

STN	Zdravotnícke elektrické prístroje. Opakované skúšky a skúšky po oprave zdravotníckych elektrických prístrojov.	STN EN 62353 36 4893
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Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 05/15

Obsahuje: EN 62353:2014, IEC 62353:2014

Oznámením tejto normy sa od 09.10.2017 ruší
STN EN 62353 (36 4893) z augusta 2009

120777



Úrad pre normalizáciu, metrológiu a skúšobníctvo SR, odbor SÚTN, 2015
Podľa zákona č. 264/1999 Z. z. v znení neskorších predpisov sa môžu slovenské technické normy rozmnožovať a rozširovať iba so súhlasom Úradu pre normalizáciu, metrológiu a skúšobníctvo SR.

EUROPEAN STANDARD

EN 62353

NORME EUROPÉENNE

EUROPÄISCHE NORM

October 2014

ICS 11.040

Supersedes EN 62353:2008

English Version

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2017-10-09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.

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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

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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	-



IEC 62353

Edition 2.0 2014-09

INTERNATIONAL STANDARD

NORME INTERNATIONALE



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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IEC 62353

Edition 2.0 2014-09

INTERNATIONAL STANDARD

NORME INTERNATIONALE



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

INTERNATIONAL
ELECTROTECHNICAL
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INTERNATIONALE

PRICE CODE **XB**
CODE PRIX

ICS 11.040

ISBN 978-2-8322-1847-1

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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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.

This second edition cancels and replaces the first edition of IEC 62353 published in 2007.

This edition constitutes a technical revision. The principle revisions are:

- a) clarification in 5.3.4.1 that measurements of leakage currents based on test configurations derived from IEC 60601-1 are an allowable alternative method and the inclusion of informative explanation in Annex A;
- b) revision of the PROTECTIVE EARTH RESISTANCE requirements for MEDICAL ELECTRICAL SYSTEMS using multiple socket outlets to take account of IEC 60601-1:2005/AMD1:2012 on the safe allowed values of protective earth resistance of plugged-in equipment;
- c) the inclusion of expected minimum insulation resistance values in Table 2; and
- d) a reordering of the sequence of testing in Annex B.

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

FDIS	Report on voting
62A/942/FDIS	62A/953/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 stability 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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- withdrawn,
- replaced by a revised edition, or
- amended.

NOTE The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

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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/AMD1:2012¹.

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.

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

The MANUFACTURER may have defined necessary measurement settings and methods including performance assurance tests in the instructions for use or other ACCOMPANYING DOCUMENTS. This standard provides consistent test procedures.

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

Testing of the electrical installation, including the SUPPLY MAINS and associated wiring, in medical locations is excluded from this standard. Such tests are covered by IEC 60364-7-710 or national equivalents,

2 Normative references

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.

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*
IEC 60601-1:1988/AMD1:1991
IEC 60601-1:1988/AMD 2:1995

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*²
IEC 60601-1:2005/AMD1:2012

IEC 60417, *Graphical symbols for use on equipment*. Available from: <<http://www.graphical-symbols.info/equipment>>

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

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 1 000 V a.c. and 1 500 V d.c. – Equipment for testing, measuring or monitoring of protective measures – Part 1: General requirements*

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² There exists a consolidated edition 3.1 including IEC 60601-1:2005 and its Amendment 1 (2012).