International Standard 5362

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Anaesthetic reservoir bags

Ballons réservoirs d'anesthésie

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Foreword

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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

Printed in Switzerland

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.

7 Capacity

The capacity of the bag shall be subject to a tolerance of ± 15 % of the nominal capacity when tested as follows :

Place the bag in a tank of water, the lower opening of the bag, if present, being sealed. Whilst held vertically, fill the bag with water with the top rim of the opening held 25 mm above the surface of the water in the tank. Then measure the volume of water contained in the bag.

8 Neck

8.1 Neck for connecting to conical fittings of 22 mm size

The bag shall be adequately reinforced at the neck and shall be constructed to give a satisfactory fit on male conical fittings of 22 mm size in accordance with ISO 5356/1.

The axial length of the neck of bags designed to fit 22 mm male conical fittings shall be not less than 25 mm, and not more than 35 mm.

8.2 Neck designed for use with breathing attachments of 15 mm size

The bag shall be adequately reinforced at the neck and shall be constructed to give a satisfactory fit on male conical fittings of 15 mm size in accordance with ISO 5356/1.

Alternatively, the bag shall have a plain (unreinforced) neck suitable for mounting on an adaptor of which the cylindrical portion has a diameter of 18 mm and an axial length of approximately 18 mm in accordance with ISO 5356/1.

8.3 Neck reinforcement

Any reinforcement at the neck of the bag involving the use of separate components shall provide continuous secure attachment under conditions of normal use, as for example, when the bag is used for manual intermittent positive pressure ventilation.

8.4 Neck design

The body and neck shall be designed and assembled in such a way that they may not effect a valve-like action under normal conditions for use.

9 Pressure-volume test

Under the conditions described below, the pressure head of water shall be not less than 30 cmH_2O and at any time during the test shall not exceed 50 cmH_2O. After this test the bag shall revert to its original capacity within a tolerance of $^{+10}_{0}$ % on the actual capacity.

Place the bag in a tank of water, the lower opening of the bag, if present, being sealed. Whilst held vertically, fill the bag with water with the top rim of the opening held 25 mm above the surface of the water in the tank. Connect to the neck of the bag a bung of appropriate size through which a tube of not less than 10 mm bore is inserted, and of sufficient length to give a pressure head of 50 cmH_2O. Add water by means of a funnel through the tube connected to the bag in order for the volume of water to correspond to four times the nominal capacity of the bag. Determine the pressure head.

The test shall be conducted over a period not exceeding 5 min with water at a temperature of 20 ± 3 °C.

NOTES

1 The electrical conductivity of a bag which has undergone this test may be reduced, and may result in failure to meet requirements of the appropriate electrical resistance tests.

2 Further consideration may be given to the compliance of bags made of materials showing marked changes of extensibility with temperature.

10 Electrical conductivity

The electrical characteristics of bags made of electrically conductive material for use with flammable anaesthetic agents shall be specified and tested in accordance with ISO 2878 and ISO 2882 respectively, or with the requirements of the appropriate national authorities.

11 Marking

The marking shall be legible and durable and shall include the following :

a) the mark or code indicating the manufacturer and, if desired, the name or trade mark of the supplier;

b) the nomical capacity (see clauses 5 and 7);

c) anaesthetic reservoir bags made of conductive material shall be marked in accordance with IEC Publication 601-1;

d) anaesthetic reservoir bags made of conductive material shall be coloured black, and those made of non-conductive material shall be of any colour except black.

NOTE — It is recommended that reservoir bags should be additionally marked with the date (month and year) of manufacture.