

INTERNATIONAL STANDARD

NORME INTERNATIONALE

**Medical electrical equipment –
Part 2-49: Particular requirements for the basic safety and essential performance
of multifunction patient monitoring equipment**

**Appareils électromédicaux –
Partie 2-49: Exigences particulières pour la sécurité de base et les performances
essentielles des appareils de surveillance multifonction des patients**



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COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment

FOREWORD

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

This second edition cancels and replaces the first edition of IEC 60601-2-49, published in 2001. This edition constitutes a technical revision to the new structure of IEC 60601-1:2005 (third edition).

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/886/FDIS	62D/908/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.

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

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability 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,
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INTRODUCTION

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of MULTIFUNCTION PATIENT MONITORING EQUIPMENT. It amends and supplements IEC 60601-1 (third edition, 2005): *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard.

The aim of this second edition is to bring this particular standard up to date with reference to the third edition of the general standard through reformatting and technical changes.

The requirements of this particular standard take priority over those of the general standard.

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, permit any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this Annex AA does not form part of the requirements of this standard.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 * Scope

Replacement:

This particular standard applies to BASIC SAFETY and ESSENTIAL PERFORMANCE requirements of MULTIFUNCTION PATIENT MONITORING EQUIPMENT as defined in 201.3.63, hereafter referred to as ME EQUIPMENT. This particular standard applies to ME EQUIPMENT used in a hospital environment as well as when used outside the hospital environment, such as in ambulances and air transport.

ME EQUIPMENT intended for use under extreme or uncontrolled environmental conditions outside the hospital environment, such as in ambulances and air transport, shall comply with this particular standard. Additional standards may apply to ME EQUIPMENT for those environments of use.

The scope of this standard is restricted to ME EQUIPMENT intended for connection to a single PATIENT that has either two or more APPLIED PARTS or MULTIPLE FUNCTIONS on an APPLIED PART.

This standard does not specify requirements for individual monitoring functions such as ECG, invasive pressure and pulse oximetry. The particular standards related to these physiological parameters specify requirements from the perspective of stand-alone ME EQUIPMENT. This particular standard addresses the differences related to MULTIFUNCTION PATIENT MONITORING EQUIPMENT, since such equipment has a broader INTENDED USE than this stand-alone ME EQUIPMENT.

201.1.2 Object

Replacement:

The object of this particular standard is to establish BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for MULTIFUNCTION PATIENT MONITORING EQUIPMENT as defined in 201.3.63.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

¹ The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.