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BREATHING ATTACHMENTS FOR ANAESTHETIC PURPOSES FOR HUMAN USE



STANDARDS ASSOCIATION OF AUSTRALIA

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Australian and New Zealand Intensive Care Society
Australian Chamber of Commerce
Australian Society of Anaesthetists
Confederation of Australian Industry
Metal Trades Industry Association of Australia
Royal Australasian College of Surgeons
State Departments of Health

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PREFACE

This standard was prepared by the Association's Committee on Anaesthetic Equipment and Medical Breathing Machines. It supersedes AS T37—1966, Breathing Attachments for Anaesthetic Apparatus.

The standard relies heavily on work done in this area by BSI* and ISO/TC 121/SC 1† on specifications for breathing attachments for anaesthetic apparatus. Among a number of differences from ISO practice, this standard specifies the connection port for the reservoir bag on a circle absorber unit as female.

Although this standard specifies requirements for breathing attachments, it alone cannot ensure the satisfactory gas-tight seal required for safe anaesthesia, as the circuit is constructed of a variety of components outside the scope of this standard. It is therefore strongly recommended that all anaesthetic circuits should be pressure tested before use. A satisfactory result requires a leak of less than 1 L/min with a pressure of 4 kPa. A low pressure gauge with 22 mm conical tapers has been incorporated in circuits in Fig. B1(a) to illustrate this.

The standard describes two methods to reduce the risk of incorrect connection of circle system hoses, one by the use of male/female taper connections and the other by the use of colour coding.

The physical characteristics of plastics materials pose particular problems in that the dimensions of fittings may have to vary slightly from those specified for the metal components in order to make a satisfactory fit. A gauging test for conical fittings made of plastics materials is therefore included in this standard.

Several components of breathing systems, e.g. carbon dioxide absorbers and Ayres T-pieces, have a side arm to receive anaesthetic gases from the common gas outlet of an anaesthetic machine or other gas source. The dimensional requirements of these 'fresh gas inlets' are therefore also specified in this standard.

Provision is made for the 23 mm conical fittings for vaporizers which are *unsuitable* for use in the breathing system. Usually such vaporizers impose a high resistance.

This standard may require reference to the following standards:

AS 1721	General Purpose Metric Screw Threads
AS K185	Colours for Specific Purposes
BS 2050	Electrical Resistance of Conducting and Antistatic Products made from Flexible Polymeric Material.

*British Standards Institution.

†International Organization for Standardization.

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STANDARDS ASSOCIATION OF AUSTRALIA**Australian Standard
for
BREATHING ATTACHMENTS FOR ANAESTHETIC PURPOSES FOR HUMAN USE****FOREWORD**

In anaesthetic practice several components must be joined together to provide a suitable breathing system. The connections are usually cone and socket joints, and have been made in a variety of sizes. The lack of standardization has frequently given rise to problems in connecting equipment made by different manufacturers.

The aim of this standard is to provide ready interchangeability, particularly in time of emergency. Only two sizes of conical fitting (nominal 22 mm and 15 mm) have therefore been specified for general use. Apparatus for the administration of anaesthetics to small children should have the smaller size of conical fittings throughout, except for the face-mask connection. No attempt has been made to introduce standardization of design except in so far as size and sequence of joint fittings are concerned, but wherever possible the practice of fitting elastomeric components over rigid (male) fittings is recommended.

It should be noted that the standard does not automatically obviate the possibility that some flow-direction-sensitive components may be misconnected, and it is stressed that the avoidance of this hazard must remain the responsibility of the user. Appendix B illustrates some widely used systems where cone and socket joints are employed.

With respect to the choice of materials, it was considered that encouragement should be given to the development of both design and materials having, in particular, freedom from deformation under practical working conditions of use and at the same time being light in weight. In recognition of the possibilities in the development of new materials, a guide to these properties has been incorporated in Clause 4.

It is recognized that the reservoir bag connection to the circle has been a serious cause of misconnection and disconnection. The use of a female 22 mm port exclusively here for breathing tubes may, in obviating

misconnection, increase the rate for disconnection. Provision has been made for a retention fitting, unspecified except that it shall be non-obtrusive and compatible with the standard 22 mm fitting. While conical fittings are satisfactory for light weight components, the need for more substantial fittings to support heavy or fragile components is met by the screw-threaded, weight-bearing connectors.

Factors governing the design of these connections include that they be robust, simple, readily sterilizable, and easy to engage and disengage by hand. Further, they should, as far as practicable, be compatible with the other requirements of this standard and they should reduce the likelihood of disconnection and inadvertent misconnection. Nevertheless, it remains the responsibility of the user to check that the system is correctly and securely assembled.

It is recognized that single-use total anaesthetic circuits are in use. Components within such total circuits should not be compatible with fittings described in this standard. However, the patient connection port and connection to the common gas outlet should be as described in this standard.

Coloured corrugated tubing may be used as part of the breathing attachments in accordance with this standard (see Clause 10.4). This type of tubing is now in common use and is satisfactory for use with non-flammable anaesthetic agents. The use of flammable anaesthetic agents in Australia is now less than 0.5 percent of all anaesthetics administered. It is for this reason that this standard allows the use of corrugated tubing which is coloured. It is usually not suitable for use with flammable anaesthetic agents, but has the advantage that it is of light weight and readily identifiable as correctly assembled into the patient circuit. Unless this coloured corrugated tubing is conductive, it must not be used with flammable anaesthetic agents.

SPECIFICATION

1 SCOPE. This standard specifies basic requirements for breathing attachments for anaesthetic apparatus, including the sequence and dimensions of cone and socket joints (conical fittings) of 15 mm and 22 mm sizes used for adult and paediatric purposes.

A conical fitting of 30 mm size is specified for use with outlets suitable for attachment of a spirometer. A 23 mm conical fitting is specified for vaporizers and manifold attachments outside the breathing system. The basic requirements for fresh gas inlets to components of breathing systems are also specified.

The standard also deals with dimensions and form of screw-threaded, weight-bearing connections for use with attachments for anaesthetic apparatus and ventilators.

2 APPLICATION. The 15 mm and 22 mm cones are intended primarily for use with breathing attachments. The 23 mm and 30 mm cones are intended for other applications which are not within the breathing circuit. Screw-threaded, weight-bearing connections may be used to produce a more permanent connection between components than that provided by the cone and socket joint.

They are particularly designed to allow heavy components to be safely mounted at the outlet from an anaesthetic or breathing machine to the inlet of a breathing system.

3 DEFINITIONS. For the purpose of this standard, the following definitions apply:

3.1 Inhalation anaesthesia apparatus (includes gas machine and anaesthetic machine)—equipment intended for dispensing and delivering gases and vapours used in anaesthetic practice into a breathing system.

3.2 Breathing attachments—components intended to make up or complete a breathing system.

3.3 Common gas outlet—that port through which the dispensed mixture from the anaesthetic apparatus is delivered to the breathing system.

NOTE: Definitions given in Clauses 3.1 and 3.3 are related to function. In structural terms the gas outlet port will be known by the component of which it is a part, e.g. vaporizer outlet, machine outlet, cabinet outlet.

3.4 Breathing system—gas pathways in direct connection with the patient through which intermittent or reciprocating gas flow occurs and into which a mixture of controlled composition may be dispensed.

3.5 Inspiratory port (of a circle absorber or ventilator)—that opening through which gases and/or vapours may pass during inspiration.

3.6 Expiratory port (of a circle absorber or ventilator)—that opening through which gases and/or vapours may pass during expiration.

3.7 Patient-connection port—that opening of any component at the patient end of a breathing system to which an endotracheal connector or a face mask is normally attached.

3.8 Adaptor (for reservoir bag or corrugated tubing)—component to one end of which corrugated

tubing or the neck of a reservoir bag may be semi-permanently attached, the other end being a male or female conical fitting, as required.

3.9 Flow-direction-sensitive component—component through which the gas flow is in one specified direction only for its proper functioning and/or patient safety.

3.10 Non-rebreathing valve—valve which prevents the inspiration of any expired gas.

3.11 Fresh gas inlet connector—that part on the breathing system to which the fresh gas supply tube is attached. This inlet may be a nipple over which elastomeric tubing is attached or a screw-threaded fitting.

3.12 Fresh gas supply tube—elastomeric flexible tube conveying gases from the common gas outlet of the anaesthetic machine or other gas source to the fresh gas inlet of the breathing system.

4 MATERIALS FOR RIGID COMPONENTS FOR BREATHING ATTACHMENTS. Rigid components for breathing attachments shall be made of materials complying with the following requirements under clinical conditions:

- (a) *Resistance to deformation and to wear.* Components should be resistant to wear in relation to the intended purpose. Under normal conditions of use, materials used shall not permanently deform.
- (b) *Weight.* Lightness is particularly desirable in components used in association with tracheal tubes and tracheostomy tubes.
- (c) *Freedom from cold welding characteristics.* Components shall be capable of ready disconnection under all circumstances. Certain materials have been shown to exhibit the phenomenon known as 'cold welding' and their use shall be avoided.
- (d) *Corrosion resistance.* Components shall be resistant to corrosion or other deleterious effects caused by anaesthetic vapours and gases, disinfectants and other agents likely to be employed under conditions of normal use. Resistance to carbon dioxide absorbents, e.g. soda-lime, is important in the case of the canister and related fittings.
- (e) *Freedom from risk of self-ignition or incendive sparking.* Materials liable to the emission of pyrophoric particles shall not be used.
- (f) *Type of material for fittings.* Male conical fittings should be of rigid material, but female sockets may be made either of elastomeric or rigid material.

5 ELECTRICAL CONDUCTIVITY. With the exception of tracheal tubes and tracheal tube connectors, non-metallic components designated for use with flammable anaesthetics shall be specified, tested and marked in accordance with BS 2050.

6 STERILIZATION. Unless designated as disposable, components of breathing attachments shall resist deterioration by methods of cleaning, disinfection and sterilization as recommended by the