IEC 80601-2-26

Edition 1.0 2019-05

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

IEC 80601-2-26:2019-05(en-fr)

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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 80601-2-26 has been prepared by a Joint Working Group of IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice, and ISO subcommittee SC3: Lung ventilators and related equipment, of ISO technical committee 121: Anaesthetic and respiratory equipment.

This publication is published as a double logo standard.

This document cancels and replaces the third edition of IEC 60601-2-26 published in 2012. This edition constitutes a technical revision to align with Amendment 1:2012 of IEC 60601-1:2005, new versions of collateral standards and amendments thereto.

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

FDIS	Report on voting
62D/1666/FDIS	62D/1681/RVD

Full information on the voting for the approval of this document can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by xxx P members out of yyy having cast a vote.

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

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

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
– "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 80601 International Standard, published under the general title *Medical electrical equipment,* can be found on the IEC website.

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

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- withdrawn,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

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committees that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

INTRODUCTION

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROENCEPHALOGRAPHS. It amends and supplements IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard.

The aim of this document is to bring this particular standard up to date with reference to the edition 3.1 of the general standard and new versions of collateral standards and amendments thereto through 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 document.

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 part of the 80601 International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROENCEPHALOGRAPHS as defined in 201.3.204, hereafter also referred to as ME EQUIPMENT or ME SYSTEM. This document is applicable to ELECTROENCEPHALOGRAPHS intended for use in professional healthcare facilities, the EMERGENCY MEDICAL SERVICES ENVIRONMENT or the HOME HEALTHCARE ENVIRONMENT.

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

– phono-photic stimulators;
– EEG data storage and retrieval;
– ME EQUIPMENT particularly intended for monitoring during electroconvulsive therapy.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title or 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 follows.

The clause or subclause applies to ME EQUIPMENT, as default. For ME EQUIPMENT with the corresponding safety measure or function not completely integrated into the ME EQUIPMENT but instead implemented in an ME SYSTEM, the ME EQUIPMENT MANUFACTURER specifies in the ACCOMPANYING DOCUMENTS which functionality and safety requirements are provided by the ME SYSTEM to comply with this document. The ME SYSTEM is verified accordingly.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document.

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 201.3.204.

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1 The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

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.

IEC 60601-1-2:2014 and IEC 60601-1-6:2013 apply as modified in Clause 202 and 206, respectively. IEC 60601-1-3, IEC 60601-1-9 and IEC 60601-1-10 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 or ME SYSTEM under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

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

For brevity, IEC 60601-1 and IEC 60601-1:2005/AMD1:2012 are 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 document 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, etc.). The changes to the text of the general standard and applicable collateral standards 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 3.147, additional definitions in this document 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, etc.

The term "this document" 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.

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

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

Replacement:

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*

IEC 60601-1-6:2013, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 60601-1-12:2014, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

IEC 60601-2-2:2017, *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

201.3 Terms and definitions

For the purpose of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2013, IEC 60601-1-11:2015, IEC 60601-1-12:2014 and IEC 60601-2-2:2017 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An index of defined terms is found beginning on page 34.

Addition:

201.3.201
CHANNEL
hardware and/or software selection of a particular electroencephalographic voltage between ELECTRODES for purposes of display, recording, or transmission

201.3.202
ELECTRODE
sensor that is applied to the scalp, cerebral cortex, or subdural locations to detect electrical activity of the brain

201.3.203
ELECTROENCEPHALOGRAM
EEG
presentation (on screen or paper) of the variation with time of voltages taken from ELECTRODES, whose positions are specified

201.3.204
ELECTROENCEPHALOGRAPH
ME EQUIPMENT or ME SYSTEM to produce an ELECTROENCEPHALOGRAM

201.3.205
LEAD WIRE
cable connected between an ELECTRODE and either a PATIENT CABLE or the ELECTROENCEPHALOGRAPH

201.3.206
NEUTRAL ELECTRODE
reference point for differential amplifiers and/or interference suppression circuits

201.3.207
PATIENT CABLE
multiwire cable or junction box used to connect LEAD WIRES to the ELECTROENCEPHALOGRAPH

201.4 General requirements

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

201.4.3 ESSENTIAL PERFORMANCE

Additional subclause:

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 amplitude and rate of variation	201.12.1.102
Input dynamic range and differential offset voltage	201.12.1.103
Input noise	201.12.1.104
Frequency response	201.12.1.105
Common mode rejection	201.12.1.106
or	
Indication of invalid data	201.12.4.101

For ELECTROENCEPHALOGRAPHS having more than 10 identical EEG CHANNELS, testing 10 of these CHANNELS is sufficient to verify ESSENTIAL PERFORMANCE.

201.5 General requirements for testing ME EQUIPMENT

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

201.5.4 Other conditions

Addition:

aa) If necessary for the purpose of conducting the test, the INTERNAL ELECTRICAL POWER SOURCE may be replaced by an external battery or DC power supply to provide the necessary test voltage.

bb) 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

Replacement:

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 8.7 and 8.8 of the general standard and prior to the tests specified in 201.12.1.102 to 201.12.1.106 of this particular standard.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

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

201.6.6 Mode of operation

Replacement:

ELECTROENCEPHALOGRAPHS 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 ELECTROENCEPHALOGRAPH is specified as being protected against the effects of defibrillation:

Parts of the ELECTROENCEPHALOGRAPH (for example PATIENT CABLES) specified as being protected against the effects of defibrillation shall be marked with symbol 26 or 27 of Table D.1 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

201.7.9.2.2 Warning and safety notices

Addition:

If protection against the effects of defibrillation is provided (see 201.8.5.5.1), the instructions for use shall include a warning that defibrillator protection requires the use of MANUFACTURER-specified ACCESSORIES, including PATIENT CABLES and LEAD WIRES.

Additional subclause:

201.7.9.2.101 Additional instructions for use

The instructions for use shall also include the following.

a) The INTENDED USE including environment of use.

   Likely misuse should be identified by RISK ANALYSIS and disclosed, if necessary (e.g. "not suitable for electro-cerebral inactivity (ECI) determination").

b) The procedures necessary for safe operation.

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

d) Information whether the ELECTROENCEPHALOGRAPH incorporates means to protect the PATIENT against burns when used with HF SURGICAL EQUIPMENT and advice 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 HF SURGICAL EQUIPMENT.

e) * The need for regular testing of the ELECTROENCEPHALOGRAPH and its ACCESSORIES.

f) Precautions to take when using a defibrillator on a PATIENT, if APPLIED PARTS not protected against the effects of defibrillation are being used; a description of how the discharge of a defibrillator affects the ELECTROENCEPHALOGRAPH.

g) The subsequent operation of the ELECTROENCEPHALOGRAPH after interruption of SUPPLY MAINS exceeding 30 s (see 201.11.8).

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

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

   – accuracy of signal reproduction;

– input dynamic range and maximum offset voltage;
– noise;
– frequency range and bandwidth;
– common mode rejection
– a description of all functions;
– a description of waveform displays (if applicable).

j) * Any known susceptibilities to electromagnetic phenomena.

k) If applicable, limitations of multipurpose CHANNELS (e.g. that these CHANNELS are not suitable for monitoring and of ECG or EMG) and to which clauses of applicable standards (e.g. IEC 80601-2-xx) they were tested, if any.

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

Additional subclause:

201.8.1.101 * Multipurpose CHANNEL(S)

If the ELECTROENCEPHALOGRAPH allows CHANNELS to be used for signals other than EEG, then this facility shall be tested to applicable clauses of relevant standards as specified by the MANUFACTURER in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection.

201.8.5.2.3 * PATIENT leads or PATIENT cables

Addition:

Any detachable ELECTRODE connector of a LEAD WIRE shall, when separated from the ELECTRODE, have an air clearance between connector pins and a flat surface of at least 0,5 mm.

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, the ELECTROENCEPHALOGRAPH 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 within 30 s after exposure to the defibrillation voltage.

For defibrillator testing, the ELECTROENCEPHALOGRAPH shall be operated using the PATIENT CABLES and LEAD WIRES specified by the MANUFACTURER.

- Common mode test

Addition:

Compliance is checked according to Figure 201.101.