



ASA CLINICAL STATEMENT | DISINFECTION OF INTRACAVITY AND SEMI-CRITICAL ULTRASOUND TRANSDUCERS

Endorsements: N/A

The Australasian Sonographers Association (ASA) advises members that disinfection of intracavity ultrasound transducers, and those used on non-intact skin or known infectious patients, must meet relevant recognised standards. This applies to all intracavity transducers such as those used for:

- intra oral examinations
- transvaginal examinations
- transoesophageal examinations
- transrectal examinations
- and all transducers used for scanning over open wounds, irritated or broken skin, or patients with known highly transmissible infections such as MRSA⁸

Definitions: N/A

Background

Early The requirements in this statement are based on the following current Australian and New Zealand standards:

AS/NZS 4815:2006 Office-based health care facilities – Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment.¹

AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organisations.²

Throughout Australia and New Zealand, the reprocessing of reusable medical equipment and devices must meet current best practice and be consistent with current national standards.³

When reusable equipment and devices are used in a health care setting the reprocessing processes used must be consistent with relevant national and international standards, in conjunction with the manufacturers' guidelines. A traceability process must be in place which can identify the patient, the procedure and the equipment used, and there should be processes to plan and manage reprocessing requirements, including additional controls for novel and emerging infections.

Discussion

Reusable medical devices that are used in contact with mucous membranes, such as intracavity ultrasound transducers, and transducers that have had contact with blood or body fluids, are classified as semi-critical medical devices [4,8] and require cleaning followed by high-level disinfection (HLD) at a minimum. HLD is also recommended for ultrasound transducers used externally to scan infectious patients⁹, and all interventional procedures where there is broken skin⁹. Such chemical disinfectants used must be labelled as instrument grade disinfectant.

It is also recommended that sterile covers are used on all ultrasound transducers that are deployed in a semi-critical clinical setting. After use, the cover is removed, the transducer is cleaned and HLD is still required as there is no guarantee that the integrity of the transducer cover has not been breached.

Recommendations

- In Australia, intracavity ultrasound transducers are categorised as Class IIb, semi-critical reusable instruments requiring high-level instrument grade disinfection.
- Instrument grade disinfectants and disinfecting systems to be used on these instruments must be classified Class IIb medical devices or higher and listed on the Australian Register of Therapeutic Goods (ARTG), managed by the Therapeutic Goods Administration (TGA).⁵
- New Zealand health services are required to adhere to these standards (and any latest revisions) through the Ministry of Health's Health and Disability Service Standards⁶ and supporting legislation.⁷

Approved products for high-level disinfection

- A list of current TGA approved agents and systems for high-level disinfection can be found on their website.⁵

Additional considerations

The following should always be adhered to when using high-level disinfectants on ultrasound equipment.

- Transducer manufacturers' guidelines for cleaning and disinfecting ultrasound equipment. This is to ensure that the disinfecting agent is compatible for use with the type and model of transducer to be disinfected.
- Disinfectant manufacturers' safety recommendations and instructions, and labelled conditions for use. Users should always take care when handling disinfectants due to the potentially hazardous nature of the materials. Refer to the disinfectant manufacturer's safety data sheets (SDS) that provide physical and chemical properties of the disinfecting agent; correct safety procedures for chemical storage, handling, transporting and disposal; health and environmental hazards; and emergency information.
- Relevant work health and safety (WH&S) protocols should be developed in line with WH&S regulations. It is recommended that all staff are made familiar with these protocols.

It is recommended that this ASA Clinical Statement be read in conjunction with the following ASA and other guidelines:

- Infection prevention and control guidelines for sonographers (ASA, updated 2021)
- Guidelines for reprocessing ultrasound transducers (2017)⁸; Australian College for Infection Prevention and Control and Australasian Society for Ultrasound in Medicine (ASUM)
- Guidelines for cleaning transvaginal ultrasound transducers between patients (2017); World Federation for Ultrasound in Medicine and Biology¹⁰
- Australian guidelines for the prevention and control of infection in healthcare (2019); National Health and Medical Research Council (NHMRC)
- National Safety and Quality Health Service Standards. 2nd edn (2021); Australian Commission on Safety and Quality in Health Care (ACSQHC).
- 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) Cartan Costello, Jocelyne M Basseal, Yang Yang, James Anstey, Konstantin Yastrebov AJUM Vol 23:2(103-110) 2020 <https://doi.org/10.1002/ajum.12205>

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2. Australian/New Zealand Standard. AS/NZS 4187:2014 Reprocessing of Reusable Medical Devices in Health Service Organisations. Standards Australia and Standards New Zealand. 2014
3. Australian Commission on Safety and Quality in Health Care. National Safety and Quality Health Service Standards. 2nd edn. Sydney: ACSQHC. 2017. **(updated May 2021)**
4. NHMRC. Australian Guidelines for the Prevention and Control of Infection in Healthcare **(2019) V11.9 published 7/2021**. This is a live document online, and the following link will take the user to the most recent version. <https://app.magicapp.org/#/guideline/Jn37kn/section/jNDMVn>
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9. Costello C, Basseal JM, Yang Y, Yastrebov, K Anstey J, Abramowicz JS, Evans DH. 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). AJUM Vol 23:2(103-110) 2020
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