

Compliance and Risk Management Q&A



Standards

Is there a standard that covers the maintenance and repair of medical equipment in Australia and New Zealand?

Yes, the "AS/NZS 3551:2012 Management programs for medical equipment" standard outlines procedures required to develop management programs for medical equipment.

These include protocols and procedures for procurement, acceptance, maintenance activities throughout the service life of the medical equipment, and finally disposal of medical equipment at the end of its operational life.

Is there a legal requirement to comply with this standard?

Yes, Sections 25 and 91 of the Electricity (Safety) Regulations 2010 requires any person(s) or

organisation(s) that use, repair or maintain medical devices to comply with the AS/NZS 3551:2012 standard.

Is 'Test and Tag' in accordance to the AS/NZS 3760 standard an acceptable alternative to having my medical equipment serviced in accordance with AS/NZS 3551:2012 standard?

No, "Test and Tag" and AS/NB 3760:2010 apply to domestic appliances and only covers electrical safety using different parameters to the AS/NZS 3551:2012 standard.

The AS/NZS 3551:2012 standard adds performance testing ensuring a device functions correctly and safely, this is not covered by Test and Tag.

Types of Equipment

What is defined as a medical device and what equipment is covered by the AS/NZS 3551:2012 standard?

AS/NZS 3551:2012 defines a medical device as "any instrument, apparatus or appliance, including software, whether used alone or in combination, together with any accessories necessary for correct operation, which 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 the patient."

Does the standard only apply to electrical equipment?

No, the AS/NZS 3551:2012 standard applies to both electrical medical equipment (e.g. electric bed) and non-electrical equipment (e.g. a hydraulic patient lifter).

What types of equipment at my care facility does the standard apply to?

The AS/NZS 3551:2012 standard applies to equipment such as:

- hospital and rest home beds
- patient handling and lifting equipment — including mobile and fixed (ceiling) patient lifting equipment
- pressure redistributing mattress and seating systems
- syringe and infusion pumps
- ventilators and nebulisers and other equipment used with patient.

What sort of equipment does the standard NOT apply to?

The AS/NZS 3551:2012 standard does not apply to equipment such as domestic appliances (e.g. microwave ovens, toasters, heaters). This type of equipment is covered by AS/NZS 3760:2010 Safety and inspection of electrical equipment.

Responsibility

To whom does the standard apply?

The AS/NZS 3551:2012 standard applies to public and private hospitals, rest homes, healthcare centers and clinics, and service entities responsible for supporting the safe use of medical equipment.

The standard is applicable regardless of whether the medical equipment is owned by the responsible organisation, privately owned, on loan, on trial or donated.

Who can service the medical equipment at my care facility?

Inspection, testing, preventative maintenance and repair of medical equipment should be performed by trained, skilled and qualified service technicians familiar with the requirements of the AS/NZS 3551:2012 standard.

TIP — if your current service provider is not familiar with the AS/NZS 3551:2012 standard you may be putting your staff and patients/residents at risk. Limit your exposure to an adverse event by taking the necessary steps to managing risk.

How often should preventative maintenance be carried out on medical equipment?

The AS/NZS 3551:2012 requires medical equipment to undergo preventative maintenance in accordance with manufacturers' specifications. Hence the frequency for preventative maintenance differs for different medical equipment, but it is very common that most equipment is required to undergo at least annual preventative maintenance.

Arjo

How we can help you ensure your equipment is fit for purpose!

Arjo's Preventative Maintenance agreements offer a wide range of options to suit your needs. All designed to optimise the performance of your medical equipment and meet the required standards.

Our highly skilled service technicians are equipped to install, service and repair both:

- the full Arjo product range
- third party equipment

including medical beds, patient lifts, therapeutic surfaces, showering and hygiene systems, and other related medical products.

Preventative Maintenance intervals:

Preventative Maintenance (PM) intervals are determined by the manufacturers recommendations. Arjo recommends annual PMs for Medical Beds, Pumps, Mattresses and Alternating Mattress systems, and biannual PMs for Patient lifters / Hoists and Slings. Arjo recommends the same service intervals for third party equipment covered by the Arjo Care package.

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