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Pressure regulators for use with medical gases —

Part 3: Pressure regulators integrated with cylinder valves (VIPRs)

Détendeurs pour l'utilisation avec les gaz médicaux —

Partie 3: Détendeurs intégrés dans les robinets des bouteilles à gaz (VIPR)

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, SC 6, *Medical gas systems*.

This second edition cancels and replaces the first edition (ISO 10524-3:2005), which has been technically revised. It also incorporates the Amendment ISO 10524-3:2005/Amd 1:2013.

The main changes compared to the previous edition are as follows:

a) introduction of the acronym VIPR for designating the valve with integrated pressure regulator as in ISO 10297 and ISO 22435[9];

b) extension of the scope to include VIPRs with a nominal inlet pressure up to 30 000 kPa (300 bar);

c) restructuring of the document to the new ISO template and associated renumbering;

d) removal of the requirements for VIPRs fitted with flow-metering devices, flow gauges and adjustable pressure regulators;

e) alignment with the common requirements of ISO 10524-1 and ISO 10524-2;

f) addition of cross-reference to ISO 10297 for all requirements concerning the MAIN SHUT-OFF;

g) rationalization of impact test requirements to comply with ISO 10297 and requirements for drop testing in alignment with ISO 11117;

h) introduction of endurance testing on the flow selector, non-return valve and PRESSURE REGULATOR;

i) introduction of type testing with the intended gas;

j) introduction of a complete test schedule;

k) review of all type tests;

l) reference to ISO 15996 for *residual pressure device* (RPD);

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m) introduction of requirements for usability;

n) consideration of avoidance of stainless steel for parts in contact with oxygen.

A list of all parts in the ISO 10524 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

VALVES WITH INTEGRATED PRESSURE REGULATORS (VIPRs) are used to reduce high cylinder pressure to a lower pressure suitable for use with medical equipment or for delivery of gas to a patient.

These functions cover a range of inlet and outlet pressures and flows which require specific design characteristics. It is important that the operating characteristics of VIPRs are specified and tested in a defined manner.

A VIPR is normally coupled to a device which controls the gas flow, such as a flow control device or a fixed orifice.

This document pays particular attention to:

— use of suitable materials;

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

— gas-specificity;

— cleanliness;

— type testing;

— marking;

— information supplied by the manufacturer.

This document should be read in conjunction with ISO 10524-1, ISO 10524-2 and ISO 10524-4.

In this document, the following print types are used.

— Requirements and definitions: Roman type.

— Informative material appearing outside of tables, such as notes, examples and references: smaller type. Normative text of tables are also in a smaller type.

— *Test specifications*: *italic type*.

— TERMS DEFINED IN CLAUSE 3 OR AS NOTED: SMALL CAPITALS TYPE.

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to usage described in ISO/IEC Directives, Part 2:2016, Annex H. For the purposes of this document, the auxiliary verb:

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

— "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex B. Annex B contains rationale statements for some of the requirements of this document. It provides additional insight into the reasoning that led to the requirements and recommendations that have been incorporated into this document. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this document, but will expedite any subsequent revisions.

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Pressure regulators for use with medical gases —

Part 3:
Pressure regulators integrated with cylinder valves (VIPRs)

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1 *Scope

This document specifies design, type testing, and marking requirements for cylinder valves with integrated PRESSURE REGULATORS [as defined in 3.26 and referred to hereafter as VALVES WITH INTEGRATED PRESSURE REGULATORS (VIPRs)] intended for the administration of medical gases in the treatment, management, diagnostic evaluation and care of patients or for gases used for driving surgical tools.

Examples of gases include oxygen, medical air and oxygen/nitrous oxide mixtures.

This document applies to VIPRs mounted on refillable cylinders with a WORKING PRESSURE up to 30 000 kPa (300 bar) intended to be filled in cylinder filling facilities or on self-filling systems as used in homecare applications.

VIPRs covered by this document are pressure pre-set and provided with a PRESSURE OUTLET and/or pre-set FLOW OUTLET(S).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 5145, *Gas cylinders — Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning*

ISO/TR 7470, *Valve outlets for gas cylinders — List of provisions which are either standardized or in use*

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

ISO 10297:2014, *Gas cylinders — Cylinder valves — Specification and type testing*

ISO 10297:2014/Amd1:2017, *Pressure drums and tubes*

ISO 11117, *Gas cylinders — Valve protection caps and valve guards — Design, construction and tests*

ISO 11363-1, *Gas cylinders — 17E and 25E taper threads for connection of valves to gas cylinders — Part 1: Specifications*

ISO 13341, *Gas cylinders — Fitting of valves to gas cylinders*

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

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

ISO 15245-1, *Gas cylinders — Parallel threads for connection of valves to gas cylinders — Part 1: Specification*

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ISO 15996, *Gas cylinders — Residual pressure valves — Specification and type testing of cylinder valves incorporating residual pressure devices*

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

EN 13544-2:2002+ A1:2009, *Respiratory therapy equipment — Part 2: Tubing and connectors*

IEC 60601-1+ A1:2012, *Medical electrical equipment — Part 1: General requirements for safety*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
ACCURACY OF FLOW
difference between the indicated flow and the measured flow

Note 1 to entry: Expressed as a percentage.

3.2
CONTENT INDICATOR
device that displays the amount of gas remaining in the cylinder

Note 1 to entry: The content can be expressed either in percentage of content, volume of gas or cylinder pressure.

3.3
FILLING ADAPTOR
means of connecting the VIPR FILLING PORT to the filling system allowing a cylinder fitted with a *VIPR* (3.26) to be filled or vented

Note 1 to entry: This is not part of the VIPR.

Note 2 to entry: It may also be referred to as a filling tool.

3.4
FILLING PORT
connector on the *VIPR* (3.26) through which the cylinder is filled

3.5
FILLING PORT NON-RETURN VALVE
valve which remains closed in normal use thus preventing the flow out of the *VIPR's filling port* (3.4) until opened by insertion of an appropriate means and which then permits flow in either direction

Note 1 to entry: Some FILLING PORT NON-RETURN VALVES may also be opened by the pressure of the incoming gas.

3.6
FLOW OUTLET
outlet intended to deliver a controlled flow of gas

3.7
FLOW SELECTOR
means for selecting the flow and indicating the flow selected

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