



Medical electrical equipment

Part 2.26: Particular requirements for the basic safety and essential performance of electroencephalographs (IEC 60601-2-26:2012 (ED. 3.0), MOD)



AS 60601.2.26:2018

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- Australasian College of Physical Scientists and Engineers in Medicine
- Australian and New Zealand College of Anaesthetists
- Australian Chamber of Commerce and Industry
- Australian College of Perioperative Nurses
- Australian Radiation Protection and Nuclear Safety Agency
- Australian Society of Anaesthetists
- Certification Body Australia (Certification Interests Australia)
- College of Biomedical Engineering, Engineers Australia
- Department of Defence (Australian Government)
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Part 2.26: Particular requirements for the basic safety and essential performance of electroencephalographs (IEC 60601-2-26:2012 (ED. 3.0), MOD)

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Preface

This Standard was prepared by the Australian members of the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment, to supersede AS/NZS 3200.2.26:2005, *Medical electrical equipment, Part 2.26: Particular requirements for safety—Electroencephalographs*.

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 basic safety and essential performance requirements for electroencephalographs used in a clinical environment (such as a hospital or physician's office).

This Standard amends and supplements the general Standard IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*.

This Standard is an adoption with national modifications, and has been reproduced from, IEC 60601-2-26:2012 (ED. 3.0), *Medical electrical equipment — Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs*. Appendix ZZ lists the variations 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 particular Standard” should read “this 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 to which they apply. A “normative” appendix is an integral part of a Standard, whereas an “informative” appendix is only for information and guidance.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

**Part 2-26: Particular requirements for the basic safety
and essential performance of electroencephalographs**

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 60601-2-26 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 of IEC 60601-2-26 published in 2002. This edition constitutes a technical revision to the new structure of the third edition (2005) of IEC 60601-1.

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

FDIS	Report on voting
62D/990/FDIS	62D/1012/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 collateral 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 ELECTROENCEPHALOGRAPHS. 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 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 * Scope

Replacement:

This particular standard applies to BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROENCEPHALOGRAPHS (EEG) as defined in 201.3.63, hereafter referred to as ME EQUIPMENT. This standard is applicable to ME EQUIPMENT used in a clinical environment (e.g., hospital, physician's office, etc.).

This standard does not cover requirements for other equipment used in electroencephalography such as:

- phono-photoc stimulators;
- electroencephalographic telemetry;
- EEG data storage and retrieval;
- ME EQUIPMENT particularly intended for monitoring during electro-convulsive therapy;
- ambulatory electroencephalographic recorders.

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 particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ELECTROENCEPHALOGRAPHS as defined in 201.3.63.

201.1.3 Collateral standards

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.

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

IEC 60601-1-2 applies as modified in Clause 202. IEC 60601-1-3 and IEC 60601-1-10² do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

² IEC 60601-1-10:2007, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

201.2 Normative references

Clause 2 of the general standard applies, except as follows:

Amendment:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

Addition:

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

IEC 60601-2-27:2011, *Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment*

201.3 Terms and definitions

NOTE An index of defined terms is found beginning on page 29.

For the purpose of this document, the terms and definitions given in IEC 60601-1:2005 apply, except as follows:

201.3.63

MEDICAL ELECTRICAL EQUIPMENT

Replacement:

ELECTROENCEPHALOGRAPH

ME EQUIPMENT

device to produce an ELECTROENCEPHALOGRAM

Additional definitions:

201.3.201

CHANNEL

hardware and/or software selection of a particular electroencephalographic LEAD for purposes of display, recording, or transmission

[SOURCE: IEC 60601-2-25:2011, definition 201.3.202, modified – The definition has been changed to refer to an electroencephalographic rather than an electrocardiographic LEAD.]

201.3.202

ELECTROENCEPHALOGRAM

EEG

presentation (on screen or paper) of the variation with time of voltages taken from ELECTRODES, whose positions are specified

[SOURCE: IEC 60050-891:1998, 891-04-23, modified – The wording of the definition has been changed slightly.]

201.3.203

ELECTRODE

sensor that is applied to the scalp or is inserted into a region of the brain to detect electrical activity