SLOVENSKI STANDARD
SIST EN 60601-2-49:2002

01-junij-2002

Medicinska električna oprema - 2-49. del: Posebne varnostne zahteve za pacientovo večfunkcijsko nadzorovalno opremo (IEC 60601-2-49:2001)

Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment (IEC 60601-2-49:2001)

Medizinische elektrische Geräte - Teil 2-49: Besondere Festlegungen für die Sicherheit von multifunktionalen Patientenüberwachungsgeräten (IEC 60601-2-49:2001)

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Appareils électromédicaux - Partie 2-49: Règles particulières de sécurité des appareils de surveillance multifonction des patients (CEI 60601-2-49:2001)

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Ta slovenski standard je istoveten z: **EN 60601-2-49:2001**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN 60601-2-49:2002 **en**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-49

October 2001

ICS 11.040.55

English version

Medical electrical equipment
Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
(IEC 60601-2-49:2001)

Appareils électromédicaux
Partie 2-49: Règles particulières
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This European Standard was approved by CENELEC on 2001-10-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CENELEC
European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

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Ref. No. EN 60601-2-49:2001 E

Foreword

The text of document 62D/409/FDIS, future edition 1 of IEC 60601-2-49, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-49 on 2001-10-01.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2002-07-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2004-10-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annex ZA is normative and annexes AA, BB, EE, KK and ZB are informative.
Annexes ZA and ZB have been added by CENELEC.

In this standard, the following print types are used:
– requirements, compliance with which can be tested, and definitions: roman type;
– explanations, advice, notes, general statements and exceptions: smaller roman type;
– *test specifications: italic type;*
– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

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Endorsement notice

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The text of the International Standard IEC 60601-2-49:2001 was approved by CENELEC as a European Standard without any modification.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC 60601-1	1988	Medical electrical equipment	EN 60601-1	1990
+ A1	1991	Part 1: General requirements for safety	+ A1	1993
			+ corr. July	1994
+ A2	1995		+ A2	1995
			+ A13	1996
IEC 60601-1-4	1996	Medical electrical equipment	EN 60601-1-4	1996
+ A1	1999	Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems	+ A1	1999

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Annex ZB
(informative)

Other international publications mentioned in this standard with the references of the relevant European publications

Publication	Year	Title	EN/HD	Year
IEC 60513	1994	Fundamental aspects of safety standards for medical electrical equipment	-	-
IEC 60529	1989	Degrees of protection provided by enclosures (IP Code)	EN 60529	1991
			+ corr. May	1993
+ A1	1999		+ A1	2000

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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 3, rue de Varembé Geneva, Switzerland
Telefax: +41 22 919 0300 e-mail: inmail@iec.ch IEC web site http://www.iec.ch

Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE S

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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:

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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.

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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.

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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.

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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).

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

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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:

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"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)

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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

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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

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***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

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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;

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