

Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use (ISO 9919:2005)

ICS 11.040.10

National foreword

This British Standard is the UK implementation of EN ISO 9919:2009. It is identical to ISO 9919:2005. It supersedes BS EN ISO 9919:2005 which is withdrawn.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.

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

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 July 2009.
© BSI 2009

ISBN 978 0 580 65478 7

Amendments/corrigenda issued since publication

Date	Comments

English Version

**Medical electrical equipment - Particular requirements for the
basic safety and essential performance of pulse oximeter
equipment for medical use (ISO 9919:2005)**

Appareils électromédicaux - Règles particulières de
sécurité et performances essentielles du matériel utilisé
pour les oxymètres de pouls à usage médical (ISO
9919:2005)

Medizinische elektrische Geräte Besondere Festlegungen
für die grundlegende Sicherheit und die wesentlichen
Leistungsmerkmale von Pulsoximetriegegeräten für den
medizinischen Gebrauch (ISO 9919:2005)

This European Standard was approved by CEN on 14 March 2009.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, 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

Foreword

The text of ISO 9919:2005 has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 9919:2009 by 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 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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 9919:2005.

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 EC Directive.

For relationship with EC 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, 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 9919:2005 has been approved by CEN as a EN ISO 9919:2009 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 of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities 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)/Subclause(s) of this European Standard	Essential Requirements (Ers) of EU Directive 93/42/EEC	Qualifying remarks/Notes
All	1, 2, 3	
4.101, 4.102	3, 6	
4.103	6, 9.1	
6.1	2,9.1, 13.1	
-	12.1a)	This relevant Essential Requirement is not addressed in this European Standard.
6.1 d)	13.3 (a):	This relevant Essential Requirement is not fully addressed in this European Standard
6.1	13.3 (f)	This relevant Essential Requirement is not fully addressed in this European Standard
6.1	13.6 (h)(2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
6.1	13.6 (h)(3rd paragraph)	This relevant Essential Requirement is not addressed in this European Standard
6.8.2 aa) 21	7.5 (3rd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
6.8.2	13.6 (q)	This relevant Essential Requirement is not addressed in this European Standard: covered by EN ISO 13485: 2003, subclause 4.2.3

Table ZA.1 (continued)

Clause(s)/Subclause(s) of this European Standard	Essential Requirements (Ers) of EU Directive 93/42/EEC	Qualifying remarks/Notes
6.1 d) 1st dash	13.1	
6.1 d) 4 th dash	12.4	
6.1 f)	9.1, 13.1	
6.1 aa)	10.3	
6.1 bb)	13.3 f), 13.6 h)	
6.1 cc)	13.3 c), 13.3 m)	
6.1 dd)	13.3 e)	
6.8.2	6, 13.6	
6.8.2 aa) 1)	13.6 b)	
6.8.2 aa) 2)	11.4.1, 13.6 j)	
6.8.2 aa) 3)	13.6 b), 13.6 f), 13.6 k), 13.6 l)	
6.8.2 aa) 4)	13.6 b), 13.6 p)	
6.8.2 aa) 5)	13.6 b)	
6.8.2 aa) 7)	13.6 d)	
6.8.2 aa) 11), 6.8.2 aa) 12)	13.6 c)	
6.8.2 aa) 13), 6.8.2 aa) 14), 6.8.2 aa) 15), 6.8.2 aa) 16), 6.8.2 aa) 17),	13.6 b)	
6.8.2 aa) 19)	13.6 g)	
6.8.2 aa) 20)	13.6 c), 13.6 d)	
6.8.2 aa) 21)	13.4	
6.8.3 aa) 1), 6.8.3 aa) 2)	13.6 d)	
10.1.1	8.3	
19.4	12.6	
20.4	12.6	
21	4, 5, 9.2, 12.7.1	
29, 30, 31	11.2.1	
32	11.1.1, 11.2.1, 11.2.2	
33, 34, 35	11.2.1	
36	9.2, 11.3.1, 12.5	
42	12.7.5, 12.8.2	
42.3	6	
43.101	7.1, 7.3, 9.3	
44.6	7.6	
44.7	8.1, 8.4, 8.6	
46	10.2	
48	7.1, 7.2, 7.5, 8.2	

Table ZA.1 (continued)

Clause(s)/Subclause(s) of this European Standard	Essential Requirements (Ers) of EU Directive 93/42/EEC	Qualifying remarks/Notes
48	7.5 (1 st paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
49	4, 12.2, 12.3	
50	6, 10.1, 14	
50.101.2	6a)	This relevant Essential Requirement is not fully addressed in this European Standard
51	6	
51.101	9.1, 10.1 10.2	
52	12.1	
57.3	12.7.4	
101	10.1, 10.2, 12.4	
102.1	2, 3, 4, 5, 6, 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, 14	
102.2	9.1, 13.1	
103	10.2	
201	2, 6, 9.1, 10.2, 12.2, 12.3, 12.4	

WARNING - Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

Contents

Page

Foreword	vii
Introduction	viii
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 General requirements and requirements for tests	7
4.101 Other test methods	7
4.102 Acceptance criteria	8
4.103 Pulse oximeter equipment, parts and accessories	8
5 Classification	8
6 Identification, marking and documents	8
6.1 Marking on the outside of equipment or equipment parts	8
6.8.1 General	9
6.8.2 Instructions for use	9
6.8.3 Technical description	11
7 Power input	11
8 Basic safety categories	11
9 Removable protective means	11
10 Environmental conditions	12
10.1 Transport and storage	12
11 Not used	12
12 Not used	12
13 General	12
14 Requirements related to classification	12
14.6 Types B, BF and CF equipment	12
15 Limitation of voltage and/or energy	12
16 Enclosures and protective covers	12
17 Separation	12
18 Protective earthing, functional earthing and potential equalization	12
19 Continuous leakage currents and patient auxiliary currents	13
19.4 Tests	13
20 Dielectric strength	13
20.4 Tests	13
21 * Mechanical strength	13
21.5 13	13
21.101 * Shock and vibration	13
21.102 * Shock and vibration for transport	14
22 Moving parts	15
23 Surfaces, corners and edges	15
24 Stability in normal use	15

25	Expelled parts	15
26	Vibration and noise	16
27	Pneumatic and hydraulic power	16
28	Suspended masses	16
29	X-Radiation.....	16
30	Alpha, beta, gamma, neutron radiation and other particle radiation	16
31	Microwave radiation	16
32	Light radiation (including lasers).....	16
33	Infra-red radiation.....	16
34	Ultraviolet radiation.....	16
35	Acoustical energy (including ultrasonics).....	16
36	* Electromagnetic compatibility.....	17
37	Locations and basic requirements	17
38	Marking, accompanying documents	17
39	Common requirements for category AP and category APG equipment	17
40	Requirements and tests for category AP equipment, parts and components thereof	17
41	Requirements and tests for category APG equipment, parts and components thereof	17
42	Excessive temperatures	18
43	Fire prevention.....	18
43.101	* Pulse oximeter equipment used in conjunction with oxidants	18
43.101.1	Ignitable material	18
43.101.2	Sparking.....	19
44	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility.....	19
44.6	* Ingress of liquids	19
44.7	Cleaning, sterilization and disinfection	19
45	Pressure vessels and parts subject to pressure	19
46	Human errors	20
47	Electrostatic charges	20
48	Biocompatibility.....	20
49	Interruption of the power supply	20
49.101	Power-failure alarm condition.....	20
49.102	Pulse oximeter equipment operation following interruption of the power supply.....	20
49.102.1	Settings and data storage following short interruptions or automatic switchover.....	20
49.102.2	Operation following long interruptions	20
50	Accuracy of operating data	21
50.101	* SpO ₂ accuracy of pulse oximeter equipment	21
50.101.1	* Specification	21
50.101.2	Determination of SpO ₂ accuracy.....	21
50.102	Accuracy under conditions of motion.....	22
50.103	Accuracy under conditions of low perfusion	22
50.104	Pulse rate accuracy.....	23
51	Protection against hazardous output.....	23
51.101	* Data update period	23
51.102	Detection of pulse oximeter probe and probe cable extender fault.....	23

52	Abnormal operation and fault-conditions	23
53	Environmental tests	24
54	General	24
55	Enclosures and covers	24
56	Components and general assembly	24
57	Mains parts, components and layout.....	24
58	Protective earthing — Terminals and connections	24
59	Construction and layout.....	24
101	* Signal inadequacy	24
102	* Pulse oximeter probes and probe cable extenders	25
102.1	General	25
102.2	Labelling.....	25
103	Saturation pulse information signal.....	25
104	Alarm systems.....	25
201.1.2 *	Assignment of priority	25
201.5.4 *	Default alarm preset	26
201.8	Alarm signal inactivation states	26
201.8.3	Indication and access.....	26
105	Appendices of IEC 60601-1:1988.....	26
Annex AA (informative)	Rationale.....	27
Annex BB (informative)	Skin temperature at the pulse oximeter probe	38
Annex CC (informative)	Determination of accuracy.....	42
Annex DD (informative)	Calibration standards.....	50
Annex EE (informative)	Guideline for evaluating and documenting SpO ₂ accuracy in human subjects.....	51
Annex FF (informative)	Simulators, calibrators and functional testers for pulse oximeter equipment	58
Annex GG (informative)	Concepts of equipment response time	68
Annex HH (informative)	Reference to the Essential Principles	72
Annex II (informative)	Environmental aspects.....	74
Annex JJ (informative)	Index of defined terms.....	76
Bibliography		78

Tables

Table AA.1 — Qualitative assessment of pulse oximeter equipment shock and vibration environment.....	28
Table AA.2 — Allowable maximum temperatures for skin contact with medical electrical equipment applied parts (adapted from Table 22, IEC/CDV 60601-1:2004)	30
Table BB.1 — Pulse oximeter probe safe application time and source	40
Table EE.1 — Example of target plateaus and ranges	54
Table HH.1 — Correspondence between this International Standard and the Essential Principles	72
Table II.1 — Environmental aspects addressed by clauses of this International Standard.....	75

Figures

Figure CC.1 — Synthesized calibration data (base case)	43
Figure CC.2 — Constant offset has been added to base case	44
Figure CC.3 — Tilt has been added to base case	45
Figure CC.4 — Graphical representation for the definition of local bias (Test sensor SpO_2 as a function of reference S_R)	46
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)	46
Figure EE.1 — Example of desaturation-time profile	54
Figure FF.1 — Sample calibration curve for pulse oximeter equipment	60
Figure FF.2 — Interface of a functional tester that uses a photodiode and LED to interact with a pulse oximeter probe	61
Figure FF.3 — Interface of a functional tester that uses a dye mixture	62
Figure FF.4 — Interface of a functional tester that uses a liquid crystal modulator	63
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	65
Figure FF.6 — Calibration of high-variability pulse oximeter probe in controlled desaturation study on five test subjects	66
Figure FF.6 — Calibration of high-variability pulse oximeter probe in controlled desaturation study on five test subjects (<i>continued</i>)	67
Figure GG.1 — Illustration of fidelity of pulse oximeter equipment performance in tracking saturation changes	68
Figure GG.2 — Illustration of effect of different averaging times on fidelity	69
Figure GG.3 — Graphic representation of components of alarm system delay	70
Figure GG.4 — Illustration of the effects of different averaging times on a more rapid and noisier desaturation signal	71

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 shall not be held responsible for identifying any or all such patent rights.

ISO 9919 (IEC 60601-2-54) was prepared jointly by 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*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This second edition cancels and replaces the first edition (ISO 9919:1992), which has been technically revised.

Introduction

The approximation of arterial haemoglobin saturation and pulse rate using pulse oximetry is common practice in many areas of medicine. This International 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 committee's reasoning 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 **SpO₂ 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 **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.

This International Standard is a Particular Standard, based on IEC 60601-1:1988, including Amendments 1 (1991) and 2 (1995), hereafter referred to as the General Standard. The General Standard is the basic standard for the safety of all medical electrical equipment used by or under the supervision of qualified personnel in the general medical and patient environment; it also contains certain requirements for reliable operation to ensure safety.

The General Standard has associated Collateral Standards and Particular Standards. The Collateral Standards include requirements for specific technologies and/or hazards and apply to all applicable equipment, such as medical systems, EMC, radiation protection in diagnostic X-ray equipment, software, etc. The Particular Standards apply to specific equipment types, such as medical electron accelerators, high frequency surgical equipment, hospital beds, etc.

NOTE Definitions of Collateral Standard and Particular Standard can be found in IEC 60601-1:1988, 1.5 and A.2, respectively.

To facilitate the use of this International Standard, the following drafting conventions have been applied.

The changes to the text of IEC 60601-1:1988, the General Standard, as supplemented by the Collateral Standards, are specified by the use of the following words.

- “Replacement” means that the indicated clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.
- “Addition” means that the relevant text of this Particular Standard is a new element (e.g. subclause, list element, note, table, figure) additional to the General Standard.
- “Amendment” means that existing text of the General Standard is partially modified by deletion and/or addition as indicated by the text of this Particular Standard.

To avoid confusion with any amendments to the General Standard itself, a particular numbering has been employed for elements added by this International Standard: clauses, subclauses, tables and figures are numbered starting from 101; additional list items are lettered aa), bb), etc. and additional annexes are lettered AA, BB, etc.

In this International Standard, the following print types are used:

- requirements, compliance with which can be tested, and definitions: roman type;
- notes and examples: smaller roman type;
- description of type of document change, and test specifications: *italic type*;
- terms defined in Clause 2 of the General Standard IEC 60601-1:1988 or in this Particular Standard: **bold type**.

Throughout this Particular Standard, text for which a rationale is provided in Annex AA is indicated by an asterisk (*).

Medical electrical equipment — Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use

1 Scope

IEC 60601-1:1988, Clause 1 applies, except as follows.

Amendment (add at the end of 1.1):

This International Standard specifies particular requirements for the basic safety and essential performance of **pulse oximeter equipment** intended for use on humans. This includes any part necessary for **normal use**, e.g. the **pulse oximeter monitor**, **pulse oximeter probe**, **probe cable extender**.

These requirements also apply to **pulse oximeter equipment**, including **pulse oximeter monitors**, **pulse oximeter probes** and **probe cable extenders**, that has 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 on **patients** in healthcare institutions as well as on **patients** in home care.

* This International Standard is not applicable to **pulse oximeter equipment** intended for use in laboratory research applications nor to oximeters that requires a blood sample from the **patient**.

This International Standard is not applicable to **pulse oximeter equipment** solely intended for foetal use.

This International Standard is not applicable to remote or slave (secondary) devices that display **SpO₂** values that are located outside of the **patient environment**.

The requirements of this International Standard which replace or modify requirements of IEC 60601-1:1988 and its Amendments 1 (1991) and 2 (1995) are intended to take precedence over the corresponding general requirements.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 14155-1:2003, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14155-2:2003, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

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 15223:2000, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

Amendment 1:2002.

Amendment 2:2004.

IEC 60068-2-6:1995, *Environmental testing — Part 2-6: Tests — Test Fc. Vibration (sinusoidal)*

IEC 60068-2-27:1987, *Environmental testing — Part 2-27: Tests — Test Ea and guidance. Shock*

IEC 60068-2-32:1975, *Environmental testing — Part 2-32: Tests — Test Ed. Free fall*

Amendment 1:1982

Amendment 2:1990

IEC 60068-2-64:1993, *Environmental testing — Part 2-64: Test methods — Test Fh. Vibration, broad-band random (digital control) and guidance*

IEC 60079-4:1975, *Electrical apparatus for explosive gas atmospheres — Part 4: Method of test for ignition temperature*

Amendment 1:1995

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

IEC 60601-1:1988¹⁾, *Medical electrical equipment — Part 1: General requirements for safety*

Amendment 1:1991

Amendment 2:1995

IEC 60601-1-1:2000, *Medical electrical equipment — Part 1-1: General requirements for safety — Collateral standard: Safety requirements for medical electrical systems*

IEC 60601-1-2:2001, *Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-1-4:1996, *Medical electrical equipment — Part 1-4: General requirements for safety — Collateral Standard: Programmable electrical medical systems*

Amendment 1:1999

IEC 60601-1-6:2004, *Medical electrical equipment — Part 1-6: General requirements for safety — Collateral standard: Usability*

IEC 60601-1-8:2003, *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 60825-1:2001, *Safety of laser products — Part 1: Equipment classification, requirements and user's guide*

IEC 60825-2:2000, *Safety of laser products — Part 2: Safety of optical fibre communication systems (OFCS)*

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in IEC 60601-1:1988, Clause 2, as amended by the Collateral Standards, and the following apply.

NOTE For convenience, the sources of all defined terms used in this International Standard are given in Annex JJ.

1) Currently under revision as IEC/CDV 60601-1:2004.

3.1

accuracy

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

NOTE 1 See 50.101.2.2 for the method of calculating the **SpO₂ accuracy of pulse oximeter equipment**.

NOTE 2 See also discussion in Annex CC.

NOTE 3 Adapted from ISO 3534-1:1993.

3.2

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. See also Annex EE.

3.3

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, **SaO₂**, which **pulse oximeter equipment** estimates and reports as **SpO₂**.

3.4

data update period

interval in which the **pulse oximeter equipment** algorithm provides new valid data to the display or the **signal output port**

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.

3.5

declared range

that portion of the **displayed range** (3.7) of **SpO₂** and pulse rate values over which there is specified **accuracy**

3.6

demonstration mode

mode in which simulated **patient-numbers** or **patient-waveforms** are displayed

NOTE The display in the **demonstration mode** can be mistaken for real-time **patient** data if not properly identified.

3.7

displayed range

range of **SpO₂** and pulse-rate values that can be displayed by the **pulse oximeter equipment**

NOTE This range can extend beyond the **declared range** (3.5).

3.8

fractional oxyhaemoglobin

fractional saturation (obsolete)

FO₂Hb

oxyhaemoglobin concentration cO₂Hb divided by the **total haemoglobin concentration, ctHb**

NOTE 1 This is represented mathematically as:

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

where

cO_2Hb is the concentration of oxyhaemoglobin;

$ctHB$ is the concentration of total haemoglobin.

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

NOTE 2 **Fractional oxyhaemoglobin** is the term used by the National Committee for Clinical Laboratory Sciences (NCCLS) for this ratio.

NOTE 3 NCCLS denotes “concentration” by a prefixed letter c, while in the past the convention of square brackets, e.g. $[O_2Hb]$, was used.

NOTE 4 NCCLS^[5] uses the following notations:

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

3.9 functional oxygen saturation

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

NOTE 1 This is represented mathematically as:

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

NOTE 2 The NCCLS^[5] term for this ratio is haemoglobin oxygen saturation, and its notation is SO_2 .

3.10 functional tester

test device which presents **pulse oximeter equipment** with a signal having a predictable value of **ratio** (3.22) so that the **operator** can observe the resulting displayed value of **SpO_2** , and compare it to the expected value derived from the **manufacturer's** calibration curve for that particular **pulse oximeter equipment**

NOTE 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. See also FF.4.

3.11 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 $S_{R,i}$, or given by:

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

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

NOTE 2 See also **mean bias** (3.13) and discussion in Annex CC.

NOTE 3 Adapted from ISO 3534-1:1993.

3.12 manufacturer

natural or legal person with responsibility for the design, the manufacture, the packaging, the reprocessing, the marking, or the **accompanying documents of pulse oximeter equipment, pulse oximeter monitors, pulse oximeter probes, probe extender cables** or the adaptation of those items, regardless of whether these operations are carried out by that person him/herself or on his/her behalf by a third party

NOTE Adapted from IEC/CDV2 60601-1:2004, definition 3.54.

3.13 mean bias

B

mean difference between the test and reference values, preserving sign

NOTE 1 For **pulse oximeters**, this is represented mathematically as:

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

where

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

SpO_{2i} is the i th **SpO₂** datum;

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

NOTE 2 See also **local bias** (3.11) and discussion in Annex CC.

NOTE 3 When defined in this way, **mean bias** is the average of all **local bias** values, b_i .

3.14 normalized

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

3.15 operator settings

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

3.16 precision

closeness of agreement between independent test results obtained under stipulated conditions

NOTE 1 For **pulse oximeter equipment**, it is expressed as the standard deviation of the residuals, s_{res} , represented mathematically as:

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

where

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

$(\text{SpO}_{2i} - \text{SpO}_{2\text{fit},i})$ is the difference between the i th **SpO₂** datum and the value of the fitted curve corresponding to the i th reference oxygen saturation value, S_{Ri} .

NOTE 2 See also discussion in Annex CC.

NOTE 3 Adapted from ISO 3534-1:1993.

3.17

probe cable extender

cable that connects **pulse oximeter monitor** to **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**.

3.18

pulse oximeter equipment

medical electrical equipment for the non-invasive estimation of **functional oxygen saturation** of arterial haemoglobin (**SpO₂**) 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.

3.19

pulse oximeter monitor

part of the **pulse oximeter equipment** that encompasses the electronics, display and user interface, excluding the **pulse oximeter probe** and **probe cable extender**

NOTE The **pulse oximeter monitor** can consist of multiple pieces of hardware in separate locations, for example, a telemetry system in which the **applied part** and primary display are in physically different locations.

3.20

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.

3.21

pulse oximeter probe fault

abnormal condition of the **pulse oximeter probe** or **probe cable extender**, that, if not detected, could compromise **patient safety**

NOTE **Patient safety** can be compromised by providing incorrect values, by exposing the **patient** to high **pulse oximeter probe** temperatures or by introducing a risk of electric shock.

3.22 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 . See also FF.4.

3.23 * reprocessing

any activity, not specified in the **accompanying documents**, that renders a used product ready for re-use

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.

3.24 SaO_2

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

NOTE 1 See 50.101.2.2 for requirements on acceptable methods of measurement of SaO_2 .

NOTE 2 SaO_2 is **functional oxygen saturation** in arterial blood (see 3.9).

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

3.25 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 ^[56].

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

3.26 total haemoglobin concentration ctHb

sum of concentrations of all haemoglobin species including, but not limited to, oxyhaemoglobin (cO_2Hb), methaemoglobin ($cMetHb$), deoxyhaemoglobin ($cHHb$), sulfhaemoglobin ($cSuHb$) and carboxyhaemoglobin ($cCOHb$)

NOTE See also reference [16].

4 General requirements and requirements for tests

IEC 60601-1:1988, Clauses 3 and 4 apply, except as follows.

Addition:

4.101 Other test methods

The **manufacturer** may use type tests different from those detailed within this International Standard if a degree of safety and performance equivalent to that defined in this International Standard is obtained. In the event of dispute, the methods specified herein shall be used as the reference methods.

4.102 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 documents** performance levels better than those specified within this International Standard, these **manufacturer**-specified levels become the acceptance levels.

EXAMPLE For a specified level of **SpO₂ accuracy** of 1 %, the **pulse oximeter equipment** is required to have 1 % **SpO₂ accuracy** for all requirements, e.g. during EMC tests.

4.103 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 is intended to ensure 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 is intended to ensure 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. See also 6.8.2 aa) 11) and 6.8.2 aa) 12).

5 Classification

IEC 60601-1:1988, Clause 5 applies.

6 Identification, marking and documents

IEC 60601-1:1988, Clause 6 applies, except as follows.

6.1 Marking on the outside of equipment or equipment parts

Replacement:

d) *Minimum requirements for marking on **equipment** and on interchangeable parts*

If the size of the **pulse oximeter equipment** does not permit all the markings specified in this clause in the General Standard (IEC 60601-1:1988) and this International Standard, at least the following shall be marked on the **pulse oximeter equipment**:

- the name of the **manufacturer**; and
- a serial number (or Symbol 3.16 from ISO 15223:2000) or lot identifying number or batch identifying number (or Symbol 3.14 from ISO 15223:2000); and
- the words “Attention, consult **accompanying documents**” or Symbol ISO 7000-0434;
- if not provided with an **SpO₂** alarm, a statement to the effect “No SpO₂ Alarms” or Symbol IEC 60417-5319.

Replacement:

- f) Model or type reference
- a serial number (or Symbol 3.16 from ISO 15223:2000) or lot or batch (or Symbol 3.14 from ISO 15223:2000) identifying number
- detachable **pulse oximeter probes** shall be marked with type number and a batch (or Symbol 3.14 from ISO 15223:2000) or serial number (or Symbol 3.16 from ISO 15223:2000) on them or on the packaging as appropriate.
- **reprocessed pulse oximeter probes** shall be marked as such.

Addition:

aa) Displayed values

The **pulse oximeter monitor** shall display **functional oxygen saturation** in units of percent **SpO₂** and shall be marked as % **SpO₂** or **SpO₂**. Display of pulse rate shall be in units of reciprocal minutes (1/min), for example, beats/min. All other displayed measured values shall be marked in appropriate units

bb) Do not re-use

If the **pulse oximeter probe** is not for re-use, the package or the **pulse oximeter probe** itself shall be marked with an indication that the **pulse oximeter probe** is not for re-use, or with Symbol 3.2 from ISO 15223:2000.

If the **pulse oximeter probe** is for single **patient** use, the package or the **pulse oximeter probe** itself shall be marked with an indication that the **pulse oximeter probe** is for single **patient** use.

cc) Sterile

Packages shall be marked with Symbols 3.20 through 3.24 from ISO 15223:2000, where appropriate.

dd) Expiration date

Where appropriate, an indication of the time limit for safe use with Symbol 3.12 from ISO 15223:2000. The date shall be expressed as four digits for the year and two digits for the month and where appropriate, two digits for the day. The date shall be adjacent to the symbol.

ee) The **pulse oximeter monitor** and its parts shall be marked with regard to proper disposal, as appropriate.

6.8.1 General

Amendment, add after the first sentence:

The documents may be made available by electronic means provided that the **user** is afforded the opportunity to request the **accompanying documents** in paper form.

6.8.2 Instructions for use

Addition:

aa) Additional general information:

The instructions for use shall indicate the following:

- 1) that the **pulse oximeter equipment** is calibrated to display **functional oxygen saturation**;

- 2) 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.

- 3) any types of interference known to influence the function or **accuracies** of the **pulse oximeter equipment**;

EXAMPLES Ambient light (including photodynamic therapy); physical movement (**patient** and imposed motion); diagnostic testing; low perfusion; electromagnetic interference; electrosurgical units; dysfunctional haemoglobin; presence of certain dyes; inappropriate positioning of the **pulse oximeter probe**.

- 4) the **displayed ranges** of **SpO₂** and pulse rate;

- 5) description of the **data update period**, the effect of data averaging and other signal processing on the displayed and transmitted data values of **SpO₂** and pulse rate, along with the **alarm condition delay** and **alarm signal generation delay** in any selectable operating mode that affects these properties;

NOTE See also Annex GG for an example of how to assess and describe response time graphically.

- 6) if **physiological alarm conditions** are provided and automatic self-test of **alarm signal** generation is not provided, the method for **operator**-initiated testing of **alarm signal** generation;
- 7) if the **pulse oximeter equipment** requires in-service calibration, a suitable calibration procedure;
- 8) a description of the signal inadequacy indicator and its function. If there is a waveform, the 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 Clause 101.

- 9) if the **pulse oximeter equipment** is provided with adjustable **alarm limits**, the range of adjustment of the **alarm limits**;
- 10) if no **SpO₂** or pulse rate **alarm condition** is provided, a statement to that effect;
- 11) for **pulse oximeter monitors**, the **pulse oximeter probe(s)** with which the **pulse oximeter monitor** has been validated and tested for compliance with this International Standard. The list may be made available by electronic means (see also 4.103);
- 12) for **pulse oximeter probes** and **probe cable extenders**, the **pulse oximeter monitor(s)** with which they have been validated and tested for compliance with this International Standard. The list may be made available by electronic means (see also 4.103);
- 13) the recommended maximum application time for each type of **pulse oximeter probe** at a single site;
- 14) 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;
- 15) a description of the sequence of actions required by the **operator** for permitting temperatures greater than 41 °C (see 42.3);
- 16) the maximum temperature that can be obtained at the **pulse oximeter probe**-tissue interface if the **pulse oximeter equipment** is provided with an **operator**-adjustable control for permitting temperatures greater than 41 °C (see 42.3);

- 17) if the **pulse oximeter equipment** is provided with temperature capability such that the **pulse oximeter probe** can operate at greater than 41 °C, a statement to the effect that temperature settings greater than 41 °C shall not be used on patients less than one year of age.
- 18) all necessary information, as regards toxicity and/or action on tissues, about materials with which the **patient** or any other person can come into contact;
- 19) if **pulse oximeter probes** are delivered in sterile packaging, the instructions for use shall contain the necessary information regarding how to re-sterilize in the event of damage to the sterile packaging, if re-sterilization is permissible;
- 20) for each **pulse oximeter probe** and **probe cable extender**, a caution statement to the effect that probes and cables are designed for use with specific monitors. The user and/or operator needs to verify the compatibility of the monitor, probe, and cable before use, otherwise patient injury can result;
- 21) the specified use of the **pulse oximeter probe** regarding:
 - **patient** population (e.g. age, weight);
 - part of the body or type of tissue applied to; and
 - application (e.g. environment, frequency of use, location, mobility);
- 22) information concerning the disposal of the **pulse oximeter equipment** or components thereof.

6.8.3 Technical description

Addition:

aa) Additional general information:

The technical description shall include the following:

- 1) * 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** (see also Annex FF);
- 2) a statement to the effect that, if there is independent demonstration that a particular calibration curve is accurate for the combination of a **pulse oximeter monitor** and a **pulse oximeter probe**, then a functional tester can measure the contribution of a monitor to the total error of a monitor/probe system. The functional tester can then measure how accurately a particular **pulse oximeter monitor** is reproducing that calibration curve. See also Annex FF.

7 Power input

IEC 60601-1:1988, Clause 7 applies.

8 Basic safety categories

IEC 60601-1:1988, Clause 8 applies.

9 Removable protective means

IEC 60601-1:1988, Clause 9 applies.

10 Environmental conditions

IEC 60601-1:1988, Clause 10 applies, except as follows.

10.1 Transport and storage

Amendment (add at end of paragraph):

Packaging of sterile **equipment** or **equipment** parts shall ensure sterile conditions until opened or damaged or until its expiration date is reached.

Consideration should be given to the disposal of packaging waste.

11 Not used

12 Not used

13 General

IEC 60601-1:1988, Clause 13 applies.

14 Requirements related to classification

IEC 60601-1:1988, Clause 14 applies, except as follows.

14.6 Types B, BF and CF equipment

Amendment [add at the end of the list element c)]:

Applied parts of pulse oximeters shall be type BF or type CF applied parts.

15 Limitation of voltage and/or energy

IEC 60601-1:1988, Clause 15 applies.

16 Enclosures and protective covers

IEC 60601-1:1988, Clause 16 applies.

17 Separation

IEC 60601-1:1988, Clause 17 applies.

18 Protective earthing, functional earthing and potential equalization

IEC 60601-1:1988, Clause 18 applies.

19 Continuous leakage currents and patient auxiliary currents

IEC 60601-1:1988, Clause 19 applies, except as follows.

19.4 Tests

Amendment:

h) 9)

Replace the second sentence of the first paragraph "Alternatively...immersed" with:

Pulse oximeter probes marked for temporary immersion using the IP code second characteristic numeral 7 of IEC 60529 shall be **patient leakage current** tested as follows:

*Immerse that part of the **pulse oximeter probe** marked for temporary immersion in a normal saline (0,9 g/l NaCl in H₂O) solution that is maintained at a temperature between 20 °C and 25 °C, for 60 s. While the **pulse oximeter probe** is still immersed, measure **patient leakage current**.*

20 Dielectric strength

IEC 60601-1:1988, Clause 20 applies, except as follows.

20.4 Tests

Addition:

aa) **Pulse oximeter probes** marked for temporary immersion using the IP code second characteristic numeral 7 of IEC 60529 shall be dielectrically tested as follows:

*Immerse only that part of the **pulse oximeter probe** marked for temporary immersion in a normal saline (0,9 g/l NaCl in H₂O) solution that is maintained at a temperature between 20 °C and 25 °C. After 60 s and while that part of the **pulse oximeter probe** is still immersed, perform the tests for dielectric strength as specified in 20.4 a) of IEC 60601-1:1988.*

21 * Mechanical strength

IEC 60601-1:1988, Clause 21 applies, except as follows.

21.5

Amendment (add between "safety hazard" and "as a"):

and shall function normally

Addition:

21.101 * Shock and vibration

Pulse oximeter equipment or its parts not intended for use during **patient** transport outside a 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, **pulse oximeter equipment** shall not cause a **safety hazard** and shall function normally.

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

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

NOTE **Pulse oximeter equipment** tested and complying with the requirements in 21.5 of IEC 60601-1:1988 is considered to comply with this requirement.

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

- frequency range: 10 Hz to 2 000 Hz;
- resolution: 10 Hz;
- acceleration amplitude:
 - 10 Hz to 100 Hz: $1,0 \text{ (m/s}^2\text{)}^2\text{/Hz}$;
 - 100 Hz to 200 Hz: -3 db per octave;
 - 200 Hz to 2 000 Hz: $0,5 \text{ (m/s}^2\text{)}^2\text{/Hz}$;
- duration: 10 min per perpendicular axis (3 total).

21.102 * Shock and vibration for transport

Pulse oximeter equipment or its parts, intended for use during **patient** transport outside a 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, **pulse oximeter equipment** shall not cause a **safety hazard** and shall function normally.

NOTE **Equipment** tested and complying with the requirements in 21.102 in total or part, is considered to comply with the corresponding requirements of 21.101.

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

- peak acceleration: $1\,000 \text{ m/s}^2$ (102 g);
- 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, using the following conditions:

- frequency range: 10 Hz to 2 000 Hz;

- resolution: 10 Hz;
 - acceleration amplitude:
 - 10 Hz to 100 Hz: $5,0 \text{ (m/s}^2\text{)}^2\text{/Hz}$;
 - 100 Hz to 200 Hz: -7 db per octave ;
 - 200 Hz to 2 000 Hz: $1,0 \text{ (m/s}^2\text{)}^2\text{/Hz}$;
 - duration: 30 min per perpendicular axis (3 total).
- c) For **mobile pulse oximeter equipment**, free fall to IEC 60068-2-32, using Procedure 1 and the following conditions:
- height: 0,1 m;
 - number of falls: one;
 - direction: vertical, (normal operating position).
- d) For **portable pulse oximeter equipment**, free fall to IEC 60068-2-32, using Procedure 2 and the following conditions:
- height: 0,25 m;
 - number of falls: one;
 - direction: on each of the six surfaces.

For **portable pulse oximeter equipment** that is intended to be used with a carrying case, that case may be applied to the **equipment** during this test.

22 Moving parts

IEC 60601-1:1988, Clause 22 applies.

23 Surfaces, corners and edges

IEC 60601-1:1988, Clause 23 applies.

24 Stability in normal use

IEC 60601-1:1988, Clause 24 applies.

25 Expelled parts

IEC 60601-1:1988, Clause 25 applies.