

INTERNATIONAL STANDARD

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Medical electrical equipment –

Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment

Appareils électromédicaux –

Partie 2-49: Règles particulières de sécurité des appareils de surveillance multifonction des patients

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment

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 co-operation 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 this 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 interested National Committees.
- 3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, 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 of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-2-49 has been prepared by subcommittee 62D: Electro-medical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this standard is based upon the following documents:

FDIS	Report on voting
62D/409/FDIS	62D/412/RVD

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 3.

Annexes AA, BB, EE and KK are for information only.

In this Particular Standard the following print types are used:

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

The committee has decided that the contents of this publication will remain unchanged until 2006. At this date, the publication will be:

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- withdrawn;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

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

Withdrawn

INTRODUCTION

This Particular Standard concerns the safety of multifunction patient monitoring equipment. It amends and supplements IEC 60601-1 (second edition 1988), hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard, entitled “*Medical electrical equipment – Part 1: General requirements for safety*”.

A “General guidance and rationale” for the requirements of this Particular Standard is included in annex AA.

It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this Standard.

An asterisk (*) by a clause or subclause number indicates that some explanatory notes are given in Annex A of this Particular Standard.

At the time of the publication of this Particular Standard, work was in progress to create a joint ISO/IEC collateral standard addressing “General requirements and guidelines for the application of alarms in medical electrical equipment”. It is intended to harmonize this standard with the above-mentioned collateral standard after its publication.

Withhold

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment

SECTION ONE – GENERAL

This section of the General Standard applies except as follows:

1 Scope and object

*1.1 Scope

This Particular Standard applies to the safety requirements of MULTIFUNCTION PATIENT MONITORING EQUIPMENT as defined in subclause 2.2.101.

The scope of this standard is restricted to EQUIPMENT having either more than one APPLIED PART or more than one SINGLE FUNCTION, intended for connection to a single PATIENT.

This standard does not specify requirements for individual monitoring functions.

1.2 Object

The object of this Particular Standard is to specify requirements for the safety of MULTIFUNCTION PATIENT MONITORING EQUIPMENT.

1.3 Particular Standards

Addition:

This Particular Standard refers to IEC 60601-1 (1988): *Medical electrical equipment – Part 1: General requirements for safety* as amended by its amendment 1 (1991) and amendment 2 (1995).

For brevity, Part 1 is referred to in this Particular Standard either as the “General Standard” or as the “General Requirement(s)”.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard. 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” is used to make reference to the General Standard and this Particular Standard taken together.

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 take priority over those of the General Standard and Collateral Standard mentioned above.

1.5 Collateral standards

Addition:

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

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral standard: Programmable electric medical systems*
Amendment 1 (1999)

Withhold