INTERNATIONAL STANDARD

ISO 10083

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Oxygen concentrators for use with medical gas pipeline systems

Concentrateurs d'oxygène pour l'utilisation avec des systèmes de tuyauterie 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.

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.

International Standard ISO 10083 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Sub-Committee SC 6, *Medical gas systems*.

Annexes A, B and C of this International Standard are for information only.

Introduction

The purpose of this International Standard is to specify performance and safety requirements for oxygen concentrators connected to medical gas pipeline systems. The basic requirement of the oxygen concentrator is to provide a safe, reliable local source of oxygen-enriched air of sufficiently high oxygen concentration to supply medical needs. Special consideration has to be given to providing a safe system with adequate reserves since life support is dependent on a non-failing supply.

There is more than one way of achieving a high concentration of oxygen. This International Standard specifies requirements for the molecular sieve type of oxygen concentrator, also known as a pressure swing adsorber (PSA). Other types will be included when they are at a stage where they can be applied practically to hospital pipeline systems.

This International Standard does not purport to guarantee the suitability of the product gas for all clinical procedures, nor does it necessarily imply cost advantages over other methods of oxygen supply; it does, however, lay down the minimum requirements for those circumstances in which hospital authorities choose this method of supply.

Oxygen concentrators for use with medical gas pipeline systems

1 Scope

This International Standard specifies requirements for an oxygen concentrator system including a reserve supply, for use with medical gas pipeline systems which comply with ISO 7396, comprising a pressure swing adsorber (PSA) system and its source of air supply. It includes requirements for safety, quality, purity and availability of supply. It also specifies the air source for oxygen concentrators.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

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

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

ISO 7396:1987, *Non-flammable medical gas pipeline systems.*

IEC 364-2:1970, *Electrical installations of buildings — Part 2: Fundamental principles.*

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 (non-flammable medical gas) pipeline system: Central supply system with control equipment, a pipeline distribution system and terminal units at the point where non-flammable medical gases may be delivered.

3.2 medical oxygen concentrator: System, with dedicated air compressors, comprising molecular sieve devices by means of which oxygen-enriched air is produced from ambient air.

3.3 primary supply: That part of the medical oxygen concentrator system which supplies the pipeline distribution system.

3.4 secondary supply: That part of the medical oxygen concentrator system which automatically supplies the pipeline distribution system when the primary supply fails.

3.5 reserve supply: That part of the medical oxygen concentrator system, which operates automatically, to supply the pipeline distribution system in the event of a failure of the primary and secondary supplies.

3.6 control equipment: Those items which are necessary to maintain the set pressures and the oxygen concentration within the control limits, such as pressure regulators, oxygen analysers, relief valves, alarm initiators, manual and automatic valves.

3.7 pipeline distribution system: That part of a pipeline system linking the source of supply to the terminal units, including any necessary branch isolation valves and any additional line pressure regulators required to reduce further the pressure in a part of the distribution system, downstream of the source of supply.

3.8 terminal unit: Outlet assembly (inlet for vacuum), in a medical gas pipeline distribution system, at which the user makes connections and disconnections.

NOTE 1 The requirements for terminal units are specified in ISO 9170 [3].

3.9 shut-off valve; isolation valve: Manual or automatic valve which prevents flow in both directions when closed.

3.10 non-return valve: Valve which permits flow in one direction only.

3.11 gas-specific: Having characteristics which prevent interchangeability and thereby allow assignment to one gas service only.

3.12 pressure-safety valve: Valve to limit the pressure in the pipeline downstream of the pressure regulators.

3.13 pressure relief valve: Valve to limit the pressure downstream of any operating pressure line regulator.

3.14 operating alarm: Visual, or visual and auditory, alarm to indicate the necessity for technical staff to adjust the supply or correct a malfunction.

3.15 emergency alarm: Visual or auditory alarm to indicate to technical or medical staff that the supply is outside normal operating limits.

3.16 nominal operating pressure: Pressure at which the system is designed to operate.

3.17 rated capacity: Flow that the oxygen concentrator system can maintain continuously without the secondary supply (if provided) or reserve supply coming into operation.

3.18 molecular sieve device: Device that increases the oxygen concentration of ambient air by adsorbing nitrogen and some other gaseous components.

3.19 product gas: Oxygen-enriched air produced by the molecular sieve process.

3.20 oxygen 93 %: Oxygen-enriched air containing not less than 90 % and not more than 96 % (V/V) oxygen, the remainder comprising predominantly argon and/or nitrogen.

3.21 pressure vessel: Container which holds or can withstand a pressure higher than atmospheric pressure.

4 Materials

4.1 Compatibility with oxygen

The components of medical oxygen concentrator systems, including any components connected to any outlet of the molecular sieve device which come into contact with oxygen-enriched air, shall be compatible with oxygen 99 % under all operating conditions, and shall be clean and free from oil, grease and particulate matter.

The anti-corrosion properties of all components against oxygen, moisture and surrounding materials should also be considered.

Components should be of materials as specified in annex A of ISO 7396:1987.

NOTE 2 Compatibility involves both combustibility and ease of ignition. Materials which burn in air burn violently in pure oxygen, particularly under pressure. Similarly, materials which can be ignited in air require lower ignition energies in oxygen. Many such materials may be ignited by friction, at a valve seat or stem packing, by adiabatic compression, produced when oxygen at high pressure is rapidly introduced into a system at low pressure.

4.2 Cleaning

All pipes, valves and fittings in contact with the product gas in normal use or under single-fault condition shall be cleaned and degreased before assembly.

Precautions should be taken to maintain cleanliness during installation.

5 Requirements

5.1 General

NOTE 3 A typical oxygen concentrator system is shown in figure B.1.

5.1.1 The system shall comprise a primary, a secondary and a reserve supply and shall be designed for automatic operation.

5.1.2 The product gas from both the primary and secondary supplies shall comply with clause 8.

5.1.3 The plant shall be designed, manufactured and tested in accordance with the current national pressure vessel codes.

5.1.4 All electrical wiring shall comply with IEC 364-2.

5.2 Air supply

5.2.1 Each molecular sieve device shall have at least one air compressor.

NOTE 4 Each compressor may be arranged to supply other molecular sieve devices in the event of failure of its own molecular sieve device (see figure B.1).

5.2.2 Air compressors within the medical oxygen concentrator system shall be provided with a filter for protection of components.

5.3 Filtration

Downstream of the molecular sieve device there shall be a filter of 0,3 µm coalescing type 99 % efficiency to ensure that the product gas meets the particulate requirements of clause 8.

5.4 Booster compressor

If compressors are used to compress oxygen 93 % to the pipeline distribution pressure, they shall be of a design compatible with oxygen 99 % and shall be provided for each molecular sieve device.

5.5 Reserve supplies

The reserve supply shall be as specified in ISO 7396 with the amendments in 5.5.1 to 5.5.4.

5.5.1 Either

a) the reserve supply shall be oxygen 93 %; or

b) if national regulations endorsed by national medical professional societies regard oxygen 93 % and oxygen 99 % as totally interchangeable, the reserve supply shall be oxygen 93 % or oxygen 99 %.

5.5.2 The reserve supply shall have the rated capacity of the plant as specified in 6.1 a), and shall be capable of supplying the rated capacity for a minimum of 1 h from attached cylinders. (See B.4.)

5.5.3 The reserve supply shall be a supply system with pressure vessels (e.g. cylinders) comprising primary and secondary supplies, with automatic changeover.

5.5.4 The reserve supply shall discharge gas into the pipeline distribution system downstream of the non-return valve installed in the product gas line from the oxygen concentrator system.

5.6 Pressure control equipment

The oxygen concentrator supply system shall include a duplex pressure regulating and relief valve assembly designed to maintain pipeline distribution pressure as shown in figure B.1.

5.7 Control and monitoring

5.7.1 The control system shall include an oxygen analyser to monitor and display the oxygen concentration of the product gas continuously. This device shall include compensation for temperature and barometric pressure variations to ensure an accuracy of ± 1 % of the measured value over all operating conditions.

5.7.2 The control system shall include a device which continuously records the oxygen concentration of the product gas.

5.7.3 The control system shall effect automatic changeover as follows:

— from primary to secondary supply in the event of failure (pressure or oxygen concentration) of the primary supply;

— from secondary supply to the reserve supply in the event of failure (pressure or oxygen concentration) of the secondary supply.

5.7.4 A second independent oxygen analyser complying with 5.7.1 and 5.7.2 shall be provided to monitor and display the final concentration of the product gas continuously.

5.7.5 The analyser specified in 5.7.4 shall be provided with means to isolate automatically the primary and secondary supplies immediately upstream of the reserve supply if oxygen purity outside the limits specified in 5.1.2 is detected.

5.7.6 The control unit shall be designed so that shutting off or failure of one of the compressors or molecular sieve devices shall not affect the operation of the other units.

5.7.7 The control system shall monitor the oxygen concentration of the output of the reserve supply filling system (if included) and shall automatically isolate the filling system if a concentration outside the limits specified in clause 8 is detected.

5.8 Alarms

5.8.1 Operating alarms shall be provided to indicate

a) a changeover from primary to secondary supply;

b) that the reserve supply is in operation;

c) that the secondary reserve supply is in operation;

d) the activation of fault-monitoring devices included within the system;

e) a decrease in reserve supply below 50 % of its normal pressure.

5.8.2 Emergency alarms shall be provided to indicate

a) a decrease in oxygen concentration below specification;

b) a deviation from the pipeline distribution pressure according to ISO 7396.

5.9 Filling reserve supply

5.9.1 If equipment for filling the reserve supply is an element of an oxygen concentrator system, it shall comply with national standards and with the requirements specified in 5.9.1.1 to 5.9.1.6.

5.9.1.1 All compressors shall comply with clause 4.

5.9.1.2 Any detachable connectors shall be gas-specific and, in the case of cylinder connectors, they shall be in accordance with ISO 407 or ISO 5145 or the relevant national standard.

5.9.1.3 Means shall be provided to ensure that reserve supply filling only occurs during periods of low hospital demand and to prevent the filling operation taking product gas in preference to the hospital supply.

5.9.1.4 Means shall be provided to terminate reserve supply filling when the filling pressure, specified by the manufacturer, is attained.

5.9.1.5 Means shall be provided for safe pressure relief of the filling system.

5.9.1.6 The high-pressure manifold shall be designed to withstand 1,5 times the maximum supply pressure and shall be equipped with a safety relief valve, set to operate at 130 % of the maximum pressure and capable of discharging the full output flow of the filling compressor.

5.9.2 An oxygen concentrator shall not be connected to allow the filling of cylinders or pressure vessels that are designed and dedicated for oxygen 99 %.

5.10 Gas specificity

The connectors for all pressure vessels in the reserve supply, if user-detachable, shall be gas-specific.

6 Information

6.1 The manufacturer shall provide the following information:

a) the rated capacity of the plant, expressed in litres per minute, corrected to STP (standard temperature and pressure: 0 °C and 101,3 kPa) and referred to STPD (standard temperature and pressure, dry air: 0 °C, 101,3 kPa and 0 % relative humidity) inlet conditions when operating continuously at its normal operating pressure and delivering an oxygen concentration as specified in clause 8;

b) instructions for installation and use;

c) instructions for maintenance in accordance with annex A;

d) air source requirements (see also annex B);

e) the range of temperature, pressure and humidity of the inlet air and ambient temperature conditions for which the plant is designed;

f) if the oxygen concentrator plant is being used for cylinder filling, manuals shall be provided.

6.2 The manufacturer shall provide certification to confirm that the plant has operated for a continuous period of 72 h with checks made on the functioning of the complete system. These checks shall include all automatic operations such as starting, shut-down and operation of the condition monitoring and analysing equipment to ensure that the system operates within the design parameters.

7 Identification

The primary, secondary and reserve supplies of an oxygen concentrator system shall be labelled with the oxygen concentration.

8 Product gas

At the continuous rated capacity of the plant, the product gas quality shall comply with the following:

a) minimum oxygen concentration: 90 % (V/V) to 96 % (V/V), the balance being predominantly argon and/or nitrogen;

b) maximum carbon monoxide concentration: 5 mg/kg;

c) maximum carbon dioxide concentration: 300 mg/kg;

d) maximum particulate contamination 0,5 $\mu g/m^3$;

e) maximum hydrocarbon contamination 0,5 mg/m^3;

f) maximum dewpoint: – 40 °C at standard atmospheric pressure.