INTERNATIONAL STANDARD

IEC 60601-2-13

[ISO 8835-1]

Second edition
1998-05

Medical electrical equipment –

Part 2-13:
Particular requirements for the safety of anaesthetic workstations

Appareils électromédicaux –

Partie 2-13:
Règles particulières de sécurité pour les appareils d'anesthésie

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Terminology, graphical and letter symbols

For general terminology, readers are referred to IEC 60050: *International Electrotechnical Vocabulary* (IEV).

For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams.*

* See web site address on title page.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-13: Particular requirements for the safety of ANAESTHETIC WORKSTATIONS

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international cooperation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in the preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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6) Attention is drawn to the possibility that some elements of this International Standard may be subject to patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-2-13/Ed. 2 was developed by the Joint Working Group of ISO/TC 121/SC 1, Breathing attachments and anaesthetic machines, and IEC/SC 62D, Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition of IEC 60601-2-13 cancels and replaces the first edition published in 1989.

This second edition constitutes a technical revision.

The text of this Particular Standard is based on the following documents:

FDIS	Report on voting
62D/249/FDIS	62D/282/RVD

Full information on the voting for the approval of this Particular Standard can be found in the report on voting indicated in the above table.

Annex DD forms an integral part of this standard.

Annexes AA, BB, CC, EE, FF and GG are for information only.

A bilingual version of this standard may be issued at a later date.

In this Particular Standard, the following print types are used:

– requirements, compliance with which can be tested, and definitions: roman type;

– notes, explanations, advice, introductions, general statements and references: smaller roman type;

– *test specifications: italic type;*

– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD IEC 60601-1 OR IN THIS PARTICULAR STANDARD: SMALL CAPITALS

INTRODUCTION

This Particular Standard specifies particular requirements for ANAESTHETIC WORKSTATIONS for inhalational anaesthesia intended for human use. It applies in conjunction with IEC 60601-1 (including the amendments). The relationship of this Particular Standard with IEC 60601-1 is explained in 1.3.

All pressures are expressed as differences from ambient atmospheric pressure.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-13: Particular requirements for the safety of ANAESTHETIC WORKSTATIONS

Section one – General

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies, except as follows:

Addition

1.2 This Particular Standard presents particular requirements for ANAESTHETIC WORKSTATIONS for inhalational anaesthesia intended for human use supplied complete, as well as particular requirements for individual devices which are intended to be part of an ANAESTHETIC WORKSTATION.

It is the intent of this Particular Standard that both complete ANAESTHETIC WORKSTATIONS and individual devices be commercially available to allow users to configure an ANAESTHETIC WORKSTATION to meet the needs of their clinical practice in conformance with their national regulations. To this end the standard has been structured in such a way as to clearly define interfaces and to identify particular requirements pertinent to specific devices currently available.

Attention is drawn to recommendations for patient monitoring during anaesthesia made by many national clinical and regulatory bodies. These recommendations include, but are not limited to, monitoring of the patient's electrocardiogram, blood pressure, body temperature and pulse oximetry.

NOTE – Although this Particular Standard does not mandate the use of the MONITORING DEVICES referred to in the paragraph above, manufacturers of ANAESTHETIC WORKSTATIONS are encouraged to make provision for such monitors so that the user can more easily assimilate their data output and so that the alarm function of the various monitors can be integrated.

To facilitate data transfer capability between different MONITORING DEVICES, a “bus” or data transfer system may be used.

ANAESTHETIC WORKSTATIONS and/or their components intended for use with flammable anaesthetic agents are not covered by this standard, nor are dental analgesia apparatus.

1.3 Particular Standards

Addition:

This Particular Standard amends and supplements a set of IEC publications, hereinafter referred to as “General Standard”, consisting of

IEC 60601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety*
Amendment 1, amendment 2,

IEC 60601-1-1: 1992, *Medical electrical equipment – Part 1: General requirements for safety, 1. Collateral Standard: Safety requirements for medical electrical systems*
Amendment 1

IEC 60601-1-2: 1993, *Medical electrical equipment – Part 1: General requirements for safety, 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests*

For brevity, IEC 60601-1 is referred to in this Particular Standard either as the “General Standard” or as the “General Requirement(s)”, and IEC 60601-1-1 and IEC 60601-1-2 as the “Collateral Standards”.

The term “this standard” covers this Particular Standard, used together with the General Standard and Collateral Standards.

The numbering of sections, clauses, and subclauses of this Particular Standard corresponds with that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

“Addition” means that the text of this Particular Standard is additional to the requirements of the General Standard.

“Amendment” means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Clauses, subclauses, figures and tables which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Clauses and subclauses to which there is a rationale are marked with an asterisk*. These rationales can be found in an informative annex BB. Annex BB is not part of this Particular Standard and only gives additional information; it can never be the subject of testing.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard applies without modification.

Where it is intended that any part of the General Standard or Collateral Standards, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

A requirement of this Particular Standard replacing or modifying requirements of the General Standard or Collateral Standards takes precedence over the corresponding General Requirement(s).

2 Terminology and definitions

This clause of the General Standard applies together with the definitions given in ISO 4135, ISO 9703-1, ISO 9703-2 and the following additional definitions:

2.101 ALARM DEVICE

Device which provides a visual and/or auditory signal when an alarm condition is present.

2.102 ANAESTHETIC VAPOUR DELIVERY DEVICE (concentration calibrated vaporizer)

Device which provides the vapour of an anaesthetic agent in a controllable concentration.

2.103 ANAESTHETIC WORKSTATION

Assembly of devices and their associated monitoring, alarm, and PROTECTION DEVICES which control the flow and composition of the fresh gas delivered during anaesthesia.

NOTE – The ANAESTHETIC WORKSTATION may include an ANAESTHETIC VAPOUR DELIVERY DEVICE(s), an anaesthesia ventilator, an anaesthesia breathing system, and an anaesthetic gas scavenging system in whole or in part.

2.104 APPLIED PART

FRESH GAS OUTLET, if provided, and all the other parts of the ANAESTHETIC WORKSTATION intended to be connected with the patient or with the anaesthesia breathing system.

2.105 BIAS

Constant or systematic error which manifests itself as a persistent deviation of the method average from the accepted reference value.

2.106 CONTINUOUS DISPLAY

Display where the value is updated continuously or at a clinically appropriate frequency.

2.107 DEFAULT CONDITIONS; DEFAULT SETTINGS

Those operating parameters within the equipment, which are pre-set at the factory or by the operator and which, without further intervention, are restored when the equipment is turned on.

2.108 DISABLE

To prevent the response of a functioning device.

2.109 FRESH GAS OUTLET; COMMON GAS OUTLET

That port through which the dispensed mixture of anaesthetic gases and vapour is delivered.

2.110 GAS FLOWMETER

Device which indicates the volume of a specific gas or gas mixture passing in a unit of time.

2.111 GAS FLOW CONTROL SYSTEM

Device or assembly that controls the flow of gas(es) or gas mixtures.

2.112 GAS MIXER

Device which receives separate supplies of oxygen and other medical gas(es) and which delivers the mixed gases in concentrations adjustable by the operator.

2.113 INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY DEVICE

Operator-detachable ANAESTHETIC VAPOUR DELIVERY DEVICE designed to be used with specified equipment from different manufacturers.

2.114 MACHINE GAS PIPING

All pipework, including unions, from unidirectional valves in the pipeline inlets and from the outlets of the PRESSURE REGULATORS to the flow control system, as well as the piping connecting the flow control system and the piping connecting the ANAESTHETIC VAPOUR DELIVERY DEVICE to the FRESH GAS OUTLET. It includes piping leading to and from pneumatic alarm systems, gauges, oxygen flush and gas power outlets.

2.115 MONITORING DEVICE

Device which continuously or repeatedly measures and indicates the value of a variable to the operator.

2.116 NON-INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY DEVICE

ANAESTHETIC VAPOUR DELIVERY DEVICE designed to be used only with equipment specified by the manufacturer.

NOTE – These devices may or may not be operator-detachable.

2.117 POWER SUPPLY

Any source of energy, other than that generated directly by the human body or by gravity, that makes the device function.

2.118 PRECISION

That quality which characterizes the ability of a device to give for the same value of the quantity measured, indications which agree amongst themselves, not taking into consideration the systematic errors associated with variations of the indications.

2.119 PRESSURE REGULATOR

Gas pressure reducing and controlling device designed to provide a constant outlet pressure over a specified range of inlet pressures.

2.120 PROTECTION DEVICE

Device which, without intervention of the operator, protects the patient from hazardous output due to incorrect delivery of energy or substances.

2.121 SMART ALARM SYSTEM

Alarm system which, based on monitored information from clinical or technical variables, is designed to make logic decisions and, therefore, without operator intervention, to have the ability, for example, to allocate more than one priority for the same alarm condition, or to suppress, temporarily, the activation of an alarm.

2.122 SILENCING

To suppress, temporarily, the auditory component of an alarm.

3 General requirements

This clause of the General Standard applies except as follows:

3.6

Additional items:

aa) Short and open circuits of components or wiring which can increase temperatures (see section seven).

*bb) An oxidant leak which is not detected by, for example, alarm or periodic inspection, shall be considered a normal condition and not a single-fault condition.

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

6.1 Marking on the outside of equipment or equipment parts:

*j) Power input

Addition:

The input marking required in 6.1 j) of the General Standard 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.

*k) Mains power output

Addition:

The requirement on marking of auxiliary mains socket outlets of 6.1 k) in the General Standard shall apply to each auxiliary mains socket outlet and shall be given in amperes.

If auxiliary mains socket outlets can accept a mains plug, the auxiliary mains socket outlet shall be marked with symbol 14 of table D.1 of the General Standard.

Additional items:

aa) Each operator – accessible gas inlet and outlet shall be durably marked with either the gas name or chemical symbol in accordance with ISO 5359. This marking shall be clearly legible, and if colour coding is used, it shall be in accordance with ISO 32.

bb) The FRESH GAS OUTLET, if operator accessible, shall be durably marked. This marking shall be clearly legible.

cc) The ANAESTHETIC WORKSTATION and/or its components and/or packaging shall include the following information as applicable:

- the symbol "STERILE" together with the method of sterilization;
- the batch code, preceded by the symbol "LOT", or the serial number;
- an indication of the date, expressed as the year and month, by which the device can be used safely;
- an indication that the device is for single use;

  NOTE – Symbol No. 1051 given in ISO 7000 may be used.
- any special storage and/or handling conditions;
- any warning or precautions to be taken;
- for active medical devices, the year of manufacture except for single use devices and those covered by the date of expiry;
- the recommended method(s) of cleaning, disinfection, and sterilization;
- the 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;
- the name or trade name and address of the manufacturer and, if applicable, the distributor/supplier;
- if the intended purpose of the device is not obvious to the operator, the component or its packaging shall be provided with details necessary to identify the device and the contents of the packaging;
- any special operating instructions.

dd) The ANAESTHETIC WORKSTATION and/or its components shall be marked with the rated supply pressure(s) to which the equipment may be connected.

ee) All operator-detachable components or devices, which can be misconnected, and which are flow direction-sensitive shall be durably marked with a clearly legible arrow indicating the correct direction of gas flow.

ff) Where appropriate, detachable components shall be identified in terms of batches.

gg) Controls for gas flows or anaesthetic vapour output shall be durably marked with a clearly legible indication to inform the operator which action(s) is/are required to increase/ decrease the gas flow or vapour output.

6.3 Marking of controls and instruments

Additional items:

aa) All cylinder and pipeline pressure gauges or indicators shall be graduated and clearly marked or displayed in units of kPa × 100 when the anaesthetic workstation is in use. The markings and graduations shall be clearly identified with the gauges or indicators with which they are associated.

NOTE – Additional marking for example bar may be used.

Each gas-specific pressure gauge or indicator shall be identified by clear and durable marking using the gas name or the chemical symbol in accordance with ISO 5359. If colour coding is used it shall be in accordance with ISO 32.

Pressure gauges or indicators for measuring pressure in the anaesthesia breathing system shall be graduated in units of pascals and/or cm H_2O.

bb) Each flow adjustment control of a single gas supply and/or its surroundings, shall be identified and durably marked with the gas name or the chemical symbol in accordance with ISO 5359. This marking shall be clearly legible, and if colour coding is used, it shall be in accordance with ISO 32.

The concentration adjustment control of a GAS MIXER and/or its surroundings shall be identified and durably marked with the gas name(s) or the chemical symbol(s) in accordance with ISO 5359. This marking shall be clearly legible, and if color coding is used, it shall be in accordance with ISO 32. The scale including the minimum and maximum concentration marks of the gas mixture control of a GAS MIXER shall be marked to indicate the concentration of oxygen (% V/V) in the delivered gas.

If applicable the point of reference for reading the flow indication shall be identified.

cc) For ANAESTHETIC VAPOUR DELIVERY DEVICE(s)

Either the maximum and minimum filling levels shall be marked on the liquid level indicator, or the actual usable volume shall be clearly displayed.

The 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 in abbreviated form as given in the following list:

– Desflurane – "DES" or "D"
– Enflurane – "ENF" or "E"
– Halothane – "HAL" or "H"
– Isoflurane – "ISO" or "I"
– Methoxyflurane – "MET" or "M"
– Sevoflurane – "SEV" or "S"

If colour coding is used, it shall be in accordance with column 2 (colour) of table CC.1.

The units in which the control of the ANAESTHETIC VAPOUR DELIVERY DEVICE is graduated shall be indicated.

Graduated controls shall be marked with "0" or "Off", or with both if the 0 position is not also the off position, or with "Standby" if the "Off" is not provided.

dd) The oxygen flush control shall be durably marked with one of the following:

- "OXYGEN FLUSH"
- "O_2 FLUSH"
- "O_2 +"

This marking shall be clearly legible, and if colour coding is used, it shall be in accordance with ISO 32.

6.8 Accompanying documents

6.8.2 Instructions for use:

a) General information

Addition:

The manufacturer/supplier of an ANAESTHETIC WORKSTATION or individual device which is intended for use in an ANAESTHETIC WORKSTATION and which delivers energy or substances, shall provide a list of the appropriate monitoring, alarm and PROTECTION DEVICES which are not an integral part of the ANAESTHETIC WORKSTATION, or individual device, as specified in this Particular Standard (see 51.101.1).

To protect the patient against hazardous output, a statement to the effect that the monitor(s), alarm(s) and PROTECTION DEVICE(s) listed by the manufacturer of the ANAESTHETIC WORKSTATION and complying with this Particular Standard, should be used whenever the ANAESTHETIC WORKSTATION is being operated.

The instructions for use shall state the conditions under which the measured values are displayed, for example ambient temperature and pressure saturated (ATPS), body temperature and pressure saturated (BTPS), standard temperature and pressure dry (STPD).

The instructions for use shall state whether or not the ANAESTHETIC WORKSTATION is suitable for use in a magnetic resonance imaging (MRI) environment.

j) Environmental protection

Addition:

The instructions for use shall contain a statement to the effect that, if combinations of more than one item of medical electrical equipment, including the ANAESTHETIC WORKSTATION, are used with non-medical equipment, the safety of medical electrical systems shall comply with IEC 60601-1-1.

Additional items:

*aa) The instructions for use shall contain a statement to the effect that to avoid explosion hazards, flammable anaesthetic agents such as diethyl-ether and cyclopropane shall not be used in this ANAESTHETIC WORKSTATION. Only anaesthetic agents which comply with the requirements for non-flammable anaesthetic agents of this Particular Standard are suitable for use in this ANAESTHETIC WORKSTATION.

bb) The instructions for use shall describe methods of verifying alarm functions.

cc) If auxiliary mains socket outlet(s) accept a standard mains plug, the instructions for use shall contain a warning relating to symbol No. 14 of table D.1 of the General Standard to the effect that the connection of equipment to the auxiliary mains socket-outlet(s) may increase the leakage currents to values exceeding the allowable limits.

dd) The instructions for use shall contain instructions for testing for correct assembly and connection of each gas supply system.

ee) The instructions for use shall contain the operating characteristics and location of any pressure relief devices fitted to the ANAESTHETIC WORKSTATION.

ff) The instructions for use shall contain the pressure and flow characteristics of any gas power outlet(s) throughout the range of rated inlet pressures, and at twice the maximum rated inlet pressure (see 10.2.101).

gg) The instructions for use shall contain the specifications of the oxygen failure alarm system(s) and if applicable the associated gas cut-off device(s).

hh) If the ANAESTHETIC WORKSTATION is fitted with a gas mixing system, the instructions for use shall contain a specification of the leakage from one gas inlet to the other, including the design pressure(s) and the recommended range of flows from the gas mixing system.

jj) The instructions for use shall contain the recommended service interval.

kk) The instructions for use shall contain the required operational characteristics of anaesthetic ventilator(s) supplied or recommended for use with the ANAESTHETIC WORKSTATION.

ll) The instructions for use shall contain, if appropriate, the required operational characteristics of anaesthesia breathing system(s) and anaesthetic gas scavenging system(s) recommended for use with the ANAESTHETIC WORKSTATION.

mm) The instructions for use provided by the manufacturer of an ANAESTHETIC VAPOUR DELIVERY DEVICE(s) or the manufacturer of an ANAESTHETIC WORKSTATION fitted with (an) ANAESTHETIC VAPOUR DELIVERY DEVICE(s), shall provide the following information:

1) instructions for fitting the ANAESTHETIC VAPOUR DELIVERY DEVICE(s), if appropriate;

2) details of the performance of the ANAESTHETIC VAPOUR DELIVERY DEVICE(s) including, the effects of variation in ambient temperature, ambient pressure, tilting, back pressure, sub-atmospheric pressure, input flow and gas mixture;

3) instructions for filling the ANAESTHETIC VAPOUR DELIVERY DEVICE(s);

4) the volume of anaesthetic agent required to fill the reservoir of the ANAESTHETIC VAPOUR DELIVERY DEVICE(s) from the minimum to the maximum filling level, and the total capacity;

5) if the ANAESTHETIC VAPOUR DELIVERY DEVICE(s) should not be used between "Off" and the first graduation above zero, a statement to this effect;

6) the carrier gas, gas flow(s) and technique(s) recommended for testing the accuracy of the ANAESTHETIC VAPOUR DELIVERY DEVICE(s);

nn) The instructions for use shall contain information about cleaning and/or sterilization prior to use.

oo) The manufacturer shall disclose in the instructions for use the minimum detectable volume, the accuracy of the indicated volumes and the resolution of the volume monitor when tested according to the method in 51.105.3.

pp) The instructions for use shall include a statement that an alternative means of intermittent positive pressure ventilation shall be available whenever the ANAESTHETIC WORKSTATION is in use.

qq) If alarm limits are factory pre-set, the manufacturer shall disclose the alarm threshold in the accompanying documents.

rr) The manufacturer/supplier of the ANAESTHETIC WORKSTATION shall disclose any latex based components and their location.

ss) If applicable, for reusable components, the instruction for use shall contain information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the component to be sterilized, and any restriction on the number of reuses.

tt) If applicable, the instructions for use shall contain information on precautions to be taken against any special, unusual risks related to the disposal of components of the ANAESTHETIC WORKSTATION.

uu) The manufacturer shall specify the configuration(s) and condition(s) under which clause 24 of the General Standard are met.

vv) The instructions for use shall contain the location and instructions relevant to any filter elements replaceable by the operator.

6.8.3 Technical description

6.8.3 a) General

Addition:

The technical description shall give accuracies, display resolutions and ranges of displayed values and calibrated controls.

NOTE – Accuracies should be expressed as maximum zero error (BIAS) quoted directly in appropriate units plus a sensitivity error (linearity, PRECISION), for example quoted as a percentage of the reading.

Additional items:

aa) Disclosure of interdependence of controls, where applicable.

bb) Disclosure of all information necessary to check that an ANAESTHETIC WORKSTATION and/or its devices is/are installed correctly and are in correct working order, and information on the nature and frequency of maintenance operations necessary to ensure continuing safety and correct operation.

cc) If the ANAESTHETIC WORKSTATION or its components are provided with a reserve POWER SUPPLY, the functioning after a switch-over to the reserve POWER SUPPLY shall be described.

SECTION TWO – ENVIRONMENTAL CONDITIONS

The clauses and subclauses of this section of the General Standard apply except as follows:

10 Environmental conditions

This clause of the General Standard applies except as follows:

10.2.1 Environment

Addition:

The environmental conditions in this subclause apply unless otherwise specified by the manufacturer.

Additional subclause:

10.2.101 Pneumatic power

The ANAESTHETIC WORKSTATION shall operate and meet the requirements of this Particular Standard throughout the range of inlet pressures specified by the manufacturer, and shall cause no safety hazard under a single fault condition of twice the maximum rated inlet pressure specified by the manufacturer.

In addition, if the ANAESTHETIC WORKSTATION is intended to be connected to either:

– a medical gas pipeline system complying with ISO 7396 via terminal units complying with ISO 9170 and flexible hose connections complying with ISO 5359, or

– a PRESSURE REGULATOR complying with ISO 10524,

the range of pressures specified shall cover the range specified in these standards.

NOTE – Internal PRESSURE REGULATORS may be required to accommodate the range of operating pressures and single fault condition of maximum inlet pressures.

The time-weighted average input flow required by the medical equipment for each gas type shall not exceed 60 l/min at a pressure of 280 kPa measured at the gas inlet port.

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

The clauses and subclauses of this section of the General Standard apply except as follows:

19 Continuous leakage currents and patient auxiliary currents

This clause of the General Standard applies except as follows:

***19.4** h) Measurement of the patient leakage current

Addition:

12) The patient leakage current shall be measured from all APPLIED PARTS classified as the same type (see 14.6 of the General Standard). All these parts shall be connected together electrically with the exception of parts connected to the protective earth terminal which shall be tested separately from the parts not so connected.

SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

The clauses and subclauses of this section of the General Standard apply.

SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

The clauses and subclauses of this section of the General Standard apply except as follows:

36 Electromagnetic compatibility

This clause of the General Standard applies except as follows:

Addition:

The ANAESTHETIC WORKSTATION, or the individual devices which together make up a complete ANAESTHETIC WORKSTATION, shall either continue to function and meet the requirements of this Particular Standard or may fail, but without causing a safety hazard, when tested in accordance with IEC 60601-1-2.

If an anomaly occurs, such as display interruption, false alarm, loss of function without the integrity of the associated monitoring, alarm and PROTECTION DEVICEs being compromised, this shall not be considered a safety hazard, provided it is possible to restore normal operation within 30 s after the electromagnetic disturbance has been applied.

SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

The clauses and subclauses of this section of the General Standard apply except as follows:

37 Locations and basic requirements

This clause of the General Standard applies except as follows:

Additional subclauses:

***37.101** Anaesthetic agents which are ignited by the test in annex DD of this Particular Standard shall be regarded as flammable anaesthetic agents.

NOTE – Examples of such agents in use are diethyl-ether and cyclopropane.

***37.102** Anaesthetic agents which are not ignited by the test in annex DD of this Particular Standard shall be regarded as non-flammable anaesthetic agents.

NOTE 1 – An example of such an agent in use is halothane (2-bromo, 2-chloro 1,1,1-trifluoroethane).

NOTE 2 – National authorities may decide that the test results according to annex DD are to be demonstrated by the manufacturer of the anaesthetic agent concerned.

38 Marking, accompanying documents

This clause of the General Standard does not apply.

39 Common requirements for category AP and category APG equipment

This clause of the General Standard does not apply.

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

This clause of the General Standard does not apply.

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

This clause of the General Standard does not apply.

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

The clauses and subclauses of this section of the General Standard apply except as follows:

*43 Fire prevention

This clause of the General Standard applies except as follows:

Addition:

In order to reduce the risk to patients, to other persons or to the surroundings due to fire, ignitable material, 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 is determined in accordance with IEC 60079-4, using the oxidizing conditions present under normal and single fault condition.

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

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 oxidizing 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 and disinfection

This clause of the General Standard applies accept as follows:

44.3 Spillage

Addition:

The ANAESTHETIC WORKSTATION and its components shall be so constructed that spillage does not wet parts which, when wet can cause a safety hazard.

Compliance is checked by the test given in 44.3 of the General Standard.

44.7 Cleaning, sterilization and disinfection

Amendment:

All components not specified by the manufacturer as single patient use, which come into contact with the exhaled patient gas that may be rebreathed, shall be capable of being sterilized or disinfected, unless means are provided for bacterial/viral filtration prior to rebreathing.

49 Interruption of the POWER SUPPLY

This clause of the General Standard applies except as follows:

Additional subclauses:

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

Compliance is checked by inspection and functional testing.

49.102 In the event that the electrical POWER SUPPLY falls below the minimum specified by the manufacturer of the ANAESTHETIC WORKSTATION, there shall be an alarm of at least medium priority complying with ISO 9703-1 and ISO 9703-2.

When the ANAESTHETIC WORKSTATION is equipped with a reserve electrical POWER SUPPLY, in the event that the mains electricity POWER SUPPLY fails and there is automatic switchover to a reserve electrical POWER SUPPLY, there shall be a low priority signal with an auditory component complying with ISO 9703-1 and ISO 9703-2.

Compliance is checked by inspection and functional testing.

49.103 If a reserve electrical POWER SUPPLY is provided, there shall be a means to determine the current status of the reserve.

SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

The clauses and subclauses of this section of the General Standard apply except as follows:

51 Protection against hazardous output

This clause of the General Standard applies except as follows:

Additional subclauses:

51.101 Monitoring, alarm and PROTECTION DEVICES

51.101.1 General

The particular requirements for the monitoring, alarm, and PROTECTION DEVICES apply when the ANAESTHETIC WORKSTATION is operating under normal POWER SUPPLY condition.

To protect against certain hazards each ANAESTHETIC WORKSTATION or individual device that delivers energy or substances in controlled quantity for use in an ANAESTHETIC WORKSTATION, shall be either:

a) provided with the monitoring, alarm, and PROTECTION DEVICEs specified in this standard, or

b) if such devices are not integrated or otherwise provided with the ANAESTHETIC WORKSTATION, the manufacturer of the individual device shall provide information about which monitoring, alarm and PROTECTION DEVICEs are required to ensure that the complete ANAESTHETIC WORKSTATION complies with this International Standard (see 6.8.2 a)).

Compliance is checked by examination of the ANAESTHETIC WORKSTATION, or by examination of the accompanying documents of the individual device(s).

51.102 General requirements for alarms

51.102.1 The auditory and visual characteristics of electrically-generated alarm signals shall comply with ISO 9703-1 and ISO 9703-2 unless otherwise specified in this Particular Standard.

***51.102.2** If an alarm can be disabled by the operator, there shall be a visual indication that it has been disabled.

51.102.3 The SILENCING of an auditory alarm by the operator shall not prevent an alarm from being activated by a new or different alarm condition.

51.102.4 The set points of alarms shall be indicated either continuously or on operator demand.

51.102.5 Unless a SMART ALARM SYSTEM is provided, any automatic change of alarm priority, shall not be to a priority level lower than the level specified within this Particular Standard, and shall only occur after activation of the alarm.

51.102.6 If an operator-adjustable change of alarm priority is provided, it shall not be to a priority level lower than the level specified within this Particular Standard.

51.102.7 If an interface for a remote device is provided, the interface shall be designed so that a failure in the remote device will not affect the correct functioning of the ANAESTHETIC WORKSTATION.

51.102.8 In order to prevent nuisance alarms, the auditory components of alarms shall allow disabling by the operator until the ANAESTHETIC WORKSTATION is connected to the patient.

51.103 High priority signal

51.103.1 When a high priority signal is activated and when the condition causing the alarm has cleared, the auditory signal shall reset automatically.

When a high priority signal that is specified as a high priority signal in this Particular Standard is activated and when the condition causing the alarm has cleared, it shall be possible for the operator to determine the alarm variable that led to the alarm condition, and that a high priority signal had been activated.

51.103.2 The maximum time for which the auditory signal can be silenced shall be 120 s.

51.104 Medium priority signal

51.104.1 The auditory alarm signal shall reset automatically when the condition causing the alarm has cleared. The maximum time for which the auditory signal can be silenced shall be 120 s.

51.105 Ventilatory monitoring, alarm and PROTECTION DEVICES

51.105.1 Operating requirements

Means shall be provided to ensure that the specified monitoring, alarm and PROTECTION DEVICES of the ANAESTHETIC WORKSTATION are enabled and functioning prior to its use (see clause 111).

51.105.2 Anaesthesia breathing system pressure

51.105.2.1 Pressure monitoring

The ANAESTHETIC WORKSTATION shall be provided, in accordance with 51.101.1, with a means to display continuously the pressure in the anaesthesia breathing system.

51.105.2.2 Pressure alarm

51.105.2.2.1 The pressure monitor shall have associated ALARM DEVICES designed to activate a high priority signal complying with ISO 9703-1 and ISO 9703-2 when the pressure in the anaesthesia breathing system:

– exceeds the limit for high pressure;

– exceeds a limit of continuing positive pressure for longer than (15 ± 1) s.

Compliance is checked by the method given in 51.105.2.2.2.

51.105.2.2.2 *After the recommended calibration and warm-up procedures have been completed, connect the anaesthesia breathing system supplied or recommended by the manufacturer, to a test lung, and induce a pressure rise in the breathing system. Verify that the pressure monitor is functioning. Adjust continuing positive airway pressure alarm limits to the maximum value, if applicable. This alarm shall sound (15 ± 1) s after airway pressure reaches this alarm limit. Permit the pressure in the anaesthesia breathing system to continue to rise until the high pressure alarm limit is reached, at which time this alarm shall sound. Verify the presence and activation of both visual and auditory high priority signals in both conditions.*

51.105.2.2.3 If a low pressure alarm is provided, it shall be at least a medium priority signal complying with ISO 9703-1 and ISO 9703-2.

Test for compliance by visual inspection, and functional testing by means of simulating the alarm condition in accordance with the accompanying documents.

51.105.2.3 Pressure limitation

The ANAESTHETIC WORKSTATION shall be provided, in accordance with 51.101.1, with a means to limit the pressure at the patient connection port. During both normal condition and under single fault condition this pressure shall not exceed 12,5 kPa (125 cm H_2O).

NOTE – A reservoir bag complying with ISO 5362 may be considered as a pressure limiting device for an anaesthetic workstation without an anaesthetic ventilator or when the anaesthetic ventilator is in the manual or spontaneous ventilation mode.

When the ANAESTHETIC WORKSTATION is provided, in accordance with 51.101.1, with an anaesthesia ventilator, an operator adjustable pressure limitation shall be provided.

Compliance is checked by introducing a pressure rise at the patient connection port of the anaesthesia breathing system supplied or recommended by the manufacturer and by verifying that the pressure limiting requirement is met.

51.105.3 Exhaled volume

51.105.3.1 The ANAESTHETIC WORKSTATION shall be provided, in accordance with 51.101.1, with a device to monitor the patient's exhaled tidal and/or minute volume. The accuracy of the displayed value shall be ±20 % of actual reading above 100 ml tidal volume, or ±20 % of actual reading above 3 l/min minute volume. See clause 6.8.2 oo) for disclosure requirements below 100 ml tidal volume and 3 l/min minute volume.

Compliance is checked by visual and mechanical inspection and by the method given in 51.105.3.2.

NOTE – In certain situations, for example paediatric breathing systems, measurement of exhaled volume may not accurately reflect tidal and/or minute volume. In these situations, adequacy of ventilation may be monitored more accurately by other means, for example capnography.

51.105.3.2 *Connect the anaesthesia breathing system specified by the manufacturer to a test lung (see table 101) and ventilate the test lung under the appropriate conditions described in table 101 until measured exhaled volumes are stable.*

Table 101 – Test conditions for expiratory volume tests

Adjustable parameter	Test condition		
	Adult use	Paediatric use	Neonatal use
Tidal volume V_T (ml) derived from pressure sensor on test lung (V_T = C multiplied by P_{max})	500	300	30
Frequency f (min^{-1})	10	20	30
I/E ratio	1:1,5 to 1:2,5	1:1,0 to 1:1,5	1:1,0 to 1:1,5
Resistance R (kPa/l/s)	0,5 % ± 10 %	2 % ± 10 %	5 % ± 10 %
Isothermal compliance C (ml/kPa)	500 % ± 5 %	200 % ± 5 %	10 % ± 5 %
NOTE – The accuracies for C and R apply over the ranges of the measured parameters.			

51.105.3.3 An alarm complying with ISO 9703-1 and ISO 9703-2 of at least medium priority shall be activated if the patient's exhaled volume falls below an operator-adjustable minimum. If the medium priority signal is delayed, the delay shall not exceed 90 s. The delay may be operator-adjustable. Compliance is checked by the method given in 51.105.3.4.

51.105.3.4 *Connect the exhaled volume monitor to an anaesthesia breathing system according to the manufacturer's instructions. Set the adjustable alarm delay, if provided, to its maximum setting. Ventilate a test lung until the monitor readings are stable. Reduce the volume of ventilation until the exhaled volume falls below the operator-adjustable low volume alarm setting. Confirm that the medium priority signal annunciates within 90 s.*

51.105.4 Ventilatory carbon dioxide concentration monitoring

The ANAESTHETIC WORKSTATION shall be provided, in accordance with 51.101.1, with a means to monitor continuously the patient's ventilatory carbon dioxide. The carbon dioxide monitor shall comply with ISO 9918.

Compliance is checked by visual inspection.

51.105.5 Inspiratory oxygen concentration monitoring and alarm

The ANAESTHETIC WORKSTATION shall be provided, in accordance with 51.101.1, with a device to monitor the concentration of oxygen in the inspiratory gas. The monitor shall comply with ISO 7767.

NOTE – The monitoring of the oxygen concentration in the fresh gas is recommended.

The oxygen monitor shall be provided with an adjustable low concentration alarm. A high priority signal complying with ISO 9703-1 and ISO 9703-2 shall be annunciated within 30 s after the inspiratory oxygen concentration falls below the low oxygen concentration alarm limit. This 30 s time shall include any delay time and the response time. The low oxygen concentration alarm shall not be adjustable below 18 % (*V/V*) oxygen.

If a high inspiratory oxygen concentration alarm is provided, it shall not be of high priority.

Compliance is checked by visual inspection, and functional testing by generating an oxygen concentration below the set alarm limit.

NOTE – Simulation of cyclical breathing patterns may be required.

51.105.6 Oxygen supply failure

51.105.6.1 Oxygen supply failure alarm

51.105.6.1.1 The ANAESTHETIC WORKSTATION shall be provided with an oxygen supply failure alarm to indicate when the supply pressure, whether derived from a pipeline or from a cylinder, has fallen below that specified by the manufacturer of the ANAESTHETIC WORKSTATION (see 6.8.2 gg)).

If electronically generated, the alarm shall be a high priority signal complying with ISO 9703-1 and ISO 9703-2.

If pneumatically generated, the auditory alarm shall be at least 7 s in duration, and when tested as described in ISO 3746, its A-weighted sound pressure level shall be at least 2 dB above a white background level of 55 dB.

Pneumatically generated alarm signals shall derive their energy from the oxygen supply source.

51.105.6.2 Oxygen supply failure protection

51.105.6.2.1 The ANAESTHETIC WORKSTATION shall be provided with a gas cut-off device which shall be activated when the oxygen supply pressure drops below the minimum value specified by the manufacturer of the ANAESTHETIC WORKSTATION and shall perform one of the following functions:

a) cut off the supply of all gases other than oxygen to the FRESH GAS OUTLET;

b) cut off the supply of all gases other than oxygen and air to the FRESH GAS OUTLET;

c) progressively reduce the flow of all other gases while maintaining the pre-set oxygen flow or proportion of oxygen until the supply of oxygen finally fails, at which point the supply of other gases shall be shut off;

d) progressively reduce the flow of all other gases, except air, while maintaining the preset oxygen flow or proportion of oxygen until the supply of oxygen fails, at which point the supply of all other gases, except air, shall be shut off.

NOTE – The gas cut-off device may also open the inspiratory pathway to the atmosphere.

51.105.6.2.2 The oxygen supply failure alarm shall be activated before the gas cut-off device stops the flow of any gas other than oxygen.

51.105.6.2.3 The sole means of resetting the gas cut-off device shall be the prior restoration of the oxygen supply pressure to a level above that specified by the ANAESTHETIC WORKSTATION manufacturer.

51.105.7 Protection against delivery of oxygen concentration below that of ambient air

51.105.7.1 The ANAESTHETIC WORKSTATION shall be provided with a device to protect against an operator selected delivery of a mixture of oxygen and nitrous oxide having an oxygen concentration below that of ambient air, either in the fresh gas or in the inspiratory gas. If an override mechanism is provided, its activation shall be clearly indicated.

Compliance is checked by visual inspection and functional testing.

51.105.8 Anaesthetic vapour concentration monitoring

If an ANAESTHETIC VAPOUR DELIVERY DEVICE is provided, the ANAESTHETIC WORKSTATION shall be provided, in accordance with 51.101.1, with a device to monitor the concentration of anaesthetic vapour in the inspiratory gas. The monitor shall comply with the requirements of ISO 11196.

NOTE – Monitoring of anaesthetic vapour concentration in the fresh gas and the expiratory gas is recommended.

*51.105.9 Anaesthesia breathing system disconnect alarm

The ANAESTHETIC WORKSTATION shall be provided, in accordance with 51.101.1, with at least a medium priority alarm complying with ISO 9703-1 and ISO 9703-2, that activates in the event of a complete disconnection in the anaesthesia breathing system.

NOTE 1 - Alarms considered to comply with the above include, but are not limited to, low pressure, low CO_2, and low volume.

NOTE 2 - MONITORING DEVICES indicate specific alarm conditions and do not differentiate between possible causes.

51.105.9.1 Test for complete disconnect

Disconnect, in turn, each operator-detachable connection of the anaesthetic ventilator and/or anaesthesia breathing system recommended by the manufacturer. Use the test method(s) specified by the manufacturer, and verify that the alarm(s) is/are activated.

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

The clauses and subclauses of this section of the General Standard apply except as follows:

54 General

This clause of the General Standard applies except as follows:

54.3 Inadvertent changing of settings

Replacement:

NOTE – All manually-operated controls (mechanical, pneumatic, or electrical) should be designed so as to minimize unintentional change from their set position.

Additional subclause:

*54.101 Failure of monitors and alarms

If a monitoring and/or ALARM DEVICE has an ANAESTHETIC WORKSTATION control function, a single fault condition shall not cause the monitoring/alarm and control function to become ineffective simultaneously.

56 Components and general assembly

This clause of the General Standard applies except as follows:

56.1 General

Additional item:

aa) The ANAESTHETIC WORKSTATION and parts thereof shall be designed and manufactured to minimize health risks due to substances leached or leaking from the device or its components during normal use. Particular attention shall be paid to the toxicity of materials and their compatibility with substances and gases with which they enter into contact during normal use or routine procedures.

Evidence shall be held by the manufacturer.

57 Mains parts, components and layout

This clause of the General Standard applies except as follows:

57.2 Mains connectors, appliance inlets and the like

Additional items:

aa) The exception in 57.2 e) of the General Standard 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 standard mains plug.

The number of operator-accessible auxiliary mains socket outlets that can accept a standard mains plug on a fully configured ANAESTHETIC WORKSTATION shall not exceed a total of four.

57.3 POWER SUPPLY cords

*a) Application

Amendment:

The mains supply cord of an electrically powered ANAESTHETIC WORKSTATION and/or its components shall be a non-detachable cord or shall be protected against accidental disconnection.

Compliance is checked by inspection and, for equipment which is provided with an appliance coupler, by subjecting the detachable cord for 1 min to an axial pull of force as shown in table 102. During the test the mains connector shall not become disconnected from the appliance inlet.

Table 102 – Force of axial pulls

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

*57.6 Mains fuses and over-current releases

Amendment:

The ANAESTHETIC WORKSTATION and each auxiliary mains socket outlet which can accept a standard mains plug shall be provided with separate fuses or over-current releases as required for a single equipment in 57.6 of the General Standard.

These fuses or over-current releases shall be designed such that the ANAESTHETIC WORKSTATION including the auxiliary mains socket outlets shall maintain normal function with each auxiliary mains socket outlet loaded to the maximum rating.

When each auxiliary mains socket outlet in turn is additionally overloaded by a factor of 7,5 ± 2,5, all remaining auxiliary mains socket outlets and the ANAESTHETIC WORKSTATION shall maintain normal function.

Compliance is checked by visual inspection and functional testing.

Additional clauses:

101 Medical gas supply systems

101.1 Medical gas cylinder connections

The ANAESTHETIC WORKSTATION shall be provided with means of connection to a reserve oxygen supply.

Connections for medical gas cylinders shall comply with ISO 407 or ISO 5145.

102 Medical gas pipeline inlet connections

102.1 If pipeline inlet connections are fitted to an ANAESTHETIC WORKSTATION, they shall comply with ISO 5359. If the ANAESTHETIC WORKSTATION is intended for use with a medical gas pipeline system, each gas inlet connection (outlet connection for vacuum) shall include pipeline hose inlets for connection to pipelines specified in ISO 7396. These inlets shall be the body fittings specified in ISO 5359.

102.2 Each pipeline inlet connection shall be provided with a filter having a pore size not exceeding 100 µm. The filter(s) shall be removable for the purposes of cleaning and/or replacement.

102.3 Means shall be provided to limit reverse gas flow from gas input ports of the same gas to 100 ml/min under normal conditions.

The reverse flow of gases from one to another input port of a different gas type shall not exceed 10 ml/h under normal conditions.

If under single fault condition, the reverse flow of gases from one to another input port of a different gas type can exceed 10 ml/h, means shall be provided to prevent a safety hazard, for example by means of an alarm.

Evidence of compliance with these requirements, either by test or by other methods, shall be provided by the manufacturer where appropriate.

103 Medical gas supply pressure monitoring

103.1 The ANAESTHETIC WORKSTATION shall be provided with a device to monitor continuously the pressure or content of each gas supplied at cylinder pressure. The scale of the MONITORING DEVICE shall extend to a pressure of at least 33 % greater than either the filling pressure of the cylinder or the full indication position at a temperature of (20 ± 3) °C.

Means shall be provided to monitor simultaneously the pressure or contents of all gas cylinders.

103.2 The ANAESTHETIC WORKSTATION shall be provided with a device to monitor continuously the pressure of each gas supplied by pipeline from central supplies. The MONITORING DEVICE shall measure the pipeline gas pressure upstream of the unidirectional valve. The MONITORING DEVICE shall be capable of indicating a pressure not less than 33 % greater than the pipeline inlet design pressure.

103.3 The maximum error of the MONITORING DEVICE(s) shall not exceed ± (4 % of the full scale reading + 8 % of the actual reading).

104 Medical gas supply PRESSURE REGULATORS

There shall be a PRESSURE REGULATOR(s) complying with ISO 10524 for each gas supplied from cylinders.

105 MACHINE GAS PIPING

105.1 The total leakage from

a) that part of the MACHINE GAS PIPING which extends from any gas service between unidirectional valves and the flow control system, and

b) the piping between the inlet connections for cylinders and PRESSURE REGULATORS

shall not exceed 150 ml/min (corrected to 20 °C) when it is pressurized to maximum and minimum design pressure. This test shall be repeated for each gas service. All other gas inlet connections shall be open to atmosphere during the test.

105.2 There shall be no hazard for patients, operators, or third persons arising if the MACHINE GAS PIPING is subjected to the pressure which may occur during any single fault condition.

105.3 The maximum gas leakage to atmosphere between the outlet of the flow control valve(s) and/or gas mixing system and the FRESH GAS OUTLET shall not exceed 50 ml/min at a pressure of 3 kPa. This requirement shall also be met with the ANAESTHETIC VAPOUR DELIVERY DEVICE, if fitted:

a) turned "On";

b) turned "Off";

c) removed, if operator-detachable.

NOTE – Many flow control systems allow a continous basal flow of oxygen. This should not be confused with leakage to atmosphere.

Compliance is checked by leakage measurement at (20 ± 3) °C.

106 Gas flow metering

106.1 Each flowmeter and flow control system 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 shall be graduated in units of litres per minute.

For flows of 1 l/min or below, the flow may 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 WORKSTATION.

106.2 The accuracy of the graduations of any flowmeter or flow control system shall be within ±10 % of the indicated value when discharged into an ambient atmosphere of 101,3 kPa at an operating temperature of 20 °C.

106.3 There shall not be more than one flow adjustment control for any single gas delivered to the FRESH GAS OUTLET. If there is a separate flow adjustment control for each gas they shall meet the following requirements:

– for rotary style flow controls the oxygen knob shall have a physical profile in accordance with figure 101;

– the oxygen knob shall have a diameter not less than any of the diameters of the knobs controlling all other gases;

– for rotary adjustment controls a counter clockwise rotation shall cause an increase in flow and conversely, a clockwise rotation shall cause a decrease in flow;

– the stem of each rotary flow adjustment control shall be captive so that it cannot be disengaged from its housing without the use of tools;

– all rotary style flow adjustment knobs for gases other than oxygen, shall be round and their surface finish seration shall not exceed a depth of 1 mm.

NOTE 1 – Attention is drawn to the fact that the requirement in this clause may be contrary to the convention for direction of rotation for electronic controls.

NOTE 2 – Devices to prevent delivery of oxygen percentage below that of ambient air are not to be considered flow controls (see clause 51.105.7).

106.4 If the GAS FLOW CONTROL SYSTEM includes provision for carbon dioxide, when the carbon dioxide flow control valve is fully open the flow of carbon dioxide shall not exceed 600 ml/min.

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

Compliance is checked by inspection.

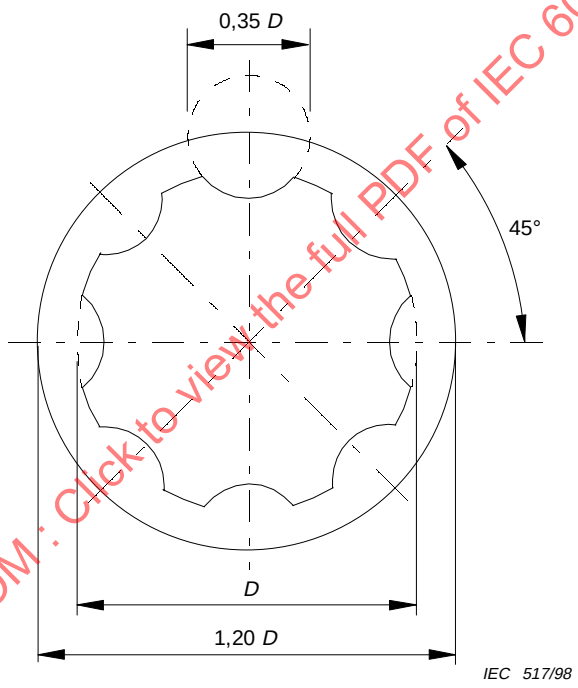

Figure 101 – Profile of oxygen flow control knob for applications other than ANAESTHETIC VAPOUR DELIVERY DEVICE flow control

107 GAS MIXER

107.1 The gas mixture control scale shall indicate the concentration of oxygen (% *V/V*) in the delivered gas, including the minimum and maximum concentration marks. The range of oxygen concentrations shall be indicated either continuously, or on operator demand.

107.2 At any flow and pressure given in the instructions for use, the oxygen concentration shall be within ±5 % (*V/V*) of the set or indicated value.

107.3 The outlets of anaesthetic gas mixing systems which are not built into the ANAESTHETIC WORKSTATION shall be either screw-threaded connectors (for example nut and nipple) or quick connectors (female), and they shall not be interchangeable with the inlet connectors.

*108 ANAESTHETIC VAPOUR DELIVERY DEVICE

108.1 General

Non-concentration calibrated ANAESTHETIC VAPOUR DELIVERY DEVICE(s) shall not be used.

Compliance is checked by visual inspection.

108.2 Connectors

If conical connectors are used at the inlet and outlet of an operator-detachable ANAESTHETIC VAPOUR DELIVERY DEVICE, they shall be of 23 mm size in accordance with ISO 5356-1. The connector at the inlet shall be male and that at the outlet shall be female. All other systems of connectors for ANAESTHETIC VAPOUR DELIVERY DEVICES shall ensure that the devices can only be fitted so that the gas flow through it is in the intended direction.

Compliance is checked by visual inspection and functional testing.

108.3 Controls

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 DEVICE. It shall not be possible to set the control above the calibrated range. Means shall be provided to prevent the unintentional operation of the ANAESTHETIC VAPOUR DELIVERY DEVICE on control.

Compliance is checked by visual inspection and functional testing.

108.4 Rotary control on ANAESTHETIC VAPOUR DELIVERY DEVICE(S)

If a rotary control is provided on the ANAESTHETIC VAPOUR DELIVERY DEVICE, the anaesthetic vapour shall increase when the control is turned anti-clockwise.

Compliance is checked by visual inspection and functional testing.

NOTE – Attention is drawn to the fact that the requirement in this clause may be contrary to the convention for direction of rotation for electronic controls.

108.5 Contamination

Means shall be provided to prevent contamination of the contents of one ANAESTHETIC VAPOUR DELIVERY DEVICE with another anaesthetic agent.

Compliance is checked by visual inspection and functional testing.

108.6 Overfilling

When operated in accordance with the manufacturer's instructions, it shall not be possible to overfill the ANAESTHETIC VAPOUR DELIVERY DEVICE such that:

a) its performance is affected;

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

Compliance with 108.6 a) is checked by the method given in 108.8, but with the ANAESTHETIC VAPOUR DELIVERY DEVICE filled to the maximum possible level.

Compliance with 108.6 b), is checked by visual inspection.

***108.7 Delivered concentration without applied back pressure**

When the ANAESTHETIC VAPOUR DELIVERY DEVICE is tested as described in 108.8, using the carrier gas and analytical technique recommended by the manufacturer (see 6.8.2 mm) 6)), the following requirements shall be met:

a) *The delivered concentration at all graduations other than "Off", "Standby" or "0" position if this is also the off position, 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.*

b) *The delivered concentration when the ANAESTHETIC VAPOUR DELIVERY DEVICE control is in the off position, the standby position, or the "0" position if this is not also the off position, shall not exceed 0,03 % (V/V).*

108.8 Method of test for the accuracy of delivered concentration without applied back pressure

108.8.1 For NON-INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY DEVICE

108.8.1.1 *Test the ANAESTHETIC VAPOUR DELIVERY DEVICE on the ANAESTHETIC WORKSTATION with the anaesthesia breathing system recommended by the manufacturer or supplier (see 6.8.2).*

Connect an anaesthetic vapour analyzer to the FRESH GAS OUTLET of the ANAESTHETIC WORKSTATION or, if applicable, to the inspiratory port of the anesthetic ventilator recommended by the manufacturer.

Check to ensure that the components downstream of the ANAESTHETIC VAPOUR DELIVERY DEVICE will not affect the test results, for example by absorbing the volatile agents, by imposing time delays on response, or by leakage.

108.8.1.2 *Place the ANAESTHETIC WORKSTATION with the specified test equipment and anaesthetic agent in the test room for at least 3 h at 20 °C ± 3 °C and maintain this temperature throughout the test procedure.*

108.8.1.3 *Fill the ANAESTHETIC VAPOUR DELIVERY DEVICE with the appropriate anaesthetic agent to approximately half of the maximum usable volume, and leave it stand for at least 45 min.*

NOTE – These 45 min may be within the three-hour period specified in 108.8.1.2.

If the manufacturer recommends that when power is applied to the ANAESTHETIC VAPOUR DELIVERY DEVICE, a warm up period be allowed before use, power shall be applied for at least that period before testing. This period may be within the 45 min.

108.8.1.4 *Set the ANAESTHETIC VAPOUR DELIVERY DEVICE to the on position at the maximum concentration setting. Purge the ANAESTHETIC VAPOUR DELIVERY DEVICE for 3 min at a flow of 2 l/min.*

108.8.1.5 *With the ANAESTHETIC VAPOUR DELIVERY DEVICE in the off, "0" or, if applicable, standby position, set the gas flow through the ANAESTHETIC WORKSTATION to (2 ± 0,2) l/min. Ensure that the pressure at the FRESH GAS OUTLET is within the range –0,5 kPa to +0,5 kPa of ambient atmospheric pressure.*

Maintain the gas flow for 1 min and measure the average concentration of vapour for the next minute.

108.8.1.6 *Repeat the procedure described in 108.8.1.5 with the ANAESTHETIC VAPOUR DELIVERY DEVICE set to each of the other settings and in the order given in table 103. If the ANAESTHETIC VAPOUR DELIVERY DEVICE is not marked with the concentration settings given in table 103, use the nearest settings on the ANAESTHETIC VAPOUR DELIVERY DEVICE. If any setting given in table 103 is equidistant between settings on the ANAESTHETIC VAPOUR DELIVERY DEVICE, use the lower setting on the ANAESTHETIC VAPOUR DELIVERY DEVICE.*

108.8.1.7 *Repeat the sequence of measurements described in 108.8.1.5 and 108.8.1.6 but using a fresh gas flow of (8 ± 0,8) l/min.*

Table 103 – Settings to be used for testing accuracy of delivered concentration

Order of test	Setting (% *V/V* of anaesthetic vapour)
1	off, standby, and zero, if separately marked
2[1)]	lowest graduation above zero
3	10 % FS
4	20 % FS
5	50 % FS
6	75 % FS
7	maximum graduation (full scale)
[1)] If 10 % of full scale (FS) is the lowest graduation, step 2 is omitted.	

108.8.2 For INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY DEVICES

108.8.2.1 *Test the ANAESTHETIC VAPOUR DELIVERY DEVICE on a calibrated test rig capable of supplying the necessary gas flow and pressures required by the test conditions.*

Connect an anaesthetic vapour analyzer to measure concentration in the outlet flow of the ANAESTHETIC VAPOUR DELIVERY DEVICE.

Check to ensure that the components downstream of the ANAESTHETIC VAPOUR DELIVERY DEVICE will not affect the test results, for example by absorbing the volatile agents, by imposing time delays on response, or by leakage.

108.8.2.2 *Place the ANAESTHETIC VAPOUR DELIVERY DEVICE with the specified test equipment and anaesthetic agent in the test room for at least 3 h at 20 °C ± 3 °C and maintain this temperature throughout the test procedure.*

108.8.2.3 *Carry out the actions specified in 108.8.1.3 and 108.8.1.4.*

108.8.2.4 *With the ANAESTHETIC VAPOUR DELIVERY DEVICE in the off, "0" or, if applicable, standby position, set the gas flow through the ANAESTHETIC VAPOUR DELIVERY DEVICE to (2 ± 0,2) l/min. Ensure that the pressure at the ANAESTHETIC VAPOUR DELIVERY DEVICE outlet is within the range –0,5 kPa to +0,5 kPa of ambient atmospheric pressure.*

Maintain the gas flow for 1 min and measure the average concentration of vapour for the next minute.

108.8.2.5 *Repeat the procedure described in 108.8.2.4 with the device settings and gas flows specified in 108.8.1.6 and 108.8.1.7.*

108.9 Delivered vapour concentration with applied back pressure

When the ANAESTHETIC VAPOUR DELIVERY DEVICE is tested by the method given in 108.10 with the carrier gas and the analytical technique recommended by the manufacturer (see 6.8.2 mm) 6)), the following requirements shall be met:

a) *the delivered concentration at all graduations other than off, standby, or the zero position if this is also the off position, from the ANAESTHETIC VAPOUR DELIVERY DEVICE shall not deviate from the indicated value by no more than +30 % or –20 % from the concentration setting or by no more than +7,5 % or –5 % of the maximum setting, whichever is the greater.*

b) *the delivered concentration when the ANAESTHETIC VAPOUR DELIVERY DEVICE control is in the off position, the standby position or the zero position if this is also the off position, shall not exceed 0,05 % (V/V).*

108.10 Method of test for the accuracy of delivered vapour concentration with applied back pressure

108.10.1 For NON-INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY DEVICES

108.10.1.1 *Carry out the actions specified in clauses 108.8.1.1 and 108.8.1.2.*

108.10.1.2 *Fill the ANAESTHETIC VAPOUR DELIVERY DEVICE with the appropriate anaesthetic agent to approximately half of the maximum usable volume, and leave it to stand for at least 45 min.*

NOTE – These 45 min may be within the three-hour period specified in 108.8.1.2.

If the manufacturer recommends that when power is applied to the ANAESTHETIC VAPOUR DELIVERY DEVICE, a warm up period be allowed before use, power shall be applied for at least that period before testing. This period may be within the 45 min.

108.10.1.3 *Set the ANAESTHETIC VAPOUR DELIVERY DEVICE to the on position at the maximum concentration setting. Purge the ANAESTHETIC VAPOUR DELIVERY DEVICE for 3 min at a flow of 2 l/min.*

108.10.1.4 *With the ANAESTHETIC VAPOUR DELIVERY DEVICE in the off, zero or, if applicable, the standby position, set the gas flow through the ANAESTHETIC WORKSTATION to 2 ± 0,2 l/min and adjust the ventilator to give (15 ± 2) breaths/min at an I:E ratio of 1:2 ± 20 % with the inspiratory flow control set to maximum.*

NOTE – For an ANAESTHETIC WORKSTATION in which the fresh gas flow is determined by the ventilator settings, set these to give a minute volume of (2 ± 0,2) l.

Introduce a maximum pressure fluctuation of (2 ± 0,3) kPa (above ambient) at the FRESH GAS OUTLET ensuring that the decay time during the expiration period (from 100 % of the FRESH GAS OUTLET pressure at the end of the inspiration period to 33 % of this pressure) is less than 0,6 s.

NOTE – This can be achieved by using a test lung having a compliance of 0,2 l/kPa and an appropriate resistance.

Maintain the pressure fluctuations for 4 min and measure the concentration of anaesthetic vapour delivered during the last one minute period. Calculate the average vapour concentration in the total delivered gas flow during this one minute period and compare this value with the setting of the ANAESTHETIC VAPOUR DELIVERY DEVICE.

108.10.1.5 *Repeat the procedure described in 108.10.1.4 with the ANAESTHETIC VAPOUR DELIVERY DEVICE set to each of the other settings and in the order given in table 103. If the ANAESTHETIC VAPOUR DELIVERY DEVICE is not marked with the concentration settings given in table 103, use the nearest settings on the ANAESTHETIC VAPOUR DELIVERY DEVICE. If any setting given in table 103 is equidistant between settings on the ANAESTHETIC VAPOUR DELIVERY DEVICE, use the lower setting on the ANAESTHETIC VAPOUR DELIVERY DEVICE.*

108.10.1.6 *Repeat the procedure in 108.10.1.5 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.*

NOTE – For an ANAESTHETIC WORKSTATION in which the fresh gas flow is determined by the ventilator settings, set these to give a minute volume of (8 ± 0,8) l.

108.10.2 For INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY DEVICES

108.10.2.1 *Carry out the actions specified in 108.8.2.1, 108.8.2.2, 108.10.1.2, and 108.10.1.3.*

108.10.2.2 *With the* ANAESTHETIC VAPOUR DELIVERY DEVICE *in the off, zero or, if applicable, the standby position, set the gas flow through the* ANAESTHETIC VAPOUR DELIVERY DEVICE *to (2 ± 0,2) l/min and adjust the test rig to give (15 ± 2) breaths/min at an I:E ratio of 1:2 ± 20 % with the inspiratory flow control set to maximum.*

NOTE – For an ANAESTHETIC WORKSTATION in which the fresh gas flow is determined by the ventilator settings, set these to give a minute volume of (2 ± 0,2) l.

Introduce a maximum pressure fluctuation of (2 ± 0,3) kPa (above ambient) at the FRESH GAS OUTLET *ensuring that the decay time during the expiration period (from 100 % of the* FRESH GAS OUTLET *pressure at the end of the inspiration period to 33 % of this pressure) is less than 0,6 s.*

NOTE – This can be achieved by using a test lung having a compliance of 0,2 l/kPa and an appropriate resistance.

Maintain the pressure fluctuations for 4 min and measure the concentration of anaesthetic vapour delivered during the last one minute period. Calculate the average vapour concentration in the total delivered gas flow during this one minute period and compare this value with the setting of the ANAESTHETIC VAPOUR DELIVERY DEVICE.

108.10.2.3 *Repeat the procedure described in 108.10.2.2 using the sequence of measurements specified in 108.10.1.5 and 108.10.1.6.*

108.11 Delivered vapour concentration immediately after oxygen flush

When the ANAESTHETIC VAPOUR DELIVERY DEVICE *is tested as described in 108.12 it shall meet the accuracy requirements of clause 108.9.*

108.12 Method of test for the accuracy of delivered vapour concentration immediately after oxygen flush

108.12.1 For NON-INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY DEVICES

108.12.1.1 *Follow the test procedure in 108.10.1.1 to 108.10.1.5, but with a flow of (8 ± 0,8) l/min. Instead of introducing a pressure fluctuation at the* FRESH GAS OUTLET *of (2 ± 0,3) kPa, activate the oxygen flush for 2 s out of each of 10 consecutive five second cycles.*

Immediately after termination of the last flush determine the average anaesthetic vapour concentration over a period of 1 min and compare this value with the setting of the ANAESTHETIC VAPOUR DELIVERY DEVICE.

108.12.2 For INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY DEVICES

108.12.2.1 *Follow the test procedure in 108.10.2.1 and 108.10.2.2.*

108.12.2.2 *Set the ANAESTHETIC VAPOUR DELIVERY DEVICE to deliver the concentration setting as described in 108.10.1.5.*

108.12.2.3 *Set the gas flow through the ANAESTHETIC VAPOUR DELIVERY DEVICE to (8 ± 0,8) l/min and apply an intermittent back pressure at the ANAESTHETIC VAPOUR DELIVERY DEVICE outlet of 10 kPa for 2 s out of each of 10 consecutive five-second cycles.*

108.12.2.4 *Immediately after termination of the last flush determine the average anaesthetic vapour concentration over a period of 1 min and compare this value with the setting of the ANAESTHETIC VAPOUR DELIVERY DEVICE.*

108.12.2.5 *Repeat the test procedure using an intermittent sub-atmospheric pressure of 10 kPa in place of the positive pressure specified in 108.12.2.3.*

108.13 Vapour output during oxygen flush

When the ANAESTHETIC VAPOUR DELIVERY DEVICE is tested as described in 108.14 the output of anaesthetic vapour shall not increase by more than 20 %.

108.14 Method of test for delivered vapour output during oxygen flush

108.14.1 For NON-INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY DEVICES

108.14.1.1 *Follow the test procedure in 108.10.1.1 to 108.10.1.5, but with a flow of 8 min ± 0,8 l/min. Instead of introducing a pressure fluctuation at the FRESH GAS OUTLET of 2 kPa ± 0,3 kPa, measure the output of anaesthetic vapour [concentration of vapour × volume of gas] for 1 min before and then during a ten-second activation of the oxygen flush.*

Compare these two measurements expressed as volume of vapour per unit of time.

NOTE – The volume of gas may be determined, for example by integrating flow or by collecting the gas during the specified period.

108.14.2 For INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY DEVICES

108.14.2.1 *Follow the test procedure in 108.12.2.1 to 108.12.2.3 but instead of applying an intermittent back pressure measure the output of anaesthetic vapour [concentration of vapour × volume of gas] for 1 min before and then during a ten-second application of a steady back pressure of 10 kPa.*

Compare these two measurements expressed as volume of vapour per unit of time.

NOTE – The volume of gas may be determined, for example by integrating flow or by collecting the gas during the specified period.

108.14.2.2 *Repeat the test procedure in 108.14.2.1 using a steady sub-atmospheric pressure of 10 kPa.*

109 Oxygen flush

109.1 The ANAESTHETIC WORKSTATION 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.

109.2 The oxygen flush shall have only one off position.

NOTE – The oxygen flush should be designed and positioned to minimize accidental operation by equipment or personnel pressing against it.

109.3 The flush shall be operable with one hand and shall be self-closing. The flush shall deliver oxygen from the FRESH GAS OUTLET to atmosphere at a steady flow of between 25 l/min and 50 l/min, measured at atmospheric pressure, when oxygen is delivered to the flush at its design pressure.

109.4 For anaesthetic gas delivery systems that allow INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY DEVICES to be fitted, the flow of gas from the oxygen flush shall be delivered to the FRESH GAS OUTLET without passing through an ANESTHETIC VAPOUR DELIVERY DEVICE.

When the FRESH GAS OUTLET is open to atmosphere, the pressure at the outlet from the ANAESTHETIC VAPOUR DELIVERY DEVICE shall neither increase by more than 10 kPa above its normal working pressure nor decrease by more than 10 kPa below its normal working pressure when the oxygen flush is operated.

Compliance is checked by functional testing.

110 FRESH GAS OUTLET

110.1 If an operator-accessible FRESH GAS OUTLET is provided, there shall be not more than one and, if present, it shall be one of the following:

a) a coaxial 22 mm/15 mm conical connector complying with ISO 5356-1, or

b) a screw-threaded weight-bearing connector complying with ISO 5356-2, or

c) a quick connector as shown in figure 102, or

d) a 15 mm female connector complying with ISO 5356-1, or

e) a connector with an outside screw thread M16 × 1,5 mm.

NOTE – An operator-accessible FRESH GAS OUTLET should have a means to prevent accidental disconnection.

110.2 For conical connectors, the supporting structure of the FRESH GAS OUTLET shall permit the simultaneous application of a bending moment of 3 Nm on, and a torque of 3 Nm around, the axis without permanent deformation or displacement of the mountings of the FRESH GAS OUTLET.

If the FRESH GAS OUTLET includes a screw-threaded, weight-bearing connector complying with ISO 5356-2, its supporting structure shall permit the simultaneous application of a bending moment of 10 Nm on, and a torque of 24 Nm around, the axis without permanent deformation or displacement of the mountings of the FRESH GAS OUTLET.

111 Checklist

Each ANAESTHETIC WORKSTATION shall be provided with a checklist of the test and operating procedures which have to be performed prior to its use.

NOTE – These procedures may be performed either automatically, in whole or in part, or by the operator.

Manufacturers of individual devices intended for use in an ANAESTHETIC WORKSTATION shall provide details of those tests and procedures that are to be incorporated into the checklist for the ANAESTHETIC WORKSTATION.

The user who assembles an ANAESTHETIC WORKSTATION from separate devices shall provide a checklist comprising the details of the tests and procedures which shall be incorporated into the checklist for the ANAESTHETIC WORKSTATION.

SECTION ELEVEN – ANAESTHETIC VENTILATOR, ANAESTHESIA BREATHING SYSTEM AND ANAESTHETIC GAS SCAVENGING SYSTEM

112 Anaesthetic ventilator

Addition:

112.1 Cleaning, disinfection and sterilization

All parts of the anaesthetic ventilator which are subject to contamination by exhaled gases and which are intended to be re-used shall be able to be disinfected or sterilized by the method(s) recommended by the manufacturer (see also 6.8.2 ee)).

112.2 The breathing gas exhaust port shall comply with ISO 8835-2.

112.3 Inspiratory and expiratory ports shall be male and shall comply with ISO 5356-1 or ISO 5356-2.

NOTE – For MONITORING, ALARM and PROTECTION DEVICEs see 51.105.2.1, 51.105.2.2, 51.105.3.1, 51.105.3.3 and 51.105.9.

113 Anaesthesia breathing systems

113.1 If an anaesthesia circle breathing system is supplied, it shall comply with ISO 8835-2.

114 Anaesthetic gas scavenging systems

114.1 If an anaesthetic gas scavenging system, or any component(s) thereof, is supplied with the ANAESTHETIC WORKSTATION, it (they) shall comply with ISO 8835-3.

115 Suction equipment

115.1 Suction equipment provided as part of the ANAESTHETIC WORKSTATION shall comply with ISO 10079-1, ISO 10079-2 and ISO 10079-3.

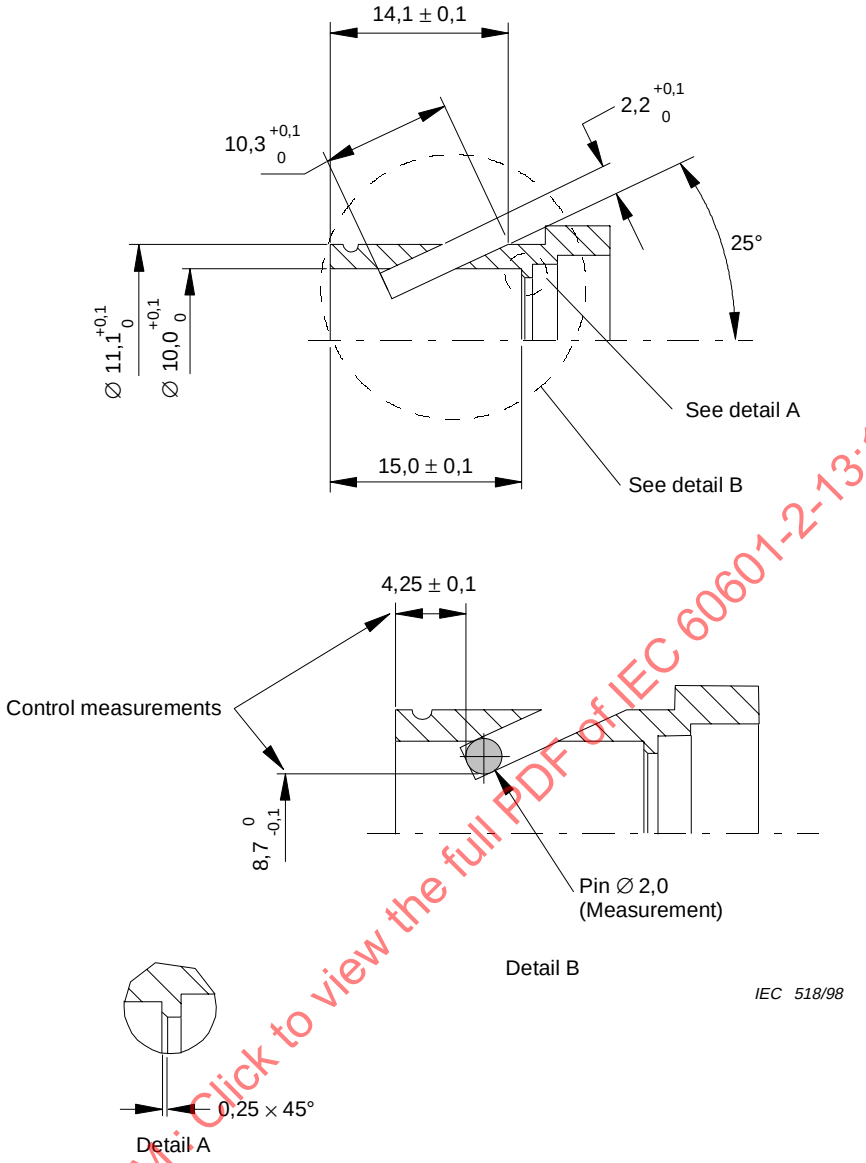

Figure 102 – ANAESTHETIC WORKSTATION – COMMON GAS OUTLET according to Swedish standard SS 87 524 30

Annexes

Appendices/Annexes of the General Standard apply except as follows:

Appendix L

References – Publications mentioned in this standard

Appendix L of the General Standard applies except as follows:

Additions:

IEC 60079-3:1990, *Electrical apparatus for explosive gas atmospheres – Part 3: Spark-test apparatus for intrinsically safe circuits*

IEC 60079-4:1975, *Electrical apparatus for explosive gas atmospheres – Part 4: Method of test for ignition temperature*

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*

IEC 60601-1-1:1992, *Medical electrical equipment – Part 1: General requirements for safety – 1. Collateral standard: Safety requirements for medical electrical systems*

IEC 60601-1-2:1993, *Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral standard: Electromagnetic compatibility*

ISO 32:1977, *Gas cylinders for medical use – Marking for identification of content*

ISO 407:1991, *Small medical gas cylinders – Pin index yoke-type valve connections*

ISO 3746:1995, *Acoustics – Determination of sound power levels of noise sources using sound pressure – Survey method using an enveloping measurement surface over a reflecting plane*

ISO 4135:1995, *Anaesthesiology – Vocabulary*

ISO 5145:1990, *Cylinder valve outlets for gases and gas mixtures – Selection and dimensioning*

ISO 5356-1:1996, *Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets*

ISO 5356-2:1987, *Anaesthetic and respiratory equipment – Conical connectors* – Part 2: Screw-threaded, weight-bearing connectors

ISO 5359:1989, *Low-pressure flexible connecting assemblies (hose assemblies) for use with medical gas systems*

ISO 5362:1986, *Anaesthetic reservoir bags*

ISO 7396:1987, *Non-flammable medical gas pipeline systems*

ISO 7767:1988, *Oxygen analyzers for monitoring patient breathing mixtures – Safety requirements*

ISO 8835-2, *Inhalational anaesthesia systems – Part 2: Anaesthetic circle breathing systems*

ISO 8835-3:1997, *Inhalational anaesthesia systems – Part 3: Anaesthetic gas scavenging systems – Transfer and receiving systems*

ISO 9170:1990, *Terminal units for use in medical gas pipeline systems*

ISO 9703-1:1992, *Anaesthesia and respiratory care alarm signals – Part 1: Visual alarm signals*

ISO 9703-2:1994, *Anaesthesia and respiratory care alarm signals – Part 2: Auditory alarm signals*

ISO 9918:1993, *Capnometers for use with humans – Requirements*

ISO 10079-1:1991, *Medical suction equipment – Part 1: Electrically powered suction equipment – Safety requirements*

ISO 10079-2:1992, *Medical suction equipment – Part 2: Manually powered suction equipment*

ISO 10079-3:1992, *Medical suction equipment – Part 3: Suction equipment from vacuum or pressure source*

ISO 10524:1995, *Pressure regulators and pressure regulators with flow metering devices for medical gas systems*

ISO 11196:1995, *Anaesthetic gas monitors*

SS 87 524 30, *Anaesthetic equipment – Connectors for medical gases*

Annex AA
(informative)

Bibliography

ISO 5358:1992, *Anaesthetic machines for use with humans*

ISO/CD 7396-1, *Non-flammable medical gas pipeline systems*

BS 5252:1976, *Framework for colour coordination for building purposes*

DIN 6164-2:1980, *DIN colour chart – Part 2: Specification of colour samples*

USA Federal Standard 595a, Colors – Vol. 1 [1)]

Munsell Book of Color [2)]

Pantone Colours [3)]

SS 01 91 03, CIE tristimulus values and chromaticity coordinates for the colour samples in SS 1 91 02

NFPA Publication 53M [4)] – Fire hazards in oxygen-enriched atmospheres

1) Available from Superintendent of Documents, US Government Printing Office, Washington DC 20402, USA.

2) Available from Munsell Color, 2441 N. Calvert Street, Baltimore MD 21218, USA.

3) Available from Letraset UK Ltd., 195 Waterloo Road, London SE1, United Kingdom.

4) Available from the National Fire Protection Association, 1 Batterymarch Park, PO Box 9101, Quincy MA 02269-9101, USA.

Annex BB
(informative)

Rationale

NOTE – The clause numbers in this annex refer to the clauses in this Particular Standard to which the rationales apply.

3.6 bb) A fault which is not detected can exist for a long time. Under these circumstances it is not acceptable to regard a further fault as a second fault which can be disregarded. Such an undetected first fault should be regarded as a normal condition.

An undetected oxygen leak is an important example. It should be considered as a normal condition if it is not detected by an alarm or by periodic inspection or unless the system is considered infallible.

6.1 j) The marking of the ANAESTHETIC WORKSTATION input and the sum of the input in amperes gives information to the user and operator on the minimum mains fuse ratings needed in different situations. This information is needed to prevent current overload and electrical failure of the equipment in critical situations.

6.1 k) The marking of each auxiliary mains socket outlet with its output in amperes gives information to users and operators on the current ratings of the fuses of each auxiliary mains socket outlet. This information is needed to prevent current overload and electrical failure of the equipment in critical situations.

6.8.2 aa) It is very important that the user and 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.

19.4 h) See rationale to 2.1.5 and figure 1 of the General Standard.

37.101/37.102 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 may therefore, according to this Particular 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 DD. 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.

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);

– temperature 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 the General Standard, the objective in the design of the equipment must be to ensure that under both normal and single fault conditions and under the oxidizing 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, for example a fuse or a resistor within a sealed compartment.

Minimum ignition temperatures for a large number of specific materials are well established in published literature, although usually only for ambient air and pure oxygen environments. The minimum ignition temperature may be critically dependent upon the concentration of oxidant present. If ignition temperatures for other materials or different oxygen concentrations are required these may 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, for example airborne particles of paper or cotton.

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

However, if materials with a low ignition temperature and a very low thermal capacity, for example cotton wool, paper or organic fibre accumulations, are present then it may not be possible to determine the surface temperatures attained during exposure to spark energy, and specific tests, such as ignition tests, may be necessary to assume safety under these conditions.

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

The temperature value is based on the minimum hotplate 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 on 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 upon 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 for a pure oxygen environment, even under a single fault condition. The particular combination of material, oxidant and temperature determines whether a fire will occur, not the single value of any one of these variables.

51.102.2 There is frequently more than one member to an anaesthesia team assigned to the care of one patient in the operating room. Often members of a care team may be relieved (for example surgery longer than 8 h, bathroom breaks, etc.) during a case. Also, the ANAESTHETIC WORKSTATION may be left in a standby condition when one case has finished, and another is to follow. In these circumstances, a "new" operator must be made aware that an alarm previously had been disabled.

51.105.9 The committee generally agreed that currently there is no way to indicate reliably the failure of breathing system integrity (for example partial or even complete disconnection of the breathing system). Under certain specific circumstances, CO_2 monitoring, (low) pressure monitoring, (low) volume monitoring anaesthetic vapour monitoring, or O_2 monitoring may indicate, or contribute to the detection of loss of breathing system integrity. It is for these reasons that a medium priority alarm has been provided for the monitors mentioned. The manufacturer, in the accompanying documents, shall indicate which monitor, or combination of monitors, are most likely to indicate that disconnection may have occurred.

54.101 This clause prevents the use of a MONITORING DEVICE to control an actuator, which would lead to a malfunction of the actuator being undetected in case of a monitor and/or ALARM DEVICE failure.

57.3 a) Accidental disconnection could be hazardous for the patient, because of hypo-ventilation or low inspired oxygen, etc.

57.6 A short circuit of other equipment connected to the auxiliary mains socket-outlet must not affect the normal function of the life support function of the ANAESTHETIC WORKSTATION.

108 There are hazards that may arise from interaction between conventional ANAESTHETIC VAPOUR DELIVERY DEVICE(s) and the oxygen flush on an ANAESTHETIC WORKSTATION for example.

1) If the ANAESTHETIC VAPOUR DELIVERY DEVICE is mounted downstream of the oxygen flush, the high flow rate (75 l/min) during a flush can cause the mass output from the ANAESTHETIC VAPOUR DELIVERY DEVICE to increase. In some cases this could cause liquid anaesthetic agent to be forced out of the ANAESTHETIC VAPOUR DELIVERY DEVICE during a flush.
2) If the ANAESTHETIC WORKSTATION piping has a high resistance to flow, the pressure at the ANAESTHETIC VAPOUR DELIVERY DEVICE during a flush can be high enough to cause a so-called "pumping effect "which may increase the output concentration of the ANAESTHETIC VAPOUR DELIVERY DEVICE.