BSI Standards Publication

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

National foreword

This British Standard is the UK implementation of EN ISO 5359:2014+A1:2017. It supersedes BS EN ISO 5359:2014, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/121/1, Breathing attachments and anaesthetic machines.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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

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of an identical text or by endorsement, at the latest by April 2015, and conflicting national standards shall be withdrawn at the latest by October 2017.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

Foreword to Amendment A1

The text of this Amendment EN ISO 5359:2014/A1:2017 to the EN ISO 5359:2014 from Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" of the International Organization for Standardization (ISO) has been taken over as an amendment to the European Standard by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment" the secretariat of which is held by BSI.

This Amendment to the European Standard EN ISO 5359:2014 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2018, and conflicting national standards shall be withdrawn at the latest by November 2020.

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

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.

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

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard 'within the meaning of Annex ZA, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO
ISO 1307:2006	EN ISO 1307:2008	ISO 1307:2006
ISO 1402:2009	EN ISO 1402:2009	ISO 1402:2009
ISO 8033:2006	EN ISO 8033:2006	ISO 8033:2006
ISO 9170-1:2008	EN ISO 9170-1:2008	ISO 9170-1:2008
ISO 14155:2011	EN ISO 14155:2011	ISO 14155:2011
ISO 14971:2007	EN ISO 14971:2012	ISO 14971:2007
ISO 15001:2010	EN ISO 15001:2011	ISO 15001:2010

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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 5359:2014/Amd 1:2017 has been approved by CEN as EN ISO 5359:2014/A1:2017 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request [M/023 concerning the development of European Standards related to medical devices] to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative 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.

NOTE 1 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 with Directive 93/42/EEC as amended by 2007/47/EC. 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.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 93/42/EEC [OJ L 169]

Essential requirements of Directive 93/42/EEC	Clause(s)/subclause(s) of this EN	Remarks/Notes
7.3	4.5.1, 4.7.2	
7.5	4.5.2, 6.1.6, 7.3, 2nd dash	First paragraph: first sentence covered. Second paragraph: covered for phthalates. Third paragraph: covered for phthalates in the Instructions for Use.
7.6	6.3.1	
9.1	4.6.2.1, 4.6.7, 4.6.8, 4.6.9, 4.6.10, 4.6.11	
9.2, first and second indents only	4.5.2, 4.5.4, 4.6.2, 4.6.3, 4.6.5	Second indent covered for temperature and pressure
9.3	4.5.1, 4.7.1, 4.7.2	And via normative reference to ISO 15001
12.7.1	4.6.2, 4.6.3, 4.6.4, 4.6.5	
12.7.4	4.6.7, 4.6.8, 4.6.9	
12.8.1	4.6.4	Covered for maintenance of flow when the hose is compressed

Essential requirements of Directive 93/42/EEC	Clause(s)/subclause(s) of this EN	Remarks/Notes
13.2	6.2	The use of colour codes of harmonised standards is mandatory in the EU. Covered for the use of gas-specific colour coding only.
13.3 b)	6.3.2	
13.3 e)	6.1.5	
13.6 d)	7.3 first dash	Covered for details of the nature and frequency of maintenance and calibration
13.6 q)	7.3, last dash	

WARNING 1 Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 Other Union legislation may be applicable to the products falling within the scope of this standard.

Contents

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), 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.

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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,

— [A1] oxygen 93 [A1],

— 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.