IEC TR 62354

Edition 3.0 2014-09

TECHNICAL REPORT

General testing procedures for medical electrical equipment

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

PRICE CODE XH

ICS 11.040

ISBN 978-2-8322-1856-3

CONTENTS

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.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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

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

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

13.2.1 RISK MANAGEMENT PROCESS

13.2.4 Durability and legibility of marking

13.2.5 Battery markings

13.2.8 POTENTIAL EQUALIZATION TERMINAL

13.2.14 USABILITY of ME EQUIPMENT

13.3.1 Humidity preconditioning

13.3.2 Impedance of PE connection

13.3.7 CREEPAGE DISTANCES and AIR CLEARANCES

13.3.12 Instability (in transport position; excluding transport; from horizontal and vertical forces and from unwanted lateral movement)

13.3.13 Castors and wheels (Force for propulsion, movement over a threshold)

13.3.14 Safety catch evaluation

13.3.17 Overflow

13.3.18 Spillage

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

13.4.9 PATIENT LEAKAGE CURRENT

13.4.14 Sound pressure level measurements

13.4.16 X-radiation (ionizing radiation) measurement

13.4.20 Interruption of power supply

13.4.28 Rechargeable battery overcharge/discharge

13.4.29 Mains transformers

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

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

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

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

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

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

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

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

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

INTRODUCTION

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

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

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

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

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

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

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

a) test results should be reproducible within defined limits. When considered necessary, the test method should incorporate a statement as to its limit of uncertainty;

b) where the sequence of tests can influence the results, the correct sequence should be specified.

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

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

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

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

GENERAL TESTING PROCEDURES FOR MEDICAL ELECTRICAL EQUIPMENT

1 Scope and object

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

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

2 Normative references

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

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

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

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

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

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

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

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)*
IEC 60529:1989/AMD1:1999[1]

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/AMD1:2012[3]

---

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

---

4 Withdrawn and replaced by ISO 11135:2014.