



International

This is a preview of ISO 5362:2024. [Click here to purchase the full version from the ANSI store.](#)

ISO 5362

**Anaesthetic and respiratory
equipment – Anaesthetic
reservoir bags**

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

**Fifth edition
2024-07**

This is a preview of ISO 5362:2024. Click [here](#) to purchase the full version from the ANSI store.



COPYRIGHT PROTECTED DOCUMENT

© ISO 2024

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 General requirements	2
5 Materials	2
5.1 General.....	2
5.2 Biocompatibility evaluation of the breathing gas pathways.....	2
5.3 Material recommendations.....	2
6 Design requirements	2
6.1 General.....	2
6.2 Designated size.....	2
6.3 Leakage.....	2
6.4 Necks.....	3
6.5 <i>Tails</i>	4
6.6 Elastic resistance.....	5
6.7 Elastic recovery.....	5
7 Requirements for <i>anaesthetic reservoir bags</i> supplied sterile	5
8 Packaging	5
9 Information supplied by the manufacturer	6
9.1 General.....	6
9.2 Marking.....	6
Annex A (informative) Rationale	7
Annex B (normative) Leakage test	8
Annex C (normative) Determination of designated size	9
Annex D (normative) Test for security of attachment of <i>plain neck</i> to a 22 mm cone conical connector	10
Annex E (normative) Test for security of attachment of <i>adaptor of assembled neck</i>	11
Annex F (normative) Test for elastic resistance and elastic recovery	12
Annex G (informative) Recommendations for materials	13
Annex H (informative) Hazard identification for risk assessment	14
Bibliography	15

This is a preview of ISO 5362:2024. [Click here to purchase the full version from the ANSI store.](#)

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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.

This is a preview of ISO 5362:2024. [Click here to purchase the full version from the ANSI store.](#)

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](#).