Anaesthetic and respiratory equipment - Anaesthetic reservoir bags (ISO 5362:2024)

EESTI STANDARDIMIS- JA AKREDITEERIMISKESKUS
ESTONIAN CENTRE FOR STANDARDISATION AND ACCREDITATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 5362:2024 sisaldab Euroopa standardi EN ISO 5362:2024 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 5362:2024 consists of the English text of the European standard EN ISO 5362:2024.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 31.07.2024.	Date of Availability of the European standard is 31.07.2024.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

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English Version

Anaesthetic and respiratory equipment - Anaesthetic reservoir bags (ISO 5362:2024)

Matériel d'anesthésie et de réanimation respiratoire - Ballons réservoirs d'anesthésie (ISO 5362:2024)

Anästhesie- und Beatmungsgeräte - Anästhesie-Reservoirbeutel (ISO 5362:2024)

This European Standard was approved by CEN on 12 May 2024.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 5362:2024) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2025, and conflicting national standards shall be withdrawn at the latest by January 2025.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 5362:2019.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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Endorsement notice

The text of ISO 5362:2024 has been approved by CEN as EN ISO 5362:2024 without any modification.

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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.

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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For an explanation of 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 www.iso.org/iso/foreword.html.

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”.]