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 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
Web www.iso.org

Published in Switzerland

Contents

Page

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 asterix (*) 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 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*