AS EN 45502.1—2002
EN 45502-1:1997



Australian Standard™

# Active implantable medical devices

# Part 1: General requirements for safety, marking and information to be provided by the manufacturer



Standards Australia

This Australian Standard was prepared by Committee HE-012, Surgical Implants. It was approved on behalf of the Council of Standards Australia on 26 June 2002 and published on 28 June 2002.

---

The following are represented on Committee HE-012:

Australian Chamber of Commerce and Industry

Australian College of Operating Room Nurses

Australian Dental Association

Australian Industry Group

Australian Orthopaedic Association

Commonwealth Department of Health and Ageing

Department of Defence (Australia)

Medical Industry Association of Australia Inc

Neurological Society of Australasia

Royal Australasian College of Surgeons

Royal Perth Hospital

The Australian Society for Biomaterials

The University of New South Wales

The University of Sydney

---

**Keeping Standards up-to-date**

Standards are living documents which reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued. Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments which may have been published since the Standard was purchased.

Detailed information about Standards can be found by visiting the Standards Australia web site at www.standards.com.au and looking up the relevant Standard in the on-line catalogue.

Alternatively, the printed Catalogue provides information current at 1 January each year, and the monthly magazine, *The Australian Standard*, has a full listing of revisions and amendments published each month.

We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Contact us via email at mail@standards.com.au, or write to the Chief Executive, Standards Australia International Ltd, GPO Box 5420, Sydney, NSW 2001.

---

*This Standard was issued in draft form for comment as DR 02173.*

Australian Standard™

# Active implantable medical devices

# Part 1: General requirements for safety, marking and information to be provided by the manufacturer

First published as AS EN 45502.1—2002.



Published by Standards Australia International Ltd
GPO Box 5420, Sydney, NSW 2001, Australia

ISBN 0 7337 4681 0

# PREFACE

This Standard has been developed to assist in the process of implementation of the Australian Medical Device legislation.

After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian, rather than an Australian/New Zealand Standard, through the Joint Standards Australia/Standards New Zealand Committee HE-012 on Surgical Implants.

This Standard is identical with and has been reproduced from EN 45502-1:1997, *Active implantable medical devices — Part 1: General requirements for safety, marking and information to be provided by the manufacturer*.

The objective of this Standard is to specify requirements for active implantable medical devices for safety, marking and information to be provided by the manufacturer.

This Standard provides for the use of the following Australian/New Zealand Standards as equivalents to the International Standards referenced herein:

| *Reference to International Standard or other publication* | | *Equivalent Australian/New Zealand Standard* | |
|---|---|---|---|
| ISO | | AS/NZS | |
| 8601 | Data elements and interchange formats; information interchange; representation of dates and times | 3802 | Data elements and interchange formats - Information interchange - Representation of dates and times |
| IEC | | AS/NZS | |
| 60601-1 | Medical electrical equipment: Part 1: General requirements for safety | 3200.1.0 | Medical electrical equipment — Part 1.0: General requirements for safety — Parent Standard |
| 60601-1-2 | Medical Electrical Equipment – Part 1: General requirements for safety – 2 collateral standard: Electromagnetic compatibility – Requirements and test methods | 3200.1.2 | Medical electrical equipment — Part 1.2: General requirements for safety — Collateral Standard: Electromagnetic compatibility — Requirements and tests |
| 60601-1-4 | Medical electrical equipment: Part 1: General requirements for safety. 4 Collateral standard: Programmable electrical medical systems | 3200.1.4 | Medical electrical equipment — Part 1.4: General requirements for safety — Collateral Standard: Programmable electrical medical systems |
| 60601-2-27 | Medical electrical equipment – Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment | 3200.2.27 | Approval and test specification — Medical electrical equipment — Particular requirements for safety — Electrocardiographic monitoring equipment |

As this Standard is reproduced from a European Standard, the following applies:

(a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.

(b) In the source text 'this European Standard' should read 'this Australian Standard'.

(c) A full point substitutes for a comma when referring to a decimal marker.

# CONTENTS

Introduction ..... v

1 Scope ..... 1

2 Normative references ..... 2

3 Definitions ..... 3

4 Symbols and abbreviations (optional) ..... 5

5 General requirements for non-implantable parts ..... 5

6 (Vacant) ..... 5

7 General arrangement of the packaging ..... 5

8 General markings for active implantable medical devices ..... 6

9 Markings on the sales packaging ..... 6

10 Construction of the sales packaging ..... 8

11 Markings on the sterile pack ..... 9

12 Construction of the non-reusable pack ..... 10

13 Markings on the active implantable medical device ..... 10

14 Protection from unintentional biological effects being caused by the active implantable medical device ..... 11

15 Protection from harm to the patient or user caused by external physical features of the active implantable medical device ..... 13

16 Protection from harm to the patient caused by electricity ..... 13

17 Protection from harm to the patient caused by heat ..... 14

18 Protection from ionizing radiation released or emitted from the active implantable medical device ..... 14

19 Protection from unintended effects caused by the device ..... 15

20 Protection of the device from damage caused by external defibrillators ..... 16

21 Protection of the device from changes caused by high power electrical fields applied directly to the patient ..... 17

22 Protection of the active implantable medical device from changes caused by miscellaneous medical treatments ..... 18

CONTENTS

23 Protection of the active implantable medical device from mechanical forces. .....18

24 Protection of the active implantable medical device from damage caused by electrostatic discharge .....20

25 Protection of the active implantable medical device from damage caused by atmospheric pressure changes .....21

26 Protection of the active implantable medical device from damage caused by temperature changes. .....21

27 Protection of the active implantable medical device from electromagnetic non-ionizing radiation .....22

28 Accompanying documentation .....22

Annexes

A (informative)
Relationship between the clauses of this standard and Annex 1 of Directive 90/385/EEC .....27

B (informative)
Relationship between the clauses of this standard and the essential requirements (90/385/EEC) listed in Annex A .....37

C (informative)
Notes on EN 45502-1 .....39

D (informative)
Bibliography .....46

# INTRODUCTION

This standard specifies general requirements for ACTIVE IMPLANTABLE MEDICAL DEVICES, to provide basic assurance of safety for both patients and users.

To minimize the likelihood of a device being misused, this standard also details comprehensive requirements for MARKINGS and for other information to be supplied as part of the documentation with any ACTIVE IMPLANTABLE MEDICAL DEVICE.

For particular types of ACTIVE IMPLANTABLE MEDICAL DEVICE, the general requirements are supplemented or modified by the requirements of particular standards which are in preparation† as separate Parts of EN 45502. A requirement of such a particular standard takes priority over the corresponding requirement of this general standard. Where particular standards exist, this general standard should not be used alone. Special care is required when applying this general standard alone to ACTIVE IMPLANTABLE MEDICAL DEVICES for which no particular standard has yet been published.

NOTES

AUSTRALIAN STANDARD

# Active implantable medical devices

## Part 1: General requirements for safety, marking and information to be provided by the manufacturer

### 1 Scope

This Part 1 of EN 45502 specifies requirements that are generally applicable to ACTIVE IMPLANTABLE MEDICAL DEVICES. For particular types of ACTIVE IMPLANTABLE MEDICAL DEVICES, these essential requirements are supplemented or modified by the requirements of particular standards which form additional parts of this European Standard.

The tests that are specified in EN 45502 are type tests and are to be carried out on samples of a device to show compliance.

This Part of EN 45502 is applicable not only to ACTIVE IMPLANTABLE MEDICAL DEVICES that are electrically powered but also to those powered by other energy sources (for example by gas pressure or by springs).

This Part of EN 45502 is also applicable to some non-implantable parts and accessories of the devices (see note 1).

NOTE 1 The device that is commonly referred to as an ACTIVE IMPLANTABLE MEDICAL DEVICE may in fact be a single device, a combination of devices, or a combination of a device or devices and one or more accessories. Not all of these parts are required to be either partially or totally implantable, but there is a need to specify some requirements of non-implantable parts and accessories if they could affect the safety or performance of the implantable device.

NOTE 2 The terminology used in this European Standard is intended to be consistent with the terminology of Directive 90/385/EEC.

---

† At present (July 1997) particular standards for implantable cardiac pulse generators, implantable cardiac defibrillators, implantable infusion pumps, implantable neurostimulators, and cochlear implants are in preparation.