INTERNATIONAL STANDARD

ISO 5359

First edition
1989-12-01

Low-pressure flexible connecting assemblies (hose assemblies) for use with medical gas systems

Flexibles basse pression (flexibles) utilisés dans les systèmes de gaz médicaux

Reference number
ISO 5359 : 1989 (E)

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International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Printed 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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 5359 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment.*

Annexes A, B and C form an integral part of this International Standard. Annexes D, E, F and G are for information only.

Introduction

a) 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 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 specification includes those requirements considered necessary to prevent foreseeable hazards arising from the use of hose assemblies. Users should be continually alert to the possibility of damage being caused by external factors and it is therefore essential that regular inspection and repair is undertaken to ensure that hose assemblies continue to meet the requirements of this International Standard. For this reason suppliers of hose assemblies are required to give recommendations for inspection and repair that the user should follow. Recommended minimum requirements for servicing are given for information in annex D.

b) 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). Dimensions of DISS connectors are given in annex A and dimensions of NIST connectors are given in annex B. These annexes, which are integral parts of this International Standard, also detail those gases and gas mixtures for which DISS and NIST connectors have been allocated. Annex C details test methods.

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 designs should be non-interchangeable with each other in any one health care facility.

Annex E gives recommendations for materials and is for information only.

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Low-pressure flexible connecting assemblies (hose assemblies) for use with medical gas systems

1 Scope

This International Standard specifies requirements for hose assemblies for use with medical gas supply systems for clinical applications.

Requirements are given for the design, performance, identification and testing of hose assemblies used for conveying the medical gases listed in table 1.

Hose assemblies with connectors as defined in 3.7, 3.8, 3.9 and 3.10 and as illustrated in figure 1, are intended for use in the following situations:

a) between a pipeline terminal unit and medical equipment (see figure 2);

b) between the fixed pipeline system and a terminal unit of that system at which the user makes connections and disconnections (see figure 3);

c) between a terminal unit at the end of the fixed pipeline system and a second terminal unit or a quick-connector socket (see figure 4);

d) for connection between an emergency supply and a fixed pipeline system (see figure 5);

e) for connection between a medical gas pressure regulator and medical equipment.

Certain types of equipment contain internally installed hose assemblies which cannot be removed by the user, or maintained without dismantling the equipment, e.g. overhead pendant tracks and some hinged arm booms (see figure 6). These are not included in the scope of this International Standard.

This International Standard does not include requirements for electrical conductivity.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

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

ISO 262 : 1973, *ISO general purpose metric screw threads — Selected sizes for screws, bolts and nuts.*

ISO 263 : 1973, *ISO inch screw threads — General plan and selection for screws, bolts and nuts — Diameter range* 0,06 in *to* 6 in.

ISO 1307 : 1983, *Rubber and plastics hoses — Bore diameters and tolerances on length.*

ISO 1402 : 1984, *Rubber and plastics hoses and hose assemblies — Hydrostatic testing.*

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

ISO 8033 : 1985, *Rubber and plastics hose — Determination of adhesion between components.*

3 Definitions

For the purposes of this International Standard the following definitions apply.

3.1 low-pressure flexible connecting assembly (hose assembly): Assembly which consists of a hose with permanently attached gas-specific supply and equipment connectors which is designed to conduct a medical gas at pressures between 300 kPa and 1 400 kPa and for use with a vacuum service at pressures between 40 kPa and 90 kPa below atmospheric pressure.

3.2 supply connector: That gas-specific part of a hose assembly by means of which it may be connected to a gas source.

3.3 equipment connector: That gas-specific part of a hose assembly which is connected to

a) medical equipment, in situations described in clause 1a) and 1e);

b) terminal units, in situations described in clause 1b) and 1c);

c) fixed pipeline, as described in clause 1d).

3.4 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.

3.5 medical gas supply system: Either

a) a non-flammable medical gas pipeline system comprising a central supply system, control equipment, a pipeline distribution system and terminal units at the point where non-flammable medical gases or vacuum may be required;

or

b) any other installation having no permanent pipeline system but employing a medical gas supply source complete with pressure regulators.

3.6 terminal unit: Outlet assembly (inlet for vacuum) in a medical gas supply system at which the user makes connections and disconnections.

3.7 hose insert: That portion of a connector which is pushed into and secured within the bore (lumen) of the hose.

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

NOTE — This will usually consist of a probe and socket with check valve.

3.9 DISS (diameter-index safety system) connector: Range of male and female components intended to maintain gas specificity by allocation of a set of different diameters to the mating connectors for each particular gas.

3.10 NIST (non-interchangeable screw-threaded) connector: 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.

3.11 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.

3.12 gas-specific: Having characteristics which prevent interchangeability, thereby allowing assignment to one gas or vacuum service only.

3.13 maximum operating pressure: Maximum pressure for which the hose assembly is intended for use.

4 Materials and cleaning

All components and hose assemblies shall be supplied clean and free from oil, grease and particulate matter. Precautions shall be taken to maintain cleanliness during transport and storage.

NOTES

1 Any method of cleaning and degreasing may be used which effectively removes all surface dirt and hydrocarbons, and which leaves no residue itself. Chemical cleaning methods will normally require a subsequent washing and drying process to remove residues.

2 Recommendations for materials used in the construction of hose assemblies are given in annex E.

5 General requirements for tests of hoses and hose assemblies

When carrying out tests to assess compliance with the requirements given in clauses 6 and 7, the following conditions shall be used:

a) the test medium shall be medical air;

b) all tests shall be carried out at a temperature of 23 °C ± 2 °C.

6 Hoses

6.1 The requirements given in 6.3, 6.4, 6.5, 6.6, 6.7 and 6.8 shall be met for each batch of hose supplied, using at least one different sample for each test.

NOTES

1 It should be ensured that the hose has sufficient time to reach the required ambient temperature if used or stored in rooms at different temperatures.

2 Users of hose assemblies should be aware that certain materials soften at temperatures exceeding 25 °C when the rate at which hose kinks, deforms and occludes is increased.

6.2 The internal diameter of hoses shall be in accordance with ISO 1307.

NOTES

1 The nominal internal diameter of the hose should be selected to meet national requirements for pressure drop and medical gas flow.

2 Vacuum hose should have a minimum internal diameter of 6,3 mm.

6.3 When tested as described in subclause 7.3 of ISO 1402: 1984, the minimum bursting pressure of hose used for all services except vacuum shall be 5 000 kPa (50 bar) or four times its design operating pressure, whichever is the greater.

6.4 When tested as described in C.1, the hose shall comply with the following requirement. When the pressure is increased from 50 kPa to 1 400 kPa, the increase in outside diameter shall not exceed 5 % of the original diameter.

6.5 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.

6.6 When tested for resistance to occlusion as described in C.2, the reduction in flow shall not exceed 10 % and the hose shall show no visible deformation.

6.7 When tested as described in ISO 8033, the adhesion strength shall be at least 1,5 kN/m.

6.8 When tested as described in subclause 7.2 of ISO 1402 : 1984, using a test pressure of 1 400 kPa, the change in length at proof pressure shall not exceed ± 5 %.

7 Connectors and hose assemblies

7.1 The design, dimensions and allocation of services to DISS connectors shall be as shown in figures A.1 to A.8 and tables A.1 to A.3, all in annex A.

7.2 The design, dimensions and allocation of services to NIST connectors shall be as shown in figures B.1 to B.4 and tables B.1 to B.4, all in annex B.

7.3 Hose assemblies shall terminate at one end with a supply connector and at the other end with an equipment connector (see figure 1).

NOTE 1 — Attention is drawn to a possible hazard of ejection arising from the use of quick-connectors with hose assemblies at high pressures.

The supply connector shall be one of the following:

a) a quick-connect probe;

b) the nut and nipple of a DISS or NIST connector;

c) the body of a DISS or NIST connector.

The equipment connector shall be one of the following:

d) a quick-connect probe;

e) a terminal unit or quick-connect socket;

f) the nut and nipple of a DISS or NIST connector;

g) the body of a DISS or NIST connector.

NOTE 2 — ISO 5358 requires the provision of the body of a non-interchangeable gas-specific connector as the inlet connector for oxygen and nitrous oxide on anaesthetic machines.

7.4 If the body of a DISS or NIST connector includes a check valve which is opened when the nipple is inserted, the check valve shall completely seal the end of the hose assembly when the nipple is removed so that there are no bubbles released when tested as described in C.3.

7.5 Hoses shall be attached to the hose inserts of connectors by means of compression swaging, a crimped ferrule or other method which meets the requirements of 7.7 and 7.9.

The sleeve or ferrule shall be fitted by means of special purpose tools which provide a reproducible crimping performance meeting the requirements of 7.7.

7.6 It shall be impossible to remove the fitted sleeve or ferrule without it becoming unfit for reuse.

No worm screw drive or similar detachable clips or clamps shall be used to secure the hose to the hose insert.

No tape or other packing material shall be inserted between the hose and the hose insert.

7.7 A sample of each day's production of hose assemblies, when tested as described in C.4, shall have no visible movement between the fixing device securing the hose to the connectors and the end of the connectors.

NOTE — Attention is drawn to the sampling procedures given in ISO 2859.

7.8 When a sample of each day's production of hose assemblies is tested as described in C.5, the pressure drop shall not exceed 10 %.

7.9 Each hose assembly, when tested for leakage as described in C.3, shall either give no bubbles when tested under water or shall give a leak rate no greater than 0,1 kPa (1×10^{-2} mbar) l/s when using leak detection equipment.

7.10 Each hose assembly shall be tested to ensure that it has the correct gas-specific connectors at each end, either by joining the ends together, if each end is fitted with mating halves of a DISS or NIST connector, or by using a jig with gas-specific connectors. (See figure C.1.)

8 Flow and pressure loss performance

The maximum pressure drop through a hose assembly 5 m long shall not exceed 10 % of the nominal operating pressure at the design flow for gases and 15 % of the nominal operating pressure at the design flow for vacuum.

NOTES

1 Users should be aware that the pressure loss will be increased by

a) coiling and kinking of the hose assembly;

b) exceeding the flow for which the hose assembly is designed;

c) the type of any quick-connect coupling which may be used;

d) the inclusion of a check valve.

Users should also be aware that the available pressure at the equipment end of the assembly will be reduced by

e) the use of long hoses and the use of multiple connectors (hence extension hose assemblies are not recommended);

f) operating the medical gas supply system at a lower pressure than that for which it was designed.

For the reasons stated above, it is impossible to give specific figures for performance, but some typical test results are provided for information in annex F.

2 The pressure loss through a hose assembly forming part of a pipeline distribution system installed upstream (downstream for vacuum) of a terminal unit should be allowed for in the design of that system (see clause 7.1 of ISO 7396 : 1987).

9 Identification and marking

9.1 General

Identification of hose assemblies shall be by means of the gas name or chemical symbol in accordance with ISO/TR 7470. If colour coding is used it shall be in accordance with ISO 32 unless otherwise required by national regulations.

In addition, it shall be possible to identify the supplier/manufacturer of the hose assembly by means of a marking on the swaged sleeve, ferrule or other fixing device used to attach the hose to the hose insert of the connectors, or by such a sleeve or ferrule or tag permanently fitted for the specific purpose of such identification.

9.2 Marking of connectors

9.2.1 Connectors at both ends of the hose assembly shall be permanently marked with the symbol of the gas for which the hose assembly is intended, in accordance with table 1 and may be further identified by colour and name.

9.2.2 Lettering used in marking shall be not less than 2,5 mm high and shall not be obscured when the hose is attached and the hose assembly is complete. It shall be legible to a person having visual acuity (corrected if necessary) of at least 1 standing 0,5 m from the connector, at an illuminance of 215 lx.

9.2.3 Lettering shall be of a permanent nature, e.g. stamped or embossed, not painted or stencilled.

9.3 Identification and marking of hose

9.3.1 The hose used for hose assemblies may be identified in a permanent manner for the gas which it is intended to convey by means of colour coding in accordance with ISO 32 unless otherwise required by national regulations. Any such identification shall use contrasting colours and be by means of one or more of the following:

a) hose coloured throughout its length;

b) bands of colour applied to both ends of the hose, e.g. by means of a ferrule or coloured sleeve;

c) a coloured disc at both ends.

9.3.2 Any colour-coded sleeve or ferrule shall be coloured over its entire length.

9.3.3 If bands of colour are used in accordance with 9.3.1b), the following shall apply:

a) they shall be permanently located on the hose adjacent to the connectors;

b) they shall be of a width not less than 25 mm;

c) they shall extend completely around the circumference of the hose.

9.3.4 Hose which is not suitable for operating at pressures up to 1 400 kPa shall be permanently marked with the maximum operating pressure for which the hose is intended for use. The lettering shall contrast with the hose material colour and be legible to a person having visual acuity (corrected, if necessary) of at least 1 standing 1 m from the hose, at an illuminance of 215 lx.

10 Cleaning and packaging

After manufacture and assembly, hose assemblies shall be thoroughly cleaned to remove any particulate matter and dried. Finally, the hose assembly shall be purged with medical air and immediately packaged.

Table 1 — Symbols used for medical gases
(See ISO/TR 7470)

Medical gas or gas mixture	Symbol (identified on connector components)
Oxygen	O_2
Nitrous oxide	N_2O
Oxygen/nitrous oxide mixture 50 % O_2 (*V*/*V*)	O_2/N_2O
Medical air	AIR [1]
Vacuum	VAC [1]
Air/oxygen mixture	AIR/O_2 [1]
Nitrogen	N_2
Helium	He
Helium/oxygen mixture [2] [O_2 < 20 % (*V*/*V*)]	He/O_2
Oxygen/helium mixture [He ⩽ 80 % (*V*/*V*)]	O_2/He
Oxygen/carbon dioxide mixture [CO_2 ⩽ 7 % (*V*/*V*)]	O_2/CO_2
Carbon dioxide	CO_2
Carbon dioxide/oxygen mixture [CO_2 > 7 % (*V*/*V*)]	CO_2/O_2
Cyclopropane	C_3H_6
Special gas mixture 1	[3]
Special gas mixture 2	[3]

1) Terms in the appropriate language may be used.

2) Helium/oxygen mixtures [O_2 < 20 % (*V*/*V*)] are not respirable at atmospheric pressure.

3) For limited experimental applications. Symbols for these special gas mixtures should conform with the chemical symbols of the constituents.

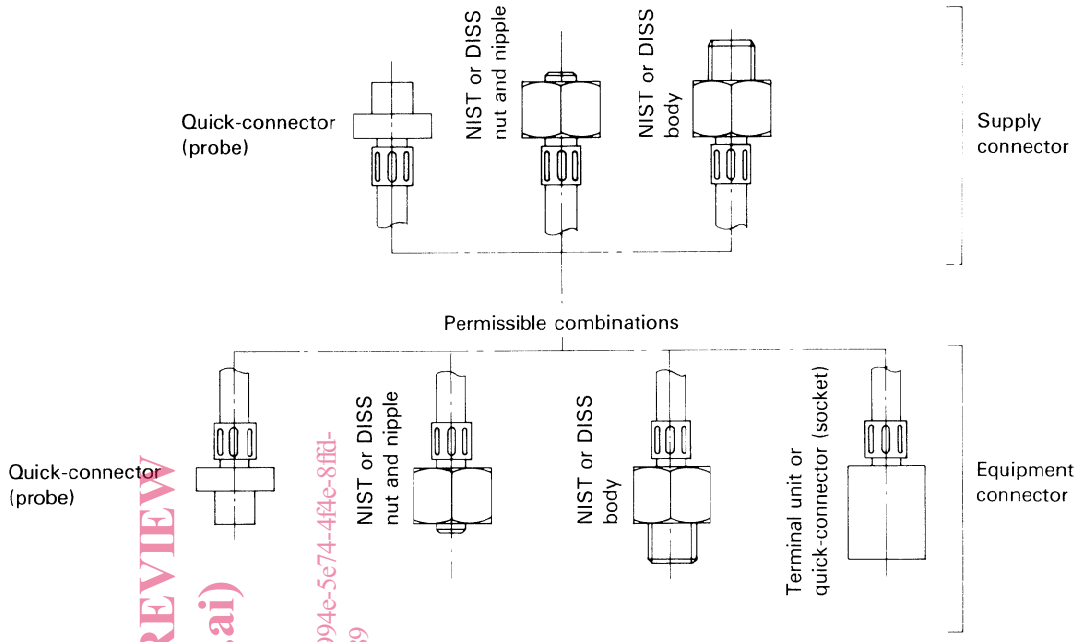

Figure 1 — Permitted end-connectors on hose assemblies

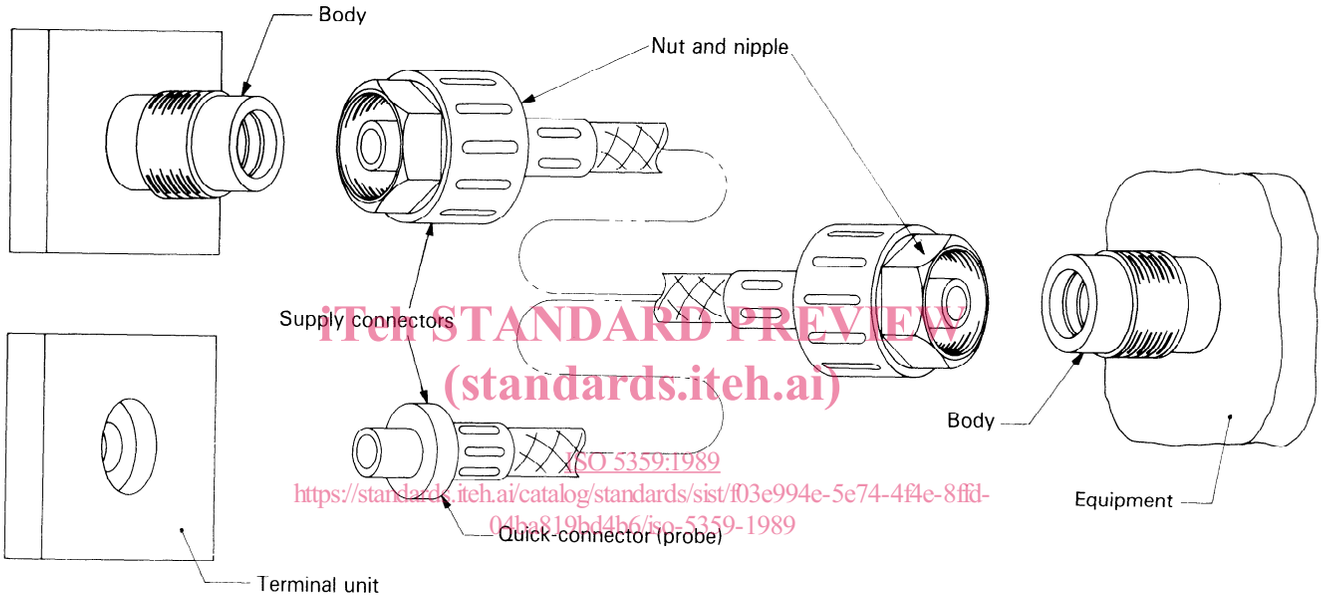

Figure 2 — Typical connectors for hose assemblies to medical equipment