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Oxygen analyzers for monitoring patient breathing mixtures — Safety requirements

Analyseurs d'oxygène pour le contrôle des mélanges gazeux respirés par un malade — Prescriptions de sécurité

Reference number
ISO 7767 : 1988 (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 approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 7767 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment.*

Annexes N and P of this International Standard are given for information only.

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Introduction

The measurement and monitoring of the level of oxygen present in a gaseous mixture has become a common practice in many areas of clinical medicine. These include anaesthesia, respiratory therapy, paediatrics, and intensive care. A variety of devices are currently available which are intended for these applications. This International Standard establishes minimum safety requirements based on parameters that are believed to be achievable within the limitations of existing technology.

Annex N 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 into this International Standard. Annex P contains a bibliography of other pertinent literature.

Oxygen analyzers for monitoring patient breathing mixtures — Safety requirements

Section 1 : General

1 Scope

ISO 7767 is one of a series of International Standards based on IEC 601-1 : 1977; in IEC 601-1 : 1977 (the "General Standard"), this type of International Standard is referred to as a "Particular Standard". As stated in 1.3 of IEC 601-1 : 1977, the requirements of this International Standard take precedence over those of IEC 601-1 : 1977.

The scope and object given in clause 1 of IEC 601-1 : 1977 applies except that 1.1 shall be replaced by the following.

> This International Standard specifies safety requirements for oxygen analyzers, as defined in 3.8 (in this International Standard) intended for use in determining the oxygen level in breathing gas mixtures administered to patients. Both sampling and non-sampling oxygen analyzers are covered.

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

a) anaesthetic machines and breathing systems;

b) ventilators;

c) baby incubators;

d) oxygen concentrators (domiciliary or clinical).

Oxygen analyzers intended for use in laboratory research applications are outside the scope of this International Standard.

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 listed below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 5356-1 : 1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 1 : Cones and sockets.*

ISO 5356-2 : 1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 2 : Screw-threaded weight-bearing connectors.*

IEC 79-3 : 1972, *Electrical apparatus for explosive gas atmospheres — Part 3 : Spark test apparatus for intrinsically-safe circuits.*

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

IEC 601-1 : 1977, *Safety of medical electrical equipment — Part 1 : General requirements.*

3 Definitions

For the purposes of this International Standard, the definitions given in clause 2 of IEC 601-1 : 1977 apply together with the following additional definitions.

3.1 alarm: Warning signal that is activated when the oxygen reading reaches or exceeds the alarm limit.

3.2 alarm limit: Oxygen reading at which the alarm is first activated.

NOTE — This occurs either when

a) a decreasing oxygen level reaches the low alarm limit;

b) an increasing oxygen level reaches the high alarm limit.

3.3 alarm set-point: Alarm limit adjustment control or display value which indicates the oxygen reading at which the alarm will be activated (the indicated alarm limit).

NOTE — Depending on the construction and design of the equipment, the alarm limit and alarm set-point may differ from each other.

3.4 alarm system: Those parts of the oxygen analyzer which

a) establish the alarm limit(s);

b) detect when the indicated oxygen level exceeds the alarm limit(s);

c) provide a warning signal when the alarm limit(s) is (are) exceeded.

3.5 caution signal: Indication meaning that caution or prompt action is required.

NOTE — Examples of such a condition are a change from mains to battery power in a mains-operated device, or the battery test mode activated.

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

3.7 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.

3.8 oxygen analyzer: Device that measures and indicates the oxygen level in a gaseous mixture.

3.9 oxygen level: Concentration of oxygen in a gaseous mixture.

NOTE — This may be expressed in any suitable unit such as percent by volume or partial pressure in kPa (or mmHg).

3.10 oxygen reading: Measured oxygen level as indicated by the oxygen analyzer.

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

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

3.13 response time: Time required for the oxygen analyzer to achieve a 10 % to 90 % response to a step change in oxygen level.

3.14 sensing area: Part of the oxygen analyzer that is in direct contact with the gas mixture of which the oxygen level is to be measured.

NOTE — An example of such a part is the membrane surface of an oxygen-sensing electrode.

3.15 shelf life: Period during which the oxygen analyzer or any of its components are stored in its original container according to the accompanying documents.

3.16 useful life: Period of time during which the performance of an oxygen analyzer or any of its components meets the requirements of this International Standard, when used and maintained according to the accompanying documents.

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

3.18 warning signal: Indication of danger, meaning that urgent action is required.

4 General requirements and general requirements for tests

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 a dispute, the methods specified in this International Standard shall be used as the reference methods.

The requirements given in clauses 3 and 4 of IEC 601-1 : 1977 apply except for the following addition:

In 4.5, add the following:

— at 20 °C if the tests are to be carried out at any nominal temperature within the operating temperature range of the oxygen analyzer;

— unless otherwise specified in individual test methods, with dry test gas mixtures that have a relative humidity below 2 %;

— at ambient atmospheric pressure.

NOTES

1 Room air is considered to be 20,9 % oxygen.

2 Care should be taken to ensure that room air used for testing is not contaminated, e.g. from exhaust ducts, etc., and has a relative humidity below 95 %.

5 Classification

The requirements given in clause 5 of IEC 601-1 : 1977 apply.

NOTE — Oxygen analyzers used in the home (for example, to monitor oxygen concentrators) should be designated as Class II equipment due to the fact that the protective earthing in many homes may be inadequate or nonexistent.

6 Identification, marking and documents

The requirements given in clause 6 of IEC 601-1 : 1977 apply except for the following additions and modifications:

a) In 6.1, replace item d) by the following:

If the size of the oxygen analyzer does not permit the complete marking as specified throughout this clause, at least the following shall be marked on the oxygen analyzer: the name of the manufacturer; a serial number or lot or batch-identifying number; and symbol number 14 in table D.1 of IEC 601-1 : 1977.

b) In 6.1, add the following to item f):

Oxygen analyzers shall be marked with a serial number or other lot or batch-identifying number.

c) In 6.1, add the following to item q):

Oxygen analyzers shall be marked with the words "Not for use in breathing systems", if applicable (see clause 62.1).

d) In 6.1, add additional items as follows:

y) marking on the outside of the oxygen analyzer shall additionally include the following:

— for oxygen analyzers not intended for use with inhalation anaesthetic agents, the phrase "Not for use with inhalation anaesthetic agents", if applicable (see clause 60.1).

— a statement that the operator should see the accompanying documents for the effect of moisture on accuracy, if applicable.

— symbol number 14 in table D.1.

— the words "Will not withstand mechanical shock", if applicable (see clause 21.1), and symbol number 14 in table D.1.

— the alarm set-point of the oxygen level, if the oxygen analyzer is provided with a non-adjustable oxygen level alarm.

z) the following shall either be marked on the body of the oxygen analyzer or be permanently attached to the oxygen analyzer:

— abridged operating instructions which shall include an indication of the period of time necessary, following a change in oxygen level, for the oxygen reading to stabilize.

NOTE — Markings related to controls should be visible and/or legible to an operator having a visual acuity (corrected if necessary) of at least 1 when the operator is 1 m in front of the oxygen analyzer at an illuminance of 215 lux. Markings should be clearly identified with their associated displays or visual indicators.

e) In 6.7, replace item a) by the following:

If visual indicators are used on the oxygen analyzer, with the exception of alphanumeric displays, their colouring shall conform to the following requirements:

1) Red shall be used to indicate to the operator that the oxygen analyzer or a portion of it has failed.

2) Flashing red shall be used to denote an emergency condition requiring an immediate response by the operator.

3) Yellow shall be used to denote a condition in which there is need for caution or re-check, or in which an unexpected delay is experienced.

4) Green shall be used to indicate that the oxygen analyzer is ready for use or in normal operation.

5) Blue shall be used only as an advisory indicator.

The function of all lights and displays shall be marked.

Compliance shall be checked by functional test and inspection.

NOTE — Visual indicators and their associated markings should be visible and/or legible to an operator having visual acuity (corrected if necessary) of at least 1 when the operator is located 1 m in front of the oxygen analyzer at an illuminance of 215 lux.

f) In 6.8.2, 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 analyzer.

2) A description of the principles of operation of the oxygen analyzer, 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 clauses 50.3, 50.4 and 50.5);

— the stability of measurement accuracy (see clauses 50.6 and 50.7);

— the response time (see clauses 50.8 and 50.9);

— the oxygen level alarm range and its accuracy (see clauses 50.10, 50.11 and 50.12);

— the operating and non-operating temperature ranges (see clause 61);

— for sampling-type oxygen analyzers, the gas diversion rate (see clause 63.3);

— power requirements;

— time from switching on to obtaining specified operating performance.

4) Details of 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 clause 44.5);

— interfering gases or vapours (see clause 60);

— mechanical shock (see clauses 21.1 and 21.2);

— cyclic pressure (see clause 62);

— barometric pressure or pressure at the site of use of the oxygen analyzer;

— fluctuations in line or battery voltage;

— ageing of the oxygen sensor or of the oxygen analyzer itself (see clause 64).

NOTE — If the oxygen level is displayed in units of oxygen concentration, the accompanying documents should contain an explanation that readings in concentration units are correct only under the pressure at which the oxygen analyzer is calibrated.

5) The expected useful life of the oxygen sensors, if they are intended to be replaced during the useful lifetime of the oxygen analyzer. The useful life shall be stated as the number of hours, days, or months of continuous use in dry, 100 % (V/V) oxygen at 23 °C during which the oxygen analyzer meets the requirements given in 50.3, 50.5, 50.6 and 50.8 of this International Standard (see clause 64).

NOTES

1 Other operating conditions may also be used as a basis for useful life.

2 The shelf life of oxygen sensors should be stated.

3 The expected useful life of other expendable components of the oxygen analyzer, for example batteries, should be stated under specified conditions of use.

6) An illustration of the features of the oxygen analyzer indicating the location of all operating controls, adjustments and system components (e.g., the battery compartment) necessary for correct operation and on-site servicing by the user.

7) Instructions for operation of the oxygen analyzer, including the following:

— pre-use checking and calibration;

— routine inspection and testing;

— recommended methods for cleaning and disinfection or sterilization.

8) A description of an in-service test using room air as the calibration gas.

9) Illustrated service information, including:

Instructions for preventive maintenance and service calibration, and those adjustments that are necessary to maintain the oxygen analyzer in correct operating conditions, as well as a description of those adjustments and replacements that can be performed by the operator.

10) A description of the correct installation of the oxygen analyzer and the connection of the oxygen sensor or sampling tubing. The maximum permissible distance of separation between the oxygen analyzer and the sensing area shall be stated.

NOTE — If the oxygen analyzer requires a sensor cable or sampling tubing for connection from the oxygen analyzer to the sensing area, the cable or tubing should be of sufficient length to reduce the likelihood of its being elongated beyond its elastic limit and being stressed at the connection points. In the event that the sensor cable becomes disconnected, this should be indicated by an alarm.

11) Unless it can be demonstrated that the oxygen analyzer is not susceptible to electromagnetic interference, a warning statement in the instructions for use to the effect that the function of the oxygen analyzer may be adversely affected by the operation of such equipment as high frequency apparatus, short-wave or micro-wave equipment in the vicinity.

12) If the lowest temperature that the oxygen analyzer can withstand during transport is higher than − 40 °C and/or if the highest temperature the oxygen analyzer can withstand during transport is lower than 70 °C, the recommended temperature shall be stated in the accompanying documents and the transport package shall be printed with a notice indicating the restrictions on temperature during transport.

NOTE — Attention is drawn to the bibliography given in annex P.

7 Power input

The requirements given in clause 7 of IEC 601-1 : 1977 apply.

Section 2 : Safety requirements

8 Basic safety categories

The requirements given in clause 8 of IEC 601-1 : 1977 apply.

9 Removable protective means

The requirements given in clause 9 of IEC 601-1 : 1977 apply.

10 Special environmental conditions

The requirements given in clause 10 of IEC 601-1 : 1977 apply.

11 Special measures with respect to safety

The requirements given in clause 11 of IEC 601-1 : 1977 apply.

12 Single fault condition

The requirements given in clause 12 of IEC 601-1 : 1977 apply with the following addition:

Applicable single fault conditions are short and open circuits of the sensor and associated circuitry which

— cause sparks to occur, or

— increase the energy of sparks, or

— increase temperatures.

Section 3 : Protection against electric shock hazards

13 General

The requirements given in clause 13 of IEC 601-1 : 1977 apply.

14 Requirements related to classification

The requirements given in clause 14 of IEC 601-1 : 1977 apply.

15 Limitation of voltage and/or current

The requirements given in clause 15 of IEC 601-1 : 1977 apply.

16 Enclosures and protective covers

The requirements given in clause 16 of IEC 601-1 : 1977 apply.

17 Insulation and protective impedances

The requirements given in clause 17 of IEC 601-1 : 1977 apply together with the following additional item:

g) Deterioration of parts due to anaesthetic agents and oxygen should be taken into account.

18 Earthing and potential equalization

The requirements given in clause 18 of IEC 601-1 : 1977 apply. See also clauses 19 and 39.3.

19 Continuous leakage currents and patient auxiliary currents

The requirements given in clause 19 of IEC 601-1 : 1977 apply except as follows:

In item e), add the following:

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

— for non-sampling (continuous monitoring) oxygen analyzers, at the oxygen sensor;

— for sampling (intermittent) oxygen analyzers, at the junction of the sampling tubing and the body of the oxygen analyzer.

20 Dielectric strength

The requirements given in clause 20 of IEC 601-1 : 1977 apply.

Section 4 : Protection against mechanical hazards

21 Mechanical strength

The requirements given in clause 21 of IEC 601-1 : 1977 are replaced by the following:

21.1 Free-standing oxygen analyzers

Such oxygen analyzers (that is, those not manufactured as an integral, inseparable component of a larger system) and all separable components, such as oxygen sensors shall either:

a) meet the requirements given in 50.3 and 50.8 and, if applicable 50.10, 50.12 and 50.13; electrically live parts shall not be accessible, compliance being checked by the test given in 21.2; or

b) be marked with the warning to the effect that it does not meet this requirement (see 6.1), with a similar warning appearing in the accompanying documents.

21.2 Test method

21.2.1 Principle

Determination of the accuracy of the oxygen reading, the response time and, if applicable, the alarm accuracy after the oxygen analyzer and all separable components have been subjected to a mechanical shock.

21.2.2 Procedure

Attach the unpackaged items to be tested rigidly to a shock machine table. Apply three shocks in both directions along three mutually perpendicular axes of each test item (a total of 18 shocks to each item), taking care to ensure the following:

— that the shape of the shock pulse is in accordance with figure 1;

— that the oscillogram of the shock pulse includes a time approximately 33 ms (3 D) long;

— that the acceleration amplitude (A) of the ideal half-sine pulse is 300 m/s^2 (30 × gravity) and its duration (D) is 11 ms;

— that the measured acceleration pulse is contained between the broken line boundaries shown in figure 1;

— that the measured velocity change (which may be obtained by integration of the acceleration pulse) is within the limits $V_i \pm 0{,}1\ V_i$, where the velocity change associated with the ideal pulse is:

$$V_i = 2 \times \frac{A \times D}{\pi} = 2 \times \frac{300 \times 0{,}011}{3{,}141\ 6} = 2{,}1 \text{ m/s};$$

— that the integration to determine velocity change extends from 4,4 ms (0,4 D) before the pulse to 1,1 ms (0,1 D) after the pulse.

Inspect the oxygen analyzer to check that the appearance and condition of the oxygen analyzer, including the enclosure and warning or display indications or markings, have not been damaged or have not deteriorated in such a way as to prevent normal operation of the oxygen analyzer and that no electrically live parts have become accessible.

Reattach any separable components to the oxygen analyzer and carry out the test for measurement accuracy as described in clause 50.4 and the test for response time as described in clause 50.9 and, if the oxygen analyzer is fitted with an oxygen level alarm, a test for oxygen level alarm limit as described in clause 50.11.

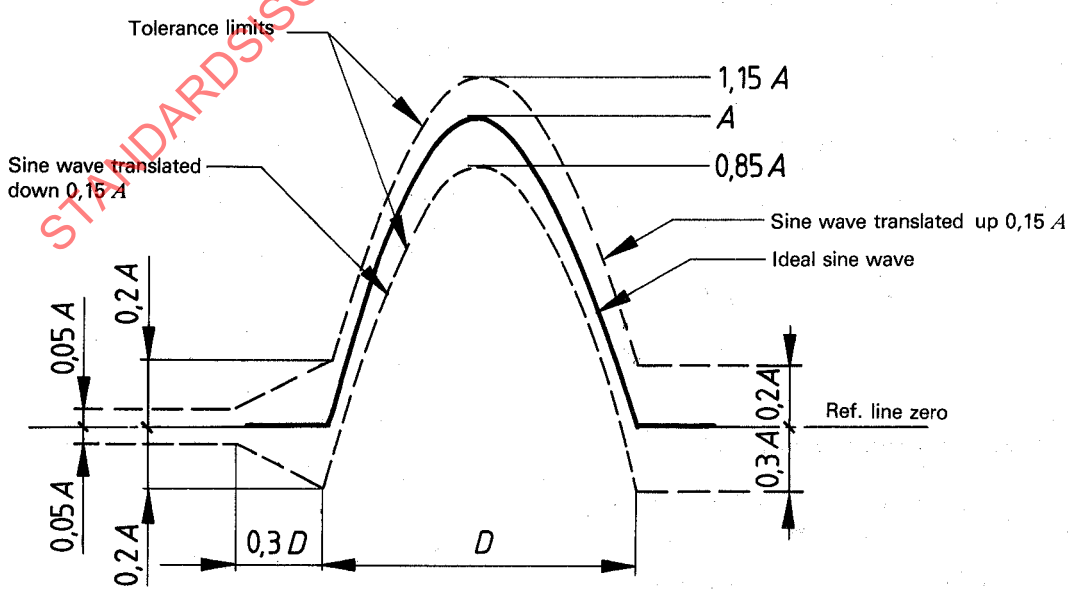

Figure 1 — Half-sine shock pulse configuration and its tolerance limits

21.2.3 Expression of results

Express the results as described in relevant subclauses of clause 50 and report any damage or accessibility of electrically live parts.

22 Moving parts

The requirements given in clause 22 of IEC 601-1 : 1977 apply.

23 Surfaces, corners and edges

The requirements given in clause 23 of IEC 601-1 : 1977 apply.

24 Stability and transportability

The requirements given in clause 24 of IEC 601-1 : 1977 apply.

25 Expelled parts

The requirements given in clause 25 of IEC 601-1 : 1977 apply.

26 Vibration and noise

The requirements given in clause 26 of IEC 601-1 : 1977 apply.

27 Pneumatic and hydraulic power

The requirements given in clause 27 of IEC 601-1 : 1977 apply.

28 Suspended masses

The requirements given in clause 28 of IEC 601-1 : 1977 apply.

Section 5 : Protection against hazards from unwanted or excessive radiation

29 X-radiation

The requirements given in clause 29 of IEC 601-1 : 1977 apply.

30 Beta, gamma, neutron radiation and other particle radiation

The requirements given in clause 30 of IEC 601-1 : 1977 apply.

31 Microwave radiation

The requirements given in clause 31 of IEC 601-1 : 1977 apply.

32 Light radiation (including visual radiation and lasers)

The requirements given in clause 32 of IEC 601-1 : 1977 apply.

33 Infra-red radiation

The requirements given in clause 33 of IEC 601-1 : 1977 apply.

34 Ultra-violet radiation

The requirements given in clause 34 of IEC 601-1 : 1977 apply.

35 Acoustical energy (including ultrasonics)

The requirements given in clause 35 of IEC 601-1 : 1977 apply, together with the following additional requirement:

If an oxygen analyzer is included as a part of, or is integral to, another item of equipment, the relevant standards for the equipment shall apply.

36 Electromagnetic compatibility

The requirements given in clause 36 of IEC 601-1 : 1977 apply.

NOTE — Attention is drawn to the bibliography in annex P.

Section 6 : Protection against hazards of explosion in medically used rooms

37 General

The requirements given in clause 37 of IEC 601-1 : 1977 are replaced by the following:

Oxygen analyzers not designed for use with flammable anaesthetic agents shall comply with the requirements given in 37.1 to 37.4.4.

37.1 Oxygen analyzers not intended for use in the presence of flammable anaesthetics, and which contain electrical circuits which may be a source of ignition in enclosed compartments within which anaesthetic mixtures are produced, guided or used shall meet the requirements given in clause 43 of this International Standard.

37.2 Oxygen analyzers designed for use with flammable anaesthetic agents (see 37.3) shall comply with the requirements for anaesthetic proof category G equipment (APG) given in clauses 38, 39, 40, and 41 of IEC 601-1 : 1977.

37.3 Anaesthetic agents shall be considered as flammable unless, when tested according to the method described in 37.4, the following criteria are met.

a) In the spark ignition test with an ignition probability of less than 10^{-3}, ignition does not occur with any of the following circuits:

i) a resistive circuit at a d.c. voltage of 20 V with a current of 1 A and at a d.c. voltage of 100 V with a current of 0,15 A,

ii) an inductive circuit with a d.c. current of 0,2 A with an inductance of 10 mH and at a d.c. current of 60 mA with an inductance of 1 000 mH,

iii) 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.

b) In the surface ignition test, ignition does not occur at a temperature below 300 °C.

37.4 Flammability of anaesthetic agents shall be tested as follows.

37.4.1 Principle

Two methods are used. In the first, the most ignitable concentration of an anaesthetic agent mixed with oxygen and/or nitrous oxide is exposed to a spark, and in the second, the surface ignition temperature of mixtures is determined.

37.4.2 Test gases

Two test gases are used:

a) for the spark ignition test, the most ignitable concentration of the anaesthetic agent mixed with oxygen and/or nitrous oxide;

b) for the surface ignition test, the anaesthetic agent mixed with oxygen and nitrous oxide in varying proportions in successive tests.

37.4.3 Apparatus

The following apparatus is needed:

a) for the spark ignition test

— the test apparatus for explosive mixtures or atmospheres described in IEC 601-1 : 1977 or in IEC 79-3,

— the measuring circuits illustrated in figures 29 and 31 in IEC 601-1 : 1977;

b) for the surface ignition test, the test apparatus described in IEC 79-4, but with the modification that the vessel is covered with a lid which prevents diffusion, but lifts easily if there is an explosion.

37.4.4 Procedure

Proceed as follows:

a) for the spark ignition test, carry out the test described in IEC 79-3;

b) for the surface ignition test, carry out the test described in IEC 79-4 but with the modification that the anaesthetic agent is mixed with oxygen and nitrous oxide in varying proportions in successive tests.

38 Classification, marking and accompanying documents of anesthetic-proof equipment

The requirements given in clause 38 of IEC 601-1 : 1977 apply.

39 Common requirements for "AP" and "APG" equipment

The requirements given in clause 39 of IEC 601-1 : 1977 apply except as follows:

In 39.3, add an additional item as follows:

k) Any oxygen analyzer classified and marked APG shall provide a continuous current path for electrostatic charges from the sensing area to earth and the resistance shall be no greater than 1 MΩ (see also clauses 19 and 41).

Compliance shall be checked by the test given in 39.4.

39.4 Test method

39.4.1 Principle

Measurement of the electrical resistance between the sensing area of the oxygen analyzer and earth.

39.4.2 Procedure

Place the oxygen analyzer on a conductive plate. Using a suitable resistance meter, measure the resistance between the sensing area and the following:

— the conductive metal plate;

— the protective earth terminal;

— the terminal for potential equalization.

40 Requirements and tests for anaesthetic-proof equipment, equipment parts or components (AP)

The requirements given in clause 40 of IEC 601-1 : 1977 apply.

41 Requirements for anaesthetic-proof category G equipment, equipment parts or components

The requirements given in clause 41 of IEC 601-1 : 1977 apply.

Section 7 : Protection against excessive temperatures, fire and other hazards, such as human errors

42 Excessive temperatures

The requirements given in clause 42 of IEC 601-1 : 1977 apply except as follows:

Replace 42.3 by the following:

42.3 Applied parts which come intentionally in contact with the patient and which are not intended to supply heat to the patient shall not have surface temperatures exceeding 41 °C.

43 Fire prevention

The requirements given in clause 43 of IEC 601-1 : 1977 apply together with the following additional requirements:

43.3 In order to eliminate the risk of fires caused by electrical components which may be a source of ignition in oxygen or nitrous oxide enriched atmospheres (or mixtures of gases containing anaesthetic agents referred to in clause 37), at least one of the following requirements shall be met.

a) Electrical components shall be separated from compartments in which accumulations of such gases can occur by a barrier complying with the requirements given in 43.4.

b) Compartments containing electrical components shall be ventilated according to the requirements given in 43.5.

c) Electrical components which in normal use and single fault condition can be a source of ignition shall comply with the requirements given in 43.7.

43.4 Any barrier required under the provisions of 43.3 a) shall be sealed at all joints and at any holes for cables, shafts, or other purposes. Compliance shall be checked by the following methods, as appropriate:

— inspection;

— by compliance test for enclosures with restricted breathing given in 40.5 e) of IEC 601-1 : 1977;

— if under normal use conditions a pressure difference exists between the spaces separated by the barrier, the test method given in 43.6.

43.5 The ventilation required in 43.3 b) shall be such that when tested by the method described in 43.6, the oxygen level in the enclosed compartment containing electrical components shall not exceed 4 % above the ambient oxygen level; if this requirement is met by forced ventilation, an alarm shall be provided to warn of failure of the ventilation.

43.6 Oxygen levels in enclosed compartments shall be tested as follows.

43.6.1 Principle

Measurement of the oxygen level in the enclosed compartment is measured after the oxygen analyzer is operated for 18 h under single fault conditions.

43.6.2 Procedure

Place the oxygen analyzer in a room in which the air exchange is between 3 and 10 room volumes per hour. Set the oxygen flow through the oxygen analyzer so that it equals the maximum flows of oxygen and nitrous oxide under normal conditions. Switch off the mains supply and measure the oxygen level in the enclosed compartment. Operate the oxygen analyzer under single fault conditions with the least favourable control setting selected and with the mains voltage deviating by ± 10 %, if applicable. After 18 h, switch off the supply mains and measure the oxygen level in the enclosed compartment.

43.6.3 Expression of results

Record the oxygen levels measured at the beginning and the end of the 18 h period.

43.7 Electrical circuits which can produce sparks or generate a high surface temperature and can be a source of ignition shall be so designed that in normal use and single fault condition, no ignition occurs; under these conditions, the product of the effective open circuit voltage and effective short circuit current shall not exceed 10 VA in each circuit.

43.8 The surface temperature of components which may constitute a source of ignition shall not exceed 300 °C.

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

The requirements given in clause 44 of IEC 601-1 : 1977 apply except as follows:

a) Replace 44.3 by the following:

44.3 Spillage

44.3.1 Oxygen analyzers shall be so constructed that spillage does not wet parts which, if wetted, may cause a safety hazard.

Compliance shall be checked by the test given in 44.3.2.

44.3.2 Position the oxygen analyzer as in normal use. Pour 200 ml of water steadily on an arbitrarily chosen point on the top surface of the oxygen analyzer. After this the oxygen analyzer shall comply with the requirements of this International Standard.

b) Replace 44.5 by the following:

44.5 Humidity and condensation effects

44.5.1 Humidity effects

When operated in accordance with the instructions for use, oxygen analyzers shall maintain ± 3 % (*V*/*V*) measurement accuracy when used with air or comparable gas mixtures having any relative humidity between 0 % and 100 %;

The corrected oxygen reading shall be between 17,4 % (*V*/*V*) and 24,4 % (*V*/*V*) oxygen.

NOTE — These requirements may be met with the addition of an adaptor, if required.

Compliance shall be checked by the test given in 44.5.2.

44.5.2 Test method

44.5.2.1 Principle

Determination of the accuracy of the oxygen reading over a two-hour period of exposure of the oxygen sensor to a high relative humidity (non-condensing) after calibration in dry air.

44.5.2.2 Test gases

Dry room or compressed air as the calibration gas mixture and humidified room or compressed air having a relative humidity between 95 % and 100 % (non-condensing) shall be used as the test gas mixture.

44.5.2.3 Procedure

Hold the ambient temperature of the oxygen analyzer constant to within ± 1 °C of a nominal value within the operating range of the oxygen analyzer (see 61.1). Hold the temperature and calibration of the test gas mixtures delivered to the sensing area constant at ± 2 °C. Deliver the calibration and test gas mixtures to the sensing area at ambient barometric pressure. Set up the oxygen analyzer for the measurement of humidified gases as described in the accompanying documents (for example, by attachment of an adaptor or orientation of the oxygen sensor). Maintain the oxygen analyzer and oxygen sensor in the same position throughout the test.

Ensure that the oxygen sensor is at a temperature of 35 °C ± 2 °C and that the oxygen analyzer is at ambient temperature. Calibrate the oxygen analyzer according to the accompanying documents using the calibration gas mixture. Do not re-calibrate the oxygen analyzer during the test period. Expose the sensing area to the test gas mixture for a continuous period of 2 h. For continuous monitoring oxygen analyzers, record the oxygen reading at least once every 15 min. For intermittent sampling oxygen analyzers, sample the test gas mixture at least once every 15 min and record the oxygen reading. In either case, record the temperature to an accuracy of ± 0,2 °C and the barometric pressure to an accuracy of ± 0,2 % of the reading every time an oxygen reading is recorded.

44.5.2.4 Expression of results

If the oxygen readings are not already in partial pressure use, convert each oxygen reading to partial pressure, *P*, for example in kilopascals using the equation:

$$P = (R/100) \times B$$

where

R is the oxygen reading in percent (*V*/*V*) oxygen;

B is the barometric pressure, for example in kilopascals.

Correct each oxygen reading for the dilution effect of 100 % water vapour at the temperature and barometric pressure of each reading, using the following equation:

$$A = \frac{\frac{B}{B - V_t} \times P}{B} \times 100$$

where

A is the corrected oxygen reading in percent (*V*/*V*) oxygen;

B is the barometric pressure, for example in kilopascals;

V_t is the vapour pressure of water, for example in kilopascals at temperature *t*;

t is the temperature of the humidified test gas in degrees Celsius;

P is the oxygen partial pressure, for example in kilopascals.

Table 1 lists the vapour pressure of water at selected temperatures.

Table 1 — Vapour pressure over water

Temperature °C	Pressure kPa	Pressure mmHg
33	4,90	37,7
34	5,19	39,9
35	5,48	42,2
36	5,79	44,6
37	6,12	47,1

44.5.3 Condensation effects

Oxygen analyzers intended for use in a breathing system shall meet the following requirements.

Either

a) Oxygen analyzers shall maintain the oxygen measurement accuracy specified in 50.3 and 50.5 and the response time specified in 50.8. If the manufacturer recommends or supplies an attachment for use when measuring gases of high humidity, these requirements shall be met with the attachment in place.

or

b) Compliance shall be checked by the test given in 44.5.4.

If the oxygen analyzer does not meet these requirements, a cautionary notice shall be included in the accompanying documents.

44.5.4 Test method

44.5.4.1 Principle

Determination of the accuracy of the oxygen reading and the response time over a two-hour period of exposure of the oxygen sensor to a relative humidity of 100 % (condensing) after calibration in dry air.

44.5.4.2 Test gases

Dry room or compressed air as the calibration gas mixture and humidified room or compressed air having a relative humidity of 100 % (condensing) shall be used as the test gas mixture.

44.5.4.3 Procedure

Carry out the procedure described in 44.5.2 ensuring that the test gas is delivered to the sensing area in a fully saturated condensing state and that condensate forms at the sensing area. In addition, measure the response time by the method described in 50.9 after recording each oxygen reading.

44.5.4.4 Expression of results

Express the results as described in 44.5.2.4.

45 Pressure vessels and parts subject to pressure

The requirements given in clause 45 of IEC 601-1 : 1977 apply.

46 Human errors

The requirements given in clause 46 of IEC 601-1 : 1977 apply together with the following additional clause:

46.13 Manual warning signal override

If a manual control is provided to override the low oxygen level alarm, it shall only override the auditory warning signal and shall automatically cancel after not more than 120 s following its most recent activation.

47 Electrostatic charges

The requirements given in clause 47 of IEC 601-1 : 1977 apply.

48 Materials in applied parts in contact with the body of the patient

The requirements given in clause 48 of IEC 601-1 : 1977 apply.

49 Interruption of the power supply

The requirements given in clause 49 of IEC 601-1 : 1977 apply.

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

50 Accuracy of operating data

The requirements given in clause 50 of IEC 601-1 : 1977 apply together with the following additional requirements:

50.3 Measurement accuracy

Oxygen readings shall be within ± 3 % (V/V) oxygen of the actual oxygen level.

NOTE — This tolerance includes errors from all sources associated with the oxygen analyzer, such as its oxygen sensor, electrical circuits, calibration method, and display resolution.

Compliance shall be checked by the method given in 50.4.

50.4 Determination of measurement accuracy

50.4.1 Principle

Determination of the accuracy of the oxygen reading at a number of oxygen levels across the full range of the oxygen analyzer.

50.4.2 Test gases

At least the following four mixtures of oxygen and nitrogen shall be used:

15 %, 21 %, 40 %, and 60 % (V/V) oxygen.

Ensure that the gas mixtures are dry, are pre-mixed, and that the oxygen level is known to within ± 0,5 % (V/V) oxygen.

50.4.3 Procedure

Operate the oxygen analyzer as described in the accompanying documents. Hold the ambient temperature of the oxygen analyzer and the temperature of the test gas mixture delivered to the oxygen sensor constant to within ± 1 °C of a nominal value within the operating range specified for the oxygen analyzer.

NOTE — The test gas mixtures need not be at ambient temperature.

Calibrate the oxygen analyzer as described in the accompanying documents. Deliver one of the test gas mixtures to the sensing area at ambient barometric pressure. Ensure that the oxygen analyzer is in equilibrium with the test gas mixture and that the oxygen analyzer is at ambient temperature. After a period of at least three times the response time stated in the accompanying documents, record the oxygen reading indicated by the oxygen analyzer. Repeat the procedure with the other gas mixtures.

50.4.4 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.

50.5 Digital readings

If an oxygen analyzer displays the oxygen reading digitally, there shall be:

a) at least two digits;

b) a means for indicating that the oxygen reading is above the specified range of the display.

NOTE — This requirement may be met, for example, by a two-digit display that flashes or by a three-digit display that reads greater than 100 % (V/V) oxygen when the reading exceeds 100 % (V/V) oxygen, for instance, during calibration.

50.6 Stability of measurement accuracy

Oxygen analyzers shall maintain the measurement accuracy specified in 50.3, 50.4 and 50.5 for a period of at least 8 h continuous use.

Compliance shall be checked by the test given in 50.7.

50.7 Test method

50.7.1 Principle

Determination of the accuracy of the oxygen reading in the central part of the oxygen measurement range of the oxygen analyzer during an eight-hour period after calibration.

50.7.2 Test gas

A dry pre-mixture of oxygen and nitrogen containing oxygen at a level between 20 % and 80 % of the full scale oxygen reading indicated on the oxygen analyzer shall be used, the oxygen level being known to within ± 0,5 % (V/V) oxygen.

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.

50.7.3 Procedure

Operate the oxygen analyzer as described in the accompanying documents. Hold the ambient temperature of the oxygen analyzer and the temperature of the test gas mixture delivered to the sensing area constant to within ± 1 °C of a nominal value within the operating temperature range as specified in the accompanying documents.

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

Calibrate the oxygen analyzer 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 analyzer is at ambient temperature. Expose the sensing area to the test gas for a continuous period of 8 h, ensuring that the oxygen analyzer is maintained in the same position during the whole period. For continuous monitoring oxygen analyzers, record the oxygen reading at least once every 15 min. For intermittent sampling oxygen analyzers, sample the test gas mixture at least once every 15 min and record the oxygen reading.

50.7.4 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.

50.8 Response time

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 given in 50.9.

50.9 Test method

50.9.1 Principle

Measurement of the time taken for the oxygen analyzer to respond to changes in oxygen level at the sensing area.

50.9.2 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 analyzer shall be used.

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.

50.9.3 Procedure

Hold the ambient temperature of the oxygen analyzer 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 analyzer 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 analyzer is at ambient temperature.

Expose the sensing area to a test gas mixture with an oxygen level equivalent to 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 analyzer (R_1). Expose the sensing area to a test gas mixture with an oxygen level equivalent to 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 analyzer (R_2). With the oxygen analyzer measuring R_2, re-expose the sensing area to the 95 % to 100 % full-scale oxygen reading test gas mixture. Measure the interval, to the nearest second, 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:

$$R_4 = R_2 + (0{,}9 \times [R_1 - R_2])$$

$$R_3 = R_2 + (0{,}1 \times [R_1 - R_2]).$$

Finally, with the oxygen analyzer measuring R_1, re-expose the sensing area to the 20 % to 25 % full-scale oxygen reading test gas mixture. Measure the interval, to the nearest second, from the time at which the oxygen reading is 10 % of the change above the initial reading, (R_6) 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_5) is:

$$R_5 = R_1 + (0{,}9 \times [R_1 - R_2])$$

$$R_6 = R_1 + (0{,}1 \times [R_1 - R_2]).$$

50.9.4 Expression of results

Report the times taken to reach the R_4 and R_6 readings.

NOTES

1 See also the requirements of clauses 21.1, 44.5.1, 61.3, 62, and 64.1.

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

50.10 Oxygen level alarms

If an oxygen level alarm system is provided, it shall meet the following requirements:

a) The alarm shall be both visual and auditory.

b) The alarm limit shall lie within ± 2 % (V/V) oxygen of the alarm set-point in the range of 10 % (V/V) to 60 % (V/V) oxygen and within ± 5 % (V/V) oxygen of the alarm set-point elsewhere throughout the range.

Compliance shall be checked by the test given in 50.11.

50.11 Test method for oxygen level alarm limit

50.11.1 Principle

Determination of the alarm limit values and the alarm set-point values at a number of oxygen readings across the range of the alarm system.

50.11.2 Procedure

Hold the ambient temperature of the oxygen analyzer constant to within ± 1 °C of a nominal value within the operating temperature range specified in the accompanying documents. Generate at least four stable oxygen readings that span the range of the alarm system in approximately equal steps, by varying the oxygen level delivered to the sensor, or by electrically stimulating the oxygen sensor, or by adjusting the calibration control.

For each oxygen reading, adjust the alarm limit control so that the alarm is deactivated. Slowly adjust the alarm limit control until the alarm is activated. For each oxygen reading, record the alarm limit value. i.e., the indicated oxygen reading, and the corresponding alarm set-point value, i.e., the most precise set-point indication at the point of first activation of the alarm.

NOTE — An alarm may be of a type that is activated at an oxygen reading above (high alarm) or below (low alarm) the alarm limit. An oxygen analyzer may have either or both types of alarm.

50.12 Low alarm limit requirements

If an adjustable low alarm limit is provided, it shall not be adjustable below an alarm set-point value of 15 % (V/V) oxygen. If a non-adjustable low alarm limit is provided, the alarm set-point value shall not be below 15 % (V/V) oxygen.

There shall be a visual indication to the user when a low alarm limit is adjusted to an alarm set-point value below 21 % (V/V) oxygen.

NOTE — This requirement may be met by methods such as red markings on the low alarm limit control in the range below 21 % (V/V) oxygen, or a caution signal that is activated when the low alarm limit control is set below 21 % (V/V) oxygen, or markings on the oxygen analyzer itself.

50.13 Displays

Oxygen level displays shall be marked with the appropriate units of measurement.

NOTE — Displays should not be obscured by the hand normally adjusting the control(s) associated with the display.

51 Protection against incorrect output

The requirements given in clause 51 of IEC 601-1 : 1977 apply together with the following additional requirements:

51.5 Function and position of controls

Check or test controls for battery condition or signal operation and signal override shall automatically return from the check, test or override position, unless these functions are carried out automatically when switching to the operating mode.

The positions of measurement and test controls shall be clearly distinguishable.

Calibration controls shall include means to prevent an inadvertent change from the intended position (for example, by recessing the control or by providing a locking mechanism).

NOTE — All other controls should also include means to prevent inadvertent changes from the intended positions and should have clearly distinguishable positions.

Section 9 : Fault conditions causing overheating and/or mechanical damage; environmental tests

52 Fault conditions causing overheating and/or mechanical damage

The requirements given in clause 52 of IEC 601-1 : 1977 apply.

53 Environmental tests

The requirements given in clause 53 of IEC 601-1 : 1977 apply.

Section 10 : Constructional requirements

54 General

The requirements given in clause 54 of IEC 601-1 : 1977 apply.

55 Enclosures and covers

The requirements given in clause 55 of IEC 601-1 : 1977 apply.

56 Components and general assembly

The requirements given in clause 56 of IEC 601-1 : 1977 apply except as follows:

In 56.8, add the following:

— warning signals provided with the oxygen analyzer for monitoring oxygen levels shall be both visual and auditory.

— caution signals provided with the oxygen analyzer shall be visual.

NOTE — Visual indicators may be accompanied by a display. Caution signals may be accompanied by an auditory signal.

In 56.10, add an additional item as follows:

d) Movement of controls — For controls that consist of a movable part and a non-movable part, movement upwards, to the right, or clockwise shall increase the control function. Rotary gas flow controls are exempt from this requirement.

NOTES

1 The separation between control knobs, switches, toggles, pinwheels, or push buttons should conform to the recommendations given in ISO 7249 and ISO 7250. (See annex P.)

2 Controls and their associated markings should be visible and/or legible to an operator having visual acuity (corrected if necessary) of at least 1 when the operator is located at least 1 m in front of the oxygen analyzer at an illuminance of 215 lux. Markings should be clearly identified with their associated controls.

57 Mains parts components and layout

The requirements given in clause 57 of IEC 601-1 : 1977 apply.

58 Protective earth terminals

The requirements given in clause 58 of IEC 601-1 : 1977 apply.

59 Construction and layout

The requirements given in clause 59 of IEC 601-1 : 1977 apply.

Section 11 : Additional requirements

60 Interfering gas and vapour effects

60.1 Oxygen analyzers 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 2; or

b) if the body of the oxygen analyzer is marked "Not for use with inhalation agents" or equivalent, the oxygen analyzer 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 2. 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 60.2.

Table 2 — Inhalation anaesthetics and other interfering gases and vapours

Gas or vapour (Balance dry oxygen)	Level Volume %
Helium	80 %
Nitrous oxide[1)]	80 %
Diethyl ether (flammable anaesthetic)	10 %
Carbon dioxide	10 %
Halothane[1)]	6 %
Enflurane[1)]	5 %
Isoflurane[1)]	5 %
Methoxyflurane[1)]	1 %
1) Inhalation anaesthetic agent	

60.2 Compliance shall be tested as follows.

60.2.1 Principle

Determination of the accuracy of the oxygen reading in the presence of interfering gases and vapours given in table 2.

60.2.2 Test gases

Dry pre-mixtures of oxygen and the interfering gas or vapour at the level given in table 2, the oxygen levels being known to within ± 2 % (V/V), shall be used.

60.2.3 Procedure

Carry out the test described in 50.4 with the following modification.

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

60.2.4 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.

61 Environmental temperature limitations

61.1 Operating temperature range

Oxygen analyzers shall meet the requirements given in 50.3 and 50.8 over a sample gas and ambient temperature range of 15 °C to 40 °C.

Compliance shall be checked by the test given in 61.2.

61.2 Test method

61.2.1 Principle

Determination of the accuracy of the oxygen reading and the response time after equilibrating the oxygen analyzer at the extremes of the specified operating temperature range.

61.2.2 Procedure

Place the oxygen analyzer in an atmosphere of room air at 40 °C ± 1 °C having a relative humidity of less than 95 % until it has reached equilibrium.

NOTE — Equilibrium can be verified by a suitable means, such as placing a thermistor inside the oxygen analyzer.

Carry out the test for measurement accuracy as described in 50.4 and the test for response time as described in 50.9 except that both the oxygen analyzer and the test gases are to be maintained at 40 °C ± 2 °C during both tests.

Repeat the procedure at the test temperature of 15 °C ± 1 °C.

61.2.3 Expression of results

Express the results as described in 50.4 and 50.9 at both test temperatures.

61.3 Non-operating temperature range

The oxygen analyzer shall meet the requirements given in 50.3 and 50.8, after it has been subjected to the extremes of the specified non-operating temperature range as detailed in the accompanying documents.

Compliance shall be checked by the test given in 61.4.

61.4 Test method

61.4.1 Principle

Determination of the accuracy of the oxygen reading and the response time at normal operating temperature after the oxygen analyzer, as packaged for transport, has been sub-

jected to the extremes of the specified non-operating temperature range.

61.4.2 Procedure

Place the oxygen analyzer, as packaged for transport, in an atmosphere of room air having a relative humidity of less than 95 %, at the lower of the following temperatures until it has reached equilibrium:

a) 70 °C ± 1 °C;

b) the highest temperature recommended during transport, as marked on the transport package.

NOTE — Equilibrium can be verified by a suitable means, such as placing a thermistor inside the oxygen analyzer.

Maintain the oxygen analyzer at this temperature for 4 h after equilibrium is attained.

Return the packaged oxygen analyzer to room temperature, unpack it and install it so that it is ready for use, as described in the accompanying documents.

Carry out the test for measurement accuracy as described in 50.4 and the test for response time as described in 50.9.

Repeat the procedure equilibrating the packaged oxygen analyzer at the higher of the following temperatures:

a) − 40 °C ± 1 °C;

b) the lowest temperature recommended during transport, as marked on the transport package.

61.4.3 Expression of results

Express the results as described in 50.4 and 50.9 at both test temperatures.

62 Cyclic pressure

62.1 Oxygen analyzers shall either meet the requirements given in 50.3 and 50.8 following exposure to cyclic positive pressure of 10 kPa (100 cm H_2O) and negative pressure of 1,5 kPa (15 cm H_2O) in the breathing system, or be marked with the warning "not for use in breathing systems" and a similar warning shall appear in accompanying documents.

Compliance shall be checked by the test given in 62.2.

62.2 Accuracy shall be tested as follows.

62.2.1 Principle

Determination of the accuracy of the oxygen reading and the response time after exposure of the sensing area to cyclic pressure.

62.2.2 Procedure

Expose the sensing area to a cyclic pressure waveform such that a positive pressure with respect to ambient of 10 kPa ± 1 kPa (100 cm H_2O ± 10 cm H_2O) and a negative pressure with respect to ambient of 1,5 kPa ± 0,2 kPa (15 cm H_2O ± 2 cm H_2O) are each maintained, in turn, for not less than 2 s each. Cycle the pressures at a rate of 0,167 Hz ± 0,017 Hz (10 cycles/minute ± 1 cycle/minute) for 10 min.

Carry out the test for measurement accuracy as described in 50.4 and the test for response time as described in 50.9.

62.2.3 Expression of results

Express the results as described in 50.4 and 50.9.

63 Gas leakage and sampling loss

63.1 The rate of leakage of a non-sampling oxygen analyzer shall not be greater than 20 ml/min.

NOTE — This requirement ensures that when fitted to a breathing system its 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 63.2.

63.2 The accuracy shall be tested as follows.

63.2.1 Apparatus

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

63.2.2 Procedure

Assemble the oxygen analyzer 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 flow meter 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 flow necessary to maintain this pressure. This leakage flow shall be as specified in clause 63.1.

63.3 The rate at which a sampling oxygen analyzer 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 tests given in 63.4.

63.4 The rate of gas withdrawal shall be tested as follows.

63.4.1 Principle

Measurement of the rate at which a sampling (intermittent) oxygen analyzer withdraws gas from a simulated breathing system.

63.4.2 Test gas

Pressurized air at room temperature shall be used.

63.4.3 Apparatus

A pressure gauge having an accuracy within ± 0,3 kPa, and a flowmeter having an accuracy to within ± 10 % of the rate at which the oxygen analyzer withdraws gas from the breathing system as stated in the accompanying documents shall be used.

63.4.4 Procedure

Assemble the apparatus as described in 63.2.2 but using the flow meter specified in 63.4.3. Adjust the pressurized air source to 3 kPa and monitor the flowmeter reading for 1 min.

63.5 A means shall be provided to collect the gas from the oxygen analyzer.

64 Replacement of oxygen sensor

64.1 The accuracy of the oxygen reading and stability of measurement accuracy in response time shall meet the requirements given in 50.3, 50.5, 50.6 and 50.8 respectively over a period of time, as described by the manufacturer in the accompanying documents.

Compliance shall be checked by the test given in 64.2.

64.2 The accuracy shall be tested as follows.

64.2.1 Principle

Determination of the accuracy of the oxygen reading, the stability of measurement accuracy and the response time over a period of time.

64.2.2 Test gas

A dry gas mixture containing oxygen at a level greater than 98 % (V/V) shall be used.

64.2.3 Procedure

Hold the ambient temperature of the oxygen analyzer and the temperature of the test gas mixture 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.

Deliver the test gas to the sensing area at ambient barometric pressure. Verify that the requirements given in 50.3, 50.5, 50.6 and 50.8 have been met.

Expose the sensing area to the test gas for at least 31 days.

NOTE — The ambient and test gas temperatures may vary over the full operating temperature range specified in accompanying documents during this period.

At the end of the period, carry out the test for measurement accuracy as described in 50.4, stability of measurement accuracy as described in 50.7, and response time as described in 50.9.

64.2.4 Expression of results

Express the results as described in 50.4, 50.7 and 50.9, before and after the exposure period.

65 Auditory signal frequency

The fundamental frequency of auditory signals shall lie between 200 Hz and 3 000 Hz.

NOTE — The fundamental frequency of auditory signals should lie between 200 Hz and 1 000 Hz. Auditory warning signals should be cyclic, that is on-off, two-tone, or warbling, and should be repeated at a rate of between 0,2 Hz and 1 Hz (between 1 cycle per five seconds and 1 cycle per second). Additional work is in progress on alarm signals in ISO/TC 121.

66 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 analyzer shall not be interchangeable with the breathing system connection port or with the oxygen sensor connection port.

Annexes

Annexes A to M given in IEC 601-1 : 1977 and Amendment 1 to IEC 601-1 : 1977 together with annexes N and P in this International standard apply.

Annex N
(informative)

Rationale

This annex provides a concise rationale for the important requirements of this International Standard and is intended for those who are familiar with the subject of the 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 Standard necessitated by those developments.

The clauses in this annex have been so numbered to correspond to the clauses in the Standard to which they refer. The numbering is, therefore, not consecutive.

Introduction

This annex presents the rationale on which the requirements and, where necessary, the test methods are based. To the extent possible, it summarizes the discussions which were carried on by the participants in the meetings of the subcommittee that developed this International Standard.

N.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 non-medical uses. 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.

N.3 Definitions

N.3.1 Alarm

The distinction between the terms "alarm", "alarm limit", "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 warning signal that occurs when the oxygen reading exceeds the alarm limit. The alarm set-point differs from the alarm limit as follows: the alarm set-point value is the oxygen reading at which the alarm limit control or display indicates the alarm will activate, whereas the alarm limit value is the oxygen reading when the alarm first activates. 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.

N.3.6 Display

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).

N.3.8 Oxygen analyzer

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 analyzer for use in direct patient monitoring applications.

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

N.3.9 Oxygen level

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 analyzers 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 analyzer scales in percent oxygen.

N.3.10 Oxygen reading

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 analyzer and the error (again, the accuracy) of the reference method by which the gas mixture oxygen level was analyzed (for example, gas chromatography).

N.3.14 Sensing area

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 analyzer system. The actual oxygen sensor may be remote, as in the case of a sampling type analyzer.

N.6 Identification, marking and documents

a) and b) [6.1 d) and 6.1 f)] Analyzer 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) [6.1 y) and 6.1 z)] Instructions: since it is common for oxygen analyzers to be operated in areas where the personnel using them change frequently, it is likely that full instructions 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 analyzer 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 analyzer correctly and safely. It is recognized that there are limitations to the amount of information that can be placed on the analyzer 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 analyzer itself, referring the user to the accompanying documents for details and cautions.

e) [6.7 a)] Red indicators are reserved for warning signals. Flashing red is further restricted to indications of imminent (patient) danger. Continuous red may be used to indicate instrument malfunctions requiring immediate operator attention as well as patient danger.

Yellow indicators are reserved for cautionary signals. Operator attention is required, but not necessarily immediate operator action.

Green indicators are reserved for indications of satisfactory function. Green is not intended to be used as a power-on indicator, unless the analyzer is ready for use and operating within tolerance without any warm-up delay. For example, it is not acceptable to have a green power-on indicator that illuminates sitmultaneously with a yellow warm-up delay indicator. In a case such as this, the green indicator illuminates only after the yellow indicator extinguishes.

Blue indicators may not be used for any of the applications reserved for red, flashing red, yellow or green, in order to avoid confusion. Blue may only indicate information that has no connotation of good, marginal or poor performance of the analyzer or the monitored function(s).

There are no colour restrictions on displays, such as dot matrix displays or cathode ray tubes. Displays are generally monochromatic and are usually used to convey detailed information. The implication of the requirements of this International Standard is that if a monochromatic display is used, separate coloured indicators are to be used to alert the operator to warning or caution conditions. A single indicator of each required colour may be used, however, with the display providing the information on the nature of the problem.

f 10) [6.8.2 a)] Accompanying documents — It has been noted by some users that some oxygen analyzers 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 analyzers, 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.

f 11) [6.8.2 a)] Electromagnetic interference — Electromagnetic susceptibility is considered to be an important, but difficult to solve, medical device problem. Bibliography [1] in this International Standard deals best with the problem, although it has its deficiencies. It does not include interference due to electrocautery devices in setting electromagnetic field levels for susceptibility testing. Electrocautery devices are the best-known primary offenders in terms of electromagnetic emissions. For these reasons, it was decided to compromise on a warning in the accompanying documents to educate the device user.

There are no generally accepted specifications for minimum levels of electromagnetic interference to which medical devices should not be susceptible. When a recognized standard exists, this will be taken into account in the revision of this International Standard.

f 12) [6.8.2 a)] An oxygen analyzer may be exposed to temperatures in the range of − 40 °C to + 70 °C during transport. The extremes are those that might reasonably be expected to be met in transport by air, land or sea. The objective of this requirement is to assure that an analyzer will still be operable after exposure to these temperature extremes during transport.

It is recognized that some types of oxygen sensor probably cannot withstand extremely low temperatures and that their response time or expected useful life, or both, are likely to be adversely effected. To account for this and to allow such oxygen sensors to be used because of their other desirable benefits, a narrower non-operating temperature range is permitted, provided that a notice to that effect is printed on the transport package and the actual range is disclosed in the accompanying documents. It is left to the manufacturer's discretion to determine the details of such precautionary instructions.