Advisory Statement A18/06

Requirement for High Level Disinfection of Ultrasound Transducers

Purpose
To remind practices that in accordance with the Diagnostic Imaging Accreditation Scheme (DIAS) requirements of Standard 1.6, Healthcare Associated Infection, ultrasound transducers which come in contact with broken skin, mucous membranes, blood or bodily fluids must undergo high-level disinfection using an instrument grade disinfection method approved by the Therapeutic Goods Administration (TGA), in accordance with the manufacturer's instructions for use.

This Advisory Statement should be read in conjunction with the requirements of DIAS Standard 1.6 in its entirety.

Issue
Each ultrasound procedure involves contact between the ultrasound transducer and the patient's skin, mucous membranes, or sterile tissues. Many potentially infectious agents may be transmitted by improperly maintained, cleaned and disinfected ultrasound equipment, including transducers. Failing to meet minimum infection control standards, including the proper cleaning and reprocessing of ultrasound equipment and transducers, increases the risk of harming human health by transmitting harmful pathogens.

Pathogens of concern which can be transmitted by ultrasound procedures include Staphylococcus aureus, multi-resistant gram-negative organisms, Chlamydia trachomatis, and viruses such as human immunodeficiency virus and human herpes virus.

Effective infection prevention and control is central to providing safe, high quality health care.

Requirements
It is a requirement of Standard 1.6, Healthcare Associated Infection that a practice providing ultrasound services has a documented infection control policy setting out the requirements for disinfecting ultrasound transducers which is consistent with the requirements of the Therapeutic Goods Order No.54 – Standard for Disinfectants and Sterilants (TGO54) or its equivalent.

TGO54 requires all semi-critical medical devices such as ultrasound transducers which come in contact with broken skin, mucous membranes, blood or bodily fluids, to be reprocessed by cleaning, followed by high-level disinfection using an instrument grade disinfection method approved by the TGA. High level disinfection methods may include:

- liquid, high-level instrument grade chemical disinfectants
- automated, high-level disinfection systems either chemical or light-based
- high-level instrument grade disinfectant wipes.

Approved high-level disinfection methods are listed on the Australian Register of Therapeutic Goods (ARTG). Only these approved high-level disinfection methods, when used in accordance with the manufacturer's instructions, meet the requirements of TGO54.
Care should be taken to ensure that the method selected is compatible with the ultrasound equipment being processed.

In relation to ultrasound equipment, the requirements of TGO54 and therefore Standard 1.6, Healthcare Associated Infection, will not be met if a practice is using a disinfection method which cannot provide high-level disinfection. The following do not provide high-level disinfection:

- alcohol wipes
- anti-bacterial tablets, solutions or units specific to infant feeding items
- stain removing powders or solutions.

Under the DIAS, the use of disinfection methods which are not compliant with TGO54 may be grounds for refusal of accreditation, or conditional accreditation, on public health and safety grounds.

In addition to cleaning and disinfection requirements, there are other measures for reducing the incidence and risk of infection, and preventing the transmission of infectious agents which should be included in a practice’s Healthcare Associated Infection Control policy and procedures. In relation to ultrasound transducers, this would include information about how infection control is practiced, for example:

- how and where transducers are stored after cleaning and high-level disinfection
- use and disposal of single-use, high quality transducer covers where transvaginal and transrectal procedures are performed.

For more information

See the Australasian Society for Ultrasound in Medicine’s Guidelines for Reprocessing Ultrasound Transducers for guidance on methods of high level disinfection.

Practices should also refer to the DIAS User Guide for Practices Applying for Accreditation for clarifying information about the evidentiary requirements for Standard 1.6, and contact their Accréditator for further information and advice.

Practices should also refer to and consider advice in the DIAS Advisory Statement 17/02 regarding the use of light-based disinfection systems for the purposes of high-level disinfection.
### Diagnostic Imaging Accreditation Scheme
#### Advisory Statement A18/06

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Links to other statements or advisory documents
- User Guide for Practices Applying for Accreditation
- DIAS Advisory Statement 17/02 regarding the use of light-based disinfection systems for the purposes of high-level disinfection.

Notes (if applicable) | N/A |