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Anaesthetic and respiratory equipment — Compatibility with oxygen

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

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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.

Annex A
(informative)

Examples of cleaning procedures

A.1 General

A.1.1 General guidelines

A cleaning programme that results in an increase in the degree of cleanliness of the component after each cleaning operation should be selected. It then becomes a matter of processing the component through a series of cleaning methods, or several cycles within a single cleaning method, or both, in order to achieve the desired final degree of cleanliness.

It may be possible to obtain the desired degree of cleanliness in a single operation, but many cleaning methods must progress in several stages, such as initial cleaning, intermediate cleaning and final cleaning. It is essential that each stage be isolated from previous stages by appropriate rinsing, drying and purging operations.

Of particular importance is the removal of lint, dust and organic matter such as oil and grease. These contaminants are relatively easily ignited in oxygen and oxygen-enriched atmospheres.

It is essential that cleaning, washing and draining methods ensure that dead-end passages and possible traps are adequately cleaned.

A.1.2 Initial cleaning

Initial cleaning should be used to remove gross contaminants such as excessive oxide or scale build-up, large quantities of oil, grease and particulate matter.

Initial cleaning reduces the quantity of contaminants, thereby increasing the useful life and effectiveness of the cleaning solutions used in subsequent cleaning operations.

A.1.3 Intermediate cleaning

Intermediate cleaning generally consists of subjecting the part to caustic or acid-cleaning solutions to remove solvent residues and residual contaminants. The cleaning environment and handling procedures used for intermediate cleaning operations are more critical than those used for initial cleaning. It is essential that the cleaning environment and solutions be appropriately controlled in order to maximize solution efficiency and to minimize the introduction of contaminants that might compromise subsequent cleaning operations.

A.1.4 Final cleaning

A.1.4.1 When components are required to meet very high degrees of cleanliness, they should be subjected to a final cleaning. Final cleaning is generally performed using chemical cleaning methods. At this stage, protection from recontamination by the cleaning solutions or the environment becomes critical and may require strict controls, such as those found in classified clean rooms.

A.1.4.2 The final cleaning stage involves drying and purging operations followed by sealing to protect against recontamination and packaging to prevent damage during storage and transportation.

A.2 Selection of cleaning methods

In order to decide on the most practicable methods of cleaning, the following factors should be considered:

a) the type (e.g. organic, inorganic) and form (e.g. particulate, film, fluid) of contaminants;

b) the configuration of the part to be cleaned;

c) the base material or coating of the part to be cleaned;

d) initial condition of the part to be cleaned;

e) the required final cleanliness of the part to be cleaned;

f) environmental impact and lawful disposal of hazardous waste products generated by the cleaning method;

g) effects of the selected cleaning methods on the mechanical, chemical and thermal properties of the part to be cleaned.

A.3 Cleaning methods

A.3.1 General

It is essential that the cleaning method ensure that all surfaces of the component are cleaned. The methods described are applicable to most metallic materials. However, special precautions may be necessary for non-metallic components.

A.3.2 Categories

Cleaning methods can be categorized as mechanical, chemical or both. Some cleaning operations are enhanced by combining mechanical and chemical methods, such as mechanical agitation of a chemical solution.

Some mechanical cleaning methods such as abrasive blasting, tumbling, grinding and wire brushing on finished machine components can damage surfaces, remove protective coatings and work-harden metals. It is essential that sensitive surfaces of the component be protected before such methods are used on that component.

Chemical cleaning methods can cause damage. Corrosion, embrittlement or other surface modifications can occur. Crevice corrosion can occur, particularly in brazed or welded assemblies. Solvent cleaning solutions are often damaging to non-metals. The supplier of the non-metals should be consulted or samples should be tested to ensure that the solvent will not cause damage. If acidic or caustic chemical cleaners are used, it is essential that the chemical residue on the components be neutralized and/or removed immediately after cleaning.

A.3.3 Mechanical cleaning

A.3.3.1 General

Mechanical cleaning methods use mechanically-generated forces to remove contaminants from the components. Examples of mechanical cleaning methods are rinsing, abrasive blasting, tumbling and blowing. Details of these and other methods are discussed in A.3.3.2 to A.3.3.8.

A.3.3.2 Abrasive blast cleaning

A.3.3.2.1 Abrasive blast cleaning entails the forceful impingement of abrasive particles against the surfaces to be cleaned in order to remove scale, rust, paint and other foreign matter. The abrasive particles are entrained in a gas or liquid stream. A variety of systems can be used to propel the abrasive particles, e.g. airless abrasive blast blades or vane-type wheels, pressure blast nozzles or suction (induction) blast nozzles. Propellant gases should be oil-free.

A.3.3.2.2 Typical abrasive particle materials include metallic grit and shot, natural sands, manufactured oxide grit, carbide grit, walnut shells and glass beads. The specific abrasive particle material used should be suitable for performing the intended cleaning without depositing contaminants that cannot be removed by additional operations, such as high velocity blowing, vacuuming and purging.

A.3.3.2.3 Care needs to be taken to minimize the removal of material from the component parent metal. This cleaning method might not be suitable for components or systems with critical surface finishes or dimensional tolerances.

A.3.3.3 Wire brush or grinding cleaning

A.3.3.3.1 Wire brushing or grinding methods generally use a power-driven wire brush, a non-metallic fibre-filled brush or an abrasive wheel. These are used to remove scale, weld slag, rust, oxide films and other surface contaminants. Wire brushes can be used dry or wet. The wet condition results when brushes are used in conjunction with caustic cleaning solutions or cold water rinses.

A.3.3.3.2 These mechanical methods can imbed brush or grinding material particles in the surface being cleaned. The selection of cleaning brushes depends upon the component or parent material. Non-metallic brushes are suitable for most materials to be cleaned. Carbon steel brushes should not be used on aluminium, copper or stainless steel alloys. Any wire brushes previously used on carbon steel components should not be used subsequently on aluminium or stainless steel. Wire brushing and grinding can affect dimensions, tolerances and surface finishes.

A.3.3.4 Tumbling

This method involves rolling or agitation of parts within a rotating barrel or vibratory tub. An abrasive or cleaning solution is added to the container. The container action (rotation or vibration) imparts relative motion between the components to be cleaned and the abrasive medium or cleaning solution. This method can be performed with dry or wet abrasives. The component size may vary from a large casting to a delicate instrument component, but mixing different components in one container should be avoided. Damage can occur from one component impacting on another. Tumbling can be used for descaling, deburring, burnishing and general washing. Some factors to be considered in barrel cleaning are the component size and shape, type of abrasive, abrasive size, load size, barrel rotational speed and ease of component/abrasive separation.

A.3.3.5 Swab, spray and dip cleaning

These are three methods of applying cleaning solutions to the component surfaces. Each method has its particular advantages. Swabbing is generally used only to clean small selected areas. Spraying and dipping are used for overall cleaning. These methods are generally employed with caustic, acid or solvent cleaning methods, all of which are discussed in A.3.4.5, A.3.4.6 and A.3.4.8.

A.3.3.6 Vacuuming and blowing

These methods remove contaminants using currents of clean, dry, oil-free air or nitrogen. These methods can be used to remove loose dirt, slag, scale and various particles, but they are not suitable for the removal of surface oxides, greases and oils.

A.3.3.7 Pig cleaning

Long continuous pipelines can be cleaned *in situ* using pigs. A pig is a piston-like cylinder with peripheral seals that can be pushed through a pipeline using compressed gas, typically nitrogen. The pig can be equipped with scrapers and wire brushes. Pairs of pigs can carry slugs of liquid cleaning agents between them. Hence, a train of pigs can transport isolated slugs of liquids through a pipeline to produce various levels of cleanliness and rinsing. The mechanical and chemical suitability of the solvents, scrapers and wire brushes should be ensured.

A.3.3.8 Ultrasonic cleaning

Ultrasonic energy can be used in conjunction with a variety of chemical cleaning agents to produce intimate contact between the components and the cleaning agent to aid the removal of lightly adhering or embedded particles from solid surfaces. It is generally employed in solvent cleaning of small components, precious metals and components requiring a very high degree of cleanliness.

A.3.4 Chemical cleaning

A.3.4.1 General

The methods described in A.3.4.2 to A.3.4.9 are based on achieving an interaction between the cleaning solution and the surface of the component to aid the removal of the contaminant by subsequent mechanical methods. The interaction can involve surface activation, contaminant breakdown, oxide conversion and hydrophobic or hydrophilic transformations.

A.3.4.2 Hot water cleaning

Hot water cleaning is used to remove gross organic and particulate contamination from components by the use of low to moderate heat, detergent and some mechanical agitation. Equipment used during hot water cleaning consists of a spray system or a cleaning vat with or without suitable agitation of the solution. Hot water cleaning with detergent can be used where steam is not necessary to free and fluidize contaminants. Consideration should be given to the size, shape and the number of components to assure adequate contact between surfaces of the components and the solution. The solution temperature should be that recommended by the manufacturer of the detergent. Water-soluble contaminants are removed by prompt flushing with sufficient quantities of clean water before the cleaning agents have had time to precipitate. The components are then dried by blowing with dry, oil-free air or nitrogen, which can be heated to shorten the drying time.

A.3.4.3 Detergent cleaning

This method relates to the cleaning of vessels, piping systems or components either externally or internally. Detergents are supplied in powder, crystal or concentrated liquid form. They are prepared for use by mixing with water to form aqueous solutions. Prepared solutions can be used in static tanks or vessels for the immersion of components, or the solution can be re-circulated by pump or jetted on to or through the component. Some types of detergent are toxic and/or corrosive. Properties of detergent materials should be checked with their manufacturer or supplier.

A.3.4.4 Steam cleaning

Steam cleaning is used to remove contaminants, especially organic and particulate, from components by the use of pressure, heat and sometimes detergents. Some organic contaminants are removed by decreasing their viscosity or thinning them with steam heat. A detergent that disperses and emulsifies the organic contaminants, allowing the rinsing off of the contaminants by the condensed steam, can be added. The system should provide control over the flows of the steam, water and detergent to maximize the efficiency of the detergent's chemical action, the heating effect of the steam and the scrubbing action of the steam jet.