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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

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.
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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]

3.3
ACCOMPANYING DOCUMENT
document accompanying ME EQUIPMENT, an ME SYSTEM, equipment or an ACCESSORY and containing information for the RESPONSIBLE ORGANIZATION or operator, particularly regarding basic safety and essential performance

[IEC 60601-1:2005, definition 3.4]

3.4
APPLIED PART
part of ME EQUIPMENT that in normal use necessarily comes into physical contact with the patient for ME EQUIPMENT or an ME SYSTEM to perform its function

[IEC 60601-1:2005, definition 3.8]

3.5
APPLIED PART LEAKAGE CURRENT
current flowing from MAINS PARTS and the ACCESSIBLE CONDUCTIVE PARTS of the enclosure to the APPLIED PARTS

3.6
CLASS I
term referring to electrical equipment in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution in that means are provided for accessible parts of metal or internal parts of metal to be protectively earthed

[IEC 60601-1:2005, definition 3.13]

3.7
CLASS II
term referring to electrical equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions

NOTE CLASS II ME EQUIPMENT can be provided with a functional earth terminal or a functional earth conductor.

[IEC 60601-1:2005, definition 3.14]

3.8
DETACHABLE POWER SUPPLY CORD
flexible cord intended to be connected to electrical equipment by means of a suitable appliance coupler for mains supply purposes

[IEC 60601-1:2005, definition 3.21]

3.9
EARTH LEAKAGE CURRENT
current flowing from the MAINS PART through or across the insulation into the protective earth conductor

[IEC 60601-1:2005, definition 3.25]

3.10
ELECTRICAL SAFETY
protection within an equipment which limits the effects of electrical current on a patient, user or other individuals in accordance with IEC 60601-1

NOTE Safety is defined as freedom from unacceptable risk (refer to ISO 14971:2007, definition 2.24).

3.11
EQUIPMENT LEAKAGE CURRENT
current flowing from MAINS PARTS to earth via the protective earth conductor and ACCESSIBLE CONDUCTIVE PARTS of the enclosure and APPLIED PARTS

3.12
F-TYPE ISOLATED (FLOATING) APPLIED PART (herein F-TYPE APPLIED PART)
APPLIED PART in which the patient connections are isolated from other parts of the ME EQUIPMENT to such a degree that no current higher than the allowable patient leakage current flows if an unintended voltage originating from an external source is connected to the patient, and thereby applied between the patient connection and earth

NOTE F-TYPE APPLIED PARTS are either TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS.

[IEC 60601-1:2005, definition 3.29]

3.13
FUNCTIONAL CONNECTION
connection, electrical or otherwise, including those intended to transfer signals, data, power or substances

NOTE Connection to a fixed SUPPLY MAINS socket-outlet, whether single or multiple, is not considered to result in a FUNCTIONAL CONNECTION.

[IEC 60601-1:2005, definition 3.33]

3.14
INSPECTION
combination of all means for verification and assessment of a status quo

3.15
INTERNAL ELECTRICAL POWER SOURCE
electrical power source for operating equipment that is a part of the equipment and which produces electrical current from some other form of energy

EXAMPLE Chemical, mechanical, solar, or nuclear.

NOTE An INTERNAL ELECTRICAL POWER SOURCE can be inside the principal part of equipment, attached to the outside, or contained in a separate enclosure.

[IEC 60601-1:2005, definition 3.45]

3.16
MAINS PART
electrical circuit that is intended to be connected to the SUPPLY MAINS

NOTE 1 The MAINS PART includes all conductive parts that are not separated from the SUPPLY MAINS by at least one means of protection.

NOTE 2 For the purpose of this definition, the protective earth conductor is not regarded as a part of the MAINS PART.

[IEC 60601-1:2005, definition 3.49]

3.17
MAINS PLUG
part, integral with or intended to be attached to a POWER SUPPLY CORD of electrical equipment, to be inserted into a mains socket-outlet

[IEC 60601-1:2005, definition 3.50]

3.18
MAINS VOLTAGE
voltage of a SUPPLY MAINS between two line conductors of a polyphase system or voltage between the line conductor and the neutral conductor of a single-phase system

[IEC 60601-1:2005, definition 3.54]

3.19
MAINTENANCE
combination of all technical and administrative means, including supervising ones, to keep or restore a unit in working condition

3.20
MANUFACTURER
natural or legal person with responsibility for the design, manufacture, packaging, or labelling of ME EQUIPMENT, assembling an ME SYSTEM, or adapting ME EQUIPMENT or an ME SYSTEM, regardless of whether these operations are performed by that person or on that person's behalf by a third party

NOTE 1 ISO 13485 defines "labelling" as written, printed or graphic matter

– affixed to a medical device or any of its containers or wrappers, or

– accompanying a medical device,

related to identification, technical description, and use of the medical device, but excluding shipping documents. In this standard, that material is described as markings and ACCOMPANYING DOCUMENTS.

NOTE 2 "Adapting" includes making substantial MODIFICATIONS to ME EQUIPMENT or an ME SYSTEM already in use.

NOTE 3 In some jurisdictions, the RESPONSIBLE ORGANIZATION can be considered a MANUFACTURER when involved in the activities described.

NOTE 4 Adapted from ISO 14971:2007, definition 2.8.

[IEC 60601-1:2005, definition 3.55]

3.21
MEDICAL ELECTRICAL EQUIPMENT
ME EQUIPMENT
electrical equipment having an APPLIED PART or transferring energy to or from the patient or detecting such energy transfer to or from the patient and which is:

a) provided with not more than one connection to a particular SUPPLY MAINS, and

b) intended by its MANUFACTURER to be used:

1) in the diagnosis, treatment, or monitoring of a patient, or

2) for compensation or alleviation of disease, injury or disability

NOTE 1 ME EQUIPMENT includes those ACCESSORIES as defined by the MANUFACTURER that are necessary to enable the normal use of the ME EQUIPMENT.

NOTE 2 Not all electrical equipment used in medical practice falls within this definition (e.g. *in vitro* diagnostic equipment).

NOTE 3 The implantable parts of active implantable medical devices can fall within this definition, but they are excluded from the scope of IEC 60601-1.

[IEC 60601-1:2005, definition 3.63]

3.22
MEDICAL ELECTRICAL SYSTEM
ME SYSTEM
combination, as specified by its MANUFACTURER, of items of equipment, at least one of which is ME EQUIPMENT to be inter-connected by FUNCTIONAL CONNECTION or by use of a MULTIPLE SOCKET-OUTLET

NOTE 1 Equipment, when mentioned in this standard, should be taken to include ME EQUIPMENT.

NOTE 2 ME SYSTEM includes those ACCESSORIES as defined by the MANUFACTURER that are necessary to enable the normal use of the ME SYSTEM.

[IEC 60601-1:2005, definition 3.64]

3.23
MODIFICATION
changing constructional or functional features of ME EQUIPMENT or an ME SYSTEM in a way not described in its ACCOMPANYING DOCUMENTS

NOTE This definition may not be confused with "change of ACCESSORIES" because this means changing of ME EQUIPMENT or ME SYSTEMS in a way described in its ACCOMPANYING DOCUMENTS.

3.24
MULTIPLE SOCKET-OUTLET
MSO
one or more socket-outlets intended to be connected to, or integral with, flexible cables or cords or ME EQUIPMENT for SUPPLY MAINS or equivalent voltage

NOTE A MULTIPLE SOCKET-OUTLET can be a separate item or an integral part of equipment.

[IEC 60601-1:2005, definition 3.67]

3.25
NON-DETACHABLE POWER SUPPLY CORD
POWER SUPPLY CORD fixed to equipment

3.26
NORMAL CONDITION
condition in which all means provided for protection against hazards are intact

[IEC 60601-1:2005, definition 3.70]

3.27
PATIENT ENVIRONMENT
any volume in which intentional or unintentional contact can occur between a patient and parts of the ME EQUIPMENT or ME SYSTEM or between a patient and other persons touching parts of the ME EQUIPMENT or ME SYSTEM

NOTE It is difficult to define dimensions for the volume in which diagnosis, monitoring or treatment occurs. The dimensions for the PATIENT ENVIRONMENT given in Figure D.1 have been justified in practice.

[IEC 60601-1:2005, definition 3.79]

3.28
PATIENT LEAKAGE CURRENT
current:
– flowing from the patient connections via the patient to earth, or

– originating from the unintended appearance of a voltage from an external source on the patient and flowing from the patient via the patient connections of an F-TYPE APPLIED PART to earth

[IEC 60601-1:2005, definition 3.80]

3.29
PERMANENTLY INSTALLED
term meaning electrically connected to the SUPPLY MAINS by means of a permanent connection that can only be detached by the use of a tool

[IEC 60601-1:2005, definition 3.84]

3.30
POWER SUPPLY CORD
flexible cord, fixed to or assembled with electrical equipment for connection to SUPPLY MAINS

[IEC 60601-12005, definition 3.87]

3.31
PROTECTIVE EARTH RESISTANCE
resistance between any ACCESSIBLE CONDUCTIVE PART, which has to be connected for safety purposes to the protective earth terminal, and the

– protective connector of the MAINS PLUG, or
– protective connector of the appliance inlet, or
– protective conductor permanently connected to the SUPPLY MAINS

Resistance between protective connectors at each end of a DETACHABLE POWER SUPPLY CORD

3.32
PUTTING INTO SERVICE
first use of the ME EQUIPMENT or ME SYSTEM after setting up at the RESPONSIBLE ORGANIZATION

NOTE This will be the first application of RECURRENT TESTS.

3.33
RECURRENT TEST
test, at a defined time interval, carried out for the assessment of safety

3.34
REFERENCE VALUE
value documented for the assessment of subsequent measurements

3.35
REPAIR
means for reconstitution of a defined condition