# 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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Consolidated versions of some IEC publications including amendments are available. For example, edition numbers 1.0, 1.1 and 1.2 refer, respectively, to the base publication, the base publication incorporating amendment 1 and the base publication incorporating amendments 1 and 2.

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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.
2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all the interested National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.
4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
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.