INTERNATIONAL STANDARD

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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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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 **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 **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 **SpO_2** 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 60601-1:1988[1)], *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 **SpO_2 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, **SaO_2**, which **pulse oximeter equipment** estimates and reports as **SpO_2**.

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 **SpO_2** 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 **SpO_2** 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)
FO_2Hb
oxyhaemoglobin concentration cO_2Hb 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);

— sulfhaemoglobin (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 $\mathbf{SpO_2}$, 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 $\mathbf{SpO_2}$ 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 $\mathbf{SpO_2}$ **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 ($\mathbf{SpO_2}$) and an accepted reference value ($\mathbf{SaO_2}$)

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 $\mathbf{SpO_2}$ versus S_R, 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 ith 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:

$$B = \frac{\sum_{i=1}^{n} \left(\mathrm{SpO}_{2i} - S_{\mathrm{R}i} \right)}{n}$$

where

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

SpO_{2i} is the ith **SpO_2** datum;

$S_{\mathrm{R}i}$ is the ith 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:

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