SLOVENSKI STANDARD
oSIST prEN ISO 5362:2023

01-marec-2023

Anestezijska in dihalna oprema - Dihalni baloni (ISO/DIS 5362:2023)

Anaesthetic and respiratory equipment - Anaesthetic reservoir bags (ISO/DIS 5362:2023)

Anästhesie- und Beatmungsgeräte - Anästhesie-Reservoirbeutel (ISO/DIS 5362:2023)

Matériel d'anesthésie et de réanimation respiratoire - Ballons réservoirs d'anesthésie (ISO/DIS-5362:2023)

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ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

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DRAFT INTERNATIONAL STANDARD

ISO/DIS 5362

ISO/TC **121**/SC **2**

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Anaesthetic and respiratory equipment – Anaesthetic reservoir bags

ICS: 11.040.10

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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 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).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee *121*, *Anaesthetic and respiratory equipment* Subcommittee SC 2, *Airways and related equipment*.

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

The main changes compared to the previous edition are as follows:

- this document has been rewritten to follow the format of ISO 18190 *General requirements for airways and related equipment.* The requirements in this device-specific standard take precedence over any conflicting requirements in the general standard. All common requirements that appear in the General standard have been removed from this document.
- 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.
- neck *adaptors* can be either 22 mm cones or sockets

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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.

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Anaesthetic and respiratory equipment – Anaesthetic reservoir bags

1 Scope

This document specifies requirements for single-use and reusable *anaesthetic reservoir bags* for use with anaesthetic and ventilator breathing systems. It includes requirements for the design of the neck, size designation, elasticity and, where relevant, electrical resistance.

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

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

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

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

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

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

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NOTE: *The defined terms given in 3 are highlighted throughout the text using italic font.*

3.1

adaptor

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

(Source ISO 4135:2021[1] definition 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 4135:2021[1], definition 3.6.1.3 modified by adding “and distensible”)

3.3

assembled neck

neck incorporating an *adaptor* (3.1)

3.4

plain neck

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

3.5

tail

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

4 General requirements

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

5 Materials

5.1 General

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

5.2 Biological 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.5.2.

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.

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6.3 Leakage

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

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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.6.3.

6.4 Necks

6.4.1 *Anaesthetic reservoir bags* shall have either *plain necks* or *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;

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

c) not become detached from 22 mm cone connectors 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.

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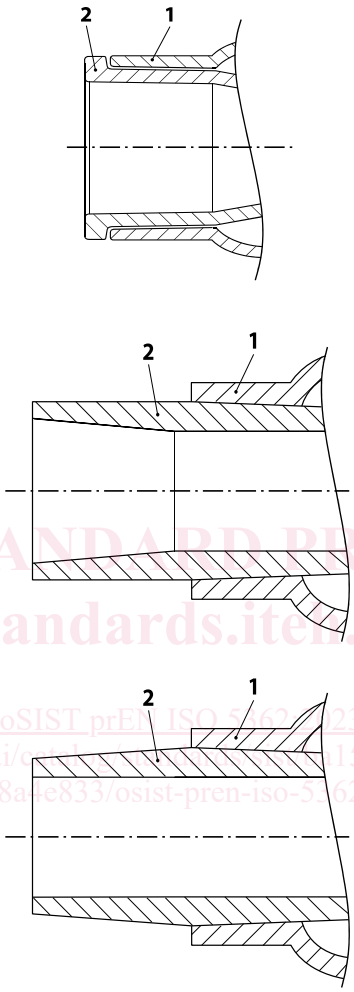
6.4.3 *Assembled necks* of *anaesthetic reservoir bags* shall incorporate an *adaptor* (see Figure 1) bearing either a cone or socket conical connector conforming with ISO 5356-1.

NOTE: Rationale for this requirement is given in A.6.4.3.

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.



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Key

1 neck of *anaesthetic reservoir bag*

2 *adaptor*

Figure 1 — Examples of *assembled necks* with *adaptors*

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 functional testing.

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.

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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 2 x the designated size per minute, for 2 min.

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 be marked with the following:

a) the designated size (see 6.2);

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

NOTE: Rationale for this requirement is given in A.9.2 b).

Check conformance by inspection.

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