TC 121

International Standard ISO 5367

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Breathing tubes used with anaesthetic apparatus and ventilators

Tuyaux de ventilation pour appareils d'anesthésie et ventilateurs

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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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 5367 was prepared by Technical Committee ISO/TC 121, *Anaesthetic equipment and medical breathing machines*.

ISO 5367 was first published in 1980. This second edition cancels and replaces the first edition, of which sub-clauses 3.2, 3.3 and 5.2 have been technically revised.

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Breathing tubes used with anaesthetic apparatus and ventilators

0 Introduction

This International Standard is one of a series dealing with anaesthetic equipment and medical breathing machines, and is supplementary to ISO 5356. It is primarily concerned with basic requirements for breathing tubes, including means of connection and conductivity.

1 Scope and field of application

This International Standard specifies basic requirements for breathing tubes used with anaesthetic apparatus and some ventilators, and applies also to those breathing tubes which may have other components integrally attached.

Provision is made for breathing tubes having plain ends (either cylindrical or tapered) or ends incorporating conical fittings.

Breathing tubes for special purposes, such as those used with some ventilators, double lumen tubes and paediatric breathing systems, are excluded from the scope of this International Standard.

2 References

ISO 468, *Surface roughness — Parameters, their values and general rules for specifying surfaces.*

ISO 2878, *Rubber, vulcanized — Antistatic and conductive products — Determination of electrical resistance.*

ISO 2882, *Rubber, vulcanized — Antistatic and conductive products for hospital use — Electrical resistance.*

ISO 5356, *Breathing attachments for inhalation anaesthetic apparatus, lung ventilators and resuscitators*

- *Part 1 : Conical fittings and adaptors.* [1]
- *Part 2 : Screw threaded weight bearing fittings.* [1]

IEC Publication 601-1, *Safety of medical electrical equipment — Part 1 : General requirements.*

3 Definitions

3.1 breathing tube (anaesthesia breathing system) : Large-bore, non-rigid tube, usually corrugated, used to convey gases and/or vapours between the anaesthetic machine and/or some ventilators and the patient.[2]

3.2 patient end : That end of the breathing tube which is intended to be connected to the Y-piece or other appropriate component near the patient.

3.3 machine end : That end of the breathing tube which is intended to be connected to the anaesthesia machine or ventilator.

3.4 conductive (anti-static) : Pertaining to breathing tubes and any integrally attached components with electrical conductivity satisfying specified limits under the conditions of test.

3.5 non-conductive : Pertaining to breathing tubes and any integrally attached components with insufficient electrical conductivity to meet specified limits under the conditions of test.

3.6 disposable : Intended for single use.

3.7 compliance : Volume/pressure relationship as determined from the gradient of the volume/pressure curve at a specified pressure, expressed as millilitres per kilopascal (ml/kPa) [or millilitres per centimetre of water (ml/cmH_2O)] per metre length of tube.

4 Design

Breathing tubes, whether of corrugated construction or otherwise, shall have either plain ends (either cylindrical or tapered) or ends incorporating conical fittings.

A loop for suspending the tube may be provided near one of the ends.

1) At present at the stage of draft.

2) Definition taken from ISO 4135, *Anaesthesiology — Vocabulary.*

5 Dimensions

5.1 Length

The length of breathing tubes shall be designated by the nominal overall length, expressed in metres, when measured in the relaxed condition.

5.2 Internal diameter

The internal diameter of the body of the breathing tube shall be not less than 18,0 mm.

6 Materials

NOTE — Because of the continuing rapid developments of new materials, no strict standards relative to materials are provided other than the following.

6.1 Breathing tubes shall be made of suitable materials which shall be reasonably resistant to anaesthetic agents.

6.2 Unless designated and marked as disposable, the tube shall be resistant to ordinary methods of cleaning, disinfection, and sterilization, as recommended by the manufacturer or supplier. It is desirable that non-disposable breathing tubes shall withstand accepted methods of steam sterilization.

NOTE — Attention is drawn to the absorption of volatile anaesthetic agents and other substances by breathing tubes. These agents and substances may be subsequently liberated and may pose a hazard.

7 Test conditions

All tests shall be conducted at 20 ± 3 °C after conditioning at this temperature for at least 1 h.

8 Means of connection

8.1 Plain ends

Both the machine end and the patient end of breathing tubes with plain ends shall make a satisfactory fit with the conical fitting of nominal 22 mm size in accordance with ISO 5356/1. Plain ends shall additionally comply with the requirements of 8.3 and 8.4 and their internal diameter shall be not less than 19,0 mm.

8.2 Ends incorporating conical fittings

The conical fittings shall be designed to give an effective fit with the relevant fittings specified in ISO 5356/1 and shall comply with the test requirements of 8.3 and 8.4. Where disposable tubes are supplied in pairs permanently attached to a Y-piece, the patient connection port of that Y-piece shall be 22 mm/15 mm male/female coaxial fittings in accordance with ISO 5356/1.

8.3 Disengagement load for connections

No detectable movement shall be observed when each end of the breathing tube is subjected to the following test.

8.3.1 Dip the end in distilled water and engage it with the appropriate conical fitting complying with the requirements of ISO 5356/1. Engagement shall be up to or beyond the major diameter of the conical fitting, which shall have a surface finish not rougher than 0,8 µm (roughness number N 6) determined in accordance with ISO 468.

NOTE — Strictly, it would also be necessary to specify the engagement forces involved in connecting the conical fittings. For the purpose of this test, however, such requirements were not considered to be readily practicable and it has been assumed that conical fittings would be engaged by hand as in normal clinical practice.

8.3.2 Apply a tensile load of 15 N along the linear axis of the tube for not less than 1 min. The load shall be applied at least 250 mm from the end of the connector for conical fittings of 22 mm size, and at least 200 mm from the end of the connector in the case of tubing connected to conical fittings of 15 mm size.

8.4 Gas-tightness of connections

Leakage as demonstrated by the escape of air bubbles shall not occur when each end of the breathing tube is subjected to the following test.

8.4.1 Dip the end in distilled water and engage it with the appropriate conical fitting as described in 8.1 and 8.2.

8.4.2 Apply an internal gas pressure of not less than 10 kPa (100 cmH_2O) above the ambient pressure whilst the connection is immersed in water.

9 Occlusion and flexibility test

The lumen shall not be appreciably occluded when wound in a helix around a 50 mm diameter core with

a) the minimum tension required to maintain contact with the core, and

b) the loops of tubing being maintained in wall-to-wall contact.

10 Compliance

10.1 The compliance (see 3.7) of breathing tubes shall be determined as follows.

10.1.1 Block one end of the breathing tube and provide the other end with means of injecting a known volume of air.

10.1.2 Mount the specimen in such a manner so as not to impede movement, for example by floating it on water.

10.1.3 Subject the specimen to inflation with a known volume of air to a gauge pressure of 10 kPa (100 cmH_2O).

10.1.4 Record the volume of air required for a stable internal pressure (see 10.1.3).

10.1.5 Determine the overall length of the test specimen at the ambient pressure.

10.1.6 Determine the compliance of the specimen expressed as millilitres per kilopascal (or millilitres per centimetre of water) per metre length.

10.2 The manufacturer shall, when required, provide information to the user on the compliance range of the product.

NOTE — The compliance of breathing tubes varies according to sterilization processes, usage and storage conditions. Normally the compliance of a new tube at a pressure of 10 kPa (100 cmH_2O) should not exceed 10 ml/kPa (1 ml/cmH_2O) per metre length of tube.

11 Electrical conductivity

11.1 The electrical characteristics of tubes and any integrally attached components made of conductive material for use with flammable anaesthetic agents shall be specified and tested in accordance with ISO 2878 and ISO 2882 respectively, or with the requirements of the appropriate national authorities.

12 Colour

Breathing tubes made of conductive material shall be coloured black, and those made of non-conductive material shall be of any colour except black.

13 Marking

13.1 Marking of breathing tubes

Breathing tubes shall be legibly and durably marked as follows :

a) the name or trademark of the manufacturer;

b) the date (year and month or week) of manufacture;

c) breathing tubes made of conductive material shall be marked in accordance with IEC Publication 601-1.

13.2 Marking of packages

Packages containing disposable breathing tubes shall be marked in accordance with 13.1 and shall additionally be clearly marked as follows :

a) the words "STERILE" or "NON-STERILE", as appropriate;

b) words indicating "for single use".

Both disposable and non-disposable breathing tubes made of non-conductive materials and, if provided, integrally attached components made of non-conductive materials shall be supplied in a package clearly marked "NON-CONDUCTIVE".