



BSI Standards Publication

Medical electrical equipment

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

National foreword

This British Standard is the UK implementation of EN ISO 80601-2-85:2021. It is identical to ISO 80601-2-85:2021.

The UK participation in its preparation was entrusted to Technical Committee CH/121/9, Lung Ventilators & Related Equipment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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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-
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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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of an identical text or by endorsement, at the latest by October 2021, and conflicting national standards shall be withdrawn at the latest by April 2024.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.

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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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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 *StO₂ 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 *StO₂ accuracy* of *cerebral tissue oximeter equipment*.

Annex EE presents a guideline for an in-vivo (human subjects) *controlled desaturation study* for the *verification* of *StO₂ 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 *StO₂ 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 2700-1:2019², *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 *StO₂ 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* (*StO₂* or *rSO₂*), 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 *StO₂*.

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:

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

where $StO_{2\text{fit},i}$ 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

S_{Ri} is the i^{th} reference oxygen saturation value.

Note 1 to entry: Additional information also is found with the term *local bias* and in the discussion in Annex CC.

Note 2 to entry: When defined in this way, *mean bias* is the average of all *local bias* values, b_i .

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

201.3.214

operator settings

current state of any *cerebral tissue oximeter monitor* controls, including *alarm settings*

[SOURCE: ISO 80601-2-61:2017^[3], 201.3.213, modified.]

201.3.215

precision

closeness of agreement between independent test results obtained under stipulated conditions

$$s_{res} = \sqrt{\frac{\sum_{i=1}^n (StO_{2i} - StO_{2fit,i})^2}{n-2}}$$

where

n is the number of data pairs in the sample within the range of interest;

$(StO_{2i} - StO_{2fit,i})$ is the difference between the i^{th} StO_2 datum and the value of the fitted curve corresponding to the i^{th} reference oxygen saturation value, S_{Ri} .

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

Note 2 to entry: s_{res} is the sample standard deviation of the residuals.

[SOURCE: ISO 80601-2-61:2017^[3], 201.3.214, modified.]

201.3.216

probe cable extender

cable that connects a *cerebral tissue oximeter monitor* to a *cerebral tissue oximeter probe*

Note 1 to entry: Not every *cerebral tissue oximeter equipment* utilizes a *probe cable extender*.

Note 2 to entry: A *probe cable extender* can be an *applied part*.

[SOURCE: ISO 80601-2-61:2017^[3], 201.3.215, modified.]

201.3.217

probe fault

abnormal condition of the *cerebral tissue oximeter probe* or *probe cable extender* which, if not detected, could cause *patient harm*

Note 1 to entry: *Patient harm* can be caused by providing incorrect values, by exposing the *patient* to high *cerebral tissue oximeter probe* temperatures or by introducing a *risk* of electric shock.

[SOURCE: ISO 80601-2-61:2017^[3], 201.3.216, modified.]

201.3.218

* remanufacturing

DEPRECATED: reprocessing

any activity, which is not specified in the *accompanying document*, that renders a product suitable for use or reuse

Note 1 to entry: Such activities are often referred to as refinishing, restoring, recycling, refurbishing or repairing.

Note 2 to entry: Such activities can occur in healthcare facilities.

Note 3 to entry: The term “*remanufactured*” is used to designate the corresponding status.

[SOURCE: ISO 80601-2-61:2017^[3], 201.3.221, modified — Replaced ‘reprocessed’ with ‘*remanufactured*’.]

201.3.219

SaO₂

fraction of functional haemoglobin in arterial blood that is saturated with oxygen

Note 1 to entry: *SaO₂* is *functional oxygen saturation* in arterial blood. Additional information is found in 201.3.211.

Note 2 to entry: *SaO₂* is normally expressed as a percentage (by multiplying the fraction by 100 %).

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

201.3.220

SavO₂

composite of the oxygenation state of the arterial and jugular venous blood to derive a reference for *StO₂*, as described by

$$SavO_2 = R \times SaO_2 + (1 - R) \times SjvO_2$$

where *R* is the fraction of arterial blood and $(1 - R)$ is the fraction of jugular venous blood

Note 1 to entry: 201.12.1.101.2 contains requirements for collection of data from *controlled desaturation studies*.

Note 2 to entry: *SavO₂* is normally reported as a percentage (multiplying the fraction by 100 %). *R* is the relative weighting of the sampled arterial blood and jugular venous blood oxygenation, and is based on the assumed arterial:venous blood volumes in the cerebral tissue beneath the *probe*.

201.3.221

SjvO₂

fraction of functional haemoglobin in jugular venous blood that is saturated with oxygen

Note 1 to entry: 201.12.1.101.2 contains requirements for collection of data from *controlled desaturation studies*.

Note 2 to entry: *SjvO₂* is normally expressed as a percentage (multiplying the fraction by 100 %).

201.3.222

SpO₂

estimate of *SaO₂* made by *pulse oximeter equipment*

Note 1 to entry: Two-wavelength *pulse oximeter equipment* cannot compensate for the interference caused by the presence of dyshaemoglobins in their estimation of *SaO₂*.

Note 2 to entry: *SpO₂* is normally reported as a percentage (multiplying the fraction by 100 %).

[SOURCE: ISO 80601-2-61:2017^[3], 201.3.223]

201.3.223

SphanO₂

functional haemoglobin oxygen saturation in the *tissue haemoglobin phantom* liquid

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

Note 2 to entry: *SphanO₂* is normally expressed as a percentage (by multiplying the fraction by 100 %).

201.3.224

S_R

reference haemoglobin oxygen saturation

Note 1 to entry: For *verification* based on a *controlled desaturation study*, S_R is replaced with S_{avO_2} ; for *verification* based on phantoms, with S_{phanO_2} .

Note 2 to entry: S_R is normally expressed as a percentage (by multiplying the fraction by 100 %).

201.3.225

StO_2

rSO_2

cerebral tissue oxygenation

estimate of *functional oxygen saturation* of haemoglobin in cerebral tissue below the *probe* made by *cerebral tissue oximeter equipment*

Note 1 to entry: StO_2 is often expressed in the medical literature as rSO_2 (regional oxygen saturation) and both notations are considered interchangeable in this document.

Note 2 to entry: StO_2 is normally expressed as a percentage (multiplying the fraction by 100 %).

201.3.226

tissue haemoglobin phantom

artificial physical model that exhibits optical properties approximating in-vivo biological conditions which includes turbid media and haemoglobin, blood or other haemoglobin-simulating material

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

201.3.227

total haemoglobin concentration

ctHb

sum of concentrations of all haemoglobin species in a medium including, but not limited to, oxyhaemoglobin (cO_2Hb), methaemoglobin ($cMetHb$), deoxyhaemoglobin ($cHHb$), sulfhaemoglobin ($cSHb$) and carboxyhaemoglobin ($cCOHb$)^[7]

Note 1 to entry: CLSI denotes “concentration” by a prefixed letter c, while in the past the convention of square brackets, e.g. $[O_2Hb]$, was used.

Note 2 to entry: CLSI (Clinical and Laboratory Standards Institute)^[7] uses the following notations:

- oxyhaemoglobin (O_2Hb);
- deoxyhaemoglobin (HHb);
- carboxyhaemoglobin ($COHb$);
- methaemoglobin ($MetHb$);
- sulfhaemoglobin ($SuHb$); and
- total haemoglobin (tHb).

Note 3 to entry: When total haemoglobin concentration is used in the context of tissue or a tissue haemoglobin phantom, it refers to the concentration per tissue volume (spatial average) or per volume of turbid liquid, respectively, usually given in micromoles per litre ($\mu M/l$). In the context of CO-oximetry of whole blood, it refers to the concentration per volume of blood, usually given in g/dl.

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

201.4 General requirements

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

Addition:

201.4.3.101 * Additional requirements for *essential performance*

Additional *essential performance* requirements are found in the subclauses listed in Table 201.101.

Table 201.101 — Distributed *essential performance* requirements

Requirement	Subclause
For <i>cerebral tissue oximeter equipment</i> provided with an <i>alarm system</i> that includes the capability to detect a <i>physiological alarm condition</i> : [<i>StO₂ accuracy</i> and <i>limit alarm conditions</i>] ^a	201.12.1.101 208.6.1.2.101
or generation of a <i>technical alarm condition</i> ^a	201.11.8.101.1 201.12.4 201.13.101
For <i>cerebral tissue oximeter equipment</i> not provided with an <i>alarm system</i> that includes the capability to detect a <i>physiological alarm condition</i> : <i>StO₂ accuracy</i> ^a	201.12.1.101
or indication of abnormal operation ^a	201.12.4 201.13.101
^a Subclause 202.8.2 indicates methods of evaluating the performance of <i>cerebral tissue oximeters</i> as acceptance criteria following specific tests required by this document.	

201.4.102 Additional requirements for acceptance criteria

Many of the clauses and subclauses within this document establish acceptance criteria for performance aspects. These acceptance criteria shall always be met.

When the *manufacturer* specifies in the *accompanying document* performance levels better than those specified within this document, these *manufacturer*-specified levels become the acceptance levels.

For a *manufacturer*-specified (declared) level of *StO₂ accuracy* of 10 %, the *cerebral tissue oximeter equipment* is still required to exhibit less than 4 % *StO₂* deviation during *immunity* tests (see 202.8.1.101 d)). If the *cerebral tissue oximeter equipment* has a *manufacturer*-specified (declared) *accuracy* of 3 % then it shall have less than ±3 % *StO₂* deviation for all requirements (e.g. during *immunity* tests).

201.4.103 Additional requirements for *cerebral tissue oximeter equipment, parts and accessories*

- a) The *cerebral tissue oximeter equipment*, as well as all individual parts and *accessories* specified for use with a *cerebral tissue oximeter monitor*, shall conform with all requirements specified in this document. This includes all combinations of parts or *accessories* that are specified by a *manufacturer* for use in *cerebral tissue oximeter equipment*.

NOTE 1 This requirement ensures *basic safety* and *essential performance* of parts and *accessories* of the *cerebral tissue oximeter equipment*, in combination with their intended *cerebral tissue oximeter monitors*.

NOTE 2 *Cerebral tissue oximeter monitors* are sometimes used with *cerebral tissue oximeter probes* and cables from different *manufacturers*. This requirement ensures the compatibility of such combinations.

- b) All specified combinations of *cerebral tissue oximeter equipment*, as well as all individual parts and *accessories* specified for use with a *cerebral tissue oximeter monitor*, shall be disclosed in the instructions for use.

NOTE 3 Additional information is found in 201.7.9.2.1.101 g) and 201.7.9.2.14.101 a) and b).

201.5 General requirements for testing of *ME equipment*

Clause 5 of the general standard applies.

201.6 Classification of *ME equipment* and *ME systems*

Clause 6 of the general standard applies.

201.7 *ME equipment* identification, marking and documents

201.7.1.101 *Information to be supplied by the manufacturer*

The *information supplied by the manufacturer* of *cerebral tissue oximeter equipment* and its accessories shall conform with ISO 20417:2020.

In applying ISO 20417:2020, the terms in this document and those in IEC 60601-1:2005+AMD1:2012+A2:2020 shall be used as follows.

- a) The term "*accompanying information*" shall assume the same meaning as *accompanying documents*.
- b) The term "*medical device*" shall assume the same meaning as *ME equipment*.
- c) The term "*user*" shall assume the same meaning as *operator*.
- d) The term "*patient*" shall include animals.

Check conformance by application of ISO 20417:2020.

Clause 7 of the general standard applies, except as follows:

201.7.2.3 Consult *accompanying documents*

Replacement:

The *cerebral tissue oximeter equipment* shall be marked with the *safety sign* for the mandatory action: 'follow instructions for use', ISO 7010-M002 (see IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012/COR1:2014, Table D.2, Number 10).

Addition:

201.7.2.9.101 IP classification

- a) Notwithstanding the requirements of IEC 60601-1:2005+AMD1:2012+AMD 2:2020, 7.2.9, the *enclosure of ME equipment* shall be marked with the IP classification required by 201.11.6.5.101.

b) If some or all of the protection against the ingress of water or particulate matter is provided by a carrying case, then

- 1) the degree of protection provided by the *enclosure* shall be marked on the *enclosure*; and
- 2) the degree of protection provided by the carrying case shall be marked on the carrying case.

EXAMPLE If for *portable ME equipment*, the *enclosure* provides the protection against the ingress of particulate matter and the carrying case provides the protection against the ingress of water, the *enclosure* of the *ME equipment* would be marked IP2X and the carrying case would be marked IPX2.

c) An *enclosure* or a carrying case that is classified IPX0 need not be marked as such.

d) If an *enclosure* does not provide the minimum required degree of protection against the ingress of water, it shall be marked 'keep dry' or with Symbol ISO 7000-0626 (see Table 201.D.1.101, Symbol 2).

Check conformance by inspection and by application of the tests and criteria of IEC 60601-1:2005+AMD1:2012, 7.1.2 and 7.1.3.

201.7.2.101 Additional requirements for marking on the outside of ME equipment parts

a) If a *cerebral tissue oximeter monitor* is not provided with a low StO_2 alarm condition, a statement to the effect "No StO_2 Alarms" or Symbol IEC 60417-5319 (DB-2002-10) (see Table 201.D.1.101, Symbol 3).

b) For a *remanufactured cerebral tissue oximeter probe*, marked as such.

Check conformance by inspection.

201.7.4.3 Units of measurement

IEC 60601-1:2005+AMD1:2012, 7.4.3 applies, except as follows:

Amendment (add to the bottom as a new row in Table 1):

Cerebral tissue oxygenation shall be expressed in percent and shall be marked as %.

201.7.9.2 Instructions for use

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.9.2 applies, except as follows:

Addition:

201.7.9.2.1.101 Additional general requirements

The instructions for use shall indicate the following:

- a) for each *cerebral tissue oximeter equipment* and *cerebral tissue oximeter probe*, the specified use of the *cerebral tissue oximeter equipment* and *cerebral tissue oximeter probe* regarding:
 - 1) whether *cerebral tissue oximeter probe* replacement or repositioning requires re-establishment of baseline;

- b) that the *cerebral tissue oximeter equipment* displays StO_2 or rSO_2 ;
- c) the range of the peak wavelengths of the light emitted by the *cerebral tissue oximeter probe*;
- d) the maximum optical output power of the light emitted by the *cerebral tissue oximeter probe*;
- e) description of the effect on displayed and transmitted StO_2 data values by:
 - 1) the data averaging and other signal processing,
 - 2) the *data update period*,
 - 3) the *alarm condition delay*,
 - 4) the *alarm signal generation delay*, and
 - 5) the effects of any selectable operating mode on the previous 4 list items;

NOTE 1 Annex GG provides an example of how to assess and describe response time graphically.

- f) the *displayed ranges* of StO_2 ;
- g) if no *alarm system* that includes the capability to detect an *StO_2 physiological alarm condition* is provided, a statement to that effect and Symbol IEC 60417-5319 (DB-2002-10) (see Table 201.D.1.101, Symbol 3) may be used for this indication;
- h) for *cerebral tissue oximeter monitors*, the list of *cerebral tissue oximeter probe(s)* and *probe cable extenders* with which the *cerebral tissue oximeter monitor* has been *verified* and tested for conformance with this document. This may be made available by electronic means;

NOTE 2 Additional information is found in 201.4.103.

- i) the *verification* method used to assess the *accuracy*;
- j) a statement to the effect that performance assessment based on in-vivo and in-vitro methods are not equivalent;

NOTE 3 In-vivo *verification* involves testing on a variety of human subjects in a clinical setting and captures inter-subject variability. In-vitro *verification* involves testing with reproducible tissue phantom(s) in a controlled, non-clinical laboratory setting. Both methods can differ in the level of uncertainty and its sources.

- k) information to indicate that StO_2 values from different *cerebral tissue oximeters* might not be directly comparable;
- l) *accuracy*, A_{rms} ;
- m) *mean bias*, B ;
- n) $\pm$ standard deviation of the bias; and

NOTE 4 Standard deviation refers to the differences between the test and reference values, StO_2 and S_R . Refer to Annex CC.

- o) if trend accuracy is provided, the method used to determine trend accuracy.

Check conformance by inspection of the instructions for use.

201.7.9.2.2.101 Additional requirements for warnings and safety notices

For each *cerebral tissue oximeter probe* and *probe cable extender*, the instructions for use shall include:

- a) a warning to the effect that *probes* and cables are designed for use with specific monitors;
- b) a warning statement to the effect that the *responsible organization* or *operator* needs to confirm the compatibility of the monitor, probe and cable before use, or patient injury can result; and
- c) a warning statement to the effect that misapplication of a *probe* with excessive pressure for prolonged periods can induce pressure injury.

Check conformance by inspection of the instructions for use.

201.7.9.2.9.101 Additional requirements for operating instructions

The instructions for use shall indicate the following:

- a) a description of the signal inadequacy indicator and its function, if applicable;
- b) the recommended maximum application time for each type of *cerebral tissue oximeter probe* at a single site;
- c) the IP classification of the *cerebral tissue oximeter equipment enclosure*;
 - 1) If applicable, the IP classification on any carrying case provided with the *cerebral tissue oximeter equipment*.
 - 2) A brief description of the meaning of any IP classification.

EXAMPLE IPX2 means this *cerebral tissue oximeter* is protected against harmful effects of dripping water when tilted at 15° according to IEC 60529.

- d) if the *cerebral tissue oximeter equipment* is provided with a capability such that the *cerebral tissue oximeter probe* can operate at a temperature greater than 41 °C, specific instructions emphasizing the importance of proper *cerebral tissue oximeter probe* application, without excessive pressure; and
 - 1) In addition, specific instructions for any changes in recommended maximum application time when using temperatures greater than 41 °C.
- e) The *declared range* of *alarm limit* adjustment.

201.7.9.2.14.101 Additional requirements for accessories, supplementary equipment, used material

The instructions for use shall include the following:

- a) for *cerebral tissue oximeter probes*, the *cerebral tissue oximeter monitor(s)* and *probe cable extenders* with which the *cerebral tissue oximeter probes* have been *verified* and tested for conformance with this document;

NOTE 1 Additional information is found in 201.4.103.

- 1) The list may be made available by electronic means.

- b) for *probe cable extenders*, the *cerebral tissue oximeter monitor(s)* and *cerebral tissue oximeter probes* with which the *probe cable extenders* have been *verified* and tested for conformance with this document.

NOTE 2 Additional information is found in 201.4.103.

- 1) The list may be made available by electronic means.

Check conformance by inspection of the instructions for use and inspection of the risk management file for the identification of any residual risks and any adverse effect of any recommended accessory.

201.7.9.3.1.101 * Additional general requirements

The technical description shall include a statement to the effect that a *functional tester* cannot be used to assess the *accuracy* of a *cerebral tissue oximeter probe* or a *cerebral tissue oximeter monitor*.

NOTE Additional information is found in Annex FF.

Check conformance by inspection.

201.8 Protection against electrical hazards from ME equipment

Clause 8 of the general standard applies, except as follows:

Addition:

201.8.3.101 Additional requirements for classification of *applied parts*

Applied parts of cerebral tissue oximeter equipment shall be type BF or type CF *applied parts*.

Check conformance by inspection.

201.8.5.5.1.101 Defibrillation protection

Applied parts of cerebral tissue oximeter equipment expected to be used in an environment where defibrillators are common, shall be classified as *defibrillation-proof applied parts*.

Check conformance by inspection and inspection of the risk management file for assessment of a need for the applied part to be classified as defibrillation-proof applied part.

NOTE Some examples of environments where defibrillators are common include the operating room, emergency department, cardiac catheterization laboratory, and intensive care units.

201.8.7.4.7.101 Additional requirements for measurement of the *patient leakage current*

Cerebral tissue oximeter probes marked for temporary immersion shall:

- a) conform to IPX7 of IEC 60529:1989+AMD1:1999+AMD2:2013;
- b) be tested for *patient leakage current* according to 8.7.4.7 f) of the general standard.

Check conformance by the relevant tests of the general standard.

201.9 Protection against mechanical *hazards* of *ME equipment* and *ME systems*

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation *hazards*

Clause 10 of the general standard applies, except as follows:

201.10.4 Lasers

Replacement:

- aa) Depending on the light source used in a *cerebral tissue oximeter probe*, the relevant requirements of IEC 60825-1:2014 or IEC 62471:2006 shall apply to a *cerebral tissue oximeter probe*.
- bb) In the case of laser fibre optics, the requirements of IEC 60825-2:2004+AMD1:2006+AMD2:2010 shall apply.

NOTE IEC 60601-2-57^[2] does not apply because there are no intended photobiological effects.

Check conformance by application of the requirements of IEC 60825-1:2014, IEC 60825-2:2004+AMD1:2006+AMD2:2010, and IEC 62471:2006 as applicable.

201.11 Protection against excessive temperatures and other *hazards*

Clause 11 of the general standard applies, except as follows:

201.11.1.2.2 *Applied parts not intended to supply heat to a patient*

Amendment (add at the end of 11.1.2.2):

- aa) The *cerebral tissue oximeter probe*-tissue interface shall be evaluated when the skin temperature is initially at 35 °C for each *cerebral tissue oximeter monitor* and *cerebral tissue oximeter probe* indicated in the instructions for use.

NOTE Additional information is found in Annex BB.

If the surface temperature of the *cerebral tissue oximeter probe* at the tissue interface is capable of exceeding 41 °C, then

- bb) the *cerebral tissue oximeter equipment* shall have an *operator*-adjustable control for activating any elevated temperature mode that exceeds 41 °C;
 - 1) A deliberate sequence of *operator* actions shall be required to activate this mode.
 - 2) The instructions for use shall describe this sequence of *operator* actions.
- cc) the *cerebral tissue oximeter equipment* shall provide a means to limit the duration of an elevated temperature mode in excess of 41 °C;
 - 1) The duration of the elevated temperature mode shall not exceed 4 h at 43 °C or 8 h at 42 °C.
- dd) the instructions for use shall include a statement to the effect that the use of temperature settings greater than 41 °C requires special attention in *patients* with susceptible skin, such as neonates, geriatric *patients* or burn victims;

- ee) the *cerebral tissue oximeter equipment* shall indicate when it is in the elevated temperature mode; and
- ff) the technical description shall describe the test method used to measure the maximum temperature at the *cerebral tissue oximeter probe-tissue* interface.
- 1) When performing the temperature measurements for the *cerebral tissue oximeter probe-tissue* interface, as specified in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 11.1.3, the test method disclosed in the technical description may be utilized.

NOTE Additional information is found in BB.3.

Addition:

201.11.6.5.101 * Additional requirements for ingress of water or particulate matter into the ME equipment or ME system

- a) The *enclosure* of a *cerebral tissue oximeter equipment* shall provide a degree of protection to the harmful ingress of water of at least an IPX1 for *cerebral tissue oximeter equipment*.
- b) The *enclosure* of *transportable cerebral tissue oximeter equipment* shall provide a degree of protection to the harmful ingress of water of at least an IPX2 for *cerebral tissue oximeter equipment*.
- 1) For *portable ME equipment* that is only intended to be used within a protective case, this requirement may be met while the *ME equipment* is inside the case.

NOTE 1 Additional requirements for ingress of water or particulate matter into the *enclosure* of *cerebral tissue oximeter equipment* intended for use in the *home healthcare environment* are found in IEC 60601-1-11 and in the *emergency medical services environment* are found in IEC 60601-1-12.

NOTE 2 See also 201.8.7.4.7.

Check conformance according to the tests of IEC 60529:2013 with the cerebral tissue oximeter equipment placed in the least favourable position of normal use and by inspection. After these procedures, confirm that basic safety and essential performance are maintained.

201.11.6.7 Sterilization of ME equipment or ME system

Amendment (add note before conformance test):

NOTE Additional requirements are found in 11.6.6 of IEC 60601-1:2005+AMD1:2012.

Addition:

201.11.8.101 Additional requirements for interruption of the power supply/supply mains to ME equipment

201.11.8.101.1 Technical alarm condition for power supply failure

- a) If *cerebral tissue oximeter equipment* is equipped with an *alarm system* that detects a *physiological alarm condition*, the *alarm system* shall provide at least a *medium priority technical alarm condition* to indicate when the power supply falls outside the values specified for normal operation.

NOTE After the loss of power, the *alarm system* is not expected to repeat *alarm signals* indefinitely.

- b) If the function of the *cerebral tissue oximeter equipment* is maintained by the switchover to an *internal electrical power source*, the supply failure *medium priority technical alarm condition* shall not be activated.
 - 1) Any such switchover to an *internal electrical power source* shall be indicated by an *information signal* or a *low priority technical alarm condition*.

Check conformance by functional testing.

201.11.8.101.2 Settings and data storage following short interruptions or automatic switchover

When the *supply mains* to the *cerebral tissue oximeter equipment* is interrupted for less than 30 s or automatic switchover to an *internal electrical power source* occurs:

- a) no change of clinical *operator* settings shall occur, including the mode of operation; and
- b) all stored *patient* data shall remain available.

NOTE 1 The *cerebral tissue oximeter equipment* does not have to continue to operate during the interruption of the *supply mains*.

NOTE 2 Settings include *operator settings*, *responsible organization* settings, and the mode of operation.

Check conformance by observing the cerebral tissue oximeter equipment settings and stored patient data and then interrupting the supply mains for a period of between 25 s and 30 s by disconnecting the power supply cord. After reestablishment of power, the above settings and stored data shall be the same.

201.11.8.101.3 Operation following long interruptions

- a) The instructions for use shall disclose the operation of the *cerebral tissue oximeter equipment* after the *supply mains* has been interrupted when the “on-off” switch remains in the “on” position and is restored after a period of time longer than 30 s.
- b) A *cerebral tissue oximeter* shall provide a *technical alarm condition* at least 5 min prior to the time that it can no longer function in accordance with the *manufacturer’s* specification when powered from the *internal electrical power source*.

Check conformance by inspection of the instructions for use.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

Addition:

201.12.1.101 * StO_2 accuracy of cerebral tissue oximeter equipment

201.12.1.101.1 * Specification

- a) The StO_2 accuracy of *cerebral tissue oximeter equipment* shall be determined as a root-mean-square difference over the *declared range* of 50 % to 85 % of the *reference haemoglobin oxygen saturation*, S_R .

- b) StO_2 accuracy shall be less than or equal to 10,0 % StO_2 over the *declared range* of 50 % to 85 % S_R .
- 1) StO_2 accuracy specifications over additional ranges may be provided as long as the range is greater than 20 %.
- EXAMPLE A specified StO_2 accuracy of 8 % for 50 % to 85 % S_R and 7 % for 50 % to 80 % S_R .
- c) The instructions for use of *cerebral tissue oximeter equipment* shall disclose:
- 1) the StO_2 accuracy; and
 - 2) its *declared range*.
- d) StO_2 accuracy information shall be accompanied by a note reminding the reader that, because *cerebral tissue oximeter equipment* measurements are statistically distributed, only about two-thirds of *cerebral tissue oximeter equipment* measurements can be expected to fall within $\pm A_{rms}$ of the reference measurement over the *declared range*.
- e) The instructions for use may additionally disclose StO_2 trend accuracy.
- 1) If provided, the StO_2 trend accuracy shall be reported over the *declared range* of 50 % to 85 % S_R .
- f) When a *cerebral tissue oximeter monitor* is suitable for use with a variety of *cerebral tissue oximeter probes*, StO_2 accuracy information shall be made available for each type of *cerebral tissue oximeter probe* indicated in the instructions for use.
- g) The following results of the *accuracy* performance studies shall be provided in the instruction for use:
- 1) a scatter plot, i.e. StO_2 versus S_R , and the parameters (slope, intercept, correlation coefficient) of a regression line calculated within the limits of the *declared range*;
 - i) The plot should contain grid lines and a line of identity ($y=x$);
 - 2) a Bland and Altman plot [i.e., $(StO_2 - S_R)$ versus $(StO_2 + S_R)/2$].
- h) In case of *in-vivo verification*, population *mean bias* (μ_0), between-subject variance (σ_μ^2), within-subject variance (σ^2), and upper 95 % and lower 95 % limits of agreement shall be provided as outlined in Section 3 of Reference [28].
- 1) In case the plots show noticeable outliers, the following shall be provided:
 - i) a discussion of the state of health, subject characteristics, test setup, test *procedure*, and any other factors that might have affected these data points; and
 - ii) a discussion of how the outlier(s) do not raise safety and performance concerns regarding the *accuracy* of the *cerebral tissue oximeter*.
- i) Three statistical metrics (*accuracy*, A_{rms} , *mean bias*, B , $\pm$ standard deviation of the bias) and the plots shall be provided:
- 1) for all subjects pooled (in case of *verification* by a *controlled desaturation study*); and

- 2) for all required *ctHb* values pooled (in case of phantom desaturation).
- j) The *accuracy* statements (*accuracy*, A_{rms} , *mean bias*, B , $\pm$ standard deviation of the bias) and the plots shall be provided for each combination of *cerebral tissue oximeter probe* and *cerebral tissue oximeter monitor* listed in the instructions for use.

Check conformance by following the requirements of 201.12.1.101.2 and by inspection of the accompanying document as well as the information that is available to the responsible organization upon request.

201.12.1.101.2 * Data collection for determination of *StO₂* accuracy

- a) The claims of *StO₂* accuracy and trend accuracy, if provided, shall be supported by a *controlled desaturation study* or *tissue haemoglobin phantom* measurements taken over the full *declared range* of the reference S_R or between +3 % of the lower value and –3 % of the upper value for which *StO₂* accuracy is claimed.

NOTE 1 In a *controlled desaturation study*, the *SavO₂* is not controlled directly, so for a desaturation of 100 % to 70 % *SaO₂*, the *SavO₂* range will vary from subject to subject.

- 1) The range of human demographics represented in the *controlled desaturation study* shall be disclosed, including anatomy, physiology and pathophysiology.
- 2) Data points should be recorded with comparable density over the full *declared range*.

EXAMPLE 1 A *controlled desaturation study* supporting a *declared range* of *StO₂* accuracy from 55 % *SavO₂* to 80 % *SavO₂* can be supported with *SavO₂* data collected over the range of 58 % *SavO₂* to 77 % *SavO₂*.

- b) The *controlled desaturation study* shall conform with the requirements of ISO 14155:2020.
- c) The *residual risk* inherent in a controlled hypoxia study on healthy adult volunteers, can be reduced to a non-significant level by following recommended additional *procedures*^[30].
- d) The *accuracy of cerebral tissue oximeter equipment* for paediatric patients shall be supported via:
 - 1) a convenience sample study on the intended population; or
 - 2) a desaturation study on a *tissue haemoglobin phantom* constructed to represent the targeted paediatric population.

NOTE 2 The *accuracy of cerebral tissue oximeter equipment* for paediatric patients cannot be supported via a *controlled desaturation study* of adult subjects.

NOTE 3 Additional information is found in Annexes AA, DD and EE.

- e) Any types of interference known to influence or affect the *StO₂* accuracy:
 - 1) need not be stated as part of the *StO₂* accuracy specification; but
 - 2) shall be disclosed in the instructions for use.

EXAMPLE 2 Ambient light (including photodynamic therapy); physical movement (*patient* and imposed motion); diagnostic testing; electromagnetic interference; HF surgical equipment; dysfunctional haemoglobin; presence of certain dyes; inappropriate positioning of the *cerebral tissue oximeter probe*; low *total haemoglobin concentration*; excessive thickness of extracerebral tissue.

- f) A summary of the test methods used to establish the StO_2 accuracy claims shall be disclosed:
- 1) in the technical description; and
 - 2) the instructions of use.

201.12.1.101.3 * Data analysis for determination of StO_2 accuracy

- a) For each *declared range* specified, StO_2 accuracy of the *cerebral tissue oximeter equipment* shall be stated in terms of the root-mean-square (rms) difference between measured values (StO_{2i}) and reference values (S_{Ri}), as given by Formula (1), for the number of paired samples (n).

$$A_{rms} = \sqrt{\frac{\sum_{i=1}^n (StO_{2i} - S_{Ri})^2}{n}} \quad (1)$$

- b) For each *declared range* specified, StO_2 trend accuracy, if provided, of the *cerebral tissue oximeter equipment* shall be disclosed by the *manufacturer* along with the method of determination.

NOTE 1 At the time of this document, there is no consensus on the methods for reporting trend accuracy.

NOTE 2 The concepts of bias and precision as given in ISO 3534-2:2006^[6] and ambiguity^[80] also have value in representing the *accuracy* of *ME equipment*. The decision to require the form of StO_2 accuracy stated above is based on the belief that it will be more widely understood by the general community of clinical *operators* and on the recognition that in some cases it represents the overall StO_2 accuracy of *cerebral tissue oximeter equipment* better than do bias and precision.

NOTE 3 Attention is also drawn to ISO/IEC Guide 99 (VIM)^[9] and ISO/IEC Guide 98-3 (GUM)^[10] as well as the documents of ISO/TC 69, *Applications of statistical methods*, for determination of accuracy and precision.

- c) In case of *in-vivo verification* by a *controlled desaturation study*, the standard reference for the StO_2 accuracy as read by *cerebral tissue oximeter equipment* shall be traceable to $SavO_2$ values obtained from *CO-oximeter* analysis of simultaneously drawn arterial and jugular venous blood.
- 1) The assumption on the ratio of arterial and venous compartment sizes, R , shall be disclosed in the instructions for use.

NOTE 4 See definition 201.3.220, Note 2 to entry.

- 2) The *CO-oximeter* shall have a specified performance of 1 % (1 standard deviation) or better over the range for SaO_2 and $SjvO_2$ blood draws.
- 3) Quality assurance, including maintenance and *procedures* for assessing *CO-oximeter* performance that are required in laboratories reporting clinical data shall be utilized for the *CO-oximeter*.

NOTE 5 Additional information is found in Annex EE.

- d) In case of *in-vitro verification* (phantom), the reference method for the assessment of StO_2 accuracy shall be disclosed in the instructions for use.
- 1) The performance of the reference method shall be appropriately *verified*.

NOTE 6 Additional information on phantoms is found in Annex DD.

201.12.1.101.4 Characteristics of the study used for determination of StO_2 accuracy

- a) If in-vivo methods are used, the summary of the clinical study report used to assess StO_2 accuracy shall:
 - 1) state whether the test subjects were sick or healthy;
 - 2) describe their skin colour, age and gender; and
 - 3) be disclosed in the *accompanying document*.
- b) If in-vitro methods are used, the summary of the phantom study used to assess StO_2 accuracy shall state the main characteristics of the experiment as listed in DD.4.2.

Check conformance by inspection of the accompanying document.

201.12.4 Protection against hazardous output

Addition:

201.12.4.101 * Data update period

- a) There shall be an indication that StO_2 is not current when the *data update period* is greater than 30 s.
 NOTE The *data update period* can be shorter than 30 s.
- b) If the *cerebral tissue oximeter equipment* is equipped with an *alarm system* that detects any *physiological alarm conditions*, the *alarm system* shall provide at least a *low priority alarm condition* to indicate when the *data update period* exceeds 30 s.
- c) *Cerebral tissue oximeter equipment* that is not equipped with an *alarm system* that detects any *physiological alarm condition* shall indicate when the *data update period* exceeds 30 s.
 - 1) The indication shall be described in the instructions for use.
- d) If the *cerebral tissue oximeter equipment* is equipped with a *functional connection* (see 201.102), an indication that the *data update period* exceeds 30 s shall be included in the data stream.

Check conformance by inspection.

201.12.4.102 * Signal inadequacy

- a) An indicator of signal inadequacy shall be provided to the *operator* when the displayed StO_2 value is potentially incorrect.
 - 1) Symbol ISO 7000-0435 (see Table 201.D.1.101, Symbol 1) may be used for this indication.
 - 2) The *accompanying document* shall include a description:
 - i) of the indicator; and
 - ii) of its function.

EXAMPLE Signal inadequacy indicated by a visual *information signal* or a *low priority alarm signal*.

- b) If the *cerebral tissue oximeter equipment* is equipped with a *functional connection* (see 201.102), then signal inadequacy shall be included in the data stream (see Table HH.201).

Check conformance by inspection.

201.13 Hazardous situations and fault conditions for ME equipment

Clause 13 of the general standard applies, except as follows:

Addition:

201.13.101 Detection of *probe faults* and *probe cable extender faults*

- a) If the *cerebral tissue oximeter equipment* is equipped with an *alarm system* to detect any *physiological alarm conditions*, the *alarm system* shall provide a *technical alarm condition* to indicate when any wire in the *cerebral tissue oximeter probe cable* or *probe cable extender* is opened or shorted to any other wire in the *cerebral tissue oximeter probe cable*; that compromises *basic safety* or *essential performance*.
- b) *Cerebral tissue oximeter equipment* that is not equipped with an *alarm system* that detects any *physiological alarm conditions* shall visually indicate the presence of *probe faults*.
- 1) The indication shall be described in the instructions for use.

EXAMPLE Indication of abnormal operation by blank display.

Check conformance with the following test:

- c) *Disconnect the cerebral tissue oximeter probe from the cerebral tissue oximeter equipment and place it in series with a circuit with which each cerebral tissue oximeter probe wire can be opened or shorted to any other cerebral tissue oximeter probe wire. Do not test unused wires in the cerebral tissue oximeter probe cable or probe cable extender.*
- d) *Repeat for any probe cable extender.*
- e) *Confirm either that a probe fault is indicated by the cerebral tissue oximeter monitor or that the cerebral tissue oximeter equipment continues normal operation.*

201.14 Programmable electrical medical systems (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME equipment

Clause 15 of the general standard applies, except as follows:

Addition:

201.15.3.5.101 * Additional requirements for rough handling**201.15.3.5.101.1 * Shock and vibration (robustness)**

- a) *Cerebral tissue oximeter equipment* or its parts shall have adequate mechanical strength when subjected to mechanical stress caused by *normal use*, pushing, impact, dropping and rough handling.
- b) *Stationary equipment* is exempt from the requirements of this subclause.
- c) After the following tests, the *cerebral tissue oximeter* shall:
 - 1) maintain *basic safety* and *essential performance*; and
 - 2) conform with the requirements of 201.12.1 and 201.12.4.

NOTE 1 A *cerebral tissue oximeter* tested and conforming with a more severe requirement is considered to conform with the corresponding requirement of this subclause.

Check conformance with the following tests:

- d) *Shock test in accordance with IEC 60068-2-27:2008^[1], using the following conditions:*

NOTE 2 This represents IEC/TR 60721-4-7:2001^[11], Class 7M2.

- 1) *test type: Type 1, or*
 - *peak acceleration: 150 m/s² (15 g),*
 - *duration: 11 ms,*
 - *pulse shape: half-sine,*
 - *number of shocks: 3 shocks per direction per axis (18 total);*

or

- 2) *test type: Type 2*
 - *peak acceleration: 300 m/s² (30 g),*
 - *duration: 6 ms,*
 - *pulse shape: half-sine,*
 - *number of shocks: 3 shocks per direction per axis (18 total).*

- e) *Broad-band random vibration test in accordance with IEC 60068-2-64:2008+AMD1:2019, using the following conditions:*

NOTE 3 This represents IEC/TR 60721-4-7:2001+ AMD1:2003^[11], Classes 7M1 and 7M2.

- 1) *acceleration amplitude:*
 - *10 Hz to 100 Hz: 1,0 (m/s²)²/Hz;*
 - *100 Hz to 200 Hz: -3 dB per octave;*
- 2) *duration: 10 min per perpendicular axis (3 total).*

f) Confirm that basic safety and essential performance are maintained following the tests.

201.15.3.5.101.2 * Shock and vibration for a *transit-operable cerebral tissue oximeter* during operation

- a) A *cerebral tissue oximeter* and its parts, including applicable *accessories*, intended for *transit-operable* use (during *patient* transport inside a healthcare facility) shall have adequate mechanical strength when subjected to mechanical stress caused by *normal use*, pushing, impact, dropping and rough handling while operating.
- b) For this test, the *cerebral tissue oximeter* and its parts, and applicable *accessories*, shall be mounted using the mounting *accessories* indicated in the *accompanying documents*.

NOTE 1 If more than one mounting system is described in the *accompanying documents*, multiple tests are required.

NOTE 2 A *cerebral tissue oximeter* tested and conforming with a more severe requirement is considered to conform with the corresponding requirement of this subclause.

- c) During the following test, a *cerebral tissue oximeter* shall maintain *basic safety* and *essential performance* and shall not exhibit an StO_2 deviation greater than $\pm 4\%$. Do not confuse maximum deviation with *accuracy*, A_{rms} , of the *cerebral tissue oximeter*. The maximum deviation allowed during this test is usually considerably smaller than the value of A_{rms} .
- d) During this testing, *alarm limits* for StO_2 shall be set to their least sensitive levels.

Check conformance by performing the following tests:

- e) Shock test in accordance with IEC 60068-2-27:2008^[1], using the following conditions:

1) test type: Type 1,

- peak acceleration: 50 m/s^2 (5 g);
- duration: 6 ms;
- pulse shape: half-sine;
- number of shocks: 3 shocks per direction per axis (18 total);

- f) Broadband random vibration test in accordance with IEC 60068-2-64:2008+AMD1:2019, using the following conditions:

1) acceleration amplitude:

- 10 Hz to 100 Hz: $0,33 \text{ (m/s}^2\text{)}^2\text{/Hz}$;
- 100 Hz to 500 Hz: -6 dB per octave ;

2) duration: 30 min per perpendicular axis (3 total).

- g) Free fall in accordance with IEC 60068-2-31:2008, using Procedure 1 and the following conditions:

1) fall height:

- i) for mass $\leq 1 \text{ kg}$, 0,25 m