



Decontamination of Diagnostic Ultrasound Transducers Clinical Practice Standard

Contents

1. Purpose.....	2
2. Scope.....	2
3. Considerations	2
4. General Information	3
5. Medical Instrument Classification.....	3
6. Staffing Responsibilities	4
7. Documentation.....	4
8. Partnering with Consumers.....	5
9. Compliance Monitoring	5
10. Definitions	5
11. Relevant Legislation.....	6
12. Relevant Standards.....	6
13. Relevant WA Health Policies	6
14. Acknowledgement.....	6
15. References.....	7
Appendix 1: Chemicals Approved by the Therapeutic Goods Administration and WACHS	9
Appendix 2: Equipment considerations	11
Appendix 3: Decontamination of Non-Critical Ultrasound Transducers (e.g. Transabdominal)	13
Appendix 4: Decontamination of Semi-Critical Diagnostic Ultrasound Transducers (Intracavity).....	15
Appendix 5: Reference Guide Tables for cleaning ultrasound transducers ⁴	19
Appendix 6: Flow chart reference guide for reprocessing ultrasound transducers ⁴	21
Appendix 7: Infection Prevention and Control Considerations ⁴	23

1. Purpose

As a patient safety initiative to prevent transmission of infection, the purpose of this Clinical Practice Standard (CPS) is to establish minimum practice standards for the decontamination of diagnostic ultrasound transducers throughout the WA Country Health Service (WACHS). This CPS may be used in conjunction with specific site departmental requirements.

Information excluded from this CPS comprises:

- specific procedural guidelines for sterilisation i.e. operating theatres
- procedural guidelines for specific diagnostic ultrasound transducers.

2. Scope

All medical, nursing, midwifery and allied health staff employed within WACHS. All health care professionals are to work within their scope of practice appropriate to their level of training and responsibility. Further information can be found via [HealthPoint](#).

Clinicians who decontaminate reusable medical instruments must be skilled in all necessary procedures. Formal training in medical device cleaning and disinfection is recommended. The expectation is minimum standard training is completed by ultrasound healthcare workers including hand hygiene and aseptic technique.⁴

3. Considerations

All diagnostic ultrasound transducers must be processed in accordance with manufacturer's instructions and Material Safety Data Sheet (MSDS).^{1,2}

The following relevant resources are essential reference material to be applied in conjunction with the information found in this CPS:

- AS/NZS 4187-2014: Reprocessing of reusable medical devices in health service organizations¹
- AS/NZS 4185-2006: Office-based health care facilities - Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment
- Department of Health WA OD 0404/12 [Prevention of Cross Infection in Diagnostic Ultrasound](#)²
- NHMRC [Australian Guidelines for the Prevention and Control of Infection in Healthcare](#) (2010)³
- WACHS [Infection Prevention and Control Policy](#)
- [Australasian Society for Ultrasound in Medicine \(ASUM\) and Australasian College for Infection Prevention Control \(ACIPC\) joint Guidelines for Reprocessing of Ultrasound Transducers](#)⁴

4. General Information

Studies have shown there is some risk of microbial transmission during diagnostic ultrasound examination. This risk increases significantly with the use of transducers that come into contact with blood, body fluids or broken skin. To reduce the risk of transmitting microorganisms on diagnostic transducers meticulous cleaning, disinfection or sterilisation is essential to reduce microbial load by at least 99%.^{1,4}

Diagnostic Ultrasound Transducers include^{2,4}

- transducers that may come into contact with intact or non-intact skin
- intracavity transducers (transvaginal (TV), transrectal (TR), transoesophageal (TOE))
- transducers used during ultrasound guided biopsy or infiltration
- transducers used in ultrasound guided interventional procedures
- transducers used within a sterile environment (such as operating theatres).

5. Medical Instrument Classification

The transmission of infections on transducers and equipment is related to the presence or absence and the number and virulence of the microorganism, the type of procedure i.e. invasive or non-invasive and the actual body site where the transducer is used i.e. intact skin or non-intact skin.^{2,5,6} The Spaulding classification system adopted globally and by the Centers for Disease Control and Prevention⁸ allows for risk of infection adjustments based on the contact sites and instruments may be classified as critical, semi critical and non-critical. The level of terminal processing required by medical devices is based on the classification.

Spaulding Classification of Risk.^{1,8,9}

Item Category	Item Definition	Method of decontamination
Critical	Items entering sterile tissue, the body cavity, the vascular system and non-intact mucous membranes e.g. surgical instruments	Require cleaning followed by sterilisation; Steam sterilisation Low temperature methods e.g. Ethylene oxide, Plasma
Semi-critical	Items that make contact directly or indirectly with intact mucous membranes or non-intact skin e.g. endotransducers, transducers	Require cleaning followed by high-level disinfection (HLD) at a minimum; however sterilisation of these items is strongly recommended. Low temperature sterilisation HLD (OPA)
Non-critical	Objects that come into contact with intact skin but not mucous membranes e.g. Crutches, BP cuffs	Require cleaning followed by low or intermediate level disinfection

Transabdominal ultrasound transducers are classified as a non-critical items requiring cleaning only, however low level disinfection (LLD) may be appropriate in specific circumstances. Intracavity ultrasound transducers are classified as semi-critical items requiring cleaning sterilisation or high level chemical disinfection³ as the minimum standard. Where available and compatible, high level disinfection is preferable via an automated processor to ensure standardisation and minimise clinician exposure to hazardous substances.

Refer to [Appendix 6](#), Flow charts 1 and 2 for reprocessing guidance when completing your risk assessment prior to commencement of a procedure.

6. Staffing Responsibilities

Clinicians who clean and disinfect reusable diagnostic ultrasound transducers must be skilled to perform the process of cleaning, disinfection and sterilisation. It is a requirement that the appropriate health and safety protocols are followed and staff are familiar with site specific protocols and manufacturer's guidelines.^{1,2,4}

7. Documentation

Document all findings in relation to the diagnostic ultrasound procedure, assessment, management and outcome as per site specific protocol.
Consider any relevant patient health record sections and forms as relevant to the clinical treatment area or treatment professional discipline.

Failure to accurately and legibly record, and understand what is recorded, in patient health records may contribute to a decrease in the quality and safety of patient care. Refer to WACHS [Documentation Clinical Practice Standard](#).

Recommended Documentation for Decontamination of Ultrasound Transducers

Records of HLD must be kept in accordance with the requirements specified in AS/NZS4187:2014 (Clause 2.4.3.2 (a)) to ensure a system of traceability is in place to enable recall procedures to be followed in case of decontamination failure.

AS/NZS4187:2014 requires the following parameters to be documented:

- The date reprocessing occurred.
- The type of transducer and unique identification number, (e.g. serial number).
- The person responsible for the cleaning and disinfection and release of the transducer for use.
- The batch numbers and expiry dates of the disinfectant and any chemical indicator test strips used to check minimum recommended concentration (MRC).

For manual HLD processes:

- Record the immersion time in and out of the HLD, and where applicable the temperature of the solution; results of chemical indicator test strips used to check MRC and completion of the final rinse to remove HLD residues.

For automated HLD processes:

- Record the process cycle for automated cleaning and / or disinfection.

For HLD wipes:

- Record the batch number and expiry dates of the products used for cleaning, HLD and neutralisation.

8. Partnering with Consumers

- Consider cultural, ethical and communication requirements.
- Consideration to the patient's wishes and "What Matters to Them".
- Provide opportunity for the patient, family and carer to be actively involved in the care by providing information to share decision making.

9. Compliance Monitoring

Compliance with this CPS can be monitored by auditing documentation and process, reviewing trends through the Clinical Incident Management Systems and investigations, and quality improvement activity, as required. Compliance with this CPS should be reported to relevant site governance committees.

Failure to comply with this policy may constitute a breach of the WA Health Code of Conduct (Code). The Code is part of the [Employment Policy Framework](#) issued pursuant to section 26 of the [Health Services Act 2016](#) (HSA) and is binding on all WACHS staff which for this purpose includes trainees, students, volunteers, researchers, contractors for service (including all visiting health professionals and agency staff) and persons delivering training or education within WACHS.

Incidents involving non-compliance of cleaning between patients are to be reported, investigated, and monitored via the relevant clinical incident management reporting system.

WACHS staff are reminded that compliance with all policies is mandatory.

10. Definitions

Cleaning	The removal of contamination from an item to the extent necessary for further processing or for intended use ¹
Decontamination	The process of cleaning, disinfection or sterilisation of diagnostic ultrasound transducers.
Disinfection	The destruction of many microorganisms (including human pathogens) using thermal or chemical means. Unlike sterilisation, disinfection is not effective against high numbers of bacterial endospores. Disinfectants are classified by grade as follows: <ul style="list-style-type: none"> • Low-level instrument grade: disinfectant that kills vegetative bacteria, some fungi and some viruses. • Intermediate-level instrument grade: disinfectant that kills vegetative bacteria, Mycobacteria, viruses and most fungi but not bacterial endospores. • High-level instrument grade: disinfectant that kills all microorganisms with the exception of high numbers of bacterial endospores⁴
MSDS – Material Safety Data Sheet	These provide important information about chemical substances. Suppliers of chemical agents shall provide Product Data Bulletins and MSDS for all chemical agents and provide the user with validation that the chemical complies with the recommendations of AS 41874.

Printed or saved electronic copies of this policy document are considered uncontrolled.
Always source the current version from [WACHS HealthPoint Policies](#).

<p>Sterilisation</p>	<p>Destroys microorganisms on reusable medical devices (RMDs) rendering them free from viable microorganisms. Moist heat sterilisation, low temperature sterilisation (e.g. hydrogen peroxide gas or plasma, liquid paracetic acid , low temperature steam formaldehyde and ethylene oxide) and dry heat sterilisation are the principal processes used by Health Service Organisations to sterilise RMDs</p> <p>Moist heat sterilisation is the preferred process for sterilisation of RMDs where the item to be processed (including its packaging, if used) is able to withstand this process. Where an item cannot withstand a moist heat sterilising process, a suitable alternative sterilising process will be necessary, e.g. a low temperature gas or plasma, or liquid chemical sterilising process.¹</p>
-----------------------------	--

11. Relevant Legislation

(Accessible via: Government of Western Australia (State Law Publisher or ComLaw))

- Occupational Safety and Health Act 1984
- Occupational Safety and Health Regulations 1996
- Privacy Act 1988
- Public Sector Management Act 1994
- State Records Act 2000

12. Relevant Standards

[National Safety and Quality Health Services \(NSQHS\) Standards](#) Version 2

- Clinical Governance for Health Service Organisations Standard
- Preventing and Controlling Healthcare Associated Infections

13. Relevant WA Health System Policies

- OD 0404/12 [Prevention of Cross Infection in Diagnostic Ultrasound](#)
- OD 0651/16 [Clinical and Related Waste Management Policy](#)
- OD 0641/15 [Management of Occupational Exposure to Blood and Body Fluids in the Health Care Setting](#)

14. Acknowledgement

Acknowledgment is made of the previous SMHS / WACHS site endorsed work used to compile this Clinical Observation and Assessment Clinical Practice Standard.

Acknowledgement is made to South West and Kimberley Infection Prevention and Control.

References

1. Joint Technical Committee HE-023, Processing of Medical and Surgical Instruments and Equipment. AS/NZS 4187:2014. Sydney: Standards Australia 2014.
2. Western Australia Department of Health. Operational Directive: [Prevention of Cross Infection in Diagnostic Ultrasound](#) (OD 0404/12). East Perth: Western Australia Department of Health; 2012.
3. National Health and Medical Research Council (NHMRC). [Australian Guidelines for the Prevention and Control of Infection in Healthcare](#). Canberra: NHMRC; 2010: [Accessed 12 April 2017](#).
4. Basseal JM, Westerway SC, Juraja M, van de Mortel T, McAuley TE, Rippey J, et al. [Guidelines for reprocessing ultrasound transducers](#). Australas J Ultrasound Med 2017; 20: 30–40. Accessed 12 April 2017.
5. Nyhsen C, Humphreys H, Koerner R, Grenier N, Brady A, Sidhu P, [Nicolau C](#), [Mostbeck G](#), [D'Onofrio M](#), [Gangi A](#), [Claudon M](#). Infection prevention and control in ultrasound – best practice recommendations from the European Society of Radiology Ultrasound Working Group. Insights Imaging 2017
6. Australian Government DoH TGA. [The Regulation of Medical Devices](#) 2011.
7. Basseal JM, Westerway SC, Hyett J. Analysis of the integrity and breakage rate of covers used in trans-vaginal ultrasound examinations. Ultrasound Obstetrics Gynaecology 2018;52 (supply 1):138-139
8. Centers for Disease Control [Guideline for Disinfection and Sterilization in Healthcare Facilities](#), 2008. Accessed 12 April 2017.
9. Favero MS, Bond WW. Chemical disinfection of medical and surgical materials. In: Block SS, ed. *Disinfection, Sterilization and Preservation*. 5th ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2001:881-918.
10. Abramowicz JS, Evans DH, Fowlkes JB, Marsal K and terHaar G. WFUMB Safety Committee. Guidelines for Cleaning Transvaginal Ultrasound Transducers Between Patients. Ultrasound Med Biol 2017;43(5):1076-1079
11. Therapeutic Goods Order No. 54 - [Standard for Disinfectants and Sterilants](#). Canberra: Office of Legislative Drafting and Publishing, Attorney-General's Department; 2009. Accessed 12 April 2017.
12. Tristel. [Tristel products - healthcare - ultrasound/radiology](#).

13. Standards Australia & Standards New Zealand. Office-based health care facilities: Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment (AS/NZS 4815:2006). Sydney, NSW: Standards Australia/Standards New Zealand; 2006. Accessed 15 January 2014.
14. Administration US FDA. [FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices](#). 2015. Accessed 11 May 2017.
15. Australian Government DoH. 2018. [Advisory Statement A18/06: Requirement for high level disinfection of ultrasound transducers](#). Accessed 30 January 2019.

Appendix 1: Chemicals Approved by the Therapeutic Goods Administration and WACHS

- Ortho-Phthalaldehyde (OPA) can be used in either manual processing or in automated processors.
- Peracetic acid and high concentrations of hydrogen peroxide can only be used in automated processors that prevent staff exposure.
- Products are not interchangeable, thus manufacturer instructions and the MSDS must be followed regarding product use with individual machines. Refer to the: Therapeutic Goods Administration (TGA) website.
- Ventilation must remove toxic vapours generated by, or emitted from, cleaning or disinfecting agents¹⁰
- Hypochlorite (Milton) and Virkon are NOT recognised by the TGA as high level instrument grade disinfectant and therefore must not be used to decontaminate diagnostic ultrasound transducers.^{10,11}

Intracavity ultrasound transducers are categorised as Class IIb semi-critical reusable instruments requiring high level disinfection/low temperature sterilisation. Disinfectants for use in Australia in both manual and automated systems are regulated by the TGA, therefore only chemicals registered with the TGA as high level instrument grade disinfectants are to be used for diagnostic ultrasound transducers^{3,9} these include.^{1,2,4,10,11}

Hydrogen Peroxide (used with the Trophon EPR™ System)

Low temperature sterilisation system. The Trophon EPR™ is designed to provide high level disinfection of ultrasound transducers.

The Trophon EPR™ system consists of a multiple use instrument, combined with a single use disinfectant, delivered from a multi-dose cartridge.⁶

No rinsing is required at the completion of the cycle.

Peracetic Acid (as in the STERIS System™)

Low temperature sterilisation system. This has been recommended for use by Australian Sonographers Association (ASA)²

A specific automated processor is required to perform high level disinfection for diagnostic ultrasound transducers.

Ortho-Phthalaldehyde (OPA)

OPA is an instrument grade liquid disinfectant recommended for the purposes of high level disinfectants of clean, heat sensitive, semi-critical medical devices. It does not sterilize items.

The high level disinfection claim for CIDEX™ OPA is a minimum of 12 minutes at 20°C if soaking in a manual system. Where OPA is used within an automated system the parameters of 5 minutes at 25°C is to be attained. Check with the manufacturers of automated reprocessors for specific compatibility statements. The use of OPA requires the user to wear personal protective equipment. If adequate air circulation is not available, a fume cabinet may be necessary.²

CIDEX™ OPA must be neutralized using Glycine prior to disposal of the solution. 25g of glycine (free base) should be used to neutralize one gallon of CIDEX OPA solution with the minimum recommended neutralization time being one hour. Discard solution into the drain and flush drain thoroughly with water. Refer to MSDS.

Chlorine Dioxide (used with the Tristel Wipes System™)

While Chlorine Dioxide is TGA approved for disinfecting ultrasound transducers, concerns have been raised about the method of application. It is therefore recommended that the manufacturer's (Tristel™) instructions are strictly adhered to thereby ensuring all surface areas are cleaned adequately and kept in contact with the active ingredient for the appropriate length of time.¹² In addition, users must be trained in the appropriate disinfection techniques, in keeping with the [Australian Guidelines for the Prevention and Control of Infection in Healthcare](#) (2010).^{2,3}

Appendix 2: Equipment considerations

- Equipment must be serviced and calibrated in accordance with the manufacturer's recommendations to ensure reliability and accuracy
- Specific sites may have variation in equipment that may need to be updated or modified to meet Australian Standards and TGA requirements.

Sheaths

Where sheaths are used they are to meet minimum requirements i.e. thick enough to resist tearing or perforation during use, and be validated by the sheath manufacturer for use with the diagnostic transducer. Sterile sheaths do not replace the need to clean and disinfect the diagnostic transducer before and after every patient use. "Items incapable of being sterilised may require use of an instrument sheath. Such items shall be processed to the highest level possible for that item between reuses."¹³

Wherever possible transducers used for TV and TR ultrasound procedures are to be sheathed in a disposable impermeable cover validated by the manufacturer for the specific use and disposed of between each patient. Care is to be taken to ensure the sheath is not overstretched as this may result in perforation and detachment during the procedure. It is essential the sheath is sterile or appropriate for use in a semi-critical site. Condoms have been known to break during use and therefore have not been validated for use⁹. A material other than latex is to be used for patients who are known to be latex sensitive.

Personal Protective Equipment (PPE) Considerations^{1,3}

Select PPE appropriate to the decontamination procedure being undertaken. The possibility of splashing by blood, bodily fluids and hazardous substances is not necessarily predictable and all those likely to encounter splashing are to wear PPE in accordance with the Australian Standards.³

Where PPE available is reusable ensure it is:

- decontaminated after use
- stored away from potential contamination sources
- regularly maintained
- documented as required according to site protocol.

The following PPE must meet AS/NZ¹ Standards:

- Gowns - Fluid repellent gowns that provide full skin protection for arms and legs. They are to be changed if soiled.
- Gloves - Single use. Two pairs of mid arm length non-sterile gloves impervious to the cleaning and disinfectant agents. PVC and neoprene gloves have been found to retain or absorb Glutaraldehyde on extended exposure. Nitrile rubber or butyl rubber provides optimal achievable protection. Latex gloves provide protection for approximately 45 minutes however the issue of latex allergy will impact on the choice of gloves. For latex sensitive individuals gloves made from alternative products such as nitrile, butyl rubber, vinyl and neoprene are available.

However, consideration needs to be given to the suitability of the material for use with cleaning and disinfecting agents being used.

- Eye Protection - Where splashing of the concentrated solution may occur, chemical safety goggles are to be used. Face shields are to be used for the processing of all transducers.
- Respiratory Protective Mask - P2 respirator is used.
- Enclosed Footwear.

Cleaning Equipment

Select equipment appropriate to the cleaning process being undertaken.

Equipment may include:

- enzyme detergent
- detergent wipes (refer to manufacturer's instructions for material compatibility between device and cleaning product)
- adequate sink and bench area
- soft bristle brush
- lint free cloth
- detergent MSDS
- water of suitable quality and temperature
- log sheet to record details of cleaning process
- timer with alarm.

Sterilisation/ Disinfection Equipment

Select equipment appropriate to the disinfectant process being undertaken, referring to manufacturer's instructions. Equipment may include:

- adequate sink and bench area
- thermometer as per manufacturer's instructions
- spill Kit
- log sheet to record details of sterilisation/ disinfection
- disinfectant chemical
- disinfectant MSDS
- timer with alarm.

Environment Equipment

- Extraction fans / DFS.

Appendix 3: Decontamination of Non-Critical Ultrasound Transducers (e.g. Transabdominal)

- DoH OD 0404/12 [Prevention of Cross Infection in Diagnostic Ultrasound](#)
- AS/NZS 4187-2014 outlines household detergents and soaps are not recommended due to their high foaming properties which increases the residue left behind.¹
- A disposable transducer cover i.e. sheath may be required to cover the transducer prior to use. In the event of blood or bodily fluid contamination the transducer is to be decontaminated **as per an intracavity transducer - Refer to Appendix 4 – Decontamination of Semi-Critical Ultrasound Transducers (Intracavity)**

Key points prior to commencing procedure^{1-3,9}

- Hand hygiene must be performed before and after touching a patient, equipment or surroundings.
- PPE – gown, gloves, safety glasses, masks, or face shields must be worn according to site protocol and/or manufacturer's directions when decontaminating diagnostic ultrasound transducers.

Cleaning Process

Manually remove ultrasound gel prior to cleaning. LLD may be done using a TGA-approved disposable cleaning wipe or system intended for use on medical devices, or a fresh solution of appropriate cleaning agent.⁴

Preparation

- Cleaning solution: Make up fresh enzymatic detergent solution to the manufacturer's instructions for reprocessing each transducer. Fresh solution prevents cross contamination. Do not use household detergents.
- Don a pair of disposable gloves and remove and discard transducer cover and gel taking care not to contaminate the transducer, equipment or environment
- With gloves on disconnect the transducer from the ultrasound machine (according to manufacturer's instructions)

Immersion

- Immerse transducer and connection according to the manufacturer's directions (some transducers cannot be fully immersed).
- Whenever practical, leave the transducer immersed in the detergent solution when performing all subsequent cleaning steps to prevent the production of aerosols of contaminated fluid.

Cleaning

- Wash all debris from outer surfaces by brushing and wiping the instrument.
- Use a soft bristle brush to gently clean.
- Use of non-abrasive and lint-free cleaning tools will prevent damage to the transducer.
- Check that all visible debris has been removed.
- Inspect single use brush and replace if bristles are frayed, bent, if the shaft is kinked or the brush is otherwise damaged.
- Bristles are ineffective in cleaning and damaged brushes may damage transducers.

Rinsing

- Rinse outer surfaces of the transducer with clean water.
- Rinse all removable parts with clean water.
- Clean running water is to be used to remove all traces of detergent prior to disinfection.
- The use of clean water for each transducer will limit the potential for cross infection.
- The amount of water required to thoroughly rinse the transducer after cleaning will vary according to the design and length of the instrument.

Drying

- Dry the outer surfaces of the transducer with a soft, lint-free disposable cloth.
- Dispose of all lint free cloths and disposable gloves.

Post Cleaning

- Perform air leakage / electrical integrity checks where indicated.
- All diagnostic transducers are to be dried and stored in a well-ventilated, dry enclosed storage cupboard. They are not to be stored in their cases as this may become a source of contamination.
- If specific cabinet not available, minimum standard is a clean disposable cover applied to the transducer to minimise risk of environmental contamination.⁴
- Perform hand hygiene
- Ensure documentation is completed according to site specific protocol.

Appendix 4: Decontamination of Semi-Critical Diagnostic Ultrasound Transducers (Intracavity)

- DoH OD 0404/12 Prevention of Cross Infection in Diagnostic Ultrasound
- AS/NZS 4187-2014 outlines household detergents and soaps are not recommended due to their high foaming properties which increase the residue left behind¹.
- Wherever possible, transducers used for TV and TR ultrasound procedures are to be covered in a disposable impermeable sheath validated by the manufacturer for the specific use and changed for each patient. At the end of each procedure the sheath is to be discarded and transducer must be cleaned immediately prior to sterilisation or disinfection.¹⁰
- Sterile sheaths do not replace the need to clean and disinfect the transducer before and after patient use.
- The decontamination of semi-critical diagnostic ultrasound transducers comprises a cleaning process followed by a disinfection/sterilisation process
- HLD of semi-critical diagnostic ultrasound (intracavity) transducers is preferred via an automated processor wherever possible. Please refer to manufacturer's instructions.

Key points prior to commencing procedure^{1-3,9}

- Hand hygiene must be performed before and after touching a patient, equipment or surroundings.
- PPE – gown, gloves, safety glasses, masks, or face shields must be worn according to site protocol and/or manufacturer's directions when decontaminating diagnostic ultrasound transducers.

Cleaning Process

Cleaning is an essential prerequisite for all effective disinfection processes because organic residue may prevent the disinfectant from contacting the transducer being processed and may also bind and inactivate chemical disinfectants.^{1,4,14}

Preparation

- Cleaning solution: make up fresh enzymatic detergent solution to the manufacturer's instructions for reprocessing each transducer. Fresh solution prevents cross contamination. Do not use household detergents.
- Don a pair of disposable gloves and remove and discard transducer cover and gel taking care not to contaminate transducer, equipment and or environment.
- With gloves on disconnect the transducer from the ultrasound machine (according to manufacturer's instructions).
- Leak testing to be performed prior to immersion in cleaning fluid. (according to manufacturer's instructions)

Immersion

- Non-immersible diagnostic transducers i.e. TOE, TR, TV are to be processed according to manufacturers' instructions.
- Immerse transducer and connection according to the manufacturer's directions (some instruments are not fully immersible).
- Whenever practical, leave the transducer immersed in the detergent solution when performing all subsequent cleaning steps to prevent the production of aerosols of contaminated fluid.

Cleaning

- Wash all debris from outer surfaces by brushing and wiping the instrument.
- Use a soft bristle brush to gently clean.
- The use of non-abrasive and lint-free cleaning tools will prevent damage to the transducer.
- Check that all visible debris has been removed.
- Inspect single use brush and replace if frayed, bent, if the shaft is kinked or the brush is otherwise damaged.
- Bristles are ineffective in cleaning and damaged brushes may damage transducers.

Rinsing

- Rinse outer surfaces of the transducer with water.
- Rinse all removable parts with clean water.
- Clean running water is to be used to remove all traces of detergent prior to disinfection.
- The use of clean water for each transducer will limit the potential for cross infection.
- The amount of water required to thoroughly rinse the transducer after cleaning will vary according to the design and length of the instrument.

Drying

- Dry the outer surfaces of the transducer with a soft, lint-free disposable cloth.
- Dispose of all lint free cloths and disposable gloves.

Post Cleaning

- Perform hand hygiene.
- Ensure documentation is completed according to site specific protocol.
- It is important the transducer is thoroughly cleaned, rinsed and fluid is removed and the transducer is dry before sterilisation/disinfection. The most critical factor is thorough meticulous manual cleaning.

Disinfection Process

- All semi-critical diagnostic ultrasound transducers are to be cleaned and disinfected or sterilised according to the manufacturer's instructions. On completion of cleaning, where available the disinfection process is to take place via an automated reprocessor i.e. Automated Flexible Endoscope Reprocessor (AFER) or sterilizer i.e. Sterrad). This method is preferable to ensure standardisation and minimise exposure to hazardous substances.
- Use liquid chemical high level disinfectant only for heat sensitive components that cannot be sterilised.
- Only chemicals approved by the TGA as high level instrument grade disinfectants are to be used for intracavity ultrasound transducers.
- Disinfectant MSDS must be available, read and followed in the preparation and disinfection process.
- The disinfectant solution may require the use of a DFS or an approved system – refer to manufacturer instructions and site specific protocol.

Preparation

- Prepare the disinfectant according to the manufacturer's instructions and MSDS.
- Follow the manufacturer's recommendations of concentration, time and temperature to achieve high level disinfection.
- Test the minimum recommended concentration of the disinfectant.
- Test on each day of use or more frequently as dictated by the number of transducers being reprocessed.
- The MRC may not be used to extend the use-life claim of the disinfectant.
- Use a disinfectant specific test strip.
- Keep a log of the test results.

Manual disinfection

Immersion

- Immerse the transducer according to manufacturer's instructions.
- If transducers have channels/ports flush with disinfectant so that all air bubbles are expelled. Ensure that disinfectant is seen to emerge from any ports. It is essential to expel all air from the channels in order to ensure that all internal surfaces are in contact with the disinfectant i.e. endoscopes.
- Leave the transducer immersed in the disinfectant for the time/ temperature/ concentration required to achieve high level disinfection according to the manufacturer's and TGA recommendations.
- Any channel entrances must be under the surface of the disinfectant to ensure that no air enters the channels.
- Only use containers that allow for the immersion of the transducer and which can be cleaned.

- Cleaning adaptors remain attached until after final rinsing and drying. This helps to overcome the potential for error that may occur due to failure to correctly reconnect all lumens.
- Use a timer with an alarm to ensure that accurate immersion times are achieved. It must be noted that the transducer must not be left in the chemical agent for longer than the recommended time due to the possibility of damage: the soaking periods are to be timed.
- A fluid thermometer with digital readout is recommended to constantly monitor temperature of the disinfectant.
- Documentation of processing parameters must be completed.

Purge with air

- Follow the manufacturer's instructions.
- Remove transducer (and any buttons/valves/caps) from disinfectant, taking care to avoid drips and splashes.
- Purging of any / all channels preserves the concentration and volume of the disinfectant and prevents exposure from drips and spills.

Rinsing

- Immerse transducer and (any buttons/valves/caps) rinse in water according to the manufacturer's instructions.
- Rinsing removes any chemical residue that may cause injury to skin and mucous membranes.
- Always use sterile water for rinsing; tap water may re-contaminate the transducer.
- Flush any lumen and channels to remove all traces of disinfectant.
- Check the disinfectant manufacturer's instructions as different disinfectants may require differing quantities of water to ensure the removal of disinfectant residue when flushing channels.

Drying

- At the end of the sterilisation/disinfection process all transducers are to be dried thoroughly.

Storage

- Store in a well-ventilated, dry, enclosed storage cupboard which permits full length, vertical hanging on appropriate support structures. It is recommended that a specific cabinet is used, however if one is not available the minimum standard recommended is a clean disposable cover applied to the transducer to mitigate risks from environmental contaminants.⁴

Post Disinfection

- Perform hand hygiene.
- Ensure documentation completed according to site specific protocol.

Appendix 5: Reference Guide Tables for cleaning ultrasound transducers⁴

Table 1: Reference guide to cleaning ultrasound transducers in the Emergency Medicine Department.

Transducer	Procedure	Use of transducer cover	Recommended cleaning method Low-Level Disinfection (LLD) or High-Level Disinfection (HLD)
External	Normal intact skin	No	LLD
	Open wound, for example ulcers	Yes	HLD
	Intact infected skin	No	HLD
		Yes	HLD*
	US-guided interventional procedure For example, joint aspiration; abscess drainage; foreign body removal; suprapubic bladder tap; nerve block	Yes	HLD*
	Peripheral IV line insertion	Yes	HLD*
	CVC / PICC insertion	Yes	HLD*
Pleural tap, ascites tap or drainage	Yes	HLD	
Intracavity	Transvaginal	Yes	HLD

Table 2: Reference guide to cleaning ultrasound transducers in the Radiology Department.

Transducer	Procedure	Use of transducer cover	Recommended cleaning method Low-Level Disinfection (LLD) or High-Level Disinfection (HLD)
External	Intact skin	No	LLD
	Open wound, for example ulcers	Yes	HLD
	Intact infected skin	No	HLD
		Yes	HLD*
External* Needle-guided procedures	MSK injection	Yes	HLD*
	Joint aspiration; abscess drainage; foreign body removal; suprapubic bladder tap; nerve block	Yes	HLD*
	Peripheral IV line insertion	Yes	HLD*
	CVC / PICC insertion	Yes	HLD*
	Pleural tap, ascites tap or drainage	Yes	HLD
Intracavity	Transvaginal	Yes	HLD
	Transrectal / TRUSS	Yes	HLD
	Intraoperative	Yes	HLD

*LLD can be performed if the transducer is classified as non-critical. Non-critical transducers do not contact non-intact skin, blood or mucous membranes. If the transducer comes in direct contact with non-intact skin, blood or mucous membranes transducers should be cleaned with HLD irrespective of the use of a transducer cover. If transducer cover is broken during a procedure, then HLD must be performed.

Table 3: Reference guide to cleaning ultrasound transducers in the O&G Department.

Transducer	Procedure	Use of transducer cover	Recommended cleaning method Low-Level Disinfection (LLD) or High-Level Disinfection (HLD)
External	Intact skin	No	LLD
	Non-intact skin	Yes	HLD
External* Needle-guided procedure	Amniocentesis CVS Suprapubic bladder tap for urine retention	Yes	HLD*
Intracavity	Transvaginal	Yes	HLD
Intraoperative		Yes	HLD

Table 4: Reference guide to cleaning ultrasound transducers in the Vascular Department.

Transducer	Procedure	Use of transducer cover	Recommended cleaning method Low-Level Disinfection (LLD) or High-Level Disinfection (HLD)
External	Intact skin	No	LLD
	Intact infected skin	No	HLD
		Yes	HLD*
	Ulcerated skin	Yes	HLD
Internal Ultrasound-guided surgical procedure	IVUS probe	Not reusable – discard after use	
Intraoperative		Yes	HLD

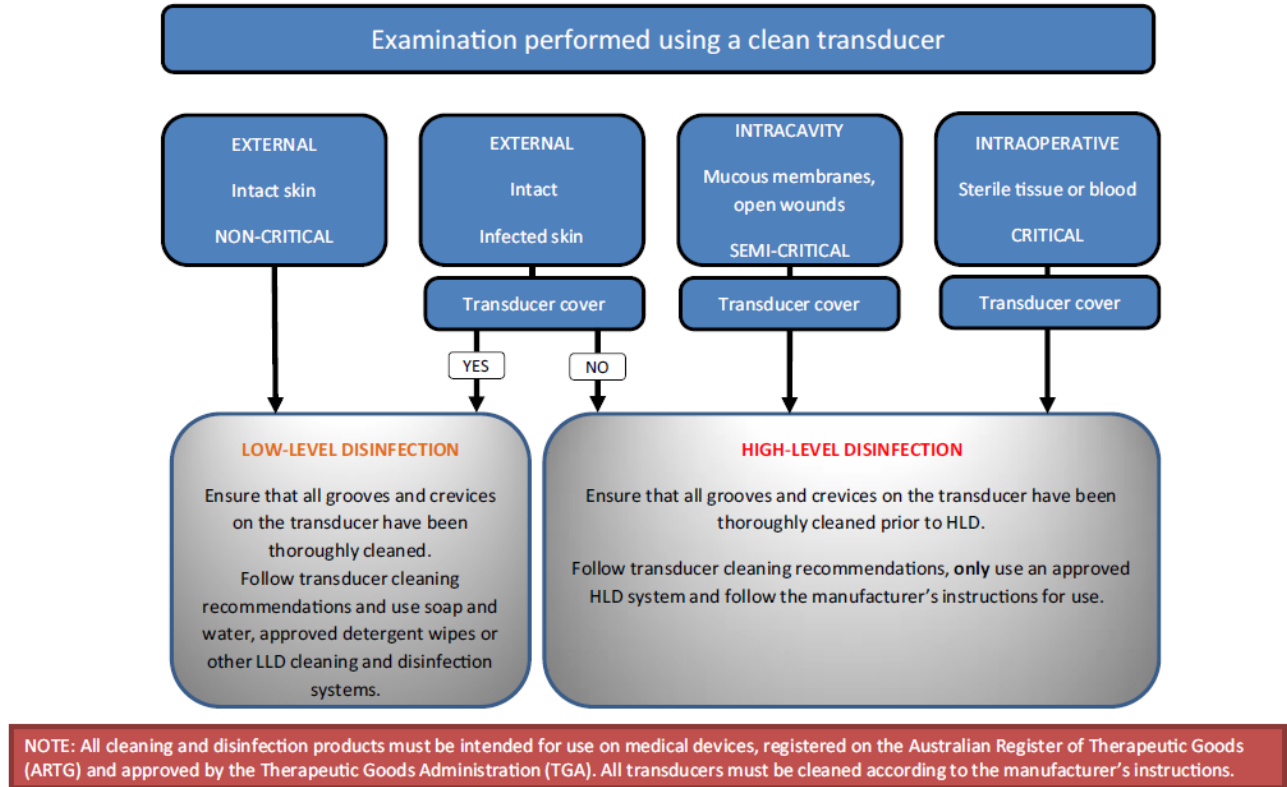
Table 5: Reference guide to cleaning ultrasound transducers in the Cardiac Department.

Transducer	Procedure	Use of transducer cover	Recommended cleaning method Low-Level Disinfection (LLD) or High-Level Disinfection (HLD)
External	Intact skin	No	LLD
	Intact infected skin	No	HLD
		Yes	HLD*
Internal	TOE	Yes	HLD
		No	HLD
	Epicardial echo	Yes	HLD
Intracardiac	Interventional	Not reusable – discard after use	
Intraoperative		Yes	HLD

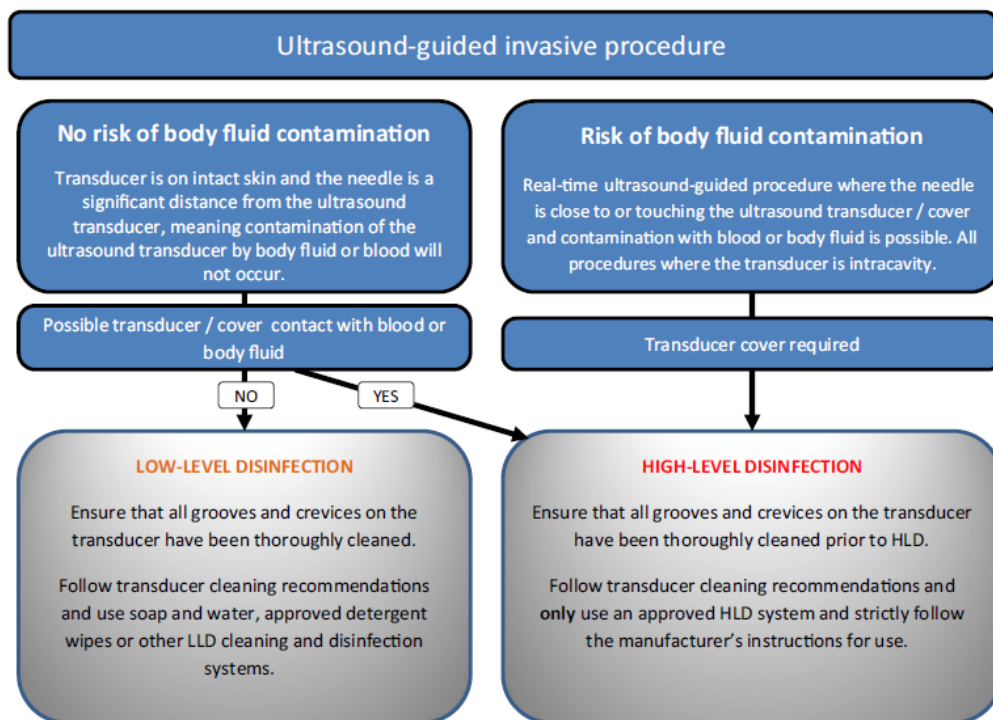
*LLD can be performed if the transducer is classified as non-critical. Non-critical transducers do not contact non-intact skin, blood or mucous membranes. If the transducer comes in direct contact with non-intact skin, blood or mucous membranes transducers should be cleaned with HLD irrespective of the use of a transducer cover. If transducer cover is broken during a procedure, then HLD must be performed.

Appendix 6: Flow chart reference guide for reprocessing ultrasound transducers⁴

Flow chart 1: Cleaning the ultrasound transducer after an ultrasound examination.



Flow chart 2: Cleaning the ultrasound transducer after an ultrasound-guided procedure.



NOTE: All cleaning and disinfection products must be intended for use on medical devices, registered on the Australian Register of Therapeutic Goods (ARTG) and approved by the Therapeutic Goods Administration (TGA). All transducers must be cleaned according to the manufacturer's instructions.

Appendix 7: Infection Prevention and Control Considerations⁴

Ultrasound procedures can cause spread of infectious agents via improperly cleaned and disinfected ultrasound transducers and accessories. If the transducer **has the potential to come into contact with body fluids**, non-intact skin, or mucous membranes, transducer should be cleaned with HLD irrespective of the use of a transducer cover. Failure to meet infection control standards including proper cleaning and disinfection of ultrasound equipment and transducers increases the risk of transmitting harmful pathogens.¹⁵

1. Agents potentially transmitted by ultrasound procedures

Organisms of particular concern include the following:⁴

- Staphylococcus aureus (including MRSA)
- Vancomycin-resistant enterococci
- Multi-resistant gram-negative organisms
- Carbapenem-resistant enterobacteraciae
- Mycobacterium tuberculosis complex
- Non-tuberculosis 'atypical' mycobacteria
- *Clostridium difficile*. High level disinfection has been found to inactive *C.difficile* spores.
- Neisseria gonorrhoeae, Chlamydia trachomatis, Treponema pallidum (syphilis), Mycoplasma genitallium. These organisms may not be removed by low-level disinfection wipes.
- Blood-borne viruses (hepatitis B virus, Hepatitis C virus, human immunodeficiency virus). Inadequate cleaning prior to disinfection may limit the effectiveness of disinfection allowing the virus to persist.
- Human herpes virus I and 2.
- Human papilloma viruses (HPV). Low level disinfection may not remove HPV from ultrasound transducers.

2. Ultrasound gel recommendations

- Ultrasound gels may be sterile or non-sterile. Gel product not labelled as sterile are not sterile. Non-sterile gel should be used for low risk examination on intact skin
- Heating of gel isn't recommended due to the risk of bacterial contamination. If warm gel is necessary, dry heat is the preferred method⁴
- Do not decant (non-sterile) gel into bottles. Single use bottles only (outbreaks have occurred due to contamination due to decanting products).

3. Inpatients on transmission-based precautions

For patients under transmission-based precautions a single use bottle or sachet of gel should be used.

4. Standard precautions

Standard precautions are applied to all patients in the inpatient and non-inpatient setting. For non-inpatients with a known multi-resistant organism, risk assessment may be required. Use a single use bottle or sachet of gel as indicated.

5. Equipment cleaning

Any equipment that has been in contact with the patient or operator should be cleaned with a detergent / disinfectant wipe or solution between use including leads to the transducer, the keyboard, ultrasound holder, gel containers, and the bed.

6. Hand hygiene

Hand hygiene per National Hand Hygiene program.

This document can be made available in alternative formats on request for a person with a disability

Contact:	Area Chief Medical Imaging Technologist (M. Melville)		
Directorate:	Nursing and Midwifery Services	TRIM Record #	ED-CO-15-94402
Version:	3.00	Date Published:	24 April 2019

Copyright to this material is vested in the State of Western Australia unless otherwise indicated. Apart from any fair dealing for the purposes of private study, research, criticism or review, as permitted under the provisions of the *Copyright Act 1968*, no part may be reproduced or re-used for any purposes whatsoever without written permission of the State of Western Australia.