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Oxygen concentrators for medical use — Safety requirements

Concentrateurs d'oxygène à usage médical — Exigences de sécurité

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Foreword

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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 8359 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment.*

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

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Oxygen concentrators for medical use — Safety requirements

0 Introduction

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

Oxygen concentrators fall into the following two main classes according to the means by which the gases are separated:

a) membrane oxygen concentrators in which oxygen selectively permeates a membrane;

b) pressure swing adsorbers (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 O. 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. This annex does not form an integral part of the standard.

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.

Section one — General

1 Scope and field of application [1]

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

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

> This International Standard specifies safety requirements for oxygen concentrators, as defined in 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 adsorbers (see clause 0) as alternative methods of concentrating oxygen may become available and it is not intended that this International Standard should restrict future developments.

2 References

ISO 3744, *Acoustics — Determination of sound power levels of noise sources — Engineering method for free-field conditions over a reflecting plane.*

IEC Publication 601-1, *Safety of medical electrical equipment — Part 1: General requirements.* [2]

IEC Publication 651, *Sound level meters.*

3 Definitions

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

> **applied part:** The oxygen concentrator outlet.

1) See also annex O (in this International Standard).

2) Cross-references to specific clauses, sub-clauses, etc. in IEC Publication 601-1 apply to the first edition published in 1977 and Amendment No. 1 to IEC Publication 601-1 published in 1984.

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

3.1 administration accessories: All accessories for conducting the product gas from the oxygen concentrator outlet to the patient, e.g. tubing, humidifier, breathing system, mask or nasal cannulae, but excluding any fixed tubing extensions.

3.2 oxygen concentrator outlet: The port of the oxygen concentrator from which the product gas flows.

3.3 flow adjuster: A device which controls the flow of the product gas.

3.4 flow indicator: A device which shows the volume of gas passing through the oxygen concentrator in a unit of time.

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

3.6 outlet pressure: The gauge pressure at the oxygen concentrator outlet under the test flow conditions.

3.7 oxygen analyser: A device which measures and quantitatively indicates the concentration of oxygen present in a gaseous mixture.

3.8 oxygen concentrator: A device which by separating out nitrogen from ambient air provides oxygen-enriched air.

3.9 product gas: The output from the oxygen concentrator consisting of respirable oxygen-enriched air.

4 General requirements and general requirements for tests

The requirements given in clauses 3 and 4 of IEC Publication 601-1 apply.

5 Classification

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

— in 5.1, delete "CLASS III EQUIPMENT";

— in 5.5, delete "ANAESTHETIC PROOF EQUIPMENT" and "ANAESTHETIC PROOF CATEGORY G EQUIPMENT";

— in 5.6, delete all except for "CONTINUOUS OPERATION".

6 Identification, markings and documents

The requirements given in clause 6 of IEC Publication 601-1 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 seated or standing 1 m from the oxygen concentrator at an illuminance of 215 lx.

NOTE — 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.

— Delete 6.1 r).

— In 6.1, add the following additional items:

y) The marking on the outside shall also include the following:

1) A warning against removal of the covers by unauthorized persons.

2) A warning "**NO SMOKING OR NAKED FLAMES**".

3) The nominal concentration of oxygen in the product gas expressed as a percentage of oxygen by volume (V/V) at a flow of 2 l/min.

4) The statement "USE NO OIL OR GREASE".

z) The flow indicator shall be marked to indicate the output.

— Replace 6.7 a) by the following[1]:

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

1) Continuous red shall be used to indicate to the operator that the oxygen concentrator 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.

1) See also annex O (in this International Standard).

4) Green shall be used to indicate that the oxygen concentrator 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.

— In 6.8.2a), add the following:

The instructions for use shall also include the following information:

1) The intended use of the oxygen concentrator (e.g. in respiratory care, at home or in hospital).

2) At least one type of humidifier which is suitable for use with the oxygen concentrator. [1)]

3) The statement "USE OF CERTAIN HUMIDIFIERS NOT SPECIFIED FOR USE WITH THIS OXYGEN CONCENTRATOR MAY IMPAIR THE PERFORMANCE".

4) The preferred location of any humidifier in the administration accessories.

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

6) A statement of the time taken to reach a stated performance after the oxygen concentrator has been switched on.

7) A statement that the air intake of the oxygen concentrator should be located in a well ventilated space so as to avoid airborne pollutants or fumes.

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

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

— In 6.8.2d), add the following:

The instructions for use shall also include the following information:

1) 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. [1)]

2) The statement "THE USE OF SOME ADMINISTRATION ACCESSORIES NOT SPECIFIED FOR USE WITH THIS OXYGEN CONCENTRATOR MAY IMPAIR THE PERFORMANCE".

— In 6.8.3a), add the following [1)]:

The technical description shall also include the following information:

1) A table or graph showing values of oxygen concentration as a function of flow at specified operator settings at an outlet pressure of nominal zero.

2) The maximum recommended flow, expressed in litres per minute.

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

4) The maximum outlet pressure when the oxygen concentrator is operated according to the method given in 50.14 (in this International Standard).

5) The maximum A-weighted sound pressure level, in decibels (dB), when the oxygen concentrator is operated under the test conditions specified in clause 26.2 (in this International Standard).

6) If a pressure-relief mechanism is provided, the range of pressures, in kilopascals, at which the mechanism operates.

7) The nominal concentration of oxygen in the product gas expressed as a percentage of oxygen by volume (V/V) at a flow of 2 l/min.

8) A statement of the concentration of oxygen in the product gas expressed as a percentage of oxygen by volume (V/V) at the maximum recommended flow.

9) Details of any degradation of performance when the oxygen concentrator is used over an altitude range of between 0 m and 4 000 m above sea level.

— In 6.8.3d), add the following:

The technical description shall additionally include the following information:

The ambient temperature range in which the oxygen concentrator is intended to be used.

7 Power input

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

1) See also annex O (in this International Standard).

Section two — Safety requirements

8 Basic safety categories

The requirements given in clause 8 of IEC Publication 601-1 do not apply as they are not relevant to oxygen concentrators.

9 Removable protective means

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

10 Special environmental conditions

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

11 Special measures with respect to safety

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

12 Single fault condition

The requirements given in clause 12 of IEC Publication 601-1 apply.

Section three — Protection against electric shock hazards

13 General

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

14 Requirements related to classification

The requirements given in clause 14 of IEC Publication 601-1 apply except that 14.3 shall be deleted.

15 Limitation of voltage and/or current

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

16 Enclosures and protective covers

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

17 Insulation and protective impedances

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

18 Earthing and potential equalization

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

19 Continuous leakage currents and patient auxiliary currents

The requirements given in clause 19 of IEC Publication 601-1 apply.

20 Dielectric strength

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

Section four — Protection against mechanical hazards

21 Mechanical strength

The requirements given in clause 21 of IEC Publication 601-1 apply except that 21.2, 21.3 and 21.4 shall be deleted.

22 Moving parts

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

23 Surfaces, corners and edges

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

24 Stability and transportability

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

25 Expelled parts

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

26 Vibration and noise [1)]

The requirements given in clause 26 of IEC Publication 601-1 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 given 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 Publication 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 flow 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.

27 Pneumatic and hydraulic power

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

28 Suspended masses

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

1) See also annex O (in this International Standard).

Section five — Protection against hazards from unwanted or excessive radiation

29 X-radiation

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

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

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

31 Microwave radiation

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

32 Light radiation (including visual radiation and lasers)

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

33 Infra-red radiation

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

34 Ultraviolet radiation

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

35 Acoustical energy (including ultrasonics)

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

36 Electromagnetic compatibility

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

Section six — Protection against the hazards of explosions in medically used rooms

37 General

The requirements given in clause 37 of IEC Publication 601-1 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.

38 Classification, marking and accompanying of anaesthetic-proof equipment

The requirements given in clause 38 of IEC Publication 601-1 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.

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

The requirements given in clause 39 of IEC Publication 601-1 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.

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

The requirements given in clause 40 of IEC Publication 601-1 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.

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

The requirements given in clause 41 of IEC Publication 601-1 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 seven — Protection against excessive temperatures, fire and other hazards, such as human errors

42 Excessive temperatures

The requirements given in clause 42 of IEC Publication 601-1 apply except for the following modifications:

— Amend 42.1 (last entry in table Xa) as follows[1]:

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

— Replace 42.3 by the following:

42.3.1 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 42.3.2.

42.3.2 *Use the test apparatus described in annex N (in this International Standard). With the variable restrictor fully open, set the flow adjuster to give approximately the maximum flow recommended by the manufacturer in the technical description. Operate the oxygen concentrator for 0,5 h and re-adjust the flow so that exactly the maximum flow 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 after 1 h.*

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

42.3.3 The gas temperature at the oxygen concentrator outlet shall not exceed 41 °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 42.3.2 with the oxygen concentrator in an atmosphere maintained at the maximum temperature at which the manufacturer recommends it should be used.

43 Fire prevention[1]

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

43.3 In order to minimize the risk of fire in normal use or in single fault conditions at least one of the following requirements shall be satisfied:

a) electrical components shall be separated from compartments in which accumulations of oxygen 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 or single fault conditions, can be a source of ignition, shall comply with the requirements given in 43.7.

43.4 Any barrier required under the provision of 43.3a) shall be sealed at all joints and holes for cables or for other purposes.

Compliance shall be checked by inspection and, if applicable, by the compliance test for sealed enclosures given in 40.5e) in IEC Publication 601-1.

If, in normal use, a pressure difference of 0,4 kPa or greater exists between the spaces separated by the barrier, the compliance test described in 43.6 shall be used.

43.5 The ventilation required under the provision of 43.3b) shall be such that the oxygen concentration in the compartment containing electrical components shall not exceed 25 % (V/V). If this requirement is met by forced ventilation, a failure alarm shall be provided.

Compliance shall be checked by the test given in 43.6.

43.6 *Measure the oxygen concentration under the following conditions:*

a) rupture or leakage of any component which carries oxygen-enriched air in close proximity to the test compartment;

b) selection of the least favourable control settings, e.g. highest oxygen concentration or maximum flow;

c) supply mains voltage variation from + 10 % to − 15 %.

The oxygen concentration shall be measured for such a period that the highest possible concentration of oxygen occurs and is maintained for 0,5 h.

The oxygen concentration measured shall not exceed the specified value.

43.7 Electrical circuits which can produce sparks or generate increased surface temperatures and which might otherwise be a source of ignition shall be designed so that in

1) See also annex O (in this International Standard).