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 It supersedes BS EN ISO 9919:2009 which is withdrawn.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

EUROPEAN STANDARD

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EN ISO 80601-2-61

April 2011

ICS 11.040.10

Supersedes EN ISO 9919:2009

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 Pulsoximetriegeräten (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.

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

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 80601-2-61:2011: E

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.

INTERNATIONAL STANDARD **ISO 80601-2-61:2011(E)**

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, SaO_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, ctHb, in the blood

$$FO_2Hb = \frac{cO_2Hb}{c\text{tHb}}$$

NOTE 1 cO_2Hb is the concentration of oxyhaemoglobin; ctHb 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)

$$\frac{100 \times cO_2Hb}{cO_2Hb + c\text{HHb}}$$

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 (SaO_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, or given by:

$$b_i = SpO_{2\,\mathrm{fit},i} - S_{Ri}$$

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

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

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

NOTE 1 n is the number of data pairs in the sample within the range of interest, SpO_{2i} is the ith SpO_2 datum; S_{Ri} is the ith 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

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

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

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
ctHb
sum of concentrations of all haemoglobin species in the blood including, but not limited to, oxyhaemoglobin (cO_2Hb), methaemoglobin (cMetHb), deoxyhaemoglobin (cHHb), sulfhaemoglobin (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 $\pm A_{rms}$ 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).

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

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.

NOTE 3 It is not appropriate to use SaO_2 values calculated from measurements made by blood gas analysers that actually measure PaO_2 (arterial oxygen pressure) rather than SaO_2.

NOTE 4 Additional information is found in Annex EE.

201.12.1.101.2.3 Characteristics of the clinical study population

The summary of the clinical study report used to assess SpO_2 ACCURACY shall state whether the test subjects were sick or healthy and shall describe their skin colour, age and gender. This information shall be disclosed in the ACCOMPANYING DOCUMENT.

Check compliance by inspection of the ACCOMPANYING DOCUMENT.

201.12.1.102 Accuracy under conditions of motion

If a MANUFACTURER claims that the PULSE OXIMETER EQUIPMENT is accurate during motion, ACCURACY specifications during motion shall be disclosed in the instructions for use.

A summary of the test methods used to establish the ACCURACY claims during motion shall be disclosed in the technical description. The summary should include the average percentage modulation (of the infrared signal as an indicator of pulsatile signal strength) in quiescent and motion periods during the test.

Check compliance by inspection of the instructions for use and technical description.

201.12.1.103 ACCURACY under conditions of low perfusion

If a MANUFACTURER claims that the PULSE OXIMETER EQUIPMENT is accurate under conditions of low perfusion, ACCURACY specifications under these conditions shall be disclosed in the instructions for use.

A summary of the test methods used to establish the ACCURACY claims under conditions of low perfusion shall be disclosed in the technical description. The summary should include percentage modulation of the infrared signal as an indicator of pulsatile signal strength.

Check compliance by inspection of the instructions for use and technical description.

201.12.1.104 Pulse rate ACCURACY

Pulse rate ACCURACY shall be stated as the root-mean-square (rms) difference between paired pulse rate data recorded with the PULSE OXIMETER EQUIPMENT and with a reference method. Pulse rate ACCURACY shall be stated either over the full claimed range of the PULSE OXIMETER EQUIPMENT or as separate pulse rate ACCURACY specifications over segments of that range. The reference method for the computation of pulse rate ACCURACY may be an electronic pulse simulator, ECG heart rate, palpated pulse, thoracic auscultation or a second PULSE OXIMETER EQUIPMENT which has been qualified by comparison to one of these references. The reference method for the determination of pulse rate ACCURACY shall be disclosed in the technical description.

Check compliance by inspection.

201.12.4 Protection against hazardous output

Additional subclauses:

201.12.4.101 * DATA UPDATE PERIOD

There shall be an indication that SpO_2 or pulse rate data is not current when the DATA UPDATE PERIOD is greater than 30 s. The DATA UPDATE PERIOD time may be shorter than 30 s. A maximum DATA UPDATE PERIOD for saturation and pulse rate shorter than 30 s is recommended for continuous neonatal monitoring and diagnostic applications.

If the PULSE 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.

PULSE 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. The indication shall be described in the instructions for use.

Check compliance by inspection.

201.12.4.102 * Signal inadequacy

An indicator of signal inadequacy shall be provided to the OPERATOR when the displayed SpO_2 or pulse rate value is potentially incorrect. Symbol ISO 7000-0435 (see Table D.2.101, Symbol 12) may be used for this indication. A description of the indicator and its function shall be provided in the ACCOMPANYING DOCUMENT.

EXAMPLE Signal inadequacy indicated by a visual INFORMATION SIGNAL or a LOW PRIORITY ALARM SIGNAL.

NOTE A non-NORMALIZED pulse waveform display satisfies this requirement for a signal inadequacy indicator. A NORMALIZED waveform does not satisfy this requirement and can mask an unreliable signal.

Check compliance by inspection.

201.13 HAZARDOUS SITUATIONS and fault conditions

IEC 60601-1:2005, Clause 13 applies, except as follows:

Additional subclauses:

201.13.101 Detection of PULSE OXIMETER PROBE faults and PROBE CABLE EXTENDER faults

If the PULSE 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 PULSE OXIMETER PROBE cable or PROBE CABLE EXTENDER is opened or shorted to any other wire in the PULSE OXIMETER PROBE cable or PROBE CABLE EXTENDER that causes other than normal operation.

PULSE OXIMETER EQUIPMENT that is not equipped with an ALARM SYSTEM that detects any PHYSIOLOGICAL ALARM CONDITIONS shall visually indicate the presence of PULSE OXIMETER PROBE FAULTS. The indication shall be described in the instructions for use.

EXAMPLE Indication of abnormal operation by blank display.

Check compliance with the following test:

a) Disconnect the PULSE OXIMETER PROBE from the PULSE OXIMETER EQUIPMENT and place it in series with a circuit with which each PULSE OXIMETER PROBE wire can be opened or shorted to any other PULSE OXIMETER PROBE wire. Do not test unused wires in the PULSE OXIMETER PROBE cable or PROBE CABLE EXTENDER.

b) Repeat for any PROBE CABLE EXTENDER.

c) Verify that either a PULSE OXIMETER PROBE FAULT is indicated or that the PULSE OXIMETER EQUIPMENT continues normal operation.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

IEC 60601-1:2005, Clause 14 applies.

201.15 Construction of ME EQUIPMENT

IEC 60601-1:2005, Clause 15 applies, except as follows:

Additional subclauses:

201.15.3.5.101 * Additional requirements for rough handling

201.15.3.5.101.1 * Shock and vibration

NOTE Additional requirements for shock and vibration of PULSE OXIMETER EQUIPMENT intended for use in the HOME HEALTHCARE ENVIRONMENT are found in IEC 60601-1-11.

PULSE OXIMETER EQUIPMENT or its parts not intended for use during professional transport of a PATIENT outside a professional healthcare facility shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, pushing, impact, dropping and rough handling. STATIONARY EQUIPMENT is exempt from the requirements of this subclause.

After the following tests, the PULSE OXIMETER EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE.

Compliance is checked with the following tests:

a) Shock test in accordance with IEC 60068-2-27:2008, using the following conditions:

NOTE 1 This represents IEC/TR 60721-4-7:2001, Class 7M2.

1) test type: Type 1, or

- *peak acceleration: 150 m/s^2 (15g),*
- *duration: 11 ms,*
- *pulse shape: half-sine,*
- *number of shocks: 3 shocks per direction per axis (18 total);*

2) test type: Type 2

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

NOTE 2 PULSE OXIMETER EQUIPMENT tested and complying with the requirements in IEC 60601-1:2005, 15.3.4.1 is considered to comply with this requirement.

b) Broad-band random vibration test in accordance with IEC 60068-2-64:2008, using the following conditions:

NOTE 3 This represents IEC/TR 60721-4-7:2001, Classes 7M1 and 7M2.

3) acceleration amplitude:

- *10 Hz to 100 Hz: 1,0 (m/s^2)^2/Hz;*

— *100 Hz to 200 Hz: –3 dB per octave;*

— *200 Hz to 2 000 Hz: 0,5 $(m/s^2)^2/Hz$;*

4) ** duration: 10 min per perpendicular axis (3 total).*

NOTE 4 A duration of 30 min per perpendicular axis (3 total) is recommended.

c) *Following these tests, verify that* BASIC SAFETY *and* ESSENTIAL PERFORMANCE *is maintained.*

201.15.3.5.101.2 * Shock and vibration for professional transport

PULSE OXIMETER EQUIPMENT or its parts, intended for use during professional transport of a PATIENT outside a professional healthcare facility, shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, pushing, impact, dropping and rough handling.

After the following tests, the PULSE OXIMETER EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE.

NOTE 1 ME EQUIPMENT tested and complying with the relevant requirement in 201.15.3.5.101.2 in total or part, is considered to comply with the corresponding requirements of 201.15.3.5.101.1.

Compliance is checked with the following tests:

a) *Shock test in accordance with IEC 60068-2-27:2008, using the following conditions:*

NOTE 2 This represents IEC/TR 60721-4-7:2001, Class 7M3.

1) *test type: Type 1, or*

— *peak acceleration: 300 m/s^2 (30g),*

— *duration: 11 ms,*

— *pulse shape: half-sine,*

— *number of shocks: 3 shocks per direction per axis (18 total);*

2) *test type: Type 2*

— *peak acceleration: 1 000 m/s^2 (100g),*

— *duration: 6 ms,*

— *pulse shape: half-sine,*

— *number of shocks: 3 shocks per direction per axis (18 total).*

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

NOTE 3 This represents IEC/TR 60721-4-7:2001, Class 7M3.

3) *acceleration amplitude:*

— *10 Hz to 100 Hz: 5,0 $(m/s^2)^2/Hz$;*

— *100 Hz to 200 Hz: –7 dB per octave;*

— *200 Hz to 2 000 Hz: 1,0 $(m/s^2)^2$/Hz;*

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

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

NOTE 4 This represents IEC/TR 60721-4-7:2001, Class 7M2.

5) *fall height:*

— *for mass <1 kg, 0,25 m;*

— *for mass between 1 kg and <10 kg, 0,1 m;*

— *for mass between 10 kg and <50 kg, 0,05 m;*

— *for mass ⩾50 kg, 0,01 m;*

6) ** number of falls: 1 in each specified attitude.*

NOTE 5 2 falls in each specified attitude is recommended.

For PORTABLE PULSE OXIMETER EQUIPMENT that is intended to be used with a carrying case, that case may be applied to the ME EQUIPMENT during this test.

d) *Verify that BASIC SAFETY and ESSENTIAL PERFORMANCE is maintained.*

201.15.101 Mode of operation

PULSE OXIMETER EQUIPMENT shall be suitable for CONTINUOUS OPERATION.

NOTE 1 Moving the PULSE OXIMETER PROBE to a new site on the body is NORMAL USE and is considered CONTINUOUS OPERATION.

NOTE 2 Intermittent use of PULSE OXIMETER EQUIPMENT on one PATIENT or among PATIENTS is NORMAL USE and is considered CONTINUOUS OPERATION.

Check compliance by inspection.

201.16 ME SYSTEMS

IEC 60601-1:2005, Clause 16 applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, Clause 17 applies.

New clauses:

201.101 * PULSE OXIMETER PROBES and PROBE CABLE EXTENDERS

201.101.1 General

All PULSE OXIMETER PROBES and PROBE CABLE EXTENDERS shall comply with the requirements of this International Standard, whether they are produced by the MANUFACTURER of the PULSE OXIMETER MONITOR, by another entity ("third party manufacturer" or healthcare provider) or are REPROCESSED.

MANUFACTURERS of REPROCESSED PULSE OXIMETER PROBES and PROBE CABLE EXTENDERS shall perform testing to ensure that all PULSE OXIMETER EQUIPMENT specifications are met with each model of PULSE OXIMETER MONITOR with which the PULSE OXIMETER PROBE or PROBE CABLE EXTENDER is intended to be used. The ACCOMPANYING DOCUMENT of REPROCESSED PULSE OXIMETER PROBES and PROBE CABLE EXTENDERS shall list all PULSE OXIMETER MONITORS with which compatibility is claimed.

It is the responsibility of the MANUFACTURER to VALIDATE their PROCESSES to ensure that any new or REPROCESSED product complies with the requirements of this International Standard.

Check compliance by the tests of this International Standard.

201.101.2 Labelling

The MODEL OR TYPE REFERENCE of at least one PULSE OXIMETER MONITOR shall be included in the ACCOMPANYING DOCUMENT provided with each PULSE OXIMETER PROBE, compliant with 201.101.1.

Statements shall be included in the ACCOMPANYING DOCUMENT of each PULSE OXIMETER PROBE or PROBE CABLE EXTENDER to the effect that:

a) probes are designed for use with specific monitors;

b) the operator is responsible for checking the compatibility of the monitor, probe and cable before use; and

c) incompatible components can result in degraded performance.

Additional information is found in 201.101.1.

Check compliance by inspection of the ACCOMPANYING DOCUMENT.

201.102 Saturation pulse INFORMATION SIGNAL

If a variable-pitch auditory INFORMATION SIGNAL is provided to indicate the detection of a pulse and the relative $Sp\mathrm{O}_2$ level, the pitch change shall follow the $Sp\mathrm{O}_2$ reading, e.g. the pitch decreases as the $Sp\mathrm{O}_2$ reading decreases.

Check compliance by inspection.

201.103 SIGNAL INPUT/OUTPUT PART

201.103.1 General

BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained during failure of equipment connected to or the disruptions of connections to SIGNAL INPUT/OUTPUT PARTS of PULSE OXIMETER EQUIPMENT.

Check compliance by functional testing and inspection of the RISK MANAGEMENT FILE.

201.103.2 Connection to electronic health record

PULSE OXIMETER EQUIPMENT should be equipped with a SIGNAL INPUT/OUTPUT PART that permits data transmission from the PULSE OXIMETER EQUIPMENT to an electronic health record. The data transmitted should include:

a) PULSE OXIMETER EQUIPMENT identification

— This may be provided by MODEL OR TYPE REFERENCE, serial number and the software unique identifier of the PULSE OXIMETER EQUIPMENT.

— This may be provided by a unique device identifier (UDI).

b) the SpO_2 reading

c) if provided, the pulse rate

d) if PULSE OXIMETER EQUIPMENT is equipped with an ALARM SYSTEM that detects any ALARM CONDITIONS, the ALARM SYSTEM status including:

— the ALARM LIMITS;

— the presence of any ALARM CONDITIONS;

— the occurrence of any ALARM SIGNAL inactivation.

The data transmission should be capable of being provided with a NETWORK/DATA COUPLING in accordance with ASTM F2761-09.

201.103.3 Connection to a distributed alarm system

For PULSE OXIMETER EQUIPMENT that is equipped with an ALARM SYSTEM that detects a PHYSIOLOGICAL ALARM CONDITION, the ALARM SYSTEM should be equipped with a SIGNAL INPUT/OUTPUT PART that permits connection to a DISTRIBUTED ALARM SYSTEM. The data transmission should be capable of being provided with a NETWORK/DATA COUPLING in accordance with ASTM F-2761-09.

Check compliance by inspection.

201.103.4 Connection for remote control

PULSE OXIMETER EQUIPMENT may be equipped with a SIGNAL INPUT/OUTPUT PART for connection for external control of the PULSE OXIMETER EQUIPMENT. The data transmission should be capable of being provided with a NETWORK/DATA COUPLING in accordance with ASTM F-2761-09.

Check compliance by inspection.

202 Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests

IEC 60601-1-2:2007 applies except as follows:

202.6.2.1.1 IMMUNITY TEST LEVELS

Subclause 6.2.1.1 of IEC 60601-1-2:2007 applies, except as follows:

Amendment (add after note 2):

NOTE 3 PULSE OXIMETER EQUIPMENT is not considered LIFE-SUPPORTING ME EQUIPMENT OR ME SYSTEM.

202.6.2.1.7 PATIENT simulation

Subclause 6.2.1.7 of IEC 60601-1-2:2007 applies, except as follows:

Amendment (delete the following from the first bullet):

For ME EQUIPMENT and ME SYSTEMS without a manual sensitivity adjustment,

Replacement (the second bullet with the following):

— During immunity testing, the PULSE OXIMETER EQUIPMENT shall be tested at an SpO_2 reading within the calibrated range that is at least 5 % different from that of a noise-induced value and less than (100 % minus the SpO_2 ACCURACY of the PULSE OXIMETER EQUIPMENT).

NOTE 2 The noise-induced value could be a value, e.g. where $R = 1$ or R is the ratio of the gain from the IR channel to the gain from the red channel. Other noise-induced values have been observed.

— The pulse rate shall be different from that of the noise-induced signal frequency and within the specified range of the pulse rate display.

— The SpO_2 and pulse rate signal may be derived from a PATIENT simulator for these tests.

202.6.2.1.10 * Requirements

Subclause 6.2.1.10 of IEC 60601-1-2:2007 is replaced by:

Under the IMMUNITY TEST LEVELS specified in IEC 60601-1-2:2007, 6.2, PULSE OXIMETER EQUIPMENT shall be able to provide BASIC SAFETY and ESSENTIAL PERFORMANCE.

The following conditions associated with BASIC SAFETY and ESSENTIAL PERFORMANCE shall apply:

a) No permanent degradation or loss of function which is not recoverable, due to damage of ME EQUIPMENT (components) or software, or loss of data shall be observed at any IMMUNITY TEST LEVEL specified in IEC 60601-1-2:2007, 6.2 and 202.6.2.3 aa).

b) Operation within specified SpO_2 ACCURACY limits and pulse rate ACCURACY limits or generation of either a TECHNICAL ALARM CONDITION or an indication of abnormal operation.

c) Any temporary degradation of performance or interruption of an intended operation at immunity testing according to IEC 60601-1-2:2007, 6.2.2, 6.2.4, 6.2.5 and 6.2.7 shall recover from any disruption within 30 s without OPERATOR intervention.

d) No change of operating mode.

e) No inappropriate delivery of energy to the PATIENT shall occur at any IMMUNITY TEST LEVEL specified in IEC 60601-1-2:2007, 6.2 and 202.6.2.3 aa).

202.6.2.3 * Radiated RF electromagnetic fields

Subclause 6.2.3.1 a) of IEC 60601-1-2:2007 applies, except as follows:

Addition:

In addition to these requirements, PULSE OXIMETER EQUIPMENT intended for use during professional transport of a PATIENT outside the professional healthcare facility shall comply with 202.6.2.1.10 at the IMMUNITY TEST LEVEL of 20 V/m (80 % amplitude-modulated at 1 000 Hz) over the range of 80 MHz to 2,5 GHz (additional information is found in IEC 60601-1-2:2007, Table 9).

Check compliance by application of the tests in IEC 60601-1-2:2007, 6.2. Evaluate the response of the PULSE OXIMETER EQUIPMENT during and after these tests in accordance with above.

208 Medical electrical equipment — Part 1-8: General requirements for safety — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

IEC 60601-1-8:2006 applies except as follows:

Additional subclauses:

208.6.1.2.101 * Additional requirements for ALARM CONDITION priority

If the 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 ALARM CONDITION for low SpO_2 level.

NOTE A high SpO_2 level ALARM CONDITION can enhance PATIENT safety for certain clinical applications, e.g. neonatal monitoring.

Check compliance by inspection.

208.6.5.4.101 * Additional requirements for DEFAULT ALARM PRESET

If the PULSE OXIMETER MONITOR is equipped with an ALARM SYSTEM to detect a low SpO_2 level PHYSIOLOGICAL ALARM CONDITION, the ALARM LIMIT in the MANUFACTURER-configured ALARM PRESET for the SpO_2 level PHYSIOLOGICAL ALARM CONDITION shall not be less than 85 % SpO_2[30] [64].

Unless the low SpO_2 ALARM LIMIT is displayed continuously, the low SpO_2 ALARM LIMIT of any OPERATOR-configured ALARM PRESET shall not be less than the low SpO_2 ALARM LIMIT stored in the DEFAULT ALARM PRESET.

Check compliance by functional testing.

208.6.8.5.101 Additional requirements for ALARM SIGNAL inactivation states, indication and access

The MANUFACTURER-configured default AUDIO PAUSED or ALARM PAUSED interval of PULSE OXIMETER EQUIPMENT shall not exceed 2 min.

Check compliance by functional testing.

Addition:

IEC 60601-1:2005, Annexes apply, except as follows:

Annex C
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, Annex C applies, except as follows:

Addition:

201.C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

Additional requirements for marking on the outside of PULSE OXIMETER EQUIPMENT or their parts or ACCESSORIES are found in Table 201.C.101.

Table 201.C.101 — Marking on the outside of PULSE OXIMETER EQUIPMENT or its parts

Description of marking	Subclause
Any particular storage and/or handling instructions	201.7.2.101 a)
Follow instructions for use safety sign	201.7.2.3
For ACCESSORIES, any particular storage and/or handing instructions	201.7.2.4.101 b)
For ACCESSORIES, date after which it should not be used	201.7.2.4.101 a)
For latex-containing ACCESSORIES, so indicated	201.7.2.13.101
For packages containing latex, so indicated	201.7.2.17.101 a)
For packaging containing parts intended for single-use, so indicated	201.7.2.17.101 b)
For packaging, a description of the contents	201.7.2.17.101 a)
For packaging, reference to batch, type or serial number	201.7.2.17.101 a)
If applicable, IP classification of carrying case	201.7.2.9
If applicable, keep dry	201.7.2.9
If applicable for packaging, indicate sterile contents	201.7.2.17.101 a)
If applicable for a PULSE OXIMETER PROBE for single-PATIENT use, so indicated	201.7.2.101 g)
If applicable for a PULSE OXIMETER PROBE for single-use, so indicated	201.7.2.101 h)
If applicable for a PULSE OXIMETER PROBE, serial number or batch identifying number	201.7.2.101 f)
If applicable for a REPROCESSED PULSE OXIMETER PROBE, so indicated	201.7.2.101 i)
If applicable, date after which it should not be used	201.7.2.101 e)
If not provided with low SpO_2 LIMIT ALARM CONDITION, so indicated	201.7.2.101 d)
Indication of mode where APPLIED PART temperature can exceed 41 °C	201.11 d)
Indication of state where SpO_2 value or pulse rate might be invalid because of inadequate signal	201.12.4.102
IP classification of ENCLOSURE	201.7.2.9
Proper disposal	201.7.2.101 c)
Serial number or lot identifying number or batch identifying number	201.7.2.101 b)
Units of measure of oxygen saturation	201.7.4.3

201.C.2 ACCOMPANYING DOCUMENTS, general

Additional requirements for ACCOMPANYING DOCUMENTS of PULSE OXIMETER EQUIPMENT are found in Table 201.C.102.

Table 201.C.102 — ACCOMPANYING DOCUMENTS, general

Description of disclosure	Subclause
For PULSE OXIMETER PROBES or PROBE CABLE EXTENDERS, incompatible components can result in degraded performance	201.101.2 c)
For PULSE OXIMETER PROBES or PROBE CABLE EXTENDERS, probes are designed for use with specific monitors	201.101.2 a)
For PULSE OXIMETER PROBES or PROBE CABLE EXTENDERS, the OPERATOR is responsible for checking compatibility prior to use	201.101.2 b)
For PULSE OXIMETER PROBES, a compatible PULSE OXIMETER MONITOR	201.101.2
For REPROCESSED PULSE OXIMETER PROBES or PROBE CABLE EXTENDERS, list of compatible PULSE OXIMETER MONITORS	201.101.1
Summary of the clinical study report	201.12.1.101.2.3

201.C.3 ACCOMPANYING DOCUMENTS, instructions for use

Additional requirements for the instructions for use of PULSE OXIMETER EQUIPMENT are found in Table 201.C.103.

Table 201.C.103 — ACCOMPANYING DOCUMENTS, instructions for use

Description of disclosure	Subclause
Biocompatibility information	201.7.9.2.14.101 c)
Date of issue or the revision of the instructions for use	201.7.9.2.1.101 i)
DECLARED RANGES of SpO_2 and SpO_2 ACCURACY by PULSE OXIMETER PROBE	201.12.1.101.1
Description of the signal adequacy indicator and if a waveform whether or not it is NORMALIZED	201.7.9.2.9.101 a)
DISPLAYED RANGES of SpO_2 and pulse rate	201.7.9.2.1.101 e)
For each PULSE OXIMETER EQUIPMENT and PULSE OXIMETER PROBE, specified use	201.7.9.2.1.101 a)
For each PULSE OXIMETER MONITOR, list of compatible PULSE OXIMETER PROBES or PROBE CABLE EXTENDERS	201.7.9.2.1.101 g)
For each PULSE OXIMETER PROBE, range of peak wavelengths and optical output power and its utility	201.7.9.2.1.101 c)
For PROBE CABLE EXTENDERS, the list of compatible PULSE OXIMETER MONITORS and PULSE OXIMETER PROBES	201.7.9.2.14.101 b)
For PULSE OXIMETER EQUIPMENT not provided with an ALARM SYSTEM that includes the capability to detect PHYSIOLOGICAL ALARM CONDITIONS, means of indication of abnormal operation	201.13.101
For PULSE OXIMETER PROBES or PROBE CABLE EXTENDERS, probes are designed for use with specific monitors	201.7.9.2.2.101 a)
For PULSE OXIMETER PROBES or PROBE CABLE EXTENDERS, the OPERATOR is responsible for checking compatibility prior to use	201.7.9.2.2.101 b)
For PULSE OXIMETER PROBES, the list of compatible PULSE OXIMETER MONITORS and PROBE CABLE EXTENDERS	201.7.9.2.14.101 a)
If applicable, ACCURACY specifications under motion	201.12.1.102

Table 201.C.103 *(continued)*

Description of disclosure	Subclause
If applicable, ACCURACY specifications in low perfusion	201.12.1.103
Pulse rate ACCURACY	201.12.1.104
If applicable, separate ACCURACY specifications under 65 % SaO_2	201.12.1.101.1
If equipped with adjustable ALARM LIMITS, the range of adjustment	201.7.9.2.9.101 b)
If equipped with an ALARM SYSTEM that includes the capability to detect PHYSIOLOGICAL ALARM CONDITIONS and automatic self-test of ALARM SIGNAL generation is not provided, a method for testing	201.7.9.2.8.101
If not equipped with an ALARM SYSTEM that includes the capability to detect PHYSIOLOGICAL ALARM CONDITIONS, description of the indication that the DATA UPDATE PERIOD exceeds 30 s	201.12.4.101
If no SpO_2 and pulse rate ALARM CONDITIONS, so indicated	201.7.9.2.1.101 f)
If permitted for sterile PULSE OXIMETER PROBES, resterilization information	201.7.9.2.14.101 d)
If single-use, characteristics and technical factors if re-used	201.7.9.2.1.101 h)
If the APPLIED PART temperature can exceed 41 °C, instructions emphasizing the importance of proper application and any changes in the recommended maximum application time	201.7.9.2.9.101 e)
If the APPLIED PART temperature can exceed 41 °C, temperature settings greater than 41 °C shall not be used on PATIENTS with susceptible skin	201.11 c)
If the APPLIED PART temperature can exceed 41 °C, the sequence of OPERATOR actions needed to activate	201.11 a)
Interference known to influence the SpO_2 ACCURACY	201.12.1.101.2.1
IP classification and its meaning for ENCLOSURE and, if applicable, carrying case	201.7.9.2.9.101 d)
Latex-containing components	201.7.2.13.101
Only 2/3 of measurements are expected to fall within the DECLARED RANGE of SpO_2 ACCURACY	201.12.1.101.1
Operation of PULSE OXIMETER EQUIPMENT following SUPPLY MAINS interruption longer than 30 s	201.11.8.101.3
Recommended maximum application time for a PULSE OXIMETER PROBE at a single site	201.7.9.2.9.101 c)
Specified combinations of PULSE OXIMETER EQUIPMENT	201.4.103
That the PULSE OXIMETER EQUIPMENT displays FUNCTIONAL OXYGEN SATURATION	201.7.9.2.1.101 b)
The DATA UPDATE PERIOD, effect of data averaging, ALARM CONDITION and ALARM SIGNAL GENERATION DELAY on displayed and transmitted SpO_2 and pulse rate values	201.7.9.2.1.101 d)
Warning to the effect that misapplication of a PULSE OXIMETER PROBE with excessive pressure for prolonged periods can induce pressure injury	201.7.9.2.2.101 c)

201.C.4 ACCOMPANYING DOCUMENTS, technical description

Additional requirements for the technical description of PULSE OXIMETER EQUIPMENT are found in Table 201.C.104.

Table 201.C.104 — ACCOMPANYING DOCUMENTS, technical description

Description of disclosure	Subclause
FUNCTIONAL TESTER cannot be used to assess ACCURACY	201.7.9.3.1.101
If the APPLIED PART temperature can exceed 41 °C, the method used to measure APPLIED PART temperature	201.11 e)
Reference method used for pulse rate ACCURACY	201.12.1.104
Summary of methods used to establish SpO_2 ACCURACY	201.12.1.101.2.1
Summary of methods used to establish SpO_2 ACCURACY in low perfusion	201.12.1.103
Summary of methods used to establish SpO_2 ACCURACY under motion	201.12.1.102

Annex D
(informative)

Symbols on marking

IEC 60601-1:2005, Annex D applies, except as follows:

Addition:

Table 201.D.2 — Additional symbols on marking

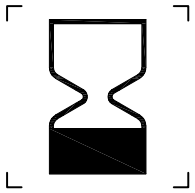
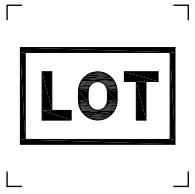
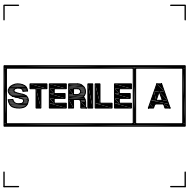
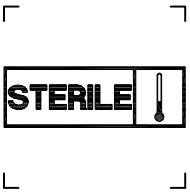
No	Symbol	Reference	Title
1		ISO 7000-0626 (Symbol 5.8 ISO 15223-1:2007)	**Keep away from rain** **(Keep dry)**
2	 (YYYY-MM)	ISO 7000-2607 (Symbol 5:12 ISO 15223-1:2007)	**Use by date**
3		ISO 7000-2492 (Symbol 5.14 ISO 15223-1:2007)	**Batch code**
4		ISO 7000-2493 (Symbol 5.15 ISO 15223-1:2007)	**Catalogue number**
5		ISO 7000-2498 (Symbol 5.16 ISO 15223-1:2007)	**Serial number**
6		ISO 7000-2499 (Symbol 5:20 ISO 15223-1:2007)	**Sterile**

Table 201.D.2 *(continued)*

No	Symbol	Reference	Title
7		ISO 7000-2500 (Symbol 5.21 ISO 15223-1:2007)	**Sterilized using aseptic processing techniques**
8		ISO 7000-2501 (Symbol 5.22 ISO 15223:2007)	**Sterilized using ethylene oxide**
9		ISO 7000-2502 (Symbol 5.23 ISO 15223-1:2007)	**Sterilized using irradiation**
10		ISO 7000-2503 (Symbol 5.24 ISO 15223-1:2007)	**Sterilized using steam or dry heat**
11		ISO 7000-2725 form B	**Contains or presence of natural rubber latex**
12		ISO 7000-0435	**Malfunction**

Additional Annexes:

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This annex provides a rationale for some requirements of this document and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this document necessitated by those developments.

Pulse oximetry facilitates PATIENT care by providing an approximation of arterial haemoglobin saturation with oxygen, and allows for the possibility of early detection of the catastrophic complications associated with PATIENT hypoxaemia and hyperoxaemia.

Current technology requires an adequate concentration of haemoglobin, a pulsatile change in blood flow, and light transmission through a tissue bed to approximate the *in vivo* haemoglobin oxygen saturation. PULSE OXIMETER EQUIPMENT is not typically capable of functioning effectively during cardiopulmonary bypass or at extreme low-flow states, and is not at present intended as a means for the measurement of blood flow or blood volume.

Given these limitations, PULSE OXIMETER EQUIPMENT does not provide precise measurements of arterial haemoglobin saturation. The presently marketed *in vivo* PULSE OXIMETER EQUIPMENT is not a replacement for measurement of blood samples by *in vitro* optical oximeters. The values derived from pulse oximetry are not a measurement of blood or solid-tissue oxygen tension. Pulse oximetry provides no direct indication of oxygen delivery to tissue, or of tissue oxygen consumption.

AA.2 Rationale for particular clauses and subclauses

The numbering of the following rationale corresponds to the numbering of the clauses in this document. The numbering is, therefore, not consecutive.

Subclause 201.1.1 — Scope

Equipment used in research applications is often experimental or intended primarily for non-medical uses. Imposition of the requirements of this International Standard on equipment used for research might unduly limit development of beneficial new techniques or equipment.

Definition 201.3.221 — REPROCESSING

The term REPROCESSING was chosen, instead of terms such as remanufacturing or refurbishing, because the committee was looking for the widest possible term. Any activity, outside the instructions given by the MANUFACTURER, for subsequent reuse is considered REPROCESSING. This includes cleaning and reuse of a single-use PROBE, as well as using a used single-use PROBE as the raw material for a remanufacturing PROCESS to create a “new” PROBE for use.

Subclause 201.4.101 — Additional requirements for ESSENTIAL PERFORMANCE

Sufficient ACCURACIES of SpO_2 and pulse rate are necessary for PULSE OXIMETER EQUIPMENT to be suitable for its intended purpose and are required to prevent adverse PATIENT events, as is expected by the essential principles of safety and performance.[2] When limit ALARM CONDITIONS are provided, OPERATORS rely on the proper operation of limit ALARM CONDITIONS to alert them to take appropriate actions based on the condition of the PATIENT.

PULSE OXIMETER EQUIPMENT is expected to maintain these capabilities or indicate to the OPERATOR that it cannot perform these tasks.

Subclause 201.7.9.3.1.101 — Additional general requirements

The appropriate application of FUNCTIONAL TESTERS has been misunderstood by some OPERATORS or RESPONSIBLE ORGANIZATIONS. See Annex FF for a discussion of this issue.

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

Fluids commonly found in the care environment include saline, blood and body fluids. Maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE following reasonably foreseeable encounters with fluids protects OPERATORS and PATIENTS from unacceptable RISKS.

Subclause 201.12.1.101 — SpO_2 ACCURACY of PULSE OXIMETER EQUIPMENT

SpO_2 ACCURACY is affected by the combination of the PULSE OXIMETER MONITOR, any cable, the PULSE OXIMETER PROBE and human tissue. Figure FF.6 shows an example of a PULSE OXIMETER PROBE that degrades SpO_2 ACCURACY because of calibration variability between different test subjects.

Subclause 201.12.1.101.1 — Specification

There was considerable discussion about the minimum acceptable SpO_2 ACCURACY specification of PULSE OXIMETER EQUIPMENT. Ideally, PULSE OXIMETER EQUIPMENT would deliver high SpO_2 ACCURACY (<1 %) with all PULSE OXIMETER PROBES and application sites. However, due to well-known limitations in current pulse oximetry technology, that level of SpO_2 ACCURACY is not routinely achievable.

Therefore, the committee had to consider the following question: “What is the minimum acceptable SpO_2 ACCURACY for safe and effective use of PULSE OXIMETER EQUIPMENT?”

Due to the diverse applications of PULSE OXIMETER EQUIPMENT, minimum performance requirements are not universal. Two general categories of use can be described as monitoring and diagnosis.

— Monitoring can be defined as the use of trends and/or ALARM SIGNALS to facilitate the early detection of saturation or pulse rate changes.

— Diagnosis — or diagnostic use — can be defined as measurement of SpO_2 as an estimate of SaO_2 to facilitate diagnosis or guide therapy.

Diagnostic applications usually require higher SpO_2 ACCURACY. Regardless of the specified SpO_2 ACCURACY, inherent limitations in SpO_2 ACCURACY can necessitate arterial blood sample analysis.

Based on clinical experience and the historical use of PULSE OXIMETER EQUIPMENT, SpO_2 ACCURACY less than 4 % is acceptable for many monitoring applications. Clinicians on the committee expressed concerns that PULSE OXIMETER EQUIPMENT specified with SpO_2 ACCURACY in excess of 4,0 % at 1 standard deviation (8,0 % at 2 standard deviations) might lead to mistreatment in clinical practice. Even though greater SpO_2 ACCURACY is usually more desirable, and frequently attainable, this figure represents a clinically acceptable tradeoff between lower SpO_2 ACCURACY and greater flexibility in PULSE OXIMETER PROBE placement and performance.

The committee agreed that it is important to provide a uniform basis for comparing different PULSE OXIMETER EQUIPMENT. That is why this particular standard requires that SpO_2 ACCURACY be specified over the 70 % to 100 % SaO_2 range, as well as why SpO_2 ACCURACY is permitted to be specified over other ranges (e.g. 1 % over the range 90 % to 100 % SaO_2).

The SpO_2 ACCURACY of PULSE OXIMETER EQUIPMENT partially depends on the SaO_2 of the PATIENT[67]. Currently designed PULSE OXIMETER EQUIPMENT is generally more accurate at SaO_2 levels above 90 % than they are below 80 %. Limiting the span over which the SpO_2 ACCURACY is stated more realistically communicates the true performance in the range of interest. The span for PULSE OXIMETER EQUIPMENT that specifies SpO_2 ACCURACY below 65 % SaO_2 is limited to 20 % to avoid biasing the low saturation SpO_2 ACCURACY (by averaging in the better performance of the higher ranges).

Subclause 201.12.1.101.2.1 — Data collection

During a CONTROLLED DESATURATION STUDY, it is often difficult to achieve a target SaO_2, particularly at the lower end of the SaO_2 range. Attempts should be made at least to achieve a measured SaO_2 within 3 % SpO_2 of the stated range of SpO_2 ACCURACY.

The SpO_2 ACCURACY of PULSE OXIMETER EQUIPMENT depends strongly on the optical interaction of the PULSE OXIMETER PROBE'S emitted and collected light and the PATIENT'S blood-perfused tissues. The correlation of the measured pulsatile change in light transmission through blood-perfused tissues and the underlying arterial oxygen saturation depends, among other things, on the spectral content of the PULSE OXIMETER PROBE'S emitted light and interaction of the PULSE OXIMETER PROBE optics and the skin surface. Since these complex wavelength-dependent interactions are not assessed nor reproduced by PULSE OXIMETER EQUIPMENT FUNCTIONAL TESTERS and simulators, such devices cannot possibly characterize or VALIDATE the true ACCURACY of the PULSE OXIMETER PROBE/PULSE OXIMETER MONITOR combinations. FUNCTIONAL TESTERS can be used to VERIFY the functionality of PULSE OXIMETER MONITORS and the electrical integrity of the PULSE OXIMETER PROBES. (See also Annex FF.)

Subclause 201.12.1.101.2.2 — Data analysis

CO-OXIMETERS have an inherent inaccuracy that will influence SpO_2 ACCURACY assessment[20][38]. To reduce PULSE OXIMETER EQUIPMENT inaccuracy, the inaccuracy of the reference CO-OXIMETER'S measurement of SaO_2 needs to be controlled.

The committee is not aware of a practical or traceable PROCEDURE that allows a MANUFACTURER or RESPONSIBLE ORGANIZATION to VERIFY SaO_2 ACCURACY of a CO-OXIMETER. To minimize the influence of the CO-OXIMETER inaccuracy in the A_{rms} measurement, careful attention should be paid to ensure that the CO-OXIMETER is performing within its specified performance capability. VERIFICATION of correct operation by use of the CO-OXIMETER MANUFACTURER'S recommended maintenance PROCEDURES is necessary, but is not sufficient to ensure a traceable, accurate measurement. Further quality assurance PROCEDURES for VERIFYING CO-OXIMETER ACCURACY are needed.

EXAMPLE 1 CLSI[14].

EXAMPLE 2 College of American Pathologists[29].

Subclause 201.12.4.101 — DATA UPDATE PERIOD

PULSE OXIMETER EQUIPMENT is required to provide an indication that the displayed SpO_2 value is not current if the DATA UPDATE PERIOD of SpO_2 exceeds 30 s. Subclause 201.7.9.2.1.101 includes a requirement to disclose the DATA UPDATE PERIOD in the ACCOMPANYING DOCUMENTS. However, there is no requirement that limits the duration of the DATA UPDATE PERIOD. The additional requirement that "there shall be an indication that the displayed value is not current" was added by the committee based on potentially significant delays that can occur between an event that activates an ALARM CONDITION, and the actual generation of the ALARM SIGNALS. The displayed SpO_2 value does not reflect changes in the measured SpO_2 value until completion of each update period. If an event that activates an ALARM CONDITION, such as PATIENT desaturation, occurs just after the display is updated, a significant delay could occur between the event and the generation of the ALARM SIGNALS. This could create a HAZARDOUS SITUATION for the PATIENT if the DATA UPDATE PERIOD is long.

To mitigate this potentially HAZARDOUS SITUATION, the committee believes it is important for the PULSE OXIMETER EQUIPMENT to provide an indication to the OPERATOR when the displayed SpO_2 value has not been updated in the last 30 s, and as such, can be invalid. This provides the OPERATOR timely information to assess the PATIENT'S condition and take appropriate action, if necessary.

Subclause 201.12.4.102 — Signal inadequacy

Clinicians assume that SpO_2 ACCURACY degrades under various physiological and environmental conditions, and they wish to see an indicator of performance degradation. They generally assume that the plethysmographic display will reveal performance degradation due to motion and poor pulsatile signal strength. Consequently, clinicians would like to require the display of the non-NORMALIZED plethysmogram. (It is also generally assumed that the plethysmograms that are NORMALIZED in amplitude will hide significant changes in signal strength. Signal strength is the time varying component of the infrared waveform.)

In fact, many factors contribute to degradation of signal adequacy with potential loss of ACCURACY. Changes of the plethysmogram can be sensitive to noise and changes in signal strength, but plethysmographic changes are not specific to factors that degrade ACCURACY versus factors that corrupt the plethysmogram but do not degrade ACCURACY. These factors can include, but are not limited to: signal strength, noise frequency and amplitude, source of noise, plethysmographic morphology, ambient light intensity and sensor positioning and alignment.

Ideally, it would be beneficial to provide a means for assessment of signal adequacy as it relates to general performance, including confidence in measurement ACCURACY. Although this would best be accomplished by a comprehensive real-time assessment of signal adequacy and a visual indication of said status, it can also be accomplished in a clinically acceptable manner, e.g. with an appropriately scaled plethysmographic display.

A non-scaled plethysmographic display can lack the resolution to reveal clinically significant changes in signal strength in the low range. Therefore, scaling of the plethysmographic display to increase resolution in the low signal-strength range can enhance the utility of the plethysmogram for assessing changes in signal strength.

Subclause 201.15.3.5.101 — Additional requirements for rough handling

ME EQUIPMENT, including PULSE OXIMETER EQUIPMENT, in NORMAL USE will be subjected to mechanical stresses (e.g. vibration, shock) and could randomly be subjected to additional stresses. Therefore, ME EQUIPMENT needs to be robust enough to withstand the vibration, shock, bumps and drops that it will encounter in NORMAL USE.

These tests were chosen by first qualitatively assessing the relative severity of the scenarios within various locations [i.e. HOME HEALTHCARE ENVIRONMENT and professional healthcare facility environment and transport vehicles (wings and wheels)] on various sizes and types of ME EQUIPMENT (i.e. HAND-HELD, PORTABLE and MOBILE). The result of the committee's analysis for the various types of shock and vibration that can be experienced is shown in Table AA.1.

Rationale for combining HOME HEALTHCARE ENVIRONMENT and professional healthcare facility environment: the committee recognized that for the case of shock, vibration and bump, the environment in the home should be slightly less severe than that expected in the professional healthcare facility. The committee chose to combine these two categories, both for simplicity and because many pieces of ME EQUIPMENT are routinely moved from the professional healthcare facility to the HOME HEALTHCARE ENVIRONMENT and vice versa.

After qualitative assessment, the committee assessed the International Standards in the IEC 60068 series relevant for environmental testing, and their respective rationales, as well as the IEC 60721 series of guidance documents.

Table AA.1 — Qualitative assessment of PULSE OXIMETER EQUIPMENT shock and vibration environment

ME EQUIPMENT category	Location											
	Standard environments						Transport vehicles					
	Home			Healthcare facility			Wheels			Wings/Rotary		
MOBILE	D1	S1	V1	D1	S2	V1	D1	S3	V2	D1	S3	V3
PORTABLE	D1	S2	V0	D1	S2	V1	D1	S3	V2	D1	S3	V3
HAND-HELD	D3	S1	V0	D3	S2	V1	D3	S3	V2	D3	S3	V3
STATIONARY	None			None			Not applicable					

S = shock; V = vibration; D = drop

Rating: 0 = no test, 1 = least severe or 7M1[a]; 2 = moderate severity or 7M2; 3 = most severe or 7M3

[a] The 7Mx designations are defined in IEC 60721-3-7:1995.

In selecting the requirements, the committee reviewed other sources for material related to these tests (e.g. FDA Reviewers Guidance[35] for premarket notification submissions, Mil Std 810) but found the best fit was with IEC 60721-3-7:1995 and its companion IEC/TR 60721-4-7:2001. This International Standard mapped well to the requirements defined in Table AA.1. The aforementioned International Standard specifies 3 classes of mechanical conditions: 7M1, 7M2 and 7M3. The committee found that classes 7M2 and 7M3 best represent the conditions seen during transport of a PATIENT within a professional healthcare facility and professional transport of a PATIENT outside a professional healthcare facility, respectively. The committee agreed that different tests and test levels should be applied to ME EQUIPMENT intended for use in a professional healthcare facility versus ME EQUIPMENT intended for use during professional transport of a PATIENT outside the professional healthcare facility.

VERIFYING that the ME EQUIPMENT is functioning within the MANUFACTURER'S specifications while the vibration (random and sinusoidal) tests are being conducted was not believed necessary. This line of thought was considered and it was decided that the test done in this manner would be overly burdensome and would only add a minimum additional level of safety to the ME EQUIPMENT that would not outweigh the costs. VERIFYING proper functioning after completion of the tests is believed adequate.

Subclause 201.15.3.5.101.1 — Shock and vibration

ME EQUIPMENT, including PULSE OXIMETER EQUIPMENT, in NORMAL USE, used within a professional healthcare facility will be subjected to these mechanical stresses (e.g. vibration, shock) and could randomly be subjected to additional stresses. Therefore, ME EQUIPMENT intended to be used in the professional healthcare facility needs to be robust enough to withstand the vibration and shock testing described by IEC 60721-3-7 level 7M2. IEC 60721-3-7 indicates that this class applies to use at, and direct transfer between, locations with only low-level vibrations, or with medium-level shocks. Careful handling and transfer of products is expected in these environments.

The committee chose the duration of 10 min for the random vibration test even though the duration recommended by IEC 60721-3-7 is 30 min to maintain testing compatibility with ISO 9919:2005. The committee intends to increase the duration to 30 min in the future with the first amendment to this standard.

Subclause 201.15.3.5.101.2 — Shock and vibration for professional transport

ME EQUIPMENT, including PULSE OXIMETER EQUIPMENT, in NORMAL USE, used for professional transport of a PATIENT outside a professional healthcare facility will be subjected to these mechanical stresses (e.g. vibration, shock, bump and drop) and could randomly be subjected to additional stresses. Therefore, ME EQUIPMENT intended to be used for professional transport of a PATIENT outside a professional healthcare facility needs to be robust enough to withstand the mechanical strength testing described by IEC 60721-3-7 level 7M3. IEC 60721-3-7 indicates that in addition to the conditions covered by class 7M2, class 7M3 applies to use at, and direct transfer between, locations with significant vibrations, or with high-level shocks. Rough handling and transfer of ME EQUIPMENT is expected in these environments.

There are no established generalized test programmes that exactly reproduce the variety of vibration and shock conditions that ME EQUIPMENT can meet when installed in a range of land vehicles and aircraft. Therefore the dynamic tests specified in this subclause have been chosen because ME EQUIPMENT tested to these levels are likely to withstand the dynamic disturbances routinely seen during use in the range of vehicles and aircraft (including helicopters) likely to be used to transport PATIENTS.

The use of ME EQUIPMENT in road ambulances, fixed wing and rotary wing aircraft, naval vessels, etc. can require additional tests and VERIFICATION of safety when used in these different environments.

For free-fall testing described in IEC 60068-2-32, the committee used the rationale for the various levels to gauge the severity of the test based on Table AA.1 of this rationale. The category of the test level chosen for PORTABLE ME EQUIPMENT was PORTABLE cases. The committee agreed that PULSE OXIMETER EQUIPMENT should be required to meet a level of drop-testing for the professional transport environment. The committee also agreed that much PULSE OXIMETER EQUIPMENT is likely to be supplied with a protective or carrying case for use in transport environments. The committee agreed that it would be an adequate test for PORTABLE ME EQUIPMENT to be dropped while in their carrying cases, as this would be most like the real world environment. For MOBILE ME EQUIPMENT, a less severe level was chosen since wheeled ME EQUIPMENT is typically heavier.

The committee chose 1 fall in each specified attitude for the free fall test even though IEC 60721-3-7 recommends 2 falls to maintain testing compatibility with ISO 9919:2005. The committee intends to increase the number of falls to 2 in the future with the first amendment to this standard.

Subclause 201.101 — PULSE OXIMETER PROBES and PROBE CABLE EXTENDERS

PULSE OXIMETER PROBES and PROBE CABLE EXTENDERS are as important in establishing the safety and ACCURACY of the complete PULSE OXIMETER EQUIPMENT as is the PULSE OXIMETER MONITOR itself. Subclause 201.101 establishes that the MANUFACTURER of the PULSE OXIMETER PROBE or PROBE CABLE EXTENDER (including a MANUFACTURER of a REPROCESSED PULSE OXIMETER PROBE or PROBE CABLE EXTENDER) is responsible for the separately testable properties (e.g. biocompatibility) of their components as well as for the affected combined properties. This MANUFACTURER is responsible for testing the affected combined properties for their PULSE OXIMETER PROBE or PROBE CABLE EXTENDER when used with any PULSE OXIMETER EQUIPMENT they have specified as compatible. The affected combined properties include at least ACCURACY, EMC, electrical safety, and protection against excessive temperature at the PULSE OXIMETER PROBE-tissue interface. As an example of a possible effect of REPROCESSING on biocompatibility, glutaraldehyde sterilization of silicone rubber materials can result in impregnation of the material with solvent, which if not sufficiently removed by subsequent processing can cause a chemical burn when that PROCESS is not described (and therefore VALIDATED) in the ACCOMPANYING DOCUMENTS.

Subclause 202.6.2.2.1 — Requirements

The radiated immunity environment during professional transport of a PATIENT outside the professional healthcare facility (e.g. land and air ambulances) is harsher than the typical in-healthcare facility environment mainly due to the presence of multiple two-way radio communication systems. In both of these environments, PULSE OXIMETER EQUIPMENT meeting the requirements of IEC 60601-1-2:2007 should be adequately protected from unintentional sources of electromagnetic interference. The additional testing needed to qualify PULSE OXIMETER EQUIPMENT for professional transport environment outside the healthcare facility need only address this additional threat.

Subclause 202.6.2.3 — Radiated RF electromagnetic fields

Two-way communication devices are used to transmit both voice and PATIENT data. Experience has shown that typical field strengths[24] measured in this environment can be as high as 20 V/m. Voice data typically have modulation bandwidths that exceed 1 kHz with a centre-point of 1 kHz. The committee chose a single test point to represent the typical information modulation band. A signal with 80 % amplitude modulation at 1 kHz was chosen, and is consistent with the base radiated immunity standard IEC 61000-4-3:2006 that also uses an 80 % amplitude-modulated signal at 1 kHz. A 20 V_{rms}/m 80 % amplitude-modulated signal has a peak-to-peak amplitude of 90,5 V. The change to 20 V/m is also compatible with the requirements of the FDA reviewer's guidance[35].

Subclause 208.6.1.2.101 — Additional requirements for ALARM CONDITION priority

The language in the previous versions of this International Standard is similar, except that the introductory phrase is "If intended for continuous monitoring…"[9]. This language led to extended discussions among committee members and their advisors as to just what were the circumstances in which low SpO_2 level ALARM CONDITIONS are required. Terms such as "continuous monitoring" and "unattended monitoring" are sufficiently ambiguous to require extensive clarification, and might be interpreted to include sleep studies, which do not require PHYSIOLOGICAL ALARM CONDITIONS at all. The committee finally agreed that OPERATORS and RESPONSIBLE ORGANIZATIONS should know when they require a PULSE OXIMETER MONITOR to have PHYSIOLOGICAL ALARM CONDITIONS, so that the useful contribution of this particular standard would be to ensure that PULSE OXIMETER MONITORS having no PHYSIOLOGICAL ALARM CONDITIONS are labelled appropriately (see 201.7.2.101 and 201.7.9.2.1.101 f)), and that if such ALARM CONDITIONS are included, there is an ALARM CONDITION for the parameter that is usually most important, i.e. low SpO_2.

Some PULSE OXIMETER MONITORS can have TECHNICAL ALARM CONDITIONS for PULSE OXIMETER EQUIPMENT-related variables, such as low battery, but no PHYSIOLOGICAL ALARM CONDITIONS. Such PULSE OXIMETER MONITORS are not required to have a low SpO_2 level ALARM CONDITION.

Subclause 208.6.5.4.101 — Additional requirements for DEFAULT ALARM PRESET

85 % SpO_2 is a generally accepted lower ALARM LIMIT for most clinical situations; however lower ALARM LIMITS can be desirable in particular clinical conditions. The OPERATOR is permitted to set lower ALARM LIMITS during NORMAL USE.

In selecting 85 % as the minimum MANUFACTURER-configured default ALARM LIMIT for the low SpO_2 level ALARM CONDITION, a compromise was made between two clinical requirements. One requirement was that PULSE OXIMETER EQUIPMENT should act as an early indicator of distress in a PATIENT with relatively normal oxygenation. In this situation, it would be good clinical practice to select a default ALARM LIMIT above the "knee" of the oxyhaemoglobin dissociation curve that provides as much margin of safety as is practical. The second requirement is to avoid frequent ALARM SIGNALS not necessarily requiring clinical intervention, which might "desensitize" caregivers to ALARM SIGNALS. In this case, one might argue for a default ALARM LIMIT low enough to guarantee that most ALARM CONDITIONS would be meaningful by anyone's measure. It was acknowledged that in both clinical situations, many, if not most, OPERATORS were likely to rely on the default low SpO_2 ALARM LIMIT.

Another factor that was considered is that many examples of PULSE OXIMETER EQUIPMENT intended for continuous monitoring allow RESPONSIBLE ORGANIZATION-configured or OPERATOR-configured default ALARM LIMITS and that for specific monitoring settings, default ALARM LIMITS that were more closely tailored to the needs of the PATIENTS and OPERATORS in that setting could be selected. Given these considerations, a lower limit of 85 % for the MANUFACTURER-configured default ALARM LIMIT was felt to be an acceptable compromise that best met both clinical requirements.

Annex BB
(informative)

Skin temperature at the PULSE OXIMETER PROBE

BB.1 Summary

A literature review relating to temperature requirements leads to the conclusion that it is appropriate and conservative to retain the 41 °C limit for infants (PATIENTS up to 1 year of age) and to apply the limits of 42 °C for 8 h and 43 °C for 4 h for older PATIENTS.

BB.2 Literature review

The committee has taken the use of *external* heat to produce a 35 °C surface temperature, in the *absence* of strong peripheral circulation, as being worst case. Although strong local perfusion can lead to a skin temperature of 35 °C or above, forced convective heat transfer by blood increases the effective thermal conductivity of the skin. Thus, if the 35 °C temperature is endogenously produced, a given heat input from the PULSE OXIMETER PROBE will produce less temperature rise.

In this International Standard, the committee has adopted the FDA's 35 °C rule for the test environment, and made explicit an interpretation that "ambient" temperature, as used in the FDA guidance[34], can be taken as local skin temperature when the PULSE OXIMETER PROBE is not energized. Heat generated by the light-emitting diodes of a PULSE OXIMETER PROBE primarily dissipates through the skin of the PATIENT, not to the surrounding air. Thus the PATIENT'S skin temperature (without the PULSE OXIMETER PROBE) is much more important in determining the temperature to which the PULSE OXIMETER PROBE/skin interface eventually rises than is the temperature of the surrounding air. It is therefore appropriate for skin temperature, rather than air temperature, to be specified.

The same 35 °C maximum skin temperature appears in this International Standard for neonates as for adults. 35 °C is a sufficient maximum, even though infant incubators can be adjusted to raise abdominal skin temperature as high as 37 °C. In the absence of strong local perfusion, the skin of the extremities is several degrees cooler than the skin of the abdomen, as indicated in the following literature:

— Templeman and Bell[73] showed mean heel temperatures near 33 °C, when abdominal temperature was regulated in the 36 °C to 37 °C range, in both air-heated incubators and radiant warmers;

— Malin and Baumgart[55] showed, in a radiant warmer environment, mean heel temperatures were 4,5 °C below mean rectal temperature when the abdominal wall temperature was 35,5 °C, but only about 2 °C below at 37,5 °C;

— Topper and Stewart[74] studying the use of heated water pads to supplement radiant warmers, found back and abdomen temperatures were nearly equal, but mean foot temperature was about 2,1 °C lower (heating pad on) and 2,6 °C lower (heating pad off);

— Seguin[68] studied the distorting effects on incubator servo control of heated transcutaneous sensors. During the control phase, with the transcutaneous sensor not in use, mean foot temperature was 33,4 °C, for an oesophageal temperature of 36,9 °C. This work was with radiant warmers, servo-controlled for abdominal skin probe temperature of 36,5 °C to 37 °C;

— Harpin *et al*.[42] studying the responses of newborns to overheating, in air-heated incubators, showed a consistent pattern in which hand temperature was 1,5 °C to 5 °C below rectal temperature when the baby was at the low end of the "thermoneutral" range, to about 0,5 °C below rectal temperature when the baby was overheated. The authors interpreted the higher hand temperatures as consistent with stronger local circulation.

— Greenhalgh, *et al.*[40] studied PATIENTS scheduled for removal of redundant skin (abdominoplasty, breast reduction surgery). PULSE OXIMETER PROBES were applied and left in place for 8 h (or less if significant pain was noted) and set at 42,5 °C, 43 °C, 43,5 °C, and 44 °C. They found that PULSE OXIMETER PROBES were safe up to a temperature of 43 °C for at least 8 h on well-perfused skin.

There is little experimental evidence supporting the possibility that the natural damage-repair mechanism of skin is weaker when circulation is poor and whether that could lead to a lower threshold temperature for thermal injury[77]. An early direct experiment[60] done on pigs showed no effect of local perfusion on injury threshold. More recent experiments, also on pigs[47] [50], showed that in the presence of high local pressure (100 mmHg) over a large area (51 mm to 57 mm diameter) it is hard to define a threshold temperature for injury. Greater injury occurred, e.g. at 35 °C than at 25 °C, but some injury occurred at 25 °C. Any recommended safe temperature threshold for PULSE OXIMETER PROBES should be accompanied by the usual caution that PULSE OXIMETER PROBES need to be applied to avoid excessive pressure. Given this precaution, the recommended temperature thresholds appear safe in view of the most pessimistic literature values. In this way, the effects of poor perfusion that probably existed in some of the experimental subjects who were studied have been included.

Table BB.1 shows the committee's best estimates of the safe skin temperature thresholds implied by each of many reports in the clinical literature. The inconsistencies among these reports arise from at least two causes.

— All the available data for neonates come from studies of transcutaneous blood gas monitoring, in which the observed variable is usually the temperature of the transcutaneous sensor core. Skin temperature is an uncontrolled variable, which we have estimated as being 1 °C below transcutaneous sensor core temperature, but which can actually vary more widely[32][45][48][49].

— Important variables, including the ACCURACY of temperature measurements and the varying physiology of PATIENTS, were not addressed consistently in many of these experiments.

To interpret each report, the threshold safe temperature was taken to be the level at which no blisters were observed. Erythema, which might imply heat-induced hyperaemia, or might imply thermal damage to part of the thickness of the epidermis (commonly called a first-degree burn), was taken as marginally acceptable, since recovery from simple reddened skin is typically rapid. Blisters are unambiguously recognizable as injuries and imply damage to basal cells in the epidermis (a second-degree burn). If the duration of exposure was less than 8 h, the committee arrived at the safe 8 h temperature using the rule of thumb of Moritz and Henriques[59] that doubling exposure time reduces the safe temperature by 1 °C.

The literature references fall, for the most part, into two groups. There are many citations of work with transcutaneous monitors, which apply for the most part to neonates. Another group of documents represent burn-threshold studies with adult volunteers. Only a few references apply to subjects in the intermediate age group.

Reviewing the estimates in Table BB.1 led to the following conclusions:

— 42 °C should be safe for infants (including neonates), but there are enough conflicting results to warrant caution. For this reason, it is recommended that the traditional 41 °C limit for infant applications not be increased and that the default setting of 41 °C be retained.

— 43 °C for 8 h should be safe for adults, but there have been few studies since the classic work of Moritz *et al.;* and the results of Wienert *et al.* suggest caution. For that reason, it was concluded that the justifiable limit for adults is 42 °C for 8 h, and (using Moritz's rule), 43 °C for 4 h.

It is appropriate and conservative to retain the 41 °C limit for infants (PATIENTS up to 1 year of age) and to apply the limits of 42 °C for 8 h and 43 °C for 4 h for older PATIENTS, based on the observation that dermal circulation is immature before 1 year of age[64] and that in other structural respects the skin is adult-like by this age[63].

Table BB.1 — PULSE OXIMETER PROBE safe application time and source

Reference	Safe skin temperature for n h	Safe skin temperature for 8 h
Neonates		
Boyle, 1980[25]	43 °C for 4 h to 7 h	>42 °C
Bucher, 1986[26]	41 °C for 24 h	>42 °C
Cabal, 1981[17]	42,5 °C for 4 h	>41,5 °C
Eberhard, 1975[30]	41 °C for up to 84 h	>42 °C
Eberhard, 1976[32]	43 °C for 4 h "eliminate[d] the risk of blister formation *almost* entirely". 42 °C was "tolerated well [for] up to 24 h."	42 °C
Fanconi, 1996[33]	41 °C for up to 24 h, in the absence of eugenol	>41 °C
Golden, 1981[39]	<42 °C for 2 h	<40 °C
Huch, 1981[46]	44 °C for 1 h (appears to be a purposely conservative guess. No data presented)	41 °C
Laptook, 1981[52]	43 °C for 4 h	42 °C
Löfgren, 1983[53]	<43 °C for 8 h	42 °C
Monaco, 1981[57]	43 °C, 3 h to 4 h	42 °C
Schachinger, 1983[66]	<43 °C, 2 h. No original data presented	<41 °C
Venus, 1981[75]	44 °C, up to 6 h	43 °C
Intermediate ages		
Poler, 1992[62]	43 °C for period of application of pulse oximeter	43 °C
Adults		
Greenhalgh, 2004[40]	43 °C for 8 h	43 °C
Manzinger, 1990[56]	Rats, not humans. Water baths at 60 °C, 75 °C, and 90 °C, for 4 s, 10 s, or 15 s	Results generally support Moritz
Moncrief, 1979[58]	44 °C for 6 h (this is a review article, not an experimental report, and might actually be based on Moritz[59][60]	>43 °C
Moritz, 1947[59]	44 °C for 5 h	>43 °C
Poler, 1992[62]	43 °C for period of application of pulse oximeter	43 °C
Vyas, 1988[76]	43 °C for 8 h	43 °C
Wienert, 1983[77]	<43 °C for 8 h	<43 °C

BB.3 Test methods

This International Standard does not require a particular method of measuring the skin temperature beneath the PULSE OXIMETER PROBE. There are many different widely known and accepted methods of measuring surface temperatures. Different PULSE OXIMETER PROBE MANUFACTURERS have evolved their own methods of measuring temperature, using either human test subjects or thermo-mechanical simulators. It would be impractical today to find a single universally acceptable test method, and the excellent thermal safety record of pulse oximetry suggests that such a method is not necessary. PULSE OXIMETER PROBE designers who wish to take advantage of the higher temperatures should keep the following cautions in mind.

— Measurement tolerances are required to be evaluated carefully. The MANUFACTURER should know the true ACCURACY of temperature measurement when designing PULSE OXIMETER PROBES for use at temperatures above 41 °C since a higher temperature reduces the margin of safety.

— Temperature sensors are required to be small enough so as not to distort the measurement. The largest temperature sensors that have been found acceptable have characteristic dimensions near 0,5 mm (e.g. the bead of a thermocouple welded from 0,25 mm wire). Often still smaller temperature sensors are used.

— The temperature sensor is required to not reduce the measured peak temperature by conducting a significant amount of heat away from the measurement region. Thus, it would usually be inappropriate to use the copper-constantan type T thermocouples that are common in medical investigation, since the high thermal conductivity of the copper wire could cause a falsely low temperature measurement.

— The temperature sensor is required to be located precisely at the warmest point on the interface between the skin and the PULSE OXIMETER PROBE. This is often, but not invariably, a point on the PULSE OXIMETER PROBE that is midway between the two LED chips that are typically used in emitters. The warmest point is found by testing.

— Experimental methods are required to be adequate to ensure that recommended temperature limits are met under “reasonable worst case” conditions. As an example, reasonable worst case for neonatal PULSE OXIMETER PROBES might include the following conditions.

  — The PATIENT has poor peripheral circulation. There is therefore little forced-convection heat transfer by blood to increase the effective thermal conductivity of surface tissue.

  — The LEDs in the PULSE OXIMETER PROBE are driven at the maximum current which the PULSE OXIMETER MONITOR is capable of providing during normal operation (this condition can occur when the PATIENT has very dark skin or a thick foot).

  — An active heat source is in use to raise the baby's abdominal skin temperature artificially to 37 °C.

It is not our intention to require that every model of PULSE OXIMETER PROBE be tested directly on “worst-case” PATIENTS. The MANUFACTURER should select methods for evaluation of the thermal performance of the PULSE OXIMETER PROBE that lead to confident prediction of thermal safety on such PATIENTS.

Annex CC
(informative)

Determination of ACCURACY

CC.1 General

This annex discusses both the formulas used to evaluate the quality of PULSE OXIMETER EQUIPMENT measurements, and the names that are assigned to those formulas.

It has been common for the SpO_2 ACCURACY specifications of PULSE OXIMETER EQUIPMENT to be stated in terms such as "±2 %, one standard deviation." In this International Standard, the committee has chosen a different name for the recommended SpO_2 ACCURACY measure, while retaining essentially the same formula (a value of $n - 1$ is replaced with n) that has been in common use. We recommend definitions of LOCAL BIAS, MEAN BIAS, and PRECISION that are consistent with common engineering usage, but slightly different from the meanings of these terms, as they have sometimes been used in the pulse oximetry literature. The reasons for our recommendations are explained in this annex. We also discuss the term "ambiguity," which was introduced by Severinghaus et al.[69], and explain our belief that the term ACCURACY can perform a similar function.

CC.2 ACCURACY, bias and PRECISION

CC.2.1 Definitions

The terms ACCURACY, bias and PRECISION have all been used in a variety of ways. *The compilation of ASTM standard definitions* (ASTM, 7th ed., 1990) assembles 11 definitions of ACCURACY, 9 of bias, and 19 of PRECISION, all taken from ASTM documents. We have chosen specific definitions that are consistent with the general definitions appearing in ASTM E456-96 [8]. The definitions in ASTM E456-96, with their associated notes, are as follows:

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

NOTE 1 The term accuracy, when applied to a set of test results, involves a combination of a random component and of a common systematic error or bias component.

bias
the difference between the expectation of the test results and an accepted reference value

NOTE 2 Bias is the total systematic error as contrasted to random error. There can be one or more systematic error components contributing to the bias. A larger systematic difference from the accepted reference value is reflected by a larger bias value.

NOTE 3 Expectation is a statistical term which can be interpreted approximately as the mean of the values that would be obtained if the measurement were made many times.

precision
the closeness of agreement between independent test results obtained under stipulated conditions

NOTE 4 Precision depends on random errors and does not relate to the true value or the specified value.

NOTE 5 Precision is usually expressed in terms of imprecision and computed as a standard deviation of the test results. Less precision is reflected by a larger standard deviation.

NOTE 6 "Independent test results" means results obtained in a manner not influenced by any previous result on the same or similar test object. Quantitative measures of precision depend critically on the stipulated conditions. Repeatability and reproducibility conditions are particular sets of extreme stipulated conditions.

CC.2.2 Effects of offset and linearity errors

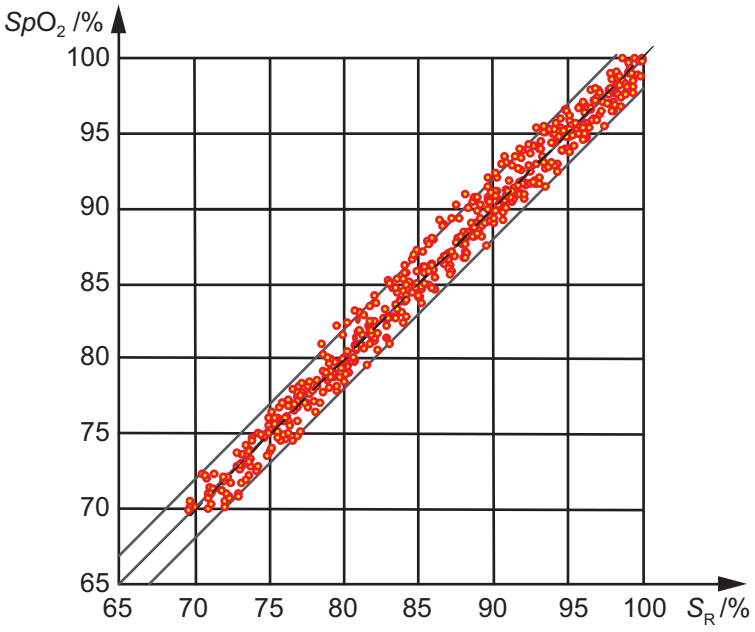
The committee's choice of definitions was influenced by considering three synthesized data sets, which might have resulted from a CONTROLLED DESATURATION STUDY, and that are shown in Figures CC.1 to CC.3. The horizontal axis in each of these figures represents oxygen saturation readings (S_{Ri}) taken from a reference system, and the vertical axis represents oxygen saturation readings (SpO_{2i}) from the PULSE OXIMETER EQUIPMENT under test. Reference lines shown on the charts are the line of identity (at which test and reference devices give equal readings) and the other two lines represent deviations of ±2 % from the line of identity.

The three figures differ only in the nature of the simple modifications made to one basic data set:

— Figure CC.1, the base case, was created so that a regression line fitted to the data falls almost perfectly on the line of identity (slope is 1,00 and mean offset is 0).

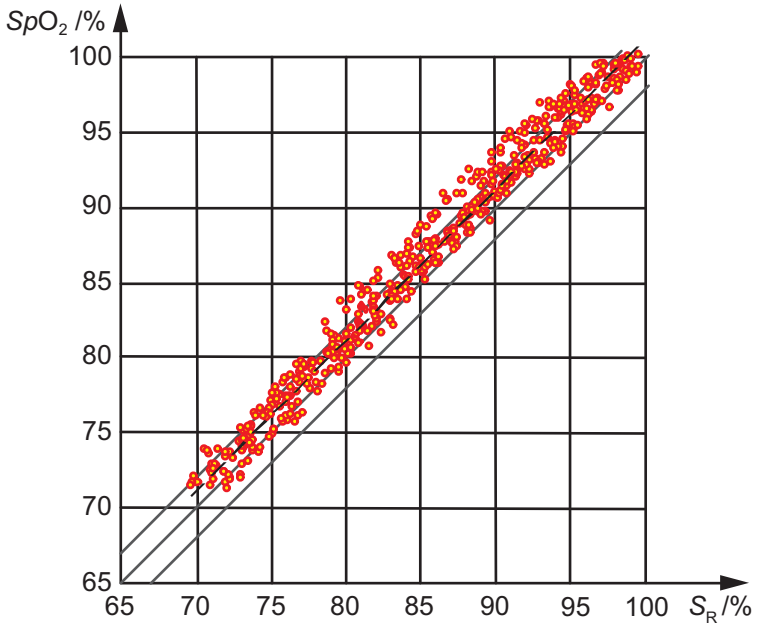
— Figure CC.2 was created from Figure CC.1 by adding a constant 1,5 unit offset to each y value.

— Figure CC.3 was created from Figure CC.1 by adding an x-dependent error to each value: $y\,(x) = 0{,}1x - 8{,}6523$, so that the added error is zero near the centre of the graph, positive at the right, and negative at the left. The adjustment formula was chosen to give zero mean additional error.



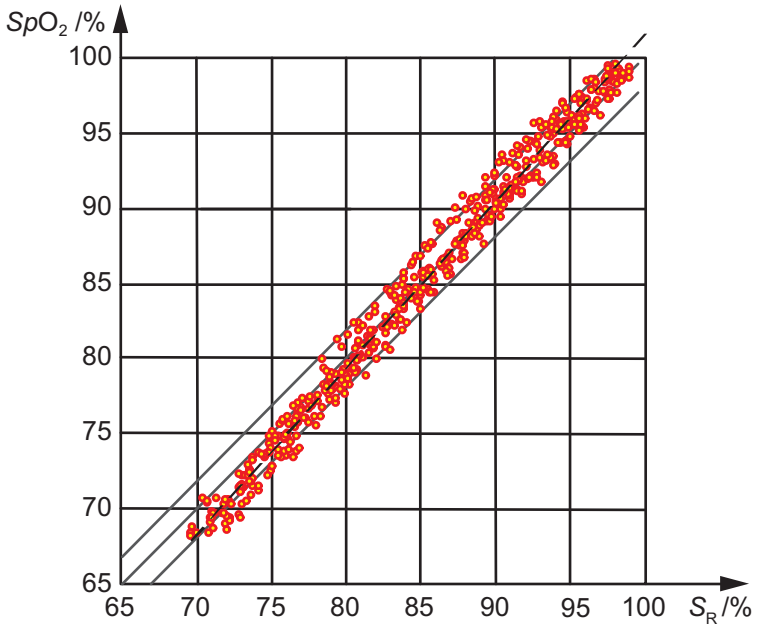
Test sensor SpO_2 as a function of reference S_R
Negligible MEAN BIAS (0,02 %)
Regression line slope = 1,000
s_{res} = 1,034 % $B_S = 0$
A_{rms} = 1,033 % P_S = 1,033
Trend line formula: $y = 1{,}000\ 2\ x + 0{,}02$

Figure CC.1 — Synthesized calibration data (base case)



Test sensor SpO_2 as a function of reference S_R
MEAN BIAS 1,5 %
Regression line slope is still 1,000
s_{res} = 1,035 % B_S = 1,5
A_{rms} = 1,823 % P_S = 1,033
Trend line formula: y = 1,000 2 x + 1,48

Figure CC.2 — Constant offset has been added to base case



Test sensor SpO_2 as a function of reference S_R
Negligible MEAN BIAS (0,001 %)
Regression line slope is now 1,100
s_{res} = 1,034 % B_S = 0
A_{rms} = 1,332 % P_S = 1,333
Trend line formula: y = 1,100 2 x – 8,67

Figure CC.3 — Tilt has been added to base case

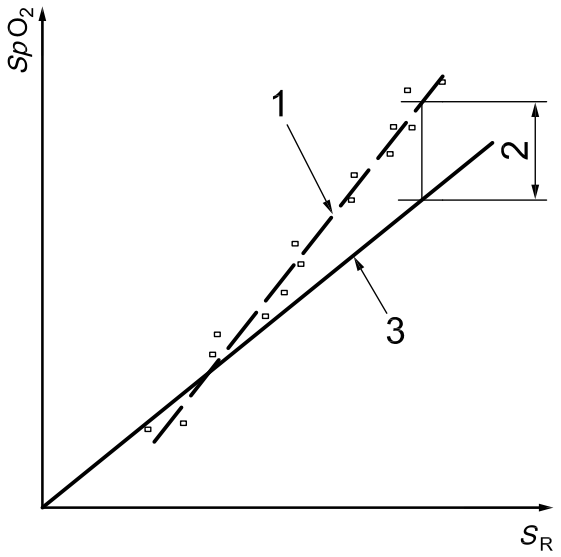
CC.2.3 **Bias** (see Figures CC.4 and CC.5)

LOCAL BIAS (indicated here by b) at a given value of x, is the difference between the y-value of the regression line at that coordinate and the y-value of the line of identity, i.e.

$$b_i = SpO_{2\text{fit},i} - S_{\text{R}i} \qquad i = 1 \ldots n \tag{CC.1}$$

MEAN BIAS is a single number (indicated here by B), representing the whole data set. It is the mean difference of the test and reference values, preserving sign;

$$B = \frac{\sum_{i=1}^{n} (SpO_{2i} - S_{\text{R}i})}{n} \tag{CC.2}$$



Key

SpO_2 pulse oximeter oxygen saturation

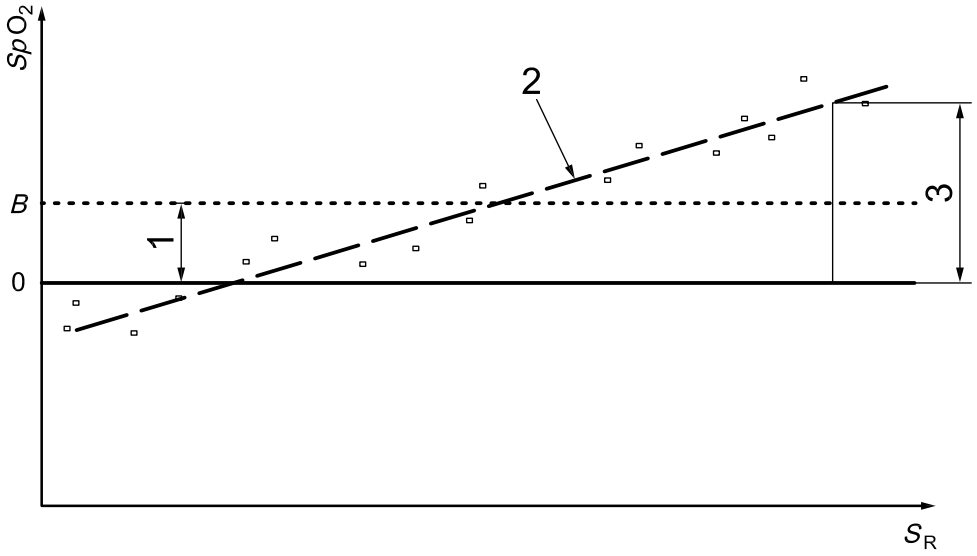
S_R reference oxygen saturation

1 regression line

2 LOCAL BIAS

3 line of identity

Figure CC.4 — Graphical representation for the definition of LOCAL BIAS
(Test sensor SpO_2 as a function of reference S_R)



Key

SpO_2 pulse oximeter oxygen saturation

S_R reference oxygen saturation

1 mean bias

2 regression line

3 LOCAL BIAS

Figure CC.5 — Graphical representation for the definition of LOCAL BIAS and MEAN BIAS
(Test sensor SpO_2 as a function of reference S_R)

When defined in this way, MEAN BIAS is, as it should be, the average of all LOCAL BIAS values, as shown in Equation 4.

$$B = \frac{\sum_{i=1}^{n}(SpO_{2i} - S_{Ri})}{n} = \frac{\sum_{i=1}^{n}\left[(SpO_{2i} - SpO_{2fit,i}) + (SpO_{2fit,i} - S_{Ri})\right]}{n} = 0 + \frac{\sum_{i=1}^{n} b_i}{n} \qquad \text{(CC.4)}$$

The zero term on the right hand side results from the regression that defines SpO_{2fit}, and the second term simply recognizes the definition of b in the first paragraph.

Figures CC.1 and CC.3 both exhibit a MEAN BIAS of zero, while Figure CC.2 has a MEAN BIAS of 1,5 units. The value of LOCAL BIAS is everywhere zero in Figure CC.1, consistently 1,5 units in Figure CC.2, and in Figure CC.3 follows the formula $b = 0{,}100\ 2\ x - 8{,}67$.

CC.2.4 PRECISION

Figure CC.3 represents a case that sometimes occurs in pulse oximetry, especially when a new model of PULSE OXIMETER PROBE is being developed for use with the calibration curves that are built into an existing PULSE OXIMETER MONITOR. The fact that there is a variable offset between test and reference values in this data set implies that it is useful to make a distinction between LOCAL BIAS and MEAN BIAS. Real data sets can have more complex dependencies of bias on S_R, but this example will suffice to show what happens to various data-characterization formulae when LOCAL BIAS varies with saturation.

We support defining PRECISION as the standard deviation of the residuals (s_{res}), given by Equation CC.5[44].

$$s_{res} = \sqrt{\frac{\sum_{i=1}^{n} \left(SpO_{2i} - SpO_{2fit,i} \right)^2}{(n-2)}} \qquad \text{(CC.5)}$$

where

n is the number of data pairs in the sample;

$SpO_{2i} - SpO_{2fit,i}$ is the difference between the ith SpO_2 datum and the value of the fitted curve corresponding to the ith reference value.

S_{Ri}. s_{res} can intuitively be recognized as the scatter of data points about the best-fit calibration curve. It is a measure of the scatter to be expected in multiple measurements made with the same PULSE OXIMETER EQUIPMENT at a given oxygen saturation, taking into account both variations among PATIENTS and repeatability of the ME EQUIPMENT electronics and software.

NOTE In Figures CC.1, CC.2, and CC.3, s_{res} has a consistent value near 1,034 %. All three data sets have the same scatter of data points with respect to the best-fit regression line, and the nearly identical values of s_{res} reflect that fact. The presence of bias in two of these figures has no effect on our measure of PRECISION.

CC.2.5 ACCURACY

As suggested by the definition that appears in ASTM E 456-96, we want ACCURACY to represent a combination of the systematic and random components of error. The definition which has long been used by many MANUFACTURERS is the root-mean-square (rms) difference between measured values (SpO_{2i}) and reference values (S_{Ri}), as given by Equation CC.6.

$$A_{rms} = \sqrt{\frac{\sum_{i=1}^{n} \left(SpO_{2i} - S_{Ri} \right)^2}{n}} \qquad \text{(CC.6)}$$

The committee believes that most MANUFACTURERS, when stating PULSE OXIMETER EQUIPMENT SpO_2 ACCURACY as a "standard deviation," have actually been computing A_{rms}. At least one MANUFACTURER has internally used the abbreviation SDI, meaning "standard deviation with respect to the line of identity". This is a misnomer, since A_{rms} is not a standard deviation. What is important is that the measure itself is useful. Engineers will recognize A_{rms} as being very similar to the common measurement "rms error". It is a way of averaging the absolute values of errors over the full measurement range.

NOTE Note the use of n in the denominator of the expression for A_{rms} rather than $n - 1$, which would be used if A_{rms} were a standard deviation. The difference in the numerical value is typically trivial. The appearance of $n - 1$ in the definition of standard deviation arises from the fact that only $n - 1$ of the samples that comprise the standard deviation can be freely chosen (statisticians say that there are "$n - 1$ degrees of freedom"). The nth sample is constrained in value because the definition of standard deviation includes the difference from a mean, implying that the nth sample is chosen so that the mean has the known value. There is no such constraint on the calculation of A_{rms}, because the expression does not include any predetermined parameter, such as a mean.

Understanding that A_{rms} is not a standard deviation is important in avoiding error in calculating oximeter SpO_2 ACCURACY. If one were to create a spreadsheet column containing all the differences, $SpO_{2i} - S_{Ri}$, and instruct the spreadsheet software to calculate the standard deviation of the data, the result would not be A_{rms} (in fact, as noted below, it would be P_S, a measure of PRECISION developed by Severinghaus *et al.*[69]). Standard deviation, for any variable x, is indicated in Equation CC.7.

$$s_x = \sqrt{\frac{\sum_{i=1}^{n} (x_i - \bar{x})^2}{n-1}} \qquad \text{(CC.7)}$$

where $\bar{x}$ is the mean of all the values of x_i.

Comparing this to the expression for A_{rms}, you can see that in A_{rms} there is no subtraction of a mean value. A_{rms} does *not* measure scatter about a mean value. It measures the difference between test values and reference values. The numerical differences between A_{rms} and P_{S} can be seen in the captions of Figures CC.1 to CC.3.

A_{rms} is affected both by random scatter and by MEAN BIAS and LOCAL BIAS.

In Figure CC.1, because LOCAL BIAS is negligible over the entire range (resulting in negligible MEAN BIAS as well), A_{rms} = 1,033 %, which is nearly equal to s_{res}. The fact that A_{rms} and s_{res} are close to 1 % is consistent with the visual observation that most data in Figure CC.1 lie within the ±2 % reference lines on the graph. In a normal distribution, we expect 95 % of observations to lie within two standard deviations of the mean.

In Figure CC.2, with a consistently large offset (i.e. a constant LOCAL BIAS resulting in a non-zero MEAN BIAS), A_{rms} has increased to 1,823 %.

In Figure CC.3, with *zero* MEAN BIAS but a varying LOCAL BIAS, A_{rms} has the intermediate value of 1,332 %. Because the LOCAL BIAS in Figure CC.3 is almost everywhere less in absolute magnitude than the constant offset in Figure CC.2, it is appropriate that our measure of overall $Sp\text{O}_2$ ACCURACY be lower in Figure CC.3 than in Figure CC.2 (i.e. Figure CC.3 exhibits better $Sp\text{O}_2$ ACCURACY than Figure CC.2).

CC.2.6 Analysis

Now we wish to discuss the relationship between the definitions used above and the terms used by two respected sources that have been influential in the clinical literature of pulse oximetry. Bland and Altman[23] campaigned effectively against the misuse of correlation coefficients in comparing two methods of measurement, and introduced a useful graphical method of examining the data from comparison experiments. Severinghaus *et al.*[69] introduced definitions of bias and PRECISION that were based on the Bland and Altman method, and also defined the new term, ambiguity, as the sum of PRECISION and bias.

In the following paragraphs, we use the symbols B_{S} and P_{S}, for the definitions of bias and PRECISION that were used by Severinghaus. He defined bias as the mean difference of the test and reference values, preserving sign[72] as indicated in Equation CC.8.

$$B_{\text{S}} = \frac{\sum_{i=1}^{n} (Sp\text{O}_{2i} - S_{\text{R}i})}{n} \qquad \text{(CC.8)}$$

By no coincidence, this is identical to our definition of MEAN BIAS. We have adopted Severinghaus's language for the definition, with the additional recognition that PULSE OXIMETER EQUIPMENT calibration studies sometimes exhibit variation of bias with saturation, so that it is useful to distinguish between LOCAL BIAS and MEAN BIAS.

Severinghaus *et al.* defined PRECISION as the "standard deviation of the bias";

$$P_{\text{S}} = \sqrt{\frac{\sum_{i=1}^{n} (Sp\text{O}_{2i} - S_{\text{R}i} - B_{\text{S}})^2}{n-1}} \qquad \text{(CC.9)}$$

This measure is different from our recommended definition of PRECISION. One perspective is that P_S is the root-mean-square (rms) deviation of differences from MEAN BIAS, while s_{res} is the rms deviation of differences from LOCAL BIAS. Recall that s_{res} was the same in Figures CC.1 through CC.3. Compare what happens to P_S in these three cases:

— in Figure CC.1, P_S = 1,033 (identical to s_{res});

— in Figure CC.2, P_S = 1,033 (in this case, P_S has the desirable property of a "precision" measure, of responding to scatter about the regression line but not responding to the constant offset reflected in the non-zero value of MEAN BIAS);

— in Figure CC.3, P_S = 1,333 (P_S has increased to match A_{rms}. Because LOCAL BIAS is variable, it causes an increase in P_S, even though the random component of error, as measured by s_{res}, has not changed.)

Bland and Altman, in discussing the example in their Figure 2, say "…there is no obvious relation between the difference and the mean. Under these circumstances we can summarize the lack of agreement by calculating the bias, estimated by the mean difference $\bar{d}$ and the standard deviation of the differences (s)". Thus, Bland and Altman's $\bar{d}$ is equivalent to Severinghaus's B_S, and their s is equivalent to his P_S. Bland and Altman have pointed out that the utility of the standard deviation of differences appears when there is no obvious relation between the difference and the mean. As our Figure CC.3 illustrates, the presence of variable local offset makes it preferable to use a different measure of random error.

Finally, we consider the term ambiguity, which Severinghaus *et al.*[69] introduced, as the sum of bias and PRECISION:

$$A_S = B_S + P_S \tag{CC.10}$$

The value of this term as a figure of merit is that it combines in single number components of both systematic and random error. It can be shown that our recommended SpO_2 ACCURACY measure, A_{rms}, has a similar property, so that it should not be necessary to use both A_{rms} and ambiguity in analysing the results of a particular experiment. The proof begins with the mathematical identity indicated in Equation 11.

$$\sum_{i=1}^{n} x_i^2 = \sum_{i=1}^{n} \left(x_i - \bar{x}\right)^2 + \frac{\left(\sum_{i=1}^{n} x_i\right)^2}{n} \tag{CC.11}$$

For x_i we use the difference, $SpO_{2i} - S_{Ri}$. Expansion and substitution lead to a demonstration that

$$A_{rms} \approx \sqrt{P_S{}^2 + B_S{}^2} \tag{CC.12}$$

Some readers can find it convenient to use this formula as a route to computing A_{rms}. If the differences between test and reference oximeter readings are entered in one column of a spreadsheet, B_S will be the mean of that column and P_S will be its standard deviation.

Annex DD
(informative)

Calibration standards

Some previously published standards appear to mandate that PULSE OXIMETER EQUIPMENT be calibrated directly against *in vitro* blood analysis using CO-OXIMETERS. This annex presents two such published documents and explains when the committee thinks *in vitro* analysis is required and when it is not.

The American Association for Respiratory Care (AARC) *Clinical Practice Guideline: Pulse Oximetry*[16] says:

> "7.2 To validate pulse oximeter equipment readings, incorporate or assess agreement between $Sp\mathrm{O}_2$ and arterial oxyhaemoglobin saturation ($Sa\mathrm{O}_2$) obtained by direct measurement, these measurements should be initially performed simultaneously and then periodically re-evaluated in relation to the patient's clinical state."

We read the AARC position as a clinical practice guideline that does not address the issue as to how the original calibration of PULSE OXIMETER EQUIPMENT should be established. This committee believes that the AARC's guideline is appropriate in the clinical context. For a variety of reasons, PULSE OXIMETER EQUIPMENT readings on individual PATIENTS can differ from CO-OXIMETER readings, so that it is always appropriate in clinical use to confirm $Sp\mathrm{O}_2$ readings using a more accurate measurement. This statement is consistent with the point of view expressed in AA.1.

The FDA's *Draft Guidance Document: Pulse Oximeters Premarket Notification Submissions*[35] directly addresses the issue of the MANUFACTURER'S original calibration. It says, in Section 7.1:

> "We recommend you follow Clause 50 and Annex EE.2, Procedure for invasive laboratory testing on healthy volunteers, of ISO 9919[1)] or equivalent method to validate the $Sp\mathrm{O}_2$ accuracy specifications of your pulse oximeter system by comparing each value from your system and a simultaneous value from co-oximetry of an arterial blood sample."

This committee has taken the position that the use of secondary standard PULSE OXIMETER EQUIPMENT is permissible. When data are taken on multiple PATIENTS, so that statistics can be developed, the committee feels that it is appropriate to use PULSE OXIMETER EQUIPMENT that have been calibrated against CO-OXIMETERS as secondary standards for the calibration of other PULSE OXIMETER EQUIPMENT. This needs to be done with proper attention to error propagation, so that the $Sp\mathrm{O}_2$ ACCURACY claims that are made are clearly justified. In the clinical laboratory conditions under which secondary standard calibrations are conducted, many of the known sources of error in pulse oximetry are virtually eliminated. Examples of such sources of error are low perfusion, EMI, motion, nail polish, PULSE OXIMETER PROBE mispositioning and ambient light. The efficacy of the secondary standard calibration PROCESS is demonstrated by the fact that secondary standard testing of PULSE OXIMETER PROBES of a given type over many years has consistently produced identical results and has resulted in a 20 year history of safe and increasing utilization of pulse oximetry.

1) ISO 9919:2005 is the predecessor of this document.

Annex EE
(informative)

Guideline for evaluating and documenting SpO_2 ACCURACY in human subjects

EE.1 General

This annex is provided as a guideline for evaluating and documenting the SpO_2 ACCURACY of PULSE OXIMETER EQUIPMENT. The methods described in this annex are applicable to both new PULSE OXIMETER EQUIPMENT and modified PULSE OXIMETER EQUIPMENT or parts whenever human testing is required.

NOTE Subclause 201.12.1.101.2.1 requires that any study conducted to evaluate the SpO_2 ACCURACY of PULSE OXIMETER EQUIPMENT shall comply with ISO 14155:2011.

This annex describes testing methods for assessing the SpO_2 ACCURACY of PULSE OXIMETER EQUIPMENT. It does not prescribe medical practice, proper safety PROCEDURES or institutional review board (IRB) or ethics committee (EC) PROCESSES.

Two types of tests in which human subjects are used for evaluating SpO_2 ACCURACY of PULSE OXIMETER EQUIPMENT are described. Either type can be performed in the laboratory or the intended environment of use.

a) Invasive testing: the SpO_2 ACCURACY of PULSE OXIMETER EQUIPMENT is measured by comparing SpO_2 readings of the PULSE OXIMETER EQUIPMENT to values of SaO_2 determined with a CO-OXIMETER. Two types of individual could participate in invasive studies:

   — healthy volunteers who consent to induced hypoxia and arterial blood sampling as part of the experimental PROCEDURE (see EE.2);

   — PATIENTS in whom arterial blood samples are available for analysis (see EE.4.1).

b) Non-invasive testing: the SpO_2 ACCURACY of PULSE OXIMETER EQUIPMENT is measured by comparing SpO_2 readings to values obtained using a secondary standard PULSE OXIMETER EQUIPMENT, which can be used as a transfer standard because its calibration is directly traceable to a CO-OXIMETER.

EE.2 PROCEDURE for invasive laboratory testing on healthy volunteers

EE.2.1 Purpose of an invasive CONTROLLED DESATURATION STUDY

The general purpose of invasive CONTROLLED DESATURATION STUDIES is to VALIDATE the SpO_2 ACCURACY of PULSE OXIMETER EQUIPMENT in comparison to "gold-standard" measurements of blood SaO_2 by a CO-OXIMETER. This is achieved through paired observations of SpO_2 and SaO_2 values over the specified SpO_2 ACCURACY range (e.g. 70 % to 100 % SaO_2) of the PULSE OXIMETER EQUIPMENT on a group of healthy adult volunteers. The fraction of inspired oxygen (FiO_2) delivered to test subjects is varied to achieve a series of targeted steady-state saturation periods. Arterial blood samples are periodically taken from an indwelling arterial catheter for use in the comparison.

The method described below involves PROCEDURES that need to be supervised by qualified personnel. Subjects have an artery cannulated and then are exposed to inspired oxygen concentrations lower than room air. Accordingly, this study method always requires protocol approval by an IRB or EC, including informed consent of the subjects.

EE.2.2 Scope of an invasive CONTROLLED DESATURATION STUDY

This invasive CONTROLLED DESATURATION STUDY method is used to VALIDATE the SpO_2 ACCURACY of PULSE OXIMETER EQUIPMENT under well-controlled, optimal laboratory conditions on healthy adult subjects. This method can be used during specifically defined non-optimal conditions such as subject movement or low pulse-amplitude states.

EE.2.3 Methods

EE.2.3.1 Study population

The following parameters should be considered.

a) Number and source of subjects

— The study should include a sufficient number of subjects to attain the statistical significance necessary to demonstrate a specified SpO_2 ACCURACY.

— Subjects should be healthy adult volunteers.

— For the broadest application to the largest group of PATIENTS, the subjects should vary in their physical characteristics to the greatest extent possible.

NOTE The characteristics of the subjects can be limited due to safety reasons or availability, e.g. only female subjects being available to VALIDATE a paediatric finger PULSE OXIMETER PROBE due to their meeting the criteria for finger size.

b) Subject inclusion and exclusion criteria

— The study protocol should define the inclusion/exclusion criteria.

— Subjects participate in the study on a voluntary basis.

— All subjects should be in good health at the time of the study. Unless specified otherwise in the protocol, the following values could be applied: COHb < 3 %, MetHb < 2 %, ctHb > 10 g/dl; these values are not intended to be a comprehensive determination of “good health”.

— Inclusion criteria should serve the purpose of the study. (Examples are not intended to be comprehensive.)

EXAMPLE 1 Both male and female subjects.

EXAMPLE 2 Specific finger size.

EXAMPLE 3 Healthy adult subjects capable of undergoing controlled hypoxaemia to the levels called for in the protocol with minimal medical RISK.

— Examples of exclusion criteria (not intended to be comprehensive).

EXAMPLE 4 Smokers or individuals exposed to high levels of carbon monoxide that result in elevated carboxyhaemoglobin levels, unless specific dyshaemoglobins are called for in the study protocol.

EXAMPLE 5 Individuals subject to conditions that result in elevated levels of methaemoglobin, unless specific dyshaemoglobins are called for in the study protocol.

EXAMPLE 6 Subjects who would be placed at undue medical RISK associated with any PROCEDURES called for in the protocol (e.g. arterial cannulation or hypoxia).

EXAMPLE 7 Age.

c) Criteria for study termination

— Study protocol should define circumstances and/or subject response to the PROCEDURE that becomes grounds for study termination.

EXAMPLE The subject is discovered to meet one of the pre-defined exclusion criteria (e.g. elevated methaemoglobin level).

EE.2.3.2 Apparatus

EE.2.3.2.1 CO-OXIMETER for measuring SaO_2 and CO-OXIMETER MANUFACTURER-recommended PROCEDURES and supplies.

EE.2.3.2.2 Materials for arterial catheterization and blood sampling.

EE.2.3.2.3 Means for recording SpO_2 values, which can be manual or automated.

EE.2.3.2.4 PULSE OXIMETER EQUIPMENT to be tested. See also EE.2.3.4 c).

EE.2.3.2.5 Means for delivering a medical grade oxygen-nitrogen mixture of varying FiO_2 levels to the subject (e.g. pre-mixed high-pressure cylinders or gas-mixing device).

EE.2.3.3 PROCEDURE

To perform an invasive CONTROLLED DESATURATION STUDY:

a) The study protocol should describe the specific conditions of the test (e.g. optimal laboratory conditions, subject motion, low pulse amplitude). The use of warming equipment or other warming means can be utilized to improve circulation and pulse amplitude at a PULSE OXIMETER PROBE site.

b) After a catheter is placed in the artery, PULSE OXIMETRY PROBES to be evaluated are attached to the subject's fingers, forehead, nose, ears or other body surfaces as appropriate. PULSE OXIMETER PROBES can be covered with opaque material to prevent optical interference (light from one PULSE OXIMETER PROBE or another source reaching the photodetector of an adjacent PULSE OXIMETER PROBE).

NOTE Further details of the proper techniques and maintenance of the arterial line are beyond the scope of this International Standard. The radial artery is typically used.

c) The protocol should specify criteria and methods for determining stability of the SaO_2 at the PULSE OXIMETER PROBE site.

EXAMPLE 1 A stable plateau on the PULSE OXIMETER EQUIPMENT under test.

EXAMPLE 2 A stable plateau on a reference PULSE OXIMETER EQUIPMENT.

EXAMPLE 3 A real-time measurement of expired respiratory gases.

d) The breathing circuit is fitted to the subject and the subject breathes a mixture of oxygen and nitrogen. Carbon dioxide can be added to the inspired gas mixture to maintain normal carbon dioxide levels and to prevent respiratory alkalosis secondary to hyperventilation caused by hypoxia.

e) FiO_2 is reduced or increased to bring the subject near target levels. Desaturation to the lowest level (e.g. 70 % SaO_2) is conducted in a stepwise PROCESS targeting a number of saturation plateaus (periods in which the saturation is relatively stable). The number of saturation plateaus finally accepted as valid is represented by a value M.

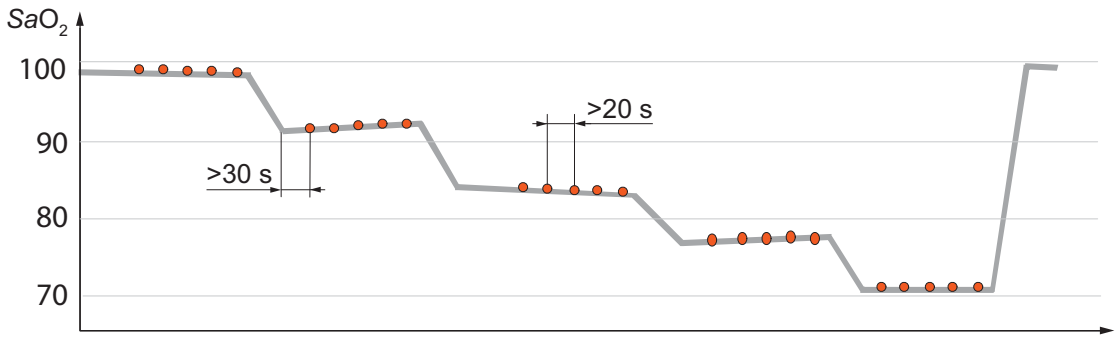
f) When combined across subjects, these M plateaus should result in a distribution of collected and pooled data pairs spanning the specified SaO_2 range. See also EE.2.3.4 b) and EE.2.3.4 g).

g) Within each saturation plateau level, draw N blood samples and pair with the corresponding SpO_2 values.

EXAMPLE A study design is shown in Table EE.1 and Figure EE.1. In this example, $M = 5$ and $N = 5$. The values in this example are not intended to be limiting in the number of plateaus or numbers of samples per plateau.

Table EE.1 — Example of target plateaus and ranges

SaO_2 **plateau range** %	**Target number of samples**
100 to 97	5
97 to 92	5
92 to 85	5
84 to 78	5
77 to 70	5
Total	25



Points are SaO_2 values at the time of the blood draws.

Figure EE.1 — Example of desaturation-time profile

h) For each subject, $M \times N$ blood draws provide (SaO_2, SpO_2) data pairs for analysis [see EE.2.3.4 f)]. These data pairs are either acquired simultaneously or correlated in time to accommodate physiological and PULSE OXIMETER EQUIPMENT delays.

NOTE The values of M and N can vary by subject, given the ability to reach and maintain the targeted plateau levels.

i) When the reference system's blood saturation stabilizes at an acceptable plateau level, blood sampling can begin. After a change in plateau level, readings should be allowed to stabilize for at least 30 s to allow SaO_2 to reach equilibrium at the PULSE OXIMETER PROBE site.

j) Care should be taken for the sampling, handling and analysis of blood to ensure the SaO_2 ACCURACY of the CO-OXIMETRY measurement. PROCEDURES for the sampling, handling and analysis of blood are found elsewhere[18].

k) The protocol should define the time interval between successive samples within a plateau to ensure that samples are independent. In determining this interval, consideration should be given to allowing the blood circulation to flush and replace the haemoglobin at the PULSE OXIMETER PROBE site and to the averaging time of the PULSE OXIMETER EQUIPMENT.

EE.2.3.4 Data analysis

An invasive CONTROLLED DESATURATION STUDY data analysis is performed as follows.

a) Paired SpO_2 and SaO_2 data points are pooled for all subjects and the A_{rms} is calculated using the formula given in 201.12.1.101.2.2.

b) Pooled data values are required to include SaO_2 levels within 3 % of the endpoints of the SpO_2 ACCURACY range, e.g. 70 % to 100 %. SpO_2 ACCURACY calculations are required to include data pairs with SaO_2 values that span at least 73 % to 97 % (per 50.101.2.1).

c) For PULSE OXIMETER MONITORS that place an upper limit on displayed SpO_2 (e.g. 99 % or 100 %), a means that does not bias the A_{rms} result should be used.

EXAMPLE 1 Include only observations where SpO_2 readings are less than the upper display limit.

EXAMPLE 2 Statistically down-weight those values with $SpO_2 = 100$ % (e.g. treat observations of 100 % as censored, as is done in the analysis of survival data).

EXAMPLE 3 Configure the data-collection system to record values of $SpO_2 > 100$ %.

NOTE A_{rms} describes the combined bias and PRECISION of SpO_2 readings, and by limiting display values, the assumptions of a normal distribution are violated.

d) Points collected with SaO_2 values beyond the specified SpO_2 ACCURACY range (e.g. within 3 % of the endpoints) are excluded, unless the protocol specifically requires these samples to be included.

NOTE Arbitrarily including or excluding such data points allows MANUFACTURERS to manipulate the SpO_2 ACCURACY specification to their advantage.

e) Data pairs can be rejected if, determined retrospectively, they were taken during conditions that were outside of the scope of the testing as defined in the protocol.

EXAMPLE 1 An unstable SpO_2 plateau.

EXAMPLE 2 If the clinical study record indicated that there were difficulties with the blood draw (e.g. excessive bubbles).

EXAMPLE 3 The CO-OXIMETER experienced error conditions.

f) The total number of acceptable data pairs acquired during the study needs to be sufficient to demonstrate statistically the specified SpO_2 ACCURACY. For example, about 20 blood samples are acquired from each of at least 10 subjects, resulting in at least 200 data pairs. Specific numbers of samples and subjects can vary, if properly justified using statistical methods.

g) The distribution of SaO_2 values in the pooled data set needs to be made with comparable density over the full claimed range. For example, approximately 1/3 of the data should fall within each of the following ranges: 70 % to 79 %, 80 % to 89 %, and 90 % to 100 % SaO_2.

EE.3 PROCEDURE for non-invasive laboratory testing on healthy volunteers

a) In non-invasive testing, the SpO_2 ACCURACY of PULSE OXIMETER EQUIPMENT is measured by comparing SpO_2 readings of the PULSE OXIMETER EQUIPMENT to values obtained with secondary standard PULSE OXIMETER EQUIPMENT. This method utilizes healthy volunteers who consent to induced hypoxia as part of the experimental PROCEDURE.

Since the calibration of the secondary standard PULSE OXIMETER EQUIPMENT is directly traceable to a CO-OXIMETER, the secondary standard PULSE OXIMETER EQUIPMENT can be used as a transfer standard.

The method for non-invasive laboratory testing on healthy volunteers follows the protocol described in EE.2 for invasive tests with the following exceptions.

b) The reference values are SpO_2 readings obtained from a secondary standard PULSE OXIMETER EQUIPMENT replacing the SaO_2 values measured with a CO-OXIMETER.

c) Blood sampling is not utilized.

d) The calibration of the secondary standard PULSE OXIMETER EQUIPMENT and the treatment of the data analysis are traceable to a CO-OXIMETER.

e) The total number of acceptable data pairs acquired during the study needs to be sufficient to demonstrate statistically the specified SpO_2 ACCURACY.

— For example, one possible profile for acquiring data follows the plateau scheme described in EE.2.3.3 e) through EE.2.3.3 h), i.e. about 20 sampling periods, during plateaus, are achieved in each of at least 10 subjects, resulting in at least 200 sets of data pairs.

— Other profiles are possible, i.e. continuous data collection during gradual changes in saturation, independent of plateaus, relating sample pairs in time.

Specific numbers of samples and subjects as well as the analysis technique need to be justified using statistical methods.

f) The PROCEDURES for item c) and item d) are described in the test report.

g) The A_{rms} value, as defined in 201.12.1.101.2.2, is expressed relative to the “gold-standard” CO-OXIMETER and includes the error of the secondary standard PULSE OXIMETER EQUIPMENT.

EE.4 PROCEDURE for testing on PATIENTS

EE.4.1 Invasive testing on PATIENTS

The SpO_2 ACCURACY of PULSE OXIMETER EQUIPMENT is measured by comparing SpO_2 readings of the PULSE OXIMETER EQUIPMENT to values of SaO_2 determined by a CO-OXIMETER.

In a clinical environment, the primary responsibility is PATIENT care. SpO_2 measurements from PATIENTS in that environment when compared to measurements from a CO-OXIMETER in that environment can be degraded because data collection cannot always be well controlled. Both measurements are better controlled under laboratory conditions.

In a clinical environment, measurements from PULSE OXIMETER EQUIPMENT and CO-OXIMETERS are often subject to non-optimal conditions and are difficult to match reliably due to circulatory instabilities or dynamics.

The PATIENT’S clinical condition should be considered when placing any PULSE OXIMETER PROBE in relation to the arterial sampling site. Whenever possible, the PULSE OXIMETER PROBE should be observing blood that is part of the same circulatory stream as the artery from which blood is taken.

Generating the number of data pairs necessary to demonstrate statistically the specified SpO_2 ACCURACY over the specified range can require a large number of PATIENTS.

NOTE 1 Blood samples can be withdrawn either as a needed part of clinical care or solely for the purposes of the study, as specified in an approved study protocol.

NOTE 2 Using single needle punctures as a source of arterial blood is likely to result in unstable SpO_2 values.

The total number of acceptable data pairs acquired during the study needs to be sufficient to demonstrate statistically the specified SpO_2 ACCURACY. The distribution of reference values in the pooled data set needs to be made with comparable density over the full claimed range. Specific numbers of samples and subjects as well as the analysis technique need to be justified using statistical methods.

EE.4.2 Non-invasive testing on PATIENTS

The SpO_2 ACCURACY of PULSE OXIMETER EQUIPMENT is measured by comparing SpO_2 readings of the test PULSE OXIMETER EQUIPMENT to values obtained with secondary standard PULSE OXIMETER EQUIPMENT that is traceable to CO-OXIMETER SaO_2 values.

In a clinical environment, the primary responsibility is PATIENT care. SpO_2 measurements from PATIENTS in that environment can be degraded because data collection cannot always be well controlled. SpO_2 measurements are better controlled under laboratory conditions.

In a clinical environment, measurements from PULSE OXIMETER EQUIPMENT are often subject to non-optimal conditions and are difficult to match reliably, due to circulatory instabilities or dynamics.

The PATIENT'S clinical condition should be considered when placing PULSE OXIMETER PROBES. Whenever possible, the test and secondary standard PULSE OXIMETER PROBES should be observing blood that is part of the same regional circulation.

Generating the number of data pairs sufficient to demonstrate statistically the specified SpO_2 ACCURACY over the specified range can require a large number of PATIENTS or observations.

The total number of acceptable data pairs acquired during the study needs to be sufficient to demonstrate statistically the specified SpO_2 ACCURACY. The distribution of reference values in the pooled data set needs to be made with comparable density over the full claimed range. Specific numbers of samples and subjects as well as the analysis technique need to be justified using statistical methods.

The A_{rms} value is expressed relative to the "gold-standard" CO-OXIMETER and includes the error of the secondary standard PULSE OXIMETER EQUIPMENT.

Annex FF
(informative)

Simulators, calibrators and FUNCTIONAL TESTERS for PULSE OXIMETER EQUIPMENT

FF.1 General

The committee recognized that FUNCTIONAL TESTERS have become commonly available and are incorrectly perceived by some RESPONSIBLE ORGANIZATIONS as being calibrators. This annex addresses appropriate uses of each type of tester.

A variety of devices can be used to test PULSE OXIMETER EQUIPMENT. Some of these devices are provided by the MANUFACTURERS of PULSE OXIMETER EQUIPMENT, some by independent tester MANUFACTURERS, and some by research laboratories. The committee felt that it would be helpful to suggest standard terms that can be used in describing these devices, in the interest of improving RESPONSIBLE ORGANIZATIONS' understanding of the capabilities of particular testers. The need for this discussion is made greater by two somewhat unusual characteristics of PULSE OXIMETER EQUIPMENT.

— Unlike many other types of ME EQUIPMENT, PULSE OXIMETER EQUIPMENT is not designed to be calibrated after it leaves the factory.

— There is today no accepted method of VERIFYING the correct calibration of a PULSE OXIMETER PROBE and PULSE OXIMETER MONITOR combination other than testing on human beings.

All available tools for testing PULSE OXIMETER EQUIPMENT, at the time of writing, are properly called FUNCTIONAL TESTERS. 201.7.9.3.1.101 aa) requires the instruction manuals of PULSE OXIMETER EQUIPMENT to state that FUNCTIONAL TESTERS cannot in general be used to measure the SpO_2 ACCURACY OF PULSE OXIMETER PROBES and PULSE OXIMETER MONITORS. This annex is intended to clarify the reasons for this requirement as well as semantic issues. Terms such as simulator, calibrator and tester have several common meanings, which can contribute to misunderstanding of the actual capability of a particular device. We have recommended specific uses of the terms “calibrator” and “functional tester,” when these terms are applied to pulse oximetry. This annex explains the difference between FUNCTIONAL TESTERS and other types of testing devices, and suggests the correct way to use of FUNCTIONAL TESTERS. It also explains why it is inappropriate to use measurements made with FUNCTIONAL TESTERS to support SpO_2 ACCURACY claims for PULSE OXIMETER PROBES or PULSE OXIMETER MONITORS, with the limited exception permitted by the text of 201.7.9.3.1.101 bb).

FF.2 What is a simulator?

In conventional usage, a simulator is a test device that stands in for the human PATIENT. For example, simulators for invasive and non-invasive blood pressure and for electrocardiograph signals are well accepted substitutes for a PATIENT. The measurement ACCURACY for testing ME EQUIPMENT using a simulator can be expected to be comparable to that seen monitoring PATIENTS. A finite possibility of some additional inaccuracy exists due to errors in the simulator.

There is, at the time of writing, no simulator for pulse oximetry that reproduces the optical properties of a broad range of PATIENTS well enough to warrant its use in determining the SpO_2 ACCURACY of any PULSE OXIMETER MONITOR and PULSE OXIMETER PROBE combination. Various simulators are available that are suitable for specific engineering purposes related to development and testing of PULSE OXIMETER EQUIPMENT.

FF.3 What is a calibrator?

A calibrator, as the term is conventionally used, is a test device that can be to adjust the ACCURACY of ME EQUIPMENT. A calibrator is typically a very accurate simulator that is used to adjust the ME EQUIPMENT'S calibration. Although PULSE OXIMETER EQUIPMENT has no means to adjust its calibration, the committee felt that the least of semantic evils would be to recommend a special use of the term “calibrator.” A pulse oximetry calibrator (POC) would be a high-ACCURACY simulator, capable of producing signals or optical responses indistinguishable from those that come from a human PATIENT or test subject. With currently available PULSE OXIMETER EQUIPMENT, it is generally not possible to improve the ACCURACY of calibration of a specific combination of PULSE OXIMETER EQUIPMENT/PULSE OXIMETER PROBE using a POC. The POC is used to measure the error with which the oximeter measures oxygen saturation on one or more simulated PATIENTS. If the error is found to be unacceptable, the typical cure is to replace the defective components or redesign the ME EQUIPMENT. Another difference between the POC and other sorts of calibrators is the difficulty of reducing the error contribution of the POC to the level expected of calibrators. A calibrator should be at least four to ten times more accurate than the equipment being calibrated. Given the typical PULSE OXIMETER EQUIPMENT $Sp\mathrm{O}_2$ ACCURACY of ± 2 % $Sp\mathrm{O}_2$, a POC should ideally characterize the ACCURACY of any PULSE OXIMETER MONITOR/PULSE OXIMETER PROBE combination with an error of less than 0,5 % $Sp\mathrm{O}_2$.

FF.4 How is PULSE OXIMETER EQUIPMENT calibrated presently?

PULSE OXIMETER EQUIPMENT is unlike other ME EQUIPMENT, in that as of this writing, no simulators have been proven adequate for use as PULSE OXIMETER EQUIPMENT calibrators. The interaction of light and human tissue upon which pulse oximetry depends is complex. At least one effort is underway to produce a properly VALIDATED POC [43] [44] that would model at least some of the optical intricacies, but no such effort has yet been completed successfully.

Thus, the primary method of determining the $Sp\mathrm{O}_2$ ACCURACY of PULSE OXIMETER EQUIPMENT is to compare its readings with the readings of a CO-OXIMETER (which determines by optical measurements *in vitro* the concentration of several forms of haemoglobin in arterial blood). See also EE.2.

PULSE OXIMETER EQUIPMENT, as manufactured to date, is never calibrated in the same sense that an invasive blood pressure transducer can be calibrated. Various manual or automatic adjustments are possible for the PULSE OXIMETER EQUIPMENT, e.g. to set gains or cancel amplifier offsets, but these are all adjusted against ordinary electronic reference standards (e.g. an offset adjustment to bring the reading of a voltmeter to zero). The basic relationship between optical signals derived from the PATIENT and the displayed value of $Sp\mathrm{O}_2$ is determined by the MANUFACTURER for a particular combination of PULSE OXIMETER MONITOR and PULSE OXIMETER PROBE. This standard refers to this as RATIO or R that is stored in firmware and never adjusted. Much contemporary PULSE OXIMETER EQUIPMENT uses a concept of a MODULATION RATIO or the RATIO OF RATIOS, which can be approximated as indicated in Equation FF.1.

$$R = \frac{\log_{10}(\max._{\mathrm{red}} / \min._{\mathrm{red}})}{\log_{10}(\max._{\mathrm{IR}} / \min._{\mathrm{IR}})} \approx \frac{(AC_{\mathrm{red}} / DC_{\mathrm{red}})}{(AC_{\mathrm{IR}} / DC_{\mathrm{IR}})} \qquad \text{(FF.1)}$$

where

AC_{red} is the magnitude of the time-modulating component in the red wavelength signal;

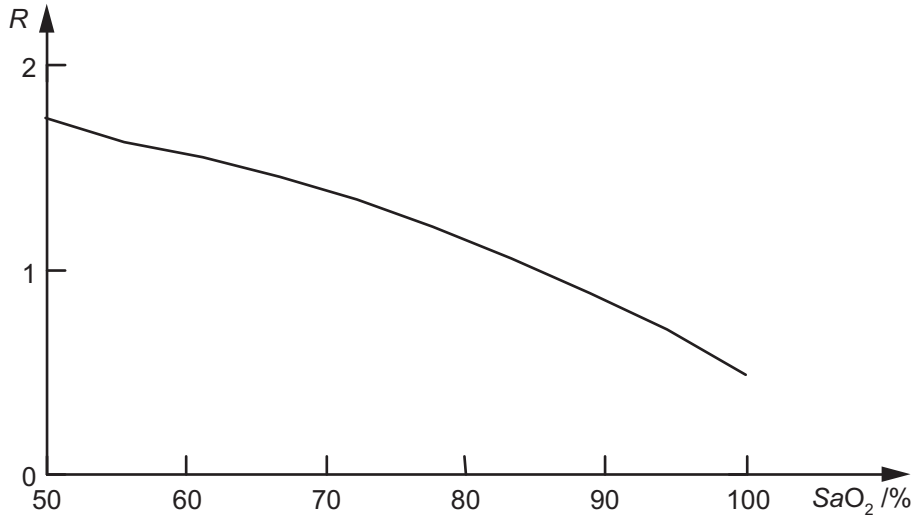
AC_{IR} is the magnitude of the time-modulating component in the infrared wavelength signal;

DC_{red} is the magnitude of the non-modulating component in the red wavelength signal;

DC_{IR} is the magnitude of the non-modulating component in the infrared wavelength signal.

NOTE This approximate formula is cited only to provide a concrete example to support the following calibration curve discussion; accurate oximeters are designed around a variety of mathematical approaches, each of which requires some sort of empirical calibration curve.

An empirically determined calibration curve, such as that illustrated in Figure FF.1, allows the PULSE OXIMETER EQUIPMENT to derive the displayed SpO_2 from the observed R. The PROCEDURE to determine the calibration curve is called a CONTROLLED DESATURATION STUDY. It typically involves providing healthy volunteer test subjects with breathing mixtures having reduced oxygen content. Arterial blood samples are drawn and measured with a CO-OXIMETER, and the CO-OXIMETER readings are plotted against R values observed during the interval when the blood is being drawn. The PROCESS should be carefully conducted, to avoid a wide variety of possible errors. CONTROLLED DESATURATION STUDIES can also be conducted by comparing the readings of the PULSE OXIMETER EQUIPMENT under test to "secondary standard" PULSE OXIMETER EQUIPMENT that have previously been calibrated against CO-OXIMETERS. This approach avoids the need to draw arterial blood but still always requires the use of human test subjects.



Red/IR modulation RATIO, R, as a function of arterial oxygen saturation

Figure FF.1 — Sample calibration curve for PULSE OXIMETER EQUIPMENT

This curve shows the observed value of R for various values of SaO_2 determined with a CO-OXIMETER. PULSE OXIMETER EQUIPMENT software uses this curve to determine the relationship between an observed value of R and a displayed SpO_2 value.

FF.5 What is a FUNCTIONAL TESTER?

Every PULSE OXIMETER EQUIPMENT tester intended to generate simulated signals on the market at the time of writing is a FUNCTIONAL TESTER. Two principal characteristics of FUNCTIONAL TESTERS are as follows.

— An appropriate FUNCTIONAL TESTER allows the RESPONSIBLE ORGANIZATION to determine whether the PULSE OXIMETER EQUIPMENT is performing as the MANUFACTURER designed it to perform, without in any way determining whether the design was correct.

— A FUNCTIONAL TESTER has limited ability to determine whether any PULSE OXIMETER PROBE is performing as the MANUFACTURER designed it to perform (more will be said about the limitations below) and can never determine whether the design was correct.

A FUNCTIONAL TESTER presents the PULSE OXIMETER EQUIPMENT with a signal having a predictable value of R, so that the RESPONSIBLE ORGANIZATION can observe the resulting displayed value of SpO_2, and evaluate it in comparison to expectations for that particular PULSE OXIMETER MONITOR model. If the tester MANUFACTURER knows the calibration curve that has been designed into a particular PULSE OXIMETER MONITOR, the MANUFACTURER can accurately produce the R value which ought to lead to a particular value of SpO_2, e.g. 85 %. Then the PULSE OXIMETER EQUIPMENT can be evaluated for its ability to reproduce the calibration curve that was designed into it. Any error exceeding the combined error specifications of the PULSE OXIMETER

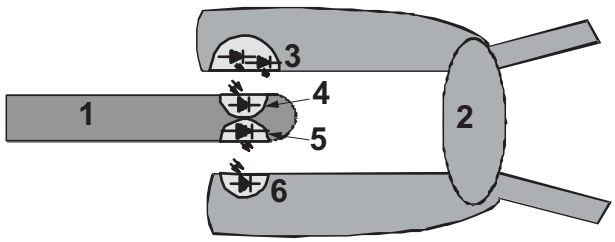
EQUIPMENT and the tester suggests that either the PULSE OXIMETER EQUIPMENT or the tester requires repair or replacement.

An accurate reading of SpO_2 on a FUNCTIONAL TESTER never implies that the PULSE OXIMETER EQUIPMENT is accurate on human beings. All that is being evaluated by the tester is the PULSE OXIMETER MONITOR'S ability to reproduce the calibration curve that the MANUFACTURER designed into it; this calibration curve might not be accurate. The following detailed observations are chosen to emphasize this point.

— Some FUNCTIONAL TESTERS are designed to connect electrically to the input of the PULSE OXIMETER MONITOR in place of the PULSE OXIMETER PROBE. This type of tester cannot evaluate the optical properties of the PULSE OXIMETER PROBE, which are known to be very important for calibration. This family of testers has limited abilities to test the optical properties of PULSE OXIMETER EQUIPMENT.

— Some FUNCTIONAL TESTERS are electronic modulators having an optical interface to the PULSE OXIMETER EQUIPMENT. The PULSE OXIMETER PROBE is applied to an optomechanical "finger" of some sort, and modulated optical signals are delivered to the detector of the PULSE OXIMETER PROBE. While such testers can appear to evaluate the PULSE OXIMETER PROBE, they usually only test the most basic properties of the PULSE OXIMETER PROBE; that its light sources and detector are active and that no disabling shorts or open circuits exist. The same determination can be made by applying the PULSE OXIMETER PROBE to the OPERATOR'S own finger and observing that the PULSE OXIMETER EQUIPMENT displays some value of SpO_2. This type of FUNCTIONAL TESTER simply uses the PULSE OXIMETER PROBE as a tool to deliver a desired test signal to the electronics of the PULSE OXIMETER EQUIPMENT.

— Several brands of FUNCTIONAL TESTER have an optomechanical "finger" containing a detector, which picks up light from the PULSE OXIMETER PROBE'S light emitter, and a light-emitting diode (LED) which delivers modulated light to the PULSE OXIMETER PROBE'S detector (see Figure FF.2). This is one example of the optically interfaced tester described above. If the PULSE OXIMETER PROBE'S red LED were of the wrong wavelength for the calibration curve in use, this would definitely cause the oximeter to be inaccurate in actual use on PATIENTS. The FUNCTIONAL TESTER would be unable to detect this error, as would the PULSE OXIMETER EQUIPMENT under test, so that inaccurate PULSE OXIMETER EQUIPMENT might well appear to be accurate. Some MANUFACTURERS produce PULSE OXIMETER PROBES with a variety of different wavelengths. The PULSE OXIMETER MONITOR uses something like a resistor within the PULSE OXIMETER PROBE to select the correct calibration curve from a defined set of available curves. The instruction for selection of the correct curve is given to the oximeter by means of a coding device, such as a resistor, that is carried by the PULSE OXIMETER PROBE. An important quality control requirement in new or REPROCESSED PULSE OXIMETER PROBES is close matching of emitter wavelength (and wavelength distribution) to the calibration code in the PULSE OXIMETER PROBE. Currently available FUNCTIONAL TESTERS cannot VERIFY the correctness of the value of the centre wavelength.



Key

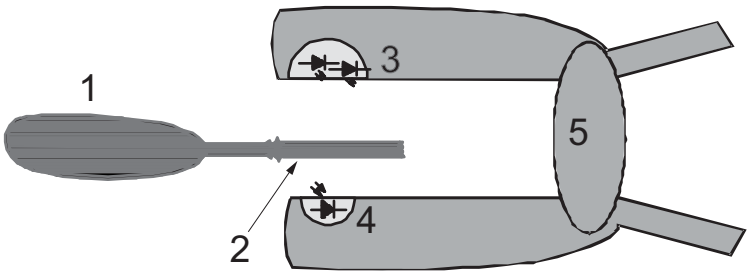
1 test finger
2 sensor
3 2 LEDs
4 photodiode
5 LED
6 photodiode

Figure FF.2 — Interface of a FUNCTIONAL TESTER that uses a photodiode and LED to interact with a PULSE OXIMETER PROBE

— Some FUNCTIONAL TESTERS provide comprehensive tests for all possible shorts and opens in the PULSE OXIMETER PROBE. While this is a valuable test, electrical integrity is a necessary, but not sufficient, condition for ACCURACY.

— In a PULSE OXIMETER PROBE, the colour of the plastic cushion or bandage that touches the PATIENT'S skin has an important effect on the calibration of the PULSE OXIMETER EQUIPMENT. If a bandage were badly stained, this could affect the SpO_2 ACCURACY of the PULSE OXIMETER PROBE in actual use. The types of FUNCTIONAL TESTER described above are insensitive to the presence of the stain. This "bandage colour" issue actually identifies a larger sphere of concern. The SpO_2 ACCURACY of PULSE OXIMETER EQUIPMENT is affected strongly by the interacting optical properties of both the PATIENT'S tissue and every part of the surrounding optical environment. FUNCTIONAL TESTERS are insensitive to such effects. A true pulse oximetry calibrator, when it appears, will need to reproduce faithfully this complex interaction. An implication is that the documentation accompanying any POC that eventually comes to market should include a discussion as to which physical and physiological aspects of PULSE OXIMETER EQUIPMENT performance are replicated, and which are not.

One class of FUNCTIONAL TESTERS has inherent sensitivity to the wavelength distributions of PULSE OXIMETER EQUIPMENT'S emitter. Such testers work by modulating optically the light emitted by the PULSE OXIMETER PROBE'S own emitter, and conducting the modulated light to the PULSE OXIMETER PROBE'S detector. One such tester family works by modulating the amount of a dye solution that is forced between the PULSE OXIMETER PROBE'S emitter and detector (see Figure FF.3). Another such family uses a liquid crystal device to modulate the light en route from emitter to detector (see Figure FF.4). Such testers can be designed to cause wavelength-dependent modulation approximating the dependence of haemoglobin's optical absorption on wavelength. In principle they could also be designed to approximate the important effects of tissue scattering on oximeter calibration (although we know of no published evidence that this has yet been done). For such testers to approach the status of true POCs, they would also need to reproduce the optical interactions of human tissue with the coloured materials that surround emitter and detector. At the present state of the art, we believe that this class of FUNCTIONAL TESTER should not be assumed to come any closer to being true SpO_2 ACCURACY testers than the other classes of FUNCTIONAL TESTER. They can be compared to other testers on the usual basis of comparing test equipment — trade-off among cost, convenience, durability, versatility and reproducibility of results.

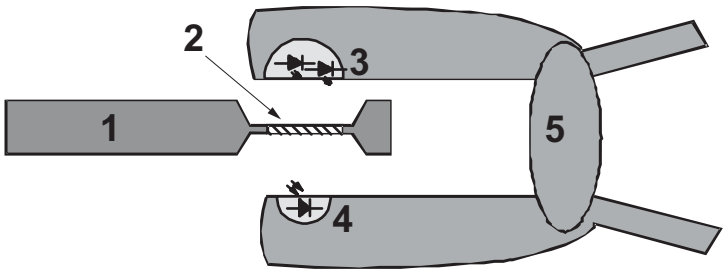


Key

1 bladder with dye mixture
2 variable-gap optical cell
3 2 LEDs
4 photodiode
5 sensor

NOTE By squeezing the bladder, the amount of dye that is forced between the plates of the optical cell is varied.

Figure FF.3 — Interface of a FUNCTIONAL TESTER that uses a dye mixture



Key

1 test finger
2 liquid crystal modulator
3 2 LEDs
4 photodiode
5 sensor

Figure FF.4 — Interface of a FUNCTIONAL TESTER that uses a liquid crystal modulator

Some MANUFACTURERS of new or REPROCESSED PULSE OXIMETER PROBES have claimed that their PULSE OXIMETER PROBES are routinely shown to be accurate by testing with FUNCTIONAL TESTERS. Such evidence has so far been insufficient to reflect the true performance of PULSE OXIMETER EQUIPMENT, given the limitations of FUNCTIONAL TESTERS.

FF.6 Beyond FUNCTIONAL TESTERS

How will we know when a true PULSE OXIMETER EQUIPMENT calibrator has been developed? Such a device would be recognized by the way it is used and by the nature of the published experimental results that VALIDATE its capabilities. Its properties would be as follows.

— The PULSE OXIMETER PROBE of PULSE OXIMETER EQUIPMENT is applied to a part of the POC that approximates the dynamic optical behaviour of a body part for which the PULSE OXIMETER PROBE is designed. The optical simulation should include the interaction that occurs between the PULSE OXIMETER PROBE'S materials and human tissue, in which light repeatedly leaves and re-enters the tissue, reflecting from the materials of the PULSE OXIMETER PROBE.

— The POC can be set to simulate the optical behaviour of the simulated body part for a PATIENT having selected oxygen saturation, $Sa\mathrm{O}_2$, causing the PULSE OXIMETER EQUIPMENT to display an $Sp\mathrm{O}_2$ reading.

— VALIDATION experiments will have established that the reading induced in the PULSE OXIMETER EQUIPMENT by the POC matches within the stated simulation $Sp\mathrm{O}_2$ ACCURACY the reading that the same PULSE OXIMETER MONITOR and PULSE OXIMETER PROBE would give on a PATIENT. The basic VALIDATION experiment that should be done many times and under many conditions, is as follows.

1) Apply an oximeter PULSE OXIMETER PROBE to a human being whose $Sa\mathrm{O}_2$ is determined by measuring arterial blood samples in a multi-wavelength oximeter (e.g. CO-OXIMETER).

2) Observe the $Sp\mathrm{O}_2$ value displayed by the PULSE OXIMETER EQUIPMENT. It does not matter whether this number is accurate.

3) Apply the same oximeter and PULSE OXIMETER PROBE to the POC, with the POC set to simulate the same $Sa\mathrm{O}_2$ that was seen on the human subject.

4) Observe the $Sp\mathrm{O}_2$ value displayed by the PULSE OXIMETER EQUIPMENT.

5) Calculate the error of the POC as the difference between the two $Sp\mathrm{O}_2$ values.

— The VALIDATION of POC performance should include testing over the following ranges of conditions.

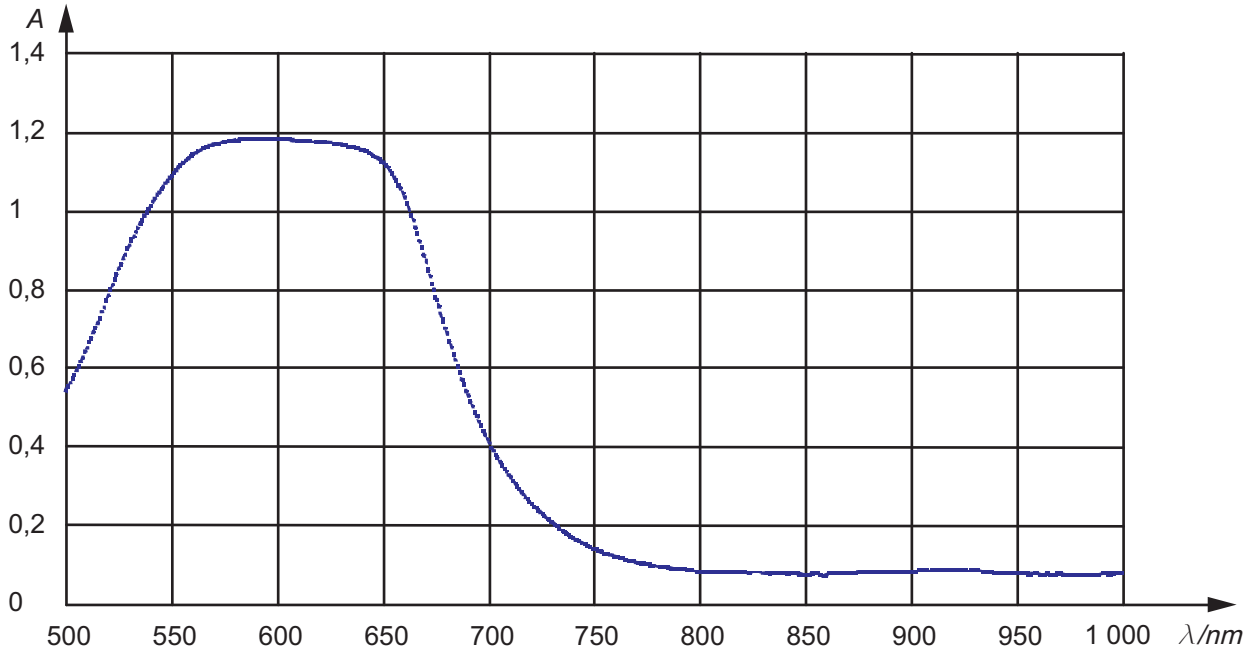
6) Many different brands of PULSE OXIMETER EQUIPMENT, having emitters of the widest available variety of wavelength distributions.

7) Many different PULSE OXIMETER PROBES designed for use with the chosen body part, including the widest available variety of shapes and material colours. Testing should preferably include use of "challenge" PULSE OXIMETER PROBES that are known to be very inaccurate in use on PATIENTS. The POC is required to cause the oximeter to exhibit exactly the same inaccuracy that the real PATIENT does.

8) Testing should preferably include use of a particular class of challenge PULSE OXIMETER PROBES that are known to produce very different SpO_2 readings when tested on different human volunteers having the same value of SaO_2. As an example of such a PULSE OXIMETER PROBE, Figure FF.5 shows the reflectance spectrum of a particular blue bandage material which has been shown to give extremely variable performance from one PATIENT to another. This is not a material that would be used in any commercial PULSE OXIMETER PROBE; it was specifically selected to demonstrate the variable calibration that would result when compared to a standard PULSE OXIMETER PROBE. Figure FF.6 displays this extremely variable calibration, compared to a standard PULSE OXIMETER PROBE. This PULSE OXIMETER PROBE could not be accurate on all PATIENTS, no matter what calibration curve was used in the oximeter. If a POC has not been VALIDATED in testing with such PULSE OXIMETER PROBES (which implies that a particular PULSE OXIMETER PROBE/OXIMETER EQUIPMENT combination could appear accurate when tested on the POC but be inaccurate on many PATIENTS), this limitation should be disclosed clearly in the documentation accompanying the POC, and the users of the POC should be advised of the importance of testing PULSE OXIMETER EQUIPMENT on a variety of human volunteers. In order to test meaningfully the behaviour of these variable-calibration challenge PULSE OXIMETER PROBES, the POC would presumably have to be adjustable to simulate one of several different human subjects.

Test many PATIENTS or volunteer test subjects at each SaO_2 level where the POC is specified for use. Special emphasis should be given to testing at the lowest values of SaO_2 at which the POC is specified for use, because PULSE OXIMETER EQUIPMENT errors tend to be larger at low saturation.

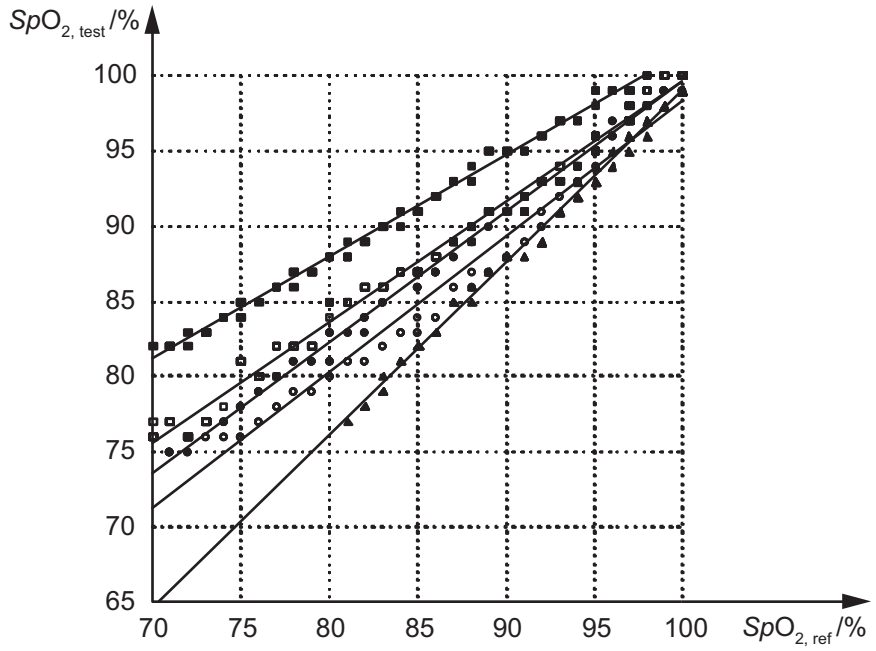
The ACCURACY specification of the POC does not include any component for inaccuracy of the PULSE OXIMETER EQUIPMENT under test (compare this to the typical FUNCTIONAL TESTER specification, such as ±1 % SpO_2 ± stated oximeter SpO_2 ACCURACY). It is the purpose of the POC to determine the SpO_2 ACCURACY of the PULSE OXIMETER EQUIPMENT, without direct human testing. In this sense, the POC will be a secondary standard, with CONTROLLED DESATURATION STUDY testing on humans retaining the role of "gold standard." See also EE.3.



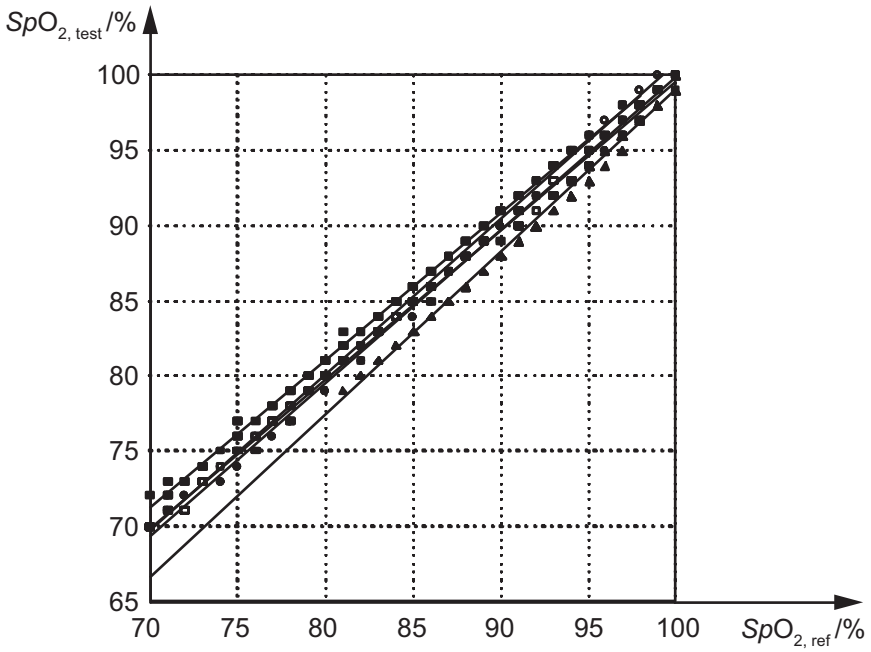
A absorbance, measured in reflection

λ optical wavelength

Figure FF.5 — Absorbency of blue bandage material (measured in reflection) used in a special test PULSE OXIMETER PROBE with great PATIENT-to-PATIENT variability of calibration



a) Comparison of blue test PULSE OXIMETER PROBE to standard production PULSE OXIMETER PROBE



b) Comparison of one standard production PULSE OXIMETER PROBE to another

Key

$SpO_{2,\ test}$ test SpO_2

$SpO_{2,\ ref}$ reference SpO_2

Figure FF.6 a) shows a test of a blue test PULSE OXIMETER PROBE (left index finger) as a function of reference PULSE OXIMETER PROBE (left little finger). Figure FF.6 b), shows a test of a PULSE OXIMETER PROBE (left middle finger) as a function of the reference PULSE OXIMETER PROBE (left little finger). A separate regression line is shown for each of five test subjects.

Figure FF.6 — Calibration of high-variability PULSE OXIMETER PROBE in CONTROLLED DESATURATION STUDY on five test subjects

Annex GG
(informative)

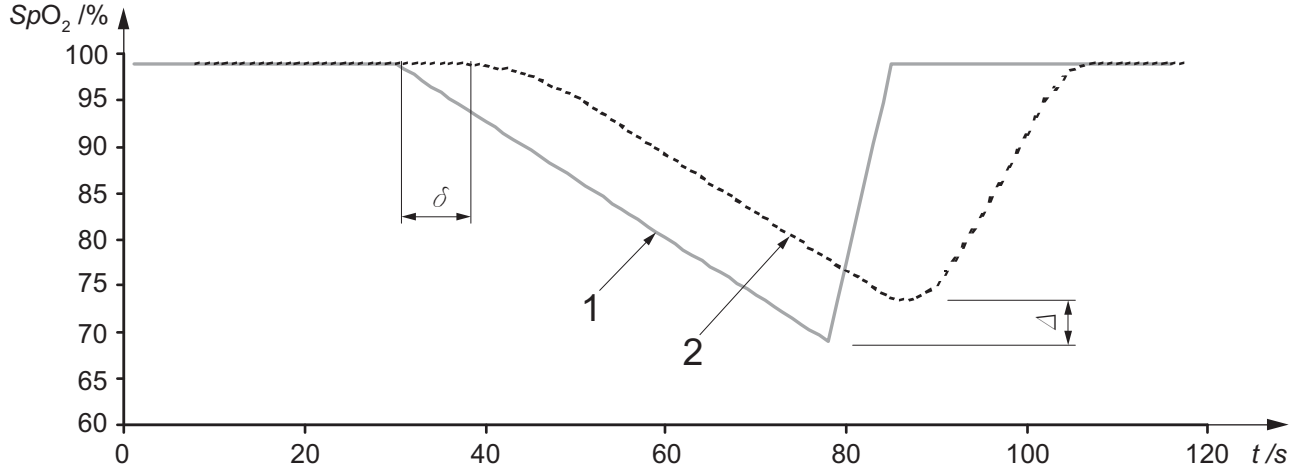
Concepts of ME EQUIPMENT response time

GG.1 General

There can be trade-offs between accurately tracking the magnitude of changes in saturation and minimizing the effects of noise. In general, faster response times can cause PULSE OXIMETER EQUIPMENT to be more vulnerable to noise, but can allow them to follow the actual saturation more closely. The response of some devices can be optimized for particular clinical situations. There are two important concepts in describing PULSE OXIMETER EQUIPMENT response. One is the *fidelity* in tracking saturation changes. The other is the *delay* from the time that an event occurs (the SaO_2 changes at the measurement site) until the display indicates the change or the generation of ALARM SIGNALS. "Fidelity" and "delay" are influenced by PULSE OXIMETER EQUIPMENT design and OPERATOR-SETTINGS. PULSE OXIMETER EQUIPMENT design can include signal processing and conditioning times and data transmission delays. Adjustable controls can set, e.g. averaging time and ALARM SIGNAL GENERATION DELAY.

GG.2 Fidelity

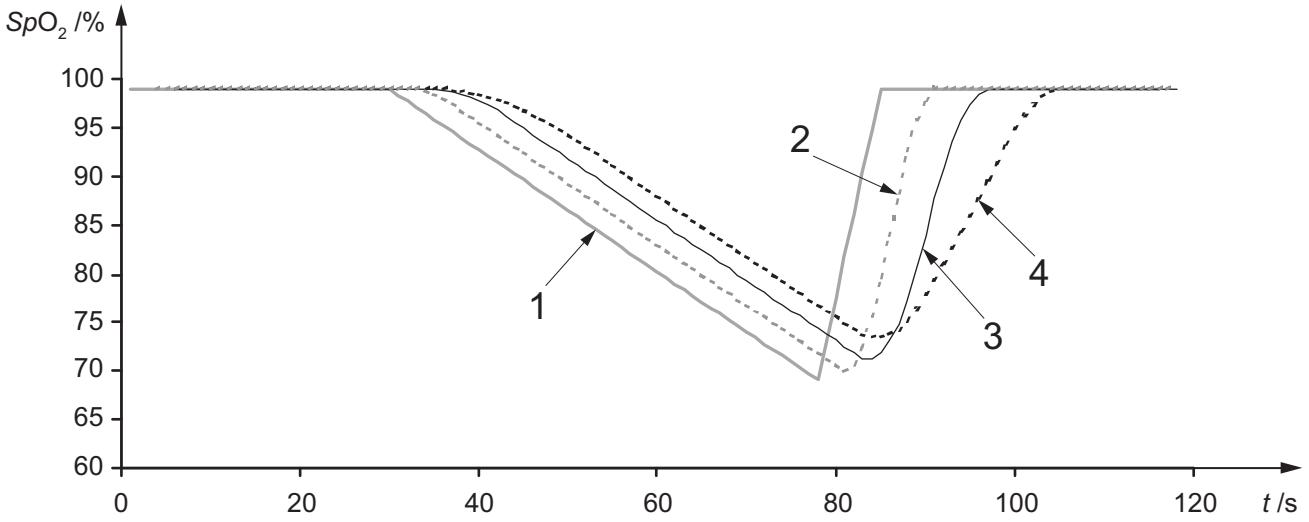
Fidelity can be described graphically by showing the range of responses of the PULSE OXIMETER EQUIPMENT to a change in saturation. Figure GG.1 illustrates a simulated response of PULSE OXIMETER EQUIPMENT to a change in saturation. Figure GG.2 illustrates the simulated effect of different averaging times on the response of the PULSE OXIMETER EQUIPMENT.



Key

1 SaO_2
2 displayed SpO_2
Δ saturation deviation
δ time delay
SpO_2 saturation
t time

Figure GG.1 — Illustration of fidelity of PULSE OXIMETER EQUIPMENT performance in tracking saturation changes



Key

1 SaO_2
2 displayed SpO_2, faster averaging
3 displayed SpO_2, normal averaging
4 displayed SpO_2, slower averaging
SpO_2 saturation
t time

Figure GG.2 — Illustration of effect of different averaging times on fidelity

The symbols δ and Δ in Figure GG.1 do not refer to any particular requirement in this International Standard. They are illustrated here as possible points of interest, in that these are the likely areas of SpO_2 ACCURACY that can be affected by different averaging or filtering techniques response curves. The span depicted by the symbol δ represents a time lag before changes in saturation are reflected in the processed SpO_2 value. This lag can be caused by, for example, the time required for data acquisition, signal conditioning, and algorithm processing. The deviation denoted by Δ illustrates a lack of fidelity in reproducing the degree of change in a transient desaturation. Δ is generally affected by, for example, signal averaging and/or the DATA UPDATE PERIOD.

The importance of the errors, δ and Δ, introduced by the processing of the SpO_2 parameter as well as the detection of ALARM CONDITIONS and the subsequent generation of ALARM SIGNALS that the purchasers of PULSE OXIMETER EQUIPMENT need to consider for the applications in their clinical practice [see 201.7.9.2.101 d)] are well illustrated in Reference [54].

GG.3 Effects of delays

Delays can be described graphically, for example, by showing the response of the PULSE OXIMETER EQUIPMENT using Figure GG.3. The time from t_1 to t_2 is the ALARM CONDITION DELAY and the time from t_2 to t_3 is the ALARM SIGNAL GENERATION DELAY.

A possible PROCEDURE to measure the sum of the ALARM CONDITION DELAY and ALARM SIGNAL GENERATION DELAY of PULSE OXIMETER EQUIPMENT is described below.

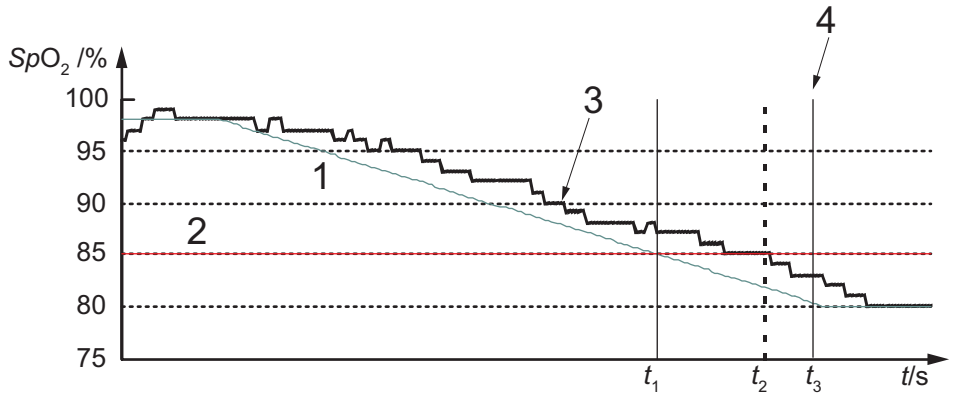
— A simulator is set to start at a saturation level of e.g. 98 %.

— This level should be simulated for a period of time that is sufficient to allow stabilization of the PULSE OXIMETER EQUIPMENT (device) under test.

— The simulator then changes the saturation level in a linear ramp function with a predefined slope (or any other predefined function) down to a given end-value (e.g. 5 % below the ALARM LIMIT).

— The sum of the ALARM CONDITION DELAY and ALARM SIGNAL GENERATION DELAY is defined as the time from having the simulated saturation passing the ALARM LIMIT threshold (e.g. 85 % or the default low saturation ALARM LIMIT) to the time the ALARM SYSTEM generates the appropriate ALARM SIGNAL.

Figure GG.3 illustrates the components of ALARM SIGNAL GENERATION DELAY.



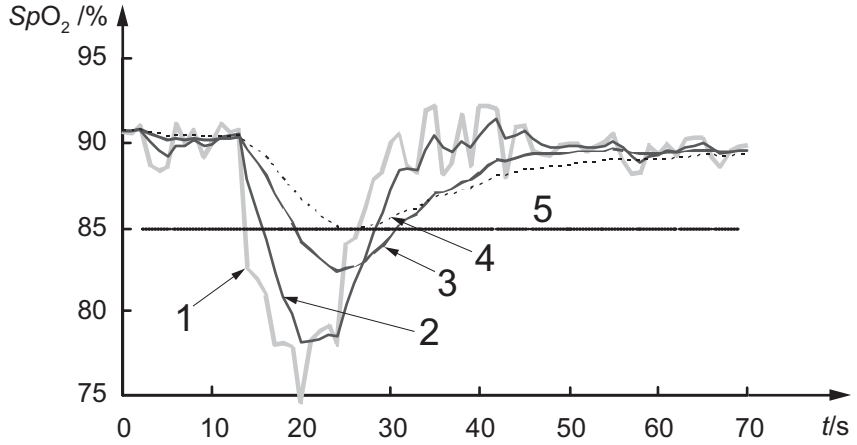
Key

1	SaO_2
2	alarm limit
3	displayed SpO_2
4	ALARM SIGNAL generation
SpO_2	saturation
t	time
t_1, t_2, t_3	see GG.3

Figure GG.3 — Graphic representation of components of ALARM SYSTEM delay

The delay due to the PULSE OXIMETER EQUIPMENT processing and averaging is $t_2 - t_1$, the ALARM CONDITION DELAY. The interval $t_3 - t_2$, the ALARM SIGNAL GENERATION DELAY, is attributed to the ALARM SYSTEM strategy and the communication time to the ALARM SIGNAL generation device or DISTRIBUTED ALARM SYSTEM (e.g. PATIENT monitor or central station). Thus, the overall ALARM SYSTEM delay time is $t_3 - t_1$.

Figure GG.4 represents a faster desaturation slope and a more realistic, noisier saturation signal. Curves 3 and 4 underestimate the depth of the fall in saturation. Curve 2, faster averaging, can cross a low saturation ALARM LIMIT sooner than curve 3, normal averaging, or curve 4, slower averaging, which might not cause an ALARM CONDITION at all. The benefit of normal and slower averaging is to smooth out the otherwise noisy signal and reduce the number of FALSE POSITIVE ALARM CONDITIONS.



Key

1	unprocessed SpO_2
2	displayed SpO_2, faster averaging
3	displayed SpO_2, normal averaging
4	displayed SpO_2, slower averaging
5	ALARM LIMIT
SpO_2	saturation
t	time

Figure GG.4 — Illustration of the effects of different averaging times on a more rapid and noisier desaturation signal

Annex HH
(informative)

Reference to the essential principles of safety and performance of medical devices in accordance with ISO/TR 16142

This International Standard has been prepared to support the essential principles of safety and performance of PULSE OXIMETER EQUIPMENT as medical devices according to ISO/TR 16142:2006. This International Standard is intended to be acceptable for conformity assessment purposes.

Compliance with this International Standard provides one means of demonstrating conformance with the specific essential principles of ISO/TR 16142:2006. Other means are possible.

Table HH.1 — Correspondence between this International Standard and the essential principles

Clause/subclause of this International Standard	Corresponding essential principle	Comments
all	1	
all, 201.4, 201.4.3, 201.4.101, 201.7.2, 201.101.1, 208	2	
all, 201.4, 201.4.101, 201.4.102, 201.101.1	3	
201.11.8.101, 201.15.3.5.101, 201.101.1	4	
201.15.3.5.101, 201.101.1	5	
201.4, 201.7.9.2, 201.11, 201.12.1, 201.12.4, 201.101.1, 208	6	
201.11, 201.101.1	7.1, 7.2	
201.11	7.3	
—	7.4	Not applicable
201.11	7.5	
201.11.6.5.101, 201.101.1	7.6	
201.11	8.1	
—	8.1.1	Not applicable
—	8.1.2	Not applicable
201.11	8.2	
201.7.2.17.101, 201.101.1	8.3	
201.11	8.4	
—	8.5	Not applicable
201.11	8.6	
201.4.103, 201.7.2, 201.7.2.101, 201.7.9.2.14.101, 201.12.4.101, 201.101.1, 201.101.2, 208	9.1	
201.15.3.5.101, 201.101.1, 202	9.2	
201.11	9.3	
201.12.1, 201.12.4.101, 201.12.4.102, 201.101.1	10.1	
201.12.4.101, 201.12.4.102, 201.102, 208	10.2	

Table HH.1 (*continued*)

Clause/subclause of this International Standard	Corresponding essential principle	Comments
201.7.4.3	10.3	
201.10, 201.101.1	11.1.1	
201.10	11.2.1	
201.10, 201.101.1	11.2.2	
202	11.3.1	
201.7.9.2.1.101 c)	11.4.1	
—	11.5.1	Not applicable
—	11.5.2	Not applicable
—	11.5.3	Not applicable
201.14	12.1	
201.11.8.101, 208	12.2	
201.11.8.101, 208	12.3	
201.7.2.101, 201.12.4.102, 208	12.4	
201.101.1, 202	12.5	
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—	12.7.2	Not applicable
—	12.7.3	Not applicable
201.8, 201.15	12.7.4	
201.11, 201.15, 201.101.1	12.7.5	
—	12.8.1	Not applicable
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