SLOVENSKI STANDARD

SIST EN 62353:2008

01-april-2008

Medicinska elektriļ na oprema ï Ponavljalni preskus in preskus po popravilu medicinske elektriļ ne opreme (IEC 62353:2007) (IEC 62353:2007)

Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment (IEC 62353:2007)

Medizinische elektrische Geräte - Wiederholungsprüfungen und Prüfung nach Instandsetzung von medizinischen elektrischen Geräten (IEC 62353:2007)

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Appareils électromédicaux - Essai récurrent et essai après réparation d'un appareil électromédical (CEI 62353:2007)

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Ta slovenski standard je istoveten z: EN 62353:2008

ICS:

11.040.01

SIST EN 62353:2008 **en,fr**

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 62353

January 2008

ICS 11.040

English version

Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment

(IEC 62353:2007)

Appareils électromédicaux - Essai récurrent et essai après réparation d'un appareil électromédical (CEI 62353:2007)

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This European Standard was approved by CENELEC on 2007-09-11. 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.

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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, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the 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 62353:2008 E

Foreword

The text of document 62A/564/FDIS, future edition 1 of IEC 62353, prepared by SC 62A, Common aspects of electrical equipment used in medical practice, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 62353 on 2007-09-11.

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)	2008-08-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2010-10-01

In this standard, the following print types are used:

– requirements and definitions: roman 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 USED THROUGHOUT THIS STANDARD THAT HAVE BEEN DEFINED IN CLAUSE 3: IN SMALL CAPITALS.

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:

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– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

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– “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 A.

Annex ZA has been added by CENELEC.

_____

Endorsement notice

The text of the International Standard IEC 62353:2007 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60335	NOTE	Harmonized in EN 60335 series (partly modified).
IEC 60601-1	NOTE	Harmonized as EN 60601-1:2006 (not modified).
IEC 60601-1-1	NOTE	Harmonized as EN 60601-1-1:2001 (not modified).
IEC 60950	NOTE	Harmonized in EN 60950 series (partly modified).
IEC 60950-1	NOTE	Harmonized as EN 60950-1:2006 (modified).

IEC 61010	NOTE	Harmonized in EN 61010 series (partly modified).
IEC 61557-2	NOTE	Harmonized as EN 61557-2:1997 (not modified). IEC 61557-2:2007 has been harmonized as EN 61557-2:2007 (not modified).
IEC 61557-4	NOTE	Harmonized as EN 61557-4:1997 (not modified). IEC 61557-4:2007 has been harmonized as EN 61557-4:2007 (not modified).
IEC 62020	NOTE	Harmonized as EN 62020:1998 (not modified).
ISO 13485	NOTE	Harmonized as EN ISO 13485:2003 (not modified).
ISO 14971	NOTE	Harmonized as EN ISO 14971:2007 (not modified).

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Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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 60364-7-710	-[1)]	Electrical installations of buildings - Part 7-710: Requirements for special installations or locations - Medical locations	-	-
IEC 60417	Data-base	Graphical symbols for use on equipment	-	-
IEC 61010-1	-[1)]	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements	EN 61010-1 + corr. June	2001[2)] 2002
IEC 61010-2-010	-[1)]	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of material	EN 61010-2-010	2003[2)]
IEC 61010-031	-[1)]	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 031: Safety requirements for hand-held probe assemblies for electrical measurement and test	EN 61010-031	2002[2)]
IEC 61140	-[1)]	Protection against electric shock - Common aspects for installation and equipment	EN 61140	2002[2)]
IEC 61557-1	-[1)]	Electrical safety in low voltage distribution systems up to 1 000 V a.c. and 1 500 V d.c. - Equipment for testing, measuring or monitoring of protective measures - Part 1: General requirements	EN 61557-1	2007[2)]

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[1)] Undated reference.

[2)] Valid edition at date of issue.

INTERNATIONAL STANDARD

NORME INTERNATIONALE

IEC
CEI
62353

First edition
Première édition
2007-05

Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment

Appareils électromédicaux – Essai récurrent et essai après réparation d'un appareil électromédical

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Commission Electrotechnique Internationale
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Pour prix, voir catalogue en vigueur

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT – RECURRENT TEST AND TEST AFTER REPAIR OF MEDICAL ELECTRICAL EQUIPMENT

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of 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, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). 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. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International Standard IEC 62353 has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62A/564/FDIS	62A/572/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 2.

In this standard, the following print types are used:

– requirements and definitions: roman 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 USED THROUGHOUT THIS STANDARD THAT HAVE BEEN DEFINED IN CLAUSE 3: IN SMALL CAPITALS.

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 A.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result 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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- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

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MEDICAL ELECTRICAL EQUIPMENT – RECURRENT TEST AND TEST AFTER REPAIR OF MEDICAL ELECTRICAL EQUIPMENT

1 Scope

This International Standard applies to testing of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS, or parts of such equipment or systems, which comply with IEC 60601-1, before PUTTING INTO SERVICE, during MAINTENANCE, INSPECTION, SERVICING and after REPAIR or on occasion of RECURRENT TESTS to assess the safety of such ME EQUIPMENT or ME SYSTEMS or parts thereof. For equipment not built to IEC 60601-1 these requirements may be used taking into account the safety standards for the design and information in the instructions for use of that equipment.

This standard contains tables with allowable values relating to different editions of IEC 60601-1. For the purpose of this standard, the application of measuring methods is independent of the edition according to which the ME EQUIPMENT OR ME SYSTEM is designed.

This standard contains:

– "general requirements", which contain clauses of general concern, and
– "particular requirements", further clauses handling special types of ME EQUIPMENT or ME SYSTEMS and applying in connection with the "General requirements".

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NOTE 1 At this stage, there are no particular requirements.

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This standard is not suitable to assess whether ME EQUIPMENT or ME SYSTEMS or any other equipment comply with the relevant standards for their design.

This standard does not define requirements for REPAIR, exchange of components and MODIFICATION of ME EQUIPMENT or ME SYSTEMS.

NOTE 2 All MAINTENANCE, INSPECTION, SERVICING, and REPAIR done in accordance with MANUFACTURER's instructions maintain the conformity to the standard used for the design of the equipment. Otherwise conformity to applicable requirements have to be assessed and verified.

This standard is also applicable to tests after REPAIR. The testing shall be defined according to the extent of work performed and applicable guidance from the MANUFACTURER.

This standard is not intended to define time intervals for RECURRENT TESTS. If such intervals are not defined by the MANUFACTURER, Annex F may be used to help establish such intervals.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60364-7-710, *Electrical installations of buildings – Part 7-710: Requirements for special installations or locations – Medical locations*

IEC 60417, *Graphical symbols for use on equipment*

IEC 61010-1, *Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements*

IEC 61010-2-010, *Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of materials*

IEC 61010-031, *Safety requirements for electrical equipment for measurement, control and laboratory use – Part 031: Safety requirements for hand-held probe assemblies for electrical measurement and test*

IEC 61140, *Protection against electric shock – Common aspects for installation and equipment*

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IEC 61557-1, *Electrical safety in low voltage distribution systems up to 1000 V a.c. and 1500 V d.c. – Equipment for testing, measuring or monitoring of protective measures – Part 1: General requirements*

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3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

NOTE Some of the definitions have to be different than those in IEC 60601-1, as different measuring methods are used.

3.1
ACCESSIBLE CONDUCTIVE PART
part of the ME EQUIPMENT other than an APPLIED PART, which is accessible to the patient, to the operator in contact with the patient or can come in contact with the patient

NOTE It is necessary that other accessible parts comply with their respective safety requirements.

3.2
ACCESSORY
additional part for use with equipment in order to:

– achieve the intended use,
– adapt it to some special use,
– facilitate its use,
– enhance its performance, or
– enable its functions to be integrated with those of other equipment

[IEC 60601-1:2005, definition 3.3]

3.3
ACCOMPANYING DOCUMENT
document accompanying ME EQUIPMENT, an ME SYSTEM, equipment or an ACCESSORY and containing information for the RESPONSIBLE ORGANIZATION or operator, particularly regarding basic safety and essential performance

[IEC 60601-1:2005, definition 3.4]

3.4
APPLIED PART
part of ME EQUIPMENT that in normal use necessarily comes into physical contact with the patient for ME EQUIPMENT or an ME SYSTEM to perform its function

[IEC 60601-1:2005, definition 3.8]

3.5
APPLIED PART LEAKAGE CURRENT
current flowing from MAINS PARTS and the ACCESSIBLE CONDUCTIVE PARTS of the enclosure to the APPLIED PARTS

3.6
CLASS I
term referring to electrical equipment in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution in that means are provided for accessible parts of metal or internal parts of metal to be protectively earthed

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[IEC 60601-1:2005, definition 3.13]

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3.7
CLASS II
term referring to electrical equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions

NOTE CLASS II ME EQUIPMENT can be provided with a functional earth terminal or a functional earth conductor.

[IEC 60601-1:2005, definition 3.14]

3.8
DETACHABLE POWER SUPPLY CORD
flexible cord intended to be connected to electrical equipment by means of a suitable appliance coupler for mains supply purposes

[IEC 60601-1:2005, definition 3.21]

3.9
EARTH LEAKAGE CURRENT
current flowing from the MAINS PART through or across the insulation into the protective earth conductor

[IEC 60601-1:2005, definition 3.25]

3.10
ELECTRICAL SAFETY
protection within an equipment which limits the effects of electrical current on a patient, user or other individuals in accordance with IEC 60601-1

NOTE Safety is defined as freedom from unacceptable risk (refer to ISO 14971:2007, definition 2.24).

3.11
EQUIPMENT LEAKAGE CURRENT
current flowing from MAINS PARTS to earth via the protective earth conductor and ACCESSIBLE CONDUCTIVE PARTS of the enclosure and APPLIED PARTS

3.12
F-TYPE ISOLATED (FLOATING) APPLIED PART (herein F-TYPE APPLIED PART)
APPLIED PART in which the patient connections are isolated from other parts of the ME EQUIPMENT to such a degree that no current higher than the allowable patient leakage current flows if an unintended voltage originating from an external source is connected to the patient, and thereby applied between the patient connection and earth

NOTE F-TYPE APPLIED PARTS are either TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS.

[IEC 60601-1:2005, definition 3.29]

3.13
FUNCTIONAL CONNECTION
connection, electrical or otherwise, including those intended to transfer signals, data, power or substances

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NOTE Connection to a fixed SUPPLY MAINS socket-outlet, whether single or multiple, is not considered to result in a FUNCTIONAL CONNECTION.

[IEC 60601-1:2005, definition 3.33]

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3.14
INSPECTION
combination of all means for verification and assessment of a status quo

3.15
INTERNAL ELECTRICAL POWER SOURCE
electrical power source for operating equipment that is a part of the equipment and which produces electrical current from some other form of energy

EXAMPLE Chemical, mechanical, solar, or nuclear.

NOTE An INTERNAL ELECTRICAL POWER SOURCE can be inside the principal part of equipment, attached to the outside, or contained in a separate enclosure.

[IEC 60601-1:2005, definition 3.45]

3.16
MAINS PART
electrical circuit that is intended to be connected to the SUPPLY MAINS

NOTE 1 The MAINS PART includes all conductive parts that are not separated from the SUPPLY MAINS by at least one means of protection.

NOTE 2 For the purpose of this definition, the protective earth conductor is not regarded as a part of the MAINS PART.

[IEC 60601-1:2005, definition 3.49]