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

Appareils électromédicaux — Règles particulières de sécurité et performances essentielles du matériel utilisé pour les oxymètres de pouls à usage médical

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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	
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

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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 SpO₂ as a function of reference S_R) 46

Figure CC.5 — Graphical representation for the definition of local bias and mean bias (Test sensor SpO₂ 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 (*continued*) 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.

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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 (*).

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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*

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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

c_{O_2Hb} is the concentration of oxyhaemoglobin;

c_{tHB} 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);
- sulfhaemoglobin (SuHb); and
- total haemoglobin (tHb).

3.9 functional oxygen saturation iTeh STANDARD PREVIEW
percentage saturation given by the oxyhaemoglobin concentration (c_{O_2Hb}) divided by the sum of the oxyhaemoglobin concentration and the deoxyhaemoglobin concentration (c_{HHb})
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NOTE 1 This is represented mathematically as:

$$\frac{100 \cdot c_{O_2Hb}}{c_{O_2Hb} + c_{HHb}}$$

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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 **SpO₂**, 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 **SpO₂** 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 **SpO₂ 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 (**SpO₂**) and an accepted reference value (**SaO₂**)

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 **SpO₂** 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:

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