SVENSK STANDARD SS-EN 62353

Fastställd	Utgåva	Sida	Ansvarig kommitté
2014-12-18	2	1 (1+64)	SEK TK 62

Elektrisk utrustning för medicinskt bruk – Återkommande provning och provning efter reparation

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

Som svensk standard gäller europastandarden EN 62353:2014. Den svenska standarden innehåller den officiella engelska språkversionen av EN 62353:2014.

Nationellt förord

Europastandarden EN 62353:2014

består av:

– **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
– **IEC 62353, Second edition, 2014 - Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment**

utarbetad inom International Electrotechnical Commission, IEC.

Tidigare fastställd svensk standard SS-EN 62353, utgåva 1, 2008, gäller ej fr o m 2017-10-09.

ICS 11.040.00

Denna standard är fastställd av SEK Svensk Elstandard,
som också kan lämna upplysningar om **sakinnehållet** i standarden.
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Standarder underlättar utvecklingen och höjer elsäkerheten

Det finns många fördelar med att ha gemensamma tekniska regler för bl a mätning, säkerhet och provning och för utförande, skötsel och dokumentation av elprodukter och elanläggningar.

Genom att utforma sådana standarder blir säkerhetsfordringar tydliga och utvecklingskostnaderna rimliga samtidigt som marknadens acceptans för produkten eller tjänsten ökar.

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SEK är Sveriges röst i standardiseringsarbetet inom elområdet

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Stora delar av arbetet sker internationellt

Utformningen av standarder sker i allt väsentligt i internationellt och europeiskt samarbete. SEK är svensk nationalkommitté av International Electrotechnical Commission (IEC) och Comité Européen de Normalisation Electrotechnique (CENELEC).

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Arbetet i de tekniska kommittéerna är öppet för alla svenska organisationer, företag, institutioner, myndigheter och statliga verk. Den årliga avgiften för deltagandet och intäkter från försäljning finansierar SEKs standardiseringsverksamhet och medlemsavgift till IEC och CENELEC.

Var med och påverka!

Den som deltar i SEKs tekniska kommittéarbete har möjlighet att påverka framtida standarder och får tidig tillgång till information och dokumentation om utvecklingen inom sitt teknikområde. Arbetet och kontakterna med kollegor, kunder och konkurrenter kan gynnsamt påverka enskilda företags affärsutveckling och bidrar till deltagarnas egen kompetensutveckling.

Du som vill dra nytta av dessa möjligheter är välkommen att kontakta SEKs kansli för mer information.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 62353

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)

This European Standard was approved by CENELEC on 2014-10-09. 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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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

Ref. No. EN 62353:2014 E

SEK Svensk Elstandard

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	-

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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.
2) The formal decisions or agreements of 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 IEC National Committees.
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8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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

- reconfirmed,
- 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.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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.

[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*

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