SESLHD PROCEDURE COVER SHEET

NAME OF DOCUMENT	Sterilisation: Reprocessing Equipment - Preventative Maintenance
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EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	Director Clinical Governance and Medical Services
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KEY TERMS	Reprocessing Equipment, Preventative Maintenance, Reusable Medical Device, Sterilisation
SUMMARY	The document outlines the procedure for planning and undertaking preventative maintenance of reprocessing equipment.

Sterilisation: Reprocessing Equipment – Preventative Maintenance

SESLHDPR/503

1. POLICY STATEMENT

All equipment used for reprocessing Reusable Medical Devices (RMDs) is periodically tested, and planned preventative maintenance contracts are in place.

2. BACKGROUND

Installation qualification, operational qualification and performance qualification are successfully completed and documented before preventative maintenance can be scheduled.
Any deviation from the data determined during the Annual Performance Requalification is reviewed during periodic tests, and preventative maintenance of the reprocessing equipment.

3. RESPONSIBILITIES

3.1 Employees will:

- Comply with the requirements of this procedure
- Report non-compliance with this procedure

3.2 Line Managers will:

- Support compliance with this procedure

3.3 District Managers/ Service Managers will:

- Ensure Service Agreements are in place with the manufacturer of the reprocessing equipment or qualified service provider for planned preventative maintenance
- Ensure the manufacturer of the reprocessing equipment or qualified service provider is aware of the requirement of this procedure
- Obtain a written service agreement with a detailed procedure for each planned preventative maintenance, and the frequency at which it is to be carried out
- Obtain a written report upon completion of the preventative maintenance.

3.4 Medical staff will:

Nil

4. PROCEDURE

4.1 Preventative maintenance carried out on Washer Disinfectors (WD) employing thermal disinfection for RMDs, hollowware and anaesthetic equipment by the manufacturer or qualified service provider (sponsor) must include the following:

Test	Brief description of test	Requirements
Cleaning Efficacy - Load	Carried out on a reference load in a cycle without disinfection and drying stage, and the use of test soils or cleaning indicators containing soils listed in ISO 15883-5	Quarterly
Thermal Disinfection - Load	Carried out on a reference load in a cycle without washing stage and the use of temperature recorder and temperature sensors	Quarterly
Verification of calibration of all measuring equipment fitted to the WD	Carried out with the use of test instrument which calibration is certified by a suitable certification body	Quarterly
Chemical Dosing	Carried out by method specified by manufacturer, or by using Volumetric Method given in ISO15883-1 2006	Quarterly

4.2 Preventative maintenance carried out on the sterilisers by the manufacturer or qualified service provider (sponsor) must include:

Test	Brief description of test	Requirements
Information to be supplied by the manufacturer on the maintenance, tests and frequency they should be carried out	Maintenance/recalibration as recommended by manufacturer or annually	Maintenance/recalibration shall be verified periodically in accordance with 4.3.3 ISO 17765-1-A, system complying with the applicable clauses ISO 13485 or ISO 10012 shall be specified for the calibration of all equipment, including instrumentation used for

4.3 Preventative maintenance carried out on all associated equipment by the manufacturer or qualified service provider (sponsor) will include:

Test	Brief description of test	Requirements
Information to be supplied by the manufacturer on the Maintenance, tests and the frequency they should be carried out	Maintenance/recalibration as recommended by manufacturer or annually	Maintenance/recalibration shall be verified periodically in accordance with AS and ISOs listed as normative references in the AS/NZ4187:2014

5. DOCUMENTATION

- Written service agreements and procedures supplied by the manufacturer or qualified service provider (sponsor)
- Written reports supplied by the manufacturer or qualified service provider (sponsor).

6. AUDIT

Peer Review Audit

7. REFERENCES

AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organisation.

8. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
April 2016	1	SESLHD Sterilisation Resource Group
June 2016	1	To Executive Sponsor for endorsement
July 2016	1	To Clinical and Quality Council for endorsement
July 2016	1	Approved by Clinical and Quality Council
October 2019	2	SESLHD Sterilising Working Party (SSWP) conducted a minor review. Background information updated. Approved by Executive Sponsor. Formatted by Executive Services prior to publishing.