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

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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 62353:2008 sisaldab Euroopa standardi EN 62353:2008 ingliskeelset teksti.	This Estonian standard EVS-EN 62353:2008 consists of the English text of the European standard EN 62353:2008.
Standard on kinnitatud Eesti Standardikeskuse 20.02.2008 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 20.02.2008 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 25.01.2008.	Date of Availability of the European standard text 25.01.2008.
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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)

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

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.

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

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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:

– “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.

Annex ZA has been added by CENELEC.

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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).

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)]

[1)] Undated reference.

[2)] Valid edition at date of issue.

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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".

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

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*

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*

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]