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Pulse oximeters for medical use — Requirements

Oxymètres pulsés à usage médical — Prescriptions

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Contents

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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.

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.

International Standard ISO 9919 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Sub-Committee SC 3, *Lung ventilators and related equipment*.

Introduction

The approximate measurement of haemoglobin saturation through the use of pulse oximetry has become an increasingly common practice in many areas of clinical medicine. These include but are not limited to anaesthesia, respiratory therapy, paediatrics and intensive care. This International Standard specifies minimum safety requirements based on parameters that are believed to be achievable within the limits of existing technology.

Annex L contains a rationale for the most important requirements. It is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this International Standard.

Pulse oximeters for medical use — Requirements

Section 1: General

1.1 Scope

ISO 9919 is one of a series of International Standards based on IEC 601-1; in IEC 601-1 (the "General Standard"), this type of International Standard is referred to as a "Particular Standard". As stated in 1.3 of IEC 601-1:1988, the requirements of this International Standard take precedence over those of IEC 601-1.

The scope and object given in clause 1 of IEC 601-1:1988 apply except that 1.1 shall be replaced by the following:

This International Standard specifies requirements for the safety of pulse oximeters, as defined in 1.3.12, intended for use in the approximate measurement of the saturation of human arterial haemoglobin, non-invasively.

The field of application includes, but is not limited to

a) perioperative use;

b) adult critical care application;

c) paediatric and neonatal applications;

d) general determination of saturation on hospitalized and non-hospitalized patients.

Pulse oximeters intended for use in laboratory research applications and bench-type oximeters that require a blood sample from the patient are outside the scope of this International Standard.

1.2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 9703-1:1992, *Anaesthesia and respiratory care alarm signals — Part 1: Visual alarm signals.*

IEC 601-1:1988, *Safety of medical electrical equipment — Part 1: General safety requirements.*

IEC 801-2:1991, *Electromagnetic compatibility for industrial-process measurement and control equipment — Part 2: Electrostatic discharge requirements.*

1.3 Definitions

For the purposes of this International Standard, the definitions given in clause 2 of IEC 601-1:1988 apply, with the following additional definitions.

1.3.1 alarm: Warning signal.

1.3.2 alarm set-point: Setting of the adjustment control or display value which indicates the SpO_2, at or beyond which the alarm is intended to be activated.

NOTE 1 Terms such as "alarm limits" or "alarm threshold" are frequently used to describe the same function.

1.3.3 alarm system: Those parts of the pulse oximeter which

a) establish the alarm set-point(s);

b) activate an alarm when the SpO_2 is less than or equal to the low alarm set-point, if provided, or is equal to or greater than the high alarm set-point, if provided.

1.3.4 calibration range: Range of SpO_2 values over which the pulse oximeter has been tested and calibrated.

1.3.5 default setting; default limits: Parameters first active on power-up of the device.

1.3.6 display range: Range of SpO_2 values that may be indicated by the pulse oximeter.

1.3.7 display update period: Number of seconds or events, i.e. pulses, between possible changes in the displayed values.

1.3.8 fractional saturation: That saturation given by the oxyhaemoglobin divided by the total haemoglobin, represented mathematically as

$$\frac{O_2Hb}{Hb_{total}}$$

1.3.9 functional saturation: That saturation given by the oxyhaemoglobin divided by the sum of the oxyhaemoglobin and the deoxyhaemoglobin, represented mathematically as

$$\frac{O_2Hb}{(O_2Hb + HHb)}$$

1.3.10 probe: Component containing the applied part of the pulse oximeter intended to come in direct contact with the patient.

NOTE 2 With some pulse oximeters, the probe may be considered an accessory.

1.3.11 probe fault: Condition including, but not limited to, a probe component failure or the disconnection of the probe from either the pulse oximeter or from the patient.

1.3.12 pulse oximeter: Device for determination of saturation of haemoglobin non-invasively from light signals of at least two wavelengths transmitted through or reflected from tissues.

NOTE 3 The measurement principle depends on a changing signal caused by the pulsatile nature of blood flow.

1.3.13 SaO_2: Percent haemoglobin saturation with oxygen in systemic arteries.

1.3.14 SpO_2: Percent haemoglobin saturation with oxygen, either fractional or functional, as measured by a pulse oximeter and displayed as a percentage.

1.3.15 total Hb: Sum of all haemoglobin species including, but not limited to, O_2Hb, met Hb (methaemoglobin), HHb, and COHb (carboxyhaemoglobin).

1.4 General requirements

The requirements given in clause 3 of IEC 601-1:1988 apply with the following addition.

3.1.1 Packaging of equipment shall be of sufficient strength to ensure the intended use of the equipment.

3.1.2 For sterile equipment, packaging shall ensure sterile conditions until opened, damaged or until its expiration date is reached or exceeded.

3.10 Devices dependent on software shall be designed in such a way as to minimize the risks arising from errors in the program.

1.5 General requirements for tests

The requirements given in clause 4 of IEC 601-1:1988 apply with the following addition.

4.12 Test methods other than those specified in this International Standard but of equal or greater accuracy may be used to verify compliance with the requirements of this International Standard. However, in the event of dispute, the methods specified in this International Standard shall be used as the reference methods.

1.6 Classification

The requirements given in clause 5 of IEC 601-1:1988 apply except as follows.

In **5.6** delete all but "continuous operation".

1.7 Identification marking and documents

The requirements given in clause 6 of IEC 601-1:1988 apply with the following additions and modifications.

1.7.1 In **6.1**, replace item b) by the following.

If the size of the pulse oximeter does not permit the complete marking as specified throughout this clause, at least the following shall be marked on the pulse oximeter:

1) the name of the manufacturer;

2) a serial number, or lot- or batch-identifying number;

3) symbol number 14 in table DI of IEC 601-1:1988;

4) If not provided with a low SpO_2 alarm, the words "not for continuous monitoring".

1.7.2 In **6.1**, add the following to item f):

— a serial number, or other lot- or batch-identifying number;

— detachable applied parts shall be marked with type number and a batch or serial number on them or on the packaging as appropriate.

1.7.3 In **6.1**, add additional items as follows:

aa) Displays of percent saturation shall be marked as %SpO_2. All displayed measured values shall be marked in appropriate units.

bb) The package or the probe itself shall be marked if the probe is for "single use".

cc) Packages shall be marked with the word "sterile" where appropriate.

dd) Where appropriate, an indication of the time limit for completely safe use, expressed as the year and month, shall be given.

1.7.4 Clause **6.7** of IEC 601-1:1988 shall apply with the following modification.

Dot matrix, alphanumeric displays, and computer-generated graphics are not considered to be indicator lights. Compliance shall be checked by functional tests and inspections.

1.7.5 In **6.8.2**, add the following items:

The instructions for use shall additionally include the following information:

i) Additional information

1) If the pulse oximeter is provided with adjustable alarm limits, the range of adjustment.

2) Appropriate methods of disinfection and/or sterilization of both the probe and the body of the pulse oximeter, where applicable. If probes are delivered in sterile packaging, the instructions for use shall contain the necessary information regarding how to re-sterilize or dispose of the probe in the event of damage to the sterile packaging and/or the probe.

3) The display update period of the pulse oximeter and the conditions under which it was determined.

4) The calibration range of the pulse oximeter.

5) The display range of the pulse oximeter.

6) Any types of interference known to influence the function of the pulse oximeter at the time that the instructions for use were prepared.

NOTE 4 Typical causes of interference include, but are not limited to, ambient light, movement, electromagnetic interference, artifacts, dysfunctional haemoglobin, and certain dyes.

7) A warning to the effect that the pulse oximeter may interfere with magnetic resonance imaging (MRI) procedures.

8) If the pulse oximeter requires in-service calibration, a suitable calibration procedure.

9) The means to accomplish alarm silencing, for example, during probe disconnection, probe off the finger, etc. and method for manual self-testing of the alarm circuitry if an automatic self-test is not provided.

10) If applicable, the default limits for the alarm(s) or any other user-adjustable controls which are set when the pulse oximeter is switched on.

11) Whether the pulse oximeter is calibrated to display functional or fractional saturation.

12) If the pulse oximeter displays a visual indication of the patient's pulse (e.g. by waveform or straight bar graph), a statement of whether or not that display is proportional to the pulse volume.

13) If no low SpO_2 alarm is provided, directions not to use the pulse oximeter for continuous monitoring.

14) The accompanying documents shall specify probes which may be used with the pulse oximeter.

15) Parts in contact with the patient: the manufacturer shall also state in the accompanying documents the recommended application time for each probe at a single site.

16) Accuracy: the accuracy and the range of haemoglobin saturation with oxygen over which the accuracy of the pulse oximeter is claimed shall be disclosed. The manufacturer shall also disclose whether the calibration was to functional or fractional saturation. Test methods shall be available from the manufacturer upon request.

If measurement of pulse rate is provided, the manufacturer shall disclose in the accompanying documents the accuracy of the pulse rate measurement, and the range over which accuracy is claimed. The test

methods shall be available from the manufacturer on request.

17) The instructions for use shall include all necessary information about materials with which the patient or user may come into contact, as regards toxicity and/or action on tissues.

18) The characteristics of alarms provided.

19) If unusual risks are related to the disposal of the equipment or parts thereof including batteries and/or rechargeable batteries, the manufacturer shall specify those items in the instructions for use. There will be an additional statement as to whether the manufacturer is able to dispose of the listed items.

20) If applicable, the manufacturer shall list relevant certifications and state the date of their authorizations.

1.8 Power point

The requirements given in clause 7 of IEC 601-1:1988 apply.

Section 2: Environmental conditions

2.1 Basic safety categories

The requirements given in clause 8 of IEC 601-1:1988 apply.

2.2 Removable protective means

The requirements given in clause 9 of IEC 601-1:1988 apply.

2.3 Environmental conditions

The requirements given in clause 10 of IEC 601-1:1988 apply.

2.4 Special measures with respect to safety

Not used.

2.5 Single fault condition

Not used.