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.

International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet central@iso.ch
X.400 c=ch; a=400net; p=iso; o=isocs; s=central

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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.

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.

Section 5: Protection against hazards from unwanted or excessive radiation

5.1 X-radiation

The requirements given in clause 29 of IEC 601-1:1988 apply.

5.2 Alpha, beta, gamma, neutron radiation and other particle radiation

Under consideration.

5.3 Microwave radiation

Under consideration.

5.4 Light radiation (including lasers)

Under consideration.

5.5 Infrared radiation

Under consideration.

5.6 Ultraviolet radiation

Under consideration.

5.7 Acoustical energy (including ultrasonics)

Under consideration.

5.8 Electromagnetic compatibility

The requirements given in clause 36 of IEC 601-1:1988 apply, with the following addition:

36.1 The requirements given in IEC 601-1-2 apply.

Section 6: Protection against hazards of ignition and flammable anaesthetic mixtures

6.1 Locations and basic requirements

The requirements given in clause 37 of IEC 601-1:1988 apply, with the following additions:

Anaesthetic agents which are ignited by the test in annex P of this International Standard are classified as flammable anaesthetic agents.

Oxygen monitors specified for use with flammable anaesthetic agents shall be classified and marked as CATEGORY APG EQUIPMENT and shall comply with the requirements of APG EQUIPMENT in IEC 601-1:1988.

NOTE: For example diethyl ether and cyclopropane are such flammable anaesthetic agents and halothane is a nonflammable anaesthetic agent.

6.2 Marking, accompanying documents

The requirements given in clause 38 of IEC 601-1:1988 apply.

6.3 Common requirements for category AP and category APG equipment

The requirements given in clause 39 of IEC 601-1:1988 apply.

6.4 Requirements and tests for category AP equipment, parts and components thereof

The requirements given in clause 40 of IEC 601-1:1988 apply.

6.5 Requirements and tests for category APG equipment, parts and components thereof

The requirements given in clause 41 of IEC 601-1:1988 apply.

Section 7: Protection against excessive temperatures and other safety hazards

7.1 Excessive temperatures

The requirements given in clause 42 of IEC 601-1:1988 apply.

7.2 Fire prevention

The requirements given in clause 43 of IEC 601-1:1988 apply, with the following addition:

In order to reduce the risk to patients, other persons or the surroundings due to fire, ignitable material, under normal and single fault conditions, shall not, at the same time, be subjected to conditions in which:

- the temperature of the material is raised to its minimum ignition temperature, and
- an oxidant is present.

The minimum ignition temperature is determined in accordance with IEC 79-4 using the oxidizing conditions present under normal and single fault conditions. Compliance is checked by determining the temperature to which the material is raised under normal and single fault condition.

If sparking can occur under normal or single fault conditions, the material subjected to the energy dissipation of the spark shall not ignite under the oxidizing conditions present. Compliance is checked by observing if ignition occurs under the most unfavourable combination of normal conditions with a single fault.

7.3 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection

The requirements given in clause 44 of IEC 601-1:1988 apply.

7.4 Pressure vessels and parts subject to pressure

Not applicable.

7.5 Human errors

Not used.

7.6 Electrostatic charges

Not used.

7.7 Materials in applied parts in contact with body of patient

Not used.

7.8 Interruption of power supply

The requirements given in clause 49 of IEC 601-1:1988 apply.

Section 8: Accuracy of operating data and protection against hazardous output

8.1 Accuracy of operating data

The requirements given in clause 50 of IEC 601-1:1988 apply.

8.2 Protection against hazardous output

The requirements given in clause 51 of IEC 601-1:1988 apply, with the following additions:

51.5 Measurement accuracy

The difference between the mean oxygen reading and the oxygen level shall be within ±3 % (*V/V*) over the range specified in table 1. Compliance shall be checked by the test given in 51.5.3.

51.5.1 Display range

The oxygen reading displayed on a digital display shall not be limited to 100 %. If digital displays are used, there shall be an indication when the overrange value exceeds 99 (two-digit display) or 100 (three-digit display), plus the monitor error. Compliance shall be checked by the test given in 51.5.2.

51.5.2 Display range test method

Compliance shall be checked by simulating the appropriate out-of-range condition.

51.5.3 Oxygen level test method

Oxygen readings are taken at a number of oxygen levels spanning the oxygen monitor measurement range.

Test gases of a composition accuracy equal to or better than 1/5 of the tolerance of the requirements stated in 51.5 as determined by gravimetric methods shall be used for these tests. Alternative methods of certifying gas composition accuracy may be substituted for the gravimetric method if the alternative method can be shown to be equivalent to or better than the gravimetric method.

51.5.3.1 Dry gas

The oxygen monitor shall be set up in accordance with the accompanying documents and tested using the dry test gas mixtures given in table 1, under the conditions stated in 1.4.

Table 1 — Dry gas mixtures

Oxygen % (*V/V*) (Balance nitrogen)
15
21
40
60
100

51.5.3.2 Water-saturated gas

This requirement does not apply to oxygen monitors intended solely for use in dry gas mixtures.

The oxygen monitor shall be set up in accordance with the accompanying documents.

Operate the monitor in accordance with the manufacturer's instructions for a minimum of 1 h using gas saturated at (37 ±3) °C.

At the end of this period, perform an accuracy test using the gas mixtures given in table 2 (with a dry gas accuracy specified in 51.5.3) saturated at (37 ±3) °C.

Table 2 — Water-saturated gas test mixtures

Oxygen % (*V/V*) (Balance nitrogen)
15
21
40
60
100

Oxygen monitors shall maintain the accuracy required in 51.5 after readings are corrected for volumetric changes caused by humidity as specified in the accompanying documents.

51.6 Drift of measurement accuracy

The oxygen monitor shall meet the requirements specified in 51.5 for a minimum of 8 h when used in accordance with the accompanying documents.

Compliance shall be checked by the test given in 51.6.1

51.6.1 Water-saturated gas

This requirement does not apply to oxygen monitors intended solely for use in dry gas mixtures.

Continue to operate the oxygen monitor as specified in 51.5.3.2, sampling for gas test mixtures in table 2 every 2 h for a minimum of 8 h.

51.6.2 Dry gas

If the oxygen monitor is tested by the method in 51.6.1, this subclause does not apply.

The oxygen monitor shall be set up in accordance with the accompanying documents and using ambient conditions described in 51.5.3.1. Connect the oxygen monitor to a supply of dry air at (23 ± 2) °C.

Operate the monitor for a minimum of 1 h.

At this time, perform an accuracy test using the dry gas method as described in 51.5.3.1 and using the test gas mixtures given in table 1.

Continue to operate for a minimum of 8 h, repeating the accuracy test every 2 h.

51.7 Pressure effects

51.7.1 General

Oxygen monitors shall either:

a) meet the requirements given in 51.5 following exposure of the sampling site to a nominal positive pressure of 10 kPa (100 cmH_2O) and a nominal negative pressure of 1,5 kPa (15 cmH_2O) for 5 s each for 20 cycles:

or

b) be marked with a warning "NOT FOR USE IN BREATHING SYSTEMS" and a similar warning shall appear in the accompanying documents (see Section 6).

Compliance shall be checked by the test given in 51.7.2.

51.7.2 Test for pressure effects

51.7.2.1 Principle

The accuracy of the oxygen monitor is determined after exposure of the sensor to pressure cycling.

51.7.2.2 Procedure

Cycle the pressure at the sampling site between a positive pressure with respect to ambient of (10 ± 1) kPa [(100 ± 10) cmH_2O] and a negative pressure with respect to ambient of (1,5 ± 0,2) kPa [(15 ± 2) cmH_2O] for not less than 5 s each. Repeat this procedure 20 times, then carry out the test for measurement accuracy using the dry gas method as described in 51.5.3.1 using the gases listed in table 1.

51.8 Alarms

51.8.1 Alarm annunciation shall comply with the requirements of ISO 9703-1 and ISO 9703-2.

51.8.2 The set points of adjustable alarms shall be indicated continuously or on operator demand.

51.8.3 If a means of temporarily silencing the auditory alarm(s) is provided, this silencing shall not exceed 120 s.

51.8.4 If provided, a remote alarm extension shall be arranged so that a failure in the remote circuit will not affect the correct functioning of the local alarm.

51.8.5 The oxygen monitor shall have a low-oxygen alarm set point. The low-oxygen alarm set point shall not have a default setting lower than 18 %. If, by special provision, the low-oxygen alarm set point can be set below 18 % (*V/V*), there shall be a separate continuous visual indication when the monitor is so set.

51.8.6 The low- and high-oxygen alarms shall activate for:

a) low-oxygen alarm: oxygen readings less than or equal to the low-oxygen alarm set point.

b) high-oxygen alarm (if provided): oxygen readings greater than or equal to the high-oxygen alarm set point.

A low-oxygen alarm shall cause at least a medium-priority annunciation. A high-oxygen alarm (if provided) shall cause at least a medium-priority annunciation.

51.8.7 If alarm parameters are adjustable by the operator, means shall be provided to prevent unintentional change of such adjustable settings.

NOTE: Prevention of unintentional change may be achieved by a deliberate sequence of operator actions, a recess or guard over the control.

51.8.8 Compliance shall be checked by inspection and by simulation of the alarm conditions in accordance with the accompanying documents.

51.9 Function and position of controls

Check or test controls which validate battery condition or signal operation and signal override shall automatically return from the check or test position.

Calibration controls shall include means to prevent an inadvertent change from the intended position.

Section 9 - Abnormal operation and fault conditions; environmental tests

9.1 Abnormal operation and fault conditions

The requirements given in clause 52 of IEC 601-1:1988 apply.

9.2 Environmental tests

The requirements given in clause 53 of IEC 601-1:1988 apply.

Section 10 - Constructional requirements

10.1 General

The requirements given in clause 54 of IEC 601-1:1988 apply.

10.2 Enclosures and covers

Not used.

10.3 Components and general assembly

The requirements given in clause 56 of IEC 601-1:1988 apply.

10.4 Mains parts, components and layout

The requirements given in clause 57 of IEC 601-1:1988 apply.

10.5 Protective earthing — Terminals and connections

The requirements given in clause 58 of IEC 601-1:1988 apply.

10.6 Construction and layout

The requirements given in clause 59 of IEC 601-1:1988 apply.

Section 11 - Additional requirements

11.1 Interfering gas and vapour effects

11.1.1 Interference with measurement accuracy

Oxygen monitors shall either:

a) have not more than 2 % (*V/V*) oxygen interference with measurement accuracy in the presence of any of the gases or vapours at the levels listed in table 3, or

b) if the body of the oxygen monitor is marked "Not for use with inhalation agents" or equivalent, the oxygen monitor shall not have more than 2 % (*V/V*) oxygen interference with measurement accuracy in the presence of helium or carbon dioxide at the levels listed in table 3. If the oxygen interference is greater than 1 % (*V/V*) this shall be stated in the accompanying documents.

Compliance shall be checked by the test given in 11.1.2.

Table 3 — Inhalation anaesthetics and other interfering gases and vapours

Gas or vapour level (Balance: mixture of 30 % O_2/70 % N_2O, except where noted)	
Helium	50 %, balance O_2
Carbon dioxide	5 %
Nitrous oxide (N_2O)	80 %, balance O_2
Halothane	4 %
Enflurane	5 %
Isoflurane	5 %
Sevoflurane	5 %
Desflurane	15 %
Nitric oxide (NO)	50 ppm in a balance of 30 % O_2 /70 % N_2 (see NOTE)
Diethyl ether	20 % (APG only)

NOTE: The NO and O_2 components of the mixture must be introduced in such a manner as to minimize the formation of NO_2 at the measuring point.

11.1.2 Compliance tests

11.1.2.1 Principle

Determination of the accuracy of the oxygen reading in the presence of interfering gases and vapours given in table 3.

11.1.2.2 Test gases

Use dry premixtures of 30% oxygen and 70% nitrous oxide and the interfering gas or vapour at the level given in table 3, the oxygen levels being known to within ± 0,6 % (*V/V*).

11.1.2.3 Procedure

Carry out the test described in 51.5.3.1 with the following modification:

Expose the sensing area to the test gas for a continuous period of 2 h, ensuring that both the oxygen monitor and the oxygen sensor are maintained in the same condition during the whole period. Repeat the procedure for each applicable mixture given in table 3.

11.1.2.4 Expression of results

Correct the oxygen readings for changes in barometric pressure, if the errors due to this effect equal or exceed ± 0,1 % (*V/V*) oxygen, and report the corrected readings.

11.2 Contamination of breathing systems

In a diverting oxygen monitor, means shall be provided to prevent contamination of the breathing system.

11.3 Gas leakage and sampling loss

11.3.1 Requirement: the rate of leakage of a non-diverting oxygen monitor shall not be greater than 20 ml/min.

NOTE: This requirement ensures that, when fitted to a breathing system, the rate of leakage at a continuous pressure of 3 kPa (30 cmH_2O) does not increase by more than 20 ml/min.

Compliance shall be checked by the test given in 11.3.2.2. The accuracy shall be tested as described in 11.3.1.1 and 11.3.1.2.

11.3.1.1 Apparatus: a pressure gauge having an accuracy within ± 0,3 kPa and a flowmeter having an accuracy with ± 2 ml/min shall be used.

11.3.1.2 Procedure: assemble the oxygen monitor so that the oxygen sensor is installed in a dimensionally suitable port of a test apparatus containing an inlet fitting to which a test gas and air flowmeter are attached. Connect the pressure gauge to a third port of the test apparatus. Slowly open the flowmeter to raise the pressure in the test apparatus to 3 kPa. Determine the flowrate necessary to maintain this pressure. This leakage flow shall be as specified in 11.3.1.

11.3.2 Requirement: the rate at which a diverting oxygen monitor withdraws gas from a breathing system (the gas diversion rate) shall not exceed 1,15 times the value stated in the accompanying documents.

Compliance shall be checked by the test described in 11.3.2.1 to 11.3.2.4.

11.3.2.1 Principle: measurement of the rate at which a diverting (intermittent) oxygen monitor withdraws gas from a simulated breathing system.

11.3.2.2 Test gas: pressurized air at room temperature.

11.3.2.3 Apparatus:

1) pressure gauge having an accuracy within ± 0,3 kPa;

2) flowmeter having an accuracy to within ± 2 % of the rate at which the oxygen monitor withdraws gas from the breathing system as stated in the accompanying documents;

3) exhaust port, to collect or route the diverted gas from the oxygen monitor, which is incompatible with the inlet port of the oxygen monitor.

11.3.2.4 Procedure: assemble the apparatus as described in 11.3.3.3. Adjust the pressurized air source to 3 kPa and monitor the flowmeter reading for 1 min.

11.4 Connections

If an oxygen sensor is intended to be connected to the breathing system through a T-piece, the breathing system connection ports of the T-piece shall be 15 mm and/or 22 mm conical connectors in accordance with ISO-5356-1 or ISO 5356-2.

If the oxygen sensor is mounted directly into the T-piece, the oxygen sensor connection port of the T-piece shall not be interchangeable with the breathing system connection ports of the T-piece.

The sampling gas and outlet ports of a sampling oxygen monitor shall not be interchangeable with the breathing system connection port or with the oxygen sensor connection port.

11.5 Response time

11.5.1 Requirement

The response time shall not be greater than 1,15 times the value stated in the accompanying documents.

Compliance shall be checked by the test described in 11.5.2.

11.5.2 Test method

11.5.2.1 Principle: measurement of the time taken for the oxygen monitor to respond to changes in oxygen level at the sensing area.

11.5.2.2 Test gases: two mixtures of oxygen and nitrogen that contain levels of oxygen equal to 95 % to 100 % of the full-scale oxygen reading and between 20 % and 25 % of the full-scale oxygen reading indicated on the oxygen monitor.

NOTE: If a reading of 21 % (*V/V*) oxygen lies within the required range, room air or compressed air may be used as the test gas mixture.

11.5.2.3 Procedure: Hold the ambient temperature of the oxygen monitor and the temperature of the test gas mixtures delivered to the sensing area constant to within ± 1 °C of a nominal value within the operating temperature range specified in the accompanying documents.

NOTE: The test gas mixture need not be at ambient temperature.

Calibrate the oxygen monitor at its full-scale reading as described in the accompanying documents.

Deliver the test gas mixture to the sensing area at ambient barometric pressure. Ensure that the oxygen sensor is in equilibrium with the test gas mixture and that the oxygen monitor is at ambient temperature.

Expose the sensing area to a test gas mixture with an oxygen level concentration of 95 % to 100 % of the full-scale oxygen reading. After a period of at least three times the response time as stated in the accompanying documents, record the oxygen reading indicated by the oxygen monitor (R_1). Expose the sensing area to a test gas mixture with an oxygen level concentration of 20% to 25% of the full-scale oxygen reading. After a period of at least three times the response time as stated in the accompanying documents, record the oxygen reading indicated by the oxygen monitor (R_2). With the oxygen monitor measuring R_2, re-expose the sensing area to the 95% to 100% full-scale oxygen reading test gas mixture. Measure the interval from the time at which the oxygen reading is 10% of the change above the initial reading (R_3) to the time at which the oxygen reading is 90% of the change above the initial oxygen reading that is, when the oxygen reading (R_4) is:

$R_4 = R_3 + (0,9\,[R_1 - R_2])$
$R_3 = R_2 + (0,1\,[R_1 - R_2])$

Finally, with the oxygen monitor measuring R_4, re-expose the sensing area to the 20 % to 25 % full-scale oxygen reading test gas mixture. Measure the interval from the time at which the oxygen reading is 10 % of the change below the initial reading (R_5), to the time at which the oxygen reading is 90 % of the change below the initial oxygen reading, that is, when the oxygen reading (R_6) is:

$R_5 = R_1 - (0,9\,[R_1 - R_2])$
$R_6 = R_1 - (0,1\,[R_1 - R_2])$

11.5.2.4 Expression of results: report as the response time the times taken to reach the R_4 and R_5 readings.

NOTE 1: See also the requirements of 2.3, 4.1 and 7.3.

NOTE 2: The reported response time is the slowest that occurs when any one of the above-referenced conditions is varied over its full range.

Annexes

Annexes A to M of IEC 601-1:1988 apply.

Annex N
(normative)

Test for nonflammability of anaesthetic agents

N.1 General

Tests of anaesthetic agents which, according to 37.9 of this International Standard, shall be regarded as nonflammable anaesthetic agents and to which the requirements of Section 6 of IEC 601-1 do not apply are given in P.1 and P.2.

N.2 Spark ignition tests

Spark ignition tests shall be carried out with the most ignitable concentration of the anaesthetic agent mixed with the gases oxygen and/or nitrous oxide in which the anaesthetic agent is more ignitable using the test apparatus described in Appendix F of IEC 601-1:1988, and in IEC 79-3.

With an ignition probability of less than 10^{-3}, ignition shall not occur:

- in a resistive circuit at a d.c. voltage of 20 V with a current of 1,0 A and at a d.c. voltage of 100 V with a current of 0, 15 A;
- in an inductive circuit at a d.c. current of 200 mA with an inductance of 10 mH and at a d.c. current of 60 mA with an inductance of 1000 mH;
- in a capacitive circuit at a d.c. voltage of 100 V with a capacitance of 1 µF and at a d.c. voltage of 20 V with a capacitance of 20 µF.

The measuring circuits are illustrated in figures 29 and 31 of IEC 601-1:1988.

N.3 Surface temperature ignition tests

Determination of the ignition temperature shall be carried out with apparatus and procedures based on IEC 79-4, with the following additional requirements.

- Fill the test vessel with a mixture of oxygen and nitrous oxide in different proportions in successive tests, and

- cover the vessel with a lid which prevents diffusion but lifts easily if an explosion occurs.

The ignition temperature shall not be less than 300 °C.

Annex O
(informative)

Rationale

This annex provides a concise rationale for the important requirements and, where necessary, the test methods, of this International Standard and is intended for those who are familiar with the subject of the International Standard but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for its proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate any revision of the specification necessitated by those developments. The clauses in this annex have been numbered to correspond to the clauses in the main body of this International Standard to which they refer. The numbering is, therefore, not consecutive.

1.1 Scope

There exists a great variety of devices for the measurement of oxygen level. The scope excludes devices used in laboratory research applications. Devices used in these applications are often experimental or intended primarily for nonmedical use.

Imposition of the requirements of this International Standard on devices used for research might unduly limit development of beneficial new techniques or devices.

It is expected that some devices that are not intended for clinical applications may eventually become used in the clinical environment. They would then be subject to the provisions of this International Standard if, for instance, the manufacturer suggested (for example, through advertising) applications that fall within the scope of this International Standard.

1.3 Definitions

1.3.1 The distinction between the terms "alarm", "alarm system" and "alarm set-point" are important because they tend to be used imprecisely and somewhat interchangeably. Alarm is used in this International Standard only to refer to the high priority signal that occurs when the oxygen reading crosses the alarm set-point. The alarm set-point value is the oxygen reading at which the alarm limit control or display indicates the alarm will activate. The alarm system comprises all of the preceding elements. The alarm set-point definition implies that the alarm set-point value need not be continuously displayed, but is capable of being readily displayed.

1.3.6 The term "display" is used to denote any device which visually conveys information to the operator. The term "visual indicator" is used to denote only those displays which present an indication of a condition, such as on (lamp illuminated) or off (lamp not illuminated).

1.3.13 The term "oxygen level" was deliberately chosen and defined to allow oxygen readings in any accepted units, such as partial pressure or percent by volume. Oxygen level refers to the actual concentration of oxygen in a gas mixture.

NOTE: Most oxygen monitors operate according to the partial pressure of oxygen present. Since, in medical applications, the gases measured are mixed by known volumes, it is normal practice to graduate monitor scales in percent (by volume) oxygen.

1.3.15 The term "oxygen reading" refers to the measured concentration of oxygen in the gas mixture. The oxygen reading will, in general, be different from the oxygen level. The magnitude of this difference will be the sum of the error (that is, the accuracy) of the monitor and the error (again, the accuracy) of the reference method by which the gas mixture oxygen level was analyzed (for example, gas chromatography).

1.3.19 The term "sensing area" is not intended to be a synonym for "oxygen sensor". It is, rather, intended to define that location in the gaseous environment being measured at which oxygen molecules are considered to pass into the oxygen monitor system. The actual sensor may be remote, as in the case of a sampling-type monitor.

1.6.1 Identification, marking and documents

a) and b) Monitor markings: it is essential that users be able to identify the manufacturer, catalogue number and serial number of any medical device in order that problems, questions or complaints regarding the device can be communicated expeditiously. The absence of such information can, under some circumstances, render the instrument useless.

d) Instructions: since it is common for oxygen monitors to be operated in areas where the personnel using them change frequently, it is likely that training will not be given in the use of an individual manufacturer's unit.

Thus, it was generally agreed that some instructions and precautions needed to be placed on the monitor itself, in addition to the detailed information contained in the accompanying documents. The requirement for instructions is intended to specify, in general, the minimum level of information that an unfamiliar user would need to operate the monitor correctly and safely. It is recognized that there are limitations to the amount of information that can be placed on the monitor without creating clutter or confusion. Thus, for this requirement, as well as throughout this entire clause, manufacturers are required to warn only of the more serious potential hazards on the monitor itself, referring the user to the accompanying documents for details and cautions.

6.3 Markings of controls and instruments: since oxygen level may be stated in a number of different units of measure, such as % (*V/V*) oxygen, kPa or mmHg, it is necessary that the oxygen display be marked with the appropriate units of measure.

6.8.2 f) 10) Accompanying documents: it has been noted by some users that some oxygen monitors have cables or sample tubing that are of insufficient length to be safely and conveniently mounted on apparatus, such as an anaesthetic machine. It is difficult to specify universal lengths for all monitors, since the required lengths may vary depending on the application. This requirement asks only that manufacturers recognize this problem and adequately inform users of the procedure for correct use.

2.3 Operating temperature range-temperature as high as 40 °C are often encountered in incubators. Temperatures as low as −15 °C may be encountered during transport.

3.7 It is essential that the leakage current is limited because the monitor may come into contact with pacemaker leads or other conduction paths to the patient.

6.1 Since the worldwide use of flammable anaesthetics is becoming rare, a monitor that has a restricted use is considered acceptable.

Two levels of safety for explosion hazards are set. The first, less stringent, level is for the monitor body and oxygen sensor in a flammable environment not in direct communication with a patient (ambient atmosphere in an operating room). If there are no sparks possible, only thermal energy could ignite a flammable gas mixture and thus the temperature maximum has been specified. If there could be sparks, the maximum level of energy in the electrical circuit is additionally specified. This level is based on the ignition energy of the most flammable mixtures of diethyl ether and air.

The second, more stringent, level is for oxygen sensors that are placed in a breathing system in direct communication with breathing gas mixtures and the patient airway. In this case, the supply voltage is restricted and, if sparks are possible, the maximum level of electrical circuit

energy is specified, in addition. This level is based on the ignition energy level of the most flammable mixture of diethyl ether and oxygen.

7.2 Fire prevention

Reports of fire caused by medical devices are unusual. However, when such fires occur in the hospital environment they can have tragic consequences.

The risk of a fire is fundamentally determined by the three elements which are necessary in order to start a fire:

— ignitable material (fuel);

— a temperature equal or above the minimum ignition temperature of the material, or sparks with energy dissipation equal to or above the minimum ignition energy of the materials;

— an oxidant.

Therefore, following the basic safety concepts of IEC 601-1, the objective in the design of the equipment must be to ensure that under both normal and single fault conditions and under the oxidizing conditions to which the material may be exposed, the temperature of any material is not raised to its minimum ignition temperature or the spark energy does not exceed the material ignition energy level. Alternatively, contained ignition may occur provided it is self-limiting so that no hazard is created, e.g. a fuse or a resistor within a sealed compartment.

Minimum ignition temperatures for a large number of specific materials are well established in published literature, although normally only for ambient air and pure oxygen environments. The minimum ignition temperature may be critically dependent upon the concentration of oxidant present. If ignition temperatures for other materials or different oxygen concentrations are required, these may be determined using the methods and apparatus described in IEC 79-4.

In considering the ignitable material, particular attention should be paid to materials which may accumulate during prolonged use, e.g. airborne particles of paper or cotton.

The risk of fire directly caused by sparking of electrical circuits is generally considered insignificant in medical equipment, as temperature rise resulting from the power dissipation caused by a spark will not normally reach the ignition temperature of the solid materials generally used when following good design practice.
However, if materials with a low ignition temperature and a very low thermal capacity, e.g. cotton, wool, paper or organic fibre accumulation, are present then it may not be possible to determine the surface temperatures attained during exposure to spark energy and specific tests, such as ignition tests, may be necessary to assure safety under these condition.

In certain standards currently in use, the requirements to minimize fire risk are based on limitation of temperature, electrical energy and oxidant concentration to absolute values.

The temperature value is based on the minimum hotplate ignition temperature for fire-retardant cotton in 100 % oxygen, which is given in the American NFPA publication 53M as 310 °C. The assumption was therefore made that 300 °C was an acceptable temperature limit in medical equipment with oxygen-enriched atmospheres.

The origin of the electrical energy values which have been used is less clear and it would seem that, in the absence of specific controlled tests, figures have been adopted from other published standards. However, simple tests and detailed analysis of the known factors involved in causing an oxygen fire show that these figures can be either over-restrictive or potentially hazardous depending, in particular, on the manner in which the power may be dissipated and the proximity and type of any "fuel" present.

It is now generally accepted that there are no single or univerally applicable ranges of temperature, energy and concentration of oxidant which can ensure safety under all circumstances. Ultimately, electrical energy is only significant in respect of its ability to raise the temperature of ignitable materials, and this in turn depends upon the particular configuration and the proximity of any ignitable materials.

Under single fault conditions in a typical electrical circuit the possible number of failure modes is very high. In this case full assurance of safety may only be possible by the use of appropriate hazard and safety analysis procedures, taking into consideration the three basic elements, i.e. material, temperature and oxidant.

An appropriate design might limit the electrical energy in the circuit to ensure that temperatures remain below the minimum air ignition temperature under the normal conditions, and seal compartments and add forced ventilation to ensure that the oxygen-content does not exceed that of the ambient air under single fault condition.

Alternatively, it may be appropriate to limit the electrical energy to ensure temperatures below the minimum ignition temperature for a pure oxygen environment, even under single fault condition.

The particular combination of material, oxidant and temperature determines whether a fire will occur, not a single value of any one of these variables.

8.2 "51.5" Measurement accuracy

The accuracy of the oxygen reading is of major importance due to the critical applications of oxygen monitors.

In this International Standard, accuracy takes into account all errors in the measurement system introduced between the sensing area and the displayed oxygen reading as perceived by the operator. This includes sampling system errors, oxygen sensor errors, electrical circuit errors, calibration errors and play errors, among others.
The maximum error allowance of ± 3 % (*V/V*) oxygen satisfies the criteria of effective function for all three primary areas of medical use: anaesthesia, paediatrics and respiratory therapy. For anaesthesia, the requirement is particularly critical, because a patient being maintained on an indicated 21 % (*V/V*) oxygen reading would, in most cases, suffer no ill effects if the oxygen level were between 18 % (*V/V*) and 24 % (21 % ± 3 %) (*V/V*) oxygen. Below an oxygen level of 18 % (*V/V*) oxygen, primary organ function could begin to be compromised. The maximum error allowance of ± 3 % (*V/V*) oxygen is considered by paediatric anaesthesiologists to be the maximum acceptable error in the normal range of their applications between 40 % (*V/V*) and 60 % (*V/V*) oxygen. The requirements of respiratory therapy are also satisfied. For diagnostic measurements where 90 % (*V/V*) to 100 % (*V/V*) oxygen is delivered (the most rigid need), an error of ± 3 % (*V/V*) oxygen is the maximum permissible. Therefore, a maximum error allowance of ± 3 % (*V/V*) oxygen has been chosen for the entire range of 0 % (*V/V*) to 100 % (*V/V*) oxygen.

A simple, effective calibration method would be

a) place the sensing area in 100 % (*V/V*) oxygen;
b) adjust the calibration control so that the oxygen reading is 100 % (*V/V*) oxygen;
c) place the sensing area in room air and verify that the oxygen reading is 21 % ± 3 % (*V/V*) oxygen.

The use of single-point calibration methods (for example, only air) is discouraged, since anomalies such as nonlinearities and zero offsets would not be detected.

The four points specified in the test method (51.6.1) have been chosen to allow a reasonably simple procedure for checking accuracy. For instance, an oxygen monitor with a span of 0 % (*V/V*) to 100 % (*V/V*) oxygen might be tested at 0 % (*V/V*) and 100 % (*V/V*) oxygen. One of the

two other points could be room air. The fourth point could then be a pre-mixed calibration standard of ± 0,5 % (*V/V*) oxygen accuracy and containing between 40 % (*V/V*) and 80 % (*V/V*) oxygen. High purity mixtures of 0 % (*V/V*) and 100 % (*V/V*) oxygen are easily and inexpensively obtainable, as is dry room air. Premixed gas standards of better than ± 0,5 % (*V/V*) oxygen accuracy are not so readily available. Thus, this accuracy value was chosen.

NOTE: For further information, see bibliography in Annex P.

The requirement for digital displays was included to avoid unsafe situations such as display that indicates 99 % (*V/V*) oxygen when the actual electrical signal to the display is well over 100 % (*V/V*) oxygen. Such a display with a maximum reading of 99 would hide an otherwise clear device error or out-of-calibration state. Solutions to this problem include:

a) a three-digit display;
b) an indicator for oxygen levels above the specified range of the display.

8.2 "51.7.1" and **"51.7.2"** It is reasonable that users should expect that a monitor will not drift beyond its stated accuracy for a period of at least 8 h after it has been calibrated according to the accompanying documents. It is felt reasonable to require that the monitor's calibration be confirmed at the change of each eight-hour working shift when in continuous use.

This requirement implies that the stability will be within the specified limits at any constant temperature within the operating temperature range.

8.2 "51.8" This requirement does not deal with the «problem» of oxygen level changes due to breathing circuit pressure changes based on the fundamental physical principle of operation of oxygen monitors - that is, that they measure the partial pressure of oxygen which is a function of ambient pressure. Instead, this requirement deals with permanent mechanical changes to oxygen sensors due to imposed cyclical pressure changes. The pressure extremes of + 10 kPa and − 1,5 kPa are considered clinically relevant pressures that are attained.

8.2 "51.9.1.4" A low alarm limit that can be adjusted or is pre-set to a set-point value below 18 % (*V/V*) oxygen is considered unsafe. It is important to recognize that due to the cumulative nature of the permissible measurement and alarm accuracy errors, a monitor with a low alarm limit that is adjusted to a set-point value of 18 % (*V/V*) oxygen may begin to alarm at an oxygen level as low as 15 % (*V/V*) oxygen (with a corresponding alarm limit of 18 % (*V/V*) oxygen) or at an oxygen level as high as 21 % (*V/V*) oxygen (with a corresponding alarm limit of 18 % (*V/V*) oxygen).

8.2 "51.10" An operator unaware that checking of test controls can cause a control to be permanently left in one position can lead to the mistaken assumption that oxygen levels are being measured when, in fact, they are not. An example would be a battery check that indicated good battery condition when the display indicates 20 % (*V/V*) to 22 % (*V/V*) oxygen. Distinguishable control positions are necessary to determine what is being displayed on multifunction displays.

Inadvertent changes in the calibration control position will result in the display of erroneous measurements.

Controls should operate according to stereotyped expectations to discourage inappropriate control settings.

11.1 One of the principal applications of oxygen monitors is in anaesthesia. It is essential that operators are informed of any additional errors in the oxygen reading that may be introduced as a result of cross-sensitivity of the oxygen sensor to any of the gases or vapours likely to be encountered during anaesthesia. An interference greater than ± 2 % (*V/V*) oxygen is not permitted since, even though stated in the accompanying documents, it could produce an unsafe condition in the hands of a user unaware of this type of interference. An interference of

less than ± 1 % (*V/V*) oxygen is considered insignificant and, therefore, the value need not be stated.

The use of oxygen for the balance of the mixture allows the test to identify interference errors that may occur during normal anaesthesia use.

The operator should be aware that in some monitors the combination of a low battery and interfering gases or vapours can be especially misleading.

11.2 Sampled gas in a diverting oxygen monitor may be returned to the breathing system. Also, backflow may be used to dehumidify a sampling line. The possibility of cross-contamination shall be guarded against in all modes of ventilation.

11.3 Sensors mounted in T-pieces have contributed to leakage in breathing systems due to both poor seals at the sensor and incorrect 22 mm connectors on the T-piece. As the breathing system normally contains a number of various components, it is essential that the maximum leakage rate from the oxygen monitor be as low as possible. Otherwise, it will be impossible to achieve an acceptably low maximum leakage rate for the breathing system.

When sampling monitors withdraw gas from the breathing system, it may have a significant effect on the gas volume delivered to the patient. The requirement to provide information on the sampling gas flowrate provides the user with the information necessary to assess its significance for various clinical situations. In closed circuit systems, high gas withdrawal flowrates are not acceptable with regard to patient safety and pollution effects.

Since oxygen monitor manufacturers usually do not manufacture the fittings with which their T-pieces must mate, testing is performed with standard 22 mm fittings.

11.4 While it is recognized that the expected life may vary considerably as a function of test conditions, it is important that the operator is given some indication of the expected life of the monitor's expendable components. Manufacturers are required to express expected life by the same conventions, so that the user has a consistent set of information on which to base clinical and financial decisions.

The conditions for determining expected useful life were chosen somewhat arbitrarily to represent routine environments in which oxygen monitors will be operated in anaesthesia and respiratory therapy applications. The conditions will yield a conservative estimate of expected useful life, since they are a combination of that which tends to be a "worst case" environment for all sensing techniques employed at the time that this International Standard was developed.

In the test method, oxygen monitor function is evaluated at 85 % of expected useful life rather than at 100 % of expected useful life. This allows the stated useful life to be at or closer to the nominal value rather than at the worst case value, allowing for variations between individual sensors. A tolerance of ± 1 day is included to allow the test to begin and conclude when personnel are available.

11.6 Operators (especially those unfamiliar with the characteristics of a specific monitor) should be given some indication of the period of time required for a reading to reach steady state after a change in oxygen level has been introduced. It is felt that the 90 % response time represents a reasonable approximation to steady state conditions and would thus indicate to the operator how long he or she should wait in order to ensure that a stable reading has been reached. With such information, calibration errors are less likely to occur. In the test method, the measured response time is allowed to be as much as 1,15 times slower than the value stated by the manufacturer. This allows the stated response time to be at or closer to the nominal value rather than at the worst-case value, allowing for variations between individual sensors. The response time is measured with both increasing and decreasing oxygen levels, since response time can be a function of the direction of the change in oxygen level.

Annex P
(informative)

Bibliography

[1] ISO 32:1977, *Gas cylinders for medical use - Marking for identification of content.*

[2] ISO 4135:1995, *Anaesthesiology - Vocabulary.*

[3] ISO 5359:1989, *Low-pressure flexible connecting assemblies (hose assemblies) for use with medical gas systems.*

[4] ISO 7250:1996, *Basic human body measurements for technological design.*

[5] ANSI/AAMI HE 48-1993, *Human Factors Engineering.*

ICS 11.040.10

Descriptors: medical equipment, artificial breathing apparatus, anaesthetic equipment, monitoring equipment, accident prevention, oxygen, gas analyzers, classification, specifications, safety requirements, protection against mechanical hazards, protection against electric shocks, radiation protection, fire protection.

Price based on 30 pages