INTERNATIONAL STANDARD

IEC 60601-2-13

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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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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).