SLOVENSKI STANDARD
SIST EN ISO 8359:2000

01-januar-2000

Naprave za koncentriranje kisika za uporabo v medicini - Varnostne zahteve (ISO 8359:1996)

Oxygen concentrators for medical use - Safety requirements (ISO 8359:1996)

Sauerstoff-Konzentratoren für medizinische Zwecke - Sicherheitsanforderungen (ISO 8359:1996)

Concentrateurs d'oxygene a usage médical - Prescriptions de sécurité (ISO 8359:1996)

Ta slovenski standard je istoveten z: **EN ISO 8359:1996**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST EN ISO 8359:2000 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8359

December 1996

ICS 11.040.10

Descriptors: see ISO document

English version

Oxygen concentrators for medical use - Safety requirements (ISO 8359:1996)

Concentrateurs d'oxygène à usage médical - Prescriptions de sécurité (ISO 8359:1996)

Sauerstoff-Konzentratoren für medizinische Zwecke Sicherheitsanforderungen (ISO 8359:1996)

This European Standard was approved by CEN on 1996-09-28. CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

The European Standards exist in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart,36 B-1050 Brussels

Foreword

The text of the International Standard ISO 8359:1996 has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 1997, and conflicting national standards shall be withdrawn at the latest by June 1998.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 8359:1996 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZA (normative).

Annex ZA (normative)
Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

Publication	Year	Title	EN	Year
ISO 3744	1994	Acoustics - Determination of sound power level of noise sources - Engineering method for free-filed conditions over a reflecting plane	EN ISO 3744	1995

INTERNATIONAL STANDARD

ISO 8359

Second edition
1996-12-15

Oxygen concentrators for medical use — Safety requirements

Concentrateurs d'oxygène à usage médical — Prescriptions de sécurité

Reference number
ISO 8359:1996(E)

Contents

International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

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.