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ISO 15002

Second edition
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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)].

5.4.1.2 Filtration

A gas supply inlet shall be provided with a filter which:

a) is replaceable;

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

Evidence of conformity 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.

5.4.2 Outlet connector

The outlet connector shall be one of the following:

a) a fixed nipple in accordance with EN 13544-2;

b) a threaded connector in accordance with EN 13544-2 or equivalent regional or national standard;

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

Compliance shall be checked by visual inspection.

5.4.3 *Mechanical strength

The flow-metering device shall meet the requirements of 5.4.4 and 5.4.6.3, 5.4.7.3 and 5.4.8.2 after containing a pressure of 1 000 kPa for 5 min.

The test for mechanical strength is given in 6.2.

5.4.4 Leakage

The total internal leakage with the flow control valve closed with a torque of 0,4 N·m (or in the case of a flow-metering device with multiple fixed orifices, with the means of selection set to zero) shall not exceed 0,3 ml/min (which is equivalent to 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 (which is equivalent to 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 6.3.

5.4.5 Connection to rail systems

If a flow-metering device fitted with a gas supply inlet complying with 5.4.1.1 c) or d) is intended by the manufacturer to be supported by a rail system complying with ISO 19054, it shall be provided with one of the following devices complying with ISO 19054:

— a rail clamp;

— an equipment mount;

— an equipment mount pin.

5.4.6 Requirements for flow-metering devices incorporating a flowmeter and a flow control valve

5.4.6.1 Scales and indicators

Flowmeters shall be graduated in units of litres per minute (l/min) or for flows equal to or less than 1 l/min in units of millilitres per minute (ml/min).

The indicator of a flowmeter shall be visible to the user at all flowrates, including zero flow.

Compliance shall be checked by visual inspection.

5.4.6.2 Legibility

The indicated value of the flowmeter shall be legible to an operator having visual acuity of 1 (corrected if necessary), 1 m from the flowmeter with an illuminance of 215 lx.

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.

5.4.6.3 Accuracy of flow

The accuracy of the flow at any graduation of a flowmeter with a maximum flow greater than 1 l/min shall be within $\pm$ 10 % of the indicated value for flows between 10 % and 100 % of full scale or $\pm$ 0,5 l/min, whichever is greater, when the flow is discharged into ambient atmosphere and corrected to reference conditions (see 6.1.3).

The accuracy of the flow at any flow graduation of a flowmeter with a maximum flow of 1 l/min or less shall be within $\pm$ 10 % of full scale when the flow is discharged into ambient atmosphere and corrected to reference conditions (see 6.1.3).

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

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

To enhance accuracy and to reduce the hazard of electrostatic discharge, it is recommended that means to minimize the buildup of electrostatic charges both inside and outside the flowmeter tube and its housing be provided.

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.

5.4.6.4 Flow control valve

NOTE The flow control valve can be situated upstream or downstream of the flowmeter [see Figures B.1 a) and B.1 b)]. The position affects the accuracy of flow at different supply pressures and resistance in the output.

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

Compliance shall be tested by attempting to remove the knob and spindle without the use of a tool.

5.4.6.4.2 *****The flow control valve shall be designed so that the flow increases when the knob is turned anticlockwise.

Compliance shall be checked by visual inspection.

5.4.7 Requirements for flow-metering devices incorporating a flowgauge and a fixed orifice with a flow control valve

5.4.7.1 Scale

5.4.7.1.1 The range of the flowgauge scale shall extend to a flow at least 33 % greater than the maximum flow specified by the manufacturer.

5.4.7.1.2 The flowgauge shall be graduated in units of litres per minute (l/min).

Compliance with these requirements shall be checked by visual inspection.

5.4.7.2 Legibility

The indicated value of a flowgauge shall be legible to an operator having a visual acuity of 1 (corrected if necessary), 1 m from the flowgauge with an illuminance of 215 lx.

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.

5.4.7.3 Accuracy of flow

The accuracy of the flow at any graduation of a flowgauge shall be within $\pm$ 10 % of the indicated value for flows between 10 % and 100 % of full scale or $\pm$ 0,5 l/min, whichever is greater, when the flow is discharged into ambient atmosphere and corrected to reference conditions (see 6.1.3).

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

Evidence of conformity with this requirement 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.

5.4.7.4 Flow control valve

NOTE The flow control valve can be situated upstream or downstream of the flowgauge. The position affects the accuracy of flow at different supply pressures and resistance in the output.

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

Compliance shall be tested by attempting to remove the knob and spindle without the use of a tool.

5.4.7.4.2 *The flow control valve shall be designed so that the flow increases when the knob is turned anticlockwise.

Compliance shall be checked by visual inspection.

5.4.7.5 Flowgauge

5.4.7.5.1 If a Bourdon tube flowgauge is used, it shall conform to EN 837-1 (except for the minimum nominal size) and shall meet the requirements in 5.4.7.1, 5.4.7.2, 5.4.7.5.2 and 5.4.7.5.3.

The requirements in 5.4.7.1, 5.4.7.2, 5.4.7.5.2, 5.4.7.5.3 and 5.4.7.5.5 also apply to other types of flowgauge.

5.4.7.5.2 If the flowgauge connector is threaded, the thread shall comply with EN 837-1 or a regional or national standard.

5.4.7.5.3 The flowgauge shall be class 2,5 or better in accordance with EN 837-1.

5.4.7.5.4 The flowgauge shall be calibrated for the intended fixed orifice.

5.4.7.5.5 Evidence of conformity with the requirements of 5.4.7.5.1 to 5.4.7.5.4 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.

5.4.8 Requirements for flow-metering devices with one or more fixed orifices with means of selection

5.4.8.1 Legibility

The set value of the fixed orifice in use shall be legible to an operator having visual acuity of 1 (corrected if necessary), 1 m from the flow-metering device with an illuminance of 215 lx.

5.4.8.2 Accuracy of flow

The actual flow shall be within ± 20 % of each stated value, for flows greater than 1,5 l/min.

The actual flow shall be within ± 30 % of each stated value for flows of 1,5 l/min or less.

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

Evidence of conformity with this requirement 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.

5.4.8.3 Flow setting

5.4.8.3.1 If there are multiple orifices, the tangential force required at the maximum radius of the flow-selecting device to change from the “off” position and from one setting to another shall be not less than 5 N and not more than 50 N.

Evidence of compliance with this requirement 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.

5.4.8.3.2 *The flow-selecting device should self-centre on each flow setting and should minimize the likelihood of selection of positions of no flow (e.g. between adjacent settings) except for the zero flow setting.

Compliance is checked by functional testing.

5.4.8.3.3 *If a flow-metering device with multiple fixed orifices can be set between adjacent settings so that there is no flow to the outlet, a warning to this effect shall be placed on the device.

5.4.8.4 Removal of a fixed orifice

Removal of a fixed orifice shall require the use of a tool.

Compliance shall be tested by attempting to remove a fixed orifice without the use of a tool.

5.4.8.5 *Means of flow selection

The means of flow selection shall be captive such that it cannot be disengaged without the use of a tool.

Compliance shall be tested by attempting to remove the means of flow selection without the use of a tool.

If the means of flow selection is rotary, it shall be designed so that the flow increases when turned anticlockwise.

Compliance shall be checked by visual inspection.

5.5 Constructional requirements

5.5.1 *Cleanliness

Components of flow-metering devices in contact with medical gases during normal use shall meet the cleanliness requirements of ISO 15001.

Evidence of conformity 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.

5.5.2 *Lubricants

If lubricants are used, they shall be compatible with oxygen, the other medical gases and their mixtures in the temperature range specified in 5.3.3 up to the test pressure of 1 000 kPa.

Evidence of conformity 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.

5.5.3 Inadvertent disassembly

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

Evidence of conformity 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.

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.

When a flow-metering device is tested with a gas other than that for which it is intended, the flows shall be corrected using the conversion coefficients given in Table 1.

Conversion coefficients are given in Table 1, where:

flowrate of intended gas = flowrate of test gas × conversion coefficient.

Table 1 — Conversion coefficients

Intended gas[a]	Conversion coefficient	
	Test gas air	Test gas nitrogen
Air	1	0,98
Oxygen	0,95	0,93
Nitrogen	1,02	1
Nitrous oxide	0,81	0,79
Carbon dioxide	0,81	0,79
Helium	2,69	2,65
Xenon	0,47	0,46
[a] Flow of intended gas = Flow of test gas × conversion coefficient.		

6.1.4 Measuring devices

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

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 fully or set the means of flow selection to the maximum flow;

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 the test pressure for 5 min;

e) return the flow-metering device to p_1 and carry out the tests to demonstrate that the requirements given in 5.4.4 and 5.4.6.3, 5.4.7.3 and 5.4.8.2 are still met.

6.3 Test method for leakage

6.3.1 Internal leakage

Test the device with gas at p_1 supplied to the gas supply inlet with the flow control valve closed with a torque of 0,4 N·m (or in the case of a flow-metering device with multiple fixed orifices, with the means of selection set to zero). Carry out this test after the tests for mechanical strength and accuracy have been carried out.

6.3.2 External leakage

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

6.4 Test method for durability of markings and colour coding

Rub markings and colour by hand, without undue pressure, first for 15 s with a clean cloth soaked with distilled water, then for 15 s with a clean cloth soaked with ethanol and then for 15 s with a clean cloth soaked with isopropanol. Verify that the markings required in 7.1.1 and 7.1.2 are still legible.

7 Marking, colour coding and packaging

7.1 Marking

7.1.1 Flow-metering devices and their gas-specific components shall be durably and legibly marked with the symbol of the relevant gas in accordance with Table 2. In addition to the symbol, the name of the gas may be used. The test for durability of markings is given in 6.4.

Table 2 — Medical gases, marking and colour coding

Name	Symbol	Colour coding
Oxygen	O_2	White [a]
Nitrous oxide	N_2O	Blue [a]
Medical air	Air	Black-White [a]
Helium	He	Brown [a]
Carbon dioxide	CO_2	Grey [a]
Xenon	Xe	Bright green [b]
Mixtures of the above gases	[c]	[c]

NOTE The word “Air” may be expressed in the relevant national languages.

[a] In accordance with ISO 32.

[b] In accordance with EN 1089-3:2004, Table A.1.

[c] In accordance with the mixture components.

NOTE The colour coding for xenon has been changed from light brown to bright green since the text of ISO 15002 was agreed by ISO/TC 121/SC 6, so as to align with the colour coding on low-pressure hose assemblies (ISO 5359) and transportable gas cylinders (EN 1089-3).

In addition, flow-metering devices shall be clearly and durably marked with the following:

— the name and/or the trademark of the manufacturer or distributor;

— means to ensure traceability, such as type, batch or serial number and year of manufacture;

— the rated inlet pressure, p_1;

— the direction for increasing the flow;

— point on the indicator for reading the flow on a flowmeter with a tube;

— the inlet pressure or range of inlet pressures for which the flow-metering device is calibrated;

— “USE NO OIL” or the symbol shown in Figure 1.

The words “USE NO OIL” may be expressed in the relevant national language.

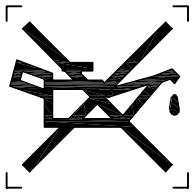


Figure 1 — Symbol for “USE NO OIL”

7.1.2 Flow control valves and means of flow selection shall be clearly and durably marked with the direction for increasing the flow.

7.1.3 The test for durability of markings is given in 6.4.

7.2 Colour coding

7.2.1 If colour coding is used, it shall comply with Table 2 or relevant regional or national standards.

Compliance shall be checked by visual inspection.

7.2.2 Colour coding shall be durable.

The test for durability of colour coding is given in 6.4.

7.3 Packaging

7.3.1 Flow-metering devices and spare parts shall be sealed to protect against particulate contamination and packaged to prevent damage during storage and transportation.

7.3.2 Packages shall provide a means of identification of the contents.

Compliance shall be checked by visual inspection.

8 Information to be supplied by the manufacturer

8.1 Flow-metering devices shall be accompanied by documents containing at least a technical description, instructions for use and an address to which the user can refer. The accompanying documents shall be regarded as a component part of flow-metering devices.

8.2 Instructions for use shall contain all information necessary to operate the flow-metering device in accordance with its specifications and shall include an explanation of the function of controls and the connection and disconnection of detachable parts and accessories. Instructions for use shall include indications on recognized accessories and detachable parts if the use of other accessories and parts can degrade the minimum safety level. Instructions for use shall give detailed instructions for the safe performance of cleaning, inspection and preventive maintenance to be performed by the operator or by authorized persons, and shall indicate the frequency of such activities. A list of recommended spare parts shall be provided. The meaning of figures, symbols, warning statements and abbreviations on the flow-metering device shall be explained in the instructions for use.

NOTE Examples of symbols to be used with medical devices are given in ISO/TR 15223.

8.3 Particular attention shall be given to the following safety-related items:

— the danger of fire or explosion arising from use of lubricants not recommended by the manufacturer;

— the danger of changing the connectors on flow-metering devices;

— the danger of disassembling the flow-metering device while under pressure;

— the effect on the accuracy of flowrate which may result from varying inlet pressure;

— the effect on the accuracy of flowrate which may result from varying outlet resistance;

— the effect on the accuracy of flowrate due to variations in ambient temperature from 0 °C to +40 °C;

— for flow-metering devices with multiple fixed orifices, a warning that the device should be set only at a defined flow setting (i.e., not between adjacent settings);

— for flow-metering devices with multiple fixed orifices, the effect of setting the device between defined flow settings;

— for flow-metering devices with multiple fixed orifices, a statement that the device does not indicate that a flow is occurring.

Annex A
(informative)

Rationale

This annex provides a rationale for some requirements of this International Standard and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this International Standard necessitated by those developments.

The following paragraphs provide the rationale for certain text in the body of this International Standard. The numbering therefore is not consecutive.

A.2 Mainly dated references are used in this International Standard. As stated in the preamble of the European Medical Device Directive 93/42/EEC, manufacturers have to "take account of technology and practice existing at the time of design and of technical and economical considerations compatible with a high level of protection of health and safety". This is to ensure that a manufacturer does not design against a moving target (i.e. a standard which is revised after completion of the specification), before the device is placed on the market. Having only dated references will ensure that design specifications are developed using clearly defined standards that reflect the generally acknowledged state of the art at the time of design, except for emerging hazards requiring amendments of existing standards.

SG1 of the Global Harmonization Task Force (GHTF) (www.ghtf.org) is developing a guideline, SG1/N044[8], which addresses the need to use dated references.

A.5.3.1 Flow-metering devices for different gases are often made with interchangeable components or subassemblies. The requirement for compatibility with oxygen should therefore be applied to flow-metering devices for all gases.

A.5.3.2 Flow-metering devices for different gases are often made with interchangeable components or subassemblies. The requirement for the ignition temperature of non-metallic components should therefore be applied to flow-metering devices for all gases.

A.5.4.3 The pressure of 1 000 kPa was selected because this is the highest pressure in the worst case scenario in a medical gas pipeline system complying with ISO 7396-1 or a pressure regulator complying with ISO 10524-1 or ISO 10524-3.

A.5.4.8.3.2 and **A.5.4.8.3.3** A dangerous situation could arise if the flow-selecting device can be unintentionally set to a position where no flow occurs. Therefore the design of the flow-selecting device should minimize the possibility of this happening. A warning of this possible hazard is therefore required in the instructions for use.

A.5.4.6.4.2, A.5.4.7.4.2, A.5.4.8.5 This matter was extensively debated by the subcommittee. It was pointed out that EN 13220:1998 and ISO 15002:2000 mandate anticlockwise rotation for flow control valves and that on most pneumatic devices anticlockwise rotation increases the controlled parameter. However, it was also pointed out that there is no uniformity in the direction of rotation among flow-metering devices with multiple fixed orifices currently on the market and that on most electrical devices clockwise rotation increases the controlled parameter. The subcommittee could not agree on this matter. Therefore it took a vote and voted in favour (6 in favour; 3 against, 1 abstention) of anticlockwise rotation for increasing the flow.

The following points were made:

1) IEC 601-1:1977 had a reference to both conventions.

2) IEC 60601-1:1988 was silent on this matter.

3) ISO 14971:2007 “Risk management” requires *inter alia* the reduction of usability risks to acceptable levels.

4) IEC 60601-1-6:2006 “Usability” defines a process to minimize usability errors.

Both standards (ISO 14971:2007 and IEC 60601-1-6:2006) have become mandatory references in IEC 60601-1:2005.

IEC 60601-1-6:2006 is superseded by IEC 62366:2007, which will apply to all medical devices. As a consequence manufacturers will have to validate the direction of flow increase for its target market and might have to use the alternative construction subclause to deviate from 5.4.8.4.

A.5.5.1 Flow-metering devices for different gases are often made with interchangeable components or subassemblies. The requirement for cleanliness should therefore be applied to flow-metering devices for all gases.

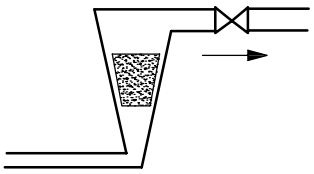
A.5.5.2 Flow-metering devices for different gases are often made with interchangeable components or subassemblies. The requirement for lubricants should therefore be applied to flow-metering devices for all gases.

Annex B
(informative)

Arrangements of flow-metering systems and devices

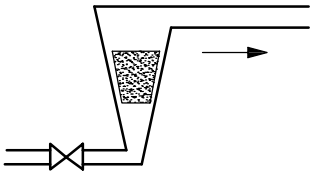
B.1 Examples of flow-metering devices are shown in Figure B.1.

Figure B.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.



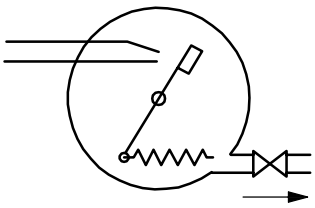
a) Measuring tube with flow control valve downstream

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



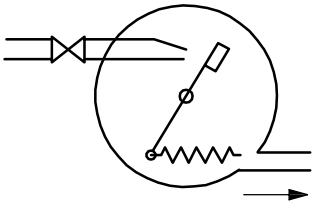
b) Measuring tube with flow control valve upstream

Figure B.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 that is controlled by a flow control valve fitted downstream of the orifice.



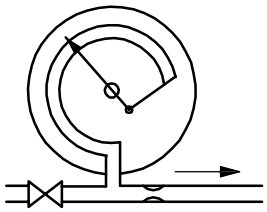
c) Paddle with a fixed orifice with flow control valve downstream

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



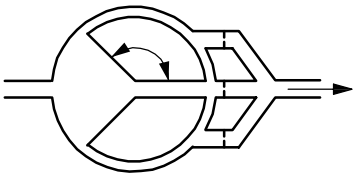
d) Paddle and a fixed orifice with flow control valve upstream

Figure B.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).



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

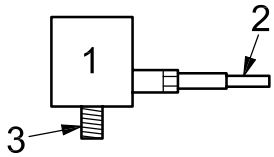
Figure B.1 f) shows a system which comprises multiple fixed orifices. The change from the "off" position and from one setting to another can be achieved, for example, by turning a knob.



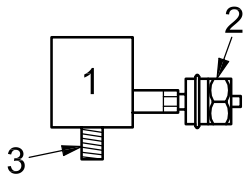
f) Multiple fixed orifices with selection knob

Figure B.1 — Examples of flow-metering systems

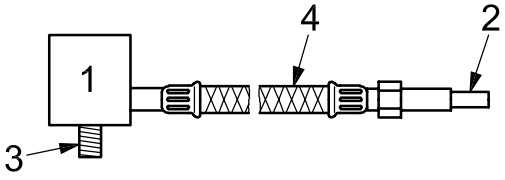
B.2 Examples of gas supply inlets are shown in Figure B.2.



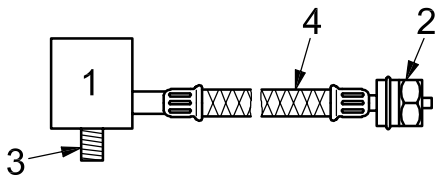
a) Flow-metering device with a probe as gas supply inlet



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



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



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

Key

1 flow-metering device
2 gas supply inlet
3 outlet connector
4 hose

Figure B.2 — Examples of gas supply inlets

Annex C
(informative)

Environmental aspects

Planning and design of products applying to this International Standard should consider the environmental impact from the product during its life cycle. The environmental impact generated by a flow-metering device for connection to terminal units of medical gas pipeline systems is mainly restricted to the following occurrences:

— impact at local environment caused by leakage;

— impact at local environment caused by wrong connection;

— the danger of fire or explosion due to the use of unsuitable materials or lubricants or leakage;

— cleaning.

To highlight the importance of reducing the environmental burden, this International Standard addresses requirements or recommendations intended to decrease environmental impact caused by those aspects.

See Table C.1 for a mapping of the life cycle of a flow-metering device for connection to terminal units of medical gas pipeline systems to aspects of the environment.

Table C.1 — Environmental aspects addressed by this International Standard

	Environmental aspects (inputs and outputs)	**Product life cycle**			
		Production and preproduction Stage A	**Distribution (including packaging)** Stage B	**Use** Stage C	**End of life** Stage D
			Addressed in clause/subclause		
1	Resource use	—	—	—	—
2	Energy consumption	—	—	—	—
3	Emissions to air	—	—	5.4.4	—
4	Emissions to water	—	—	—	—
5	Waste	—	—	5.4.4	—
6	Noise	—	—	—	—
7	Migration of hazardous substances	—	—	5.1 5.2 5.3	—
8	Impacts on soil	—	—	—	—
9	Risks to the environment from accidents or misuse	—	7.1 7.2 8	5.1 5.2 5.3 5.4.3 5.5.1 5.5.2 5.5.3 8	—

Bibliography

[1] ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

[2] ISO 10524-1:2006, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

[3] ISO 10524-3:2005, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves*

[4] ISO/TR 15223:1998[1)], *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

[5] IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

[6] IEC 60601-1-6:2006, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*

[7] IEC 62366:2007, *Medical devices — Application of usability engineering to medical devices*

[8] PARRY, J.G., Oxygen delivery failure, *Anesthesia*, **60**, pp 290-291, 2005

[9] SG1/N044, *Role of Standards in the Assessment of Medical Devices*

[10] EN 13220:1998, *Flow-metering devices for connection to terminal units of medical gas pipeline systems*

1) International Standard withdrawn; replaced by ISO 15223-1:2007 and ISO 15223-2:—.

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Price based on 21 pages