SLOVENSKI STANDARD
oSIST prEN ISO 5367:2012

01-junij-2012

Anestezijska in dihalna oprema - Dihalni seti in priključki (ISO/DIS 5367:2012)

Anaesthetic and respiratory equipment - Breathing sets and connectors (ISO/DIS 5367:2012)

Anästhesie- und Beatmungsgeräte - Atemsets und Verbindungsstücke (ISO/DIS 5367:2012)

Matériel d'anesthésie et de réanimation respiratoire - Circuits respiratoires et de connecteurs (ISO/DIS 5367:2012)

Ta slovenski standard je istoveten z: **prEN ISO 5367**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

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EUROPEAN STANDARD

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English Version

Anaesthetic and respiratory equipment - Breathing sets and connectors (ISO/DIS 5367:2012)

Matériel d'anesthésie et de réanimation respiratoire - Circuits respiratoires et de connecteurs (ISO/DIS 5367:2012)

Anästhesie- und Beatmungsgeräte - Atemsets und Verbindungsstücke (ISO/DIS 5367:2012)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 215.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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

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Foreword

This document (prEN ISO 5367:2012) 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 document is currently submitted to the parallel Enquiry.

Endorsement notice

The text of ISO/DIS 5367:2012 has been approved by CEN as a prEN ISO 5367:2012 without any modification.

DRAFT INTERNATIONAL STANDARD ISO/DIS 5367

ISO/TC **121**/SC **2** Secretariat: **ANSI**

Voting begins on **2012-02-23** Voting terminates on **2012-07-23**

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Anaesthetic and respiratory equipment — Breathing sets and connectors

Matériel d'anesthésie et de réanimation respiratoire — Circuits respiratoires et de connecteurs

[Revision of fourth edition (ISO 5367:2000)]

ICS 11.040.10

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

In accordance with the provisions of Council Resolution 15/1993 this document is circulated in the English language only.

Conformément aux dispositions de la Résolution du Conseil 15/1993, ce document est distribué en version anglaise seulement.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 5367 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment, Working Group (WG 3)* which consisted of experts from ISO/TC 121 subcommittees SC 1, SC 2, and SC 3.

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 use of symbols, disclosure of intended patient category, flow resistance, and compliance;
- added an annex for a rationale;
- added annex for hazard identification for risk assessment;
- revised test method annexes for resistance to flow, security of attachments, leakage, and compliance;
- added 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 and labelling 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 system 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. Whilst such test methods do not address product variability, the limits required also take this into account.

Terms defined in this document are set in **bold type**.

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

Throughout this 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 in SI notation and is not allowed in ISO documents; rounded cmH_2O values are given for information only to allow comparison to medical literature and related **breathing system** standards.

Anaesthetic and respiratory equipment — Breathing sets and connectors

1 Scope

* This International Standard specifies basic requirements for **antistatic** and non-**antistatic breathing sets**, **breathing tubes**, and **breathing tubes** supplied to be cut to length, intended to be used with anaesthetic apparatus and ventilators, humidifiers and nebulizers. It also 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 manufacturers' instructions.

This International Standard is applicable to **breathing sets** and **breathing tubes** having ends incorporating **adaptors** with conical connectors (**assembled ends**) or with **plain ends** (either cylindrical or tapered).

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, such as those used with ventilators having special **compliance**, pressure, or breathing frequency requirements.

NOTE 1 Examples of these **breathing sets** may include High Frequency Oscillatory Ventilation, (HFOV), or High Frequency Jet Ventilation (HFJV).

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

Requirements for exhalation valves, exhaust valves, and **adjustable pressure-limiting (APL) valves** and reservoir bags, if provided, are not covered by this standard.

NOTE 3 ISO 80601-2-12, ISO 80601-2-13 and ISO 5362 cover these.

NOTE 4 Certain aspects of heated wire **breathing tubes** are discussed in ISO 8185 [1].

2 Normative references

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

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

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

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