

AS/NZS 3200.3.1:1998
IEC 60601-3-1:1996

AS/NZS 3200.3.1

Australian/New Zealand Standard™

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

**Part 3.1: Essential performance
requirements for transcutaneous
oxygen and carbon dioxide partial
pressure monitoring equipment**

[IEC title: Medical electrical equipment, Part 3-1: Essential performance requirements for transcutaneous oxygen and carbon dioxide partial pressure monitoring equipment]

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This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE/3, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 1 May 1998 and on behalf of the Council of Standards New Zealand on 7 May 1998. It was published on 5 July 1998.

The following interests are represented on Committee HE/3:

Australasian College of Physical Scientists and Engineers in Medicine
Australasian Society for Ultrasound in Medicine
Australian Dental Association
Australian Institute of Radiography
Australian Radiation Laboratory
Australian Society of Anaesthetists
College of Biomedical Engineering Institution of Engineers Australia
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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 60601-3-1996, *Medical electrical equipment, Part 3-1: Essential performance requirements for transcutaneous oxygen and carbon dioxide partial pressure monitoring equipment* 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).

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.

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

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:

<i>Reference to International Standard or other publication</i>	<i>Australian/New Zealand Standard</i>
IEC	AS
60601-1 Medical electrical equipment Part 1: General requirements for safety	3200.1.0 Approval and test specification— Medical electrical equipment— General requirements for safety— Parent Standard (NZS 6150)

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

These performance requirements, while different in presentation from ASTM standard specification for transcutaneous gas monitoring devices for oxygen and carbon dioxide F984-86, are closely aligned with those requirements.

Essential performance requirements for transcutaneous oxygen and carbon dioxide partial pressure monitoring equipment constitute a Part 3 of IEC 601, as long as these requirements for the functional performance do not directly affect safety.

A particular standard for functional performance does not normally specify minimum levels of performance but requires the disclosure of the functional performance of the equipment in a standardized way in order that users, manufacturers and test authorities have a common understanding of the parameters concerned.

A Part 3 contains the terminology, terms and definitions applicable to a particular kind of medical electrical equipment as well as the tests to be used in order that a manufacturer's declared performance can be tested in a uniform and acceptable way.

The numbering of clauses and subclauses of this Particular Standard do not relate to those of the General Standard IEC 601-1.

A 'Guidance and rationale' section for the more important requirements is given in annex A.

Clauses or subclauses for which there are explanatory notes in annex A 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 practices or as a result of developments in clinical technology. However, this annex does not form part of the requirements of this Particular Standard.