

The Australasian Sonographers Association (ASA) advises all members that disinfection of intracavity ultrasound transducers must meet relevant recognised standards, as described below. This applies to all intracavity transducers, such as those used for:

- intra oral examinations
- transvaginal examinations
- transoesophageal examinations
- transrectal sonographic examinations.

The requirements in this Practice Update 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, reusable medical devices must meet jurisdictional and manufacturer reprocessing standards.[3] Reusable medical devices that come into contact with mucous membranes or non-intact skin, such as intracavity ultrasound transducers, are classified as 'semi-critical medical devices'[4] and require cleaning followed by high-level disinfection at a minimum. Such chemical disinfectants must be labelled 'instrument grade disinfectant'.

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 Standards* [6] and supporting legislation.[7]

Approved products for high-level disinfection

TGA approved agents and systems for high-level disinfection include:

- ortho-phthalaldehyde* (OPA)
- hydrogen peroxide*, used with the Trophon EPR* System
- chlorine dioxide, used with the Tristel Wipes* System
- peracetic acid*, used with the STERIS System
- glutaraldehyde*
- UV-C radiation, used in the Antigermix* System.

* Indicates TGA approved product at Class IIb or above. A public summary for each approved item is available from the ARTG.

The term 'Cidex' is often associated with OPA, but is a trade name for various antimicrobial/disinfection solutions manufactured by Johnson & Johnson.

- Cidex OPA – active ingredient OPA
- Nu-Cidex – active ingredient peracetic acid
- Cidex Plus – active ingredient glutaraldehyde.

The ASA advises that sodium hypochlorite (Milton) and Virkon are NOT recognised by the TGA as high-level instrument grade disinfectants.

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. Some equipment manufacturers' guidelines for disinfection of ultrasound equipment are listed below.
- Disinfectant manufacturers' safety recommendations and instructions, and labelled conditions for use. Users should take care at all times 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) and occupational health and safety (OH&S) regulations. It is recommended that appropriate WH&S/OH&S protocols are developed and all staff are made familiar with these protocols.

The ASA does not recommend any particular disinfecting agent or system. The decision to use a specific disinfecting agent or system should be based on the requirements, resources and limitations of each ultrasound department.

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

- *Intimate examinations, consent and chaperones* (ASA, 2015)
- *Infection prevention and control guidelines for sonographers* (ASA, 2012)
- *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 Biology [9]
- *Australian guidelines for the prevention and control of infection in healthcare* (2010); National Health and Medical Research Council (NHMRC)
- *National Safety and Quality Health Service Standards*. 2nd edn (2017); Australian Commission on Safety and Quality in Health Care (ACSQHC).

Manufacturer information for cleaning and disinfection of ultrasound equipment

- GE Healthcare searchable online register of compatible cleaning, disinfection and gel products
http://www3.gehealthcare.com/en/Products/Categories/Ultrasound/Ultrasound_Probes
- Phillips disinfectant and cleaning solutions compatibility tables
<http://www.phillips.com.au/healthcare/resources/feature-detail/transducer-care-cleaning/disinfectants>
- Siemens Healthineers Transducer product-specific Approved Pre-Cleaners and High Level Disinfectants for Transducers (Disinfection Guides)
<https://www.healthcare.siemens.com.au/ultrasound/transducer-disinfection-guides>
- Canon Medical Systems guides for cleaning, disinfection, and sterilization of diagnostic ultrasound transducers, and transducer accessories
https://global.medical.canon/products/ultrasound/more_information/guideforcleaning
- Mindray transducer cleaning guidelines and equipment documents
<https://www.mindrayultrasound.com.au/brochures>

References

1. Australian/New Zealand Standard. *AS/NZS 4815:2006 Office-based health care facilities – Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment*. Standards Australia and Standards New Zealand. 2006.
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.
4. NHMRC. *Australian Guidelines for the Prevention and Control of Infection in Healthcare*. Commonwealth of Australia. 2010.
5. Therapeutic Goods Administration. *Summary of disinfectant regulation*. Australian Government. 11 Apr 2012. <https://www.tga.gov.au/node/4398>. Accessed June 2017
6. New Zealand Standard. *NZS 8134.3:2008. Health and Disability Services (Infection Prevention and Control) Standards*. Standards New Zealand. 2008.
7. New Zealand Government. *Health and Disability Services (Safety) Act (2001) and amendments*
8. 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.
9. Abramowicz JS, Evans DH, Fowlkes JB, Maršal K, terHaar G. WFUMB Safety Committee. Guidelines for cleaning transvaginal ultrasound transducers between patients. *J Ultrasound Med Biol*. 2017 May; 43(5):1076–9.