IEC 60601-2-26

Edition 3.0 2012-05

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs

Appareils électromédicaux –
Partie 2-26: Exigences particulières pour la sécurité de base et les performances essentielles des électroencéphalographes

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CONTENTS

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

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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 standard[1] 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-photic 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.

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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.*

IEC 60601-1-2 applies as modified in Clause 202. IEC 60601-1-3 and IEC 60601-1-10[2] 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

[SOURCE: IEC 60601-2-25:2011, definition 201.3.208 modified – The definition has been changed to refer specifically to an electroencephalographic application.]

201.3.204
GAIN
ratio of the amplitude of the output signal to the amplitude of the input signal

Note 1 to entry GAIN is expressed in mm/μV.

201.3.205
LEAD
voltage between ELECTRODES

[SOURCE: IEC 60601-2-27:2011, definition 201.3.206]

201.3.206
LEAD WIRE
cable connected between an ELECTRODE and either a PATIENT CABLE or the ME EQUIPMENT

[SOURCE: IEC 60601-2-27:2011, definition 201.3.208]

201.3.207
NEUTRAL ELECTRODE
reference point for differential amplifiers and/or interference suppression circuits, not intended to be used to calculate any LEAD

[SOURCE: IEC 60601-2-25:2011, definition 201.3.213]

201.3.208
PATIENT CABLE
multiwire cable used to connect LEAD WIRES to ME EQUIPMENT

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

Addition:

201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements

Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101.

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Accuracy of signal reproduction	201.12.1.101.1
Input dynamic range and differential offset voltage	201.12.1.101.2
Input noise	201.12.1.101.3
Frequency response	201.12.1.101.4
Common mode rejection	201.12.1.101.5

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.4 Other conditions

Addition:

aa) Unless otherwise stated, tests shall be carried out with the ACCESSORIES and the recording materials specified by the MANUFACTURER.

For ME EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE, if the test result is affected by the INTERNAL ELECTRICAL POWER SOURCE voltage, then the test shall be performed using the least favourable INTERNAL ELECTRICAL POWER SOURCE voltage specified by the MANUFACTURER. If necessary for the purpose of conducting the test, an external battery or d.c. power supply may be used to provide the necessary test voltage.

The values used in test circuits, unless otherwise specified, shall have at least an accuracy as given below:

– resistors: ± 1 %;
– capacitors: ± 10 %;
– inductors: ± 10 %;
– test voltages: ± 1 %.

201.5.8 *Sequence of tests

Amendment:

Tests called for in 201.8.5.5.1 of this particular standard and in 8.5.5 of the general standard shall be carried out prior to the LEAKAGE CURRENT and dielectric strength tests described in subclauses 8.7 and 8.8 of the general standard and prior to the tests specified in subclause 201.12.1.101 of this particular standard.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.2 Protection against electric shock

Replacement of the last paragraph:

APPLIED PARTS shall be classified as TYPE BF or TYPE CF APPLIED PARTS (see 7.2.10 and 8.3 b) of the general standard).

201.6.6 Mode of operation

Replacement:

ME EQUIPMENT shall be classified for CONTINUOUS OPERATION.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

*201.7.2.1 Minimum requirements for marking on ME EQUIPMENT and on interchangeable parts

Addition:

If the ME EQUIPMENT is specified as being protected against the effects of defibrillation:

Parts of ME EQUIPMENT (for example, PATIENT CABLES or sensors) specified as being protected against the effects of defibrillation shall be marked with symbol 26 or 27 of Table D.1 in Appendix D of the general standard according to the classification as TYPE BF APPLIED PART or TYPE CF APPLIED PART.

201.7.9.2 Instructions for use

Additional subclause:

201.7.9.2.101 Additional instructions for use

The instructions for use shall also include:

a) The INTENDED USE/INTENDED PURPOSE including environment of use.

   Likely misuse should be identified by risk analysis and disclosed if necessary (e.g. 'not for determination of brain death').

b) The procedures necessary for safe operation.

c) Instructions for connecting a POTENTIAL EQUALIZATION CONDUCTOR, if applicable.

d) That conductive parts of ELECTRODES and associated connectors for APPLIED PARTS, including the NEUTRAL ELECTRODE, should not contact other conductive parts including earth.

e) Advise for the OPERATOR regarding whether the ME EQUIPMENT incorporates means to protect the PATIENT against burns when used with high frequency surgical equipment. Advice shall be given regarding the location of ELECTRODES and LEAD WIRES etc, to reduce the hazard of burns in the event of a defect in the neutral electrode connection of the high frequency surgical equipment.

f) *The need for regular testing of the ME EQUIPMENT and its ACCESSORIES.

g) Precautions to take when using a defibrillator on a PATIENT; a description of how the discharge of a defibrillator affects the ME EQUIPMENT; a warning that defibrillator protection requires use of MANUFACTURER specified ACCESSORIES including LEAD WIRES and PATIENT CABLES. The specification (or type-number) of such accessories shall be disclosed (see 201.8.5.5.1).

h) The choice and application of specified PATIENT CABLES and LEAD WIRES; the choice and application of ELECTRODES.

i) The subsequent operation of the ME EQUIPMENT after interruption of SUPPLY MAINS exceeding 30 s (see 201.11.8).

j) Any HAZARD due to simultaneous use of other PATIENT-connected ME EQUIPMENT, for example, a cardiac pacemaker or other electrical stimulators.

k) Technical specifications for the ME EQUIPMENT of sufficient detail to allow the OPERATOR to understand what is being measured and any limitations. Minimally this shall include:

   – frequency range and bandwidth;
   – a description of all functions;
   – a description of waveform displays (if applicable).

l) *Any known susceptibilities to electromagnetic phenomena.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.1 Fundamental rule of protection against electrical shock

Addition:

201.8.101 Multipurpose channel(s)

If ELECTROENCEPHALOGRAPHS allow CHANNELS to be used for signals other than EEG, then this facility shall be tested to applicable clauses of relevant standards.

Compliance is checked by inspection.

201.8.3 Classification of APPLIED PARTS

Replacement of items a), b), and c):

The APPLIED PART of the ME EQUIPMENT shall be TYPE BF APPLIED PART or TYPE CF APPLIED PART.

Compliance is checked by inspection.

201.8.5.2.3 PATIENT LEADS

Addition:

NOTE 101 For EMC (ELECTROMAGNETIC COMPATIBILITY) and physical cable management, LEADS of ELECTROENCEPHALOGRAPH are usually kept short and tied together. Therefore any LEAD which falls off will stay in the vicinity of the PATIENT'S head, therefore there are no additional requirements for conductive connections to the part of the LEAD which connects to the ELECTRODE (PATIENT-side).

201.8.5.5 DEFIBRILLATION-PROOF APPLIED PARTS

201.8.5.5.1 Defibrillation protection

Addition:

If protection against the effects of defibrillation is provided for ME EQUIPMENT the following tests shall be performed:

For defibrillator testing the ME EQUIPMENT is operated using the PATIENT CABLES as specified by the MANUFACTURER.

The following requirements and tests apply in addition to the requirements and tests as specified in 8.5.5.1 of the general standard.

- **Common mode test**

Addition:

Within 30 s after exposure to the defibrillation voltage, the ME EQUIPMENT shall resume normal operation in the previous operating mode, without loss of any OPERATOR settings or stored data, and shall continue to perform its intended function as specified in this particular standard.

Compliance is checked according to Figure 201.101.

For ME EQUIPMENT of CLASS I, apply the test voltage between all LEAD WIRES (E_2...E_x), including the NEUTRAL ELECTRODE E_N, connected together and the PROTECTIVE EARTH TERMINAL. Energize the ME EQUIPMENT for these tests.

In the case of ME EQUIPMENT of CLASS II and ME EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE, apply the test voltage between all LEAD WIRES, including the NEUTRAL ELECTRODE, connected together and the FUNCTIONAL EARTH TERMINAL and/or metal foil in close contact with the ENCLOSURE. Energize the ME EQUIPMENT for these tests.

Test ME EQUIPMENT having an INTERNAL ELECTRICAL POWER SOURCE, which is rechargeable from the SUPPLY MAINS with and without the SUPPLY MAINS connection if the ME EQUIPMENT is capable of operating while connected to SUPPLY MAINS.

Set the GAIN of the ME EQUIPMENT such that a 0,5 mV signal produces a maximum display deflection without clipping the signal. With S2 closed and S3 open, adjust the 10 Hz sine wave generator to produce a 0,5 mV peak-to-valley output signal. Open switch S2 and close S3.

Connect S1 to position A and charge the capacitor C. After about 10 s, connect S1 to position B. Leave in position B for 200 ms ± 50 %. Allow recovery to begin opening S2 to remove residual voltages from the ME EQUIPMENT.

Immediately close S2 and open S3. Within 30 s, verify that the recorded test signal is not less than 0,5 mV peak-to-valley referred to the input.

Repeat the above test with the polarity of the high voltage source reversed. Repeat the tests with positive and negative polarities 5 times.

The ME EQUIPMENT shall resume normal operation in the previous operating mode, without loss of any OPERATOR settings or stored data within 30 s and shall continue to perform its intended function as specified in this particular standard.