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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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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.

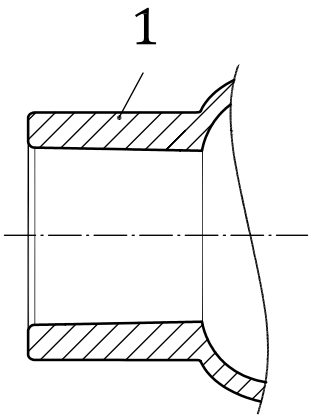
6.4.3 *Assembled necks* of *anaesthetic reservoir bags* shall incorporate an *adaptor* (see Figure 1) bearing either a conical cone or socket connector conforming with ISO 5356-1.

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

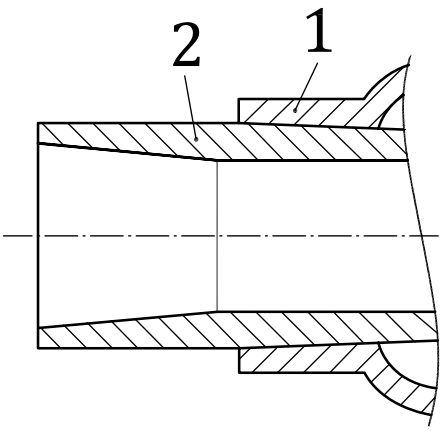
Check conformance by inspection.

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.

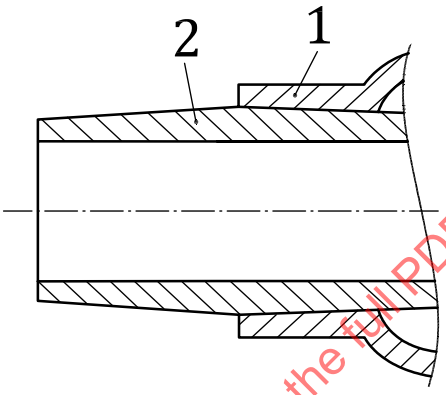
Check conformance by the test given in Annex E.



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.

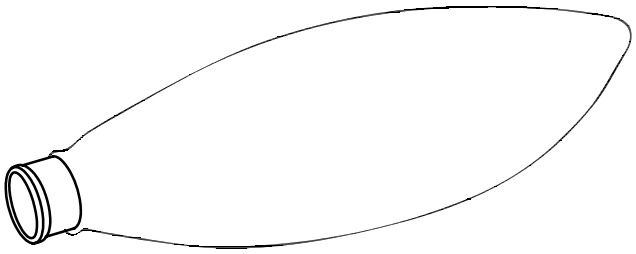
Check conformance by inspection.

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

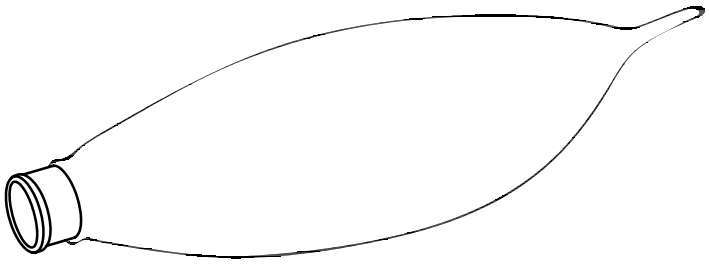
6.5.3 *Tails* shall be at the opposite end to the neck.

Check conformance by inspection.

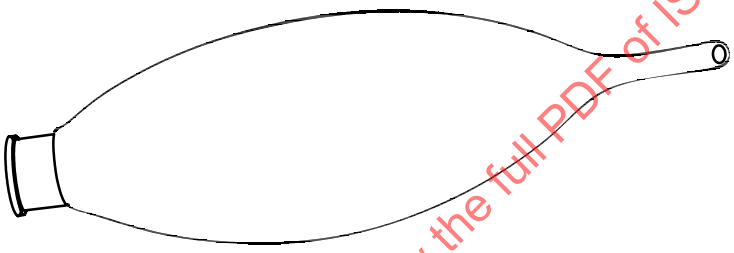
NOTE See Figure 2 for examples of *anaesthetic reservoir bags* with and without *tails*.



a) *Anaesthetic reservoir bag* with no *tail*



b) *Anaesthetic reservoir bag* with closed *tail*



c) *Anaesthetic reservoir bag* with open *tail*

Figure 2 — Examples of *anaesthetic reservoir bags* with and without *tails*

6.6 Elastic resistance

The elastic resistance of *anaesthetic reservoir bags* shall not generate an internal pressure less than 3,0 kPa or more than 6,0 kPa when subjected to a constant flowrate of air equal to two times the designated size per minute, for (120 ± 2) s.

Check conformance by the test given in Annex F.

6.7 Elastic recovery

Anaesthetic reservoir bags shall revert to within 10 % of their designated size within 30 min of being subjected to the test for elastic resistance (see 6.6).

Check conformance by the test given in Annex F.

7 Requirements for *anaesthetic reservoir bags* supplied sterile

The requirements of ISO 18190:2016, Clause 7, shall apply.

8 Packaging

The requirements of ISO 18190:2016, Clause 8, shall apply.

9 Information supplied by the manufacturer

9.1 General

The requirements of ISO 20417 and ISO 18190:2016, Clause 9, shall apply.

9.2 Marking

Anaesthetic reservoir bags shall, in addition to the requirements in 9.1, be marked with the following:

a) the designated size (see 6.2);

b) only *anaesthetic reservoir bags* that are antistatic shall be coloured black or bear yellow-coloured marking.

NOTE Rationale for this requirement is given in A.4.

Check conformance by inspection.

Annex A
(informative)

Rationale

A.1 Biocompatibility evaluation of the breathing gas pathways

Anaesthetic reservoir bags can be supplied in an unfinished state (e.g. without a neck *adaptor*), to manufacturers of breathing systems. It is then the responsibility of the breathing system manufacturer, not the unfinished bag manufacturer, to carry out the biocompatibility evaluation of their system including the *anaesthetic reservoir bag*.

A.2 Leakage

Most leakage and pressure tests involving breathing systems and apparatus are performed at 60 cmH_2O (6 kPa). However *anaesthetic reservoir bags* have to distend before they reach that pressure. They have to be able to reach a pressure of at least 30 cmH_2O (3 kPa), which makes that a suitable pressure to measure their leakage.

A.3 Assembled necks

The reservoir bag port connector on an anaesthetic breathing system has been the subject of concern due to reports of misconnections as it was easily confused with the inspiratory and expiratory ports of a circle absorber or anaesthetic ventilator as they are all 22 mm conical connector cones. The technical subcommittee responsible for anaesthetic breathing systems has agreed to transition from a 22 mm ISO 5356-1 cone to a 22 mm ISO 5356-1 socket if the bag mount is adjacent to the inspiratory and expiratory connections. If the bag mount is remote e.g. on a swivel arm then it can remain as a cone connector, hence the reason why this document allows neck adaptors to be either a cone or socket.

A.4 Colour marking

The colour black has for many years been associated with *anaesthetic reservoir bags* that are manufactured from antistatic materials and therefore safe to use with flammable anaesthetic agents and gasses such as ether and cyclopropane. Although the use of such flammable agents and gasses are rare nowadays, the association of the colour black with antistatic is still strong. To prevent any confusion *anaesthetic reservoir bags* manufactured from non-antistatic materials should not therefore be coloured black.

Annex B
(normative)

Leakage test

B.1 Principle

Leakage rate is measured by applying and maintaining an internal gas pressure by introducing air into the *anaesthetic reservoir bag* and recording the flowrate of air required to maintain that internal pressure. This will test for leakage from the body of the *anaesthetic reservoir bag*. In the case of *anaesthetic reservoir bags* with *assembled necks*, it will also test for leakage between the *anaesthetic reservoir bag*, and the *adaptor*. In the case of *anaesthetic reservoir bags* with *plain necks*, it will also test for leakage between the connection of the *anaesthetic reservoir bag* neck and a conical connector.

B.2 Apparatus

B.2.1 An appropriate 22 mm cone or socket conical connector conforming with ISO 5356-1.

B.2.2 Means of applying and maintaining an internal pressure of (3 ± 0,3) kPa.

B.2.3 Suitable safety cage, for surrounding the inflated *anaesthetic reservoir bag*.

B.2.4 Means of recording the flowrate of air required to maintain the specified internal gas pressure in the *anaesthetic reservoir bag* being tested, accurate to within 5 % of the flowrates specified in 6.3.

B.3 Procedure

B.3.1 Carry out the test procedure at an ambient temperature of (23 ± 2) °C.

B.3.2 Fit the neck of the *anaesthetic reservoir bag* to the 22 mm conical connector, closing off the *tail* if this is open-ended.

B.3.3 Increase the internal pressure to (3 ± 0,3) kPa by introducing air into the *anaesthetic reservoir bag* and allow this pressure to stabilize.

B.3.4 Record the flowrate of air required to maintain this internal pressure.

B.3.5 Verify that this meets the requirements specified in 6.3.

Annex C
(normative)

Determination of designated size

C.1 Principle

The nominal capacity is determined by measuring the volume of water required to fill an empty *anaesthetic reservoir bag* submerged in water. The designated size is then derived from the nominal capacity.

C.2 Apparatus

C.2.1 Means of filling an *anaesthetic reservoir bag* with water and determining the amount of water required within an accuracy of 1 % of the nominal capacity.

C.2.2 Tank of water of temperature (23 ± 2) °C and means of maintaining water at that temperature.

C.3 Procedure

C.3.1 Place the *anaesthetic reservoir bag* in the tank of water, having previously sealed any additional opening. Hold the *anaesthetic reservoir bag* vertically with the top rim of the neck above the surface of the water.

C.3.2 Fill the *anaesthetic reservoir bag* to the top of the rim of the neck with water maintained at a temperature of (23 ± 2) °C , noting the volume of water, in litres or millilitres, required to fill the *anaesthetic reservoir bag*.

C.3.3 Verify that the designated size is within the tolerance of the nominal capacity as specified in 6.2.

Annex D
(normative)

Test for security of attachment of *plain neck* to a 22 mm cone conical connector

D.1 Principle

The security of attachment of a *plain neck* to a 22 mm cone conical connector is tested by applying a tensile load along the linear axis of the neck and noting whether the neck becomes detached from the connector.

D.2 Apparatus and materials

D.2.1 Test connector comprising a 22 mm cone conical connector, with recess, made of metal and dimensioned as specified in ISO 5356-1.

D.2.2 Means of applying a tensile load, of (40 ± 4) N at a rate of (50 ± 5) mm/min along the linear axis of the neck of the *anaesthetic reservoir bag*.

D.3 Procedure

D.3.1 Carry out the test procedure at an ambient temperature of (23 ± 2) °C.

D.3.2 Fit the neck over the test connector so that the entire length of the neck is engaged.

D.3.3 Apply a tensile load of (40 ± 4) N, at a rate of (50 ± 5) mm/min, at a point not less than 100 mm from the open end of the neck along the linear axis of the neck and maintain the load of (40 ± 4) N for >1 min.

D.3.4 Verify that the neck does not become detached from the test connector.

Annex E
(normative)

Test for security of attachment of *adaptor* of *assembled neck*

E.1 Principle

The security of attachment of the *assembled neck adaptor* to the *anaesthetic reservoir bag* is tested by applying a tensile load along the linear axis of the neck and noting whether the *adaptor* becomes detached from the *anaesthetic reservoir bag*.

E.2 Apparatus

E.2.1 Means of securing the *adaptor*, so that it withstands a tensile load of (40 ± 4) N when applied along the linear axis of the neck for 1 min.

E.2.2 Means of applying the tensile load, of (40 ± 4) N at a rate of (50 ± 5) mm/min along the linear axis of the neck of the *anaesthetic reservoir bag* and maintaining this load for 1 min.

E.3 Procedure

E.3.1 Carry out the test procedure at an ambient temperature of (23 ± 2) °C.

E.3.2 Secure the *adaptor* so that the part incorporated into the neck is not distorted.

E.3.3 Apply a tensile load of (40 ± 4) N, at a rate of (50 ± 5) mm/min at a point not less than 100 mm from the open end of the neck, along the linear axis of the neck and maintain this load for >1 min.

E.3.4 Verify that the *adaptor* does not become detached from the *anaesthetic reservoir bag*.