Summary of standards, regulatory bodies and advisory statements

- There is a complex, interrelated network of rules, regulators, guidelines and advisory statements. A summary is provided to help navigate these complex waters for those interested.

- *The Australasian Society for Ultrasound in Medicine (ASUM)* is the leading multidisciplinary medical ultrasound society advancing the clinical practice of diagnostic medical ultrasound.
- *The Australasian College for Infection Prevention and Control (ACIPC)* is the peak body for Infection Prevention and Control professionals in Australasia.
- Following an 18-month collaboration, ASUM and ACIPC produced consensus guidelines in 2017 'Guidelines for reprocessing Ultrasound Transducers' to replace ASUM's B2 guidelines that were general, largely aspirational and provided little practical guidance to the clinician as to the best practice of infection control. In contrast, the 2017 guidelines provide clear advice to clinicians about the best practice of infection control related to cleaning/reprocessing of ultrasound probes.
- Under the *Therapeutic Goods Act 1989*, all medical devices must be included on the *Australian Register of Therapeutic Goods (ARTG)* maintained by the Australian Government Department of Health, *Therapeutic Goods Administration*. In order to be included on the ARTG, devices are assessed to ensure they are of acceptable safety and quality, perform as intended and are then classified according to clinical risk. Ultrasound probes are classified as IIB (medium-to-high risk) re-useable medical devices.
- *Standards Australia* is an organisation recognised through a Memorandum of Understanding with the Australian government as the peak non-government standards development body in Australia. Standards Australia produces standards on a wide range of goods and services from consumer goods to medical standards that are adopted by various regulatory and accreditation bodies as either voluntary or mandatory. Standards Australia produced standards AS/NZS4187:2014 and AS/NZS4185:2006, which form the basis upon which ASUM/ACIPC guidelines are based.
- *Standard 4187* is important. Using the Spaulding classification system, it sub-categorises ultrasound probes into non-critical, semi-critical and critical devices depending on their exposure to infective risk during use that in turn, determines the level of cleaning required. Ultrasound probes that come into contact with unbroken and uninfected skin are categorised and non-critical and require low-level cleaning after use. Ultrasound probes that come into contact or close proximity to broken skin, blood, body fluids, infected tissue or mucus membranes are categorised as semi-critical require high-level cleaning after use and may require the use of a protective sheath during use.
- The Australian Government Department of Health *Diagnostic Imaging Accreditation Scheme (DIAS)* is a mandatory system of registration and compliance standards necessary for all providers of diagnostic imaging seeking Medicare remuneration. Some but not all ICUs have registered with DIAS for purposes of accessing Medicare payments. In July 2018, DIAS issues an *Advisory Statement A18/06* reminding practices that compliance with its own standard.
- *1.6 Health Care-associated Infection* mandated use of high-level disinfectant on semi-critical medical devices such as ultrasound devices using disinfectants compliant with *Therapeutic Goods Order Number 54, Standards for Disinfectants and sterilants (TGO54).*
- Compliance with the ASUM/ACIPC guidelines is mandatory for all ICUs registered with DIAS for the purposes of Medicare income. More importantly, the guidelines are the standards against which all practitioners of ultrasound may be compared against for the purposes of accreditation or litigation.