SLOVENSKI PREDSTANDARD

OSIST prEN ISO 10083:2005

januar 2005

Sistemi za koncentriranje kisika za uporabo s sistemi napeljav za medicinske pline (ISO/DIS 10083:2004)

(istoveten prEN ISO 10083:2004)

Oxygen concentrator supply systems for use with medical gas pipeline systems (ISO/DIS 10083:2004)

ICS 11.040.10

Referenčna številka
OSIST prEN ISO 10083:2005(en;fr;de)

EUROPEAN STANDARD

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DRAFT
prEN ISO 10083

October 2004

ICS

English version

Oxygen concentrator supply systems for use with medical gas pipeline systems (ISO/DIS 10083:2004)

Systèmes d'approvisionnement concentrateurs d'oxygène pour utilisation dans des réseaux de distribution de gaz médicaux (ISO/DIS 10083:2004)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 215.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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 Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (prEN ISO 10083:2004) 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 document is currently submitted to the parallel Enquiry.

This document 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).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

Endorsement notice

The text of ISO 10083:2004 has been approved by CEN as prEN ISO 10083:2004 without any modifications.

ANNEX ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42 EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42 EEC.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZA. confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

DRAFT INTERNATIONAL STANDARD ISO/DIS 10083

ISO/TC **121**/SC **6** Secretariat: **ANSI**

Voting begins on: **2004-10-07**

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Oxygen concentrator supply systems for use with medical gas pipeline systems

Systèmes d'approvisionnement concentrateur d'oxygène pour utilisation dans des réseaux de distribution de gaz médicaux

[Revision of first edition (ISO 10083:1992)]

ICS 11.040.10

ISO/CEN PARALLEL ENQUIRY

The CEN Secretary-General has advised the ISO Secretary-General that this ISO/DIS covers a subject of interest to European standardization. **In accordance with the ISO-lead mode of collaboration as defined in the Vienna Agreement, consultation on this ISO/DIS has the same effect for CEN members as would a CEN enquiry on a draft European Standard.** Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month FDIS vote in ISO and formal vote in CEN.

In accordance with the provisions of Council Resolution 15/1993 this document is circulated in the English language only.

Conformément aux dispositions de la Résolution du Conseil 15/1993, ce document est distribué en version anglaise seulement.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 10083 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, Medical gas systems

This second edition cancels and replaces the first edition (1992), which has been technically revised.

Annexes A, B, C, D, E, F, G, H, I, J, K, L and M are given for information only.

Introduction

This purpose of this International Standard is to specify minimum safety and performance requirements for oxygen concentrator supply systems used to deliver oxygen 90+ to a pipeline distribution system. Oxygen 90+ is a generic term, developed by the subcommittee and intended to include the range of oxygen concentrations produced by oxygen concentrator supply systems. National, regional or local regulations may stipulate the minimum concentration of oxygen to be produced by an oxygen concentrator supply system, or the range of concentrations which the supply system shall produce.

Oxygen concentrators can be used to deliver oxygen-enriched air to a medical gas pipeline system as a substitute for medical oxygen. Oxygen concentrators may be combined with sources of supply containing 100% medical oxygen (i.e. in cylinders or cryogenic vessels).

Oxygen concentrators can supply a product gas with an oxygen concentration variable within a specified range (e.g. 93 ± 3%) depending on the characteristic of the concentrator and the flow supplied. The oxygen concentration supplied will therefore vary from 90 to 100% in normal operating conditions.

The selection of oxygen 90+ is a decision of the healthcare facility and outside the scope of this standard. This standard should not be construed as an endorsement or recommendation of one concentration of oxygen over another. The use of supply systems with oxygen concentrators may require the approval of regional or national authorities.

A supply system with oxygen concentrators can be installed at the time of the installation of the pipeline distribution system or as a replacement or augmentation of an existing supply system. A supply system with oxygen concentrators can be supplied as a package and may be installed by a third party. In this case the manufacturer of the oxygen concentrator supply system must provide the installer with appropriate information for installation and testing before connecting the supply system to the pipeline distribution system and before use.

Objectives of this standard are to ensure the following:

- appropriate introduction of an oxygen concentrator supply system into a health care facility;

- acceptable quality of the oxygen 90+ delivered by the system;

- continuous supply of oxygen 90+;

- use of suitable materials;

- cleanliness of components;

- correct installation;

- provision of appropriate control, monitoring and alarm systems for the supply system;

- testing, commissioning and certification.

It is intended for use by those persons involved in the design, construction, inspection or operation of health care facilities. Those persons involved in the design, manufacture, calibration or testing of equipment intended to be connected to a pipeline system supplied by an oxygen concentrator supply system should also be aware of the contents of this document.

Annex K contains rationale statements for some of the requirements of ISO 10083. It is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this International Standard. The clauses and subclauses marked with **R** after their number have corresponding rationale contained in annex K. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this International Standard, but will expedite any subsequent revisions.

Oxygen concentrator supply systems for use with medical gas pipeline systems

1 Scope

1.1 This standard specifies requirements for design and installation of an oxygen concentrator supply system for use with a pipeline distribution system.

1.2 Oxygen concentrators for domiciliary use are excluded from the scope of this standard.

NOTE Requirements for oxygen concentrators for domiciliary use are specified in ISO 8359.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 407:1991, *Small medical gas cylinders - Pin-index yoke-type valve connections.*

ISO 3746:1995, *Acoustics – Determination of sound power levels of noise sources using sound pressure – Survey method using an enveloping measurement surface over a reflecting plane.*

ISO 5145:1990, *Cylinder valve outlets for gases and gas mixtures - - Selection and dimensioning.*

ISO 5359:2000, *Low-pressure hose assemblies for use with medical gases.*

ISO 7396-1:2002, *Medical gas pipeline systems – Part 1: Pipelines for compressed medical gases and vacuum.*

ISO/TR 7470:1998, *Valve outlets for gas cylinders -- List of provisions which are either standardized or in use.*

ISO 9703-1:1992, *Anaesthesia and respiratory care alarm signals – Part 1: Visual alarm signals.*

ISO 14971:2000, *Medical devices – Risk management -- Part 1: Application of risk analysis.*

ISO 15001:2003, *Anaesthetic and respiratory equipment---compatibility with oxygen.*

ISO 21969, *High-pressure flexible connections for use with medical gases.*

EN 286-1:2002, *Simple unfired pressure vessels designed to contain air or nitrogen – Part 1: Pressure vessels for general purposes.*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
commissioning
proof of function to verify that the agreed system specification is met and is accepted by the user or his representative

3.2
control equipment
those items necessary to maintain the oxygen 90+ supply within the specified operating parameters

Examples are pressure regulators, pressure-relief valves, alarms, sensors and oxygen monitors.

3.3 cylinder bundle
pack or pallet of cylinders linked together with a single connector for filling and emptying

3.4
gas-specific
having characteristics which prevent connections between different gas services

3.5
manifold
device for connecting the outlet(s) of one or more cylinders or cylinder bundles of the same medical gas to the pipeline system

3.6
manufacturer
the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

3.7
medical gas pipeline system
complete system which comprises a supply system, a monitoring and alarm system and a pipeline distribution system with terminal units at the points where medical gases or vacuum may be required

3.8
nominal distribution pressure
pressure which the medical gas pipeline system is intended to deliver at the terminal units

3.9
non-return valve
valve which permits flow in one direction only

3.10
operating alarm
alarm to indicate to technical staff that it is necessary to replenish the supply or to correct a malfunction

3.11
oxygen concentrator
device which produces oxygen 90+ from ambient air by extraction of nitrogen

3.12
oxygen concentrator supply system
supply system containing one or more oxygen concentrators

3.13
oxygen concentrator unit
source of supply for oxygen 90+ comprising compressor(s), sieve bed(s) and at least one storage vessel

3.14
oxygen 90+ storage vessel
pressurized container to store oxygen 90+

3.15
oxygen 90+
medical gas produced by an oxygen concentrator and meeting the specifications in section 4.5 of this International Standard

3.16
peak demand
maximum anticipated oxygen flowrate required by a health care facility

NOTE This is commonly expressed in litres per minute.

3.17
pipeline distribution system
that part of a medical gas pipeline system linking the supply system to the terminal units

3.18
pressure regulator
device which reduces the inlet pressure of a gas and maintains its set outlet pressure within specified limits

3.19
pressure-relief valve
valve which opens to atmosphere at a preset pressure and which is intended to prevent excess positive pressure

3.20
primary source of supply
that portion of the supply system that normally delivers the medical gas to the pipeline distribution system

3.21
reserve source of supply
that portion of the supply system which delivers the medical gas to the pipeline distribution system in the event of failure or exhaustion of both the primary and secondary sources of supply

3.23
secondary source of supply
that portion of the supply system that delivers the medical gas to the pipeline distribution system in the event of failure or exhaustion of the primary source of supply

3.24
shut-off valve
valve which prevents flow in both directions when closed

3.25
single fault condition
condition in which a single means for protection against a safety hazard in equipment is defective or a single external abnormal condition is present

3.26
source of supply
that portion of the supply system with associated control equipment which supplies the pipeline distribution system