

PD IEC/TR 62354:2014



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General testing procedures for medical electrical equipment

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

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

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TECHNICAL REPORT

General testing procedures for medical electrical equipment

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**GENERAL TESTING PROCEDURES
FOR MEDICAL ELECTRICAL EQUIPMENT**

FOREWORD

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The main task of IEC technical committees is to prepare International Standards. However, a technical committee may propose the publication of a technical report when it has collected data of a different kind from that which is normally published as an International Standard, for example "state of the art".

IEC 62354, which is a technical report, has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 2009. This edition constitutes a technical revision intended to align the guidance in this technical report with Amendment 1 to IEC 60601:2005. Several tests have been updated and additional test procedures added. The following tests have been added or significantly revised:

- 13.2.1 RISK MANAGEMENT PROCESS
- 13.2.4 Durability and legibility of marking
- 13.2.5 Battery markings

- 13.2.8 POTENTIAL EQUALIZATION TERMINAL
- 13.2.14 USABILITY OF ME EQUIPMENT
- 13.3.1 Humidity preconditioning
- 13.3.2 Impedance of PE connection
- 13.3.7 CREEPAGE DISTANCES and AIR CLEARANCES
- 13.3.12 Instability (in transport position; excluding transport; from horizontal and vertical forces and from unwanted lateral movement)
- 13.3.13 Castors and wheels (Force for propulsion, movement over a threshold)
- 13.3.14 Safety catch evaluation
- 13.3.17 Overflow
- 13.3.18 Spillage
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- 13.4.9 PATIENT LEAKAGE CURRENT
- 13.4.14 Sound pressure level measurements
- 13.4.16 X-radiation (ionizing radiation) measurement
- 13.4.20 Interruption of power supply
- 13.4.28 Rechargeable battery overcharge/discharge
- 13.4.29 Mains transformers

This technical report is intended to be read in conjunction with IEC 60601-1:1988 (including the collateral provisions of IEC 60601-1-1:2000) and IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
62A/936/DTR	62A/947/RVC

Full information on the voting for the approval of this technical report can be found in the report on voting indicated in the above table.

In this technical report, the terms defined in Clause 2 of IEC 60601-1:1988 or Clause 3 of IEC 60601-1:2005 are printed in SMALL CAPITALS.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

A bilingual version of this publication may be issued at a later date.

INTRODUCTION

IEC/TR 60513, *Fundamental aspects of safety standards for medical electrical equipment* published by IEC sub-committee 62A provided the basis for inclusion of the test methods for ME EQUIPMENT in the safety standards.

"Technical requirements and test methods are interrelated elements of product standards and should always be considered together.

Product standards should identify where medically informed judgements are required in deciding whether a particular requirement applies.

Wherever possible, the standards should contain test specifications for completely and clearly checking compliance with the technical requirements. In some cases, a compliance statement such as 'visual inspection', 'manual testing' or similar is adequate for this purpose if such a method gives an accurate assessment.

It should be easy to recognize which test methods apply to each technical requirement. Appropriate headings should designate the appropriate test and a reference should be made to the clause containing the requirement. This also applies for references which are made to other relevant test standards."

It was deemed necessary to support IEC 60601-1 with guidelines for general testing PROCEDURES for MEDICAL ELECTRICAL EQUIPMENT.

In developing the test PROCEDURES, the advice given in IEC/TR 60513 and ISO/IEC Guide 51 was considered as follows:

- a) test results should be reproducible within defined limits. When considered necessary, the test method should incorporate a statement as to its limit of uncertainty;
- b) where the sequence of tests can influence the results, the correct sequence should be specified.

There is also growing support for the idea that all the test PROCEDURES for ME EQUIPMENT should be found within one international standard.

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*, highlights the need for a single series of requirements covering test PROCEDURES.

IEC/TR 60513 includes a major new principle referring to testing:

"In specifying minimum safety requirements, provision is made for assessing the adequacy of the design PROCESS where this provides an appropriate alternative to the application of laboratory testing with specific pass/fail criteria, (e.g. in assessing the safety of new technologies such as programmable electronic systems)."

GENERAL TESTING PROCEDURES FOR MEDICAL ELECTRICAL EQUIPMENT

1 Scope and object

This technical report applies to MEDICAL ELECTRICAL EQUIPMENT (as defined in Subclauses 3.63 of IEC 60601-1:2005 and 2.2.15 of IEC 60601-1:1988), hereinafter referred to as ME EQUIPMENT.

The object of this technical report is to provide guidance on general testing PROCEDURES according to IEC 60601-1:1988 (including the collateral provisions of IEC 60601-1-1:2000) and IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012.

2 Normative references

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

IEC 60086-4, *Primary batteries – Part 4: Safety of lithium batteries*

IEC 60127-1, *Miniature fuses – Part 1: Definitions for miniature fuses and general requirements for miniature fuse-links*

IEC 60252-1, *AC motor capacitors – Part 1: General – Performance, testing and rating – Safety requirements – Guide for installation and operation*

IEC 60364-4-41, *Low voltage electrical installations – Part 4-41: Protection for safety – Protection against electric shock*

IEC 60417, *Graphical symbols for use on equipment*. Available from: <http://www.graphical-symbols.info/equipment>

IEC/TR 60513, *Fundamental aspects of safety standards for medical electrical equipment*

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)*
IEC 60529:1989/AMD1:1999¹

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*²
IEC 60601-1:1998/AMD1:1991
IEC 60601-1:1998/AMD2:1995

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012³

¹ A consolidated version 2.1 (2001) exists that includes IEC 60529:1989 and its Amendment 1:1999.

² The second edition of IEC 60601-1, cancelled and replaced by the third edition in 2005.

³ A consolidated version 3.1 (2012) exists that includes IEC 60601-1:2005 and its Amendment 1:2012.

IEC 60601-1-2, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*

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

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

IEC 61672-1, *Electroacoustics – Sound level meters – Part 1: Specifications*

IEC 61672-2, *Electroacoustics – Sound level meters – Part 2: Pattern evaluation tests*

IEC 62133, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications*

ISO 17665-1, *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11135-1, *Medical devices – Validation and routine control of ethylene oxide sterilization*⁴

ISO 11137-1, *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

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

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

ISO 80000-1, *Quantities and units – Part 1: General*

3 Terms, definitions, abbreviations and acronyms

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:1988 and IEC 60601-1:2005 apply.

NOTE 1 Where the terms “voltage” and “current” are used in this document, they mean the r.m.s. values of an alternating, direct or composite voltage or current unless stated otherwise.

NOTE 2 An index of defined terms is found beginning on page 209.

NOTE 3 When used in the body of this document, N/A means “Not applicable”.

⁴ Withdrawn and replaced by ISO 11135:2014.

3.2 Abbreviations and acronyms

Abbreviation	Term
a.c.	Alternating current
d.c.	Direct current
DUT	Device under test
MAR	Mean angle resolvable
MD	Measuring device
ME	MEDICAL ELECTRICAL
RH	Relative humidity
r.m.s.	Root mean square
SI	System international
SIP/SOP	SIGNAL INPUT/OUTPUT PART

4 Types of tests

4.1 GENERAL

“TYPE TESTS” are required for verifying the BASIC SAFETY and ESSENTIAL PERFORMANCE of the product design.

NOTE 1 The tests described in this technical report can also be used by the MANUFACTURER to ensure the quality of the product and the manufacturing PROCESS. See Annex I.

A test need not be carried out if analysis shows that the condition being tested has been adequately evaluated by other tests or methods.

The results of the RISK ANALYSIS should additionally be used to determine which combination(s) of simultaneous faults should be tested.

NOTE 2 The test results might render it necessary to revise the RISK ANALYSIS.

When testing the ME EQUIPMENT, relevant information provided by the MANUFACTURER in the instruction for use should be taken into account.

Before commencing testing, the ME EQUIPMENT under test (the device under test or DUT) should be disconnected from the SUPPLY MAINS. If not possible, special precautions should be taken to prevent HARM to the personnel performing the tests and measurements or other individuals who might be affected.

Connections such as data lines or functional earth conductors can act like PROTECTIVE EARTH CONNECTIONS. Such additional, but unintentional, PROTECTIVE EARTH CONNECTIONS can create measurement errors.

Unless otherwise specified in IEC 60601-1, ME EQUIPMENT is to be tested under the least favourable working conditions. The working conditions are specified in the ACCOMPANYING DOCUMENTS. The least favourable working conditions are to be documented for every test where they apply.

Considering the ambient temperature, humidity and pressure described in the technical description, tests should be performed at the worst-case extremes depending on the test and the effects of these parameters on the test results. If the test is not impacted by these parameters, then test can be conducted anywhere within the specified range.

4.2 Visual inspection

Covers and housings should be opened only:

- if required in the instructions for use for the ME EQUIPMENT, or
- if specified in this technical report, or
- if there is an indication of a HAZARD or HAZARDOUS SITUATION.

Special attention should be paid to the following:

- all fuses accessible from the outside should be marked (type, ratings) on the ME EQUIPMENT or marked by reference and specified in the ACCOMPANYING DOCUMENTS;
- the markings are legible and complete;
- any damage;
- relevant ACCESSORIES should be assessed together with the ME EQUIPMENT (e.g. DETACHABLE or FIXED POWER SUPPLY CORDS, PATIENT leads, tubing etc.);
- all required documentation, such as instructions for use, is present and complete and reflects the current revision of the ME EQUIPMENT.

5 State of the ME EQUIPMENT

Some tests specified in this document are conducted in the NORMAL CONDITION whilst others are conducted in SINGLE FAULT CONDITIONS.

NORMAL CONDITION and SINGLE FAULT CONDITIONS are described in both IEC 60601-1:1988 and IEC 60601-1:2005.

6 Number of samples

TYPE TESTS are performed on a representative sample of the item being assessed.

Multiple samples can be utilized simultaneously if the validity of the results is not significantly affected.

7 Applicable test items to the clauses of IEC 60601-1

Table 2, Table 5 and Table 10 relate the test PROCEDURES described in this technical report to the relevant subclauses of IEC 60601-1:2005. When applicable, these tables also provide a cross reference to the relevant subclauses of IEC 60601-1:1988.

Annex G and Annex H contain an index of the tests in this technical report sorted by the relevant subclause in IEC 60601-1:2005. Annex I and Annex J contain the lists sorted in alphabetical order by test title.

8 Sequence of tests

Unless stated otherwise, the tests in this technical report are to be sequenced in such a way so that the results of any test do not influence the results of other tests. Tests should, if applicable, be performed in the sequence indicated in Annex A, unless otherwise stated by particular standards.

However, this does not preclude the possibility of conducting a test that preliminary inspection suggests might cause failure.

The tests for radiation HAZARDS, biocompatibility, USABILITY, alarm systems, PEMS and electromagnetic compatibility can be performed independently from the tests specified in the present document.

The tests specified for ME SYSTEMS should be performed in the same sequence as the tests for ME EQUIPMENT.

9 General testing condition

The following general testing conditions should be applied:

- a) After the DUT has been set up for NORMAL USE, tests are carried out under the least favourable working conditions which are specified in the ACCOMPANYING DOCUMENTS.
- b) The DUT is to be shielded from other influences (for example, draughts) that might affect the validity of the tests.
- c) In cases where ambient temperatures cannot be maintained, the test conditions are to be consequently modified and results adjusted accordingly.
- d) Qualified personnel are to perform these tests. Qualifications include training on the subject, knowledge, experience, and acquaintance with the relevant technologies and regulations. The personnel should be able to assess safety and should be able to recognize possible consequences and HAZARDS arising from non-conforming ME EQUIPMENT.
- e) ACCESSORIES for the ME EQUIPMENT, which can affect the safety of the DUT or the results of the measurements, should be included in the tests. ACCESSORIES included in the tests are to be documented.
- f) All tests are to be performed in such a manner that no unacceptable RISK arises for testing personnel, PATIENTS or other individuals.
- g) If not otherwise stated, all values for current and voltage are effective values (r.m.s.) or d.c. values as appropriate.
- h) All tests performed should be comprehensively documented. The documentation should contain as a minimum the following data:
 - identification of the testing body (e. g. company, department);
 - names of the persons, who performed the testing and the evaluation(s);
 - identification of the ME EQUIPMENT (e. g. type, serial number, inventory number) and the ACCESSORIES tested;
 - measurements (measured values, measuring method, measuring equipment, environmental conditions);
 - date and signature of the individual, who performed the evaluation; and
 - if applicable, the ME EQUIPMENT tested should be marked/identified accordingly.
- i) In addition to TYPE TESTS, the MANUFACTURER of the ME EQUIPMENT can establish the testing interval and the extent of testing for periodic inspection and has to disclose it in the ACCOMPANYING DOCUMENTS. In establishing the testing interval, the following considerations should be taken into account:
 - the level of RISK of the ME EQUIPMENT as described in the RISK MANAGEMENT FILE,
 - the frequency of its use,
 - the operating environment,
 - type of ME EQUIPMENT (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. for older ME EQUIPMENT), it can be established by a competent person. In defining the level of RISK, the above factors and the

recommendations of the MANUFACTURER should be taken into account. The testing interval for periodic inspection can be set in the range of 6 months to 36 months.

- j) In the event of the necessity for repairs or modifications after a failure or the likelihood of a failure during the sequence of tests, the testing laboratory and the supplier of the ME EQUIPMENT can agree, either upon the use of a new sample on which all relevant tests are to be carried out again or, preferably, upon making all the necessary repairs or modifications after which only relevant tests are repeated.
- k) Unless otherwise specified in IEC 60601-1, ME EQUIPMENT is to be tested under the least favourable working conditions. The working conditions are specified in the ACCOMPANYING DOCUMENTS. The least favourable working conditions shall be documented for every test where they apply.
- l) ME EQUIPMENT having operating values that can be adjusted or controlled by the OPERATOR is adjusted as part of the tests to values least favourable for the relevant test, but in accordance with the instructions for use.
- m) If the test results are influenced by the inlet pressure and flow or chemical composition of the cooling liquid, the test is to be carried out within the limits for these characteristics as prescribed in the technical description.
- n) Where cooling water is required, potable water is to be used.
- o) Except in special cases, such as PATIENT supports and waterbeds, contact with ME EQUIPMENT is supposed to be made with:
 - one hand, simulated for LEAKAGE CURRENT measurements by a metal foil of 10 cm × 20 cm (or less if the total ME EQUIPMENT is smaller);
 - one finger, straight or bent in a natural position, simulated by a standard test finger (Figure F.1) provided with a stop plate; or
 - an edge or slit that can be pulled outwards allowing subsequent entry of a finger, simulated by a combination of test hook (Figure F.2) and standard test finger.

10 Power sources for tests

10.1 General

- a) Where test results are influenced by deviations of the supply voltage from its RATED value, the effect of such deviations is to be taken into account.
- b) ME EQUIPMENT for a.c. only should be tested with a.c. at RATED frequency (if marked) ± 1 Hz for a RATED frequency between 0 Hz and 100 Hz and ± 1 % for a RATED frequency above 100 Hz. ME EQUIPMENT marked with a RATED frequency range is to be tested at the least favourable frequency within that range.
- c) ME EQUIPMENT designed for more than one RATED voltage, or for both a.c. and d.c., is to be tested in conditions related to the least favourable voltage and nature of supply, for example, number of phases (except for single-phase supply) and type of current. It might be necessary to perform some tests more than once in order to establish which supply configuration is least favourable.
- d) ME EQUIPMENT for d.c. only is to be tested with d.c. When performing the tests, the possible influence of polarity on the operation of the ME EQUIPMENT is to be taken into consideration.
- e) Unless otherwise specified by this technical report, ME EQUIPMENT is to be tested at the least favourable RATED voltage within the relevant range. It might be necessary to perform some of the tests more than once in order to establish the least favourable voltage.
- f) ME EQUIPMENT for which alternative ACCESSORIES or components specified by the MANUFACTURER are available is to be tested with those ACCESSORIES or components that give the least favourable conditions.
- g) If the instructions for use specify that ME EQUIPMENT is intended to receive its power from a separate power supply, it is to be connected to such a power supply.

10.2 Connection to a separate power source

If ME EQUIPMENT is specified for connection to a separate power source, other than the SUPPLY MAINS, either the separate power source should be considered as part of the ME EQUIPMENT and all relevant requirements of this standard should apply, or the combination should be considered as an ME SYSTEM.

NOTE What was formerly referred to, in the first and second editions of IEC 60601-1, as a "specified power supply" is now considered either as another part of the same ME EQUIPMENT or as another electrical equipment in an ME SYSTEM.

10.3 Connection to an external d.c. power source

If ME EQUIPMENT is specified for power supplied from an external d.c. power source, no HAZARD, other than absence of function, should develop when a connection with the wrong polarity is made and the ME EQUIPMENT should provide ESSENTIAL PERFORMANCE as described in the ACCOMPANYING DOCUMENTS when connection is subsequently made with the correct polarity.

NOTE The external d.c. power source can be a SUPPLY MAINS or another item of electrical equipment. In the latter case, the combination is considered to be an ME SYSTEM.

10.4 Source of power for ME EQUIPMENT

ME EQUIPMENT is either powered by an INTERNAL ELECTRICAL POWER SOURCE, specified for connection to a separate power supply, or is suitable for connection to SUPPLY MAINS, either independently or in combination, as long as only one connection to mains is provided. This is checked by inspection of the ACCOMPANYING DOCUMENTS.

10.5 SUPPLY MAINS for testing ME EQUIPMENT

SUPPLY MAINS used for testing ME EQUIPMENT have the following characteristics:

- voltage dips, short interruptions and voltage variations on the SUPPLY MAINS as described in IEC 60601-1-2;
- no voltage in excess of 110 % or lower than 90 % of the NOMINAL value between any of the conductors of the system or between any of these conductors and earth;
- voltages that are practically sinusoidal and forming a practically symmetrical supply system in case of polyphase supply;
- a frequency of not more than 1 kHz;
- a frequency deviation of ≤ 1 Hz from the NOMINAL value up to 100 Hz and ≤ 1 % from the NOMINAL value from 100 Hz to 1 kHz;
- the protective measures as described in IEC 60364-4-41.

NOTE If ME EQUIPMENT is intended to be operated from a SUPPLY MAINS with characteristics different from the SUPPLY MAINS described in this subclause, additional SAFETY measures might be necessary.

- a d.c. voltage (as measured by a moving coil meter or equivalent method) having a peak-to-peak ripple not exceeding 10 % of the average value.

Where peak-to-peak ripple exceeds 10 % of the average value, the peak voltage has to be applied.

The characteristics of electrical power source used to power the DUT should be evaluated as described in Annex L.

11 Measurement and test equipment

11.1 General requirements

- The measurement and test equipment should comply with requirements of the IEC 61010 series of standards.
- In NORMAL USE the measurement equipment should not expose the person doing the testing or other individuals to unacceptable RISKS.
- The accuracy of the measuring functions within the range marked or declared by the measurement equipment manufacturer should be specified in the test data sheet. See also 11.2.
- The measurement equipment used for the tests should be tested and calibrated at regular intervals according to the information given by its manufacturer and should be traceable to national or international standards. Calibration should be performed by a calibration laboratory with a quality management system in accordance with ISO/IEC 17025.
- For the tests, PROTECTIVE EARTH CONNECTIONS can be interrupted in the measuring devices, if protection against electric shock is guaranteed by another means of IEC 61010-1.
- In the measurement equipment, an electrical separation of the measurement circuits, including measuring device (MD), from the SUPPLY MAINS including its PROTECTIVE EARTH CONDUCTOR should be guaranteed.

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

- It is recommended to use dedicated test equipment (e.g. dielectric withstand tester, ground bonding and continuity tester, etc.).
- The test equipment should be capable of providing all voltages and currents needed for the range of tests to be performed (e.g. for dielectric testing: voltage and current; for ground bond: current and impedance).
- The test equipment should be easily adaptable to different test requirements. Most modern testers provide this flexibility through programmability plus an ability to recall previously stored test setups on demand.
- The test equipment should be designed so that normal variations in line voltage and connected load do not cause the output voltage and current measured at the DUT to rise above or fall below the levels required for the test. This improves test repeatability and greatly reduces inconsistencies in measurements.
- The test equipment should have a well-designed front panel with easily read digital displays of measurements, settings, and pass/fail indicators. Audible alarms are also desirable. An ability to hold an alarm condition after operator acknowledgment can be useful for later analysis of the fault. All panel items should be clearly marked so that the function of each is readily apparent to anyone looking at the test equipment for the first time.
- The START TEST button, where applicable, should be large, well marked, and protected in a way that prevents accidental activation of a test. The STOP TEST button, where applicable, should also be easily identified (preferably bright red) and placed so as to be quickly found in an emergency.
- Pushbuttons for setting, storing, or recalling test values, alarm limits, and test sequences should be clearly marked and easily operated by test personnel.
- Modern test equipment is equipped with some type of standard data communication interface for connection to remote data processing, computer, or control equipment. The typical interfaces are an IEEE-488 general-purpose interface bus and an RS232 serial communication line.

11.2 Accuracy

The accuracy of the measurement and test equipment measurement range should meet the following typical specifications:

- voltage up to 1 000 V (d.c. up to 1 kHz): $\pm 1,5$ %;
- voltage, 1 000 V and above (d.c. up to 20 kHz): ± 3 %;
- current up to 5 A (d.c. up to 60 Hz): $\pm 1,5$ %;
- current, 5 A and above (d.c. up to 5 kHz): $\pm 2,5$ %;
- LEAKAGE CURRENT: $\pm 3,5$ %;
- power above 1 W and up to 3 kW: ± 3 %;
- power factor: $\pm 0,05$ %;
- frequency: $\pm 0,2$ %;
- resistance: ± 5 %;
- temperature (thermocouple not included) below 100 °C: ± 2 °C;
- temperature (thermocouple not included) 100 °C up to 500 °C: ± 3 %;
- time, 1 s and above: ± 1 %;
- linear dimensions up to 1 mm: $\pm 0,05$ mm;
- linear dimensions, 1 mm up to 25 mm: $\pm 0,1$ mm;
- linear dimensions, 25 mm and above: $\pm 0,5$ %;
- mass, 100 g up to 5 kg: ± 2 %;
- mass, 5 kg and above: ± 5 %;
- force: ± 6 %;
- torque: ± 10 %;
- angles: ± 1 degree;
- relative humidity: ± 6 % RH;
- barometric air pressure: $\pm 0,01$ MPa;
- gas and fluid pressure (for static measurement): ± 5 %.

11.3 Safety criteria for selection

The measurement and test equipment should be selected so that the test operator cannot be accidentally subjected to hazardous voltages and currents such as those used for a dielectric strength test, a line voltage leakage test, or a protective earthing connection and continuity test. It is recommended to use measurement and test equipment which includes safety interlocks that provide protection by automatically shutting down the HIGH VOLTAGE output whenever a safety switch on the DUT is opened. Cables used for HIGH VOLTAGE output and ground clips should be flexible, well insulated, and able to be repeatedly plugged into and removed from the front panel over a long period of time without becoming frayed, worn, or ineffective.

11.4 Calibration

The reference standards (e.g. voltage, current, impedance) used by the equipment supplier for calibrating measurement and test equipment should be certified and traceable to national standards. This ensures sustained integrity of calibration accuracy and compliance with IEC/ISO 17025.

To establish uniform requirements for traceability of calibrations, calibration intervals and to ensure consistent and repeatable test results, reference the specifications included in Annex M.

12 Treatments of unit symbols and measured values

Numeric indications of parameters are to be expressed in SI units according to ISO 31 except the base quantities listed in Table 1. These units can be expressed in the indicated units, which are outside the SI units system.

Table 1 – Units outside the SI units system that may be used

(IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012, Table 1)

Base quantity	Unit	
	Name	Symbol
Plane angle	Revolution	r
	Grade	gon or grade
	Degree	°
	Minute of angle	'
	Second of angle	"
Time	Minute	min
	Hour	h
	Day	d
Energy	Electron volt	eV
Volume	Litre	l ^a
Pressure of respiratory gases, blood, and other body fluids	Millimetres of mercury	mmHg
	Centimetres of water	cmH ₂ O
Pressure of gases	Bar	bar
	Millibar	mbar
^a For consistency, in international standards only the symbol "l" is used for litre, although the symbol "L" is also given in ISO 80000-1.		

For application of SI units, their multiples and certain other units, ISO 80000-1 applies.

13 PROCEDURES for testing, including particular conditions

13.1 General

The following subclauses contain a framework for performing tests that are required by IEC 60601-1:2005. These are presented as a series of test PROCEDURES. They are divided into three groups:

- tests performed by inspection of the DUT;
- test performed with the DUT not energized; and
- tests performed with the DUT energized.

Each test PROCEDURE is written as a sheet describing:

- a) equipment needed for the test;
- b) safety precautions during the test;
- c) test sample preparation;
- d) test conditions;
- e) test set-up and PROCEDURE; and

f) presentation of the test results.

13.2 Tests to be performed by inspection

Table 2 lists those tests that are performed by inspection of the DUT.

Table 2 – Tests to be performed by inspection

Test per IEC/TR 62354		Clause in IEC 60601-1:1988	Clause in 60601-1:2005+AMD1:2012
No.	Description		
13.2.1	RISK MANAGEMENT PROCESS		4.2, 4.5
13.2.2	Ratings on critical components	56.1	4.8, 4.9, 11.3 and 15.4
13.2.3	Determination of APPLIED PARTS and ACCESSIBLE PARTS		4.6, 5.9, 8.4.2, 9.2.1
13.2.4	Durability and legibility of marking	6.1, 6.2	7.1.2, 7.1.3
13.2.5	Battery markings	6.8.2, 56.7	7.3.3, 15.4.3
13.2.6	PATIENT leads and PATIENT cables		8.5.2.3
13.2.7	Plugs, sockets		8.6.6
13.2.8	POTENTIAL EQUALIZATION TERMINAL	18	8.6.7
13.2.9	MAINS TERMINAL DEVICE	57.5 b)	8.11.4.2 e)
13.2.10	Sharp edges	23	9.3
13.2.11	HAZARDS associated with support systems	21.3	9.8.1, 9.8.3.1, 9.8.4, 9.8.5
13.2.12	Construction requirements for fire ENCLOSURE of ME EQUIPMENT		11.3
13.2.13	Marking, conductor colours, indicator lights and controls and ACCOMPANYING DOCUMENTS	6.1, 6.2, 6.3, 6.4, 6.6, 6.7, 6.8	7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9
13.2.14	USABILITY of ME EQUIPMENT		12.2, 15.1, 7.1.1

13.2.1 RISK MANAGEMENT PROCESS

Standard(s) IEC 60601-1:2005+AMD1:2012	Subclause(s): 4.2, 4.5	13.2.1 RISK MANAGEMENT PROCESS
a) Equipment needed for the test: N/A, if not otherwise specified within the RISK MANAGEMENT FILE.		
b) Safety precautions during the test: According to specification in the RISK MANAGEMENT FILE.		
c) Test sample preparation: One representative test sample. If applicable according to the specification in the RISK MANAGEMENT FILE.		
d) Test conditions: If applicable according to the specification in the RISK MANAGEMENT FILE		
e) Test set-up and PROCEDURE: Inspection of the RISK MANAGEMENT FILE If applicable according to the specification in the RISK MANAGEMENT FILE.		
f) Presentation of the test results: Subclause 4.2.2: The MANUFACTURER has/does not have a policy for determining criteria for RISK acceptability; The MANUFACTURER has/ does not have a RISK MANAGEMENT plan for the particular ME EQUIPMENT or ME SYSTEM under consideration; and The MANUFACTURER has/has not prepared a RISK MANAGEMENT FILE containing the RISK MANAGEMENT RECORDS and other documentation required by this standard for the particular ME EQUIPMENT or ME SYSTEM under consideration. The documents need to be in accordance with ISO 14971. Subclause 4.2.3.1.a): The MANUFACTURER has/has not provided OBJECTIVE EVIDENCE that requirements outside of the IEC 60601-1 series are adequate. NOTE This clause is filled in within the RISK MANAGEMENT FILE only if the MANUFACTURER'S result indicates that requirements within IEC 60601-1 series are inadequate. Subclause 4.2.3.1.b): The MANUFACTURER has/has not provided RECORDS in the RISK MANAGEMENT FILE to demonstrate that, after applying the specific requirements of this standard, the acceptance criteria determined by the MANUFACTURER are satisfied. Subclause 4.2.3.1.c): The MANUFACTURER has/has not provided RECORDS in the RISK MANAGEMENT FILE demonstrate that the RESIDUAL RISK is acceptable using the criteria for RISK acceptability recorded in the RISK MANAGEMENT plan, i.e. no unacceptable RISK remains. Subclause 4.2.3.2 (if applicable): The MANUFACTURER has/has not provided RECORDS in the RISK MANAGEMENT FILE for HAZARDS or HAZARDOUS SITUATIONS that are identified for the particular ME EQUIPMENT or ME SYSTEM but are not specifically addressed in this standard or its collateral or particular standards. Subclause 4.5 (if applicable): The MANUFACTURER has/has not provided RECORDS in the RISK MANAGEMENT FILE that: – an alternative RISK CONTROL measure or test method is acceptable; – can demonstrate through scientific data or clinical opinion or comparative studies that: • the RESIDUAL RISK that results from applying the alternative RISK CONTROL measure or test method remains acceptable, and • is comparable to the RESIDUAL RISK that results from applying the requirements of this standard.		

13.2.2 Ratings on critical components

Standard(s): IEC 60601-1:2005	Subclause(s): 4.8, 4.9, 11.3 and 15.4	13.2.2 Ratings on critical components				
a) Equipment needed for the test: N/A						
b) Safety precautions during the test: N/A						
c) Test sample preparation: One representative test sample. No preparation necessary.						
d) Test conditions: Do not energize the DUT during this test.						
e) Test set-up and PROCEDURE: Examine the circuit diagrams for the DUT to identify any critical components. Identify the types and manufacturers of these components using the parts lists. Obtain the data sheets and/or drawings from each manufacturer that are required to assess whether these components are working within their specified ratings. If the operating conditions cannot be established from the circuit analysis, then determine these ratings based on other tests e.g. heating test, WORKING VOLTAGE etc. Do not check flammability ratings of materials unless the MANUFACTURER has implemented a fire ENCLOSURE. In that case, only subject materials to flammability rating testing (according to Subclause 11.3 of IEC 60601-1:2005) that are either part of the fire ENCLOSURE or are inside the fire ENCLOSURE. This assessment should include the flammability rating of all plastics (i.e. PCBs, connectors, fans, insulators, bobbins, relay housings, plastic fuse holders, sleeving, insulated cables, plastic ENCLOSURES etc.). Only plastics of sufficient size to influence the spread of fire need be assessed. Where several small amounts of a plastic are in the same vicinity then the cumulative effect should be taken into account.						
f) Presentation of the test results:						
TABLE: List of critical components						
Object/ Part No	MANUFACTURE R/ Trademark	Type / Model	Technical data	Operating within ratings (Y/N)	Standard	Mark(s) of conformity
TABLE: Resistance to fire						
Item	Material/type	Manufacturer	Declared rating	Approval		

13.2.3 Determination of APPLIED PARTS and ACCESSIBLE PARTS

Standard(s): IEC 60601-1:2005+AMD1:2012	Subclause(s): 4.6, 5.9, 8.4.2, 9.2.1	13.2.3 Determination of APPLIED PARTS and ACCESSIBLE PARTS
a) Equipment needed for the test: 1) Unjointed test finger 2) Jointed test finger (Figure F.1) 3) Test pin (Figure F.3) 4) Force gauge 5) Weight 6) Test hook (Figure F.2) 7) Watch (indicating seconds) 8) Test rod		
b) Safety precautions during the test: Use normal laboratory safety PROCEDURES during this test.		
c) Test sample preparation: One representative test sample. No preparation necessary.		
d) Test conditions: Do not energize the DUT during this test.		
e) Test set-up and PROCEDURE: 1) Identify APPLIED PARTS by inspection of the ME EQUIPMENT and ACCOMPANYING DOCUMENTS. Determination of an ACCESSIBLE PART (electrical, hazardous moving, etc.) should be made using test probes (joined and/or rigid test finger, test pin, test hook, test rod). Refer also to Subclause 4.6 of IEC 60601-1:2005/AMD1:2012. 2) Apply the test fingers and pin without force unless a force is specified. Any parts that the test finger or test pin touches are considered to be accessible. 3) Apply the standard test finger in a bent or straight position: – to all positions of ME EQUIPMENT when operated as in NORMAL USE – if ME EQUIPMENT can be opened without the use of a TOOL or if the instructions for use describe opening, do this after opening ACCESS COVERS and removal of parts, including lamps, fuses and fuse holders. 4) Apply the standard test finger without appreciable force to all apertures in an attempt to contact hazardous parts (electrical or moving). Apply the test finger to the aperture's openings in every possible way. Do not tilt floor mounted ME EQUIPMENT that has a mass in any operational condition exceeding 45 kg. 5) Test ME EQUIPMENT which its technical description indicates should be mounted into a cabinet in its final mounting position. 6) Test openings into which the standard test finger cannot be put by inserting a straight, unjointed test finger with a force of 30 N. If the finger enters, repeat the test using the standard test finger by pushing the finger through the opening if necessary. 7) Insert the test hook in all relevant openings and the pull it with a force of 20 N for 10 s in a direction substantially perpendicular to the surface of the relevant opening. After applying the test hook, inspect the interior using the standard test finger. 8) Identify any additional parts that become accessible using the standard test finger and by inspection.		

13.2.3 Determination of APPLIED PARTS and ACCESSIBLE PARTS (continued)

Standard(s): IEC 60601-1:2005+AMD1:2012	Subclause(s): 4.6, 5.9, 8.4.2, 9.2.1	13.2.3 Determination of APPLIED PARTS and ACCESSIBLE PARTS
9) Conductive parts of actuating mechanisms of electrical controls that are accessible after removal of handles, knobs, levers and the like are regarded as ACCESSIBLE PARTS. 10) Conductive parts of actuating mechanisms are not considered accessible if removal of handles, knobs, etc. requires the use of a TOOL and inspection of the MANUFACTURER'S RISK MANAGEMENT FILE demonstrates the relevant part is unlikely to become detached unintentionally during the useful life of the ME EQUIPMENT. 11) Take any actions the OPERATOR should perform in NORMAL USE (with or without a TOOL) that increase the accessibility of parts (e.g. opening doors, removing covers, adjusting controls, replacing consumable material, removing parts). 12) For rack- and panel-mounted ME EQUIPMENT, install the ME EQUIPMENT according to the MANUFACTURER'S instructions. For such ME EQUIPMENT, the OPERATOR is assumed to be in front of the panel. 13) Other than contacts of plugs, connectors and socket outlets, the test pin does not contact parts other than those specified in Subclause 8.4.2 c) of IEC 60601-1:2005. Insert in all possible positions with a force up to 1 N. 14) Openings in the top or for the adjustment of preset controls are such that access with the test rod does not contact parts other than those specified in Subclause 8.4.2 c) of IEC 60601-1:2005. Insert in all possible positions with a force up to 10 N. If the instructions for use specify a different TOOL for the adjustment of preset controls, repeat the test using that TOOL.		
f) Presentation of the test results: List of APPLIED PARTS:		
TABLE: APPLIED PARTS		
Location		Remarks

13.2.4 Durability and legibility of marking

Standard(s): IEC 60601-1:2005+AMD1:2012	Subclause(s): 7.1.2, 7.1.3	13.2.4 Durability and legibility of marking
a) Equipment needed for the test: 1) Cloth rag 2) Stop watch/clock (indicating seconds) 3) Distilled water 4) Ethanol 96 % as defined in the European Pharmacopoeia as a reagent in the following terms: C ₂ H ₆ O (MW46.07). 5) Isopropyl alcohol – Isopropyl alcohol is defined in the European Pharmacopoeia as a reagent in the following terms: C ₃ H ₈ O (MW60.1). 6) Light regulation means 7) Lux meter 8) 1 m / 30° gauge 9) Protective gloves		
b) Safety precautions during the test: Perform this test in a well-ventilated area. Use appropriate protective gloves when conducting durability of markings test.		
c) Test sample preparation: One sample of marking nameplates attached to the DUT as specified by the MANUFACTURER.		
d) Test conditions: 1) Consider the effect of NORMAL USE on markings while evaluating durability. 2) Do not energize the DUT during this test.		
Marking location		
Use of marking		
Material		
Held by		
Applied surface material		
e) Test set-up and PROCEDURE: 1) Durability: Perform the rubbing test using distilled water, methylated spirit and isopropyl alcohol. Rub the markings by hand without undue pressure: – first for 15 s with a cloth rag soaked with distilled water, – then for 15 s with a cloth rag soaked with methylated spirit, – and then 15 s with a cloth rag soaked with isopropyl alcohol. 2) Legibility: Position the DUT or its part in the OPERATOR'S intended viewing position, or at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 1 m. Select the least favourable ambient luminance level in the range of 100 lx to 1 500 lx. The observer who has a visual acuity, corrected if necessary, of 0 on the log minimum angle of resolution (log MAR) scale or 6/6 (20/20), and is able to read N6 of the Jaeger test card, in normal room lighting conditions (approximately 500 lx), needs to correctly perceive the marking from their position. The observer correctly perceives the marking from the viewpoint.		

13.2.4 Durability and legibility of marking *(continued)*

Standard(s): IEC 60601-1:2005+AMD1:2012	Subclause(s): 7.1.2, 7.1.3	13.2.4 Durability and legibility of marking		
f) Presentation of the test results:				
TABLE: Durability and legibility of marking				
Marking	Legible (Y/N)	Curled (Y/N)	Edge lifted (Y/N)	Observation
The marking was/was not damaged.				
The label was/was not easily removed.				

13.2.5 Battery markings

Standard(s) IEC 60601-1:2005	Subclause(s): 7.3.3	13.2.5 Batteries
a) Equipment needed for the test: N/A		
b) Safety precautions during the test: N/A		
c) Test sample preparation: One representative test sample. No preparation necessary.		
d) Test conditions: Do not energize the DUT during this test.		
e) Test set-up and PROCEDURE: Visual inspection		
f) Presentation of the test results: The battery compartment was/was not marked with the type of battery and the mode of insertion (if applicable). The battery compartment was/was not designed to prevent the RISK of accidentally short-circuiting the battery. The battery compartment was/was not ventilated to minimize the RISK of accumulation and ignition when using batteries from which gases are likely to result in an unacceptable RISK if the gases escape during charging or discharging. The compartment for batteries intended to be changed only by SERVICE PERSONNEL with the use of a TOOL was/was not marked with an identifying marking referring to information provided in the ACCOMPANYING DOCUMENTS. The battery compartment was/was not marked with a warning indicating that only trained personnel can replace the batteries or fuel cells if the incorrect replacement would result in an unacceptable RISK. Identifying marking referring to the ACCOMPANYING DOCUMENTS was/was not provided. The design of the battery charging circuit does/does not prevent overcharging. The primary lithium batteries (cells and assemblies of cells) used in ME EQUIPMENT do/do not comply with the marking requirements of IEC 60086-4. The secondary lithium batteries (cells and assemblies of cells) used in ME EQUIPMENT do/do not comply with the marking requirements of IEC 62133. The INTERNAL ELECTRICAL POWER SOURCE in ME EQUIPMENT does/does not provide an appropriately RATED device that protects against fire due to excessive current if the cross-sectional area and layout of the internal wiring or the rating of connected components can give rise to a fire in case of a short circuit. Protective device(s) have/do not have the adequate breaking capacity to interrupt the maximum fault current (including short-circuit current) that can flow. Justification for omission of fuses or OVER-CURRENT RELEASES was/was not included in the RISK MANAGEMENT FILE. Means of preventing insertion or replacement of a battery incorrectly was/was not provided where an unacceptable RISK might occur.		

13.2.6 PATIENT leads or PATIENT cables

Standard(s): IEC 60601-1:2005+AMD1:2012	Subclause(s): 8.5.2.3	13.2.6 PATIENT leads
a) Equipment needed for the test: 1) Calliper 2) Unjointed test finger 3) Dielectric strength tester 4) Force gauge		
b) Safety precautions during the test: Use normal laboratory safety PROCEDURES during this test.		
c) Test sample preparation: One representative test sample. No preparation necessary.		
d) Test conditions: 1) Do not energize the DUT during this test. 2) This test applies to any connector for electrical connections on a PATIENT lead or cable containing a conductive part that is not separated from all PATIENT CONNECTION(S) by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAXIMUM MAINS VOLTAGE. "Said part" refers to the "...conductive part of the connector that is not separated from all PATIENT connections...."		
e) Test set-up and PROCEDURE: The connector should be constructed so that said part cannot become connected to earth or a possible hazardous voltage while the PATIENT CONNECTION(S) contacts the PATIENT. 1) Verify whether said part comes into contact with a flat conductive plate. 2) Measure the AIR CLEARANCE between connector pins and a flat surface. 3) If said part can be plugged into a mains socket, said part should be protected from making contact with parts at MAINS VOLTAGE by at least one insulating means that provides a specified CREEPAGE DISTANCE and a dielectric strength of 1 500 V for 1 min. 4) Apply the straight unjointed test finger in the least favourable position against the access openings with a force of 10 N.		
f) Presentation of the test results: The said part did/did not come into contact with a flat conductive plate of not less than 100 mm diameter. The AIR CLEARANCE between connector pins and a flat surface was/was not at least 0,5 mm. If able to be plugged into a mains socket outlet, the insulating means did/did not provide a CREEPAGE DISTANCE of at least 1,0 mm. If able to be plugged into a mains socket outlet, there was/was no indication of dielectric breakdown between the said part and the insulating means. The rigid test finger did/did not make electrical contact with the said part.		

13.2.7 Plugs, sockets

Standard(s): IEC 60601-1:2005	Subclause(s): 8.6.6	13.2.7 Plugs, sockets
a) Equipment needed for the test: 1) Callipers		
b) Safety precautions during the test: Use normal laboratory safety PROCEDURES during this test.		
c) Test sample preparation: One representative test sample. No preparation necessary.		
d) Test conditions: Do not energize the DUT during this test. This test applies where the connection between the SUPPLY MAINS and the DUT or between separate parts of the DUT that can be operated by the OPERATOR is made via a plug and socket device. This also applies if interchangeable parts are PROTECTIVELY EARTHED.		
e) Test set-up and PROCEDURE: Visual inspection and dimensional measurement of the connector pins.		
f) Presentation of the test results: The PROTECTIVE EARTH CONNECTION was/was not made before and interrupted after the supply connections were made or interrupted.		

13.2.8 POTENTIAL EQUALIZATION TERMINAL

Standard(s): IEC 60601-1:2005+AMD1:2012	Subclause(s): 8.6.7	13.2.8 POTENTIAL EQUALIZATION TERMINAL
a) Equipment needed for the test: N/A		
b) Safety precautions during the test: Use normal laboratory safety PROCEDURES during this test.		
c) Test sample preparation: One representative test sample. No preparation necessary.		
d) Test conditions: Do not energize the DUT during this test. This test applies to ME EQUIPMENT that provides a terminal for the connection of a POTENTIAL EQUALIZATION CONDUCTOR.		
e) Test set-up and PROCEDURE: Visual inspection.		
f) Presentation of the test results: The terminal was/was not accessible to the OPERATOR with the DUT in any of its possible NORMAL USE positions. Accidental disconnection was/was not avoided in NORMAL USE. The terminal does/does not allow the conductor to be detached without the use of a TOOL. The terminal was /was not used for a PROTECTIVE EARTH CONNECTION. The terminal was/was not marked with symbol IEC 60417-5021(2002-10). The instruction for use does/does not contain information on the function and use of the POTENTIAL EQUALIZATION CONDUCTOR together with a reference to the requirements of IEC 60601-1:2005 for ME SYSTEMS. The POWER SUPPLY CORD does /does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR.		

13.2.9 MAINS TERMINAL DEVICE

Standard(s): IEC 60601-1:2005	Subclause(s): 8.11.4.2 e)	13.2.9 MAINS TERMINAL DEVICE																
a) Equipment needed for the test: 1) Calliper																		
b) Safety precautions during the test: Use normal laboratory safety PROCEDURES during this test.																		
c) Test sample preparation: Stripping of insulation.																		
d) Test conditions: Do not energize the DUT during this test.																		
e) Test set-up and PROCEDURE: 1) Strip 8 mm of insulation off of the end of a flexible conductor that has a cross-sectional area as specified in Table 3 and that is used for connection to a MAINS TERMINAL DEVICE.																		
Table 3 – NOMINAL cross-sectional area of conductors of a POWER SUPPLY CORD (IEC 60601-1:2005, Table 17)																		
<table><tr><th>RATED current (<i>I</i>) of ME EQUIPMENT A</th><th>NOMINAL cross-sectional area mm² Cu</th></tr><tr><td><i>I</i> ≤ 6</td><td>0,75</td></tr><tr><td>6 < <i>I</i> ≤ 10</td><td>1</td></tr><tr><td>10 < <i>I</i> ≤ 16</td><td>1,5</td></tr><tr><td>16 < <i>I</i> ≤ 25</td><td>2,5</td></tr><tr><td>25 < <i>I</i> ≤ 32</td><td>4</td></tr><tr><td>32 < <i>I</i> ≤ 40</td><td>6</td></tr><tr><td>40 < <i>I</i> ≤ 63</td><td>10</td></tr></table>			RATED current (<i>I</i>) of ME EQUIPMENT A	NOMINAL cross-sectional area mm² Cu	<i>I</i> ≤ 6	0,75	6 < <i>I</i> ≤ 10	1	10 < <i>I</i> ≤ 16	1,5	16 < <i>I</i> ≤ 25	2,5	25 < <i>I</i> ≤ 32	4	32 < <i>I</i> ≤ 40	6	40 < <i>I</i> ≤ 63	10
RATED current (<i>I</i>) of ME EQUIPMENT A	NOMINAL cross-sectional area mm² Cu																	
<i>I</i> ≤ 6	0,75																	
6 < <i>I</i> ≤ 10	1																	
10 < <i>I</i> ≤ 16	1,5																	
16 < <i>I</i> ≤ 25	2,5																	
25 < <i>I</i> ≤ 32	4																	
32 < <i>I</i> ≤ 40	6																	
40 < <i>I</i> ≤ 63	10																	
2) Leave a single wire of the stranded conductor free and secure the rest of the conductor to the terminal to simulate a fully introduced conductor.																		
3) Bend the free wire in every possible direction without pulling back the insulating sheath and without making sharp bends around partitions.																		
4) Any contact between the free wire and any other part that short-circuits a MEANS OF PROTECTION constitutes a failure.																		

13.2.9 MAINS TERMINAL DEVICE *(continued)*

Standard(s): IEC 60601-1:2005	Subclause(s): 8.11.4.2 e)	13.2.9 MAINS TERMINAL DEVICE
f) Presentation of the test results:		
TABLE: MAINS TERMINAL DEVICE		
Conductor stripped:	Contact to other parts:	MEANS OF PROTECTION short-circuited: Yes/No

13.2.10 Sharp edges

Standard(s): IEC 60601-1:2005+AMD1:2012	Subclause(s): 9.3	13.2.10 Sharp edges												
a) Equipment needed for the test: N/A														
b) Safety precautions during the test: Use normal laboratory safety PROCEDURES during this test.														
c) Test sample preparation: One representative sample with fully loaded options/ACCESSORIES, consisting of the complete ENCLOSURE in its normal position.														
d) Test conditions: Accessible edges or corners of the DUT, except those required for proper functioning of the ME EQUIPMENT were assessed. Do not energize the DUT during this test.														
e) Test set-up and PROCEDURE: Surfaces described below are judged for sharp edges.														
Surface	Material	Observations												
f) Presentation of the test results:														
<table border="1"> <tr> <th colspan="2">TABLE: Sharp edges</th> </tr> <tr> <th>Edge location</th> <th>Unacceptable RISK present <u>Yes/No</u></th> </tr> <tr> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> </tr> </table>			TABLE: Sharp edges		Edge location	Unacceptable RISK present <u>Yes/No</u>								
TABLE: Sharp edges														
Edge location	Unacceptable RISK present <u>Yes/No</u>													
The edges and corners were/were not considered to be rounded and smooth.														
The HAZARDS related to sharp edges are/are not included in the RISK MANAGEMENT FILE.														

13.2.11 HAZARDS associated with support systems

Standard(s): IEC 60601-1:2005+AMD1:2012	Subclause(s): 9.8.1, 9.8.3.1, 9.8.4, 9.8.5	13.2.11 HAZARDS associated with support systems
a) Equipment needed for the test: N/A		
b) Safety precautions during the test: Use normal laboratory safety PROCEDURES during this test.		
c) Test sample preparation: One representative sample with fully loaded options/ACCESSORIES, consisting of the complete ENCLOSURE in its normal position.		
d) Test conditions: Do not energize the DUT during this test.		
e) Test set-up and PROCEDURE: The DUT is evaluated for HAZARDS associated with support systems based on visual inspection of the ME EQUIPMENT and on inspection of the documentation provided.		
f) Presentation of the test results: The construction of the support, suspension or actuation system is/is not designed based upon determination of TENSILE SAFETY FACTOR and the TOTAL LOAD. Means of attachment of ACCESSORIES are/are not designed such that any possibility of incorrect attachment that could result in an unacceptable RISK is avoided. The RISK ANALYSIS of support systems does/does not consider HAZARDS arising from static, dynamic, vibration, impact and pressure loading, foundation and other movements, temperature, environmental, manufacture and service conditions. All likely failure effects were/were not considered in the RISK ANALYSIS. These include excessive deflection, plastic deformation, ductile or brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep, material deterioration and residual stresses resulting from the manufacturing PROCESSES, e.g. machining, assembling, welding, heat treatment or surface coating. The ACCOMPANYING DOCUMENTS contain/do not contain instructions on attachment of structures to a floor, wall, ceiling, etc. making adequate allowances for quality of the materials used to make the connection and list the required materials. Additionally advice/no advice on checking the adequacy of the surface of the structure to which the parts will be attached. Additionally, the ACCOMPANYING DOCUMENTS provide/do not provide instructions that once the MECHANICAL PROTECTIVE DEVICE has been activated, SERVICE PERSONNEL are to be called and the MECHANICAL PROTECTIVE DEVICE has to be replaced before the ME EQUIPMENT can be used again. The DUT is/is not marked properly. The DUT does/does not require a MECHANICAL PROTECTIVE DEVICE. Where required, the MECHANICAL PROTECTIVE DEVICE is/is not designed on the basis of TOTAL LOAD, which includes SAFE WORKING LOAD when applicable.		

13.2.11 HAZARDS associated with support systems (continued)

Standard(s): IEC 60601-1:2005+AMD1:2012	Subclause(s): 9.8.1, 9.8.3.1, 9.8.4, 9.8.5	13.2.11 HAZARDS associated with support systems
The MECHANICAL PROTECTIVE DEVICE has/does not have the TENSILE SAFETY FACTORS for all parts correct selected. The MECHANICAL PROTECTIVE DEVICE activates/does not activate before travel (movement) produces an unacceptable RISK. The MECHANICAL PROTECTIVE DEVICE takes into account/does not account for continuous activation and MECHANICAL PROTECTIVE DEVICE intended for single activation. It did/did not become obvious that the MECHANICAL PROTECTIVE DEVICE has been activated. The MECHANICAL PROTECTIVE DEVICE requires/does not require the use of a TOOL to be reset or replaced. Further use of the ME EQUIPMENT is/is not impossible until the MECHANICAL PROTECTIVE DEVICE has been replaced. The marking is/is not adjacent to the MECHANICAL PROTECTIVE DEVICE or so located that its relation to the MECHANICAL PROTECTIVE DEVICE is obvious to the person performing service or repair. There was / was no damage to the MECHANICAL PROTECTIVE DEVICE that would affect its ability to perform its intended function. Support system parts are/are not impaired by wear.		

13.2.12 Construction requirements for fire ENCLOSURE of ME EQUIPMENT

Standard(s): IEC 60601-1:2005	Subclause(s): 11.3	13.2.12 Construction requirements for fire ENCLOSURE of ME EQUIPMENT																								
a) Equipment needed for the test: 1) Calliper 2) Metric gauge pins 3) Inclinator																										
b) Safety precautions during the test: Use normal laboratory safety PROCEDURES during this test.																										
c) Test sample preparation: One representative test sample.																										
d) Test conditions: Do not energize the DUT during this test.																										
e) Test set-up and PROCEDURE: 1) Flammability ratings of materials are to be checked only where the MANUFACTURER has implemented a fire ENCLOSURE and only if the materials used as part of the fire ENCLOSURE or inside of the fire ENCLOSURE are subject to flammability rating requirements according to Subclause 11.3 of IEC 60601-1:2005. Part of this assessment should include the flammability rating of all plastics (i.e. PCBs, connectors, fans, insulators, bobbins, relay housings, plastic fuse holders, sleeving, insulated cables, insulated wire, plastic ENCLOSURES, etc). NOTE Only plastics of sufficient size to influence the spread of fire need be assessed Where several small amounts of a plastic are in the same vicinity then the cumulative effect should be taken into account. 2) Inspect bottom and side ENCLOSURE openings in accordance with Subclause 11.3.b) 1) and 2) of IEC 60601-1:2005. 3) Inspect the ENCLOSURE and any baffle or flame barrier in accordance with Subclause 11.3 b) 3) of IEC 60601-1:2005.																										
f) Presentation of the test results: <table><tr><th colspan="4">TABLE: Resistance to fire</th></tr><tr><th>Item</th><th>Material/type</th><th>Manufacturer</th><th>Flame rating</th></tr><tr><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td></tr></table> Insulated wire used within a fire ENCLOSURE has/does not have a flammability rating of FV-1 or better; Connectors, printed circuit boards and insulating material on which components are mounted have/do not have a flammability classification of FV-2 or better.			TABLE: Resistance to fire				Item	Material/type	Manufacturer	Flame rating																
TABLE: Resistance to fire																										
Item	Material/type	Manufacturer	Flame rating																							

13.2.12 Construction requirements for fire ENCLOSURE of ME EQUIPMENT (continued)

Standard(s): IEC 60601-1:2005	Subclause(s): 11.3	13.2.12 Construction requirements for fire ENCLOSURE of ME EQUIPMENT
The bottom has no openings/has openings complying with Figure 1 constructed with baffles according to Figure 2 or is made of metal perforated according to Table 4 or is made with a metal screen with a mesh not exceeding 2 mm by 2 mm center to center and a wire diameter of at least 0,45 mm. Key A Part or component of the ME EQUIPMENT that is considered to be a source of fire. This consists of an entire component or part of the ME EQUIPMENT if it is not otherwise shielded, or the unshielded portion of a component that is partially shielded by its casing. B Projection of the outline of A on the horizontal plane. C Inclined line that traces out the minimum area of the bottom and sides to be constructed as specified in 11.3 b) 1) and 11.3 b) 2). This line projects at a 5° angle from the vertical at every point around the perimeter of A and is oriented so as to trace out the maximum area. D Minimum area of the bottom to be constructed as specified in 11.3 b) 1) [of the General Standard]. Figure 1 – Area of the bottom of an ENCLOSURE as specified in 11.3 b) 1) (IEC 60601-1:2005, Figure 39) Y = twice X but never less than 25 mm ① Baffle plates (may be below the bottom of the ENCLOSURE) ② Bottom of the ENCLOSURE Figure 2 – Baffle (IEC 60601-1:2005, Figure 38)		

13.2.12 Construction requirements for fire ENCLOSURE of ME EQUIPMENT *(continued)*

Standard(s): IEC 60601-1:2005	Subclause(s): 11.3	13.2.12 Construction requirements for fire ENCLOSURE of ME EQUIPMENT
Table 4 – Acceptable perforation of the bottom of an ENCLOSURE (IEC 60601-1:2005, Table 25)		
Minimum thickness mm	Maximum diameter of holes mm	Minimum spacing of holes centre to centre mm
0,66	1,14	1,70 (233 holes/645 mm ²)
0,66	1,19	2,36
0,76	1,15	1,70
0,76	1,19	2,36
0,81	1,91	3,18 (72 holes/645 mm ²)
0,89	1,90	3,18
0,91	1,60	2,77
0,91	1,98	3,18
1,00	1,60	2,77
1,00	2,00	3,00
Sides have no/have openings within the area that is included within the incline line C in Figure 1. The ENCLOSURE, any baffle or flame barrier is/is not made of metal (except magnesium) or non-metallic materials RATED FV-2 or better for TRANSPORTABLE ME EQUIPMENT and FV-1 or better for FIXED or STATIONARY ME EQUIPMENT. For constructions according to Table 4 and metal screen mesh, see above.		

13.2.13 Marking, conductor colours, indicator lights and controls and ACCOMPANYING DOCUMENTS

Standard(s) IEC 60601-1:2005+AMD1:2012	Subclause(s): 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9	13.2.13 Marking, conductor colours, indicator lights and controls and ACCOMPANYING DOCUMENTS
a) Equipment needed for the test: N/A		
b) Safety precautions during the test: N/A		
c) Test sample preparation: One representative test sample. No preparation necessary.		
d) Test conditions: Do not energize the DUT during this test. Evaluate the marking and the ACCOMPANYING DOCUMENTS provided with the DUT.		
e) Test set-up and PROCEDURE: Evaluate the markings on the DUT, the colours of insulation and indicators and controls, and the ACCOMPANYING DOCUMENTS provided with the DUT against the requirements in the standard.		
f) Presentation of the test results: 1) IEC 60601-1:1988: The markings on the outside of ME EQUIPMENT or ME EQUIPMENT parts do/do not satisfy the requirements of Subclause 6.1. The markings on the inside of ME EQUIPMENT or ME EQUIPMENT parts do/do not satisfy the requirements of Subclause 6.2. The marking of controls and instruments do/do not satisfy the requirements of Subclause 6.3. Any symbols do/do not satisfy the requirements of Subclause 6.4. The colours of the insulation of conductors do/do not satisfy the requirements of Subclause 6.5. The colours of indicator lights and controls do/do not satisfy the requirements of Subclause 6.7. The ACCOMPANYING DOCUMENTS do/do not satisfy the requirements of Subclause 6.8.		
2) IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012: The markings on the outside of ME EQUIPMENT or ME EQUIPMENT parts do/do not satisfy the requirements of Subclause 7.2. The markings on the inside of ME EQUIPMENT or ME EQUIPMENT parts do/do not satisfy the requirements of Subclause 7.3. The marking of controls and instruments do/do not satisfy the requirements of Subclause 7.4. Any safety signs do/do not satisfy the requirements of Subclause 7.5. Any symbols do/do not satisfy the requirements of Subclause 7.6. The colours of the insulation of conductors do/do not satisfy the requirements of Subclause 7.7. The colours of indicator lights and controls do/do not satisfy the requirements of Subclause 7.8. The ACCOMPANYING DOCUMENTS do/do not satisfy the requirements of Subclause 7.9.		

13.2.14 USABILITY of ME EQUIPMENT

Standard(s) IEC 60601-1:2005+AMD1:2012	Subclause(s): 12.2, 15.1, 7.1.1	13.2.14 Usability of ME EQUIPMENT
a) Equipment needed for the test: N/A		
b) Safety precautions during the test: N/A		
c) Test sample preparation: No preparation necessary.		
d) Test conditions: N/A.		
e) Test set-up and PROCEDURE: Evidence of compliance with this subclause and all requirements of this standard referring to inspection of the USABILITY ENGINEERING file are satisfied if the MANUFACTURER has: – established a USABILITY ENGINEERING PROCESS; – established acceptance criteria for USABILITY; and – demonstrated that the acceptance criteria for USABILITY have been met.		
f) Presentation of the test results: The MANUFACTURER has/has not elaborated a USABILITY ENGINEERING file. The MANUFACTURER has/has not elaborated a USABILITY specifications document. The MANUFACTURER has/has not established a USABILITY validation plan The MANUFACTURER has/has not identified known or foreseeable HAZARDS related to USABILITY, analysed these HAZARDS according ISO 14971 and are included in the RISK MANAGEMENT FILE.		

13.3 Measurements and tests performed on non-energized equipment

Table 5 lists those measurements and tests that are performed on a non-energized DUT.

Table 5 – Measurements and tests performed on non-energized equipment

Test per IEC/TR 62354		Clause in IEC 60601-1:1988	Clause in 60601-1:2005
No.	Description		
13.3.1	Humidity preconditioning	4.10, 44.5	5.7
13.3.2	Impedance of PE connection	18 f)	8.6.4
13.3.3	Dielectric strength	20.4	8.8.3
13.3.4	Ball pressure	59.2 b)	8.8.4.1
13.3.5	Resistance to environmental stress		8.8.4.2
13.3.6	Thermal cycling		8.9.3.4
13.3.7	CREEPAGE DISTANCES and AIR CLEARANCES	59.2	8.9.4
13.3.8	Strain relief (cord anchorage)	57.4 a)	8.11.3.5
13.3.9	Cord guard flexing (cord bending)	57.4 b)	8.11.3.6
13.3.10	Access to hazardous moving parts		9.2.1
13.3.11	Gaps		9.2.2.2
13.3.12	Instability(in transport position; excluding transport; from horizontal and vertical forces and from unwanted lateral movement)	24	9.4.2.1, 9.4.2.2, 9.4.2.3, 9.4.3.1, 9.4.3.2
13.3.13	Castors and wheels (force for propulsion, movement over a threshold)		9.4.2.4.2, 9.4.2.4.3
13.3.14	Handle loading	21 c)	9.4.4
13.3.15	Safety catch evaluation	28.3	9.8.1, 9.8.2
13.3.16	Support loading	28.4	9.8.3
13.3.17	Overflow	44.2	11.6.2
13.3.18	Spillage	44.3	11.6.3
13.3.19	Leakage	44.4	11.6.4, 13.2.6
13.3.20	Ingress of water or particulate matter	44.6	11.6.5
13.3.21	Cleaning, sterilization and disinfection	44.7	11.6.6, 11.6.7
13.3.22	Push (rigidity)	21	15.3.2
13.3.23	Impact	21; 22	15.3.3
13.3.24	Drop impact	21.5; 21.6	15.3.4
13.3.25	Rough handling	21.6	15.3.5, 9.4.2.4.3
13.3.26	Mould stress relief		15.3.6
13.3.27	Actuating parts of controls (Knob pull and limitation of movement)	56.10 b) and c)	15.4.6.1, 15.4.6.2
13.3.28	Construction of transformers		15.5.3

13.3.1 Humidity preconditioning

Standard(s): IEC 60601-1:2005+AMD1:2012	Subclause(s): 5.7	13.3.1 Humidity preconditioning		
a) Equipment needed for the test: 1) Environment chamber with control over humidity in the range of (93 ± 3) % relative humidity (RH) and temperature in the range of (20 ± 2) °C to (30 ± 2) °C 2) Relative humidity and temperature recording equipment				
b) Safety precautions during the test: Use normal laboratory safety PROCEDURES during this test.				
c) Test sample preparation: This test is to be applied only to those ME EQUIPMENT parts likely to be influenced by the climatic conditions that are simulated by the test. One representative test sample. Prior to conditioning, parts of the DUT (covers) that could be removed without the use of TOOLS were removed and separately placed in the chamber. During conditioning, cable entrances and/or a conduit opening were left open. Do not energize the DUT during this test.				
d) Test conditions: A humidity chamber having relative humidity of 93 % ± 2 % is set to any convenient temperature (<i>T</i>) between 20 °C and 32 °C. The DUT, before being placed in the chamber, is brought to a temperature between <i>T</i> and (<i>T</i> + 4) °C and kept at this temperature for a minimum of 4 h.				
e) Test set-up and PROCEDURE: 1) Place the DUT in the humidity chamber and kept it there for: – 2 days (48 h) for ordinary (IPX0) ME EQUIPMENT or ME EQUIPMENT parts. – 7 days (168 h) for IPX1 – IPX8 . – If the RISK MANAGEMENT PROCESS suggests that the ME EQUIPMENT might be exposed to high humidity for extended periods (such as ME EQUIPMENT intended for out-door use), the period should be extended appropriately (for IEC 60601-1:2005 only). During this time the temperature of the air in the chamber is maintained at <i>T</i> ± 2 °C. 2) While still in the humidity chamber, but after all parts have been placed back on the DUT, the dielectric strength test according to Subclause 13.3.3 of IEC 60601-1:2005 should be performed for a period of 1 min between applicable parts. 3) Then the DUT is removed from the chamber, placed in a normal environment (temperature approximately <i>T</i>, humidity 45 % – 65 %) and 1 h later (for the IEC 60601-1:1988 only) LEAKAGE CURRENT tests are performed according to Subclauses 13.4.7 – 13.4.12 of IEC 60601-1:2005.				
f) Presentation of the test results:TABLE: Humidity preconditioning				
Identification of ME EQUIPMENT and its parts/IP rating	Soak temperature °C	Soak humidity % RH	Soak duration h	Remarks

13.3.2 Impedance of PE connection

Standard(s): IEC 60601-1:2005+AMD1:2012	Subclause(s): 8.6.4	13.3.2 Impedance of PE connection		
a) Equipment requested for the testing: 1) Adjustable a.c. current source with a frequency of 50 Hz,60 Hz or d.c. and with a no-load voltage not exceeding 6 V, which is able to produce 25 A or 1,5 times the highest RATED current of the relevant circuit(s), whichever is greater (± 10 %) 2) Suitable voltmeter and ammeter 3) Assorted connectors and cables 4) Shunt, or 5) Ground bond tester				
b) Safety precautions during the test: Use normal laboratory safety PROCEDURES during this test. High current testing can cause excessive localized heating of conductive parts and possible burns. An operator wearing conductive jewellery needs to take precautions to ensure contact with the high current test circuit is prevented.				
c) Test sample preparation: One representative test sample.				
d) Test conditions: Do not energize the DUT during this test.				
e) Test set-up and PROCEDURE: 1) A test current of 25 A or 1,5 times the highest RATED current of the relevant circuit(s), whichever is greater (± 10 %), from a current source with a frequency of 50 Hz , 60 Hz or d.c. and with a no-load voltage not exceeding 6 V, is passed for 5 s to 10 s through: – the PROTECTIVE EARTH TERMINAL or the protective earth contact in the APPLIANCE INLET or the protective earth pin in the MAINS PLUG and each PROTECTIVELY EARTHED part – each protectively earthed part or the MAINS PLUG of any DETACHABLE POWER SUPPLY CORD supplied or specified by the MANUFACTURER, when attached to the ME EQUIPMENT, and any part of the ME EQUIPMENT that is PROTECTIVELY EARTHED. Where a DETACHABLE POWER SUPPLY CORD is neither supplied nor specified, test using a 3 m long cord of appropriate cross sectional area based on IEC 60601-1:2005+AMD1:2012 clause 8.11.3.3 and Table 17. 2) The voltage drop between the earth terminal and the part to be earthed is measured, and the resistance between these two points is to be calculated. 3) The test instrument leads impedance should be considered.				
f) Presentation of the test results:				
TABLE: Impedance of PE connection				
Test location	Test current (I) A	Duration s	Measured voltage (U) V	Resistance (R) Ω
R = U/I				
The calculated resistance:				
() did not exceed 100 mΩ for PERMANENTLY INSTALLED ME EQUIPMENT, and for ME EQUIPMENT with an APPLIANCE INLET;				
() did not exceed 200 mΩ for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD.				

13.3.3 Dielectric strength

Standard(s): IEC 60601-1:2005+AMD1:2012	Subclause(s): 8.8.3	13.3.3 Dielectric strength
a) Equipment needed for the test: Dielectric strength a.c. and/or d.c tester (HiPot) as appropriate. In order to ensure standardized control of test voltage in time, testers with program controlled test voltage are recommended. Manual adjustment of the test voltage in certain circumstances can be valuable. The test equipment should display the current measurement through the insulation. Alternatively, where needed, current can be measured using an ammeter in series providing it has sufficient protection against the HIGH VOLTAGE of the test. Adding series connected impedances can protect the ammeter from HIGH VOLTAGE. For older dielectric strength test equipment, any means to measure ramp time (stop watch, watch or clock) can be used. Provide elements ensure spatial separation between test operator and DUT located together with eventual auxiliary measuring devices in HIGH VOLTAGE area.		
b) Safety precautions during the test: The DUT, test equipment, test leads and any auxiliary equipment and components should not be accessible upon commencement of the HIGH VOLTAGE. Provide adequate markings and warnings at the testing location. Give special consideration to the possibility someone might come into contact with the HIGH VOLTAGE. Design the test station so that accidental touching of parts at HIGH VOLTAGE is not possible. Test operators should not be able to keep test probes in their hands during HIGH VOLTAGE activation. Put precautions in place to prevent conductive liquids from being near the test station. Take steps (including training) to ensure that the test operator is not distracted during the test. (Conversations with others or telephone calls for example). Test operator(s) are properly trained, authorized and physically/mentally able to perform the test.		
c) Test sample preparation: 1) The configuration(s) of the DUT must allow all safety insulations to be tested according to the insulation diagram. 2) Observe standard requirements that allow for short-circuiting of either circuit side of the electrical test node and the removal of specified components. 3) When testing across more than one safety insulation, give consideration to the effects different impedances have on the safety insulation involved and over-voltage stressing of particular safety insulation in the test circuit path. In such test situations, a separate test of each safety insulation using the applicable dielectric strength test voltage might be necessary. 4) Tightly cover ENCLOSURES or their parts made of non-conductive material with foil. Place foil so that it does not bridge the safety insulation under test but does test all applicable areas. 5) The surface of cables and lead wires connected to the DUT should be treated as parts of the DUT ENCLOSURE. 6) The surface of mains power cords can be exempt from wrapping with foil and inclusion as an electrical test node based on relevant analysis of the component.		

13.3.3 Dielectric strength (continued)

Standard(s): IEC 60601-1:2005+AMD1:2012	Subclause(s): 8.8.3	13.3.3 Dielectric strength		
d) Test conditions: Connect test circuits (switches and relay contacts closed) and do not energize the DUT. If necessary (to prevent battery powered DUT's from being energized), use a solid piece of insulation to block one pole of the battery. Perform testing immediately after humidity preconditioning treatment, after any required sterilization PROCEDURE, and after reaching the steady state operating from the excessive temperature test.				
e) Test set-up and PROCEDURE: 1) Prior to the test, discuss the equipment design, insulation diagram and appropriate test strategy with the MANUFACTURER. Determine the dielectric strength voltage and waveform to be applied across each safety insulation and circuit arrangement including any components to be removed and any circuits to be short-circuited. 2) Where appropriate, apply two MEANS OF PROTECTION according to IEC/TR 60513. 3) Perform the testing across the single MEANS OF PROTECTION safety insulation prior to the two MEANS OF PROTECTION safety insulation. 4) Perform each dielectric strength test in the sequence by applying not more than half the test voltage, then ramping the voltage over a 10 s period, holding for 1 min and ramping over a 10 s period to less than half the test voltage. 5) Breakdown (current that rapidly increases in an uncontrolled manner) constitutes a failure. Corona discharge or a single momentary flashover is not regarded as insulation breakdown. 6) Observing the linear relationship between a change in the dielectric strength test voltage to change in current through the safety insulation can provide useful information about the safety insulation.				
f) Presentation of the test results: There was/was no indication of dielectric breakdown.				
TABLE: Dielectric strength				
Insulation under test (area from insulation diagram)	Insulation type: (BI-BASIC / SI-SUPPLEMENTARY / DI-DOUBLE / RI-REINFORCED) (for IEC 60601-1:1988) (Functional / one MOOP / two MOOP / one MOPP/ two MOPP) (for IEC 60601-1:2005)	WORKING VOLTAGE V	Test voltage V	Remarks

13.3.4 Ball pressure

Standard(s): IEC 60601-1:2005+AMD1:2012	Subclause(s): 8.8.4.1	13.3.4 Ball pressure			
a) Equipment needed for the test: 1) Ball pressure apparatus (Figure F.4) 2) Heating cabinet with temperature measuring device 3) Calliper with magnifying feature or additional magnifying equipment 4) Watch/clock 5) Support for specimen with place to embed thermocouple					
b) Safety precautions during the test: No special safety precaution required.					
c) Test sample preparation: Special preparation of the insulating material might be necessary in order to be able to perform the test. The thickness of the material to be tested should be at least 2,5 mm (radius of the ball).					
d) Test conditions: The temperature in the heating cabinet should be brought up to a temperature related to the use of the insulating material. For example: – 75 ± 2 °C or maximum ambient operating temperature specified in the technical description ± 2 °C plus the temperature rise that was determined during the test for normal heating (test 13.4.17) of the relevant part of the insulating material, whichever is the higher (for parts of the ENCLOSURE and other external insulating parts); or – 125 °C ± 2 °C or maximum ambient operating temperature specified in the technical description ± 2 °C plus the temperature rise that was determined during the test for normal heating (test 13.4.17) of the relevant part of the insulating material, whichever is the higher (for parts of insulating material which support uninsulated parts of the MAINS PART).					
e) Test set-up and PROCEDURE: 1) The heating cabinet is brought up to the pre-determined temperature. The cabinet temperature should be uniform and maintained for 1 h. 2) The insulating material to be tested is placed in the cabinet on a solid horizontal support. 3) The ball pressure apparatus is placed upon the insulating material to be tested. 4) The ball is withdrawn after 1 h and the diameter of the impression made by the ball is measured with a slide calliper.					
f) Presentation of the test results:					
Part name	Material	Thickness mm	Temperature rise during normal heating	Temperature during test	Diameter of impression

13.3.5 Resistance to environmental stress

Standard(s): IEC 60601-1:2005	Subclause(s): 8.8.4.2	13.3.5 Resistance to environmental stress
a) Equipment needed for the test: 1) An oxygen cylinder with a capacity at least 10 times the volume of the test samples. The cylinder has the means to suspend the test sample and to be filled with oxygen and hold pressure of 2,1 MPa $\pm$ 70 kPa. 2) Commercial oxygen that is not less than 97 % pure. 3) Clock or watch to measure time. 4) A means to heat the test sample to 70 °C $\pm$ 2 °C.		
b) Safety precautions during the test: Use normal laboratory safety PROCEDURES during this test. Careful consideration to the handling of concentrated oxygen under pressure including the flammability of such mixture.		
c) Test sample preparation: Disassemble the DUT so that ceramic materials, beads and insulating material of heating conductors may be inspected. Acquire parts that are used for safety insulation and are made of natural latex rubber for the test. Suspend these parts within the oxygen cylinder.		
d) Test conditions: Prior to inspection of safety insulation parts, consider the MANUFACTURER'S recommendations for the environment and EXPECTED SERVICE LIFE including the wear of parts within the DUT that could result in the disposition of dust or conductive particles that could impact CREEPAGE DISTANCES or AIR CLEARANCES. For insulation parts made of natural latex rubber provide an environment of oxygen at 2,1 MPa $\pm$ 70 kPa at a temperature of 70 °C $\pm$ 2 °C for 96 h.		
e) Test set-up and PROCEDURE: 1) Ceramic material not tightly sintered, and the like, and beads alone are checked by inspection, that they are not used as SUPPLEMENTARY or REINFORCED INSULATION. 2) Insulating material in which heating conductors are embedded is also checked by inspection, that it is not used as two MEANS OF PROTECTION. 3) The CREEPAGE DISTANCES and AIR CLEARANCES of any MEANS OF PROTECTION are not to be reduced below the values specified in Subclause 8.9 of IEC 60601-1:2005 caused by environmental stresses including impairment by deposition of dirt or dust resulting from wear of parts. 4) Parts of natural latex rubber are aged in an atmosphere of oxygen under pressure. The samples are suspended freely in an oxygen cylinder, the effective capacity of the cylinder is at least 10 times the volume of the samples. The cylinder is filled with commercial oxygen not less than 97 % pure, to a pressure of 2,1 MPa $\pm$ 70 kPa. 5) The samples are kept in the cylinder at a temperature of 70 °C $\pm$ 2 °C for 96 h. Immediately afterwards, they are taken out of the cylinder and left at room temperature for at least 16 h. After the test, the samples are examined. Cracks visible to the naked eye constitute a failure.		
f) Presentation of the test results: Ceramic material not tightly sintered, and the like, and beads alone are not/are used as SUPPLEMENTARY or REINFORCED INSULATION. Insulating material in which heating conductors are embedded is/is not used as TWO MEANS OF PROTECTION. Cracks visible to the naked eye were/were not found upon inspection of natural latex rubber after exposure to oxygen at pressure and temperature as specified herein.		

13.3.6 Thermal cycling

Standard(s): IEC 60601-1:2005	Subclause(s): 8.9.3.4	13.3.6 Thermal cycling
a) Equipment needed for the test: 1) Environmental chamber 2) Dielectric strength tester		
b) Safety precautions during the test: Use normal laboratory safety PROCEDURES during this test.		
c) Test sample preparation: This test is to be applied only to ME EQUIPMENT containing insulating compound forming solid insulation between conductive parts and insulating compound forming a cemented joint with other insulating parts.		
Insulating compound	Description	Location
1)		
2)		
One representative test sample. Do not energize the DUT during this test.		
d) Test conditions: 1) For situations where insulating compound forms solid insulation between conductive parts, a single finished sample is tested. The sample is subjected to the thermal cycling PROCEDURE, followed by humidity preconditioning according to Subclause 5.7 of IEC 60601-1:2005 for 48 h only and then followed by a dielectric strength test except that the test voltage is multiplied by 1,6. 2) For situations where insulating compound forms a cemented joint with other insulating parts, the reliability of the joint is checked by testing three samples. If a winding of solvent-based enamelled wire is used, it is replaced for the test by a metal foil or by a few turns of bare wire, placed close to the cemented joint. The three samples are then tested as follows. – One of the samples is subjected to the thermal cycling PROCEDURE. Immediately after the last period at highest temperature during thermal cycling it is subjected to a dielectric strength test except that the test voltage is multiplied by 1,6. – The other two samples are subjected to the thermal cycling PROCEDURE and after the last cycle, are subjected to humidity preconditioning according to Subclause 5.7 of IEC 60601-1:2005 for 48 h only, followed by a dielectric strength test except that the test voltage is multiplied by 1,6.		