SLOVENSKI STANDARD
oSIST prEN ISO 80601-2-85:2020

01-maj-2020

Medicinska električna oprema - 2-85. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za cerebralno oksimetrijo (ISO/DIS 80601-2-85:2020)

Medical electrical equipment - Part 2-85: Particular requirements for basic safety and essential performance of cerebral tissue oximeter equipment (ISO/DIS 80601-2-85:2020)

Medizinische elektrische Geräte - Teil 2-85: Besondere Anforderungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Geräten für die zerebrale Oxymetrie (ISO/DIS 80601-2-85:2020)

Appareils électromédicaux - Partie 2-85: Exigences particulières pour la sécurité de base et les performances essentielles des oxymètres pour tissu cérébral (ISO/DIS 80601-2-85:2020)

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Medical electrical equipment —

Part 2-85:
Particular requirements for basic safety and essential performance of cerebral tissue oximeter equipment

ICS: 11.040.10

This document is circulated as received from the committee secretariat.

This draft is submitted to a parallel vote in ISO and in IEC.

ISO/CEN PARALLEL PROCESSING

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care*, and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC 62D, *Electromedical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This first edition of ISO 80601-2-85 includes an alignment with Amendment 1 of both the third edition of IEC 60601-1 and the second edition of IEC 60601-1-8, as well as the fourth edition of IEC 60601-1-2, the third edition of IEC 60601-1-6, the second edition of IEC 60601-1-11 and IEC 60601-1-12.

A list of all the parts of the ISO/IEC 80601 series is available on the ISO website.

Introduction

The approximation of cerebral tissue oximetry is increasingly used in many areas of medicine. This document covers *basic safety* and *essential performance* requirements achievable within the limits of existing technology.

Annex AA contains a rationale for some of the requirements. It is included to provide additional insight into the reasoning of the committees that led to a requirement and identifying the *hazards* that the requirement addresses.

Annex BB is a literature survey relevant to the determination of the maximum safe temperature of the interface between a *cerebral tissue oximeter probe* and a *patient's* tissue.

Annex CC discusses both the formulae used to evaluate the *StO_2 accuracy* of *cerebral tissue oximeter equipment* measurements, and the names that are assigned to those formulae.

Annex DD presents guidance on using in-vitro methods for assessing the performance of *cerebral tissue oximeter equipment*.

Annex EE presents a guideline for a *controlled desaturation study* for the *verification* of *cerebral tissue oximeter equipment*.

Annex FF is a description of *functional testers* for use with *cerebral tissue oximeter equipment*.

Annex GG describes concepts of *cerebral tissue oximeter equipment* response time.

Annex HH describes data interface requirements.

Annex II is a comparison between human desaturations (in-vivo) and *tissue haemoglobin phantom* desaturations (in-vitro) for assessing *StO_2 accuracy*.

Annex JJ contains Reference to the *essential principles*.

This publication 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;
- *Instructions, test specifications and terms defined in Clause 3 of the general standard, in this document or as noted: 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;

In referring to the structure of this document, the term

- "clause" means one of the numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201.7 includes subclauses 201.7.1, 201.7.2) and
- "subclause" means a numbered subdivision of a clause (e.g. 201.7.1, 7.2 and 201.7.2.1 are all subclauses of Clause 201.7).

References to clauses within this document are preceded by the term “Clause” followed by the clause number. References to subclauses within this document 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 Annex H 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; and
- “may” is used to describe permission (e.g. a permissible way to achieve compliance with a requirement or test);
- "can" is used to describe a possibility or capability; and
- "must" is used to express an external constraint.

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 AA.

Medical electrical equipment — Part 2-85: Particular requirements for basic safety and essential performance of cerebral tissue oximeter 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 document applies to *basic safety* and *essential performance* of *cerebral tissue oximeter equipment*, that employs light at multiple wavelengths to derive a quantitative measure of oxygen saturation of haemoglobin within the volume of tissue sampled under the *probe* attached to the head. The *cerebral tissue oximeter equipment* can be based on continuous light, frequency domain or time domain technologies. This document applies to *ME equipment* used in a hospital environment as well as when used outside the hospital environment, such as in ambulances and air transport. Additional standards may apply to *ME equipment* for those environments of use.

NOTE 1 *Cerebral tissue oximeters* are sometimes referred to as near infrared spectroscopy equipment in medical literature.

Not included within the scope of this document are:

— invasive tissue or vascular oximeters;

— oximeters that require a blood sample from the *patient*;

— equipment measuring dissolved oxygen;

— *ME equipment*, or part thereof, that measures path-length-dependent haemoglobin change. The requirements for functional near-infrared spectroscopy equipment are found in ISO 80601-2-71 [2];

— *ME equipment*, or part thereof, that measures arterial saturation based on pulsatile changes in tissue optical properties (SpO_2). The requirements for pulse oximeter equipment are found in ISO 80601-2-61 [2];

— *ME equipment*, or part thereof, that claims to monitor tissue in other parts of the body other than the head.

These requirements also apply to *cerebral tissue oximeter equipment*, including *cerebral tissue oximeter monitors*, *cerebral tissue oximeter probes* and *probe cable extenders*, which have been *remanufactured*.

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.

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1 The general standard is IEC 60601-1:2005+AMD1:2012.

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 except in 201.11 and in 201.7.2.13 and 201.8.4.1 of the general standard.

NOTE 2 See also 4.2 of the general standard. "The general standard" is IEC 60601-1:2005+AMD1:2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

This document can also be applied to *ME equipment* and their *accessories* used for compensation or alleviation of disease, injury or disability.

This document is not applicable to remote or slave (secondary) equipment that displays StO_2 values that are located outside of the *patient environment*.

NOTE 3 *ME equipment* that provides selection between diagnostic and monitoring functions is expected to meet the requirements of the appropriate document when configured for that function.

This document is a particular standard in the IEC 60601-1 and ISO/IEC 80601 series of standards.

201.1.2 Object

Replacement:

The object of this document is to establish particular *basic safety* and *essential performance* requirements for *cerebral tissue oximeter equipment* [as defined in 201.3.202] and its *accessories*.

NOTE *Accessories* are included because the combination of the *cerebral tissue oximeter monitor* and the *accessories* needs to be adequately safe. *Accessories* can have a significant impact on the *basic safety* or *essential performance* of *cerebral tissue oximeter equipment.*

201.1.3 Collateral standards

Amendment (add after existing text):

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

IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-11 and IEC 60601-1-12 apply as modified in Clauses 202, 206, 208, 211 and 212 respectively. IEC 60601-1-3[4] does 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, including the collateral standards, as appropriate for the particular *ME equipment* under consideration, and may add other *basic safety* or *essential performance* requirements.

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

For brevity, IEC 60601-1:2005+AMD1:2012 is referred to in this document as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this document corresponds to those 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 “2xx” where xx is the final digits of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 208.4 in this document addresses the content of Clause 4 of the IEC 60601-1-8 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 document.

"Addition" means that the text of this document 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 document.

Subclauses or figures that are additional to those of the general standard are numbered starting from 201.101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures that are additional to those of a collateral standard are numbered starting from 2xx, 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 document" is used to make reference to the general standard, any applicable collateral standards and this particular document taken together.

Where there is no corresponding clause or subclause in this document, the section, 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 document.

201.2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 Informative references are listed in the Bibliography.

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

Replacement:

ISO 7000:2019, *Graphical symbols for use on equipment — Registered symbols*

ISO 7010:2019, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

ISO 15223-1:—[2], *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

IEC 60529:2013, *Degrees of protection provided by enclosures (IP code)*

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 60601-1-6:2010+AMD1:2013, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance —Collateral standard: Usability*

IEC 60601-1-8:2006+AMD1:2012, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

IEC 60825-1:2014, *Safety of laser products - Part 1: Equipment classification and requirements*

Addition:

ISO 14155:2011, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 16142-1:2016, *Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

ISO 17664:2017, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

IEC 60068-2-27:2008+AMD1:2013, *Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock*

IEC 60068-2-31:2008, *Environmental testing — Part 2-31: Tests — Test Ec: Rough handling shocks, primarily for equipment-type specimens*

IEC 60068-2-64:2008, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance*

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 used in the emergency medical services environment*

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2 Under preparation. Stage at the time of publication: ISO DIS 15223-1:2020.

299 IEC 62366-1:2015, *Medical devices — Part 1: Application of usability engineering to medical devices*

300 IEC 60601-2-2:2009, *Medical electrical equipment - Part 2-2: Particular requirements for the basic safety*
301 *and essential performance of high frequency surgical equipment and high frequency surgical accessories*

302 IEC 62471:2006, *Photobiological safety of lamps and lamp systems*

303 AAMI 2700-1:2019 (formerly ASTM F2761-09), *Medical devices and medical systems — Essential safety*
304 *requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1:*
305 *General requirements and conceptual model*

306 201.3 Terms and definitions

307 For the purposes of this document, the terms and definitions given in ISO 16142-1:2016, ISO 17664:2017,
308 IEC 60601-1:2005+AMD 1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2010+AMD 1:2013,
309 IEC 60601-1-8:2006+AMD 1:2012, IEC 60601-1-11:2015, IEC 60601-1-12:2014, IEC 62366-1:2015,
310 IEC 60601-2-2:2009, AAMI 2700-1:2019 and the following apply.

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

312 – IEC Electropedia: available at http://www.electropedia.org/

313 – ISO Online browsing platform: available at http://www.iso.org/obp

314 NOTE An alphabetized index of defined terms is found in Annex KK.

315 **201.3.201**
316 ***accuracy***
317 ***A_{rms}***

318 closeness of agreement between a test result and the true value

319 Note 1 to entry: 201.12.1.101.2 contains methods for estimating the *StO_2 accuracy* of *cerebral tissue oximeter*
320 *equipment*.

321 Note 2 to entry: Additional information is found in Annexes CC, DD, EE and II.

322 Note 3 to entry: In this document, *accuracy* (A_{rms}) is stated in terms of the root mean square difference. See
323 201.12.1.101.3.

324 [SOURCE: ISO 3534-2:2006 [5] 3.3.1, modified, with Notes to entry replaced]

325 **201.3.202**
326 ***cerebral tissue oximeter***
327 ***cerebral tissue oximeter equipment***
328 *ME equipment* for the noninvasive estimation of *functional oxygen saturation* of haemoglobin in cerebral
329 tissue below the *probe* (*StO_2* or *rSO_2*), based on light interacting with tissue

330 Note 1 to entry: *Cerebral tissue oximeter equipment* comprises a *cerebral tissue oximeter monitor*, a *probe cable*
331 *extender*, if provided, and a *cerebral tissue oximeter probe*, which can be combined in a single assembly.

332 Note 2 to entry: Light is more technically referred to as electromagnetic radiation (optical radiation). This document
333 uses the common term.

334 Note 3 to entry: Measurements are based upon light interacting with all tissue under the *probe* to determine *StO_2*.

