

Specification for

Suction catheters for use in the respiratory tract

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Committees responsible for this British Standard

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- Association of Anaesthetists of Great Britain and Ireland
- Association of British Health Care Industries
- Association of Veterinary Anaesthetists of Great Britain and Ireland
- British Anaesthetic and Respiratory Equipment Manufacturers' Association
- British Association of Otolaryngologists
- British Paediatric Association
- British Rubber Manufacturers' Association
- British Surgical Trades Association
- Department of Health
- Medical Sterile Products Association

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National foreword

This British Standard has been prepared under the direction of the Health Care Standards Policy Committee and is identical with ISO 8836:1988 "*Suction catheters for use in the respiratory tract*", prepared by Technical Committee 121, Anaesthetic and respiratory equipment, of the International Organization for Standardization (ISO).

The International Standard ISO 8836 also included the following introduction. Suction catheters are commonly inserted through tracheal and tracheostomy tubes (see ISO 5361-1, ISO 5361-2, ISO 5361-3, ISO 5361-4, ISO 5366-2 and ISO 7228).

The need for this International Standard arises from the considerable international trade in suction catheters; at the same time there is a need to provide a range of sizes which will prove acceptable for clinical purposes.

Annex A gives recommendations for materials and Annex B gives recommendations for the finish and design of catheters. A bibliography listing those International Standards referred to for information is given in Annex C.

Cross-references. The Technical Committee has reviewed the provisions of ISO 468:1982, to which reference is made in the text, and has decided that they are acceptable for use in conjunction with this standard. ISO 468:1982 is related to BS 1134 "*Assessment of surface texture*" Part 1:1988 "*Methods and instrumentation*".

The reference in the introduction and/or Annex C to ISO 4135:1979, ISO 5361-1:1988, ISO 5361-2:1984, ISO 5361-3:1984, ISO 5361-4:1987, ISO 5366-2:1985 and ISO 7228:1985 are given for information only.

In clauses 9.1 and 9.2, reference is made to the possibility of marking unit containers and outer packages with symbol No. 1051 given in ISO 7000. This symbol, which is described in draft Addendum No. 1 to ISO 7000, has yet to be incorporated into a revision of the 1984 edition of ISO 7000 and details of it are given for information in National appendix Z.

Additional information. Annex A to this standard details an implantation test taken from the US Pharmacopoeia. The test is widely recognized internationally and is included in ISO 8836 as there is no International Standard for assessing biocompatibility of medical devices. However, in the UK it is common practice to assess the biological hazard of medical devices by the principles and methods given in BS 5736 "*Evaluation of medical devices for biological hazards*". For all practical purposes the implantation test given in Annex A may be taken as being equivalent to the test described in BS 5736-2 "*Method of testing by tissue implantation*", which also includes additional guidance, in particular regarding the assessment of results.

In Annex A reference is also made to the possible use of a cell tissue culture test. Attention is drawn to the method given in BS 5736 "*Evaluation of medical devices for biological hazards*" Part 10 "*Method of test for toxicity to cells in culture of extracts from medical devices*".

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 10, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

1 Scope

This International Standard specifies requirements for suction catheters intended for use in suction of the respiratory tract. It covers suction catheters that are supplied either sterile or non-sterile and those that are intended either for single use or to be reused.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards. ISO 468:1982, *Surface roughness — Parameters, their values and general rules for specifying requirements*.

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 adaptor¹⁾

specialized connector to establish functional continuity between otherwise disparate or incompatible components

3.2 connector¹⁾

fitting to join together two or more components

3.3 effective length

length of the shaft

3.4 eye

aperture in the patient end of the catheter

3.5 machine end

that end of the catheter which is intended to be connected to a source of vacuum

NOTE It may either incorporate a connector or have a conical expansion to facilitate the insertion of a connector.

3.6 patient end

that end of the catheter which is intended to be inserted into the patient

3.7 shaft

that part of a suction catheter between the connector or conical expansion at the machine end and the tip

3.8 suction catheter

flexible tube designed for introduction into the respiratory tract to remove material by suction

3.9 tip

extremity of the patient end

3.10 vacuum control device

means provided at the machine end of the catheter to control the flow of air and entrained material

4 Dimensions and size designation

4.1 Dimensions

The outside diameter and the minimum inside diameter of suction catheters shall be as given in Table 1 or Table 2, as appropriate.

NOTE For the purposes of this International Standard, the Charrière gauge system of size is based on the outside diameter of the shaft gauged in steps of thirds of a millimetre; the Charrière gauge size is not an SI unit. It is anticipated that the use of suction catheters manufactured in Charrière sizes will decline in the future and the use of metric size catheters will become prevalent. It is therefore intended to revise this International Standard five years after its publication to delete reference to the Charrière gauge sizes.

4.2 Size designation

The size of suction catheters shall be designated by the following characteristics:

- a) the outside diameter of the shaft, expressed in millimetres;
- b) the nominal effective length, expressed in millimetres, with a tolerance of $\pm 5\%$.

The size shall be expressed according to the following designation example:

6 mm (18 F) × 500 mm

or

6 mm (18 Ch) × 500 mm

NOTE For recommendations regarding the appropriate size of suction catheter, attention is drawn to the following article: ROSEN, M. and HILLARD, E.K., The use of suction in clinical medicine, *Br. J. Anaesth.*, **32**, 1960: pp. 486–504.

¹⁾ Definitions taken from ISO 4135.