AS 60601.2.23:2018

Australian STANDARD

Medical electrical equipment

Part 2.23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment (IEC 60601-2-23:2011 (ED. 3.0), MOD)

STANDARDS Australia

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Australian Radiation Protection and Nuclear Safety Agency
Australian Society of Anaesthetists
Certification Body Australia (Certification Interests Australia)
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Medical electrical equipment

Part 2.23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment (IEC 60601-2-23:2011 (ED. 3.0), MOD)

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Preface

This Standard was prepared by the Australian members of Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment, to supersede AS/NZS 3200.2.23—2001, *Medical electrical equipment*, Part 2.23: *Particular requirements for safety—Transcutaneous partial pressure monitoring equipment*.

After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian Standard rather than an Australian/New Zealand Standard.

The objective of this Standard is to specify the requirements for basic safety and essential performance of transcutaneous partial pressure monitoring equipment. This Standard applies to transcutaneous monitors used with adults, children and neonates, and it includes the use of these devices in fetal monitoring during birth.

This Standard is an adoption with national modifications, and has been reproduced from, IEC 60601-2-23:2011 (ED. 3.0), *Medical electrical equipment —- Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment*. Appendix ZZ lists the variations to IEC 60601-2-23:2011 for the application of this Standard in Australia.

As this document has been reproduced from an International Standard, the following applies:

(a) In the source text 'this International Standard' should read 'Australian Standard'.

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

Australian or Australian/New Zealand Standards that are identical adoptions of international normative references may be used interchangeably. Refer to the online catalogue for information on specific Standards.

The terms 'normative' and 'informative' are used in Standards to define the application of the appendices or annexes to which they apply. A 'normative' appendix or annex is an integral part of a Standard, whereas an 'informative' appendix or annex is only for information and guidance.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International standard IEC 60601-2-23 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 1999 and constitutes a technical revision. This edition of IEC 60601-2-23 was revised to align structurally with the 2005 edition of IEC 60601-1.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/885/FDIS	62D/907/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of TRANSCUTANEOUS PARTIAL PRESSURE MONITORING EQUIPMENT. It amends and supplements IEC 60601-1 (third edition, 2005): *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard.

The aim of this third edition is to bring this particular standard up to date with reference to the third edition of the general standard through reformatting and technical changes.

The requirements of this particular standard take priority over those of the general standard.

A “General guidance and rationale” for the more important requirements of this particular standard is included in Annex AA. It is considered that 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, Annex AA does not form part of the requirements of this Standard.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of TRANSCUTANEOUS PARTIAL PRESSURE MONITORING EQUIPMENT as defined in 201.3.63 and hereinafter referred to as ME EQUIPMENT, whether this ME EQUIPMENT is stand alone or part of a system.

This standard applies to transcutaneous monitors used with adults, children and neonates, and it includes the use of these devices in foetal monitoring during birth.

This standard does not apply to haemoglobin saturation oximeters or to devices applied to surfaces of the body other than the skin (for example conjunctiva, mucosa).

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the General Standard.

201.1.2 Object

Replacement:

The object of this particular standard is to establish BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for TRANSCUTANEOUS PARTIAL PRESSURE MONITORING EQUIPMENT as defined in 201.3.63.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

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1 The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*