

BS EN ISO 80601-2-61:2011



BSI Standards Publication

Medical electrical equipment

Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO 80601-2-61:2011)

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National foreword

This British Standard is the UK implementation of EN ISO 80601-2-61:2011. It supersedes BS EN ISO 9919:2009 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/121/5, Lung ventilators, tracheal tubes and related equipment.

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

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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Amendments issued since publication

Date	Text affected
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English Version

**Medical electrical equipment - Part 2-61: Particular requirements
for basic safety and essential performance of pulse oximeter
equipment (ISO 80601-2-61:2011)**

Appareils électromédicaux - Partie 2-61: Exigences
particulières pour la sécurité de base et les performances
essentielles pour les oxymètres de pouls (ISO 80601-2-
61:2011)

Medizinische elektrische Geräte - Teil 2-61: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von Pulsoximetriegegeräten
(ISO 80601-2-61:2011)

This European Standard was approved by CEN on 17 March 2011.

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

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

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN ISO 80601-2-61:2011) 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 2011, and conflicting national standards shall be withdrawn at the latest by October 2011.

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

This document supersedes EN ISO 9919:2009.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

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

Endorsement notice

The text of ISO 80601-2-61:2011 has been approved by CEN as a EN ISO 80601-2-61:2011 without any modification.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means to conforming to Essential Requirements of the New Approach Directive 93/42/EEC, Council Directive of 14 June 1993 on the approximation of the laws of the Member States concerning medical devices" (Medical Device Directive).

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this European standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
all	1, 2, 3	
201.4	1, 2, 3, 6	
201.4.3	1, 2	
201.4.101	2, 3	
201.4.102	3, 6	
201.4.103	6, 9.1	
201.7	12.9, 13	
201.7.2.3	13.2, 13.3 j), 13.3 k)	
201.7.2.9	2, 9.1, 13.1	
201.7.2.13.101	13.3 k)	
201.7.2.17.101	8.3, 13.1, 13.2, 13.3 b), 13.3 d), 13.3 f), 13.5	
201.7.2.101	9.1, 12.4, 13.2, 13.3 b), 13.3 d), 13.3 e), 13.3 f), 13.3 k), 13.5	
201.7.2.4.101	13.3 e), 13.3 i)	
201.7.4.3	10.3	
201.7.9.1	13.3.a)	
201.7.9.2.1.101	6, 13.6	
201.7.9.2.1.101 a), 201.7.9.2.1.101 b)	13.4	
201.7.9.2.1.101 c)	11.4.1, 13.6 j)	
201.7.9.2.1.101 d)	13.6 b)	
201.7.9.2.1.101 e)	13.6 b), 13.6 p)	
201.7.9.2.1.101 f)	13.4	

Table ZA.1 — (continued)

Clause(s)/sub-clause(s) of this European standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
201.7.9.2.1.101 g)	13.6 c)	
201.7.9.2.1.101 h)	13.6 h)	
201.7.9.2.1.101 i)	13.6 q)	
201.7.9.2.2.101	13.6 c), 13.6 d)	
201.7.9.2.8.101	13.6 i)	
201.7.9.2.9.101 b)	13.6 a)	
201.7.9.2.9.101 c), d) & e)	13.6 a), 13.6 b)	
201.7.9.2.14.101 a) & b)	13.6 c)	
201.7.9.2.14.101 c)	7.5	
201.7.9.2.14.101 d)	13.6 g)	
201.7.9.3.1.101	13.6 d)	
201.8	12.6, 12.7.4	
201.9	12.7.1	
201.10	11.2.1, 11.2.2	
201.11	6, 7.1, 7.2, 7.3, 7.5, 8.1, 8.2, 8.4, 8.6, 9.3, 12.7.5, 12.8.2	
201.11.6.5.101	7.6	
201.11.8.101	4, 12.2, 12.3	
201.12.1	6, 10.1, 6a	
201.12.4	6	
201.12.4.101	9.1, 10.1, 10.2	
201.12.4.102	10.1, 10.2, 12.4	
201.14	12.1, 12.1 a)	
201.15	12.7	
201.15.3.5.101	4, 5, 9.2, 12.7.1	
201.101.1	2, 3, 4, 5, 6, 6 a), 7.1, 7.6, 8.3, 9.1, 9.2, 10.1, 11.1.1, 11.2.2, 12.5, 12.6, 12.7.1, 12.7.5	
201.101.2	9.1, 13.1	
201.102	10.2	
202	9.2, 11.3.1, 12.5	
208	2, 6, 9.1, 10.2, 12.2, 12.3, 12.4	

WARNING — Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 80601-2-61 was prepared by a Joint Working Group of Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electromedical equipment*.

This first edition of ISO 80601-2-61 cancels and replaces the second edition of ISO 9919:2005, which has been revised to harmonize it with the third edition of IEC 60601-1:2005.

In this standard, the following print types are used.

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS TYPE.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

Introduction

The approximation of arterial haemoglobin saturation and pulse rate using pulse oximetry is common practice in many areas of medicine. This standard 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 committee that led to a requirement and identifying the HAZARDS that the requirement addresses.

Annex BB is a literature survey relevant to the determination of the maximum safe temperature of the interface between a PULSE OXIMETER PROBE and a PATIENT'S tissue.

Annex CC discusses both the formulae used to evaluate the SpO_2 ACCURACY of PULSE OXIMETER EQUIPMENT measurements, and the names that are assigned to those formulae.

Annex DD presents guidance on when *in vitro* blood calibration of PULSE OXIMETER EQUIPMENT is needed.

Annex EE presents a guideline for a CONTROLLED DESATURATION STUDY for the calibration of PULSE OXIMETER EQUIPMENT.

Annex FF is a tutorial introduction to several kinds of testers used in pulse oximetry.

Annex GG describes concepts of PULSE OXIMETER EQUIPMENT response time.

Medical electrical equipment —

Part 2-61:

Particular requirements for basic safety and essential performance of pulse oximeter equipment

201.1 Scope, object and related standards

IEC 60601-1:2005, Clause 1 applies, except as follows:

201.1.1 * Scope

Subclause 1.1 of The general standard is replaced by:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of PULSE OXIMETER EQUIPMENT intended for use on humans, hereafter referred to as ME EQUIPMENT. This includes any part necessary for NORMAL USE, including the PULSE OXIMETER MONITOR, PULSE OXIMETER PROBE, and PROBE CABLE EXTENDER.

These requirements also apply to PULSE OXIMETER EQUIPMENT, including PULSE OXIMETER MONITORS, PULSE OXIMETER PROBES and PROBE CABLE EXTENDERS, which have been REPROCESSED.

The intended use of PULSE OXIMETER EQUIPMENT includes, but is not limited to, the estimation of arterial oxygen haemoglobin saturation and pulse rate of PATIENTS in professional healthcare institutions as well as PATIENTS in the HOME HEALTHCARE ENVIRONMENT.

This International Standard is not applicable to PULSE OXIMETER EQUIPMENT intended for use in laboratory research applications nor to oximeters that require a blood sample from the PATIENT.

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 standard are not covered by specific requirements in this standard except in 201.11 and in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This standard can also be applied to PULSE OXIMETER EQUIPMENT and their ACCESSORIES used for compensation or alleviation of disease, injury or disability.

This International Standard is not applicable to PULSE OXIMETER EQUIPMENT intended solely for foetal use.

This International Standard is not applicable to remote or slave (secondary) devices that display SpO_2 values that are located outside of the PATIENT ENVIRONMENT.

201.1.2 Object

Subclause 1.2 of The general standard is replaced by:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for PULSE OXIMETER EQUIPMENT [as defined in 201.3.216] and its ACCESSORIES.

NOTE ACCESSORIES are included because the combination of the PULSE OXIMETER MONITOR and the ACCESSORIES needs to be safe. ACCESSORIES can have a significant impact on the BASIC SAFETY and ESSENTIAL PERFORMANCE of PULSE OXIMETER EQUIPMENT.

201.1.3 Collateral standards

IEC 60601-1:2005, subclause 1.3 applies with the following addition:

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

IEC 60601-1-3 does not apply.

NOTE Additional requirements for ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT are found in IEC 60601-1-11.

201.1.4 Particular standards

Subclause 1.4 of The general standard is replaced by:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

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

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

The numbering of sections, clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 208.6 in this particular standard addresses the content of Clause 6 of the 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 particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

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

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 206 for IEC 60601-1-6, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding section, clause or subclause in this particular standard, 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 standard.

201.2 Normative references

The following referenced documents are indispensable for the application of this document. The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE Informative references are listed in the bibliography beginning on page 76.

IEC 60601-1:2005, Clause 2 applies, except as follows:

Replacement:

IEC 60529:2001, *Degrees of protection provided by enclosures (IP code)*

IEC 60601-1-2:2007, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic compatibility — Requirements and tests*

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

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

IEC 60825-1:2007, *Safety of laser products — Part 1: Equipment classification and requirements*

Addition:

ISO 7000/IEC 60417:2004, *Graphical symbols for use on equipment — Index and synopsis*

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

ISO 14937:2000, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 15223-1:2007, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 15223-1:2007/Amd.1:2008

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

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

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

IEC 60601-1-9:2007, *Medical electrical equipment — Part 1-9: General requirements for basic safety and essential performance — Collateral Standard: Requirements for environmentally conscious design*

IEC 60601-1-10:2007, *Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance — Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

IEC 60601-1-11:2010, *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 60825-2:2004, *Safety of laser products — Part 2: Safety of optical fibre communication systems (OFCS)*
IEC 60825-2:2004/Amd.1:2006

IEC/TR 60878:2003, *Graphical symbols for electrical equipment in medical practice*

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

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 apply, except as follows.

NOTE An alphabetized index of defined terms is found beginning on page 81.

Addition:

201.3.201

ACCURACY

closeness of agreement between a test result and an accepted reference value

NOTE 1 Subclause 201.12.1.101.2.2 provides the method of calculating the SpO_2 ACCURACY of PULSE OXIMETER EQUIPMENT.

NOTE 2 Additional information is found in Annex CC.

NOTE 3 Adapted from ISO 3534-2:2006, 3.3.1.

201.3.202

CONTROLLED DESATURATION STUDY

hypoxaemia induced in a human subject performed under laboratory conditions

NOTE This can also be referred to as a controlled hypoxaemia (breathdown) study. Additional information is found in Annex EE.

201.3.203

CO-OXIMETER

multiwavelength, optical blood analyser that measures TOTAL HAEMOGLOBIN CONCENTRATION and the concentrations of various haemoglobin derivatives

NOTE The relevant CO-oximetry value is functional saturation of arterial blood, SoO_2 , which PULSE OXIMETER EQUIPMENT estimates and reports as SpO_2 .

201.3.204

DATA UPDATE PERIOD

interval in which the PULSE OXIMETER EQUIPMENT algorithm provides new valid data to the display or the SIGNAL INPUT/OUTPUT PART

NOTE 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.

201.3.205

DECLARED RANGE

that portion of the DISPLAYED RANGE of SpO_2 and pulse rate values over which there is specified ACCURACY

201.3.206

DISPLAYED RANGE

range of SpO_2 and pulse rate values that can be displayed by the PULSE OXIMETER EQUIPMENT

NOTE The DISPLAYED RANGE can extend beyond the DECLARED RANGE.

201.3.207

FRACTIONAL OXYHAEMOGLOBIN

FO_2Hb

fractional saturation (deprecated)

oxyhaemoglobin concentration cO_2Hb divided by the TOTAL HAEMOGLOBIN CONCENTRATION, cHb , in the blood

$$FO_2Hb = \frac{cO_2Hb}{cHb}$$

NOTE 1 cO_2Hb is the concentration of oxyhaemoglobin; cHb is the concentration of total haemoglobin.

NOTE 2 This is sometimes reported as a percentage (multiplying the fraction by 100).

NOTE 3 FRACTIONAL OXYHAEMOGLOBIN is the term used by the Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS or National Committee for Clinical Laboratory Sciences) for this ratio.

NOTE 4 CLSI denotes "concentration" by a prefixed letter c , while in the past the convention of square brackets, e.g. $[O_2Hb]$, was used.

NOTE 5 CLSI^[13] uses the following notations:

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

201.3.208

FUNCTIONAL OXYGEN SATURATION

percentage saturation given by the oxyhaemoglobin concentration (cO_2Hb) divided by the sum of the oxyhaemoglobin concentration and the deoxyhaemoglobin concentration ($cHHb$)

$$\frac{100 \times cO_2Hb}{cO_2Hb + cHHb}$$

NOTE The CLSI^[13] term for this ratio is haemoglobin oxygen saturation, and its notation is SO_2 .

201.3.209

FUNCTIONAL TESTER

test device which presents PULSE OXIMETER EQUIPMENT with a signal having a predictable value of RATIO so that the OPERATOR can observe the resulting displayed value of SpO_2 , and compare it to the expected value derived from the calibration curve for that particular PULSE OXIMETER EQUIPMENT

NOTE 1 The ACCURACY of the SpO_2 value given by the PULSE OXIMETER EQUIPMENT depends in part on whether the calibration curve of the PULSE OXIMETER MONITOR properly reflects the optical characteristics of the PULSE OXIMETER PROBE and PULSE OXIMETER PROBE-tissue interaction. FUNCTIONAL TESTERS are not able to confirm the SpO_2 ACCURACY of the calibration curve or sufficiently assess the optical characteristics of PULSE OXIMETER PROBES to determine their proper calibration. Additional information is found in FF.4.

NOTE 2 Not all FUNCTIONAL TESTERS and PULSE OXIMETER EQUIPMENT are compatible. FUNCTIONAL TESTERS can vary in pulse simulation methods, pulse contours, and amplitude. A FUNCTIONAL TESTER might not accurately reproduce the calibration of the PULSE OXIMETER EQUIPMENT and can yield different results between PULSE OXIMETER EQUIPMENT.

201.3.210

LOCAL BIAS

b

difference between the expectation of the test results (SpO_2) and an accepted reference value (SoO_2)

NOTE 1 For PULSE 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 SpO_2 versus S_{R_i} , or given by:

$$b_i = SpO_{2\text{fit},i} - S_{R_i}$$

where $SpO_{2\text{fit},i}$ is the value of the curve fitted to the test data at the i th reference oxygen saturation value, S_{R_i} .

NOTE 2 Additional information is found with the term MEAN BIAS and in the discussion in Annex CC.

NOTE 3 Adapted from ISO 3534-2:2006, 3.3.2.

201.3.211

MEAN BIAS

B

mean difference between the test and reference values, preserving sign

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

NOTE 1 n is the number of data pairs in the sample within the range of interest, SpO_{2i} is the i th SpO_2 datum; S_{R_i} is the i th reference oxygen saturation value.

NOTE 2 Additional information also is found with the term LOCAL BIAS and in the discussion in Annex CC.

NOTE 3 When defined in this way, MEAN BIAS is the average of all LOCAL BIAS values, b_i .

201.3.212

NORMALIZED

displayed at constant amplitude, independent of the actual magnitude of the signal being displayed

201.3.213

OPERATOR-SETTINGS

current state of any PULSE OXIMETER MONITOR controls, including ALARM SETTINGS

201.3.214

PRECISION

closeness of agreement between independent test results obtained under stipulated conditions

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

NOTE 1 n is the number of data pairs in the sample within the range of interest; $(SpO_{2i} - SpO_{2\text{fit},i})$ is the difference between the i th SpO_2 datum and the value of the fitted curve corresponding to the i th reference oxygen saturation value, S_{R_i} .

NOTE 2 Additional information is found in Annex CC.

NOTE 3 Adapted from ISO 3534-2:2006, 3.3.4.

201.3.215

PROBE CABLE EXTENDER

cable that connects a PULSE OXIMETER MONITOR to a PULSE OXIMETER PROBE

NOTE 1 Not every PULSE OXIMETER EQUIPMENT utilizes a PROBE CABLE EXTENDER.

NOTE 2 A PROBE CABLE EXTENDER can be an APPLIED PART.

201.3.216

PULSE OXIMETER EQUIPMENT

ME EQUIPMENT for the non-invasive estimation of FUNCTIONAL OXYGEN SATURATION of arterial haemoglobin (SpO_2) from a light signal interacting with tissue, by using the time-dependent changes in tissue optical properties that occur with pulsatile blood flow

NOTE 1 PULSE OXIMETER EQUIPMENT comprises a PULSE OXIMETER MONITOR, a PROBE CABLE EXTENDER, if provided, and a PULSE OXIMETER PROBE, which can be combined in a single assembly.

NOTE 2 Light is more technically referred to as electromagnetic radiation (optical radiation). This International Standard uses the common term.

201.3.217

PULSE OXIMETER MONITOR

part of the PULSE OXIMETER EQUIPMENT that encompasses the electronics, display and OPERATOR-EQUIPMENT INTERFACE, excluding the PULSE OXIMETER PROBE and PROBE CABLE EXTENDER

NOTE A PULSE 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 in physically different locations.

201.3.218

PULSE OXIMETER PROBE

part of the PULSE OXIMETER EQUIPMENT that includes the APPLIED PART and transducer component

NOTE 1 The terms sensor and transducer have also been used for PULSE OXIMETER PROBE.

NOTE 2 The PULSE OXIMETER PROBE typically consists of a cable and a rigid or flexible assembly containing two photo emitters and a photo detector.

201.3.219

PULSE OXIMETER PROBE FAULT

abnormal condition of the PULSE OXIMETER PROBE or PROBE CABLE EXTENDER, that, if not detected, could cause PATIENT HARM

NOTE PATIENT HARM can be caused by providing incorrect values, by exposing the PATIENT to high PULSE OXIMETER PROBE temperatures or by introducing a RISK of electric shock.

201.3.220

RATIO

MODULATION RATIO

RATIO OF RATIOS

R

basic quantity derived by PULSE OXIMETER EQUIPMENT from time-dependent light intensity measurements

NOTE PULSE OXIMETER EQUIPMENT uses an empirical calibration curve to derive SpO_2 from R . Additional information is found in FF.4.

201.3.221

* REPROCESSING

any activity, not specified in the ACCOMPANYING DOCUMENT, that renders a product suitable for use or reuse

NOTE 1 Such activities are often referred to as refinishing, restoring, recycling, refurbishing, repairing or remanufacturing.

NOTE 2 Such activities can occur in healthcare facilities.

NOTE 3 The term "reprocessed" is used to designate the corresponding status.

201.3.222

SaO_2

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

NOTE 1 Subclause 201.12.1.101.2.2 provides the method for determining acceptable methods of measurement of SaO_2 .

NOTE 2 SaO_2 is FUNCTIONAL OXYGEN SATURATION in arterial blood (additional information is found 201.3.209).

NOTE 3 SaO_2 is normally expressed as a percentage (multiplying the fraction by 100).

201.3.223

SpO_2

estimate of SaO_2 made by PULSE OXIMETER EQUIPMENT

NOTE 1 Two-wavelength PULSE OXIMETER EQUIPMENT cannot compensate for the interference caused by the presence of dyshaemoglobins in their estimation of SaO_2 ^[71].

NOTE 2 SpO_2 is normally reported as a percentage (multiplying the fraction by 100).

201.3.224

TOTAL HAEMOGLOBIN CONCENTRATION

cHb

sum of concentrations of all haemoglobin species in the blood including, but not limited to, oxyhaemoglobin (cO_2Hb), methaemoglobin ($cMetHb$), deoxyhaemoglobin ($cHHb$), sulphaemoglobin ($cSuHb$) and carboxyhaemoglobin ($cCOHb$)^[27]

201.4 General requirements

IEC 60601-1:2005, Clause 4 applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

IEC 60601-1:2005, subclause 4.3 applies, except as follows:

Additional subclause:

201.4.101 * 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 PULSE OXIMETER EQUIPMENT provided with an ALARM SYSTEM that includes the capability to detect a PHYSIOLOGICAL ALARM CONDITION: SpO_2 ACCURACY ^a , PULSE RATE ACCURACY and limit ALARM CONDITIONS	201.12.1.101 201.12.1.104 208.6.1.2.101
or generation of a TECHNICAL ALARM CONDITION	201.11.8.101.1 201.12.4 201.13.101
For PULSE OXIMETER EQUIPMENT not provided with an ALARM SYSTEM that includes the capability to detect a PHYSIOLOGICAL ALARM CONDITION: SpO_2 ACCURACY ^a and PULSE RATE ACCURACY	201.12.1.101 201.12.1.104
or indication of abnormal operation	201.12.4 201.13.101
^a Subclause 202.6.2.1.7 indicates methods of evaluating SpO_2 ACCURACY and PULSE RATE ACCURACY as acceptance criteria following specific tests required by this standard.	

201.4.102 Additional requirements for acceptance criteria

Many of the test clauses within this International Standard 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 International Standard, these MANUFACTURER-specified levels become the acceptance levels.

EXAMPLE For a specified level of SpO_2 ACCURACY of 1 %, the PULSE OXIMETER EQUIPMENT is required to have 1 % SpO_2 ACCURACY for all requirements, e.g. during electromagnetic compatibility (EMC) tests.

201.4.103 Additional requirements for PULSE OXIMETER EQUIPMENT, parts and ACCESSORIES

The PULSE OXIMETER EQUIPMENT, as well as all individual parts and ACCESSORIES specified for use with a PULSE OXIMETER MONITOR, shall comply with all requirements specified in this International Standard. This includes all combinations of parts or ACCESSORIES that are specified by a MANUFACTURER for use in PULSE OXIMETER EQUIPMENT.

NOTE 1 This requirement ensures BASIC SAFETY and ESSENTIAL PERFORMANCE of parts and ACCESSORIES of the PULSE OXIMETER EQUIPMENT, in combination with their intended PULSE OXIMETER MONITORS.

NOTE 2 PULSE OXIMETER MONITORS are frequently used with PULSE OXIMETER PROBES and cables from different MANUFACTURERS. This requirement ensures the compatibility of such combinations.

All specified combinations of PULSE OXIMETER EQUIPMENT, as well as all individual parts and ACCESSORIES specified for use with a PULSE OXIMETER MONITOR, shall be disclosed in the instructions for use. Additional information is found in 201.7.9.2.1 g) and 201.7.9.2.14.101 a) and b).

201.5 General requirements for testing of ME EQUIPMENT

IEC 60601-1:2005, Clause 5 applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, Clause 6 applies.

201.7 ME EQUIPMENT identification, marking and documents

IEC 60601-1:2005, Clause 7 applies, except as follows:

201.7.2.3 Consult ACCOMPANYING DOCUMENTS

IEC 60601-1:2005, subclause 7.2.3 applies, except as follows:

Replacement:

The PULSE OXIMETER EQUIPMENT shall be marked with the safety sign for the mandatory action: 'follow instructions for use', ISO 7010-M002. (Additional information is found in IEC 60601-1:2005+TC1, Table D.2, Number 10).

201.7.2.9 IP classification

IEC 60601-1:2005, subclause 7.2.9 applies, except as follows:

Notwithstanding the requirements of IEC 60601-1:2005, 7.2.9, the ENCLOSURE of ME EQUIPMENT shall be marked with the IP classification required by 201.11.6.5.101. If some or all of the protection against the ingress of water or particulate matter is provided by a carrying case, then the degree of protection provided by the ENCLOSURE shall be marked on the ENCLOSURE and 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.

An ENCLOSURE or a carrying case that is classified IPX0 need not be marked as such. 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 ISO 15223-1:2007, Symbol 5.8 (see Table 201.D.2, Symbol 1).

Compliance is checked by inspection and by application of the tests and criteria of IEC 60601-1:2005, 7.1.2 and 7.1.3.

Additional subclauses:

201.7.2.101 Additional requirements for marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

ME EQUIPMENT, parts or ACCESSORIES shall be CLEARLY LEGIBLY marked as follows.

- a) Any particular storage and handling instructions.
- b) A serial number or ISO 15223-1:2007, Symbol 5.16 (see Table D.2.101, Symbol 5) or lot identifying number or batch identifying number or ISO 15223-1:2007, Symbol 5.14 (see Table D.2.101, Symbol 3).
- c) The PULSE OXIMETER MONITOR, its parts and ACCESSORIES with regard to proper disposal, as appropriate.
- d) If a PULSE OXIMETER MONITOR is not provided with a low SpO_2 ALARM CONDITION, a statement to the effect "No SpO_2 Alarms" or Symbol IEC 60417-5319 (DB-2002-10) (see IEC 60601-1-8:2006, Table C.1, Symbol 3).

If applicable, ME EQUIPMENT, parts or ACCESSORIES shall be CLEARLY LEGIBLY marked as follows.

- e) With an indication of the date, after which it should not be used, expressed as the year and month. ISO 15223-1:2007, Symbol 5.12 (see Table D.2.101, Symbol 2) may be used.
- f) For a detachable PULSE OXIMETER PROBE, with a lot identifying number or batch identifying number or ISO 15223-1:2007, Symbol 5.14 (see Table D.2.101, Symbol 3) or serial number ISO 15223-1:2007, Symbol 5.16 (see Table D.2.101, Symbol 5) on it or on the packaging, as appropriate.
- g) For a PULSE OXIMETER PROBE for single-PATIENT use, the package or the PULSE OXIMETER PROBE itself marked with an indication that the PULSE OXIMETER PROBE is for single-PATIENT use.
- h) For a PULSE OXIMETER PROBE for single-use, the package or the PULSE OXIMETER PROBE itself marked with an indication that the PULSE OXIMETER PROBE is for single-use. ISO 15223-1:2007, Symbol 5.2 (see IEC 60601-1:2005, Table D.1, Symbol 28) may be used. For a specific MODEL OR TYPE REFERENCE, the indication of single-use shall be consistent.

NOTE For the purposes of this standard, repositioning the PULSE OXIMETER PROBE on the same PATIENT as indicated in the instructions for use is considered single-use.

- i) For a REPROCESSED PULSE OXIMETER PROBE, marked as such.

Check compliance by inspection of the EXPECTED SERVICE LIFE in the RISK MANAGEMENT FILE and by inspection.

201.7.2.4.101 Additional requirements for ACCESSORIES

ACCESSORIES shall be marked with:

- a) where appropriate, an indication of the date after which the ACCESSORY should not be used expressed as the year and month. ISO 15223-1:2007, Symbol 5.12 (see Table D.2.101, Symbol 2) may be used.
- b) any particular storage or handling instructions.

Check compliance by inspection of the EXPECTED SERVICE LIFE in the RISK MANAGEMENT FILE and by inspection.

201.7.2.13.101 Additional requirements for physiological effects

All latex-containing ACCESSORIES shall be CLEARLY LEGIBLY marked as containing latex. Symbol ISO 7000-2725 (DB2004-01) (see Table D.2.101, Symbol 11) may be used. All latex-containing components shall be disclosed as such in the instructions for use.

Check compliance by inspection.

201.7.2.17.101 Additional requirements for protective packaging

Packages of ME EQUIPMENT, parts or ACCESSORIES shall be CLEARLY LEGIBLY marked:

- a) with the following:
 - a description of the contents.
 - an identification reference to the batch, type or serial number or ISO 15223-1:2007, Symbols 5.14, 5.15, 5.16 (see Table D.2.101, Symbols 3, 4, 5).
 - for packages containing latex, the word 'LATEX', or Symbol ISO 7000-2725 (see Table D.2.101, Symbol 11).

- if applicable, the word "STERILE," or one of ISO 15223-1:2007, Symbols 5.20 to 5.24 (see Table D.2.101, Symbol 7 to 10). Packaging of sterile ME EQUIPMENT, parts or ACCESSORIES shall ensure sterile conditions until opened or damaged or until its expiration date is reached.
- b) for those containing parts intended for single-use, with the words "SINGLE USE", "DO NOT REUSE", "NOT FOR REUSE", Symbol ISO 7000-1051 or Symbol ISO 15223-1:2007, 5.2 (see IEC 60601-1:2005, Table D.1, Symbol 28). For a specific MODEL OR TYPE REFERENCE, the indication of single-use shall be consistent.

Consideration should be given to the disposal of packaging waste.

Check compliance by inspection.

201.7.4.3 Unit of measure

IEC 60601-1:2005, subclause 7.4.3 applies, except as follows:

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

FUNCTIONAL OXYGEN SATURATION shall be expressed in units of per cent SpO_2 and shall be marked as % SpO_2 or SpO_2 .

Pulse rate shall be expressed in units of reciprocal minutes (1/min).

201.7.9.1 Additional general requirements

Amendment (replace the first dash with):

- Name or trade name and address of:
 - the MANUFACTURER; and
 - where the MANUFACTURER does not have an address within the locale, an authorized representative within the locale,

to which the RESPONSIBLE ORGANIZATION can refer;

201.7.9.2.1.101 Additional general requirements

The instructions for use shall indicate the following:

- a) for each PULSE OXIMETER EQUIPMENT and PULSE OXIMETER PROBE, the specified use of the PULSE OXIMETER EQUIPMENT and PULSE OXIMETER PROBE regarding:
 - PATIENT population;
EXAMPLE 1 Age, weight
 - part of the body or type of tissue applied to; and
 - application;
EXAMPLE 2 Environment, frequency of use, location, mobility
- b) that the PULSE OXIMETER EQUIPMENT is calibrated to display FUNCTIONAL OXYGEN SATURATION;
- c) the range of the peak wavelengths and maximum optical output power of the light emitted by the PULSE OXIMETER PROBE and a statement to the effect that information about wavelength range can be especially useful to clinicians;

EXAMPLE Clinicians performing photodynamic therapy.

d) a description of the effect on displayed and transmitted SpO_2 and pulse rate data values by:

- data averaging and other signal processing,
- the DATA UPDATE PERIOD,
- the ALARM CONDITION DELAY, and
- ALARM SIGNAL GENERATION DELAY

including the effects of any selectable operating mode that affects these properties;

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

- e) the DISPLAYED RANGES of SpO_2 and pulse rate;
- f) if no ALARM SYSTEM that includes the capability to detect an SpO_2 or pulse rate PHYSIOLOGICAL ALARM CONDITION is provided, a statement to that effect;
- g) for PULSE OXIMETER MONITORS, the PULSE OXIMETER PROBE(S) and PROBE CABLE EXTENDERS with which the PULSE OXIMETER MONITOR has been VALIDATED and tested for compliance with this International Standard (additional information is found in 201.4.103). The list may be made available by electronic means;
- h) if the PULSE OXIMETER EQUIPMENT or its parts are intended for single-use, information on known characteristics and technical factors known to the MANUFACTURER that could pose a RISK if the PULSE OXIMETER EQUIPMENT or its parts would be re-used; and
- i) date of issue or the revision of the instructions for use.

201.7.9.2.2.101 Additional requirements for warnings and safety notices

The instructions for use shall include:

- a) for each PULSE OXIMETER PROBE and PROBE CABLE EXTENDER, a warning to the effect that probes and cables are designed for use with specific monitors;
- b) a warning to the effect that the responsible organization and/or operator needs to verify the compatibility of the monitor, probe, and cable before use, otherwise patient injury can result; and
- c) a warning to the effect that misapplication of a PULSE OXIMETER PROBE with excessive pressure for prolonged periods can induce pressure injury.

201.7.9.2.8.101 Additional requirements for start-up PROCEDURE

If an ALARM SYSTEM that includes the capability to detect PHYSIOLOGICAL ALARM CONDITIONS is provided and automatic self-test of ALARM SIGNAL generation is not provided, the instructions for use shall include a method for OPERATOR-initiated testing of ALARM SIGNAL generation.

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 there is a waveform, a statement as to whether or not it is NORMALIZED shall be provided;

NOTE This statement is important in determining whether the pulse waveform meets the requirements of 201.12.4.102.

- b) if the PULSE OXIMETER EQUIPMENT is provided with adjustable ALARM LIMITS, the range of adjustment of the ALARM LIMITS;
- c) the recommended maximum application time for each type of PULSE OXIMETER PROBE at a single site;
- d) the IP classification of the PULSE OXIMETER EQUIPMENT ENCLOSURE and, if applicable, on any carrying case provided with the PULSE OXIMETER EQUIPMENT along with a brief description of that classification's meaning;

EXAMPLE IPX1 = This pulse oximeter is protected against harmful effects of dripping water per IEC 60529.

- e) if the PULSE OXIMETER EQUIPMENT is provided with temperature capability such that the PULSE OXIMETER PROBE can operate at greater than 41 °C, specific instructions emphasizing the importance of proper PULSE OXIMETER PROBE application, without excessive pressure. In addition, specific instructions for any changes in recommended maximum application time when using temperatures greater than 41 °C.

201.7.9.2.14.101 Additional requirements for ACCESSORIES, supplementary equipment, used material

The instructions for use shall include the following:

- a) for PULSE OXIMETER PROBES, the PULSE OXIMETER MONITOR(S) and PROBE CABLE EXTENDERS with which the PULSE OXIMETER PROBES have been VALIDATED and tested for compliance with this International Standard (additional information is found in 201.4.103). The list may be made available by electronic means;
- b) for PROBE CABLE EXTENDERS, the PULSE OXIMETER MONITOR(S) and PULSE OXIMETER PROBES with which the PROBE CABLE EXTENDERS have been VALIDATED and tested for compliance with this International Standard (additional information is found in 201.4.103). The list may be made available by electronic means;
- c) information regarding toxicity or the effect on tissues of materials with which the PATIENT or any other person can come into contact and information on residual RISKS for children, pregnant or nursing women and, if applicable, any appropriate precautionary measures;
- d) if a PULSE OXIMETER PROBE is delivered in sterile packaging, a description of how to re-sterilize it, if permissible, in the event of damage to the sterile packaging.

Check compliance by inspection of the RISK MANAGEMENT FILE for residual RISKS and by inspection.

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 PULSE OXIMETER PROBE or a PULSE OXIMETER MONITOR (additional information is found in Annex FF).

The technical description should provide descriptions on how the RESPONSIBLE ORGANIZATION can VERIFY operation of the PULSE OXIMETER EQUIPMENT. If the use of a FUNCTIONAL TESTER is specified, the technical description should indicate the MODEL OR TYPE REFERENCE and its software unique identifier of at least one FUNCTIONAL TESTER that is compatible with the basic functions of the PULSE OXIMETER EQUIPMENT (e.g. able to generate a display of SpO_2 and pulse rate).

Check compliance by inspection.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

IEC 60601-1:2005, Clause 8 applies, except as follows:

Additional subclause:

201.8.3.101 Additional requirements for classification of APPLIED PARTS

APPLIED PARTS of PULSE OXIMETER EQUIPMENT shall be TYPE BF or TYPE CF APPLIED PARTS.

Check compliance by inspection.

201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, Clause 9 applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

IEC 60601-1:2005, Clause 10 applies, except as follows:

Replace subclause 10.4 with:

Depending on the light source used in a PULSE OXIMETER PROBE, the relevant requirements of IEC 60825-1:2007 or IEC 62471:2006 shall apply to a PULSE OXIMETER PROBE.

In the case of laser fibre optics, the requirements of IEC 60825-2:2004+A1:2006 shall apply.

Compliance is checked by application of the requirements of IEC 60825-1:2007, IEC 62471:2006 and IEC 60825-2:2004+A1:2006, as applicable.

201.11 Protection against excessive temperatures and other HAZARDS

IEC 60601-1:2005, Clause 11 applies, except as follows:

Addition (add at the end of subclause 11.1.2.2):

The PULSE OXIMETER PROBE-tissue interface shall be evaluated when the skin temperature is initially at 35 °C for each PULSE OXIMETER MONITOR and PULSE OXIMETER PROBE with which it is intended to be used. Additional information is found in Annex BB.

If the surface temperature of the PULSE OXIMETER PROBE at the tissue interface is capable of exceeding 41 °C, then:

- a) the PULSE OXIMETER EQUIPMENT shall have an OPERATOR-adjustable control for activating any elevated temperature mode that exceeds 41 °C. A deliberate sequence of OPERATOR actions shall be required to activate this mode. The instructions for use shall describe this sequence of OPERATOR actions;
- b) the PULSE OXIMETER EQUIPMENT shall provide a means to limit the duration of an elevated temperature mode in excess of 41 °C. The duration of the elevated temperature mode shall not exceed 4 h at 43 °C or 8 h at 42 °C;
- c) 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, burn victims;
- d) the PULSE OXIMETER EQUIPMENT shall indicate when it is in the elevated temperature mode;

- e) the technical description shall describe the test method used to measure the maximum temperature at the PULSE OXIMETER PROBE-tissue interface. When performing the temperature measurements for the PULSE OXIMETER PROBE-tissue interface, as specified in IEC 60601-1:2005, 11.1.3, the test method disclosed in the technical description may be utilized. Additional information is found in BB.3.

Additional subclause:

201.11.6.5.101 * Additional requirements for ingress of water or particulate matter into ME EQUIPMENT or ME SYSTEM

NOTE Additional requirements for ingress of water or particulate matter into the ENCLOSURE of PULSE OXIMETER EQUIPMENT intended for use in the HOME HEALTHCARE ENVIRONMENT are found in IEC 60601-1-11.

The ENCLOSURE of a PULSE OXIMETER EQUIPMENT shall provide a degree of protection to the harmful ingress of water of:

- at least an IPX2 for PULSE OXIMETER EQUIPMENT intended for use during professional transport of a PATIENT outside a professional healthcare facility; and
- at least an IPX1 for PULSE OXIMETER EQUIPMENT not intended for use during professional transport of a PATIENT outside a professional healthcare facility.

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.

Check compliance according to the tests of IEC 60529:2001 with the PULSE OXIMETER EQUIPMENT placed in the least favourable position of NORMAL USE and by inspection. After these PROCEDURES, VERIFY that BASIC SAFETY and ESSENTIAL PERFORMANCE are maintained.

201.11.8.101 Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT

201.11.8.101.1 Supply failure TECHNICAL ALARM CONDITION

If PULSE 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.

If the function of the PULSE 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. Any such switchover to an INTERNAL ELECTRICAL POWER SOURCE shall be indicated by an INFORMATION SIGNAL or a LOW PRIORITY TECHNICAL ALARM CONDITION.

Check compliance by functional testing.

201.11.8.101.2 Settings and data storage following short interruptions or automatic switchover

When the SUPPLY MAINS to the PULSE OXIMETER EQUIPMENT is interrupted for less than 30 s or automatic switchover to an INTERNAL ELECTRICAL POWER SOURCE occurs, all settings and all stored PATIENT data shall be preserved unchanged.

NOTE 1 The PULSE 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 compliance by observing the PULSE 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

The instructions for use shall disclose the operation of the PULSE 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 that is longer than 30 s.

Check compliance by inspection of the instructions for use.

201.12 ACCURACY of controls and instruments and protection against hazardous outputs

IEC 60601-1:2005, Clause 12 applies, except as follows:

201.12.1 ACCURACY of controls and instruments

Additional subclauses:

201.12.1.101 * SpO_2 accuracy of pulse oximeter equipment

201.12.1.101.1 * Specification

The SpO_2 ACCURACY of PULSE OXIMETER EQUIPMENT shall be a root-mean-square difference of less than or equal to 4,0 % SpO_2 over the range of 70 % to 100 % SaO_2 . The SpO_2 shall be indicated as FUNCTIONAL OXYGEN SATURATION and shall not be indicated as FRACTIONAL OXYHAEMOGLOBIN.

The DECLARED RANGES of SpO_2 and SpO_2 ACCURACY over those ranges shall be disclosed in the instructions for use. The SpO_2 ACCURACY shall be stated over the range 70 % to 100 % (additional information is found in 50.101.2.1). SpO_2 ACCURACY information shall be accompanied by a note reminding the reader that, because PULSE OXIMETER EQUIPMENT measurements are statistically distributed, only about two-thirds of PULSE OXIMETER EQUIPMENT measurements can be expected to fall within $\pm 4_{rms}$ of the value measured by a CO-OXIMETER. When a PULSE OXIMETER MONITOR is suitable for use with a variety of PULSE OXIMETER PROBES, SpO_2 ACCURACY information shall be made available for each type of PULSE OXIMETER PROBE.

Additional SpO_2 ACCURACY specifications over other ranges may also be provided.

EXAMPLE 1 A specified SpO_2 ACCURACY of ± 4 % for 70 % to 80 % SaO_2 .

EXAMPLE 2 A specified SpO_2 ACCURACY of ± 2 % for 80 % to 90 % SaO_2 .

EXAMPLE 3 A specified SpO_2 ACCURACY of ± 1 % for 90 % to 100 % SaO_2 .

If SpO_2 ACCURACY claims below 65 % SaO_2 are made, SpO_2 ACCURACY shall be stated in an additional range over a span of saturation not to exceed 20 % SaO_2 .

EXAMPLE 4 A specified SpO_2 ACCURACY range of 60 % to 80 % SaO_2 .

EXAMPLE 5 A specified SpO_2 ACCURACY range of 60 % to 70 % SaO_2 .

Check compliance by following the requirements of 201.12.1.101.2 and by inspection of the ACCOMPANYING DOCUMENT.

201.12.1.101.2 Determination of SpO_2 ACCURACY

201.12.1.101.2.1 * Data collection

The claims of SpO_2 ACCURACY shall be supported by CONTROLLED DESATURATION STUDY measurements taken over the full range of SaO_2 values +3 % of the lower value and –3 % of the upper value for which SpO_2 ACCURACY is claimed.

EXAMPLE 1 A CONTROLLED DESATURATION STUDY supporting a claimed range of SpO_2 ACCURACY from 70 % SaO_2 to 100 % SaO_2 can be supported with SaO_2 data collected over the range of 73 % SaO_2 to 97 % SaO_2 .

The CONTROLLED DESATURATION STUDY shall comply with the requirements of ISO 14155:2011.

Data points should be recorded with comparable density over the full range claimed.

NOTE Additional information is found in Annex EE.

Any types of interference known to influence or affect the SpO_2 ACCURACY need not be stated as part of the SpO_2 ACCURACY specification, but shall be disclosed in the instructions for use.

EXAMPLE 2 Ambient light (including photodynamic therapy); physical movement (PATIENT and imposed motion); diagnostic testing; low perfusion; electromagnetic interference; HF SURGICAL EQUIPMENT; dysfunctional haemoglobin; presence of certain dyes; inappropriate positioning of the PULSE OXIMETER PROBE.

A summary of the test methods used to establish the SpO_2 ACCURACY claims shall be disclosed in the technical description.

FUNCTIONAL TESTERS or PATIENT simulators shall not be used to VALIDATE the SpO_2 ACCURACY of PULSE OXIMETER EQUIPMENT.

NOTE Some FUNCTIONAL TESTERS or PATIENT simulators can be used to VERIFY aspects of design changes of a PULSE OXIMETER MONITOR but not a PULSE OXIMETER PROBE.

201.12.1.101.2.2 * Data analysis

For each range specified, SpO_2 ACCURACY of the PULSE OXIMETER EQUIPMENT shall be stated in terms of the root-mean-square (rms) difference between measured values (SpO_{2i}) and reference values (S_{Ri}), as given by Equation (1).

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

NOTE 1 The concepts of bias and PRECISION as given in ASTM E456-96 (Reference [8]) and ambiguity as given in Reference [69] also have value in representing the ACCURACY of ME EQUIPMENT. The decision to require the form of SpO_2 ACCURACY stated above (which has been traditional in pulse oximetry, although under the misnomer “standard deviation”) 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 SpO_2 ACCURACY of PULSE OXIMETER EQUIPMENT better than do bias and PRECISION.

NOTE 2 Attention is also drawn to ISO/IEC Guide 99^[12] (VIM) and ISO/IEC Guide 98-3^[13] (GUM) as well as the documents of ISO/TC 69, *Applications of statistical methods*, for determination of ACCURACY and PRECISION.

The standard reference for the SpO_2 ACCURACY as read by PULSE OXIMETER EQUIPMENT shall be traceable to SaO_2 values obtained from CO-OXIMETER analysis of simultaneously drawn arterial blood. The CO-OXIMETER should have a specified SaO_2 performance of 1 % (1 standard deviation) or better over the range for which the MANUFACTURER makes SpO_2 ACCURACY claims. Quality assurance, including maintenance and calibration, PROCEDURES for assessing CO-OXIMETER performance that are required in laboratories reporting clinical data shall be utilized for the CO-OXIMETER. Particular attention shall be given to the range for which the MANUFACTURER makes SpO_2 ACCURACY claims.