INTERNATIONAL STANDARD

ISO 7767

Second edition
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Oxygen monitors for monitoring patient breathing mixtures — Safety requirements

Analyseurs d'oxygène pour le contrôle des mélanges gazeux respirés par le patient — Exigences de sécurité

Reference number
ISO 7767:1997(E)

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 7767 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment,* Subcommittee 3, *Lung ventilators and related equipment.*

This second edition cancels and replaces the first edition (ISO 7767:1988), which has been technically revised.

Annex N forms an integral part of this International Standard. Annexes O and P are for information only.

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Introduction

ISO 7767 is one of a series of standards developed for specific medical electrical equipment (a Particular Standard) based on IEC 601-1:1988, *Medical electrical equipment - Part 1: General requirements for safety* (The General Standard). ISO 7767:1988 referenced the first edition of IEC 601-1 published in 1977 and this International Standard references the second edition, published late in 1988.

Annex O provides a rationale for specific requirements.

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Section 1: General

1.1 Scope

ISO 7767 is one of a series of International Standards based on 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 given in clause 1 of IEC 601-1:1988 applies except that **1.1** shall be replaced by the following:

This International Standard specifies safety requirements for oxygen monitors, as defined in clause 1.3.14, intended for use in determining the oxygen level in gas mixtures. Both diverting and non-diverting oxygen monitors are covered.

The field of application includes, but is not limited to:

a) anaesthetic machines and breathing systems;
b) ventilators;
c) infant incubators;
d) oxygen concentrators.

Devices that do not "measure and indicate" are not intended to be covered by this International Standard. For instance, a device that has no function other than to signal an alarm at a specific oxygen level would not be considered to be an oxygen monitor for use in direct patient monitoring applications.

The phrase "in a gaseous mixture" implies that devices that measure or monitor oxygen in a liquid phase (for example, blood gas analyzer or indwelling catheters) are not covered by this International Standard.

Oxygen monitors intended for use in laboratory research applications 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 agreement based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the standards listed below:

ISO 5356-1:1996, *Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets.*

ISO 5356-2:1996, *Anaesthetic and respiratory equipment -Conical connectors - Part 2: Screw-threaded weight-bearing connectors.*

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

ISO 9703-2:1994, *Anaesthesia and respiratory care alarm signals - Part 2: Auditory alarm signals.*

IEC 79-3:1990, *Electrical apparatus for explosive gas atmospheres - Part 3: Spark test apparatus for explosive gas atmospheres.*

IEC 79-4:1975, *Electrical apparatus for explosive gas atmospheres - Part 4: Method of test for ignition temperature.*

IEC 601-1:1988, *Medical electrical equipment - Part 1: General requirements for safety.*

IEC 601-1-2:1993, *Medical electrical equipment — Part 1: General requirements for safety. 2. Collateral standard: Electromagnetic compatibility - Requirements and tests.*

1.3 Definitions

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

1.31.1 alarm: Warning signal of an alarm system.

1.31.2 alarm set-point: Setting of the adjustment control or display value which indicates the oxygen level at or beyond which the alarm is intended to be activated (indicated alarm limit).

1.3.3 alarm system: Those parts of the oxygen monitor which a) establish the alarm set point(s); b) activate an alarm when the oxygen level is less than or equal to the low alarm set-point, or is equal to or greater than the high alarm set-point.

1.3.4 default (alarm or setting): Those operating parameters within the system which are preset at the factory or by the operator and which the system itself sets, without further intervention, when it is turned on.

1.3.5 delay time: With respect to a step change in oxygen concentration or partial pressure at the sampling site, the time required for the monitor to register 10 % of the step change.

1.3.6 display: Device that visually indicates quantitative or qualitative information.

1.3.7 diverting oxygen monitor: Oxygen monitor which transports the gas mixture from the sampling site to the sensing area.

1.3.8 expected service life: Period during which the performance of an oxygen monitor or any of its components is expected to meet the requirements of this International Standard when used and maintained according to the accompanying documents.

1.3.9 high priority alarm: Combination of auditory and visual signals indicating that immediate operator response is required.

1.3.10 interference with measurement accuracy: Difference between the oxygen reading in the presence of an interfering gas mixture and the oxygen reading in a corresponding mixture in which the interfering gas or vapour fraction has been replaced by nitrogen.

1.3.11 low priority alarm: Visual signal, or combination of auditory and visual signals, indicating that prompt operator response is required.

1.3.12 medium priority alarm: Combination of auditory and visual signals indicating that prompt operator response is required.

1.3.13 oxygen level: Concentration of oxygen in a gaseous mixture expressed as volume fraction in percent (*V/V*) or as partial pressure (in kilopascals).

1.3.14 oxygen monitor: Device that measures and indicates the oxygen level in a gaseous mixture.

1.3.15 oxygen reading: Measured oxygen level as indicated by the oxygen monitor.

1.3.16 oxygen (or other gases) % (*V/V*): Level of oxygen (or other gas) in a mixture expressed as volume fraction in percent.

1.3.17 partial pressure: Pressure that each gas in a gas mixture could exert if it alone occupied the volume of the mixture at the same temperature.

1.3.18 response time: Time required for an oxygen monitor to achieve a 90 % change to a step function (delay response to a step change in oxygen level plus rise time).

1.3.19 rise time: Time for an oxygen monitor to change from 10 % to 90 % of a step function.

1.3.20 sensing area: Part of the sensor at which oxygen is detected.

1.3.21 sensor: Part of the oxygen monitor which is sensitive to the presence of oxygen.

1.3.22 shelf life: Period during which the oxygen monitor or any of its components are stored in its original container under conditions in accordance with the accompanying documents.

1.4 General requirements and general requirements for tests

Clauses 3 and 4 of IEC 601-1:1988 apply, together with the following additions:

3.6 Add the following text:

3.6 i) short and open circuits of the sensor and associated circuitry which increase temperature

3.6 j) An oxidant leak which is not detected, by e.g. an alarm or periodic inspection, shall be considered a normal condition and not a single fault condition.

4.5 Add the following text:

For reference tests a temperature of (23 ±2) °C, relative humidity of (60 ±15) % and atmospheric pressure between 68 kPa and 108 kPa shall be used.

Add the following section:

4.12 Other test methods

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

1.5 Classification

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

1.6 Identification, marking and documents

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

6.1 d) Replace the text in item d) by the following:

If the size of the oxygen monitor does not permit the complete marking as specified throughout this clause, at least the following shall be marked on the oxygen monitor: the name of the manufacturer and the serial number; and symbol number 14 given in table D.1 of IEC 601-1:1988.

6.1 q) Add the following text:

Oxygen monitors not meeting the requirements of section 8.2 (51.8.1) shall be marked with the words, "Not for use in breathing systems".

Add additional items as follows:

Oxygen monitors not meeting the requirements of section 11.1 (60.1 a.) shall be marked with the words "Not for use with inhalation anaesthetic agents".

If moisture affects the accuracy of the oxygen measurement, then the monitor shall be marked with symbol number 14 given in table D.1 of IEC 601-1:1988..

The alarm set-point of the oxygen level shall be marked, if the oxygen monitor is provided with a non-adjustable oxygen level alarm.

If the oxygen monitor or parts thereof are suitable for use in an MRI environment, they shall be so marked.

6.3 Add the following text:

6.3 g) Oxygen level displays shall be in percent (volume fraction) or in kilpascals.

6.8.2 a) Add the following to item a):

The instructions for use shall additionally include the following information:

1) A description of the purpose and intended use of the oxygen monitor.

2) A description of the principles of operation of the oxygen monitor, including the relationship between gas concentration and its partial pressure and the effects of humidity.

3) A detailed specification including the following:

- the oxygen level measurement range and the accuracy of measurement [see 8.2 (51.5, 51.5.1, 51.6.1 and 51.6.2)];
- the stability of measurement accuracy [see 8.2 (51.7.1 and 51.7.2)];
- the response time [see 11.5 (65.1)];
- the oxygen level alarm range and its accuracy [see 8.2 (51.9)];

- for diverting oxygen monitors, the range of diversion flows]see 11.3 (62.3)];
- time from switching on to obtaining specified operating performance.

4) Information about any effect on stated function due to the following:

- humidity or condensation including, for example, any adverse effects if an adaptor is provided to improve the function of the sensor in the presence of condensation or particulate water [see 8.2 (51.6.2)];
- interfering gases or vapours [see 11.1 (60.1)];
- cyclic pressure [see 8.2 (51.8)];
- barometric pressure or pressure at the site of use of the oxygen monitor;

5) Over the expected lifetime specified by the manufacturer, the accuracy requirements specified in 8.2 (51.5 through 51.8) and the response-time requirements in 11.5 shall be met under the conditions specified in this International Standard.

6) The expected service life of other expendable components of the oxygen monitor (e.g. batteries).

7) Instructions for pre-use checking and calibration.

8) Operational details for oxygen monitor or parts thereof which are marked suitable for use in an MRI environment.

1.7 Power input

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

Not used.

2.3 Environmental conditions

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

Section 3: Protection against electric shock hazards

3.1 General

The requirements given in clause 13 of IEC 601-1:1988 apply.

3.2 Requirements related to classification

The requirements given in clause 14 of IEC 601-1:1988 apply.

3.3 Limitation of voltage and/or energy

The requirements given in clause 15 of IEC 601-1:1988 apply.

3.4 Enclosures and protective covers

The requirements given in clause 16 of IEC 601-1:1988 apply.

3.5 Separation

The requirements given in clause 17 of IEC 601-1:1988 apply.

3.6 Protective earthing, functional earthing and potential equalization

The requirements given in clause 18 of IEC 601-1:1988 apply.

3.7 Continuous leakage currents and patient auxiliary currents

The requirements given in clause 19 of IEC 601-1:1988 apply, with the following additions.

19.1 e) Add the following text:

The patient leakage current shall be measured at the following positions:

- for non-diverting oxygen monitors, at the oxygen sensor;
- for diverting oxygen monitors, at the connection port of the sampling tube.

3.8 Dielectric strength

The requirements given in clause 20 of IEC 601-1:1988 apply.

Section 4: Protection against mechanical hazards

4.1 Mechanical strength

The requirements given in clause 21 of IEC 601-1:1988 apply.

4.2 Moving parts

The requirements given in clause 22 of IEC 601-1:1988 apply.

4.3 Surfaces, corners and edges

The requirements given in clause 23 of IEC 601-1:1988 apply.

4.4 Stability in normal use

The requirements given in clause 24 of IEC 601-1:1988 apply.

4.5 Expelled parts

The requirements given in clause 25 of IEC 601-1:1988 apply.

4.6 Vibration and noise

The requirements given in clause 26 of IEC 601-1:1988 apply with the following addition:

1) Vibration and noise shall be limited to non-hazardous levels.

4.7 Pneumatic and hydraulic power

Under consideration.

4.8 Suspended masses

The requirements given in clause 28 of IEC 601-1:1988 apply.