

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

ICS 11.040.01

National foreword

This British Standard is the UK implementation of EN 62353:2008. It is identical with IEC 62353:2007.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electromedical equipment in medical practice, to Subcommittee CH/62/1, Common aspects of electrical equipment used in medical practice.

A list of organizations represented on CH/62/1 can be obtained on request to its secretary.

BSI, as a member of CENELEC is obliged to publish EN 62353 as a British Standard. However, attention is drawn to the fact that during the development of this European Standard, the UK committee voted against its approval as a European Standard.

The United Kingdom objected to the publication of this standard for the following reasons:

It is based on testing practice used in continental Europe. It contains test configurations which deviate from those in IEC 60601-1 (which is the standard that manufacturers use in their design processes) and would not be comparable. There are aspects of the testing protocols and test limit values which UK experts do not agree with and therefore users are advised to treat results with caution.

Well established methods of test and guideline documents from engineering institutions and the Medicines and Healthcare products Regulatory Agency (MHRA) exist for safety testing of medical electrical equipment.

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

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 May 2008

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ISBN 978 0 580 54254 1

Amendments/corrigenda issued since publication

Date	Comments

**Medical electrical equipment -
Recurrent test and test after repair of medical electrical equipment
(IEC 62353:2007)**

Appareils électromédicaux -
Essai récurrent et essai après réparation
d'un appareil électromédical
(CEI 62353:2007)

Medizinische elektrische Geräte -
Wiederholungsprüfungen und Prüfung
nach Instandsetzung von medizinischen
elektrischen Geräten
(IEC 62353:2007)

This European Standard was approved by CENELEC on 2007-09-11. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 62A/564/FDIS, future edition 1 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 was approved by CENELEC as EN 62353 on 2007-09-11.

The following dates were fixed:

- | | | |
|--|-------|------------|
| – latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement | (dop) | 2008-08-01 |
| – latest date by which the national standards conflicting with the EN have to be withdrawn | (dow) | 2010-10-01 |

In this standard, the following print types are used:

- requirements and definitions: roman type;
- informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
- TERMS USED THROUGHOUT THIS STANDARD THAT HAVE BEEN DEFINED IN CLAUSE 3: IN SMALL CAPITALS.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 62353:2007 was approved by CENELEC as a European Standard without any modification.

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

1 Scope

This International Standard applies to testing of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS, or parts of such equipment or systems, which comply with IEC 60601-1, 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 60601-1:2005, 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.