Irish Standard
I.S. EN ISO 5359:2014

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

I.S. EN ISO 5359:2014

Incorporating amendments/corrigenda/National Annexes issued since publication:

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Údarás um Chaighdeáin Náisiúnta na hÉireann

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.

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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.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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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of an identical text or by endorsement, at the latest by April 2015, and conflicting national standards shall be withdrawn at the latest by October 2017.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.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means to conforming to Essential Requirements of the New Approach Directive 93/42/EEC, Council Directive of 14 June 1993 on the approximation of the laws of the Member States concerning medical devices" (Medical Device Directive).

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this International Standard and Directive 93/42/EEC

Clause(s)/subclause(s) of this International Standard	Corresponding essential requirements of Directive 93/42/EEC	Qualifying remarks/notes
4.5.3, 4.7.1, 6.3.1	7.2	
4.5.1, 4.7.2	7.3	
4.5.2, 6.1.6, 7.3, 2nd dash	7.5	partially covered for phthalates; provision of rationale for using phthalates with the information to be provided not required
6.3.1	7.6	
4.6.2.1, 4.6.7, 4.6.8, 4.6.9, 4.6.10, 4.6.11	9.1	
4.5.2, 4.5.4, 4.6.2, 4.6.3, 4.6.5	9.2, first and second indents only	second indent covered for temperature and pressure
4.5.1, 4.7.1, 4.7.2	9.3	and via normative reference to ISO 15001
4.6.2, 4.6.3, 4.6.4, 4.6.5	12.7.1	
4.6.7, 4.6.8, 4.6.9	12.7.4	
4.6.4	12.8.1	
6.1, 6.2, 7	13.1	
6.2	13.2	only gas-specific colour coding is addressed.
6.1.2, 6.1.3, 7.2, 2nd dash	13.3 a)	only covered if the name and address of the authorized representative is placed on the label, if applicable
6.3.2	13.3 b)	
6.1.5	13.3 e)	
7.3 first dash, 7.4	13.6 d)	installation is not applicable

7.3 first dash	13.6 i)	
7.3, last dash	13.6 q)	
NOTE Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance to the Medical Devices Directive 93/42/EEC. This means that risks have to be reduced ‘as far as possible’, ‘to a minimum’, ‘to the lowest possible level’, ‘minimized’ or ‘removed’, according to the wording of the corresponding essential requirement.		

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this International Standard.

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I.S. EN ISO 5359:2014

INTERNATIONAL STANDARD

ISO 5359

Fourth edition
2014-10-01

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

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.

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

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received. www.iso.org/patents

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.