SLOVENSKI STANDARD
SIST EN ISO 15001:2010

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Nadomešča:
SIST EN ISO 15001:2004

Anestezijska in respiratorna oprema - Združljivost s kisikom (ISO 15001:2010)

Anaesthetic and respiratory equipment - Compatibility with oxygen (ISO 15001:2010)

Anästhesie- und Beatmungsgeräte - Verträglichkeit mit Sauerstoff (ISO 15001:2010)

Matériel d'anesthésie et respiratoire - Compatibilité avec l'oxygène (ISO 15001:2010)

Ta slovenski standard je istoveten z: **EN ISO 15001:2010**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST EN ISO 15001:2010 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15001

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English Version

Anaesthetic and respiratory equipment - Compatibility with oxygen (ISO 15001:2010)

Matériel d'anesthésie et de réanimation respiratoire - Compatibilité avec l'oxygène (ISO 15001:2010)

Anästhesie- und Beatmungsgeräte - Verträglichkeit mit Sauerstoff (ISO 15001:2010)

This European Standard was approved by CEN on 26 May 2010.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN ISO 15001:2010) 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 European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2010, and conflicting national standards shall be withdrawn at the latest by December 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 15001:2004.

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.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 15001:2010 has been approved by CEN as a EN ISO 15001:2010 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 2007/47/EC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 2007/47/EC.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the relevant Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive EU 2007/47/EC

Clause(s)/subclause(s) of this European Standard	Essential requirements (ERs) of EU Directive 2007/47/EC	Qualifying remarks/Notes
All	7.2, 7.3, 9.2, 12.7.4	This standard specifies minimum requirements for the oxygen compatibility of materials, components and devices that can come into contact with oxygen in normal or single fault condition.

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 15001

Second edition
2010-06-01

Anaesthetic and respiratory equipment — Compatibility with oxygen

Matériel d'anesthésie et de réanimation respiratoire — Compatibilité avec l'oxygène

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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 15001 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 15001:2003), subclauses of which have been technically revised.

Introduction

Oxygen, pure or mixed with other medical gases, is widely used in medical applications. Because patients and clinical personnel are often in close proximity to devices used with oxygen, the risk of serious injury is high if a fire occurs in an oxygen-enriched atmosphere. A common cause of fire is the heat produced by adiabatic compression, and the presence of hydrocarbon and particulate contaminants facilitates ignition. Some combustion products, especially some non-metals (e.g. plastics, elastomers and lubricants) are toxic and thus patients remote from that equipment and who are receiving oxygen from a medical gas pipeline system might be injured when a problem occurs. Other equipment which is in close proximity to the equipment using oxygen, or that utilizes oxygen as its source of power, can be damaged or fail to function properly if there is a problem with the oxygen equipment.

Reduction or avoidance of these risks depends on the choice of appropriate materials, cleaning procedures and correct design and construction of equipment so that it is compatible with oxygen under the conditions of use.

This International Standard gives recommendations for the selection of materials and the cleaning of components made from them, for use in oxygen and oxygen-enriched atmospheres.

Annex F contains rationale statements for some of the requirements of this International Standard. It is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated into this International Standard. The clauses and subclauses marked with an asterisk (*) after their number have corresponding rationale contained in Annex F. 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.

It is expected that particular device standards will make reference to this horizontal International Standard and may, if appropriate, strengthen these minimum requirements.

Particular device standards may specify that some requirements of this International Standard may apply for medical gases other than oxygen.

Anaesthetic and respiratory equipment — Compatibility with oxygen

1* Scope

This International Standard specifies requirements for the oxygen compatibility of materials, components and devices for anaesthetic and respiratory applications, which can come into contact with oxygen in normal condition or in single fault condition at gas pressures greater than 50 kPa.

Additionally, this International Standard gives general guidelines for the selection of materials and components based on available data on their oxygen compatibility, and for carrying out a risk analysis, including addressing the toxicity of products of combustion and/or decomposition.

Aspects of compatibility that are addressed by this International Standard include cleanliness, resistance to ignition and the toxicity of products of combustion and/or decomposition at the design, manufacturing, maintenance and disposal stages.

This International Standard does not apply to biocompatibility.

This International Standard is applicable to anaesthetic and respiratory equipment that is within the scope of ISO/TC 121, e.g. medical gas pipeline systems, pressure regulators, terminal units, medical supply units, flexible connections, flow-metering devices, anaesthetic workstations and lung ventilators.

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

3 Terms and definitions

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

3.1
adiabatic compression
compression process that occurs without transfer of heat into or out of a system

3.2
auto-ignition temperature
temperature at which a material will spontaneously ignite under specified conditions

3.3
lethal concentration
LC_{50}
concentration of a gas (or a gas mixture) in air, administered by a single exposure during a short period of time (24 h or less) to a group of young adult albino rats (males and females) which leads to the death of half of the animals in at least 14 d

[ISO 10298:2010, definition 3.1]

3.4
oxygen index
minimum concentration of oxygen by volume percentage in a mixture of oxygen and nitrogen introduced at (23 ± 2) °C that will just support combustion of a material under specified test conditions

[ISO 4589-2:1996, definition 3.1]

3.5
qualified technical person
person who by virtue of education, training or experience knows how to apply physical and chemical principles involved in the reactions between oxygen and other materials

3.6
single fault condition
condition in which a single means for reducing a risk is defective or a single abnormal condition is present

[IEC 60601-1:2009, definition 3.116]

3.7
threshold limit value
TLV
concentration in air to which nearly all workers may be exposed during an 8 h working day and a 40 h working week without adverse effect according to the current knowledge

3.8
oxygen-enriched mixture
mixture that contains more than 23,5 % volume fraction of oxygen

4 Cleanliness

4.1* Unless otherwise specified in particular device standards, surfaces of components that come into contact with oxygen during normal operation or single fault condition shall:

a)* for applications in the pressure range of 50 kPa to 3 000 kPa, not have a level of hydrocarbon contamination greater than 550 mg/m^2.

The manufacturer shall determine and ensure that the level of particle contamination is suitable for the intended application(s);

b)* for applications at pressures greater than 3 000 kPa:

— not have a level of hydrocarbon contamination greater than 220 mg/m^2;

— not have particles of size greater than 100 µm.

These requirements shall be met either by an appropriate method of manufacture or by use of an appropriate cleaning procedure. Compliance shall be checked either by verification of the cleanliness of the components or by validation of the cleaning procedure or the manufacturing process.

This International Standard does not specify quantifiable cleaning procedures or validation methods for them in relation to the values in a) and b) above. However, Annex A gives examples of known cleaning procedures and Annex B gives examples of methods for validation of cleaning procedures.

NOTE The values of 550 mg/m^2 and 220 mg/m^2 for hydrocarbon contamination are taken from ASTM G93-03[21] and the value of 3 000 kPa is taken from EIGA IGC 33/06/E[49].

4.2 Means to identify components and devices that have been cleaned for oxygen service in accordance with this International Standard shall be provided.

4.3 Cleaning compounds and methods shall be compatible with the materials, components and devices to be cleaned.

Evidence of compliance shall be provided by the manufacturer upon request.

NOTE Regional or national regulations can require the provision of evidence to a notified body or competent authority upon request.

4.4 Means (e.g. packaging and information supplied by the manufacturer) shall be provided to maintain the cleanliness of components and devices that have been cleaned for oxygen service in accordance with this International Standard.

5* Resistance to ignition

Devices designed for pressures greater than 3 000 kPa shall not ignite when submitted to a pneumatic impact test according to procedures described in the relevant product standards at a test pressure of 1,2 × the nominal inlet pressure.

If lubricants are used, the lubricated device shall be tested.

NOTE 1 Pneumatic impact test methods are given in ISO 10524-1[5], ISO 10524-2[6], ISO 10524-3[7], ISO 10297[3], ISO 21969[54] and ISO 7291[2] and can be used for similar devices where a device standard does not exist or does not include such a test.

NOTE 2 In the case of pure oxygen, the risk of ignition increases with the pressure. In the case of gas mixtures containing oxygen, the risk of ignition increases with the partial pressure of oxygen.

6 Risk management

6.1 The manufacturer of medical devices shall carry out a risk management process in accordance with ISO 14971. This should include oxygen fire hazards (see Annexes C and D), resistance to ignition (see Clause 5) and toxicity (see Annex E), cleaning procedures (see Annex A), design considerations (see Annex C) and selection of materials (see Annex D).

NOTE 1 ASTM G88-05[20] gives an example of oxygen fire hazard and risk analysis.

NOTE 2 Examples of oxygen fire hazards are given in ASTM G63-99[16] and ASTM G94-05[22].

NOTE 3 Typical “oxygen-compatible” lubricants can generate toxic products during combustion or decomposition.

NOTE 4 Annexes D and E contain information on toxicity.

6.2 The specific hazards of toxic products of combustion or decomposition from non-metallic materials (including lubricants, if used) and potential contaminants shall be addressed. Some potential products of combustion and/or decomposition for some commonly available non-metallic materials are listed in Table D.7.