Public Health Regulation Division
Diviżjoni Regolazzjoni Saħħa Pubblika
Ministry for Health, the Elderly and Community Care

STANDARDS AND CRITERIA FOR ANAESTHETIC MACHINE SAFETY - 2010

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GENERAL CONSIDERATIONS

This document outlines minimum safety features for anaesthetic machines in clinical practice. It provides guidance to specialist anaesthetists and other healthcare personnel, administrators and regulatory bodies when considering whether an anaesthetic machine is suitable for clinical practice in Malta.[1] [2]

The aim of this document is that all anaesthetic machines in clinical use should eventually be compliant with the current standards of the Malta Standards Authority (MSA).

The current standard MSA-EN 60601-2-13: 2006. "Medical electrical equipment. Particular requirements for the safety and essential performance of anaesthetic systems" has been structured to allow user(s) to configure an anaesthetic system in conformance with professional guidelines and to meet the needs of their clinical practice.

The anaesthetic system (AS) comprises the anaesthetic gas delivery system (AGDS), the anaesthetic breathing system (ABS), the anaesthetic gas transfer and delivery system (AGSS), the anaesthetic vapour delivery device (AVDD), the anaesthetic ventilator (AV), other devices and their respective monitoring device(s) (MD(s)), alarm system(s) and protection device(s) (PD(s).[3]

It is the specialist anaesthetist's duty to determine whether the failure of a machine to reach these newer standards represents enough of a threat to patient safety in order to render it obsolete.

This document applies in a general sense wherever anaesthesia is administered. It is the responsibility of the practitioner to give special attention when this document is applied to a particular case.

The criteria defining obsolescence that are described in this document relate to the gas and vapour delivery portion of the machine. Other professional documents cover: anaesthetic ventilators, suction systems or anaesthetic gas scavenging systems, alternative equipment used for the delivery of anaesthesia (e.g. anaesthesia drug infusion devices) and monitoring equipment, whether integral to or separate from the machine, except as required by MSA standards.

The document "Recommendations for Standards of Monitoring during Anaesthesia and Recovery", 2007, published by The Association of Anaesthetists of Great Britain and Ireland (AAGBI) should also be followed.[4]

Wherever general anaesthesia is administered an anaesthetic machine which satisfies the criteria as specified in this document shall be used.[5]

This document shall not prejudice the requirements for placing on the market and putting into service

of anaesthetic machines, or components there of, that comply with the relevant National or European Regulations, in particular, the Medical Devices Regulations (L.N. 47 of 2003, as amended). In terms of placing on the market and putting into service, the "safety features" defined in this document shall not be confused and shall not replace the "safety requirements" listed in Schedule 1 of the Medical Devices Regulations (L.N. 47 of 2003, as amended).[6]

It should also be noted that whilst this document may refer to re-assessment, re-testing, upgrades or modifications to anaesthetic machines, such procedures must always be carried out in full accordance with the instructions of the original manufacturer. Any changes to the device without the manufacturer's approval which modify the intended uses or functions of the device may result in the production of a legally different product and in such case the user will be considered as the legally liable person for that "new" product in terms of L.N. 47 of 2003, as amended.

Manufacturers of medical devices have a legal obligation to supply Instructions For Use (IFU) which cover not only how to use the device but also a description of intended use of the device. Using the device outside of the IFU removes much of the manufacturer's responsibility and transfers it on to the user. Manufacturers should produce IFUs which are easy to read and understand; a summary of important points or key instructions is advantageous. These should be available on or close to the equipment.[7]

Further legal interpretation on any issues dealing with the Medical Devices Regulations (L.N. 47 of 2003, as amended) may be sought from the MSA.

This document will be reviewed periodically. It is the specialist anaesthetist's responsibility to follow the current version. The Department of Health Services Standards (DHCSS) will not be responsible for consequences arising from subsequent changes in circumstances such as evolution in technology and practice. In such instances the practitioner is also referred to professional literature published after the publication date of this document.

SAFETY ASSESSMENT

Anaesthetic machines are to be assessed for safety in accordance with the original manufacturer's IFU or recommendations. With respect to compliance with the safety features specified in this document, assessments shall be carried out by a specialist anaesthetist at least once every year. Such assessments should not be confused with enforcement procedures or responsibilities under the Medical Devices Regulations (L.N. 47 of 2003 as amended).

This assessment will result in a classification of each machine into one or more of the following 5 groups.

Group 1: Anaesthetic machines that fail to comply with one more features specified in section 1 (Essential safety features).

Anaesthetic machines in this group are to be removed. If they can be upgraded in accordance with the original manufacturer's instructions to meet the requirements of section 1, they may be returned to clinical practice only after re-assessment confirms full compliance with all essential safety features

specified in this document and any other relevant regulations e.g. the Medical Devices Regulations (L.N. 47 of 2003, as amended).

Group 2: Anaesthetic machines that meet all of the features of section 1 but fail to comply with one or more of the features mentioned in section 2 (Relative safety features).

Anaesthetic machines in this group are to enter an update or replacement process, in accordance with the original manufacturer's instructions or recommendations, for which planning should start immediately. By a date stipulated by the inspectorate team of the DHCSS, all anaesthetic machines in this group must either have been upgraded to comply with all the safety features specified in this document and any other relevant regulations or have been removed from clinical use

Group 3: Anaesthetic machines that do not comply with one or more of the requirements of section 3 (Other safety features) whether or not they comply with the features of sections 1 and 2.

Anaesthetic machines in this group must be withdrawn from clinical use no later than 6 months from the date on which their lack of compliance with section 3 was documented.

Group 4: Anaesthetic machines that comply with all the safety features in this document.

Anaesthetic machines in this group are not excluded from clinical use. These machines require assessment of other safety areas not covered in this document and future reassessment.

Group 5: Anaesthetic machines unsafe for clinical use for reasons not mentioned in the above groups.

Such instances include:

- Failure to meet electrical safety requirements;
- Lack of appropriate monitoring equipment;
- Unreliability;[8]
- Being in a damaged or worn out condition and beyond economic repair;
- Following an investigation of an adverse event as specified in the Medical Devices Regulations (L.N. 47 of 2003, as amended), the device is deemed to be unsafe for use;
- There is lack of compliance with the Medical Devices Regulations (L.N. 47 of 2003, as amended) in any way whatsoever. The principal, but not sole, evidence of compliance is the CE-mark. Devices bought second-hand from other European Union (EU) Member States or from the European Economic Area (EEA) are excluded from this provision. Devices bought from outside the EU or EEA and put into service before 31st January 2003 are also excluded from this requirement. For the sake of clarification, devices bought second-hand from outside the EU or EEA from 31st January 2003 onwards must comply with the EU legislations in place at the time of there putting into service in Malta.
- Time expired lifecycle of the medical device. Heavy use or irregular maintenance may reduce the lifecycle; limited use may extend it.

Anaesthetic machines in this group, regardless of the reason are not to be used forthwith.

Section 1: ESSENTIAL SAFETY FEATURES

- Connections for medical gas cylinders shall be non-interchangeable between different gas services e.g. pin index safety system in order to prevent the mounting of a cylinder on an incorrect yoke. [9] [10]
- The AGDS shall be connected to a reserve oxygen supply that could be automatically activated e.g. an oxygen cylinder that is functionally attached to the AGDS.
- Non-interchangeable gas hose connectors must be present on any gas inlet socket to prevent incorrect gas hose connections. Pipeline inlet connections for the AGDS shall be the body fittings as specified below: screw-threaded: Diameter-Index Safety System (DISS); Non-Interchangeable Screw-Threaded (NIST); Sleeve Index System (SIS); non-screw-threaded: Quick connectors of differing design that must be gas-specific and non-interchangeable with each other.[11]
- The AGDS shall be equipped with a means to monitor the pressure or content of each gas supplied at cylinder pressure. The AGDS shall be capable of displaying the pressure or cylinder contents continuously. This display shall be visible from the front of the AGDS. The AGDS shall be equipped with a means to monitor continuously the pressure of each gas supplied by a medical gas pipeline system. This indication shall be visible from the front of the AGDS.
- Oxygen supply failure alarm system: The AGDS shall be provided with an oxygen supply failure alarm system to indicate when the oxygen supply, whether derived from a pipeline or from a cylinder, has fallen below a predetermined critical level specified by the manufacturer. The alarm system shall generate an auditory alarm system to warn the operator.
- .Oxygen supply failure protection: The AGDS shall be designed so that whenever the oxygen supply is reduced below the manufacturer-specified minimum oxygen continues to flow from the common gas outlet, the delivered oxygen concentration shall not decrease below 19% at the common gas outlet.
- If a bank of flowmeters is fitted, the oxygen flowmeter shall be placed at one extremity.
- If there is a separate flow adjustment flow control for each gas they shall meet the following requirement: - there shall not be more than one flow adjustment control for any single gas delivered to the fresh gas outlet (FGO) under normal condition(s) (NC).
- For rotary style flow controls the oxygen knob shall have a physical profile in accordance with the figure and shall have a diameter not less than any of the diameters of the knobs controlling all the other gases. Tactile identification of the oxygen flow control knob should be possible.
- Protection against selection of oxygen concentration below that of ambient air: The AGDS shall be provided with means to prevent the unintentional selection of a mixture of oxygen and nitrous oxide having an oxygen concentration below that of ambient air e.g. an O2/N2O proportioning system.
- Protection against cross-contamination of anaesthetic agents: means shall be provided to prevent contamination of the contents of one AVDD with another volatile anaesthetic agent e.g. a vaporiser interlock system.[12]
- Vaporisers with mechanical rotary dials must increase the delivered anaesthetic vapour when the dial is rotated in an anti-clockwise direction.
- FGO: if an operator-accessible FGO is provided, there shall be not more than one, it shall be visible from the operator's position, and shall be a coaxial 22 mm/15 mm conical connector. An operator-accessible FGO should have a means to prevent unintentional disconnection from the ABS.

- Pressure limitation: the AS shall either be equipped with a means to limit the pressure at the patient connection port during both NC and Single fault condition (SFC) to less than 12,5 kPa (125 cm H2O) e.g. an adjustable pressure-limiting (APL) valve or other means of automatically preventing dangerously high and/or prolonged pressures in the breathing system.
- AGSS: AGSS connections must be of a diameter that is different (e.g. 19mm or 30m) from the other connections used in the breathing system. Connectors between subassemblies of AGSS transfer and receiving systems shall be designed to prevent misassembly. Such connections shall be incompatible with those used for medical gas pipeline systems, hose assemblies, breathing systems and other AGSS components.
- When each functional sub-system of the AS is enabled, its associated MD(s) and alarm system(s) must be automatically activated. IFU of AS(s) and/or individual devices shall provide information on the method of enabling the AS or individual device(s) including the MD(s), Alarm system(s) and PD(s) required. Checklist: each AS shall be provided with a checklist(s) of the procedures recommended by the manufacturer to be performed prior to each use of the AS. Note 1: The procedure may be performed automatically, in whole or in part, or by the operator. Note 2: Attention is drawn to additional checklists established by regional or national medical associations, or government agencies. Note 3: The use of electronic displays integral to, or provided with the AS or the device/system to provide such a checklist is permitted.
- Adequate maintenance of the anaesthetic machine must be possible and according to the manufacturer's recommendations. Replacement parts of suitable quality and appropriately qualified, certified service personnel must be available and must be authorised by the manufacturer. As a result of these prerequisites the anaesthetic machine can continue to operate to its original performance specification.

Section 2: RELATIVE SAFETY FEATURES

- Continuing pressure alarm. The AS shall either be equipped with a means to annunciate a high priority alarm signal when the pressure in the ABS exceeds the set alarm limit(s) for continuing positive pressure longer than 15s.
- The emergency oxygen flush device shall have only one "off" position. The oxygen flush shall be designed to minimise the risk of accidental operation by equipment or personnel pressure against it.
- Pneumatic power supply: means shall be provided to prevent unintentional operation of the "off" switch. Electrical power supply: means shall be provided to prevent unintentional operation of the "off" switch.
- If an anaesthetic machine requires electrical power for normal operation the anaesthetic machine must be connected to a backup power supply e.g. an internal or external battery, uninterruptible power supply (UPS) or institutional stand-by generator.[13] The IFU shall contain a description of the functioning of the AS or individual device after interruption of the power supply, and where applicable the functioning of the AS or individual devices after a switch-over to a reserve power supply. Interruption of power supply/supply mains to medical electrical equipment (ME equipment): ME equipment shall be so designed that an interruption and restoration of the power supply shall not result in a hazardous situation other than interruption of its intended function. The AGDS shall be so designed that in the event of an
- Electrical power supply failure the supply of gas shall either be unaffected, or an alternative means of gas delivery is made available.
- An alarm signal of at least medium priority shall be activated in the event of an electrical

power supply failure (i.e. below the minimum specified by the manufacturer). Note: electrical power supply failure includes both mains and reserve electrical power source (REPS). REPS: part of equipment that temporarily supplies power to the electrical system in the event of an interruption of the primary electrical supply. An alarm signal of at least low priority shall be activated when there is an automatic switchover to a REPS. There shall be a means to determine the state of any REPS. Note: e.g. an indication whether the output is within the manufacturer's specified range.

Section 3: OTHER SAFETY FEATURES

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

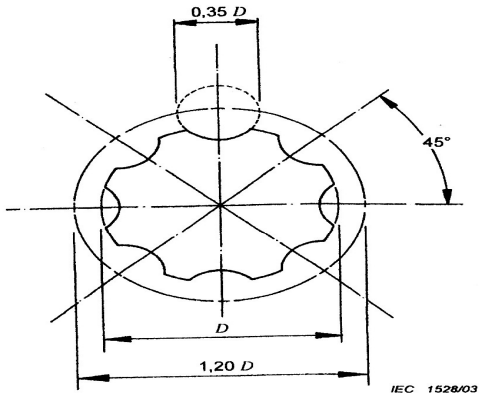

Figure 101 – Profile of oxygen flow control knob for applications other than anaesthetic vapour delivery device flow control (See 106.3)

DEFINITIONS

- Specialist anaesthetist: a medical practitioner who is legally allowed to practice independently the specialty of anaesthesia in Malta.
- Anaesthetic machine: equipment for dispensing and delivering medical and anaesthetic gases and vapours into a breathing system.
- Alarm condition: condition that occurs when a variable that is being monitored by an alarm system equals or falls outside the set alarm limit(s).
- Alarm limit: value(s) which are set by the manufacturer, the device, the user or operator, which define the threshold range of the alarm condition.
- Alarm signal: signal, the purpose of which is to alert the operator of an abnormal condition in the patient or the equipment that may develop into a safety hazard which requires operator awareness or action.
- Basic safety: freedom from unacceptable risk directly caused by physical hazards when ME equipment is used under normal condition and single fault condition.
- Risk: combination of probability of occurrence of harm and the severity of that harm.
- Normal condition: condition in which all means provided for protection against hazards are intact.
- Single fault condition: condition in which a single means for reducing a risk is defective or a single abnormal condition is present. The requirement that ME equipment is single fault safe effectively puts a lower limit on the probability of occurrence of harm from a hazard. If this probability is achieved then the risk of the hazard is acceptable. In all cases where this discussion refers to the severity or probability of a particular hazard, it is intended to refer to the probability or severity of the harm resulting from that hazard. Single fault safe is a characteristic of ME equipment that assures basic safety during its expected service life.
- Expected service life: maximum period of useful life as defined by the manufacturer.
- Normal use: operation, including routine inspection and adjustments by any operator, and stand-by, according to the instructions for use.
- Operator: person handling equipment.
- Alarm system: system that is intended to make the operator(s) aware of an alarm condition, in the patient or equipment, by means of its alarm signal(s).
- Anaesthetic gas delivery system: assembly of components which controls and delivers the fresh gas into the anaesthetic breathing system. NOTE, may include flow control system, flow meters and/or a gas mixing system and anaesthetic gas delivery system piping.
- Anaesthetic gas delivery system piping: all pipework, including unions, from unidirectional valves in the pipeline inlets and from the outlets of the pressure regulator(s), to the flow control system, as well as the piping connecting the flow control system and the piping connecting the anaesthetic vapour delivery device to the fresh gas outlet. It includes piping leading to and from pneumatic alarm system(s), pressure indicators, oxygen flush gas power outlets.
- Anaesthetic breathing system: those inspiratory and expiratory pathways through which gas flows at respiratory pressure between the fresh gas inlet, the patient connection port and the exhaust valve or exhaust port[14].
- Fresh gas inlet: that port through which fresh gas is supplied to the ABS.
- Patient connection port: port at the patient end of an anaesthetic breathing system intended for connection to devices such as a tracheal or tracheostomy tube connector, or the connector to a face mask or supraglottic device.

- Exhaust valve: valve through which waste gas (es) are discharged to the atmosphere or to an AGSS. NOTE: such a valve might not be an adjustable pressure-limiting valve.
- Exhaust port: that port through which waste gas (es) are discharged to the atmosphere or to an anaesthetic gas scavenging system (AGSS).
- Fresh-gas outlet, common gas outlet: port through which the mixture of anaesthetic gas and vapour is delivered from the anaesthetic machine.
- Anaesthetic system (anaesthetic workstation): inhalational anaesthetic system that contains an anaesthetic gas delivery system an anaesthetic breathing system and the required monitoring device(s), alarm system(s)and protection device(s). The AS can also include, but is not limited to, AVDD(s), AV(s), anaesthetic gas scavenging systems, and their associated MD(s), Alarm system(s) and PD(s).
- AVDD device which provides the vapour of an anaesthetic agent in a controllable concentration.
- AV: automatic device, which is connected via the ABS to the patient's airway and is designed to provide ventilation of the patient during anaesthesia.
- Annunciation, annunciate, annunciating: communication of alarm signal(s) to the operator.
- MD: device which continuously or repeatedly measures and indicates the value of a variable to the operator.
- Power supply: source of energy other than that generated directly by the human body or by gravity that makes the device function.
- PD: device which, without intervention by the operator protects the patient from hazardous output due to incorrect delivery of energy or substances. .
- REPS: see Section 2, 4th bullet.
- AGSS: system that is connected to the exhaust port of an anaesthetic breathing system, or to associated equipment, or which is integrated into an anaesthetic system (workstation) for the purpose of conveying expired and excess anaesthetic gases to an appropriate place of discharge. NOTE. Functionally, an anaesthetic gas scavenging system comprises three different parts: a transfer system, a receiving system and a disposal system. These three functionally discreet parts can be either separate or sequentially combined in part or in total. In addition, one or more parts of an anaesthetic gas scavenging system can be sequentially combined with an anaesthetic breathing system (e.g. as in an anaesthetic ventilator) to include the transfer system or transfer and receiving systems.
- Active AGSS: anaesthetic gas scavenging system in which the gas flow in the disposal system results from a powered device.
- Extract flow: flow of gas from the transfer system and receiving system of an AGSS at the entry to the disposal system**.**
- Power device: that part of the disposal system of an active AGSS which generates the extract flow**.**
- Receiving system: that part of an AGSS which provides an interface between the transfer system and the disposal system.
- Disposal system: that part of an active AGSS by means of which the expired or excess anaesthetic gases are conveyed from the receiving system to the point of discharge by a power device**.** NOTE. The point of discharge can be, for example, the exterior of a building or a non-recirculating extract ventilation system.
- Transfer system: that part of an AGSS which transfers expired and/or excess anaesthetic gases from the exhaust port of a breathing system, or associated equipment, to the receiving system**.**

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