RATIFIED EUROPEAN TEXT

EN740:1998

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This ratified text was approved by CEN/CENELEC in its three official languages on the date given below. Under CEN/CENELEC rules, BSI is obliged to publish its national transposition within six months of this date.

This ratified text was approved on

1998-03-02

EUROPEAN STANDARD
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EN 740

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Descriptors: anaesthetic equipment, modules, safety requirements, detail specifications

English version

Anaesthetic workstations and their modules - Particular requirements

Systèmes d'anesthésie et leurs modules - Règles particulières

Anästhesie-Arbeitsplätze und ihre Module - Besondere Festlegungen

This European Standard was approved by CEN on 2 March 1998.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 1999, and conflicting national standards shall be withdrawn at the latest by February 1999.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

This European Standard specifies particular requirements for anaesthetic workstations and their modules. It applies in conjunction with EN 60601-1: 1990. As stated in 1.3 of EN 60601-1 : 1990 the requirements in this European Standard take priority over those of EN 60601-1 : 1990. Clauses and subclauses additional to those in EN 60601-1 : 1990 are numbered beginning '101'. Additional annexes are lettered beginning 'AA'. Additional figures and tables are numbered beginning '101'. Additional items in lettered lists are lettered beginning 'aa)'.

Annex BB contains rationale statements for this European Standard. The clauses which have corresponding rationale statements are marked with R after their number.

Because this standard has been developed and structured in the way described in the scope, particular attention is drawn to the clarification printed in bold type in 51.101.

The following date has been fixed:

- latest date of withdrawal of a conflicting national standard (dow) 1998-06-13

Annexes AA, CC, DD, EE, FF, GG, HH, JJ, KK, LL, MM, NN, QQ, RR and TT are normative parts of this European Standard. Annexes BB, PP, SS and ZA are given for information.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Section 1: General

1 R: Scope

Clause 1 of EN 60601-1 : 1990 applies with the following amendment:

This European Standard provides particular requirements for modules which, although considered as individual devices in their own right, may be utilized, in conjunction with other relevant devices, to form an anaesthetic workstation to a given specification.

It is the intent of this European Standard that both anaesthetic workstations supplied complete and individual modules be commercially available to users to allow the configuration of an anaesthetic workstation to meet the needs of their clinical practice. To this end, this European Standard has been structured in such a way as to identify clearly particular requirements of specific modules currently available. Different configurations of anaesthetic workstations are illustrated in table 101 .

This European Standard also specifies the particular requirements for emergency anaesthetic equipment (see table 102).

For the purpose of this European Standard a module is defined as a self-contained unit of an anaesthetic workstation that performs a specific task or class of tasks in support of the major function of the anaesthetic workstation.

Such modules are e.g. anaesthetic gas delivery, anaesthetic vapour delivery, anaesthetic ventilators, anaesthetic breathing systems, anaesthetic gas scavenging systems (AGSS), specific monitoring, alarm and protection modules.

This European Standard also specifies particular requirements for the transfer and receiving system of an active AGSS intended to reduce the exposure of hospital personnel to anaesthetic gases and vapours and specifies the inlet flow conditions for which systems should be designed.

Although this European Standard does not specify the provision of patient monitors, attention is drawn to recommendations for patient monitoring during anaesthesia made by many national clinical and regulatory bodies.

Manufacturers of anaesthetic workstations are encouraged to make provision for additional monitors as well as for devices for the intravenous administration of drugs (see annex SS 'Bibliography' for appropriate equipment standards) so that the user can assimilate more easily the data output and so that the alarm function of the various monitors can be integrated.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

Appendix L of EN 60601-1 : 1990 applies with the following additions:

EN 475	Medical devices - Electrically-generated alarm signals
EN 737-1	Medical gas pipeline systems Part 1: Terminal units for compressed medical gases and vacuum
prEN 737-3	Medical gas pipeline systems Part 3: Pipelines for compressed medical gases and vacuum
EN 737-4	Medical gas pipeline systems Part 4: Terminal units for anaesthetic gas scavenging systems
prEN 737-6	Medical gas pipeline systems Part 6: Dimensions of probes for terminal units for compressed medical gases and vacuum
EN 738 -1	Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow metering devices
EN 739 : 1998	Low pressure flexible hose assemblies for use with medical gases
EN 850	Transportable gas cylinders - Pin-index, yoke-type valve outlet connections for medical use
EN 864	Medical electrical equipment - Capnometers for use with humans - Particular requirememts
EN 980	Graphical symbols for use in the labelling of medical devices
EN 1041	Information supplied by the manufacturer with medical devices
EN 1089-3	Transportable gas cylinders - Cylinder identification - Part 3: Colour coding
EN 1280-1 : 1997	Agent specific filling systems for anaesthetic vaporizers - Part 1 : Rectangular keyed filling systems
EN 1281-1	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets

EN 1281-2	Anaesthetic and respiratory equipment - Conical connectors Part 2: Screw-threaded weight-bearing connectors (ISO 5356-2 : 1987, modified)
EN 1820	Anaesthetic reservoir bags
prEN 12342	Breathing tubes intended for use with anaesthetic apparatus and ventilators
EN ISO 4135	Anaesthesiology - Vocabulary (ISO 4135 : 1995)
prEN 12598	Oxygen monitors for patient breathing mixtures - Particular requirements
EN ISO 8185-1	Humidifiers for medical use - Part 1 : General requirements for humidification systems (ISO/DIS 8185-1 : 1997)
EN ISO 10079-1	Medical suction equipment - Electrically powered suction equipment - Safety requirements (ISO 10079-1: 1991 including Technical corrigendum 1 : 1992 and Technical Corrigendum 2 : 1993)
EN ISO 10079-2	Medical suction equipment Part 2: Manually powered suction equipment (ISO 10079-2 : 1992)
EN ISO 10079-3	Medical suction equipment Part 3: Suction equipment powered from vacuum or pressure source (ISO 10079-3 : 1992)
EN ISO 11196	Anaesthetic gas monitors (ISO 11196 : 1995 including Technical Corrigendum 1 : 1997)
EN 60601-1: 1990	Medical electrical equipment Part 1: General requirements for safety (IEC 60601-1 : 1988)
EN 60601-1-1	Medical electrical equipment Part 1: General requirements for safety 1: Collateral standard: Safety requirements for medical electrical systems (IEC 60601-1-1 : 1992)
EN 60601-1-2	Medical electrical equipment Part 1: General requirements for safety 2. Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2 : 1993)
EN 60801-2	Electromagnetic compatibility for industrial-process measurement and control equipment Part 2: Electrostatic discharge requirements (IEC 801-2 : 1991)
IEC 60079-3	Electrical apparatus for explosive gas atmospheres Part 3: Spark-test apparatus for intrinsically-safe circuits

IEC 60079-4	Electrical apparatus for explosive gas atmospheres Part 4: Method of test for ignition temperature
ISO 2878	Rubber, vulcanized - Antistatic and conductive products - Determination of electrical resistance
ISO 2882	Rubber, vulcanized - Antistatic and conductive products for hospital use - Electrical resistance limits
EN ISO 3746	Acoustics - Determination of sound power levels of noise sources using sound pressure - survey method using an enveloping measurement surface over a reflecting plane (ISO 3746 : 1995)
ISO 9360	Anaesthetic and respiratory equipment - Heat and moisture exchangers for use in humidifying respired gases in humans

3 Terminology and definitions

Clause 2 of EN 60601-1 : 1990 applies together with EN ISO 4135 and the following amendments and additions.

In 2.1.5, replace the text with the following:

2.1.5 R: applied part: The fresh gas outlet, if provided, and all other parts of the anaesthetic workstation intended to be connected with the patient or with the anaesthetic breathing system.

Add the following:

3.1 anaesthetic workstation: System for the administration of inhalation anaesthesia which includes one or more actuator modules, their particular monitoring and alarm modules and essential hazard protection modules.

3.2 R: module: Self-contained unit of an anaesthetic workstation that performs a specific task or class of tasks in support of the major function of the anaesthetic workstation.

3.3 R: actuator module: Module which performs the task of delivery of energy or substances in controlled quantities

3.4 R: monitoring module: Module which performs the task of displaying or indicating a variable to the operator.

3.5 R: alarm module: Module which performs the task of providing a visual and/or audible alarm signal(s) when an alarm condition is present.

3.6 R: protection module: Module which, without intervention of the operator, performs the task of protecting the patient against hazardous output due to incorrect delivery of energy or substances.

3.7 anaesthetic gas scavenging system; AGSS: System which is connected to the exhaust port(s) of an anaesthetic workstation or which is integrated into an anaesthetic workstation for the purpose of conveying expired and/or excess anaesthetic gases to an appropriate place of discharge.

> NOTE: Functionally, an AGSS comprises three different parts, a transfer system, a receiving system and a disposal system. These three functionally discrete parts may be either separate or sequentially combined in part or in total. In addition, one or more parts of an AGSS may be sequentially combined with a breathing system to include the transfer system or transfer and receiving system.

3.8 gas mixing system: Device or assembly which receives separate supplies of oxygen and other medical gas(es) and which delivers the mixed gases in operator-adjustable concentrations.

3.9 machine gas piping: All pipework, including unions, from unidirectional valves in the pipeline inlets and from the pressure regulator outlets to the flow meter controls and auxiliary gas outlets. It includes piping leading to and from pneumatic alarm systems, gauges and oxygen flush valves.

3.10 flow control system: Device or assembly that controls the flow of gas(es).

3.11 anaesthetic vapour delivery module; vaporizer: Device or assembly where anaesthetic agent is transformed from the liquid to the gaseous phase and is mixed in a controllable concentration with the fresh gas or breathing gas.

3.12 pressure regulator: Gas pressure reducing and controlling device designed to provide a constant delivery pressure over a range of variable inlet pressures and/or flows.

3.13 emergency anaesthetic equipment: Transportable system for the administration of inhalation anaesthesia which includes but is not limited to one or more actuator modules, their recommended particular monitoring and alarm modules and particular hazard protection modules for use e.g. in the open field for rescue operation, in disaster areas or in areas where anaesthesia is not normally administered.

3.14 medical gas supply system:

Either

a) a medical gas pipeline system comprising a central supply system, control equipment, a pipeline distribution system and terminal units at the point where non-flammable medical gases or vacuum may be required; or

b) any other installation having no permanent pipeline system but employing a medical gas supply source complete with pressure regulators.

3.15 R: flammable anaesthetic agent: Anaesthetic agent which is ignited by the test specified in annex AA of this European Standard.

3.16 R: non-flammable anaesthetic agent: Anaesthetic agent which is not ignited by the test specified in annex AA of this European Standard.

3.17 anaesthetic ventilator: Automatic actuator module which is connected to the patient's airway and is designed to augment or provide ventilation of the patient during anaesthesia.

3.18 fresh-gas outlet; common gas outlet: That port through which the dispensed mixture from the anaesthetic gas delivery module is delivered to the anaesthetic breathing system.

3.19 anaesthetic gas: Gas and/or the vapour of a volatile agent used in anaesthesia.

3.20 anaesthetic gas delivery module: Actuator module which controls the flow and composition of the fresh gas delivered during anaesthesia. It may consist of a flow control system, flow meters and/or a gas mixing system and may be combined with an anaesthetic vapour delivery module.

3.21 enabled condition: One of the conditions necessary to make an action possible.

3.22 draw-over vaporizer: Calibrated vaporizer intended to be installed in a breathing system from which the flow of a gas vapour mixture is produced by lowering the pressure at its outlet below that at its inlet by the patient's inspiratory effort or by mechanical means.

3.23 permanent connection: Connection which can be detached only by the use of a tool.

3.24 anaesthetic breathing system: Those inspiratory and expiratory gas pathways, excluding the anaesthetic ventilator, between the fresh gas outlet and the patient connection port which contain gas at respiratory pressure.

NOTE: Gas pathways exclusively concerned with AGSS are not regarded as part of an anaesthetic breathing system.

3.25 circle system: Anaesthetic breathing system in which the direction of gas flow through separate inspiratory and expiratory pathways is determined by e.g. unidirectional valves and in which the two pathways form a circle.

3.26 circle absorption system: Circle system incorporating a carbon dioxide absorber.

3.27 circle absorber assembly: That part of a circle system which comprises a carbon dioxide absorber, ports for connection to breathing tubes and which may include a reservoir bag port, a fresh gas inlet and an APL valve.

3.28 fresh-gas inlet: That port on a breathing attachment through which the dispensed mixture from the anaesthetic gas delivery module is delivered to the anaesthetic breathing system.

3.29 respiratory gas-conducting components: All components of the anaesthetic ventilator and the anaesthetic breathing system which are in contact with the patient's inhaled gas during any form of ventilation.

NOTE 1: Such components are e.g. anaesthetic breathing systems, anaesthetic breathing system attachments, ventilator bellows, microbial filters, adjustable pressure limiting (APL) valves and CO_2-absorber assemblies.

NOTE 2: When sampled gas is returned to the anaesthetic breathing system the gas sampling line is considered to be a respiratory gas conducting component.

3.30 transfer system: That part of an AGSS, which may or may not incorporate tubing, which transfers expired and/or excess anaesthetic gases from the exhaust port of the anaesthetic breathing system and/or anaesthetic ventilator to the receiving system and which may contain a means of pressure relief.

NOTE: See also 3.7 and figure 106 of this European Standard.

3.31 transfer tube: That part of an AGSS which transfers expired and/or excess gases from the anaesthetic breathing system and/or anaesthetic ventilator to the receiving system.

3.32 receiving system: That part of an AGSS which provides an interface between the transfer system and the disposal system and may contain means of sub-atmospheric and/or positive pressure relief.

3.33 receiving hose: That part of an AGSS which transfers expired and/or excess gases from the receiving system to the disposal system.

3.34 disposal system: Means by which the expired or excess anaesthetic gases are conveyed from the receiving system to an appropriate place of discharge.

NOTE: A place of discharge may be, for example, the exterior of a building or a non-recirculating extract ventilation system.

3.35 power device: That part of the disposal system of an AGSS which provides the gas flow for scavenging.

3.36 AGSS terminal unit: Connection point between the receiving system and the disposal system.

3.37 maximum extract flow: Highest flow of gas at the entry to the disposal system which can be accommodated without exceeding the limitations for induced flow or sub-atmospheric pressure.

3.38 minimum extract flow: Lowest flow of gas at the entry to the disposal system which ensures that the permissible spillage to atmosphere is not exceeded.

3.39 induced flow: That flow at the inlet of the transfer system which is caused by the sub-atmospheric pressure generated in the AGSS.

3.40 spillage: Volume of expired or excess anaesthetic gas which cannot be accommodated by the AGSS over a given period.

3.41 clearly legible: Visual attribute of information displayed by the equipment that allows the operator to discern (or identify) qualitative or quantitative values or functions under a specific set of environmental conditions.

3.42 operator's position: Intended orientation of the operator with respect to the equipment for normal use according to the instructions for use.

4 General requirements and general requirements for test

4.1 Modifications to clause 3 of EN 60601-1 : 1990

Anaesthetic workstations shall comply with EN 60601-1-1. Clause 3 of EN 60601-1 : 1990 applies with the following additions:

3.1 Add the following to 3.1:

All parts of an anaesthetic workstation and its modules shall be designed and manufactured to minimize health risks by reducing the leaching of substances from the devices during normal use to levels below those assumed to be non-toxic.

3.6. Add the following items:

3.6aa) **R:** Applicable single fault conditions are short or open circuits of components or wiring which can
- cause sparks to occur, or
- increase the energy of sparks, or
- increase temperatures (see Section seven of this European Standard.)

3.6 bb) **R:** An oxidant leak which is not detected by e.g. an alarm or periodic inspection shall be considered a normal condition and not a single fault condition.

4.2 Modifications to clause 4 of EN 60601-1 : 1990

Clause 4 of EN 60601-1 : 1990 applies with the following additions:

4.5 aa) If not stated otherwise gas leakage values shall be measured at an ambient pressure of 101,3 kPa and 20 °C or shall be corrected to these conditions.

4.101 Type testing of modules of anaesthetic workstations

For type testing of modules of an anaesthetic workstation only the appropriate clause(s) as listed in annex CC of this European Standard shall apply to demonstrate compliance with this European Standard.

For the purpose of this European Standard the phrase "shall be operated with" shall be interpreted to mean that:

- either, the workstation is equipped with the module or,
- the module is intended to be added to the system before the workstation is used.

5 Classification

Clause 5 of EN 60601-1 : 1990 applies with the following addition:

NOTE: An anaesthetic workstation may have applied parts of different types.

6 Identification, marking and documents

Clause 6 of EN 60601-1 : 1990 applies with the following additions and modifications:

In clause 6, second dash add the following:

- see annex QQ of this European Standard for compliance.

In 6.1 j), replace the first sentence with the following:

R: The rated input marking required in 6.1j) of EN 60601-1 : 1990 shall be given in amperes for the anaesthetic workstation and for the sum of the current ratings for the anaesthetic workstation and the auxiliary mains socket outlets.

Replace 6.1 k) with the following:

R: Each auxiliary mains socket outlet shall be marked with the maximum allowed output in amperes.

- If auxiliary mains socket outlets(s) can accept a mains plug, the auxiliary mains socket outlet(s) shall be marked with symbol 14 of table DI, annex D in EN 60601-1 : 1990.

In 6.1 add the following additional items:

6.1 aa) All operator-detachable, flow-direction-sensitive components, breathing attachments or modules shall be clearly and durably marked with an arrow showing direction of gas flow.

6.1 bb) Each gas-specific inlet and outlet shall be identified by clear and durable marking using gas name or chemical symbol in accordance with EN 739. If colour coding is used in addition it shall be in accordance with EN 1089-3. See Special National Conditions in Annex TT.

6.1 cc) Respiratory gas conducting components

- Marking of a ventilator port

The ventilator port on an anaesthetic breathing system, if provided, shall be marked with the word 'VENTILATOR' or an appropriate symbol.

- Marking of a reservoir bag port

The connection port(s) for reservoir bag(s) shall be marked with the word 'BAG' or with a symbol to denote 'bag' (see also 107.1.3).

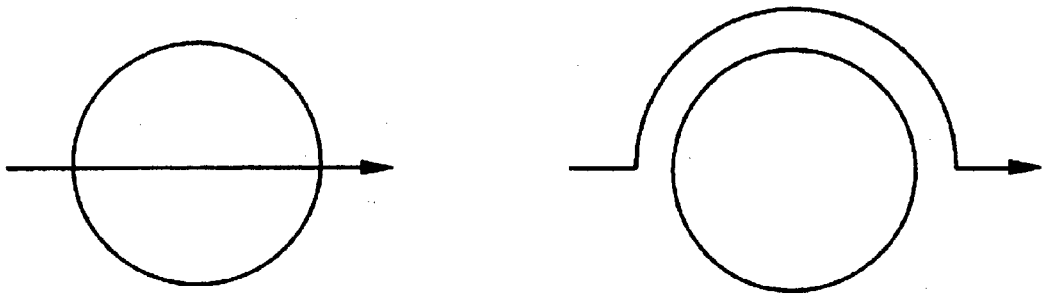
- Marking of antistatic and conductive parts

Anaesthetic breathing systems, breathing attachments and integrally-attached non-metallic components made of antistatic or conductive materials in accordance with 39.3 b) of EN 60601-1 : 1990 shall be clearly marked with the word 'ANTISTATIC' or 'CONDUCTIVE' (see 107.2).

NOTE: They can also bear a continuous indelible yellow-coloured line throughout their length.

- Bypass to carbon dioxide-absorber assemblies
If a means of bypassing the absorbent is provided, its control shall be marked either 'absorber on', and 'absorber off' and/or with the symbols given in figure 101. (see also clause 107.5).

The 'absorber-off' indicator shall be visible to the operator from a normal operating position.



On Off

NOTE 1: The symbols 'on' and 'off' may be preceded by the word 'absorber'.
NOTE 2: The 'off' position means that gas does not pass through the absorbent.

Figure 101: Symbols on CO_2 - absorber assembly control

6.1 dd) Marking of devices, labels and packaging

Devices, labels and/or packaging shall include the following information as applicable:

- If the intended purpose of the device is not obvious to the operator, the device shall be provided with instructions for use;

- The name or trademark and address of the manufacturer. For devices imported into the European Union the following shall also be included: the name and address of the person responsible or of the authorized representative of the manufacturer or the importer established within the European Community shall be provided with the device or with the accompanying documents;

- A device identification and content information;

- Where appropriate, the symbol STERILE , as specified in EN 980, together with the method of sterilization;

- Where appropriate, the batch code, preceded by the symbo LOT , as specified in EN 980, or serial number;

- Where appropriate, an indication of the date by which the device can be used in safety, expressed as the year and month;

- Where appropriate, an indication that the device is for single use;

- Any special storage and/or handling conditions;

- Any warning or precautions to take;

- For active medical devices the year of manufacture except for those covered by 6th dash above;

- Where appropriate, the recommended method(s) of cleaning, disinfection and sterilisation;

- Device packaging and/or labelling shall differentiate between the same or similar products placed on the market both sterile and non-sterile by the same manufacturer;

- Packages containing breathing attachments or complete anaesthetic breathing systems made of antistatic or conductive material shall be clearly marked with the word 'ANTISTATIC' or 'CONDUCTIVE' (see 107.2);

- The necessary instructions in the event of the sterile pack being damaged and, where appropriate, details of appropriate methods of re-sterilization.

6.1 ee) Marking of anaesthetic ventilators

The relief pressure of the maximum airway pressure protection module shall be marked on an anaesthetic ventilator not provided with an operator-adjustable pressure limiting system (see 51.113).

In 6.3 add the following additional items:

6.3 aa) Pressure displays

Gas supply pressures shall be displayed in units of kPa times 100.

NOTE: Additional units e.g. bar can be used.

Each gas specific pressure display shall be identified by the gas name or chemical symbol in accordance with EN 739.

If colour coding is used in addition it shall be in accordance with EN 1089-3. See Special National Conditions in Annex TT.

Pressures in the anaesthetic breathing system shall be displayed in Pa times 100 .

NOTE: Additional units e.g. cm H_2O can be used.

6.3 bb) Anaesthetic gas delivery modules

- Each flow adjustment control of a single gas supply and each concentration adjustment control or their surroundings shall be identified by clear and durable marking using the gas name or chemical symbol in accordance with EN 739.

If colour coding is used in addition it shall be in accordance with EN 1089-3. See Special National Conditions in Annex TT.

- The scale including the minimum and maximum concentration mark of the gas mixture control of a gas mixing system shall be marked to indicate the concentration of oxygen % (V/V) in the delivered gas.

- The oxygen flush control shall be clearly marked with one of the following:

• 'oxygen flush'
• 'O_2 flush'
• 'O_2 +'

- The value to which the pressure at the fresh-gas outlet is limited shall be marked near to the fresh gas outlet.

- The point of reference for reading the float shall be marked on the flow meter assembly.

6.3 cc) Anaesthetic vapour delivery modules

- The maximum and minimum filling levels shall be marked on the liquid level indicator. As an alternative the actual usable volume shall be clearly displayed.

- Each operator-detachable anaesthetic vapour delivery module shall be marked with either the words 'see instructions for use' or the symbol for 'Attention, consult accompanying documents' (No.14 in table DI of EN 60601-1 : 1990).

- If operator-accessible the anaesthetic vapour delivery module or the anaesthetic agent reservoir and/or filling port shall be marked with the generic name of the anaesthetic agent. The control activating the delivery of a specific anaesthetic agent shall be marked with the generic name in full spelling or abbreviated form.

If colour coding is used it shall be in accordance with Annex HH.

- The unit in which the control of the anaesthetic vapour delivery module is graduated shall either be marked on the control or shall be clearly displayed.

- Graduated controls if provided shall be marked '0' or 'off' or with both if the zero-position is not also the 'off'-position.

In 6.6, add the following additional item

aa) See 6.1 bb) of this European Standard.

In 6.7 add the following additional item

aa) Requirements for visual alarm indications are given in 51.114.

In 6.8.2 a) add the following additional items:

- EN 1041 shall apply.

- Instructions for use shall include information about the purpose and intended use of the anaesthetic workstation and/or its modules.

- The manufacturer/supplier of the anaesthetic workstation or actuator module(s) shall provide a list of the necessary monitoring, alarm and protection module(s) which are not an integral part of the anaesthetic workstation or actuator module(s) as specified in this European Standard (see table 101 or 102 respectively).

- The instructions for use shall state that the monitoring, alarm and protection module(s) listed in 6.8.2 a) third additional dash, i.e. which are not an integral part of the anaesthetic workstation or actuator module(s) are required to protect against hazardous output and that they have to be in compliance with this European Standard.

- The instructions for use shall contain a warning statement to the effect that when in use the anaesthetic workstation shall have not more than four operator-accessible auxiliary mains socket outlets.

- The instructions for use shall contain the conditions under which measured values are displayed (e.g. BTPS (Body Temperature Pressure Saturated), ATPS (Ambient Temperature Pressure Saturated), STPD (Standard Temperature Pressure Dry))

In 6.8.2 add the following additional items:

aa) The instructions for use of category APG anaesthetic workstations shall include statements to the effect that:

- This anaesthetic workstation has been constructed to comply with the requirements for category APG equipment.

- Any modification to the anaesthetic workstation may compromise its safety in the presence of flammable anaesthetic agents.

- Provided that the following precautions are strictly observed this anaesthetic workstation is safe to use with flammable anaesthetic agents such as diethyl-ether and cyclopropane:

  - The discharge of flammable anaesthetic agents or mixtures whilst the anaesthetic breathing system is disconnected is to be avoided.

  - Only equipment classified and marked as APG should be used within 5 cm of any point of possible emission of flammable anaesthetic agents or mixtures.

  - Only equipment classified and marked as AP or APG should be used within 25 cm of any point of possible emission of flammable anaesthetic agents.

bb) R: The instructions for use of anaesthetic workstations marked as APG but having parts which are not category APG shall include full information to identify such parts.

cc) R: The instructions for use of category APG anaesthetic workstations shall include a warning statement to the effect that:

- When using agents forming flammable mixtures only antistatic or electrically conductive components shall be used in the anaesthetic breathing system. This does not apply to tracheal tubes, tracheal tube connectors and oropharyngeal airways.

dd) R: The instructions for use of anaesthetic workstations not specified as category APG equipment shall include a statement to the effect that:

- To avoid explosion hazards, flammable anaesthetic agents such as ether and cyclopropane shall not be used in this anaesthetic workstation. Only anaesthetic agents which comply with the requirements for non-flammable anaesthetic agents in this European Standard are suitable for use in this anaesthetic workstation.

NOTE: It is recommended that manufacturers of inhalation/volatile anaesthetic agents should state in their labelling whether the agent complies with the tests set out in annex AA of this European Standard and is therefore safe for use in anaesthetic workstations not classified APG.

ee) R: The instructions for use of anaesthetic workstations not specified as category APG shall include a statement to the effect that:

- Burns can occure if antistatic or electrically-conductive breathing tubes are used while high-frequency electric surgery equipment is in use. Therefore, such breathing tubes are not recommended.

ff) If auxiliary mains socket outlet(s) accept a standard mains plug the instructions for use shall contain a warning relating to symbol 14 of EN 60601-1: 1990 required in 6.1 k) of this European Standard to the effect that:

- The connection of equipment to the auxiliary mains socket outlet(s) can increase the patient leakage currents to values exceeding the allowable limits in the event of a defective protective earth conductor.

gg) The instructions for use shall contain information on methods of cleaning and/or sterilization prior to use.

hh) Information about anaesthetic gas delivery modules

Instructions for use shall contain:

- If the anaesthetic workstation is fitted with a gas mixing system an instruction to disconnect the anaesthetic workstation from the gas supply after use to prevent contamination or pollution of the pipeline system.

- A schematic flow diagram.

- The pressure at which the gas cut-off device specified in 51.110 is activated, if provided.

ii) Information about anaesthetic vapour delivery modules

If the anaesthetic workstation is fitted with an anaesthetic vapour delivery module by the manufacturer or it is intended that a recommended anaesthetic vapour delivery module is to be fitted according to the manufacturer's instructions, the following shall be contained in the instructions for use:

- details of the anaesthetic vapour delivery module performance, including the effects of variation in ambient temperature, ambient pressure, tilting, back pressure, input flow and gas mixture composition;

- instructions for use of any agent specific filling device(s) with which the anaesthetic vapour delivery module is fitted;

- the carrier gas and gas flow(s) which were used for calibration of the anaesthetic vapour delivery module and, if the anaesthetic workstation is recommended for use with an anaesthetic ventilator, the anaesthetic ventilator settings used when calibrating the anaesthetic vapour delivery module;

- a statement that the anaesthetic vapour delivery module should not be used between 'off' and the first graduation above zero, if the anaesthetic vapour delivery module cannot be calibrated in this range;

- if applicable, the volume of agent required to fill the agent reservoir from the minimum to the maximum filling level, and the total capacity;

- instructions for testing for correct connection of any operator-detachable anaesthetic vapour delivery module;

- advice on handling and transportation and storage.

jj) Information about respiratory gas conducting components

The instructions for use shall contain the following information:

- A schematic diagram of the gas flow within the anaesthetic breathing system and the anaesthetic ventilator module identifying their components and their location(s).

- The volume, resistance and compliance of anaesthetic breathing systems supplied complete. Resistance shall be disclosed for flows of 60 l/min for adult use, 30 l/min for paediatric use and 5 l/min for neonatal use.

- If the fresh gas utilization is stated the test method shall be disclosed.

- For circle absorber assemblies:

• a diagram of the absorber bypass mechanism, if present;

• the material specification of the carbon dioxide absorbent recommended for use in the absorber;

• instruction for draining water from the absorber assembly, if applicable;

• instruction to check the colour change of the absorbent;

• the proportion of gas which does not pass through the absorbent with the by-pass control, if fitted, in the 'on' position. The operating conditions and the method(s) of testing shall be disclosed;

• the internal compliance of the circle absorber assembly, measured with the carbon dioxide absorbent container filled with fresh absorbent of the type recommended by the manufacturer, and expressed as a volume in millilitres at 3 kPa (30 cm H_2O);

• the volume of the carbon dioxide absorbent container(s) expressed in millilitres;

• instructions for changing the carbon dioxide absorbent, cleaning the absorber and maintaining the leak-tightness of the absorber;

• if the circle absorber assembly is provided with a bypass the leakage from the circle absorber assembly, measured as described in GG.11 with and without the carbon dioxide absorbent container(s) fitted;

- the pressure generated by a wet unidirectional valve when tested as described in GG.12;

- the pressure to open a wet unidirectional valve when tested as described in GG.13.

kk) Information about monitoring, alarm and protection modules

The instructions for use shall contain:

- a description of the methods of verifying alarm functions;

- details of any pressure-relief valves fitted to the anaesthetic workstation;

- details of the oxygen-failure alarm system(s) and the associated cut-off devices.

ll) Information about anaesthetic gas scavenging systems

The manufacturer shall provide the following information with AGSS components:

- the maximum and minimum allowable extract flow and differential pressure measured at the interface point between the receiving system and the disposal system or between the receiving system and the power device (see figure 106).

NOTE: This allows a disposal system to be matched to an AGSS transfer and receiving system without using the AGSS to measure the performance of the disposal system.

- the functional characteristics of particle filters according to 111.4.3

mm) Information about electromagnetic compatibility

The instructions for use shall include a warning statement to the effect that:

- The functioning of this anaesthetic workstation or module, as applicable, may be adversely affected by electromagnetic interference exceeding the levels specified in EN 60601-1-2.

NOTE: If it can be demonstrated that the anaesthetic workstation or module, as applicable, is resistant to the levels exceeding those specified in EN 60601-1-2, the instructions for use can state the appropriate higher levels to which the equipment has been tested.

nn) Information about disposal

The instructions for use shall include information about any precautions to be taken if there is a specific unusual risk associated with the disposal of the device.

oo) Information about functioning with reserve power

If the anaesthetic workstation or its modules are provided with a reserve power supply the functioning after a switch-over to the reserve power supply shall be described.

6.8.3 Technical description

In 6.8.3 a) add the following additional item :

- The technical description shall additionally include the following information:

• **R:** Accuracies, display resolutions and ranges of displayed values and calibrated controls.

NOTE: The accuracies should be expressed in the form of maximum zero error (bias) quoted directly in appropriate units plus a sensitivity error (linearity, precision), e. g. quoted as a percentage of the reading.

• Interdependence of controls, if applicable.

In 6.8.3 add the following additional items:

6.8.3 aa) Technical description of anaesthetic gas delivery modules

The technical description shall include the following:

- The pressure and flow characteristics of any gas power outlet under worst-case conditions stated by the manufacturer.

- The specified range of flows from the anaesthetic gas delivery module, if applicable.

- A statement of the composition and dryness specification for all gases to be supplied to the anaesthetic gas delivery module.

- Details of non-return valves and pressure-relief valves and their characteristics, if fitted.

6.8.3 bb) Technical description of the anaesthetic ventilator module

The technical description shall include the following information as far as applicable:

- A listing of the following pressures.

  • maximum limited pressure ($P_{lim, max}$);

  • range of values to which the maximum working pressure can be set and the means by which the maximum is assured (e.g. pressure-cycling, pressure-limiting, pressure generation) and a statement whether sub-atmospheric pressure is available in the expiratory phase;

  • minimum sub-atmospheric limited pressure ($P_{lim, min}$);

  • range of values to which the minimum sub-atmospheric working pressure can be set and the means by which the minimum is assured;

- A listing of the ranges of the following parameters:

  • cycling pressure,

  • end-expiratory pressure,

  • If there is a facility for sub-atmospheric pressure in the expiratory phase, the limiting pressure and generated pressure, if applicable, shall be listed for the expiratory phase and the inspiratory phase.

- A technical description of the means of triggering .

- The purpose, type, range and sensing position of all measuring and display devices either incorporated into the anaesthetic ventilator module or recommended by the manufacturer for use with the anaesthetic ventilator module.

In 6.8 add the following additional item:

6.8.101 Check list

Each anaesthetic workstation and its modules shall be provided with a check list(s) which summarizes the test and operating procedures recommended by the manufacturer which have to be performed by the operator prior to use (see 51.116).

The use of electronic displays, e.g. cathode ray tube (CRT), is permitted.

7 Power input

Clause 7 of EN 60601-1 : 1990 applies.

Section 2: Environmental conditions

8 Basic safety categories

Not used.

9 Removable protection means

Not used.

10 Environmental conditions

Clause 10 of EN 60601-1 : 1990 applies with the following addition:

10.101 Pneumatic power supply

If the anaesthetic workstation and its modules are intended to be connected to a medical gas supply system (either a medical gas pipeline system complying with prEN 737-3 or a pressure regulator complying with EN 738-1) they shall operate and meet the requirements of this European Standard for pneumatic power supplied throughout a range of 280 kPa to 600 kPa and shall cause no safety hazard under the single fault condition of the medical gas supply system of 1 MPa inlet pressure.

The time-weighted average over 10 s and the steady-state flow for each medical gas required by the anaesthetic workstation shall not exceed 60 l/min at a pressure of 280 kPa measured at the gas inlet port.

11 Not used

12 Not used

Section 3: Protection against electrical shock hazards

13 General

Clause 13 of EN 60601-1 : 1990 applies.

14 Requirements related to classification

Clause 14 of EN 60601-1 : 1990 applies.

15 Limitation of voltage and/or energy

Clause 15 of EN 60601-1 : 1990 applies.

16 Enclosures and protective covers

Clause 16 of EN 60601-1 : 1990 applies.

17 R: Separation

Clause 17 of EN 60601-1 : 1990 applies.

18 Protective earthing, functional earthing and potential equalization

Clause 18 of EN 60601-1 : 1990 applies.

19 Continuous leakage current and patient auxiliary currents

Clause 19 of EN 60601-1 : 1990 applies with the following addition:

In 19.4 h) add the following additional item:

12) R: Measurement of the patient leakage currents

The patient leakage current shall be measured from all applied parts classified as the same type (see 14.6 of EN 60601-1 : 1990). These parts shall be connected together electrically. Parts connected to the protective earth terminal shall be tested separately.

20 Dielectric strength

Clause 20 of EN 60601-1 : 1990 applies.

Section 4: Protection against mechanical hazards

21 Mechanical strength

Clause 21 of EN 60601-1 : 1990 applies.

22 Moving parts

Clause 22 of EN 60601-1 : 1990 applies.

23 Surfaces, corners, and edges

Clause 23 of EN 60601-1 : 1990 applies.

24 Stability in normal use

Clause 24 of EN 60601-1 : 1990 applies.

25 Expelled parts

Clause 25 of EN 60601-1 : 1990 applies.

26 Vibration and noise

Not used.

27 Pneumatic and hydraulic power

Clause 27 of EN 60601-1 : 1990 applies.

28 Suspended masses

Clause 28 of EN 60601-1 : 1990 applies.

Section 5: Protection against hazards from unwanted or excessive radiation

29 X-radiation

Clause 29 of EN 60601-1 : 1990 applies.

30 Alpha, beta, gamma, neutron radiation and other particle radiation

Clause 30 of EN 60601-1 : 1990 applies.

31 Microwave radiation

Clause 31 of EN 60601-1 : 1990 applies.

32 Light radiation (including lasers)

Clause 32 of EN 60601-1 : 1990 applies.

33 Infra-red radiation

Clause 33 of EN 60601-1 : 1990 applies.

34 Ultra-violet radiation

Clause 34 of EN 60601-1 : 1990 applies.

35 Acoustical energy (including ultrasonic)

Clause 35 of EN 60601-1 : 1990 applies.

36 Electromagnetic compatibility

Clause 36 of EN 60601-1 : 1990 applies with the following additions:

36.101 Electromagnetic compatibility

The anaesthetic workstation and its modules shall continue to function and meet the requirements of this European Standard or shall fail without causing a safety hazard when tested in accordance with EN 60601-1-2.

If an anomaly occurs, such as display interruption or alarm activation, it shall be possible to restore normal operation within 30 s after the electromagnetic disturbances have been applied.

36.102 Electrostatic discharge

Discharge shall be applied only to accessible parts and coupling planes as defined in EN 60801-2.

Section 6: R: Protection against hazards of ignition of flammable anaesthetic mixtures

37 Locations and basic requirements

Clause 37 of EN 60601-1 : 1990 applies with the following additions:

37.101 R: Anaesthetic agents which are ignited by the test in annex AA of this European Standard shall be regarded as flammable anaesthetic agents.

Anaesthetic workstations specified for use with such agents shall be classified and marked as category APG equipment and shall comply with the requirements of APG equipment in EN 60601-1 : 1990.

NOTE: Diethyl-ether and cyclopropane are such agents in use.

37.102 R: Anaesthetic agents which are not ignited by the test in annex AA of this European Standard shall be regarded as non-flammable anaesthetic agents.

Anaesthetic workstations specified for use only with such agents shall comply with clause 37.103 of this European Standard.

NOTE: Such an agent in use is, e.g. halothane (2-bromo 2-chloro 1,1,1-trifluoro- ethane).

37.103 R: Requirements for anaesthetic workstations not specified and marked as category APG equipment:

In an anaesthetic workstation not classified as category APG equipment electrical circuits which may be a source of ignition under normal condition and single fault condition in enclosed compartments within which anaesthetic mixtures with oxygen and/or nitrous oxide are produced or used, shall comply with the requirements of clause 43 of this European Standard.

38 Marking, accompanying documents

Clause 38 of EN 60601-1 : 1990 applies.

39 Common requirements for category AP and category APG equipment

Clause 39 of EN 60601-1 : 1990 applies with the following addition:

In 39.3, add the following additional item:

aa) R: An anaesthetic workstation specified and marked as APG shall provide a continuous current path for electrostatic charges from the fresh gas outlet to earth with a resistance less than 1 megaohm.

Compliance is checked by the following test:

The resistance shall be measured between the fresh gas outlet(s) and in turn

- a conductive plate on which the anaesthetic workstation is placed,
- any protective earth terminal,
- any terminal for potential equalization conductor.

40 R: Requirements and tests for category AP equipment, parts and components thereof

Clause 40 of EN 60601-1 : 1990 applies.

41 Requirements and tests for category APG equipment, parts and components thereof

Clause 41 of EN 60601-1 : 1990 applies.

Section 7: Protection against excessive temperatures, and other safety hazards

42 Excessive temperatures

Clause 42 of EN 60601-1 : 1990 applies.

43 R: Fire prevention

Clause 43 of EN 60601-1 : 1990 applies with the following addition:

In order to reduce the risk to patients, other persons or the surroundings due to fire, ignitable materials, under normal and single fault conditions, shall not, at the same time, be subjected to conditions in which:

- the temperature of the material is raised to its minimum ignition temperature; and

- an oxidant is present.

The minimum ignition temperature shall be determined in accordance with IEC 60079-4 using the oxidising conditions present under the normal and single fault condition.

Compliance is checked by determining the temperature the material is raised to under the normal and single fault condition.

If sparking can occur under normal or single fault conditions, the material subjected to the energy dissipation of the spark shall not ignite under the oxidising conditions present.

Compliance is checked by observing if ignition occurs under the most unfavourable combination of normal conditions with a single fault.

44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility

Clause 44 of EN 60601-1 : 1990 applies with the following additions:

44.3 Add:

The anaesthetic workstation and its modules shall be so constructed that spillage does not wet components which, when wetted, can cause a safety hazard.

Compliance shall be checked by the test given in 44.3 of EN 60601-1 : 1990.

44.7 Add:

44.7.101 In order to minimize the risk of infection to the patient from respiratory gas conducting components, all components specified as reusable by the manufacturer which come into contact with the inspiratory gas shall be sterile or disinfected, or sterilizable or disinfectable, or be provided with a microbial filter.

44.7.102 If a claim is made in the labelling that a device is sterile, the device shall have been sterilized using a validated method.

44.7.103 Non-sterile device packaging systems shall be designed to maintain products which are intended to be sterilized before use at their intended level of cleanliness and shall be designed to minimize the risk of microbial contamination.

45 Pressure vessels and parts subject to pressure

Clause 45 of EN 60601-1 : 1990 applies.

46 Human errors

Not used.

47 Electrostatic charges

Not used.

48 R: Materials in applied parts in contact with the body of the patient

Clause 48 of EN 60601-1 : 1990 applies.

49 Interruption of the power supply

Clause 49 of EN 60601-1 : 1990 applies with the following additions:

49.101 Means shall be provided to prevent inadvertent operation of the 'off' switch.

Compliance shall be checked by inspection.

49.102 R: Transient interruptions of the power supply shall not cause a safety hazard.

Compliance shall be checked by inspection and functional testing.

Section 8: Accuracy of operating data and protection against hazardous output

50 Accuracy of operating data

Clause 50 of EN 60601-1 : 1990 applies.

51 Protection against hazardous output

Clause 51 of EN 60601-1 : 1990 applies with the following additions:

51.101 The particular requirements of the monitoring and alarm modules apply when the anaesthetic workstation is operating under normal power supply condition.

When operating under reserve power supply, if provided, see 51.102.2 and 51.102.3

Each anaesthetic workstation or actuator module for use in an anaesthetic workstation shall be provided with means of protection against hazards from delivery of energy or substances to the patient. These means shall either be integrated into the anaesthetic workstation or the actuator module or, if not integrated, the manufacturer shall provide information about which monitoring, alarm and protection modules are necessary and how to use them (see 6.8.2 of this European Standard).

The particular requirements of these monitoring ,alarm and protection modules are specified in this document (clauses 6 and 51 and section ten) and are summarized in annex CC.

For the purpose of this European Standard the phrase "if the anaesthetic workstation is in use with a 'xxxx' module, it shall be operated with 'yyyy'" shall be interpreted to mean:

- **either,**
  the anaesthetic workstation is equipped with 'yyyy'
- **or,**
  that the 'yyyy'module is intended to be added to the system before the anaesthetic workstation is used.

51.102 Power failure alarm module

51.102.1 The anaesthetic workstation shall be operated with a driving power failure alarm which activates an audible alarm signal for at least 7 s duration if the driving power falls below the minimum value specified by the manufacturer for normal operation.

51.102.2 In case of an automatic switch-over to a reserve power supply this mode of operation shall be indicated by a low priority signal as specified in EN 475 or by a visual indicator.

In this case the applicable requirements of 51.114 also apply.

51.102.3 Devices with an internal power source shall be equipped with a means of determining the state of this power source (See 6.8.2 oo) of this European Standard).

Table 101: Anaesthetic workstation configuration for protection against hazardous output

	Monitoring and alarm modules																Protection modules			
	Power failure alarm	0_2-supply failure alarm	Inspiratory oxygen concentration		Anaesthetic agent concentration			Airway pressure			Expired volume		Breathing system integrity	CO_2 concentration			N_20 cut off	AGSS	Maximum pressure limitation	Adjustable pressure limitation
Actuator modules			M	L	M	L	H	M	L	H	M	L		M	L	H				
Driving power - electrical - pneumatical	+ +																			
Anaesthetic gas delivery - O_2		+	+	+																
- Air			+	+																
- Premixed (1)			+	+														+		
- Others			+	+													+	+		
Anaesthetic vapour delivery module					+ (2)	+ (2)	+ (2)											+		
Anaesthetic ventilator module								+	o (3)	+	+ (2)	o (3)	+						+	+ (2)
Anaesthetic breathing system			+	+				+	o	o	o (2)	o (3)	o	+	+ (3)	+			+	o

M Monitor (measurement and display)
H High level alarm
L Low level alarm
+ Requirement
o Recommendation

(1) Premixed gas of 50 % N_20 and 50 % O_2.
(2) Conditional requirement (see appropriate clause).
(3) see 51.108.1 Note.

Table 102: Emergency anaesthetic equipment configuration for protection against hazardous output

	Monitoring and alarm modules																Protection modules			
	Power failure alarm	O_2-supply failure alarm	Inspiratory oxygen concentration		Anaesthetic agent concentration			Airway pressure			Expired volume		Breathing system integrity	CO_2 concentration			N_2O cut off	AGSS	Maximum pressure limitation	Adjustable pressure limitation
Actuator modules			M	L	M	L	H	M	L	H	M	L		M	L	H				
Driving power - electrical - pneumatical	+ o																			
Anaesthetic gas delivery - O_2		o	o	o																
- Air			o	o																
- Premixed (1)			o	o														o		
- Others			o	o													+	o		
Anaesthetic vapour delivery module					o	o	o											o		
Anaesthetic ventilator module								o	o	o	o	o	o						+	o
Anaesthetic breathing system			o	o				o	o	o	o	o	o	o	o	o			+	o

M Monitor (measurement and display)
H High level alarm
L Low level alarm
+ Requirement
o Recommendation

(1) Premixed gas of 50 % N_2O and 50 % O_2.

51.103 Oxygen supply failure alarm module

51.103.1 If the anaesthetic workstation is in use with an anaesthetic gas delivery module for oxygen it shall be operated with an oxygen supply failure alarm module which generates an auditory alarm signal to indicate failure of the oxygen supply, whether that supply is derived from cylinders or from a pipeline system. This auditory alarm shall be either gas or electrically powered. If electrically powered it shall be a high priority signal as specified in EN 475 and shall comply with the applicable requirements of 51.114.

51.103.2 The gas powered auditory alarm signal shall be of at least 7 s duration and, when tested as described in EN ISO 3746, its A-weighted sound pressure level shall be at least 2 dB above a white background level of 55 dB.

51.103.3 The alarm signal shall be derived from the oxygen supply pressure.

51.103.4 If the alarm signal is gas-powered, the energy required to operate it shall be derived from the oxygen supply pressure.

51.104 Oxygen monitor and alarm module

51.104.1 Oxygen monitor

If the anaesthetic workstation is in use with an anaesthetic gas delivery module or an anaesthetic breathing system it shall be operated with an oxygen monitor in compliance with prEN 12598 and the additional requirement in 51.104.2 for measurement of the inspiratory oxygen concentration e. g. in the inspiratory limb or Y-piece (see tables 101 and 102).

51.104.2 Oxygen concentration alarm

The oxygen concentration alarm module shall be provided with an operator-adjustable lower alarm limit.

The applicable requirements of 51.114 also apply.

Compliance shall be tested by visual inspection.

51.104.3 Operating condition

When the anaesthetic workstation is in use the oxygen monitor and alarm module shall be put into operating condition in accordance with 51.116.

51.105 Anaesthetic gas monitor and alarm module

51.105.1 R: Anaesthetic gas monitor

If the anaesthetic workstation is in use with an anaesthetic vapour delivery module which can cause a safety hazard under single fault condition, it shall be operated with an anaesthetic gas monitor in compliance with EN ISO 11196 for monitoring the concentration of anaesthetic agent vapour in the inspiratory gas (see tables 101 and 102).

51.105.2 Anaesthetic gas concentration alarm

Anaesthetic gas monitors shall be provided with an operator adjustable high concentration alarm set point which annunciates at least a medium priority signal as specified in EN 475 if the measured concentration exceeds the set point.

Anaesthetic gas monitors shall be provided with an operator-adjustable low concentration alarm set point which annunciates at least a low priority signal as specified in EN 475 if the measured value falls below the set point.

The applicable requirements of 51.114 also apply.

Compliance shall be tested by visual inspection.

NOTE: Simulation of a cyclical breathing pattern can be required to perform the test(s).

51.105.3 Operating condition

When the anaesthetic workstation is in use the anaesthetic gas monitor and alarm module shall be put into operating condition in accordance with 51.116

51.106 Airway pressure monitoring and alarm module

51.106.1 Airway pressure monitor

If the anaesthetic workstation is in use with an anaesthetic ventilator module or an anaesthetic breathing system it shall be operated with a means to monitor the pressure in the anaesthetic breathing system to which the patient is exposed during the complete breathing cycle i.e. during each inspiratory and expiratory phase (see tables 101 and 102).

The accuracy of the displayed value shall be +/- (2 % of full scale reading + 4 % of actual reading).

Test for compliance by visual inspection and verification of accuracy.

51.106.2 Airway pressure alarm

If the anaesthetic workstation is in use with an anaesthetic ventilator module it shall be operated with an airway pressure alarm to annunciate a high priority signal as specified in EN 475 when the pressure in the anaesthetic breathing system:

a) exceeds the limit for high pressure; or

b) exceeds a limit for positive anaesthetic breathing system pressure continuing for longer than (15 + 1) s.

Compliance shall be tested by visual inspection and functional testing via simulating the alarm conditions in accordance with the accompanying documents.

NOTE: Simulation of a cyclical breathing pattern may be required to perform the test(s).

51.106.3 Operating condition

When the anaesthetic ventilator module is in use the airway pressure monitor and alarm module shall be put into operating condition in accordance with 51.116.

51.107 Expired volume monitor and alarm module

51.107.1 R: Expired volume monitor

If the anaesthetic workstation is in use with an anaesthetic ventilator module (except for a ventilator intended only for neonatal application) it shall be operated with a means to monitor the patient's expired tidal volume or expired minute volume.

The accuracy of the displayed value shall be +/- 20 % of actual reading above 100 ml tidal volume or 1 l minute volume.

The accuracy of readings below 100 ml tidal volume or 1 l minute volume shall be disclosed in the accompanying documents (see 6.8.3 a) of this European Standard).

Compliance shall be tested by the method given in annex DD.

51.107.2 Expired volume alarm

If a low expired volume alarm is provided it shall activate at least a low priority signal as specified in EN 475 if the patient's expired volume falls below an operator-adjustable minimum (see tables 101 and 102).

In this case the applicable requirements of 51.114 also apply.

Whenever the alarm(s), if provided, associated with the expired volume monitoring module are disabled an information signal as specified in EN 475 shall be annunciated.

Compliance shall be tested by visual inspection and functional testing via simulating an expired volume below the alarm limit.

NOTE: Simulation of a cyclical breathing pattern can be required.

51.107.3 Operating condition

When the anaesthetic ventilator module is in use the expired volume monitor and, if provided, the alarm module shall be put into operating condition in accordance with 51.116.

51.108 Anaesthetic breathing system integrity (disconnect) alarm module

51.108.1 R: Integrity (disconnect) alarm

If the anaesthetic workstation is in use with an anaesthetic ventilator it shall be operated with an anaesthetic breathing system integrity (disconnect) alarm module which shall activate at least a medium priority signal as specified in EN 475 in case of a disconnection of the patient from the anaesthetic ventilator or anaesthetic breathing system (see tables 101 and 102).

The applicable requirements of 51.114 also apply.

Test for compliance via disconnection at each operator accessible connection in sequence of the anaesthetic ventilator and anaesthetic breathing system when connected to a test lung.

NOTE: The breathing system integrity alarm can be derived from e.g. low airway pressure alarm, low CO_2-alarm or low expired volume alarm.

51.108.2 Operating condition

When the anaesthetic ventilator is in use the breathing system integrity alarm monitor and alarm module shall be put into operating condition in accordance with 51.116.

51.109 Carbon dioxide monitor and alarm module

51.109.1 Carbon dioxide monitor

If the anaesthetic workstation is in use with an anaesthetic breathing system it shall be operated with a means to monitor the patient's respired CO_2. The CO_2 monitor and alarm module shall be in compliance with EN 864 (see tables 101 and 102).

51.109.2 Carbon dioxide concentration alarm

The applicable requirements of 51.114 also apply.

51.109.3 Operating condition

When the anaesthetic workstation is in use the CO_2 monitor and alarm module shall be put into operating condition in accordance with 51.116.

51.110 Protection module for cut-off of gases other than oxygen

51.110.1 If the anaesthetic workstation is in use with an anaesthetic gas delivery module for gases other than oxygen, air or premixed gases with an oxygen content above 21 % (V/V), it shall be operated with a gas cut-off device.

This gas cut-off device shall be activated when the oxygen supply pressure falls below a value specified in the instructions for use and shall either:

a) cut off the supply of all gases other than oxygen, air and premixed gases with an oxygen content above 21 % (V/V) to the fresh gas outlet; or

b) progressively reduce the flow of all other gases (except air or premixed gases with an oxygen content above 21 % (V/V)) while maintaining the proportion of oxygen until the supply of oxygen finally fails, at which point the supply of all other gases (except air or premixed gases with an oxygen content above 21 % (V/V)) shall be cut off.

51.110.2 The gas cut-off device as specified in 51.110.1.a) shall not be activated before the oxygen supply failure alarm.

51.110.3 The sole means of resetting the gas cut-off device shall be the restoration of the oxygen supply pressure to a level above that at which the device is activated.

51.110.4 Test for compliance by visual inspection and via functional test by simulation of conditions given in 51.110.1, 51.110.2 and 51.110.3 and according to the accompanying documents.

51.111 Anaesthetic gas scavenging system

The anaesthetic workstation and its modules shall be provided with a means to route polluting gases from the exhaust port(s) to the anaesthetic gas scavenging system (AGSS).

If the anaesthetic workstation is in use with an anaesthetic gas delivery module for gases other than oxygen and air or with an anaesthetic vapour delivery module it shall be operated with an AGSS according to clause 111 (see tables 101 and 102).

51.112 Maximum airway pressure protection module

If the anaesthetic workstation is in use with an anaesthetic ventilator module and/or an anaesthetic breathing system it shall be operated with a maximum breathing pressure protection module which ensures that the maximum pressure at the patient connection port during intended use or under single fault condition shall not exceed the maximum adjustable pressure limit by more than 15 % or 1 kPa (10 cm H_2O) (whichever is greater) and shall not exceed 12,5 kPa (125 cm H_2O) (see tables 101 and 102).

NOTE: A reservoir bag complying with EN 1820 may be considered as a maximum pressure protection module for an anaesthetic workstation without an anaesthetic ventilator module or when the anaesthetic ventilator module is in the manual or spontaneous mode.

51.113 Adjustable airway pressure limitation protection module

If the anaesthetic workstation is in use with an anaesthetic ventilator module and a maximum airway pressure protection module set at a maximum pressure in excess of 8 kPa (80 cm H_2O) it shall be operated with an adjustable pressure limiting system to prevent a pressure build-up in excess of the set value. If such a system is an APL valve it shall be in compliance with 107.4. (see tables 101 and 102).

See 6.1 ee) of this European Standard for marking requirement.

NOTE: If the anaesthetic workstation is in use without an anaesthetic ventilator module the anaesthetic breathing system should be operated with an adjustable pressure limiting system (see tables 101 and 102).

51.114 Alarm signals

51.114.1 General alarm requirements

The auditory and visual characteristics of alarm signals and information signals shall comply with EN 475.

When an alarm module is initially switched on it shall have the lowest alarm priority(s) as specified in 51.102 to 51.109.

Means shall be provided to allow disabling of auditory alarm signals by the operator until the anaesthetic workstation is connected to the patient.

NOTE: This is required to prevent nuisance alarms.

51.114.1.1 If an audible alarm(s) can be disabled by the operator, there shall be a visual indication that it has been disabled.

51.114.1.2 If audible alarm silencing by the operator is provided, it shall not prevent the audible alarm from being activated by a new or different alarm condition that has been specified as high priority in this European Standard.

51.114.1.3 The set points of adjustable alarms shall be indicated continuously or on operator demand.

51.114.1.4 If a means of silencing is provided, this shall not be active for longer than 120 s.

51.114.2 High priority (warning) signal

51.114.2.1 When a high priority signal is activated and when the condition which caused the alarm has cleared the audible signal shall reset automatically.

51.114.2.2 When a high priority signal that is specified as high priority signal in this European Standard is activated and when the condition causing the alarm has cleared it shall be possible for the operator to determine the alarmed variable that led to the alarm condition. This information shall be reset only by operator interaction.

51.114.3 Medium priority (cautionary) signal

When a medium priority signal is activated and the condition causing the alarm has cleared the audible alarm signals shall reset automatically.

NOTE: The visual alarm signal can be reset automatically or by the operator.

51.114.4 Low priority (advisory) signal

If provided, the audible alarm signal for a low priority signal shall not sound for more than 3 s.

51.114.5 Information signal

An information signal, if provided, shall comply with EN 475.

51.114.6 Remote alarm extensions

If a remote alarm extension is provided it shall be designed such that a failure in the external circuit will not affect the correct functioning of the main alarm.

51.115 Emergency anaesthetic equipment

51.115.1 Monitoring, alarm and protection modules for emergency anaesthetic equipment

Emergency anaesthetic equipment shall comply with the monitoring, alarm and protection module requirements in 51.102.1, 51.110 and 51.112.

See also table 102.

NOTE 1: Emergency anaesthetic equipment should comply with the monitoring, alarm and protection module requirements in 51.102.2, 51.102.3, 51.103 to 51.109, 51.111 and 51.113 (see also table 102).

NOTE 2: Attention is drawn to the work of CEN/TC 239 'Rescue systems' on environmental conditions and testing for emergency equipment.

51.115.2 Draw-over vaporizer - requirements for emergency anaesthetic equipment

If a draw-over vaporizer is used in emergency anaesthetic equipment instead of an anaesthetic vapour delivery module it shall comply with the following:

51.115.2.1 When the draw-over vaporizer control is in the 'off' or 'zero' position the delivered concentration shall not exceed 0,1 % (V/V) when tested according to annex RR.

51.115.2.2 The delivered concentration at all settings except 'zero' or 'off' shall not deviate from the indicated value by more than +/- 50 % of the concentration setting or +/- 0,5 % (V/V) (whichever is greater) when tested according to annex RR.

51.115.2.3 If draw-over vaporizers are fitted with conical fittings at the inlet and outlet they shall be of 22 mm in accordance with EN 1281-1.

51.115.2.4 105.2.2 and 105.2.4 apply also to draw-over vaporizers.

51.115.3 If the draw-over vaporizer can be displaced during operation from its normal operating position it shall be provided with protection against hazardous output .

51.116 R: Operating condition for monitoring and alarm modules

When a specific actuator module is in use its associated monitoring and alarm module(s) as specified in clause 51 and summarized in tables 101 and 102 respectively shall be in operating condition by being enabled and functioning e.g. by following the checklist procedure as specified in 6.8.101.

Section 9: Abnormal condition and fault conditions environmental tests

52 Abnormal operation and fault conditions

Clause 52 of EN 60601-1 : 1990 applies.

53 Environmental tests

Clause 53 of EN 60601-1 : 1990 applies.

Section 10: Constructional requirements

54 R: General

Clause 54 of EN 60601-1 : 1990 applies with the following addition:

A single fault condition shall not cause a monitoring and/or alarm and/or protection module as specified in clause 51 of this European Standard and its corresponding anaesthetic workstation control function to fail in such a way that the monitoring and/or alarm and/or protection function becomes simultaneously ineffective, i.e. so that failure of the anaesthetic workstation function cannot be detected by the corresponding monitoring or alarm or protection module.

Test for compliance by simulation of a single fault condition.

55 Enclosures and covers

Clause 55 of EN 60601-1 : 1990 applies.

56 Components and general assembly

Clause 56 of EN 60601-1 : 1990 applies with the following additions:

In 56.3 a), add the following additional items:

- **R:** Means shall be provided to limit the reverse gas flow between gas inlet ports of the same gas to 100 ml/min (169 Pa · l/s) under normal operating conditions.

- **R:** The cross flow of gases from one gas inlet port to another gas inlet port of a different gas type shall not exceed 100 ml/h (2,8 kPa · l/s) under normal use and single fault condition.

Evidence shall be provided by the manufacturer.

In 56.3 add the following additional items:

aa) Medical gas cylinder connections

- Medical gas cylinder connections shall be non-interchangeable between different gas services.

- All anaesthetic workstations shall be provided with means of connection to a reserve oxygen supply.

- Each cylinder connection or group of interconnected cylinder connections shall be provided with a filter, having a pore size not exceeding 100 μm .

- If pin index yoke-type valve connections are provided, all yoke details, including the pin index safety system, shall be in accordance with EN 850.

- If the anaesthetic workstation is provided with gas cylinder connections it shall be provided with means (e.g. tools) to change and operate the gas cylinders.

- Test for compliance with first dash item to fifth dash item by visual inspection.

bb) Medical gas supply inlet connections

- **R:** If the anaesthetic workstation and its modules are intended to be connected to a medical gas supply system (either a medical gas pipeline system complying with prEN 737-3 or a pressure regulator complying with EN 738-1), each high pressure gas inlet connector shall be either the body of a Non-Interchangable Screw-Threaded (NIST) connector complying with EN 739 or a probe complying with EN 737-1 and prEN 737-6. See Special National Conditions in annex TT.

- Low-pressure hose assemblies between the anaesthetic workstation and the medical gas supply system shall comply with EN 739.

- Each pipeline inlet connection shall be provided with a filter having a pore size not exceeding 100 μm.

- Test for compliance with first dash item to third dash item by visual inspection.

57 Mains parts, components and layout

Clause 57 of EN 60601-1 : 1990 applies except as follows:

In 57.2 add the following item:

aa) R: The exception in 57.2 e) of EN 60601-1 : 1990 applying to emergency trolleys and the like shall also apply to anaesthetic workstations i.e. auxiliary mains socket outlets on an anaesthetic workstation may be of a type which can accept a mains plug.

The total number of operator-accessible auxiliary mains socket outlets that can accept a mains plug on an anaesthetic workstation shall not exceed four (see also 6.8.2 a) 5th dash of this European Standard).

If auxiliary mains socket outlet(s) can accept a mains plug the requirements of 6.1 bb) and 6.8.2 ff) of this European Standard apply.

In 57.3 add the following new item:

aa) R: The mains supply cord of an electrically-powered anaesthetic workstation or its modules shall be a non-detachable cord or shall be protected against accidental disconnection.

Compliance is checked by inspection and, for equipment when provided with an appliance coupler by the following test:

The detachable cord is subjected for 1 min to an axial pull of force as shown in table 103

During the test the mains connector shall not become disconnected from the appliance inlet.

Table 103: Pull forces for testing detachable cords

Mass of equipment kg	Pull N
Up to and including 1	30
Over 1 up to and including 4	60
Over 4	100

In 57.6 add the following additional item:

- The anaesthetic workstation and each auxiliary mains socket outlet shall be provided with separate fuses or over-current releases as required in 57.6. of EN 60601-1 : 1990.

Compliance is checked by inspection and loading all auxiliary mains socket outlets up to the maximum of their rating. Each auxiliary mains socket outlet shall in turn additionally be overloaded by a factor of 7,5 +/- 2,5. The anaesthetic workstation shall maintain its normal function.

58 Protective earthing - terminals and connections

Clause 58 of EN 60601-1 : 1990 applies.

59 Construction and layout

Clause 59 of EN 60601-1 : 1990 applies.

Section 11. Additional requirements specific to anaesthetic workstations.

101 Gas supply pressure monitors

101.1 If a gas is supplied at cylinder pressure to the anaesthetic workstation means shall be provided to monitor this pressure or the cylinder contents (see 6.3 aa) of this European Standard for further requirements).

NOTE: The pressure of gases supplied by pipeline from central supplies should be monitored.

101.2 The maximum error of all monitoring devices shall not exceed +/- (4 % of the full scale reading + 8 % of the actual reading).

101.3 Test for compliance with 101.1 by inspection and with 101.2 by verification of the accuracy.

102 Pressure regulators

There shall be a pressure regulator(s) in compliance with EN 738-1 for each gas supplied by gas cylinders to the anaesthetic workstation.

See also 10.101 of this European Standard.

Compliance is checked by inspection.

103 Machine gas piping

103.1 Machine gas piping shall withstand without rupture a pressure of at least twice its maximum operating pressure or the maximum pressure which may occur under single fault condition, whichever is greater.

See also 10.101 of this European Standard.

NOTE: The maximum test pressure can be established as the relief pressure of a pressure relief valve.

Compliance is checked by type testing or manufacturer certification.

103.2 The machine gas piping shall be designed and manufactured to minimize health risks by reducing the leaching of substances from the devices during normal use to levels below those assumed to be non-toxic.

Compliance is checked via manufacturer certification.

103.3 R: Except for venting of air or oxygen from fluidic or pneumatic elements, the leakage from the machine gas piping for each gas service before the flow control valves shall not exceed 25 ml/min (2,533 kPa · l/min) at its design pressure(s).

Compliance is checked by leakage measurement at (20 +/- 3) °C.

104 Anaesthetic gas delivery module

104.1 General requirement for anaesthetic gas delivery modules

104.1.1 An anaesthetic gas delivery module shall have means either

a) to prevent delivery of an N_2O/O_2-mixture with an oxygen concentration below 20 % (V/V) in the fresh gas or the inspiratory gas; or

b) to give an alarm at an oxygen concentration of below 20 % (V/V) in the inspiratory gas.

This means to generate the oxygen concentration alarm shall be different from the oxygen concentration alarm module required in 51.104 of this European Standard.

Compliance is checked by functional testing and visual inspection.

104.1.2 Anaesthetic gas delivery modules and all parts thereof shall be designed and manufactured to minimise health risks by reducing the leaching of substances from the devices during normal use to levels below those assumed to be non-toxic.

Compliance is checked via manufacturer certification.

104.1.3 For a rotary style of mechanical-pneumatic flow adjustment control an anti-clockwise rotation shall cause an increase in flow and conversely, a clockwise rotation shall cause a decrease in flow.

Compliance is checked by functional testing and visual inspection.

104.1.4 Means of limiting the pressure at the fresh-gas outlet shall be provided.

See marking requirement in 6.3 bb) 4th dash item.

Compliance is checked by functional testing and visual inspection.

104.1.5 The gas conducting components of the anaesthetic gas delivery module shall comply with the requirements in 103.1.

Compliance is checked by type testing or via manufacturer certification.

104.1.6 R: The maximum leakage from each gas service between the flow control valve and the fresh-gas outlet shall not exceed 50 ml/min (5,065 kPa · l/min) at a pressure of 3 kPa (30 cmH_2O).

Compliance with 104.1.6 is checked by leakage measurement.

This requirement shall be met with the anaesthetic vapour delivery module recommended by the manufacturer:

a) on,

b) off,

c) removed if it is operator-detachable.

Compliance is checked by visual inspection.

104.1.7 ***Fresh gas outlet***

See further requirements in 107.7 and 107.10.

104.1.7.1 ***R:*** If an operator-accessible fresh-gas outlet is provided, it shall be one of the following:

a) a coaxial 22 mm/15 mm conical connector in compliance with EN 1281-1 or EN 1281-2 or

b) a 15 mm female conical connector in compliance with EN 1281-1 or

c) the probe of a quick-connector according to figures 104 a) and 104 b) or

d) a male M16x1,5 mm screw-threaded connector according to figure 103 .

Compliance is checked by visual inspection.

104.1.7.2 There shall be only one functional fresh-gas outlet

Compliance is checked by visual inspection.

104.2 Flow control systems

104.2.1 To prevent incorrect adjustment of the flow of a single gas there shall be only one flow control for each gas delivered to the fresh-gas outlet.

NOTE: Devices to prevent hypoxic mixtures where oxygen is made to flow with other gas(es) are not considered to be flow controls.

104.2.2 For a rotary style of a mechanical-pneumatic flow control the shape of the knob shall meet the following requirements:

a) For rotary style flow controls the oxygen knob shall have the physically distinguishable profile in accordance with figure 102.

All rotary style flow adjustment knobs for other gases shall be round and their surface finish serration shall not exceed a depth of 1 mm.

b) The oxygen knob shall have a diameter not less than the diameter of the knobs controlling all other gases.

NOTE: It may project beyond these knobs.

104.2.3 Compliance with 104.2.1 and 104.2.2 is checked by inspection.

104.3 Flowmeters and flow calibration

104.3.1 Each flowmeter and flow control system used in an anaesthetic gas delivery module shall be calibrated for discharge into an ambient atmosphere of 101,3 kPa at an operating temperature of 20 °C.

All flowmeters and flow control systems used in the anaesthetic gas delivery module shall be graduated in units of litres per minute.

For flows of 1 l/min or below, the flow shall be expressed either in millilitres per minute or in decimal fractions of a litre per minute (with a zero before the decimal marker) subject to the method of graduation being consistent on any one anaesthetic gas delivery module.

104.3.2 The accuracy of the graduations of any flowmeter or flow control system used in the anaesthetic gas delivery module shall be within +/- 10 % of the indicated value for flows between 10 % of full scale or 300 ml/min, whichever is the greater, and 100 % of full scale when discharged into an ambient atmosphere of 101,3 kPa at an operating temperature of 20 °C.

See 6.8.3 a) of this European Standard for disclosure requirement for flowmeters below 300 ml/min.

104.3.3 If a bank of flowmeters is fitted, the oxygen flowmeter shall be placed at the left extremity.

104.3.4 Compliance with 104.3.1 to 104.3.3 is checked by inspection and by verification of the accuracy specified in 104.3.2.

104.4 Oxygen flush

104.4.1 The anaesthetic gas delivery module shall be fitted with a manually-operated single-purpose oxygen flush for the delivery of a limited but unmetered flow of oxygen directly to the fresh gas outlet. A flush shall not be provided for any other gas.

Compliance is checked by inspection.

104.4.2 The oxygen flush shall have only one 'off' position.

Compliance is checked by inspection.

NOTE: The oxygen flush should be designed and sited to minimise the risk of accidental operation by equipment or personnel pressing against it.

104.4.3 The oxygen flush shall be operable with one hand and it shall be self-closing.

Compliance is checked by inspection.

The flush shall deliver oxygen from the fresh-gas outlet to atmosphere at a steady flow of between 25 l/min and 75 l/min, measured at an atmospheric pressure of 101,3 kPa, when oxygen is delivered to the flush at its design pressure(s).

Compliance is checked by measuring the flow.

104.4.4 For anaesthetic gas delivery modules which allow interchangeable anaesthetic vapour delivery modules to be fitted the flow of gas from the oxygen flush shall be delivered to the fresh-gas outlet without passing through an anaesthetic vapour delivery module.

When the fresh-gas outlet is open to atmosphere, the pressure at the outlet from the anaesthetic vapour delivery module shall not increase by more than 10 kPa above its normal working pressure and not decrease by more than 10 kPa below its normal working pressure when the oxygen flush is operated.

Compliance is checked by functional testing. For test procedures see 105.2.9.1.

104.5 Gas mixing system

104.5.1 ***Constructional requirements***

The outlets of gas mixing systems, if operator-accessible, shall not be interchangeable with the inlet connectors.

Compliance shall be tested by visual inspection.

104.5.2 ***Accuracy of operating data of gas mixing systems***

The oxygen concentration at any flow and pressure of the delivered gas within the range given in the technical description shall be within +/- 5 % (V/V) of the indicated value. The tolerance shall not result in an oxygen concentration of less than 20 % (V/V).

See also 104.1.2.

The accuracy requirement shall apply only to marked concentration values and not between markings, unless otherwise stated by the manufacturer.

Compliance shall be tested by concentration measurement, and by simulating a pressure variation throughout the range of input pressures, as specified by the manufacturer in the accompanying documents.

104.5.3 ***Reverse gas flow***

104.5.3.1 ***R***: Means shall be provided so that the reverse flow of gas from each gas inlet to any inlet of a different gas shall not exceed 10 ml/h (16,89 kPa · ml/min) under normal operating conditions or under any single fault condition which is not alarmed.

104.5.3.2 ***R***: Means shall be provided so that the reverse flow of gas from each gas inlet to any inlet of a different gas shall not exceed 100 ml/min (10,13 kPa · l/min) during any single fault condition which is indicated by an alarm.

104.5.3.3 ***R***: The manufacturer shall provide evidence of methods by which compliance with 104.5.3.1 and 104.5.3.2 can be verified together with data supporting the validity of the methods.

105 Anaesthetic vapour delivery module

105.1 General requirements

105.1.1 If conical connectors are used at the inlet and outlet of an operator-detachable anaesthetic vapour delivery module they shall be of 23 mm size in accordance with EN 1281-1. The connector at the inlet shall be male and that at the outlet shall be female. Any other system of connectors for anaesthetic vapour delivery modules shall ensure that the anaesthetic vapour delivery module can only be fitted so that the gas flow through it is in the intended direction.

105.1.2 Anaesthetic vapour delivery modules and all parts thereof shall be designed and manufactured to minimize health risks by reducing the leaching of substances from the devices during normal use to levels below those assumed to be non-toxic.

105.2 R: Concentration-calibrated anaesthetic vapour delivery modules

105.2.1 Non-calibrated anaesthetic vapour delivery modules shall not be provided.

Compliance is checked by inspection.

105.2.2 A control to adjust the vapour concentration shall be provided.
A scale or indicator shall be provided for the calibrated range of the anaesthetic vapour delivery module. It shall not be possible to set the control above the calibrated range.

Compliance is checked by inspection.

105.2.3 Means shall be provided to prevent the simultaneous delivery of more than one anaesthetic vapour and to prevent contamination of the content of one anaesthetic vapour delivery module with another agent.

Compliance is checked by inspection.

105.2.4 When operated in accordance with the manufacturer's instructions, it shall not be possible to overfill the anaesthetic vapour delivery module such that

a) its performance is affected; and

b) the fluid level is no longer visible and/or indicated.

Compliance is checked by performing the filling procedures according to the accompanying documents.

105.2.5 Rotary dials/knobs on a mechanical-pneumatical anaesthetic vapour delivery module shall increase the delivered concentration of vapour when turned anti-clockwise. There shall be a detent for the 'off' position or for the 'zero' position if this is also the 'off' position.

Compliance is checked by inspection.

105.2.6 When tested as described in annex EE using the carrier gas recommended by the manufacturer (see 6.8.2ii) 3rd dash item of this European Standard), the following requirements shall be met:

a) When the anaesthetic vapour delivery module control is in the 'off' position, or the 'zero' position if this is also the 'off' position, the delivered concentration shall not exceed 0,03 % (V/V).

b) The delivered concentration at all graduations other than 'off', shall not deviate from the indicated value by more than +/- 20 % of the concentration setting or +/- 5 % of the maximum setting, whichever is the greater.

105.2.7 When tested as described in annex FF using the carrier gas recommended by the manufacturer (see 6.8.2 ii) 3rd dash item of this European Standard), the delivered concentration from the anaesthetic vapour delivery module shall not vary by more than +30 %/-20 % from the concentration setting or + 7,5 %/- 5 % of the maximum setting, whichever is the greater.

105.2.8 Agent specific filling systems shall comply with EN 1280-1.

NOTE: A standard prEN 1280-2 (WI : 00215063) for desflurane specific filling systems is under preparation by CEN/TC 215/WG 1 (See Annex SS)

105.2.9 ***O_2 Flush interaction***

105.2.9.1 Interchangeable anaesthetic vaporizer modules shall meet the accuracy requirements in 105.2.7 under the test procedure as described in FF.2.9 and FF.2.10 to demonstrate compatibility with 104.4.4.

105.2.9.2 For anaesthetic vapour delivery modules which are not interchangeable (e.g. have proprietary connections) and where the requirements in 104.4.4 and 105.2.9.1 have not been met the anaesthetic vapour delivery module shall :

a) meet the accuracy requirements in 105.2.7 when tested according to the test procedure in FF.2.11; and

b) have means to prevent the increase of mass output (i.e. mass/time) of anaesthetic agent during activation of the oxygen flush.

Compliance with a) is determined by concentration measurement.

Compliance with b) is demonstrated by measuring the mass output of anaesthetic agent before and during a 10 s activation of the oxygen flush with the anaesthetic vapour delivery module settings according to FF.2.7 .

106 Respiratory gas conducting components

All respiratory gas conducting components shall be designed and manufactured to minimize health risks by reducing the leaching of substances from the devices during normal use to levels below those assumed to be non-toxic.

107 Anaesthetic breathing systems

107.1 General

The requirements of clause 107 primarily address components of circle systems with carbon dioxide absorbers (circle absorption systems). This does not, however, exclude the use of other anaesthetic breathing systems for which these requirements shall be applied as appropriate.

107.2 Connectors

107.2.1 *Inspiratory port*

The inspiratory port shall be a 22 mm male conical connector with or without a coaxial 15 mm female conical connector both complying with EN 1281-1 or EN 1281-2. It shall be marked with an arrow to indicate the direction of gas flow and the axis of the port shall be either horizontal or within +/- 50 ° of the horizontal plane.

107.2.2 Expiratory port

The expiratory port shall be a 22 mm male conical connector complying with EN 1281-1 or EN 1281-2. It shall be marked with an arrow to indicate the direction of gas flow and the axis of the port shall be either horizontal or within +/- 50 ° of the horizontal plane.

107.2.3 *Connection port for reservoir bags*

The connection port for a reservoir bag shall be either a 22 mm male conical connector complying with EN 1281-1 or EN 1281-2 or an alternative connector that mates with breathing tubes or reservoir bags complying with prEN 12342 or EN 1820 respectively. This port shall be either vertical or within +/- 20 ° of the vertical axis with the port facing downwards.

For marking requirements see 6.1 cc) 2nd dash item of this European Standard.

107.2.4 *Patient connection port*

The patient connection port shall have a male 22 mm conical connector incorporating a coaxial female 15 mm conical connector both complying with EN 1281-1.

107.2.5 *Y-piece*

The machine ends of a Y-piece not permanently attached to breathing tubes shall be either 22 mm male conical connectors with a recess complying with EN 1281-1 or alternative connectors which mate with a breathing tube complying with prEN 12342.

107.2.6 *Exhaust port*

Exhaust port(s) on an anaesthetic breathing system or an anaesthetic ventilator module shall be one of the following:

a) a 30 mm male conical connector complying with EN 1281-1; or

b) a permanent or proprietary connector incompatible with those specified in EN 1281-1 and EN 737-4.

For AGSS with integrated transfer and receiving systems in which the exhaust port is not user accessible a 30 mm conical connector complying with EN 1281-1 is not required.

NOTE 1: This is to allow connection to an anaesthetic gas scavenging system.

NOTE 2: If interfacing of scavenged gases is designed, only the final connection to the AGSS should be considered the exhaust port.

107.2.7 ***Ventilator port***

If a conical ventilator port is provided to connect the breathing system to an anaesthetic ventilator, it shall be a 22 mm conical connector in accordance with EN 1281-1 or EN 1281-2.

107.2.8 ***Accessory port***

If an accessory port is provided e.g. for sampling of gases or injection of fluids it shall not be compatible with connectors as described in EN 1281-1 or EN 1281-2 and shall be provided with a means of secure attachment to the accessory port and a means of closure of the accessory port.

NOTE: Attention is drawn to the work of CEN/TC 215/WG 1 on connectors for gas sampling (See annex SS)

107.2.9 ***Other breathing attachments***

107.2.9.1 If breathing attachments are fitted with conical connectors they shall be either of 15 mm or 22 mm size complying with EN 1281-1 or EN 1281-2. Any port other than those for connection within an anaesthetic breathing system shall not be fitted with either 15 mm or 22 mm conical connectors complying with EN 1281-1 or EN 1281-2.

107.2.9.2 If incorrect direction of flow in circle absorber assemblies can present a safety hazard means shall be provided to prevent such incorrect direction of flow.
If unidirectional valves are used for this purpose and if they are detachable from the absorber unit the connectors shall be non-interchangeable with each other and incompatible with any of the connectors specified in EN 1281-1 or EN 1281-2.

107.2.9.3 If a non-rebreathing valve has more than two connection ports, those other than the gas inlet and the patient connection port shall not be 15 mm or 22 mm conical connectors complying with EN 1281-1.

107.3 Electrical conductivity

Anaesthetic breathing systems and breathing attachments intended for use with flammable anaesthetic agents shall comply with ISO 2882 when tested as described in ISO 2878.

107.4 Anaesthetic breathing systems supplied complete or assembled in accordance with the manufacturers instructions

107.4.1 ***R: Leakage***

When tested as described in GG.2, the leakage from such anaesthetic breathing systems shall not exceed 150 ml/min (15,199 kPa · l/min).

107.4.2 ***Expiratory and inspiratory resistance***

107.4.2.1 *Expiratory resistance*

When tested as described in GG.3.1 and with flows through the patient connection port of 60 l/min for adult application, the pressure generated at the patient connection port shall not exceed 0,6 kPa (6 cm H_2O).

See 6.8.2 ii) 2nd dash item of this European Standard for disclosure requirement.

107.4.2.2 *Inspiratory resistance*

When tested as described in GG.3.2 and with flows through the patient connection port of 60 l/min for adult application, the sub-atmospheric pressure generated at the patient connection port shall not exceed 0,6 kPa (6 cm H_2O).

See 6.8.2 jj) 2nd dash item of this European Standard for disclosure requirement.

107.5. APL valves

107.5.1 ***Direction of movement***

For APL valves with rotary controls, movement of the control in a clockwise direction shall progressively increase the limiting pressure.

NOTE: Movement of the control in a clockwise direction may ultimately close the valve.

107.5.2 ***Resistance to flow***

When tested as described in GG.4 the pressure drop across the APL valve, in the fully open position, shall be between 0,05 kPa and 0,3 kPa (0,5 cm H_2O and 3 cm H_2O) at an air flow of 3,0 l/min and between 0,1 kPa and 0,5 kPa (1 cm H_2O and 5 cm H_2O) at an air flow of 30 l/min.

107.5.3 ***Connectors***

The exhaust port of shrouded APL valves intended for connection to an anaesthetic gas scavenging system shall be a 30 mm male conical connector complying with EN 1281-1.

107.5.4 *R: Leakage*

If an APL valve can be fully closed, when tested as described in GG.5, the leakage in the fully closed position shall not exceed 50 ml/min (5,22 kPa · l/min).

107.6 Carbon dioxide absorbers and circle absorber assemblies

107.6.1 *Construction*

107.6.1.1 The design of the carbon dioxide absorbent container shall enable any colour change of the absorbent to be clearly visible.

107.6.1.2 Carbon dioxide absorbent containers supplied prefilled by the manufacturer shall be packaged in such a way that permits identification of the presence of the wrapper.

NOTE: This is to prevent inadvertent retention of the wrapper and to facilitate its removal by the operator prior to use.

107.6.2 *Absorber bypass mechanism*

107.6.2.1 If a means of excluding the absorbent from the gas pathway is provided, the operation of which is actuated automatically by removing the absorbent container(s), the circle absorber assembly shall meet the requirements of 107.6.3.1, 107.6.4 and 107.6.5 both with the container(s) in place and with the container(s) removed.

107.6.2.2 When the mechanism for excluding the absorbent is operator-controlled, the control shall have detents to prevent accidental movement.
(For marking requirement see 6.1 dd) of this European Standard).

107.6.2.3 Unless the absorber bypass mechanism is intended to function at an intermediate setting(s), the control shall have detents in only the 'on' and 'off' positions. The control shall be bi-stable.
The circle absorber assembly shall meet the requirements of 107.6.3, 107.6.4 and 107.6.5 with the control in the 'on' and 'off' positions.

107.6.2.4 For an absorber bypass mechanism intended to function at an intermediate setting(s), the control shall so indicate.
The circle absorber assembly shall meet the requirements of 107.6.3, 107.6.4 and 107.6.5 with the control in the 'on' and 'off' positions and at any intermediate setting of the control.

107.6.3 *R: Leakage*

107.6.3.1 Circle absorber assemblies shall be tested by the method described in GG.12 and the leakage shall be disclosed by the manufacturer. (See 6.8.2 jj) 4th dash item of this European Standard).

107.6.3.2 For assemblies with an operator-controlled bypass mechanism, when the control is in the 'off' position, the absorbent container(s) shall be removable without opening the gas pathway to the atmosphere. (See also 6.8.2 jj) 4th dash item of this European Standard).

107.6.4 ***Expiratory resistance of circle absorber assemblies***

When tested as described in GG.6 the pressure generated at the expiratory port shall not exceed 0,6 kPa (6 cm H_2O) when a flow of 60 l/min for adult application is introduced.
See 6.8.2 jj) 2nd dash item of this European Standard for disclosure requirement.

107.6.5 ***Inspiratory resistance of circle absorber assemblies***

When tested as described in GG.7 the sub-atmospheric pressure generated at the inspiratory port shall not exceed 0,6 kPa (6 cm H_2O) when a flow of 60 l/min for adult application is generated.
See 6.8.2 jj) 2nd dash item of this European Standard for disclosure requirement.

107.7 Unidirectional valves

107.7.1 ***Resistance to flow***

When tested as described in GG.8 the pressure generated by a dry valve shall not exceed 0,15 kPa (1,5 cm H_2O).

107.7.2 ***Reverse flow and dislocation***

When tested as described in GG.9 the pressure shall rise to at least 0,5 kPa (5 cm H_2O) within 5 min and the valve shall not become dislocated on application of a reverse pressure of 5,0 kPa (50 cm H_2O).

NOTE: Provisions to observe the operation of unidirectional valves are recommended.

107.7.3 ***Opening pressure***

When tested as described in GG.10, the pressure to open a dry valve shall not exceed 0,12 kPa (1,2 cm H_2O).

107.7.4 ***Inspiratory, expiratory and inspiratory-expiratory valves***

Inspiratory, expiratory and inspiratory-expiratory valves shall comply with 107.7.1, 107.7.2 and 107.7.3.

107.8 Fresh-gas inlet

The fresh gas inlet, if provided, shall have an inside diameter of not less than 4 mm and shall be one of the following:

a) a nipple with an overall length of not less than 15 mm and an outside tip diameter of 7 mm. The outer surface of the nipple shall be provided with at least one ridge or protuberance (9 +/- 0,25) mm in diameter (see figure 105 for typical examples);

b) the component of the connector with the outside thread in accordance with figure 103;

c) the probe of the quick-connector according to figures 104 a) and 104 b)

See 104.1.7 for requirements for fresh gas outlets of anaesthetic gas delivery modules.

107.9 Microbial breathing filters

NOTE: A standard for microbial breathing filters is under preparation by CEN/TC 215/WG 4 (See annex SS).

The applicable requirements of 6.8.2 jj) and clause 106 apply.

107.10 Breathing tubes and reservoir bags

Breathing tubes shall comply with prEN 12342.

Reservoir bags shall comply with EN 1820.

The applicable requirements of 6.8.2 jj) and clause 106 also apply.

107.11 Fresh-gas tubes

If a fresh-gas tube for conveying the fresh gas from the anaesthetic gas delivery module to the anaesthetic breathing system is operator-accessible, it shall have connectors in compliance with 104.1.7 and 107.8 respectively.
Such connectors shall be permanently attached to the fresh-gas hose.

108 Heat and moisture exchangers

Heat and moisture exchangers shall comply with the requirements of ISO 9360.

The applicable requirements of 6.8.2 jj) and clause 106 also apply.

109 Humidifiers

Humidifiers shall comply with EN ISO 8185-1.

The applicable requirements of 6.8.2 jj) and clause 106 also apply.

110 Suction equipment

Suction equipment shall comply with EN ISO 10079-1, EN ISO 10079-2 and EN ISO 10079-3.

111 Anaesthetic gas scavenging system (AGSS)

111.1 Patient protection requirements

111.1.1 When tested by the method described in annex KK with continuous flows of 30 l/min and 75 l/min of air into the inlet of the AGSS, the pressure rise at the inlet shall not exceed 50 Pa (0,5 cm H_2O) and 350 Pa (3,5 cm H_2O) respectively.

111.1.2

a) The requirement in 111.1.1 shall also be met when the power device in the disposal system is not operating. See KK.2.8 and KK.2.9 for test method.

b) The pressure rise at the inlet of a transfer system that has a 30 mm female conical inlet connector in compliance with clause 111.5.2 shall not exceed 1 kPa (10 cm H_2O) at a continuous flow of 30 l/min and 2 kPa (20 cm H_2O) at a continuous flow of 75 l/min. See LL.2 for test method.

c) The pressure rise at the patient connection port of a breathing system with an attached transfer system that has a permanent or proprietary inlet connector in compliance with clause 111.5.1 and 111.5.3 shall not exceed 1 kPa (10 cm H_2O) at a continuous flow of 30 l/min and 2 kPa (20 cm H_2O) at a continuous flow of 75 l/min. See LL.3 for test method.

NOTE 1: In some designs gas may be spilled into the environment.

NOTE 2: Requirements a), b) and c) specify patient protection requirements under single fault conditions.

111.1.3 ***R:*** When tested by the method described in MM.2, the sub-atmospheric pressure at the inlet of the receiving system shall not exceed 30 Pa (0,3 cm H_2O).

When tested by the method described in MM.1, the induced flow shall not exceed 50 ml/min.

111.2 R: Operator protection requirements

When tested by the method described in annex NN, the spillage to atmosphere shall not exceed 100 ml/min.

111.3 Transfer systems

111.3.1 *Inlet to interchangeable transfer systems*

The inlet to an interchangeable transfer system that incorporates a means of pressure relief shall be a 30 mm diameter female conical connector complying with 111.5.1 and 111.5.2.

111.3.2 *Inlet to non-interchangeable transfer systems*

The inlet to a transfer system that does not incorporate a means of pressure relief shall be either a permanent or a proprietary connector complying with 111.5.1 and 111.5.3.

111.3.3 *Outlet of transfer systems*

111.3.3.1 For interchangeable transfer and receiving systems the outlet of the transfer system shall be a 30 mm diameter male conical connector complying with 111.5.1 and 111.5.2.

111.3.3.2 For non-interchangeable transfer and receiving systems which are operator -detachable the outlet connector of the transfer system shall comply with 111.5.1 and 111.5.3.

111.4 Receiving systems

111.4.1 *Inlet*

111.4.1.1 The inlet of an interchangeable receiving system shall be a 30 mm diameter female conical connector complying with 111.5.1 and 111.5.2.

111.4.1.2 The inlet of an operator-detachable, non-interchangeable receiving system shall have connectors that comply with 111.5.1 and 111.5.3.

111.4.2 *Outlet*

If the receiving system and the disposal system can be detached by the operator the outlet of the receiving system shall be a type 1 terminal unit probe in compliance with EN 737-4.

NOTE 1: This design is not compatible with a 30 mm conical connector as described in EN 1281-1 or EN 1281-2.

NOTE 2: The socket of the AGSS terminal unit comprises the connection point to the disposal system. The disposal system is defined by EN 737-4 for AGSS terminal units and by EN 737-2 for the power device.

111.4.3 ***Particle filter***

If a particle filter is provided, it shall be located at the disposal side, shall be removable without the use of a tool and its functional characteristics shall be disclosed by the manufacturer (see 6.8.2 ll) 2nd dash item of this European Standard).

NOTE: It is recommended that the filter is visible.

111.4.4 ***Visual indicator***

A visual indicator shall be provided to indicate that the receiving system is working within its design disposal flow rate, as stated by the manufacturer.

111.4.5 ***Resistance to flow***

If the AGSS is equipped with a type 1 terminal unit probe, the absolute value of the resistance to flow of the receiving system shall not be less than 1 kPa (10 cm H_2O) at a flow of 50 l/min and not more than 2 kPa (20 cm H_2O) at a flow of 25 l/min when tested by the method described in annex JJ.

111.4.6 ***Hoses***

Hoses between the receiving system and the AGSS terminal unit probe shall comply with the requirements for hoses for vacuum services given in clauses 5, 6 and annex A of EN 739 : 1998

The connector between the receiving system and the receiving hose shall comply with 111.5.3.

111.5 Connectors on AGS systems

111.5.1 ***Fitting of connectors to hoses***

If connectors are fitted to hoses, the connectors shall be permanently attached to the hose.

111.5.2 ***Conical connectors***

Conical connectors shall be of 30 mm size as specified in EN 1281-1.

111.5.3 ***Permanent or proprietary connections***

Connectors between functionally discrete parts or sub-assemblies of an AGSS shall be either non operator-detachable or functionally specific to prevent misassembly. Such connectors shall be incompatible with those used for medical gas pipeline systems as specified in EN 737-2 and prEN 737-6, hose assemblies as specified in EN 739, anaesthetic breathing systems as specified in EN 1281-1 and EN 1281-2 and other AGSS components.

112 Anaesthetic ventilator modules

Anaesthetic ventilator modules shall comply with the clauses listed in annex CC.

Dimensions in millimetres

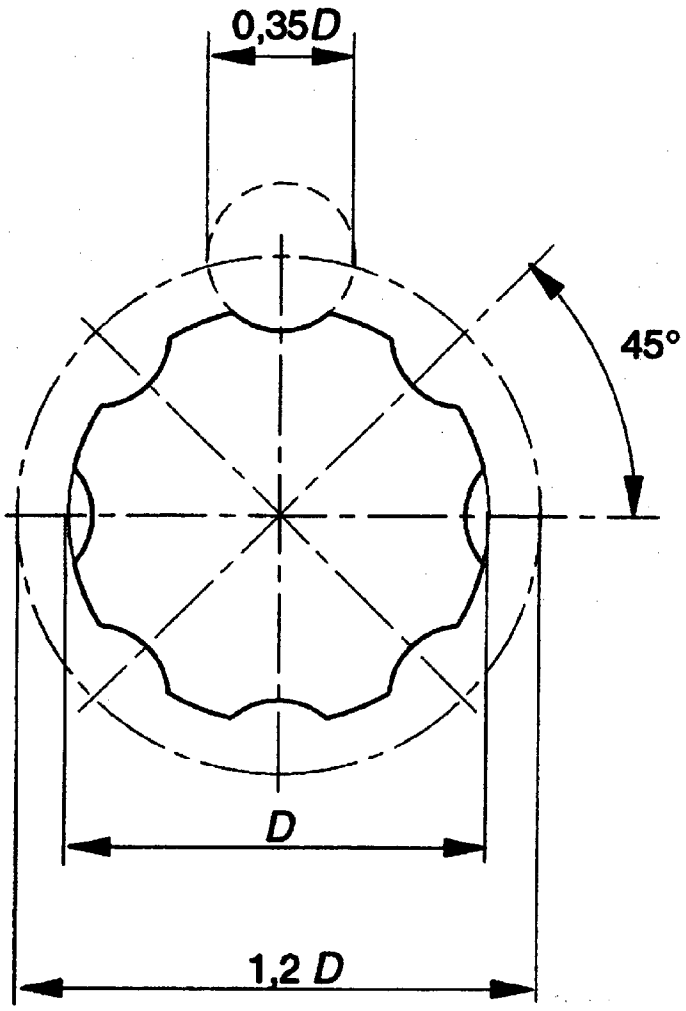


Figure 102: Profile of oxygen flow control knob for applications other than anaesthetic vapour delivery system flow control

Dimensions in millimetres

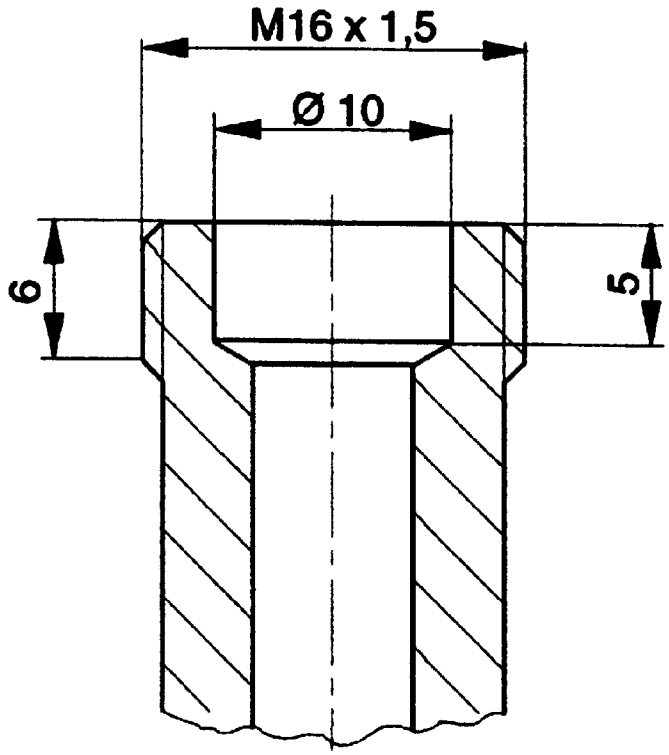
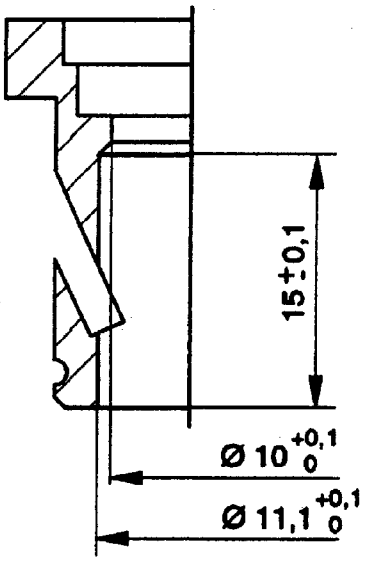
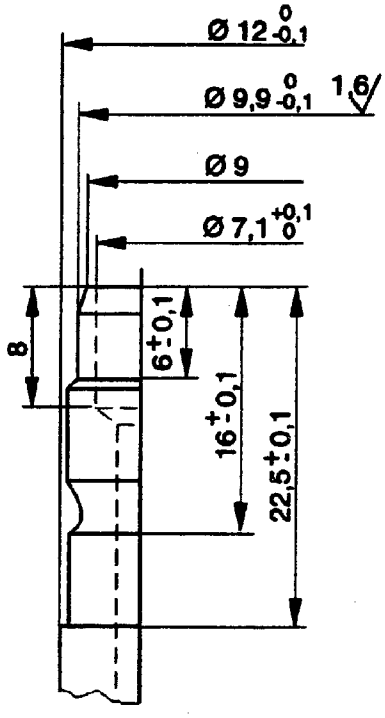


Figure 103: Screw-threaded fresh-gas connector

Dimensions in millimetres



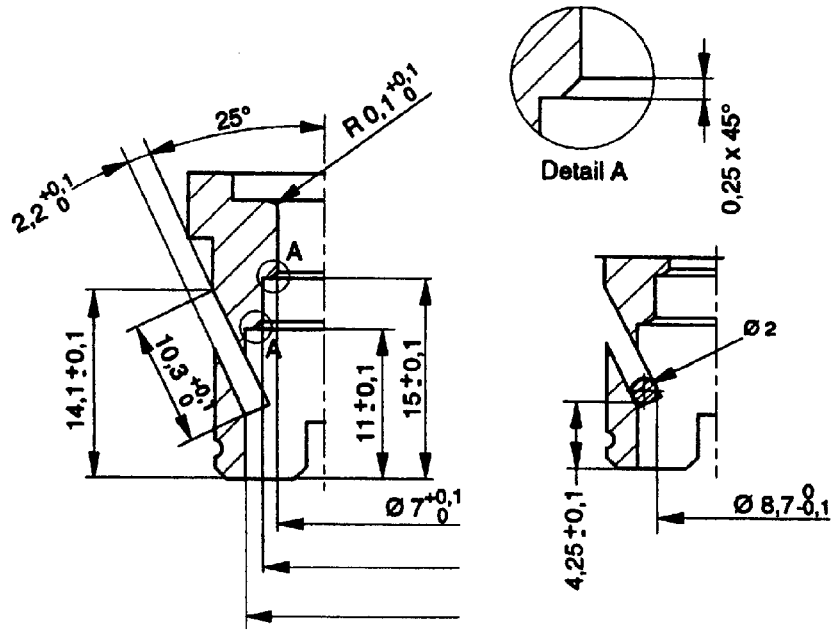
Socket



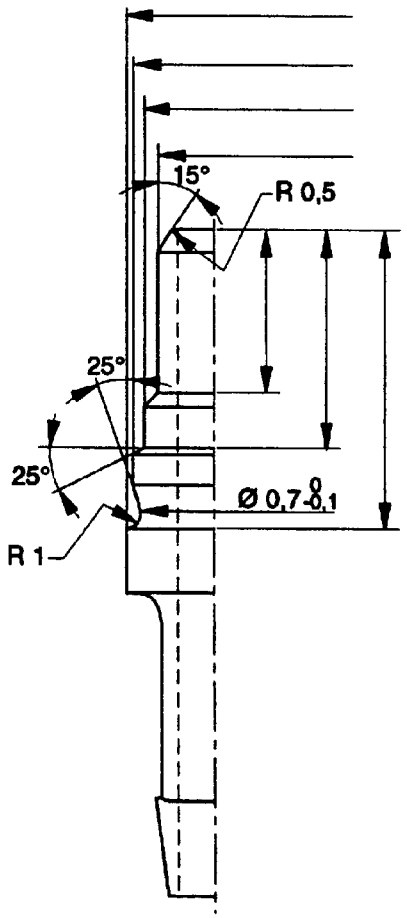
Probe

Figure 104 a): Quick connector for fresh gas (Continued)

Dimensions in millimetres



Socket



Probe

Figure 104 b): Additional measurements for quick connector for fresh gas (concluded)

Dimensions in millimetres

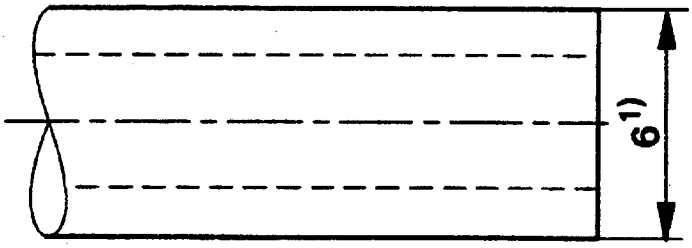


Figure 105 a) elastomeric tubing

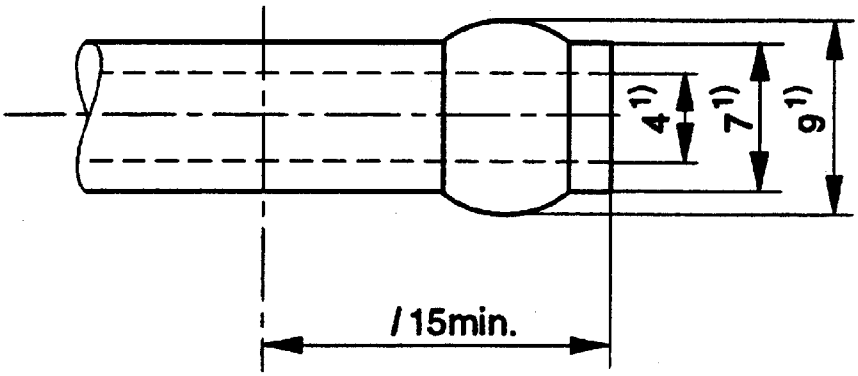
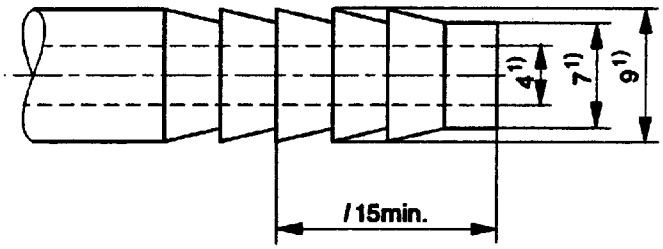


Figure 105 b) nipple



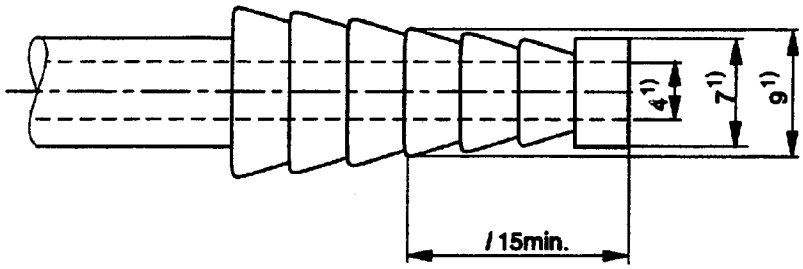


Figure 105 c) examples of nipple

1) nominal
l = length

NOTE. Alternative configurations of the nipple are permissible providing requirements for the basic dimensions are met (see examples in figure 105 c))

Figure 105: Fresh-gas inlet nipple

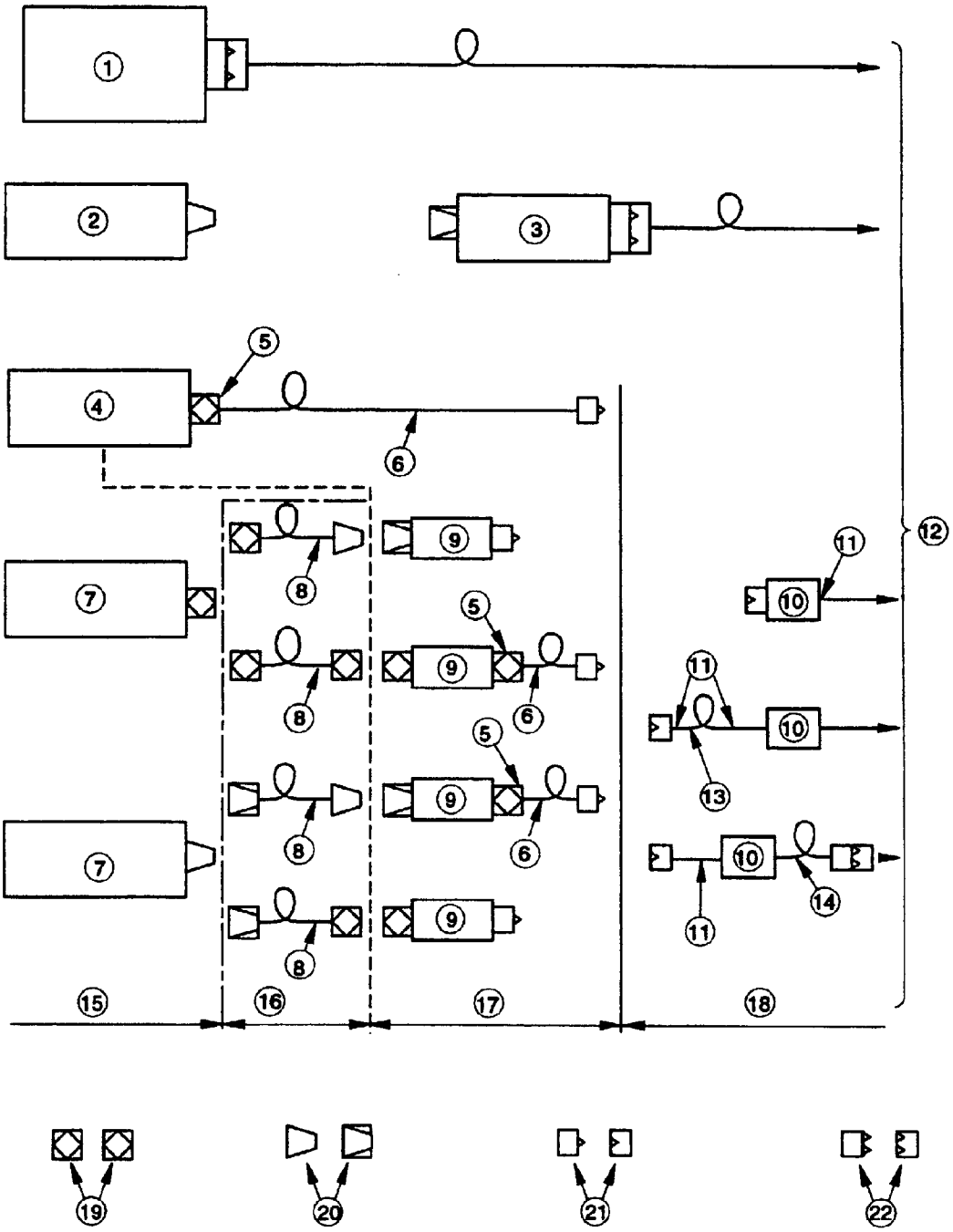


Figure 106: Schematic diagram of typical AGSS connections (continued)

1)	Apparatus including breathing system and integral transfer / receiving system and power device	11)	Permanent connection
2)	Apparatus including breathing system	12)	Discharge
3)	Transfer/receiving system and power device	13)	Flexible hose or pendant
4)	Apparatus including breathing system and integral transfer/receiving system	14)	Disposal hose
5)	Permanent or proprietary connector	15)	Limit of breathing system
6)	Receiving hose	16)	Limit of transfer system
7)	Breathing system or anaesthetic ventilator	17)	Limit of receiving system
8)	Transfer tube	18)	Limit of disposal system
9)	Receiving system	19)	Proprietary connection (functionally specific)
10)	Power device	20)	30 mm conical connection
		21)	Type 1 terminal unit probe/socket
		22)	Type 2 terminal unit probe/socket

Note 1: Type 1 terminal unit probe/socket is for negative pressure. Type 2 terminal unit probe/socket is for positive pressure (see Note 2).

Note 2: The limit between the receiving system and the disposal system as shown may not coincide with an actual physical limit such as a wall. In the arrangement shown a terminal unit on a wall would be located on the inlet to the power device.

Figure 106: Schematic diagram of typical AGSS connections (concluded)

Annexes

Appendices A to K of EN 60601-1 : 1990 apply.

Annex AA (normative) R: Test of anaesthetic agents for non-flammability

Tests of anaesthetic agents which, according to 37.101 of this European Standard, shall be regarded as non-flammable anaesthetic agents and to which the requirements of Section six of EN 60601-1 : 1990 do not apply.

AA.1 R: Spark ignition tests

Spark ignition tests shall be carried out with the most ignitable concentration of the anaesthetic agent mixed with the gases oxygen and/or nitrous oxide in which the anaesthetic agent is most ignitable using the test apparatus described in annex F of EN 60601-1 : 1990, and in IEC 60079-3.

With an ignition probability of less than 10^{-3}, ignition shall not occur:

- in a resistive circuit at a d.c. voltage of 20 V with a current of 1,0 A and at a d.c. voltage of 100 V with a current of 0,15 A.

- in an inductive circuit at a d.c. current of 200 mA with an inductance of 10 mH and at a d.c. current of 60 mA with an inductance of 1000 mH.

- in a capacitive circuit at a d.c. voltage of 100 V with a capacitance of 1 µF and at a d.c. voltage of 20 V with a capacitance of 20 µF.

The measuring circuits are illustrated in figures 29 and 31 of EN 60601-1 : 1990.

AA2.1 Surface temperature ignition tests

Determination of the igniton temperature shall be carried out with apparatus and procedures based on IEC 60079-4, with the following additional requirements:

- fill the test vessel with a mixture of oxygen and nitrous oxide in different proportions in successive tests and

- cover the vessel with a lid which prevents diffusion but lifts easily if an explosion occurs.

The ignition temperature shall not be less than 300 °C.

Annex BB (informative) Rationale

NOTE: The numbering of the following rationales correspond to the numbering of this European Standard.

BB.1 The purpose of this European Standard is to establish requirements for anaesthetic workstations with particular reference to:

- protection against electric shock

- prevention of fires in oxygen or nitrous oxide enriched atmospheres

- prevention of explosions of flammable anaesthetic agents such as ether and cyclopropane

- protection against hazards from delivery of energy or substances to the patient.

The safety requirements of EN 60601-1 against explosion of flammable anaesthetic agents are modified with less restrictive requirements on such anaesthetic workstations where exclusively anaesthetic agents which in this European Standard are defined as non-flammable anaesthetic agents, such as halothane and other halogenated compounds, are used.

This European Standard recognizes that the restrictive and expensive requirements of section six of EN 60601-1 : 1990 for preventing explosions of flammable anaesthetic agents, such as ether and cyclopropane, are unnecessary when only agents defined as non-flammable anaesthetic agents, such as halothane are used.

Even if anaesthetic agents such as halothane in this European Standard are defined as non-flammable anaesthetic agents they may form flammable mixtures with oxygen and/or nitrous oxide when tested with very high ignition energy. Annex AA establishes a lower limit of flammability (based on tests for halothane) for agents to be classified as non-flammable. The requirements of this European Standard ensure that anaesthetic workstations not intended for use with flammable anaesthetic agents and therefore not classified as category AP or APG, are nevertheless safe for use with non-flammable agents.

The recommendations for patient monitoring during anaesthesia include e.g. monitoring of the patient's ECG, blood pressure, body temperature, pulse oximetry and neurological functions (see annex SS for appropriate equipment standards).

To facilitate data transfer capability between different monitoring devices, a bus system for data transfer may be used.

BB.2.1.5 The definition of the applied part in this European Standard is the base for clarification of requirements on and measurement of patient leakage current.

Antistatic tubing is required in anaesthetic workstations of category APG and cannot be excluded for use with any anaesthetic workstation. Such tubing is considered as conductive for the patient leakage current.

It is not possible, however, to include any requirements in this European Standard on leakage currents from electrically operated attachments such as humidifiers and heating elements which may be connected in the anaesthetic breathing system because the types of such attachments which will be used in clinical work with a specific type of anaesthetic workstation cannot be anticipated by a manufacturer or by a test house.

However, parts integrated with the anaesthetic workstation such as temperature and carbon dioxide sensors which are intended to come into contact with the anaesthetic breathing system and which are electrically connected to the anaesthetic workstation are considered as parts for which requirements on leakage currents can be specified in this European Standard.

Such parts are therefore included in the definition of applied part (see figure 1 of EN 60601-1 : 1990).

BB.3.2 Module:

Such modules are e.g. the anaesthetic gas delivery, anaesthetic vapour delivery, anaesthetic breathing systems, anaesthetic ventilators, anaesthetic gas scavenging systems and specific monitoring, alarm and protection modules.

BB.3.3 Actuator module:

Such modules are e.g. the anaesthetic gas delivery, anaesthetic vapour delivery, anaesthetic breathing system and anaesthetic ventilator.

BB.3.4 Monitoring module:

Such modules are e.g. the airway pressure monitor, inspiratory oxygen monitor and expired volume monitor.

BB.3.5 Alarm module:

Such modules are e.g. the power failure alarm, O_2-supply-failure alarm or breathing system integrity alarm.

BB.3.6 Protection module:

Such modules are e.g. the gas cut-off device or the maximum pressure limitation device.

BB.3.15/BB.3.16 See the rationale to 37.101 and 37.102.

BB.4 (3.6 aa) The additional single fault conditions specified apply specifically to clause 43 of this European Standard.

BB.4 (3.6 bb) A fault which is not detected can exist for a long time. Under those circumstances it is not acceptable to regard a further fault as a second fault which can be disregarded. It is essential that such a first fault is regarded as a normal condition.

BB.6.1 j) The marking of the anaesthetic workstation power input and the sum of the power input in amperes give information on the minimum mains fuses ratings needed in different situations.

BB.6.1 k) The marking of each auxiliary mains socket outlet with its output in amperes gives information on the current ratings of the fuses of each auxiliary mains socket outlet.

BB.6.8.2 bb) Anaesthetic workstations may have parts, e.g. electric control units, which are not APG. It is essential that the discharge of flammable mixtures close to such parts is prevented.

38.7 of EN 60601-1 : 1990 requires a marking to indicate clearly which equipment parts are APG. It is considered important that this information is given in the instructions for use also.

BB.6.8.2 cc) The use of antistatic and/or electrically conductive materials in the anaesthetic breathing system of anaesthetic workstations has proved to be an effective method of eliminating explosions of flammable anaesthetic agents caused by electrostatic sparks. For such parts as tracheal tubes and oropharyngeal airways surface moisture provides the necessary conductivity and therefore antistatic materials are unnecessary.

BB.6.8.2 dd) It is very important that the operator of an anaesthetic workstation not specified as category APG is made aware that an explosion hazard exists when flammable anaesthetic agents are used.

It is also important to inform the operator as to which anaesthetic agents are suitable for use in an anaesthetic workstation not specified as APG.

BB.6.8.2 ee) Antistatic or conductive anaesthetic breathing system components are not necessary if flammable anaesthetic agents are not used. Such components might increase the risks of oxygen fires and of burns to the patient during electrosurgery, therefore their use with non-APG anaesthetic workstations is not recommended.

BB.6.8.3 a) first dash item, first bullet A zero error together with a sensitivity error is needed if a variable can pass through zero or can, in any application, cover a range such that the minimum is a small fraction of the maximum.

BB.17 Deterioration of components due to anaesthetic agents and gases should be taken into account by the manufacturer.

BB.19.4 h) 12) See rationale to 2.1.5 and figure 1 of EN 60601-1 : 1990.

BB. Section 6

The opinion of the experts in clinical anaesthesia about the explosion risk of anaesthetic agents is reflected in the following:

Resolution by ISO/TC 121 at the twelfth Meeting held in Philadelphia, 8th to 12th October, 1979.

Resolution for Plenary Session:

"The requirements for maximum electrical power and stored energy of electrical circuits in an anaesthetic breathing system distributing explosive anaesthetic gases are very restrictive. These restrictive requirements make it difficult or impossible to design electrical sensors and control circuits in or near anaesthetic breathing system. Such sensors and control circuits are necessary for the design and function of monitoring devices, e.g. of oxygen detectors or servo ventilation functions as well as measurement of physiological parameters during the use of equipment.

The above mentioned very restrictive requirements are fully justified on equipment specified for the use of highly explosive anaesthetic agents such as ether and cyclopropane. However, the situation is quite different when the much more frequently used halogenated anaesthetic agents such as halothane, methoxyflurane, or enflurane are used.

Flammability tests indicate that the electrical power and energy needed to bring these agents to ignition are sufficiently high that existing restrictive requirements for electrical circuits in the anaesthetic breathing system are not needed as with explosive agents.

After a literature search and solicitation of personal communication, the members of ISO/TC 121 do not know of any injury to patients or operating room personnel caused by ignition of halothane, enflurane or methoxyflurane during anaesthesia irrespective of the use of electrosurgical units."

BB.37.101/BB.37.102 Anaesthetic agents do not fall readily into flammable and non-flammable categories. The possibility of ignition depends not only on the agent in use, its concentration and other simultaneously used gases but also on the electrical energy, power and surface temperature that may be available to cause ignition.

Halothane, though generally regarded as safe, will form flammable mixtures with oxygen and nitrous oxide when tested with very high ignition energy. It is therefore necessary to specify a

lower ignition level of the agents under which the APG requirements on equipment are applicable and above which less restrictive requirements apply. Currently used anaesthetic agents such as halothane belong to the category above this level and can therefore, according to this European Standard, be used in anaesthetic workstations not marked as APG or AP.

Ignition tests on the most ignitable of the anaesthetic agent mixed with oxygen and/or nitrous oxide have been recommended in annex AA. The reason for using the most ignitable concentration and not clinically used concentrations is that this method is common and recognized when determining the flammability level of gas mixtures and when comparing this level with the flammability of other gas mixtures. The most ignitable concentration is also a well defined concentration which can be technically determined in test institutes specialized in such tests.

BB.37.103 Ignition tests carried out in the resistive circuit according to annex AA with the most ignitable mixture of halothane with nitrous oxide gave the following results where + = ignition; - = no ignition :

100 V: 0,22 A = 22 VA -
100 V: 0,25 A = 25 VA +
15 V: 2,70 A = 40,5 VA -
5 V: 2,80 A = 42 VA +

These figures represent ignition power levels which exceed the requirement on 10 VA for protection against fires as specified in 43.4 of EN 60601-1 : 1990.

It is therefore considered as unnecessary and misleading to specify any separate requirements on a higher level than 10 VA for protection against explosion of agents such as halothane complying with annex AA.

BB.39.3 aa) A continuous path for electrostatic charges to earth eliminates possible sparks which could ignite flammable gases.

BB.40 It is considered that in anaesthetic workstations specified for use with flammable anaesthetic agents there always exist parts, e.g. parts conducting the flammable anaesthetic agent, which only can be classified as APG and which shall be marked so. Such anaesthetic workstations, however, include parts, e.g. control units, so allocated in normal operation that they can be classified as AP.

BB.43 Reports of fire caused by medical devices are unusual. However, when such fires occur in the hospital environment they can have tragic consequences.

The risk of a fire is fundamentally determined by the three elements which are necessary in order to start a fire:

- ignitable material (fuel)

- temperatures equal to or above the minimum ignition temperature of the material or sparks with energy dissipation equal to or above the minimum ignition energy of the materials.

- an oxidant.

Therefore, following the basic safety concepts of EN 60601-1 : 1990, the objective in the design of the equipment is to ensure that under both normal and single fault conditions and under the oxidising conditions to which the material may be exposed, the temperature of any material is not raised to its minimum ignition temperature or the spark energy does not exceed the material ignition energy level. Alternatively, contained ignition may occur provided it is self limiting so that no hazard is created, eg., a fuse or a resistor within a sealed compartment.

Minimum ignition temperature for a large number of specific materials are well established in published literature, although normally only for pure oxygen and ambient air environments. The minimum ignition temperature may be critically dependent upon the concentration of oxidant present. If ignition temperatures for other materials or oxygen concentrations are required these can be determined using the methods and apparatus described in IEC 60079-4.

In considering the ignitable materials particular attention should be paid to materials which may accumulate during prolonged use, e.g. airborne particles of paper or cotton.

The risks of fire directly caused by sparking of electrical circuits is generally considered insignificant in medical equipment as temperature rise resulting from the power dissipation caused by a spark will not normally reach the ignition temperatures of the solid materials generally used when following good design practice

In certain standards currently in use the requirements to minimise fire risk are based on limitation of temperature, electrical energy and oxidant concentrations to absolute values.

The temperature value is based on the minimum hot plate ignition temperature for fire retardant cotton in 100% oxygen which is given in the American NFPA publication 53M as 310 °C. The assumption was therefore made that 300 °C was an acceptable temperature limit in medical equipment with oxygen enriched atmospheres.

The origin of the electrical energy values which have been used is less clear and it would seem that, in the absence of specific controlled tests, figures have been adopted from other published standards.

However, simple tests and detailed analysis of the known factors involved in causing an oxygen fire show that these figures can be either over-restrictive or potentially hazardous depending, in particular, on the manner in which the power may be dissipated and the proximity and type of any 'fuel' present.

It is now generally accepted that there are no single or universally applicable ranges of temperatures, energy and concentration of oxidant which can ensure safety under all circumstances. Ultimately, electrical energy is only significant in respect of its ability to raise the temperature of ignitable materials and this in turn depends on the particular configuration and the proximity of any ignitable materials.

Under single fault conditions in a typical electrical circuit the possible number of failure modes is very high. In this case full assurance of safety may only be possible by the use of appropriate hazard and safety analysis procedures, taking into consideration the three basic elements, i.e. material, temperature and oxidant.

An appropriate design might limit the electrical energy in the circuit to ensure that temperatures remain below the minimum air ignition temperature under normal conditions and seal compartments or add forced ventilation to ensure that the oxygen content does not exceed that of ambient air under a single fault condition.

Alternatively, it may be appropriate to limit the electrical energy to ensure temperatures below the minimum ignition temperature of a pure oxygen environment, even under single fault condition.

The particular combination of material, temperature and oxidant determines whether a fire will occur, not a single value of any one of these variables.

BB.48 Attention is drawn to the methods for ensuring biocompatibility being developed by CEN/TC 206.

BB.49.102 It is essential that the device continues to operate if the primary power fails, and that all the settings do not return to default setting if the supply is briefly interrupted.

BB.51.105.1 The measurement of the inspiratory concentration of the anaesthetic vapour provides appropriate protection against hazardous output.

However it is recognized that an assessment of the uptake by the patient requires additional monitoring e.g. for end tidal concentration.

BB.51.107.1 If the anaesthetic workstation is in use with an anaesthetic breathing system (but without an anaesthetic ventilator) it should be operated with a means to monitor the patient's expired tidal volume or expired minute volume (see tables 101 and 102).

BB.51.108.1 If the anaesthetic workstation is in use with an anaesthetic breathing system (but without an anaesthetic ventilator) it should be operated with an anaesthetic breathing system integrity (disconnect) alarm module (see tables 101 and 102).

BB.51.116 This can also be achieved by the monitoring and alarm module(s) being enabled and functioning automatically by switching on the anaesthetic workstation or its actuator modules.

Or, if not being enabled and functioning when the anaesthetic workstation or its actuator modules are put into use, an alarm can be generated.

BB.54 This clause prevents the use of a monitoring module to control an actuator module, which would lead to a malfunction of the actuator module being undetected in case of a monitor and/or alarm and/or protection module failure.

BB.103.3/104.1.6/107.4.1/107.5.4/107.6.3/111.2

Various countries specify maximum workplace concentration limits for N_2O and for halogenated vapours. Such limits are summarized in table BB.1 .

It is essential that the spillage limitation of 111.3 (AGSS) and the maximum leakage values for gas cylinder connections, pipeline connections, machine gas piping and breathing system are taken into account when designing means, e.g. air conditioning and hourly air exchange rate, to achieve the maximum workplace concentration limits in the clinical environment.

BB.56.3 a) 2nd dash item Evidence of compliance with the specification(s), either by test or by other methods, should be provided by the manufacturer to a notified body during conformity assessment or appropriate authorities on request.

BB.56.3 bb) first dash item Two established concepts (screw threaded and quick connector) are in use in Europe for pipeline inlet connections to an anaesthetic workstation. One design of each concept is specified in this standard.

It is essential that any newly purchased anaesthetic workstation is compatible with the system already in use .

It is therefore recommended that the purchaser ensures that only one system is used in any one hospital.

The manufacturer should draw the attention of the user and the purchaser to these options in the accompanying documents.

BB.57.2aa) Emergency equipment such as defibrillators, cardiac monitors and routine equipment such as infusion pumps has to be capable of being used anywhere in a hospital. The provision of non-standard sockets on anaesthetic workstations would prevent the unrestricted interchange of equipment and would be unacceptable to the operator. More than one auxiliary mains socket outlet may be needed according to medical practice.

An unrestricted number would, however, increase leakage currents to unacceptably high levels. As any other routine equipment which is connected to the auxiliary mains socket outlets normally will comply with the requirements of EN 60601-1 : 1990, this problem of added leakage currents is considered to be of little significance for up to four auxiliary mains socket outlets; which is the number recommended by experts in IEC/SC62D and ISO/TC 121, balancing the benefits of interchangeability against the incremental risk of exceeding tolerable leakage currents. A number of auxiliary mains socket outlets up to four may be needed according to medical experts of ISO/TC 121.

BB.57.3 aa) Accidental disconnection could be hazardous for the patient.

BB.57.6 first dash item It is essential that a short circuit of other equipment connected to the auxiliary mains socket outlet does not affect the normal function of the life support function of the anaesthetic workstation.

BB.104.1.7.1 Four established connectors are in use in Europe at the fresh-gas outlet on anaesthetic gas delivery modules or on anaesthetic workstations.

BB.104.5.3.1 The reverse gas flow from each gas inlet to every other gas inlet under normal operating conditions has been limited to the very low value of 10 ml/h which is a value comparable to that given in standards for pressure regulators. The value for reverse gas flow can be achieved by designs which step down the pressure from the inlet pressure to a lower pressure at which the gas is mixed.

Attention should be given to the possibility of reverse gas flows occurring in alarm or bypass circuits under single fault conditions.

A reverse flow of 10 ml/h over a 72 h weekend would result in less than 1 l of contaminant gas in a pipeline. This volume is considered to be a minimal hazard.

BB.104.5.3.2 When the operating conditions fall outside the normal range, alarms should be generated. Alarms can also be generated during single fault conditions. In the presence of such alarms a higher value of reverse gas flow may be accepted on the assumption that intervention by the user will occur in a short time.

BB.104.5.3.3 Evidence of compliance with the specification(s), either by test or by other methods, should be provided by the manufacturer to a notified body during conformity assessment or appropriate authorities on request.

BB.105.2: Concentration-calibrated anaesthetic vapour delivery modules produce controllable partial pressures which are independent of ambient pressure. By convention, anaesthetic vapour delivery modules are calibrated in % (V/V) at a standard atmosphere of 101,3 kPa at ambient temperature of (20 ± 3) °C.

Table BB.1: Overview of maximum workplace concentration limits

Country	N_2O ml/m³	Halothane ml/m³	Enflurane ml/m³	Isoflurane ml/m³	Short time [min] ml/m³	Year
Austria	-	5 (10)[5]	-	-	30	1993
Belgium	50	50	75	-	-	1993
Denmark	100	5	5	-	-	1992
Finland	25	1 (3)	-	-	15	1993
France	-	50	75	-	-	[3]
Germany	100[1]	5	-	-	-	1993
Great Britain	100	10	20	50	-	1994
Italy	50 (100)[4]	2	2	2	-	1994
Netherlands	80	5	75	-	-	1994
Norway	100	5	2	2	-	1992
Sweden	100 (500)	5 (10)	10 (20)	10 (20)	15	1994
Switzerland	100 (200)	5 (10)	10 (20)	10 (20)	30[2]	1994
USA (ACGIH)[6]	50	50	75	-	-	1994
USA (OSHA)[7] (NIOSH)[8]	25	0,5	-	-	-	1975

-: Not specified
[1]: Proposal for 1994
[2]: 4 times per work shift
[3]: Not known
[4]: Valid only for older operating theatres in Italy: values given are recommended
[5]: Values for short time exposure in brackets
[6]: American Conference of Governmental Industrial Hygienists
[7]: Occupational Safety and Health Association
[8]: National Institute of Occupational Safety and Health

BB.111.1.3 The objective is to limit the flow induced by the AGSS from the anaesthetic breathing system to a value very close to zero. However, to allow for practicability of testing test equipment with an accuracy of +/- 10 ml/min at a flow of 50 ml/min was identified.

BB. Annex AA See also rationale to 37.101 and 37.102 of this European Standard.

BB. Annex AA.1 The results of ignition tests with halothane carried out according to annex AA have been published by Redeker (see annex SS).

Halothane proved to be more ignitable in nitrous oxide than in oxygen. The ignition test was therefore continued with halothane in nitrous oxide. The most ignitable concentration was investigated by variation of the halothane concentration when testing with the inductive circuit. This concentration was 25% (V/V) to 28% (V/V). With 26% (V/V) halothane in nitrous oxide the results given in table BB.2 were obtained:

Table BB.2: Results of ignition tests on anaesthetic agents

Resistive circuit	Inductive circuit	Capacitive circuit:
110 V: 0,22 A - 110 V: 0,25 A + 15 V: 2,7 A - 15 V: 2,8 A +	5,8 mH: 400 mA - 5,8 mH: 450 mA - 105,0 mH: 220 mA - 105,0 mH: 240 mA + 1003,0 mH: 90 mA - 1003,0 mH: 95 mA +	1 µF: 178 V - 1 µF: 190 V + 20 µF: 38 V - 20 µF: 40 V +
+ ignition - no ignition		

When the cadmium disc in the test apparatus was oxidized by the reaction products resulting from explosions of the test mixture the minimum energy for ignition decreased slightly. The tests were made with oxidized cadmium disc.

B.B. Annex QQ.5 The ability to discriminate between the types of alarms listed in QQ.4 from a distance of 2 m will allow the operator to decide which alarm to respond to first in a facility with many devices when simultaneous alarms occur (without having to go to the first position 500 mm from the control panel). The height of 1,5 m was chosen because existing anthropometric data (derived largely from studies of military personnel) are not necessarily reflective of personnel in the hospital environment.

B.B. Annex QQ.7 The ability to see the high and medium priority indicators at a distance of 4 m and to discriminate between them is important in large operating rooms with anaesthetic workstations comprising multiple modules and the possibility of multiple simultaneous alarms. The operator can then make a decision as to which alarm to respond to first based on the alarm priority.

Annex CC (normative) Applicable requirement clauses for separate modules of an anaesthetic workstation

Module	Applicable clauses
All modules	1 to 5, 6.1a) to bb), 6.1 dd), 6.2, 6.3a) to f), 6.4 to 6.7, 6.8.1, 6.8.2a), 6.8.2 gg) mm), nn), oo), 6.8.3 a), 6.8.101, 7 to 51, 51.1 to 51.4, 51.111, 51.114, 51.116, 52 to 59, appendices A to L, annexes AA, BB, QQ
Actuator modules	
Anaesthetic gas delivery module	6.3 aa), bb), 6.8.2 hh),jj, 6.8.3 aa), 101 to 104, 106
Anaesthetic vapour delivery module	6.3 cc), 6.8.2 ii), jj), 103, 105, 106, annexes EE, FF,HH
Anaesthetic breathing system	6.1cc), 6.8.2jj), 106, 107, annex GG
Anaesthetic ventilator module	6.1cc), 6.8.2jj), 6.8.3bb), 101 to 103, 106, 107.2.6, 107.2.7, 112
Protection modules	
All protection modules	6.8.2kk)
Power failure alarm	51.102
O_2-supply failure alarm	51.103
Cut-off device	51.110
AGSS	6.8.2 ll), 111, annexes JJ, KK, LL, MM, NN, PP
Maximum pressure limitation	6.1 cc), 51.112, 106, annex GG
Adjustable pressure limitation	6.1 cc), 51.113, annex GG

Module	Applicable clauses
Monitoring & alarm modules	
All monitoring and alarm modules	6.1 cc) 3rd dash, 6.8.2kk), 51.114, 106
Inspiratory O_2 concentration	51.104
Anaesthetic gas concentration	51.105, annex HH
CO_2 concentration	51.109
Airway pressure	51.106
Expired volume	51.107, annex DD
Breathing system integrity alarm	51.108
Emergency anaesthetic equipment	
Monitoring, alarm and protection modules	51.115
Draw-over vaporizer	51.115, annex RR
Heat and moisture exchangers	6.8.2 jj), 106, 108
Humidifiers	6.8.2 jj), 106, 109
Suction equipment	110
Microbial filters	6.8.2jj), 106, 107.9
Breathing tubes	6.8.2 jj), 106, 107.10
Reservoir bags	6.8.2 jj), 106, 107.10

Annex DD (normative) Test method for expired volume monitors

DD.1 Apparatus

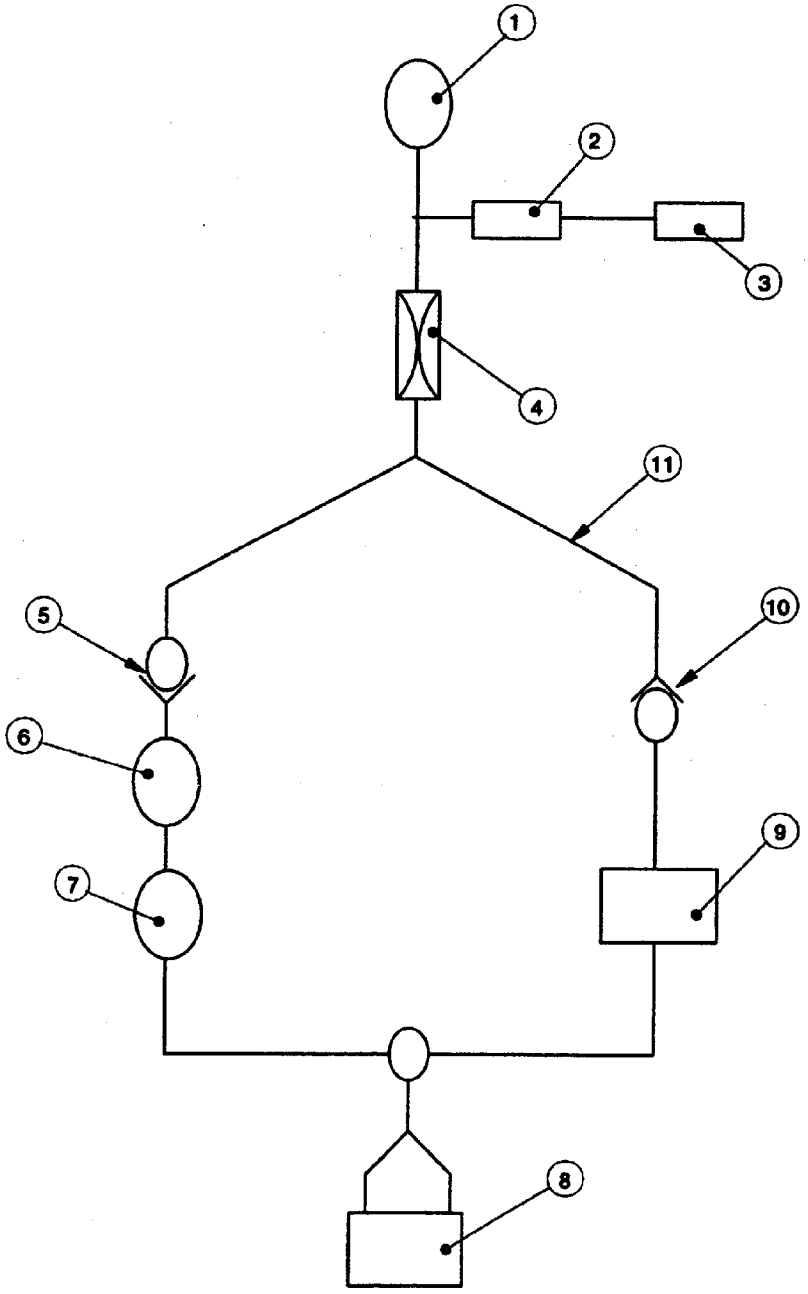
Recorder p(t) with an accuracy of ± 2 % of actual reading for verification of the monitor accuracy.

DD.2 Procedure

Confirm 51.107.2 using the test set-up as shown in figure DD.1 or connect the flow sensor to be tested with the test set-up according to the manufacturers instructions and test parameters as given in table DD.1 in accordance with the ranges specified in the accompanying documents.

Table DD.1: Test parameters for expired volume monitors

Adjustable parameter (see figure DD.1 for test configuration):					
	C	R	V_T	f	p
Adult	50	0,5	500	10	1
Paediatric	20	2	300	20	1,5
Neonatal	1	5	30	30	3
Adjustment of the tidal volume V_T (ml) on the ventilator via pressure sensor on the test lung ($V_T = C \cdot P_{max}$). I:E = 1: 2 or nearest value Frequency: f in breaths per minute Resistance: R in kPa · l^{-1} · s Compliance: C in ml/kPa Pressure: p in kPa					



1. Test lung
2. Pressure sensor
3. Recorder (p/t)
4. Resistance
5. Expiratory valve
6. Volumeter to be tested
7. Respiratory pressure gauge
8. Ventilator
9. CO_2 absorber (filled)
10. Inspiratory valve
11. Breathing system

DD.1: Test of measurement devices for expiratory volume

Annex EE (normative) Test method for accuracy of anaesthetic vapour delivery modules without applied back pressure

EE.1 General

EE.1.1 Test the anaesthetic vapour delivery module with the anaesthetic breathing system and, if applicable, anaesthetic ventilator recommended by the manufacturer or supplier (see 6.8.2). Carry out preliminary checks to ensure that components downstream of the anaesthetic vapour delivery module will not affect the test results, for example by absorbing volatile anaesthetics or imposing time delays on response or by leakage.

EE.1.2 Use the carrier gas recommended by the manufacturer (see 6.8.2 ii) of this European Standard). The accuracy of the analytical technique should be within 10 % of the tolerance specified in 105.2.6 b).

EE.2 Procedure

EE.2.1 Fit the anaesthetic vapour delivery module in position on the anaesthetic workstation.

EE.2.2 Place the anaesthetic vapour delivery module and anaesthetic agent in the test room for at least 3 h at a temperature of (20 ± 3)°C and maintain this temperature throughout the test procedure.

EE.2.3 Set the anaesthetic vapour delivery module to the 'on' position at the maximum concentration setting.
Purge the anaesthetic vapour delivery module for 3 min at a flow of 2 l/min.

EE.2.4 Fill the anaesthetic vapour delivery module with the appropriate anaesthetic agent to approximately halfway between the maximum and minimum marks on the liquid level indicator and leave it to stand for at least 45 min.

NOTE: This may be within the 3 h period specified in EE.2.2

EE.2.5 Connect a vapour analyzer to the outlet of the anaesthetic vapour delivery module or, if applicable, to the inspiratory port of the anaesthetic ventilator.
With the anaesthetic vapour delivery module in the 'off' position, set the gas flow to (2 +/- 0,2) l/min and adjust the anaesthetic ventilator, if applicable, to give (15 +/- 2) breaths/min at an I:E ratio of 1:2 ± 20 % with the inspiratory flow control set to maximum.
Ensure that any pressure fluctuation at the fresh-gas outlet is within the range - 0,5 kPa to + 0,5 kPa.

EE.2.6 For an anaesthetic workstation in which the fresh-gas flow is determined by the anaesthetic ventilator settings, set these to give a minute volume of (2 +/- 0,2) l/min.
Maintain the gas flow for 1 min and measure the concentration of vapour.

EE.2.7 Repeat the procedure described in EE.2.5 with the anaesthetic vapour delivery module set to each of the other settings and in the order as given in table EE.1.
If the anaesthetic vapour delivery module is not marked with the concentration settings given in table EE.1, use the nearest settings on the anaesthetic vapour delivery module.
If any setting given in table EE.1 is equidistant between settings on the anaesthetic vapour delivery module, use the lower setting on the anaesthetic vapour delivery module.

EE.2.8 Repeat the sequence of measurements described in EE.2.5 to EE.2.7 but using a fresh gas flow of (8 +/- 0,8) l/min.

EE.2.9 Repeat the sequence of measurements given in EE.2.7 using a gas flow and, if applicable, anaesthetic ventilator settings recommended by the manufacturer for calibrating the anaesthetic vapour delivery module. (see 6.8.2. ii) of this European Standard).

Table EE.1: Settings to be used for testing the accuracy of anaesthetic vapour delivery modules

Order of test	Setting (% (V/V) of anaesthetic agent)
1	off, and zero if separately marked
2	lowest graduation above zero
3	0,5
4	1,0
5	2,0
6	4,0
last	maximum graduation (full scale)
NOTE: If 0,5 % is the lowest graduation, step 2 is omitted.	

Annex FF (normative) Test method for anaesthetic vapour delivery module accuracy with applied back pressure

FF.1 General

FF.1.1 Test the anaesthetic vapour delivery module with the anaesthetic breathing system and, if applicable, anaesthetic ventilator recommended by the manufacturer or supplier. (see 6.8.2 ii) of this European Standard).
Carry out preliminary checks to ensure that components downstream of the anaesthetic vapour delivery module will not affect the test results, for example by absorbing volatile anaesthetics or imposing time delays on response or by leakage.

FF.1.2 Use the carrier gas and gas flow recommended by the manufacturer. (see 6.8.2 ii) of this European Standard), the accuracy of the analytical technique should be within +/- 10 % of the tolerance specified in 105.2.6 b).

FF.2 Procedure

FF.2.1 Fit the anaesthetic vapour delivery module in position on the anaesthetic workstation.

FF.2.2 Place the anaesthetic vapour delivery module and anaesthetic agent in the test room for at least 3 h at a temperature of (20 +/- 3) °C and maintain this temperature throughout the test procedure.

FF.2.3 Set the anaesthetic vapour delivery module to the 'on' position at the maximum concentration setting.
Purge the anaesthetic vapour delivery module for 3 min at a flow of 2 l/min.

FF.2.4 Fill the anaesthetic vapour delivery module with the appropriate anaesthetic agent to approximately 1/4 way above the minimum mark on the liquid level indicator and leave it to stand for at least 45 min.

NOTE: This may be within the 3 h period specified in FF.2.2.

FF.2.5 Connect a vapour analyzer to the outlet of the anaesthetic vapour delivery module or, if applicable, to the inspiratory port of the anaesthetic ventilator. With the anaesthetic vapour delivery module in the 'off'-position, set the gas flow through the anaesthetic workstation to (2 +/- 0,2) l/min and adjust the anaesthetic ventilator to give (15 +/- 2) breaths/min at an I:E ratio of 1:2 +/- 20 % with the inspiratory flow control set to maximum.

FF.2.6 Introduce a pressure fluctuation at the fresh gas outlet of (2 +/- 0,3) kPa.

NOTE: This can be achieved by using a test lung having a compliance of 200 ml / kPa and a variable resistance.

Ensure that the decay time during the expiration period from 100 % of the pressure at the end of the inspiration period to 33 % of this pressure is less than 0,6 s.

For an anaesthetic workstation in which the fresh gas flow is determined by the anaesthetic ventilator settings, set these to give a minute volume of (2 +/- 0,2) l/min.

FF.2.7 Set the anaesthetic vapour delivery module to deliver either 20 % of its maximum concentration setting or its minimum concentration if this is greater than 20 % of its maximum setting.
If the anaesthetic vapour delivery module is not marked with this concentration, use the nearest setting and if the required setting is equidistant between two settings, use the lower one.

Maintain the pressure fluctuation for 3 min and measure the concentration of anaesthetic agent delivered over a further 1 min period while maintaining the pressure fluctuation. Calculate the average vapour concentration in the total delivered gas flow.

FF.2.8 Repeat the procedure using a fresh-gas flow of (8 +/- 0,8) l/min and a pressure fluctuation at the fresh-gas outlet of (5 +/- 0,4) kPa.

For an anaesthetic workstation in which the fresh-gas flow is determined by the anaesthetic ventilator settings, set these to give a minute volume of (8 +/- 0,8) l/min.

FF.2.9 For interchangeable anaesthetic vapour delivery modules repeat the procedure using a fresh-gas flow of (8 +/- 0,8) l/min and apply an intermittent back pressure at the outlet of the anaesthetic vapour delivery module of 10 kPa for ten times for 2 s out of a 5 s cycle.
Immediately after termination of the last cycle determine the average anaesthetic agent concentration over a period of 1 min.

FF.2.10 For interchangeable anaesthetic vapour delivery modules repeat the procedure of FF.2.9 but using an intermittent negative back pressure of 10 kPa.

FF.2.11 For non-interchangeable anaesthetic vapour delivery modules activate the oxygen flush ten times for 2 s out of a 5 s cycle.

Immediately after termination of the last cycle determine the average anaesthetic agent concentration over a period of 1 min at the fresh-gas outlet or the patient connection port.

Annex GG (normative) Test methods for anaesthetic breathing systems and breathing attachments

GG.1 General

GG.1.1 In routine testing, some manufacturers use alternative methods that give comparable results but in case of dispute, the methods given in this annex shall be considered as the reference methods.

GG.1.2 The ambient temperature for the duration of each test shall be between 20 °C and 25 °C, except where otherwise stated.

GG.1.3 The accuracy of the equipment used to carry out measurements shall be +/- 5 % of the variable to be measured, except where otherwise stated. Dry air shall be used as the test gas for each test, except where otherwise stated.

GG.2 Leakage from complete anaesthetic breathing systems

GG.2.1 *Apparatus*

GG.2.1.1 Flowmeter, accurate to within +/- 5 % at indicated flows of 25 ml/min, 75 ml/min, 100 ml/min, 150 ml/min and 200 ml/min.

GG.2.1.2 Pressure-measuring device, accurate to within +/- 0,01 kPa at 3 kPa.

GG.2.2 *Procedure*

Set up the anaesthetic breathing system and seal the reservoir bag port and the patient connection port.
Fully close any valve in the anaesthetic breathing system that is designed to allow gas to leak at pressures of 3 kPa (30 cm H_2O) or below. Connect the pressure-measuring device at the patient connection port and introduce air into the fresh gas inlet until a pressure of 3 kPa is indicated. Adjust the flow of air to stabilize the pressure at 3 kPa and record the leakage flow.

GG.3 Expiratory and inspiratory resistance of a complete anaesthetic breathing system

GG.3.1 *Expiratory resistance*

GG.3.1.1 *Apparatus*

GG.3.1.1.1 Flowmeter, accurate to within +/- 5 % at flows between 3 l/min and 60 l/min.

GG.3.1.1.2 Pressure-measuring device, accurate to within +/- 0,01 kPa at 0,6 kPa.

GG.3.1.2 *Procedure*

Set up the complete anaesthetic breathing system with the fresh-gas inlet, reservoir bag port and/or ventilator port sealed and with the APL valve, if present, fully closed.

Detach the inspiratory breathing tube from the Y-piece and seal the port from which the tube has been detached.

Connect the pressure-measuring device at the patient connection port. Introduce air at the specified flows into the patient connection port.
Record the resulting pressure.

If a carbon dioxide absorber is present, carry out the test with the absorbent container(s) filled with fresh carbon dioxide absorbent of the type recommended by the manufacturer and test the system in all the operational modes in which the breathing system is intended to be used.

GG.3.2 *Inspiratory resistance*

GG.3.2.1 *Apparatus*

Use the apparatus described in GG.3.1.1.1 and GG.3.1.1.2.

GG.3.2.2 *Procedure*

Set up the complete anaesthetic breathing system with the fresh-gas inlet, reservoir bag port and ventilator port sealed and with the APL valve, if present, fully closed.

Detach the expiratory breathing tube from the Y-piece and seal the port from which the tube has been detached.

Connect the pressure-measuring device at the patient connection port.
Connect the patient connection port to a vacuum source to generate the specified air flow.
Record the resulting pressure.

If a carbon dioxide absorber is present, carry out the test with the absorbent container(s) filled with fresh carbon dioxide absorbent of the type recommended by the manufacturer and test the system in all the operational modes in which the breathing system is intended to be used.

GG.4 Resistance to flow of APL valves

GG.4.1 *Apparatus*

GG.4.1.1 Flowmeter, accurate to within +/- 5 % at flows of 3 l/min and 30 l/min.

GG.4.1.2 Pressure-measuring device, accurate to within +/- 0,01 kPa at 0,05 kPa.

GG.4.2 *Procedure*

Take the APL valve and connect the flow meter and pressure-measuring device as shown in figure GG.1. Place the valve in the orientation recommended by the manufacturer.

Open the APL valve fully and adjust the air flow through the valve to 3 l/min. Record the pressure drop across the valve. Increase the flow through the valve to 30 l/min and record the pressure drop across the valve again.

Except for valves which are intended to be mounted on a rigid base during use, invert the valve and repeat the procedure.

GG.5 Leakage from APL valves

GG.5.1 *Apparatus*

GG.5.1.1 Flowmeter, accurate to within +/- 5 % at an indicated flow of 10 ml/min.

GG.5.1.2 Pressure-measuring device, accurate to within +/- 0,3 kPa at 3 kPa.

GG.5.2 *Procedure*

Take the APL valve and connect the flow meter and pressure-measuring device as shown in figure GG.2. If the APL valve incorporates a patient protection pressure relief device, render it ineffective.

Fully close the valve. Adjust the flow of air to stabilize the pressure at 3 kPa and record the leakage flow.

GG.6 Expiratory resistance of an absorber assembly

GG.6.1 ***Apparatus***

Use the apparatus described in GG.3.1.1.1 and GG.3.1.1.2.

GG.6.2 ***Procedure***

Fill the absorber with the carbon dioxide absorbent recommended by the manufacturer. Set up the absorber assembly with the absorber in the 'on' position, with the APL valve, if fitted, fully closed and the reservoir bag removed. Connect the pressure-measuring device to the expiratory port.

Introduce air at a flow of 60 l/min into the expiratory port and record the resulting pressure.

GG.7 Inspiratory resistance of an absorber assembly

GG.7.1 ***Apparatus***

Use the apparatus described in GG.3.1.1.1 and GG. 3.1.1.2.

GG.7.2 ***Procedure***

Fill the absorber with the carbon dioxide absorbent recommended by the manufacturer. Set up the absorber assembly with the absorber in the 'on' position and the reservoir bag removed. Connect the pressure-measuring device to the inspiratory port.

Connect the inspiratory port to a vacuum source to generate an air flow of 5 l/min, 30 l/min or 60 l/min respectively and record the resulting sub-atmospheric pressure.

Repeat the procedure with the absorber in the 'off' position.

GG.8 Resistance to flow of unidirectional valves

GG.8.1 ***Apparatus***

GG.8.1.1 Flowmeter, accurate to within +/-5 % at an indicated flow of 60 l/min.

GG.8.1.2 Pressure-measuring device, accurate to within +/- 0,01 kPa at 0,15 kPa.

GG.8.2 *Procedure*

GG.8.2.1 If testing a dry unidirectional valve, connect a pressure source on the input side of the valve, connect the pressure-measuring device to record the pressure generated at the input side of the valve, and connect the flowmeter between the pressure source and the pressure-measuring device.
Adjust the flow to 5 l/min, 30 l/min or 60 l/min respectively.
Record the pressure generated.

GG.9 Reverse flow through and dislocation of unidirectional valves

GG.9.1 *Apparatus*

GG.9.1.1 Flowmeter, accurate to within +/- 5 % at an indicated flow of 63 ml/min.

GG.9.1.2 Pressure-measuring device, accurate to within +/- 0,01 kPa at a pressure of 0,5 kPa and +/- 0,03 kPa at a pressure of 5,0 kPa.

GG.9.1.3 Rigid container having a capacity of (5 +/- 0,25) l.

GG.9.1.4 Stopwatch

GG.9.2 *Procedure*

GG.9.2.1 Connect the unidirectional valve to the pressure source, pressure-measuring device, flowmeter and rigid container, as shown in figure GG.3. Adjust the flow to a constant 63 ml/min and start the stopwatch. Observe the pressure-measuring device and record the time taken for the pressure to reach at least 0,5 kPa (5 cm H_2O).

NOTE: Within the tolerance of the test apparatus, using a flow of 63 ml/min will mean that valves having a reverse flow of less than 60 ml/min will meet the requirement and those having a reverse flow of more than 70 ml/min will fail to meet the requirement.

GG.9.2.2 Adjust the flow to give a pressure reading of 5 kPa and hold this pressure for 1 min. Release the pressure and check that the valve has not become dislocated by repeating the procedure described in GG.9.2.1 and verifying that the pressure rises to at least 0,5 kPa within 5 min.

GG.10 Opening pressure of unidirectional valves

GG.10.1 ***Apparatus***

GG.10.1.1 Flowmeter, accurate to within +/- 5 % at an indicated flow of 60 ml/min.

GG.10.1.2 Pressure-measuring device, accurate to within +/- 0,01 kPa at a pressure of 0,15 kPa.

GG.10.2 ***Procedure***

GG.10.2.1 Connect a pressure source on the upstream side of the unidirectional valve and connect the pressure-measuring device to record the pressure generated at the input side of the valve, as shown in figure GG.4.

GG.10.2.2 If testing a dry unidirectional valve, allow the valve to close and determine the opening pressure by adjusting the flow of gas to 20 ml/min and recording the peak pressure obtained on the upstream side of the valve.

GG.11 Leakage from a circle absorber assembly

GG.11.1 ***Apparatus***

Use the apparatus described in GG.2.1.1 and GG.2.1.2.

GG.11.2 ***Procedure***

Set up the circle absorber assembly with the reservoir bag removed and the fresh-gas supply tube attached. Seal the reservoir bag port, expiratory port and inspiratory port. Fully close any valve that is designed to allow gas to leak at pressures of 3 kPa (30 cm H_2O) and below. Set the absorber bypass control, if present, in the 'on' position. Connect the pressure-measuring device at the reservoir bag port and introduce air into the fresh gas supply tube until a pressure of 3 kPa is indicated. Adjust the flow of air to stabilize the pressure at 3 kPa and record the leakage flow.

Repeat the test with the absorber bypass mechanism in the 'off' position and, if the mechanism is intended to function at intermediate settings, at any intermediate setting.

GG.12 Resistance to flow of unidirectional valves

GG.12.1 ***Apparatus***

GG.12.1.1 Flowmeter with an accuracy of +/- 5% at an indicated flow of 60 l/min.

GG.12.1.2 Pressure-measuring device, accurate to within +/- 10 Pa (+/- 0,1 cm H_2O).

GG.12.2 *Procedure*

GG.12.2.1 If testing a dry unidirectional valve, connect a pressure source to the input side of the valve.
Connect the pressure measuring device to record the pressure at the input side of the valve.
Connect the flowmeter between the pressure measuring device and the pressure source.
Adjust the flow to 60 l/min and record the pressure generated.

GG.12.2.2 If testing a wet unidirectional valve, connect a pressure source and pressure measuring device as described in GG.12.2.1.
Condition the valve by passing through it a flow of humidified gas at a temperature of (35 +/- 5) °C such that moisture condenses on the inner surface of the valve dome or on the visible surface of the valve itself.
Adjust the flow of heated and humidified gas to 60 l/min.
Record the pressure generated.

GG.13 Opening pressure of unidirectional valves

GG.13.1 *Apparatus*

GG.13.1.1 Flow meter with an accuracy of +/- 5% at an indicated flow of 60 ml/min.

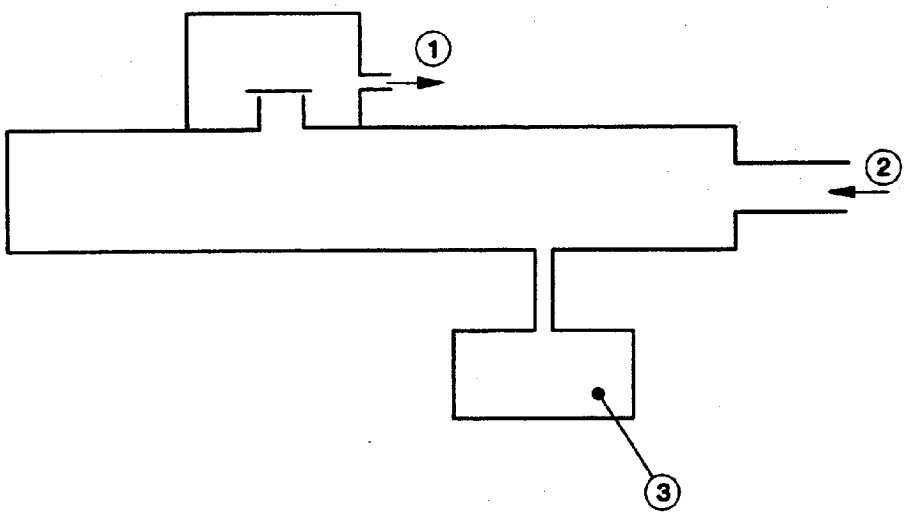
GG.13.1.2 Pressure-measuring device, accurate to within +/- 10 Pa (+/- 0,1 cm H_2O) at a pressure of 150 Pa (1,5 cm H_2O).

GG.13.2 *Procedure*

GG.13.2.1 Connect a pressure source on the input side of the unidirectional valve and connect the pressure-measuring device to record the pressure generated at the input side of the valve, as shown in figure GG.4.

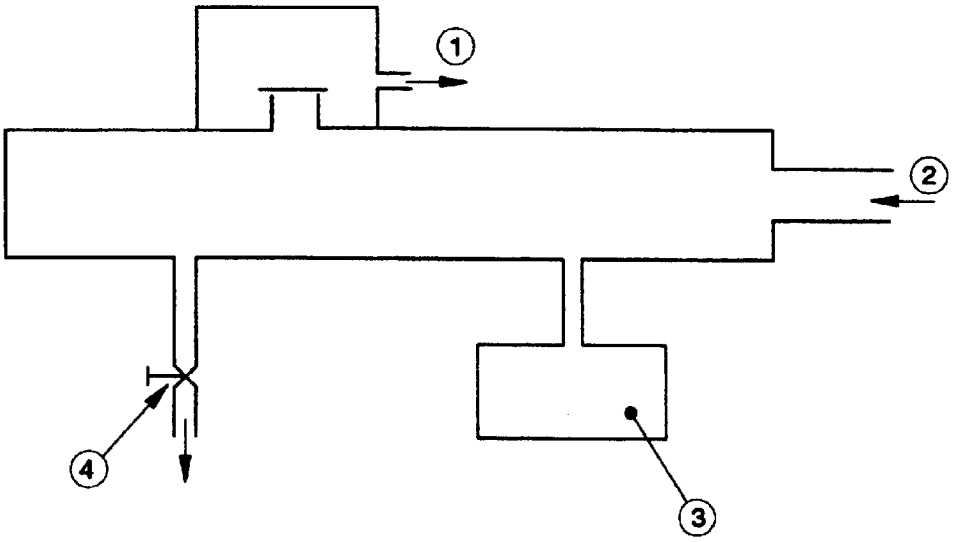
GG.13.2.2 If testing a dry unidirectional valve, allow the valve to close and determine the opening pressure by adjusting the flow of gas to 20 ml/min and recording the peak pressure obtained on the upstream side of the valve.

GG.13.2.3 If testing a wet unidirectional valve, condition the valve by passing through it a flow of humidified gas at a temperature of (35 +/- 5) °C such that moisture condenses on the inner surface of the valve dome or on the visible surface of the valve itself.
Turn of the gas flow and allow the valve to close.
Reintroduce the flow of heated and humidified gas. Determine the opening pressure by adjusting the flow of gas to 20 ml/min and recording the peak pressure obtained at the inlet to the valve.



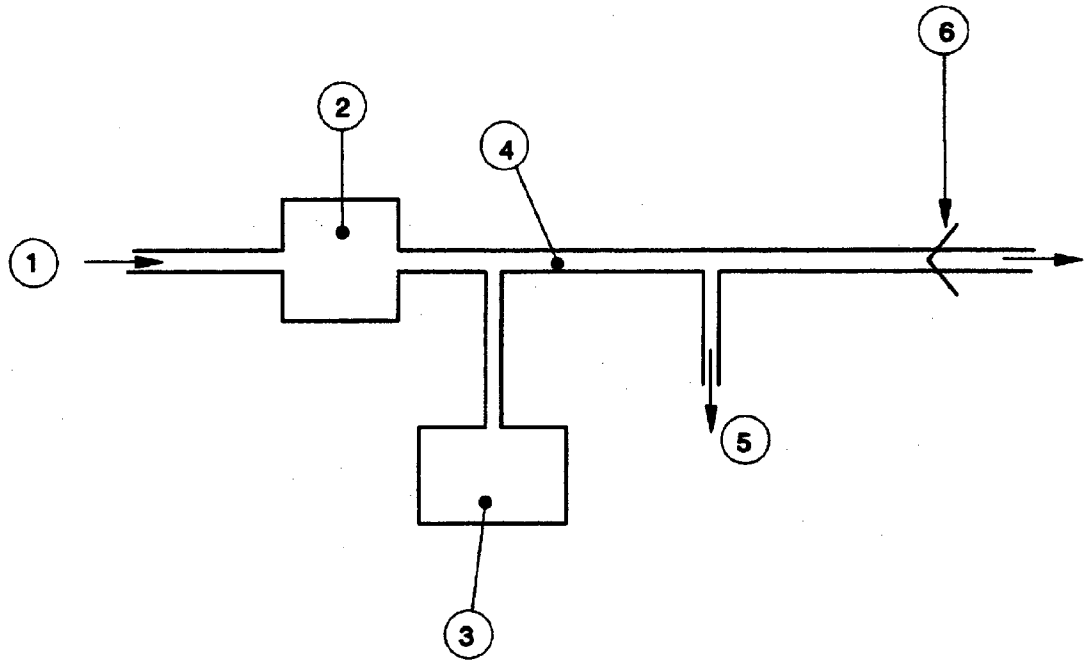
1. To atmosphere
2. Gas supply from flowmeters
3. Pressure measuring device

Figure GG.1: Resistance to flow of APL valves - Arrangement for test



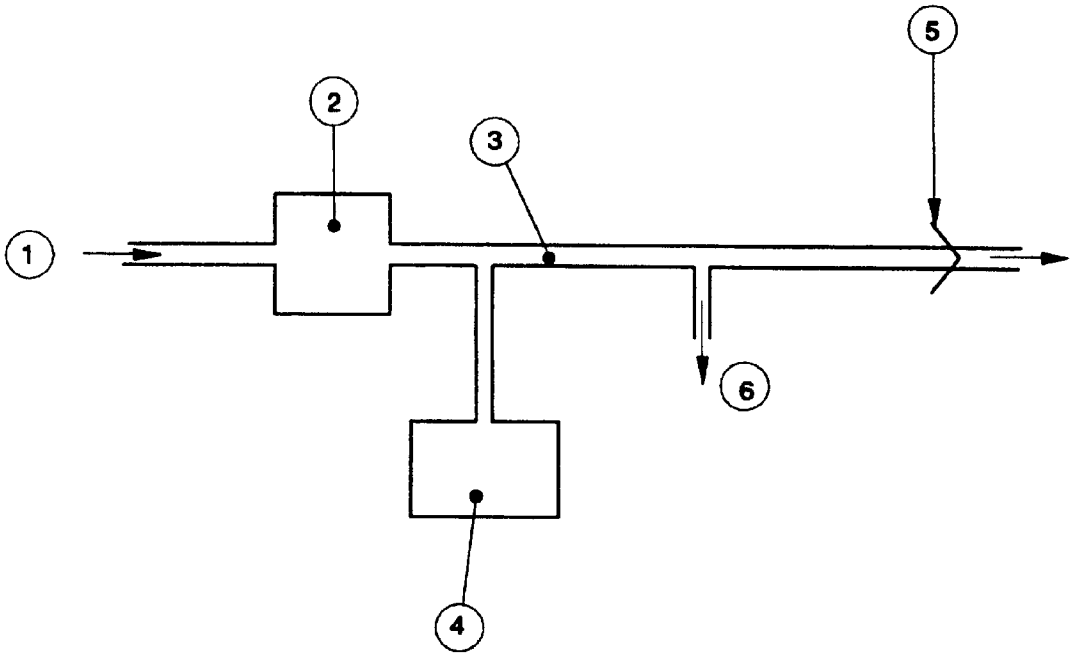
1. To atmosphere
2. Pressure measuring device
3. Gas supply from flowmeter
4. Adjustable bleed valve to atmosphere

Figure GG.2: Leakage from APL valves - Arrangement for test



1. From pressure source
2. Flowmeter
3. Rigid container
4. Thermometer
5. To pressure measuring device
6. Unidirectional valve

Figure GG.3: Reverse flow through unidirectional valves - Arrangement for test



1. From pressure source
2. Flowmeter
3. Thermometer
4. Rigid container
5. Unidirectional valve
6. To pressure measuring device

Figure GG.4: Arrangement of apparatus to test for opening pressure of unidirectional valves

Annex HH (normative) Colour coding of anaesthetic vapour delivery modules

Table 2 of EN 1280-1 : 1997 gives the colours that shall be used for colour coding of anaesthetic vapour delivery modules.

Annex JJ (normative) Test method for resistance to flow of the receiving system

JJ.1 Apparatus

JJ.1.1 A differential pressure measuring device accurate to within +/- 5 % of actual reading.
JJ.1.2 A flow measuring device accurate to within +/- 5 % of actual reading.
JJ.1.3 An adjustable power device, e.g. ejector.
JJ.1.4 Adapter with a type 1 terminal unit socket complying with EN 737-4, with a connector for pressure measurement and with an outlet for connection of the power device.

JJ.2 Procedure

JJ.2.1 Assemble the test apparatus as shown in figure JJ.1 but do not connect the receiving system. Adjust the power device such that a flow of 25 l/min air is drawn through the receiving system. Record the pressure.

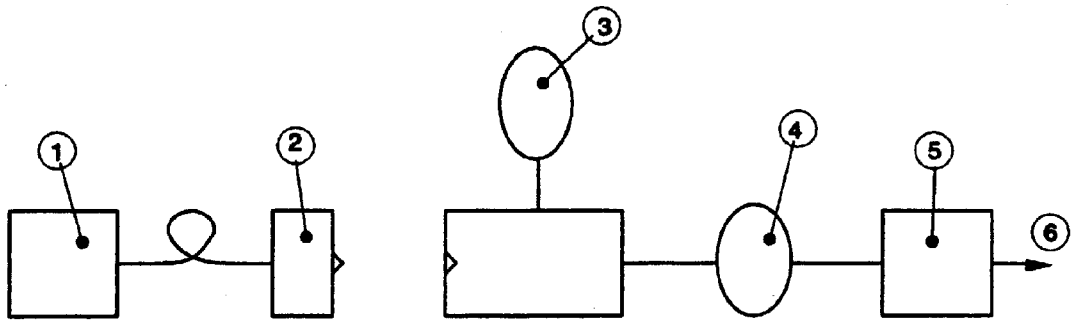
JJ.2.2 Connect the receiving system to the adapter.

JJ.2.3 Adjust the power device again to a flow of 25 l/min. Record the pressure.

JJ.2.4 Calculate the resistance of the receiving system by subtracting the pressure measured in JJ.2.1 from the pressure measured in JJ.2.3.

JJ.2.5 Disconnect the receiving system from the adapter and repeat the test procedure described in JJ.2.1 to JJ.2.4 inclusive with an air flow of 50 l/min.

NOTE: As the pressure measuring device is located on the suction side, negative pressures are measured. For pass/fail criteria the positive values of these pressures are used.



1. Receiving system
2. Adaptor
3. Pressure measuring device
4. Flow measuring device
5. Power device
6. Discharge

Figure JJ.1: Test assembly for measuring the resistance to flow of the receiving system

Annex KK (normative) Test method for flow and resistance of AGSS

KK.1 Apparatus

KK.1.1 A flow measuring device accurate to within +/- 5 % of actual reading.

KK.1.2 A pressure measuring device accurate to within +/- 5 % of actual reading.

KK.2 Procedure

KK.2.1 Set up the test apparatus and AGSS as shown in figures KK.1 and KK.2, as appropriate, but do not connect it to the inlet of the AGSS at X-X.

KK.2.2 Adjust the air flow to 30 l/min and record the pressure.

KK.2.3 Adjust the air flow to 75 l/min and record the pressure.

KK.2.4 Connect the inlet of the AGSS or the patient connection port at X-X in figure KK.1 or KK.2.

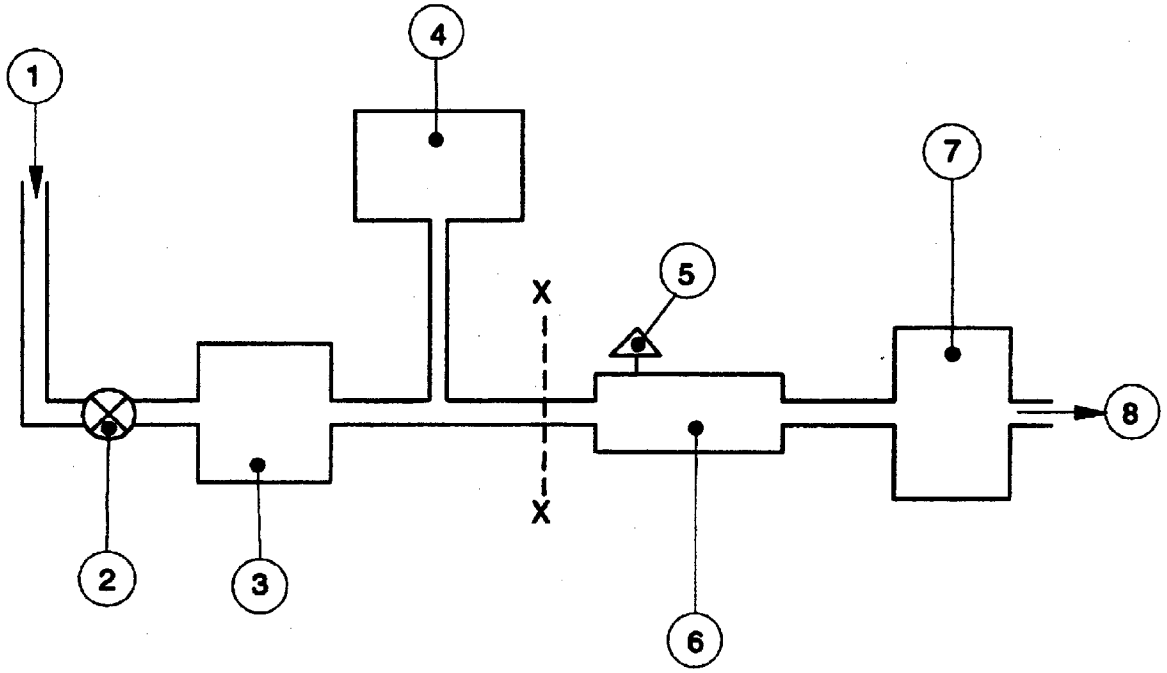
KK.2.5 Turn on the power device.

KK.2.6 Adjust the air flow to 30 l/min, record the pressure and subtract it from the pressure recorded in KK.2.2.

KK.2.7 Adjust the air flow to 75 l/min, record the pressure and subtract it from the pressure recorded in KK.2.3.

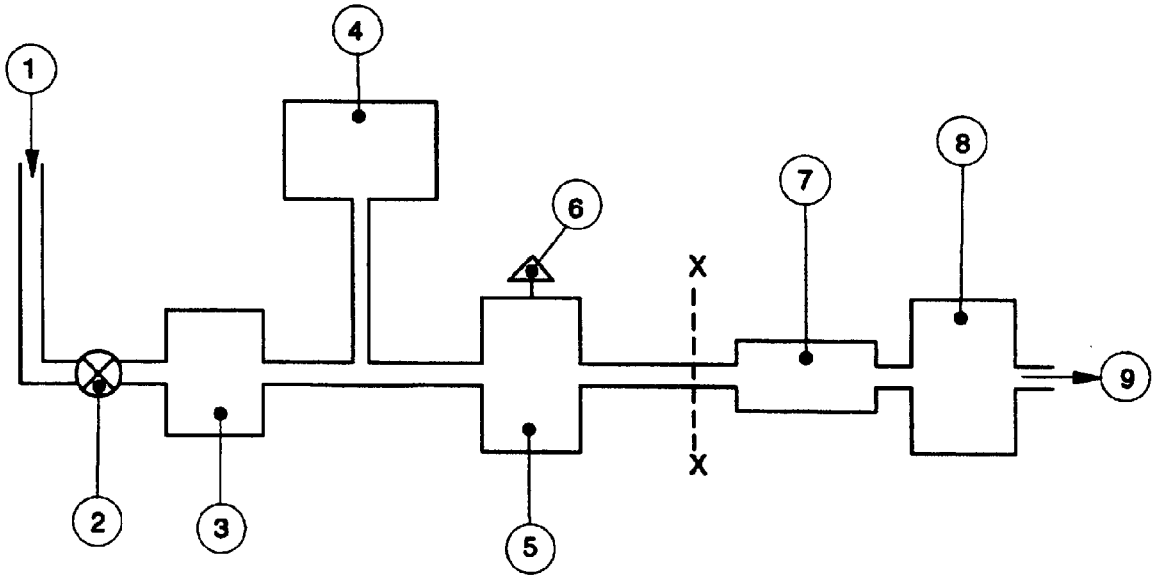
KK.2.8 Turn off the power device.

KK.2.9 Repeat KK.2.6 and KK.2.7.



1. Air supply
2. Flow control valve
3. Flow measuring device
4. Pressure measuring device
5. Means of pressure relief
6. AGSS transfer and receiving systems with means of pressure relief integrated
7. Disposal system or equivalent test device
8. Discharge

Figure KK.1: Test for flow and resistance of AGSS with means of pressure relief integrated or attached



1. Air supply
2. Flow control valve
3. Flow measuring device
4. Pressure measuring device
5. Breathing system with a means of pressure relief integrated
6. Means of pressure relief
7. Non interchangeable AGSS
8. Disposal system or equivalent test device
9. Discharge

x.....x = entry to the AGSS

Figure KK.2: Test for flow and resistance of AGSS with a means of pressure relief integrated in the breathing system

Annex LL (normative) Test method for transfer systems

LL.1 Apparatus

LL.1.1 A flow measuring device accurate to within +/- 5% of actual reading.

LL.1.2 A pressure measuring device accurate to within +/- 5% of actual reading.

LL.2 Test procedure for a transfer system that has a 30 mm female conical inlet connector

LL.2.1 Set up the test apparatus and AGSS as shown in figure LL.1, but do not connect it to the inlet of the AGSS at X-X.

LL.2.2 Adjust a flow of 30 l/min of air and record the pressure.

LL.2.3 Connect the AGSS at X-X in figure LL.1.

LL.2.4 If applicable, apply force to the transfer tube as shown in figure LL.2. The force shall be applied as proximal to the outlet of the transfer system as possible.

LL.2.5 Adjust the air flow to 30 l/min and allow steady state conditions to be achieved.

LL.2.6 Record the pressure and subtract the pressure measured in LL.2.2.

LL.2.7 Disconnect the AGSS at X-X in figure LL.1.

LL.2.8 Repeat the test procedure described from LL.2.2 to LL.2.6 inclusive with an air flow of 75 l/min.

LL.3 Test procedure for a transfer system that has a proprietary inlet connector

LL.3.1 Set up the test apparatus and AGSS as shown in figure LL.3, but do not connect it to the inlet of the AGSS at X-X.

LL.3.2 Adjust a flow of 30 l/min of air and record the pressure.

LL.3.3 Connect the AGSS at X-X in figure LL.3.

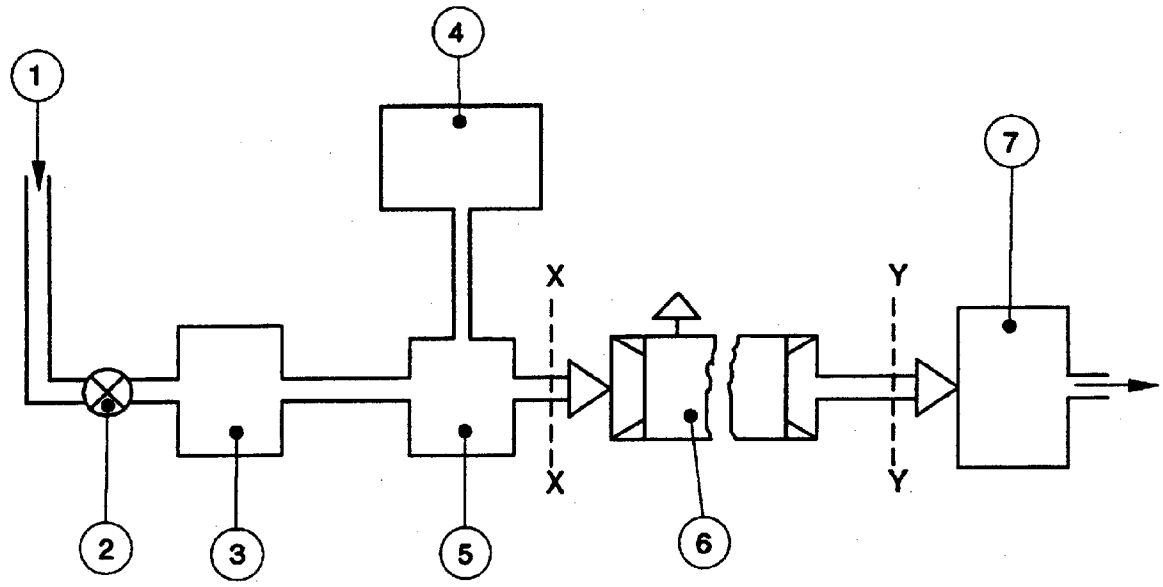
LL.3.4 If applicable, apply force to the transfer tube as shown in figure LL.2. The force shall be applied as proximal to the outlet of the transfer system as possible.

LL.3.5 Adjust the air flow to 30 l/min and allow steady state conditions to be achieved.

LL.3.6 Record the pressure and subtract the pressure measured in LL.3.2.

LL.3.7 Disconnect the AGSS at X-X in figure LL.3.

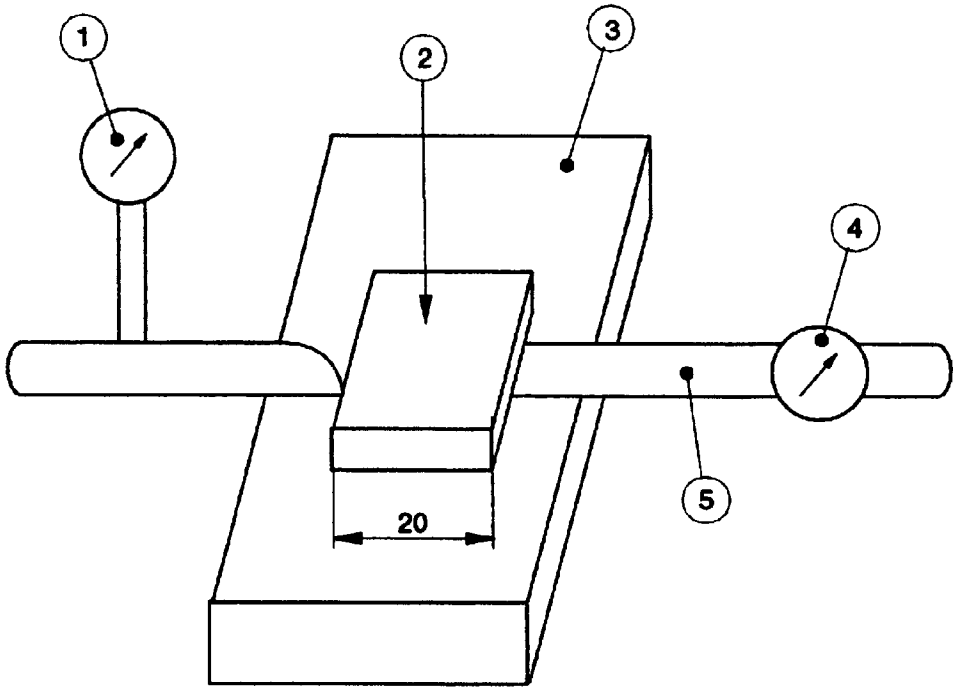
LL.3.8 Repeat the test procedure described from LL.3.2 to LL.3.6 inclusive with an air flow of 75 l/min.



1. Air supply
2. Flow control valve
3. Flow measuring device
4. Pressure measuring device
5. Pressure tab connector
6. AGSS with means of pressure relief attached or integrated
7. Receiving system

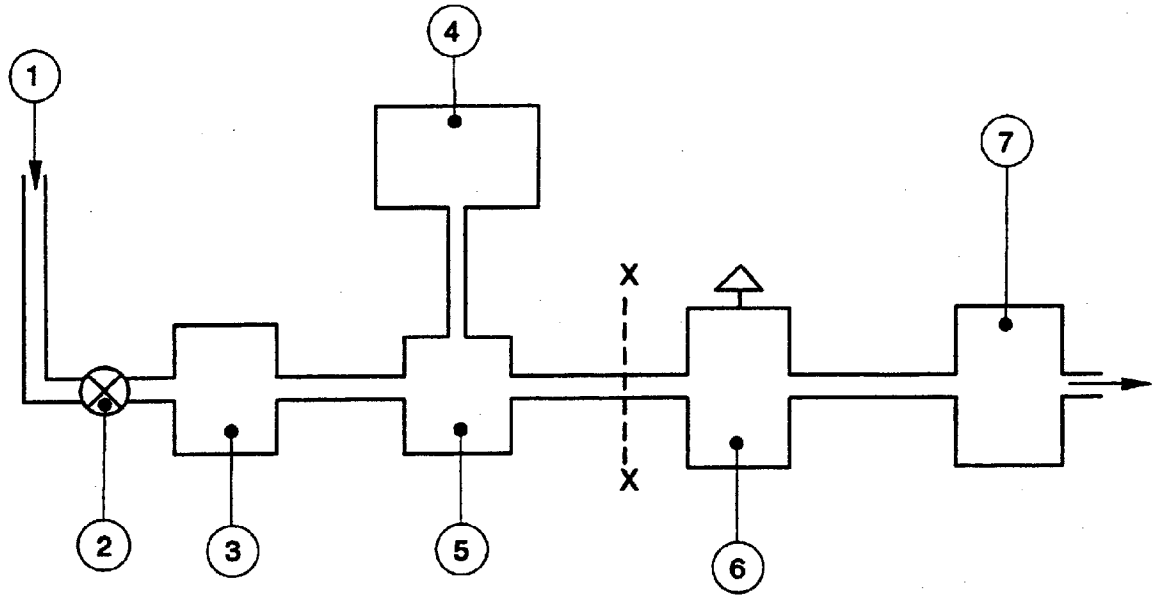
Figure LL.1: Method of test for means of pressure relief integrated in or attached to an AGSS

Dimensions in millimetres



1. Pressure gauge
2. Applied force (600 N)
3. Test pad
4. Flowmeter
5. Hose under test

Figure LL.2: Occlusion of AGSS transfer hose - Arrangement for test



1. Air supply
2. Flow control valve
3. Flow measuring device
4. Pressure measuring device
5. Pressure tab connector
6. Breathing system with means of pressure relief integrated
7. Receiving system

Figure LL.3: Method of test for means of pressure relief integrated in the anaesthetic breathing system

Annex MM (normative) Test method for induced flow and sub-atmospheric pressure of AGSS

MM.1 Induced flow

MM.1.1 ***Apparatus*** A flow metering device accurate to +/- 10 ml/min.

NOTE: A hot-wire anemometer is suitable. An example of such a flow metering device is given in figure MM.1.

MM.1.2 ***Procedure***

MM.1.2.1 Connect the flow metering device to the inlet of the AGSS or for those systems which have a detachable transfer system to the inlet of the receiving system with the disposal system operating at the maximum extract flow for which the AGSS is designed.

MM.1.2.2 Measure the flow

MM.2 Sub-atmospheric pressure

MM.2.1 ***Apparatus***

A pressure measuring device accurate to within +/- 6 Pa at 30 Pa.

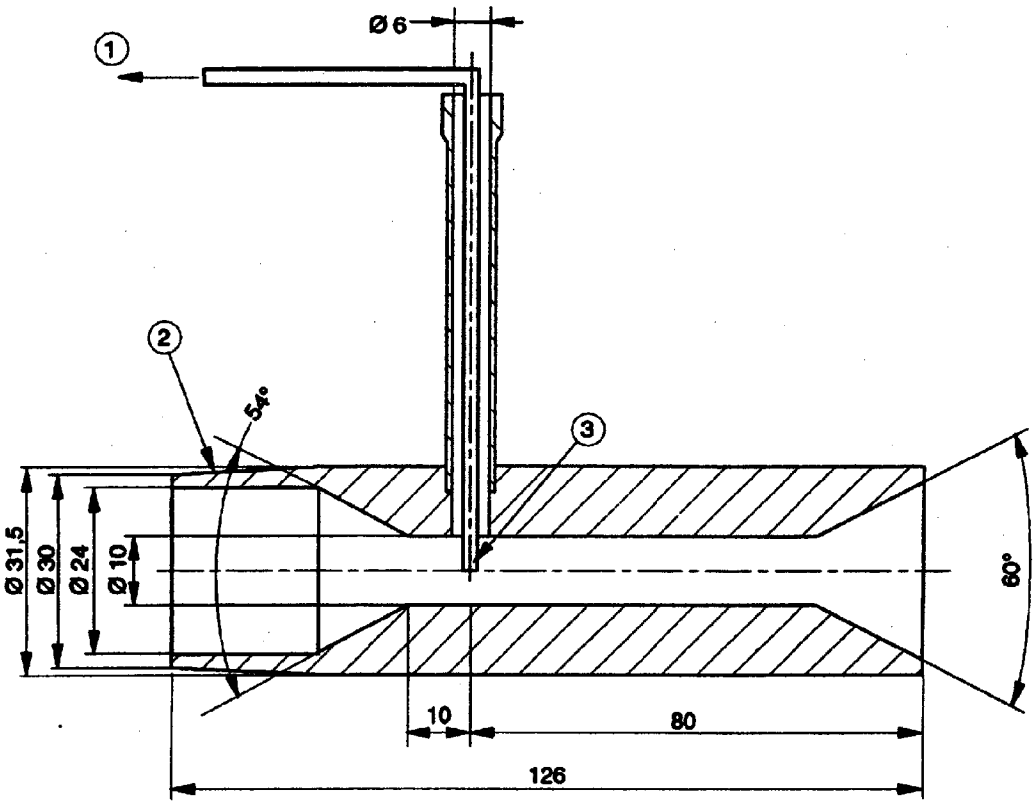
NOTE: An inclined tube manometer is appropriate.

MM.2.2 ***Procedure***

MM.2.2.1 Connect the pressure measuring device to the inlet of the transfer system as shown in figures LL.1 and LL.3 as appropriate and connect the receiving and the transfer system(s) to the disposal system, but with the flow control valve at the inlet fully closed. Operate the power device at the maximum design disposal flow rate.

MM.2.2.2 Measure the subatmospheric pressure.

Dimensions in millimetres



1. To recording instruments
2. 30 mm conical taper
3. Hot wire anemometer

Figure MM.1: Example of flow metering device for induced flow

Annex NN (normative) Test method for spillage from the transfer and receiving systems

NN.1 Apparatus

The test apparatus shall consist of a measuring box or enclosure (see figure NN.1) in which the appropriate parts of an AGSS can be installed. The air inlet of the box or enclosure shall be fully open to atmosphere and, by e.g. means of a fan, air shall be drawn through the box at a constant flow.

Means shall be provided to ensure mixing of the spilled test gas and entrained air. The method of gas sampling shall be accurate to within +/- 10 % of the actual reading.

NOTE: Gas samples should be taken from the centre of the outlet from the box.

NN.2 Calibration procedure

Place the AGSS components in the test enclosure and connect the tubing for the test gas flow and the extract flow. Set and maintain the outlet gas flow between 20 l/min and 30 l/min. Set and maintain a flow of 100 ml/min of the test gas into the calibration gas injection site. When steady-state of the test gas concentration reading is reached, record this reading and the outlet gas flow rate. Turn off the test gas flow into the calibration gas injection site (see figure NN.1).

NN.3 Test flow pattern

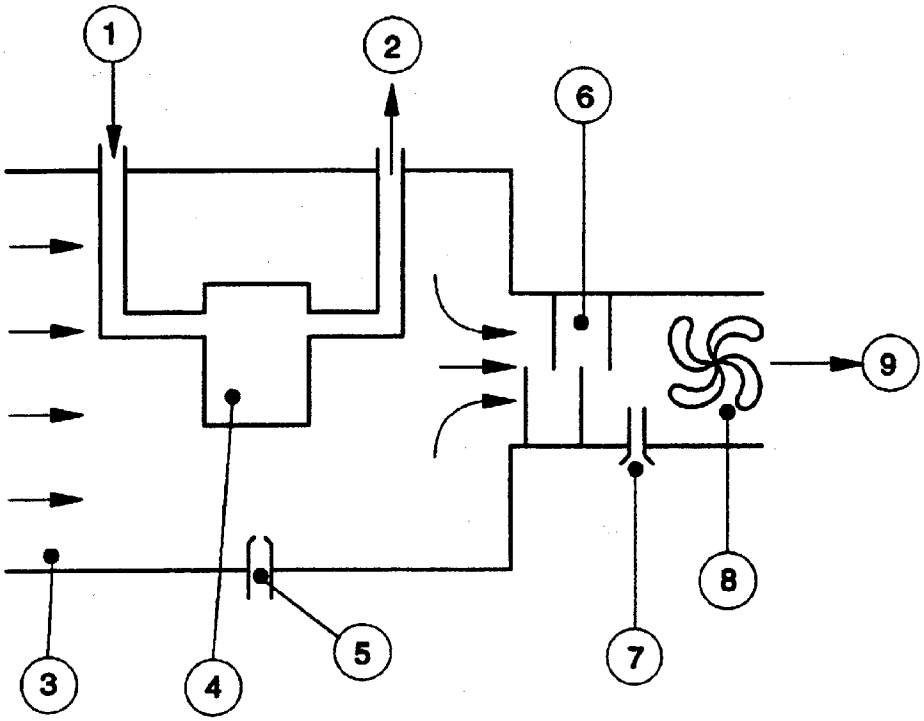
A flow of a test gas containing a tracer gas detectable in low concentrations by the sampling instrument or an undiluted gas shall be applied in the form of a half sine pulse to the inlet of the AGSS. The half sine pulse shall be as shown in figure NN.2.

NN.4 Test procedure

Assemble the test apparatus as described in NN.1 and NN.2. Set the extract flow to the minimum value for which the components are designed. Set the test gas flow to the specified flow pattern (see figure NN.2). Set and maintain the outlet gas flow to the value used for calibration (see NN.2). When the steady-state of the test gas concentration reading is reached, record this reading and the outlet gas flow rate.

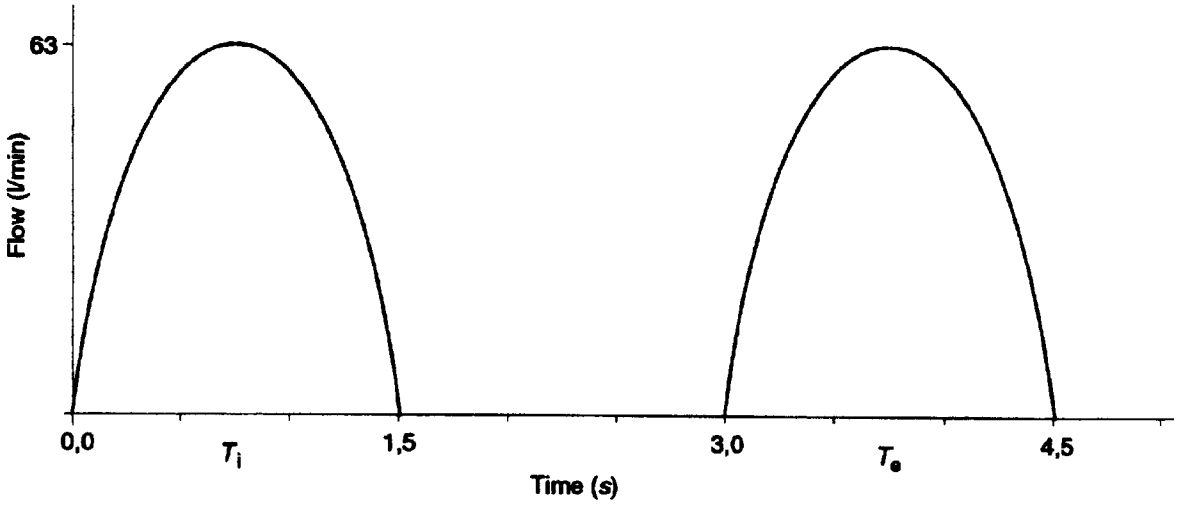
NN.5 Calculation of results

Establish the spillage by comparing the results obtained in NN.2 and NN.4.



1. Test gas flow
2. Extraction flow
3. Test enclosure
4. AGSS transfer and receiving systems
5. Calibration gas injection site
6. Mixing device
7. Test gas sampling site
8. Fan
9. Outlet gas flow

Figure NN.1: Spillage from the transfer and receiving systems of AGSS - Arrangement for test



Ti inspiratory time = 1,5 s
Te expiratory time = 1,5 s
I : E (Inspiratory : expiratory ratio) = 1 : 1

Tidal volume = 1 l
Waveform = half sine

Figure NN.2: Test flow pattern for AGSS

Annex PP (informative) Guidelines for situations in which AGSS are used with flammable anaesthetic gases and/or volatile agents

PP.1 The 'zone of risk' associated with flammable anaesthetic gases and volatile agents has been recognized as extending for 250 mm around any part of the anaesthetic breathing system or other gas pathways of anaesthetic workstation. In the case of an AGSS, the gas pathways can be considered to include any part of the system between the anaesthetic breathing system and any point into which ambient air is entrained to reduce the concentration of flammable gases below the flammability limits or to the final point of discharge to atmosphere.

PP.2 If the AGSS is marked as being suitable for use with flammable anaesthetics, it can be used for scavenging flammable anaesthetics, but the means of pressure relief (if provided) of the transfer system and the inlet port to the transfer system should be located not closer than 250 mm from any electrical socket outlet or electrical apparatus which is not marked as being APG equipment as specified in EN 60601-1 : 1990.

PP.3 If the AGSS is installed within a boom or pendant fitting, for example with other medical gas terminal units and electrical socket outlets, and it is intended that the AGSS should be suitable for use with flammable anaesthetic, the distance between the means of pressure relief (if provided) of the transfer system and the inlet to the receiving system should be greater than 250 mm.

PP.4 There should be electrical continuity between the receiving system and the anaesthetic workstation.

Annex QQ (normative) Ergonomics and symbols

QQ.1 General requirements and conditions:

- Illumination of 215 lx shall be provided.
- Measurement of ambient illumination shall be made from the control panel toward the test subject.
- Test operators shall have vision of 1, corrected if necessary.

QQ.2 Visual indicators and their associated markings and warnings integral to the anaesthetic workstation that are intended to be viewed from the operator's position shall be clearly legible when tested in accordance with clause QQ.3.

QQ.3 Place the test operator in the operator's position at a distance of 500 mm from the anaesthetic workstation. The test is passed if the test operator can correctly identify all controls and indicators, verify all qualitative and quantitative information, and read all warning statements.

QQ.4 Visual indicators integral to the anaesthetic workstation, e.g. for breathing circuit integrity, oxygen concentration, and high pressure shall be clearly legible when tested in accordance with QQ.5.

When the anaesthetic workstation is equipped by the manufacturer or supplier with a primary visual indicator, remote from the anaesthetic workstation (no display integral to the anaesthetic workstation) e.g. for breathing circuit integrity, oxygen concentration, or sustained high pressure, it shall be clearly legible when tested in accordance with QQ.5.

QQ.5 R Compliance shall be tested as follows: Position the eyes of the test operator at a distance of 2 m and an angle of 15° either side of a line perpendicular to the centre of the display or control panel at a height of 1,5 m above the floor. The test is passed if the test operator can correctly identify each of the indicators specified in QQ.4.

QQ.6 High and medium priority indicators shall be clearly legible when tested in accordance with QQ.7.

QQ.7 R Position the eye of the test operator at a distance of 4 m and at an angle of 30 ° either side of a line perpendicular to the center of the display or control panel at a height 1,5 m above the floor. The test is passed if the test operator can correctly distinguish the warning and caution indicators, and discriminate between them.

Annex RR (normative) Method of test for draw-over vaporizers used with emergency anaesthetic equipment

RR.1 General

RR.1.1 Test the emergency anaesthetic equipment with the draw-over vaporizer, anaesthetic breathing system and, if applicable, anaesthetic ventilator recommended by the manufacturer or supplier (see 6.8.2). Carry out preliminary checks to ensure that components downstream of the draw-over vaporizer will not affect the test results, for example by absorbing volatile anaesthetics or imposing time delays on response or by leakage.

RR.1.2 Use the carrier gas recommended by the manufacturer, see 6.8.2 ii), the accuracy of which should be within 10 % of the tolerance specified in 105.2.6 a).

RR.2 Procedure

RR.2.1 Connect the draw-over vaporizer to the non-rebreathing system which is required to prevent reverse flow through the draw-over vaporizer.
Connect the patient connection port of the anaesthetic breathing system to the inlet of a mechanical ventilator so that air is drawn in through the draw-over vaporizer during inspiration and expelled through the APL valve during expiration. The ventilator shall be capable of producing a minute volume of 6 l/min at 15 breaths per minute (bpm) and I:E ratio 1:1 (all figures +/- 15 %). Attention is drawn to the fact that adsorption of vapour can occur in the ventilator which has to be predetermined and corrected. Therefore an all metal piston/cylinder ventilator is preferred, e. g. Sterling pump,for the test set up.

RR.2.2 Place the emergency anaesthetic equipment and anaesthetic agent in the test room for at least 3 h at a temperature of (20 +/- 3) °C and maintain this temperature throughout the test procedure.

RR.2.3 Set the draw-over vaporizer to the 'on' position at the maximum concentration setting. Operate the ventilator for 3 min.

RR.2.4 Fill the draw-over vaporizer with the appropriate anaesthetic agent to approximately halfway between the maximum and minimum marks on the liquid level indicator and leave it to stand for at least 45 min.

NOTE: This may be within the 3 h period specified in RR.2.2

RR.2.5 Either :
a) Connect a vapour analyzer to the exhaust port of the APL valve.
Set the ventilator to the values given in RR.2.1. Run the ventilator and ensure that the pressure fluctuation at the patient connection port does not exceed -0,5 kPa to 0 kPa.
Set the draw-over vaporizer control to 'off' position or 'zero' position, if it is also the 'off' position. Run the ventilator for 1 min and measure the vapour concentration for 1 min. Calculate the mean value over 1 min, or :

b) Alternatively, connect the outlet of the APL valve to a non-absorbent flexible reservoir, e.g. a Douglas bag, through a sampling valve enabling gas to be diverted into the bag or to an exhaust AGSS. Set the sampling valve to exhaust, run the ventilator for 1 min, then select sampling for a further 1 min. Analyze 3 to 5 samples drawn from the bag and record the average value.

RR.2.6 Repeat the procedure described in RR.2.5 with the draw-over vaporizer set to each of its other settings in the order given in table EE.1. If the draw-over vaporizer is not marked with the concentration settings given in table EE.1, use the nearest settings on the draw-over vaporizer. If any setting given in table EE.1 is equidistant between settings on the draw-over vaporizer, use the lower setting on the draw-over vaporizer.

RR.2.7 For the sequence of measurements described in RR.2.5 and RR.2.6 use a fresh-gas flow of (8 +/- 0,8) l/min.

Annex SS (informative) Bibliography

EN 737-2	Medical gas pipeline systems Part 2: Anaesthetic gas scavenging disposal systems
EN 837-1	Pressure gauges Part 1: Bourdon type pressure gauges: Dimensions, metrology, requirements and testing
EN 865	Medical electrical equipment - Pulse oximeters - Particular requirements
EN 1060-1	Non-invasive sphygmomanometers Part 1: General requirements
EN 1060-2	Non-invasive sphygmomanometers Part 2: Supplementary requirements for mechanical sphygmomanometers
EN 1060-3	Non-invasive sphygmomanometers Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems
WI 00215058	Methods of testing the efficiency of microbial breathing filters for respiratory and anaesthetic equipment (In preparation by CEN/TC 215/WG 4)
	Connections for ancillaries to anaesthetic and respiratory equipment
WI 00215054	Part 1: Connectors for gas sampling tubes
WI 00215055	Part 2: Connectors for pneumatic control and alarm system tubes
WI 00215063	Agent-specific filling systems for anaesthetic vaporizers - Part 2 : Cylindrical keyed filling systems (future prEN 1280-2)
EN 60065	Safety requirements for mains operated electronic and related apparatus for household and similar general use (IEC 65 : 1985 + A1 : 1987, A2 : 1989 + A3 : 1992, Modified)
IEC 60601-2-10	Medical electrical equipment Part 2: Particular requirements for the safety of nerve and muscle stimulators
IEC 60601-2-12	Medical electrical equipment Part 2: Particular requirements for the safety of lung ventilators for medical use
IEC 60601-2-13	Medical electrical equipment Part 2: Particular requirements for the safety of anaesthetic machines

EN 60601-2-25	Medical electrical equipment Part 2: Particular requirements for the safety of electrocardiographs (IEC 60601-2-25 : 1993)
EN 60601-2-26	Medical electrical equipment Part 2: Particular requirements for the safety of electroencephalographs (IEC 60601-2-26 : 1994)
EN 60601-2-27	Medical electrical equipment Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment (IEC 60601-2-27 : 1994)
EN 60601-2-30	Medical electrical equipment Part 2: Particular requirements for the safety of automatic cycling indirect blood pressure monitoring equipment (IEC 60601-2-30 : 1995)
EN 60601-2-34	Medical electrical equipment Part 2: Particular requirements for the safety of direct blood-pressure monitoring equipment (IEC 60601-2-34 : 1994)
ISO 407	Small medical gas cylinders - Pin-index yoke-type valve connections
ISO 5359	Low-pressure flexible connecting assemblies (hose assemblies) for use with medical gas systems

NFPA Publication 53M Fire hazards in oxygen-enriched atmospheres [1)]

T. Redeker: "The flammability hazard when using halogenated agents", Physikalisch-Technische Bundesanstalt (PTB), D 38023 Braunschweig, Germany.

[1)] Available from the National Fire Protection Association, 1 Batterymarch Park, PO Box 9101, Quincy, MA 02269-9101, USA

Annex TT (normative)

SPECIAL NATIONAL CONDITIONS

Special national condition: National characteristic or practice that cannot be changed even over a long period, eg climatic conditions, electrical earthing conditions. If it affects harmonization, it forms part of the European Standard.

In the countries in which the relevant national condition applies these provisions are normative, for other countries they are informative.

56.3 bb) 1st dash item: Special national condition for all CEN members.

The requirement to use NIST connectors in accordance with EN 739 does not apply until the latest date of withdrawal of the special national condition (1998-06-13), subject to review taking into account eg. the results of a forthcoming European study.

56.3 bb) 1st dash item: Special national condition for all CEN members utilizing terminal units and probes which comply with the National Standards for Austria, France, Germany, Italy, Sweden and United Kingdom.

The requirement to comply with prEN 737-6 does not apply until the latest date of withdrawal of the special national condition, subject to review taking into account eg. the results of a forthcoming European study.

6.1 bb), 6.3 aa): Special national condition for Austria, Germany, Switzerland.

The requirement to comply with Table 1 of EN 739 : 1998 does not apply until the latest date of withdrawal of the special national condition (2006-07-01), subject to review taking into account eg. the results of a forthcoming European study and the ongoing European standardization activities of the EN 1089 series.

Annex ZA (informative) Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive 93/42/EEC.

WARNING: other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The following clauses of this standard (see Table ZA.1) are likely to support requirements of Directives (see Table ZA.1).

Compliance with these clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

TABLE ZA.1 : Correspondence between this European Standard and EU Directives

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
All	2	
1	2	
2	2	
3	1*, 2, 7.1 (3.1*, 3.4*)	
4	1, 2, 7.1, 7.5 (4[3.6bb)])	
5	2	
6	2, 3, 5, 13.1, 13.2	
6.1	2, 3, 5, 8.3 (6.1dd), 8.4 (6.1dd), 8.6 (6.1dd), 8.7 (6.1dd), 9.3 (6.1cc), 12.9, 13.1, 13.2, 13.3a) to f) , i) to m) (6.1dd), 13.4 (6.1dd), 13.5 (6.1dd)	
6..2	2, 3, 5, 13.1, 13.2	
6.3	2, 3, 5, 10.2, 10.3, 12.9, 13.1, 13.2	
6.4	2, 3, 5, 13.1, 13.2	
6.5	2, 3, 5, 13.1, 13.2	
6.6	2, 3, 5, 13.1, 13.2	
6.7	2, 3, 5, 13.1, 13.2	
6.8	2, 3, 5, 13.1, 13.2, 13.6 a) to d), f) to i)	
6.8.1	2, 3, 5, 13.1, 13.2, 13.6 a) to d), f) to i)	
6.8.2	2, 3, 4 (6.8.2a) 4th dash), 5, 7.1 (6.8.2 d*), 7.2 (6.8.2d*, 6.8.2gg), 9.1 (6.8.2a), 9.2 3rd dash, 9.3 (6.1cc), 10.1 (6.8.2a), 13.1, 13.2, 13.6 a) to d), f) to i)	
6.8.3	2, 3, 5, 10.1 (6.8.3aa), 13.1, 13.2, 13.6a) to d), f) to i)	
6.8.101	2, 3, 5, 9.2 4th dash 13.1, 13.2, 13.6a) to d), f) to i)	
7	2	

TABLE ZA.1 : Correspondence between this European Standard and EU Directives

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
10	2, 5, 9.2 2nd dash	
10.101	2, 5, 9.2 2nd dash	
13	2, 9.2 2nd dash, 12.6	
14	2, 9.2 2nd dash, 12.6	
15	2, 9.2 2nd dash, 12.6	
16	2, 9.2 2nd dash, 12.6	
17	2, 9.2 2nd dash, 12.6	
18	2, 9.2 2nd dash, 12.6	
19	2, 9.2 2nd dash, 12.6	
20	2, 9.2 2nd dash, 12.6	
21	2, 9.2 1st dash, 12.7.1	
22	2, 9.2 1st dash, 12.7.1	
23	2, 9.2 1st dash, 12.7.1	
24	2, 9.2 1st dash, 12.7.1	
25	2, 9.2 1st dash, 12.7.1	
27	2, 9.2 1st dash, 12.7.1	
28	2, 9.2 1st dash, 12.7.1	
29	2, 9.2 2nd dash	
30	2, 9.2 2nd dash	
31	2, 9.2 2nd dash	
32	2, 9.2 2nd dash	
33	2, 9.2 2nd dash	
34	2, 9.2 2nd dash	
35	2, 9.2 2nd dash ,12.7.2	
36	2, 9.2 2nd dash , 9.2 3rd dash	
37	2, 7.1, 9.3	
38	2, 7.1, 9.3	
39	2, 7.1, 9.3	
40	2, 7.1, 9.3	
41	2, 7.1, 9.3	

TABLE ZA.1 : Correspondence between this European Standard and EU Directives

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
42	12.7.5	
43	2, 7.1, 9.3, 12.7.5	
44	2, 7.2 (44.7), 7.5, 7.6, 8.1 (44.7) 8.3 (44.7), 8.4 (44.7), 8.5 (44.7), 8.6 (44.7)	
45	2	
48	2	
49	2	
50	2	
51.102	1, 2, 6, 12.8.1, 12.8.2, 12.2 (51.102.3), 12.3 (51.102.1, 51.102.2)	
51.103	1, 2, 6, 12.8.1, 12.8.2	
51.104	1, 2, 6, 12.8.1, 12.8.2	
51.105	1, 2, 6, 12.8.1, 12.8.2	
51.106	1, 2, 6, 12.8.1, 12.8.2	
51.107	1, 2, 6, 12.8.1, 12.8.2	
51.108	1, 2, 6, 12.8.1, 12.8.2	
51.109	1, 2, 6, 12.8.1, 12.8.2	
51.110	1, 2, 6, 9.2 1st dash, 12.8.1, 12.8.2	
51.111	1, 2, 7.5	
51.112	1, 2, 6, 9.2 1st dash, 12.8.1, 12.8.2	
51.113	1, 2, 6, 9.2 1st dash, 12.8.1, 12.8.2	
51.114	1, 2, 6, 9.2 1st dash, 12.8.1, 12.8.2	
51.115	1, 2, 6, 9.2 1st dash, 12.8.1, 12.8.2	
51.116	1, 2, 6, 9.2 1st dash, 12.8.1, 12.8.2	
52	1, 2, 5, 12.5	
53	2	
54	2, 7.3, 12.1, 12.7.4	

TABLE ZA.1 : Correspondence between this European Standard and EU Directives

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
55	2, 12.7.4	
56	2, 12.7.4	
57	2, 12.6, 12.7.4	
58	2, 12.6, 12.7.4	
59	2, 12.7.4	
101	2, 12.7.4	
102	2, 9.2 1st dash, 12.7.4	
103	2, 7.1, 7.5, 9.2 1st dash, 12.7.4	
104	2, 7.1, 7.5, 9.2 1st dash, 12.7.4	
104.2	2, 7.1, 7.5, 9.2 1st dash 12.7.4	
104.3	2, 7.1, 7.5, 9.2 1st dash, 10.3, 12.7.4	
104.4	2, 7.1, 7.5, 9.2 1st dash, 12.7.4	
104.5	2, 7.1, 7.5, 9.2 1st dash, 12.7.4	
105	2, 7.1, 7.5, 12.7.4	
105.1	2, 7.1, 7.5, 12.7.4	
105.2	2, 7.1, 7.5, 12.7.4	
106	2, 7.1, 7.2, 7.5, 12.7.4	
107	2, 12.7.4	
107.2	2, 12.7.4	
107.3	2, 12.7.4	
107.4	2, 12.7.4	
107.5	2, 12.7.4	
107.6	2, 12.7.4	
107.7	2, 12.7.4	
107.8	2, 12.7.4	
107.8	2, 8.1, 12.7.4	
107.10	2, 12.7.4	

TABLE ZA.1 : Correspondence between this European Standard and EU Directives

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
107.11	2, 12.7.4	
108	2, 12.7.4	
109	2, 12.7.4	
110	2, 12.7.4	
111	2, 12.7.4	
111.1	2, 12.7.4	
111.2	2, 12.7.4	
111.3	2, 12.7.4	
111.4	2, 12.7.4	
111.5	2, 12.7.4	
112	2, 12.7.4	
Annex AA	see clause 37	
Annex BB	12.4 (1.5)	
Annex CC	see all clauses	
Annex DD	see clause 51.107	
Annex EE	see clause 105	
Annex FF	see clause 105	
Annex GG	see clause 107	
Annex HH	see clauses 105 and 106	
Annex JJ	see clause 111	
Annex KK	see clause 111	
Annex LL	see clause 111	
Annex MM	see clause 111	
Annex NN	see clause 111	
Annex QQ	see clause 6	
Annex RR	see clause 51.115	

* Requirement is covered in clauses of EN 60601-1 : 1990