
**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*



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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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 asterisk (*) 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.

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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;