International Standard

ISO 5362

Anaesthetic and respiratory equipment – Anaesthetic reservoir bags

Matériel d'anesthésie et de réanimation respiratoire — Ballons réservoirs d'anesthésie

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Foreword

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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 document 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).

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This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment* Subcommittee SC 2, *Airway devices and related equipment*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fifth edition cancels and replaces the fourth edition (ISO 5362:2006), which has been technically revised.

The main changes are as follows:

— the test method using water to test the pressure required to distend the *anaesthetic reservoir bag* has been deleted and the alternative test method to test the pressure required to distend the *anaesthetic reservoir bag* using air has been made normative;

— the test method for leakage using air has been made normative;

— conical cone neck *adaptors* have been added as an alternative to conical socket neck *adaptors*; and

— this document has been rewritten to follow the format of ISO 18190.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document is primarily concerned with the design of the neck, size designation, leakage and resistance to pressure required to distend *anaesthetic reservoir bags*.

Flammable anaesthetic agents and gases are no longer in common use. However, this document still includes requirements, through reference to the airway and related devices general standard ISO 18190 for electrical conductivity so that *anaesthetic reservoir bags* designed for use with flammable anaesthetic agents/gases can still be manufactured.

Recommendations for materials are given in Annex G.

Anaesthetic and respiratory equipment – Anaesthetic reservoir bags

1 Scope

This document specifies requirements for *anaesthetic reservoir bags* for use with anaesthetic and ventilator breathing systems. It includes requirements for the design of the neck, size designation and elasticity.

This document is not applicable to special-purpose bags, for example bellows, self-inflating bags and bags for use with anaesthetic gas scavenging systems.

The requirements in this device-specific standard take precedence over any conflicting requirements in the general standard for airway devices (ISO 18190). All the common requirements that appear in the general standard for airway devices have been removed from this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 18190:2016, *Anaesthetic and respiratory equipment — General requirements for airways and related equipment*

ISO 18562-1, *Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process*

ISO 20417, *Medical devices — Information to be supplied by the manufacturer*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18190 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
adaptor
specialized connector to establish functional continuity between otherwise disparate or incompatible components

[SOURCE: ISO 4135:2022, 3.1.4.1]

3.2
anaesthetic reservoir bag
collapsible and distensible gas container which is a component in an anaesthetic breathing system

[SOURCE: ISO 4135:2022, 3.6.1.3, modified — added “and distensible”.]

3.3
assembled neck
neck incorporating an *adaptor* (3.1)

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

3.5
tail
tubular extension of the *anaesthetic reservoir bag* (3.2)

4 General requirements

The requirements of ISO 18190:2016, Clause 4, shall apply.

NOTE Annex H lists known hazards, associated with *anaesthetic reservoir bags*, that can be used as a guide for assessing the risks during the manufacturer's risk management process.

5 Materials

5.1 General

The requirements of ISO 18190:2016, Clause 5, shall apply.

5.2 Biocompatibility evaluation of the breathing gas pathways

Anaesthetic reservoir bags shall be assessed for biocompatibility of the breathing gas pathways.

Check conformance by the tests given in ISO 18562-1.

NOTE Rationale for this requirement is given in A.1.

5.3 Material recommendations

Annex G gives recommendations concerning materials from which *anaesthetic reservoir bags* can be made.

6 Design requirements

6.1 General

The requirements of ISO 18190:2016, Clause 6, shall apply.

6.2 Designated size

Anaesthetic reservoir bags shall be identified by their designated size. The designated size shall be within ±15 % of the nominal capacity and expressed in litres or millilitres as appropriate.

Check conformance by the test given in Annex C.

6.3 Leakage

Anaesthetic reservoir bags shall not leak when subjected to an internal pressure of (3 ± 0,3) kPa by more than:

a) 10 ml/min for designated sizes of 1 l or less;

b) 25 ml/min for designated sizes greater than 1 l.

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

Check conformance by the test given in Annex B.

NOTE 2 Rationale for this requirement is given in A.2.

6.4 Necks

6.4.1 *Anaesthetic reservoir bags* shall have either *plain necks* or *assembled necks.*

NOTE See Figure 1 for examples of anaesthetic reservoir bags with plain and assembled necks.

Check conformance by inspection.

6.4.2 *Plain necks* shall:

a) have an axial length of not less than 26 mm from the open end, when measured in the unstretched condition;

Check conformance by functional testing.

b) fit directly onto 22 mm conical cone connectors conforming with ISO 5356-1; and

c) not become detached from the 22 mm conical cone connector when subjected to an axial force of (40 ± 4) N for 1 min.

NOTE *Plain necks* can be reinforced and can also be designed to engage with the recess at the base of a 22 mm cone conical connector.

Check conformance by inspection and the test given in Annex D.

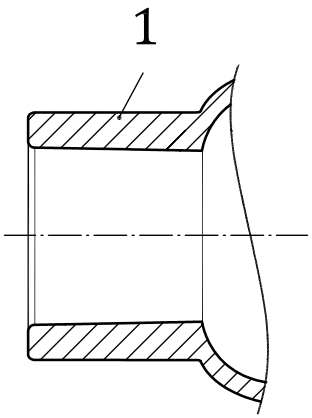
6.4.3 *Assembled necks* of *anaesthetic reservoir bags* shall incorporate an *adaptor* (see Figure 1) bearing either a conical cone or socket connector conforming with ISO 5356-1.

NOTE Rationale for this requirement is given in A.3.

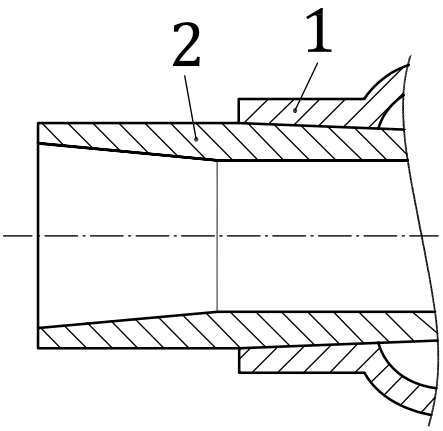
Check conformance by inspection.

6.4.4 *Assembled neck adaptors* shall not become detached from *anaesthetic reservoir bags* when subjected to an axial force of (40 ± 4) N for >1 min.

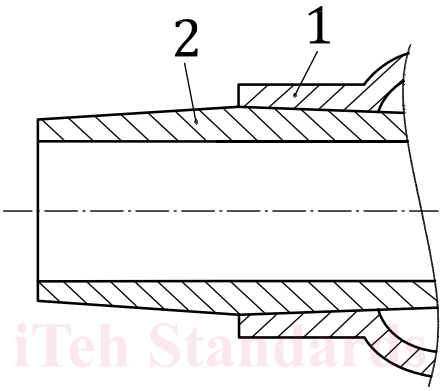
Check conformance by the test given in Annex E.



a) *Plain neck*



b) *Assembled neck* with a conical socket *adaptor*



c) *Assembled neck* with a conical cone *adaptor*

Key

1 neck of *anaesthetic reservoir bag*

2 *adaptor*

Figure 1 — Examples of *plain* and *assembled necks*

6.5 *Tails*

6.5.1 *Tails*, if open and not provided with a closure mechanism, shall have a minimum length of 20 mm.

Check conformance by inspection.

6.5.2 *Tails* may incorporate a loop for suspending the *anaesthetic reservoir bag*.

6.5.3 *Tails* shall be at the opposite end to the neck.

Check conformance by inspection.

NOTE See Figure 2 for examples of *anaesthetic reservoir bags* with and without *tails*.