

International Standard



5362

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

● Anaesthetic reservoir bags

Ballons réservoirs d'anesthésie

First edition — 1980-11-15

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UDC 615.471 : 616-089.5

Ref. No. ISO 5362-1980 (E)

Descriptors : medical equipment, anaesthesia, pressure tests, resistivity, equipment specifications.

Price based on 2 pages

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards institutes (ISO member bodies). The work of developing International Standards is carried out through ISO technical committees. Every member body interested in a subject for which a technical committee has been set up 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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council.

International Standard ISO 5362 was developed by Technical Committee ISO/TC 121, *Anaesthetic equipment and medical breathing machines*, and was circulated to the member bodies in February 1978.

It has been approved by the member bodies of the following countries :

Australia	Germany, F. R.	New Zealand
Austria	Italy	Romania
Brazil	Japan	South Africa, Rep. of
Canada	Korea, Rep. of	Sweden
Czechoslovakia	Mexico	USA
France	Netherlands	USSR

The member bodies of the following countries expressed disapproval of the document on technical grounds :

India
Ireland

Anaesthetic reservoir bags

0 Introduction

This International Standard is one of a series dealing with anaesthetic equipment and medical breathing machines and is supplementary to ISO 5356. This International Standard is primarily concerned with the design of the neck, size designation and compliance of anaesthetic reservoir bags.

The requirement that reservoir bags should be electrically conductive when used with flammable anaesthetic is widely recognized, and is of particular importance when such bags are rhythmically compressed by the anaesthetist in order to provide intermittent positive pressure respiration. Little is known about the extent of any possible fire or electrical hazards associated with the use of electrically conductive bags. While such bags reduce explosion hazards due to the generation of static electricity, they may give rise to other electrical hazards.

While it remains desirable to use conductive bags in normal anaesthetic practice, the widespread use of non-flammable anaesthetics, the development of new materials which might be used for disposable (single use) bags and an appreciation of the possible hazards referred to above, have together created a new situation. Therefore, to avoid restricting the development of new products it was considered undesirable to exclude non-anti-static (non-conductive) bags from this International Standard. However, such non-conductive bags should NEVER be used in the presence of flammable vapours.

1 Scope and field of application

This International Standard specifies requirements for reservoir bags for use with anaesthetic or breathing apparatus. It is concerned with the design of the neck, size designation, compliance and, where relevant, requirements for electrical conductivity.

Special purpose bags, for example bellows and self-expanding bags, are excluded from the scope of this International Standard.

2 References

ISO 2878, *Rubber, vulcanized — Antistatic and conductive products — Determination of electrical resistance.*

ISO 2882, *Rubber, vulcanized — Antistatic and conductive products for hospital use — Electrical resistance limits.*

ISO 5356, *Breathing attachments for anaesthetic apparatus —*

*Part 1 : Conical fittings and adaptors.*¹⁾

*Part 2 : Screw threaded weight bearing fittings.*¹⁾

IEC Publication 601-1, *Safety of medical electrical equipment — Part 1 : General requirements.*

3 Definition

anaesthetic reservoir bag : Collapsible container from which the patient may draw his tidal volume.

4 Material

4.1 The bag shall be made of suitable material which shall be reasonably resistant to anaesthetic agents.

4.2 Unless designated as disposable (for single use), the bag shall be reasonably resistant to deterioration by methods of cleaning, disinfection and sterilization as recommended by the manufacturer or the supplier. It is desirable that such products should withstand accepted methods of steam sterilization.

4.3 The sheeting forming the body of the bag shall be pliable and remain reasonably distensible when the bag is inflated to its nominal capacity. The bag shall be free from pinholes and imperfections which may affect serviceability and safety in use.

5 Size designation

The size of the bag shall be designated by the nominal capacity expressed in litres.

6 Preferred sizes

It is recommended that the range of preferred sizes should be 0,5 — 1 — 1,5 — 2 — 3 and 5 litres.

1) At present at the stage of draft.