IEC TR 60601-4-3

Edition 1.0 2015-04

TECHNICAL REPORT

Medical electrical equipment –
Part 4-3: Guidance and interpretation – Considerations of unaddressed safety aspects in the third edition of IEC 60601-1 and proposals for new requirements

IEC TR 60601-4-3:2015-04(en)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

ICS 11.040

ISBN 978-2-8322-2613-1

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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 TR 60601-4-3, 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.

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

Enquiry draft	Report on voting
62A/951/DTR	62A/973A/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.

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

Terms used throughout this technical report that have been defined in Clause 3 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD 1:2012 are printed in SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC website 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- withdrawn,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 technical report may be issued at a later date.

INTRODUCTION

At the Sydney meeting in August 1994, IEC subcommittee (SC) 62A established a procedure under which working group (WG) 14 would develop recommendations regarding problems of interpretation or application of IEC 60601-1. WG 14 is made up of experts with particular expertise in testing according to the requirements of IEC 60601-1. Many of the experts on WG 14 are employed by test laboratories with a long history of applying IEC 60601-1 to MEDICAL ELECTRICAL EQUIPMENT. While the National Committee members of SC 62A nominate these experts, their recommendations were not to be formally adopted through any official voting procedure. To reinforce this process, the Subcommittee specifically directed that the following note appear on every page of the resulting informational circular:

IMPORTANT NOTE: Per the 62A decision at Sydney (see RM3755/SC62A, August 1994), the 62A Secretary is circulating this recommendation, prepared by 62A/WG 14, regarding problems of interpretation or application of IEC 60601-1 to all P-Member NCs.

This recommendation/interpretation is the result of considerations by a group of nominated experts and has not been formally adopted through any National Committee voting procedure. Distribution is only for information.

At the November 2000 meeting of SC 62A in Tokyo, the subcommittee discussed ways and means for achieving a wider distribution of the WG 14 recommendations. At the conclusion of this discussion, the subcommittee instructed the Secretariat to develop a technical report (TR) based on the published recommendations of WG 14. This technical report is intended to convey the results of WG 14's work to interested parties such as MANUFACTURERS and test laboratories while retaining the informative nature of the material.

This first edition of IEC TR 60601-4-3 contains 93 recommendations, numbered 101 to 193. All these recommendations are based upon IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012.

The numbering starts with 101 instead of just 1 to ensure that these WG 14 recommendations (101 to 193) will not accidentally be confused with previous issued WG 14 recommendations 1 to 63, which are based on the second edition of IEC 60601-1 and published in IEC TR 62296.

This technical report may be amended from time to time as WG 14 prepares additional recommendations.

MEDICAL ELECTRICAL EQUIPMENT

Part 4-3: Guidance and interpretation – Considerations of unaddressed safety aspects in the third edition of IEC 60601-1 and proposals for new requirements

1 Scope and object

1.1 Scope

This technical report contains a series of recommendations developed by an expert working group of IEC subcommittee 62A in response to questions of interpretation of the third edition of IEC 60601-1.

This technical report is primarily intended to be used by:

– MANUFACTURERS of MEDICAL ELECTRICAL EQUIPMENT;
– test laboratories and others responsible for assessment of compliance with IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, and
– those developing subsequent editions of IEC 60601-1.

The recommendations in the first edition of IEC/TR 62296 were considered in preparing the third edition of IEC 60601-1. Similarly it is expected that these recommendations within IEC 60601-4-3 will be considered when preparing a future revision of IEC 60601-1.

1.2 Object

The object of this technical report is to make the recommendations/interpretations developed by the experts in IEC/SC 62A/WG 14 available to those interested in the application of the third edition of IEC 60601-1.

The reader is reminded that, although a majority of the National Committee members of IEC/SC 62A have approved publication of this technical report, the contents remain the opinion of the expert members of WG 14. These recommendations/interpretations are the result of considerations by this group of nominated experts and have not been formally adopted through any National Committee voting procedure. Distribution is only for information.

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 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
IEC 60601-1-8:2006/AMD1:2012

IEC 60601-1-11:2010, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

3 Recommendations

3.1 Template used for recommendations prepared by SC 62A/WG 14

The recommendations in this Technical Report are presented in tabular form using the following table structure.

WG 14 recommendation number	NNN [a]
Requirement, clause/ subclause number(s) [b]	
Source/problem [c]	
Discussion/comment [d]	
Submitter proposed recommendation [e]	
WG 14 recommendation [f]	

[a] The numbering of the recommendations in the Technical Report starts with 101 instead of just 1 to ensure that these WG 14 recommendations will not accidentally be confused with previously issued WG 14 recommendations 1 to 63, which are based on the second edition of IEC 60601-1.

[b] The clause, subclause or requirement to which the question is related. If no standard is listed, the reference is to IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012.

[c] A description of the problem as submitted to WG 14.

[d] Additional discussion or commentary provided by the submitter.

[e] The submitter's proposed resolution to the problem, if one exists.

[f] The final recommendation developed by WG 14.

3.2 Recommendation sheets

3.2.101 Total PATIENT LEAKAGE CURRENT of a ME SYSTEM

WG 14 recommendation number	101
Requirement, clause/ subclause number(s)	16.6.3
Source/problem	There is no measuring circuit or measurement method given in IEC 60601-1 for measurement of the total PATIENT LEAKAGE CURRENT of ME SYSTEMS. Input: PATIENT can be simultaneously monitored for a physiological parameter by the ME EQUIPMENT "1" and for other physiological parameter by the ME EQUIPMENT "2". The ME EQUIPMENT "1" and "2" belong to the same ME SYSTEM. The total PATIENT LEAKAGE CURRENT of the ME SYSTEM in question should be measured, but how should the measurement be performed?
Discussion/comment	–
Submitter proposed recommendation	–
WG 14 recommendation	Q1: Shall the total PATIENT LEAKAGE CURRENT of the ME SYSTEM be measured "from" and "to" all PATIENT CONNECTIONS of all APPLIED PARTS (in the ME SYSTEM) of the same type connected together? NOTE Those APPLIED PARTS belong to several individual ME EQUIPMENTS of the ME SYSTEM. WG 14 answer to Q1: No, measure only "from" (i.e. to earth) not "to" all PATIENT CONNECTIONS of the same type of APPLIED PARTS of the ME SYSTEM connected together. Reason: SINGLE FAULT CONDITION tests with SUPPLY MAINS on APPLIED PART or with SUPPLY MAINS on SIP/SOP (represent "to" measurement) are N/A for a ME SYSTEM, see subclauses 16.1 and 16.6.3. Q2: Is it adequate that the total PATIENT LEAKAGE CURRENT of the ME SYSTEM in question is measured according to subclause 8.7.4.7 h) separately for each individual ME EQUIPMENT belonging to the ME SYSTEM? WG 14 answer to Q2: No, this is not adequate. Individual tests of each item of ME EQUIPMENT or non-ME EQUIPMENT is anyway required and those individual measurements do not replace the ME SYSTEM tests of the total PATIENT LEAKAGE CURRENT. In addition: It is not explicitly written in IEC 60601-1, but WG 14 recommends measuring the total PATIENT LEAKAGE CURRENT in an ME SYSTEM by combining all APPLIED PARTS of the same type of the whole ME SYSTEM together and measuring against earth. See also Annex A, subclause 16.6.3.

3.2.102 Pollution degree for MOPP

WG 14 recommendation number	102
Requirement, clause/ subclause number(s)	8.9, 8.9.1.1
Source/problem	IEC 60601-1 does not include requirements for MOPP in regards to pollution degrees 1 and 3.
Discussion/comment	There are no clear requirements in regards to pollution degree relative to MOPP.
Submitter proposed recommendation	Use Table 12 for MOPP as provided for pollution degrees 1, 2 and 3. NOTE Pollution degree 4 is not allowed as a MOP.
WG 14 recommendation	It is recommended to use Table 12 for MOPP for pollution degrees 1, 2 and 3. NOTE Pollution degree 4 is not allowed.

3.2.103 Transients on d.c. mains

WG 14 recommendation number	103
Requirement, clause/ subclause number(s)	8.9, 8.9.1.1
Source/problem	Transients on d.c. mains (e.g. ambulance power source).
Discussion/comment	The tables are based on a.c. mains transients. What about ME EQUIPMENT that operates from a d.c. mains such as an ambulance?
Submitter proposed recommendation	Apply Tables 12 through 16 as provided for ME EQUIPMENT connected to the d.c. mains.
WG 14 recommendation	It is recommended to apply Tables 12 through 16 for ME EQUIPMENT connected to the d.c. mains. Examples: a) Pure external battery power: no MAINS TRANSIENT VOLTAGE exists. b) If the external d.c. power is derived out of an a.c. MAINS VOLTAGE (e.g. 230 V a.c.): use the concept already described in IEC 60601-1. c) If the external d.c. power is locally generated by a local generator (i.e. not derived out of MAINS VOLTAGE 230 V a.c.), e.g. by a generator of the ambulance, then use transient level Table 10, line 50 V r.m.s. for primary d.c. circuit.

3.2.104 Altitude factor for DEFIBRILLATION-PROOF APPLIED PARTS

WG 14 recommendation number	104
Requirement, clause/ subclause number(s)	8.9, 8.9.1.1
Source/problem	Use of AIR CLEARANCE altitude multiplication factor for DEFIBRILLATION-PROOF APPLIED PARTS
Discussion/comment	Should the AIR CLEARANCE multiplication factor based on altitude (reference Table 8) be used for subclause 8.9.1.15? It was mentioned that IEC 60601-2-4 could be referenced, but many APPLIED PARTS marked DEFIBRILLATION-PROOF are not in themselves defibrillators. The group felt that since the AIR CLEARANCE multiplication factor pertains to transients, it should apply. DEFIBRILLATION-PROOF TYPE CF APPLIED PARTS testing is conducted in IEC 60601-1 for three primary reasons, which include: 1) to ensure that the defibrillator energy at APPLIED PARTS does not transfer excessive energy to parts of ME EQUIPMENT that OPERATORS or other persons could touch during cardiac defibrillation; 2) to ensure that the ME EQUIPMENT does not lose more than 10 % of the total defibrillation energy across a 100 Ω resistor (see Figure 11); 3) to ensure that the ME EQUIPMENT remains functional (cardiac defibrillation recovery) within a specified period of time; As item 1 above directly relates to the CREEPAGE DISTANCE and AIR CLEARANCE requirement for subclause 8.9.1.15 and is relative to the protection of OPERATORS rather than PATIENTS, the AIR CLEARANCE multiplication factors for altitude would be taken from Table 8 column heading “Multiplication factor for MOOP”. However, these multiplication factors cause a large increase in the AIR CLEARANCE and it is doubtful that this is really necessary.
Submitter proposed recommendation	Apply the AIR CLEARANCE multiplication factor based on altitude to subclause 8.9.1.15. Also, bump the CREEPAGE DISTANCE requirements to equal those of the AIR CLEARANCE as is done throughout this edition of IEC 60601-1.
WG 14 recommendation	1) For DEFIBRILLATION-PROOF APPLIED PARTS, a minimum of 4,0 mm CREEPAGE DISTANCE and 4,0 mm AIR CLEARANCE are required. 2) For use in higher altitudes, the AIR CLEARANCE needs be corrected by a multiplication factor. According to Figure A.12 the MANUFACTURER has the choice to use MOPP instead of MOOP. The MOPP multiplication factor is less than the MOOP multiplication factor. The MOPP multiplication factor is sufficient. 3) Figure A.12 should be normative. This should be implemented in a future amendment of IEC 60601-1. 4) CREEPAGE DISTANCE requirements should be at least equal to those of the AIR CLEARANCE.

3.2.105 Defibrillation energy protection for MOOP / MOPP

WG 14 recommendation number	105
Requirement, clause/ subclause number(s)	8.9, 8.9.1.1
Source/problem	APPLIED PART separation MOP type.
Discussion/comment	Is APPLIED PART separation, for example in subclause 8.9.1.15 for DEFIBRILLATION-PROOF APPLIED PARTS, considered a MOPP or MOOP? What about MAXIMUM MAINS VOLTAGE on APPLIED PARTS? Where the separation provides MOPP, such as during MAXIMUM MAINS VOLTAGE on APPLIED PARTS or DEFIBRILLATION-PROOF APPLIED PARTS and when measuring energy from other APPLIED PARTS, then that is a MOPP, whereas when the separation provides MOOP, such as DEFIBRILLATION-PROOF APPLIED PARTS and when verifying the energy at the ENCLOSURE or at SIP/SOP, then that is a MOOP.
Submitter proposed recommendation	Consider how the separation is being used. If for MOOP then use the requirements for MOOP, if for the MOPP then use the MOPP.
WG 14 recommendation	Consider how the separation is being used. If for MOOP then use the requirements for MOOP, if for MOPP then use the requirements for MOPP. However Figure A.12 should be regarded as normative, consequently MOPP requirements are considered as satisfying both MOOP and MOPP requirements.

3.2.106 Overvoltage categories III and IV

WG 14 recommendation number	106
Requirement, clause/ subclause number(s)	8.9, 8.9.1.1
Source/problem	ME EQUIPMENT connected to overvoltage categories other than II.
Discussion/comment	IEC 60601-1 tables are based on overvoltage category II except MOOP secondary is overvoltage category I under certain conditions as defined in subclause 8.9.1.12. What about overvoltage categories I, III, IV? ME EQUIPMENT meant for connection to another overvoltage category will need to meet requirements outside of the tables provided in IEC 60601-1.
Submitter proposed recommendation	Use IEC 60664 or IEC 61010 for requirements of CREEPAGE DISTANCE, AIR CLEARANCE and DIELECTRIC STRENGTH for ME EQUIPMENT connected to SUPPLY MAINS of overvoltage category III or IV.
WG 14 recommendation	Subclause 8.9.1.11 deals with this issue, therefore, there is no need for a WG 14 recommendation.

3.2.107 Pollution degree related to different micro/macro environments

WG 14 recommendation number	107
Requirement, clause/ subclause number(s)	8.9 8.9.1.1
Source/problem	Application of pollution degree classifications.
Discussion/comment	Pollution degree initially is a micro environment exactly at the barrier concerned. However there is a relation between the micro and macro environments under certain conditions. Normally one environment is applied. Based on the design of the ME EQUIPMENT or ME SYSTEM, more than one pollution degree can be applicable to different parts.
Submitter proposed recommendation	–
WG 14 recommendation	The answer can be found in IEC 60601-1:2005/AMD1:2012, Annex M.