

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 Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

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

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CONTENTS

FOREWORD.....	5
1 Scope.....	7
2 Normative references	8
3 Terms and definitions	8
4 Requirements	16
4.1 * General requirements	16
4.2 Testing before PUTTING INTO SERVICE, after MODIFICATIONS, and after REPAIR.....	17
4.3 * RECURRENT TEST	18
5 * Tests.....	18
5.1 General.....	18
5.2 Visual INSPECTION	18
5.3 Measurements	19
5.3.1 General	19
5.3.2 Measuring of PROTECTIVE EARTH RESISTANCE	19
5.3.3 * Measurement of insulation resistance (not mandatory)	21
5.3.4 Leakage currents.....	24
5.4 Functional test	31
6 Results of test and evaluation.....	31
6.1 Reporting of results.....	31
6.2 Evaluation.....	32
Annex A (informative) General guidance and rationale.....	33
A.1 Intended audience	33
A.2 Differences between IEC 60601-1 and IEC 62353.....	34
A.3 Rationale	35
Annex B (informative) Sequence of testing	42
Annex C (normative) Requirements for the measurement equipment and for measurement circuits for PROTECTIVE EARTH RESISTANCE and leakage currents.....	44
C.1 Requirements for the measurement equipment	44
C.2 Measurement equipment for measurement of PROTECTIVE EARTH RESISTANCE	44
C.3 Measurement equipment for measurements of EQUIPMENT LEAKAGE CURRENT	45
C.4 Measurement equipment for measurements of APPLIED PART LEAKAGE CURRENT	45
Annex D (informative) PATIENT ENVIRONMENT.....	47
Annex E (normative) Allowable values for leakage currents from IEC 60601-1	48
Annex F (informative) Testing intervals	51
Annex G (informative) Example of test documentation	52
Annex H (informative) Notes on testing ME SYSTEMS.....	53
H.1 Overview	53
H.2 Guidelines for re-testing of an ME SYSTEM.....	53
H.3 Guidelines on ME SYSTEMS from the rationale annex of IEC 60601- 1:2005 /AMD1:2012	54
H.4 Examples of application of MULTIPLE SOCKET-OUTLETS (MSO)	58
Bibliography.....	60
Index of defined terms	61

Figure 1 – Measuring circuit for the measurement of PROTECTIVE EARTH RESISTANCE in ME EQUIPMENT that is disconnected from the SUPPLY MAINS	20
Figure 2 – Measuring circuit for the measurement of PROTECTIVE EARTH RESISTANCE in ME EQUIPMENT or ME SYSTEMS, which for functional reasons cannot be disconnected from the SUPPLY MAINS, or in ME EQUIPMENT or ME SYSTEMS permanently connected to the SUPPLY MAINS	20
Figure 3 – Measuring circuit for the measurement of the insulation resistance between MAINS PART and protective earth for CLASS I ME EQUIPMENT and between MAINS PART and (non-earthed) ACCESSIBLE CONDUCTIVE PARTS for CLASS I and CLASS II ME EQUIPMENT	22
Figure 4 – Measuring circuit for measurement of the insulation resistance between MAINS PART and APPLIED PARTS which make a patient connection for CLASS I or CLASS II ME EQUIPMENT	23
Figure 5 – Measuring circuit for measurement of the insulation resistance between F-TYPE APPLIED PARTS which make a patient connection and protective earth for CLASS I ME EQUIPMENT and between F-TYPE APPLIED PARTS which make a patient connection and (non-earthed) ACCESSIBLE CONDUCTIVE PARTS for CLASS I and CLASS II ME EQUIPMENT	23
Figure 6 – Measuring circuit for the measurement of ME EQUIPMENT leakage current – alternative method	26
Figure 7 – Measuring circuit for the measurement of EQUIPMENT LEAKAGE CURRENT – direct method	27
Figure 8 – Measuring circuit for the measurement EQUIPMENT LEAKAGE CURRENT – differential method	28
Figure 9 – Measuring circuit for the measurement of APPLIED PART LEAKAGE CURRENT “F-TYPE APPLIED PART” – alternative method	29
Figure 10 – Measuring circuit for the measurement of APPLIED PART LEAKAGE CURRENT – MAINS VOLTAGE on F-TYPE APPLIED PART – direct method	30
Figure 11 – Measuring circuit for the measurement of APPLIED PART LEAKAGE CURRENT for equipment with an INTERNAL ELECTRICAL POWER SOURCE – direct method	30
Figure A.1 – CLASS I ME EQUIPMENT with no earthed ACCESSIBLE CONDUCTIVE PARTS of the enclosure	37
Figure A.2 – Plugged-in CLASS I ME EQUIPMENT	37
Figure A.3 – Plugged-in CLASS II ME EQUIPMENT	38
Figure A.4 – Plugged-in CLASS I ME EQUIPMENT with mains on the APPLIED PART	38
Figure A.5 – Plugged-in CLASS II ME EQUIPMENT with mains on the APPLIED PART	39
Figure B.1 – Sequence of testing	42
Figure B.2 – Measurement of LEAKAGE CURRENTS (non-PERMANENTLY INSTALLED CLASS I ME EQUIPMENT)	43
Figure C.1 – Example of a measuring device and its frequency characteristics	46
Figure D.1 – Example of PATIENT ENVIRONMENT	47
Figure G.1 – Example of test documentation	52
Figure H.1 – Example of the construction of a MULTIPLE SOCKET-OUTLET (MSO) (accessible only with the use of a tool)	58
Figure H.2 – Examples of application of MULTIPLE SOCKET-OUTLETS (MSO)	59
Table 1 – Legends of symbols	21
Table 2 – Insulation resistance values	24
Table 3 – Allowable values for leakage currents	31
Table A.1 – Addressees and their possible interest in this standard	33
Table A.2 – Reasons for choosing different measuring methods	40

Table E.1 – Allowable values for continuous leakage currents from IEC 60601-1:1988	48
Table E.2 – Allowable values for TOUCH CURRENTS, EARTH LEAKAGE CURRENTS, PATIENT LEAKAGE CURRENTS and patient auxiliary currents under NORMAL CONDITION and SINGLE FAULT CONDITION from IEC 60601-1:2005.....	49
Table E.3 – Allowable values for PATIENT LEAKAGE CURRENTS under the special test conditions identified in 8.7.4.7 of IEC 60601-1:2005	50
Table H.1 – Some examples of ME SYSTEMS for illustration	56

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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

- 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.

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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*

3 Terms and definitions

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

NOTE Some of the definitions are necessarily different from those in IEC 60601-1, as different measuring methods are used.

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