Advisory Statement A17/02

Light based disinfection systems for use with ultrasound probes

Purpose

To advise that the Antigermix® light based disinfection systems for use with ultrasound transducer probes are considered to meet the high level disinfection requirements of Standard 1.6, Healthcare Associated Infection Standard, under the Diagnostic Imaging Accreditation Scheme (DIAS).

Issue

The following Antigermix® devices for use with ultrasound probes utilise UVC radiation as an alternative to chemical disinfection processes:

- Antigermix® S1 (AS1) for use with external or endocavity ultrasound transducers
- Antigermix® E1 (AE1) for use with transoesophageal ultrasound transducers

Each of these devices is listed on the Australian Register of Therapeutic Goods (ARTG) as Class IIB medical devices. The public summary documents for these devices indicate they perform a high level of disinfection.

Prior to 1 April 2020, it was a requirement of Standard 1.6 that a practice providing ultrasound services had to have a documented infection control policy meeting the requirements of the Therapeutic Goods Order No.54 – Standard for Disinfectants and Sterilants (TGO54) or its equivalent. Light based disinfection systems were not explicitly referred to in TGO54 as a method for performing high level disinfection.

Practices should note that from 1 April 2019, TGO54 is no longer in effect. The Therapeutic Goods Administration (TGA) has confirmed that the relevant sections of the TGA Guidelines for the Evaluation of Disinfectants are considered equivalent to TGO54 for the purposes of informing practices about the requirements for high level disinfection of semi-critical medical devices. Standard 1.6 was updated from 1 April 2020 to reflect this change.

Requirements

In 2017, the DIAS Advisory Committee reviewed documentation relating to the listing of the Antigermix devices on the ARTG, and concluded that the devices provided high level disinfection and were considered to meet the requirements of Standard 1.6.

Furthermore, the Guidelines for the Reprocessing of Ultrasound Transducers developed by the Australasian Society for Ultrasound in Medicine and the Australasian College for Infection Prevention and Control (ACIPC) recognise that TGA approved automated high level disinfection systems, either chemical or light-based, will perform high level disinfection.

For the purposes of accreditation, practices using either of the listed medical devices to disinfect ultrasound probes should include a copy of the ARTG public summary document in their Disinfection Policy as evidence of compliance with Standard 1.6.

For more information

See the Australasian Society for Ultrasound in Medicine's Guidelines for Reprocessing Ultrasound Transducers for details about the cleaning and disinfection of ultrasound transducer probes.

Practices should 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 accreditor for further information and advice.

Diagnostic Imaging Accreditation Scheme Advisory Statement A17/02

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Relevant standard	Standard 1.6, Healthcare Associated Infection
Prepared by	Secretariat, Diagnostic Imaging Accreditation Scheme Advisory Committee
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