Australasian Society for Ultrasound in Medicine

Promoting Excellence In Ultrasound

Policies and Statements

B2

Statement on the Disinfection of Transducers

Phone: +61 2 9438 2078 ● PO Box 943 Crows Nest NSW 1585 ● Email: asum@asum.com.au

Australasian Society for Ultrasound in Medicine

Policies and Statements

B2

Statement on the Disinfection of Transducers

*May 1996, **Reaffirmed** September 1999, **Revised** July 2005, September 2007, April 2011, March 2012, November 2013*

1. SCOPE

This statement provides recommendations for the cleaning and disinfection of:

- All intracavity ultrasound transducers (including, but not limited to, transvaginal, transrectal and transoesophageal
- All transducers that are likely to come into contact with broken skin
- All transducers used during ultrasound guided biopsy or injection
- All transducers used in ultrasound guided interventional procedures
- All transducers used within a sterile environment (such as operating theatres).

2. ABBREVIATIONS AND DEFINITIONS

TGA:	Therapeutic Goods Administration
MSDS:	Material Safety Data Sheet: a form supplied with the product detailing the properties of the product
TG054	Therapeutic Goods Order No.54

3. BACKGROUND

3.1 GENERAL:

Every patient must be regarded as a potential source of infection and appropriate precautions should be taken to prevent cross-infection between patient and operator. These are known as “Universal Precautions” and are promoted as an essential part of all health care institutions.

Standard precautions that should be undertaken as part of every examination include:

- Washing of hands both before and after direct patient contact
- Use of personal protective equipment where appropriate
- Maintenance of clean and/or disinfected patient equipment (as required)
- Maintenance of a clean working environment
- Correct disposal of waste.

3.2 MEDICAL INSTRUMENT CLASSIFICATION:

The risk of transmitting infections on instruments and equipment is related to the presence or absence and burden of infectious agents (number and virulence), the type of procedure (e.g. invasive versus non-invasive) and the body site where the instrument is used (e.g.

submucosal invasion versus intact skin).

The Spaulding classification system[1] suggests that contact sites for instruments may be classified as critical, semicritical or noncritical and that instruments should be classified accordingly[1].

Instruments that come into contact with intact nonsterile mucosa (or nonintact skin) are considered semi-critical instruments. Semi-critical instruments should preferably be sterile or must be a minimum of high level disinfected, after each use.

High level disinfection is necessary, even when a single use disposable probe cover is used routinely, due to the possible rupture or breeching of the transducer cover which could lead to contamination of the transducer[2].

3.3 MICROBIAL REDUCTION:

Sterilisation/disinfection represents a statistical reduction in the number of microbes present on a surface. Meticulous cleaning of the instrument is the essential key to an initial reduction of the microbial/organic load by at least 99%.

Every patient must be regarded as a potential source of infection and appropriate precautions should be taken to prevent cross-infection between patient and operator. These are known as “Universal Precautions” and are promoted throughout all health care institutions. Particularly important is the washing of hands both before and after direct patient contact[1]. Other precautions will include use of personal protective equipment where appropriate and correct handling and disposal of waste and maintenance of a clean working environment.

Potential sources of infection associated with vaginal ultrasound scanning include those organisms transmitted by blood and genital secretions such as Human Immunodeficiency Virus, Hepatitis B Virus, Hepatitis C Virus, Cytomegalovirus, Neisseria gonorrhoea, Chlamydia trachomatis, Trichomonas vaginalis[1] and Human Papilloma Virus. It should be remembered that some organisms, including some viruses, can remain infectious for days outside the body, particularly if kept moist in blood or serum.

All sterilisation/disinfection represents a statistical reduction in the number of microbes present on a surface. Meticulous cleaning of the instrument is the essential key to an initial reduction of the microbial/organic load by at least 99%[2].

The following protocol is recommended for the cleaning and preparing of intracavitary transducers between patients. These will include transvaginal, transrectal, transoesophageal and endoscopic transducers. The principles are the same for any transducers that may come into contact with body secretions.

4. MINIMUM REQUIRED PROCEDURE

Using these guidelines as a baseline the following recommendations are made for the procedures listed in section 1 (Scope).

4.1 OPERATOR TRAINING:

Health care workers who clean and disinfect reusable medical instruments must be trained in all necessary procedures. They should receive formal training in equipment cleaning and processing, disinfection and/or sterilisation at an appropriate level.

4.2 OPERATOR REQUIREMENTS:

The operator must wear a disposable (non-sterile) glove on the hand used during the procedure. Care must be taken to ensure that contaminated gloves do not contact the ultra-

sound machine or the exposed transducer cable. At the completion of the procedure the glove should be removed and disposed of in the correct receptacle and hands should be washed thoroughly in warm soap and water.

4.3 PROBE COVERS:

Prior to the use of a transducer cover, specific enquiry should be directed to the patient regarding latex sensitivity and, if appropriate, special non-latex covers may need to be utilised[3].

The most preferred option is using a cover that is at least 38 microns thick. This may include condoms, specific probe covers, surgical drapes, or surgical gloves. At the end of the procedure, using a gloved hand, the disposable cover should be removed and discarded, taking care not to contaminate the surface of the instrument.

Although the use of a disposable cover reduces the level of risk of transmission of infection or contamination, covers can be perforated or contain small, unrecognised defects[2].

4.4 CLEANING:

Cleaning is an essential prerequisite for all effective disinfection processes because organic residue may prevent the disinfectant from contacting the item being processed and may also bind and inactivate chemical disinfectants[4].

Utilising running water, all the gel should be removed from the transducer. A free-rinsing, mild alkali is preferred over neutral detergents. Use a small, soft brush to clean any crevices or angles. The current Australian standard outlines that standard household-type detergents and soaps are not a recommended cleaner due to their high foaming properties which increases the residue left behind and decreases the effectiveness of the clean. The transducer must be thoroughly cleaned and then dried with a soft, disposable towel.

4.5 DISINFECTION:

Cleaning of the transducer is an essential part of the disinfection process. However, high level disinfection, with a chemical agent is necessary for further statistical reduction in the number of infective agents on the transducer. All chemical agents utilised must be TGA approved for use as a high level disinfectant on medical devices.

High level disinfection TGA-approved chemical agents that may be used according to manufacturer instructions include:

a) Glutaraldehyde
b) *Ortho-phthalaldehyde*
c) Hydrogen peroxide

Sodium hypochlorite is not TGA approved for high level disinfection of medical equipment and is not suitable for use in disinfecting transducers.

The definitions given in TGO54 state that, when used as recommended by the manufacturer, high level disinfectants inactivate all microbial pathogens, except large numbers of bacterial endospores.

5. FURTHER RECOMMENDATIONS

5.1 The equipment manufacturer must be consulted prior to using any chemical disinfectant on their transducers and all chemical agents utilised must be TGA approved for use as a high level disinfectant on medical devices. The requirement for the use of personal protective equipment, if suggested, for each chemical agent must be followed.

5.2 Ultrasound transducers are heat sensitive items and as such will need to be disinfected using low-temperature chemical sterilising agents or systems. The ability of chemical disinfectants to effectively inactivate contaminating infectious agents depends on a number of factors, including the initial number of agents present, temperature, pH and concentration[5].

Chemical disinfectants intended to cover a range of different levels of disinfection may specify different exposure and/or temperature combinations on the product label.

The active ingredients of the disinfectant in use must also be closely monitored as recommended in the manufacturer's guidelines. However, consideration should be given to more frequent monitoring when large volumes of items are being processed.

5.3 Where liquid chemicals are used the transducer should be soaked in the solution for the recommended time and temperature (as recommended by the manufacturer), followed by rinsing under copious amounts of water and then drying. These products may have associated toxic issues and as such Personal Protective Equipment must be used along with fume cabinets and other directions as outlined on the MSDS. Efficacy must be checked daily, or as recommended by the manufacturer (with the appropriate chemical test strip indicators) to ensure that it is still at a viable strength to achieve high level disinfection.

Care should be taken to follow each disinfectant's labelled conditions for the use of their specific products. Directions for use are not interchangeable between formulations from either the same or different manufacturers.

It must be noted that the transducer must not be left in the chemical agent for longer than the recommended time due to the possibility of damage. This means that the soaking period should be timed.

5.4 It is recommended that post-disinfection rinsing is performed using sterile water as the use of tap water can reintroduce pseudomonas to the disinfected medical device.

6. ASSOCIATED DOCUMENTS

Document Name	Author
Australian/New Zealand Standard: AS/NZS4187:2003 Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities	Standards Australia and Standards New Zealand
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
Australian regulatory guidelines for medical devices Version 1.1, May 2011	Australian Government Department of Health and Ageing
Hard surface disinfectants & instrument grade disinfectants (including sterilants) Factsheet 23 October 2006 http://www.tga.gov.au/industry/disinfectants-hard-surface.htm#g3	Australian Government Department of Health and Ageing
NHMRC (2010) Australian Guidelines for the Prevention and Control of Infection in Healthcare. Commonwealth of	Australian Government National Health and Medical

Australia.	Research Council
Infection Control Policy	NSW Health
Reprocessing Intracavitary Transducers	Victorian Government Health Information

7. REFERENCES

Document Details

1. Spaulding EH, 1968 Chemical Disinfection of Medical and Surgical Materials. In: Disinfection, Sterilization and Preservation. Lawrence CA and Block SS (editors). Philadelphia: Lea and Febiger; pp. 517–31.

2. Storment JM, Monga M and Blanco JD. Ineffectiveness of Latex Condoms in Preventing contamination of the Transvaginal Ultrasound Head. *Southern Medical Journal* 1997: 90; 206–8.

3. Douglas R, Morton J, Czarny D and O'Hehir R. Prevalence of IgE-Mediated allergy to latex in hospital nursing staff. *Australian and New Zealand Journal of Medicine* 1997: 27; 165–8.

4. Muscarella LF. Are all sterilization processes alike? *AORN Journal* 1998: 67: 966–70, 973–6.

5. Chiba K. Aspects of disinfectants for control of nosocomial infections.Hokkaido Igaku Zasshi 1994: 69; 182–7.

6. Deva AK, Vickery K, Zou J, West RH, Selby W, Benn RA, Harris JP and Cossart YE. Detection of Persistent vegetative bacteria and amplified viral nucleic acid from in-use testing of gastrointestinal endoscope. *Journal of Hospital Infection* 1998: 39; 149–7.