

Technical Information Report

ANSI/AAMI/IEC TIR62354:2009

General testing procedures for medical electrical equipment



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of Medical Instrumentation



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General testing procedures for medical electrical equipment

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Abstract: This Technical Report specifies the general harmonized recommendations (conditions and procedures) for testing MEDICAL ELECTRICAL EQUIPMENT (as defined in Subclause 2.2.15 of IEC 60601-1, 2nd edition). This Technical Report is primarily intended to be used by test houses and others responsible for assessment of compliance with IEC 60601-1.

Keywords: medical electrical equipment, assessment, testing, maintenance, electrical safety

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1:2005 Technical Corrigendum 1 and 2	ANSI/AAMI ES60601-1:2005 ANSI/AAMI ES60601-1:2005/C1:2009 (amdt)	Major technical variations C1 Identical to Corrigendum 1 & 2
IEC 60601-1-2:2007	ANSI/AAMI/IEC 60601-1-2:2007	Identical
IEC 60601-2-2:2009	ANSI/AAMI/IEC 60601-2-2:2009	Identical
IEC 60601-2-4:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:2009	ANSI/AAMI/IEC 60601-2-19:2009	Identical
IEC 60601-2-20:2009	ANSI/AAMI/IEC 60601-2-20:2009	Identical
IEC 60601-2-21:2009	ANSI/AAMI/IEC 60601-2-21:2009	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004/(R)2009	Major technical variations
IEC 60601-2-47:2001	ANSI/AAMI EC38:2007	Major technical variations
IEC 60601-2-50:2009	ANSI/AAMI/IEC 60601-2-50:2009	Identical
IEC 80601-2-30:2009 and Technical Corrigendum 1	ANSI/AAMI/IEC 80601-2-30:2009 and ANSI/AAMI/IEC 80601-2-30:2009/ C1:2009 (amdt) – consolidated text	Identical (with inclusion) C1 Identical to Corrigendum 1
IEC 80601-2-58:2008	ANSI/AAMI/IEC 80601-2-58:2008	Identical
IEC/TR 60878:2009	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2009	ANSI/AAMI/IEC TIR62296:2009	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
IEC/TR 62354:2009	ANSI/AAMI/IEC TIR62354:2009	Identical
IEC/TR 80002-1:2009	ANSI/IEC/TR 80002-1:2009	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:2009	ANSI/AAMI/ISO 7199:2009	Identical
ISO 8637:2004	ANSI/AAMI RD16:2007	Major technical variations
ISO 8638:2004	ANSI/AAMI RD17:2007	Major technical variations
ISO 10993-1:2009	ANSI/AAMI/ISO 10993-1:2009	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003/(R)2009	Identical
ISO 10993-4:2002 and Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002/(R)2009 and Amendment 1:2006/(R)2009	Identical
ISO 10993-5:2009	ANSI/AAMI/ISO 10993-5:2009	Identical
ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007	Identical
ISO 10993-7:2008	ANSI/AAMI/ISO 10993-7:2008	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999/(R)2005	Identical
ISO 10993-10:2002 and Amendment 1:2006	ANSI/AAMI BE78:2002/(R)2008 ANSI/AAMI BE78:2002/A1:2006/(R)2008	Minor technical variations Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006	Identical
ISO 10993-12:2007	ANSI/AAMI/ISO 10993-12:2007	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001/(R)2006	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000/(R)2006	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2009	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002/(R)2008	Identical
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical

International designation	U.S. designation	Equivalency
ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical
ISO/TS 11135-2:2008	ANSI/AAMI/ISO TIR11135-2:2008	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006	Identical
ISO 11137-2:2006 (2006-08-01 corrected version)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006	Identical
ISO 11138-1: 2006	ANSI/AAMI/ISO 11138-1:2006	Identical
ISO 11138-2: 2006	ANSI/AAMI/ISO 11138-2:2006	Identical
ISO 11138-3: 2006	ANSI/AAMI/ISO 11138-3:2006	Identical
ISO 11138-4: 2006	ANSI/AAMI/ISO 11138-4:2006	Identical
ISO 11138-5: 2006	ANSI/AAMI/ISO 11138-5:2006	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005	Identical
ISO 11140-3:2007	ANSI/AAMI/ISO 11140-3:2007	Identical
ISO 11140-4:2007	ANSI/AAMI/ISO 11140-4:2007	Identical
ISO 11140-5:2007	ANSI/AAMI/ISO 11140-5:2007	Identical
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006	Identical
ISO 11737-1: 2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:2009	ANSI/AAMI/ISO 11737-2:2009	Identical
ISO 13408-1:2008	ANSI/AAMI/ISO 13408-1:2008	Identical
ISO 13408-2:2003	ANSI/AAMI/ISO 13408-2:2003	Identical
ISO 13408-3:2006	ANSI/AAMI/ISO 13408-3:2006	Identical
ISO 13408-4:2005	ANSI/AAMI/ISO 13408-4:2005	Identical
ISO 13408-5:2006	ANSI/AAMI/ISO 13408-5:2006	Identical
ISO 13408-6:2006	ANSI/AAMI/ISO 13408-6:2006	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003/(R)2009	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003/(R)2008	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003/(R)2008	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998/(R)2008	Identical
ISO 14161:2009	ANSI/AAMI/ISO 14161:2009	Identical
ISO 14708-3:2008	ANSI/AAMI/ISO 14708-3:2008	Identical
ISO 14708-4:2008	ANSI/AAMI/ISO 14708-4:2008	Identical
ISO 14937:2009	ANSI/AAMI/ISO 14937:2009	Identical
ISO/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2007	ANSI/AAMI/ISO 14971:2007	Identical
ISO 15223-1:2007 and A1:2008	ANSI/AAMI/ISO 15223-1:2007 and A1:2008	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006	Identical
ISO 15674:2009	ANSI/AAMI/ISO 15674:2009	Identical
ISO 15675:2009	ANSI/AAMI/ISO 15675:2009	Identical
ISO 15882:2008	ANSI/AAMI/ISO 15882:2008	Identical
ISO 15883-1:2006	ANSI/AAMI ST15883-1:2009	Major technical variations
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2005	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical (with inclusions)
ISO/TS 17665-2:2009	ANSI/AAMI/ISO TIR17665-2:2009	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006	Identical
ISO/TS 19218:2005	ANSI/AAMI/ISO 19218:2005	Identical
ISO 22442-1:2007	ANSI/AAMI/ISO 22442-1:2007	Identical
ISO 22442-2:2007	ANSI/AAMI/ISO 22442-2:2007	Identical
ISO 22442-3:2007	ANSI/AAMI/ISO 22442-3:2007	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003/(R)2009 and A1:2005/(R)2009	Identical
ISO 25539-2:2008	ANSI/AAMI/ISO 25539-2:2008	Identical
ISO 81060-1:2007	ANSI/AAMI/ISO 81060-1:2007	Identical
ISO 81060-2:2009	ANSI/AAMI/ISO 81060-2:2009	Identical

Committee representation

Association for the Advancement of Medical Instrumentation

Electrical Safety Committee

The adoption of IEC Technical Report 62354:2009 as an AAMI Technical Information Report and ANSI Technical Report was initiated by the AAMI Electrical Safety Committee and the U.S. Technical Advisory Group for IEC/SC 62A. Committee approval of the technical report does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI Electrical Safety Committee** had the following members:

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NOTE—Participation by federal agency representatives in the development of this TIR does not constitute endorsement by the federal government or any of its agencies.

Background of ANSI/AAMI adoption of IEC/TR 62354:2009

The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The United States is one of the IEC members that took an active role in the development of this technical report.

International Technical Report IEC 62354 was developed by Working Group (WG) 14, *Testing to general safety standard 60601-1*, of Subcommittee (SC) 62A, *Common aspects of electrical equipment used in medical practice*.

U.S. participation in IEC/SC 62A/WG 14 is organized through the U.S. Technical Advisory Group for IEC/SC 62A, administered by the Advanced Medical Technology Association (AdvaMed) on behalf of the United States National Committee, which is a committee of the American National Standards Institute (ANSI). AAMI administers the International Secretariat for IEC/SC 62A on behalf of the United States, and U.S. experts made a considerable contribution to this technical report.

This Technical Report specifies the general harmonized recommendations (conditions and procedures) for testing medical electrical equipment (as defined in sub-clause 2.2.15 of IEC 60601-1, 2nd edition). This Technical Report is primarily intended to be used by test houses and others responsible for assessment of compliance with IEC 60601-1

AAMI encourages its committees to harmonize their work with international documents as much as possible. The AAMI Electrical Safety Committee, together with the U.S. Technical Advisory Group for IEC/SC 62A, reviewed IEC/TR 62354 to formulate the U.S. position and comments while the document was being developed. This close collaboration helped gain widespread U.S. consensus on the document. As the U.S. Technical Advisory Group for IEC/SC 62A, AdvaMed granted AAMI permission to consider adoption of IEC/TR 62354, as an AAMI TIR. Following AAMI procedures, the AAMI Electrical Safety Committee voted to adopt the IEC Technical Report as written.

As used within the context of this document, “should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. “May” is used to indicate that a course of action is permissible within the limits of the technical information report. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

The concepts incorporated into this technical report should not be considered inflexible or static. This technical information report, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data comes to light.

Suggestions for improving this technical information report are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—Beginning with the foreword on page “xii”, ANSI/AAMI/IEC TIR62354:2009 is identical to IEC/TR 62354:2009.

INTERNATIONAL ELECTROTECHNICAL COMMISSION

GENERAL TESTING PROCEDURES FOR MEDICAL ELECTRICAL EQUIPMENT

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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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 second edition cancels and replaces the first edition published in 2005. This edition constitutes a technical revision. Several tests have been updated and additional test procedures and informative annexes added.

This technical report is intended to be read in conjunction with IEC 60601-1:1988, IEC 60601-1-1:2000 and IEC 60601-1:2005.

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

Enquiry draft	Report on voting
62A/647/DTR	62A/669/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 maintenance result 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.

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 judgments 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 60513:1994 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, IEC 60601-1-1:2000 and IEC 60601-1:2005.

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 60086-4:2000, *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*

IEC/TR 60513:1994, *Fundamental aspects of safety standards for medical electrical equipment*

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)*¹⁾
Amendment 1: 1999

IEC 60601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety*²⁾
Amendment 1:1991
Amendment 2:1995

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

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, canceled and replaced by the third edition in 2005.

IEC 60601-1-1:2000, *Medical electrical equipment – Part 1-1: General requirements for safety – Collateral Standard: Safety requirements for medical electrical systems*

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

IEC 61010-1:2001, *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*

ISO 31 (all parts), *Quantities and units*

ISO 1000, *SI units and recommendations for the use of their multiples and of certain other units*

ISO 11134, *Sterilization of health care products – Requirements for validation and routine control – Industrial moist heat sterilization*³⁾

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

ISO 11137, *Sterilization of health care products – Requirements for validation and routine control – Radiation sterilization*⁵⁾

ISO 14971:2000, *Medical devices – Application of risk management to medical devices*⁶⁾

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 202.

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

³⁾ ISO 11134 was superseded by ISO 17665-1:2006, *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*.

⁴⁾ ISO 11135 was replaced by ISO 11135-1:2007, *Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*.

⁵⁾ ISO 11137 was replaced by ISO 11137-1:2006, *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*.

⁶⁾ This first edition of ISO 14971 was replaced by a second edition in 2007.

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
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.

The tests should be performed within the ambient temperature, humidity and atmospheric pressure described in the technical description.

NOTE 3 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;
- that 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.

NOTE 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 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 within the range of environmental conditions specified in the technical description.
- 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 this technical report, ME EQUIPMENT is to be tested under the least favorable working conditions specified in the instructions for use.
- 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 favorable 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 favorable 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 favorable 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 favorable.

- 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 favorable 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 favorable 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 favorable 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 1 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.

NOTE 2 Where peak-to-peak ripple exceeds 10 % of the average value, the peak voltage must 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 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.

NOTE 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): ± 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): ± 1.5 %;
- current, 5 A and above (d.c. up to 5 kHz): ± 2.5 %;
- LEAKAGE CURRENT: ± 3.5 %;
- power above 1 W and up to 3 kW: ± 3 %;
- power factor: ± 0.05 %;
- frequency: ± 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: ± 0.05 mm;
- linear dimensions, 1 mm up to 25 mm: ± 0.1 mm;
- linear dimensions, 25 mm and above: ± 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: ± 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 include 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 and 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, 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	Liter	l ^a
Pressure of respiratory gases, blood, and other body fluids	Millimeters of mercury	mmHg
	Centimeters 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 liter, although the symbol "L" is also given in ISO 31.		

For application of SI units, their multiples and certain other units, ISO 1000 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
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	Batteries	6.8.2, 56.7	7.3.3, 15.4.3
13.2.6	PATIENT leads		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 colors, 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

13.2.1 RISK MANAGEMENT PROCESS

Standard(s) IEC 60601-1:2005	Subclause(s): 4.2, 4.5	13.2.1 RISK MANAGEMENT PROCESS
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: Inspection of the RISK MANAGEMENT FILE		
f) Presentation of the test results: The MANUFACTURER has/has not established a RISK MANAGEMENT PROCESS in accordance with Clauses 4 through 7 of ISO 14971:2000. The MANUFACTURER has/has not established a policy for determining acceptable RISK in accordance with Subclause 3.3.a) of ISO 14971:2000. The MANUFACTURER has/has not established documented criteria for determining acceptable RISK according to Subclause 3.3 e) of ISO 14971:2000. The MANUFACTURER has/has not demonstrated that the RESIDUAL RISK(S) is acceptable based on the criteria for determining acceptable RISK) Where alternative means of compliance are used, the MANUFACTURER has/has not demonstrated that the level of RESIDUAL RISK is equal to or less than the RESIDUAL RISK(S) that result from applying the requirements of the 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: <p>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).</p> <p>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.</p>						
f) Presentation of the test results:						
TABLE: List of critical components						
Object/ Part No	MANUFACTURER / 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	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: <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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. 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: <ul style="list-style-type: none"> – 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 using the standard test finger by pushing the finger through the opening if necessary. 		

13.2.3 Determination of APPLIED PARTS and ACCESSIBLE PARTS (continued)

Standard(s): IEC 60601-1:2005	Subclause(s): 4.6, 5.9, 8.4.2, 9.2.1	13.2.3 Determination of APPLIED PARTS and ACCESSIBLE PARTS																				
<p>7) Insert the test hook in all relevant openings and then 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.</p> <p>8) Identify any additional parts that become accessible using the standard test finger and by inspection.</p> <p>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.</p> <p>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.</p> <p>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).</p> <p>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.</p> <p>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.</p> <p>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.</p>																						
<p>f) Presentation of the test results:</p> <p>List of APPLIED PARTS:</p> <table><tr><th colspan="2">TABLE: APPLIED PARTS</th></tr><tr><th>Location</th><th>Remarks</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><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: APPLIED PARTS		Location	Remarks																
TABLE: APPLIED PARTS																						
Location	Remarks																					

13.2.4 Durability and legibility of marking

Standard(s): IEC 60601-1:2005	Subclause(s): 7.1.2, 7.1.3	13.2.4 Durability and legibility of marking
a) Equipment needed for the test: <div>1) Cloth rag</div> <div>2) Stop watch/clock (indicating seconds)</div> <div>3) Distilled water</div> <div>4) Methylated spirits (denatured alcohol) – Ethanol 96 % is defined in the European Pharmacopoeia as a reagent in the following terms: C₂H₆O (MW46.07).</div> <div>5) Isopropyl alcohol – Isopropyl alcohol is defined in the European Pharmacopoeia as a reagent in the following terms: C₃H₈O (MW60.1).</div> <div>6) Light regulation means</div> <div>7) Lux meter</div> <div>8) 1 m / 30° gauge</div> <div>9) Protective gloves</div>		
b) Safety precautions during the test: <div>Perform this test in a well-ventilated area.</div> <div>Use appropriate protective gloves when conducting durability of markings test.</div>		
c) Test sample preparation: <div>One sample of marking nameplates attached to the DUT as specified by the MANUFACTURER.</div>		
d) Test conditions: <div>1) Consider the effect of NORMAL USE on markings while evaluating durability.</div> <div>2) Do not energize the DUT during this test.</div>		
Marking location		
Use of marking		
Material		
Held by		
Applied surface material		

13.2.4 Durability and legibility of marking (continued)

Standard(s): IEC 60601-1:2005	Subclause(s): 7.1.2, 7.1.3	13.2.4 Durability and legibility of marking		
e) Test set-up and PROCEDURE:				
<div>1) Durability: Perform the rubbing test using distilled water, methylated spirit and isopropyl alcohol. Rub the markings by hand without undue pressure:<ul style="list-style-type: none">– 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.</div> <div>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 favorable ambient luminance level in the range of 100 lx to 1,500 lx. The observer (who has a visual acuity of 0 on the log minimum angle of resolution (log MAR) scale or 6/6 (20/20), corrected if necessary) needs to correctly perceive the marking from their position.</div> <div>The observer correctly perceives the marking from the viewpoint.</div>				
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 Batteries

Standard(s) IEC 60601-1:2005	Subclause(s): 7.3.3, 15.4.3	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 lithium batteries used in ME EQUIPMENT do/do not comply with the requirements of IEC 60086-4. 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

Standard(s): IEC 60601-1:2005	Subclause(s): 8.5.2.3	13.2.6 PATIENT leads
a) Equipment needed for the test: <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 1) Do not energize the DUT during this test. 2) This test applies to any connector for electrical connections on a PATIENT lead 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. <ol style="list-style-type: none"> 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 favorable 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	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. The RISK of accidental disconnection was/was not minimized during NORMAL USE. The terminal does not/does 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 mm ² 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 mm ² 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	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" style="margin-left: auto; margin-right: auto;"> <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> <p>The edges and corners were/were not considered to be rounded and smooth.</p> <p>The HAZARDS related to sharp edges are/are not included in the RISK MANAGEMENT FILE.</p>			TABLE: Sharp edges		Edge location	Unacceptable RISK present <u>Yes/No</u>								
TABLE: Sharp edges														
Edge location	Unacceptable RISK present <u>Yes/No</u>													

13.2.11 HAZARDS associated with support systems

Standard(s): IEC 60601-1:2005	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: <p>The construction of the support, suspension or actuation system is/is not designed based upon determination of TENSILE SAFETY FACTOR and the TOTAL LOAD.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The DUT is/is not marked properly.</p> <p>The DUT does/does not require a MECHANICAL PROTECTIVE DEVICE.</p> <p>Where required, the MECHANICAL PROTECTIVE DEVICE is/is not designed on the basis of TOTAL LOAD, which includes SAFE WORKING LOAD when applicable.</p>		

13.2.11 HAZARDS associated with support systems *(continued)*

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

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.		

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

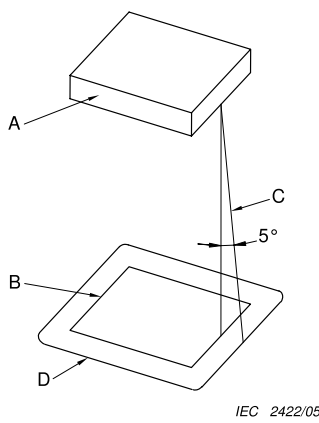
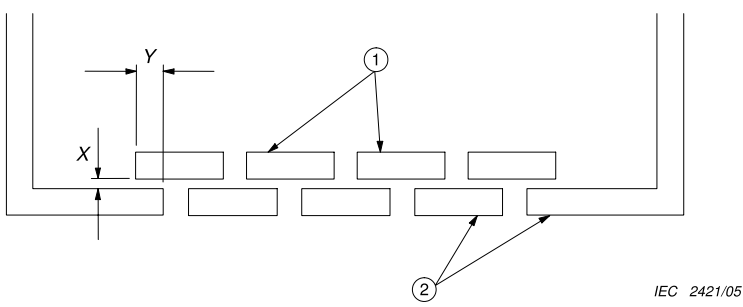
f) Presentation of the test results:

TABLE: Resistance to fire			
Item	Material/type	Manufacturer	Flame rating

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.

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
<p>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.</p>		
 <p style="text-align: right;">IEC 2422/05</p>		
<p>Key</p> <p>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.</p> <p>B Projection of the outline of A on the horizontal plane.</p> <p>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.</p> <p>D Minimum area of the bottom to be constructed as specified in 11.3 b) 1) (of IEC 60601-1).</p>		
<p>Figure 1 – Area of the bottom of an ENCLOSURE as specified in 11.3 b) 1) (IEC 60601-1:2005, Figure 39)</p>		
 <p style="text-align: right;">IEC 2421/05</p> <p style="text-align: center;">Y = twice X but never less than 25 mm</p> <p>① Baffle plates (may be below the bottom of the ENCLOSURE)</p> <p>② Bottom of the ENCLOSURE</p>		
<p>Figure 2 – Baffle (IEC 60601-1:2005, Figure 38)</p>		

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 colors, indicator lights and controls and ACCOMPANYING DOCUMENTS

Standard(s) IEC 60601-1:2005	Subclause(s): 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9	13.2.13 Marking, conductor colors, 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 colors 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 colors of the insulation of conductors do/do not satisfy the requirements of Subclause 6.5. The colors 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.		

13.2.13 Marking, conductor colors, indicator lights and controls and ACCOMPANYING DOCUMENTS (continued)

Standard(s) IEC 60601-1:2005	Subclause(s): 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9	13.2.13 Marking, conductor colors, indicator lights and controls and ACCOMPANYING DOCUMENTS
<p>2) IEC 60601-1:2005:</p> <p>The markings on the outside of ME EQUIPMENT or ME EQUIPMENT parts do/do not satisfy the requirements of Subclause 7.2.</p> <p>The markings on the inside of ME EQUIPMENT or ME EQUIPMENT parts do/do not satisfy the requirements of Subclause 7.3.</p> <p>The marking of controls and instruments do/do not satisfy the requirements of Subclause 7.4.</p> <p>Any safety signs do/do not satisfy the requirements of Subclause 7.5.</p> <p>Any symbols do/do not satisfy the requirements of Subclause 7.6.</p> <p>The colors of the insulation of conductors do/do not satisfy the requirements of Subclause 7.7.</p> <p>The colors of indicator lights and controls do/do not satisfy the requirements of Subclause 7.8.</p> <p>The ACCOMPANYING DOCUMENTS do/do not satisfy the requirements of Subclause 7.9.</p>		

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