Medical electrical equipment - Part 2-85: Particular requirements for the basic safety and essential performance of cerebral tissue oximeter equipment (ISO 80601-2-85:2021)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 80601-2-85:2021 sisaldab Euroopa standardi EN ISO 80601-2-85:2021 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 80601-2-85:2021 consists of the English text of the European standard EN ISO 80601-2-85:2021.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 14.04.2021.	Date of Availability of the European standard is 14.04.2021.
Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.10

EUROPEAN STANDARD

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EN ISO 80601-2-85

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English Version

Medical electrical equipment - Part 2-85: Particular requirements for the basic safety and essential performance of cerebral tissue oximeter equipment (ISO 80601-2-85:2021)

Appareils électromédicaux - Partie 2-85: Exigences particulières pour la sécurité de base et les performances essentielles des oxymètres pour tissu cérébral (ISO 80601-2-85:2021)

Medizinische elektrische Geräte - Teil 2-85: Besondere Anforderungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Geräten für die nicht-invasive zerebrale Oxymetrie (ISO 80601-2-85:2021)

This European Standard was approved by CEN on 21 January 2021.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 80601-2-85:2021 E

European foreword

This document (EN ISO 80601-2-85:2021) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2021, and conflicting national standards shall be withdrawn at the latest by April 2024.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-85:2021 has been approved by CEN as EN ISO 80601-2-85:2021 without any modification.

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Introduction

The estimation of blood oxygen saturation in the brain tissue by *cerebral tissue oximetry equipment* 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 into the *hazards* that the requirement addresses.

Annex BB is a literature review and provides recommendations relevant to determining 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 (phantoms) for *verification* of StO_2 *accuracy* of *cerebral tissue oximeter equipment*.

Annex EE presents a guideline for an in-vivo (human subjects) *controlled desaturation study* for the *verification* of StO_2 *accuracy* 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*.

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.

For the purposes of this document, the auxiliary verb:

— “shall” means that conformance with a requirement or a test is mandatory for conformance with this document;

— “should” means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document; and

— “may” is used to describe permission (e.g. a permissible way to achieve conformance with a requirement or test);

— "can" is used to describe a possibility or capability; and

— "must" is used to express an external constraint.

Annex C contains a guide to the marking and labelling requirements in this document.

Annex D contains a summary of the symbols referenced in this document.

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 the basic safety and essential performance of cerebral tissue oximeter equipment

201.1 Scope, object and related standards

Clause 1 of the general standard applies, except as follows.

NOTE The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020.

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[4];

— *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[3];

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

This document also applies to *cerebral tissue oximeter equipment*, including *cerebral tissue oximeter monitors*, *cerebral tissue oximeter probes* and *probe cable extenders*, that 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.

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.

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.

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 1 *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.*

NOTE 2 This document has been prepared to address the relevant International Medical Device Regulators Forum (IMDRF) *essential principles* and labelling guidances as indicated in Annex JJ.

NOTE 3 This document has been prepared to address the relevant *essential principles of safety and performance* of ISO 16142-1:2016 as indicated in Annex KK.

NOTE 4 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745[20] as indicated in Annex LL.

201.1.3 Collateral standards

Addition:

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 60601-1-2:2014+AMD1:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, IEC 60601-1-11:2015+AMD1:2020 and IEC 60601-1-12:2014+AMD1:2020 apply as modified in Clauses 202, 206, 208, 211 and 212 respectively. IEC 60601-1-3 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 define *basic safety* and *essential performance* requirements, and may modify, replace or delete requirements contained in the general standard, including the collateral standards, as appropriate for the particular *ME equipment* under consideration.

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

For brevity, IEC 60601-1:2005+AMD1:2012+AMD2:2020 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.

Clauses, subclauses or figures that 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 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 particular 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.

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

Replacement:

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

Addition:

ISO 14155:2020, *Clinical investigation of medical devices for human subjects — Good clinical practice*

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*

ISO 20417:2020, *Medical devices — Information to be supplied by the manufacturer*

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+AMD1:2019, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-11:2015+AMD1:2020, *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+AMD1:2020, *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*

ISO 80601-2-61:2017, *Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment*

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

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

AAMI 2700-1:2019[2], *Medical devices and medical systems — Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 16142-1:2016, ISO 17664:2017, ISO 20417:2020, IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, IEC 60601-1-11:2015+AMD1:2020, IEC 60601-1-12:2014+AMD2:2020, ISO 80601-2-61:2017, AAMI 2700-1:2019 and the following apply.

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

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

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

201.3.201
accuracy
A_{rms}
closeness of agreement between a test result and the true value

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

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

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

[SOURCE: ISO 3534-2:2006[6] 3.3.1, modified — Notes to entry replaced.]

201.3.202
cerebral tissue oximeter
cerebral tissue oximeter equipment
ME equipment for the non-invasive estimation of *functional oxygen saturation* of haemoglobin in cerebral tissue below the *probe* (*StO_2* or *rSO_2*), based on light interacting with tissue

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

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

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

201.3.203
cerebral tissue oximeter monitor
monitor
part of the *cerebral tissue oximeter equipment* that encompasses the measurement electronics, display and *operator interface*, excluding the *cerebral tissue oximeter probe* and *probe cable extender*

[2] Formerly ASTM F2761-09.