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INTERNATIONAL STANDARD

NORME INTERNATIONALE

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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

IEC 60601-2-49:2011

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IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland
Email: inmail@iec.ch
Web: www.iec.ch

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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).

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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.

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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

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- withdrawn,
- replaced by a revised edition, or
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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, expedite 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.

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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 standard[1] 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.

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

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IEC 60601-1-2 and IEC 60601-1-8 apply as modified in Clauses 202 and 208 respectively. IEC 60601-1-3 does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this particular standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x”, where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). 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 or applicable collateral 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 or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

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201.2 Normative references

Clause 2 of the general standard applies, except as follows.

Replacement:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.*

ISO 15223-1:2007, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*

Addition:

IEC 60601-2-2:2009, *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

IEC 60601-2-27:___[2], *Medical electrical equipment – Part 2-27, Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment*

IEC 60601-2-34:___[3], *Medical electrical equipment – Part 2-34, Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment*

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201.3 Terms and definitions

NOTE An index of defined terms is found beginning on page 50.

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 apply, except as follows:

Replacement:

201.3.63
MULTIFUNCTION PATIENT MONITORING EQUIPMENT
ME EQUIPMENT
modular or pre-configured device whose primary intended use is patient monitoring provided with not more than one connection to a particular SUPPLY MAINS, including more than one PHYSIOLOGICAL MONITORING UNIT designed to acquire physiological signals from a single PATIENT and to process those signals for display purposes and to generate ALARM SIGNALS

Additional definitions:

201.3.201
MULTIPLE FUNCTION
measurement of more than one physiological function on one APPLIED PART

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[2] Third edition, to be published.

[3] Third edition, to be published.

201.3.202
PART LEAKAGE CURRENT
current flowing from all PATIENT CONNECTION of one SINGLE FUNCTION of an APPLIED PART through the PATIENT to the remaining PATIENT CONNECTION(S) of all other SINGLE FUNCTION(S) of that same APPLIED PART under NORMAL CONDITIONS and not intended to produce a physiological effect

201.3.203
PHYSIOLOGICAL MONITORING UNIT
part of the ME EQUIPMENT whose purpose is to collect information relating to (a) physiological function(s) and to process it for monitoring and possibly also diagnostic purposes

201.3.204
SINGLE FUNCTION
measurement of one physiological function on one APPLIED PART

NOTE Examples of physiological functions are body temperature, ECG, ECG/impedance respiration, invasive and non-invasive blood pressure etc.

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements

Additional ESSENTIAL PERFORMANCE requirements for MULTIFUNCTION PATIENT MONITORING EQUIPMENT are found in subclauses listed in Table 201.101.

Table 201.101 – ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Defibrillator protection	201.8.5.5.1
Electrosurgery interference	202.6.2.101
Delays to or from a DISTRIBUTED ALARM SYSTEM	208.6.4.2

201.4.5 * Equivalent safety for ME EQUIPMENT or ME SYSTEMS

Addition:

When several particular standards simultaneously apply to MULTI-FUNCTION PATIENT MONITORING EQUIPMENT, all relevant requirements from those standards shall be applied. If requirements from particular standards are in conflict, the RISK MANAGEMENT PROCESS shall be used to identify which standard's requirement applies. In doing this, MANUFACTURERS are strongly urged to give this particular standard's requirements additional weight whenever possible.

If the alarm requirements specified in other particular standards on MULTIFUNCTION PATIENT MONITORING EQUIPMENT conflict with those of this particular standard, the alarm requirements of this particular standard shall take priority over the others.

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201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.4 Other conditions

Addition:

Unless otherwise stated, tests shall be carried out with the ACCESSORIES listed in the instructions for use.

For ME EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE, if the test result is affected by the INTERNAL ELECTRICAL POWER SOURCE voltage, then the test shall be performed using the least favourable INTERNAL ELECTRICAL POWER SOURCE voltage specified by the MANUFACTURER. If necessary for the purpose of conducting the test, an external battery or d.c. power supply may be used to provide the necessary test voltage (see 201.11.8.101).

The values used in test circuits, unless otherwise specified, shall have at least an accuracy as given below:

– resistors: ± 1 %;
– capacitors: ± 10 %;
– inductors: ± 10 %;
– test voltages: ± 1 %.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.2 * Protection against electric shock

Replacement of the last paragraph:

APPLIED PARTS shall be classified as TYPE BF or CF APPLIED PARTS (see 7.2.10 and 8.3 of the general standard). APPLIED PARTS shall be classified as DEFIBRILLATION-PROOF APPLIED PARTS (see 8.5.5 of the general standard), unless another particular standard permits non-DEFIBRILLATION-PROOF APPLIED PARTS or technical limitations prevent the design of DEFIBRILLATION-PROOF APPLIED PARTS.

201.6.6 Mode of operation

Replacement:

ME EQUIPMENT shall be classified for CONTINUOUS OPERATION (see 7.2.11).

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies with the following addition:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.2 Identification

Addition:

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When detachable, each PHYSIOLOGICAL MONITORING UNIT shall be identified by the following markings and information:

a) MANUFACTURER's name or mark;

b) designation of the model either by a name specific to the model or by reference number or reference letters;

c) serial number;

d) for ACCESSORIES of PHYSIOLOGICAL MONITORING UNITS: lot code, symbols 5.14, 5.15 and 5.16 from ISO 15223-1:2007, if applicable.

201.7.2.10 APPLIED PARTS

Addition:

For PATIENT input connections and ACCESSORIES of MULTIFUNCTION PATIENT MONITORING EQUIPMENT the following additional marking requirements shall apply:

a) Each connector of a PATIENT CONNECTION on the APPLIED PART shall be marked to identify the associated function.

NOTE Examples of associated functions are ECG, ECG/Respiration or temperature.

b) * ACCESSORIES of a ME EQUIPMENT (for example, PATIENT CABLES, TRANSDUCERS or sensors) specified as not being protected against the effects of defibrillation shall be marked with symbol 10 of Table D.1 in Annex D of the general standard (see also 201.7.9.2.9.101 e)).

201.7.9.2.9 Operating instructions

Addition:

201.7.9.2.9.101 Additional instructions for use

The operating instructions shall include the following:

a) the INTENDED USE of the ME EQUIPMENT including the environment of use;

b) that the use of the me equipment is restricted to one patient at a time;

c) instructions for connecting a potential equalization conductor, if applicable;

d) adequate information (and type number, if necessary) to identify the accessories such as PATIENT CABLES or TRANSDUCERS which need to be used to provide protection against the effect of the discharge of a cardiac defibrillator and against burns;

e) precautions to take when using a defibrillator on a PATIENT; a description of how the discharge of a defibrillator affects the ME EQUIPMENT; a warning that defibrillator protection requires use of MANUFACTURER specified ACCESSORIES, including PATIENT CABLES and TRANSDUCERS. The specification (or type-number) of such ACCESSORIES shall be disclosed. The necessary precautions to take if ACCESSORIES that are marked according to 201.7.2.10 (specified as not being protected against the effects of defibrillation) are being used.

f) advice to the clinical OPERATOR regarding whether the ME EQUIPMENT incorporates means to protect the PATIENT against burns when used with HIGH-FREQUENCY (HF) SURGICAL EQUIPMENT. Advice shall be given regarding the location of ELECTRODES and TRANSDUCERS etc. to reduce the hazards of burns in the event of a defect in the NEUTRAL ELECTRODE connection of the HF SURGICAL EQUIPMENT;

NOTE 'NEUTRAL ELECTRODE' here refers to a term defined in IEC 60601-2-2.

g) the choice and application of the specified ACCESSORIES;

h) * advice and procedures regarding testing of the ME EQUIPMENT and ACCESSORIES on a daily basis (by the clinical OPERATOR) and on a scheduled basis (as a service activity). Emphasis should be placed on how the clinician may test visual and auditory ALARM SIGNALS.

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