SVENSK STANDARD
SS-EN ISO 5359:2014

Fastställd/Approved: 2014-10-19
Publicerad/Published: 2014-10-21
Utgåva/Edition: 2
Språk/Language: engelska/English
ICS: 11.040.10; 83.140.40

SWEDISH STANDARDS INSTITUTE

Anestesi- och ventilationsutrustning – Slangmontage för medicinska gaser vid låga tryck (ISO 5359:2014)

Anaesthetic and respiratory equipment – Low-pressure hose assemblies for use with medical gases (ISO 5359:2014)

Standarder får världen att fungera

SIS (Swedish Standards Institute) är en fristående ideell förening med medlemmar från både privat och offentlig sektor. Vi är en del av det europeiska och globala nätverk som utarbetar internationella standarder. Standarder är dokumenterad kunskap utvecklad av framstående aktörer inom industri, näringsliv och samhälle och befrämjar handel över gränser, bidrar till att processer och produkter blir säkrare samt effektiviserar din verksamhet.

Delta och påverka
Som medlem i SIS har du möjlighet att påverka framtida standarder inom ditt område på nationell, europeisk och global nivå. Du får samtidigt tillgång till tidig information om utvecklingen inom din bransch.

Ta del av det färdiga arbetet
Vi erbjuder våra kunder allt som rör standarder och deras tillämpning. Hos oss kan du köpa alla publikationer du behöver – allt från enskilda standarder, tekniska rapporter och standard-paket till handböcker och onlinetjänster. Genom vår webbtjänst e-nav får du tillgång till ett lättnavigerat bibliotek där alla standarder som är aktuella för ditt företag finns tillgängliga. Standarder och handböcker är källor till kunskap. Vi säljer dem.

Utveckla din kompetens och lyckas bättre i ditt arbete
Hos SIS kan du gå öppna eller företagsinterna utbildningar kring innehåll och tillämpning av standarder. Genom vår närhet till den internationella utvecklingen och ISO får du rätt kunskap i rätt tid, direkt från källan. Med vår kunskap om standarders möjligheter hjälper vi våra kunder att skapa verklig nytta och lönsamhet i sina verksamheter.

Vill du veta mer om SIS eller hur standarder kan effektivisera din verksamhet är du välkommen in på www.sis.se eller ta kontakt med oss på tel 08-555 523 00.

Standards make the world go round

SIS (Swedish Standards Institute) is an independent non-profit organisation with members from both the private and public sectors. We are part of the European and global network that draws up international standards. Standards consist of documented knowledge developed by prominent actors within the industry, business world and society. They promote cross-border trade, they help to make processes and products safer and they streamline your organisation.

Take part and have influence
As a member of SIS you will have the possibility to participate in standardization activities on national, European and global level. The membership in SIS will give you the opportunity to influence future standards and gain access to early stage information about developments within your field.

Get to know the finished work
We offer our customers everything in connection with standards and their application. You can purchase all the publications you need from us - everything from individual standards, technical reports and standard packages through to manuals and online services. Our web service e-nav gives you access to an easy-to-navigate library where all standards that are relevant to your company are available. Standards and manuals are sources of knowledge. We sell them.

Increase understanding and improve perception
With SIS you can undergo either shared or in-house training in the content and application of standards. Thanks to our proximity to international development and ISO you receive the right knowledge at the right time, direct from the source. With our knowledge about the potential of standards, we assist our customers in creating tangible benefit and profitability in their organisations.

If you want to know more about SIS, or how standards can streamline your organisation, please visit www.sis.se or contact us on phone +46 (0)8-555 523 00

Europastandarden EN ISO 5359:2014 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 5359:2014.

Denna standard ersätter SS-EN ISO 5359:2008, utgåva 1 och SS-EN ISO 5359:2008/A1:2012, utgåva 1.

The European Standard EN ISO 5359:2014 has the status of a Swedish Standard. This document contains the official version of EN ISO 5359:2014.

This standard supersedes the Swedish Standard SS-EN ISO 5359:2008, edition 1 and SS-EN ISO 5359:2008/A1:2012, edition 1.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS Förlag AB som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS Förlag AB, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Anestesi- och respiratorutrustning, SIS/TK 329.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 5359

October 2014

ICS 11.040.10; 83.140.40

Supersedes EN ISO 5359:2008

English Version

Anaesthetic and respiratory equipment - Low-pressure hose assemblies for use with medical gases (ISO 5359:2014)

Matériel d'anesthésie et de réanimation respiratoire - Flexibles de raccordement à basse pression pour utilisation avec les gaz médicaux (ISO 5359:2014)

Anästhesie- und Beatmungsgeräte - Niederdruck-Schlauchleitungssysteme zur Verwendung mit medizinischen Gasen (ISO 5359:2014)

This European Standard was approved by CEN on 24 August 2014.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 5359:2014 E

Contents

Page

Foreword

This document (EN ISO 5359:2014) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2015, and conflicting national standards shall be withdrawn at the latest by October 2017.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 5359:2008.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 5359:2014 has been approved by CEN as EN ISO 5359:2014 without any modification.

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