INTERNATIONAL STANDARD

ISO 21969

Second edition
2009-11-01

High-pressure flexible connections for use with medical gas systems

Raccords flexibles haute pression pour utilisation avec les systèmes de gaz médicaux

Reference number
ISO 21969:2009(E)

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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 21969 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 21969:2005) which has been technically revised.

Annex A 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 in this International Standard. The clauses and subclauses marked with an asterisk (*) after their number have corresponding rationale contained in Annex A. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this International Standard, but will also expedite any subsequent revision.

High-pressure flexible connections for use with medical gas systems

1 Scope

1.1 This International Standard applies to high-pressure flexible connections intended to be connected to cylinders or cylinder bundles with nominal filling pressures up to 25 000 kPa at 15 °C for use with the following medical gases:

— oxygen;

— nitrous oxide;

— air for breathing;

— helium;

— carbon dioxide;

— xenon;

— mixtures of the gases listed above;

— air for driving surgical tools;

— nitrogen for driving surgical tools;

— oxygen-enriched air.

1.2 This International Standard applies to high-pressure flexible connections intended to connect cylinders or cylinder bundles to manifolds within sources of supply of medical gas pipeline systems complying with ISO 7396-1.

1.3 This International Standard applies to high-pressure flexible connections intended to connect a cylinder to an inlet port of medical equipment (e.g. anaesthetic workstation or lung ventilator) fitted with an integral pressure regulator complying with ISO 10524-1.

1.4 This International Standard does not apply to high-pressure flexible connections intended to be used to fill cylinders nor does it apply to low-pressure flexible hose assemblies that are covered by ISO 5359.

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

ISO 407:2004, *Small medical gas cylinders — Pin-index yoke-type valve connections*

ISO 5145:2004, *Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning*

ISO 7396-1:2007, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

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

3 Terms and definitions

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

3.1
cylinder bundle
pack or pallet of cylinders linked together with one or more connectors for filling and emptying

3.2
gas-specific
having characteristics which prevent connection between different gas services

3.3
manifold
device for connecting the outlet(s) of one or more cylinders or cylinder bundles of the same gas to the pipeline system

3.4
medical gas
any gas or mixture of gases intended for administration to patients for anaesthetic, therapeutic, diagnostic or prophylactic purposes

3.5
nominal inlet pressure
P_1
pressure for which the high-pressure flexible connection is intended to be used

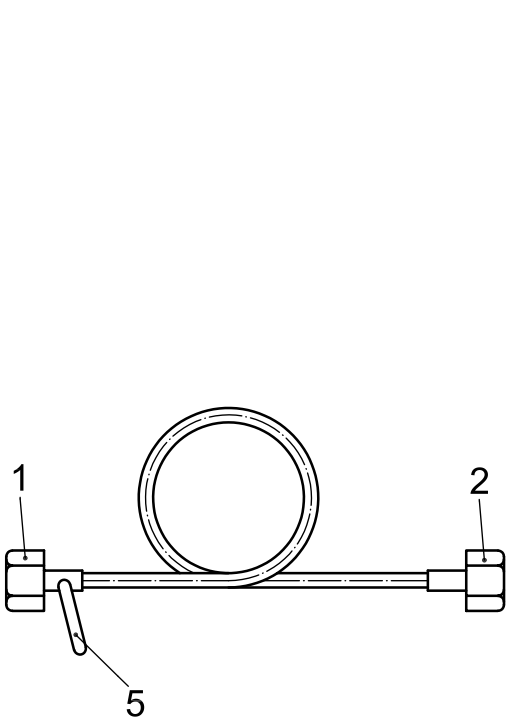
NOTE P_1 is specified by the manufacturer.

3.6
single fault condition
condition in which a single means for protection against a safety hazard in equipment is defective or a single external abnormal condition is present

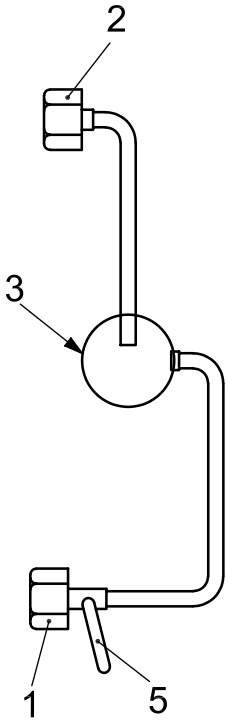
NOTE This definition was taken from IEC 60601-1.

4 Terminology

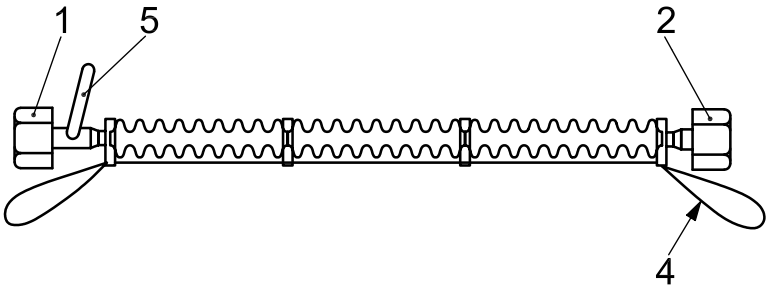
Typical examples of high-pressure flexible connections are given in Figure 1.



a) Coiled metal pipe (e.g. copper)



b) Metal (e.g. copper or stainless steel) pipe connected by a swivel



c) Corrugated metal (e.g. stainless steel) hose fitted with retaining straps

Key

1 inlet connector
2 outlet connector
3 swivel
4 restraining cable
5 handle to prevent torsion

Figure 1 — Typical examples of high-pressure flexible connections

5 General requirements

5.1 Safety

High-pressure flexible connections shall, when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, present no risks that are not reduced to an acceptable level using risk management procedures in accordance with ISO 14971 and which are connected with their intended application, in normal condition and in single fault condition.

5.2 Alternative construction

High-pressure flexible connections and components or parts thereof, using materials or having forms of construction different from those detailed in Clause 5 shall be presumed to be in compliance with the safety objectives of this International Standard if it can be demonstrated that an equivalent degree of safety is obtained (i.e. compliance with requirements presumes that risks have been mitigated to acceptable levels) unless objective evidence to the contrary becomes available.

Evidence that an equivalent degree of safety is obtained shall be provided by the manufacturer upon request.

5.3 Materials

5.3.1 * The materials in contact with the medical gases listed in 1.1, during normal use shall be resistant to corrosion and compatible with oxygen, with the other medical gases and with their mixtures in the temperature range specified in 5.3.3.

NOTE 1 Corrosion resistance includes resistance against moisture and surrounding materials.

NOTE 2 Compatibility with oxygen involves both combustibility and ease of ignition. Materials that burn in air will burn violently in pure oxygen. Many materials that do not burn in air will do so in pure oxygen, particularly under pressure. Similarly, materials that can be ignited in air require lower ignition energies for ignition in oxygen. Many such materials can be ignited by friction at a valve seat or by adiabatic compression produced when oxygen at high pressure is rapidly introduced into a system initially at low pressure.

NOTE 3 Criteria for the selection of metallic and non-metallic materials are given in ISO 15001.

5.3.2 * Non-metallic (e.g. polymer-lined or rubber-reinforced) flexible hoses shall not be used.

5.3.3 The materials shall permit the high-pressure flexible connections and their components to meet the requirements of 5.4 in the temperature range of − 20 °C to + 60 °C.

NOTE Regional or national environmental conditions may require deviation from this range of temperatures.

5.3.4 High-pressure flexible connections shall meet the requirements of this International Standard after being packed for transport and storage and after being exposed to environmental conditions as stated by the manufacturer.

5.3.5 Evidence of conformity with the requirements of 5.3.1, 5.3.3 and 5.3.4 shall be provided by the manufacturer upon request.

5.4 Design requirements

5.4.1 Inlet connector

The inlet connector, for connection to the cylinder valve, shall be gas-specific and conform to ISO 407, ISO 5145 or the relevant regional or national standard (see ISO/TR 7470 for information).

5.4.2 Outlet connector

5.4.2.1 The outlet connector shall be one of the following:

a) a connector for connection to the manifold;

b) a connector for connection to the inlet port of medical equipment; this connector shall be the cylinder valve outlet for the specific medical gas, in accordance with ISO 407, ISO 5145 or the relevant national standard (see ISO/TR 7470 for information).

5.4.2.2 Means shall be provided to prevent the installation of an incorrect high-pressure flexible connection (e.g. by the use of gas-specific connectors) at the manifold (see ISO 7396-1).

5.4.2.3 * If the outlet connector is in accordance with 5.4.2.1 b) and ISO 407, the length of the body shall be at least 15 mm to comply with dimension l_8 in Table 2 of ISO 407:2004.

5.4.3 Torsion

Means shall be provided to prevent torsion of the high-pressure flexible connection during connection and disconnection.

Evidence shall be provided by the manufacturer upon request.

5.4.4 Nominal inlet pressure

A high-pressure flexible connection for any of the medical gases listed in 1.1 shall have a nominal inlet pressure, P_1, not less than the maximum filling pressure at 15 °C of the medical gas cylinder as specified in regional or national regulations.

5.4.5 Leakage

The maximum external leakage (i.e. leakage to the atmosphere) shall not exceed 0,2 ml/min (equivalent to a pressure drop of 0,020 2 kPa·l/min) at nominal inlet pressure, P_1.

This test shall be carried out after the test for mechanical strength.

The test for leakage is given in 6.2.1.

5.4.6 Mechanical strength

High-pressure flexible connections shall be capable of withstanding $\times$ 2,25 the nominal inlet pressure, P_1, without permanent deformation.

The test for mechanical strength is given in 6.2.2.

5.4.7 Bursting pressure

The bursting pressure of a high-pressure flexible connection shall not be less than $\times$ 3 the nominal inlet pressure, P_1.

The test for bursting pressure is given in 6.2.3.

5.4.8 * Resistance to ignition

High-pressure flexible connections for the medical gases listed in 1.1 shall not ignite or show internal scorching when subjected to oxygen pressure shocks.

The test for resistance to ignition is given in 6.2.4.

5.4.9 Restraining device

If the high-pressure flexible connection consists of a portion of corrugated metal, means shall be provided to restrain the flexible connection in the event of rupture [see Figure 1 c)].

Evidence of conformity shall be demonstrated by inspection.

5.4.10 Pressure drop

The pressure drop across a high-pressure flexible connection shall not exceed the values given in Table 1. The test method for pressure drop is described in 6.2.5.

Table 1 — Requirements for flow and pressure drop

Intended use	Test pressure kPa	Test flow m^3/h[a]	Maximum pressure drop kPa
Cylinders	1 500	5	50
Cylinder bundles	1 500	50	100

[a] Test flows are specified at normal temperature and pressure.

5.5 Constructional requirements

5.5.1 Assembly

5.5.1.1 * The methods (e.g. brazing or welding) used to assemble the components of high-pressure flexible connections shall permit the joints to maintain their mechanical characteristics up to a temperature of 450 °C. Filler metals for brazing shall not contain more than a mass fraction of 0,025 % of cadmium.

Evidence shall be provided by the manufacturer upon request.

5.5.1.2 * It shall not be possible to remove either the inlet connector or the outlet connector from the high-pressure flexible connection without destroying the device.

5.5.2 * Cleaning

Surfaces of the high-pressure flexible connection in contact with the gases listed in 1.1 shall meet the cleanliness requirements of ISO 15001.

Evidence of conformity with this requirement shall be provided by the manufacturer upon request.

6 Test methods

6.1 General

6.1.1 Ambient conditions

Except where otherwise stated, tests shall be carried out at ambient temperature.

6.1.2 Test gas

In all cases carry out tests with clean, oil-free air or nitrogen with a maximum moisture content of 50 µg/g, corresponding to a dewpoint of − 48 °C at atmospheric pressure.

6.2 Type tests

6.2.1 Test method for leakage

Pressurize the high-pressure flexible connection with the test gas to the nominal inlet pressure, P_1, through one connector with the other one blanked. Measure the external leakage.

6.2.2 Test method for mechanical strength

Hydraulically pressurize the high-pressure flexible connection through one connector (with the other one blanked) to $\times$ 2,25 the nominal inlet pressure, P_1, for 5 min. Check that the high-pressure flexible connection is not permanently deformed.

6.2.3 Test method for bursting pressure

Hydraulically pressurize the high-pressure flexible connection through one connector (with the other one blanked) to $\times$ 3 the nominal inlet pressure, P_1, for 5 min. Check that the high-pressure flexible connection has not burst.

6.2.4 Test method for resistance to ignition

Expose a high-pressure flexible connection, with the outlet connector blanked, to pressure shocks from industrial oxygen (minimum 99,5 % purity and hydrocarbons less than or equal to 10 µg/g) through the inlet connector. The test equipment is shown in Figure 2. Before starting the test, the high-pressure flexible connection shall be at room temperature.

Apply a pressure shock by increasing the pressure from atmospheric pressure to the test pressure in a time of $20\,^{0}_{-5}$ ms measured upstream (see Key 10 in Figure 2) of the high-pressure flexible connection under test. Use an initial test pressure of $\times$ 1,2 nominal inlet pressure at 60 °C $\pm$ 3 °C. During the test the inlet (test) pressure shall not decrease by more than 3 %.

Apply to the high-pressure flexible connection under test a series of 20 pressure shocks at intervals of 30 s.

After each pressure shock maintain the test pressure for 10 s and then bring the pressure back to atmospheric pressure by means of the upstream outlet valve (see Key 5 in Figure 2) and hold at atmospheric pressure for at least 3 s (see Figure 3).

After the test has been completed, inspect all internal areas for damage.

Repeat this test on two additional high-pressure flexible connections.

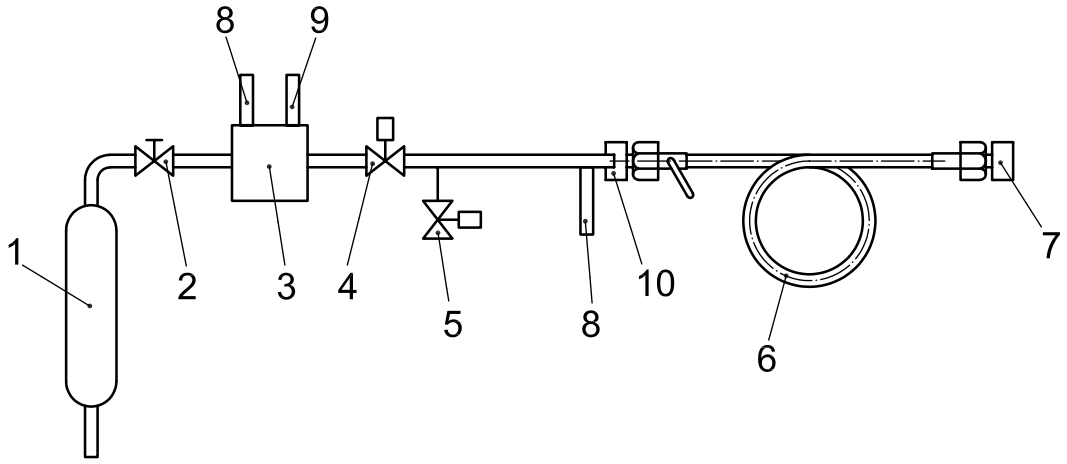
NOTE This test procedure is derived from ISO 7291.

6.2.5 Test method for pressure drop

Using an apparatus of typical configuration, as shown in Figure 4, set the test pressure (at the inlet of the high-pressure flexible connection) and the flow to the appropriate values given in Table 1. Measure the pressure drop across the high-pressure flexible connection.

6.2.6 Test method for durability of markings and colour coding

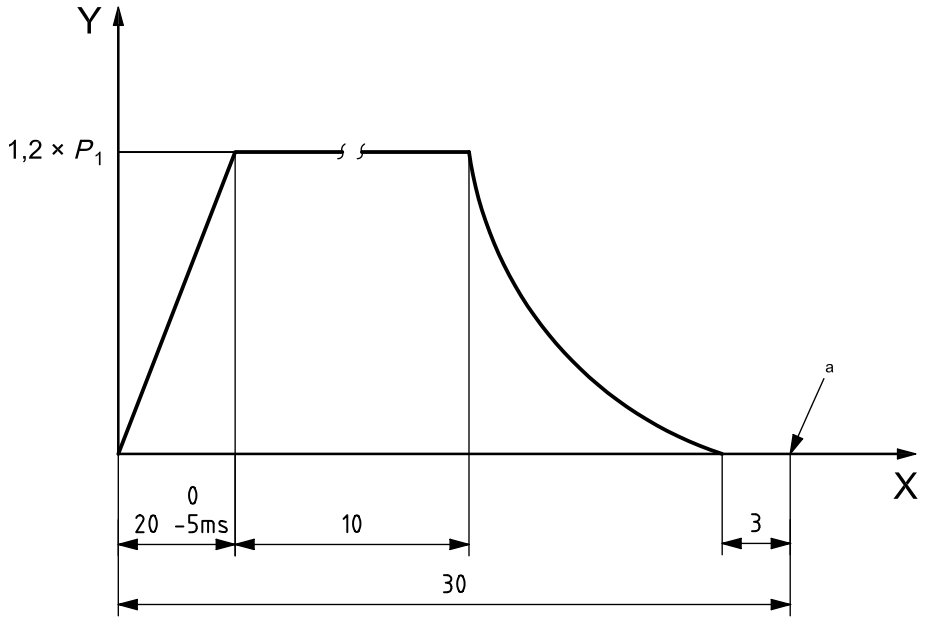
Rub markings and colour coding by hand, without undue pressure, first for 15 s with a cloth rag soaked in distilled water, then for 15 s with a cloth rag soaked in ethanol and then for 15 s with a cloth rag soaked in isopropanol. The markings shall remain legible.



Key

1	oxygen supply	6	high-pressure flexible connection under test
2	inlet valve	7	blanking plug
3	vessel with device for preheating oxygen to (60 ± 3) °C	8	pressure transducer
4	quick-opening valve	9	temperature sensor
5	outlet valve	10	measuring point

Figure 2 — Test bench for tests for resistance to ignition



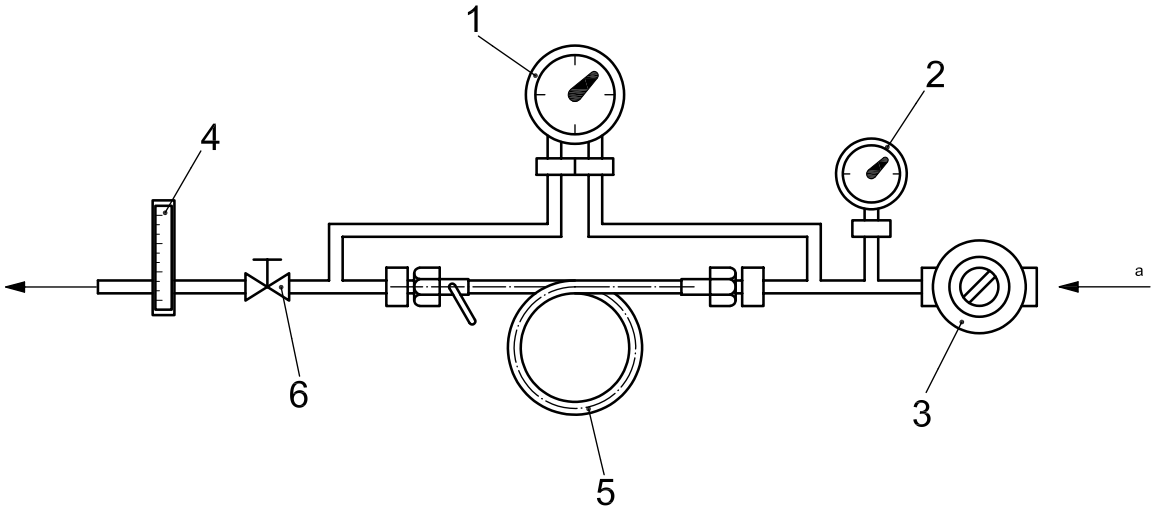
Key

X time in seconds

Y pressure

[a] Next pressure shock.

Figure 3 — Test interval



Key

1 pressure differential measuring device
2 pressure gauge
3 pressure regulator
4 flowmeter
5 high-pressure flexible connection under test
6 flow control valve

a Pressure supply.

Figure 4 — Typical apparatus for measuring the pressure drop across a high-pressure flexible connection

7 Marking, colour coding and packaging

7.1 Marking

7.1.1 High-pressure flexible connections shall be durably and legibly marked with the symbol of the relevant gas, in accordance with Table 2. In addition to the symbol the name of the gas may be used. The test for the durability of markings is given in 6.2.6.

7.1.2 In addition, high-pressure flexible connections shall be marked with the following:

— the name and/or the trademark of the manufacturer or distributor;

— means to ensure traceability such as type, batch or serial number or year of manufacture;

— the nominal inlet pressure, P_1.

7.1.3 Compliance with 7.1.1 and 7.1.2 shall be checked by visual inspection.

7.1.4 Means shall be provided to allow the installer to mark the date of installation on the device.

Compliance shall be demonstrated by inspection.

7.2 Colour coding

7.2.1 If colour coding is used, it shall be in accordance with ISO 32 or regional or national standards. See Table 2.

7.2.2 Colour coding shall be durable. The test for the durability of colour coding is given in 6.2.6.

7.3 Packaging

7.3.1 High-pressure flexible connections shall be sealed to protect against particulate contamination and packaged to prevent damage during storage and transportation.

7.3.2 Packages shall provide a means of identification of the contents.

Table 2 — Medical gases marking

Name	Symbol	Colour coding[a]
Oxygen	O_2	White
Nitrous oxide	N_2O	Blue
Air for breathing	Air[b]	Black-White
Helium	He	Brown
Carbon dioxide	CO_2	Grey
Mixtures of the above gases	According to the components	
Nitrogen for driving surgical tools	N_2	Black
Air for driving surgical tools	Air[b]	Black-White

[a] In accordance with ISO 32.

[b] National languages may be used for air.

8 Information to be supplied by the manufacturer

8.1 High-pressure flexible connections shall be accompanied by documents containing at least a technical description, including:

— the value of nominal inlet pressure, P_1;

— a statement of the intended use (i.e. for cylinders or cylinder bundles);

— instructions for installation, use and replacement;

— an address to which the user can refer.

The accompanying documents shall be regarded as a component part of high-pressure flexible connections.

8.2 The technical description shall also contain a statement of the expected lifetime of the device.

8.3 Instructions for installation shall contain all the information necessary to correctly install the high-pressure flexible connection on the manifold or the medical equipment. The flexibility characteristics shall be taken into account by giving examples of authorized and non-authorized configurations. The instructions for installation shall require that the date of installation be marked on the high-pressure flexible connection.

8.4 Instructions for use shall contain all the information necessary to connect and disconnect a high-pressure flexible connection to or from a cylinder or a cylinder bundle and shall include an explanation of the sequence of operations. Instructions for use shall give detailed instructions for the safe performance of cleaning, inspection and preventive maintenance to be performed by the operator or by authorized persons, and shall indicate the recommended frequency of such activities. If appropriate, a list of recommended spare parts shall be provided.

8.5 Instructions for replacement shall contain all the information necessary to disconnect the high-pressure flexible connection from the cylinder or the cylinder bundle and the manifold or medical equipment and to install a new one.

8.6 Particular attention shall be given, in the documentation specified in 8.2, 8.3, 8.4 and 8.5, to the following safety-related items:

a) the danger of fire or explosion arising from the use of lubricants not recommended by the manufacturer;

b) instructions to open the cylinder valve or the cylinder bundle valve slowly, due to the danger of fire or explosion arising from pressure shocks;

c) the danger of releasing a connector which is still connected to a source of pressure;

d) the danger of replacing a high-pressure flexible connection with one of lower nominal inlet pressure, P_1.

Annex A
(informative)

Rationale

The following correspond to the clauses in this International Standard marked with an asterisk (*). The numbering is, therefore, not consecutive.

A.2 Only dated references are used in this International Standard. As stated in the preamble of the European Medical Device Directive 93/42/EEC, manufacturers have "to take account of technology and practice existing at the time of design and of technical and economical considerations compatible with a high level of protection of health and safety". This is to ensure that a manufacturer does not design against a moving target (i.e. a standard which is revised after completion of the specification), before the device is placed on the market. Having only dated references will ensure that design specifications are developed using clearly defined standards that reflect the state of the art at the time of design.

SG1 of the Global Harmonization Task Force (GHTF) (http://www.ghtf.org) is developing a guideline, SG1/N044, *Role of Standards in the Assessment of Medical Devices*, which addresses the need to use dated references.

A.5.3.1 High-pressure flexible connections for different gases are often made with interchangeable components or sub-assemblies. The requirement for compatibility with oxygen should therefore be applied to high-pressure flexible connections for all gases.

A.5.3.2 Ignition of polymer-lined high-pressure flexible hoses is known to have occurred in several countries (e.g. as a result of adiabatic compression). Decomposition of certain polymers can occur at temperatures that can be produced by adiabatic compression. The products of decomposition and combustion of some polymers are known to be extremely toxic (see ISO 15001). Use of polymer-lined flexible hoses is, therefore, not permitted in this International Standard.

A.5.4.2.3 The dimension of 15 mm on the length of the body must be specified to prevent connection to the incorrect yoke on the medical equipment.

A.5.4.8 High-pressure flexible connections for different gases are often made with common components. The requirement for resistance to ignition should therefore be applied to high-pressure flexible connections for all gases.

A.5.5.1.1 The temperature of 450 °C is intended to reduce the risk of loss of mechanical integrity of high-pressure flexible connections due to fire and subsequent release of a medical gas that might support combustion.

A.5.5.1.2 It is essential to maintain the integrity and gas specificity of the device.

A.5.5.2 High-pressure flexible connections for different gases are often made with common components. The requirement for cleaning should therefore be applied to high-pressure flexible connections for all gases.

Bibliography

[1] ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

[2] ISO 5359:2008, *Low-pressure hose assemblies for use with medical gases*

[3] ISO 7291:1999, *Gas welding equipment — Pressure regulators for manifold systems used in welding, cutting and allied processes up to 300 bar*

[4] ISO/TR 7470:1988, *Valve outlets for gas cylinders — List of provisions which are either standardized or in use*

[5] ISO 10524-1:2006, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

[6] ISO 10524-2:2005, *Pressure regulators for use with medical gases — Part 2: Manifold and line pressure regulators*

[7] IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

[8] CGA E-9:2004, *Standard for Flexible PTFE-Lined Pigtails for Compressed Gas Service*

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