Government of **Western Australia**
Department of **Health**

OPERATIONAL DIRECTIVE

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Subject: PREVENTION OF CROSS INFECTION IN DIAGNOSTIC ULTRASOUND

Compliance with this Operational Directive is mandatory for all public hospitals and those private healthcare facilities, contracted to provide services to public patients.

This Operational Directive describes the minimum requirements for the cleaning and disinfection of diagnostic ultrasound transducers in Western Australian healthcare facilities. All healthcare facilities shall ensure their procedures are aligned with those described within this Operational Directive.

Introduction

Studies have shown that there is some risk of microbial transmission during ultrasound examination procedures. The risk is significantly increased with the use of intracavity transducers and /or where blood and body fluids are encountered. To prevent or minimise the risk of infection, Standard Precautions should be adhered to at all times when patient care is provided. Every patient is regarded as a potential source of infection and therefore appropriate precautions should be taken to minimise the risk of cross-infection. Standard precautions that should be undertaken as part of every examination include:

- Hand hygiene before and after each examination
- Use of personal protective equipment where appropriate
- Maintenance of clean and/or disinfected patient equipment
- Maintenance of clean working environment
- Correct disposal of waste

Classification of Medical Instruments

The risk of transmitting infection on diagnostic ultrasound transducers is related to the presence and burden of micro-organisms (number and virulence), the body site explored (submucousal or intact skin) and the type of procedure (invasive or non-invasive).

The Spaulding classification system allows for risk of infection adjustments based on the contact sites and instruments may be classified as critical, semicritical or noncritical.

Table 1: Spaulding Classification of infection risk

Critical	These items confer a high risk for infection if they are contaminated with any microorganism and must be sterile at the time of use. This includes any objects that enter sterile tissue or the vascular system, because any microbial contamination could transmit infection.
Semi-critical	These items come into contact with mucous membranes or non-intact skin, and should be single use or sterilised after each use. If this is not possible, high-level disinfection is the minimum standard of reprocessing that is acceptable.
Non-critical	These items come into contact with intact skin but not mucous membranes. Thorough cleaning is sufficient for most non-critical items after each individual use, although either intermediate or low-level disinfection may be appropriate in specific circumstances.

This operational directive provides guidance on cleaning and disinfection for the following:

- All transducers that are likely to come into contact with broken skin
- All intracavitary transducers (for example, transvaginal, transrectal, transoesophageal)
- All transducers used during ultrasound-guided biopsy or infiltration
- All transducers used in ultrasound-guided interventional procedures
- All transducers used within a sterile environment (such as operating theatres)

There are 2 relevant national documents for consideration:

1. AS/NZS 4187-2003 Cleaning, disinfecting and sterilising reusable medical and surgical instruments and equipment and maintenance of associated environments in health care facilities
2. Australian Guidelines for the Prevention and Control of Infection in Healthcare (2010)

Caution: Ultrasound transducer users must verify that the cleaning and processing procedures are in compliance with warranty requirements of the manufacturer.

OPERATOR TRAINING

All health care workers who clean and disinfect reusable medical instruments must be trained in all necessary procedures. It is required that the appropriate health and safety protocols are developed and all staff is familiar with these protocols.

GUIDELINES

1. TRANSABDOMINAL ULTRASOUND

To minimise cross infection the following is required:

1.1 Hand hygiene

Hand hygiene must be performed before and after each patient contact.

1.2 Cleaning of the ultrasound transducer

After each use, remove coupling gel from probe by wiping with a soft cloth and wash the probe with surface in lukewarm water and mild detergent with a soft sponge, gauze or cloth, removing all visible residue. Do not use harsh detergents or abrasive cleaners.

Rinse thoroughly in flowing water to remove all detergent residues. Air dry or dry with a soft cloth**.**

1.3 Patients with wounds and/or abrasions

A disposable transducer cover should be used. After use, follow point 1.2. **In event of blood or bodily fluid contamination, the protocol for probes used for intracavity ultrasound applies.**

2. INTRACAVITY ULTRASOUND

In general, intracavity ultrasound poses an increased risk of cross-infection compared to transabdominal scanning. The following scanning procedures carry significant risk of cross infection due to contact with mucous membranes and/or blood or body fluids:

- Transvaginal
- Transrectal
- Intracavity and wound
- Transoesophageal

Intracavitary ultrasound transducers are categorised as class II b (see Appendix A), semicritical reusable instruments requiring high-level instrument grade disinfection or sterilisation when appropriate (theatre sterile procedures). High level disinfection is necessary even when a single use disposable probe cover is used routinely, due to either identifiable or occult breach/perforations of the transducer cover.

To minimise cross infection the following is recommended:

2.1 Hand hygiene

Hand hygiene is an absolute pre-requisite to all reprocessing. A disposable glove must be worn on the hand holding the transducer. Care must be taken to ensure that the contaminated glove does not touch the ultrasound machine or the exposed transducer cable. At the completion, the glove should be removed and disposed of appropriately and hand hygiene performed.

2.2 Transducer Covers

Patients should be asked specifically regarding latex sensitivity and where necessary special non-latex covers should be used, e.g. non-latex surgical glove such as nitrile.

The transducer must be covered before insertion. The most preferred option is using a cover that is at least 38 microns thick. Examples of these include purpose made lubricated sheathes, surgical drape, surgical gloves or condoms.

The transducer drape should fully cover the probe, minimising the risk of possible rupture by over stretching.

At the end of the examination, the disposable cover should be removed with a gloved hand and discarded, taking care not to contaminate the surface of the transducer.

2.3 Cleaning

Cleaning of the transducer prior to disinfection is crucial as it reduces the microbial load making the disinfection process more effective. On completion of an ultrasound examination, all gel and extraneous material should be removed from the transducer using running water. Use a small, soft brush to clean any crevices or angles, being careful to avoid the elements at the probe face. All intracavity transducers must then undergo high level disinfection as a minimum standard.

2.4 Disinfection of the intracavity ultrasound transducer

Only chemicals registered with the Therapeutic Goods Administration (TGA) as high-level instrument grade disinfectants for class IIb medical devices are to be used for intracavitary ultrasound transducers and these include

- Ortho-phthalaldehyde (OPA) 0.55%
- Gluteraldehyde 2%
- Hydrogen Peroxide, used with the Trophon EPR System
- Peracetic Acid, as in STERIS system
- Chlorine Dioxide, used with the Tristel wipes system

All solutions used must be a labelled instrument grade high level disinfectant.

2.4.1 Orthophthalaldehyde (OPA)

The cleaned transducer is soaked (taking care to avoid electrical connections and cables being immersed) in a commercially available OPA solution for 10 minutes at 20 degree Celsius or higher, followed by rinsing under tap water and drying. The use of OPA requires the wearer to wear personal protective equipment. If adequate air circulation is not available, a fume cabinet may be necessary. Regular testing needs to be performed to ensure a minimal effective concentration with the use of test strips. Refer to Manufacturers instructions for possible contraindications for use.

2.4.2 Glutaraldehyde

The cleaned transducer is soaked (taking care to avoid electrical connections and cables being immersed) in a commercially available 2% glutaraldehyde solution for 20 minutes followed by rinsing under tap water and then drying. Because of the potential irritant effects of glutaraldehyde, care must be taken with its use including protective clothing. Hospitals who wish to continue using glutaraldehyde to disinfect diagnostic ultrasound probes will require a purpose built fume removal cabinet. [Purchase of cabinets will be the responsibility of the Health Service concerned.]

2.4.3 Hydrogen peroxide

An approved automated system (Trophon EPR system) using hydrogen peroxide in an option. No rinsing is required at the completion of the cycle. The manufacturer's instructions for use must be carefully followed.

2.4.4 Paracetic Acid, as in the STERIS system

This has been recommended for use by Australian Sonographers Association.

2.4.5 Chorine Dioxide, as in Tristel wipes system

While Chorine dioxide is TGA-approved for disinfecting ultrasound transducer probes, concerns have been raised about the method of application. It is therefore recommended that the manufacturers (Tristel) instructions are strictly adhered to ensure that all surface area is cleaned adequately and kept in contact with the active ingredient for the appropriate length of time. In addition, users must be trained in the appropriate disinfection techniques, in keeping with the Australian Guidelines for the Prevention and Control of Infection in Healthcare (2010).

Prior to use, ensure that the disinfectant is listed in the transducer manufacturer's manual as compatible for use with the particular model of transducer to be disinfected

Further Recommendations

All those working with ultrasound equipment are required to be familiar with policies and guidelines regarding disinfection and reprocessing.

Updates regarding the disinfection/reprocessing techniques should be circulated to appropriate staff. In particular, staff should be informed of any changes to TGA-approved agents, in a timely manner.

REFERENCES

1. Australasian Society for Ultrasound in Medicine (ASUM, 2012). Promoting Excellence in Ultrasound. B2 Statement on the Disinfection of Transducers.
2. AS/NZS 4187-2003 Cleaning, disinfecting and sterilising reusable medical and surgical instruments and equipment and maintenance of associated environments in healthcare facilities.
3. Australian Guidelines for the Prevention and Control of Infection in Healthcare (2010). National Health and Medical Research Council (NHMRC). Available at: http://www.nhmrc.gov.au/node/30290
4. A new regulatory framework for disinfectants. Therapeutic Goods Administration. Disinfectants final report to stakeholders February 2008.
5. Therapeutic Goods Order No. 54 – Standard for Disinfectants and Sterilants.
6. The Australian Sonographers Association (ASA). Disinfection of intracavity ultrasound transducers. May 2012.
7. ASUM Standards of practice press release "ASUM's stance on the use of the Tristel Wipe System for disinfection of ultrasound probes" May 2012.

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This information is available in alternative formats upon request for a person with a disability.

Appendix A: Therapeutic Goods Administration (TGA) Classification of medical devices

Classification	Level of risk of infection
Class I	Low
Class I – supplied sterile Class I – incorporating a measuring function Class IIa	Low-Medium
Class IIb	Medium-high
Class III	High
Active implantable medical devices (AIMD)	High