

AS/NZS 3200.2.36:1998
IEC 60601-2-36:1994

AS/NZS 3200.2.36

Australian/New Zealand Standard™

**Approval and test specification—
Medical electrical equipment**

**Part 2.36: Particular requirements
for safety—Extracorporeally
induced lithotripsy**

[IEC title: Medical electrical equipment, Part 2: Particular requirements
for the safety of equipment extracorporeally induced lithotripsy]

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AS/NZS 3200.2.36:1998

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE/3, Medical Electrical Equipment as a Joint Standard.

This Standard is identical with and has been reproduced from IEC 60601-2-36, *Medical electrical equipment, Part 2: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy* which modifies and supplements the corresponding Clauses of IEC 60601-1:1988, *Medical electrical equipment, Part 1: General requirements for safety* which has been adopted as AS 3200.1.0 (NZS 6150).

The Parent Standard details electrical safety requirements for all types of medical electrical equipment. A Particular Standard details additional safety requirements for a related group of medical electrical devices.

All IEC Standards have been numbered as the IEC 60xxx series, therefore references in the source text should be modified by adding 60 to the number as a prefix.

In the text of this Standard, the following print types are used:

- (a) Requirements, compliance with which can be tested and definitions
..... in large roman type
- (b) Explanations, advice, introductions, general statements, exceptions and references
..... in smaller roman type
- (c) Headings of sub-clauses and text specifications in italic type
- (d) Terms used throughout the Standard, which have been defined in Clause 2 and which are also in the index IN SMALL CAPITALS

The even numbered pages of the original publication are in French and are omitted from this version. Some other pages of the original, which relate to IEC administrative matters, are also omitted from this edition.

As this publication has been reproduced from an international Standard, the following modifications apply:

- (i) its number does not appear on each page of text and its identity is shown on the cover and title page.
- (ii) the words 'this Australian/New Zealand Standard' should replace the words 'this International Standard' wherever they appear.
- (iii) substitute a full point for a comma where it appears as a decimal marker.

The references to international Standards should be replaced by references to the following Australian or Joint Australian/New Zealand Standards:

*Reference to International Standard
or other publication*

Australian/New Zealand Standard

IEC

AS/NZS

60601-1-2

3200.1.2

Medical electrical equipment,
Part 1: General requirements for
safety, 2: Collateral
standard—Electromagnetic
compatibility—Requirements and
tests

Approval and test
specification—Medical electrical
equipment
Part 1.2: General requirements for
safety—Collateral Standard—
Electromagnetic compatibility—
Requirements and tests

The following Standards are referenced in this document. They are not International Standards. For the convenience of users of this Standard the original sources of the documents are listed below. An English version of the DIN Standard is available at Standards Australia's Sydney Information Centre and a BSEN identical copy of the EN Standard is also available there.



Documents

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European Union Standard, EN 10002/AC.1 *Tensile testing of metallic materials, Part 1: Method of test*, amendment to EN 10002-1.

German Standards Institute, DIN 50 100/02.78 *Testing of materials, continuous vibration test—Definitions, symbols, procedure, evaluation*.

The term 'informative' has been used in this Standard to define the application of the annex to which it applies. An 'informative' annex is only for information and guidance.

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INTRODUCTION

This Particular Standard supplements IEC 601-1 (second edition, 1988) *Medical electrical equipment – Part 1: General requirements for safety*, and its amendments 1 (1991) and 2 (1995), hereinafter referred to as the General Standard (see 1.3).

The requirements are followed by specifications for the relevant tests.

Following the decision taken by subcommittee 62D at the meeting in Washington in 1979, a "General guidance and rationale" section giving some explanatory notes, where appropriate, about the more important requirements is included in annex AA.

Clauses or subclauses for which there are explanatory notes in annex AA are marked with an asterisk (*).

It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the Standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this Standard.