

INTERNATIONAL  
STANDARD

ISO  
10083

Second edition  
2006-07-15

---

---

## Oxygen concentrator supply systems for use with medical gas pipeline systems

*Systèmes d'approvisionnement par concentrateurs d'oxygène pour  
utilisation dans des réseaux de distribution de gaz médicaux*



Reference number  
ISO 10083:2006(E)

© ISO 2006

**PDF disclaimer**

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

This document is a preview generated by EVS

© ISO 2006

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Published in Switzerland

# Contents

Page

Foreword.....	v
Introduction.....	vi
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	2
4 General requirements.....	4
4.1 Safety and continuity of supply.....	4
4.2* Alternative constructions.....	5
4.3 Materials.....	5
4.4 System design.....	6
4.5 Specifications for oxygen-enriched air.....	6
4.6 Cylinder filling.....	7
5 Sources of supply.....	7
5.1 General.....	7
5.2 Primary source of supply.....	8
5.3 Secondary source of supply.....	8
5.4 Reserve source of supply.....	9
5.5 Sources of supply with cylinders.....	9
5.6 Location of oxygen concentrator supply systems.....	9
6 Requirements for components.....	10
6.1 Oxygen concentrator unit.....	10
6.2 Oxygen-enriched air storage vessels.....	10
6.3 Oxygen analysers.....	11
6.4 Pressure-relief valves.....	11
6.5 Shut-off valves.....	11
6.6 Sample port.....	12
6.7 Pressure regulators.....	12
7 Monitoring and alarm systems.....	12
7.1 General.....	12
7.2 Monitoring and alarm signals.....	12
7.3 Operating alarms.....	12
7.4 Information signals.....	13
8 Marking.....	13
9 Installation.....	13
9.1 General.....	13
9.2 Electrical systems.....	13
10 Testing, commissioning and certification.....	13
10.1 General.....	13
10.2 Tests and procedures.....	14
10.3 Specific tests.....	14
10.4 Commissioning and certification.....	16
11 Information to be supplied by the manufacturer.....	16
11.1 Instructions for installation.....	16
11.2 Instructions for use.....	16
11.3 Instructions for preventive maintenance.....	17
11.4 Operational management information.....	17

11.5	“As installed” drawings.....	17
11.6	Electrical schematics.....	17
11.7	Disclosure by the manufacturer .....	17
12	Implementation of use of oxygen-enriched air .....	17
12.1	Acceptance of oxygen-enriched air .....	17
12.2	Timing.....	17
12.3	Mixing of oxygen-enriched air and oxygen .....	17
12.4	Calibration of medical equipment .....	17
12.5	Labelling.....	18
12.6	Compliance with ISO 7396-1 .....	18
Annex A (informative)	Schematic representations of oxygen concentrator supply systems .....	19
Annex B (informative)	General guidelines for location of supply systems.....	27
Annex C (informative)	Guidelines for emergency procedures .....	29
Annex D (informative)	Procedure for testing and commissioning .....	31
Annex E (informative)	Typical forms for certification of an oxygen concentrator supply system .....	32
Annex F (informative)	Recommended minimum requirements for preventive maintenance.....	35
Annex G (informative)	Recommendations for installation .....	37
Annex H (informative)	Risk and risk management.....	38
Annex I (informative)	Recommendations for sizing and capacity.....	39
Annex J (informative)	Recommendations for filling cylinders with oxygen-enriched air.....	40
Annex K (informative)	Rationale .....	41
Bibliography	.....	42

This document is a preview generated by EVS

## 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 (ISO 10083:1992), which has been technically revised.

## Introduction

This purpose of this International Standard is to specify minimum safety and performance requirements for oxygen concentrator supply systems used to deliver oxygen-enriched air to a medical gas pipeline distribution system. The minimum oxygen concentration produced by oxygen concentrator supply systems is specified. National, regional or local regulations may, however, 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. cylinders or cryogenic vessels).

Oxygen concentrators can supply a product gas with an oxygen concentration variable within a specified range depending on the characteristics of the concentrator and the flow supplied.

The decision to use oxygen-enriched air should be made at an early stage by the health care facility in accordance with regional or national regulations, and is outside the scope of this International Standard. The possible use of a mixture of oxygen-enriched air and oxygen is also a decision of the health care facility. The use of a supply system incorporating oxygen concentrator(s) may require the approval of regional or national authorities.

This International Standard should not be regarded as an endorsement or recommendation of one concentration of oxygen over another.

Regional or national regulations that require the use of gas-specific terminal units for oxygen-enriched air may exist.

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 addition to 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 International Standard are to ensure the following:

- appropriate introduction of an oxygen concentrator supply system into a health care facility;
- quality of the oxygen-enriched air delivered by the supply system;
- continuous supply of oxygen-enriched air;
- 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 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 this International Standard. 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 an asterisk (\*) 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.

This document is a preview generated by EVS

This document is a preview generated by EVS

# Oxygen concentrator supply systems for use with medical gas pipeline systems

## 1 Scope

1.1 This International Standard specifies requirements for the design and installation of an oxygen concentrator supply system for use with a medical gas pipeline distribution system that complies with ISO 7396-1.

1.2 It applies only to oxygen concentrator supply systems that produce oxygen-enriched air with an oxygen concentration not less than 90 % (see 4.5.1).

1.3 Oxygen concentrators for domiciliary use are excluded from the scope of this International 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 5145, *Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning*

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

ISO 10524-2, *Pressure regulators for use with medical gases — Part 2: Manifold and line pressure regulators*

ISO 14644-1:1999, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15001, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

ISO 21969, *High-pressure flexible connections for use with medical gas systems*

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