INTERNATIONAL STANDARD

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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

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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 (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.

5.2 Primary source of supply

5.2.1 The primary source of supply shall consist of one of the following:

a) one or more oxygen concentrator unit(s);

b) a combination of one or more oxygen concentrator unit(s) and high-pressure cylinders or cryogenic vessel(s);

c) a combination of one or more oxygen concentrator unit(s) and cryogenic vessel(s).

5.2.2 The primary source of supply shall include the following:

a) at least one oxygen-enriched air storage vessel;

b) a sample port with a shut-off valve immediately downstream of the oxygen-enriched air storage vessel;

c) pressure regulator(s);

d) filter(s);

e) an oxygen analyser.

5.2.3 The cylinder(s) or cylinder bundle(s), if fitted, shall be connected downstream of the oxygen storage vessel shut-off valve and upstream of the connection of the secondary supply.

5.3 Secondary source of supply

5.3.1 The secondary source of supply shall be permanently connected and shall automatically supply the pipeline in the event that the primary source of supply is unable to supply the pipeline.

5.3.2 The secondary source of supply shall consist of one of the following:

a) one or more oxygen concentrator units;

b) gas (oxygen or oxygen-enriched air) in cylinder(s) or cylinder bundle(s);

c) a cryogenic liquid oxygen supply.

5.3.3 If the secondary source of supply consists of one or more oxygen concentrator unit(s), it shall include the following:

a) at least one oxygen-enriched air storage vessel;

b) a sample port with a shut-off valve immediately downstream of the oxygen-enriched air storage vessel;

c) pressure regulator(s);

d) filter(s);

e) oxygen analyser(s).

5.3.4 If the secondary source of supply consists of only cylinders or cylinder bundles, the manifold shall:

a) consist of at least two banks of cylinders;

b) be supplied from one bank of cylinders at a time;

c) on depletion of one bank of cylinders switch automatically to another bank.

NOTE This configuration is needed to facilitate replenishment of the secondary source of supply without interruption of supply.

5.3.5 If an emergency electrical power supply is not available, the secondary source of supply shall not comprise only oxygen concentrator unit(s).

5.3.6 The secondary source of supply shall be connected downstream of the oxygen-enriched air storage vessel in the primary supply.

5.4 Reserve source of supply

5.4.1 The reserve source of supply shall be permanently connected and shall automatically supply the pipeline if the primary and secondary sources of supply are unable to supply the pipeline.

5.4.2 The reserve source of supply shall consist of gas (oxygen or oxygen-enriched air) in cylinders or cylinder bundles.

5.4.3 The reserve source of supply shall:

a) consist of at least two banks of cylinders;

b) be supplied from one bank of cylinders at a time;

c) on depletion of one bank of cylinders switch automatically or manually to another bank.

NOTE This configuration is needed to facilitate replenishment of the reserve source of supply without interruption of supply.

5.4.4 The point of connection for the reserve source of supply may be either upstream or downstream of the supply system shut-off valve.

5.5 Sources of supply with cylinders

NOTE A source of supply with cylinders may contain cylinders or cylinder bundles or both.

5.5.1 Each bank of cylinders shall have its cylinders connected to a manifold with its own pressure regulator. Vent valves, if fitted on manifolds, should be vented outside of the building.

5.5.2 A filter having a pore size no greater than 100 µm shall be provided between the cylinders and the first pressure regulator.

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

5.5.3 A non-return valve shall be installed at the manifold end of each flexible connection between a cylinder and the manifold.

5.5.4 The flexible connections between each cylinder and the manifold shall comply with ISO 21969.

Evidence shall be made available by the manufacturer upon request.

5.5.5 Cylinder valve outlets shall be in accordance with ISO 5145 or the relevant national standard.

Evidence shall be made available by the manufacturer upon request.

5.6 Location of oxygen concentrator supply systems

NOTE 1 Informative guidelines for location of supply systems are given in Annex B.

NOTE 2 Oxygen concentrator units may generate noise in excess of 70 dB (A-weighted).

NOTE 3 National and regional regulations concerning noise levels may exist.

NOTE 4 The location of the oxygen concentrator system should be defined by the management of the health care facility in consultation with the system supplier, using risk management principles.

5.6.1 The ambient temperature in rooms for the oxygen concentrator supply system shall be in the range 10 °C to 40 °C.

5.6.2 The intake(s) for the air compressors shall be located where there is minimal contamination from internal combustion engine exhaust (e.g. from motor vehicles), vacuum system exhausts, vents from medical gas pipeline systems, anaesthetic-gas scavenging systems, ventilation system discharges and other sources of contamination. The intake(s) shall be provided with means to prevent the ingress of insects, debris and water. Consideration shall be given to the potential effects of prevailing winds on the location of intake(s).

NOTE The above requirements are taken from ISO 7396-1.

Compliance shall be checked by visual inspection.

6 Requirements for components

NOTE Regional or national regulations concerning pressure equipment may exist.

6.1 Oxygen concentrator unit

6.1.1 An oxygen concentrator unit shall consist of:

a) a compressed air supply with at least one air compressor;

b) at least one sieve bed;

c) switching valves.

6.1.2 An air compressor may be connected to an air receiver.

6.1.3 An air receiver may be served by more than one compressor.

6.1.4 Air receivers shall:

a) comply with EN 286-1 or equivalent national standards;

b) be fitted with shut-off valve(s), an automatic drain, a pressure gauge and a pressure-relief valve.

Evidence shall be made available by the manufacturer upon request.

6.1.5 Each air receiver shall be fitted with a means of pressure control, e.g. pressure switch(es) or pressure transducer(s).

6.1.6 If venting of waste gases generated during production of oxygen-enriched air to the outside of the building is required, the vents shall be provided with means to prevent the ingress of insects, debris and precipitation. The vents shall be located remote from any air intakes, doors, windows or other openings in buildings. Consideration shall be given to the potential effects of prevailing winds on the location of the vents. Compliance shall be checked by visual inspection.

6.2 Oxygen-enriched air storage vessels

Each oxygen-enriched air storage vessel or group of oxygen-enriched air storage vessels shall:

a) comply with relevant international, regional or national standards;

b) be fitted with shut-off valve(s), a pressure gauge and a pressure-relief valve;

c) be fitted with a means of pressure control, e.g. pressure switch(es) or pressure transducer(s);

d) be arranged so that each vessel can be maintained separately.

NOTE An oxygen-enriched air storage vessel may be supplied by more than one oxygen concentrator.

6.3 Oxygen analysers

6.3.1 One or more oxygen analyser(s) shall be provided to permit the oxygen concentration from each source of supply incorporating an oxygen concentrator unit to be measured continuously.

NOTE Means to display and record oxygen concentration may be required by regional or national regulations.

6.3.2 If only one oxygen analyser is installed, appropriate measures to ensure that the correct oxygen concentration is continuously supplied shall be defined by risk management (see 4.1.1).

NOTE A second oxygen analyser may be required by regional or national regulations.

6.3.3 Controls shall be provided such that each source of supply incorporating an oxygen concentrator unit automatically shuts down if the oxygen concentration of the oxygen-enriched air produced by that source of supply falls below that specified in 4.5.1.

6.3.4 Each oxygen analyser shall be equipped with a low-concentration alarm. Means shall be provided to prevent unauthorized changes of the alarm setting.

6.3.5 Each oxygen analyser shall include compensation for temperature and barometric-pressure variations to ensure an accuracy of ± 1 % of the measured value in the range of 90 % to 100 %.

NOTE 1 National or regional regulations concerning the oxygen analyser may exist.

NOTE 2 Additional monitoring may be required to show compliance of oxygen-enriched air with national or regional regulations.

6.4 Pressure-relief valves

6.4.1 Pressure-relief valves shall comply with the supply system manufacturer's design specifications, taking into account that national or regional regulations may exist. Evidence shall be made available by the manufacturer upon request.

6.4.2 All pressure-relief valves shall close automatically when excess pressure has been released.

6.4.3 Pressure-relief valves on vessels containing oxygen or oxygen-enriched air shall be vented to the outside of the building and the vents shall be provided with means to prevent the ingress of insects, debris and precipitation. The vents shall be located remote from any air intakes, doors, windows or other openings in buildings. Consideration shall be given to the potential effects of prevailing winds on the location of the vents. Compliance is checked by inspection.

6.4.4 Means of pressure relief shall not be isolated, for example by a shut-off valve, from the pipeline or the pressure regulator to which they are connected. If a valve or a flow-limiting device is incorporated for maintenance, it shall be fully opened by the insertion of the means of pressure relief. Compliance is checked by inspection.

6.5 Shut-off valves

6.5.1 A shut-off valve shall be provided between the supply system or each source of supply and the pipeline distribution system.

6.5.2 Each source of supply shall be capable of being independently isolated using a source shut-off valve.

6.5.3 Valves which cannot be locked in the open or closed position shall be protected from improper operation.

6.5.4 Shut-off valves should only be used by authorized personnel and should not be accessible to unauthorized persons.

6.6 Sample port

A sample port with a shut-off valve shall be provided immediately upstream of the supply system shut-off valve.

6.7 Pressure regulators

Manifold and line pressure regulators, if fitted, shall comply with ISO 10524-2.

7 Monitoring and alarm systems

7.1 General

7.1.1 This clause specifies minimum requirements for operating alarms and information signals for an oxygen concentrator supply system which is intended to be connected to a medical gas pipeline system complying with ISO 7396-1.

NOTE Four different categories of monitoring and alarm systems for medical gas pipeline systems are specified in ISO 7396-1: operating alarms, emergency operating alarms, emergency clinical alarms and information signals. The status of the pipeline system to which the oxygen concentrator supply system is connected and, therefore, the provision of emergency operating alarms and emergency clinical alarms is outside the scope of this International Standard.

7.1.2 Monitoring and alarm systems shall be connected to both the normal and emergency electrical power supplies and shall be individually electrically protected.

7.2 Monitoring and alarm signals

The characteristics of the auditory and visual signals shall comply with the requirements of 6.3 of ISO 7396-1:2002.

7.3 Operating alarms

The purpose of operating alarms is to inform the technical staff that one or more components of the oxygen concentrator supply system are no longer available for use and it is, therefore, essential that action be taken.

7.3.1 The following operating alarms shall be provided:

a) malfunction of source(s) of supply incorporating an oxygen concentrator unit;

b) oxygen concentration below minimum required by the health care facility, taking into account the accuracy of the oxygen analyser;

c) low content in cylinder(s) or cryogenic vessel(s) within the primary source of supply (if fitted);

d) low content in cylinder(s) or cryogenic vessel(s) within the secondary source of supply (if fitted);

e) secondary source of supply in use;

f) content of secondary source of supply below 50 % of capacity for gas in cylinders or cylinder bundles or for liquid in cryogenic vessel(s);

g) reserve source of supply in use;

h) content of reserve source of supply below 50 % of capacity;

i) malfunction of cylinder filling system, if fitted;

j) failure of external power supply.

7.3.2 Means shall be provided, e.g. via an appropriate sensor, to permit a monitoring and alarm system complying with ISO 7396-1 to indicate the malfunctions specified in 7.3.1.

7.4 Information signals

NOTE The purpose of information signals is to inform the health care personnel that the oxygen concentrator supply system is functioning properly.

7.4.1 Information signals shall be provided on the oxygen concentrator supply system to indicate normal status.

7.4.2 Means shall be provided to permit a monitoring and alarm system complying with ISO 7396-1 to indicate normal status.

8 Marking

8.1 The primary, secondary and reserve sources of supply of an oxygen concentrator supply system shall be marked as oxygen or oxygen-enriched air, as appropriate.

NOTE Typical examples of marking methods are metal tags, stencilling, stamping and adhesive markers.

8.2 If a pipeline system for oxygen-enriched air co-exists with a pipeline system for oxygen, the two systems shall be differentiated by labelling.

9 Installation

9.1 General

Oxygen concentrator supply systems shall be installed in accordance with the requirements of this International Standard and the manufacturer's instructions.

NOTE 1 Regional, national and local regulations concerning installation may exist.

NOTE 2 Annex G contains recommendations for installation.

Evidence shall be made available by the manufacturer upon request.

9.2 Electrical systems

NOTE Regional, national and local regulations concerning electrical systems may exist.

The results of the risk analysis in 4.1.2 concerning connection of sources of supply to the emergency electrical power supply shall be taken into account.

10 Testing, commissioning and certification

10.1 General

Tests after completion of installation shall be carried out by the manufacturer or installer, witnessed by a health care facility representative and certified by an authorized person qualified in the testing of medical gas pipeline systems.

NOTE 1 An example of a procedure for testing and commissioning is given in Annex D.

NOTE 2 The aim of testing and commissioning is to verify that all safety and performance requirements of this International Standard are met.

NOTE 3 Authorized persons may be qualified within a certified quality system of the manufacturer or by a national authority or by the health care facility. In some countries, such authorization is given only to persons independent of the manufacturer.

10.2 Tests and procedures

10.2.1 The resolution and the accuracy of all measuring devices used for testing shall be appropriate for the values to be measured.

10.2.2 All measuring devices used for certification shall be calibrated.

10.2.3 The following tests and procedures shall be carried out after complete installation and before use of the system:

a) tests of sources of supply;

b) tests of monitoring and alarm systems;

c) tests for oxygen concentration;

d) tests for contaminants.

Evidence shall be provided by the manufacturer upon request.

10.3 Specific tests

10.3.1 Tests of sources of supply

10.3.1.1 General

A specific checklist for the supply system that includes all the requirements of this International Standard shall be provided by the manufacturer. Tests shall include automatic starting, automatic shutdown, automatic supply changeovers and ability to deliver the system design flow rate and specified oxygen concentration.

All components shall be tested for leakage.

10.3.1.2 Procedure

The functional and operating parameters of the supply system shall be checked from the checklist.

The supply system shall be shown to operate and meet the requirements of this International Standard when connected to the emergency electrical power supply, if provided.

The test results shall conform to the manufacturer's specifications and the requirements of this International Standard.

It shall be confirmed that the flow rate requirements specified by the health care facility are met with each source of supply.

10.3.2 Tests of monitoring and alarm system

10.3.2.1 General

All alarm systems shall be fully installed and in operation.

These tests should preferably be carried out for one function at a time.

10.3.2.2 Procedure

10.3.2.2.1 All alarm sensors shall be shown to operate with an appropriate change in the alarm condition (e.g. pressure, oxygen concentration, system changeover). Record the values at which each alarm sensor switches on and off.

10.3.2.2.2 All alarm functions, including visual and auditory signals, resetting of the auditory signals and lamp test shall be checked. The visual and auditory characteristics of the signals shall be in accordance with Clause 7, if applicable.

10.3.2.2.3 All monitors and alarms shall operate with the appropriate changes in conditions. They should operate from the normal and the emergency electrical power supplies.

10.3.2.2.4 See the requirements for monitoring and alarm signals in 7.2.

10.3.3 Tests for oxygen concentration

Tests for oxygen concentration shall be carried out on each source of supply incorporating an oxygen concentrator unit at the system design flow rate, at a test point immediately downstream of the oxygen-enriched air storage vessel(s).

10.3.4 Tests for contaminants

10.3.4.1 General

With the source of supply operating at the system design flow rate, tests for contaminants shall be carried out using validated test methods on each source of supply incorporating an oxygen concentrator unit(s), at a test point immediately downstream of the oxygen-enriched air storage vessel(s).

On completion of the tests at the concentrator unit(s), the tests shall be repeated at a test point immediately upstream of the supply system shut-off valve.

NOTE Analysis of the sample need not be performed on site, if permitted by local authorities.

10.3.4.2 Procedures

10.3.4.2.1 Particulate contamination

Test the output of each source of supply incorporating an oxygen concentrator unit(s) for particulate contamination. The contamination shall not exceed the level specified in 4.5.2.

10.3.4.2.2 Oil

The test device should measure oil present as liquid, aerosol and vapour. The total oil level shall not exceed the value given in 4.5.1.

10.3.4.2.3 Water

Test for water vapour concentration using an appropriate test device. The water concentration shall not exceed the value given in 4.5.1.

10.3.4.2.4 Carbon monoxide and carbon dioxide

Determine the concentrations of carbon monoxide and carbon dioxide using appropriate test device(s). The concentrations of carbon monoxide and carbon dioxide shall not exceed the values given in 4.5.1.

10.4 Commissioning and certification

10.4.1 Before an oxygen concentrator supply system is used, the manufacturer shall certify in writing that all tests and procedures have been completed and that the construction and components comply with this International Standard.

10.4.2 The manufacturer shall define suitable tests that shall be performed after installation in order to meet the relevant requirements of this International Standard. After installation, the installer shall certify in writing that these tests have been performed and the results meet the manufacturer's specifications.

10.4.3 Before an oxygen concentrator supply system is used, a responsible test authority shall certify in writing that all tests and procedures have been completed and that the system complies with the requirements of this International Standard. The test authority shall also certify that all drawings and manuals as required in Clause 11 have been supplied to the owner or client.

10.4.4 Certificates shall be dated and signed by the responsible test authority, the representative of the owner and the representative of the installer.

10.4.5 Regional or national regulations which apply to commissioning and certification may exist. If no regulations exist, see Annex D.

NOTE Typical forms for certification are given in Annex E.

11 Information to be supplied by the manufacturer

11.1 Instructions for installation

The manufacturer shall provide to the installer suitable instructions for installation of the complete oxygen concentrator supply system.

11.2 Instructions for use

The manufacturer shall provide to the user via the owner instructions for use of the complete oxygen concentrator supply system. Particular attention shall be paid to:

— oxygen concentrator units;

— monitoring and alarm systems;

— the danger of fire or explosion due to the use of oil and grease with oxygen systems;

— instructions for cylinder filling equipment, if provided;

— the minimum number of cylinders to be held in stock to maintain the supply of oxygen-enriched air from cylinder manifolds;

— the need to comply with national or regional regulations or standards for quality control and labelling of the cylinders filled from an oxygen concentrator unit;

— the unsuitability of oxygen-enriched air for calibrating some equipment;

— emergency procedures (see Annex C);

— implementation of use (see Clause 12).

11.3 Instructions for preventive maintenance

The manufacturer shall provide to the user, via the owner, instructions for testing, maintenance and calibration, the recommended frequency of testing, maintenance and calibration and a list of recommended spare parts.

NOTE Recommended minimum requirements for the organization of the maintenance are given in Annex F.

11.4 Operational management information

The manufacturer shall provide operational management information to the owner to enable the health care facility to draft an operational management document.

NOTE Informative guidelines for the preparation of the operational management document are being included in the next edition of ISO 7396-1 (in preparation).

11.5 “As installed” drawings

A complete set of “as installed” drawings shall be presented to the owner of the oxygen concentrator supply system, for inclusion as part of the permanent record of the pipeline system.

11.6 Electrical schematics

Electrical schematics for the complete installation shall be provided by the manufacturer to the owner.

11.7 Disclosure by the manufacturer

The manufacturer shall disclose the minimum and maximum oxygen concentrations delivered by the oxygen concentrator unit at the system design flow rate under the ambient conditions specified by the health care facility.

12 Implementation of use of oxygen-enriched air

12.1 Acceptance of oxygen-enriched air

Before the addition of oxygen-enriched air to the health care facility formulary, oxygen-enriched air should be accepted by the health care facility's medical staff, including the department of anaesthesia.

New medical staff should be informed of the use of oxygen-enriched air as part of the health care facility's quality assurance protocols.

12.2 Timing

The addition of oxygen-enriched air to the health care facility’s formulary should precede the installation of an oxygen concentrator supply system.

12.3 Mixing of oxygen-enriched air and oxygen

Clinicians shall be advised that the gas from the terminal units might be a blend of oxygen-enriched air and oxygen.

12.4 Calibration of medical equipment

Staff and clinicians shall be advised that, if calibration of medical equipment requires oxygen, the source of oxygen should not be the pipeline system or a cylinder filled with oxygen-enriched air.

12.5 Labelling

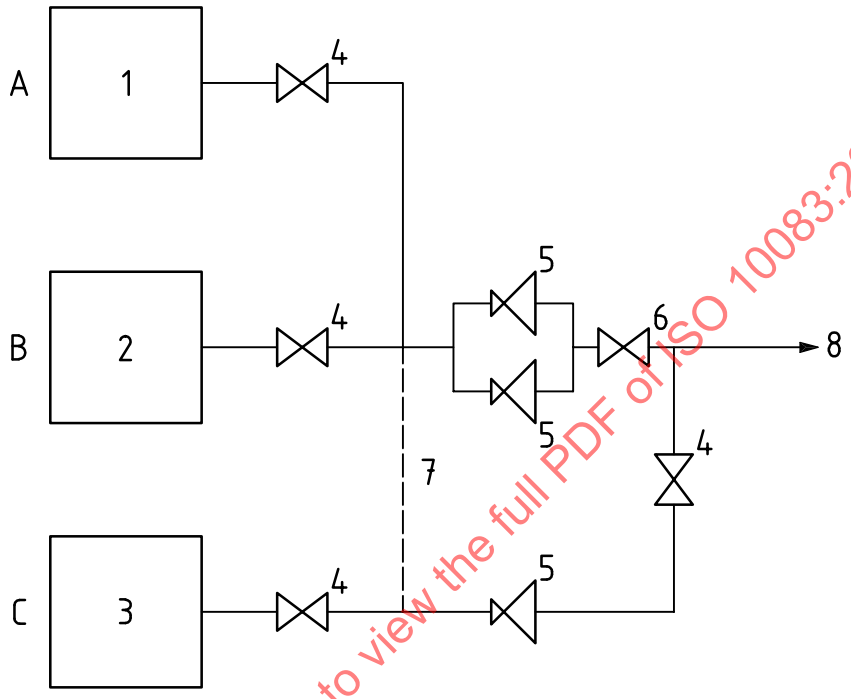
If terminal units that are gas-specific for oxygen-enriched air are not used, a decision shall be made whether to label terminal units and pipelines with the name of or symbol for oxygen or oxygen-enriched air before the oxygen concentrator supply system is used.

12.6 Compliance with ISO 7396-1

Before an oxygen concentrator supply system is first used, it shall be confirmed that the relevant tests from ISO 7396-1 have been carried out satisfactorily.

Annex A
(informative)

Schematic representations of oxygen concentrator supply systems

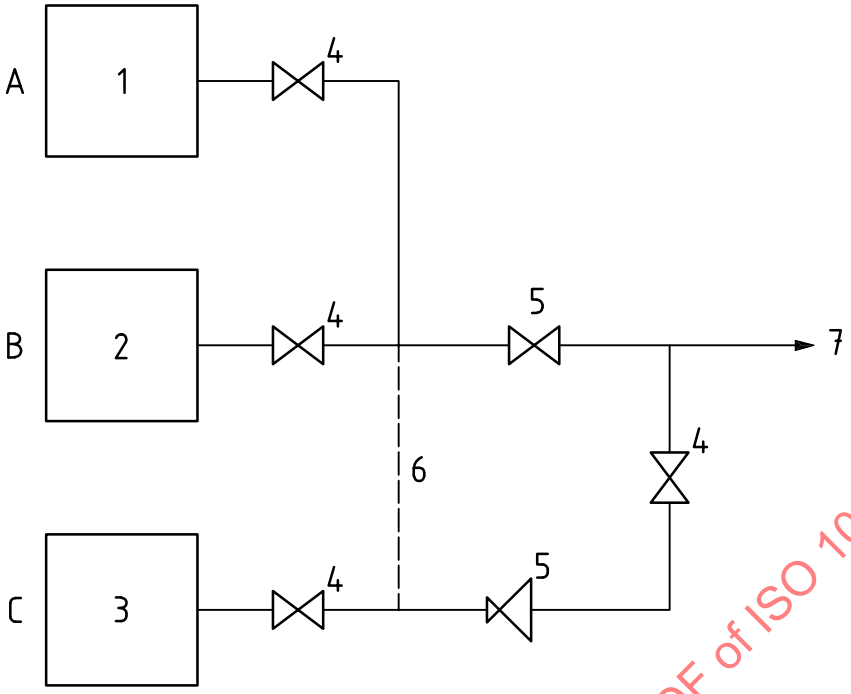


Key

A primary source of supply
B secondary source of supply
C reserve source of supply

1 oxygen concentrator unit(s)
2 high-pressure cylinders (containing either oxygen or oxygen-enriched air) or cryogenic liquid vessel(s)
3 two banks of high-pressure cylinders
4 source-of-supply shut-off valve
5 line pressure regulator
6 supply system shut-off valve
7 optional connection
8 to pipeline distribution system

Figure A.1 — Oxygen concentrator supply system with one or more oxygen concentrator unit(s) as the primary source, cylinders or cryogenic liquid vessel(s) as the secondary source and cylinders as the reserve source for a single-stage distribution system

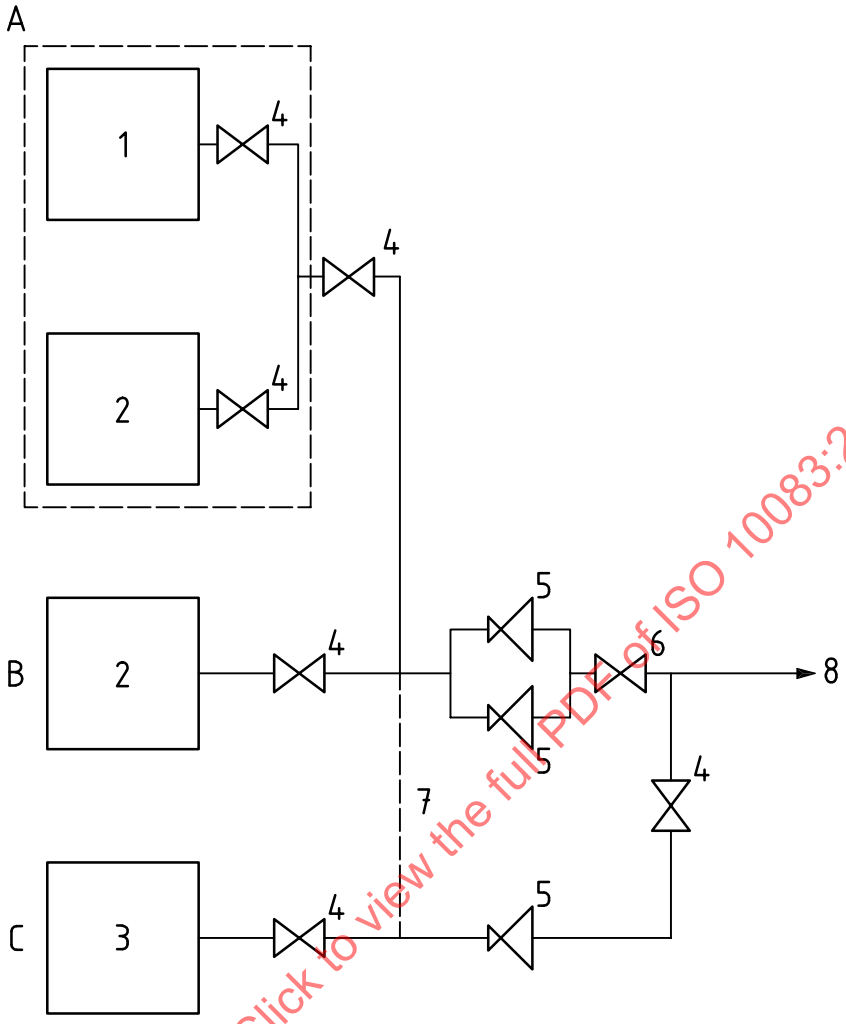


Key

A primary source of supply
B secondary source of supply
C reserve source of supply

1 oxygen concentrator unit(s)
2 high-pressure cylinders (containing either oxygen or oxygen-enriched air) or cryogenic liquid vessel(s)
3 two banks of high-pressure cylinders
4 source-of-supply shut-off valve
5 supply system shut-off valve
6 optional connection
7 to pipeline distribution system

Figure A.2 — Oxygen concentrator supply system with one or more oxygen concentrator unit(s) as the primary source, high-pressure cylinders or cryogenic liquid vessel(s) as the secondary source and high-pressure cylinders as the reserve source for a double-stage distribution system

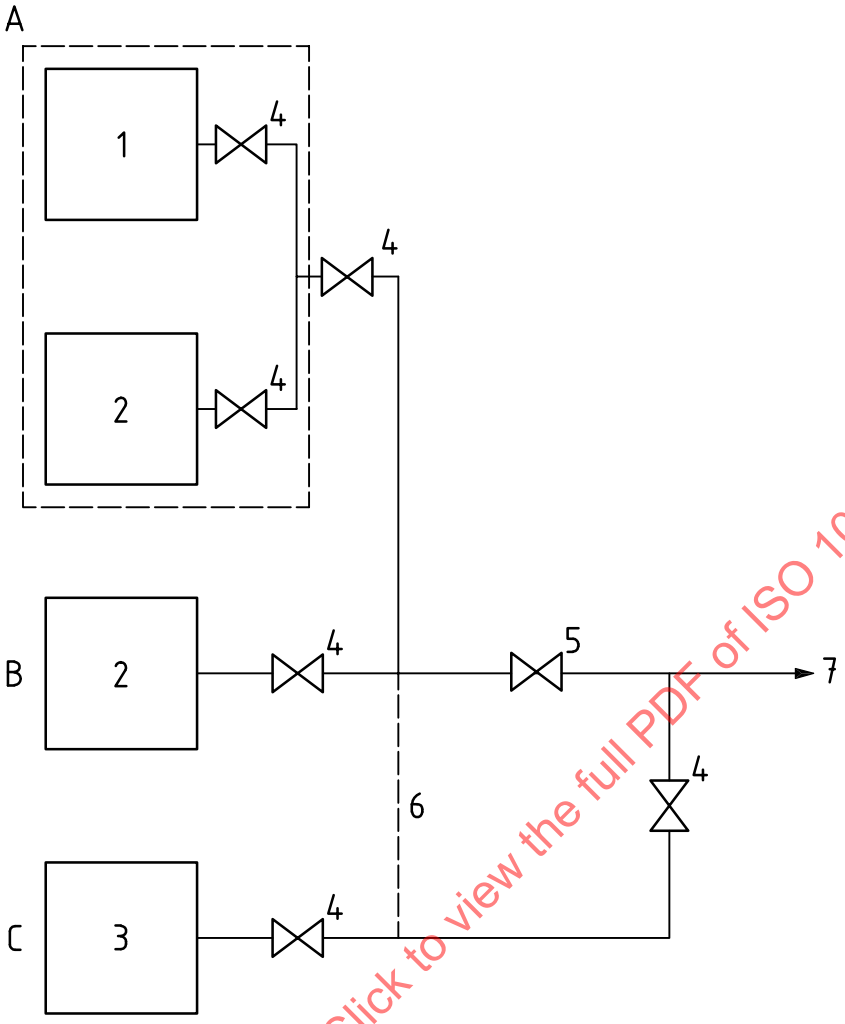


Key

A primary source of supply
B secondary source of supply
C reserve source of supply

1 oxygen concentrator unit
2 high-pressure cylinders (containing either oxygen or oxygen-enriched air) or cryogenic liquid vessel(s)
3 two banks of high-pressure cylinders
4 source-of-supply shut-off valve
5 line pressure regulator
6 supply system shut-off valve
7 optional connection
8 to pipeline distribution system

Figure A.3 — Oxygen concentrator supply system with one oxygen concentrator unit and supplementary high-pressure cylinders or cryogenic liquid vessel(s) as the primary source, high-pressure cylinders or cryogenic liquid vessel(s) as the secondary source and high-pressure cylinders as the reserve source for a single-stage distribution system

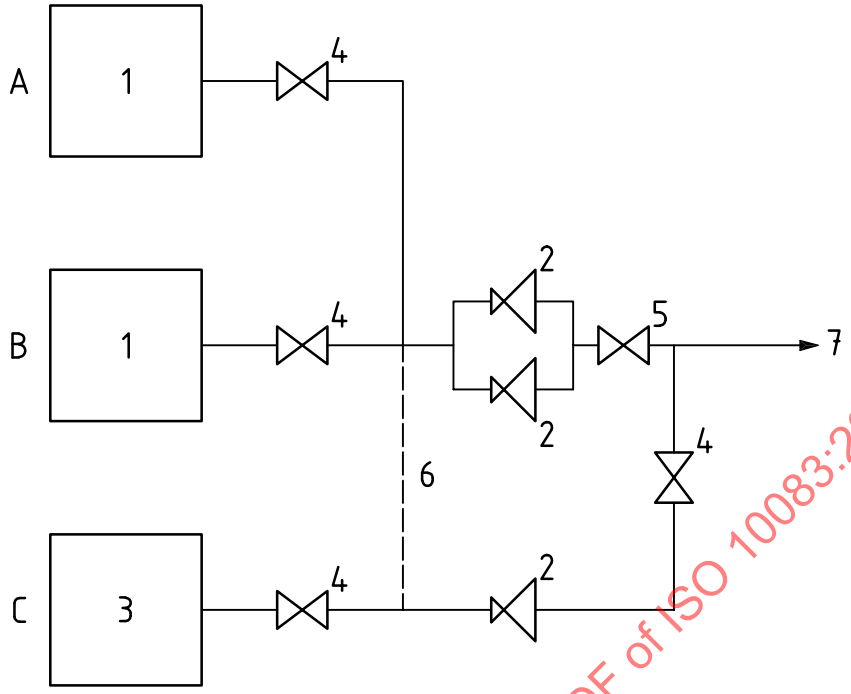


Key

A primary source of supply
B secondary source of supply
C reserve source of supply

1 oxygen concentrator unit
2 high-pressure cylinders (containing either oxygen or oxygen-enriched air) or cryogenic liquid vessel(s)
3 two banks of high-pressure cylinders
4 source-of-supply shut-off valve
5 supply system shut-off valve
6 optional connection
7 to pipeline distribution system

Figure A.4 — Oxygen concentrator supply system with one oxygen concentrator unit and supplementary high-pressure cylinders or cryogenic liquid vessel(s) as the primary source, high-pressure cylinders or cryogenic liquid vessel(s) as the secondary source and high-pressure cylinders as the reserve source of a double-stage distribution system

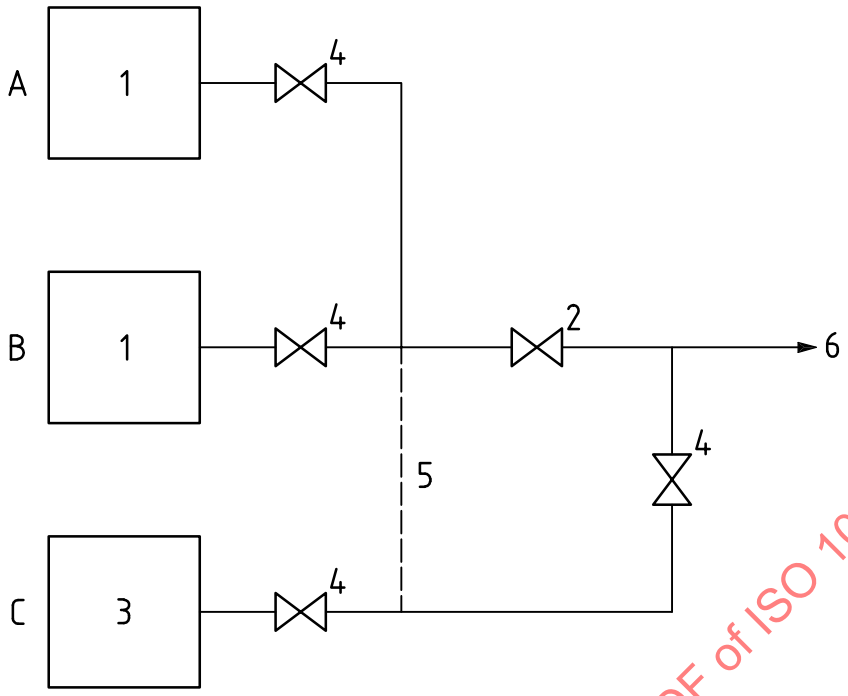


Key

A primary source of supply
B secondary source of supply
C reserve source of supply

1 oxygen concentrator unit(s)
2 line pressure regulator
3 two banks of high-pressure cylinders
4 source-of-supply shut-off valve
5 supply system shut-off valve
6 optional connection
7 to pipeline distribution system

Figure A.5 — Oxygen concentrator supply system with one or more oxygen concentrator unit(s) as the primary source, one or more oxygen concentrator units as the secondary source and high-pressure cylinders as the reserve source for a single-stage distribution system

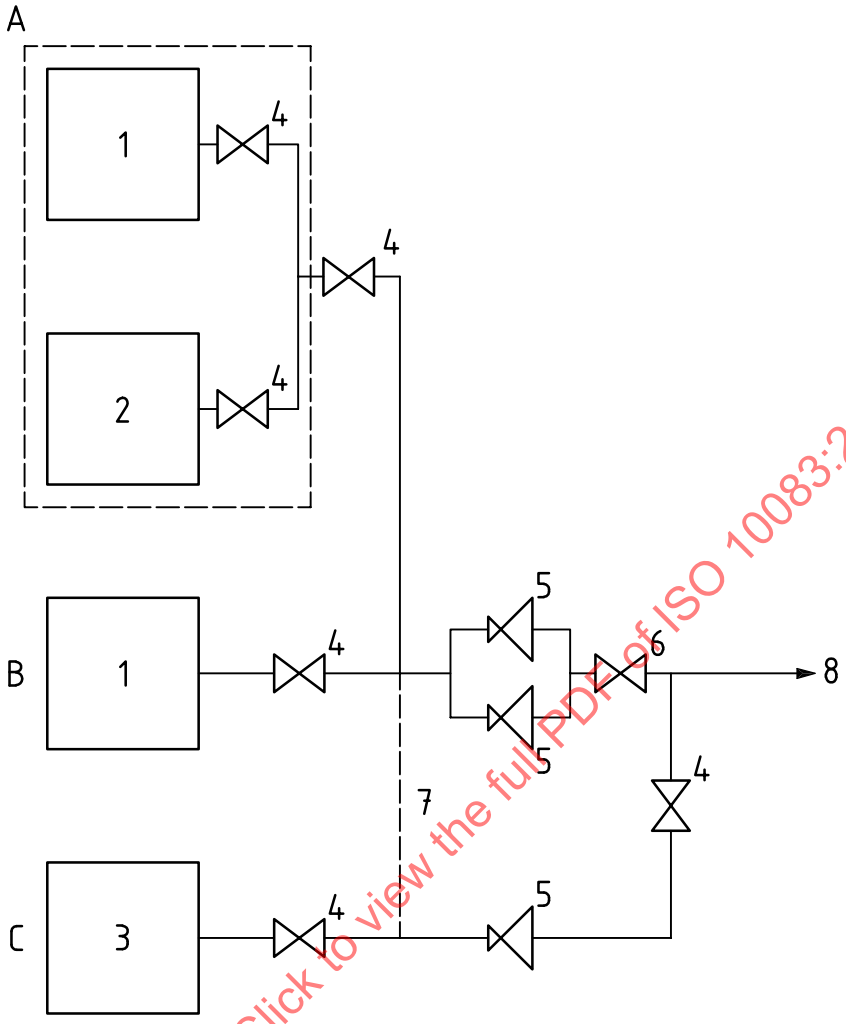


Key

A primary source of supply
B secondary source of supply
C reserve source of supply

1 oxygen concentrator unit(s)
2 supply system shut-off valve
3 two banks of high-pressure cylinders
4 source-of-supply shut-off valve
5 optional connection
6 to pipeline distribution system

Figure A.6 — Oxygen concentrator supply system with one or more oxygen concentrators unit(s) as the primary source, one or more oxygen concentrator unit(s) as the secondary source and high-pressure cylinders as the reserve source of a double-stage distribution system

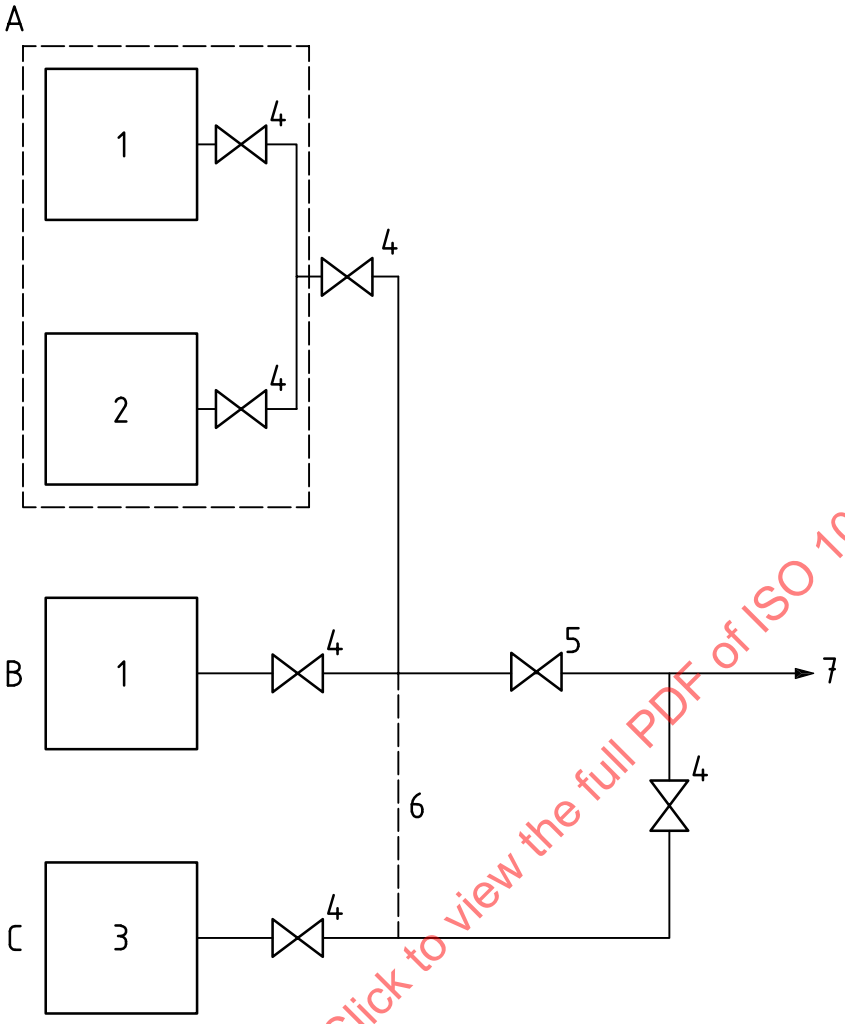


Key

A primary source of supply
B secondary source of supply
C reserve source of supply

1 oxygen concentrator unit
2 high-pressure cylinders (containing either oxygen or oxygen-enriched air) or cryogenic liquid vessel(s)
3 two banks of high-pressure cylinders
4 source-of-supply shut-off valve
5 line pressure regulator
6 supply system shut-off valve
7 optional connection
8 to pipeline distribution system

Figure A.7 — Oxygen concentrator supply system with one oxygen concentrator unit and supplementary high-pressure cylinders or cryogenic liquid vessel(s) as the primary source, an oxygen concentrator unit as the secondary source and high-pressure cylinders as the reserve source for a single-stage distribution system



Key

A primary source of supply
B secondary source of supply
C reserve source of supply

1 oxygen concentrator unit
2 high-pressure cylinders (containing either oxygen or oxygen-enriched air) or cryogenic liquid vessel(s)
3 two banks of high-pressure cylinders
4 source-of-supply shut-off valve
5 supply system shut-off valve
6 optional connection
7 to pipeline distribution system

Figure A.8 — Oxygen concentrator supply system with one oxygen concentrator unit and supplementary high-pressure cylinders or cryogenic liquid vessel(s) as the primary source, an oxygen concentrator unit as the secondary source and high-pressure cylinders as the reserve source for a double-stage distribution system

Annex B
(informative)

General guidelines for location of supply systems

B.1 A supply system should be installed, in accordance with the manufacturer's instructions, in a well-ventilated and fire-resistant room. It may be possible, depending on local conditions, for some components (e.g. cylinders) to be installed in the open air, protected from the weather and in a fenced area. Regional or national regulations which apply to the location of supply systems may exist.

B.2 Access to cylinder manifold rooms and storage areas should be level and kept clear. All doors should be capable of being opened from the inside, at any time, without a key, and should open outwards. The doors or gates for rooms or enclosures containing the source of supply should be capable of being locked. At least one emergency exit, which should be free from obstructions at all times and should lead into the open air or another safe location, should be provided.

B.3 Rooms or areas for supply systems should not be used for any other purpose.

B.4 Only nominated persons should be authorized to operate and attend the supply equipment.

B.5 Cylinders should be stored in accordance with the supplier's recommendations. One group of filled cylinders sufficient for one side of a manifold may be stored in the same room or area. Empty cylinders disconnected from the supply equipment may be stored pending their removal. Full and empty cylinders should be segregated and their respective storage areas should be labelled.

B.6 Services or containers of combustible gases or liquids should not be permitted within, or adjacent to, the supply system location.

B.7 A heating system may be used to heat supply system enclosures or storage areas, provided that no part of the heating system in contact with the air within the room can exceed a temperature of 225 °C and that cylinders are prevented from coming into contact with the heating system.

B.8 All electrical fittings in supply rooms should be located in fixed positions or protected to minimize the risk of physical damage.

B.9 Fire-fighting equipment should be provided.

B.10 The room or enclosure should be clean and well lit.

B.11 Enclosures (interior or exterior) for supply systems should conform to the following:

a) when an enclosure is located near a source of heat such as a furnace, incinerator or boiler room, its construction should prevent the cylinder temperature from exceeding 40 °C;

b) an enclosure should not be located within 3 m of open electrical conductors or transformers;

c) an enclosure should not be located adjacent to oil storage tanks;

d) an enclosure should comply with local building codes;

e) an enclosure should have concrete floors;

f) a warning notice should be displayed on both sides of each door;

EXAMPLE

Warning — Oxygen

No smoking

No open flames or sparks

No oil or grease

No combustible material to be placed within 5 m

g) fences and walls should be of a height not less than 1,75 m.

B.12 An enclosure should be easily accessible to vehicles delivering cylinders and should be at ground level or vehicle height depending on the method of unloading used.

B.13 An enclosure should be located so that no part of the enclosure is less than 3 m from any occupied building or from any roadway or footpath.

B.14 Suitable handling devices (e.g. specially designed trolleys) should be provided for the movement of cylinders.

Annex C
(informative)

Guidelines for emergency procedures

C.1 General

C.1.1 Emergencies which may result in the sudden cessation or reduction of the gas supply to one or more clinical areas can arise. Should such a problem occur, it is vital that procedures have been set up which will ensure immediate action on the following:

— communication of the problem to those persons and areas affected;

— conservation of gas;

— remedial action.

C.1.2 National or local regulations relating to fire precautions may exist.

C.2 Communication

C.2.1 Procedures should be set up to ensure that any emergency arising is immediately communicated to all clinical areas likely to be affected and to all staff involved in the maintenance of gas supplies and in remedial actions.

C.2.2 Such communication should include:

a) the nature of the emergency;

b) the likely duration of the emergency;

c) details of the gas conservation procedures to be applied;

d) the remedial actions to be taken.

C.2.3 Experienced persons in each area should be nominated to coordinate and communicate actions.

C.3 Conservation of gas supplies

C.3.1 On being notified of an emergency, the coordinator in each clinical area should reduce the use of gas from the pipeline system(s) involved to the minimum level required.

C.3.2 The staff responsible should check on, and bring into use as necessary, cylinders on reserve manifolds and cylinders held in storage or other sources at the emergency and maintenance supply assembly or at points of use.

C.3.3 If necessary, additional supplies of gas should be ordered from suppliers or other health care facilities to meet the expected duration of the emergency.

C.4 Remedial actions

C.4.1 The cause of the failure of supply should be investigated immediately and action initiated to remedy the problem.

C.4.2 The investigation may show that other areas of the health care facility, not initially affected, may need to be isolated to carry out repairs. In this case, communication and conservation procedures should be instituted in these areas before shutting off the gas supply.

C.4.3 Remedial work should be carried out under an effective method of control to maintain the integrity of the system.

C.5 Training

C.5.1 The staff responsible should be properly trained in the use of medical gases and pipeline systems and be familiar with the medical gas pipeline layout and the location of all area shut-off valves.

C.5.2 Emergency procedures should be initiated at least twice a year as an exercise. Any problems found should be corrected and necessary re-training performed.

C.5.3 Actual emergency situations should be evaluated and appropriate action taken to improve procedures and training.

C.6 Additional cylinder reserves

C.6.1 It is recommended that gas reserves in cylinders not connected to a source of supply be held in addition to reserves connected to a source of supply. The capacity of such additional supplies should be calculated to take into account the normal daily usage of the gas, the normal supply arrangements and the emergency procedures which will be taken in the event of failure of a supply system.

C.6.2 Critical care areas may require their own cylinder reserves to minimize any delay in maintaining gas supplies in an emergency. If cylinders with attached pressure regulators are used for this purpose, the pressure regulator outlet should be gas-specific and connected to a low-pressure hose assembly.

Annex D
(informative)

Procedure for testing and commissioning

D.1 Introduction

This test procedure is given as an example of how the specifications of Clause 10 may be verified so that the system may be commissioned and certified. Other procedures may be devised which validly test these specifications.

Typical forms for certification of the system are given in Annex E.

D.2 General

These tests should be carried out before filling the pipeline distribution system with oxygen-enriched air. The oxygen concentrator supply system should be isolated from the pipeline distribution system by closing the supply system shut-off valve or the source-of-supply shut-off valve(s).

D.3 Procedure

D.3.1 General

This test should be carried out on each source of supply incorporating an oxygen concentrator unit, in turn, at a test point immediately downstream of the oxygen-enriched air storage vessel(s).

D.3.2 Oxygen concentration

An oxygen analyser should be used. The oxygen concentration will have to meet the requirement in 4.5.1.

D.3.3 Particulate contamination

Test for particulate contamination using an appropriate test device. The particulate contamination will have to meet the requirement in 4.5.2.

D.3.4 Oil

Test for oil using an appropriate test device.

The oil concentration will have to meet the requirement in 4.5.1.

D.3.5 Water

Test the water vapour concentration of the oxygen-enriched air using an appropriate test device. The water concentration will have to meet the requirement in 4.5.1.

D.3.6 Carbon monoxide and carbon dioxide

The carbon monoxide and carbon dioxide concentrations should be measured using appropriate test devices. The concentrations of carbon monoxide and carbon dioxide will have to meet the requirements in 4.5.1.

Annex E
(informative)

Typical forms for certification of an oxygen concentrator supply system

Form E.1 — Specifications for oxygen-enriched air

Form _____ Sheet _____ of _____

Health care facility _____

Test of oxgen-enriched air produced by the oxygen concentrator supply system

This is to certify that the oxygen-enriched air supplied by the oxygen concentrator supply system has been tested for contaminants in accordance with Annex D of ISO 10083:2006.

Oxygen concentrator unit	**Oil contamination** $\leqslant$ 0,1 mg/m^3	**Water concentration** $\leqslant$ 67 ml/m^3	**Carbon monoxide concentration** $\leqslant$ 5 ml/m^3	**Carbon dioxide concentration** $\leqslant$ 300 ml/m^3	**Oxygen concentration** $\geqslant$ 90 % volume fraction
Measuring instrument used					

Manufacturer/installer representative

Signature _____

Authorized person

Signature _____

Form E.2 — Documentation and certificates provided

Form _____ Sheet _____ of _____

Health care facility _____

Documentation and certificates

This is to certify that the following documents and certificates have been provided:

a) pressure vessel certificate;

b) electrical inspection certificate;

c) manufacturer's instructions for use;

d) preventive maintenance schedules;

e) equipment warranties;

f) emergency procedures;

g) “as installed” drawings;

h) electrical schematics for the complete installation;

i) health care facility formulary.

Manufacturer/installer representative

Signature _____

Authorized person

Signature _____