

Australian/New Zealand Standard

Breathing attachments for anaesthetic purposes for human use

AS/NZS 2496:1995

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Breathing attachments for anaesthetic purposes for human use

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HT/7 on Anaesthetic Equipment and Medical Breathing Machines, to supersede AS 2496—1981.

In the preparation of this Standard, account was taken of ISO 5356-1, *Anaesthetic and respiratory equipment—Conical connectors—Part 1: Cones and sockets*, and ISO 5356-2, *Anaesthetic and respiratory equipment—Conical connectors—Part 2: Screw-threaded weight bearing connectors*.

The objective of this Standard is to provide users of breathing attachments with fittings that are non-interchangeable and less prone to misconnection and disconnection.

The Standard differs from ISO 5356-1 and ISO 5356-2 in that the reservoir bag connection is a male fitting at the machine end in contrast to the ISO Standards which specify a female fitting. This change has been instituted to minimize mis-connection with the breathing system. In addition, this Standard specifies colour coding for hoses in the breathing system, and a connection sequence for scavenging.

The principal differences between the 1981 edition of AS 2496 and this edition are as follows:

- (a) Requirements are given for 19 mm connectors.
- (b) Fittings and sequence for scavenging are specified.

The terms 'normative' and 'informative' have been used in this Standard to define the application of the appendix to which they apply. A 'normative' appendix is an integral part of a Standard, whereas an 'informative' appendix is only for information and guidance.

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STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Australian/New Zealand Standard**Breathing attachments for anaesthetic purposes for human use**

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, 19 mm, 22 mm, 23 mm and 30 mm sizes, used for adult and paediatric purposes.

A conical fitting of 30 mm size is specified for scavenging. 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.

The 15 mm and 22 mm cones are intended primarily for use with breathing attachments. The 19 mm, 23 mm and 30 mm cones are intended for other applications which are not within the breathing system.

22 mm 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.

2 REFERENCED DOCUMENTS The following documents are referred to in this Standard:

AS

1721 General purpose metric screw threads

2700 Colour standards for general purposes

4187 Code of practice for the cleaning, disinfecting and sterilizing of reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities.

BS

2050 Specification for electrical resistance of conducting and antistatic products made from flexible polymeric material

3 DEFINITIONS For the purpose of this Standard the definitions below apply.

3.1 Adjustable pressure limiting (APL) valve—a non-return valve system to allow the controlled release of gas from the breathing system by a variable pressure setting.

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

3.3 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.

3.4 Connector—fitting to join together two or more components.

NOTE: A specialized connector to establish functional continuity between otherwise disparate or incompatible components should be referred to as an adaptor.

3.5 Elastomeric—the tendency for any polymer to show rubber-like properties in varying degrees.

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

3.7 Flow-direction-sensitive component—component through which the gas flow is in one specified direction only for its proper functioning or patient safety (or both).

3.8 Fresh (common) gas outlet—that port through which the dispensed mixture from the anaesthetic apparatus is delivered to the breathing system.

NOTE: The definition given in Clause 3.8 is related to function. In structural terms, the gas outlet port may be known by the component of which it is a part, e.g. vaporizer outlet, machine outlet, cabinet outlet.

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

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

3.11 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.

NOTE: The definition given in Clause 3.11 is 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.

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

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

3.14 Patient connection port—that opening at the patient end of a breathing system.

3.15 Receiving system—that part of the anaesthetic gas scavenging system which provides an interface between a transfer system and a disposal system.

3.16 Reservoir bag port—opening to which a reservoir bag is attached, e.g. in a circle or in a partial rebreathing system.

3.17 Transfer system—the part of an anaesthetic gas scavenging system which transfers expired or excess anaesthetic gases (or both) from the exhaust port of a breathing system to a receiving 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* Under normal conditions of use, materials used shall not permanently deform.

NOTE: Components should be resistant to wear in relation to the intended purpose.

- (b) *Mass* The components shall be as light as possible.

NOTE: 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. The use of certain materials shown to exhibit the phenomenon known as ‘cold welding’ 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.

NOTE: 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*

NOTE: Male conical fittings should be of rigid or semi-rigid material. Female sockets may be made either of elastomeric, rigid or semi-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 intended to be for single use only, the reusable components of the breathing system, including the absorber and valves, shall be capable of being disassembled as required for cleaning and sterilization. The manufacturer shall recommend suitable methods for cleaning and sterilization. The reusable components of the breathing system shall be sterilizable. Sterilization shall be in accordance with AS 4187.

7 CONICAL FITTINGS MADE OF RIGID MATERIAL

7.1 Rigid conical fittings of 15 mm size Conical fittings of 15 mm size made of rigid material shall conform to Figure 1. The internal diameter of the conical element of the 15 mm fitting shall be not less than 11 mm.

7.2 Rigid conical fittings of 19 mm size Conical fittings of 19 mm size made of rigid material shall conform to Figure 2.

7.3 Rigid conical fittings of 22 mm size Conical fittings of 22 mm size made of rigid material, with or without a recess in the male component, shall conform to Figure 3(a) or 3(b), as appropriate. Unless the fitting is coaxial, i.e. 22 mm male and 15 mm female, the internal diameter of the fitting shall be not less than 18 mm. Male conical fittings, with the exception of that for connecting the face mask, should incorporate the recess in accordance with Figure 3(a).

NOTE: The recess is intended to allow for devices to improve the security of the attachment of the socket to the male conical fitting.

The design of male conical fittings to which a face mask may be attached should incorporate a shoulder or equivalent construction in accordance with Figure 3(b) to prevent penetration into the socket by more than 21.0 mm.

NOTE: It is recommended that the design permits the fitting of a device to ensure the secure attachment of tracheal connectors and adaptors, if so desired.

A groove or grooves may be incorporated in the mating surface of the male conical fitting to which an elastomeric socket is attached, provided that the total width of the groove or grooves at the surface of the cone does not exceed 6.0 mm and that a secure fit is provided with the female socket in accordance with Clause 10.

7.4 Rigid conical fittings of 23 mm size Conical fittings of 23 mm size made of rigid material shall conform to Figure 4.

7.5 Rigid conical fittings of 30 mm size Conical fittings of 30 mm size made of rigid material shall conform to Figure 5.

8 CONICAL FITTINGS MADE OF SEMI-RIGID PLASTICS MATERIAL EXCLUDING ELASTOMERS Cones and sockets made of semi-rigid plastics material, e.g. polyamide* polyacetal, polycarbonate, polyethylene, and excluding elastomers (see Clause 9), shall give a gastight and otherwise satisfactory fit with conical fittings of opposite gender in accordance with Clauses 7 and 9, and shall conform to the appropriate internal dimension given in Clause 7.

Such conical fittings may have their dimensions varied from those given in Figures 1 and 2, provided that, when the connector is engaged in the appropriate plug or ring gauge, shown in Figures 6 and 7, by applying an axial force of $35 \pm 3.5\text{N}$ for 15 mm connectors and $50 \pm 5\text{N}$ for 22 mm connectors, and, while maintaining the same force, rotating the connector by up to 20° , its leading edge shall lie between the minimum and maximum diameter steps of the gauge. The connectors and gauges shall be maintained at a temperature of $20 \pm 3^\circ\text{C}$ during this test.

NOTE: A disengagement test for conical connectors made of materials other than metal is currently being prepared.

9 SOCKETS MADE OF ELASTOMERIC MATERIAL Sockets made of elastomeric material shall give a satisfactory fit with a male metal conical fitting in accordance with Clause 8, as appropriate.

10 CONNECTIONS FOR RESERVOIR BAG PORT, RESERVOIR BAG AND CORRUGATED TUBING

10.1 General characteristics The connection port for a reservoir bag shall be clearly identified and, if a conical fitting, shall be a 22 mm female socket, other than the Jackson-Rees modification of the Ayres T-piece breathing system.† The connection port for a reservoir bag shall be positioned so as to minimize the risk of confusion with the inspiratory and expiratory ports.

The only conical vertical axis port shall be that for the reservoir bag. Provision should be made for a retention fitting.

10.2 Retention fitting Circle absorption systems using a reservoir bag and connecting hose should incorporate a retention fitting. The retention fitting shall not prevent the connection of a 22 mm male conical fitting, specified in Clause 7.3, to the reservoir bag port and a retention male fitting shall fit a female 22 mm cone. All 22 mm fittings with retention devices shall mate satisfactorily with the plug and ring gauges when the gauges are surface mounted (see Figure 7).

10.3 Reservoir bag tubing If a corrugated or other breathing tube is used to connect the reservoir bag, its machine-end fitting shall be male. A retention device may be fitted. Where it is intended to use this tubing to connect the patient to a ventilator, the bag end shall be female unless it is designed to have a permanently attached bag.

An intermediary adaptor which is intended for semi-permanent attachment to an elastomeric component shall, for this purpose, have at one end a nominal diameter of 25 mm (for adult use) or 18 mm (for paediatric use), as appropriate, and this end may be grooved or flanged. The other end of the adaptor shall be fitted with a female conical fitting (see Clause 7).

NOTE: Elastomeric components which have been stretched to fit such adaptors may not therefore give a satisfactory fit to a male conical fitting.

* For example, nylon

† See also Appendix B, Figure B2

10.4 Colour coding Unless it is antistatic, a tube used to connect the reservoir bag shall be light blue in colour (Colour B41 (or similar) as specified in AS 2700). The colour shall appear along the length of the tube or at its ends. If at the ends, at least 50 mm of the length of the tube shall be coloured light blue.

Unless it is antistatic and if colour coding is used, the inspiratory and expiratory hoses of the breathing system shall be colour coded white/clear.

Where a tube is used for scavenging purposes, unless it is antistatic, it shall be colour coded red (Munsell 10P hue/4/10 (or similar) as specified in AS 2700).

11 SIZE AND SEQUENCE OF CONICAL FITTINGS FOR ADULT USE

11.1 Breathing system connections

11.1.1 General Attachments for use within the breathing system should have a 22 mm male/15 mm female coaxial fitting preferably with screw-threaded, weight-bearing fittings. The inspiratory and expiratory ports shall be marked with arrows to indicate the direction of gas flow.

Appendix A gives a summary of size and sequence of fittings for breathing attachments for use with adults.

11.1.2 Patient-connection port The patient-connection port shall have a male 22 mm/15 mm female coaxial conical fitting.

11.2 Face mask fitting The face mask shall have a female 22 mm conical fitting in accordance with Clauses 7, 8 or 9, as appropriate. The face mask socket shall make a satisfactory fit with the male conical fitting in accordance with Figure 2(a).

11.3 Tracheal tube connectors Tracheal tube connectors (see Appendix B, Figure B1) with conical fittings shall have a female 22 mm conical fitting or alternatively a male 15 mm conical fitting in accordance with Clauses 7, 8 or 9. The conical element of such connectors shall have an internal diameter of not less than 11 mm.

Tracheal tube connectors with a female 22 mm conical fitting shall have an internal diameter of not less than 11 mm throughout.

11.4 Fittings for flow-direction-sensitive components

NOTE: Appendix B gives information on some widely used systems incorporating flow-direction-sensitive components.

11.4.1 General The fittings for flow-direction-sensitive components within the breathing system shall have 22 mm inlet and outlet ports as specified in Clause 7.2. The inlet and outlet ports should be so marked. The direction of gas flow shall be indicated by an arrow.

NOTE: The safe and correct function of certain components is dependent on the direction of the gas flow through them. Their safe use, however, in the circuits illustrated in Figure B1 cannot be ensured by this Standard, in that inadvertent misconnection of such components may occur. Recognition of this fact has led to the compilation of Appendix B and to the formulation of the following Clauses (Clauses 11.4.2 to 11.5) which, however, offer only a partial solution to the problems involved.

11.4.2 Security of fittings To enhance the security of patient connection and reduce the risk of misconnection, the breathing hoses of a circle system should be directly connected to the patient Y-piece, and may be permanently bonded. Taper and tubing connections should fit sufficiently firmly to avoid accidental disconnection.

Any flow-direction-sensitive component shall be secured by a non-reversible fitting. This fitting should be a screw-threaded, weight-bearing connection.

11.4.3 Assurance of mating fits To ensure that a female screw-threaded fitting cannot be connected to a male conical fitting on the absorber or ventilator expiratory port, a mechanical obstruction at the base of the male conical fitting at this point shall be provided to interfere with the rim of the nut of the female fitting. (If a plane surface is provided, it shall be of at least 35 mm diameter.) Where only conical fittings are used, care shall be taken to ensure that the component is fitted in the correct limb of the breathing system.

11.4.4 Unidirectional valves Where the unidirectional valves on a circle absorber system are capable of being detached from an absorber unit which is direction-sensitive, the method of attachment to the latter shall be by means of fittings which are non-interchangeable. Where a screw-threaded, weight-bearing fitting is required on the patient side of such a valve, it shall be in accordance with Clause 16.

11.4.5 Non-rebreathing valve When a non-rebreathing valve has more than two connection ports, those other than the gas inlet and the outlet to the patient shall **not** be of the 22 mm or 15 mm sizes of conical fittings. A conical fitting intended for scavenging shall be a 30 mm male fitting.

NOTE: The implications of these requirements for the size and sequence of fittings are summarized in Appendices A and B. Typical layouts of breathing attachments for use with adults are illustrated in Figure B1.

11.5 Inspiratory and expiratory ports The inspiratory and expiratory ports shall have male 22 mm conical fittings. The inspiratory port should incorporate a 15 mm female fitting coaxially. The expiratory port shall not incorporate a coaxial 15 mm female conical fitting.

12 FITTINGS CONNECTING ANAESTHETIC VENTILATOR, PATIENT AND HUMIDIFIER

12.1 General This Clause applies to equipment where the anaesthetic functions, e.g. dispensing or control of the gas direction in the adult patient circuit, are integrated in the ventilator.

12.2 22 mm fitting Conical fittings of nominal 22 mm size in accordance with Clause 7.3 shall be used except where the conditions of Clause 12.3 apply.

Where the inspiratory/expiratory valve mechanism is integral with the ventilator, all connectors leading from the ventilator to the patient shall be 22 mm.

The patient connection port shall be a male 22 mm/female 15 mm coaxial fitting, in accordance with Clause 7 or Clause 8, as appropriate.

12.3 Connections other than 15 mm, 19 mm, 22 mm, 23 mm and 30 mm, sizes ('non-standard' connections) Where the inspiratory/expiratory valve mechanism is part of, but removable from, the ventilator, it shall be considered part of the ventilator and shall be 'non-standard'. 'Non-standard' connections shall be chosen so as to minimize the risk of incorrect assembly of the components. The connection between the 'non-standard' inspiratory/expiratory valve mechanism and the patient shall be a 22 mm fitting in accordance with Clause 11.4.1. The patient side of the connection may also incorporate a female 15 mm fitting to make a male 22 mm/female 15 mm coaxial fitting.

Tubes attached to a humidifier which do not form part of the breathing system shall not be connected by the 15 mm, 19 mm, 22 mm, 23 mm or 30 mm conical fittings specified in Clause 7.

Where components are required to function as a single unit and are flow-sensitive, a 'non-standard' connection should be used.

13 SCAVENGING CONNECTIONS

13.1 Connecting tubing The connecting tubing should be translucent or transparent. The colour of tubing for scavenging purposes shall be as specified in Clause 10.4.