BS EN 62353:2014

BSI Standards Publication

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 It supersedes BS EN 62353:2008, which will be withdrawn on 9 October 2017.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.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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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)

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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 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• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2017-10-09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

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.

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[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.

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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 equipmentt

[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.

After testing, REPAIR or adjustment, check that the ME EQUIPMENT or ME SYSTEM is restored to the conditions necessary for intended use before being returned into service.

5.3 Measurements

5.3.1 General

For requirements for the measuring device, see Annex C.

Before testing, the ME EQUIPMENT or ME SYSTEM shall, if possible, be disconnected from the SUPPLY MAINS. If not possible, special measures shall be taken to prevent hazards to the personnel performing the tests/ measurements and other individuals who might be affected.

Connection lines such as data lines or functional earth conductors may appear to act like protective earth connections. Such additional, but unintentional earth connections can lead to incorrect measurements and shall be taken into account during tests.

Cables and cords, e.g. POWER SUPPLY CORDS, measuring leads and data cables, shall be positioned in such a way as to minimize their effect on the measurement.

Measurement of the insulation resistance according to 5.3.3 may be carried out where appropriate. This measurement shall not be carried out if it is excluded by the MANUFACTURER in the ACCOMPANYING DOCUMENTS.

5.3.2 Measuring of PROTECTIVE EARTH RESISTANCE

5.3.2.1 * General

For CLASS I ME EQUIPMENT, it shall be demonstrated that the PROTECTIVE EARTH CONDUCTOR connects all ACCESSIBLE CONDUCTIVE PARTS, which may become live in case of a fault, in a proper and safe way to either the PROTECTIVE EARTH TERMINAL of the MAINS PLUG for plugged-in equipment or to the protective earth point for PERMANENTLY INSTALLED equipment.

To evaluate the integrity of the earth conductor of the POWER SUPPLY CORD, the cord shall be flexed along its length during the measurement. If during the flexing, changes in resistance are observed, it shall be assumed that the PROTECTIVE EARTH CONDUCTOR is damaged or the connections are no longer adequate.

5.3.2.2 * Measuring conditions

Measurements shall be performed using a measuring device able to deliver a current of at least 200 mA into 500 mΩ. The open circuit voltage shall not exceed 24 V.

While low current tests (up to 1 A) are recommended, tests using up to 25 A may be used.

NOTE For low resistance values (e.g. when larger cross sectional areas and/or shorter conductor lengths are used) higher currents used for the continuity test improve the repeatability of the test result. However, testing using higher currents might not detect earth continuity problems caused by oxidation or poor contacts.

When using direct current, the measurement shall be repeated with opposite polarity. Either value measured shall not exceed the allowable value. The highest value shall be documented.

The PROTECTIVE EARTH RESISTANCE shall not exceed the following values.

a) For ME EQUIPMENT or an ME SYSTEM with NON-DETACHABLE POWER SUPPLY CORD, the resistance between the protective earth connector of the MAINS PLUG and protectively earthed ACCESSIBLE CONDUCTIVE PARTS of the ME EQUIPMENT or ME SYSTEM shall not exceed 300 mΩ (see Figure 1).

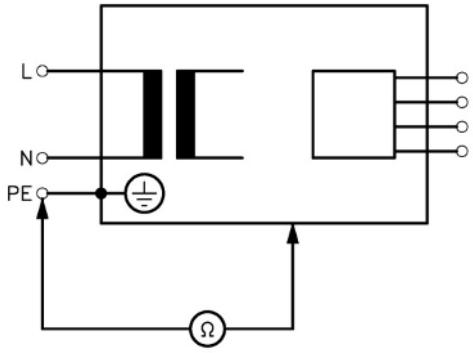
b) For ME EQUIPMENT or an ME SYSTEM with DETACHABLE POWER SUPPLY CORD, the resistance between the protective earth connector of the appliance inlet and protectively earthed

ACCESSIBLE CONDUCTIVE PARTS of the ME EQUIPMENT or ME SYSTEM shall not exceed 200 mΩ. For the POWER SUPPLY CORD itself, the resistance between the earth connections at each end shall not exceed 100 mΩ. When the DETACHABLE POWER SUPPLY CORD and the ME EQUIPMENT or ME SYSTEM are measured together, the resistance shall not exceed 300 mΩ (see Figure 1).

c) * In PERMANENTLY INSTALLED ME EQUIPMENT, the protective earth connection to the SUPPLY MAINS shall be tested as given in Figure 2. The resistance between the PROTECTIVE EARTH TERMINAL of the ME EQUIPMENT or ME SYSTEM and protectively earthed ACCESSIBLE CONDUCTIVE PARTS of the equipment, which may in case of a fault become live shall not exceed 300 mΩ. During the test no PROTECTIVE EARTH CONDUCTOR is disconnected.

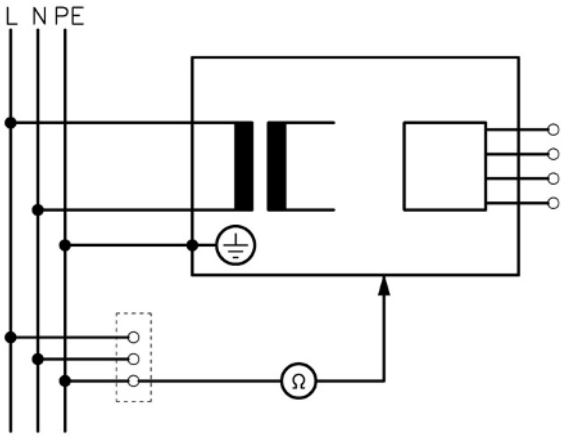
In measurements according to Figure 2, the resistance of protective earth connections in the SUPPLY MAINS may be taken into account.

d) For an ME SYSTEM with a MULTIPLE SOCKET-OUTLET, the total resistance between the protective earth connector of the MAINS PLUG of the MULTIPLE SOCKET-OUTLET and all protectively earthed ACCESSIBLE CONDUCTIVE PARTS intended to be connected to the ME SYSTEM shall not exceed 300 mΩ when connected to low-voltage TN-system installation without RCD-protection. Where RCD-protection or other protective measures, e.g. an IT power supply system, are provided, the PROTECTIVE EARTH RESISTANCE shall not exceed 500 mΩ.



(For legends, see Table 1)

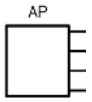
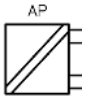
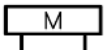
Figure 1 – Measuring circuit for the measurement of PROTECTIVE EARTH RESISTANCE in ME EQUIPMENT that is disconnected from the SUPPLY MAINS



(For legends, see Table 1)

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

Table 1 – Legends of symbols

	SUPPLY MAINS		Protective earth (ground)
L, N	SUPPLY MAINS terminals	PE	PROTECTIVE EARTH TERMINAL
	MAINS PART		APPLIED PART
	F-TYPE APPLIED PART	AP1, AP2	APPLIED PARTS with different functions
	Measuring device (see Figure C.1)		Residual current meter with frequency response as MD
	Resistance measuring device		Insulation measuring device
N.C.	NORMAL CONDITION	**S.F.C.**	SINGLE FAULT CONDITION
	CONDUCTIVE PART OF ENCLOSURE NOT PROTECTIVELY EARTHED		CONNECTION TO ACCESSIBLE CONDUCTIVE PARTS
·····	OPTIONAL CONNECTION		

5.3.3 * Measurement of insulation resistance (not mandatory)

5.3.3.1 General

The measurement of insulation resistance shall be considered, in addition to the leakage current measurement, if there is any doubt about the insulation of the equipment.

Examples of cases where insulation might be in doubt include:

– If a residual current device has tripped several times;
– if liquid has been spilled over the equipment and therefore creepage distances are in doubt; or
– if there are certain components or equipment where the insulation characteristic can change with temperature, e.g. heating elements.

5.3.3.2 Measuring conditions

When appropriate, insulation resistance shall be measured between:

– the MAINS PART and protective earth for CLASS I ME EQUIPMENT according to Figure 3,
– the MAINS PART and (non-earthed) ACCESSIBLE CONDUCTIVE PARTS for CLASS I and CLASS II ME EQUIPMENT according to Figure 3,
– the MAINS PART and APPLIED PARTS which make a patient connection according to Figure 4, with:
  - all TYPE B APPLIED PARTS being tested connected together, then
  - all F-TYPE APPLIED PARTS being tested connected together.
– F-TYPE APPLIED PARTS which make a patient connection and protective earth for CLASS I ME EQUIPMENT according to Figure 5,
– F-TYPE APPLIED PARTS which make a patient connection and (non-earthed) ACCESSIBLE CONDUCTIVE PARTS for CLASS I and CLASS II ME EQUIPMENT according to Figure 5.

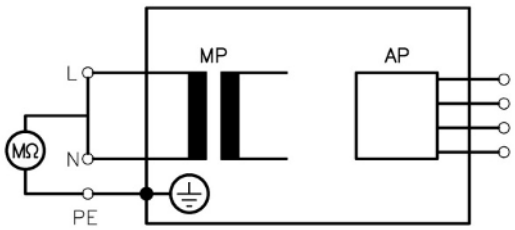
– F-TYPE APPLIED PARTS which make a patient connection and functional earth for CLASS II equipment.

The equipment is disconnected from SUPPLY MAINS and the equipment insulation resistance measured according to Figure 3, Figure 4 and Figure 5.

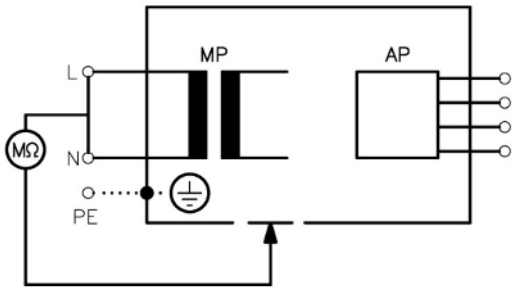
During the measurement, all switches of the MAINS PART shall be in operating position (ON), to include, as far as it is practicable, all circuits of the MAINS PART during the measurement.

Measurements of the insulation resistance shall be performed with a test voltage of 500 V (d.c.). Test voltage not lower than 250 V d.c. may be used if overvoltage protective devices are included in the test configuration.

Expected minimum insulation resistance values are given in Table 2. Lower measured values shall be investigated.



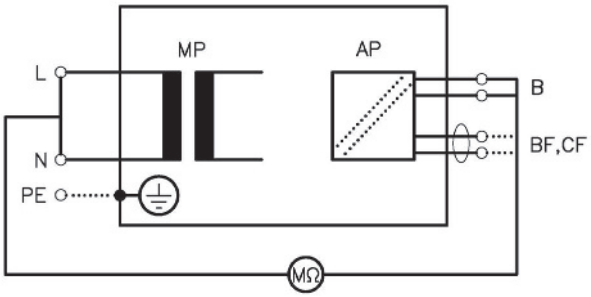
CLASS I



CLASS I and CLASS II

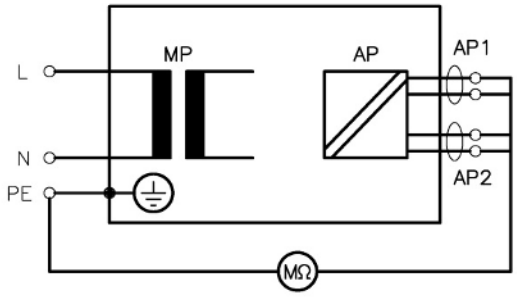
(For legends, see Table 1)

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

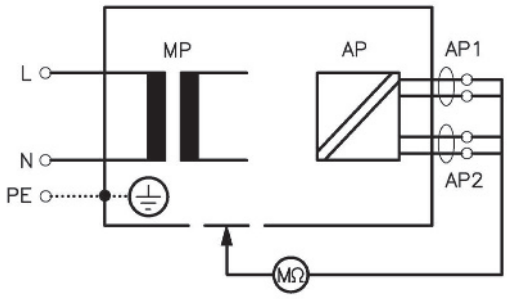


(For legends, see Table 1)

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



CLASS I



CLASS I and CLASS II

(For legends, see Table 1)

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

Table 2 – Insulation resistance values

Resistance in MΩ

Figure	CLASS I	CLASS II
3 upper	≥ 2	–
3 lower	≥ 7	≥ 7
4, TYPE B	≥ 2	≥ 7
4, F-TYPE	≥ 70	≥ 70
5	≥ 70	≥ 70

The Insulation resistance limit values in Table 2 are based on commonly accepted values. Lower insulation resistance values may still be acceptable provided they are as a result of the intended design of the ME EQUIPMENT or ME SYSTEM.

5.3.4 Leakage currents

5.3.4.1 * General

Depending on the ME EQUIPMENT or ME SYSTEM one of the following methods of measuring the EQUIPMENT LEAKAGE CURRENTS or the APPLIED PART LEAKAGE CURRENT may be used:

a) alternative method according to 5.3.4.2.2 or 5.3.4.3.2;

b) direct method according to 5.3.4.2.3 or 5.3.4.3.3;

c) differential method according to 5.3.4.2.4.

Leakage currents shall not exceed the values of Table 3.

Alternatively, for measurements of EARTH LEAKAGE CURRENT, TOUCH CURRENT and PATIENT LEAKAGE CURRENT test configurations derived from IEC 60601-1 (all editions) may be used. See Figure A.1, Figure A.2, Figure A.3, Figure A.4 and Figure A.5.

When using methods derived from IEC 60601-1 the leakage currents shall not exceed the appropriate values in Table E.1 or Table E.2 and Table E.3.

This applies to ME EQUIPMENT or ME SYSTEMS as well as to non-ME EQUIPMENT in the PATIENT ENVIRONMENT.

For equipment where insulation in the MAINS PART is not included in the measurement (e.g. by a relay which is only closed in operational condition), only the methods of b), c) and d) are applicable.

For a CLASS I ME EQUIPMENT or ME SYSTEM, a leakage current measurement may be performed only after the protective earth testing has been passed.

Additionally, before performing a direct method test for CLASS I or CLASS II ME EQUIPMENT it is advisable, for safety, to measure the insulation resistance (see Figure B.1).

For PERMANENTLY INSTALLED ME EQUIPMENT measurement of EQUIPMENT LEAKAGE CURRENT is not necessary.

NOTE 1 Open circuit of the PROTECTIVE EARTH CONDUCTOR of PERMANENTLY INSTALLED ME EQUIPMENT is not applied as a SINGLE FAULT CONDITION (see IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012, Subclause 8.1 b), 4th dash).

NOTE 2 It is assumed that the SUPPLY MAINS meets the requirements of national wiring regulations, e.g. IEC 60364-7-710.

For PERMANENTLY INSTALLED ME EQUIPMENT, the TOUCH CURRENT from ACCESSIBLE CONDUCTIVE PARTS that are not connected to protective earth shall be measured. Measurement results shall not exceed the values in Table 3.

Equipment shall be measured in the operating conditions (e.g. switch positions) that influence the leakage current. The highest value and the related condition, if relevant, shall be documented. Information from the MANUFACTURER shall be followed. Functions that initiate an intended physiological effect shall not be activated..

The measured value shall be normalized to the nominal LINE TO EARTH VOLTAGE, which value is corresponding with the nominal MAINS VOLTAGE. The actual measured LINE TO EARTH VOLTAGE shall be noted.

In general this standard does not adress the measurement of d.c. leakage currents or the measurements of patient auxillary currents. If the MANUFACTURER specifies that d.c. current or patient auxillary currents testing is necessary, then the MANUFACTURER shall give information in the ACCOMPANYING DOCUMENTS and the limits of IEC 60601-1 shall be applied.

ME EQUIPMENT or ME SYSTEMS that can be connected to SUPPLY MAINS shall be tested according to Figure 6, Figure 7, Figure 8, Figure 9 or Figure 10.

ME EQUIPMENT or ME SYSTEMS, powered only by an INTERNAL ELECTRICAL POWER SOURCE shall be tested according to Figure 11 only. This test applies to ME EQUIPMENT or ME SYSTEMS powered by an INTERNAL ELECTRICAL POWER SOURCE only when capable of delivering PATIENT LEAKAGE CURRENTS, which can endanger or harm the patient in case of failure.

For equipment in polyphase systems, the leakage current measurement according to the alternative method can result in currents exceeding the maximum allowable value in Table 3. In this case the measurement shall be made with equipment in operational condition e.g. by using a measurement according to direct or differential method.

5.3.4.2 * Measurement of EQUIPMENT LEAKAGE CURRENT

5.3.4.2.1 Applicability

This measurement is not applicable for equipment with an INTERNAL ELECTRICAL POWER SOURCE.

5.3.4.2.2 * Alternative method

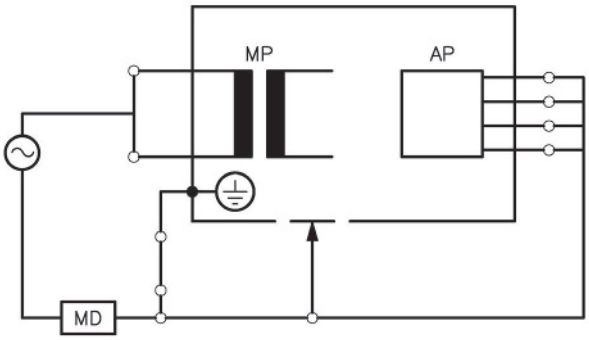
ME EQUIPMENT is separated from mains, and the EQUIPMENT LEAKAGE CURRENT is measured according to Figure 6.

NOTE 1 CLASS I ME EQUIPMENT does not need to be isolated from protective earth during measurement.

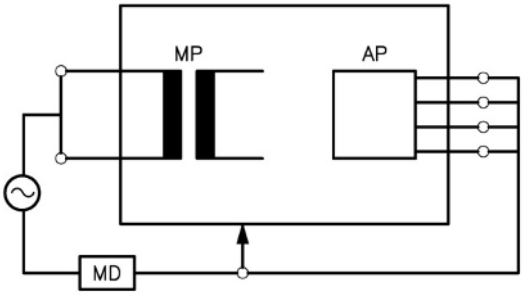
Switches in the MAINS PART shall be closed during the measurement as in operational condition to cover all insulations of the MAINS PART by the measurement.

If the value of the alternative method exceeds 1 mA, either the direct method or measurement of the TOUCH CURRENT shall be applied (allowable values in Table 3).

NOTE 2 Since the release of IEC 60601-1:2005, higher limits for EARTH LEAKAGE CURRENT are allowed, but the limits for TOUCH CURRENT are unchanged.



CLASS I



CLASS II

(For legends, see Table 1)

Figure 6 – Measuring circuit for the measurement of ME EQUIPMENT leakage current – alternative method

5.3.4.2.3 Direct method

Measurements shall be performed:

– at MAINS VOLTAGE, and
– in either position of the MAINS PLUG, if applicable, and
– according to Figure 7.

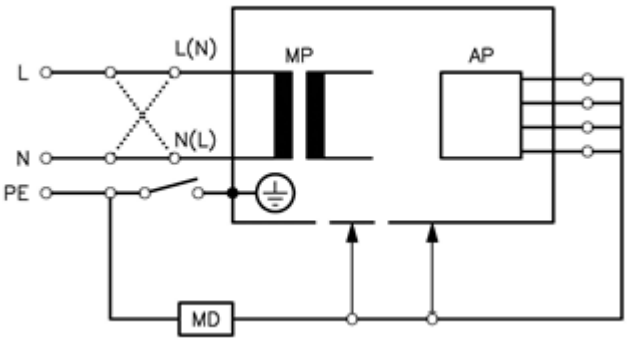
If measurements in different positions of the MAINS PLUG are applicable, the higher value shall be documented.

NOTE 1 If the measuring equipment is supplied by an IT power system, erroneous measured values will result.

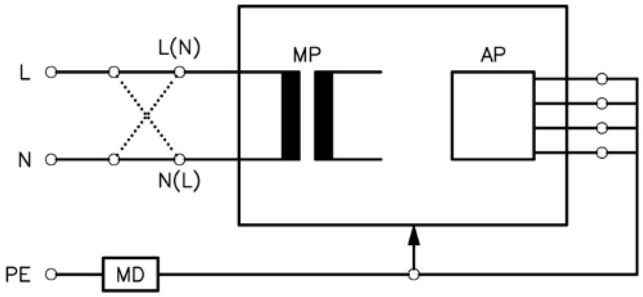
During the measurement, except for the PROTECTIVE EARTH CONDUCTOR in the POWER SUPPLY CORD, the equipment shall be isolated from earth. Otherwise the direct method is not applicable.

NOTE 2 An earth potential can be imported, for example, by external data lines.

NOTE 3 When measuring EQUIPMENT LEAKAGE CURRENT of CLASS I ME EQUIPMENT, test personel or bystanders can be endangered by an interrupt of the protective earth connection.



CLASS I



CLASS II

The device under test shall be isolated from protective earth.

(For legends, see Table 1)

Figure 7 – Measuring circuit for the measurement of EQUIPMENT LEAKAGE CURRENT– direct method

5.3.4.2.4 * Differential method

Measurements shall be performed:

– at MAINS VOLTAGE, and
– in either position of the MAINS PLUG, if applicable, and
– according to Figure 8.

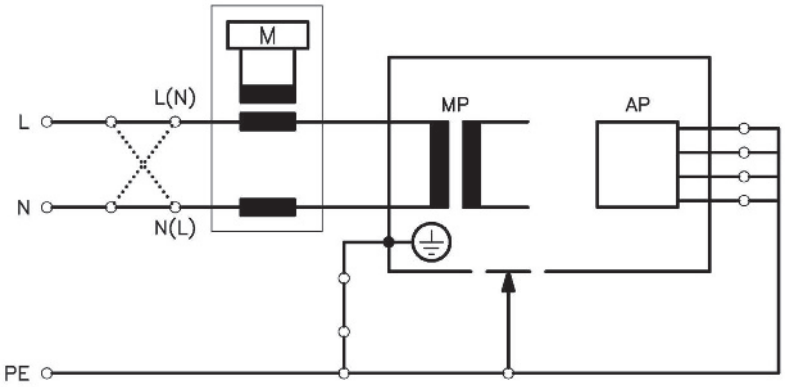
If measurements in different positions of the MAINS PLUG are applicable, the higher value shall be documented.

NOTE 1 If the measuring equipment is supplied by an IT power system, erroneous measured values will result.

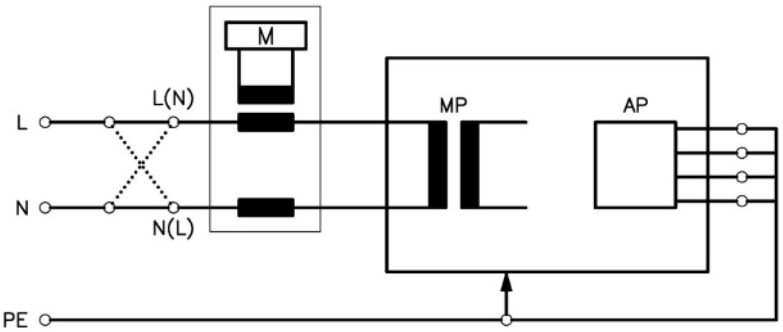
When measuring small leakage currents, attention shall be paid to information about limitations from the manufacturer of the measuring equipment.

If the value of the differential method exceeds 0,5 mA for CLASS I ME EQUIPMENT, either the direct method or measurement of the TOUCH CURRENT shall be applied (allowable values in Table 3).

NOTE 2 Since the release of IEC 60601-1:2005, higher limits for EARTH LEAKAGE CURRENT are allowed, but the limits for TOUCH CURRENT are unchanged.



CLASS I



CLASS II

(For legends, see Table 1)

Figure 8 – Measuring circuit for the measurement EQUIPMENT LEAKAGE CURRENT– differential method

NOTE 3 Some testing instruments include a 1 kΩ resistance in the probe, but this will not affect the measurement when using the differential method.

5.3.4.3 Measurement of APPLIED PART LEAKAGE CURRENT

5.3.4.3.1 General

Measurement of the APPLIED PART LEAKAGE CURRENT shall be performed on equipment.

– For TYPE B APPLIED PARTS usually no separate measurement is necessary. Such APPLIED PARTS are connected to the enclosure (see figures) and are included by the measurement of the EQUIPMENT LEAKAGE CURRENT, with the same allowable values.

– Separate measurements of TYPE B APPLIED PART leakage current are necessary only if described by the MANUFACTURER (see ACCOMPANYING DOCUMENTS).

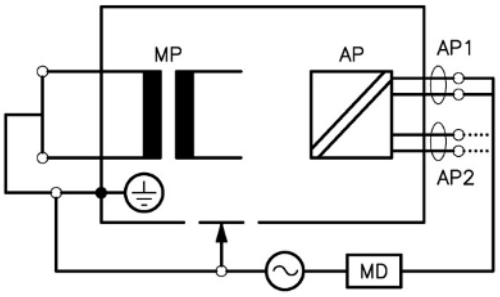
– F-TYPE APPLIED PART leakage current shall be measured from all patient connections of a single function of the APPLIED PART connected together according to Figure 9, Figure 10 or Figure 11, or as described by the MANUFACTURER. Alternatively, for TYPE CF APPLIED PARTS, measurement can be made from each patient connection in turn.

When testing ME EQUIPMENT with multiple APPLIED PARTs, connect them each in turn and comply with the applicable limits in Table 3. APPLIED PARTs not part of the measurement shall be floating.

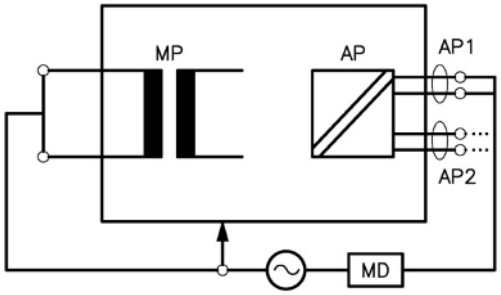
For allowable values, refer to Table 3 or Annex E.

5.3.4.3.2 * Alternative method

Measurement in ME EQUIPMENT having an F-TYPE APPLIED PART shall be performed according to Figure 9 for mains operated ME EQUIPMENT.



CLASS I



CLASS II

(For legends, see Table 1)

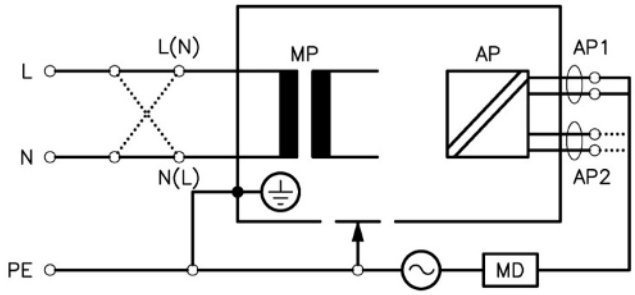
Figure 9 – Measuring circuit for the measurement of APPLIED PART LEAKAGE CURRENT "F-TYPE APPLIED PART" – alternative method

5.3.4.3.3 Direct method

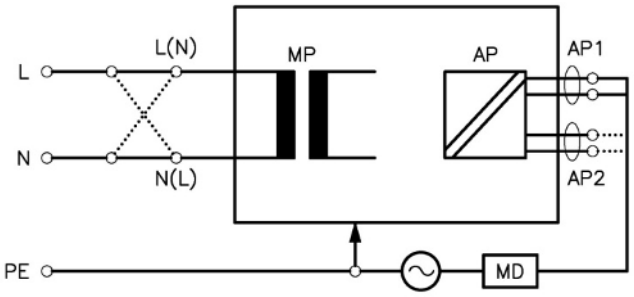
Measurements shall be performed:

– at MAINS VOLTAGE,
– in either position of the MAINS PLUG, if applicable; and
– according to Figure 10, or
– according to Figure 11 in ME EQUIPMENT having an INTERNAL ELECTRICAL POWER SOURCE.

NOTE If the measuring equipment is supplied by an IT power system, erroneous measured values will result.



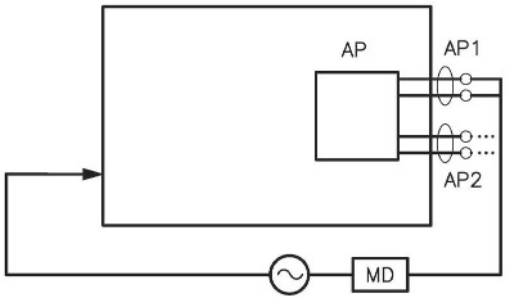
CLASS I



CLASS II

(For legends, see Table 1)

Figure 10 – Measuring circuit for the measurement of APPLIED PART LEAKAGE CURRENT – MAINS VOLTAGE on F-TYPE APPLIED PART – direct method



(For legends, see Table 1)

Figure 11 – Measuring circuit for the measurement of APPLIED PART LEAKAGE CURRENT for equipment with an INTERNAL ELECTRICAL POWER SOURCE – direct method

5.3.4.4 Measurement of TOUCH CURRENT for fixed installed equipment

This measurement is only required on ACCESSIBLE CONDUCTIVE PARTS that are not protectively earthed.

Measurements shall be performed:

– at MAINS VOLTAGE, and
– according to Figure 7.

Table 3 – Allowable values for leakage currents

Current in μA

Current	APPLIED PART		
	TYPE B	TYPE BF	TYPE CF
EQUIPMENT LEAKAGE CURRENT **– alternative method** (Figure 6)			
– for ACCESSIBLE CONDUCTIVE PARTS of CLASS I ME EQUIPMENT	1 000	1 000	1 000
– for ACCESSIBLE CONDUCTIVE PARTS of CLASS II ME EQUIPMENT	500	500	500
EQUIPMENT LEAKAGE CURRENT **– direct or differential method** (Figure 7 or Figure 8)			
– for ACCESSIBLE CONDUCTIVE PARTS of CLASS I ME EQUIPMENT	500	500	500
– for ACCESSIBLE CONDUCTIVE PARTS of CLASS II ME EQUIPMENT	100	100	100
TOUCH CURRENT (see Figure A.2 but NORMAL CONDITION and Figure A.3)			
– for ACCESSIBLE CONDUCTIVE PARTS	100	100	100
APPLIED PART LEAKAGE CURRENT **– alternative method (a.c.)**			
– according to 5.3.4.3.1 Figure 9)		5 000	50
APPLIED PART LEAKAGE CURRENT **– direct method (a.c.)**			
– according 5.3.4.3.1(Figure 10 or Figure 11)		5 000	50

NOTE 1 This table does not provide allowable values for equipment producing d.c. LEAKAGE CURRENTS.

NOTE 2 Particular standards can allow different values of LEAKAGE CURRENT. For example:

– Defibrillation paddles, TYPE CF: LEAKAGE CURRENT from APPLIED PART: 100 μA

– Mobile X-ray generators, EQUIPMENT LEAKAGE CURRENT, alternative method: 5 000 μA, direct or differential method: 2 000 μA

5.4 Functional test

The safety related functions of the equipment shall be tested. The MANUFACTURER´s recommendations shall be taken into consideration.

If necessary, the ME EQUIPMENT or ME SYSTEM should be tested with the assistance of a person familiar with the use of ME EQUIPMENT or ME SYSTEMS.

In this context, functional tests can also cover aspects of functions that are defined in particular standards in the IEC 60601 series as essential performance.

6 Results of test and evaluation

6.1 Reporting of results

All tests performed shall be documented. The set of documentation shall comprise at minimum the following data:

– identification of the testing body (e.g. company, department);

– name of the person(s) who has/have performed the testing and the evaluation(s);

– identification of the equipment/system (e.g. type, serial number, inventory number) and the ACCESSORIES tested;

– tests and measurements;

– date, type and outcome / results of:

  - visual INSPECTIONS;

- measurements (measured values, measuring method, measuring equipment);
- functional testing according to 5.4;

– concluding evaluation;

– date and confirmation of the individual who performed the evaluation; if using electronic documentation an assignment to inspector / evaluator shall be ensured.

– if applicable (decided by the RESPONSIBLE ORGANIZATION), the equipment/system tested shall be marked / identified accordingly.

For an example of test documentation, see Figure G.1.

6.2 Evaluation

The evaluation of safety of ME EQUIPMENT or ME SYSTEM shall be performed by electrically skilled persons (as defined in IEC 61140) who have the appropriate training for testing the equipment under test. If using the measurement equipment listed in Annex C, measurement uncertainties do not need to be taken into consideration for the limits.

If the safety of the ME EQUIPMENT or ME SYSTEM is not guaranteed, e.g. the tests of Clause 5 are not passed with positive results, the ME EQUIPMENT or ME SYSTEM shall be marked accordingly, and the risk from the ME EQUIPMENT or ME SYSTEM shall be documented in writing to the RESPONSIBLE ORGANIZATION.

Annex A
(informative)

General guidance and rationale

A.1 Intended audience

Table A.1 lists to whom this standard is addressed and their possible interests in this standard.

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

Addressee	Possible interest
MANUFACTURER of ME EQUIPMENT	– Description of appropriate test methods – Referencing to a standard not producing new test methods – Application of consistent test methods – Set of test methods to verify the condition of the equipment during the useful life under NORMAL CONDITION without destruction – Global test methods and test equipment – IEC 60601-1 requires tests during useful life
MANUFACTURER of testing equipment	– To develop measuring equipment which provides all the necessary test methods in one tester – To have unique test methods worldwide
Authorities	– To provide guidance in case of an existing law – No additional expertise is necessary to prove adequacy of test methods – To provide uniform testing of medical equipment for all RESPONSIBLE ORGANIZATIONS
Suppliers of ME EQUIPMENT	– To provide the necessary technical data for RECURRENT TESTS – To ensure there have been no damages during transport – To ensure the safety of the equipment after installation
RESPONSIBLE ORGANIZATIONS	– Guidance to fulfill existing national laws – To have unique test methods for each medical device – Achieve the equivalent safety level as in IEC 60601-1 – To have a guidance for RECURRENT TESTS of ME EQUIPMENT without specified test methods – To provide uniform tests for ME EQUIPMENT from different MANUFACTURERS
Service personnel (internal and external)	– To provide uniform testing of ME EQUIPMENT – To have a guidance for RECURRENT TESTS of ME EQUIPMENT without specified test methods – Guidance to fulfill existing national laws – To have unique test methods for each medical device – Achieve the equivalent safety level as in IEC 60601-1

It is assumed that users of this standard are electrotechnical experts. If suitable (standardized) measuring equipment is used, testing personnel are assumed to be adequately trained and instructed individuals. This standard addresses only experts who have adequate knowledge about equipment to be tested and adequate knowledge of all applicable standards. Therefore it has to be ensured within the organizational framework that the experts do have adequate knowledge of the applicable safety regulations, instructions for use and working instructions which are related to their work and the special requirements for the

equipment/system under test. It also shall be ensured that they continuously adapt their knowledge to the current state of the art.

This standard primarily defines the requirements for ensuring the ELECTRICAL SAFETY of ME EQUIPMENT and ME SYSTEM prior to PUTTING INTO SERVICE, during RECURRENT TESTING and after REPAIR. However, as other aspects of safety are relevant in equipment, these also have to be tested before putting equipment into service.

For functional safety tests defined in the MANUFACTURER recommendations, the functions defined as essential performance in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 and the “Particular requirements” section of the IEC 60601 standards can be used.

Examples of equipment not built to IEC 60601-1 are those complying with the IEC 60335 [1], IEC 60950 [2] and IEC 61010 series [4].

A.2 Differences between IEC 60601-1 and IEC 62353

IEC 60601-1 is a type-testing standard describing the design criteria of ME EQUIPMENT which should be proven by applying a combination of stress and destructive tests. In addition, IEC 60601-1 specifies that these tests are carried out under certain environmental conditions. These laboratory conditions cannot be guaranteed whilst testing ME EQUIPMENT in-service. Therefore, measurements requiring certain environmental conditions can only be applied consistently with difficulty and are therefore not suitable for use during in-service testing of equipment. An additional aspect is that equipment could potentially be damaged during test applications and can face a potential danger to person(s) and surroundings.

Another aspect of the design process of ME EQUIPMENT is to ensure the safety of the equipment during its expected useful life. The selection of methods and materials should contribute in this way.

As far as possible, a consensus is required to harmonise the assessment of the safe operation and testing of ME EQUIPMENT and ME SYSTEMS whilst respecting local requirements and meeting increasing demands for risk management. It is therefore necessary to describe tests beyond those of the type testing and to provide a uniform and unambiguous means of assessing the equipment's safety whilst maintaining the relation to IEC 60601-1 and minimising the risk of hazard to the person conducting the assessment.

All these aspects were considered during the creation of IEC 62353.

IEC 62353 primarily defines the requirements for ensuring the ELECTRICAL SAFETY of ME EQUIPMENT and ME SYSTEMS prior to PUTTING INTO SERVICE, during RECURRENT TESTING and after REPAIR whilst respecting the IEC 60601-1 design criteria and providing means of safer working practise to those persons involved in assessing the safety of ME EQUIPMENT and/or ME SYSTEMS.

In addition, IEC 62353 provides means to assess the aging process of ME EQUIPMENT and/or ME SYSTEMS through structured and regular INSPECTIONS.

A selection of test procedures, test methods and test intervals which can be used during the expected useful life of ME EQUIPMENT and ME SYSTEMS is described herein.

A.3 Rationale

Clause 4 – Requirements

Subclause 4.1 – General requirements

The number of tests may be reduced or tests may be omitted completely for ME EQUIPMENT where the MANUFACTURER can ensure and demonstrate with risk management according to ISO 14971 [10] that the ME EQUIPMENT is designed and manufactured with such quality that no additional safety hazard can occur. In this case the MANUFACTURER should prove and ensure that the allowed limits cannot be exceeded. The required measures may consist of special arrangement/selection of circuits, components and materials having characteristics which are not subject to alteration and are compatible with the technology of production.

National legislations can require recurrent basic visual INSPECTION in any case.

The term "all DETACHABLE POWER SUPPLY CORDS" covers the possibility of having a CLASS II equipment with a detachable supply cord including an earth conductor. Such a cord could subsequently be used with CLASS I equipment.

Subclause 4.3 – RECURRENT TEST

It could be argued that a significant increase from previously measured values indicates a problem. When this requirement was discussed, it was agreed that the equipment is safe if the value is below the limit even if there is a significant increase. So the increase of the measured values cannot be considered as the leading characteristic. However, it might be advisable to consider reducing the interval between the tests.

Clause 5 – Tests

Clause 5 comprises a series of tests, which may be used in testing before PUTTING INTO SERVICE, during RECURRENT TESTING and in testing after REPAIR. A transfer of many tests from type testing as defined in various standards is not practicable for the following reasons:

a) tests, that could damage the equipment under test, should not be applied;
b) the safety of the person(s) conducting the tests, or other individuals and/or the environment of the equipment/system should be ensured;
c) the most important parameters of safety should be determined with a minimum of tests in a simple, reproducible and comparable manner.

Subclause 5.3.2.1 – General

For this purpose, the items of equipment may be separately disconnected from their SUPPLY MAINS and from the data lines for the measurements.

Flexing of the POWER SUPPLY CORD could cause the test lead connection to the POWER SUPPLY CORD conductor terminals to become intermittent. Care should be taken to assess the cord and not these connections.

Subclause 5.3.2.2 – Measuring conditions

Commonly in standards for electrical installations there are no requirements for the values of the PROTECTIVE EARTH RESISTANCE. The values for the resistance of the protective earth are covered by the requirement for a certain cross-sectional area of the relevant PROTECTIVE EARTH CONDUCTOR in relation to the technical data of a fuse. In the first edition of IEC 60601-1, a POWER SUPPLY CORD of 3 m length was required with a minimum cross-sectional area of

0,75 mm^2. The resistance of the PROTECTIVE EARTH CONDUCTOR in this cable is about 100 mΩ. Another 100 mΩ was accepted to protect the enclosure of the equipment.

In this standard the limits for the resistance of the PROTECTIVE EARTH CONDUCTOR are 100 mΩ higher than those in IEC 60601-1. The reason for accepting these higher limits is that during the lifetime of the equipment under test, higher values may appear, e.g. caused by oxidation on connectors. These higher values are still justifiable from the safety point of view. For new equipment PROTECTIVE EARTH RESISTANCE less than 200 mΩ is expected. It is preferable to correct PROTECTIVE EARTH RESISTANCE to less than 200 mΩ after MODIFICATION or REPAIR.

This requirement is not to accept higher values in equipment where components e.g. the PROTECTIVE EARTH CONDUCTORS are repaired or changed. A value of 300 mΩ / 500 mΩ for systems was selected as it is an acceptable compromise between the requirement for lowest possible resistances and the technical possibilities within a ME SYSTEM.

Subclause 5.3.2.2 c)

Repeatedly disassembling and reassembling of a protective earth connection may result in degradation of its mechanical and electrical properties.

Any possible influence of unintended earth connections should be taken into account.

Subclause 5.3.3 – Measurement of insulation resistance

IEC 60601-1 does not consider insulation resistance measurement. For this reason local requirements or common practice can be applied to define suitable acceptance criteria in the absence of the ME EQUIPMENT MANUFACTURER's recommendations. This standard will only provide means of testing the insulation resistance.

Before IEC 60601-1 was published, some countries had standards for measuring the insulation of ME EQUIPMENT. At that time it was not possible to measure leakage currents with acceptable accuracy. Therefore according to Ohms law the resistance of the insulation was measured instead of the current through the insulation. The acceptance criteria for insulation resistance values used in several countries are mainly based upon experience from that time.

Using d.c tests can have an advantage over equivalent tests using a.c. because significant deterioration of insulation resistance will only add small amounts of additional a.c. leakage current which will be masked by the much larger amounts of capacitive leakage measured when using an a.c. test voltage. For example, and as an approximation, a deterioration of insulation resistance from 100 MΩ to 25 MΩ will add approximately 7 μA to leakage current (at 230 V). This would not register as a significant increase in measured a.c. leakage current, thus masking a potentially serious deterioration, for example due to spillage.

Generally, insulation resistance greater than 50 MΩ can be expected. However, insulation resistance not less than 1 MΩ is acceptable provided that the reasons for the low value are known and understood (e.g. mineral insulated heaters), and that the leakage currents are within the acceptable values.

Insulation resistance tests also have an important role to play in contributing to the safety of the personnel carrying out the tests provided they are carried out at the correct point in the sequence of tests.

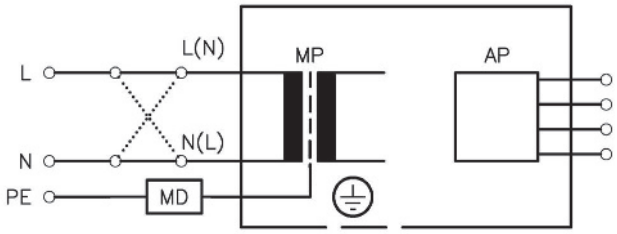
Subclause 5.3.4.1 – General

These measurements, including those using test configurations derived from IEC 60601-1, utilize the actual MAINS VOLTAGE at the test site. Therefore normalization of the measured leakage current values to the nominal LINE TO EARTH VOLTAGE is necessary.

The leakage current limits in Table 3 are the maximum allowed values after normalization.

Individual measurements of EARTH LEAKAGE CURRENT (for CLASS I ME EQUIPMENT), TOUCH CURRENT and PATIENT LEAKAGE CURRENT can be made using the test configurations shown in Figure A.1, Figure A.2, Figure A.3, Figure A.4 and Figure A.5.

Before carrying out the leakage current tests, for CLASS I ME EQUIPMENT a PROTECTIVE EARTH RESISTANCE test should first be carried out and then, for both CLASS I and CLASS II, it is advisable that either an insulation test or an EQUIPMENT LEAKAGE CURRENT test – alternative method be carried out. If these tests have been successfully passed, then the risks to personnel carrying out the leakage current tests are reduced to as low as reasonably practical.

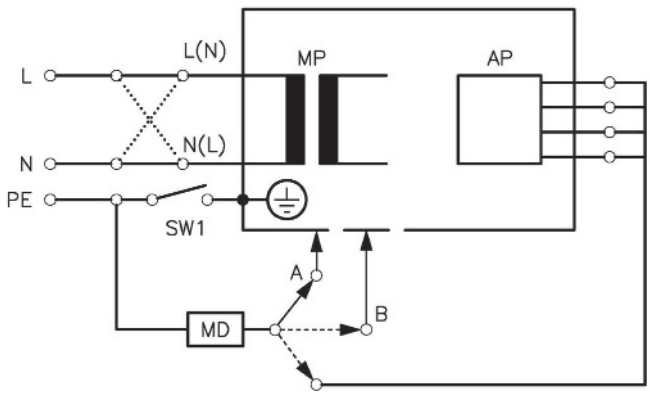


Key

For plugged-in CLASS I ME EQUIPMENT with no earthed ACCESSIBLE CONDUCTIVE PARTS of the enclosure

EARTH LEAKAGE CURRENT (Normal)	60601-1:1988	2,5 mA
	60601-1:2005	5,0 mA

Figure A.1 – CLASS I ME EQUIPMENT with no earthed ACCESSIBLE CONDUCTIVE PARTS of the enclosure



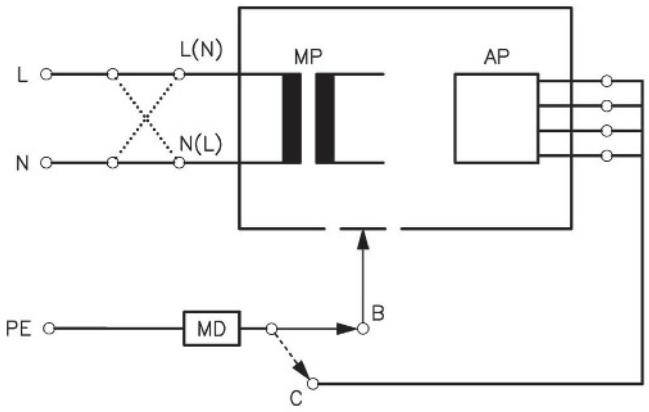
Key

For plugged-in CLASS I ME EQUIPMENT:

A =	TOUCH CURRENT (SFC) from earthed ACCESSIBLE CONDUCTIVE PARTS of the enclosure: (A is equivalent to normal EARTH LEAKAGE CURRENT)		500 μA
B =	TOUCH CURRENT (SFC) from non-earthed ACCESSIBLE CONDUCTIVE PARTS of the enclosure:		500 μA
C =	PATIENT LEAKAGE CURRENT (SFC):	TYPE B & BF	500 μA
		TYPE CF	50 μA

NOTE Closing SW1 will give Normal readings for B & C

Figure A.2 – Plugged-in CLASS I ME EQUIPMENT

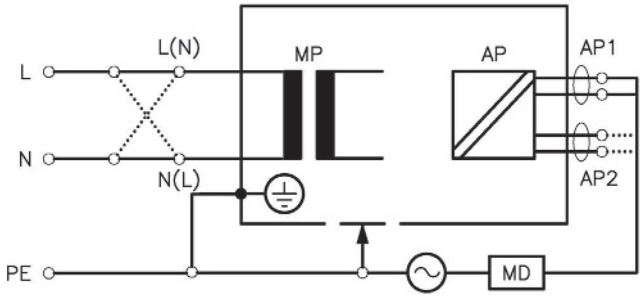


Key

For plugged-in CLASS II ME EQUIPMENT:

B =	TOUCH CURRENT (Normal) from ACCESSIBLE CONDUCTIVE PARTS of the enclosure:		100 μA
C =	PATIENT LEAKAGE CURRENT (Normal):	TYPE B & BF	100 μA
		TYPE CF	10 μA

Figure A.3 – Plugged-in CLASS II ME EQUIPMENT

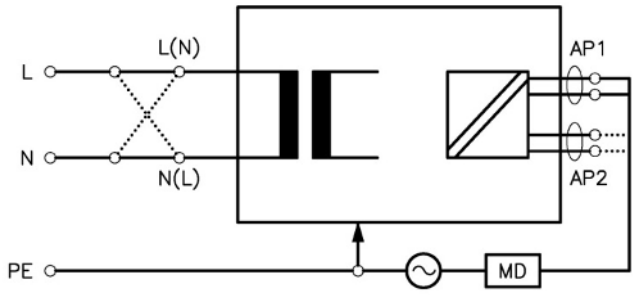


Key

For plugged-in CLASS I ME EQUIPMENT:

PATIENT LEAKAGE CURRENT (Mains on APPLIED PART):	TYPE BF	5.000 μA
	TYPE CF	50 μA

Figure A.4 – Plugged-in CLASS I ME EQUIPMENT with mains on the APPLIED PART



Key

For plugged-in CLASS II ME EQUIPMENT:

PATIENT LEAKAGE CURRENT (Mains on APPLIED PART):	TYPE BF	5 000 μA
	TYPE CF	50 μA

Figure A.5 – Plugged-in CLASS II ME EQUIPMENT with mains on the APPLIED PART

Subclause 5.3.4.2 – Measurement of EQUIPMENT LEAKAGE CURRENT

Table A.2 provides reasons for choosing between the alternative, differential or direct method for measuring EQUIPMENT LEAKAGE CURRENT.

Table A.2 – Reasons for choosing different measuring methods

Measuring method	Reasons for	Reasons against
Alternative method	– Does not need a TN-System – Only one measurement necessary (polarity of SUPPLY MAINS does not matter) – Highest safety for person doing the test (because the device under test (DUT) is disconnected from SUPPLY MAINS) – DUT does not need to be isolated during measurement	– Electronic switches in the SUPPLY MAINS of the instrument shall be shortened during test (difficult on electronic switches) – Not directly comparable to other methods (measured values are the sum of the leakage currents in both polarities measured using the direct method or the differential method. Therefore the allowable values are twice the values of the other methods.) – Not suitable for equipment with thermal heating components (leakage current in cold operation mode, may not conform to normal operation mode).
Direct method	Possibility to measure both a.c. and d.c leakage current – Highest accuracy on low leakage current measurement compared to other methods – Not influenced by the type of switching in the SUPPLY MAINS – Measures true leakage that would occur whilst the medical equipment is in typical use – Allows direct comparison with acceptance/ type approval measurements made in accordance with IEC 60601-1	– The need to interrupt PROTECTIVE EARTH TERMINAL (PE) for the measurement – by connecting a 1 kΩ resistor (MD) within the PE conductor during measurement, which could lead to increased hazard for the person conducting the measurement – on devices with high leakage current (because of a fault in the DUT) – by disconnecting the measurement device – if used in connection with other devices – The DUT shall be electrically isolated from earth during measurement, this is not possible for example for – most fixed wired imagine equipment – most fixed wired dentist chairs – devices connected to gas or water supply Measurement shall be done in each polarity of SUPPLY MAINS
Differential method	– Not influenced by the type of switch in the SUPPLY MAINS – The DUT does not need to be isolated from earth during measurement – It measures the total leakage current Increased safety for the tester as the earth is not disconnected.	– Less suitable for lower leakage current measurements – Influenced by external magnetic field, current frequency and current consumption of the DUT – Measurement is done in each polarity of SUPPLY MAINS – Accuracy and frequency range may be limited compared with the other measuring methods

Subclause 5.3.4.2.2 – Alternative method

This specific method for measuring the alternative EQUIPMENT LEAKAGE CURRENTS is advantageous because of its good reproducibility, compared to typical measurement methods on equipment in operation (as a result of using a galvanic isolation) because all mains conducting parts are shorted together and applied to the MAINS VOLTAGE at the same time.

The alternative method is not suitable for measuring devices containing active circuitry, such as relays, that can prevent all circuits of the MAINS PARTS from being measured. If there is any doubt as to the use of active circuitry, a comparative measurement can be required using a different method, to ascertain the suitability of using the alternative method.

Although the outcome of the alternative leakage currents measurement cannot directly be compared to the leakage current values as defined in IEC 60601-1, the results of the alternative EQUIPMENT LEAKAGE CURRENT measurement can, in general, be compared to the leakage current values expected when performing an open neutral test as defined in IEC 60601-1.

The allowable values for alternative method in Table 3 should be the sum of both values of each polarity using the direct method or differential method because both poles are connected to the MAINS VOLTAGE at the same time. It was decided the values for alternative method should be twice the values of IEC 60601-1 even if in most cases the insulation is not symmetrical. The only exception is made for the EQUIPMENT LEAKAGE CURRENT for CLASS II ME EQUIPMENT or ME SYSTEMS where the allowable value would be twice the 100 μA. As IEC 60601-1 allows for 500 μA in SINGLE FAULT CONDITION for TOUCH CURRENT, it was decided an equivalent value is used for the EQUIPMENT LEAKAGE CURRENT to reduce the number of different values.

Subclause 5.3.4.2.4 – Differential method

The differential method is to measure the sum of the momentary values of all currents in the active conductors of the SUPPLY MAINS. This is commonly known as the residual current, as defined in IEC 62020 [8]: vector sum of the instantaneous current flowing in the main circuit.

This sum is usually achieved from a differential transformer. Equipment without leakage current will result in zero residual current flow, as the current into the device and the current flowing in reverse are of equal value. Any leakage current does not flow back through the measuring transformer; so there is a difference of currents. This residual current is measured by means of an additional winding on a transformer; it corresponds to the leakage current.

This measuring method allows measurements on equipment which has connections to earth in addition to a protective earth connection (e.g. LAN-connection, water pipes). Equipment under test may be operated directly from mains, without the use of any isolating transformer.

The method of measuring residual current is not always practicable on equipment having electronic MAINS PARTS (e.g. switch-mode power supplies). When using this method, the information of the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM and the measurement equipment (measuring transformer) should be considered.

Subclause 5.3.4.3.2 – Alternative method

The alternative method of APPLIED PART LEAKAGE CURRENT is performed using a test voltage equal to the actual SUPPLY MAINS VOLTAGE. This measurement shall be used only on equipment with isolated APPLIED PARTS according to IEC 60601-1.

Such ME EQUIPMENT with APPLIED PART(S) is typically marked with the TYPE BF APPLIED PART-symbol () (IEC 60417-5333 (2002-10)) or the TYPE CF APPLIED PART-symbol () (IEC 60417-5335 (2002-10).

Annex B
(informative)

Sequence of testing

Figure B.1 contains a recommended sequence for performing the tests described in this standard. Figure B.2 contains an example decision chart to assist in determining which test method to apply when measuring leakage currents on non-PERMANENTLY INSTALLED CLASS I ME EQUIPMENT.

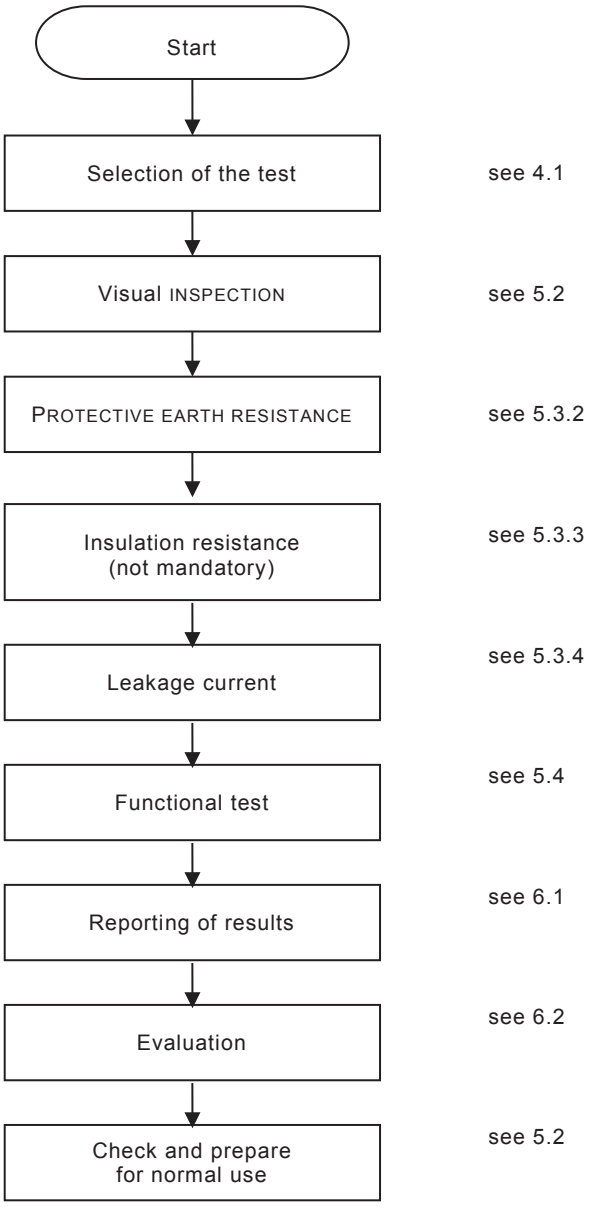


Figure B.1 – Sequence of testing

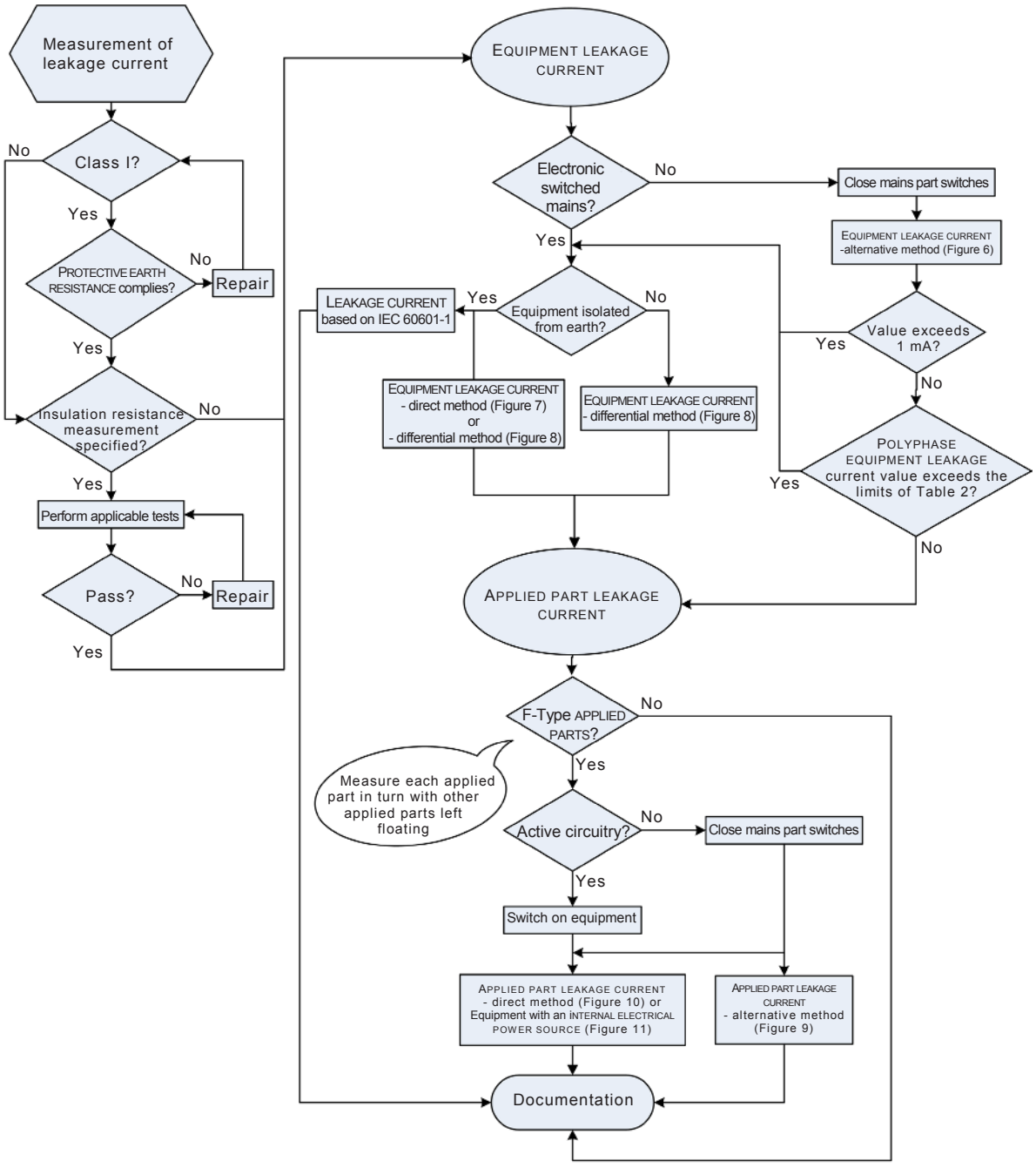


Figure B.2 – Measurement of LEAKAGE CURRENTS (non-PERMANENTLY INSTALLED CLASS I ME EQUIPMENT)

Annex C
(normative)

Requirements for the measurement equipment and for measurement circuits for PROTECTIVE EARTH RESISTANCE and leakage currents

C.1 Requirements for the measurement equipment

For measurements according to this standard only use measurement equipment complying with IEC 61010-1 with regard to the ELECTRICAL SAFETY.

The measurement equipment shall comply with IEC 61557-2 [5] and IEC 61557-4 [6] with the exception of 4.6 of 61557-2:2007 and 4.9 of 61557-4:2007 (protection against extraneous voltage requirements) for measurement equipment not intended for direct connection to a fixed installation.

NOTE IEC 61557-16 [7], a standard specifically covering test equipment designed for testing to IEC 62353, is currently in preparation and will supersede IEC 61557-2 and IEC 61557-4 for this type of test equipment when published.

The operating uncertainty of the measurements, within the range marked or declared by the MANUFACTURER, shall not exceed ± 15 % of the measured value, when calculated according to IEC 61557-1.

ACCESSORIES for testing equipment shall comply with the requirements of IEC 61010-031.

In case of supplying current above 3,5 mA for measuring APPLIED PART LEAKAGE CURRENT and PATIENT LEAKAGE CURRENT (derived from IEC 60601-1), specific means shall be implemented to prevent contact with ACCESSIBLE CONDUCTIVE PARTS of the probe. In normal use the measurement equipment shall not expose the testing person or other individuals to hazards.

The measurement equipment used for the tests shall be tested and calibrated at regular intervals according to the information given by the manufacturer of the test equipment.

If the measurement of leakage current of CLASS I ME EQUIPMENT is carried out by direct method according to 5.3.4.2.3, the protective conductor leading to the device under test (DUT) can be interrupted during test.

Any connection to earth of the DUT may result in wrong measurement data using the direct method. Therefore the set up of the measurement equipment shall ensure a galvanic separation from earth, or attention shall be drawn to the necessity of isolated positioning of the DUT by an automatic warning or by a clearly visible marking.

In the measurement equipment a galvanic separation of the measurement circuits, including measuring device MD, from the SUPPLY MAINS including its PROTECTIVE EARTH CONDUCTOR shall be guaranteed, when measuring according to 5.3.2, 5.3.4.2.3 and 5.3.4.3.1.

C.2 Measurement equipment for measurement of PROTECTIVE EARTH RESISTANCE

The measurement equipment shall:

– allow for measurements according to Figure 1 or Figure 2, and

– allow measurements according to the measuring conditions of 5.3.2.2.

C.3 Measurement equipment for measurements of EQUIPMENT LEAKAGE CURRENT

The measurement equipment for the alternative method shall:

– allow for measurements according to Figure 6.

– be performed by applying sinusoidal mains frequency and MAINS VOLTAGE for the measurement of alternative leakage currents.

In the case of supplying current above 3,5 mA for measuring APPLIED PART LEAKAGE CURRENT, specific means shall be implemented to prevent contact with ACCESSIBLE CONDUCTIVE PARTS of the probe. The measured value shall be corrected to the value corresponding with the nominal MAINS VOLTAGE.

The measurement equipment for the direct method shall:

– guarantee that the measurement results are equivalent to an evaluation with a measuring device MD according to Figure C.1; and

– measure the current as r.m.s. (a.c.).

The measurement equipment for a measurement using the differential method shall:

– guarantee that the measurement results are equivalent to an evaluation with a measuring device MD according to Figure C.1; and

– the current is determined as r.m.s. (a.c.).

NOTE If the requirements for the bandwidth cannot be fulfilled for differential method, it is recommended to use the direct method instead.

C.4 Measurement equipment for measurements of APPLIED PART LEAKAGE CURRENT

The measurement equipment for the alternative method shall:

– allow for measurements according to Figure 9;

– be performed by applying sinusoidal mains frequency and MAINS VOLTAGE for the measurement of APPLIED PART LEAKAGE CURRENTS.

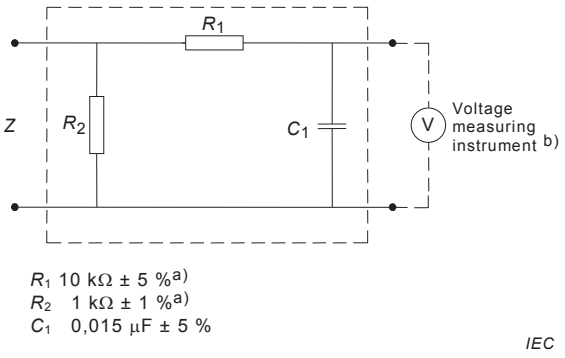
In the case of supplying current above 3,5 mA for measuring APPLIED PART LEAKAGE CURRENT, specific means shall be implemented to prevent contact with ACCESSIBLE CONDUCTIVE PARTS of the probe.The measured value shall be corrected to the value corresponding with the nominal MAINS VOLTAGE.

The measurement equipment for the direct method shall:

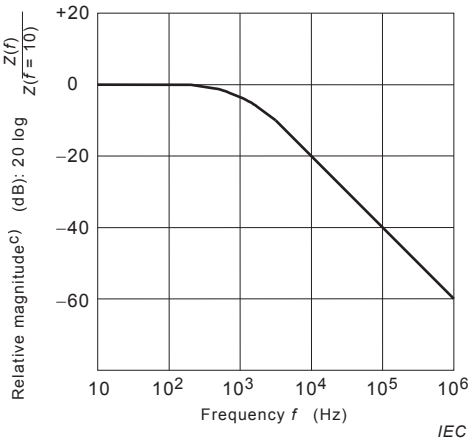
– guarantee that the measurement results are equivalent to an evaluation with a measuring device MD according to Figure C.1; and

– measure the current as r.m.s. (a.c.).

The voltage supplied to the F-TYPE APPLIED PARTS shall be sinusoidal at mains frequency and MAINS VOLTAGE. The measured value shall be corrected to the value corresponding with the nominal MAINS VOLTAGE.



a) Measuring device



b) Frequency characteristics

NOTE The network and voltage measuring instrument above are replaced by the symbol 

in the following figures.

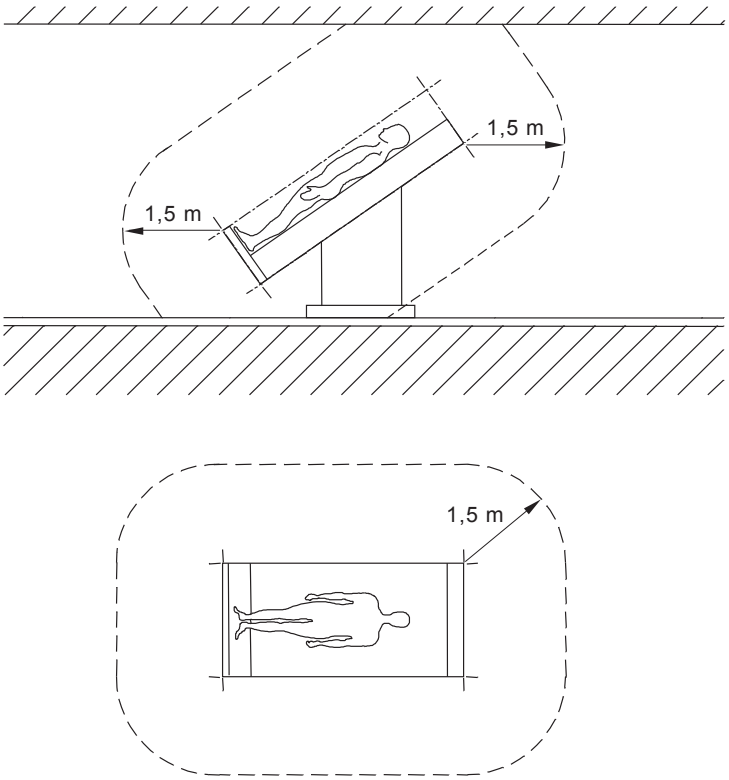
a) Non-inductive components
b) Resistance ≥ 1 MΩ and capacitance ≤ 150 pF
c) $Z(f)$ is the transfer impedance of the network, i.e. V_{out}/I_{in}, for a current of frequency f.

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

(Derived from IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012)

Annex D
(informative)

PATIENT ENVIRONMENT



NOTE The dimensions in the figure show minimum extent of the PATIENT ENVIRONMENT in a free surrounding.

Figure D.1 – Example of PATIENT ENVIRONMENT

(Derived from IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012)

Annex E
(normative)

Allowable values for leakage currents from IEC 60601-1

Table E.1 – Allowable values for continuous leakage currents from IEC 60601-1:1988[4]

Current in mA

Current		TYPE B		TYPE BF		TYPE CF	
		N.C.	S.F.C.	N.C.	S.F.C.	N.C.	S.F.C.
EARTH LEAKAGE CURRENT general		0,5	1 [a]	0,5	1 [a]	0,5	1 [a]
EARTH LEAKAGE CURRENT for EQUIPMENT according to footnotes [b] and [d]		2,5	5 [a]	2,5	5 [a]	2,5	5 [a]
EARTH LEAKAGE CURRENT for EQUIPMENT according to footnote [c]		5	10 [a]	5	10 [a]	5	10 [a]
ENCLOSURE LEAKAGE CURRENT		0,1	0,5	0,1	0,5	0,1	0,5
PATIENT LEAKAGE CURRENT according to footnote [e]	d.c	0,01	0,05	0,01	0,05	0,01	0,05
	a.c.	0,1	0,5	0,1	0,5	0,01	0,05
PATIENT LEAKAGE CURRENT (MAINS VOLTAGE on the signal input part or signal output part)		–	5	–	–	–	–
PATIENT LEAKAGE CURRENT (MAINS VOLTAGE on the APPLIED PART)		–	–	–	5	–	0,05
Patient auxiliary current [e]	d.c	0,01	0,05	0,01	0,05	0,01	0,05
	a.c.	0,1	0,5	0,1	0,5	0,01	0,05

All references in this table are to subclauses or figures in IEC 60601-1:1988.

N.C.: NORMAL CONDITION

S.F.C.: SINGLE FAULT CONDITION

NOTES on Table IV of IEC 60601-1:1988

[a] The only SINGLE FAULT CONDITION for the EARTH LEAKAGE CURRENT is the interruption of one supply conductor at a time (see 19.2 a) and Figure 16).

[b] EQUIPMENT that has no protectively earthed ACCESSIBLE PARTS and no means for the protective earthing of other equipment and which complies with the requirements for the enclosure leakage current and for the PATIENT LEAKAGE CURRENT (if applicable).

Example:

Some computers with a screened MAINS PART.

[c] Equipment specified to be PERMANENTLY INSTALLED with a PROTECTIVE EARTH CONDUCTOR which is electrically so connected that the connection can only be loosened with the aid of a tool and which is so fastened or otherwise so secured mechanically at a specific location that it can only be moved after the use of a tool.

Examples of such equipment are:

– major components of an X-ray installation such as the X-ray generator, the examination or treatment table;
– equipment with mineral insulated heaters;
– equipment with an EARTH LEAKAGE CURRENT higher than stated in Table IV, first line, which is due to compliance with requirements for radio-interference suppression.

[d] Mobile X-ray equipment and mobile equipment with mineral insulation.

[e] The maximum values for the a.c. component of the PATIENT LEAKAGE CURRENT and of the patient auxiliary current specified in Table IV refer to the a.c.-only component of the currents.

4 IEC 60601-1:1988, *Medical electrical equipment – General requirements for safety* + IEC 60601-1:1988/AMD1:1991 + IEC 60601-1:1988/AMD2:1995

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

Current in μA

Current	Description	Reference	Measuring circuit		TYPE B APPLIED PART		TYPE BF APPLIED PART		TYPE CF APPLIED PART	
					NC	SFC	NC	SFC	NC	SFC
PATIENT AUXILIARY CURRENT		8.7.4.8	FIGURE 19	D.C.	10	50	10	50	10	50
				a.c.	100	500	100	500	10	50
PATIENT LEAKAGE CURRENT	From patient connection to earth	8.7.4.7 a)	Figure 15	d.c.	10	50	10	50	10	50
				a.c.	100	500	100	500	10	50
	Caused by an external voltage on a signal input/output part	8.7.4.7 c)	Figure 17	d.c.	10	50	10	50	10	50
				a.c.	100	500	100	500	10	50
Total PATIENT LEAKAGE CURRENT[a]	With the same types of APPLIED PART connected together	8.7.4.7 a) and 8.7.4.7 h)	Figure 15 and Figure 20	d.c.	50	100	50	100	50	100
				a.c.	500	1 000	500	1 000	50	100
	Caused by an external voltage on a signal input/output part	8.7.4.7 c) and 8.7.4.7 h)	Figure 17 and Figure 20	d.c.	50	100	50	100	50	100
				a.c.	500	1 000	500	1 000	50	100

TOUCH CURRENT	– NORMAL CONDITION	100 μA
	– SINGLE FAULT CONDITION	500 μA
EARTH LEAKAGE CURRENT	– NORMAL CONDITION	5 mA
	– SINGLE FAULT CONDITION	10 mA

For PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit that supplies only this ME EQUIPMENT, a higher value of EARTH LEAKAGE CURRENT is allowed.

NOTE 1 Local regulation can establish limits for protective earth currents of the installation. See also IEC 60364-7-710.

All references in this table are to subclauses or figures in IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012.

NC = NORMAL CONDITION

SFC = SINGLE FAULT CONDITION

NOTE 2 For EARTH LEAKAGE CURRENT see 8.7.3 d).

NOTE 3 For TOUCH CURRENT see 8.7.3 c).

[a] Total PATIENT LEAKAGE CURRENT values are only applicable to equipment having multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS shall comply with the PATIENT LEAKAGE CURRENT values.

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

Current in μA

Current	Description [a]	Reference	Measuring circuit	TYPE B APPLIED PART	TYPE BF APPLIED PART	TYPE CF APPLIED PART
PATIENT LEAKAGE CURRENT	Caused by an external voltage on the PATIENT CONNECTION of an F-TYPE APPLIED PART	8.7.4.7 b)	Figure 16	Not applicable	5 000	50
	Caused by an external voltage on a metal ACCESSIBLE PART not PROTECTIVELY EARTHED	8.7.4.7 d)	Figure 18	500	500	– [c]
Total PATIENT LEAKAGE CURRENT [b]	Caused by an external voltage on the PATIENT CONNECTION of an F-TYPE APPLIED PART	8.7.4.7 b) and 8.7.4.7 h)	Figure 16 and Figure 20	Not applicable	5 000	100
	Caused by an external voltage on a metal ACCESSIBLE PART not PROTECTIVELY EARTHED	8.7.4.7 d) and 8.7.4.7 h)	Figure 18 and Figure 20	1 000	1 000	– [c]

All references in this table are to subclauses or figures in IEC 60601-1:2005.

[a] The condition referred to in Table IV of the second edition as "MAINS VOLTAGE on APPLIED PART", and treated in that edition as a SINGLE FAULT CONDITION, is treated in this edition as a special test condition. The test with MAXIMUM MAINS VOLTAGE on a non-PROTECTIVELY EARTHED ACCESSIBLE PART is also a special test condition, but the allowable values are the same as for SINGLE FAULT CONDITION. See also the rationales for 8.5.2.2 and 8.7.4.7 d).

[b] Total PATIENT LEAKAGE CURRENT values are only applicable to equipment having multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS shall comply with the PATIENT LEAKAGE CURRENT values.

[c] This condition is not tested with TYPE CF APPLIED PARTS because it is covered by the test with MAXIMUM MAINS VOLTAGE on the APPLIED PART. See also the rationale for 8.7.4.7 d).

Annex F
(informative)

Testing intervals

When the MANUFACTURER of ME EQUIPMENT/ME SYSTEMS has established, for periodic INSPECTION, the testing interval and the extent of testing, these will be disclosed in the ACCOMPANYING DOCUMENTS.

If there is no information on the testing interval for periodic INSPECTION in the ACCOMPANYING DOCUMENTS (e.g. of older equipment), it should be established individually by a competent person. In defining the degree of risk, the factors below and the recommendations of the MANUFACTURER should be taken into account, and a corresponding testing interval should be set in the range of 6 months to 36 months. If there are no other instructions from the MANUFACTURER regarding exceeding the test interval, then a tolerance of 1/6 of the test interval is proposed.

In establishing the testing interval, the following should be taken into account:

– the degree of risk of the equipment,
– the frequency of its use,
– the operation environment,
– the conditions of operation (e.g. stationary, mobile, emergency), and
– the frequency of occurrence of device failures.

For the following equipment the interval should not exceed 24 months:

ME EQUIPMENT/ME SYSTEMS for:

a) generation and application of electrical energy to directly influence the function of nerves and/or muscles response; the action of the heart, including defibrillators;
b) cardio-vascular measurement of electrical magnitudes using electrically operated measuring probes in blood vessels or on blood vessels laying bare;
c) generation and application of any energy for direct coagulation, destruction of tissue or splitting of sediments in the body;
d) direct introduction of substances and liquids into the blood circuit with the possibility of building up pressure, where the substances and liquids may be also processed or specially treated ones of the body, if their introduction is directly coupled to a gathering function;
e) artificial respiration with or without anaesthesia;
f) diagnosis by magnetic resonance imaging;
g) therapy in hyperbaric chambers;
h) hypothermic or hyperthermia therapy;
i) baby incubators; and
j) active external components of active implants, which are not in continuous use by the patient.

Annex G
(informative)

Example of test documentation

Testing organisation: Name of testing person:					Test before putting into service (reference value) ☐ Recurrent test ☐ Test after repair ☐			
Responsible organization:								
Equipment:					ID-Number:			
Type:					Production No./Serial Nr.:			
Manufacturer:					Class of protection:	I	II	Battery
Applied part type:	0	B	BF	CF	Mains connection: [1]	PIE	NPS	DPS
Accessories:								

Test: Measurement equipment:		Complies: Yes	Complies: No
Visual inspection:		☐	☐
Measurements:	measured value		
Protective earth resistance	_____ Ω	☐	☐
Insulation resistance (according to Figure ___)	_____ MΩ	☐	☐
Equipment leakage current (according to Figure ___)	_____ mA	☐	☐
Applied partleakage current (according to Figure ___)	_____ mA	☐	☐
Leakage current (based on IEC 60601-1)		☐	☐
Functional test (parameters tested):		☐	☐
		☐	☐

Deficiency / Note:

Overall assessment:

☐ No safety or functional deficiencies were detected!

☐ Deficiencies detected but no direct risk to continue clinical use. Correction required.

☐ Equipment shall be taken out of operation until deficiencies are corrected!

☐ Equipment does not comply – Modification / Exchange of components / Taking out of service is recommended!

Next recurrent test necessary in 6 / 12 / 24 / 36 months!

Name: _____ Date / Signature: _____

[1] PIE Permanent installed equipment
NPS Non- DETACHABLE POWER SUPPLY CORD
DPS DETACHABLE POWER SUPPLY CORD

Figure G.1 – Example of test documentation

Annex H
(informative)

Notes on testing ME SYSTEMS

H.1 Overview

This annex is intended to serve as additional support before PUTTING INTO SERVICE, during MAINTENANCE, INSPECTION, SERVICING and after REPAIR or on occasions of RECURRENT TESTS of ME SYSTEMS.

It is aimed at technical staff working in healthcare environments, or for external service providers and introduces typical cases that occur in the normal service life of ME SYSTEMS.

The following conditions should be met:

– the initial assessment of an ME SYSTEM for construction or MODIFICATION shows that it complies with the IEC 60601 series;

– in case of an exchange of a device or component equipment within an ME SYSTEM, an identical or previously assessed CONFIGURATION has to be used.

H.2 Guidelines for re-testing of an ME SYSTEM

H.2.1 The person performing the test should verify the compatibility of the tested ME SYSTEM with the existing documentation. Checks should be carried out with particular attention to whether components have been removed, added or changed.

NOTE The documentation contains the necessary information required for safe operation of the ME SYSTEM, e.g. necessary restrictions on usage, prohibitions of combinations with other devices or components as well as information about the time and terms of service INSPECTIONS.

It is recommended that a highly visible list of components or a reference list and a warning such as "SAFETY WARNING: tested system. Do NOT connect any other equipment to this system." be provided.

When network separation devices (network isolators) are used during assembly, the presence of those separation devices should be verified.

H.2.2 If the ME SYSTEM to be tested is consistent with the documentation, or if equipment was removed and replaced by identical or system-compliant types, it can be tested to this standard. If the ME SYSTEM, is not consistent with the documentation, or the documentation is missing, an evaluation of the ME SYSTEM is required according to Clause 16 of IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012[5].

H.2.3 The person performing the test on an ME SYSTEM needs to adhere to the MANUFACTURER'S instructions contained in the ACCOMPANYING DOCUMENTS for each device and for the ME SYSTEM.

H.2.4 Within the PATIENT ENVIRONMENT, an ME SYSTEM or a component of a system should adhere to the same leakage limits as an individual ME EQUIPMENT.

Outside of the PATIENT ENVIRONMENT, a level of security should be maintained in accordance with the applicable standards for the device.

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5 This citation refers to IEC 60601-1:2005 as amended by Amendment 1 published in 2012.

NOTE For an example of systems and protection measurements, please refer to IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012, Annex I.

H.2.5 Each device in an ME SYSTEM that has a separate SUPPLY MAINS and can be connected to or separated from the SUPPLY MAINS without the aid of a tool, should be tested individually. In addition, the ME SYSTEM must be tested as a complete unit.

NOTE For an example of systems and protection measurements, please refer to IEC 60601-1: 2005 + IEC 60601-1: 2005/AMD1:2012, Annex I.

H.2.6 The quality and the suitability of any MULTIPLE SOCKET-OUTLET used, should be evaluated during testing (see Table H.1, Figure H.1 and Figure H.2).

NOTE This figure is derived from IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012.

H.2.7 When an ME SYSTEM is split into separate ME SYSTEMS, then Clause 16 of IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012 applies, unless those separate ME SYSTEMS have been previously assessed successfully.

H.2.8 In an ME SYSTEM with MULTIPLE SOCKET-OUTLET(S), the total resistance between the earth (grounding) pin of the MAINS PLUG of the MULTIPLE SOCKET-OUTLET and all earthed ACCESSIBLE CONDUCTIVE PARTS of the ME SYSTEM are not to exceed the allowable values of 5.3.2.2 d).

H.2.9 The PROTECTIVE EARTH RESISTANCE of each system component should be measured as described in the normative part (see 5.3.2). Conductive connections not part of the protective earth circuit e.g. data lines, pipelines or similar items should be disconnected during testing.

H.3 Guidelines on ME SYSTEMS from the rationale annex of IEC 60601-1:2005 + IEC 60601-1:2005 /AMD1:2012

If RESPONSIBLE ORGANIZATIONS intend to assemble ME SYSTEMS, reference to IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012 is essential. For information, the following text is reproduced from Annex A of IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012.

Table H.1 is reproduced from Annex I of IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012 and provides some examples of assembling ME SYSTEMS but does not cover all situations and solutions.

Clause 16 – ME SYSTEMS

Increasingly, ME EQUIPMENT is being combined with other pieces of equipment that might not have originally been intended for medical application to create systems where one or more of the elements of the system come into contact with the patient. Clause 16 provides requirements to ensure the safety of the patient who could come into contact with ME SYSTEMS.

Clause 16 on ME SYSTEMS is intended to be used by MANUFACTURERS of combinations of electrical equipment that include one or more items of ME EQUIPMENT. The equipment can be separate items or can be in a single enclosure or a combination of these cases.

Clause 16 is also intended to be used by personnel from institutions for medical practice who assemble or adapt ME SYSTEMS, as they can become the MANUFACTURER by that action. In this case, engineering expertise in the application of the electrical equipment design standards is required to ensure that the ME SYSTEM complies with all requirements of Clause 16.

More and more, such ME SYSTEMS comprise equipment originally manufactured for use in different specific application fields, not necessarily medical, that are connected with each other in a direct or indirect way. ME EQUIPMENT complying with this standard can be connected with other, non-ME EQUIPMENT. The latter equipment might fully meet the requirements in the safety standards applicable in their specific application field. However, they do not always comply with the safety requirements for ME EQUIPMENT and, thereby, influence the safety of the whole ME SYSTEM. It is for this reason that the MANUFACTURER is required to apply risk management to the whole ME SYSTEM. One example of an additional hazard is the ignition of fire when an ME SYSTEM containing non-ME EQUIPMENT is used in an oxygen rich environment, possibly accidentally.

The electrical equipment can be situated either in a medically used room that is intended for diagnosis, treatment or monitoring of PATIENTS, or in a non-medically used room where no medical practice is performed. Within a medically used room, electrical equipment might be placed inside or outside a volume that is defined as PATIENT ENVIRONMENT.

There are two situations possible in medical practice.

a) Where Clause 16 does not apply

   Simultaneously operated ME EQUIPMENT, i.e. different ME EQUIPMENT connected at the same time to a patient but not connected to each other. Such ME EQUIPMENT can influence each other. For example, high-frequency surgical equipment in the operating theatre can influence patient monitoring.

   NOTE Assistance can be available from the instructions for use for each ME EQUIPMENT.

b) Where Clause 16 applies

   ME SYSTEMS, consisting of ME EQUIPMENT and possibly also non-ME EQUIPMENT, interconnected permanently or temporarily for a certain purpose such as diagnosis or treatment of a patient. Examples: ME SYSTEMS for diagnostic X-ray examination, endoscopes with video camera, PATIENT monitoring, ultrasound equipment with a personal computer, computed tomography or magnetic resonance imaging.

   The various parts of such an ME SYSTEM could be situated within the PATIENT ENVIRONMENT or outside it but still within a medically used room, or parts of the ME SYSTEM could be located in a non-medically used room containing, for example, electrical power distribution or data processing equipment.

Table H.1 – Some examples of ME SYSTEMS for illustration [a] *(1 of 3)*

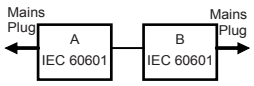
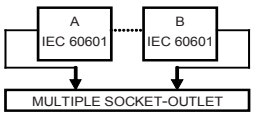
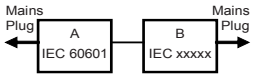
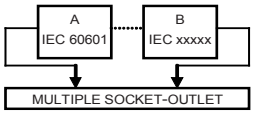
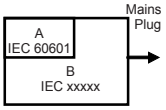
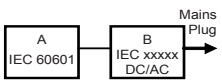
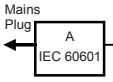
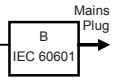
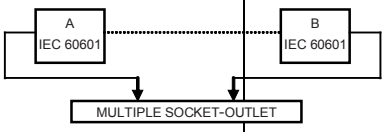
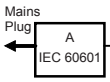
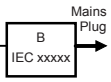
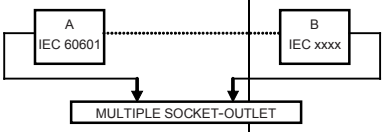
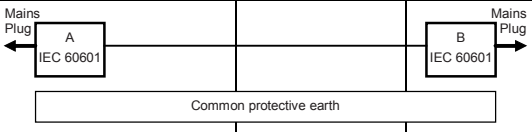
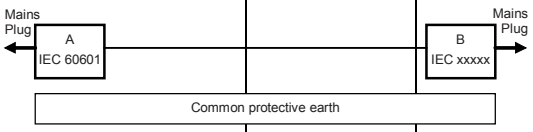
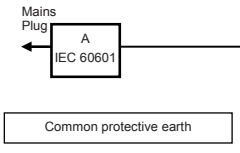
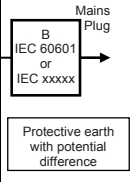
Situation No.		Medically used room		Non-medically used room	Examples of possible causes for exceeding LEAKAGE CURRENT limits	Practical means of compliance Apply 16.5 in all situations
		Inside the PATIENT ENVIRONMENT	Outside the PATIENT ENVIRONMENT			
1	**1a** Items A and B are ME EQUIPMENT				Multiplied APPLIED PARTS of the same type can cause the total PATIENT LEAKAGE CURRENT to exceed limits See Note 1.	– Verify total PATIENT LEAKAGE CURRENT
	1b Items A and B are ME EQUIPMENT powered via a MULTIPLE SOCKET-OUTLET				Earth conductor of the MULTIPLE SOCKET-OUTLET is broken See also 1a.	– Additional PROTECTIVE EARTH CONNECTION (for A or B) or, – Separating transformer
	1c Item A is ME EQUIPMENT and B is Non-ME EQUIPMENT				Due to high TOUCH CURRENT of B	– Additional PROTECTIVE EARTH CONNECTION (for B) or, – Separating transformer (for B)
	1**d** Item A is ME EQUIPMENT and B is non-ME EQUIPMENT powered via a MULTIPLE SOCKET-OUTLET				The earth conductor of the MULTIPLE SOCKET-OUTLET is broken or, Due to high TOUCH CURRENT of B	– Additional PROTECTIVE EARTH CONNECTION (for A or B) or, – Separating transformer
	1e Item A is ME EQUIPMENT powered from specified power supply in item B				Due to high TOUCH CURRENT of B	– Additional PROTECTIVE EARTH CONNECTION (for B) or, – Separating transformer (for B)
	1f Item A is ME EQUIPMENT powered from NON-ME EQUIPMENT power supply in B					

Table H.1 *(2 of 3)*

Situation No.		Medically used room: Inside the PATIENT ENVIRONMENT	Medically used room: Outside the PATIENT ENVIRONMENT	Non-medically used room	Examples of possible causes for exceeding LEAKAGE CURRENT limits	Practical means of compliance Apply 16.5 in all situations
2	**2a** Items A and B are ME EQUIPMENT				No causes of exceeding LEAKAGE CURRENT	– No further measures are necessary
	2b Items A and B are ME EQUIPMENT powered via a MULTIPLE SOCKET-OUTLET				Earth conductor of the MULTIPLE SOCKET-OUTLET is broken	– Additional PROTECTIVE EARTH CONNECTION (for A or B) , or – Separating transformer
	2c Item A is ME EQUIPMENT and item B is non-ME EQUIPMENT				Due to high TOUCH CURRENT of B See rationale for 16.5.	– Do not use metal connector housing or, – SEPARATION DEVICE
	2d Item A is ME EQUIPMENT and item B is non-ME EQUIPMENT powered via a MULTIPLE SOCKET-OUTLET				The earth conductor of the MULTIPLE SOCKET-OUTLET is broken	– Additional PROTECTIVE EARTH CONNECTION (for A or B), or – Separating transformer
3	**3a** Items A and B are ME EQUIPMENT				No causes of exceeding LEAKAGE CURRENT	– No further measures are necessary
	3b Item A is ME EQUIPMENT and item B is non-ME EQUIPMENT				Due to high TOUCH CURRENT of B See rationale for 16.5.	– Do not use metal connector housing for SIGNAL INPUT/OUTPUT PART, or – SEPARATION DEVICE
	3c Item A is ME EQUIPMENT and item B is ME EQUIPMENT or non-ME EQUIPMENT				a) Potential difference between PROTECTIVE EARTH CONNECTIONS of A and B b) Due to high TOUCH CURRENT of B See rationale for 16.5.	– Additional PROTECTIVE EARTH CONNECTION for (A), or – SEPARATION DEVICE, or – Do not use metal connector housing in the PATIENT ENVIRONMENT

[a] Derived from IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012. All references in this table are to subclauses or figures in IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012

Table H.1 *(3 of 3)*

NOTE 1 No causes of TOUCH CURRENT or EARTH LEAKAGE CURRENT exceeding limits.
NOTE 2 IEC 60601: MEDICAL ELECTRICAL EQUIPMENT in compliance with IEC 60601.
NOTE 3 IEC xxxxx: Non-medical equipment in compliance with relevant IEC safety standards.
NOTE 4 Separating transformer: see 16.9.2.1.
NOTE 5 If equipment "B" is outside the PATIENT ENVIRONMENT and if equipment "A" is a CLASS II equipment and has ACCESSIBLE CONDUCTIVE PARTS connected to the PROTECTIVE EARTH CONNECTION of equipment "B", then additional safety measures could be necessary, for example: additional protective earth for "B" or separating transformer or separation device.

H.4 Examples of application of MULTIPLE SOCKET-OUTLETS (MSO)

Figure H.1 shows an example of the construction of a MULTIPLE SOCKET-OUTLET. Figure H.2 shows some examples of application of MULTIPLE SOCKET-OUTLETS.

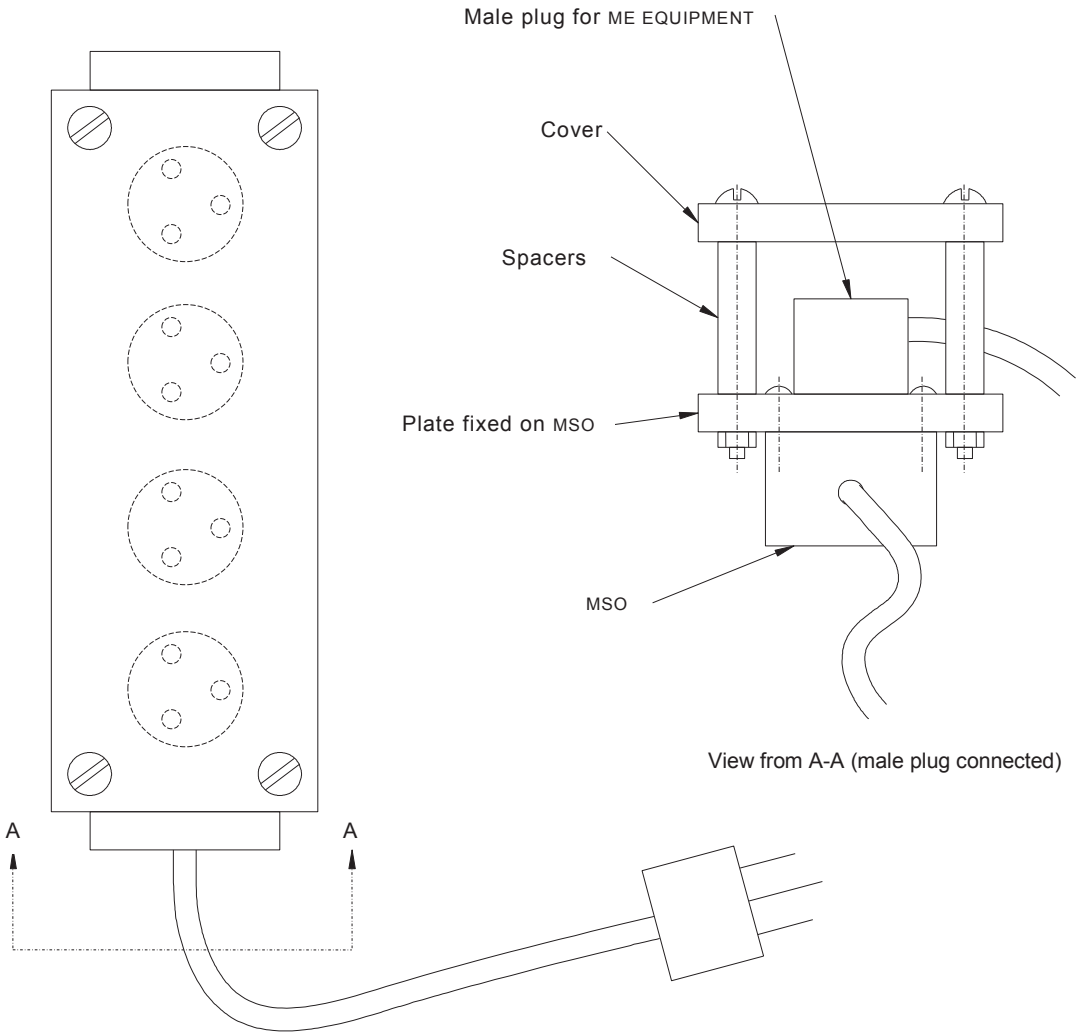


Figure H.1 – Example of the construction of a MULTIPLE SOCKET-OUTLET (MSO) (accessible only with the use of a tool)

(This figure is derived from IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012)

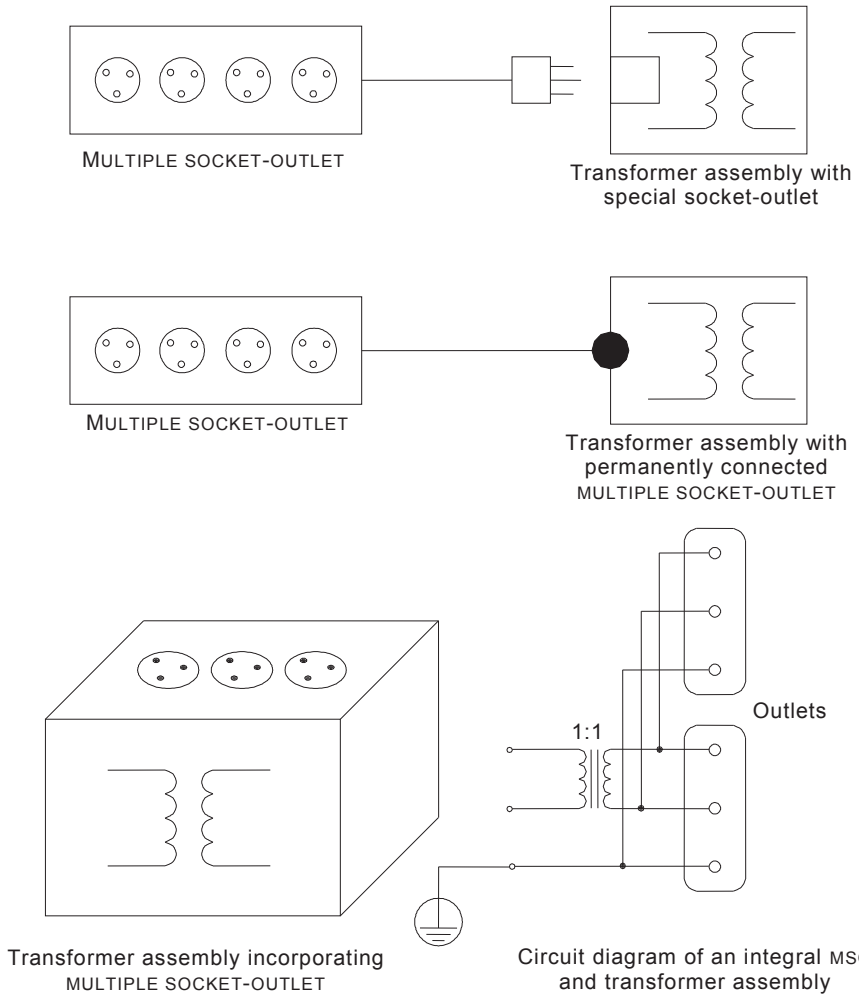


Figure H 2 – Examples of application of MULTIPLE SOCKET-OUTLETS (MSO)

(This figure is derived from IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012)

Bibliography

[1] IEC 60335 (all parts), *Household and similar electrical appliances – Safety*

[2] IEC 60950 (all parts), *Information technology equipment – Safety*

[3] IEC 60950-1, *Information technology equipment – Safety – Part 1: General requirements*

[4] IEC 61010 (all parts), *Safety requirements for electrical equipment for measurement, control and laboratory use*

[5] IEC 61557-2:2007, *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 2: Insulation resistance*

[6] IEC 61557-4:2007, *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 4: Resistance of earth connection and equipotential bonding*

[7] IEC 61557-16:___[6], *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 16: Equipment for testing the effectiveness of the protective measures of electrical equipment described in IEC 62638 and/or medical electrical equipment described in IEC 62353*

[8] IEC 62020, *Electrical accessories – Residual current monitors for household and similar uses (RCMs)*

[9] ISO 13485:2003, *Medical devices – Quality management systems – Requirements for regulatory purposes*

[10] ISO 14971:2007, *Medical devices – Application of risk management to medical devices*

[11] IEC 60364-7-710, *Electrical installations of buildings – Part 7-710: Requirements for special installations or locations – Medical locations*

[12] 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*

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