

Australian/New Zealand Standard[®]

**Anaesthetic machines—
Non-electrical—For use with
humans**

[Based on ISO 5358:1992 Anaesthetic machines for use with humans]

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Australian Society of Anaesthetists
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Anaesthetic machines— Non-electrical—For use with humans

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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 4059—1992.

The Standard is based on ISO 5358, *Anaesthetic machines for use with humans*. However, some of the requirements of that publication have been modified to take account of local conditions and use.

The objective of this Standard is to ensure that the performance and safety of non-electrical anaesthetic machines are taken into consideration in their design.

This Standard does not consider anaesthetic scavenging, as frequently, the characteristics for the scavenging are determined by features of the ventilator, the adjustable pressure relief valve and the suction system, rather than any specification of the anaesthetic machine mentioned in this Standard.

The Committee considered the need for a requirement for vaporizers which could be detached from an anaesthetic machine and which might have an increased vapour output as a result of tilting.

This Standard differs substantially from ISO 5358 in the following areas:

- (a) Colour coding of vaporizers is mandatory.
- (b) Allowable leakage of gas has been reduced (see Clauses 5, 6, 9 and 10).
- (c) Sleeve index pipeline inlet connections are specified. These connections are mandatory for Australia and recommended for New Zealand.
- (d) Pressure regulator performance is specified.
- (e) The allowable flow rate from a carbon dioxide flowmeter is restricted to 500 mL/min.
- (f) The flow control knob rotation range may be as much as 2000°.

This edition differs from the 1992 edition in the following areas:

- (i) Requirements for filling of vaporizers are included.
- (ii) The limit for gas leakage in medical gas cylinder connections has been increased to 100 mL/min.
- (iii) The limit for reverse flow rate of gases (see Clause 6) has been increased to 50 mL/min.
- (iv) The rotary flow adjustment control requires a rotation through at least 180° and not more than 2000° to adjust its associated flowmeter through the upper 90 percent of the scale range.

Tests specified in this Standard are *Type* tests which establish minimum design criteria, and are not meant as a substitute laid down in the manufacturer's service manual for vaporizers.

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**Anaesthetic machines—Non-electrical—For use with humans**

1 SCOPE This Standard specifies basic requirements for anaesthetic machines and associated components up to and including the fresh (common) gas outlet, for use with humans. It includes requirements for anaesthetic vaporizers intended for incorporation into anaesthetic machines.

This Standard does not apply to the following:

- (a) Anaesthetic machines which depend primarily on electric or electronic means for control or proper functioning.
- (b) Intermittent-flow anaesthetic machines which only deliver gas to the breathing system at varying rates in response to the patient's inspiratory efforts.
- (c) Dental nitrous oxide-oxygen analgesia machines.

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

AS

1944 Medical gas cylinder identification

2472 Valves for medical gas cylinders

2496 Breathing attachments for anaesthetic purposes for human use

2700 Colour standards for general purposes

2896 Medical gas systems—Installation and testing of non-flammable medical gas pipeline systems

2902 Medical gas systems—Low-pressure flexible connecting assemblies (hose assemblies)

ISO

3744 Acoustics—Determination of sound power levels of noise sources— Engineering methods for free-field conditions over a reflecting plane

4135 Anaesthesiology—Vocabulary

7767 Oxygen analyzers for monitoring patient breathing mixtures—Safety requirements

3 DEFINITIONS For the purpose of this Standard, the definitions given in ISO 4135 and those below apply.

3.1 Anaesthetic machine—equipment for dispensing and delivering medical anaesthetic gases and vapours into a breathing system.

3.2 Anaesthetic vaporizer—a device designed to facilitate the change of a liquid anaesthetic agent to a vapour.

3.3 Compliance—the property of the envelope enclosing a gas and measured by the volume change per unit pressure change.

3.4 Flow control valve—a device which controls the flow of any gas passing through its associated flowmeter by manual adjustment.

3.5 Flowmeter—any device which indicates the volume of a specific gas passing through it in a unit of time.

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

3.7 Gas mixer—a device which receives separate supplies of oxygen and one or more other medical gases and which delivers the mixed gases in controllable concentrations.

3.8 Machine gas piping—all pipework, including unions, from unidirectional valves in the pipeline inlets and from the outlet of the pressure regulators to the flowmeter controls and auxiliary gas outlets. It includes piping leading to and from pneumatic alarm systems, gauges and oxygen flush valves.

3.9 Minute volume—the volume of gas, expressed in litres per minute, entering or leaving the patient.

3.10 Pressure regulator—a gas pressure reducing and controlling device designed to provide a constant delivery (downstream) pressure over a range of variable inlet pressures or flows (or both).

3.11 Vaporizer chamber—the chamber in which the anaesthetic agent vapour is added to fresh gas.

3.12 Working pressure—the maximum operational pressure at a given point in the system during clinical use.

4 BASIC REQUIREMENTS FOR ANAESTHETIC MACHINES

4.1 General Ease of cleaning and the use of suitable materials for their manufacture should be taken into account in the design of anaesthetic machines.

NOTES:

- 1 Anaesthetic machines should be designed to facilitate cleaning. All exposed surfaces should be able to withstand commonly used cleaning and disinfecting agents.
- 2 The suitability of materials should be assessed in respect of their compatibility with compressed oxygen and anaesthetic gases and vapours.

4.2 Mobile anaesthetic machines Anaesthetic machines intended to be mobile should be as light as possible and easily movable. Fragile components, such as flowmeters, should be well protected and secured to minimize accidental damage.

4.3 Controls and gauges All controls and gauges shall be clearly visible to an operator having visual acuity, corrected if necessary, of at least 1.0 seated or standing 1 m in front of the anaesthetic machine at an illuminance of 215 lx.

NOTE: The markings and graduations should be readily identifiable with the controls, gauges, meters or other indicators with which they are associated. Flowmeters, gauges, controls and other displays that need to be read most frequently should be grouped together and be placed as close as possible to the operator's field of vision when he or she is in the normal position for operating the anaesthetic machine and observing the patient.

4.4 Colour coding Except for vaporizers, if colour coding is used on the anaesthetic machine, it shall be in accordance with AS 1944.

Colour coding for vaporizers shall be in accordance with Appendix A.

4.5 Built-in monitors If the anaesthetic machine has built-in monitors, the monitors shall be activated whenever the machine is placed in an operating mode.

NOTE: Monitors requiring electrical power are excluded from this requirement.

4.6 Material compatibility with gases and mixtures used in anaesthesia The selection of material and the design of components shall be done with consideration of the compatibility, ignition susceptibility and combustibility of the materials and the environment.

NOTE: Information on combustibility and compatibility of materials is given in Appendix B.

4.7 Stability An anaesthetic machine intended to be mobile shall be fitted with handles or bars which shall not obstruct or degrade the function of any of the components or attachments of the machine.

When it is tested for static stability in accordance with Appendix C, the design and distribution of mass of the mobile machine shall be such that the machine will not tip over, and it shall remain upright on a plane inclined at 8°. When tested for mobile stability in accordance with Appendix D, the machine shall not fall over at the maximum rod diameter stated by the manufacturer (see also Clause 18).

4.8 Nominal working pressure The nominal working pressure for the anaesthetic machine shall be 400 kPa.

4.9 Percentage of oxygen when air is used The anaesthetic machine shall be designed such, that when air is being delivered to the fresh (common) gas outlet, the addition of any other gas or gases shall not reduce the percentage of oxygen at the fresh (common) gas outlet to below 20 percent. An interactive device providing not less than 20 percent oxygen at all times should be provided.

4.10 Supply of carbon dioxide Where carbon dioxide is desired, carbogen (oxygen with nominal 5 percent carbon dioxide) or carbon dioxide may be used. If carbon dioxide is used, the flowmeter or flow control shall be designed so that the flow rate cannot exceed 500 mL/min.

5 MEDICAL GAS CYLINDER CONNECTIONS Medical gas cylinder connections shall comply with AS 2472.

Each cylinder connection or group of interconnected cylinder connections shall be provided with a filter, having a pore size not exceeding 100 µm, prior to delivery of the gas at a needle valve or pressure regulator.

Medical gas cylinders shall have pin index yoke-type valve connections, as specified in AS 2472.

NOTE: The yoke may also (but need not) provide for the support of the cylinder, i.e. hanger yoke.

If two or more gas supply connections are provided for the same gas, means shall be provided to limit the leakage of gas to a flow rate not exceeding 100 mL/min at a temperature of 23 ±2°C and a pressure of 101.3 kPa, from an open cylinder at a pressure of 15 MPa to any one of the following:

- (a) An empty cylinder.
- (b) The atmosphere, through a cylinder connection.
- (c) A pipeline supply.

Each cylinder connection shall be permanently and legibly marked with the name or chemical symbol of the corresponding gas.

All freestanding anaesthetic machines shall have provision for at least one cylinder of oxygen.

6 PIPELINE INLET CONNECTIONS The anaesthetic machine shall have oxygen and nitrous oxide gas specific terminal unit connections.

Unidirectional valves shall be provided such, that the reverse flow rate of gases from the anaesthetic machine to the pipelines or to atmosphere (if connections for gas cylinders are also provided) shall not exceed 50 mL/min corrected to 23°C and 101.3 kPa, at the design pressure (or pressures) in the machine piping.

If pipeline inlet connections for gases other than nitrous oxide and oxygen (outlet connections for vacuum) are provided, the connections shall be gas specific. In Australia, gas specific connections shall conform to the dimensions shown in Figure 1. In New Zealand, gas specific connections shall be either a sleeve-indexed system (see Figure 1), a diameter-indexed safety system (DISS) or a non-interchangeable screw thread (NIST).

The anaesthetic machine shall not be damaged or rendered inoperative by a pressure of 850 kPa applied to any or all pipeline inlet connections.

NOTE: AS 2896 is being revised, and the draft revision allows a maximum pipeline pressure of approximately 850 kPa during relief valve venting.

7 PRESSURE GAUGES AND PRESSURE INDICATORS

NOTE: Pressure gauges cannot accurately indicate the contents of cylinders containing liquefied gas.

7.1 General Each gas supplied at cylinder pressure to the anaesthetic machine shall be monitored by a cylinder pressure gauge or contents indicator. Gauges shall be capable of indicating a pressure not less than 33 percent greater than the maximum working pressure of the cylinder at a temperature of $23 \pm 2^\circ\text{C}$. The gauge and cylinder shall be positioned relative to one another so that it is possible for one operator to observe the gauge easily while opening the cylinder valve to check its contents.

7.2 Gas cylinder yoke Each gas cylinder yoke shall be provided with a pressure gauge or contents indicator.

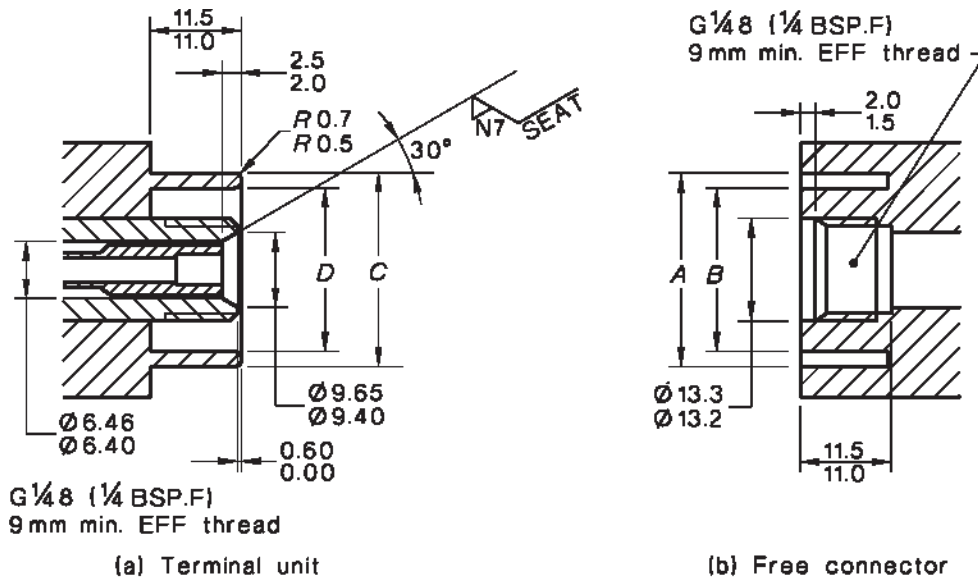
7.3 Gases supplied by pipeline Gases supplied by pipeline from central supplies may be monitored by pressure gauges or indicators. Where present, the gauges or indicators shall monitor the pressure of gas in the pipeline supply hoses upstream of the unidirectional valve (see Clause 6). If a gauge is used, it shall be capable of indicating a pressure not less than 33 percent greater than the pipeline working pressure.

7.4 Graduation All cylinder gauges and pipeline gauges indicating pressure shall be graduated in kilopascals or hundreds of kilopascals, and the units shall be clearly marked on the dial (see Clause 4.3).

7.5 Maximum permitted error The maximum error of all gauges and indicators shall not exceed ± 4 percent of the full scale reading.

7.6 Design and construction All gauges shall be designed and constructed so that when a pressure equal to the maximum pressure indicated on the dial is applied to a gauge having the pressure-sensing element removed, no parts shall be expelled free of the gauge enclosure. Gauge cases shall have means of venting to prevent case internal pressure build-up. If used, vent covers not secured to the gauge case shall be designed to open at a suitably low pressure and shall be of a resilient material that will reduce the risk of injury to personnel.

NOTE: Gauges may be furnished with restrictors in the inlet pressure connection.



Gas	A mm	B mm	C mm	D mm
Nitrous oxide	20.40 20.25	16.35 16.20	19.85 19.75	16.85 16.75
Nitrous oxide/oxygen 50/50 nom.	21.45 21.30	17.35 17.20	20.85 20.75	17.90 17.80
Carbon dioxide	22.45 22.30	18.35 18.20	21.85 21.75	18.90 18.80
Carbon dioxide in oxygen (nom. 5 percent)	23.45 23.30	19.40 19.25	22.85 22.75	19.90 19.80
Anaesthetic gas scavenging	24.50 24.35	20.40 20.25	23.90 23.80	20.90 20.80
Oxygen	25.50 25.35	21.40 21.25	24.90 24.80	21.95 21.85
Air	26.50 26.35	22.45 22.30	25.90 25.80	22.95 22.85
Suction	27.50 27.35	23.45 23.30	26.95 26.85	23.95 23.85
Variable air/oxygen mixtures	29.55 29.40	25.50 25.35	28.95 28.85	26.00 25.90

FIGURE 1 SLEEVE INDEX SYSTEM

7.7 Gauges with analogue scales All circular cylinder pressure gauges on any individual anaesthetic machine shall have equal span angles to within 10° . The span angle, from the lowest pressure indication to the maximum pressure indication, shall be not less than 180° and not more than 300° , with the lowest pressure graduation mark at the same position for each gauge. The lowest graduation mark shall be between the 6 o'clock and 9 o'clock positions on the dial.