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.

It is a requirement of Standard 1.6 that a practice providing ultrasound services must have a documented infection control policy which meets the requirements of the Therapeutic Goods Order No.54 – Standard for Disinfectants and Sterilants (TGO54) or its equivalent. Light based disinfection systems are not explicitly referred to in TGO54 as a method for performing high level disinfection.

Requirements

The DIAS Advisory Committee has reviewed the documentation relating to the listing of these devices on the ARTG and has concluded that the devices conform to standards equivalent to TGO54 in regards to high level disinfection and if used, can be 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 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 accreditor for further information and advice.

Diagnostic Imaging Accreditation Scheme Advisory Statement A17/02

Title	**Light based disinfection systems for use with ultrasound probes**
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Compliance	Mandatory

Approved by	Department of Health based on recommendations from the Diagnostic Imaging Accreditation Scheme Advisory Committee
Review date	July 2019
Information in this statement applies to	DIAS Accreditors Providers of Medicare-funded ultrasound services
Relevant standard	Standard 1.6, Healthcare Associated Infection

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Links to other statements or advisory documents	User Guide for Practices Applying for Accreditation
Notes (if applicable)	N/A