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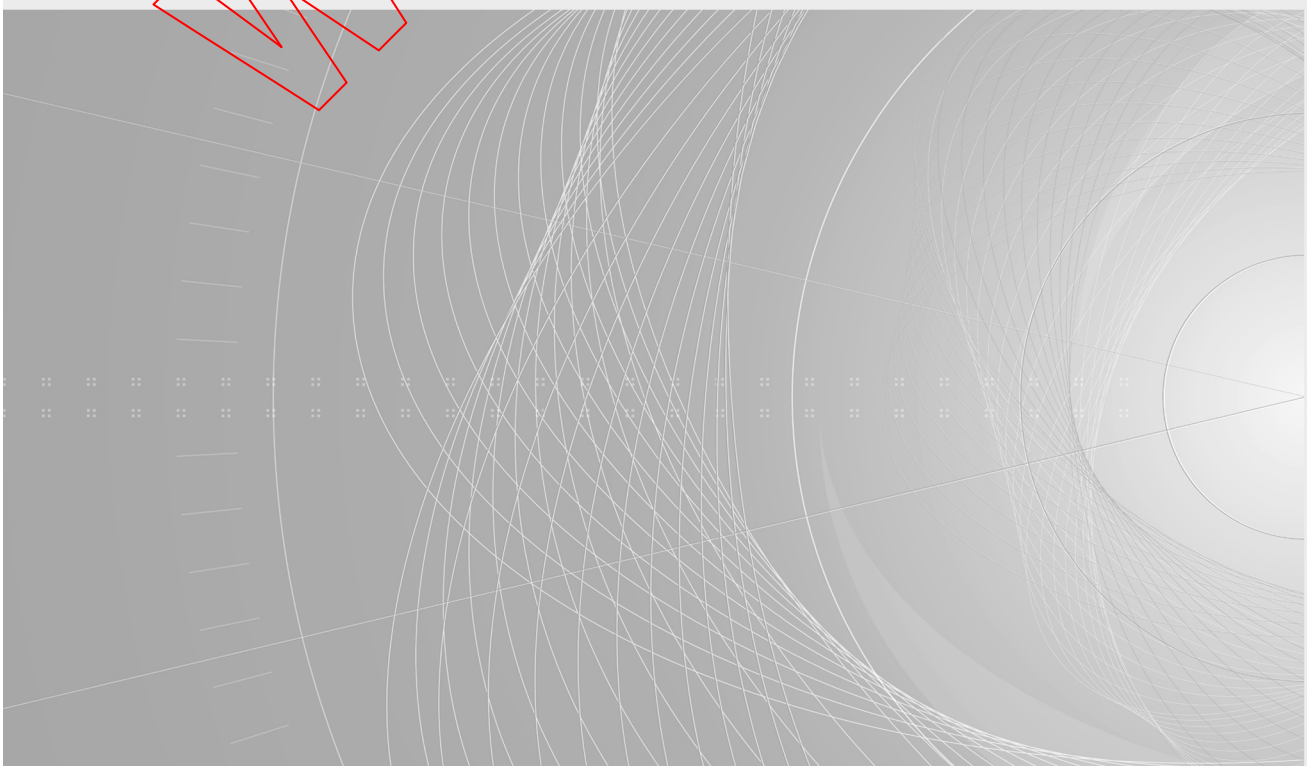
TECHNICAL REPORT

General testing procedures for medical electrical equipment



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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

GENERAL TESTING PROCEDURES FOR MEDICAL ELECTRICAL EQUIPMENT

FOREWORD

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

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

This 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- withdrawn;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*

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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 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 203.

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

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

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.

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 favourable 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 favourable for the relevant test, but in accordance with the instructions for use.

m) If the test results are influenced by the inlet pressure and flow or chemical composition of the cooling liquid, the test is to be carried out within the limits for these characteristics as prescribed in the technical description.

n) Where cooling water is required, potable water is to be used.

o) Except in special cases, such as PATIENT supports and waterbeds, contact with ME EQUIPMENT is supposed to be made with:

- one hand, simulated for LEAKAGE CURRENT measurements by a metal foil of 10 cm × 20 cm (or less if the total ME EQUIPMENT is smaller);

- one finger, straight or bent in a natural position, simulated by a standard test finger (Figure F.1) provided with a stop plate; or
- an edge or slit that can be pulled outwards allowing subsequent entry of a finger, simulated by a combination of test hook (Figure F.2) and standard test finger.

10 Power sources for tests

10.1 General

a) Where test results are influenced by deviations of the supply voltage from its RATED value, the effect of such deviations is to be taken into account.

b) ME EQUIPMENT for a.c. only should be tested with a.c. at RATED frequency (if marked) ± 1 Hz for a RATED frequency between 0 Hz and 100 Hz and ± 1 % for a RATED frequency above 100 Hz. ME EQUIPMENT marked with a RATED frequency range is to be tested at the least favourable frequency within that range.

c) ME EQUIPMENT designed for more than one RATED voltage, or for both a.c. and d.c., is to be tested in conditions related to the least favourable voltage and nature of supply, for example, number of phases (except for single-phase supply) and type of current. It might be necessary to perform some tests more than once in order to establish which supply configuration is least favourable.

d) ME EQUIPMENT for d.c. only is to be tested with d.c. When performing the tests, the possible influence of polarity on the operation of the ME EQUIPMENT is to be taken into consideration.

e) Unless otherwise specified by this technical report, ME EQUIPMENT is to be tested at the least favourable RATED voltage within the relevant range. It might be necessary to perform some of the tests more than once in order to establish the least favourable voltage.

f) ME EQUIPMENT for which alternative ACCESSORIES or components specified by the MANUFACTURER are available is to be tested with those ACCESSORIES or components that give the least favourable conditions.

g) If the instructions for use specify that ME EQUIPMENT is intended to receive its power from a separate power supply, it is to be connected to such a power supply.

10.2 Connection to a separate power source

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

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

10.3 Connection to an external d.c. power source

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

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

10.4 Source of power for ME EQUIPMENT

ME EQUIPMENT is either powered by an INTERNAL ELECTRICAL POWER SOURCE, specified for connection to a separate power supply, or is suitable for connection to SUPPLY MAINS, either