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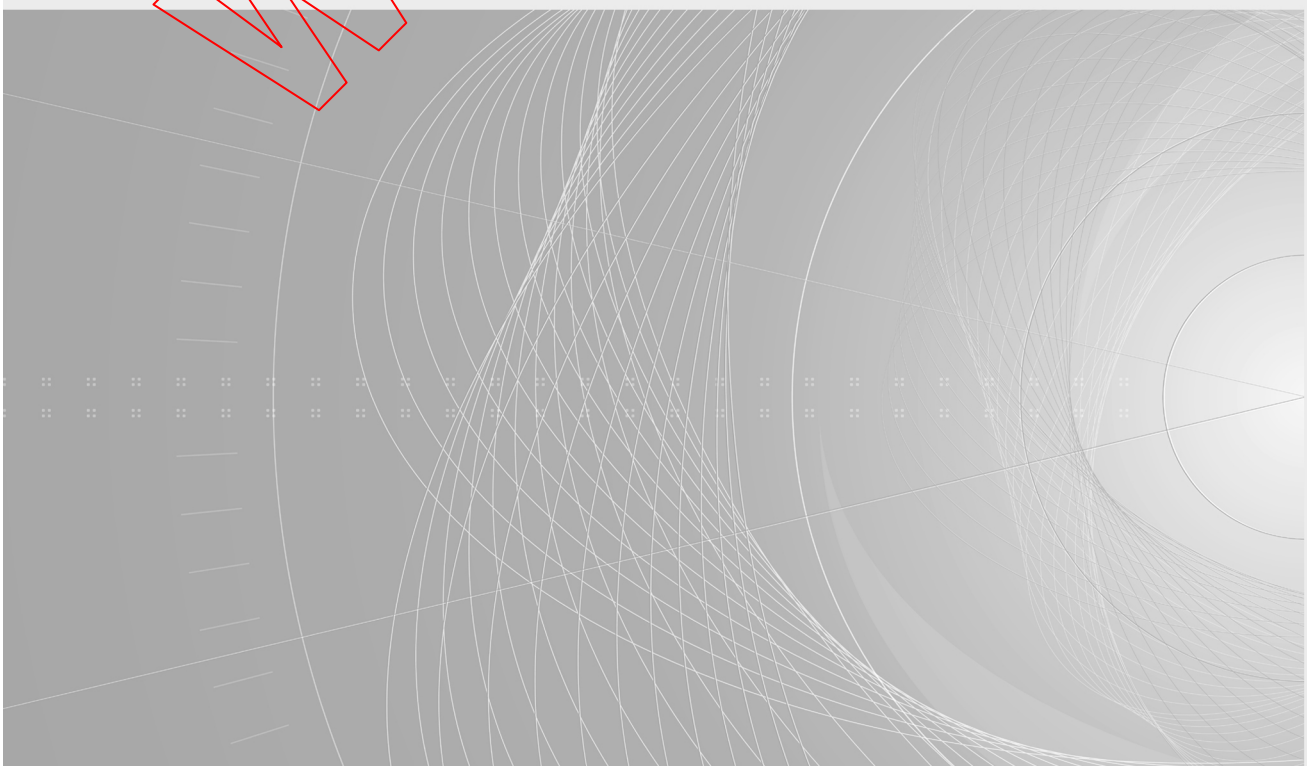
INTERNATIONAL STANDARD

Medical electrical equipment –
Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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FOREWORD

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

It is published as double logo standard.

This consolidated version of IEC 60601-2-13 consists of the third edition (2003) [documents 62D/475/FDIS and 62D/476/RVD] and its amendment 1 (2006) [documents 62D/516/CDV and 62D/537A/RVC].

The technical content is therefore identical to the base edition and its amendment and has been prepared for user convenience.

It bears the edition number 3.1.

A vertical line in the margin shows where the base publication has been modified by amendment 1.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

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

– requirements, compliance with which can be tested and definitions: roman type;
– explanations, advice, notes, general statements, exceptions and references: smaller type;
– *test specifications: italic type*;
– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR OF THIS PARTICULAR STANDARD: SMALL CAPITALS.

The committee has decided that the contents of the base publication and its amendments will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

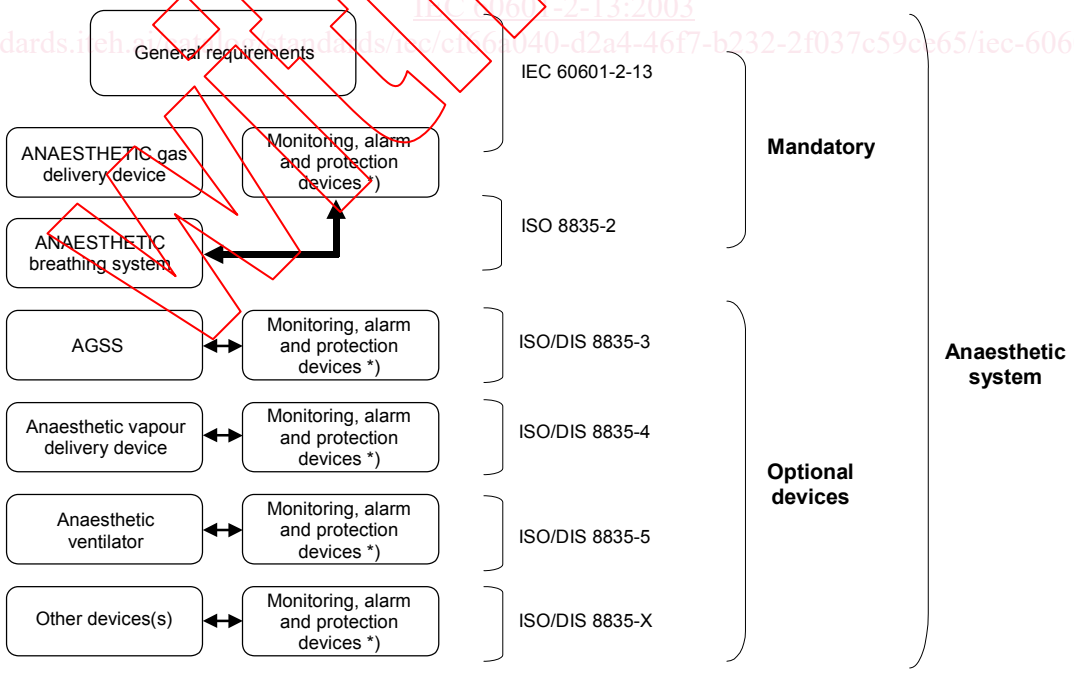
In response to requests for harmonization between the current European and International standards for anaesthetic workstations this standard has been developed by the IEC/ISO Joint Working Group to specify requirements for ANAESTHETIC SYSTEMS supplied complete, as well as requirements for individual devices which are intended to be part of an ANAESTHETIC SYSTEM. It applies in conjunction with IEC 60601-1:1988 (Including all amendments) hereafter referred to as the General Standard. As stated in 1.3 of IEC 60601-1-1988, the requirements in this standard take priority over those of the General Standard.

This standard has been structured to allow USERS to configure an ANAESTHETIC SYSTEM in conformance with professional guidelines and to meet the needs of their clinical practice. In order to achieve this aim, the standard identifies particular requirements pertinent to specific devices, and to their associated MONITORING DEVICE(S), ALARM SYSTEM(s) and PROTECTION DEVICE(S), and defines the interfaces. This standard also specifies requirements for optional devices, together with their respective MONITORING DEVICE(S), ALARM SYSTEM(S) and PROTECTION DEVICE(S).

The indicated requirements are followed by specifications for the relevant tests. An asterisk (*) denotes clauses for which there is a rationale comment in Annex AA. It is considered that knowledge of the reasons for these requirements will facilitate the proper application of the standard and be of use in any revision that may be necessitated by changes in clinical practice or as a result of developments in technology.

NOTE The decimal separator for all numeric values is "," (comma).

The following graphic representation of the structure of this standard is being provided for informational purposes only.



MEDICAL ELECTRICAL EQUIPMENT–

Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems

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:

1.1 Scope

Addition

This Particular Standard specifies safety and essential performance requirements for an ANAESTHETIC SYSTEM (as defined in 2.101.7) as well as individual devices designed for use in an ANAESTHETIC SYSTEM.

This Particular Standard does not apply to:

– ANAESTHETIC SYSTEM(S) intended for use with flammable anaesthetic agents, as determined by Annex DD,

– portable ANAESTHETIC SYSTEM(S) for use in remote sites, open fields for rescue operations or in disaster areas,

– dental analgesia apparatus.

1.2 Object

Replacement:

The object of this Particular Standard is to specify particular safety and essential performance requirements for individual devices designed for use in an ANAESTHETIC SYSTEM as well as specific requirements for the ANAESTHETIC GAS DELIVERY SYSTEM. This standard specifies requirements and defines interfaces for:

– individual devices designed for use in an ANAESTHETIC SYSTEM(S), and

– integrated ANAESTHETIC SYSTEMS.

1.3 Particular Standards

This Particular Standard amends and supplements a set of IEC publications consisting of IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*, its amendment 1 (1991) and amendment 2 (1995), hereinafter referred to as the "General Standard".

The General Standard takes into account IEC 60601-1-1:2000, *Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems* and IEC 60601-1-2 2001, *Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests.*

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.

Subclauses or figures 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.

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

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification.

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

The requirements of this Particular Standard replacing or modifying requirements of the General Standard or a Collateral Standard take precedence over the corresponding general requirement(s).

1.3.101 Related International Standards

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

IEC 60079-11:1999, *Electrical apparatus for explosive gas atmospheres – Part 11: Intrinsic safety"*

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 4135:2001, *Anaesthetic and respiratory equipment – 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 5359:2000, *Low-pressure hose assemblies for use with medical gases*

ISO 5362:2000, *Anaesthetic reservoir bags*

ISO 7396-1:2002, *Medical gas pipeline systems – Part 1: Pipelines for compressed medical gases and vacuum*

ISO 7767:1997, *Oxygen monitors for monitoring patient breathing mixtures – Safety requirements*

ISO 8835-2:1999, *Inhalational anaesthesia systems – Part 2: Anaesthetic breathing systems for adults*

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

ISO 8835-4, *Inhalational anaesthesia systems – Part 4: Anaesthetic vapour delivery devices* [1)]

ISO 8835-5, *Inhalational anaesthesia systems – Part 5: Requirements for anaesthetic ventilators* [2)]

ISO 9170-1:1999, *Terminal units for medical gas pipeline systems – Part 1: Terminal units for use with compressed medical gases and vacuum*

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 9703-3, *Anaesthesia and respiratory care alarm signals – Part 3: Guidance on application of alarms*

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

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

ISO 11196:1996, *Anaesthetic gas monitors*

ISO 15223:2000, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied*

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1) To be published.

2) To be published.

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Addition before 2.1:

An index of defined terms used in this Particular Standard is given after the annexes.

Additional definitions:

2.101.1
ALARM CONDITION
condition that occurs when a variable that is being monitored by an ALARM SYSTEM equals or falls outside the set ALARM LIMIT(S)

2.101.2
ALARM LIMIT
value(s) which are set by the manufacturer, the device, the USER or OPERATOR, which define the threshold range of the ALARM CONDITION

2.101.3
ALARM SIGNAL
signal, the purpose of which is to alert the OPERATOR of an abnormal condition in the PATIENT or the EQUIPMENT that may develop into a SAFETY HAZARD which requires OPERATOR awareness or action

2.101.4
ALARM SYSTEM
system that is intended to make the OPERATOR(S) aware of an ALARM CONDITION, in the PATIENT or EQUIPMENT, by means of its ALARM SIGNAL(S)

2.101.5
ANAESTHETIC GAS DELIVERY SYSTEM
assembly of components which controls and delivers the fresh gas into the ANAESTHETIC BREATHING SYSTEM

NOTE It may include a flow control system, flow meters and/or a gas mixing system and ANAESTHETIC GAS DELIVERY SYSTEM PIPING.

2.101.6
ANAESTHETIC GAS DELIVERY SYSTEM PIPING
all pipework, including unions, from unidirectional valves in the pipeline inlets and from the outlets of the PRESSURE REGULATOR(S) to the flow control system, as well as the piping connecting the flow control system and the piping connecting the ANAESTHETIC VAPOUR DELIVERY DEVICE to the FRESH GAS OUTLET. It includes piping leading to and from pneumatic ALARM SYSTEM(S), pressure indicators, oxygen flush and gas power outlets

2.101.7
ANAESTHETIC SYSTEM (ANAESTHETIC WORKSTATION)
inhalational ANAESTHETIC SYSTEM that contains an ANAESTHETIC GAS DELIVERY SYSTEM, an ANAESTHETIC BREATHING SYSTEM and the required MONITORING DEVICE(S), ALARM SYSTEM(S), and PROTECTION DEVICES

NOTE The ANAESTHETIC SYSTEM can also include, but is not limited to, ANAESTHETIC VAPOUR DELIVERY DEVICE(S), ANAESTHETIC VENTILATOR(S), anaesthetic gas scavenging systems, and their associated MONITORING DEVICE(S), ALARM SYSTEM(S) and PROTECTION DEVICE(S).

2.101.8
ANAESTHETIC VAPOUR DELIVERY DEVICE
device which provides the vapour of an anaesthetic agent in a controllable concentration

2.101.9
ANAESTHETIC VENTILATOR
automatic device, which is connected via the ANAESTHETIC BREATHING SYSTEM to the PATIENT'S airway and is designed to augment or provide ventilation of the PATIENT during anaesthesia

2.101.10
ANNUNCIATION, ANNUNCIATE, ANNUNCIATING
communication of ALARM SIGNALS to the OPERATOR

2.101.11
DISABLE, DISABLED
state of indefinite duration in which the ALARM SYSTEM or part of the ALARM SYSTEM does not ANNUNCIATE an auditory ALARM SIGNAL

2.101.12
LEGIBLE
displayed qualitative or quantitative information, values, functions, and/or markings discernible or identifiable to an OPERATOR with 6-6 (20/20) vision (corrected if necessary) from a distance of 1 m at a light level of 215 lux, when viewing the information, markings, etc perpendicular to and including 15° above, below, left and right of the normal line of sight of the OPERATOR

2.101.13
MONITORING DEVICE
device which continuously or repeatedly measures and indicates the value of a variable to the OPERATOR

2.101.14
NON-LATCHING ALARM SIGNAL
ALARM SIGNAL that automatically stops ANNUNCIATING when its associated ALARM CONDITION no longer exists

2.101.15
OXYGEN RICH ENVIRONMENT
environment in which the partial pressure of oxygen is greater than 275 hPa

2.101.16
POWER SUPPLY
source of energy other than that generated directly by the human body or by gravity that makes the device function

2.101.17
PROTECTION DEVICE
device which, without intervention by the OPERATOR protects the PATIENT from hazardous output due to incorrect delivery of energy or substances

2.101.18
RESERVE ELECTRICAL POWER SOURCE
part of EQUIPMENT that temporarily supplies power to the electrical system in the event of an interruption of the primary electrical supply

2.101.19
SILENCE, SILENCED
state of temporary duration in which the ALARM SYSTEM or part of the ALARM SYSTEM does not ANNUNCIATE an auditory ALARM SIGNAL

3 General requirements

This clause of the General Standard applies except as follows:

3.6 *Addition:*

An oxidant leak which is not detected by e.g. an ALARM SYSTEM or periodic inspection shall be considered a NORMAL CONDITION and not a SINGLE FAULT CONDITION.

4 General requirements for tests

This clause of the General Standard applies except as follows:

Addition:

4.101 Other test methods

The manufacturer may use type tests different from those detailed within this standard, if an equivalent degree of compliance is obtained. However, in the event of dispute, the methods specified in this standard shall be used as the reference methods.

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 (after the existing last sentence):

The RATED power input marking shall include the maximum RATED power output available to the AUXILIARY MAINS SOCKET OUTLET(S), with which the ANAESTHETIC SYSTEM is equipped.

*k) *Mains power output*

Replacement:

Each AUXILIARY MAINS SOCKET OUTLET shall be marked with its RATED output in units of amperes. If AUXILIARY MAINS SOCKET OUTLET(S) can accept a standard mains plug, the AUXILIARY MAINS SOCKET OUTLET shall be marked with symbol 14 of Table D.1 of the General Standard.

Addition:

aa) The ANAESTHETIC SYSTEM and/or its devices

The ANAESTHETIC SYSTEM and/or its devices shall be legibly marked with the following information as applicable:

1) the name or trade name and address of the manufacturer;
2) the name and address of the distributor/supplier;
3) the symbol for “batch code“, or “serial number” (see ISO 15223);
4) a LEGIBLE arrow showing the direction of flow for any OPERATOR-detachable components or devices that are flow-direction-sensitive unless designed in such a way that prevents incorrect assembly;