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General testing procedures for medical electrical equipment

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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CONTENTS

FOREWORD.....	5
INTRODUCTION.....	7
1 Scope and object.....	8
2 Normative references	8
3 Terms, definitions, abbreviations and acronyms	9
4 Types of tests.....	10
5 State of the ME EQUIPMENT	11
6 Number of samples	11
7 Applicable test items to the clauses of IEC 60601-1	11
8 Sequence of tests.....	11
9 General testing condition.....	11
10 Power sources for tests	13
11 Measurement and test equipment.....	14
12 Treatments of unit symbols and measured values.....	16
13 PROCEDURES for testing, including particular conditions	17
Annex A (informative) Sequence of testing	157
Annex B (informative) Information typically required for product safety testing (Guide)	160
Annex C (informative) Testing and measuring equipment.....	162
Annex D (informative) Suitable measuring supply circuits	163
Annex E (informative) Preventive maintenance	166
Annex F (informative) Test probes	167
Annex G (informative) Index of tests (IEC 60601-1:2005 clauses order).....	170
Annex H (informative) Index of tests for an INTERNALLY POWERED EQUIPMENT – battery only – (IEC 60601-1:2005 clauses order)	172
Annex I (informative) Index of tests (IEC 60601-1:2005 alphabetic order)	174
Annex J (informative) Index of tests for an INTERNALLY POWERED EQUIPMENT – battery only – (IEC 60601-1:2005 alphabetic order).....	176
Annex K (informative) Production line tests.....	178
Annex L (informative) Evaluation of the laboratory power source characteristics.....	182
Annex M (informative) Traceability of calibrations and calibration intervals	187
Annex N (informative) Guidance for preparation, attachment, extension, use of thermocouples and acceptance of thermocouple wire	189
Annex O (informative) Guideline for safe laboratory work.....	194
Bibliography.....	201
Index of defined terms	203
Figure 1 – Area of the bottom of an ENCLOSURE as specified in 11.3 b) 1)	35
Figure 2 – Baffle	35
Figure 3 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 1	50
Figure 4 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 2	50
Figure 5 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 3	50
Figure 6 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 4	51

Figure 7 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 5	51
Figure 8 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 6	51
Figure 9 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 7	52
Figure 10 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 8	52
Figure 11 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 9	52
Figure 12 – Human body test mass	71
Figure 13 – Application of test voltage to bridged PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS	98
Figure 14 – Application of test voltage to individual PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS	99
Figure 15 – Application of test voltage to test the delivered defibrillation energy	102
Figure 16 – Example of a measuring device and its frequency characteristics	104
Figure 17 – Measuring circuit for the EARTH LEAKAGE CURRENT of CLASS I equipment, with or without APPLIED PARTS	106
Figure 18 – Measuring circuit for the TOUCH CURRENT	109
Figure 19 – Measuring circuit for the PATIENT LEAKAGE CURRENT from the PATIENT CONNECTION to earth	111
Figure 20 – Measuring circuit for the total PATIENT LEAKAGE CURRENT with all PATIENT CONNECTIONS of all APPLIED PARTS of the same type (TYPE B APPLIED PARTS, TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS) connected together	112
Figure 21 – Measuring circuit for the PATIENT LEAKAGE CURRENT via the PATIENT CONNECTION(S) of an F-TYPE APPLIED PART to earth caused by an external voltage on the PATIENT CONNECTION(S)	114
Figure 22 – Measuring circuit for the PATIENT LEAKAGE CURRENT from PATIENT CONNECTION(S) to earth caused by an external voltage on a metal ACCESSIBLE PART that is not PROTECTIVELY EARTHED	115
Figure 23 – Measuring circuit for the PATIENT LEAKAGE CURRENT from PATIENT CONNECTION(S) to earth caused by an external voltage on a SIGNAL INPUT/OUTPUT PART	117
Figure 24 – Measuring circuit for the PATIENT AUXILIARY CURRENT	119
Figure 25 – Ratio between HYDRAULIC TEST PRESSURE AND MAXIMUM PERMISSIBLE WORKING PRESSURE	123
Figure 26 – Spark ignition test apparatus	130
Figure 27 – Maximum allowable current I as a function of the maximum allowable voltage U measured in a purely resistive circuit in an OXYGEN RICH ENVIRONMENT	132
Figure 28 – Maximum allowable voltage U as a function of the capacitance C measured in a capacitive circuit used in an OXYGEN RICH ENVIRONMENT	132
Figure 29 – Maximum allowable current I as a function of the inductance L measured in an inductive circuit in an OXYGEN RICH ENVIRONMENT	133
Figure D.1 – Measuring supply circuit with one side of the SUPPLY MAINS at approximately earth potential	163
Figure D.2 – Measuring supply circuit with SUPPLY MAINS approximately symmetrical to earth potential	163
Figure D.3 – Measuring supply circuit for polyphase ME EQUIPMENT specified for connection to a polyphase SUPPLY MAINS	163
Figure D.4 – Measuring supply circuit for single-phase ME EQUIPMENT specified for connection to a polyphase SUPPLY MAINS	164
Figure D.5 – Measuring supply circuit for ME EQUIPMENT having a separate power supply unit or intended to receive its power from another equipment in an ME SYSTEM	164
Figure F.1 – Standard test finger	167

Figure F.2 – Test hook.....	168
Figure F.3 – Test pin.....	168
Figure F.4 – Ball-pressure test apparatus	169
Figure N.1 – Thermocouple preparation	189
Figure N.2 – Securing of thermocouples	190
Figure N.3 – Example of confinement of a thermocouple.....	191
Figure N.4 – Example where thermocouple connectors need not be used	192
Table 1 – Units outside the SI units system that may be used	17
Table 2 – Tests to be performed by inspection.....	18
Table 3 – NOMINAL cross-sectional area of conductors of a POWER SUPPLY CORD	29
Table 4 – Acceptable perforation of the bottom of an ENCLOSURE	36
Table 5 – Measurements and tests performed on non-energized equipment	39
Table 6 – Testing of cord anchorages	54
Table 7 – Acceptable gaps ^a	60
Table 8 – Drop height	85
Table 9 – Test torques for rotating controls.....	91
Table 10 – Measurements and tests for equipment that is operating	92
Table 11 – Allowable maximum temperatures for skin contact with ME EQUIPMENT APPLIED PARTS	140
Table 12 – Allowable maximum temperatures for ME EQUIPMENT parts that are likely to be touched.....	140
Table 13 – Allowable maximum temperatures of parts.....	141
Table 14 – Temperature limits of motor windings	141
Table 15 – Maximum motor winding steady-state temperature	142
Table 16 – Maximum allowable temperatures of transformer windings under overload and short-circuit conditions at 25 °C (± 5 °C) ambient temperature	142
Table 17 – Test current for transformers	154
Table C.1 – IEC 60601-1:1988 + Amendment 1:1991 and Amendment 2:1995.....	162
Table D.1 – Legends of symbols for Figures D.1 to D.5.....	165
Table L.1 – Method for testing a single phase laboratory power source	184

INTERNATIONAL ELECTROTECHNICAL COMMISSION

**GENERAL TESTING PROCEDURES
FOR MEDICAL ELECTRICAL EQUIPMENT****FOREWORD**

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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 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 60513:1994 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*

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*

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 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 sterilization³⁾*

ISO 11135, *Medical devices – Validation and routine control of ethylene oxide sterilization⁴⁾*

ISO 11137, *Sterilization of health care products – Requirements for validation and routine control – Radiation sterilization⁵⁾*

ISO 14971:2000, *Medical devices – Application of risk management to medical devices⁶⁾*

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.