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
ISO 5367:2014(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

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.