

GUIDELINES OPEN ACCESS

Guidelines for Reprocessing Ultrasound Transducers: 2026

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ABSTRACT

Introduction: Ultrasound equipment is recognised as a potential source of harmful microorganisms which could lead to clinical infection. This highlights the importance of standardised infection prevention and control strategies for ultrasound practice across Australia and New Zealand. This revised guideline supersedes the similarly named 2017 guideline and was collaboratively developed by the Australasian Society for Ultrasound in Medicine (ASUM) and the Australasian College for Infection Prevention and Control (ACIPC).

Methods: A multidisciplinary working group was assembled consisting of ultrasound practitioners from varying specialty areas and infection control specialists. The guideline recommendations were informed by a review of relevant literature, national and international standards, and current Australian and New Zealand regulatory requirements. A catalyst for the revision of these guidelines was the release of the Australian Standard AS5369:2023—Reprocessing of reusable medical devices and other devices in health and non-health related facilities. Consensus was achieved through structured discussions and iterative drafting including wider stakeholder feedback.

Results: Recommendations for transducer reprocessing were based on the invasiveness of the ultrasound transducer as well as the type of human tissue it contacted during use. Particular attention is also given to the safe use of ultrasound gel, transducer covers, as well as broader considerations of standard and transmission-based precautions, including the use of aseptic technique.

Conclusion: Implementation of this guideline by ultrasound clinicians and their facilities will reduce the risk of transmission of potentially harmful microorganisms and ensure infection prevention and control practices across Australia and New Zealand are aligned with accepted national standards.

Impact Statement: This guideline outlines the Australian and New Zealand standard for infection prevention and control as it relates to ultrasound practice. This 2026 revision supersedes the similarly named 2017 guideline and was collaboratively

Abbreviations: ACIPC, Australasian College for Infection Prevention and Control; ARTG, Australian Register of Therapeutic Goods; AS/NZS4187:2014, Australian/New Zealand Standard Reprocessing of reusable medical devices in health service organisations; AS/NZS4815:2006, Australian/New Zealand Standard Office-based health care facilities—reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment; AS5369:2023, Australian Standard Reprocessing of reusable medical devices and other devices in health and non-health related facilities; ASUM, Australasian Society for Ultrasound in Medicine; AT, Aseptic technique; HLD, High level disinfection; ILD, Intermediate level disinfection; LLD, Low level disinfection; PPE, Personal protective equipment; RMD, Reusable medical device; TGA, Therapeutic Goods Administration.

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developed by the Australasian Society for Ultrasound in Medicine (ASUM) and the Australasian College for Infection Prevention and Control (ACIPC). The multidisciplinary working group used published literature, national and international standards, and relevant regulatory requirements in formulating the recommendations. This guideline should be used by clinicians and facilities using ultrasound to reduce the transmission of potentially harmful microorganisms and improve patient care.

1 | Background

The Australasian Society for Ultrasound in Medicine (ASUM) is the leading multidisciplinary medical ultrasound society creating healthier lives for all by driving ultrasound excellence. The Australasian College for Infection Prevention and Control (ACIPC) is the peak body for Infection Prevention and Control Professionals in the Australian and New Zealand region focused on leadership, promoting education and evidence-based practice outcomes for consumers in all disciplines of healthcare. This revised guideline has been based on a review of recently published evidence including the Australian Standard, AS5369:2023 [1]. The Ministry of Health in New Zealand has also recognised the AS5369:2023 as the most up-to-date standard and has recommended its adoption in their country. This guideline has been developed collaboratively by ASUM and ACIPC to establish accepted guidelines for infection prevention and control when ultrasound equipment is used in clinical practice across Australia and New Zealand and supersedes the similarly named 2017 guideline.

2 | Scope

This guideline represents the best practice standards and applies to all staff who use or reprocess ultrasound equipment, as well as the facilities that they work within. The focus of this guideline is on reusable ultrasound equipment that does not require, or is not suitable for, sterilisation. Reprocessing of endoscopic ultrasound devices with working gas/water channels is addressed by other published guidelines [2]. General infection prevention and control guidance can be found in the Australian Guidelines for the Prevention and Control of Infection in Healthcare [3]. Craft groups and healthcare facilities should consider local infection prevention and control policies and undertake site specific risk assessments when applying these guidelines.

3 | Introduction

The utilisation of ultrasound in medical imaging continues to grow and evolve owing to its portability, safety, and relatively inexpensive nature [4]. The equipment used during ultrasound examinations has been recognised as a potential source of harmful microorganisms which could lead to health-care associated infections [5–8]. Therefore, it is important for operators and facilities using ultrasound equipment to ensure they adhere to the required standards of infection prevention and control.

Ultrasound examinations require direct contact between the patient and the practitioner via an ultrasound transducer. Reusable ultrasound transducers require reprocessing to prevent the

transference of potentially harmful microorganisms between patients. The 2017 ASUM/ACIPC ultrasound transducer reprocessing guidelines were based on the Australian and New Zealand Standards of 4187:2014 and 4185:2006 which have been revised to an Australian Standard in 2023; AS5369:2023 [9–11]. In addition to incorporating amendments consistent with the updated Australian Standard this guideline revision incorporates recently published evidence and supersedes the original 2017 ASUM/ACIPC guideline [12]. In reviewing published evidence relating to infection prevention and control in ultrasound practice, it was recognised that there is a paucity of high-quality evidence and that recommendations made in this guideline are mostly based on lower levels of evidence (e.g., comparative studies, case series and reports, expert opinion, and consensus statements). This should be considered when applying this guideline into clinical practice as should any new evidence released following publication.

3.1 | Ethics Statement

This guideline was developed using a review of published literature, existing standards, and expert consensus. It did not involve the collection of new data from human participants or animals. As such, formal ethics committee approval and informed consent were not required.

4 | Reprocessing of Reusable Ultrasound Equipment

Reprocessing is a multistep process that includes cleaning, device inspection/examination, disinfection or sterilisation, and if applicable packaging and labelling [1]. Adherence to all these steps is important in ensuring ultrasound equipment is safe for ongoing use [1]. Where omissions or errors are made in the steps involved in reprocessing this invalidates the entire process and places the ultrasound equipment at higher risk of transferring potentially harmful microorganisms to the next patient [1].

4.1 | Reprocessing Environment

Consideration should be given to the workflow and environment within which reprocessing occurs. Environmental requirements are dependent upon the type of reprocessing being undertaken and should follow the recommendations in AS5369:2023. When designing or renovating facilities, the environment must be designed to support the effective processing and reprocessing of reusable materials over single use items.

Devices must be reprocessed in a dedicated reprocessing area and/or facility, or if safe and effective to do so they may be reprocessed at the point of use. When reprocessing of ultrasound

Summary

- What is already known about this topic?
 - Equipment used during ultrasound examinations has been recognised as a source of pathogenic microorganisms which could lead to health-care associated infections
 - Reusable ultrasound transducers require appropriate reprocessing to prevent the transfer of potentially harmful microorganisms between patients
 - Infection prevention and control principles must be applied to all ultrasound equipment and to the procedural technique used to perform an ultrasound examination.
- What this paper adds?
 - The recommendations in this guideline are aligned with the requirements of Australian Standard 5369:2023 and supersede the previous version published in 2017.
 - This guideline provides clear and contemporary guidance on infection prevention and control principles as they relate to ultrasound practice.
 - It provides updated recommendations on the level of disinfection required for reprocessing different types of ultrasound transducers.
- The implications of this paper?
 - Standardisation of ultrasound transducer reprocessing practices across clinical settings, reducing variability and uncertainty in infection prevention and control.
 - Improved patient safety through clearer guidance on appropriate disinfection levels, based on transducer type, ultrasound use, and assessed infection risk.
 - Support for organisational policy development, staff training, and auditing by providing evidence-based recommendations aligned across Australia and New Zealand for ultrasound transducer reprocessing.

equipment is to occur at the point of use, this ideally should be a separate area or room to the patient treatment area. If this is not possible, reprocessing and delivering patient care should not take place simultaneously, and an adequate distance is required between the patient, the patient surroundings and the reprocessing activities to minimise possible contamination of the patient or the device [1].

Principles which apply to all ultrasound reprocessing scenarios include:

- The sufficiency of the physical environment (e.g., lighting, ventilation, sinks, bench space, workstations) and other equipment necessary for reprocessing (e.g., personal protective equipment (PPE), hand hygiene stations, waste disposal).

- Ensuring the segregation of clean and dirty areas within the reprocessing environment to minimise the risk of cross contamination between devices.
- A documentation process, relevant to the area of practice.

4.2 | Cleaning and Device Inspection

All ultrasound equipment must be cleaned after each use. Cleaning aims to remove contaminants to the extent necessary for further processing or for intended use [1]. For the purposes of reprocessing, ultrasound equipment can be broadly classified into components that have:

- No direct patient contact—ultrasound machine (e.g., display, interface, and cart).
- Direct patient contact—ultrasound transducer and attached cable (if present).

Cleaning ultrasound equipment should be conducted with solutions and/or wipes that are compatible with the ultrasound device in accordance with the manufacturer's instructions. Where drying is required following cleaning, this should be with low-linting cloths or towels.

After cleaning is complete, ultrasound equipment must be visually inspected for damage or defects and, if identified, the equipment must not be used until it has been repaired or replaced. Damage or defects can prevent the effective reprocessing of ultrasound equipment leading to infection [8, 13, 14].

4.2.1 | Ultrasound Machine

Ultrasound machines are transported between clinical areas and are frequently touched by clinicians, potentially facilitating transmission between patients. This includes the components of the ultrasound machine that do not have direct patient contact (e.g., display, user interface, and workstation). Resultingly, all components of the ultrasound machine are required to undergo a minimum of cleaning between patient uses. Particular attention should be given to frequently touched areas such as keyboards, touch screens, and trackballs, which should undergo thorough cleaning and disinfection between patients, in accordance with the manufacturer's recommendations.

4.2.2 | Ultrasound Transducer and Cable

Cleaning an ultrasound transducer and cable is always required so that subsequent processing steps can occur effectively [1, 15, 16]. For ultrasound transducers and cables cleaning should remove all visible organic (e.g., blood and other body fluids) or non-organic soiling (e.g., gel) [15, 17–19]. This should occur as soon as possible following use to minimise the risk of contaminants drying onto the device. All cleaning products used on ultrasound transducers must be included on the Australian Register of Therapeutic Goods (ARTG) as a Class I or IIb agent suitable for use on medical devices that are compatible

with the medical device to be cleaned. Cleaning wipes and materials should be discarded after use and must not be used for disinfection.

4.3 | Disinfection and Sterilisation

Once clean, ultrasound equipment which has direct patient contact (e.g., transducers) must undergo disinfection or sterilisation dependent upon the infectious risk associated with their next intended use. Disinfection is a process that inactivates viable microorganisms to a level previously specified as being appropriate for a defined purpose [1]. Sterilisation is a validated process to render a product free from viable microorganisms [1]. Ultrasound transducers are heat sensitive devices and heat or steam sterilisation techniques can cause device damage. Therefore, these sterilisation methods are generally not recommended by equipment manufacturers. Low temperature sterilisation processes should only be utilised where this is approved by the manufacturer.

Systems suitable for the disinfection of ultrasound transducers fall into two broad categories.

- Manual systems—immersion in chemical solutions and/or use of chemical impregnated manual disposable wipes/sponges
- Automated disinfection systems—require the transducer to be inserted into a device or machine which then applies the disinfectant, such as chemical or Ultraviolet-C light.

The Therapeutic Goods Administration (TGA) regulates disinfectants based upon their intended use as well as their claims of effectiveness against specific microorganisms based on in vitro testing [20]. Disinfectants used on ultrasound transducers must be approved for use on medical devices and are required to be listed on the ARTG as a class IIb medical device [20]. Details about specific products listed licence class can be found by searching the ARTG website.

4.3.1 | Levels of Disinfection

The level of disinfection achieved by a disinfectant system depends on the types of microorganisms it has been proven to be effective against. Some microorganisms, such as the spores arising from spore forming microorganisms, are highly resistant to some disinfectants. This is in comparison to other microorganisms which are very sensitive to disinfectants such as, larger sized lipid enveloped viruses (e.g., SARS Co-V-2, influenza, hepatitis viruses, human immunodeficiency virus) [21, 22]. Disinfectants are categorised into low-, intermediate-, and high-levels accordingly (Table 1).

4.4 | Rinsing, Drying, Storage and Release

Rinsing the transducer allows for the removal of any residue disinfectant agent and the requirement for this is dependent upon the disinfection system used [1]. If rinsing is required then drying must be with a single-use lint-free cloth.

TABLE 1 | Definition of different levels of disinfection in accordance with AS5369:2023 [1].

Level of disinfection	Definition
Low level disinfection	Destroys all vegetative bacteria (except tubercle bacilli), lipid viruses, some nonlipid viruses, and some fungi, but not bacterial spores
Intermediate level disinfection	Kills all microbial pathogens except bacterial endospores which is bactericidal, tuberculocidal, fungicidal (against asexual spores but not necessarily dried chlamydo spores or sexual spores), and virucidal
High level disinfection	Kills all microbial pathogens, except large numbers of bacterial endospores

Following reprocessing, ultrasound transducers should be stored to minimise contamination between uses. For ultrasound transducers that have undergone high-level disinfection, this may include storage in a dedicated sealed cabinet or using the application of a protective sterile single use storage cover. Transducer covers used for storage act as a barrier to prevent environmental contamination and must not be used on patients at the time of ultrasound examinations. Sterile item storage, handling, and release are required to meet the requirements outlined in AS5369:2023 [1].

Prior to use, the user should be satisfied that the ultrasound equipment has been adequately reprocessed for the purposes of the ultrasound examination to be undertaken. If there is uncertainty about the adequacy of the level of reprocessing prior to use, then the ultrasound transducer must not be used until the appropriate reprocessing requirements have been satisfied and can be assured.

4.5 | Quality Assurance

Reprocessing requires ongoing review to ensure that the effectiveness of processes is maintained. All facilities that use ultrasound equipment are responsible for developing and monitoring reprocessing processes, policies, and procedures that are specific to their work environment and workplace. This should include periodic reassessment of reprocessing facilities and staff training, regular maintenance of reprocessing equipment, and ongoing validation of processes in accordance with the requirements of AS5369:2023.

Regular periodic audits of reprocessing should be performed (e.g., annually). Ultrasound transducers must always satisfy the reprocessing requirements before clinical use and if this cannot be assured the transducer should undergo repeat reprocessing or, if required, quarantined from clinical use until an

investigation and action plan can be undertaken to ensure reprocessing standards are being achieved [1].

4.5.1 | Staff Training and Operator Requirements

All users of ultrasound equipment must be appropriately trained in all aspects of reprocessing relevant to their practice. On commencement, all new staff should undergo a formal induction and/or orientation training program which should include:

- Modes of transmission of infection; hand hygiene; workplace health and safety issues including personal protective equipment (PPE).
- Infection prevention and control principles including standard and transmission-based precautions.
- Reprocessing of ultrasound equipment, including how to:
 - Effectively clean the ultrasound machine and transducer.
 - Determine the appropriate level of disinfection.
 - Undertake the appropriate level of disinfection.
 - Store ultrasound equipment to prevent contamination between uses.
 - Complete the required documentation and record keeping.
- Correct procedure for waste management, including its safe handling and segregation into the appropriate stream.

On completion of training, staff competency in performing reprocessing activities should be objectively assessed. Staff should not use ultrasound equipment independently until this assessment has been completed and recorded. Facilities should keep records of those trained and periodic reassessment undertaken, the timing of which should be based on local policy or guidelines. Additional staff training is required with the introduction of new ultrasound equipment, reprocessing equipment, or a change in reprocessing methods.

4.5.2 | Traceability

A system of traceability should be used for ultrasound equipment, including loan devices, which undergo HLD or sterilisation [1]. Traceability records are intended to associate a single patient care episode with a individual reprocessing cycle. Traceability labels are commonly used for this purpose and, where used, are to be included in the patient's notes or medical record.

For ultrasound transducers undergoing sterilisation or HLD, the traceability system should be sufficient to enable identification of the individual cycle and at a minimum include:

- Transducer type and unique ID number.
- Date of cleaning and the name of competent person responsible for reprocessing.
- Identification of the disinfection process details as well as the cycle number and date of sterilisation or disinfection.

- Individual patient/client identifiers according to local facility requirements.

5 | Infection Prevention and Control Considerations for Ultrasound Equipment

5.1 | Ultrasound Gel

Multiple outbreaks have been linked to bacterial contamination of ultrasound transmission gel [5]. Common infectious microorganisms have included *Burkholderia* spp. [23–26], *Acinetobacter* spp. [27], and *Pseudomonas* spp. [28]. Ultrasound gel has the potential for microbial contamination and therefore, appropriate steps must be taken to minimise the risk of potential infection.

Ultrasound gel is available in single and multi-use containers and must be registered with the ARTG. Single-use products should be discarded following each patient use and have the advantage of avoiding the potential transfer of microorganisms to subsequent patients. If multi-use gel containers are to be used, they must be:

- Cleaned between patient uses.
- Discarded if there are any visible signs of gel contamination.
- Dated at the time it is opened and discarded within the timeframe specified from the manufacturer.
- Stored appropriately and protected from contamination between uses.

Heating of reusable gel bottles is not recommended as this may support microbial growth [6]. If heating is required the risk of microbial growth should be minimised by only warming single use containers or sachets immediately prior to use. Refilling of multiuse containers should not occur due to the higher risk of microbial contamination of the container and gel [6, 27]. Sterile ultrasound gel must be used during ultrasound examinations or procedures where gel could contact mucous membranes or otherwise normally sterile tissue (e.g., wounds, skin puncture sites) [29].

5.2 | Ultrasound Transducers

Ultrasound transducers have direct patient contact, and reprocessing is aimed at mitigating the risk of transmitting pathogenic microorganisms and causing infection at the site of intended use. Risk-based classification systems aim to assess and stratify this risk and then make recommendations for different reprocessing requirements.

AS5369:2023 recognises that the infectious risk is primarily determined by how invasive the device is when being used on a patient [1]. Invasive ultrasound transducers are those that penetrate inside the body, either through a body orifice or through the surface of the body [1, 30]. For the purposes of this guideline an ultrasound transducer is considered to penetrate through the surface of the body only when it is intended to be applied directly into an open wound (non-intact skin) with visible and exposed subcutaneous tissue. Open wounds

include, for example, deep dermal burns and skin ulcers. These invasive ultrasound devices carry a higher risk of causing infection than non-invasive transducers as they bypass the natural barrier and defences presented by the skin and other components of the integumentary system [16]. Non-invasive ultrasound transducers are associated with a lower risk of causing infection as they are applied onto skin thereby benefiting from its intrinsic infection protective properties. Based on this risk assessment invasive ultrasound transducers require reprocessing with high level disinfection or sterilisation and non-invasive transducers are reprocessed using low- or intermediate-level disinfection.

Spaulding's classification further delineates invasive devices into either semi-critical or critical risk classifications based upon the sterility of the human tissue encountered during use [31]. Invasive transducers inserted into areas containing sterile tissue are classified as critical whereas those that contact non-sterile tissues such as mucous membranes (e.g., rectum, vagina) or open wounds (e.g., burns, skin ulcers) are classified as semi-critical. Non-invasive ultrasound transducers are classified into the non-critical level of risk according to Spaulding's system [1] (See Table 2).

In ultrasound practice, where uncertainty regarding the reprocessing requirements exists, undertaking a local risk assessment incorporating other risk assessment methods is recommended and supported by the AS5369:2023 [1]. These scenarios may arise in different clinical settings, patient populations, or with certain procedures involving ultrasound transducers. Examples of clinical settings where a risk assessment might be required could include resource limited areas or time critical environments. To ensure patient safety in low resource settings, the recommendations set out in this guideline should be applied within the context of the available resources, including the available disinfection options. Specific patient populations, like the immunocompromised or critically ill, may also necessitate local risk assessment and

subsequently additional risk-mitigating strategies. In some areas of ultrasound practice, such as ultrasound guided percutaneous procedures, incorporating other additional risk assessment methods may allow for a more contextualised assessment of hazards and their subsequent prioritisation [32]. Where systems, processes, and practices are demonstrably compliant with relevant standards and governance requirements, this evidence may be taken into consideration as part of the overall risk evaluation. A qualified infection prevention and control practitioner should always be engaged when undertaking local risk assessments.

5.3 | Ultrasound Transducer Covers

Ultrasound transducer covers are manufactured single-use disposable plastic covers designed to create a physical barrier between the patient and the ultrasound transducer and cable. Transducer covers are used to:

- Prevent or minimise the contamination and soiling of an ultrasound transducer or cable during use so that subsequent reprocessing may be easier to perform; and/or
- Provide an additional protective barrier between the transducer and cable and the patient, preventing or reducing the exchange of microorganisms between them.

The incidence of transducer cover integrity loss from published data is generally reported as low [33]. The available data would suggest that commercially manufactured covers have a lower failure rate when compared to other non-purpose specific manufactured covers [33]. As such, only commercially manufactured transducer covers listed on the ARTG should be used to cover a transducer. The use of other items such as dressings, condoms, plastic bags, and gloves is not recommended [34–36]. Ultrasound transducer covers should not be used as a substitute for cleaning, disinfection or sterilisation [1].

TABLE 2 | Reprocessing and storage of reusable ultrasound devices in accordance with AS5369:2023 [1].

Invasiveness of the transducer	Level of risk according to Spaulding	Spaulding's definition	Reprocessing requirements
Invasive	Critical	Ultrasound transducer intended to be introduced into or have contact with the vascular system or normally sterile areas of the body	Clean as soon as possible after use. For heat or moisture sensitive devices, sterilise using low-temperature sterilisation process. Sterility to be maintained between uses. Packaged and stored to prevent environmental contamination in a designated storage area in accordance with AS5369:2023
Invasive	Semi-critical	An ultrasound transducer that comes into contact with mucous membranes or non-intact skin	Clean as soon as possible after use followed by low-temperature sterilisation process or high-level disinfection process according to manufacturer's instructions for use. Store to prevent environmental contamination between uses
Non-invasive	Non-critical	An ultrasound transducer that comes into contact with intact skin but not mucous membranes	Clean as soon as possible after use then disinfect with compatible low-level or intermediate level Class IIB disinfectant. Store to minimise environmental contamination between uses

5.4 | Standard and Transmission-Based Precautions in Ultrasound Practice

When reusable ultrasound equipment is being used in clinical ultrasound practice, standard and transmission-based precautions should be adhered to as part of a more broadly encompassing infection prevention and control risk mitigation strategy.

5.4.1 | Standard Precautions and Aseptic Technique

As a minimum, standard precautions must be adhered to in clinical ultrasound practice. Standard precautions include hand hygiene; the use of PPE; respiratory hygiene and cough etiquette; safe use and disposal of sharps; and appropriate environmental cleaning, linen, and waste management [3].

Aseptic technique, as an element of standard precautions, aims to prevent pathogenic microorganisms, in sufficient quantity to cause infection, from being introduced into susceptible body sites by the hands of staff and from surfaces of equipment (e.g., transducers) during a procedure [3, 37]. Incorporating ultrasound transducers into a procedural aseptic technique will demand additional aseptic precautions be taken when compared to similar procedures without ultrasound guidance. These additional requirements can include the use of a sterile transducer cover, sterile gel and sterile gloves. Aseptic technique is often divided into 'Standard' or 'Surgical' where the latter is used for more technically complex procedures, of longer duration, and with large or numerous sterile areas or components [3, 37]. Correspondingly surgical aseptic technique requires more aseptic precautions such as larger critical aseptic fields, surgical hand scrub and full barrier precautions (e.g., hat, mask, eye protection, and sterile gown and gloves) [3]. More detail on aseptic technique, including procedure specific guidance, is available in the Australian Guidelines for the Prevention and Control of Infection in Healthcare [3].

5.4.2 | Transmission-Based Precautions

Transmission-based precautions (TBP) are used in situations where standard precautions alone can be insufficient to prevent infection [3]. These precautions are in addition to the requirements of standard precautions and are applied when patients are known or suspected to be infected or colonised with certain infectious agents. Examples of TBP include contact, droplet, airborne or a combination of these. Where ultrasound equipment is required in patient care areas with TBP it would be appropriate to seek further infection prevention and control advice on how ultrasound equipment used in these scenarios should be appropriately cleaned and disinfected with products that are effective against the known or suspected pathogen.

6 | Application of Infection Prevention and Control Principles to Ultrasound Practice

Outlined below are the infection prevention and control recommendations for ultrasound transducers used in a selection of

common scenarios and have been based on the principles described. Given the breadth of ultrasound use in healthcare, if an area of ultrasound equipment use is not specifically addressed below, the ultrasound practitioner and facility should interpret and apply these principles accordingly using the examples below as a guide.

6.1 | Non-Invasive Ultrasound Transducers

Non-invasive ultrasound transducers do not penetrate inside the body and are commonly used in diagnostic examinations and to aid in the performance of needle-based procedures through the surrounding skin (percutaneous procedures) [30]. Non-invasive transducers are classified as non-critical medical devices according to Spaulding's classification.

6.1.1 | Diagnostic Ultrasound Examinations

These are common ultrasound examinations that rely on the cutaneous application of an ultrasound transducer to obtain diagnostic information. Examples of these include transthoracic echocardiography, vascular, musculoskeletal, soft tissue and abdominal sonography (Figure 1).

6.1.2 | Percutaneous Procedures With Ultrasound Guidance

Ultrasound-guided percutaneous procedures involve applying an ultrasound transducer onto a patient's skin and then introducing a needle through the surrounding skin towards a target region contained within the field of view of an ultrasound transducer [38]. These transducers are considered non-invasive and examples include ultrasound guided central and peripheral vascular access techniques as well as therapeutic and diagnostic injections, aspirations, and biopsies.

There is variation in international societal guidelines on the level of disinfection required of ultrasound transducers to be used in percutaneous procedures [32]. Earlier guidelines, including ASUM/ACIPIC 2017, tended to favour recommending HLD [12, 39]. More recently, LLD has been considered appropriate by some societies [40, 41]. Since the release of earlier published guidelines, there have been improvements in the variety and availability of disinfection systems for ultrasound transducers across Australia and New Zealand. Additionally, the incorporation of ARTG listing requirements for disinfectants in the AS5369:2023 supports the better differentiation and recognition of the various levels of disinfectants suitable for use on ultrasound transducers.

Current evidence suggests that the risk of infection arising from an ultrasound guided percutaneous procedure is likely to be very low, estimated to be 0.1%–0.5% [32]. When used in accordance with the manufacturer's instructions, LLD of ultrasound transducers involved in percutaneous procedures appears to present no higher infection risk compared with HLD [17, 42]. Additionally, the use of LLD for ultrasound transducers used in percutaneous procedures has also been

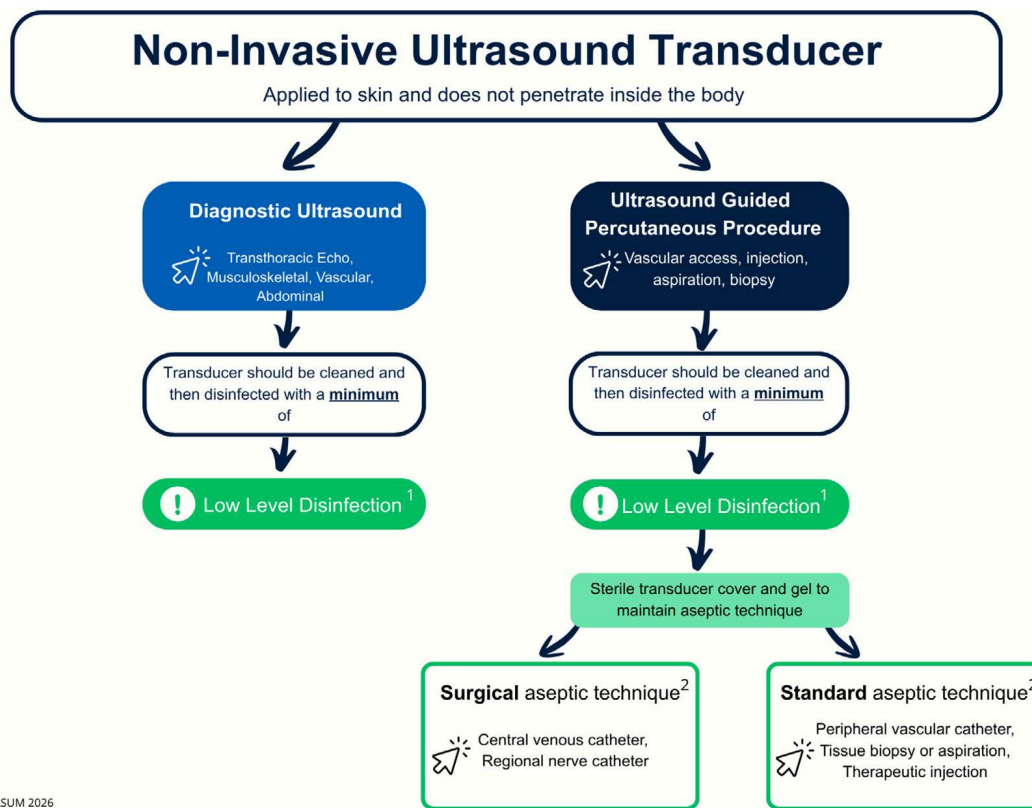


FIGURE 1 | Infection prevention and control practices required for non-invasive ultrasound transducers. ¹A higher level of disinfection may be required where a documented risk assessment identifies an increased risk of pathogen transmission or infection that is not adequately mitigated by low-level disinfection. ²For advice on infection prevention measures for different procedures refer to the Australian Guidelines for the Prevention and Control of Infection in Healthcare [3].

supported by national and international societies [30, 38, 43]. As such, ultrasound transducers used in percutaneous procedures should undergo a minimum of LLD and must be incorporated into the appropriate aseptic technique required of the procedure.

To maintain asepsis during an ultrasound guided percutaneous procedure contact between the ultrasound transducer and cable with the skin puncture site, aseptic field, and sterile device being inserted must be avoided. The use of a sterile transducer cover during the performance of an ultrasound guided percutaneous procedure should always be used where contact between these components or sites could occur. In these scenarios sterile ultrasound gel as well as transducer covers of adequate length should be used to maintain procedural aseptic technique (Figure 1).

6.2 | Invasive Ultrasound Transducers

An invasive transducer is one that penetrates inside the body, either through a body orifice or through the surface of the body [1]. According to Spaulding's classification, these ultrasound transducers would be classified as critical or semi-critical based on the sterility of the tissue the ultrasound is in contact with.

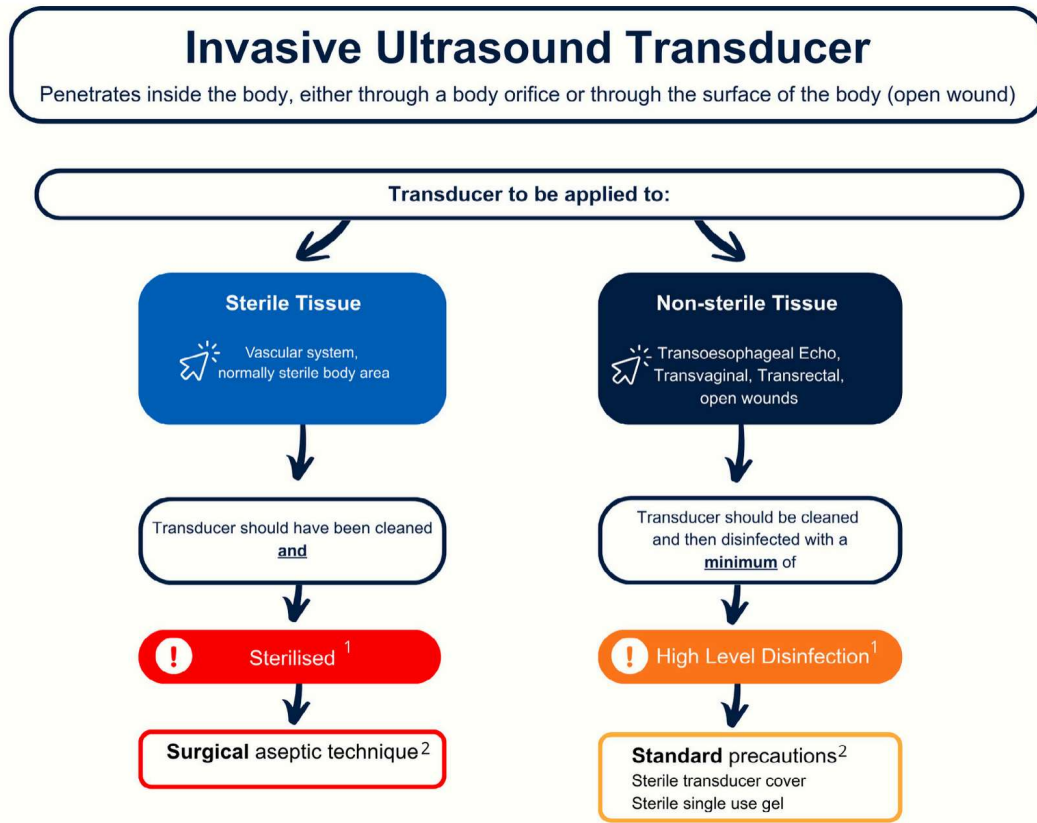
Critical ultrasound transducers are required to be sterile before use as they are intended to have contact with the vascular system or normally sterile areas of the body. The use of these transducers usually mandates a surgical aseptic technique and, as

sterility of these devices is maintained during these procedures, sterile ultrasound transducer covers are not routinely required. If ultrasound gel is required, it must be single use and sterile.

Semi-critical transducers are inserted into non-sterile areas of the body lined by mucous membranes (vagina, rectum and oesophagus) and into open wounds (e.g., skin ulcers, deep dermal burns) [30, 44]. These transducers require a minimum of HLD between uses. Sterile ultrasound transducer covers are recommended when contact with mucous membranes or open wounds is anticipated. In these scenarios covers provide an additional barrier between the patient and the transducer as well as helping to minimise transducer contamination. Single use sterile ultrasound gel should also be used when transducers are classified as semi-critical (Figure 2).

The transmission of human papilloma virus (HPV) has been identified as a concern in ultrasound examinations which involve contact with mucous membranes. HPV is highly prevalent and could be transferred between patients through contact with contaminated ultrasound equipment [45, 46]. Appropriate risk mitigating steps should be taken which include, standard precautions, transducer cover use, single use ultrasound gel, and disinfection of ultrasound transducers including the handle using a minimum of high-level disinfection [46, 47].

Invasive ultrasound transducers can also be used as a guide for needle-based procedures (e.g., transrectal ultrasound guided



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FIGURE 2 | Infection prevention and control practices required for examinations involving invasive ultrasound transducers. ¹In accordance with requirements outlined in AS5369:2023. ²Refer to the Australian Guidelines for the Prevention and Control of Infection in Healthcare [3].

biopsy). In this scenario the ultrasound transducer should be reprocessed in keeping with its site of intended use and then incorporated into the aseptic technique requirements of the procedure. If a clinical scenario was to arise where a usually non-invasive ultrasound transducer is to be used in a way that meets the definition of an invasive ultrasound transducer it should be reprocessed as an invasive transducer before it is used [30].

7 | Further General Recommendations

7.1 | Sustainability

Consideration should be given to the reduction of our carbon footprint, and where possible the aim should be to support future sustainability and preserve ecosystems. End users are encouraged to select appropriate products which also help support sustainable practices where possible [16, 48].

7.2 | Equipment Design and Procurement

At the time of ultrasound equipment procurement, consideration should be given to the implications on end users and ensuring that equipment design works within infection prevention and control guidelines. This should include consideration on workflow and factors such as ease of cleaning, storage and suitability of equipment. Involvement of ultrasound practitioners is strongly encouraged in the procurement process.

7.3 | Infection Prevention and Control Policies and Procedures Relating to Ultrasound Equipment

Infection prevention and control practitioners and other practitioners who regularly use and reprocess ultrasound equipment should be consulted and/or involved in the development of local facility policies and procedures relating to ultrasound equipment [49]. Not only does this encourage ultrasound practitioner engagement but also allows for consideration of practice specific factors ensuring the more successful implementation of recommendations into clinical practice. Facilities must recognise and provide the additional resources required to implement and perform safe and effective ultrasound equipment reprocessing (e.g., staff time, equipment and funding).

Author Contributions

Nathan Peters: conceptualization, methodology, writing – review and editing, writing – original draft, project administration, investigation. **Marija Juraja:** conceptualization, writing – review and editing, investigation, methodology. **Nicola Isles:** conceptualization, writing – review and editing, investigation, methodology. **Ellen Woodcock:** conceptualization, writing – review and editing, investigation, methodology. **Elissa Kennedy-Smith:** conceptualization, writing – review and editing, investigation, methodology. **Cartan Costello:** conceptualization, writing – review and editing, investigation, methodology. **Jo McCann:** conceptualization, writing – review and editing, investigation, methodology. **Karen Mizia:** conceptualization, writing – review and editing, investigation, methodology.

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Conflicts of Interest

C.C.—received payment for 2019 presentation sponsored by Germitec. M.J.—infection control consultancy to EGO Pharmaceuticals; Haines Medical; Clean Life Medical. N.P.; M.J., N.I., E.W., E.K.-S., J.M., K.M.—no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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