INTERNATIONAL STANDARD

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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.