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First edition
2008-06-01

Pressure regulators for use with medical gases —

Part 4: Low-pressure regulators

Détendeurs pour l'utilisation avec les gaz médicaux —

Partie 4: Détendeurs basse pression



Reference number
ISO 10524-4:2008(E)

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Published in Switzerland

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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 10524-4 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*.

ISO 10524 consists of the following parts, under the general title *Pressure regulators for use with medical gases*:

- *Part 1: Pressure regulators and pressure regulators with flow-metering devices*
- *Part 2: Manifold and line pressure regulators*
- *Part 3: Pressure regulators integrated with cylinder valves*
- *Part 4: Low-pressure regulators*

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Introduction

A low-pressure regulator is used to reduce the pressure in a medical gas pipeline system to a lower pressure suitable for use with medical equipment or for delivery of gas directly 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 low-pressure regulators are appropriately specified for their intended use and then tested in a defined manner.

A low-pressure regulator may be coupled to a device that controls the flow, such as a flow control valve or a fixed orifice. The flow can be indicated by a flowmeter or by a flowgauge.

It is essential that regular inspection and maintenance are undertaken to ensure that low-pressure regulators continue to meet the requirements of this part of ISO 10524.

This part of ISO 10524 pays particular attention to:

- safety (mechanical strength, leakage, safe relief of excess pressure and resistance to ignition);
- suitability of materials;
- gas specificity;
- accuracy;
- cleanliness;
- testing;
- marking;
- information supplied by the manufacturer.

Annex B contains rationale statements for some of the requirements of this part of ISO 10524. The clauses and subclauses marked with an asterisk (*) after their number have corresponding rationale contained in Annex B, included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this document. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this part of ISO 10524, but will expedite any subsequent revisions.