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Anaesthetic and respiratory equipment - Breathing sets and connectors (ISO 5367:2014)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 03/15

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Oznámením tejto normy sa ruší
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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 5367

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ICS 11.040.10

Supersedes EN 12342:1998+A1:2009

English Version

Anaesthetic and respiratory equipment - Breathing sets and connectors (ISO 5367:2014)

Matériel d'anesthésie et de réanimation respiratoire - Systèmes respiratoires et raccords (ISO 5367:2014)

Anästhesie- und Beatmungsgeräte - Atemsets und Verbindungsstücke (ISO 5367:2014)

This European Standard was approved by CEN on 18 July 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.

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

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Ref. No. EN ISO 5367:2014 E

Contents

Page

Foreword

This document (EN ISO 5367:2014) 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of an identical text or by endorsement, at the latest by April 2015, and conflicting national standards shall be withdrawn at the latest by October 2017.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 12342:1998+A1:2009.

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 5367:2014 has been approved by CEN as EN ISO 5367:2014 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 one means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC.

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

Table ZA 1 — Correspondence between this European Document and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/notes
5.1 4.3	7.1 (2nd, and 3rd indents)	
5.1.1 7.1 7.2	7.2	5.1.1 mandates that these devices shall satisfy the biological safety testing indicated in ISO 10993-1 7.1 and 7.2 covers the integrity of the packaging only for devices supplied sterile
4.1.1 4.1.2 5.1	7.3 first part	4.1.1, 4.1.2, and 5.1 mandates a risk assessment be carried out which does not exclude risks associated with materials and the substances with which they may come into contact.
5.1.3, 8.3.m)	7.5	Partly addressed by 5.1.3 and 8.3.m) calls specifically for a warning if phthalates are incorporated
7.1, 7.2, 8.3.a)	8.1	Partly addressed. 7.1 and 8.3.a) mandate that sterile devices are clearly marked according to EN 556–1 mandates the requirements of ISO 11607-1 to ensure that the packaging is suitable to prevent contamination during transportation and use.
7.2	8.3	Partly addressed by 7.2 which mandates the requirements of ISO 11607-1 that the packaging is suitable to prevent contamination during transportation and use.
7.1	8.4	

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/notes
7.1	8.5	
8.3.a)	8.7	Partly covered. Marked sterile if appropriate
5.3 5.4 5.5 5.6 6	9.1	Generally covered by mandating construction and testing of the interface connectors, leakage, resistance, compliance, resistance to tube collapse and kinking.
5.2 5.3 5.4 5.5 5.6 8.3 c) 8.3 d), e), f), g), m) 8.4.1 8.4.2 8.4.3 8.4.5	9.2 (first three indents)	Partly covered to address only the risk of injury in connection with their physical features by specifying sizing and marking conventions for the ID/OD of the breathing tubes, and leakage, resistance, and compliance when performance tested in accordance with parameters associated with a declared patient category.
5.3.1 5.3.2 5.3.3 5.3.5 5.3.6	12.7.4	Partly addressed for conical gas connectors only.
8 8.1 8.2 8.3 8.4	13.1	
8.1	13.2	Generally covered. Symbols are mandated in 8.1 to conform to EN 1041, ISO 7000 or ISO 15223-1
8.2 a) 8.3 i)	13.3 a)	

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/notes
8.3 c) 8.3 d) 8.3 e) and f) 8.3 g) 8.3 h)	13.3 b)	Covered for patient category, length, resistance, total compliance and internal diameter.
8.3 a)	13.3 c)	
8.3 j)	13.3 d)	
8.3.k)	13.3 e)	
8.3.b)	13.3 f)	
8.4.2 8.4.3 8.4.4 8.4.5	13.3 j)	Partly addressed with requirements for instructions for typical components or processes.
8.3 l) 8.3 m)	13.3 k)	
8.3 a)	13.3 m)	Partly addressed. Method of sterilization is addressed only as a recommendation.
8.4.5	13.5	Partly addressed. Limited to detachable connectors, which are sized in accordance with ISO 5356-1 instructs users on coaxial integrity testing
8, 8.1, 8.2, 8.3, 8.4	13.6 , a), b), c)	
8.4.4 8.3 l)	13.6 h)	Partly addressed. Risks associated with the reuse of devices marked for single use are covered partly by the risk management file and use of the informative Annex F Hazard identification for risk assessment
8.4.5	13.6 i)	Partly addressed. Details for coaxial set user tests are mandated
8.4.6	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 product(s) falling within the scope of this standard

INTERNATIONAL STANDARD

ISO 5367

Fifth edition
2014-10-15

Anaesthetic and respiratory equipment — Breathing sets and connectors

Matériel d'anesthésie et de réanimation respiratoire — Systèmes respiratoires et raccords

Reference number
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Contents

Page

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 (see 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 (see 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 2, *Airways and related equipment*.

This fifth edition cancels and replaces the fourth edition (ISO 5367:2000), which has been technically revised.

The following major changes were made:

— title and scope;

— additional normative references;

— additional terms and definitions;

— additional general requirements, including risk management, usability, clinical and biophysical research;

— requirements for coaxial tubing, revised leakage limits, and testing for flow resistance and compliance;

— revised limits for prevention of electrostatic charges;

— revised requirements for marking of packaging, including the use of symbols, disclosure of intended patient category, flow resistance and compliance;

— added an annex for rationale;

— added an annex for hazard identification for risk assessment;

— revised test method annexes for resistance to flow, security of attachments, leakage and compliance;

— added an annex for compliance with the EU Directives.

Introduction

This International Standard contains requirements for **breathing sets, breathing tubes,** and connectors that are intended to function as accessories to anaesthetic and respiratory equipment. **Breathing sets** and **breathing tubes** are characterized by certain design requirements such as a means of connection and leakage limits. Disclosure requirements for **compliance** and flow resistance values allow the user to make an informed choice when connecting these accessories to a **breathing system**. These design requirements are intended to allow operation within the limits of performance of the **anaesthetic breathing systems** and **ventilator breathing systems** with which the accessories are intended to operate.

This International Standard includes requirements for both single-use and reusable **breathing sets** and **breathing tubes**. Re-usable **breathing sets and breathing tubes** are intended to comply with the requirements of this International Standard for the recommended service life.

Certain tests are performed under constant pressure to simplify the test methodology. It is recognized that this does not reflect clinical use, where pressure is intermittent and peak pressures occur for short periods. The limits in the test methods take this into account. While such test methods do not address product variability, the limits required also take this into account.

Terms defined in this International Standard are set in **bold type**.

Throughout this International Standard, text for which a rationale is provided in Annex A is indicated by an asterisk (*).

Throughout this International Standard, all pressures are denoted in SI units of hPa with corresponding cmH_2O equivalent values rounded to the nearest whole cmH_2O.

NOTE The unit cmH_2O is not an SI notation and is not used in ISO documents; rounded cmH_2O values are given for information only to allow comparison to medical literature and related **breathing system** standards.

INTERNATIONAL STANDARD **ISO 5367:2014(E)**

Anaesthetic and respiratory equipment — Breathing sets and connectors

1 Scope

*This International Standard specifies basic requirements for **breathing sets and breathing tubes** intended to be used with **anaesthetic breathing systems**, **ventilator breathing systems**, humidifiers or nebulizers. It applies to **breathing sets** and **breathing tubes** and **patient end adaptors** supplied already assembled and to those supplied as components and assembled in accordance with the manufacturer's instructions.

This International Standard is applicable to **breathing sets** which include special components (e.g. water traps) between the **patient end** and **machine end** which are supplied already assembled.

This International Standard is not applicable to **breathing sets** and **breathing tubes** for special purposes.

EXAMPLE 1 Ventilators having special **compliance**, pressure or breathing frequency requirements.

EXAMPLE 2 High Frequency Oscillatory Ventilation, (HFOV) or High Frequency Jet Ventilation (HFJV).

EXAMPLE 3 **Breathing sets** and **breathing tubes** with special connectors for neonatal ventilation.

Provision is made for coaxial and related bifurcated, double-lumen, or multiple-lumen **breathing sets** and **breathing tubes** suitable for use with **patient end adaptors**.

NOTE 1 Examples of various types of **breathing sets** with **patient end adaptors** are depicted in Annex A.

Requirements for exhalation valves, exhaust valves, **adjustable pressure-limiting (APL) valves,** heat and moisture exchangers (HMEs), breathing filters, and reservoir bags, if provided, are not covered by this International Standard.

NOTE 2 ISO 80601-2-12, ISO 80601-2-13, ISO 9360-1[3], ISO 23328-2[4], and ISO 5362[1] cover these.

NOTE 3 Certain aspects of heated-wire **breathing tubes** are discussed in ISO 8185[2].

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.

NOTE See Annex A for information on the use of dated and undated normative references.

ISO 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

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

ISO 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

IEC 60417, *Graphical symbols for use on equipment*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-6, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*

IEC 62366, *Medical devices — Application of usability engineering to medical devices*

ISO 80601-2-12:2011, *Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*

ISO 80601-2-13:2011, *Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation*

EN 556-1:2001, *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices*

EN 1041, *Information supplied by the manufacturer with medical devices*