

SESLHD POLICY COVER SHEET



Health
South Eastern Sydney
Local Health District

NAME OF DOCUMENT	Biomedical Equipment – Testing, Tagging and Labelling
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EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	Director Corporate and Legal Services
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KEY TERMS	Electromedical, Biomedical, equipment, testing
SUMMARY	This policy establishes governance for safety and functional testing of Medical Equipment and defines the frequency of testing and labelling within the SESLHD. The policy also encompasses equipment that is used for the safe introduction of interventional procedures into clinical practice.

COMPLIANCE WITH THIS DOCUMENT IS MANDATORY
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1. POLICY STATEMENT

Medical Equipment used within the SESLHD will be subject to the practices for inspection, testing and labelling of medical equipment as defined in Australian Standard AS/NZS3551

2. AIMS

- To establish the framework for safety and functional testing of Medical Equipment within the SESLHD.
- To clearly define the frequency of testing and labelling of Medical Equipment and equipment that is used for the safe introduction of interventional procedures into clinical practice.

This policy must be adhered to in conjunction with the [Safework NSW Code of Practice – Managing electrical risks in the workplace – September 2016](#)

Note: Medical Equipment testing is performed to AS/NZS3551, general electrical equipment is tested to AS/NZS3760 which has different applications and electrical safety requirements. This policy does not cover general electrical equipment.

3. TARGET AUDIENCE

Hub General Managers, Facility Managers, Department Heads, Nurse Unit Managers, Clinical and Nursing staff, Clinical Governance.

4. RESPONSIBILITIES

4.1 General principle for use of Medical Equipment

- No Medical Equipment within the SESLHD is to be used unless it has a current safety test label attached. This applies to all new purchases, equipment evaluations, rentals and loan equipment. In the case of rentals this may be in the form of the suppliers own label dated prior to dispatch.

4.2 Frequency of testing

- The frequency of testing is as defined in AS/NZS3551 and is determined during the equipment acceptance procedure. The testing interval is normally 12 monthly but can be varied under risk assessment outcomes or as per manufacturer's recommendations as per the Standard.
- The testing interval determined at acceptance will be entered into the equipment database to schedule ongoing inspections.

Biomedical Equipment – Testing, Tagging and Labelling**SESLHDPR/622****4.3 New, Evaluation, Loan or Rental equipment**

- All equipment shall be tested on arrival at any SESLHD site prior to clinical use whether it is new, for evaluation or on loan. Rented equipment such as pressure relieving devices may forgo testing on arrival if systems are in place to ensure testing has been undertaken by the Supplier prior to dispatch.
- Service directors, Clinicians, Department Managers and Nursing Unit Managers are directly responsible in ensuring that equipment used within their areas has been acceptance tested and approved by Clinical Engineering prior to use.

4.4 Performance Verification testing

- Performance Verification testing will be undertaken at the intervals and in accordance with the tests deemed necessary during the acceptance procedure.
- In the case of equipment issued to home patients on long term loan, excepting dialysis equipment, it is the issuing departments responsibility to ensure the equipment is returned to Clinical Engineering for inspection in accordance with AS/NZS3551 before the testing due date.
- Equipment which cannot be located or cannot be accessed during routine testing by Clinical Engineering will be itemised on a report sent to the Department Manager at the end of the scheduled testing period. It is the responsibility of the Department Manager to ensure the itemised equipment is made available to Clinical Engineering for testing as soon as possible.
- It is the responsibility of the Department Manager to ensure all of their equipment is tested and that the dates indicated on the safety test labels are current.

4.5 Faulty equipment

- Faulty or damaged medical equipment shall be isolated and labelled in accordance with AS/NZS3551.
- Faulty equipment should be segregated and stored in a location where the equipment will not be used.
- Where it is suspected that faulty equipment may have contributed to an adverse patient outcome, the equipment along with all accessories and consumables associated with the equipment at that time will be immediately removed from service and isolated.

4.6 Patients own Medical Equipment

- Patients own Medical Equipment (such as CPAP devices) are to be inspected as per Policy SESLHDPD/290 – 'Electrical Devices – Patients use of personal electrical devices'.

Biomedical Equipment – Testing, Tagging and Labelling

SESLHDPR/622

4.7 Records

- A summary report of all equipment tested can be requested by the relevant Department Manager at the end of the scheduled testing period.
- The numerical results of the Performance Verification tests are retained on file in the Clinical Engineering department and are not sent to the departments.
- All records, manuals and equipment assessment reports are to be retained in accordance with the [NSW Health – General Retention and Disposal Authority – Public Health Services: Administrative Records – GDA 21](#)

5. DEFINITIONS

Acceptance Procedure: A set of processes, both administrative and technical, required to be performed before new medical equipment is released for clinical use.

Medical Equipment: Any instrument, apparatus or appliance, including software, whether used alone or in combination, together with any accessories necessary for correct operation that makes physical or electrical contact with the patient, or transfers energy to or from the patient, or detects such energy transfer to or from the patient, or is intended to diagnose, treat or monitor a patient.

Performance Verification: Testing the essential performance parameters of the medical equipment. This will require a range of physical, functional and electrical safety tests to confirm it is capable of performing safely and as intended by the manufacturer.

Safety Test Label: Labels attached to Medical Equipment and its associated detachable mains supply cable indicating the next test date, the service entity undertaking the test and that testing has been completed in accordance with AS/NZS3551.

6. DOCUMENTATION

Clinical Engineering – Equipment Database

7. REFERENCES

AS/NZS 3551:2012 – Management programs for medical equipment

AS/NZS 3760:2010 – In-service safety inspection and testing of electrical equipment
[Safework NSW Code of Practice – Managing electrical risks in the workplace - September 2016.](#)

[NSW Health – General Retention and Disposal Authority – Public Health Services: Administrative Records – GDA 21](#)

8. REVISION & APPROVAL HISTORY

Date	Revision No.	Author and Approval
June 2018	1	Converted from PD 026 – Testing, Tagging and Labelling of Biomedical Equipment to SESLHDPR/622 – Biomedical Equipment – Testing, Tagging and Labelling
July 2018	1	Major Review – Draft for Comment Endorsed by Executive Sponsor
August 2018	1	Endorsed by Executive Council
April 2020	1	Executive Sponsor updated.