INTERNATIONAL STANDARD

IEC 60601-2-49

First edition
2001-07

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.
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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.

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 medial electrical equipment". It is intended to harmonize this standard with the above-mentioned collateral standard after its publication.

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)

2 Terminology and definitions

***2.1.5**
APPLIED PART

Delete second dash.

Additional definitions:

2.2. EQUIPMENT types (classification)

2.2.101
MULTIFUNCTION PATIENT MONITORING EQUIPMENT (hereinafter referred to as EQUIPMENT)
modular or pre-configured device including more than one PHYSIOLOGICAL MONITORING UNIT designed to collect information from a single PATIENT and process it for monitoring purposes and to generate ALARMS

2.2.102
PHYSIOLOGICAL MONITORING UNIT
a part of the EQUIPMENT whose purpose is to collect information relating to (a) physiological function(s) and to process it for monitoring and summary diagnostic purposes

2.5 Currents

2.5.101
MULTIPLE FUNCTION
measurement of more than one physiological parameter

***2.5.102**
PART LEAKAGE CURRENT
current flowing from a SINGLE FUNCTION through the PATIENT to the remaining SINGLE FUNCTION (S) of the same APPLIED PART under NORMAL CONDITIONS

2.5.103
SINGLE FUNCTION
measurement of one physiological parameter

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

2.12 Miscellaneous

2.12.101
ALARM
a signal which indicates abnormal events occurring to the PATIENT or EQUIPMENT

2.12.102
INHIBITION
disabling or SILENCING and disabling an ALARM until revoked intentionally

2.12.103
LATCHED ALARM
an ALARM, the visual and auditory manifestation of which does not stop when the ALARM condition no longer exists

2.12.104
NON-LATCHED ALARM
an ALARM, the auditory or visual and auditory manifestation of which stops when the ALARM condition no longer exists

2.12.105
PHYSIOLOGICAL ALARM
a signal which either indicates that a monitored physiological function is out of specified limits or indicates an abnormal PATIENT condition

2.12.106
SILENCE
the stopping of an auditory ALARM manifestation by OPERATOR action

***2.12.107**
SILENCE/RESET
the stopping of an auditory or auditory and visual ALARM manifestation and re-enabling system response to an ALARM condition

2.12.108
SUSPENSION
disabling or SILENCING and disabling an ALARM temporarily

2.12.109
TECHNICAL ALARM
a signal which indicates that the EQUIPMENT or part(s) of the EQUIPMENT is not capable of accurately monitoring the PATIENT'S condition

5 Classification

***5.2** According to the degree of protection against electric shock:

Amendment: Delete TYPE B APPLIED PART.

5.6 According to the mode of operation:

Amendment:

Delete all but CONTINUOUS OPERATION.

6 Identification, marking and documents

6.1 Marking on the outside of the EQUIPMENT

Addition:

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

1) manufacturer's name or mark;

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

3) SERIAL NUMBER.

bb) Each PATIENT input connection on the APPLIED PART shall be marked for the function.

cc) Parts of an EQUIPMENT (for example, PATIENT CABLES or sensors) specified as not being protected against the effects of defibrillation shall be marked with symbol 14 of table DI in Appendix D of the General Standard.

6.8 ACCOMPANYING DOCUMENTS

6.8.2 Instructions for use

Addition:

aa) The instructions for use shall also include:

1) the intended use of the equipment;

2) that the use of the EQUIPMENT is restricted to one PATIENT at a time;

3) the instructions for connection of any POTENTIAL EQUALIZATION CONDUCTOR;

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

5) precautions specific to the EQUIPMENT to be taken when a defibrillator is used on a PATIENT, and effects on the EQUIPMENT of the discharge of a defibrillator;

6) safety hazard due to simultaneous use of other PATIENT-connected MEDICAL ELECTRICAL EQUIPMENT, for example, a cardiac pacemaker or other electrical stimulators;

7) if the EQUIPMENT is provided with protective means against burns to the PATIENT when used with high-frequency (HF) surgical equipment, this shall be drawn to the attention of the OPERATOR; if no such means are incorporated, advice shall be given regarding the location of ELECTRODES and TRANSDUCERS to reduce the hazards of burns in the event of a defect in the HF surgical equipment NEUTRAL ELECTRODE connection;

8) the choice and application of the specified ACCESSORIES;

9) the procedure(s) for regular checks on the correct function of the EQUIPMENT and ACCESSORIES;

10) identification with which PHYSIOLOGICAL MONITORING UNIT/S the EQUIPMENT is intended to be used;

11) methods by which the visual and auditory ALARMS may be tested by the OPERATOR;

12) the default settings (e.g. ALARM settings, modes, and filter);

13) simple fault finding methods by which the OPERATOR can locate problems if the EQUIPMENT appears not to be functioning correctly;

NOTE This relates to simple OPERATOR difficulties, not to technical malfunctions.

14) the disclosure of the subsequent operation of the EQUIPMENT when the SUPPLY MAINS to the EQUIPMENT is interrupted for more than 30 seconds;

15) the disclosure how ALARM manifestations of TECHNICAL ALARMS may be disabled if sensors, probes, or modules are intentionally disconnected by the OPERATOR;

16) a statement indicating whether or not the EQUIPMENT is suitable for connection to public mains as defined in CISPR 11;

17) adjustment ranges of all PHYSIOLOGICAL ALARM limits (see 51.102.3).

SECTION TWO – ENVIRONMENTAL CONDITIONS

This section of the General Standard applies.

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

This section of the General Standard applies except as follows:

14 Requirements related to classification

14.6 TYPES B, BF AND CF APPLIED PARTS

Addition:

EQUIPMENT shall have TYPE BF and/or CF APPLIED PARTS.

17 Separation

This clause of the general standard applies with the following addition:

aa) TYPE CF and TYPE BF APPLIED PARTS may consist of more than one SINGLE FUNCTION if the requirements of 19.1 and 56.3 for such EQUIPMENT have been met.

*17 h) *Addition:*

1. DEFIBRILLATION-PROOF APPLIED PARTS and/or PATIENT CONNECTIONS shall incorporate a means so that the defibrillator energy delivered to a 100 Ω load is reduced by a maximum of 10 per cent relative to the energy delivered to this load with the EQUIPMENT disconnected.

   Compliance is checked by the following test:

   The test circuit is shown in Fig. 101. The source generator shall have a minimum stored voltage of 5 kV, and the energy delivered to the test assembly shall be 360 J. For this test, the manufacturer's recommended ACCESSORIES such as cables, ELECTRODES and TRANSDUCERS shall be used. The test is applied to one APPLIED PART or PATIENT CONNECTION at a time). The procedure is as follows:

   a. *Connect the APPLIED PART/PATIENT CONNECTION to the test circuit. For connection methods, follow the instructions for defibrillation tests described in particular standards where available and applicable.*
   b. *Charge the capacitor to 5 kV with switch S1 in position A.*
   c. *Discharge the test circuit by actuating the switch S1 to position B, and measure the energy E1 delivered to the defibrillator tester (i.e., 100 Ω load).*
   d. *Remove the EQUIPMENT under test from the test circuit and measure the energy E2 delivered to the 100 Ω load.*
   e. *Verify that the energy E1 is at least 90 per cent of E2.*

Replacement 2nd dash:

– *After defibrillation the EQUIPMENT shall return to the previous operating mode within 30 s (unless otherwise specified in the relevant Particular Standards) without loss of any OPERATOR settings or stored data, and shall continue to perform its intended function as described in the ACCOMPANYING DOCUMENTS.*

Replacement 3rd dash:

– *(Common-mode test) The EQUIPMENT is connected to the test circuit shown in figure 50 of amendment 2 of the General Standard. The test voltage shall be applied to all PATIENT CONNECTIONS of an APPLIED PART connected together and isolated from earth. For EQUIPMENT having more than one APPLIED PART this test shall be repeated for the PATIENT CONNECTIONS of each APPLIED PART while the PATIENT CONNECTIONS of the remaining APPLIED PARTS are connected together and connected to earth.*

Replacement 4th dash:

– *(Differential-mode test) The EQUIPMENT is connected to the test circuit shown in figure 51 of amendment 2 of the General Standard. The test voltage is applied to each PATIENT CONNECTION in turn with all the remaining PATIENT CONNECTIONS of all APPLIED PARTS being connected to earth.*

Replacement 6th dash:

– *The EQUIPMENT shall be energized for this test.*

Replacement last paragraph:

After 30 s recovery time, unless a shorter time is specified by an applicable particular standard, the EQUIPMENT shall resume normal operation in the previous operating mode, without loss of any OPERATOR settings or stored data, and shall continue to perform its intended function as described in the ACCOMPANYING DOCUMENTS.

19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

The clause of the General Standard applies, except as follows:

19.1 General requirements

Replacement:

b) The specified values of the continuous earth leakage current, the enclosure leakage current, the patient leakage current, the patient auxiliary current, the part leakage current, and the total patient leakage current apply in any combination of the following conditions:

Amendment:

e) The PATIENT LEAKAGE CURRENT shall be measured (see Annex KK).

Delete TYPE B APPLIED PARTS

*19.3 Allowable values

Addition

*aa) PATIENT LEAKAGE CURRENT of TYPE BF APPLIED PARTS

PATIENT LEAKAGE CURRENT shall not exceed the values given in Table IV of the General Standard.

The PATIENT LEAKAGE CURRENT of a TYPE BF APPLIED PART shall be measured from and to all PATIENT CONNECTIONS of an APPLIED PART connected together. The measurement shall be carried out with all other PATIENT CONNECTIONS of the remaining APPLIED PARTS:

1) connected together, but not to earth, and

2) connected to earth

Compliance is checked by connecting the EQUIPMENT as shown in Annex KK Figure KK.101 and verifying that the measured currents are below the limits given in Table IV of the General Standard.

*bb) PATIENT LEAKAGE CURRENT of TYPE CF APPLIED PARTS

PATIENT LEAKAGE CURRENT shall not exceed the values given in Table IV of the General Standard.

The PATIENT LEAKAGE CURRENT of TYPE CF APPLIED PARTS shall be measured from and to each PATIENT CONNECTION in turn. The measurement shall be carried out with all other PATIENT CONNECTIONS of the remaining APPLIED PARTS:

1) connected together, but not to earth, and

2) connected to earth

Compliance is checked by connecting the EQUIPMENT as shown in Annex KK Figure KK.102 and verifying that the measured currents are below the limits given in Table IV of the General Standard.

*cc) Total PATIENT LEAKAGE CURRENT of TYPE BF AND CF APPLIED PARTS

Total PATIENT LEAKAGE CURRENT shall not exceed the values given in table 101.