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Flow-metering devices for connection to terminal units of medical gas pipeline systems

Dispositifs de mesure de débit pour raccordement aux prises murales des systèmes de distribution de gaz médicaux

Reference number
ISO 15002:2008(E)

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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 15002 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 15002:2000) which has been technically revised.

Introduction

Flow-metering devices are widely used for delivery of medical gases supplied by a medical gas supply system directly to a patient. These devices need to deliver accurate flows under varying conditions of temperature and inlet pressure. Therefore it is important that the operating characteristics be specified and tested in a defined manner.

This International Standard pays particular attention to:

— safety (mechanical strength, safe relief of excess pressure, resistance to ignition);

— gas specificity;

— cleanliness;

— suitability of materials;

— accuracy;

— testing;

— identification;

— information supplied.

Annex A contains rationale statements for some of the requirements of this International Standard. The clauses and subclauses marked with an asterix (*) after their number have corresponding rationale contained in informative Annex A, included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this International Standard. 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.

Flow-metering devices for connection to terminal units of medical gas pipeline systems

1 Scope

1.1 This International Standard is applicable to:

— flow-metering devices that are connected, either directly or by means of flexible connecting assemblies, and disconnected by the operator at terminal units of a medical gas pipeline system for flow adjustment, measurement and delivery of medical gases;

— flow-metering devices that are connected and disconnected by the operator at gas-specific connection points of devices such as pressure regulators.

1.2 This International Standard applies to:

a) flow-metering devices intended to be used with the following medical gases:

— oxygen;

— nitrous oxide;

— medical air;

— carbon dioxide;

— oxygen/nitrous oxide mixture [50 %/50 % (by volume)];

— specified mixtures of the gases listed above;

b) flow-metering devices intended to be used with the following gases:

— oxygen-enriched air;

— helium;

— xenon.

NOTE Regional or national regulations might permit use of oxygen-specific connection points for oxygen-enriched air.

1.3 This International Standard does not apply to electrical or electronic flow-metering devices.

1.4 This International Standard does not apply to gases used for driving surgical tools.

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 32, *Gas cylinders for medical use — Marking for identification of content*

ISO 5359:2008, *Low-pressure hose assemblies for use with medical gases*

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

ISO 9170-1, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

ISO 11114-3:1997, *Transportable gas cylinders — Compatibility of cylinder and valve materials with gas contents — Part 3: Autogenous ignition test in oxygen atmosphere*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

ISO 15001:2003, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

ISO 19054, *Rail systems for supporting medical equipment*

EN 837-1:1996, *Pressure gauges — Part 1: Bourdon tube pressure gauges — Dimensions, metrology, requirements and testing*

EN 1089-3:2004, *Transportable gas cylinders — Gas cylinder identification (excluding LPG) — Part 3: Colour coding*

EN 13544-2, *Respiratory therapy equipment — Part 2: Tubing and connectors*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
diameter index safety system connectors
DISS connectors
any of a range of male and female components intended to maintain gas-specificity by allocation of a set of different diameters to the mating connectors for each particular gas

3.2
flowgauge
device that measures pressure and is calibrated in units of flow

NOTE The flowgauge does not measure flow. It indicates flow by measuring the pressure upstream of a fixed orifice.

3.3
flowmeter
device that measures and indicates the flow of a specific gas

3.4
flow-metering device
device fitted with an inlet connector and an outlet connector and which incorporates one of the following:

a) a flowmeter with a flow control valve;

b) a flowgauge and a fixed orifice with a flow control valve;

c) one or more fixed orifices with a means of flow selection.

NOTE Typical examples of flow-metering systems and devices are given in Figures B.1 and B.2.

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

3.6
gas-specific connection point
that part of the socket which is the receptor for a gas-specific probe

3.7
hose insert
that portion of a connector which is pushed into and secured within the bore (lumen) of the hose

3.8
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 or her own name, regardless of whether these operations are carried out by that person or on his or her behalf by a third party

3.9
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

3.10
medical gas supply system
either

a) a medical gas pipeline system or

b) an installation having no permanent pipeline system but employing a medical gas supply source complete with pressure regulator(s)

3.11
non-interchangeable screw-threaded connector
NIST connector
range of male and female components intended to maintain gas specificity by the allocation of a set of different diameters and a left- or right-hand screw thread to the mating components for each particular gas

3.12
probe
gas-specific male component designed for acceptance by and retention in the socket

3.13
rated inlet pressure
p_1
maximum upstream pressure for which the flow-metering device is designed to operate

3.14
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

3.15
socket
female part of a terminal unit which is either integral or attached to the terminal unit base block by a gas-specific interface and which contains the gas-specific connection point

3.16
terminal unit
outlet assembly (inlet for vacuum) in a medical gas supply system at which the operator makes connections and disconnections

4 Arrangement of flow-metering systems and devices

Typical examples of flow-metering systems are shown in Annex B.

5 General requirements

NOTE Unless otherwise specified, pressures in this International Standard are expressed as gauge pressures (i.e. atmospheric pressure is defined as 0).

5.1 Safety

Flow-metering devices shall, when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, present no risks that are not reduced to an acceptable level using procedures in accordance with ISO 14971 and which are connected with their intended application, in normal conditions and in single fault conditions.

5.2 Alternative construction

Flow-metering devices, and components or parts thereof, using materials or having forms of construction different from those detailed in this clause (except for dimensions and allocation of DISS and NIST connectors and probes used as inlet connectors), shall be presumed to be in compliance with the safety objectives of this International Standard if it can be demonstrated that an equivalent degree of safety is obtained (i.e. compliance with requirements presumes that risks have been mitigated to acceptable levels) unless objective evidence to the contrary becomes available.

NOTE 1 Objective evidence might be obtained by postmarket surveillance.

Evidence of an equivalent degree of safety shall be provided by the manufacturer upon request.

NOTE 2 Regional or national regulations may require the provision of evidence to a competent authority or conformity assessment body (e.g. notified body in the European Economic Area) upon request.

NOTE 3 Attention is drawn to ISO 14971 on risk management and to the International Standards under development by ISO/TC 210.

5.3 Materials

5.3.1 *The materials in contact with the gases listed in 1.2, during normal use, shall be resistant to corrosion and compatible with oxygen and the other gases and their mixtures in the temperature range specified in 5.3.3.

NOTE 1 Corrosion resistance includes resistance against moisture and surrounding materials.

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

NOTE 3 ISO 15001 contains information on selection of metallic and non-metallic materials and other aspects of compatibility of equipment with oxygen.

5.3.2 *For flow-metering devices for all gases, the autoignition temperature of the non-metallic components in contact with the gas, including the sealing materials and lubricants (if used), shall be no lower than 160 °C.

Evidence of conformity with this requirement shall be provided by the manufacturer upon request.

NOTE 1 Regional or national regulations might require the provision of evidence to a competent authority or conformity assessment body (e.g. notified body in the European Economic Area) upon request.

The determination of the autoignition temperature shall be carried out in accordance with ISO 11114-3.

NOTE 2 The maximum permitted operating temperature of tested material is 100 °C lower than the autoignition temperature at the corresponding oxygen pressure. This safety margin is necessary because it covers both an unforeseen increase in the operating temperature and the fact that the autoignition temperature is not a constant. Values of the autoignition temperature always depend on the test method used, which does not exactly simulate all possible operating conditions.

5.3.3 The materials shall permit the flow-metering device and its components to meet the requirements of 5.4 (except 5.4.6.3, 5.4.7.3 and 5.4.8.2) in the temperature range of –20 °C to +60 °C.

5.3.4 Flow-metering devices shall meet the requirements of 5.4 after being exposed, whilst packed for transport and storage, to environmental conditions as specified by the manufacturer.

5.3.5 Springs, highly strained components and parts liable to wear which come in contact with the gas shall not be plated.

NOTE Plating could come off.

5.3.6 Evidence of conformity with the requirements of 5.3.1 to 5.3.5 shall be provided by the manufacturer upon request.

NOTE Regional or national regulations might require the provision of evidence to a competent authority or conformity assessment body (e.g. notified body in the European Economic Area) upon request.

5.4 Design requirements

5.4.1 Gas supply inlet

5.4.1.1 Inlet

The gas supply inlet shall be one of the following:

a) a probe complying with ISO 9170-1 permanently attached to the flow-metering device [see Figure B.2 a)];

b) a nut and nipple, either complying with DISS or NIST specifications in ISO 5359, or complying with an equivalent regional or national standard, permanently attached to the flow-metering device [see Figure B.2 b)];

c) a low-pressure hose assembly complying with ISO 5359 with a probe complying with ISO 9170-1 as an inlet connector and a flow-metering device as an outlet connector [see Figure B.2 c)];

d) a low-pressure hose assembly complying with ISO 5359 with a nut and nipple either complying with DISS or NIST specifications in ISO 5359, or complying with an equivalent national or regional standard, as an inlet connector and a flow-metering device as an outlet connector [see Figure B.2 d)].