

TECHNICAL REPORT

General testing procedures for medical electrical equipment
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[IEC TR 62354:2014](#)

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TECHNICAL REPORT

General testing procedures for medical electrical equipment
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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

PRICE CODE

XH

ICS 11.040

ISBN 978-2-8322-1856-3

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CONTENTS

FOREWORD.....	6
INTRODUCTION.....	9
1 Scope and object.....	10
2 Normative references	10
3 Terms, definitions, abbreviations and acronyms.....	11
3.1 Terms and definitions.....	11
3.2 Abbreviations and acronyms	12
4 Types of tests.....	12
4.1 GENERAL	12
4.2 Visual inspection.....	13
5 State of the ME EQUIPMENT	13
6 Number of samples.....	13
7 Applicable test items to the clauses of IEC 60601-1	13
8 Sequence of tests.....	13
9 General testing condition.....	14
10 Power sources for tests	15
10.1 General.....	15
10.2 Connection to a separate power source	16
10.3 Connection to an external d.c. power source.....	16
10.4 Source of power for ME EQUIPMENT.....	16
10.5 SUPPLY MAINS for testing ME EQUIPMENT	16
11 Measurement and test equipment.....	17
11.1 General requirements	17
11.2 Accuracy.....	18
11.3 Safety criteria for selection	18
11.4 Calibration	18
12 Treatments of unit symbols and measured values.....	19
13 PROCEDURES for testing, including particular conditions	19
13.1 General.....	19
13.2 Tests to be performed by inspection	20
13.3 Measurements and tests performed on non-energized equipment.....	41
13.4 Measurements and tests for equipment that is operating.....	96
Annex A (informative) Sequence of testing.....	165
A.1 Sequence of testing (IEC 60601-1:1988).....	165
A.2 Sequence of testing (IEC 60601-1:2005).....	166
Annex B (informative) Information typically required for product safety testing (Guide)	168
B.1 Purpose	168
B.2 Description	168
B.3 Intended use environment.....	168
B.4 Construction	168
B.5 List of safety-related components and relevant approvals	168
B.6 Test system	168
B.7 Power	168
B.8 Grounding.....	169

B.9	Modes of operation; configurations	169
B.10	Failure modes	169
B.11	RISK ANALYSIS according with ISO 14971	169
B.12	Software	169
B.13	Auxiliary equipment	169
B.14	Transformers and chokes	169
Annex C	(informative) Testing and measuring equipment	170
Annex D	(informative) Suitable measuring supply circuits	171
Annex E	(informative) Preventive maintenance	174
E.1	General	174
E.2	Cleaning and disinfection	174
E.3	Preventive maintenance checklist	174
E.4	OPERATOR checks	174
Annex F	(informative) Test probes	175
Annex G	(informative) Index of tests (IEC 60601-1:2005 clauses order)	177
Annex H	(informative) Index of tests for an INTERNALLY POWERED EQUIPMENT – battery only – (IEC 60601-1:2005 clauses order)	179
Annex I	(informative) Index of tests (IEC 60601-1:2005 alphabetic order)	181
Annex J	(informative) Index of tests for an INTERNALLY POWERED EQUIPMENT – battery only – (IEC 60601-1:2005 alphabetic order)	183
Annex K	(informative) Production line tests	185
K.1	Production-line dielectric voltage-withstand test	185
K.2	Production-line grounding-continuity test	186
K.3	Production-line EARTH LEAKAGE CURRENT test	186
K.4	Recommended features for specific test equipment	186
Annex L	(informative) Evaluation of the laboratory power source characteristics	189
L.1	Purpose	189
L.2	Application	189
L.3	Definitions	190
L.4	Testing	191
Annex M	(informative) Traceability of calibrations and calibration intervals	194
M.1	Purpose	194
M.2	Traceability of calibrations	194
M.3	Calibration intervals for test equipment requiring calibration	194
Annex N	(informative) Guidance for preparation, attachment, extension, use of thermocouples and acceptance of thermocouple wire	196
N.1	General	196
N.2	Preparation	196
N.3	Placement	196
N.4	Attachment	197
N.5	Extension	198
N.6	Use	199
N.7	Acceptance of thermocouples wire	199
Annex O	(informative) Guideline for safe laboratory work	201
O.1	BASIC SAFETY guidelines for working with test instruments	201
O.2	Basic guidelines for performing safety tests	203
O.3	Basic guidelines regarding test personnel and test areas	205

O.4	Contents of a documented safe environment for working in a testing laboratory	206
	Bibliography.....	207
	Index of defined terms	209
	Figure 1 – Area of the bottom of an ENCLOSURE as specified in 11.3 b) 1)	37
	Figure 2 – Baffle	37
	Figure 3 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 1	51
	Figure 4 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 2	51
	Figure 5 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 3	52
	Figure 6 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 4	52
	Figure 7 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 5	52
	Figure 8 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 6	52
	Figure 9 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 7	53
	Figure 10 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 8	53
	Figure 11 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 9	54
	Figure 12 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 10	54
	Figure 13 – Human body test mass	73
	Figure 14 – Application of test voltage to bridged PATIENT CONNECTIONS (common mode) for DEFIBRILLATION-PROOF APPLIED PARTS	103
	Figure 15 – Application of test voltage to individual PATIENT CONNECTIONS (differential mode) for DEFIBRILLATION-PROOF APPLIED PARTS	104
	Figure 16 – Application of test voltage to test the delivered defibrillation energy (energy reduction test)	108
	Figure 17 – Example of a measuring device and its frequency characteristics	110
	Figure 18 – Measuring circuit for the EARTH LEAKAGE CURRENT of CLASS I equipment, with or without APPLIED PARTS	112
	Figure 19 – Measuring circuit for the TOUCH CURRENT	115
	Figure 20 – Measuring circuit for the PATIENT LEAKAGE CURRENT from the PATIENT CONNECTION to earth	117
	Figure 21 – 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	118
	Figure 22 – 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)	120
	Figure 23 – 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	121
	Figure 24 – Measuring circuit for the PATIENT LEAKAGE CURRENT from PATIENT CONNECTION(S) to earth caused by an external voltage on a SIGNAL INPUT/OUTPUT PART	123
	Figure 25 – Measuring circuit for the PATIENT AUXILIARY CURRENT	125
	Figure 26 – Ratio between hydraulic test pressure and maximum permissible working pressure	129
	Figure 27 – Spark ignition test apparatus	136
	Figure 28 – Maximum allowable current I as a function of the maximum allowable voltage U measured in a purely resistive circuit in an OXYGEN RICH ENVIRONMENT	139

Figure 29 – Maximum allowable voltage U as a function of the capacitance C measured in a capacitive circuit used in an OXYGEN RICH ENVIRONMENT	139
Figure 30 – Maximum allowable current I as a function of the inductance L measured in an inductive circuit in an OXYGEN RICH ENVIRONMENT.....	140
Figure D.1 – Measuring supply circuit with one side of the SUPPLY MAINS at approximately earth potential.....	171
Figure D.2 – Measuring supply circuit with SUPPLY MAINS approximately symmetrical to earth potential.....	171
Figure D.3 – Measuring supply circuit for polyphase ME EQUIPMENT specified for connection to a polyphase SUPPLY MAINS	171
Figure D.4 – Measuring supply circuit for single-phase ME EQUIPMENT specified for connection to a polyphase SUPPLY MAINS	172
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.....	172
Figure F.1 – Standard test finger	175
Figure F.2 – Test hook.....	176
Figure F.3 – Test pin.....	176
Figure F.4 – Ball-pressure test apparatus	176
Figure N.1 – Thermocouple preparation.....	196
Figure N.2 – Securing of thermocouples	197
Figure N.3 – Example of confinement of a thermocouple.....	198
Figure N.4 – Example where thermocouple connectors need not be used	199
Table 1 – Units outside the SI units system that may be used	19
Table 2 – Tests to be performed by inspection.....	20
Table 3 – NOMINAL cross-sectional area of conductors of a POWER SUPPLY CORD	31
Table 4 – Acceptable perforation of the bottom of an ENCLOSURE	38
Table 5 – Measurements and tests performed on non-energized equipment	41
Table 6 – Testing of cord anchorages	56
Table 7 – Acceptable gaps ^a	62
Table 8 – Drop height	87
Table 9 – Test torques for rotating controls.....	93
Table 10 – Measurements and tests for equipment that is operating	96
Table 11 – Allowable maximum temperatures for skin contact with ME EQUIPMENT APPLIED PARTS	147
Table 12 – Allowable maximum temperatures for ME EQUIPMENT parts that are likely to be touched.....	147
Table 13 – Allowable maximum temperatures of parts.....	148
Table 14 – Temperature limits of motor windings	148
Table 15 – Maximum motor winding steady-state temperature	149
Table 16 – Maximum allowable temperatures of transformer windings under overload and short-circuit conditions at 25 °C (\pm 5 °C) ambient temperature.....	149
Table 17 – Test current for transformers	162
Table C.1 – IEC 60601-1:1988+AMD 1:1991 and AMD 2:1995.....	170
Table D.1 – Legends of symbols for Figure D.1 to Figure D.5	173
Table L.1 – Method for testing a single phase laboratory power source.....	191

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

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

- 13.2.8 POTENTIAL EQUALIZATION TERMINAL
- 13.2.14 USABILITY OF ME EQUIPMENT
- 13.3.1 Humidity preconditioning
- 13.3.2 Impedance of PE connection
- 13.3.7 CREEPAGE DISTANCES and AIR CLEARANCES
- 13.3.12 Instability (in transport position; excluding transport; from horizontal and vertical forces and from unwanted lateral movement)
- 13.3.13 Castors and wheels (Force for propulsion, movement over a threshold)
- 13.3.14 Safety catch evaluation
- 13.3.17 Overflow
- 13.3.18 Spillage
- 13.3.23 Impact
- 13.3.14 Drop impact
- 13.3.25 Rough handling
- 13.3.27 Actuating parts of controls
- 13.3.28 Construction of transformers
- 13.4.1 ESSENTIAL PERFORMANCE – Functional
- 13.4.3 Voltage mismatch
- 13.4.4 Limitation of voltage, current or energy
- 13.4.5 DEFIBRILLATION-PROOF APPLIED PART protection
- 13.4.6 Energy reduction
- 13.4.7 EARTH LEAKAGE CURRENT [IEC TR 62354:2014](#)
- 13.4.9 PATIENT LEAKAGE CURRENT <https://standards.iteh.ai/catalog/standards/sist/a1bab1cc-ae64-4405-915c-06379485cc45/iec-tr-62354-2014>
- 13.4.14 Sound pressure level measurements
- 13.4.16 X-radiation (ionizing radiation) measurement
- 13.4.20 Interruption of power supply
- 13.4.28 Rechargeable battery overcharge/discharge
- 13.4.29 Mains transformers

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

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

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

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

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

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

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

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
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INTRODUCTION

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

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

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

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

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

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

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

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

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

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

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

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

GENERAL TESTING PROCEDURES FOR MEDICAL ELECTRICAL EQUIPMENT

1 Scope and object

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

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

2 Normative references

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

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

IEC 60127-1, *Miniature fuses – Part 1: Definitions for miniature fuses and general requirements for miniature fuse-links* IEC TR 62354:2014

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ISO 11135-1, *Medical devices – Validation and routine control of ethylene oxide sterilization⁴*

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

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

IEC TR 62354:2014

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

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

3 Terms, definitions, abbreviations and acronyms

3.1 Terms and definitions

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

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

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

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

⁴ Withdrawn and replaced by ISO 11135:2014.

3.2 Abbreviations and acronyms

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

4 Types of tests

4.1 GENERAL

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

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

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

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

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

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

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

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

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

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

4.2 Visual inspection

Covers and housings should be opened only:

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

Special attention should be paid to the following:

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

5 State of the ME EQUIPMENT

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

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

6 Number of samples

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

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

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

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

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

8 Sequence of tests

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

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