Medical Devices

Calibration, testing, service and repair

Including a brief overview of AS/NZS 3551:2004

What exactly is a medical device?

The Therapeutic Goods Association defines it as;

> *"Therapeutic Goods Act 1989...*
>
> *41BD - What is a medical device*
>
> *1.A medical device is:*
>
> *a.) any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:*
> *i. diagnosis, prevention, monitoring, treatment or alleviation of disease;*
> *ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;*
> *iii. investigation, replacement or modification of the anatomy or of a physiological process;*
> *iv. control of conception;*
>
> *and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or*
>
> *b.) an accessory to such an instrument, apparatus, appliance, material or other article."*

How do I know if my equipment is a listed medical device?

The Therapeutic Goods Administration website lists all medical devices that have been approved for use in Australia, as well as their class. A search can be made by manufacturer or model. It may come as a surprise to find how much of what you use falls within this category.

What Standard does your accreditation bodies require you to meet and maintain?

In some cases, it is wholly up to the facility to determine, through consultation, what Standard is to be met. They must then be able to document that Standard and their compliance with it. This is what is required in order to gain accreditation.

It is not up to the accreditor to set the Standard. The responsibility lies with the facility to make sure they have the right information, and then make the right decision.

It may only be if something goes wrong that this decision is scrutinised.

What Standard is required for the testing of medical devices?

There is only one Standard; **AS/NZS 3551:2004, Technical management programs for medical devices.**

Its Scope and General section supplies the following;

> ***"1.1 SCOPE***
> *This Standard specifies procedures required to develop equipment management programs for medical devices. These include procedures for procurement, acceptance, fault management, routine testing and disposal of medical devices.*
>
> *This Standard deals with essential safety and performance testing. Section 4 details how to identify the safety and performance parameters that are essential for the safe operation of each device and how to determine appropriate test intervals."*
>
> ***"4.4 FREQUENCY OF TESTING***
>
> *An organization shall establish test intervals for required maintenance and inspection activities so that risks and hazards are adequately managed.*
>
> *The following factors at least shall be considered:*
>
> *(a) Manufacturer's specification.*
> *(b) Knowledge of the individual device and its usage.*
> *(c) Experience with similar equipment, internally and externally.*
> *(d) Statutory requirements.*
> *(e) An assessment of the impact of failure.*
> *(f) An assessment of the location of use.*
> *(g) An assessment of the level of use.*
> *(h) Service history.*
> *(i) The level of pre-use checking by users on a regular basis or immediately before use. Where an organization does not conduct a professional risk management analysis which takes into account*

the above factors to justify the test intervals, tests shall be performed at least annually. Where analysis is used to determine test intervals for individual items of equipment, models of equipment or groups of equipment, this analysis shall be documented.

The interval determined for a particular device or group of devices should be reviewed regularly and adjusted, as appropriate, based on the in-use performance history."

Some service providers believe that the Standard for "In-service safety inspection and testing of electrical equipment" is adequate for some equipment listed within the TGA website medical device register. This Standard, AS/NZS 3760:2003, clearly states within its own scope;

"1.1.6 - This Standard does not apply to equipment whose nature is that of a medical device as defined in AS/NZS 3551."

Its Foreword goes even further to state;

".....inspection and testing regime capable of implementation with only simple instrumentation, and performed by a person not necessarily having formal qualifications or registration,....."

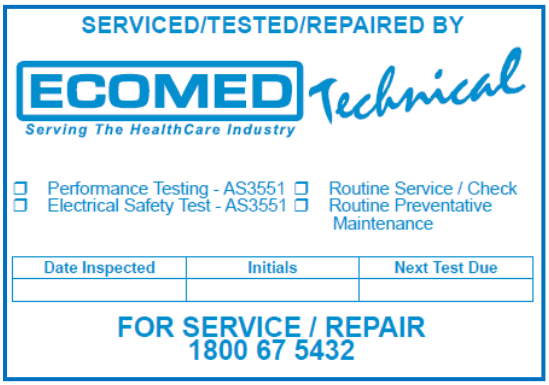
Additionally, an important clause within AS/NZS 3760:2003, which should be taken into consideration, when determining responsibility, states;

"1.2.4.2 – Responsibility for hire equipment during hire – Responsibility for testing, inspection and tagging passes to the hiree...."

How do I know what Standard is being used for my equipment?

The Standard describes in detail the labelling requirements that must be met. If your equipment has been tested to AS/NZS3551, then this will be clearly written on the testing label. It will also have the name of the company providing the test, the date of the test as well as the date that the next test is due. In addition it will have the signature or initials of the person who completed the test.

You should also ask the company providing the service to tell you what Standard they are using when testing or servicing your equipment.



What if my medical devices are brand new or still under warranty?

AS/NZS 3551 states the following requirement;

> *"4.5 ACCEPTANCE TESTING*
> *Prior to formal acceptance and commissioning the device shall also pass all the tests and inspections specified in Section 5 of this Standard."*

Section 5 of AS/NZS 3551 deals specifically with the particular test parameters for Safety and Performance testing. It refers also to additional Standards that need to be considered and understood, AS/NZS 2500, AS/NZS 3200 1.1, and AS/NZS 3002.

Warranty service and repair can still be carried out by the manufacturer or supplier of the product, in accordance with their statutory obligations. They may not, however, be capable of testing to the required Standard which also states;

> *"2.3.3 Modification of equipment*
> *(b) (i) Repair of equipment*
> *Repair of equipment should be undertaken using components sourced from the Original Equipment Manufacturer (OEM). If the decision is taken to use non-OEM sourced components, then care shall be exercised to ensure that the specification of the alternative parts are equivalent in all respects.*
> *(c) The service organization shall on completion test the equipment, at least, to the applicable test requirements of this Standard, and document all design changes and test results to the equipment….."*

Testing a medical device does not void any manufacturer warranty. It may in fact assist in identifying issues that should be addressed under warranty, but may not be apparent under normal daily usage. It is in this capacity that ECOMED Technical can work for you to ensure that you are getting all warranty support that you are entitled to.

Why should you entrust ECOMED Technical to this task?

- ✓ **ECOMED Technical has been providing biomedical engineering services to health care organisations for over 40 years**. We are the oldest privately owned biomedical engineering company in Australia.
- ✓ **We are proud to offer our clients not only product and public liability insurances, but also the added security of providing our own professional indemnity**, insurance specifically designed to protect professionals for actions taken against them either by their client or a third party for any breach of professional duty arising from an act, error or omission. We want you to be able to do your work without having to worry about ours.
- ✓ **Our core business is biomedical engineering**. This is what we do, and we do it well. Our systems provide you with the complete requirements of the Standard – complete management of your medical device assets from acceptance testing prior to clinical application through to decommissioning at the end of the devices life cycle.
- ✓ **ECOMED Technical is ISO 9001:2008 certified**. We are specifically certified with the following..... "To provide the Health Care Industry with tailored solutions in the servicing, repair, routine planned maintenance and management of medical devices."
- ✓ **Our reporting system can be tailored to your needs** – both in the level of detail required and frequency of delivery. We work hard to make sure that we integrate as seamlessly as possible into your system.
- ✓ **We test and certify to <u>the required Standard</u>, without compromise**. We would rather show you how to save costs associated with your medical devices in ways other than by providing a cheaper service.

Footnotes:

Therapeutic Goods Act 1989
41BD – What is a medical device

AS/NZS 3760:2003
Foreward
Section 1 Scope and General
1.1 Scope
1.2.4.2 Responsibility of hire equipment during hire

AS/NZS 3551:2004
Section 1 Scope and General
1.1 Scope
Section 2 Medical Device Management Program
2.3.3.(b)(i) Repair of Equipment
Section 4 Acceptance
4.4 Frequency of Testing
4.5 Acceptance Testing