Repair and Maintenance of Reprocessing Equipment and Reusable Medical Devices Procedure

1. Purpose

The purpose of this procedure is to provide guidance on the repair and maintenance of reprocessing equipment and reusable medical devices (RMDs) in the Sterilisation Services Department (SSD).

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

2. Procedure

2.1 Key principles

- Maintenance contracts for all reprocessing equipment must be secured as part of all purchasing agreements.
- Management of unscheduled maintenance or repairs must form part of the initial purchasing agreement and be attended to within the agreed timeframes.
- Requalification of all processing equipment must be completed at least annually or whenever a change is made to either an RMD or its packaging, or to the cleaning, disinfection, packaging or sterilisation processes.
- Replacement programs must exist for all reprocessing equipment to minimise service failures and maintain up-to-date processing capabilities and efficiencies in production.
- Documented records of repairs and maintenance must be kept either on paper files or electronically.
- A written report is to be obtained upon completion of all preventive maintenance.
- A copy of the Certificate of Service and Validation is to be displayed near the equipment.

2.2 Periodic preventative maintenance of reprocessing equipment, including calibration of monitoring instrumentation

- Planned maintenance is to be performed by qualified service providers at intervals recommended by the manufacturer and in compliance with the requirements of AS/NZS 4187:2014. Refer to the following tables from AS/NZS 4187:2014:
  - Table 10.1: Recommended frequency for recalibration, preventative maintenance and testing of sterilizing and associated equipment
  - Table 10.2: Recommended frequency for recalibration, preventative maintenance and testing of cleaning, disinfecting and packaging equipment.
  - Table 10.3: Recommended frequency for recalibration, preventative maintenance and testing of Automated Endoscope Reprocessors (AER).
- Electrical safety checks of all RMD reprocessing equipment are to be maintained as part of the divisional preventative maintenance program and records of maintenance must be retained in an easily accessible location.

2.3 Periodic preventative maintenance of RMDs

- Preventative maintenance of RMDs may include, as relevant:
  - inspection for alignment, sharpness etc.
  - insulation testing
  - lubrication of hinges and joins.
- Maintenance is to be undertaken in compliance with the manufacturer's Instructions for Use (IFU) and must be documented.

2.4 Faults and repairs

- Faults and deviations from required parameters must be reported to the SSD Manager/ Supervisor immediately and corrective action/s taken.
- Where a fault has the potential to impact on the quality and safety of an RMD or on operator and patient safety, the equipment shall be removed from use immediately pending repair.
- Requalification of the equipment is to be performed in the event that major works or repairs are undertaken that have the potential to affect the efficacy of the sterilisation process.

Notification of a faulty RMD

- Place a plastic clip and/or identification tag on the RMD, documenting details of the fault on an identification tag or form as defined by the site.
- Send to the SSD at the end of the procedure.
- The RMD is to be washed and reprocessed in SSD. If full disinfection cannot be completed effectively, advice should be sought from the manufacturer about how to prepare and package the RMD for transport.
- Complete a Universal Cleaning and Sterilisation Guarantee (Green Form) with evidence of thermal disinfection or sterilisation.
- Send the RMD for repair to the designated repairer.
- Where a critical RMD is not available for an extended period, the SSD Manager/ Supervisor must advise the Shift Coordinator and Perioperative Services Manager so that alternative arrangements can be made to ensure that surgery is not compromised.

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/NZS 4187:2014 and associated normative references and ensure the quality and safety of reprocessed RMDs.
- be involved in the evaluation/selection of purchased RMDs to ensure that appropriate provisions are made for the repair and maintenance over their useful life.

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/NZS 4187:2014
- 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/NZS 4187:2014.

Failure to comply with this policy 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/NZS 4187:2014 and amendment 2:2019, Reprocessing of reusable medical devices in health service organizations. Available from https://www-saiglobal-com.wachslibresources.health.wa.gov.au/online/.
2. ISO 17665-1: 2006. 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. ISO/TS 17665-2:2009. 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. St John of God Midland Public and Private Hospitals. Central Sterilisation Services Department Manual, MIC-SSD-OTH-0002.
5. 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 safety 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 Sterilisation Services Department, Sterile Processing Department, Central Supply Department. An integrated department in a Health Service Organisation that performs cleaning, disinfection and sterilisation 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	Audit of Sterilisation Services Departments Procedure Chemical and Biological Indicators and Process Challenge Devices Procedure Cleaning of Reprocessing Equipment Procedure Clinical Product Evaluation Policy Environmental Cleaning Policy Infection Prevention and Control Policy Reprocessing Reusable Medical Devices Policy Reusable Medical Devices on Loan and Instruments on Trial Procedure Thermal Disinfection of Reusable Medical Devices Procedure Tracking and Traceability of Reusable Medical Devices Procedure Validation of Cleaning, Disinfecting, Packaging and Sterilising Processes 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: 2080
National Safety and Quality Health Service (NSQHS) Standards	3.01, 3.02, 3.08, 3.10, 3.11, 3.12, 3.14, 3.15, 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	30 March 2023	30 March 2023	New procedure

10. Approval

Policy Owner	Executive Director Nursing and Midwifery Services
Co-approver	Executive Director Clinical Excellence
Contact	Coordinator of Nursing - Perioperative
Business Unit	Nursing and Midwifery - Surgical Services
EDRMS #	ED-CO-23-121723

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