IS/IEC 62353 (2007): Medical Electrical Equipmnent - Recurrent Test and Test After Repair of Medical Electrical Equipment [MHD 18: Imaging and Radiotherapy Equipment]

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भारतीय मानक

चिकित्सीय विद्युत उपस्कर — रिकरेंट परीक्षण एवं चिकित्सीय विद्युत उपस्कर की मरम्मत के बाद परीक्षण

Indian Standard

MEDICAL ELECTRICAL EQUIPMENT — RECURRENT TEST AND TEST AFTER REPAIR OF MEDICAL ELECTRICAL EQUIPMENT

ICS 11.040.01

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December 2012 **Price Group 14**

Electromedical Equipment Sectional Committee, MHD 15

NATIONAL FOREWORD

This Indian Standard which is identical with IEC 62353 : 2007 'Medical electrical equipment — Recurrent test and test after repair of medical electrical equipment' issued by the International Electrotechnical Commission (IEC) was adopted by the Bureau of Indian Standards on the recommendation of the Electromedical Equipment Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

This standard applies to testing of medical electrical equipment and medical electrical systems or parts of such equipment or systems before putting into service, during maintenance, inspection, servicing and after repair or on occasion of recurrent tests to access the safety of such Medical Electrical Equipment or Medical Electrical Systems or parts thereof.

The text of IEC Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
IEC 60601-1 : 2005 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance	IS 13450 (Part 1) : 2008 Medical electrical equipment: Part 1 General requirement for basic safety and essential performance	Identical
IEC 61140 : 2001 Protection against electric shock —Common aspects for installation and equipment	IS 9409 : 1980 Classification of electrical and electronic equipment with regard to protection against electric shock	Technically Equivalent

The technical committee has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard:

International Standard	*Title*
IEC 60364-7-710 : 2002	Electrical installations of buildings — Part 7-710: Requirements for special installations or locations — Medical locations
IEC 60417 : 2002	Graphical symbols for use on equipment
IEC 61010-1 : 2010	Safety requirements for electrical equipment for measurement, control and laboratory use — Part 1: General requirements
IEC 61010-2-010 : 2003	Safety requirements for electrical equipment for measurement, control and laboratory use — Part 2-010: Particular requirements for laboratory equipment for the heating of materials

(*Continued on third cover*)

Indian Standard

MEDICAL ELECTRICAL EQUIPMENT — RECURRENT TEST AND TEST AFTER REPAIR OF MEDICAL ELECTRICAL EQUIPMENT

1 Scope

This International Standard applies to testing of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS, or parts of such equipment or systems, which comply with IEC 60601-1, before PUTTING INTO SERVICE, during MAINTENANCE, INSPECTION, SERVICING and after REPAIR or on occasion of RECURRENT TESTS to assess the safety of such ME EQUIPMENT or ME SYSTEMS or parts thereof. For equipment not built to IEC 60601-1 these requirements may be used taking into account the safety standards for the design and information in the instructions for use of that equipment.

This standard contains tables with allowable values relating to different editions of IEC 60601-1. For the purpose of this standard, the application of measuring methods is independent of the edition according to which the ME EQUIPMENT OR ME SYSTEM is designed.

This standard contains:

– "general requirements", which contain clauses of general concern, and
– "particular requirements", further clauses handling special types of ME EQUIPMENT or ME SYSTEMS and applying in connection with the "General requirements".

NOTE 1 At this stage, there are no particular requirements.

This standard is not suitable to assess whether ME EQUIPMENT or ME SYSTEMS or any other equipment comply with the relevant standards for their design.

This standard does not define requirements for REPAIR, exchange of components and MODIFICATION of ME EQUIPMENT or ME SYSTEMS.

NOTE 2 All MAINTENANCE, INSPECTION, SERVICING, and REPAIR done in accordance with MANUFACTURER's instructions maintain the conformity to the standard used for the design of the equipment. Otherwise conformity to applicable requirements have to be assessed and verified.

This standard is also applicable to tests after REPAIR. The testing shall be defined according to the extent of work performed and applicable guidance from the MANUFACTURER.

This standard is not intended to define time intervals for RECURRENT TESTS. If such intervals are not defined by the MANUFACTURER, Annex F may be used to help establish such intervals.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

IEC 60417, *Graphical symbols for use on equipment*

IEC 61010-1, *Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements*

IEC 61010-2-010, *Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of materials*

IEC 61010-031, *Safety requirements for electrical equipment for measurement, control and laboratory use – Part 031: Safety requirements for hand-held probe assemblies for electrical measurement and test*

IEC 61140, *Protection against electric shock – Common aspects for installation and equipment*

IEC 61557-1, *Electrical safety in low voltage distribution systems up to 1000 V a.c. and 1500 V d.c. – Equipment for testing, measuring or monitoring of protective measures – Part 1: General requirements*

3 Terms and definitions

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

NOTE Some of the definitions have to be different than those in IEC 60601-1, as different measuring methods are used.

3.1
ACCESSIBLE CONDUCTIVE PART
part of the ME EQUIPMENT other than an APPLIED PART, which is accessible to the patient, to the operator in contact with the patient or can come in contact with the patient

NOTE It is necessary that other accessible parts comply with their respective safety requirements.

3.2
ACCESSORY
additional part for use with equipment in order to:

– achieve the intended use,
– adapt it to some special use,
– facilitate its use,
– enhance its performance, or
– enable its functions to be integrated with those of other equipment

[IEC 60601-1:2005, definition 3.3]

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

[IEC 60601-1:2005, definition 3.4]

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

[IEC 60601-1:2005, definition 3.8]

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

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

[IEC 60601-1:2005, definition 3.13]

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

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

[IEC 60601-1:2005, definition 3.14]

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

[IEC 60601-1:2005, definition 3.21]

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

[IEC 60601-1:2005, definition 3.25]

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

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

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

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

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

[IEC 60601-1:2005, definition 3.29]

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

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

[IEC 60601-1:2005, definition 3.33]

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

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

EXAMPLE Chemical, mechanical, solar, or nuclear.

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

[IEC 60601-1:2005, definition 3.45]

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

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

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

[IEC 60601-1:2005, definition 3.49]

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

[IEC 60601-1:2005, definition 3.50]

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

[IEC 60601-1:2005, definition 3.54]

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

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

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

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

– accompanying a medical device,

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

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

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

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

[IEC 60601-1:2005, definition 3.55]

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

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

b) intended by its MANUFACTURER to be used:

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

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

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

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

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

[IEC 60601-1:2005, definition 3.63]

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

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

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

[IEC 60601-1:2005, definition 3.64]

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

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

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

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

[IEC 60601-1:2005, definition 3.67]

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

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

[IEC 60601-1:2005, definition 3.70]

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

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

[IEC 60601-1:2005, definition 3.79]

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

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

[IEC 60601-1:2005, definition 3.80]

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

[IEC 60601-1:2005, definition 3.84]

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

[IEC 60601-12005, definition 3.87]

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

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

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

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

NOTE This will be the first application of RECURRENT TESTS.

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

3.34
REFERENCE VALUE
value documented for the assessment of subsequent measurements

3.35
REPAIR
means for reconstitution of a defined condition

3.36
RESPONSIBLE ORGANIZATION
entity accountable for the use and MAINTENANCE of an ME EQUIPMENT or an ME SYSTEM

NOTE 1 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 Education and training is included in "use".

[IEC 60601-1:2005, definition 3.101]

3.37
SERVICING
combination of all means for maintaining the ME EQUIPMENT or ME SYSTEM within requirements of the MANUFACTURER

3.38
SINGLE FAULT CONDITION
condition in which a single means for reducing a risk is defective or a single abnormal condition is present

[IEC 60601-1:2005, definition 3.116]

3.39
SUPPLY MAINS
source of electrical energy not forming part of ME EQUIPMENT or ME SYSTEM

NOTE This also includes battery systems and converter systems in ambulances and the like.

[IEC 60601-1:2005, definition 3.120]

3.40
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 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 and to reflect the fact that the measurement now applies also to parts that are normally protectively earthed.

[IEC 60601-1:2005, definition 3.129]

3.41
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 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 TYPE B APPLIED PARTS are not suitable for direct cardiac application.

[IEC 60601-1:2005, definition 3.132, modified]

3.42
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 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 TYPE BF APPLIED PARTS are not suitable for direct cardiac application.

[IEC 60601-1:2005, definition 3.133, modified]

3.43
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 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) ( ).

[IEC 60601-1:2005, definition 3.134, modified]

4 Requirements

4.1 * General requirements

The following requirements apply to:

– tests before PUTTING INTO SERVICE,

– RECURRENT TESTS, and

– tests after REPAIR.

The extent and set of tests shall be chosen to ensure sufficient information and amount of test results for assessment of the safety of the ME EQUIPMENT.

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

NOTE 1 The MANUFACTURER has to define in the instructions for use or other ACCOMPANYING DOCUMENTS (e.g. for SERVICING) necessary measurement settings and methods; this may also omit any test.

NOTE 2 For ME SYSTEMS, the responsible party, who has assembled the system, will define the necessary measurement settings and methods as required in IEC 60601-1-1.

NOTE 3 If no requirements for SERVICING are established by the MANUFACTURER also a RESPONSIBLE ORGANISATION having appropriate expertise may provide requirements for SERVICING. Appropriate expertise includes but is not limited to knowledge and experience with the relevant standards such as IEC 60601-1 including risk management, IEC 60950, IEC 61010 and local regulations.

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.

Qualified personnel shall perform these tests. Qualification shall include training on the subject, knowledge, experience and acquaintance with the relevant technologies, 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 has its own connection to SUPPLY MAINS, or 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.

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 has to 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.

If items of ME EQUIPMENT, which are combined into an ME SYSTEM by FUNCTIONAL CONNECTION, cannot be tested separately for technical reasons, 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.

All DETACHABLE POWER SUPPLY CORDS, which are available ready for use, 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 hazards arise for testing personnel, patients or other individuals.

If not otherwise stated, all values for current and voltage are the r.m.s. values of an alternating, direct or composite voltage or current.

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

Before first time operation as intended:

– of new or modified ME EQUIPMENT or ME SYSTEMS,

– of ME EQUIPMENT or ME SYSTEMS not yet tested according to Clause 5, or

– of REPAIRED ME EQUIPMENT or ME SYSTEMS,

the applicable tests as listed in Clause 5 shall be performed.

The results of these measurements are the "REFERENCE VALUE" and shall be documented together with the measuring method, as a reference for future measurements.

After any REPAIR and/or MODIFICATION of the ME EQUIPMENT, conformity to the applicable requirements of the standards used for the design of the equipment shall be assessed and verified. This shall be done by a qualified and authorized individual.

The extent of testing according to this standard shall take into account the kind of REPAIR or MODIFICATION.

4.3 * RECURRENT TEST

The applicable tests as listed in Clause 5 shall be used for 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 2 or the tables in Annex E.

If the measured values are between 90 % and 100 % of the acceptable limit, previously measured values (REFERENCE VALUE) shall be taken into consideration for the assessment of the ELECTRICAL SAFETY of the ME EQUIPMENT or the ME SYSTEM. If such previous data values are not available, reduced intervals between upcoming RECURRENT TESTS shall be taken into account.

ME SYSTEMS shall be visually inspected to determine whether the configuration is still the same as at the time of the last INSPECTION, or whether units of the ME SYSTEM have been exchanged, added or removed. Such changes shall be documented, as well as any changing of the configuration of ME SYSTEM, and will void the validity of previous REFERENCE VALUES. Measurement results/values measured after changes of the ME SYSTEM shall be documented as REFERENCE VALUES.

5 * Tests

5.1 General

Prior to testing, consult the ACCOMPANYING DOCUMENTS 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 and atmospheric pressure as present at the site of testing. Requirements for supply voltage as defined in IEC 60601-1 do not have to be fulfilled.

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 required in this standard, or
– if there is an indication of inadequate safety.

Special attention shall be paid to the following:

– all fuses accessible from the outside are complying with the data given by the MANUFACTURER (rated current, characteristics),
– safety related marking, labels and labelling is legible and complete,
– the integrity of mechanical parts,
– any damage or contamination,
– assess the relevant ACCESSORIES together with the ME EQUIPMENT or ME SYSTEM (e.g. detachable or fixed POWER SUPPLY CORDS, patient leads, tubing),
– the required documentation is present and reflects the current revision 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 normal 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 for the personnel performing the tests and 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 protective earth connections may 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 5.3.4 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 respectively 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, during the measurement the cord shall be flexed along its length. 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.

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

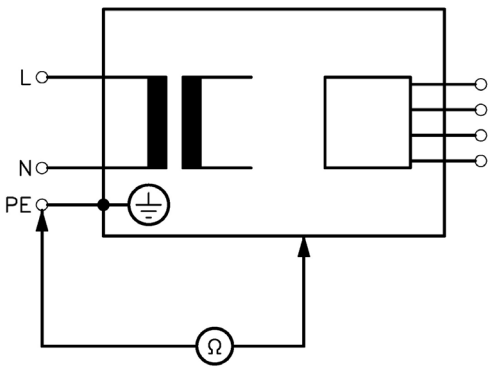
ACCESSIBLE CONDUCTIVE PARTS of the ME EQUIPMENT or ME SYSTEM shall not exceed 200 mΩ. For the POWER SUPPLY CORD itself, the resistance between the earth connections at each end shall not exceed 100 mΩ. If the DETACHABLE POWER SUPPLY CORD and the ME EQUIPMENT or ME SYSTEM are measured together, the resistance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

Additionally, DETACHABLE POWER SUPPLY CORDS kept ready for use shall be measured as well.

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.

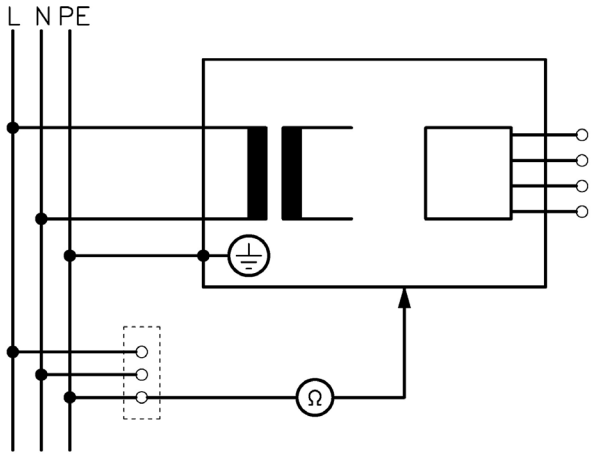
In measurements according to Figure 2, the resistance of protective earth connections in the SUPPLY MAINS may be taken into account.

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 500 mΩ.



(For legends, see Table 1)

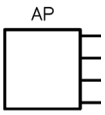
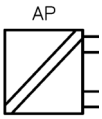
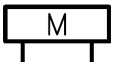
Figure 1 – Measuring circuit for the measurement of PROTECTIVE EARTH RESISTANCE in ME EQUIPMENT that is disconnected from the SUPPLY MAINS



(For legends, see Table 1)

Figure 2 – Measuring circuit for the measurement of PROTECTIVE EARTH RESISTANCE in ME EQUIPMENT or ME SYSTEM, which for functional reasons cannot be disconnected from SUPPLY MAINS, or in ME EQUIPMENT or ME SYSTEM permanently connected to 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
	Part of enclosure not protectively earthed		Connection to ACCESIBLE CONDUCTIVE PARTS
	Optional connection		

5.3.3 Leakage currents

5.3.3.1 * 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 5.3.3.2.2 or 5.3.3.3.2;

b) Direct method according to 5.3.3.2.3 or 5.3.3.3.3;

c) Differential method according to 5.3.3.2.4.

Leakage currents shall not exceed the values of Table 2.

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

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

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

Measuring of EQUIPMENT LEAKAGE CURRENT shall be performed to give same result as measured in the SINGLE FAULT CONDITION.

For PERMANENTLY INSTALLED ME EQUIPMENT measurement of EQUIPMENT LEAKAGE CURRENT is not necessary if the protective measures against electric shock in the SUPPLY MAINS are according to IEC 60364-7-710 (medical locations) and the tests thereof are done regularly.

Equipment shall be measured in all intended functional 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.

Measurements according to IEC 60601-1 (all editions) may be performed, if protection of the personnel and of the environment is guaranteed. For allowable values, refer to the tables in Annex E.

The measured value shall be corrected to the value corresponding with the nominal MAINS VOLTAGE.

This standard does not provide measuring methods and allowable values for equipment producing d.c. leakage currents. In such a case, if the MANUFACTURER determines d.c. current testing is necessary, then the MANUFACTURER shall give information in the ACCOMPANYING DOCUMENTS and the limits of IEC 60601-1 regarding d.c. currents shall be applied.

ME EQUIPMENT or ME SYSTEMS that can be connected to SUPPLY MAINS shall be tested according to Figure 3, Figure 4, Figure 5, Figure 6 or Figure 7.

ME EQUIPMENT or ME SYSTEMS, powered by an INTERNAL ELECTRICAL POWER SOURCE shall be tested according to Figure 8 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 2. 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.

5.3.3.2 Measurement of EQUIPMENT LEAKAGE CURRENT

5.3.3.2.1 Applicability

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

5.3.3.2.2 * Alternative method

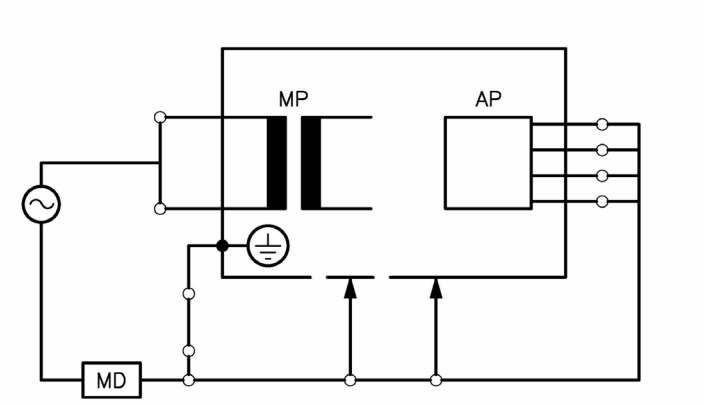
Equipment is separated from mains, and the EQUIPMENT LEAKAGE CURRENT is measured according to Figure 3.

NOTE 1 With CLASS I ME EQUIPMENT it may be necessary to measure the leakage currents separately from ACCESSIBLE CONDUCTIVE PARTS which are not connected to the protective earth conductor (different allowable value see Table 2).

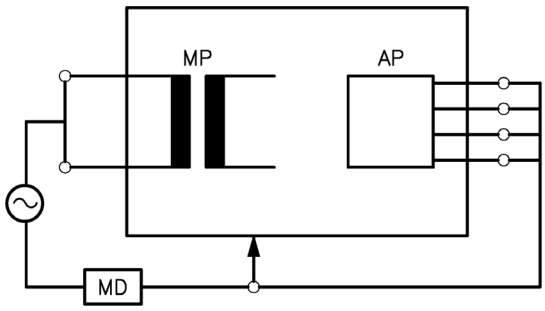
NOTE 2 CLASS I ME EQUIPMENT does not need to be isolated from protective earth during measurement

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 5 mA, other measurement methods shall be performed.



CLASS I



CLASS II

(For legends, see Table 1)

Figure 3 – Measuring circuit for the measurement of EQUIPMENT LEAKAGE CURRENT – alternative method

5.3.3.2.3 Direct method

Measurements are performed:

– at MAINS VOLTAGE, and

– in either position of the MAINS PLUG, if applicable, and

– according to Figure 4.

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

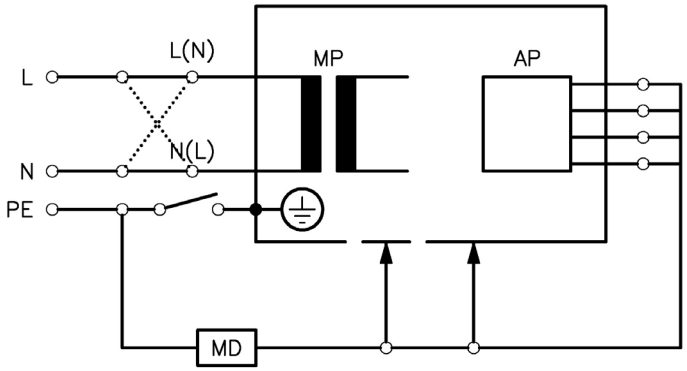
NOTE 1 In case of an IT-power system, this measurement requires a special measuring circuit, for example with its own integrated TN-system.

During the measurement the equipment shall be isolated from earth, except the protective earth conductor in the POWER SUPPLY CORD. Otherwise the direct method is not applicable.

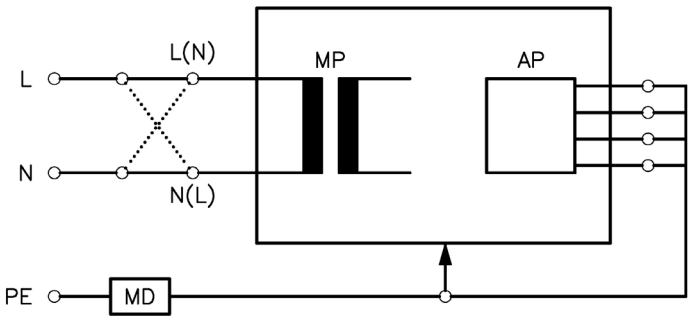
NOTE 2 An earth potential can be imported by e.g. external data lines.

NOTE 3 When measuring EQUIPMENT LEAKAGE CURRENT of CLASS I ME EQUIPMENT, special attention needs to be paid as persons can be endangered by an interrupt of the protective earth connection.

NOTE 4 In CLASS I ME EQUIPMENT, it might be necessary to measure separately the leakage currents from ACCESSIBLE CONDUCTIVE PARTs, which are not connected to the protective earth conductor (different allowable value see Table 2).



CLASS I



CLASS II

The device under test shall be isolated from protective earth.

(For legends, see Table 1)

Figure 4 – Measuring circuit for the measurement of EQUIPMENT LEAKAGE CURRENT– direct method

5.3.3.2.4 * Differential method

Measurements are performed:

– at MAINS VOLTAGE, and

– in either position of the MAINS PLUG, if applicable, and

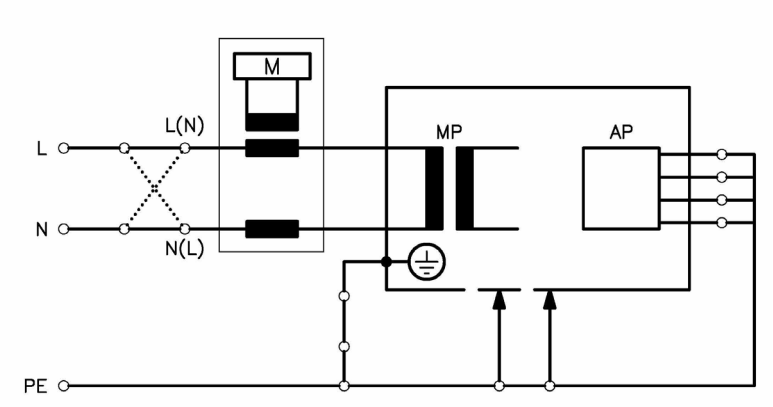
– according to Figure 5.

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

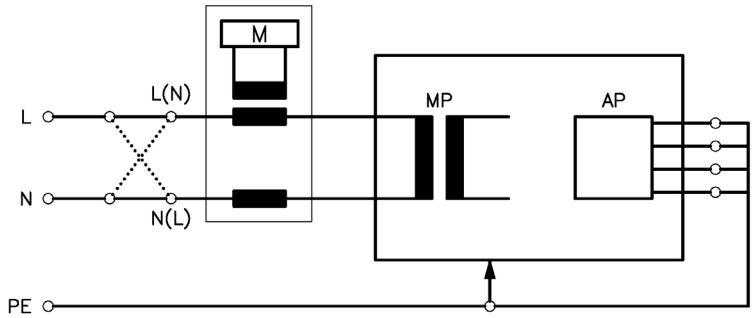
NOTE 1 In case of IT-power system, this measurement requires a special measuring circuit for example with its own integrated TN-system.

When measuring small leakage currents, attention shall be paid to the MANUFACTURER's information about limitations of the measuring equipment.

NOTE 2 In CLASS I ME EQUIPMENT, it might be necessary to measure separately the leakage currents from ACCESSIBLE CONDUCTIVE PARTs which are not connected to the protective earth conductor (for different allowable values, see Table 2).



CLASS I



CLASS II

(For legends, see Table 1)

Figure 5 – Measuring circuit for the measurement EQUIPMENT LEAKAGE CURRENT – differential method

5.3.3.3 Measurement of APPLIED PART LEAKAGE CURRENT

5.3.3.3.1 General

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

– For TYPE B APPLIED PARTs usually no separate measurement is necessary. They are connected to the enclosure (see figures) and are included by the measurement of the enclosure leakage current, with the same allowable values.

NOTE Separately measurement of TYPE B APPLIED PART leakage current has only to be done if described by the MANUFACTURER (see ACCOMPANYING DOCUMENTS).

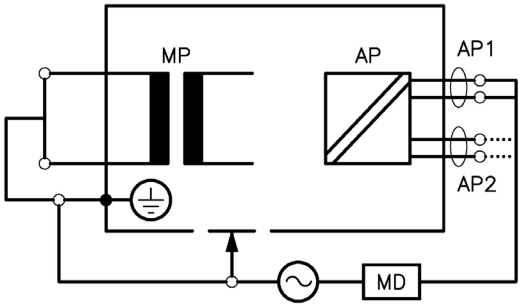
– F-TYPE APPLIED PART shall be measured from all patient connections of a single function of the APPLIED PART connected together according to Figure 6, Figure 7 or Figure 8, or as described by the MANUFACTURER.

– When testing ME EQUIPMENT with multiple APPLIED PARTs, connect them each in turn and comply with the applicable limits in Table 2, APPLIED PARTs not part of the measurement shall be left floating.

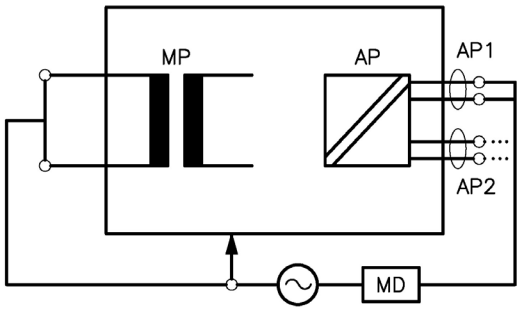
For allowable values, refer to Table 2 or Annex E.

5.3.3.3.2 * Alternative method

Measurement in ME EQUIPMENT having an F TYPE APPLIED PART is performed according to Figure 6 for mains operated ME EQUIPMENT.



CLASS I



CLASS II

(For legends, see Table 1)

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

5.3.3.3.3 Direct method

Measurements are performed:

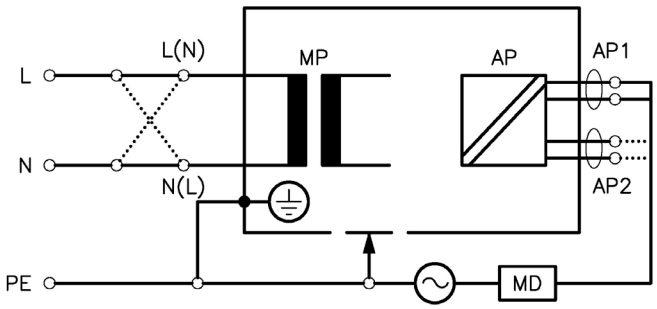
– at MAINS VOLTAGE,

– in either position of the MAINS PLUG, if applicable, and

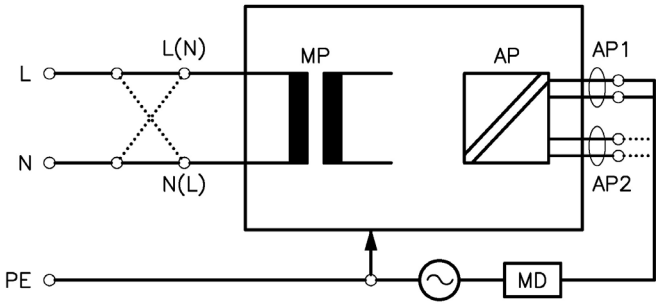
– according to Figure 7, or

– according to Figure 8 in ME EQUIPMENT having an INTERNAL ELECTRICAL POWER SOURCE.

NOTE In case of IT-power system this measurement requires a special measuring circuit for example with its own integrated TN-system.



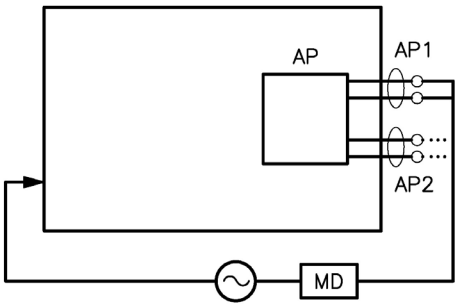
CLASS I



CLASS II

(For legends, see Table 1)

Figure 7 – 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 8 – Measuring circuit for the measurement of APPLIED PART LEAKAGE CURRENT for equipment with an INTERNAL ELECTRICAL POWER SOURCE – direct method

Table 2 – Allowable values for leakage currents

Current µA	APPLIED PART		
	Type B	Type BF	Type CF
EQUIPMENT LEAKAGE CURRENT – alternative method (Figure 3)			
– EQUIPMENT LEAKAGE CURRENT for ACCESSIBLE CONDUCTIVE PARTS of CLASS I ME EQUIPMENT connected or not connected to the protective earth conductor	1 000	1 000	1 000
– EQUIPMENT LEAKAGE CURRENT for CLASS II ME EQUIPMENT	500	500	500
EQUIPMENT LEAKAGE CURRENT – direct or differential method (Figure 4 or Figure 5)			
– EQUIPMENT LEAKAGE CURRENT for ACCESSIBLE CONDUCTIVE PARTS of CLASS I ME EQUIPMENT connected or not connected to the protective earth conductor	500	500	500
– EQUIPMENT LEAKAGE CURRENT for CLASS II ME EQUIPMENT	100	100	100
APPLIED PART LEAKAGE CURRENT – alternative method (a.c.) (Figure 6)			
– APPLIED PART LEAKAGE CURRENT		5 000	50
APPLIED PART LEAKAGE CURRENT – direct method (a.c.) (Figure 7 or Figure 8)			
– APPLIED PART LEAKAGE CURRENTS (MAINS VOLTAGE on the APPLIED PART)		5 000	50
NOTE 1 This standard does not provide measuring methods and allowable values for equipment producing d.c. leakage currents. In such a case, the MANUFACTURER should give information in ACCOMPANYING DOCUMENTS. NOTE 2 Particular standards may allow different values of leakage current			

5.3.4 * Measurement of insulation resistance

The equipment is disconnected from SUPPLY MAINS and the equipment insulation resistance measured according to Figure 9, Figure 10 and Figure 11.

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

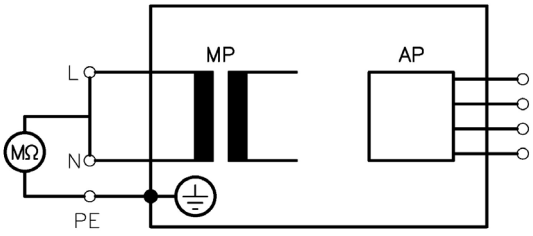
Insulation resistance measurements shall be performed with 500 V (d.c.)

NOTE To prevent damage to the equipment, a measurement of insulation resistance between APPLIED PARTS and protective earth connector, respectively enclosure, may only be performed if the equipment is suited to stand such measurement.

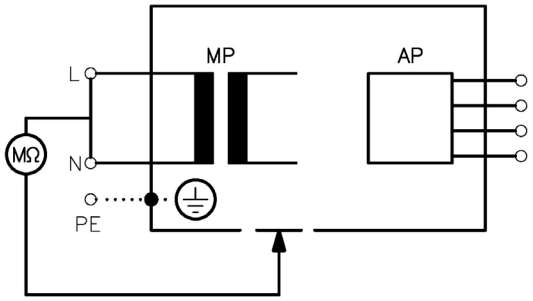
Insulation resistance shall be measured between:

– the MAINS PART and protective earth for CLASS I equipment according to Figure 9,
– the MAINS PART and (non-earthed) ACCESSIBLE CONDUCTIVE PARTS for CLASS II and CLASS II equipment according to Figure 9,
– the MAINS PART and APPLIED PARTs which make a patient connection according to Figure 10
– F-TYPE APPLIED PART which make a patient connection and protective earth for CLASS I equipment according to Figure 11,

– F-TYPE APPLIED PART which make a patient connection and (non-earthed) ACCESSIBLE CONDUCTIVE PARTS for CLASS I and CLASS II equipment according to Figure 11.



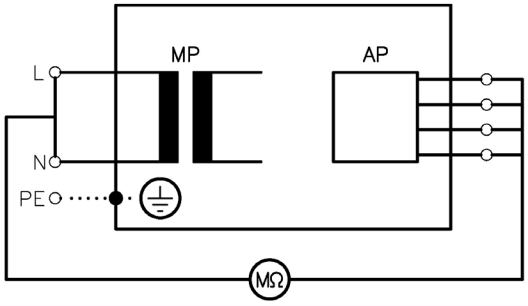
CLASS I



CLASS I and CLASS II

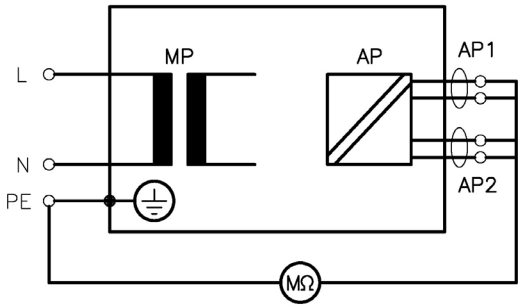
(For legends, see Table 1)

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

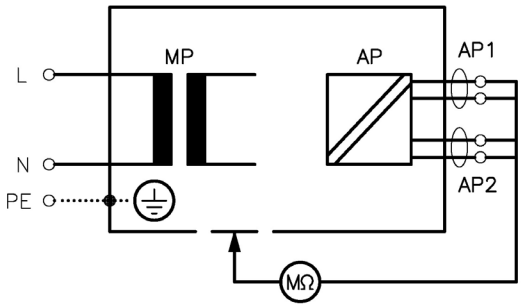


(For legends, see Table 1)

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



CLASS I



CLASS I and CLASS II

(For legends, see Table 1)

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

5.4 Functional test

The safety related functions of the equipment shall be tested according to the MANUFACTURER's recommendations, if necessary with the assistance of a person familiar with the use of the ME EQUIPMENT or ME SYSTEM.

NOTE In this context, functional tests are also tests covering aspects of functions which are defined in IEC 60601-1:2005 and 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 comprehensively. 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 applicable (decided by the RESPONSIBLE ORGANIZATION), the equipment/system tested shall be marked / identified accordingly.

For an example to 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 person(s) (as defined in IEC 61140) who has/have the appropriate training for the equipment under test.

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 emerging 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 proof 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 have to be tested before putting equipment into service as well.

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

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 cannot be deemed consistent and are therefore not always suitable for use during testing of equipment being in-service. An additional aspect is that equipment could potentially be damaged during test applications and can face a potential danger to person(s) and surrounding.

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 equipments safety whilst maintaining the relation the IEC 60601-1 and minimising the risk of hazard to the person conducting the assessment.

All these aspects were considered during the creation of the 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 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 may 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(s). Therefore it might be advisable to reduce the intervals between the tests when the measured value goes beyond the 90 % limit.

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, shall not be applied;
b) the safety of the person(s) conducting the tests, or other individuals and/or the environment of the equipment/system shall be ensured;
c) the most important parameters of safety shall 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 mains supply cable 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.

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 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 is acceptable.

Subclause 5.3.3.1 – General

This measurement utilizes the actual mains supply voltage as test level (IEC 60601-1 requires a voltage level equal to + 10% of the rated supply voltage) thus taking possible aging of the ME EQUIPMENT or ME SYSTEM into account. Such additional aging may be induced or accelerated by applying unnecessary voltages above the actual level of SUPPLY MAINS.

Table A.2 – Reasons for choosing different measuring methods

Measuring method	Reasons for	Reasons against
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 mains supply – 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 device under test [DUT]) • by disconnecting the measurement device • if used in connection with other devices – 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 mains supply
Differential method	– Not influenced by the type of switch in the mains supply – DUT does not need to be isolated during measurement – It measures the total leakage current	– Less suitable for lower leakage current measurements – Influenced by external magnetic field, current frequency and current consumption of DUT – Measurement shall be done in each polarity of mains supply – Accuracy and frequency range may be limited compared with the other measuring methods
Alternative method	– Does not need a TN-System – Only one measurement necessary (polarity of mains supply does not matter) – Highest safety for person doing the test (because DUT is disconnected from mains supply) – DUT does not need to be isolated during measurement	– Electronic switches in the mains supply 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.) – May not detect some leakage current conditions (e.g. higher leakage current by a heating element)

Subclause 5.3.3.2.2 – 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 shortened together and applied to the MAINS VOLTAGE at the same time.

The alternative method is not suitable for measuring on devices containing active circuitry such as isolation transformers, relays, switch-mode supplies etc.

The outcome of the alternative leakage currents measurement cannot directly be compared to the leakage current values as defined in IEC 60601-1.

The allowable values for alternative method 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 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 amount of different values.

Subclause 5.3.3.2.4 – 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 defined in IEC 62020: 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 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 that is not positioned insulated. 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. choppers). 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 5.3.3.3.1 – 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).

Subclause 5.3.4 – Measurement of insulation resistance

The IEC 60601-1 does not consider insulation resistance measurement as an acceptance criteria. For this reason local requirements or common practice can be applied to define suitable acceptance criteria in the absence of 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.

An insulation resistance measurement may be helpful:

– in addition or instead of the leakage current measurement for certain components or equipment (e.g. heating elements as the insulation characteristic changes with temperature);

– in addition to the leakage current measurement if there is any doubt about the insulation of the equipment (e.g. if residual current device has tripped several times or if saline has been spilled over the equipment and therefore creepage distances are in doubt).

It could be argued that a significant decrease from previously measured values indicates a problem. When this requirement was discussed it was agreed that the equipment is safe if the value is above the acceptance criteria even if there is a significant deterioration of insulation resistance. A decrease of the measured value may not be the leading characteristic. Therefore it might be advisable to reduce the test intervals in such case.

Annex B
(informative)

Sequence of testing

Figure B.1 contains a recommended sequence for performing the tests described in this standard. Figure B.2 and Figure B.3 contain decision charts to assist in determining which test method to apply when measuring leakage currents.

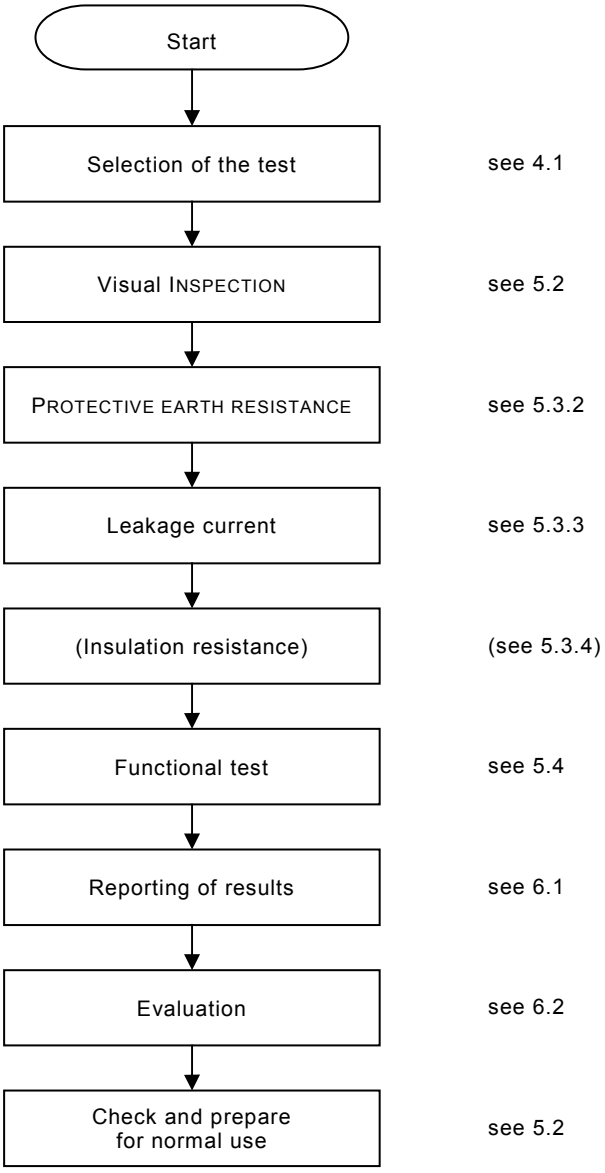


Figure B.1 – Sequence of testing

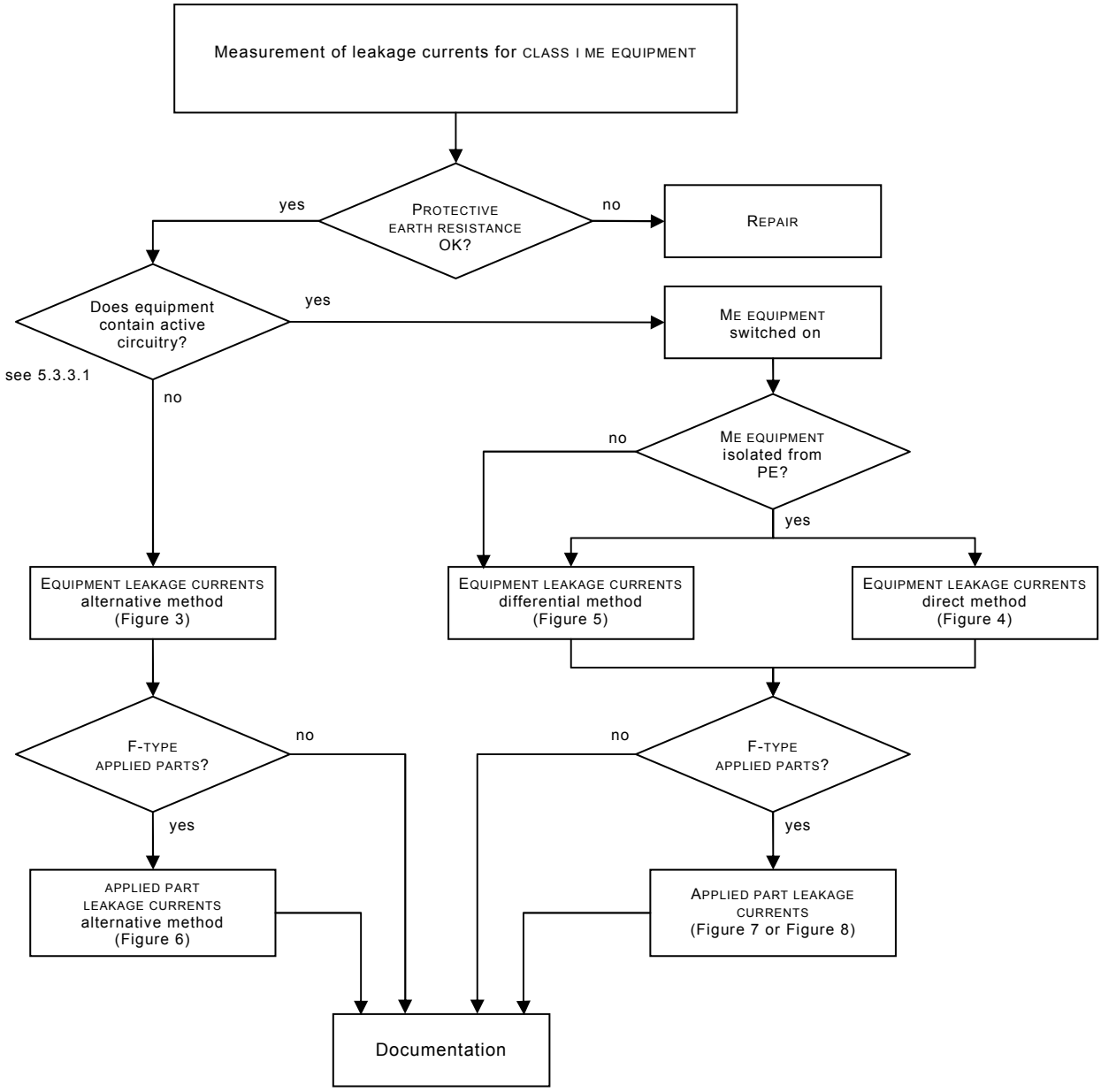


Figure B.2 – Measurement of leakage currents (CLASS I ME EQUIPMENT)

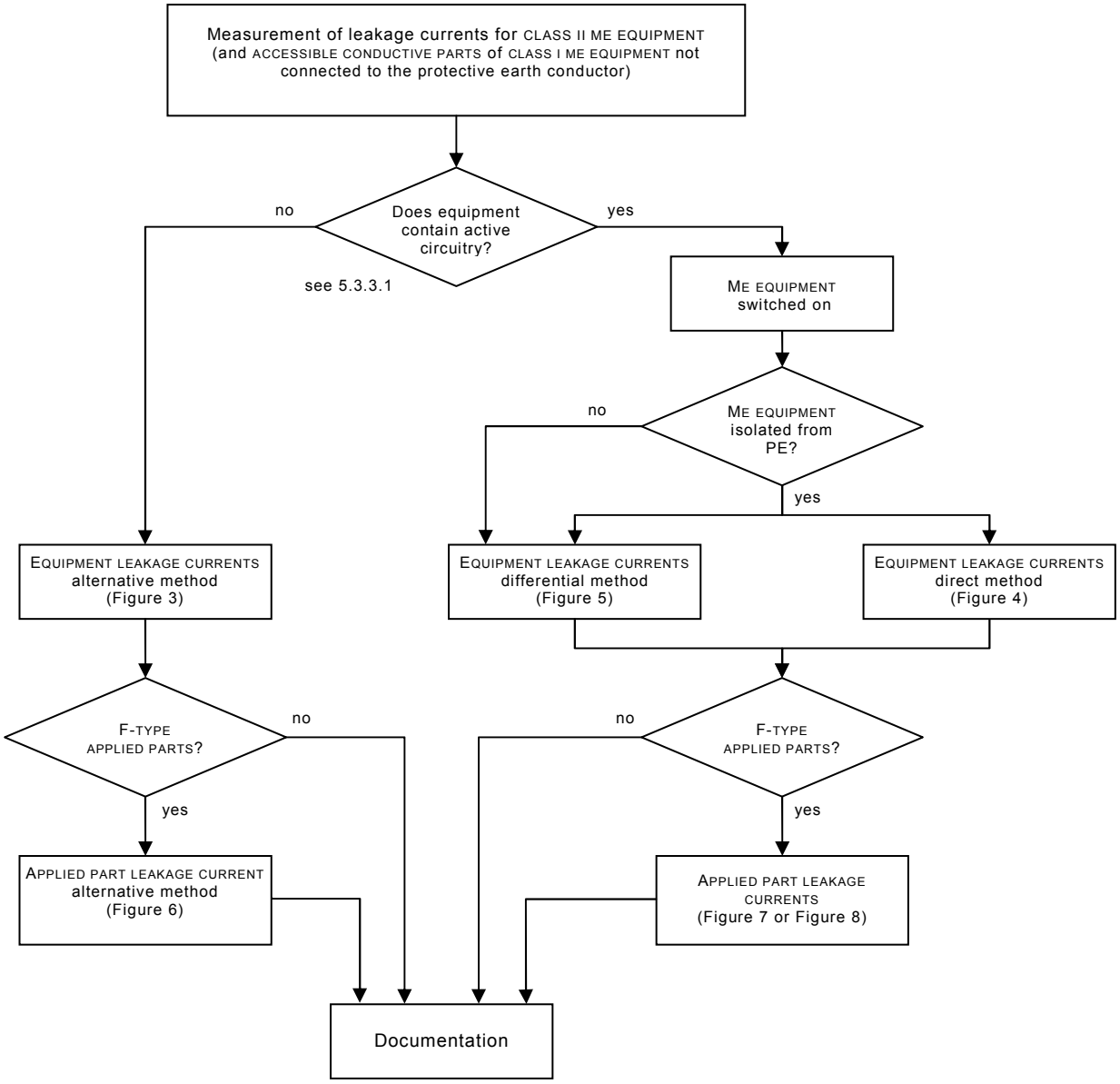


Figure B.3 – Measurement of leakage currents (CLASS II ME EQUIPMENT and ACCESSIBLE CONDUCTIVE PARTS of CLASS I ME EQUIPMENT, which are not connected to protective earth)

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 of this standard only use measurement equipment complying with IEC 61010-1 or IEC 61010-2-010 with regard to the electrical safety.

– The measurement equipment should comply with IEC 61557-2 and IEC 61557-4 with the exception of 4.6 of 61557-2 and 4.9 of 61557-4 (protection against extraneous voltage requirements) for measurement equipment not intended for direct connection to a fixed installation.

– The operating uncertainty of the measurements, within the range marked or declared by the MANUFACTURER, shall not exceed ± 10 % 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 normal use the measurement equipment shall not expose the testing person or other individuals not involved to unnecessary hazards.

– The measurement equipment used for the tests shall be tested and calibrated in regular intervals according to the information given by the MANUFACTURER.

– If the measurement of leakage current of CLASS I ME EQUIPMENT is carried out by direct method according to 5.3.3.2.3, the protective conductor leading to the device under test (DUT) can be interrupted during test. Other protective measures according to IEC 61010-1 shall take over the protection against electric shock 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 mains supply including its protective earth conductor shall be guaranteed, when measuring according to 5.3.2, 5.3.3.2.3 and 5.3.3.3.1.

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 3.

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

For safety reasons, the short circuit current shall be limited to 3,5 mA. 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 equal an evaluation with a measuring device MD according to Figure C.1;

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

– guarantee that during the measurement protection against electric shock is effective by suitable means of IEC 61010-1.

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

– guarantee that the measurement results are assessed in analogy to a measuring device MD according to Figure C.1; and

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

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 6.

The measurement of alternative leakage currents shall be performed by applying sinusoidal mains frequency and MAINS VOLTAGE.

For safety reasons, the short circuit current shall be limited to 3,5 mA. The measured value shall be corrected to the value corresponding with the nominal MAINS VOLTAGE.

The measurement equipment for the direct method shall:

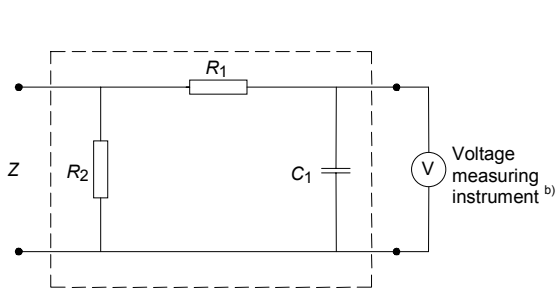
– guarantee that the measurement results equal an evaluation with a measuring device MD according to Figure C.1;

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

– guarantee that during the measurement protection against electric shock is effective by suitable means of IEC 61010-1.

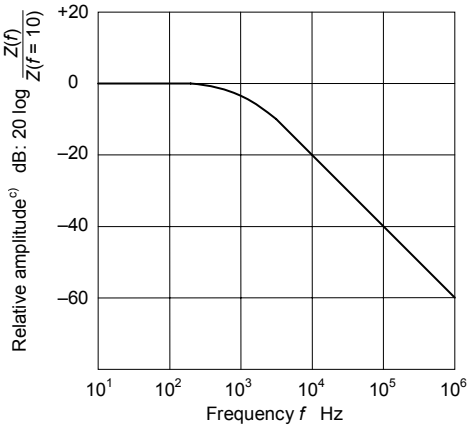
– The voltage supplied to the F-TYPE APPLIED PARTS shall be sinusoidal at mains frequency and MAINS VOLTAGE.

For safety reasons, the short circuit current shall be limited to 3,5 mA. The measured value shall be corrected to the value corresponding with the nominal MAINS VOLTAGE.



R_1 10 kΩ ± 5 %[a)]
R_2 1 kΩ ± 5 %[a)]
C_1 0,015 µF ± 5 %

a) Measuring device



b) Frequency characteristics

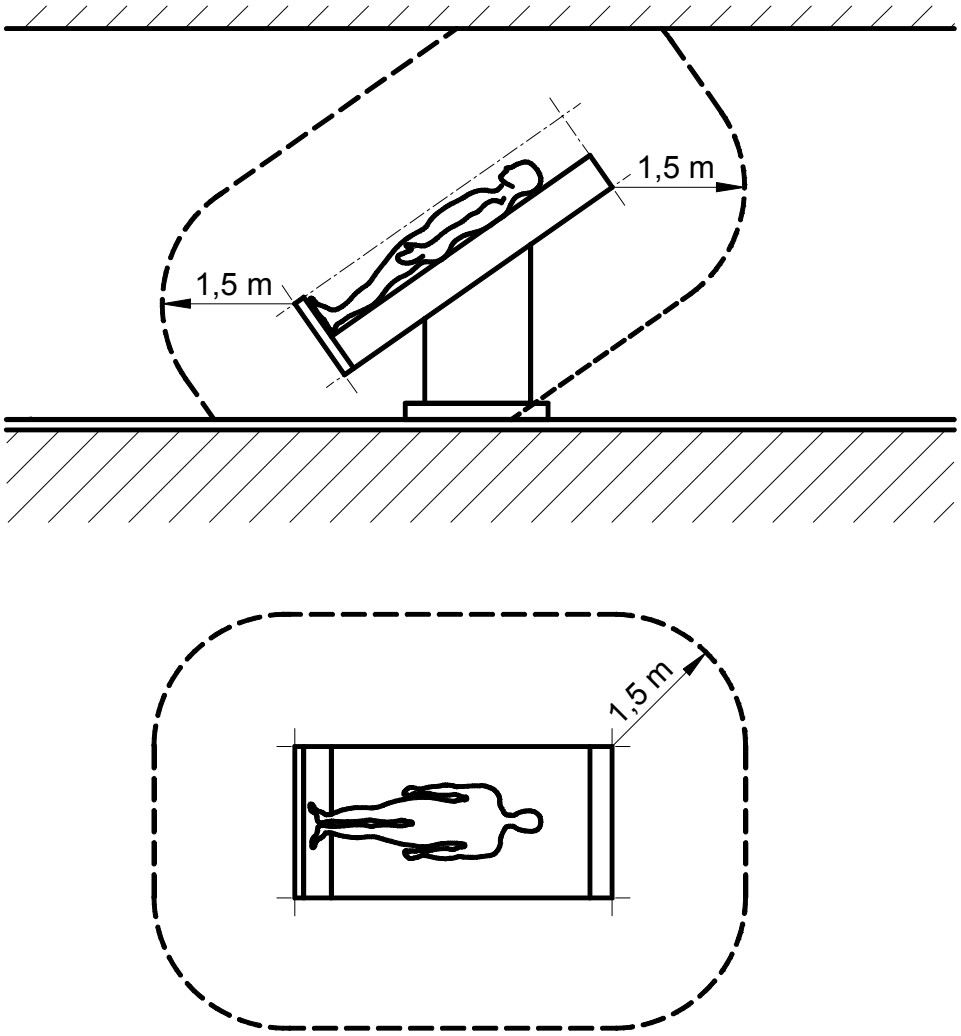
NOTE The network and voltage measuring instrument above are replaced by the symbol in the following figures.

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]

Annex D
(informative)

PATIENT ENVIRONMENT



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

Figure D.1 – Example of PATIENT ENVIRONMENT
[Derived from IEC 60601-1:2005]

Annex E
(informative)
Allowable values for leakage currents from IEC 60601-1

Table E.1 – Allowable values for continuous leakage currents from IEC 60601-1:1988 [1)]
(All references in this table are to subclauses or figures in IEC 60601-1:1988)

Current in mA

		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 notes [b] and [d]		2,5	5 [a]	2,5	5 [a]	2,5	5 [a]
EARTH LEAKAGE CURRENT for EQUIPMENT according to note [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 Note [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 according to Note [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

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 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.

1) IEC 60601-1: 1988, *Medical electrical equipment – General requirements for safety*, Amendment 1 (1991) + Amendment 2 (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

(All references in this table are to subclauses or figures in 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 15 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.

NC = NORMAL CONDITION

SFC = SINGLE FAULT CONDITON

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

(All references in this table are to subclauses or figures in 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 16 and Figure 20	1 000	1 000	– [c]

[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

The MANUFACTURER of ME EQUIPMENT/ME SYSTEMS has to establish, for periodic INSPECTION, the testing interval and the extent of testing and to disclose it in the ACCOMPANYING DOCUMENTS. In establishing the testing interval, the MANUFACTURER has to take the following into account:

– the degree of risk of the equipment,

– the frequency of its use,

– the operation-environment,

– the way of operation (e.g. stationary, mobile, emergency), and

– the frequency of occurrence of device failures.

If there is no information on the testing interval for periodic INSPECTION in the ACCOMPANYING DOCUMENTS (e.g. of older equipment), it has to be established individually by a competent person. In defining the degree of risk, the above factors and the recommendations of the MANUFACTURER have to be taken into account, and a corresponding testing interval has to be set in the range of 6 months to 36 months. For the following equipment the interval should not exceed 24 months.

a) ME EQUIPMENT/ME SYSTEMS for:
   1) generation and application of electrical energy to directly influence the function of nerves and/or muscles response; the action of the heart, including defibrillators;
   2) cardio-vascular measurement of electrical magnitudes using electrically operated measuring probes in blood vessels or on blood vessels laying bare;
   3) generation and application of any energy for direct coagulation, destruction of tissue or splitting of sediments in the body;
   4) 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;
   5) artificial respiration with or without anaesthesia;
   6) diagnosis by magnetic resonance imaging;
   7) therapy in hyperbaric chambers;
   8) hypothermic or hyperthermia therapy;
b) baby incubators; and
c) 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	☐	☐
Equipment leakage current (according to Figure ___)	_____ mA	☐	☐
Patient leakage current (according to Figure ___)	_____ mA	☐	☐
Insulation resistance (according to Figure ___)	_____ MΩ	☐	☐
		☐	☐
Functional test (parameters tested):		☐	☐
		☐	☐

Deficiency / Note:

Overall assessment:

☐ No safety or functional deficiencies were detected!

☐ No direct risk, deficiencies detected may be corrected on short term!

☐ 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

Bibliography

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

IEC 60601-1:2005, *Medical electrical equipment – General requirements for basic safety and essential performance*

IEC 60601-1-1, *Medical electrical equipment – General requirements for safety – Collateral standard: Safety requirements for medical electrical systems*

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

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

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

IEC 61557-2:1997, *Electrical safety in low voltage distribution systems up to 1000 V a.c. and 1500 V d.c. – Equipment for testing, measuring or monitoring of protective measures – Part 2: Insulation resistance*

IEC 61557-4:1997, *Electrical safety in low voltage distribution systems up to 1000 V a.c. and 1500 V d.c. – Equipment for testing, measuring or monitoring of protective measures – Part 4: Resistance of earth connection and equipotential bonding*

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

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

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

Index of defined terms

(*Continued from second cover*)

International Standard	*Title*
IEC 61010-031 : 2002	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 61557-1 : 2007	Electrical safety in low voltage distribution systems up to 1000 V a.c and 1500 V d.c — Equipment for testing, measuring or monitoring of protective measures — Part 1: General requirements

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 ‘Rules for rounding off numerical values (*revised*)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Bureau of Indian Standards

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Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards: Monthly Additions'.

This Indian Standard has been developed from Doc No.: MHD 15 (178).

Amendments Issued Since Publication

Amendment No.	Date of Issue	Text Affected

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Published by BIS, New Delhi