INTERNATIONAL STANDARD

ISO 5362

Fourth edition
2006-06-01

Anaesthetic reservoir bags

Ballons réservoirs d'anesthésie

Reference number
ISO 5362:2006(E)

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Published in Switzerland

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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 5362 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Tracheal tubes and other equipment*.

This fourth edition cancels and replaces the third edition (ISO 5362:2000), of which it constitutes a minor revision.

Introduction

This International Standard is one of a series dealing with anaesthetic and respiratory equipment. This International Standard is primarily concerned with the design of the neck, size designation and resistance to pressure required to distend anaesthetic reservoir bags.

The requirement that reservoir bags should be electrically conductive, when used with a flammable anaesthetic, is widely recognized and is of particular importance when such bags are rhythmically compressed by the anaesthetic provider in order to provide intermittent positive-pressure ventilation.

This International Standard gives requirements for both antistatic and non-antistatic bags. Only antistatic bags are suitable for use with flammable anaesthetic agents.

The reference test method given as Annex E is not practical for routine use in manufacturing control, because it involves filling the bag with water. For this reason, another test method using air rather than water has been provided for information in Annex F. This may ultimately be suitable as the reference test method if it can be shown to give results equivalent to Annex E.

A test method for leakage of bags using air rather than water is given as Annex A for information only. Recommendations for materials are given in Annex G.

Anaesthetic reservoir bags

1 Scope

This International Standard specifies requirements for antistatic and non-antistatic reservoir bags for use with anaesthetic apparatus or lung-ventilator breathing systems. It includes requirements for the design of the neck, size designation, distension and, where relevant, for electrical resistance.

This International Standard includes requirements for both single-use and reusable bags. Reusable bags are intended to comply with the requirements of this International Standard for the recommended product life.

This International Standard is not applicable to special-purpose bags, for example bellows and self-expanding bags. Bags for use with anaesthetic gas scavenging systems are not considered to be anaesthetic reservoir bags and are thus outside the scope of this International Standard.

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 4287, *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Terms, definitions and surface texture parameters*

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

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*

EN 556:1994, *Sterilization of medical devices — Requirements for medical devices to be labelled "Sterile"*

EN 980, *Graphical symbols for use in the labelling of medical devices*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
anaesthetic reservoir bag
collapsible gas container which is a component in a breathing system

[ISO 4135:2001, definition 4.1.3]

3.2
assembled neck
neck incorporating an adaptor

3.3
adaptor
specialized connector to establish functional continuity between otherwise disparate or incompatible components, one end of which is intended to be inserted into the neck of the bag, the other end having a conical connector complying with ISO 5356-1

3.4
plain neck
neck designed to fit directly over a male conical connector complying with ISO 5356-1

3.5
tail
tubular extension of the bag at the end opposite to the neck

4 General requirements

4.1 Reusable bags

Reusable bags shall comply with the requirements of this International Standard throughout the recommended product life, as given in Clause 8.

4.2 Size designation

The size of the bag shall be designated by the nominal capacity expressed in litres.

4.3 Leakage

Bags of nominal capacity 1 l or less shall not leak at a rate of more than 10 ml/min at an internal pressure of $(3 \pm 0{,}3)$ kPa.

Bags of nominal capacity greater than 1 l shall not leak at a rate of more than 25 ml/min at an internal pressure of $(3 \pm 0{,}3)$ kPa.

NOTE 1 For the purpose of this International Standard, the flowrate of air required to maintain the specified internal gas pressure is assumed to equal the leakage rate.

NOTE 2 A suitable test method is given in Annex A. This draws attention to the possible sites of leakage.

4.4 Capacity

The capacity of the bag when tested in accordance with Annex B shall be the marked value. The capacity of the bag when measured using the test method described in Annex B shall be within ±15 % of nominal capacity.

4.5 Design

4.5.1 Neck

4.5.1.1 Necks shall be either plain or assembled.

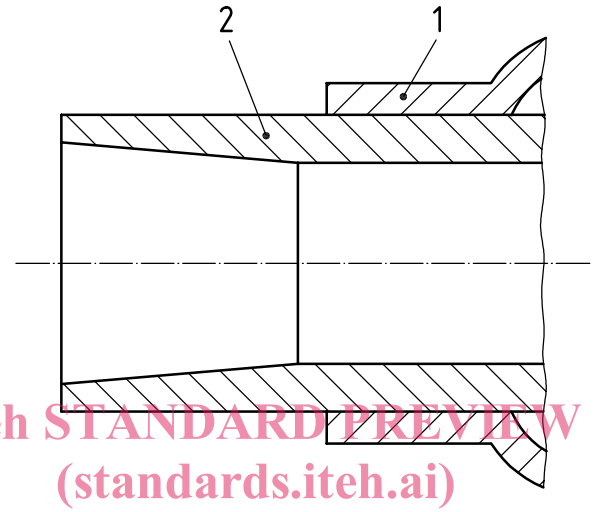
4.5.1.2 Plain necks shall fit directly on to 22 mm male conical connectors complying with ISO 5356-1, or on to adaptors that fit 15 mm or 22 mm male conical connectors complying with ISO 5356-1.

Plain necks may be reinforced internally or externally or made of a material thicker than that of the bag.

4.5.1.3 Plain necks of bags intended to fit directly on to 22 mm male conical connectors shall have an axial length of not less than 26 mm from the open end, when measured in the unstretched condition. Plain necks shall not become detached from a 22 mm male conical connector, when tested in accordance with Annex C.

Plain necks may be constructed to engage with the recess at the base of a 22 mm male conical connector.

4.5.1.4 Assembled necks shall incorporate an adaptor (see Figure 1) bearing a female conical connector in accordance with ISO 5356-1. The adaptor of the assembled neck shall not become detached from the bag, when tested in accordance with Annex D.



Key

1 neck of reservoir bag

2 adaptor, which may be flanged, grooved or recessed

Figure 1 — Typical adaptor with (female) conical connector

4.5.2 Tail

The tail, if open and not provided with a closure mechanism, shall have a minimum length of 20 mm.

A loop for suspending the bag may be provided near the tail of the bag.

4.6 Resistance to pressure required to distend the bag (pressure/volume)

4.6.1 When tested in accordance with Annex E (see E.3.6), the final pressure head shall be not less than 3,0 kPa and not more than 6,0 kPa.

4.6.2 A bag tested in accordance with Annex E shall revert within 30 min of the test to its previously measured capacity (i.e. capacity V_1, see E.3.2) within a tolerance of $\pm$ 10 %.

NOTE Another method for testing resistance to pressure to distend the bag, involving filling the bag with air rather than water, has been included for information as Annex F.

4.7 Materials

For recommendations concerning materials from which the bags are made, see Annex G.

5 Prevention of electrostatic charges

5.1 Antistatic bags shall comply with the requirements specified in IEC 60601-1:1988, 39.3b.

5.2 Bags coloured black shall be antistatic and comply with 5.1.

6 Requirements for bags supplied sterile

6.1 Sterility assurance

Bags supplied and marked as "STERILE" shall satisfy the requirements of EN 556:1994, 4.1.

6.2 Packaging for bags supplied sterile

Each bag supplied and marked as "STERILE" shall be contained in an individual pack. The pack shall serve as an effective barrier to the penetration of microorganisms and particulate material in accordance with ISO 11607-1. The pack shall permit the extraction of the contents and shall not be capable of reclosure without clearly revealing that it has been opened.

The individual pack may also contain other breathing system components.

7 Marking

7.1 Use of symbols

The requirements of 7.2 and 7.3 may be met by the use of appropriate symbols as given in ISO 7000 or EN 980.

7.2 Reusable bags

Bags intended for reuse shall be marked with the following information:

a) the name or trade mark of the manufacturer and/or supplier;

b) the nominal capacity (see 4.2);

c) for bags and integrally attached non-metallic components for use with flammable anaesthetic agents, the word "ANTISTATIC".

It is recommended that reservoir bags be additionally marked with the "USE-BY" date.

The marking should be legible, durable and resistant to the methods of cleaning and disinfection or sterilization recommended by the manufacturer.

Reusable bags may be black or coloured and/or bear an indelible yellow-coloured marking.

7.3 Single-use bags

The packaging or an insert shall be marked in accordance with 7.2 and with the words "SINGLE USE" or equivalent.

An indication shall be given if any natural rubber (latex) is present in the device.

Single-use bags may be black or coloured and/or bear an indelible yellow-coloured marking.

8 Information to be supplied by the manufacturer

Unless the bag is intended and labelled as being for single use, the manufacturer shall recommend methods of cleaning and disinfection or sterilization, and the maximum number or period of reuses. For reusable devices, the manufacturer shall indicate if any natural rubber (latex) is present in the device.

Marking, labelling and information to be supplied by the manufacturer should comply with EN 1041.