INTERNATIONAL STANDARD

ISO 80601-2-85

First edition
2021-03

Medical electrical equipment —

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

Appareils électromédicaux —

Partie 2-85: Exigences particulières pour la sécurité de base et les performances essentielles des oxymètres pour tissu cérébral

Reference number
ISO 80601-2-85:2021(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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 of 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 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 62D, *Electromedical equipment*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO and IEC 80601 series can be found on the ISO and IEC websites.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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.

Note 1 to entry: A *cerebral tissue oximeter monitor* can consist of multiple pieces of hardware in separate locations, e.g. a telemetry system in which the *applied part* and primary display are physically separated.

201.3.204
cerebral tissue oximeter probe
probe
part of the *cerebral tissue oximeter equipment* that includes the *applied part*

Note 1 to entry: The terms sensor and transducer have also been used for *cerebral tissue oximeter probe*.

Note 2 to entry: A reflectance *probe* design is the typical configuration.

201.3.205
controlled desaturation study
hypoxaemia induced in a group of human subjects performed under laboratory conditions

Note 1 to entry: This can also be referred to as a controlled hypoxaemia study. Additional information is found in Annex EE.

[SOURCE: ISO 80601-2-61:2017[3], 201.3.202]

201.3.206
CO-oximeter
multiwavelength, optical analyser that measures *total haemoglobin concentration* and the concentrations of various haemoglobin derivatives via direct measurement of a blood specimen

Note 1 to entry: The relevant CO-oximetry values for this document are *functional oxygen saturation* of arterial and jugular venous blood, SaO_2 and $SjvO_2$.

Note 2 to entry: This excludes indirect measurements that are performed by pulse oximetry and other optical measurements methods on human tissue.

[SOURCE: CLSI C46-A2: 2009, 4.1.9[7]]

201.3.207
data update period
interval in which the *cerebral tissue oximeter equipment* algorithm provides new valid data to the display or the *functional connection*

Note 1 to entry: This definition does not refer to the regular refresh period of the display, which is typically on the order of 1 s, but rather to the (typically longer) interval defined above.

[SOURCE: ISO 80601-2-61:2017[3], 201.3.204, modified.]

201.3.208
declared range
range of the *reference haemoglobin oxygen saturation* (S_R) over which there is specified *accuracy* performance

[SOURCE: ISO 80601-2-61:2017[3], 201.3.202]

201.3.209
displayed range
range of StO_2 values that can be displayed by the *cerebral tissue oximeter equipment*

Note 1 to entry: The *displayed range* can extend beyond the *declared range*.

[SOURCE: ISO 80601-2-61:2017[3], 201.3.206, modified.]

201.3.210
functional oxygen saturation
saturation given by the oxyhaemoglobin concentration (cO_2Hb) divided by the sum of the oxyhaemoglobin concentration and the deoxyhaemoglobin concentration (cHHb)

$$\frac{cO_2Hb}{cO_2Hb + cHHb}$$

Note 1 to entry: The CLSI[7] term for this ratio is haemoglobin oxygen saturation, and its notation is SO_2.

[SOURCE: CLSI C46-A2: 2009, 4.1.10.2[7]]

201.3.211
functional tester
test equipment that presents the *cerebral tissue oximeter equipment* with a tissue analogue representing a predictable value of tissue haemoglobin saturation so that the *operator* can observe the resulting displayed value of StO_2 and compare it to the expected value.

Note 1 to entry: Additional information is found in Annex FF.

Note 2 to entry: Not all *functional testers* and *cerebral tissue oximeter equipment* are compatible.

201.3.212
local bias
b

difference between the expectation of the results (StO_2) and a reference value

Note 1 to entry: For human desaturation studies, the reference is $SavO_2$.

Note 2 to entry: For phantom desaturation studies, the reference values are obtained from a reference measurement.

Note 3 to entry: For *cerebral tissue oximeter equipment*, this is, at a given value of the reference oxygen saturation, the difference between the y-value of the regression line at that coordinate and the y-value of the line of identity, in a plot of StO_2 versus S_R, or given by:

$$b_i = StO_{2\,fit,i} - S_{R,i}$$

where $StO_{2fit,i}$ is the value of the curve fitted to the test data at the i^{th} reference oxygen saturation value, $S_{R,i}$.

Note 4 to entry: Additional information is found with the term *mean bias* and in the discussion in Annex CC.

[SOURCE: ISO 80601-2-61: 2017[3], 201.3.211, modified.]

201.3.213
mean bias
B
mean difference between the test and reference values, preserving sign

$$B = \frac{\sum_{i=1}^{n} (StO_{2i} - S_{Ri})}{n}$$

where

n is the number of data pairs in the sample;

StO_{2i} is the i^{th} StO_2 datum; and