

EQUIPMENT TESTING & MAINTENANCE FACT SHEET FOR MEDICAL PRACTICES



Who requires equipment testing and maintenance?

All practices are required to have equipment testing in accordance with the Work Health and Safety Act, Australian/New Zealand Standard 3551:2012 and RACGP requirements.

Under the Work Health and Safety Act, a person conducting a business or undertaking at a workplace must ensure that electrical equipment is regularly inspected and tested by a competent person in accordance with guidance provided in AS/NZS 3760:2010 *In-service safety inspection and testing of electrical equipment*.

AS/NZS 3551:2012 *Management programs for medical devices* provides guidance for the testing and maintenance requirements of medical devices and electrical devices used in patient care areas which are excluded from AS/NZS 3760:2010. In this standard it details that each item of equipment is to be tested, as referenced below, and therefore all practices are required to test medical devices and electronic devices used in patient care areas.

Each item of equipment is—

- I. acceptance tested prior to clinical use;*
- II. subjected to routine performance verification during its useable life to detect damage, wear, component failure or changed component value which might render it unsafe; and*
- III. maintained with reference to the manufacturer's instructions*

In addition to the Work Health and Safety Act, accredited practices are guided by the RACGP *Standards for general practice (currently 4th edition)*. The standards detail that *all equipment that requires calibration or that is electrically or battery operated requires regular servicing in accordance with the manufacturer's instruction*.

What types of testing and maintenance are there?

There are a number of tests to ensure the safety, accuracy and longevity of equipment. Routine testing and maintenance can assist in mitigating the risk associated with the use of medical equipment on patients and the operators. Some of the general types of testing are summarised below.

Electrical Safety Test

Electrical safety testing is intended to ensure that risks arising from electrical hazards are maintained at acceptable levels during the useful life of the equipment. AS/NZS 3551:2012 specifies what parameters should be tested and these include (where appropriate):

- Visual inspection of external mains supply components
- Protective earthing resistance
- Insulation resistance
- Touch current
- Earth leakage current
- Patient leakage current
- Mains contact current

Performance Verification

Throughout the lifetime of medical equipment in clinical use, there is a need for regular assessment and testing of the medical equipment to ensure it is safe and continues to be safe, for its intended clinical application. It is also likely that medical equipment will, from time to time, be subject to various corrective or preventative maintenance activities. In accordance with AS/NZS 3551:2012 performance verification generally involves both physical inspection and functional testing in accordance with manufacturer guidelines (including device inputs, outputs, alarms and safety or protective functions).

Calibration

In some cases medical equipment requires calibration either periodically or when it is found to be operating outside the design specifications during routine testing.

Preventative Maintenance

Some medical equipment requires regular maintenance to keep it operating at optimum performance. In accordance with AS/NZS 3551:2012 and the RACGP *Standards for general practice (4th edition)*, equipment is required to be maintained as prescribed by the medical equipment manufacturer, but may also be influenced by local operational conditions or the environment in which the medical equipment is used. Recommended preventative maintenance activities shall be performed as an integral element of the medical equipment management program. Examples of routine preventative maintenance include replacing parts with a service kit, inspection and calibration.

Software Upgrades

An increasing amount of medical equipment now contains microprocessors or computers and as a result often rely on installed software for their operation. From time to time software needs to be upgraded or updated to add new features or to resolve bugs.

How often does equipment need to be tested and maintained?

The frequency of equipment testing and maintenance varies on an item by item basis and generally falls back to manufacturer recommendations. It is generally accepted that testing should occur **at least every 12 months** and in high use or adverse environments then this should be more frequent. Vital Resus Australia will assess your equipment and conditions and recommend testing and maintenance intervals to ensure the safety and accuracy of your equipment.



For a closer look at the specific guidance on the frequency of testing, please see a summary below.

- AS/NZS 3551:2012
 - The Australian Standards provide guidance on developing a risk assessment to establish the appropriate test and maintenance intervals which shall include, but is not limited to:
 - a) *the level of pre-use checking by users on a regular basis or immediately before use;*
 - b) *the manufacturer's recommended intervals;*
 - c) *an assessment of the impact of failure;*
 - d) *an assessment of the likelihood of failure;*
 - e) *experience with similar medical equipment, both internally and externally to the organisation;*
 - f) *knowledge of the individual medical equipment and its usage;*
 - g) *statutory requirements;*
 - h) *an assessment of the level of use; and*
 - i) *service history.*
- RACGP Standards for general practice (4th edition)
 - The RACGP Standards refer back to manufacturer recommendations as described in Criterion 5.2.1 *Equipment that requires calibration or that is electrically or battery powered needs to be serviced on a regular basis in accordance with the manufacturer's instructions to ensure it is maintained in good working order.*
- Manufacturer recommendations
 - Manufacturer recommendations vary on an item by item basis and therefore need to be reviewed separately. Through our equipment service database and many years of experience, Vital Resus Australia is able to assist in confirming the manufacturer recommendations. Based on the most common equipment items seen in practices, it is generally recommended by manufacturers to test and service (where required) equipment at least every 12 months.

Are there any other benefits of testing and maintaining medical equipment?

In addition to compliance, safety and accuracy there are a number of other benefits of testing and maintaining medical equipment. Some of these include:

Cost savings

- Preventative maintenance in accordance with manufacturer's recommendations helps improve the lifespan of equipment and therefore reduces the frequency of purchasing new equipment.
- Testing and maintenance at regular intervals helps detect any issues before they escalate and therefore control the costs associated with equipment usage and maintenance.

Quality assurance

- We understand the aim of most practices is to deliver a positive experience and outcomes for its patients. By ensuring that equipment is working in accordance with its intended use will help the practice in delivering a high quality service for patients.

What will happen if equipment is NOT tested and maintained?

- The practice and individuals involved may lose your practice accreditation or be issued a non-compliance warning.
- The practice and individuals involved may face legal action by Worksafe Australia or an injured party.
- The practice insurance cover may be invalidated.
- In the event of an accident, individuals involved may be investigated by authorities.
- Equipment may stop working and need to be replaced completely if not maintained correctly.

If you would like to **book your medical equipment testing and maintenance** now, or if you have any questions in relation to your specific medical equipment requirements, **please get in contact with Vital Resus Australia Today.**

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