SLOVENSKI STANDARD
oSIST prEN 60601-2-26:2017

01-september-2017

Medicinska električna oprema - 2-26. del: Posebne zahteve za osnovno varnost in bistvene lastnosti elektroencefalografov

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

Medizinische elektrische Geräte - Teil 2-26: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Elektroenzephalographen

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

Ta slovenski standard je istoveten z: prEN 60601-2-26:2017

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11.040.55 Diagnostična oprema Diagnostic equipment

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62D/1488/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 60601-2-26 ED4**	
DATE OF CIRCULATION: **2017-07-07**	CLOSING DATE FOR VOTING: **2017-09-29**
SUPERSEDES DOCUMENTS: **62D/1388/CD,62D/1424A/CC**	

IEC SC 62D : ELECTROMEDICAL EQUIPMENT	
SECRETARIAT: United States of America	SECRETARY: Mr Jeffrey L. Eggleston
OF INTEREST TO THE FOLLOWING COMMITTEES: ISO/TC 121/SC 3	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.
FUNCTIONS CONCERNED: ☐ EMC ☐ ENVIRONMENT	☐ QUALITY ASSURANCE ☒ SAFETY
☒ SUBMITTED FOR CENELEC PARALLEL VOTING	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING
Attention IEC-CENELEC parallel voting The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.	

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

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

NOTE FROM TC/SC OFFICERS:

This Committee Draft for Vote (CDV) was prepared by IEC/SC 62D – ISO/TC 121/SC 3/JWG 22, Electromedical diagnostic and patient monitoring equipment.

The stability date for this project will be 2022.

CONTENTS

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 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 fourth edition 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 to IEC 60601-1:2005, new versions of collateral standards and amendments thereto.

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

FDIS	Report on voting

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.

NOTE The attention of National Committees 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 or ISO 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 committee that the content of this publication be adopted for mandatory 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 (third edition, 2005, Amendment 1:2012; Corrigendum 1:2012): *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance)*, hereinafter referred to as the general standard.

The aim of this fourth edition 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 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 as defined in 201.3.204, hereafter also referred to as ME EQUIPMENT or ME SYSTEM. This standard is applicable to ELECTROENCEPHALOGRAPHS intended for use in professional healthcare facilities, the EMERGENCY MEDICAL SERVICE ENVIRONMENT or the HOME HEALTHCARE ENVIRONMENT.

This standard 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 electro-convulsive 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. If the corresponding safety measure or function is intentionally, by decision of the manufacturer, not completely integrated into the ME EQUIPMENT, but has to be realized in an ME SYSTEM, the manufacturer of the ME EQUIPMENT has to specify in its accompanying documents which functionality and safety requirements have to be provided by the connected ME SYSTEM to fulfil that clause or subclause. The ME SYSTEM, then, has to be verified accordingly.

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 201.3.204.

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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 including Amendment 1:2012.*

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.

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 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, 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 3.139, 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, 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.

201.2 Normative references

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

Amendment:

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*

Addition:

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*

201.3 Terms and definitions

NOTE An index of defined terms is found beginning on page 33.

For the purpose of this document, the terms and definitions given in IEC 60601-1:2012, 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 apply, except as follows:

Additional definitions:

201.3.201
CHANNEL
hardware and/or software selection of a particular electroencephalographic LEAD 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

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

201.3.207
NEUTRAL ELECTRODE
reference point for differential amplifiers and/or interference suppression circuits

201.3.208
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

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 Input dynamic range and differential offset voltage Input noise Frequency response Common mode rejection	201.12.1.102 201.12.1.103 201.12.1.104 201.12.1.105 201.12.1.106
or Indication of inoperable ELECTROENCEPHALOGRAPH	201.12.4.101

Box Note 1:
National committees are respectfully requested to provide feedback which of the requirements in clauses 201.12.1.102 to 201.12.1.106 constitute the essential performance of an ELECTROENCEPHALOGRAPH.
(A) Just, 201.12.1.102 Accuracy of signal reproduction
(B) All currently listed clauses 201.12.1.102 to 201.12.1.106
(C) Any other subset of 201.12.1.102 to 201.12.106; please specify
Please provide rationale for your answer.

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) If necessary for the purpose of conducting the test, the INTERNAL ELECTRICAL POWER SOURCE may be replaced by an external battery or d.c. 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

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 subclauses 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 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

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:

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 suitable for electro-cerebral inactivity (ECI) determination’).

b) The procedures necessary for safe operation.

c) That 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.