

Australian and New Zealand College of Anaesthetists (ANZCA)

Minimum Safety Requirements for Anaesthetic Machines for Clinical Practice

1. PURPOSE AND SCOPE

- 1.1 The anaesthetic machine is designed to deliver anaesthetic gases, anaesthetic vapours, oxygen and/or air via a breathing circuit to patients. Safe anaesthetic machines are essential to the provision of safe patient care.
- 1.2 This document specifies minimum safety requirements for anaesthetic machines in clinical use in Australia and New Zealand.
- 1.3 The document also provides guidance regarding whether an anaesthetic machine should be replaced.
- 1.4 The general intent of this document is that all anaesthetic machines in clinical use in Australia and New Zealand should comply with Australian/New Zealand Standards *AS/NZS 3200.2.13:2005 Medical electrical equipment – Part 2.13: Particular requirements for safety—Anaesthetic systems*¹ and *AS/NZS 4059:1996 Anaesthetic machines—Non-electrical—For use with humans*², and other relevant national standards by 1 January 2013.
- 1.5 This document does not apply to:
 - 1.5.1 Anaesthetic ventilators, anaesthetic gas scavenging systems or medical suction systems.
 - 1.5.2 Equipment used for the delivery of intravenous anaesthetic agents.
 - 1.5.3 Monitoring equipment, whether integral to or separate from the machine, except as required by *AS/NZS 3200.2.13:2005*.¹ ANZCA's monitoring recommendations are outlined in College professional document *PS18 Recommendations on Monitoring During Anaesthesia*.
 - 1.5.4 Basic draw-over systems and draw-over capable field anaesthetic machines.
 - 1.5.4.1 The use of field equipment for teaching or continuing professional development in anaesthetising locations in Australia and New Zealand is acceptable when directly supervised by anaesthetists experienced in the principles and use of such equipment and when approved by the head of department or his or her equivalent. Monitoring must comply with College professional document *PS18 Recommendations on Monitoring During Anaesthesia*.

2. ANAESTHETIC MACHINE SAFETY ASSESSMENT

- 2.1 Anaesthetic machines must be assessed for safety, reliability and functionality at least once a year by a specialist anaesthetist, or other person, with the required skill and technical knowledge.



2.2 This assessment will result in a classification of each machine into one or more of the following categories, each of which defines a specific course of action for that machine:

2.2.1 Anaesthetic machines that fail to comply with one or more of the mandatory safety requirements specified in Section 3.

Action: Anaesthetic machines in this category should be removed from clinical use. If they can be upgraded to meet the requirements of Section 3, they may be returned to clinical practice only after re-assessment confirms full compliance with all mandatory safety requirements.

2.2.2 Anaesthetic machines that meet all of the mandatory safety requirements of Section 3, but fail to comply with one or more of the recommended safety requirements of Section 4.

Action: Anaesthetic machines in this category should enter an update or replacement process for which planning should start immediately. By 1 January 2013, all anaesthetic machines in this category must either have been upgraded to comply with all the safety requirements of this document or have been removed from clinical use.

2.2.3 Anaesthetic machines that fail to comply with one or more of the safety requirements of Section 5.

Action: Anaesthetic machines in this category must be withdrawn from clinical use no later than 6 months from the date on which their lack of compliance with Section 5 was documented. 2.2.1 and 2.2.2 apply to machines that in addition fail to comply with the requirements of Sections 3 and 4.

2.2.4 Anaesthetic machines that comply with all the safety requirements of this document.

Action: Anaesthetic machines in this category are acceptable for clinical use.

2.3 Anaesthetic machines may be unsafe for clinical use for reasons other than those addressed in this document, including failure to meet electrical safety requirements, or lack of appropriate monitoring equipment

2.4 All anaesthetic machines in clinical use need to comply with safety standards/checks/tests beyond those addressed in this document (see Section 2.3). Unsafe anaesthetic machines should not be used, regardless of the reason.

3. MANDATORY SAFETY REQUIREMENTS

3.1 Connections for medical gas cylinders, yokes or regulators must be pin indexed.

3.2 A reserve supply of oxygen must be attached to the anaesthetic machine in a manner that ensures easy activation should the oxygen supply failure warning system (see Section 3.5) indicate impending failure of the external oxygen supply.

3.3 Non-interchangeable gas hose connectors must be present on all gas inlet and outlet sockets to prevent incorrect gas supply connections.

3.4 A display of gas supply line and cylinder pressures must be provided. The pressure displays must be visible from the front of the machine.

3.5 When high pressure gas supply systems are in use, an oxygen supply failure warning device must be present. This must:

- 3.5.1 Activate automatically when the oxygen supply pressure falls below a predetermined critical level.
- 3.5.2 Generate an audible alarm to warn the operator.
- 3.5.3 Cut off the supply of gases other than air or oxygen to the common fresh gas outlet.
- 3.5.4 The only means to reset the alarm will be the restoration of the oxygen supply pressure to a level above that at which the device is activated.
- 3.6 If the anaesthetic machine incorporates a gas flowmeter bank, oxygen must be the last gas to enter the common gas manifold at the top of the flowmeter tubes. The order in which the flow knobs on the rotameter are placed should be oxygen, nitrous oxide, and then air.
- 3.7 If mechanical means are provided to mix the anaesthetic gases on the anaesthetic machine, there must be only one gas flow control knob for each gas.
- 3.8 If a mechanical oxygen flow knob is provided, it must differ from the other flow control knobs so that tactile identification of the oxygen control knob is possible (for example, fluted).
- 3.9 If the anaesthetic machine is capable of delivering nitrous oxide, the machine must not deliver a hypoxic mixture. When oxygen and nitrous oxide are the only gases used, the machine must prevent delivery of a gas mixture with an oxygen concentration below that of ambient air.
- 3.10 If two or more vaporisers can be simultaneously mounted on the anaesthetic machine, a vaporiser interlock system must allow only one vaporiser to be used at a time.
- 3.11 Vaporisers with mechanical adjustment dials, when used in high pressure circuits, must increase the delivered anaesthetic vapour concentration when the dial is rotated in an anti-clockwise direction.
- 3.12 A fresh gas outlet, if provided, must be 22 mm outer diameter and 15 mm inner diameter, visible to the operator and should be capable of being connected to the breathing system in such a way as to prevent accidental disconnection.
- 3.13 A high pressure relief valve or other means of automatically preventing dangerously high and/or prolonged pressures in the breathing system must be present in the anaesthesia circuit but it is not necessary for such a device to be integral to the anaesthesia machine.
- 3.14 Anaesthetic gas scavenging system connections must be of a diameter that is different from the other connections used for the breathing system.
- 3.15 When each feature of the anaesthetic machine is enabled, any associated monitor and alarm functions must be automatically activated.
- 3.16 Adequate maintenance of the anaesthetic machine must be ongoing for the life of the unit. Any replacement parts must be of suitable quality and the work undertaken by appropriately qualified service personnel. Repair or maintenance must involve testing of key safety and performance parameters prior to patient use (see *AS/NZS 3551:2004 Technical management programs for medical devices³*).

4. RECOMMENDED SAFETY REQUIREMENTS

- 4.1 An alarm that responds to sustained high and low pressure in the patient's airway must be present.

- 4.2 The emergency oxygen flush control must be protected from accidental activation.
- 4.3 An “on/off” switch, if present, must be protected from unintended activation.
 - 4.3.1 Switching “off” an electronic anaesthetic machine during normal operation should require a confirmatory step and/or the machine should display a warning of imminent shut-down.
- 4.4 If the anaesthetic machine requires electrical power for normal operation, a backup power supply must be a part of the machine and permit normal operation for at least 30 minutes after a mains power supply failure. An alarm must be activated at the time of the mains failure and the state of the reserve power supply must be indicated while it is in use.

5. OTHER SAFETY REQUIREMENTS

- 5.1 A maintenance record and problem log should be kept for all anaesthetic machines in clinical use.
- 5.2 An anaesthetic machine should be considered for replacement if its maintenance history indicates that problems with the machine are adversely affecting clinical service to an extent that is unacceptable to the institution or which threatens patient safety, or if it cannot meet the reasonable needs of current anaesthetic practice in the facility.

RELATED ANZCA DOCUMENTS

T1 Recommendations on Minimum Facilities for Safe Administration of Anaesthesia in Operating Suites and Other Anaesthetising Locations

PS18 Recommendations on Monitoring During Anaesthesia

PS31 Recommendations on Checking Anaesthesia Delivery Systems

REFERENCES

1. Australian/New Zealand Standard AS/NZS 3200.2.13:2005 Medical electrical equipment - Part 2.13: Particular requirements for safety—Anaesthetic systems.
2. Australian/New Zealand Standard AS/NZS 4059:1996 Anaesthetic machines —Non-electrical—For use with humans.
3. Australian/New Zealand Standard AS/NZS 3551:2004 Technical management programs for medical devices.

FURTHER READING

American Society of Anesthesiologists. Guidelines for determining anesthesia machine obsolescence [Internet]. 2004. From: <http://asatest.asahq.org/publicationsAndServices/machineobsolescence.pdf>. Accessed 1 November 2010.

COLLEGE PROFESSIONAL DOCUMENTS

College professional documents are coded as follows:

TE *Training and Educational*
EX *Examinations*
PS *Professional Standards*
T *Technical*

POLICY – defined as ‘a course of action adopted and pursued by the College’. These are matters coming within the authority and control of the College.

RECOMMENDATIONS – defined as ‘advisable courses of action’.

GUIDELINES – defined as ‘a document offering advice’. These may be clinical (in which case they will eventually be evidence-based), or non-clinical.

STATEMENTS – defined as ‘a communication setting out information’.

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