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BSI Standards Publication

Anaesthetic reservoir bags (ISO 5362:2006)

bsi.

National foreword

This British Standard is the UK implementation of EN ISO 5362:2019. It is identical to ISO 5362:2006. It supersedes BS EN 1820:2005+A1:2009, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/121/5, Airways and related equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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English Version

Anaesthetic reservoir bags (ISO 5362:2006)

Ballons réservoirs d'anesthésie (ISO 5362:2006)

Anästhesie-Reservoirbeutel (ISO 5362:2006)

This European Standard was approved by CEN on 28 July 2019.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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European foreword

The text of ISO 5362:2006 has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 5362:2019 by 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of an identical text or by endorsement, at the latest by March 2020, and conflicting national standards shall be withdrawn at the latest by March 2020.

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 1820:2005+A1:2009.

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Endorsement notice

The text of ISO 5362:2006 has been approved by CEN as EN ISO 5362:2019 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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ISO 5362 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Tracheal tubes and other equipment*.

This fourth edition cancels and replaces the third edition (ISO 5362:2000), of which it constitutes a minor revision.

Introduction

This International Standard is one of a series dealing with anaesthetic and respiratory equipment. This International Standard is primarily concerned with the design of the neck, size designation and resistance to pressure required to distend anaesthetic reservoir bags.

The requirement that reservoir bags should be electrically conductive, when used with a flammable anaesthetic, is widely recognized and is of particular importance when such bags are rhythmically compressed by the anaesthetic provider in order to provide intermittent positive-pressure ventilation.

This International Standard gives requirements for both antistatic and non-antistatic bags. Only antistatic bags are suitable for use with flammable anaesthetic agents.

The reference test method given as Annex E is not practical for routine use in manufacturing control, because it involves filling the bag with water. For this reason, another test method using air rather than water has been provided for information in Annex F. This may ultimately be suitable as the reference test method if it can be shown to give results equivalent to Annex E.

A test method for leakage of bags using air rather than water is given as Annex A for information only. Recommendations for materials are given in Annex G.

INTERNATIONAL STANDARD **ISO 5362:2006(E)**

Anaesthetic reservoir bags

1 Scope

This International Standard specifies requirements for antistatic and non-antistatic reservoir bags for use with anaesthetic apparatus or lung-ventilator breathing systems. It includes requirements for the design of the neck, size designation, distension and, where relevant, for electrical resistance.

This International Standard includes requirements for both single-use and reusable bags. Reusable bags are intended to comply with the requirements of this International Standard for the recommended product life.

This International Standard is not applicable to special-purpose bags, for example bellows and self-expanding bags. Bags for use with anaesthetic gas scavenging systems are not considered to be anaesthetic reservoir bags and are thus outside the scope of this International Standard.

2 Normative references

The following referenced documents are indispensable for the application 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 4287, *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Terms, definitions and surface texture parameters*

ISO 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*

EN 556:1994, *Sterilization of medical devices — Requirements for medical devices to be labelled "Sterile"*

EN 980, *Graphical symbols for use in the labelling of medical devices*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
anaesthetic reservoir bag
collapsible gas container which is a component in a breathing system

[ISO 4135:2001, definition 4.1.3]

3.2
assembled neck
neck incorporating an adaptor