SESLHD PROCEDURE COVER SHEET

Health
South Eastern Sydney
Local Health District

NAME OF DOCUMENT	Ultrasound Reprocessing: Definitive Reprocessing of Reusable Ultrasound Transducers Between Use
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EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	Director Clinical Governance and Medical Services
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POSITION RESPONSIBLE FOR THE DOCUMENT	Infection Prevention and Control Practitioners, SSD Managers SESLHD-InfectionControl@health.nsw.gov.au
FUNCTIONAL GROUP(S)	Infection Control
KEY TERMS	High level disinfection, low level disinfection, ultrasound transducers, disinfection, cleaning, transducer, Instructions for use,
SUMMARY	The document outlines best practice decision making guidelines in determining the most appropriate cleaning, disinfection and where possible sterilisation technique for all varieties of non-lumen ultrasound transducers.

1. POLICY STATEMENT

Ultrasound procedures involve contact between an ultrasound transducer and the patient's skin, mucous membranes or sterile tissues for diagnostic purposes and/or treatments. Ultrasound transducers must be appropriately reprocessed between each and every use according to and depending on the Spaulding classification of their intended use and the transducer manufacturer's instructions.

2. BACKGROUND

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, and manufacturers instructions for use (IFU's) including the proper cleaning and reprocessing of ultrasound equipment and transducers, increases the risk of harming human health by transmitting harmful pathogens.

Ultrasound Transducer refers to external ultrasound transducers (e.g., surface, Doppler, linear transducers) and non-lumened endocavity transducers (e.g., transvaginal, transrectal and transesophageal transducers).

Reprocessing refers to the activities required to ensure that a Reusable Medical Device (RMD) is safe for its intended use. Reprocessing is a multistep process that includes cleaning, inspection and assembly, functional testing (if applicable), disinfection (if applicable), packaging and labelling, sterilisation (if applicable) and controlled storage.

Utilising the Spaulding classification to profile RMD, ultrasound transducers are classified as **non-critical**, **semi-critical** or **critical** according to the risk of transmission of microorganisms associated with their use (see section 4.2).

Depending on a risk assessment of the reprocessing environment conducted by CSSD manager and Infection Control as well as the clinical requirements of a clinical area, reprocessing of RMD may be conducted either within Central Sterilising Services Department (CSSD) or at the point of care for high-level or low-level disinfection;

Approval to conduct reprocessing at point of care will be based on

- Inventory Sufficiency and frequency of usage
- Adequate flows and space – i.e. dirty to clean flows with appropriate segregation
- Adequate ventilation systems
- Correct water quality (if required)
- Appropriately trained staff
- Distance from and universal time access to Centralised reprocessing facility.

3. RESPONSIBILITIES

3.1 Employees will:

- Comply with the requirements of this procedure and appendix 1.
- Report issues relating to unsterile or inadequately disinfected equipment and reprocessing technologies.

3.2 Line Managers will:

- Implement the requirements of this procedure to assure the quality and safety of Reprocessed RMDs
- Ensure any new ultrasound equipment is initially reviewed by the Sterilising services Manager and a method of cleaning and reprocessing in line with this procedure is approved prior to purchase
- Undertake and document a risk assessment when local reprocessing (at point of care) is implemented rather than through a centralised CSSD reprocessing
- Ensure the risk assessment has input from the SSD manager or the infection prevention and control CNC and work health and safety officer
- Initiate a look back recall exercise in the event of disinfection failure for semi-critical RMDs and critical RMDs undergoing high level chemical disinfection
- Establish a back-up reprocessing option at an approved centralised or other satellite location.

3.3 Sterilising Services Manager (or equivalent) will:

- Be involved in the overall governance of ultrasound transducers within their respective facility
- Be involved in the selection and evaluation process prior to the purchase of a RMD, to ensure compatibility with the defined cleaning processes available for use in the reprocessing facility
- Implement internal independent auditing of all remote reprocessing of any RMD across the facility.

4. PROCEDURE

The level of ultrasound transducers reprocessing is based on the Spaulding classification of the ultrasound transducer and intended use.

4.1 Cleaning

Cleaning is the essential first step in reprocessing. Improper cleaning could render subsequent disinfection or sterilization ineffective. The aim of cleaning is to remove any visible organic and inorganic material from the ultrasound transducer.

Any equipment such as keyboards and leads/cables attached to the transducer that may have been in contact with the patient or operator must be cleaned between uses, as per manufacturer instruction for use (IFU). Cleaning should include the use of a TGA

approved detergent and/or wipe or solution in accordance with SESLHDGL/029 - Infection Control: Cleaning (Shared) Patient Care Equipment Guideline.

4.2 Spaulding Classification

Each ultrasound transducer should be classified according to the Spaulding classification based on its intended use as outlined below.

4.2.1 Non-critical ultrasound transducers

- The ultrasound transducer only comes in contact with healthy intact skin, and will not contact mucous membranes, the bloodstream or sterile tissues.
- Example of procedure where the ultrasound transducer is non-critical include abdominal scans on healthy skin.
- Require a minimum of **low-level disinfection** (LLD) as described in section 4.3.1 below, before and after each use.
- Where an operator considers the Ultrasound Transducer to have been inadvertently contaminated by mucous, blood and/or any other body fluids during the course of the procedure, the reprocessing method must be conducted in accordance with the risk associated with the exposure:

4.2.2 Semi-critical ultrasound transducers

- The ultrasound transducer comes in contact with mucus membrane and/or non-intact skin (e.g. skin with abrasions, dermatitis, chapped skin, rash, psoriasis) and transducers that have had likely contact with blood/body fluids. For the purpose of this procedure, this also includes transducers used on non-intact skin or contact with mucous membranes (transducers used for vascular system access/ blocks or injections used on or near a sterile field).
- Semi-critical transducer do not contact sterile tissue or the bloodstream.
- An example would be a trans-vaginal ultrasound examination.
- Require a minimum of **high-level disinfection** (HLD) as described in section 4.3.2 below after each use
- After HLD reprocessing transducers must be stored in a clean dry place (such as clean container/ with lid lined with sterile drape; hang in dedicated cabinets with adequate ventilation) ready for the next use.
- **In the event semi-critical ultrasound transducers are used in conjunction with a sheath, the transducer still requires HLD**

4.2.3 Critical ultrasound transducers

- The ultrasound transducer contacts or enters sterile body cavities, sterile tissue or the vascular system.
- An example would be the use of the transducer intra-operatively during an US-guided liver resection
- Requires sterilisation at the CSSD/TSSU after each use and must be presented in a sterile condition ready for the next use.
- In general, critical ultrasound transducers include those used in surgical procedures and some ultrasound guided interventions- e.g. Choledochoscope and video derivatives

4.2.4 Considerations for reprocessing

- Pre-treatment, transportation, cleaning and segregation of ultrasound transducers must occur as per SESLHDPR/495 - Sterilisation: Definitive Cleaning of Reusable Medical Devices and Equipment
- Inspection of ultrasounds post cleaning, disinfection and sterilisation must occur as per SESLHDPR/306 - Sterilisation: Inspection, Assembly, Packaging and Wrapping of Post Cleaned Reusable Medical Devices (RMDs)
- Traceability systems must be in place for all semi-critical and critical Ultrasound transducer as per SESLHDPR/526 - Sterilisation: Traceability of Reprocessed Medical Devices (RMDs)
- Equipment such as Endoscope Washer-Disinfectors (EWD's) Automated Endoscope Reprocessors (AER's) washer- disinfectors (WD's), Hydrogen-Peroxide-based Nano-Nebulant disinfection systems (NNDS) , Ultra-violet C (UVC) Disinfection systems, Hydrogen-Peroxide and Formaldehyde- based Low-temperature sterilisers (LTS) and associated equipment utilised for Ultrasound Reprocessing must have appropriate monitoring and validation of equipment as per SESLHDPR/548 - Sterilisation: Routine Monitoring of Cleaning, Disinfection and Sterilisation Processes
- An OEM approved preventative maintenance program must be in place for reprocessing equipment as per SESLHDPR/503 - Sterilisation: Reprocessing Equipment - Preventative Maintenance
- Issues surrounding inadequate cleaning, disinfection or sterilisation of ultrasound transducers must be managed as per SESLHDPR/504 - Sterilisation: Control of nonconforming Reusable Medical Devices (RMD) and Recall of RMDs
- Recall procedures must also be in place as per SESLHDPR/504 - Sterilisation: Control of nonconforming Reusable Medical Devices (RMD) and Recall of RMDs.
- Ultrasound Transducers must be cleaned and disinfected as per Sterilising Department Manager Instructions and manufacturers guidelines. A guide for reprocessing is included in Section 4. Departments must seek written approval from Sterilising Department Managers.

4.3 Methods of reprocessing non-critical and semi-critical ultrasound transducers.

Ultrasound transducers must be reprocessed in line with manufacturer's guidelines to ensure compatible detergents, rinse agents and disinfectants are utilised. Ultrasound transducers must be stored safely and correctly after use.

4.3.1 Low-level disinfection (LLD)

- Intended for ultrasound transducers classified as non-critical e.g. bladder scanner
- Manually remove all ultrasound gel prior to LLD, utilising non-shedding paper towel or absorbent equivalent, followed by cleaning with a pH-neutral instrument-grade detergent wipe as per the ultrasound transducer manufacturer IFU. Note: Residual barrier wipes as used on furniture and surfaces are not suitable for use on any RMD
- Use TGA-approved disposable disinfectant wipe or multiple wipe system as per the ultrasound transducer manufacturer IFU. Note: Alcohol-based wipes must not be used. See note above re use of residual barrier wipes.

4.3.2 High-level disinfection (HLD)

- HLD methods inactivate all microbial pathogens, except large numbers of bacterial endospores
- Sheath must be removed and gross soiling, such as gel, removed at point of use prior to transport to CSSD/TSSU
- Ultrasound transducers requiring HLD by preference should be reprocessed at the CSSD using an HLD method that is approved by the transducer manufacturer. As an alternative, reprocessing may take place at the point-of-care using approved and compatible disinfectant and or low temperature sterilizing methods and following safe work procedures as developed by SSD
- Clinical areas utilising HLD at the point-of-care MUST comply with AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organisations, and any relevant amendments.

4.3.3 Transportation and Storage of Ultrasound transducers

- All Ultrasound Devices must be transported in dedicated fully enclosed and decontaminated receptacles to reduce risk of recontamination and damage during transport
- Ultrasound transducers must be stored to reduce risk of contamination of device after reprocessing. This may be on consoles, in cabinets or in/on other approved storage units
- If stored in a transport case or other enclosed receptacle, these must also be subject to audit for their hygiene status to ensure they do not retain or harbour transmissible residue
- Monitoring of storage facilities may be undertaken using calibrated luminometers utilizing Adenosine Tri-phosphate (ATP) based sampling consumables.

5. DOCUMENTATION

- SESLHDPR/548 - Sterilisation: Traceability of Reprocessed Reusable Medical Devices (RMDs)
- Each reprocessing method or machine (i.e. Nano-Nebulant Trophon, UVC etc) shall have established patient traceability record which can be manual or electronic. All Trophon & UVC systems should be equipped with a printer at time of purchase. Where printers are not present, Retro-fit of printers must take place prior to December 2021.

6. AUDIT

- As per local facility AS/NZS 4187:2014 audit requirement and frequency or following any identified breach of procedure.

7. REFERENCES

- AS-NZS 4187 2014 Reprocessing of Reusable Medical Devices in Healthcare, (& amendments.)
- Australian Guidelines for the Prevention and Control of Infection in Healthcare
- NSW Ministry of Health Policy Directive PD2017_013 - Infection Prevention and Control Policy

- Australasian Society for Ultrasound in Medicine (ASUM) 2017 Guideline for Reprocessing Ultrasound Transducers
- SESLHDGL/029 - Infection Control: Cleaning (Shared) Patient Care Equipment Guideline
- SESLHDPR/495 - Sterilisation: Definitive Cleaning of Reusable Medical Devices and Equipment
- SESLHDPR/306 - Sterilisation: Inspection, Assembly, Packaging and Wrapping of Post Cleaned Reusable Medical Devices (RMDs)
- SESLHDPR/526 - Sterilisation: Traceability of Reprocessed Medical Devices (RMDs)
- SESLHDPR/548 - Sterilisation: Routine Monitoring of Cleaning, Disinfection and Sterilisation Processes
- SESLHDPR/503 - Sterilisation: Reprocessing Equipment - Preventative Maintenance
- SESLHDPR/504 - Sterilisation: Control of nonconforming Reusable Medical Devices (RMD) and Recall of RMDs
- SESLHDPR/504 - Sterilisation: Control of nonconforming Reusable Medical Devices (RMD) and Recall of RMDs
- TGO 104: Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Order 2019

8. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
February 2021	DRAFT	New procedure
April 2021	DRAFT	Draft for comment period.
May 2021	DRAFT	Final version approved by Executive Sponsor. To be tabled at Clinical and Quality Council for approval.
June 2021	0	Endorsed by Clinical and Quality Council.

Appendix 1: Flowchart for management of Ultrasound transducers