INTERNATIONAL STANDARD

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Second edition
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Oxygen concentrators for medical use — Safety requirements

Concentrateurs d'oxygène à usage médical — Prescriptions de sécurité

Reference number
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Contents

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 8359 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

This second edition cancels and replaces the first edition (ISO 8359:1988), which has been technically revised.

Annexes A to N form an integral part of this International Standard. Annexes P and Q are for information only.

Introduction

Oxygen concentrators provide a safe source of oxygen-enriched air for patients in need. These devices raise the level of inspired oxygen by separating nitrogen or oxygen from ambient air.

Oxygen concentrators fall into two main classes according to the means whereby gas separation is effected, namely:

a) oxygen concentrators in which oxygen selectively permeates or transports through a membrane or lattice,

b) pressure swing absorbers (PSA) in which air is exposed at a certain pressure to molecular sieve material which selectively retains nitrogen and other components until they are subsequently released when the pressure is reduced.

Details of the arrangement of test apparatus for carrying out a number of the tests to check compliance with certain requirements are given in annex N.

A rationale for the most important requirements is given in annex P. It is considered that a knowledge of the reasons for the requirements will not only facilitate the proper application of this International Standard, but will expedite any subsequent revision.

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

Oxygen concentrators for medical use — Safety requirements

Section 1: General

1.1 Scope

NOTE 1 See the rationale in annex P.

ISO 8359 is one of a series of International Standards based on IEC 601-1. In IEC 601-1 (the "General Standard"), this type of International Standard is referred to as a "Particular Standard". As stated in **1.3** of IEC 601-1:1988, the requirements of this International Standard take precedence over those of IEC 601-1.

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

> This International Standard specifies safety requirements for continuous-flow oxygen concentrators, as defined in 1.3.8 (in this International Standard). This International Standard does not apply to oxygen concentrators intended to supply gas to several patients via a piped medical gas installation or to those intended for use in the presence of flammable anaesthetic and/or cleaning agents.

The scope of this International Standard is not restricted to membrane oxygen concentrators and pressure swing absorbers (see Introduction), as alternative methods of concentrating oxygen may become available and it is not intended that this International Standard should restrict future developments.

1.2 Normative references

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

ISO 3744:1994, *Acoustics — Determination of sound power levels of noise sources using sound pressure — Engineering method in an essentially free field over a reflecting plane.*

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 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.*

IEC 651:1979, *Sound level meters.*

1.3 Definitions

For the purposes of this International Standard, the definitions given in clause 2 of IEC 601-1:1988 apply, except that the definition given in 2.1.5 shall be replaced by the following:

2.1.5 applied part: Oxygen concentrator outlet.

For the purposes of this International Standard, the following definitions also apply:

1.3.1 administration accessories: All accessories for conducting the product gas from the oxygen concentrator outlet to the patient, but excluding any fixed tubing extensions.

1.3.2 oxygen concentrator outlet: Port of the oxygen concentrator from which the product gas flows.

1.3.3 flow control device: Device which controls the flow of the product gas.

1.3.4 flow indicator: Device which shows the volume of product gas passing through the oxygen concentrator in a specified unit of time.

1.3.5 operator control: Control to enable the user, without the need for tools, to cause the oxygen concentrator to perform its intended function.

1.3.6 outlet pressure: Gauge pressure at the oxygen concentrator outlet under the test flow conditions.

1.3.7 oxygen analyzer: Device which measures and quantitatively indicates the concentration of oxygen present in a gaseous mixture.

1.3.8 oxygen concentrator: Device which, by selective removal of constituents of ambient air, increases the concentration of oxygen in the product gas.

1.3.9 product gas: Output from the oxygen concentrator consisting of respirable oxygen-enriched air.

1.3.10 oxygen concentration status indicator (OCSI): Device which indicates when the proportion of oxygen in the product gas is at an abnormal level.

1.4 General requirements

The requirements given in clause 3 of IEC 601-1:1988 apply.

1.5 General requirements for tests

The requirements given in clause 4 of IEC 601-1:1988 apply.

1.6 Classification

The classification given in clause 5 of IEC 601-1:1988 applies, except for the following deletions.

— Delete **5.5**.

— In **5.6** delete all except for "continuous operation" and "intermittent operation".

1.7 Identification, marking and documents

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

— The following additional general requirement also applies.

All markings pertaining to the operation of the oxygen concentrator shall be legible to an operator having visual acuity, corrected if necessary, of at least 1,0 and seated or standing 1 m from the oxygen concentrator flooded with illuminance of 215 lux.

NOTE 2 All markings should have a luminance contrast of at least 50 % when compared with the surrounding background material.

— In **6.1 e)** add the following.

The oxygen concentrator shall be marked with its country of origin plus the address of the manufacturer.

— Delete **6.1 r)**

— To **6.1** add the following additional items.

aa) The marking on the outside shall additionally include the following:

1) a warning against removal of the cover by unauthorized persons;

2) a warning **"NO SMOKING OR NAKED FLAMES"**;

3) the nominal concentration of oxygen in the product gas, expressed as a percent volume fraction, at a flowrate of 2 l/min or at the recommended maximum flowrate;

4) the statement "USE NO OIL OR GREASE";

5) on the flow indicator, the output (e.g. output, gas flow, etc.).

— Replace **6.7 a)** by the following.

If visual indicators are used on the oxygen concentrator, with the exception of alphanumeric displays, their colouring shall conform to ISO 9703-1 and the following additional requirements:

1) continuous red shall be used to indicate to the operator that the oxygen concentrator, or a portion of it, has failed;

2) the function of all lights and displays shall be marked.

Compliance shall be checked by functional test and inspection.

— In **6.8.2 a)**, add the following.

Instructions for use shall also include the following information:

1) intended use of the oxygen concentrator;

2) at least one type of humidifier which is suitable for use with the oxygen concentrator when needed;

3) statement that use of certain humidifiers and administration accessories not specified for use with this oxygen concentrator may impair the performance;

4) preferred location of any humidifier in the administration accessories;

5) statement that in certain circumstances oxygen therapy can be hazardous and that seeking medical advice before using the machine is advisable;

6) statement of the time required from switching on the oxygen concentrator to reach a stated performance;

7) statement that the air intake of the oxygen concentrator should be located in a well-ventilated space;

8) intervals at which cleaning procedures need to be performed and the items required for such cleaning;

9) statement that no lubricants are to be used other than those recommended by the manufacturer;

10) statement that advises the operator of actions to take when the oxygen concentration status indicator indicates an abnormal oxygen concentration level;

11) statement that the oxygen concentrator should be located so as to avoid pollutants or fumes.

— In **6.8.2 d)**, add the following.

Instructions for use shall also include the following information:

A specification for at least one complete set of administration accessories which is suitable for use with the oxygen concentrator and, except for administration accessories, intended for single use, recommendations for their cleaning, sterilization and disinfection.

— In **6.8.3 a)**, add the following.

The technical description shall also include the following information:

1) table or graph showing values of oxygen concentration as a function of flowrate at specified operator settings at a nominal outlet pressure of zero;

2) maximum recommended flow, expressed in litres per minute;

3) flowrate, expressed in litres per minute, at a specified control setting at nominal outlet pressures of zero and 7 kPa;

4) maximum outlet pressure when the oxygen concentrator is operated in accordance with the method given in new clause **50.8** presented in this International Standard;

5) maximum A-weighted sound pressure level, expressed in decibels, when the oxygen concentrator is operated under the test conditions specified in new clause **26.2** presented in this International Standard;

6) if a pressure relief mechanism is provided, the range of pressures, expressed in kilopascals, at which the mechanism operates;

7) nominal concentration of oxygen in the product gas, expressed as a percent volume fraction, at a flowrate of 2 l/min or at the recommended maximum flowrate;

8) statement of the concentration of oxygen in the product gas, expressed as a percent volume fraction, at the maximum recommended flowrate;

9) statement of the oxygen concentration (with tolerances) at which the OCSI gives an indication of abnormal oxygen concentration in the product gas;

10) statement of the ranges of temperature and atmospheric pressure at which the OCSI is intended for use;

11) temperature range within which the oxygen concentrator is intended to be operated;

12) variation of oxygen concentration with flowrate over a barometric pressure corresponding to the altitude range 0 to 4000 m above sea level.

1.8 Power input

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

Section 2: Safety requirements

2.1 Basic safety categories

The requirements given in Appendix A1.2 of IEC 601-1:1988 do not apply, as they are not relevant to oxygen concentrators.

2.2 Removable protective means

The requirements given in clause 6.1 z) of IEC 601-1:1988 apply.

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.

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, except that 21.3 shall be deleted.

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

Clause 26 of IEC 601-1:1988 shall be replaced by the following requirements.

26.1 In normal use the maximum A-weighted sound pressure level (steady or peak value) of the oxygen concentrator shall not exceed 60 dB.

Compliance shall be checked by the test specified in 26.2.

26.2 Place the microphone of a sound level meter complying with the requirements for a type 1 instrument specified in IEC 651 at the position of maximum sound pressure level in the horizontal plane passing through the geometric centre of the oxygen concentrator at a radius of 1 m. The measured sound pressure level shall not exceed the specified value.

For this test, the oxygen concentrator shall be operated over its normal working range of flow, including the maximum flowrate recommended by the manufacturer. Measurements shall be taken using the frequency-weighting characteristic A and the time-weighting characteristic F on the sound level meter. The measurements shall be taken in a free field over a reflecting plane as specified in ISO 3744.

The A-weighted background level of extraneous noise shall be at least 10 dB below that measured during the test.

4.7 Pneumatic and hydraulic power

The requirements given in clause 27 of IEC 601-1:1988 apply.

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

The requirements given in clause 30 of IEC 601-1:1988 apply.

5.3 Microwave radiation

The requirements given in clause 31 of IEC 601-1:1988 apply.

5.4 Light radiation (including visual radiation and lasers)

The requirements given in clause 32 of IEC 601-1:1988 apply.

5.5 Infrared radiation

The requirements given in clause 33 of IEC 601-1:1988 apply.

5.6 Ultraviolet radiation

The requirements given in clause 34 of IEC 601-1:1988 apply.

5.7 Acoustical energy (including ultrasonics)

The requirements given in clause 35 of IEC 601-1:1988 apply.

5.8 Electromagnetic compatibility

The requirements given in clause 36 of IEC 601-1:1988 apply. In addition the requirements given in IEC 601-1-2:1992 apply.

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

6.1 Locations and basic requirements

The requirements given in clause 37 of IEC 601-1:1988 do not apply, as oxygen concentrators intended for use in the presence of flammable anaesthetic and/or cleaning agents are outside the scope of this International Standard.

6.2 Marking, accompanying documents

The requirements given in clause 38 of IEC 601-1:1988 do not apply, as oxygen concentrators intended for use in the presence of flammable anaesthetic and/or cleaning agents are outside the scope of this International Standard.

6.3 Common requirements for category AP and category APG equipment

The requirements given in clause 39 of IEC 601-1:1988 do not apply, as oxygen concentrators intended for use in the presence of flammable anaesthetic and/or cleaning agents are outside the scope of this International Standard.

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

The requirements given in clause 40 of IEC 601-1:1988 do not apply, as oxygen concentrators intended for use in the presence of flammable anaesthetic and/or cleaning agents are outside the scope of this International Standard.

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

The requirements given in clause 41 of IEC 601-1:1988 do not apply, as oxygen concentrators intended for use in the presence of flammable anaesthetic and/or cleaning agents are outside the scope of this International Standard.

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, with the following modifications.

42.1 Amend the last entry in table Xa as follows.

Equipment parts which may in normal use have unintentional contact with a patient shall not attain temperatures exceeding 50 °C if made from metal or 60 °C if made from nonmetal.

42.3 Replace the existing text by the following.

The gas temperature at the oxygen concentrator outlet shall not exceed 6 °C above ambient temperature when the oxygen concentrator is operated in accordance with the manufacturer's instructions.

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

a) Use the test apparatus described in annex N (in this International Standard). With the variable restrictor fully open, set the flowrate adjuster to give approximately the maximum flowrate recommended by the manufacturer in the technical description. Operate the oxygen concentrator for 0,5 h and readjust the flow so that exactly the maximum flowrate recommended by the manufacturer is indicated on the flowmeter of the test apparatus. Operate the oxygen concentrator for a further 9 h and take readings of the product gas temperature at intervals not exceeding 0,5 h, the first reading being taken 1 h from the onset of operation.

The temperature of the product gas shall not exceed the specified value.

b) The gas temperature at the oxygen concentrator outlet shall not exceed 46 °C when operated in accordance with the manufacturer's instructions over the range of ambient temperature recommended by the manufacturer.

Compliance shall be checked by repeating the test given in a) above with the oxygen concentrator in an atmosphere maintained at the maximum operating temperature recommended by the manufacturer.

7.2 Fire prevention

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

a) 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 simultaneously be subjected to conditions in which:

   1) the temperature of the material is raised to its minimum ignition temperature, and

   2) an oxidant is present.

b) The minimum ignition temperature is determined in accordance with IEC 79-4:1975 using the oxidizing conditions present under normal and single-fault conditions.

c) Compliance is checked by determining the temperature to which the material is raised under normal and single-fault conditions.

d) 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

The requirements given in clause 45 of IEC 601-1:1988 apply.

7.5 Human errors

The requirements given in clause 46 of IEC 601-1:1988 apply.

7.6 Electrostatic charges

The requirements given in clause 47 of IEC 601-1:1988 apply.

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

The requirements given in clause 48 of IEC 601-1:1988 apply.

7.8 Interruption of the 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, together with the following additional subclauses, apply.

50.3 Flow indicator

A flow indicator, which indicates total product gas flowrate, shall be provided on the oxygen concentrator. It shall be graduated in litres per minute and be accurate to ± 10 % of the indicated flowrate or ± 200 ml/min, whichever is greater.

Compliance shall be checked by the following test:

Use the test apparatus described in annex N (in this International Standard). With the variable restrictor completely open, set the flow adjuster on the oxygen concentrator so that the flow indicator shows 20 % of the maximum flowrate stated by the manufacturer. Operate the oxygen concentrator for 15 min and measure the flowrate of the product gas using the flowmeter of the test apparatus. Repeat the procedure at the indicated 100 % flow and at the indicated 50 % flow. If a fixed orifice device is used to regulate flow, each orifice shall be tested.

The flowrate shown on the flow indicator shall be within the tolerance specified.

50.4 Oxygen concentration

The concentration of oxygen in the product gas, at a flowrate of 2 l/min, shall not be more than 3 % volume fraction below the value stated by the manufacturer in the accompanying documents.

Compliance shall be checked by the following test:

Use the test apparatus described in annex N in this International Standard and set the mains voltage 10 % above the rated supply voltage. With the variable restrictor completely open, set the flow adjuster to give an output of approximately 2 l/min, or at the recommended maximum flowrate. Operate the oxygen concentrator for 0,5 h and then adjust the flowrate to exactly 2 l/min, or at the recommended maximum flowrate, as indicated on the flowmeter of the apparatus. Operate the oxygen concentrator for a further 1 h and take five consecutive readings of the concentration of oxygen in the product gas, as displayed on the oxygen analyser at intervals of 1 min. Repeat the test with the mains voltage set 15 % below the rated supply voltage.

The concentration of oxygen in the product gas shall be within the tolerance specified.

50.5 Mean oxygen concentration

When the oxygen concentrator is operated at the maximum flowrate recommended by the manufacturer in the technical description, the mean concentration of oxygen in the product gas over an 8-h period shall be not more than 3 % volume fraction below the value stated by the manufacturer in the accompanying documents and no individual reading of oxygen content shall vary by more than ± 3 % volume fraction from the mean.

Compliance shall be checked by the following test:

Use the apparatus described in annex N (in this International Standard) and set the mains voltage 10 % above the rated supply voltage. With the variable restrictor completely open, set the flow adjuster to give approximately the maximum flowrate recommended by the manufacturer in the technical description. Operate the oxygen concentrator for 0,5 h and readjust the flowrate so that exactly the maximum flowrate recommended by the manufacturer is indicated on the flowmeter of the test apparatus. Operate the oxygen concentrator for

a further 9 h and take readings of the concentration of oxygen in the product gas, as indicated on the oxygen analyser, averaged over 1 min at intervals of 0,5 h, the first reading being taken after 1 h. Calculate the arithmetic mean of the readings obtained. Repeat the test with the mains voltage set 15 % below the rated supply voltage.

The mean concentration of oxygen in the product gas and the individual readings shall be within the tolerances specified.

50.6 Tolerance on flowrate

When the oxygen concentrator is set to the maximum flowrate recommended by the manufacturer in the technical description and operated for 8 h, the mean of the flowrates recorded at intervals of 0,5 h over that period shall be within ± 10 % of the stated value or ± 0,5 l/min, whichever is greater, and no individual reading shall vary by more than ± 10 % of the mean value.

Compliance shall be checked by the following test:

During the test given in **50.5**, note the flowrate from the oxygen concentrator, as indicated on the flowmeter of the test apparatus, at the same time as taking readings of the concentration of oxygen in the product gas. Calculate the arithmetic mean of the flowrate readings obtained.

The mean of the flowrates recorded and the individual flowrates shall be within the tolerances specified.

50.7 Backpressure effect

The change in the maximum recommended flowrate when a backpressure of 7 kPa is applied shall be within ± 10 % of the figure stated by the manufacturer in the technical description.

Compliance shall be checked by the following test:

Use the test apparatus described in annex N (in this International Standard). Set the flowrate from the oxygen concentrator so that its flow indicator shows the maximum flowrate recommended by the manufacturer in the technical description. Adjust the variable restrictor in the test apparatus to give a backpressure of 7 kPa. Operate the oxygen concentrator for 15 min and record the flowrate indicated on the flowmeter of the test apparatus. Subtract this figure from the manufacturer's recommended flowrate to give the change in flowrate when a backpressure of 7 kPa is applied.

The change in flowrate shall be within the tolerance specified.

50.8 Outlet pressure

The maximum outlet pressure shall be within ± 10 % of the value stated by the manufacturer in the technical description.

Compliance shall be checked by the following test:

Use the test apparatus described in annex N (in this International Standard). Operate the oxygen concentrator at the maximum flowrate recommended by the manufacturer in the technical description and adjust the variable restrictor to stop the flow. Record the pressure indicated. The pressure indicated shall be within the tolerance specified.

8.2 Protection against hazardous output

The requirements given in clause 51 of IEC 601-1:1988 apply, except for the following modifications.

51.1 Replace the existing text by the following:

51.1 Flow control device

The oxygen concentrator shall be fitted with a flow control device.

Compliance shall be checked by inspection.

NOTE 3 The flow control device should be provided with a means to prevent adjustments by the patient.

51.2 Replace the existing text by the following.

51.2 Filter

A filter capable of retaining particles of 10 µm diameter or greater shall be provided between the oxygen-concentrating elements and the oxygen concentrator outlet.

Compliance shall be checked by inspection.

Add the following subclause.

51.5 Oxygen concentration status indicator

An oxygen concentration status indicator shall be provided to warn the operator when the oxygen concentration in the product gas is below 82 % volume fraction.

Compliance shall be checked by verifying that an oxygen concentration status indicator indicates when the oxygen concentration in the product gas is below 82 % volume fraction at temperatures between 10 °C and 40 °C. Compliance shall also be checked by simulating conditions which cause lower oxygen concentrations in the product gas than the stated value.

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

See subclause 4.10 and clause 10 of IEC 601-1:1988.

Section 10: Constructional requirements

10.1 General

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

10.2 Enclosures and covers

The requirements given in clauses 16, 21 and 24 of IEC 601-1:1988 apply.

10.3 Components and general assembly

The requirements given in clause 56 of IEC 601-1:1988 apply, with the following additions and modifications.

56.8 Add the following requirements.

1) Indication of continued mechanical and electrical function or of malfunction shall be provided on the oxygen concentrator.

Compliance shall be checked by operating the oxygen concentrator and, inducing the following faults individually, where applicable:

a) compressor failure;

b) pump failure;

c) cycle failure;

d) pressure failure;

e) vacuum failure.

2) A nonresettable elapsed-time indicator showing the total operating time, in hours, shall be provided on the oxygen concentrator.

Compliance shall be checked by inspection.

56.9 Replace the existing text by the following.

Preset controls shall either be inside the casing or shall require the use of a tool for adjustment.

Compliance shall be checked by inspection.

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 clauses

11.1 Auditory indicators

Any auditory indicator provided with the oxygen concentrator shall announce in a tone distinctly different from the sounds generated by the oxygen concentrator during normal operation, in order to avoid masking.

If an oxygen concentrator of the domiciliary type is intended to be used in a health care facility, the auditory indicators shall comply with the requirements of ISO 9703-2.

11.2 Indication of loss of mains power

An auditory alarm shall be provided to indicate when mains power has been interrupted.

Compliance shall be checked by inspection.

Annexes

Annexes A to M given in IEC 601-1:1988, together with annexes N, P and Q in this International Standard apply.

Annex N

(normative)

Test apparatus

N.1 Apparatus

N.1.1 Flowmeter, accurate to within ± 2 % of the flow to be measured.

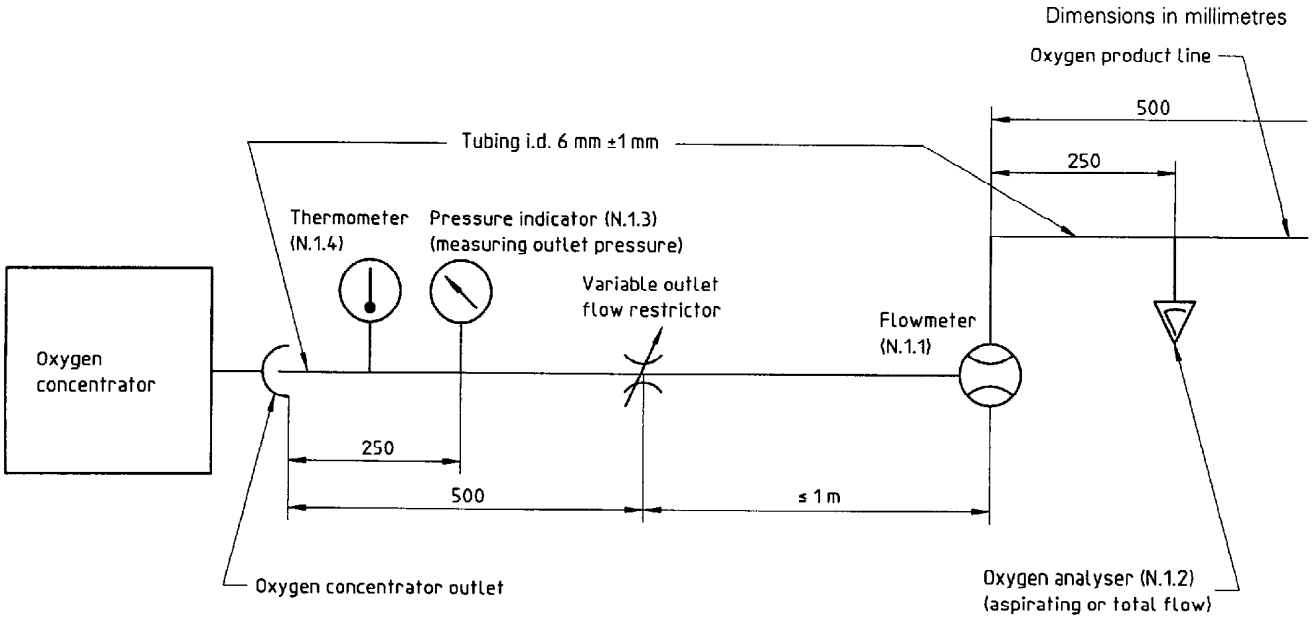
N.1.2 Oxygen analyser, accurate to within ± 1 % of the oxygen concentration to be measured and which gives a reading equal to at least 90 % of the actual oxygen concentration within 10 s of exposure of the sensing element to the gas flow. If a pump is required to aspirate the gas sample, it shall neither reduce the pressure at the outlet of the flowmeter to below atmospheric nor draw air back through the open end of the tube.

N.1.3 Pressure indicator, accurate to within ± 2 % of the pressure to be measured.

N.1.4 Thermometer, accurate to within ± 0,5 °C of the temperature to be measured.

N.2 Test assembly

Assemble the apparatus as shown in figure N.1 using tubing with an internal diameter of 6 mm ± 1 mm.



NOTE — Ambient temperature shall be measured simultaneously.

Figure N.1 — Test apparatus

Annex P

(informative)

Rationale statement

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 this 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 the proper application of this International Standard. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate any revision of this International Standard necessitated by those developments.

Remarks made in this annex apply to the relevant clause or subclause in this International Standard; the numbers, therefore, are not consecutive.

1.1 Scope

This International Standard does not apply to institutional pressure swing absorber devices (molecular sieve devices) which use the separation principle to deliver oxygen of a specified minimum concentration to a hospital or similar distribution system at a minimum pressure of 400 kPa. The performance and safety requirements for such devices vary considerably from those for the portable oxygen concentrators covered in this International Standard.

1.7 Identification, marking and documents

— **6.7 a)** The use of the existing standardized colour system for visible indicators decreases the likelihood of patient and operator error.

— **6.8.2 a)** It was recognized that the supplier cannot be required to test or approve all types of humidifiers which might be used with the oxygen concentrator. Such equipment, which requires a high pressure, might seriously degrade the performance of the oxygen concentrator.

— **6.8.2 d)** The supplier is required to recommend oxygen administration accessories which are suitable for use with the oxygen concentrator because administration accessories suitable for use with medical gas pipeline or cylinder regulators may not be satisfactory.

— **6.8.3 a)** These performance data provide important information concerning the functioning of oxygen concentrators. It is necessary that the user understand these data for safe and effective prescription.

4.6 Vibration and noise

It is essential that the noise level be related to patient acceptability and comfort. It is desirable to reduce the noise level as far as possible for devices which interfere with sleeping. It is recognized that oxygen concentrators (pressure swing absorbers) may have both a steady sound level and a peak sound level. The peak sound pressure level was considered to be the more likely to be obtrusive to the patient during continuous machine performance.

7.1 Temperatures outside the specified range may constitute a thermal hazard.

7.2 Fire prevention

It is important that particular care be taken to reduce the fire hazard of oxygen concentrators because they may contain gas of high oxygen concentration.

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

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

— ignitable material (fuel);

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

— 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 oxygen concentrations are required, these may be determined using the methods and apparatus described in IEC 79-4.

In considering the ignitable materials, 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 accumulations, are present then it may not be possible to determine the surface temperatures attained during exposure to spark energy, and specific tests, e.g. ignition tests, may be necessary to assure safety under these conditions.

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 overrestrictive 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 universally 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 normal conditions, and seal compartments or add forced ventilation to ensure that the oxygen content does not exceed that of ambient air under a 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 conditions.

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

8.1 Accuracy of operating data

8.1.1 A medical need was expressed for these accuracies. The design of a molecular sieve oxygen concentrator is such that oxygen concentration decreases with increasing flowrate, whilst the total volume of oxygen delivered generally increases with flowrate. Oxygen administration by flowrate adjustment should be accurate and related to the device used for administration, the patient minute ventilation and the desired arterial blood oxygen concentration.

8.1.2 There is a medical need for accurate oxygen concentrations. Deviations within ± 3 % oxygen concentration were considered to be achievable by the manufacturer and were acceptable medically.

Measurement of stability of oxygen concentration over a long period is necessary to give a meaningful result.

8.1.3 A medical need was expressed for flowrate stability without attention on the part of the patient for this period of time. The maintenance of a stable flowrate with its resultant oxygen concentrator is, therefore, important to the patient.

8.2.1 Flow control device

A flow control device was considered necessary to match the output of the oxygen concentrator to variations in the needs of the patient.

It was considered that in some clinical circumstances a deterrent to operator adjustment of flowrate was important. The presence of this deterrent might remind the patient to consult the physician before making any flowrate change.

8.2.3 Oxygen concentration status indicator (OCSI)

An OCSI was considered necessary to indicate to the operator when the concentrator is delivering product gas with an oxygen concentration below 82 % volume fraction.

10.3.1.1 Function indicator

It was considered advisable that some mechanism be available to inform the operator whether or not the oxygen concentrator is performing adequately during continued operation.

10.3.1.2 Elapsed-time indicator

An elapsed-time indicator is essential for maintenance procedures.

Annex Q

(informative)

Bibliography

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

[2] ASTM F 1464-93, *Standard specification for oxygen concentrators for domiciliary use.*

[3] NFPA 53:1994, *Fire hazards in oxygen-enriched atmospheres.*

ICS 11.040.10

Descriptors: medical equipment, oxygen, concentrators, classification, specifications, safety requirements, protection against mechanical hazards, protection against electric shocks, radiation protection, heat protection, fire protection, manufacturing requirements, marking.

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