
**Anaesthetic and respiratory
equipment — Breathing sets and
connectors**

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



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Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 General requirements	4
4.1 Risk management.....	4
4.2 Usability.....	4
4.3 Clinical evaluation.....	5
4.4 Biophysical or modelling research.....	5
4.5 Test methods.....	5
4.6 Recommended service life.....	5
5 Specific requirements	5
5.1 Materials.....	5
5.2 Length.....	5
5.3 Means of connection.....	6
5.4 Leakage.....	7
5.5 Resistance to flow.....	7
5.6 Compliance.....	8
6 Prevention of electrostatic charges	9
7 Requirements for breathing sets and breathing tubes supplied sterile	9
7.1 Sterility assurance.....	9
7.2 Packaging of breathing sets and breathing tubes supplied sterile.....	9
8 Marking	10
8.1 General.....	10
8.2 Marking of breathing sets and breathing tubes.....	10
8.3 Marking of packages.....	10
8.4 Information to be supplied by the manufacturer.....	12
Annex A (informative) Rationale	13
Annex B (informative) Hazard identification for risk assessment	23
Annex C (normative) Test for security of attachment of plain end to conical connector	24
Annex D (normative) Test for security of attachment of adaptor to breathing tube	25
Annex E (normative) Test for leakage	26
Annex F (normative) Measurement of resistance to flow	28
Annex G (normative) Test for increase in flow resistance with bending	31
Annex H (normative) Test for compliance	33
Bibliography	35

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 cmH₂O equivalent values rounded to the nearest whole cmH₂O.

NOTE The unit cmH₂O is not an SI notation and is not used in ISO documents; rounded cmH₂O 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 **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*