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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 62353:2015 sisaldab Euroopa standardi EN 62353:2014 ingliskeelset teksti.	This Estonian standard EVS-EN 62353:2015 consists of the English text of the European standard EN 62353:2014.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 31.10.2014.	Date of Availability of the European standard is 31.10.2014.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment (IEC 62353:2014)

Appareils électromédicaux - Essai récurrent et essai après réparation d'un appareil électromédical (CEI 62353:2014)

Medizinische elektrische Geräte - Wiederholungsprüfungen und Prüfung nach Instandsetzung von medizinischen elektrischen Geräten (IEC 62353:2014)

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Foreword

The text of document 62A/942/FDIS, future edition 2 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 approved by CENELEC as EN 62353:2014.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2015-07-09
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2017-10-09

This document supersedes EN 62353:2008.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

Endorsement notice

The text of the International Standard IEC 62353:2014 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 Series	NOTE	Harmonized as EN 60335 Series.
IEC 60950 Series	NOTE	Harmonized as EN 60950 Series.
IEC 60950-1	NOTE	Harmonized as EN 60950-1.
IEC 61010 Series	NOTE	Harmonized as EN 61010 Series.
IEC 61557-2:2007	NOTE	Harmonized as EN 61557-2:2007 (not modified).
IEC 61557-4:2007	NOTE	Harmonized as EN 61557-4:2007 (not modified).
IEC 61557-16 [1)]	NOTE	Harmonized as EN 61557-16 [1)] (not modified).
IEC 62020	NOTE	Harmonized as EN 62020.
ISO 13485:2003	NOTE	Harmonized as EN ISO 13485:2012 (not modified).
ISO 14971:2007	NOTE	Harmonized as EN ISO 14971:2012 (not modified).
IEC 60364-7-710	NOTE	Harmonized as HD 60364-7-710.
IEC 61010-2-010	NOTE	Harmonized as EN 61010-2-010.

[1)] To be published.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu

Publication	Year	Title	EN/HD	Year
IEC 60417-DB	-	Graphical symbols for use on equipment	-	-
IEC 60601-1	1988	Medical electrical equipment - Part 1: General requirements for safety	EN 60601-1 + corr. July	1990 1994
+ A1	1991		+ A1 + A1/corr. July	1993 1994
+ A2	1995		+ A2	1995
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1 + corr. March + corr. May	2006 2010 2014
+A1	2012		+ A1 + A1/corr. July	2013 2014
IEC 61010-1	-	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements	EN 61010-1	-
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	EN 61010-031	-
IEC 61140	-	Protection against electric shock - Common aspects for installation and equipment	EN 61140	-
IEC 61557-1	-	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	-

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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 60601-1:1988 (second edition) and its amendments and IEC 60601-1: 2005 (third edition) and its amendments, 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 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 is not applicable to the assembly of ME SYSTEMS. For assembling ME SYSTEMS see Clause 16 of IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012[1].

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

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 should be assessed and verified, before the tests of this standard are performed.

This standard is also applicable to tests after REPAIR.

IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012 requires that, as part of the RISK MANAGEMENT PROCESS, the MANUFACTURER considers how the safety of ME EQUIPMENT or an ME SYSTEM can be ensured during product lifetime. As part of the risk management process the MANUFACTURER may have identified MAINTENANCE procedures. This includes defining the respective tests for ME EQUIPMENT or for ME SYSTEM.

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[1] This citation refers to IEC 60601-1:2005 as amended by Amendment 1 published in 2012.