Thermal Disinfection of Reusable Medical Devices Procedure

1. Purpose

The purpose of this procedure is to provide guidance on the requirements for thermal disinfection of reusable medical devices (RMDs).

This procedure applies to all WA Country Health Service (WACHS) healthcare workers that use or reprocess RMDs.

2. Procedure

Thermal disinfection is one method that can be used to disinfect RMDs. It is used when the RMD cannot withstand moist heat or low temperature sterilisation processes.

2.1 Disinfection of cleaned RMDs

- Prior to thermal disinfection, the RMD is to be thoroughly cleaned. Effective thermal disinfection is dependent on the achievement of a low bioburden and the absence of heat-resistant microorganisms.
- The minimum surface temperature-time relationships for thermal disinfection are outlined in AS 5369:2023, Table 6.1 *Common holding times for thermal disinfection using moist heat to achieve A0 of 600*.
- All parts of the item need to be subjected to moist heat at or above the recommended temperature for the recommended duration.
- To avoid the risk of cross infection, respiratory equipment is to be washed and thermally disinfected after each use using a validated mechanical washer as per the manufacturer's instructions for use (IFU).

2.2 Thermal disinfection

- RMDs that can be thermally disinfected must be checked, assembled to a standard configuration specified by the user area and packaged on a workstation designated for that task.
- Each thermally disinfected RMD will have a quality control document inside the sealed plastic bag with a label to indicate "Clean only by means of thermal disinfection" with the following details:
  - date
  - set type and description of RMD
  - initial of staff member assembling
  - initial of staff member checking
  - comments column.

3. Roles and Responsibilities

Health Service Organisations are responsible for ensuring adequate resources and support is provided to all staff to ensure a safe working environment.

SSD Manager/Supervisor is to implement the requirements of this document to ensure the processing of RMDs is compliant with AS 5369:2023 and associated normative references and ensure the quality and safety of reprocessed RMDs.

SSD staff must comply with the requirements of this document and report non-compliance to the SSD Manager/Supervisor or Perioperative Services Manager.

All staff are required to work within policies and guidelines to make sure that WACHS is a safe, equitable and positive place to be.

4. Monitoring and Evaluation

4.1 Monitoring

Regular monitoring will contribute to compliance with relevant Standards, good quality patient outcomes and improved staff satisfaction.

The SSD Manager/Supervisor or Perioperative Services Manager is responsible for ensuring that:

- monitoring of compliance with this document is carried out in line with AS 5369:2023
- risk assessments are completed, outcomes evaluated, and actions taken as required.

4.2 Evaluation

Review of this document will be coordinated by the Surgical Services Program Team in collaboration with key stakeholders including relevant Advisory Forums.

5. Compliance

This procedure is a mandatory requirement under the *Therapeutic Goods Act 1989* (Cwlth) and AS 5369:2023.

Failure to comply with this procedure may constitute a breach of the WA Health Code of Conduct (Code). The Code is part of the Integrity Policy Framework issued pursuant to Section 26 of the *Health Services Act 2016* (WA) and is binding on all WACHS staff which for this purpose includes trainees, students, volunteers, researchers, contractors for service (including all visiting health professionals and agency staff) and persons delivering training or education within WACHS.

WACHS staff are reminded that compliance with all policies and procedures is mandatory.

6. References

1. AS 5369:2023 Reprocessing of reusable medical devices and other devices in health and non-health related facilities. Available from https://www-saiglobal-com.wachslibresources.health.wa.gov.au/online/.
2. ANSI/AAMI ISO 17665-1: 2006 (R2013). Sterilization of health care products – Moist Heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices. Available from https://www-saiglobal-com.wachslibresources.health.wa.gov.au/online/.

3. AAMI/ISO/TIR 17665-2:2009 (R2016). Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1. Available from https://www-saiglobal-com.wachslibresources.health.wa.gov.au/online/.
4. Women and Newborn Health Service. Hospital Sterile Supply Department Policy and Procedure Manual - HSSD reprocessing activities. King Edward Memorial Hospital Sterile Supply Department (HSSD), 2021.

7. Definitions

Term	Definition
Instructions for use (IFU)	Information provided by the manufacturer for the intended user detailing how the device can be used safely for its intended purpose.
Reusable medical device (RMD)	A medical device designated or intended by the manufacturer as suitable for processing and reuse. Clarification notes: 1. This is not a medical device that is designated or intended by the manufacturer for single use only. 2. An RMD is presented for use either as an individually packaged RMD or as more than one RMD assembled and packaged together as a group or set. For the purposes of this document, the term RMD includes a loan RMD and a trial RMD and applies to all reusable devices that require reprocessing.
Sterilisation Services Department (SSD)	Also known as Central Sterilising Services Department, Sterile Processing Department, Central Supply Department. An integrated department in a Health Service Organisation that performs cleaning, disinfection and sterilising actions on RMDs and manages storage of sterile stock and consumables.

8. Document Summary

Coverage	WACHS wide
Audience	All WACHS healthcare workers that use or reprocess reusable medical devices.
Records Management	Non Clinical: Records Management Policy Clinical: Health Record Management Policy
Related Legislation	*Therapeutic Goods Act 1989* (Cwlth) *Health Services Act 2016* (WA)
Related Mandatory Policies / Frameworks	Clinical Governance, Safety and Quality Policy Framework National Safety and Quality Health Service Standards Accreditation Policy – MP 0134/20
Related WACHS Policy Documents	Environmental Cleaning Policy Infection Prevention and Control Policy Reprocessing Reusable Medical Devices Policy Reusable Medical Devices on Loan and Instruments on Trial Procedure Storage, Handling and Transport Requirements for Sterile Stock Procedure Quality Management and Validation for the Reprocessing of Reusable Medical Devices Procedure
Other Related Documents	WACHS Sterilisation Services: Policies, Procedures and Resources List
Related Forms	Nil
Related Training Packages	Nil
Aboriginal Health Impact Statement Declaration (ISD)	ISD Record ID: 1883
National Safety and Quality Health Service (NSQHS) Standards	3.01, 3.02, 3.07, 3.08, 3.10, 3.11, 3.12, 3.13, 3.14, 3.17
Aged Care Quality Standards	Nil
National Standards for Mental Health Services	Nil

9. Document Control

Version	Published date	Current from	Summary of changes
1.00	9 March 2023	9 March 2023	New procedure
1.01	1 October 2024	9 March 2023	Minor amendments to related docs due to rescindments
1.02	25 October 2024	9 March 2023	Minor amendment to update AS 5369:2023
1.03	13 December 2024	9 March 2023	Minor amendments to update references and correct notation of AS 5369:2023

10. Approval

Policy Owner	Executive Director Nursing and Midwifery
Co-approver	Executive Director Clinical Excellence
Contact	Coordinator of Nursing – Perioperative
Business Unit	Nursing and Midwifery – Surgical Services
EDRMS #	ED-CO-22-500959

This document can be made available in alternative formats on request.