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*

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-enriched air supply system within the specified operating parameters

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

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

3.4
double-stage pipeline distribution system
pipeline distribution system in which gas is initially distributed from the supply system at a higher pressure than the nominal distribution pressure, this higher pressure (nominal supply system pressure) then being reduced to the nominal distribution pressure by additional line pressure regulators

3.5
gas-specific
having characteristics which prevent connections between different gas services

3.6
manifold
device for connecting the outlet(s) of one or more cylinders or cylinder bundles for the same medical gas to the pipeline system

3.7
manufacturer
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

3.8
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

3.9
nominal distribution pressure
pressure which the medical gas pipeline system is intended to deliver at the terminal units

3.10
nominal supply system pressure
pressure of gas which the supply system is intended to deliver at the inlet to the line pressure regulator

3.11
non-return valve
valve which permits flow in one direction only

3.12
operating alarm
alarm to indicate to technical staff that it is necessary to replenish the supply or to correct a malfunction

3.13
oxygen concentrator
device which produces oxygen-enriched air from ambient air by extraction of nitrogen

3.14
oxygen concentrator supply system
supply system containing one or more oxygen concentrator units

3.15
oxygen concentrator unit
component of source of supply that produces oxygen-enriched air

3.16
oxygen-enriched air storage vessel
pressurized container to store oxygen-enriched air

3.17*
oxygen-enriched air
gas produced by an oxygen concentrator

NOTE Regional or national regulations may specify the name, symbol and color coding for oxygen-enriched air.

3.18
peak demand
maximum anticipated oxygen flow rate required by a health care facility

NOTE This is commonly expressed in litres per minute.

3.19
pipeline distribution system
that portion of a medical gas pipeline system linking the supply system to the terminal units

3.20
pressure regulator
device which reduces the inlet pressure of a gas and maintains its set outlet pressure within specified limits

3.21
pressure-relief valve
device activated at a preset pressure and intended to relieve excess pressure

3.22
primary source of supply
that portion of the supply system which supplies the pipeline distribution system

3.23
reserve source of supply
that portion of the supply system which supplies the complete, or portion(s) of the, pipeline distribution system in the event of failure or exhaustion of both the primary and secondary sources of supply

3.24
safety
freedom from unacceptable risk

3.25
secondary source of supply
that portion of the supply system which supplies the pipeline distribution system in the event of exhaustion or failure of the primary source of supply

3.26
shut-off valve
valve which prevents flow in both directions when closed

3.27
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

3.28
single-stage pipeline distribution system
pipeline distribution system in which gas is distributed from the supply system at the nominal distribution pressure

3.29
source of supply
that portion of the supply system with associated control equipment which supplies the pipeline distribution system

3.30
supply system
assembly which supplies the pipeline distribution system and which includes all sources of supply

3.31
system design flow rate
flow rate calculated from the maximum flow rate requirement of the health care facility and corrected by the diversity factor(s)

3.32
terminal unit
outlet assembly (inlet for vacuum) in a medical gas pipeline system at which the operator makes connections and disconnections

4 General requirements

4.1 Safety and continuity of supply

4.1.1 Oxygen concentrator supply systems shall, when installed, commissioned, operated in normal use and maintained in accordance with the instructions of the manufacturer, cause no safety hazard which could reasonably be foreseen using risk analysis procedures in accordance with ISO 14971 and which is connected with their intended application, in the normal condition or in a single-fault condition.

4.1.2 In order to ensure continuity of supply, the manufacturer of the supply system shall determine, in cooperation with the health care facility management, and using risk management procedures in accordance with ISO 14971, whether a source of supply incorporating oxygen concentrator unit(s) shall be connected to a suitable emergency power supply. The results of such activity shall be recorded and made part of the permanent record of the medical gas pipeline system.

NOTE 1 Loss of mains electrical power or water supply is considered a single-fault condition.

NOTE 2 Some risks and risk management measures are given in Annex H.

NOTE 3 Risk management may require that critical components [e.g. air compressor(s)] be rated for continuous service.

NOTE 4 See ISO/TR 16142 for more information.

4.1.3 Control equipment shall be designed so that any component can be maintained without interrupting the gas supply to the pipeline distribution system.

4.1.4 The system shall be designed so that maintenance or failure of any component shall not require the isolation of two sources of supply at the same time.

4.1.5 An oxygen concentrator supply system shall cause no interruption of supply in the normal condition or in a single-fault condition.

NOTE Loss of mains electrical power or water supply is a single-fault condition.

4.1.6 Shutting off or failure of an oxygen concentrator unit shall not affect the delivery of gas from the oxygen concentrator supply system to the pipeline distribution system.

NOTE An oxygen concentrator takes a certain time to achieve the specified concentration of oxygen after a prolonged shutdown.

4.1.7 The oxygen concentrator supply system shall be designed and manufactured to minimize the risk of creating an electromagnetic field. National or regional regulations concerning electromagnetic compatibility may exist.

4.1.8 Measures shall be taken to minimize electrical and mechanical hazards. National or regional regulations concerning such hazards may exist.

4.1.9 Potential hazards arising from the implementation and use of oxygen-enriched air within the health care facility shall be reduced and controlled using risk management procedures in accordance with ISO 14971. The results of this activity shall be implemented via the instructions for use. See Clause 12.

4.2* Alternative constructions

Installations and components, or parts thereof, using materials or having forms of construction different from those detailed in this International Standard shall be accepted if it can be demonstrated that an equivalent degree of safety and performance is obtained. The evidence of an equivalent degree of safety and performance shall be provided by the manufacturer.

NOTE Regional or national regulations may require the provision of evidence to a notified body or competent authority upon request.

4.3 Materials

4.3.1 Compatibility with oxygen

4.3.1.1 All components of an oxygen concentrator supply system that are liable to come into contact with compressed air, oxygen or oxygen-enriched air shall be compatible with oxygen under the operating conditions specified by the manufacturer, taking into account the requirements of 4.1.1.

NOTE 1 Criteria for the selection of metallic and non-metallic materials are given in ISO 15001.

NOTE 2 Compatibility with oxygen or oxygen-enriched air involves both combustibility and ease of ignition. Materials which burn in air will burn violently in pure oxygen or oxygen-enriched air. Many materials which do not burn in air will do so in pure oxygen or oxygen-enriched air, particularly under pressure. Similarly, materials which can be ignited in air require less energy to ignite in oxygen or oxygen-enriched air. Many such materials may be ignited by friction at a valve seat or by adiabatic compression produced when oxygen or oxygen-enriched air at high pressure is rapidly introduced into a system initially at low pressure.

4.3.1.2 If lubricants are used, they shall be compatible with oxygen at the operating conditions of the supply system.

Evidence of compliance with 4.3.1.1 and 4.3.1.2 shall be made available by the manufacturer upon request.

4.3.1.3 The specific hazards of toxic products of combustion or decomposition from non-metallic materials (including lubricants, if used) and potential contaminants shall be addressed.

Evidence of compliance with 4.3.1.3 shall be made available by the manufacturer upon request.

NOTE 1 Some potential products of combustion and/or decomposition for some commonly available non-metallic materials are listed in Table D.7 of ISO 15001:2003.

NOTE 2 Typical “oxygen-compatible” lubricants can generate toxic products on combustion or decomposition.

4.3.2 Cleanliness

All components of an oxygen concentrator supply system that are liable to come into contact with compressed air, oxygen or oxygen-enriched air shall meet the cleanliness requirements of ISO 15001. Such components shall be protected from contamination prior to and during installation.

Evidence of compliance shall be made available by the manufacturer upon request.

NOTE Examples of cleaning procedures are given in ISO 15001.

4.3.3 Resistance to corrosion

The manufacturer shall disclose, upon request, evidence of the corrosion resistance of the materials used for oxygen concentrator supply system components in contact with oxygen-enriched air.

NOTE Corrosion resistance includes resistance against the influence of moisture and the surrounding materials.

4.3.4 Exposure to cylinder pressure

Components which may be exposed to cylinder pressure in the normal or a single-fault condition shall function in accordance with their specifications after being exposed to a pressure of 1,5 × cylinder working pressure for 5 min.

Evidence shall be provided by the manufacturer upon request.

4.4 System design

An oxygen concentrator supply system shall be designed by the manufacturer in consultation with the health care facility, using risk management principles, to deliver the system design flow rate specified by the health care facility at the nominal supply system pressure which permits the pressure at the terminal units to be maintained within the range specified in ISO 7396-1.

NOTE Design specifications, such as pressure and flow rate, should take into account circumstances such as daily flow rate increases, peak demand and seasonal increases. See Annex I for information on sizing.

4.5 Specifications for oxygen-enriched air

4.5.1 National or regional regulations which apply to oxygen-enriched air produced by an oxygen concentrator supply system may exist. Where such regulations do not exist, the oxygen-enriched air shall comply with the following at system design flow rate:

a) minimum oxygen concentration — 90 % volume fraction of oxygen

b) maximum carbon monoxide concentration — 5 ml/m^3

c)	maximum carbon dioxide concentration	300 ml/m^3
d)	maximum oil concentration	0,1 mg/m^3 measured at ambient temperature and pressure and corrected to 0 °C
e)	maximum water vapour concentration	67 ml/m^3

NOTE 1 The balance of the gas comprises predominantly argon and nitrogen.

NOTE 2 Other terms may be used by national or regional regulations.

4.5.2 Oxygen-enriched air shall be filtered immediately downstream of the oxygen concentrator unit(s) to maintain the particulate contamination below the level provided by ISO Class 5 in Table 1 of ISO 14644-1:1999.

Evidence shall be provided by the manufacturer upon request.

4.5.3 Means shall be provided to indicate the status of filter elements (e.g. by measuring the pressure drop across the filter).

Compliance with this subclause shall be checked by inspection.

4.6 Cylinder filling

If an oxygen concentrator unit is used to fill cylinders with oxygen-enriched air, the following conditions shall be met:

a) Means shall be provided to ensure that cylinder filling does not affect delivery of oxygen-enriched air to the pipeline distribution system.

b) A sample port with a shut-off valve shall be provided adjacent to the filling system.

NOTE 1 Regional or national regulations that apply to the filling of transportable cylinders may exist.

NOTE 2 Regional or national regulations that apply to the cylinder filling system may exist.

NOTE 3 Recommendations for filling cylinders with oxygen-enriched air are provided in Annex J.

5 Sources of supply

NOTE Schematic representations of oxygen concentrator supply systems are shown in Annex A.

5.1 General

5.1.1 An oxygen concentrator supply system shall be designed for automatic operation, and shall contain the following sources of supply (see Annex A):

a) a primary source of supply;

b) a secondary source of supply;

c) a reserve source of supply.

5.1.2 Each source of supply shall be capable of delivering the system design flow rate, which is determined by the health care facility, at the nominal supply system pressure which permits the pressure at the terminal units to be maintained within the range specified in ISO 7396-1. See I.4 in Annex I.

NOTE An oxygen compressor may be needed to maintain the nominal supply system pressure.

5.1.3 A non-return valve and a shut-off valve shall be fitted immediately downstream of each source of supply.