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Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases

Matériel d'anesthésie et de réanimation respiratoire — Flexibles de raccordement à basse pression pour utilisation avec les gaz médicaux

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.

This fourth edition cancels and replaces the third edition (ISO 5359:2008) and the Amendment ISO 5359:2008/Amd 1:2011, which has been technically revised as follows:

— deletion of the requirements on the dimensions and allocation of connectors (see ISO 18082);

— addition of definitions of terms;

— addition of requirements on risk management, usability, clinical investigation and leaching of substances;

— amendment of the marking requirements and requirements for information to be provided by the manufacturer.

Introduction

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 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. 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,

— prevention of cross-connections,

— cleanliness,

— testing,

— identification, and

— information supplied.

Requirements on respiratory therapy tubing are covered by ISO 17256, which refers to ISO 80369-2 on small bore connectors for breathing systems and driving gases.

While 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, and one gas-specific quick connector system for use on low pressure hose assemblies. The three systems of non-interchangeable screw-threaded connectors are the diameter index safety system (DISS), the non-interchangeable screw-threaded (NIST) system and the sleeve indexed system (SIS). Dimensions and allocation of these connectors to medical gases are not specified in this International Standard.

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.

Anaesthetic and respiratory equipment — 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,

— medical air,

— helium,

— carbon dioxide,

— xenon,

— specified mixtures of the gases listed above,

— oxygen-enriched air,

— air for driving surgical tools,

— nitrogen for driving surgical tools,

and for use with vacuum.

1.2 *It applies to hose assemblies operating at pressures up to 1 400 kPa and for vacuum systems at pressures not greater than 60 kPa absolute.

1.3 This International Standard does not specify the dimensions and allocation of the gas-specific inlet and outlet connectors for the hose assemblies.

NOTE 1 Specifications for the dimensions and allocation of diameter index safety system (DISS) connectors are specified in CGA V-5 [28].

NOTE 2 Specifications for the dimensions and allocation of sleeve indexed system (SIS) connectors are specified in AS 2896 [23].

NOTE 3 Dimensions and allocation of non-interchangeable screw-threaded (NIST) connectors are specified in ISO 18082 [11].

NOTE 4 Terminal units designed for quick connectors are specified in ISO 9170-1.

1.4 This International Standard does not specify requirements for coaxial hoses used for the supply and removal of air for driving surgical tools.

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

NOTE Environmental aspects are dealt with in Annex B.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1307:2006, *Rubber and plastics hoses — Hose sizes, minimum and maximum inside diameters, and tolerances on cut-to-length hoses*

ISO 1402:2009, *Rubber and plastics hoses and hose assemblies — Hydrostatic testing*

ISO 8033:2006, *Rubber and plastics hoses — Determination of adhesion between components*

ISO 9170-1:2008, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

ISO 14155:2011, *Clinical investigation of medical devices for human subjects — Good clinical practice*

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

ISO 15001:2010, *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
accessory
additional component for use with equipment in order

— to perform its intended use,

— to adapt the equipment to some special use,

— to facilitate the use of the equipment,

— to enhance the performance of the equipment,

— to enable the functions of the equipment to be integrated with those of other equipment

[SOURCE: IEC 60788:2004, 3.6]

3.2
accompanying document
document accompanying a medical device or an *accessory* (3.1) and containing information for the *responsible organization* (3.22) or operator, particularly regarding *basic safety* (3.3)

[SOURCE: IEC 60601-1:2005, 3.4, modified — by replacing *medical electrical equipment*, *medical electrical system* by *medical device* and by deleting *essential performance* at the end of the definition.]

3.3
basic safety
freedom from unacceptable risk directly caused by physical *hazards* (3.7) when a medical device is used under normal condition and *single fault condition* (3.24)

[SOURCE: IEC 60601-1:2005, 3.10, modified — by replacing *medical electrical equipment*, *medical electrical system* by *medical device*.]

3.4
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

EXAMPLE *Non-interchangeable screw-threaded connector* (3.16) (NIST connector), diameter-index safety system connector (DISS connector), sleeve index system connector (SIS connector).

3.5
gas-specific
having characteristics which prevent connections between different gas services

[SOURCE: ISO 7396-1:2007, 3.14]

3.6
harm
physical injury or damage to the health of people or animals, or damage to property or the environment

[SOURCE: ISO 14971:2007, 2.2, modified — by adding "or animals".]

3.7
hazard
potential source of *harm* (3.6)

[SOURCE: ISO 14971:2007, 2.3]

3.8
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* (3.5) *connector* (3.4)

[SOURCE: ISO 4135:2001, 1.4.9]

3.9
hose insert
portion of a *connector* (3.4) which is pushed into, and secured within, the bore (lumen) of the hose

[SOURCE: ISO 4135:2001, 1.4.7]

3.10
inlet connector
gas-specific (3.5) part of a hose assembly which is connected to a medical gas supply system

3.11
low-pressure hose assembly
assembly that consists of a flexible hose with permanently attached *gas-specific* (3.5) *inlet connectors* (3.10) and *outlet connectors* (3.18) and which is designed to conduct a medical gas at pressures less than 1 400 kPa

[SOURCE: ISO 9170-1:2008, 3.5]

3.12
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging, or labelling of a medical device, assembling a system, or adapting a medical device before it is placed on the market or put into service, regardless of whether these operations are carried out by that person or on that person's behalf by a third party

Note 1 to entry: Attention is drawn to the fact that the provisions of national or regional regulations can apply to the definition of manufacturer.

Note 2 to entry: ISO 13485 [9] defines "labelling" as written, printed or graphic matter

— affixed to a medical device or any of its containers or wrappers, or

— accompanying a medical device, related to identification, technical description, and use of the medical device, but excluding shipping documents. In this standard, that material is described as markings and *accompanying documents* (3.2).

Note 3 to entry: "Adapting" includes making substantial modifications to a medical device already in use.

Note 4 to entry: In some jurisdictions, the *responsible organization* (3.22) can be considered a manufacturer when involved in the activities described.

[SOURCE: ISO 14971:2007, 2.8, modified — by replacing Note 2 and adding Notes 3 and 4.]

3.13
maximum operating pressure
<hose assembly> maximum pressure for which the hose assembly is intended to be used

3.14
medical gas
any gas or mixture of gases intended for administration to patients for anaesthetic, therapeutic, diagnostic or prophylactic purposes, or for surgical tool applications

[SOURCE: ISO 4135:2001, 1.1.1]

3.15
medical gas pipeline system
complete system which comprises a supply system, a monitoring and alarm system and a distribution system with *terminal units* (3.26) at the points where *medical gases* (3.14) or vacuum are required

[SOURCE: ISO 7396-1:2007, 3.29]

3.16
non-interchangeable screw-threaded connector
NIST 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

[SOURCE: ISO 9170-1:2008, 3.10]

3.17
normal use
operation, including routine inspection and adjustments by any operator, and standby, according to the instructions for use

Note 1 to entry: Normal use should not be confused with *intended use*. While both include the concept of use as intended by the *manufacturer* (3.12), intended use focuses on the medical purpose while normal use incorporates not only the medical purpose, but maintenance, service, transport, etc. as well.

[SOURCE: IEC 60601-1:2005, 3.71]

3.18
outlet connector
gas-specific (3.5) part of a hose assembly which is connected to the point where gas is delivered

3.19
oxygen-enriched air
gas produced by an oxygen concentrator

Note 1 to entry: Regional or national regulations might specify the name, symbol and colour coding for oxygen-enriched air.

[SOURCE: ISO 7396-1:2007, 3.37, modified — by adding Note 1.]

3.20
probe
gas-specific (3.5) male component designed for acceptance by, and retention in, the *socket* (3.25)

[SOURCE: ISO 9170-1:2008, 3.11]

3.21
quick connector
pair of non-threaded *gas-specific* (3.5) components that can be easily and rapidly joined together by a single action of one or both hands without the use of tools

[SOURCE: ISO 9170-1:2008, 3.12]

3.22
responsible organization
entity accountable for the use and maintenance of a medical device

Note 1 to entry: The accountable entity can be, for example, a hospital, an individual clinician or a layperson. In home use applications, the patient, operator and responsible organization can be one and the same person.

Note 2 to entry: Education and training is included in "use."

[SOURCE: IEC 60601-1:2005, 3.101, modified — by replacing *medical electrical equipment* and *medical electrical system* by *medical device*.]

3.23
risk
combination of the probability of occurrence of *harm* (3.6) and the severity of that harm

[SOURCE: ISO/IEC Guide 51:1999, 3.2]

3.24
single fault condition
condition in which a single means for reducing a *risk* (3.23) is defective or a single abnormal condition is present

Note 1 to entry: See IEC 60601–1:2005, 4.7 and 13.2 for conditions in which a single means for reducing a risk is defective or a single abnormal condition is present.

[SOURCE: IEC 60601-1:2005, 3.116, modified — by adding the Note.]

3.25
socket
female part of a *terminal unit* (3.26) which is either integral or attached to the base block by a *gas-specific* (3.5) interface and which contains the gas-specific connection point

[SOURCE: ISO 9170-1:2008, 3.14]

3.26
terminal unit
outlet assembly (inlet for vacuum) in a *medical gas* (3.14) supply system at which the operator makes connections and disconnections

[SOURCE: ISO 9170-1:2008, 3.15]

4 General requirements

4.1 Risk management

The manufacturer of a low pressure hose assembly, shall follow a risk management process in accordance with ISO 14971. Any unacceptable risk shall be mitigated by the following

a) design features which prevent the hazard;

b) inclusion of a means of protection;

c) inclusion of a monitoring and/or alarm system;

d) safety and handling advice by way of marking or labelling.

If the inclusion of such risk mitigation measures is not feasible, the instructions for use shall contain:

— a statement recommending that such risk mitigation measures be added prior to the use of the low pressure hose assembly;

— sufficient specification of such risk mitigation measures.

Check compliance by inspection of the risk management file and, if applicable, the instructions for use.

4.2 Usability

The manufacturer shall address, in a usability engineering process, the risk resulting from poor usability (see IEC 60601-1-6 and IEC 62366).

Check compliance by inspection of the usability engineering file.

4.3 Clinical investigation

Where appropriate, clinical investigations shall be performed under the conditions for which performance is claimed and documented in the risk management file. The clinical investigations shall comply with the requirements of ISO 14155.

Check compliance by inspection of the risk management file.

NOTE A clinical investigation can be either

a) a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, where there is demonstration of equivalence of the device to the device to which the data relates, and the data adequately demonstrates compliance with the relevant essential requirements, or

b) a critical evaluation of the results of all clinical investigations made, or

c) a critical evaluation of the combined clinical data provided in a) and b).

4.4 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.

NOTE It has been reported that when using “quick connectors” there is a potential hazard when disconnecting from the terminal unit. There can be a release of pressure that can cause a sudden unpredictable movement of the hose resulting in injury to the operator and other personnel or damage to the equipment.

