Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Active medical devices

Introduction and overview of requirements

Version 1.1, August 2023

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About

Active medical devices are a subset of devices that use energy to operate. This document includes guidance on the requirements that specifically apply to these devices.

Introduction

Active medical devices

An active medical device is a device that—to operate—uses and converts energy in a significant way. For a device to be an active device, the form of energy does not include gravitational or directly provided human energies.

From the *Therapeutic Goods (Medical Devices) Regulations 2002*
active medical device:

a) means a medical device that is intended by the manufacturer:

   i. to depend for its operation on a source of electrical energy or other source of energy (other than a source of energy generated directly by a human being or gravity); and

   ii. to act by converting this energy; but

b) does not include a medical device that is intended by the manufacturer to transmit energy, a substance, or any other element, between an active medical device and a human being without any significant change in the energy, substance or other element being transmitted.

Software that is a medical device is an active medical device.

Active devices can run from internal or external power sources.

Some example active devices include:

- pacemakers (electrical energy),
- electric hospital beds (electrical energy),
- gas-powered suction pumps (pressure energy),
- software (electrical energy—software is a controlling agent for an electrical device),
- active warming blankets (electrical and thermal energies),
- X-ray machines (electrical and ionising electromagnetic radiation energies),
- surgical lasers (electrical and electromagnetic radiation energies),
- lung ventilators (electrical and pressure energies),
- ultrasound machines (electrical and acoustic energies); and
- implanted diagnostic and monitoring devices (for example, to monitor the movement of a knee joint) that use energy scavenged from a human biological system (electrical, chemical, thermal, and mechanical energies).

Energy-using devices that are not active

Devices that are powered solely by gravity or directly by a human being are not active devices. Examples of these devices include:

- gravity fed intravenous infusion sets,
- non-powered traction systems,
- hand-operated bag/valve/mask respirators/resuscitators; and
- hand-powered drills.

Some devices are intended by their manufacturer to transmit energy, a substance, or another element between an active medical device and a human being without any significant change occurring to the element being transmitted. These devices are not active. For example:

- electroencephalograph (EEG) leads (purely passive reduction in electrical signal); and
- tubing sets (reduction in transferred pressure along the tubing).

Summary of active medical device requirements

Manufacturers of active medical devices must consider all classification rules and must meet all of the relevant Essential Principles. The following Essential Principles and classification rules within the *Therapeutic Goods (Medical Devices) Regulations 2002* are specific to active medical devices:

The requirements are outlined in	which is located in the	and
Essential Principle 9.2—Minimisation of risks associated with use of medical devices	Essential Principles, Schedule 1, *Therapeutic Goods (Medical Devices) Regulations 2002*	outlines requirements for the risk of reciprocal interference involving other devices
Essential Principle 12—Medical devices connected to or equipped with an energy source	Essential Principles, Schedule 1, *Therapeutic Goods (Medical Devices) Regulations 2002*	outlines requirements for the safety and performance of active devices.
Part 4—Special rules for active medical devices	Classification rules, Schedule 2, *Therapeutic Goods (Medical Devices) Regulations 2002*	provides information for determining the classification of an active device.
Part 5.4—Medical devices that record patient images or that are anatomical models, etc.	Classification rules, Schedule 2, *Therapeutic Goods (Medical Devices) Regulations 2002*	provides information for determining the classification of active devices that are: • used to record patient images, • that are anatomical models (e.g., virtual 3D-models), or • that are used to generate virtual 3D-models.
Part 5.7 Special rules relating to active implantable medical devices	Classification rules, Schedule 2, *Therapeutic Goods (Medical Devices) Regulations 2002*	provides information for determining the classification of active implantable medical devices and associated medical devices.

Further information on the classification of active medical devices is available at Classification of active medical devices (including software-based medical devices).

Different forms of energy

The following table describes different forms of energy to help manufacturers that fall within the definition of active medical device.

Form	Description	Comments	Medical Device Examples
Chemical energy	Stored in batteries, liquids, gases, fuel, etc.		Chemical hot/cold packs
Elastic energy	Energy is stored when something is stretched, squashed, etc.	Includes clockwork-powered devices, spring-powered devices, elastically-powered devices, etc. Although human power is often applied to these devices in order to elastically deform, compress, or stretch them, the energy of operation is a transformation of the stored potential energy into kinetic energy.	• Spring-loaded syringe drivers • Bellows drains
Electrical energy	Electrical energy is used to drive the action of the device, for example, turn a motor, emit heat, emit light, or emit electrical signals.	Mains (230V grid) power and batteries are the primary sources of electrical energy, although there are other methods of generating electric energy.	• Blood gas analysers (which measure electric potential relating to concentrations of gases in blood) • Electric devices such as drills • All electronic devices and computers • Software (used to control a computer)
Radioactivity	Stored in the nuclei of atoms where energy is released from bonds in the nucleus rather than via the release of the electrons (see Electric energy above).	The decay of isotopes is used for medical imaging and for cancer treatments (radiation oncology).	Radioactive seeds/beads

Form	Description	Comments	Medical Device Examples
Magnetic energy	Magnetic potential energy is closely related to electric potential energy (see above). A magnetic field can also impart energy to a particle within it.	Electric motors operate from magnetic fields interacting with electric currents in order to rotate. An alternator or electric generator works in the reverse: a (motor) generator is externally rotated, resulting in the generation of an electrical current.	• Magnetic Resonance Imaging (MRI) machines use a magnetic field (and also radio waves) to excite particles within biological tissues • Electric dentist drills
Electromagnetic radiation	Electromagnetic radiation is a flow of electromagnetic energy waves ranging from very long-wavelength radio waves to microwave, infrared, visible, ultraviolet, and X-rays, through to very short-wavelength gamma rays.	Electromagnetic radiation is microscopic kinetic (movement) energy.	• UV phototherapy cabinets (for treating psoriasis); and • X-ray imaging and therapy devices
Thermal energy	Thermal (or heat) energy is microscopic movement energy. It is often realised as infrared waves.	Hot water packs are not active devices as there is no change in the form of energy.	• Electric warming blankets • Respiratory humidifiers • Chemical heat packs
Pressure energy	Pressure is stored as potential energy and is often converted to kinetic (movement energy) via conversion of a high-pressure source to a low pressure one.	The conversion is then from an amount of potential energy to an amount of kinetic energy and a smaller remaining amount of potential energy.	Air turbine- powered dentist drill — a flow of released compressed air (potential pressure energy) pushes on the blades of the turbine (this is a conversion of potential to kinetic energy) and transfers some of this airflow into rotation of the turbine shaft
Sound/acoustic/ Sonic	Sound or acoustic energy is a form of kinetic energy, realised as sound/air-pressure waves.	Many of these devices derive their primary power from an electrical source.	• Ultrasound imagers • Hearing aids • Ultrasonic nebulisers • Tinnitus maskers • Lithotripters

Electromedical safety standards

Electromedical devices are powered by electricity—mains, battery and low-powered devices. Examples are pacemakers, pulse oximeters, and blood-pressure monitors.

There are potential safety risks to the patient and/or user if the medical device:

- causes the patient and/or user unintended exposure to electrical currents; and
- interferes with or affects another electromedical device—Electromagnetic Compatibility (EMC).

Guidance for manufacturers

If you are a manufacturer of an electromedical device, you must demonstrate compliance with:

- Essential Principle 9.2: Minimisation of risks associated with use of medical devices; and
- Essential Principle 12: Medical devices connected to or equipped with an energy source.

The most common way to demonstrate compliance is to meet a standard published by an Australian or international standards agency, or a similar standard. If you choose to use other voluntary standards or methods, you must hold evidence that your chosen approach is applicable to your device and that its application satisfies the requirements of the Regulations. The use of standards is not mandatory.

Standards that are commonly used to demonstrate compliance are detailed in the table below:

Standard	Description
IEC 60601-1: Medical electrical equipment—Part 1: General requirements for basic safety and essential performance	Applies to the basic safety and essential performance of all general medical electrical equipment such as defibrillators, electrical beds, ECG monitors
IEC 60601-1-2: Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic disturbances – Requirements and tests	Specifies general requirements and tests for EMC of medical equipment. Collateral standards serve as the basis for specific standards by applying additional requirements to those prescribed in the associated general standard(s).
IEC 61010-1: Safety requirements for measurement, control, and laboratory use - General requirements	This international standard is applicable for some medical devices that are not in direct contact with patients. Example include bench-top sterilisers and ex vivo tissue-processing equipment

Medical devices that connect to the public mains electricity supply

In Australia, the public mains electricity supply is 230 volts, 50 Hz. In accordance with *AS/NZS 3112—Approval and test specification—Plugs and socket-outlets*, electrical equipment must be connected to a mains electricity supply using a plug with active and neutral pins partially insulated and with Australian-specific pin configuration.

In addition, AS/NZS 3551—Technical management programs for medical devices requires that a transparent plug cover should be used if the plugs are re-wireable. For moulded plugs, it is preferable that the plug cover is transparent but this requirement is not mandatory.

More information is available at ERAC Standards.

Electrical safety requirements

AS/NZS 3820—Essential safety requirements for electrical equipment is listed by Electrical Safety Regulatory Authorities as one part of the safety requirements that apply to suppliers of electrical equipment in Australia. Other requirements also apply depending on the laws of the specific state(s) and territory(ies) in which you intend to supply your device. More information is available at EESS – Essential Safety Criteria.

Electromagnetic Compatibility (EMC)

EMC and the influence of the expected environment should be considered when determining the risks associated with the use of your device. Environments include domestic, clinical, and critical-care areas. EMC requirements also apply to battery-powered devices.

The first step in determining compliance with EMC requirements is to perform a thorough risk analysis. Ideally, your analysis should be undertaken as part of your overall risk management process. The risk analysis must form the basis for specifying EMC test requirements.

You should consider the highest potential-risk environment to determine the amount and type of testing required; the aforementioned standards provide guidance on these aspects. You may also need to consider specialised aspects not covered by a standard. It is generally expected that EMC testing be conducted by an accredited test laboratory due to the highly specialised nature of the testing.

You should include testing for:

- emissions—IEC 60601-1-2, clause 7 that covers:
  - the protection of radio services and other equipment Clause 7.1; and
  - the protection of the public mains network clause 7.2. Mains network testing is not applicable to battery-powered devices unless a battery charger forms part of the device
- immunity—IEC 60601-1-2, clause 8
  - IEC 60601-1-2 has differing specification of immunity test levels according to the environments of intended use:
  - professional healthcare environments
  - home healthcare environments
  - special environments

Essential Principle 13.4 of the Therapeutic Goods (Medical Devices) Regulations 2002 requires you to provide information in the Instructions for Use for your device to allow your users to manage the electromagnetic environment in the intended clinical setting.

Non-medical electrical equipment used in a medical electrical system shall comply with IEC and ISO EMC standards applicable to that equipment. Non-medical electrical equipment used in a medical electrical system for which the intended electromagnetic environment could result in the loss of basic safety or essential performance of the medical electrical system due to the non-electrical medical equipment should be tested according to the requirements of IEC 60601-1-2.

EMC compliance may be demonstrated by justifying essential performance via the risk analysis as indicated in IEC 60601-1-2. If such an analysis demonstrates that your device does not pose any inherent hazards, either alone or in connection with other equipment, then the following minimum EMC requirements may apply:

- labelling or Instructions for Use that indicate that the device was not tested to clinical EMC requirements; and

- evidence to support the Australian Communications and Media Authority (ACMA) licencing requirements.

Medical devices are exempt from the ACMA EMC labelling requirements as they must comply with the more stringent requirements described by the Essential Principles, except for those incorporating radio-communications transmitters (see below).

Telecommunications and Radio-Communications Transmitters

The Australian Communications and Media Authority (ACMA) is responsible for the regulation of broadcasting, the Internet, radio-communications, and telecommunications. This includes transmission methods such as Bluetooth and WiFi. The ACMA administers regulatory systems relating to:

- telecommunications equipment,
- radio-communications equipment,
- electromagnetic compatibility (EMC), and
- electromagnetic energy (EME).

Medical devices with telecommunications ports must comply with ACMA requirements, for example, in-home patient-monitoring devices that have modem ports.

Medical devices with radio-communications transmitters must comply with ACMA requirements for radio-communications standards, for example, wrist-worn sphygmomanometers that connect to a mobile phone using Bluetooth.

However, electrically-powered medical devices do not require compliance with the ACMA standards for electromagnetic compatibility, as they must comply with the more stringent requirements described in the Essential Principles. See Electromagnetic Compatibility (EMC).

Active implantable medical devices (AIMDs) that utilise radio communications and the associated external radio transceiver must also comply with ACMA radio spectrum requirements. Examples include external programmers and data-loggers.

The ACMA Radiocommunications Class Licence (Low Interference Potential Devices) 2015 (also known as the LIPD Class Licence) makes specific allowance for some kinds of low-power radio communications for AIMDs, including those using Medical Implant Communications Systems (MICS) and Medical Body Area Network System (MBANS), under specific conditions.

Further details are available on the ACMA website.

Radioactive medical devices

All medical devices that are radioactive are active medical devices.

Radioactive medical devices are radioactive products that do not have a pharmacological, immunological, or metabolic action, or that are administered locally rather than systemically, for example:

- Brachytherapy spheres are active implantable medical devices. Their primary mode of action is radiation, and the basis for the therapeutic claims for the product are that the radiation affects the tissue irradiated. The mechanism of such action on the tissue is physical in nature. The only way that such an action can take place is via an energy conversion at the tissue interface. The precise nature of the energy conversion can vary, and could include temperature effects, denaturing of cellular molecules, or other physical interaction that leads to tumour cell death.
- In vivo imaging agents (such as barium meals) are regulated in Australia as medicinal products.

The TGA regulates the supply of radioactive medical devices in Australia.

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), and state and territory authorities, regulate the use of radioactive materials. More information is available on the ARPANSA website. The TGA uses the expertise of ARPANSA when assessing radioactive devices.

Radiating medical devices

The TGA regulates the supply of radiating medical devices in Australia.

Manufacturers of radiating medical devices must comply with Essential Principle 11. Examples of radiating medical devices include:

- medical lasers,
- phototherapy devices,
- X-ray machines; and
- dental curing lamps.

Radiating beauty therapy products such as:

- solariums,
- laser combs,
- dermal abrasion devices (or dermal abrasion products that apply energy to the patient),
- skin rejuvenation devices (or skin rejuvenation products that apply energy to the patient); and
- hair removal products that apply energy to the patient.

are not medical devices unless:

- therapeutic claims are made or

the product is:

- surgically invasive
- invasive via a body orifice

NOTE: The regulatory requirements for cosmetic products (including radiating beauty therapy products) are currently under review and their regulatory status may change.

The TGA regulates the supply of radiating medical devices in Australia.

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), and state and territory authorities regulate the use of radiating medical devices and the use of radiating beaty therapy products on human beings. More information is available on the ARPANSA website. The TGA uses the expertise of ARPANSA when assessing radioactive medical devices.

Programmed and programmable medical devices

A subset of active medical devices are those that are:

- programmed,
- programmable; or
- software.

These are medical devices incorporating as a component part, or fully comprising, software or programmed or programmable hardware; for example, devices that incorporate:

- firmware
- field-programmable gate arrays (FPGAs)
- electronic programmable read only memory (EPROM)
- flash memory
- static or dynamic random-access memory (RAM)
- electronics (both analogue and digital)

as a component part or parts.

Please note, the use of the terms ‘programmed’ or ‘programmable’ refers to the means of operation (that is, a device that operates according to a form of instruction set), not to whether device is intended to be programmed by a user or not. That is, the programming of the device could be intended to be undertaken by the manufacturer or by the user, or both. Device programming can also be intended to be undertaken both prior to and/or after supply.

Specific requirements

Essential Principle 12.1 has specific requirements that apply to programmed and programmable devices, including with respect to:

- design, development, production, and maintenance
- cyber security
- the management of data and information

Specific guidance on the cyber-security requirements for medical devices is available at Cyber security for medical devices and IVDs.

Specific classification rules also apply to programmed and programmable devices. Further information is available in the guidance on Classification of active medical devices.

Software

Software often forms an integral part of an electronic device, for example, in a pacemaker or patient monitor. In these cases, the software is a part of the device and is not considered to be a separate or distinct device.

Software that fits the definition of a medical device in its own right requires separate entry on the ARTG, which means that the sponsor must lodge an application with the TGA to include the device in the ARTG.

The international standard *IEC 62304 Medical device software—Software life cycle processes* addresses requirements that are specific to software, while the *IEC 62366 Medical devices—*

Application of usability engineering to medical devices standard addresses useability engineering requirements for all devices, including those that are wholly or partially software-based. The TGA considers these standards as representing the state-of-the-art for medical device software design and development, and usability, respectively.

The labelling requirements apply to medical device software, regardless of whether it is:

- downloaded from the Internet
- installed from electronic media, such as a USB drive or a CD
- pre-installed on a device

Manufacturers need to ensure that the product information, such as the graphical user interface, screenshots, electronic media labels, and product demos meet the requirements of Essential Principle 13.

The Regulations include a specific Essential Principle relating to labelling of software-based devices: Essential Principle 13B Software—version numbers and build numbers. This principle requires devices that are software, or that incorporate software, to include the current version and build numbers of the software to be made accessible by, and identifiable to, users of the device. The current version number and current build number of the software must be in English but may also be in any other language.

Further information on the regulation of software is available in the guidance: How the TGA regulates software-based medical devices.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication (update to archived ARGMD section 13).	Devices Emerging Technology and Diagnostics	July 2022
V1.1	Amendments for clarity	Devices Application Section	August 2023

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Reference/Publication #