
**Pretočni merilniki za priključitev na končne dele napeljav za medicinske pline
(ISO/DIS 15002:2006)**

Flow-metering devices for connection to terminal units of medical gas pipeline systems (ISO/DIS 15002:2006)

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July 2006

ICS 11.040.10

Will supersede EN 13220:1998

English Version

Flow-metering devices for connection to terminal units of medical gas pipeline systems (ISO/DIS 15002:2006)

Dispositifs de mesure de débit pour raccordement aux
prises murales des systèmes de distribution de gaz
médicaux (ISO/DIS 15002:2006)

Durchflussmesseinrichtungen zum Anschluss an
Entnahmestellen von Rohrleitungssystemen für
medizinische Gase (ISO/DIS 15002:2006)

This draft European Standard is submitted to CEN members for second parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 215.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Foreword

This document (prEN ISO 15002:2006) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI.

This document is currently submitted to the second parallel Enquiry.

This document will supersede EN 13220:1998.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

Endorsement notice

The text of ISO 15002:2006 has been approved by CEN as prEN ISO 15002:2006 without any modifications.

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DRAFT INTERNATIONAL STANDARD ISO/DIS 15002.2

ISO/TC 121/SC 6

Secretariat: ANSI

Voting begins on:
2006-07-06

Voting terminates on:
2006-09-06

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

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

[Revision of first edition (ISO 15002:2000)]

ICS 11.040.10

ISO/CEN PARALLEL ENQUIRY

The CEN Secretary-General has advised the ISO Secretary-General that this ISO/DIS covers a subject of interest to European standardization. **In accordance with the ISO-lead mode of collaboration as defined in the Vienna Agreement, consultation on this ISO/DIS has the same effect for CEN members as would a CEN enquiry on a draft European Standard.** Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month FDIS vote in ISO and formal vote in CEN.

In accordance with the provisions of Council Resolution 15/1993 this document is circulated in the English language only.

Conformément aux dispositions de la Résolution du Conseil 15/1993, ce document est distribué en version anglaise seulement.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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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 15002.2 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, which has been technically revised.

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Introduction

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 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 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 flow adjustment, 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 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 (% volume fraction)

— 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 1 Regional or national regulations may permit use of oxygen-specific connection points for oxygen-enriched air.

NOTE 2 Medical air can be produced by air compressor systems or by proportioning systems (see ISO/FDIS 7396-1).

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 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 32:1977, *Gas cylinders for medical use — Marking for identification of content.*

ISO 5359:2000, *Low-pressure hose assemblies for use with medical gases.*

ISO 9170-1:1999, *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 atmospheres.*

ISO 14971:2000, *Medical devices — Application of risk management to medical devices.*

ISO 19054:2005, *Rail systems for supporting medical equipment.*

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

EN 13544-2:2002, *Respiratory therapy equipment — Part 2: Tubing and connectors*

3 Terms and definitions

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

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3.1

diameter index safety system connectors

DISS 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

flowgauge

device that measures pressure and that 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 that 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