INTERNATIONAL STANDARD

ISO 15002

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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 15002:2000(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 3.

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 15002 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*.

Annex A of this International Standard is for information only.

Introduction

This International Standard pays particular attention to:

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

— gas specificity;

— cleanliness of materials;

— suitability of materials;

— accuracy;

— testing;

— identification;

— information supplied.

Throughout this International Standard, a subclause for which a rationale is provided in annex A is indicated by a boldface capital **R.**

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 which 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 measurement and delivery of medical gases;

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

1.2 It applies only to flow-metering devices for the following medical gases:

— oxygen,

— nitrous oxide,

— air for breathing,

— carbon dioxide,

— helium,

— xenon,

— specified mixtures of the gases listed above,

— oxygen/nitrous oxide mixture 50/50 (% volume fraction).

1.3 This International Standard is not applicable to electrical or electronic flow-metering devices.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

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

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

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, *Medical devices — Application of risk management to medical devices.*

EN 12218, *Rail systems for supporting medical equipment.*

3 Terms and definitions

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

3.1
DISS connectors
diameter index safety system connectors
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
flow gauge
gauge which measures pressure differential and which is calibrated in units of flowrate

NOTE The flow gauge indicates flowrate 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 that incorporates one of the following:

a) a flowmeter and flow control valve

b) a flow gauge and a fixed orifice with a flow control valve

c) multiple fixed orifices with means of selection

3.5
gas-specific
having characteristics which prevent interchangeability and thereby allow assignment to one gas or vacuum service only

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

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
any gas or mixture of gases intended for administration to patients for therapeutic, diagnostic or prophylactic purposes, or for surgical tool applications

3.9
medical gas pipeline system
complete system which comprises a source of supply, a pipeline distribution system and terminal units at the points where medical gases or vacuum may be used

3.10
medical gas supply system
medical gas pipeline system or any other installation having no permanent pipeline system but employing a medical gas source complete with pressure regulator(s)

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

3.12
placing on the market
the first making available, in return for payment or free of charge, of a device other than a device intended for clinical investigation, with a view to distribution and/or use

3.13
probe
male component designed for acceptance by and retention in the socket

3.14
rated inlet pressure
p_1
maximum upstream pressure for which the flow-metering device is designed to operate

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

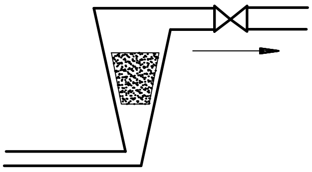
3.15
single fault condition
condition in which a single means for protection against a safety hazard in equipment is defective or a single external abnormal condition is present

3.16
socket
that female part of a terminal unit which is either integral or attached to the base block by a gas-specific interface and which contains the gas-specific connection point

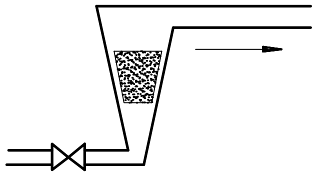
3.17
terminal unit
outlet assembly (inlet for vacuum) in a medical gas supply system at which the operator makes connections and disconnections

4 Arrangement of flow-metering systems and devices

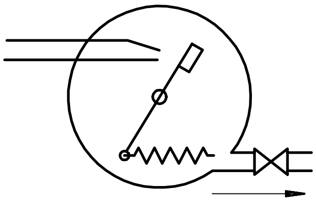
4.1 Typical examples of flow-metering systems are shown in Figure 1.



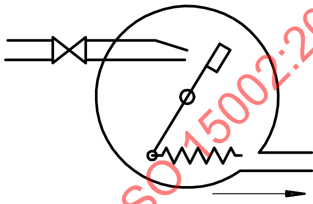
a) Measuring tube with flow control valve downstream



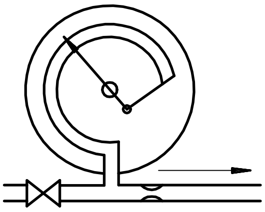
b) Measuring tube with flow control valve upstream



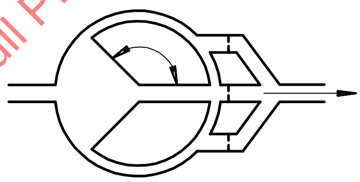
c) Paddle and a fixed orifice with flow control valve downstream



d) Paddle and a fixed orifice with flow control valve upstream



e) Flow gauge and a fixed orifice with flow control valve upstream



f) Multiple fixed orifices with selection knob

Figure 1 — Examples of flow-metering systems

Figure 1 a) shows a system which comprises a vertical measuring tube whose cross-section increases upwards and in which a float is lifted by the action of the gas flow. The float settles at a height which is a function of the flowrate, which is controlled by a flow control valve fitted downstream of the tube.

Figure 1 b) shows the same system as in a) with the flow control valve fitted upstream of the tube.

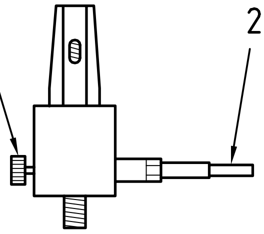
Figure 1 c) shows a system which comprises a paddle connected to a return spring which is located at the outlet of a fixed orifice. The paddle is pushed by the action of the gas flow and settles at a position which is a function of the flowrate, which is controlled by a flow control valve fitted downstream of the orifice.

Figure 1 d) shows the same system as in c) with the flow control valve fitted upstream of the orifice.

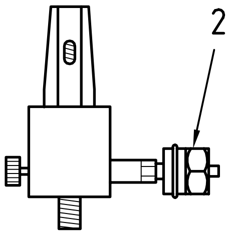
Figure 1 e) shows a system which comprises a pressure gauge measuring the pressure upstream of a fixed orifice. The pressure is a function of the flowrate, which is controlled by a flow control valve fitted upstream of the pressure gauge. The pressure gauge is calibrated in units of flowrate (flow gauge).

Figure 1 f) shows a system which comprises multiple fixed orifices. The change from the "off" position and from one setting to another can be achieved, for example, by turning a knob.

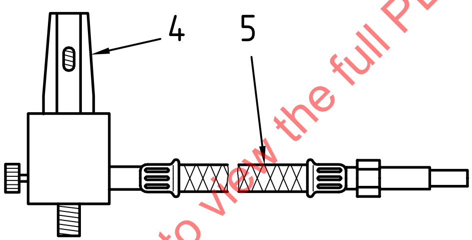
4.2 Typical examples of flow-metering devices are shown in Figure 2.



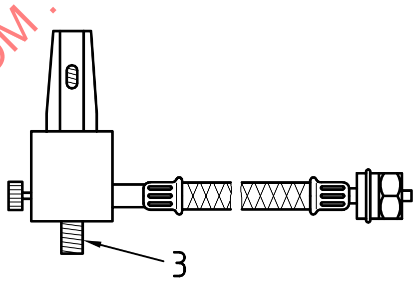
a) Flow-metering device with a probe as inlet connector



b) Flow-metering device with a DISS or NIST nut and nipple as inlet connector



c) Flow-metering device with a hose and a probe as inlet connector



d) Flow-metering device with a hose and a DISS or NIST nut and nipple as inlet connector

Key

1 Flow control valve
2 Inlet connector
3 Outlet connector
4 Measuring tube
5 Hose

Figure 2 — Typical examples of flow-metering devices

5 General requirements

5.1 Safety

Flow-metering devices shall, when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, cause no safety hazard which could be foreseen, using risk analysis procedures in accordance with ISO 14971, which is connected with their intended application, in normal condition and in single fault condition.

5.2 R Alternative construction

Flow-metering devices and components or parts thereof, using materials or having forms of construction different from those detailed in clause 5 of this International Standard (except for dimensions and allocation of DISS and NIST connectors and probes used as inlet connectors) shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained.

Such evidence shall be provided by the manufacturer.

5.3 Materials

5.3.1 The materials in contact with the gas shall be compatible with oxygen and the intended medical gas or gas mixture in the temperature range specified in 5.3.2.

NOTE 1 Compatibility with oxygen involves both combustibility and ease of ignition. Materials which burn in air will burn violently in pure oxygen. Many materials which do not burn in air will do so 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 by adiabatic compression produced when oxygen at high pressure is rapidly introduced into a system initially at low pressure.

NOTE 2 Compatibility with oxygen includes resistance to corrosion from moisture and surrounding materials.

NOTE 3 ISO 15001 deals with the compatibility of medical equipment with oxygen.

5.3.2 The materials shall permit the flow-metering device and its components to meet the requirements of 5.4 (except 5.4.6) in the temperature range of −20 °C to + 60 °C.

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

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

NOTE Plating could come off.

5.3.5 R Evidence of conformity with the requirements of 5.3.1, 5.3.2, 5.3.3 and 5.3.4 shall be provided by the manufacturer.

5.4 Design requirements

5.4.1 Inlet connector

5.4.1.1 The inlet connector shall be one of the following:

a) a probe complying with ISO 9170-1 [see Figure 2 a)];

b) a DISS or NIST nut and nipple complying with ISO 5359 [see Figure 2 b)];

c) an assembly consisting of a hose insert, a length of hose and a probe complying with ISO 9170-1 [see Figure 2 c)];

d) an assembly consisting of a hose insert, a length of hose and a DISS or NIST nut and nipple complying with ISO 5359 [see Figure 2 d)].

5.4.1.2 These assemblies shall comply with ISO 5359 except that the outlet connector is replaced by an outlet connector complying with 5.4.2 a).

Compliance shall be checked by visual inspection.

5.4.2 Outlet connector

The outlet connector shall be one of the following:

a) a permanently connected hose insert;

b) a proprietary fitting, with or without a hose insert.

Compliance shall be checked by visual inspection.

5.4.3 R Filtration

A filter shall be provided which:

a) is located upstream of the flow-metering device;

b) is replaceable;

c) has openings not exceeding 100 µm or equivalent mesh.

Evidence shall be provided by the manufacturer.

5.4.4 Scales and indicators

5.4.4.1 All flow-metering devices shall be graduated in units of litres per minute (l/min).

NOTE For flowrates of less than 1 l/min, the flow-metering devices may be graduated in millilitres per minute (ml/min).

5.4.4.2 Unit graduations in flow-metering device scale increments shall be not less than the stated accuracy at a given flowrate, or not less than 1 l/min for flowrates greater than 10 l/min.

5.4.4.3 The indicator of a flow-metering device shall be visible to the user at all flowrates, including zero flow.

5.4.4.4 The scale of the flow-metering device shall be legible to an operator having a visual acuity (corrected if necessary) of one, sitting or standing 1 m from the flow-metering device at a light level of 215 lx and viewing the flowmeter perpendicular and including 90° above, below, left of and right of the operator’s direct line of vision.

5.4.4.5 Compliance with the requirements of 5.4.4.1 to 5.4.4.4 shall be checked by visual inspection.

5.4.5 Mechanical strength

The flow-metering device shall meet the requirements of 5.4 after containing for 10 min or relieving a pressure of 1 000 kPa.

The test for mechanical strength is given in 6.2.

5.4.6 Accuracy of flowrate

The flowrate at any graduation of a flow-metering device shall be within ± 10 % of the indicated value for flowrates between 10 % and 100 % of full scale or ± 0,5 l/min, whichever is greater. For flowrates below 10 % of full scale, the accuracy shall be disclosed by the manufacturer.

For flow-metering devices for measuring flowrates less than or equal to 1 l/min, the accuracy of the flowrate at any flowrate graduation shall be within ± 10 % of the full scale.

The accuracy shall be measured throughout the range of inlet pressures specified by the manufacturer, when the flow is discharged into ambient atmosphere, after the test for mechanical strength has been carried out.

The test for accuracy of flowrate is given in 6.3.

To enhance accuracy and to reduce the hazard of static discharge, means should be provided to minimize the build-up of electrostatic charges, both inside and outside the flowmeter tube and its housing.

5.4.7 Flow control valve

5.4.7.1 The control knob and the valve spindle shall be designed such that they cannot be disengaged without the use of a tool.

The flow control valve should be designed so that the flowrate increases when the knob is turned counter-clockwise.

5.4.7.2 Compliance with the requirements of 5.4.7.1 shall be checked by visual inspection.

5.4.8 Leakage

The total internal leakage with the flow control valve closed with a torque of 0,4 N·m shall not exceed 0,3 ml/min (0,030 3 kPa·l/min) at p_1, after the tests for mechanical strength and accuracy have been carried out.

The total external leakage (to the atmosphere) shall not exceed 0,5 ml/min (0,050 6 kPa·l/min) at p_1 after the tests for mechanical strength and accuracy have been carried out.

The test for leakage is given in 6.4.

5.4.9 R Resistance to ignition

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 not be lower than 160 °C.

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

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

NOTE 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.

5.4.10 Connection to rail systems

If a flow-metering device fitted with an inlet connector complying with 5.4.1.1 c) or d) is intended to be supported by a rail system complying with EN 12218, it shall be provided with one of the following devices complying with EN 12218:

— a rail clamp;

— an equipment mount;

— an equipment mount pin.

5.5 Constructional requirements

5.5.1 R Cleaning

The components of flow-metering devices for all gases shall be supplied clean and free from oil, grease and particulate matter.

Evidence shall be provided by the manufacturer.

NOTE 1 Any method of cleaning and degreasing which effectively removes all surface dirt and hydrocarbons, and which leaves no residue itself, may be used. Chemical cleaning methods will normally require subsequent washing and drying processes to remove residues.

NOTE 2 Examples of cleaning procedures are described in ISO 15001.

5.5.2 R Lubricants

If lubricants are used, they shall be compatible with oxygen, the other medical gases and their mixtures in the temperature range specified in 5.3.2 up to the test pressure of 1 000 kPa.

Evidence shall be provided by the manufacturer.

5.5.3 Loosening torque

The torque required to remove the inlet connector from the flow-metering device shall be greater than or equal to 12 N·m.

The test for loosening torques is given in 6.5.

5.5.4 Flow-setting torque

If there are multiple fixed orifices, the torque required to change from the "off" position and from one setting to another shall be not less than 0,5 N·m and the control shall self-centre at each setting.

The test for operating torques is given in 6.5.

5.5.5 R Inadvertent disassembly

Means shall be provided to prevent inadvertent disassembly of the flow-metering device.

Evidence shall be provided by the manufacturer.

6 Test methods

6.1 General

6.1.1 Ambient conditions

Except where otherwise stated, tests shall be carried out at 23 °C ± 2 °C.

6.1.2 Test gases

Except where otherwise specified, tests shall be carried out with clean, oil-free dry air, nitrogen or the specific gas with a maximum moisture content of 50 µg/g (50 ppm) corresponding to a dew point of −48 °C at atmospheric pressure.

6.1.3 Reference conditions

Flowrates shall be corrected to 23 °C and 101,3 kPa.

If a flow-metering device is tested with a gas other than the specific gas, flowrates shall be converted.

Conversion coefficients are given in Table 1, where flowrate of intended gas = flowrate of test gas × conversion coefficient.

Table 1 — Conversion coefficients

Test gas	Conversion coefficient for					
	Air	Oxygen	N_2O	CO_2	Helium	Xenon
Air	1	0,95	0,81	0,81	2,69	0,47
Nitrogen	0,98	0,93	0,79	0,79	2,65	0,46

6.2 Test method for mechanical strength

Compliance shall be determined by following the procedure below:

a) seal or plug the flow-metering device outlet;

b) open the flow control valve;

c) subject the flow-metering device to a test pressure of 1 000 kPa;

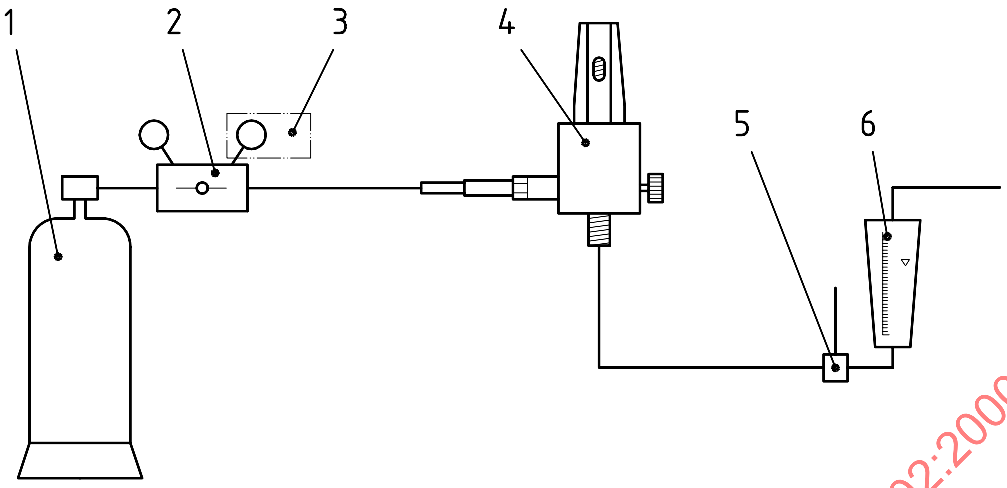
d) verify that the flow-metering device is capable of containing for 10 min or safely relieving the test pressure;

e) return the flow-metering device to p_1 and carry out the tests for accuracy and leakage given in 6.3 and 6.4.

6.3 Test method for accuracy of flowrate

Test the accuracy of flowrate, using the equipment shown in Figure 3, after the test for mechanical strength has been carried out.

This test shall be carried out at the maximum and minimum inlet pressures specified by the manufacturer.



Key

1 Gas supply
2 Pressure regulator
3 Calibrated gauge
4 Test sample with flow control valve
5 Thermometer
6 Calibrated flowmeter

Figure 3 — Equipment for testing accuracy of flowrate

6.4 Test method for leakage

6.4.1 Internal leakage

The device shall be tested with gas at p_1 supplied to the inlet connector with the flow control valve closed with a torque of 0,4 N·m after the tests for mechanical strength and accuracy have been carried out.

6.4.2 External leakage

The device shall be tested with gas at p_1 supplied to the inlet connector, with the flow control valve open and the outlet sealed or plugged after the tests for mechanical strength and accuracy have been carried out.

6.5 Test method for loosening and operating torques

Measure the torques using an appropriate torque spanner.

Check that multiple orifices self-centre by visual inspection.

6.6 Test method for durability of markings and colour coding

Rub markings and colour by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with ethanol and then for 15 s with a cloth rag soaked with isopropanol. Carry out this test at ambient temperature.

Check for durability by visual inspection.