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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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International Electrotechnical Commission
Международная Электротехническая Комиссия

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CONTENTS

FOREWORD 4

1 Scope 6
2 Normative references 7
3 Terms and definitions 7
4 Requirements 14
4.1 * General requirements 14
4.2 Testing before PUTTING INTO SERVICE, after MODIFICATIONS, and after REPAIR 15
4.3 * RECURRENT TEST 16
5 * Tests 16
5.1 General 16
5.2 Visual INSPECTION 16
5.3 Measurements 17
5.4 Functional test 29
6 Results of test and evaluation 30
6.1 Reporting of results 30
6.2 Evaluation 30

Annex A (informative) General guidance and rationale 31
Annex B (informative) Sequence of testing 38
Annex C (normative) Requirements for the measurement equipment and for measurement circuits for PROTECTIVE EARTH RESISTANCE and leakage currents 41
Annex D (informative) PATIENT ENVIRONMENT 44
Annex E (informative) Allowable values for leakage currents from IEC 60601-1 45
Annex F (informative) Testing intervals 48
Annex G (informative) Example of test documentation 49

Bibliography 50

Index of defined terms 51

Figure 1 – Measuring circuit for the measurement of PROTECTIVE EARTH RESISTANCE in ME EQUIPMENT that is disconnected from the SUPPLY MAINS 18
Figure 2 – Measuring circuit for the measurement of PROTECTIVE EARTH RESISTANCE in ME EQUIPMENT or ME SYSTEM, which for functional reasons cannot be disconnected from SUPPLY MAINS, or in ME EQUIPMENT or ME SYSTEM permanently connected to mains 19
Figure 3 – Measuring circuit for the measurement of EQUIPMENT LEAKAGE CURRENT – alternative method 22
Figure 4 – Measuring circuit for the measurement of EQUIPMENT LEAKAGE CURRENT– direct method 23
Figure 5 – Measuring circuit for the measurement EQUIPMENT LEAKAGE CURRENT – differential method 24

Figure 6 – Measuring circuit for the measurement of APPLIED PART LEAKAGE CURRENT "F-TYPE APPLIED PART" – alternative method 25

Figure 7 – Measuring circuit for the measurement of APPLIED PART LEAKAGE CURRENT – MAINS VOLTAGE on F-TYPE APPLIED PART – direct method 26

Figure 8 – Measuring circuit for the measurement of APPLIED PART LEAKAGE CURRENT for equipment with an INTERNAL ELECTRICAL POWER SOURCE – direct method 26

Figure 9 – Measuring circuit for the measurement of the insulation resistance between MAINS PART and protective earth for CLASS I equipment and between MAINS PART and (non-earthed) ACCESSIBLE CONDUCTIVE PARTS for CLASS I and CLASS II equipment 28

Figure 10 – Measuring circuit for measurement of the insulation resistance between MAINS PART and APPLIED PARTS which make a patient connection 28

Figure 11 – Measuring circuit for measurement of the insulation resistance between F-TYPE APPLIED PARTS which make a patient connection and protective earth for CLASS I equipment and between F-TYPE APPLIED PARTS which make a patient connection and (non-earthed) ACCESSIBLE CONDUCTIVE PARTS for CLASS I and CLASS II equipment 29

Figure B.1 – Sequence of testing 38

Figure B.2 – Measurement of leakage currents (CLASS I ME EQUIPMENT) 39

Figure B.3 – Measurement of leakage currents (CLASS II ME EQUIPMENT and ACCESSIBLE CONDUCTIVE PARTS of CLASS I ME EQUIPMENT, which are not connected to protective earth) 40

Figure C.1 – Example of a measuring device and its frequency characteristics 43

Figure D.1 – Example of PATIENT ENVIRONMENT 44

Figure G.1 – Example of test documentation 49

Table 1 – Legends of symbols 20

Table 2 – Allowable values for leakage currents 27

Table A.1 – Addressees and their possible interest in this standard 31

Table A.2 – Reasons for choosing different measuring methods 35

Table E.1 – Allowable values for continuous leakage currents from IEC 60601-1:1988 45

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 46

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 47

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.

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

FDIS	Report on voting
62A/564/FDIS	62A/572/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 maintenance result 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.

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]