

BS EN 62353:2014



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

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National foreword

This British Standard is the UK implementation of EN 62353:2014. It is identical to IEC 62353:2014. It supersedes BS EN 62353:2008, which will be withdrawn on 9 October 2017.

The UK committee voted against the first edition of this standard, however, the issues raised previously have now been resolved in this edition.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/1, Common aspects of Electrical Equipment used in Medical Practice.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

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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.

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

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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 (dop) 2015-07-09
implemented at national level by
publication of an identical national
standard or by endorsement
- latest date by which the national (dow) 2017-10-09
standards conflicting with the
document have to be withdrawn

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

<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	-

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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).

3.1**ACCESSIBLE CONDUCTIVE PART**

an electrically conductive part of the ME EQUIPMENT other than an APPLIED PART, which is accessible to the patient or to the operator in contact with the patient or can come in contact with the patient

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

[SOURCE: IEC 60601-1:2005, 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

[SOURCE: IEC 60601-1:2005, 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

[SOURCE: IEC 60601-1:2005, 3.8, modified – The notes in the original definition have been deleted because they were only internally relevant to the source document.]

3.5**APPLIED PART LEAKAGE CURRENT**

current flowing between an F-TYPE APPLIED PART and all of the following as applicable:

- MAIN PARTS and
- ACCESSIBLE CONDUCTIVE PARTS of the enclosure;

caused by an external voltage on the F-TYPE APPLIED PART.

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

[SOURCE: IEC 60601-1:2005, 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 1 to entry: CLASS II ME EQUIPMENT can be provided with a functional earth terminal or a functional earth conductor.

[SOURCE: IEC 60601-1:2005, 3.14]

3.8

CONFIGURATION

term that refers to software settings or hardware settings of ME EQUIPMENT, or the arrangement and interconnection of ME EQUIPMENT and any other equipment that form an ME SYSTEM, that are appropriate for an intended clinical application

3.9

DETACHABLE POWER SUPPLY CORD

flexible cord intended to be connected to electrical equipment by means of a suitable appliance coupler for mains supply purposes

[SOURCE: IEC 60601-1:2005, 3.21]

3.10

EARTH LEAKAGE CURRENT

current flowing from the MAINS PART through or across the insulation into the PROTECTIVE EARTH CONDUCTOR

[SOURCE: IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012, 3.25, modified – Reference to the functional earth connection removed.]

3.11

ELECTRICAL SAFETY

status of protective measures within an equipment/system designed and produced in accordance with IEC 60601-1 which limit the effects of electrical current on a patient, user or other individuals in accordance with this standard

Note 1 to entry: Safety is defined as freedom from unacceptable risk (refer to ISO 14971:2007, definition 2.24).

3.12

EQUIPMENT LEAKAGE CURRENT

total current flowing from MAINS PARTS to earth via

- a) the PROTECTIVE EARTH CONDUCTOR and ACCESSIBLE CONDUCTIVE PARTS of the enclosure and APPLIED PARTS (differential and alternative method), or
- b) the ACCESSIBLE CONDUCTIVE PARTS of the enclosure and APPLIED PARTS (direct method)

3.13

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 1 to entry: F-TYPE APPLIED PARTS are either TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS.

[SOURCE: IEC 60601-1:2005, 3.29]

3.14

FUNCTIONAL CONNECTION

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

Note 1 to entry: Connection to a fixed SUPPLY MAINS socket-outlet, whether single or multiple, is not considered to result in a FUNCTIONAL CONNECTION.

[SOURCE: IEC 60601-1:2005, 3.33]

3.15

INSPECTION

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

3.16

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

[SOURCE: IEC 60601-1:2005, 3.45]

3.17

LINE-TO-EARTH VOLTAGE

voltage between a line conductor and earth/ground.

[SOURCE: IEC 60050-195:1998, 195-05-03, modified – Replaced "reference earth at a given point of an electrical circuit" with "earth/ground".]

3.18

MAINS PART

part of electrical equipment forming a circuit that is intended to be connected to the SUPPLY MAINS

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

Note 2 to entry: For the purpose of this definition, the PROTECTIVE EARTH CONDUCTOR is not regarded as a part of the MAINS PART.

[SOURCE: IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012, 3.49]

3.19

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

[SOURCE: IEC 60601-1:2005, 3.50, modified – A note referring to IEC 60083 and IEC 60309-1 has been deleted.]

3.20

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

[SOURCE: IEC 60601-1:2005, 3.54]

3.21**MAINTENANCE**

combination of all technical and administrative means, including supervisory ones, to keep ME EQUIPMENT or an ME SYSTEM in a normal working condition or restored to normal working condition

3.22**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 to entry: ISO 13485 [9]³ 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 to entry: "Adapting" includes making substantial MODIFICATIONS to ME EQUIPMENT or an ME SYSTEM already in use.

Note 3 to entry: In some jurisdictions, the RESPONSIBLE ORGANIZATION can be considered a MANUFACTURER when involved in the activities described.

Note 4 to entry: Adapted from ISO 14971:2007 [10], definition 2.8.

[SOURCE: IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012, 3.55]

3.23**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:
 - in the diagnosis, treatment, or monitoring of a patient, or
 - for compensation or alleviation of disease, injury or disability

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

Note 2 to entry: Not all electrical equipment used in medical practice falls within this definition (e.g. some *in vitro* diagnostic equipment).

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

[SOURCE: IEC 60601-1:2005, 3.63, modified – Two notes in the original definition have been deleted because they were only internally relevant to the source document.]

3.24**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

³ Numbers in square brackets refer to the Bibliography.

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

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

[SOURCE: IEC 60601-1:2005, 3.64, modified – A second note to entry has been added.]

3.25

MODIFICATION

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

Note 1 to entry: This definition should not be confused with “change of ACCESSORIES” because the latter means changing of ME EQUIPMENT or ME SYSTEMS in a way described in its ACCOMPANYING DOCUMENTS.

3.26

MULTIPLE SOCKET-OUTLET

MSO

one or more socket-outlets intended to be connected to, or integral with, flexible cables, cords or ME EQUIPMENT providing SUPPLY MAINS or equivalent voltage

Note 1 to entry: A MULTIPLE SOCKET-OUTLET can be a separate item or an integral part of equipment.

[SOURCE: IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012, 3.67]

3.27

NON-DETACHABLE POWER SUPPLY CORD

POWER SUPPLY CORD fixed to equipment

3.28

NORMAL CONDITION

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

[SOURCE: IEC 60601-1:2005, 3.70]

3.29

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 1 to entry: 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.

[SOURCE: IEC 60601-1:2005, 3.79, modified – A note to entry has been added.]

3.30

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

[SOURCE: IEC 60601-1:2005, 3.80]

3.31

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

[SOURCE: IEC 60601-1:2005, 3.84]

3.32

POWER SUPPLY CORD

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

[SOURCE: IEC 60601-1:2005, 3.87]

3.33

PROTECTIVE EARTH CONDUCTOR

conductor to be connected between the PROTECTIVE EARTH TERMINAL and an external protective earthing system

[SOURCE: IEC 60601-1:2005, 3.93]

3.34

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

3.35

PROTECTIVE EARTH TERMINAL

terminal connected to conductive parts of CLASS I equipment for safety purposes. This terminal is intended to be connected to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR

[SOURCE: IEC 60601-1:2005, 3.95]

3.36

PUTTING INTO SERVICE

first use of the ME EQUIPMENT or ME SYSTEM after setting up at the RESPONSIBLE ORGANIZATION

Note 1 to entry: This may be the first application of RECURRENT TESTS.

3.37

RECURRENT TEST

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

3.38

REFERENCE VALUE

value documented for the assessment of subsequent measurements

Note 1 to entry: These values are likely to be determined by tests carried out at PUTTING INTO SERVICE.

3.39

REPAIR

means for restoring to a safe, functional, NORMAL CONDITION.

3.40

RESPONSIBLE ORGANIZATION

entity accountable for the use and MAINTENANCE of an ME EQUIPMENT or an ME SYSTEM

Note 1 to entry: The accountable entity can be, for example, a hospital, an individual clinician or a layperson. In home use applications, the patient, operator and RESPONSIBLE ORGANIZATION can be one and the same person.

Note 2 to entry: Education and training are included in “use”.

[SOURCE: IEC 60601-1:2005, 3.101]

3.41

SERVICING

combination of all means for maintaining the ME EQUIPMENT or ME SYSTEM within requirements of the MANUFACTURER

3.42

SINGLE FAULT CONDITION

condition of ME EQUIPMENT in which a single means for reducing a risk is defective or a single abnormal condition is present

[SOURCE: IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012, 3.116]

3.43

SUPPLY MAINS

source of electrical energy not forming part of ME EQUIPMENT or an ME SYSTEM

Note 1 to entry: This also includes battery systems and converter systems in ambulances and the like.

[SOURCE: IEC 60601-1:2005, 3.120]

3.44

TOUCH CURRENT

leakage current flowing from the enclosure or from parts thereof, excluding patient connections, accessible to any operator or patient in normal use, through an external path other than the PROTECTIVE EARTH CONDUCTOR, to earth or to another part of the enclosure

Note 1 to entry: The meaning of this term is the same as that of “ENCLOSURE LEAKAGE CURRENT” in the first and second editions of IEC 60601-1. The term has been changed to align with IEC 60950-1 [3] and to reflect the fact that the measurement now applies also to parts that are normally protectively earthed.

[SOURCE: IEC 60601-1:2005, 3.129]

3.45

TYPE B APPLIED PART

APPLIED PART complying with the specified requirements of IEC 60601-1 to provide protection against electric shock, particularly regarding allowable PATIENT LEAKAGE CURRENT and patient auxiliary current

Note 1 to entry: A TYPE B APPLIED PART is marked with symbol IEC 60417-5840 (2002-10) () or if classified as defibrillation-proof, with symbol IEC 60417-5841 (2002-10) ().

Note 2 to entry: TYPE B APPLIED PARTS are not suitable for direct cardiac application.

[SOURCE: IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012, 3.132, modified – The Note 1 to entry has been modified to make specific reference to the contents of the symbols for an APPLIED PART and a defibrillation-proof APPLIED PART. Note 3 to entry has been deleted.]

3.46

TYPE BF APPLIED PART

F-TYPE APPLIED PART complying with the specified requirements of IEC 60601-1 to provide a higher degree of protection against electric shock than that provided by TYPE B APPLIED PARTS

Note 1 to entry: A TYPE BF APPLIED PART is marked with symbol IEC 60417-5333 (2002-10) () or if classified as defibrillation-proof, with symbol 60417-5334 (2002-10) ().

Note 2 to entry: TYPE BF APPLIED PARTS are not suitable for direct cardiac application.

[SOURCE: IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012, 3.133, modified – The Note 1 to entry has been modified to make specific reference to the contents of the symbols for a TYPE BF APPLIED PART and a defibrillation-proof TYPE BF APPLIED PART". Note 3 to entry has been deleted.]

3.47

TYPE CF APPLIED PART

F-TYPE APPLIED PART complying with the specified requirements of IEC 60601-1 to provide a higher degree of protection against electric shock than that provided by TYPE BF APPLIED PARTS

Note 1 to entry: A TYPE CF APPLIED PART is marked with symbol IEC 60417-5335 (2002-10) () or if classified as defibrillation-proof, with symbol 60417-5336 (2002-10) ().

[SOURCE: IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012, 3.134, modified – The Note 1 to entry has been modified to make specific reference to the contents of the symbols for an F-TYPE APPLIED PART and a defibrillation-proof F-TYPE APPLIED PART". Note 2 to entry and Note 3 to entry have been deleted.]

4 Requirements

4.1 * General requirements

The following requirements apply to:

- tests before PUTTING INTO SERVICE,
- RECURRENT TESTS, and
- tests after REPAIR.

The extent of testing shall ensure there is enough information to make an assessment of the safety of the ME EQUIPMENT or ME SYSTEMS.

Information provided by the MANUFACTURER shall be taken into account (see also 7.9.2.13 of IEC 60601-1: 2005).

The RESPONSIBLE ORGANISATION may omit certain tests based on MANUFACTURERS' written information or ACCOMPANYING DOCUMENTS.

For ME SYSTEMS, the responsible party who has assembled the system shall define the necessary measurement settings and methods (see Annex H).

If no requirements for SERVICING are established by the MANUFACTURER, a RESPONSIBLE ORGANIZATION having appropriate expertise shall establish requirements for SERVICING. Appropriate expertise includes but is not limited to knowledge and experience with the relevant design standards such as IEC 60601-1 including risk management, IEC 60950 [2], IEC 61010 [4] and local regulations.

NOTE A RESPONSIBLE ORGANISATION having appropriate expertise can also take responsibility for modifying MANUFACTURER'S proposals based on local conditions of use and risk assessment.

The tests as described in Clause 5 are the basis to define the extent of testing of ME EQUIPMENT or ME SYSTEMS designed and built in compliance with IEC 60601-1.

Competent personnel shall perform these tests. Competence shall include training on the subject, knowledge, experience and acquaintance with the relevant technologies, design standards and local regulations. The personnel assessing the safety shall be able to recognize possible consequences and risks arising from non-conforming equipment.

Each individual equipment of an ME SYSTEM which can be connected/disconnected from SUPPLY MAINS without the use of a tool, shall be tested individually. Additionally the ME SYSTEM as a whole shall be tested to avoid a situation where aging of individual equipment can result in unacceptable values (see Annex H).

An ME SYSTEM that is connected with a MULTIPLE SOCKET-OUTLET to SUPPLY MAINS shall be treated during the tests like a single item of equipment.

If the ME SYSTEM, or a part of it, is connected to SUPPLY MAINS via a separating transformer, the transformer shall be included in the measurements.

In ME SYSTEMS, where more than one ME EQUIPMENT are interconnected by data cables or other means, e.g. by electrically conducting mountings or cooling water pipes, the testing of PROTECTIVE EARTH RESISTANCE shall be performed on every single equipment.

When equipment combined into an ME SYSTEM by FUNCTIONAL CONNECTION, cannot be tested separately for technical reasons, then the complete ME SYSTEM shall be tested.

ACCESSORIES of the ME EQUIPMENT, which can affect the safety of the equipment under test or the results of the measurements, shall be included in the tests. ACCESSORIES included in the tests shall be documented.

DETACHABLE POWER SUPPLY CORDS that are available and expected to be used with ME EQUIPMENT or ME SYSTEM, shall be inspected and the PROTECTIVE EARTH RESISTANCE shall be measured according to 5.3.2.

All tests shall be performed in such manner that no hazardous situations arise for testing personnel, patients or other individuals.

If not otherwise stated, all currents are the r.m.s. values.

4.2 Testing before PUTTING INTO SERVICE, after MODIFICATIONS, and after REPAIR

The test methods of this standard can be used:

- by the MANUFACTURER for final testing, and
- for testing before PUTTING INTO SERVICE.

NOTE 1 Results of these measurements are the REFERENCE VALUE and can be documented together with the measuring method, as a reference for future measurements.

NOTE 2 If provided within the MANUFACTURER'S ACCOMPANYING DOCUMENTS, final production testing can replace on-site testing before PUTTING INTO SERVICE when it is acceptable to the RESPONSIBLE ORGANIZATION.

After REPAIR of ME EQUIPMENT or ME SYSTEMS, the safety status needs to be verified.

NOTE 3 This can be done by using tests listed in Clause 5.

After any REPAIR and/or upgrade of the ME EQUIPMENT in accordance with the MANUFACTURER's instructions, the equipment shall be assessed to the requirements of this standard prior to returning to service.

After any REPAIR and/or MODIFICATION of the ME EQUIPMENT conducted not in accordance with MANUFACTURER's instructions, the changes to the equipment shall be assessed with respect to

the applicable design standards, and to the requirements of this standard prior to returning to service.

The extent of testing according to this standard shall take into account the nature of the REPAIR or MODIFICATION. The testing shall be defined according to the extent of work performed and applicable guidance from the MANUFACTURER.

4.3 * RECURRENT TEST

The applicable tests as listed in Clause 5 shall be used for the RECURRENT TEST.

The values found in these tests shall be documented together with the measuring method and shall be assessed. The values measured shall not exceed the acceptable limit as defined in Table 3 or the tables in Annex E.

NOTE Previously measured values (REFERENCE VALUES) can be taken into consideration when assessing the ELECTRICAL SAFETY of the ME EQUIPMENT or the ME SYSTEM.

ME SYSTEMS shall be visually inspected to determine whether the ME SYSTEM CONFIGURATION is still the same as at the time of the last INSPECTION, or whether any equipment making up the ME SYSTEM has been exchanged, added or removed.

Such changes shall be documented, as well as any changes to the hardware CONFIGURATION of the ME SYSTEM, and will void the validity of previous REFERENCE VALUES. Measurement results/values of leakage currents measured after changes of the ME SYSTEM shall be documented as REFERENCE VALUES.

5 * Tests

5.1 General

Prior to testing, the ACCOMPANYING DOCUMENTS shall be consulted to identify the MANUFACTURER'S MAINTENANCE recommendations including any special conditions and precautions that shall be taken into account.

NOTE The recommended sequence of the tests to be performed is defined in Figure B.1.

The tests may be performed at the ambient temperature, humidity, atmospheric pressure and MAINS VOLTAGE as present at the site of testing.

5.2 Visual INSPECTION

Covers and housings shall be opened only:

- if required in the ACCOMPANYING DOCUMENT of the ME EQUIPMENT or ME SYSTEM; or
- if there is an indication of inadequate safety.

Special attention shall be paid to the following:

- safety related marking, labels and labeling are legible and complete;
- the integrity of mechanical parts;
- any damage or contamination e.g. any evidence of spillage;
- assess the relevant ACCESSORIES together with the ME EQUIPMENT or ME SYSTEM (e.g. detachable or fixed POWER SUPPLY CORDS, patient leads, tubing); and
- the required documentation is available and reflects the current revision and/or CONFIGURATION of the ME EQUIPMENT or ME SYSTEM.