INTERNATIONAL STANDARD

ISO 5359

Second edition
2000-11-01

Low-pressure hose assemblies for use with medical gases

Flexibles basse pression utilisés dans les systèmes de gaz médicaux

Reference number
ISO 5359:2000(E)

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.ch
Web www.iso.ch

Printed in Switzerland

Contents

Page

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 3.

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 5359 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.

This second edition cancels and replaces the first edition (ISO 5359:1989). The major differences from the 1989 edition are the removal of dimensional specifications for diameter-index safety system (DISS) connectors and the allocation of connectors to nitric oxide/nitrogen mixtures and xenon.

Annex A of this International Standard is for information only.

0 Introduction

0.1 General

This International Standard has been prepared in response to the need for a safe method of connecting medical equipment to a fixed medical gas pipeline system or other medical gas supply system such that hose assemblies carrying different gases, or the same gas at different pressures, cannot be interchanged. Fixed medical gas pipelines, once installed, are rarely disturbed and are subjected to commissioning procedures to avoid the possibility of cross-connections or contamination of the medical gas conveyed. However, hose assemblies are subjected to physical wear and tear, misuse and abuse throughout their relatively short service life and are frequently connected to, and disconnected from, the medical equipment and the fixed pipeline.

While recognizing that no system is absolutely safe, this International Standard includes those requirements considered necessary to prevent foreseeable hazards arising from the use of hose assemblies. Operators should be continually alert to the possibility of damage being caused by external factors, and therefore regular inspection and repair should be undertaken to ensure that hose assemblies continue to meet the requirements of this International Standard.

This International Standard pays particular attention to:

— suitability of materials;

— gas-specificity;

— cleanliness;

— testing;

— identification;

— information supplied.

Rationales for some of the requirements of this International Standard are given in annex A. Such requirements are indicated by the letter "R" after the clause number in the main text.

0.2 Standardization of screw-threaded connectors for use in hose assemblies

Whilst the desirability of achieving agreement on a single International Standard for screw-threaded connectors has never been in doubt, the present pattern of usage has made such agreement impossible. Nevertheless fears that proliferation of individual national standards or practice will eventually result in potentially dangerous cross-connection between components for different gases have led to the choice of two screw-threaded connector systems for inclusion in this International Standard.

The two systems of connectors, which are mutually non-interchangeable, are DISS (diameter-index safety system) and NIST (non-interchangeable screw-threaded). Tables 1 and 5 detail those gases and gas mixtures for which NIST and DISS connectors have been allocated. Dimensions of NIST connectors are given in Tables 2, 3 and 4 and Figures 2, 3, 4 and 5. Dimensions of DISS connectors may be obtained from the Compressed Gas Association Inc., 1725 Jefferson Davis Highway, Arlington, VA 22202, USA.

As an alternative to the screw-threaded connector, a “quick-connector” which is gas-specific may be used at the inlet (outlet for vacuum) of the hose assembly, i.e. to connect the hose assembly to the fixed pipeline. Quick-connector systems of differing design should be non-interchangeable with each other in any one health care facility.

Low-pressure hose assemblies for use with medical gases

1 Scope

1.1 This International Standard specifies requirements for low-pressure hose assemblies intended for use with the following medical gases:

— oxygen;

— nitrous oxide;

— air for breathing;

— helium;

— carbon dioxide;

— xenon;

— specified mixtures of the gases listed above;

— air for driving surgical tools;

— nitrogen for driving surgical tools;

— nitric oxide/nitrogen mixtures;

— vacuum.

It is intended in particular to ensure gas-specificity and to prevent cross-connection between systems conveying different gases.

These hose assemblies are intended to be used at pressures less than 1 400 kPa.

1.2 This International Standard specifies the allocation of non-interchangeable screw-threaded (NIST) connectors and diameter-index safety system (DISS) connectors to medical gases and specifies the dimensions of non-interchangeable screw-threaded (NIST) connectors.[1)]

1.3 This International Standard does not specify:

— requirements for coaxial hoses used for the supply and disposal of air for driving surgical tools;

— requirements for electrical conductivity.

1.4 This International Standard does not specify the intended uses of hose assemblies.

---

1) Details and dimensions of DISS connectors can be obtained from the Compressed Gas Association Inc., 1725 Jefferson Davies Highway, Arlington, VA 22202, USA.

NOTE Some examples of intended use specified in other International Standards are as follows:

a) between a terminal unit and medical equipment (ISO 9170-1, ISO 8835-1, ISO 10651-1);

b) between the fixed pipeline system and a terminal unit of that system (ISO 7396-1, ISO 11197);

c) between a terminal unit and a second terminal unit (ISO 7396-1);

d) between an emergency supply and an emergency and maintenance inlet point of a pipeline system (ISO 10524, ISO 7396-1);

e) between an emergency supply and medical equipment (ISO 10524, ISO 8835-1, ISO 10651-1).

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

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

ISO 1307:1992, *Rubber and plastics hoses for general-purpose industrial applications — Bore diameters and tolerances, and tolerances on length*.

ISO 1402:1994, *Rubber and plastics hoses and hose assemblies — Hydrostatic testing*.

ISO 8033:1991, *Rubber and plastics hose — Determination of adhesion between components*.

ISO 9170-1:1999, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*.

ISO 14971[2)], *Medical devices — Application of risk management to medical devices*.

ISO 15001[2)], *Anaesthetic and respiratory equipment — Compatibility with oxygen*.

EN 1089-3, *Transportable gas cylinders — Gas cylinder identification — Part 3: Colour coding*.

3 Terms and definitions

For the purposes of this International Standard, the following terms and definitions apply. Examples of use of some of these terms to describe permitted inlet and outlet connectors for hose assemblies are given in Figure 1.

3.1
DISS connector
diameter-index safety system connector
any of a range of male and female components intended to maintain gas-specificity by the allocation of a set of different diameters to the mating connectors for each particular gas

2) To be published.

3.2
gas-specific
having characteristics which prevent interchangeability, thereby allowing assignment to only one gas service or vacuum service

3.3
hose assembly check valve
valve which is normally closed and which allows flow in either direction when opened by the insertion of an appropriate gas-specific connector

3.4
hose insert
that portion of a connector which is pushed into and secured within the bore (lumen) of the hose

3.5
inlet connector
that gas-specific part of a hose assembly which is connected to a medical gas supply system

3.6
low-pressure hose assembly
assembly which consists of a flexible hose with permanently attached gas-specific inlet and outlet connectors which is designed to conduct a medical gas at pressures less than 1 400 kPa

3.7
maximum operating pressure
maximum pressure for which the hose assembly is intended to be used

3.8
medical gas
any gas or mixture of gases intended to be administered to patients for therapeutic, diagnostic or prophylactic purposes, or for surgical tool applications

NOTE For the purposes of this International Standard, this term includes medical vacuum.

3.9
medical gas pipeline system
central supply system with control equipment, a pipeline distribution system and terminal units at the points where medical gases or vacuum may be required

3.10
medical gas supply system
medical gas pipeline system, or any other installation having no permanent pipeline system but employing a medical gas source complete with pressure regulators

3.11
NIST connector
non-interchangeable screw-threaded connector
any of a range of male and female components intended to maintain gas-specificity by the allocation of a set of different diameters and a left- or right-hand screw thread to the mating components for each particular gas

3.12
outlet connector
that gas-specific part of a hose assembly which is connected to the point where gas is delivered

3.13
probe
non-interchangeable male component designed for acceptance by and retention in the socket

3.14
quick connector
pair of non-threaded gas-specific components which can be easily and rapidly joined together or separated by a single action of one or both hands without the use of tools

3.15
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

3.16
socket
female part of a terminal unit which is either integral or attached to the base block by a gas-specific interface and which contains the gas-specific connection point

3.17
terminal unit
outlet assembly (inlet for vacuum) in a medical gas supply system at which the operator makes connections and disconnections

4 General requirements

4.1 Safety

Hose assemblies shall, when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, cause no safety hazard which could be foreseen using risk analysis procedures in accordance with ISO 14971 and which is related to their intended application, in normal condition and in single fault condition.

4.2 R Alternative construction

Hose assemblies and components or parts thereof, using materials or having forms of construction different from those detailed in this International Standard (except for dimensions and allocation of NIST and allocation of DISS connectors) shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained. Such evidence shall be provided by the manufacturer.

4.3 Materials

4.3.1 The materials in contact with the gas shall be compatible with oxygen, the other medical gases and their mixtures in the temperature range specified in 4.3.2.

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

NOTE 2 Compatibility with oxygen involves both combustibility and ease of ignition. Materials which burn in air will burn violently in pure oxygen. Many materials which do not burn in air will do so in pure oxygen, particularly under pressure. Similarly, materials which can be ignited in air require lower ignition energies for ignition in oxygen. Many such materials may be ignited by adiabatic compression produced when oxygen is rapidly introduced into a system initially at low pressure. See also ISO 15001.

4.3.2 The materials shall permit the hose assemblies and their components to meet the requirements of 4.4 in the temperature range of –10 °C to + 40 °C.

4.3.3 Hose assemblies shall be capable, while packed for transport and storage, of withstanding exposure to environmental conditions as stated by the manufacturer.

4.3.4 R Evidence of conformity with the requirements of 4.3.1, 4.3.2 and 4.3.3 shall be provided by the manufacturer.

4.4 Design requirements

4.4.1 Hose internal diameter

4.4.1.1 The internal diameter (bore) of hoses shall be in accordance with ISO 1307.

4.4.1.2 Hoses for compressed medical gases shall have a nominal internal diameter of at least 5 mm.

4.4.1.3 Hoses for vacuum shall have a nominal internal diameter of at least 6,3 mm.

4.4.2 Mechanical strength

4.4.2.1 R The minimum bursting pressure of hoses used for all services (except vacuum) shall be not less than 5 600 kPa at 23 °C and not less than 4 000 kPa at 40 °C. Evidence shall be provided by the manufacturer.

4.4.2.2 The hose assemblies shall resist the following axial tensile forces for 60 s:

a) hoses for compressed medical gases: 600 N;

b) hoses for vacuum: 300 N.

The test for mechanical strength is given in 5.5.

4.4.3 Deformation under pressure

4.4.3.1 When the pressure is increased from 50 kPa to 1 400 kPa (from 50 kPa to 500 kPa for vacuum), the increase in outside diameter shall not exceed 5 % of the original diameter.

4.4.3.2 When the pressure is increased from 50 kPa to 1400 kPa (from 50 kPa to 500 kPa for vacuum), the change in length shall not exceed 5 % of the original length.

The test for deformation under pressure is given in 5.6.

4.4.4 Resistance to occlusion

Under the following conditions, the reduction of a flowrate of 20 l/min shall not exceed 10 %, and the hose shall show no visible deformation:

a) hoses for compressed medical gases:

   internal pressure: 320 kPa

   compressing force: 400 N;

b) hoses for vacuum:

   internal pressure: 90 kPa sub-atmospheric

   compressing force: 300 N.

The test for resistance to occlusion is given in 5.7.

4.4.5 Adhesion strength

If the hose construction is of the type covered by ISO 8033, the adhesion strength between component layers when tested according to ISO 8033 shall be at least 1,5 kN/m.

4.4.6 Flexibility of hoses

The unsupported and unpressurized hose shall be capable of being formed to an inner radius of ten times the internal diameter of the hose without visible kinking.

4.4.7 Gas specificity

4.4.7.1 Hose assemblies for different gases shall have gas-specific connectors for each gas.

4.4.7.2 Hose assemblies for the same gas for different nominal operating pressures shall have gas-specific connectors for each pressure (e.g. the supply of air for driving surgical tools and air for breathing).

The test for gas-specificity is given in 5.4.

4.4.8 End connectors

4.4.8.1 Hose assemblies shall terminate at one end with an inlet connector and at the other end with an outlet connector (see Figure 1).

4.4.8.2 R The inlet connector shall be either:

— a probe complying with ISO 9170-1; or

— the nut and nipple of a NIST or DISS connector.

4.4.8.3 The outlet connector shall be one of the following:

— a probe complying with ISO 9170-1;

— the nut and nipple of a NIST or DISS connector;

— the body of a NIST or DISS connector;

— a terminal unit or a gas-specific connection point in accordance with ISO 9170-1:1999, except for 4.4.6 and 4.4.7 of that International Standard.

4.4.9 Design of NIST connectors

Design, dimensions and allocation of services to NIST connectors shall comply with Tables 1, 2, 3 and 4 and Figures 1 to 5.

Compliance shall be verified by measurement and visual inspection.

4.4.10 Design of DISS connectors

Allocation of services to DISS connectors[3)] shall comply with Table 5.

Compliance shall be verified by measurement and visual inspection.

---

3) Details and dimensions of DISS connectors can be obtained from the Compressed Gas Association Inc., 1725 Jefferson Davies Highway, Arlington, VA 22202, USA.