# INTERNATIONAL STANDARD

ISO 5359

Third edition 2008-06-15

## Low-pressure hose assemblies for use with medical gases

Flexibles de raccordement à basse pression pour utilisation avec les gaz médicaux

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

This third edition cancels and replaces the second edition (ISO 5359:2000), which has been technically revised.

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#### 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 recognising 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:

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gas-specificity;

suitability of materials;

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— cleanliness; https://standards.iteh.ai/catalog/standards/sist/564a4806-8b26-4cf3-9ade-4e2920f8ad29/iso-5359-2008

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 asterisk (\*) 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 practices will eventually result in potentially dangerous cross-connection between components for different gases have led to the choice of three screw-threaded connector systems for inclusion in this International Standard.

The three systems of connectors, which are non-interchangeable, are diameter-index safety system (DISS), non-interchangeable screw-threaded (NIST) and sleeve indexed system (SIS). Tables 1 and 5 detail those gases and gas mixtures for which DISS, NIST and SIS 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 can be obtained from the Compressed Gas Association Inc., 1725 Jefferson Davis Highway, Arlington, VA 22202, USA. Dimensions of SIS connectors can be obtained from Standards Australia, GPO Box 476 Sydney, New South Wales, 2001, Australia.

As an alternative to the screw-threaded connector, a "quick connector" which is gas-specific can 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.

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### Low-pressure hose assemblies for use with medical gases

#### Scope

	* This International Standard specifies requirements for low-pressure hose assemblies intended for use the following medical gases:
—	oxygen;
	nitrous oxide;

- helium;
- carbon dioxide;

medical air;

xenon;

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- specified mixtures of the gases listed above;
- ISO 5359:2008 oxygen-enriched air; https://standards.iteh.ai/catalog/standards/sist/564a4806-8b26-4cf3-9ade-
- air for driving surgical tools;
- nitrogen for driving surgical tools;
- 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 for use at maximum operating pressures of less than 1 400 kPa.

- This International Standard specifies the allocation of (NIST), (DISS), (SIS) connectors to medical gases and specifies the dimensions of non-interchangeable screw-threaded (NIST) connectors.
- 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.

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

- between a terminal unit and medical equipment (ISO 9170-1, IEC 60601-2-12<sup>[7]</sup>, IEC 60601-2-13<sup>[8]</sup>);
- between the fixed pipeline system and a terminal unit of that system (ISO 7396-1[10], ISO 11197[13]);

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- 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 10524-1<sup>[12]</sup>, ISO 7396-1);
- e) between an emergency supply and medical equipment (ISO 10524-1, ISO 10524-3<sup>[16]</sup>, IEC 60601-2-12, IEC 60601-2-13).

#### 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 1307, Rubber and plastics hoses — Hose sizes, minimum and maximum inside diameters, and tolerances on cut-to-length hoses

ISO 1402, Rubber and plastics hoses and hose assemblies — Hydrostatic testing

ISO 8033, Rubber and plastics hoses — Determination of adhesion between components

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

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

ISO 15001, Anaesthetic and respiratory equipment — Compatibility with oxygen

EN 1089-3:2004, Transportable gas cylinders — Gals Cylinder (identification (excluding LPG) — Part 3: Colour coding https://standards.iteh.ai/catalog/standards/sist/564a4806-8b26-4cB-9ade-4e2920f8ad29/iso-5359-2008

AS 2896-1998, Medical gas systems — Installations and testing of non-flammable medical gas pipeline systems

#### 3 Terms and definitions

For the purposes of this document, 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

#### 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 that consists of a flexible hose with permanently attached gas-specific inlet and outlet connectors and 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 document, this term includes vacuum.

#### 3.9

#### medical gas pipeline system STANDARD PREVIEW

central supply system with control equipment, a pipeline distribution system and terminal units at the points where medical gases or vacuum can be required or any other installation having no permanent pipeline system but employing a medical gas source complete with pressure regulators

### 3.10 <u>ISO 5359:2008</u>

### NIST connector https://standards.iteh.ai/catalog/standards/sist/564a4806-8b26-4cf3-9ade-

### non-interchangeable screw-threaded connector iso-5359-2008

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

#### 3.11

#### outlet connector

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

#### 3 12

#### oxygen-enriched air

gas produced by an oxygen concentrator

NOTE Regional or national regulations might specify the name, symbol and colour coding for oxygen-enriched air.

#### 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 that 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

#### SIS connector

#### sleeve-index 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

#### 3.17

#### 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

#### 3.18

#### terminal unit

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

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