IEC TR 60601-4-3

Edition 2.0 2018-12

TECHNICAL REPORT

colour inside

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 60601-4-3:2018-12en)

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

About the IEC
The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications
The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

IEC Catalogue - webstore.iec.ch/catalogue
The stand-alone application for consulting the entire bibliographical information on IEC International Standards, Technical Specifications, Technical Reports and other documents. Available for PC, Mac OS, Android Tablets and iPad.

IEC publications search - webstore.iec.ch/advsearchform
The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,…). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished
Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and also once a month by email.

Electropedia - www.electropedia.org
The world's leading online dictionary of electronic and electrical terms containing 21 000 terms and definitions in English and French, with equivalent terms in 16 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary
67 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

IEC Customer Service Centre - webstore.iec.ch/csc
If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

IEC TR 60601-4-3

Edition 2.0 2018-12

TECHNICAL REPORT

colour inside

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

ICS 11.040.01

ISBN 978-2-8322-6278-8

Warning! Make sure that you obtained this publication from an authorized distributor.

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

____

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

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 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.

This second edition cancels and replaces the first edition of IEC 60601-4-3 published in 2015. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition: addition of 47 new recommendations.

The text of this document is based on the following documents:

Enquiry draft	Report on voting
62A/1236/DTR	62A/1258A/RVDTR

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

Terms used throughout this document that have been defined in Clause 3 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD 1:2012, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-11:2010, IEC 60601-1-11:2015 and IEC 60601-1-12:2014 are printed in SMALL CAPITALS.

A list of all parts in the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

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

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

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

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

At the Sydney meeting in November 1993, 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 second edition of IEC TR 60601-4-3 contains 143 recommendations, numbered 101 to 243. All these recommendations are based upon IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, and IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-11:2010, IEC 60601-1-11:2015 and IEC 60601-1-12:2014.

The numbering starts with 101 instead of just 1 to ensure that these WG 14 recommendations (101 to 243) will not accidentally be confused with previous issued WG 14 recommendations 1 to 63, which are based on IEC 60601-1:1998 and published in IEC TR 62296:2009.

This document 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

This part of IEC 60601, which is a Technical Report, contains a series of recommendations developed by an expert working group of IEC subcommittee 62A in response to questions of interpretation of IEC 60601-1:2005 and related collateral standards in the IEC 60601 series.

This document 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, IEC 60601-1:2005/AMD1:2012, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-11:2010, IEC 60601-1-11:2015 and IEC 60601-1-12:2014;

– 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 future revisions of IEC 60601-1 and related collateral standards in the IEC 60601 series.

The object of this document is to make the recommendations/interpretations available to those interested in the application of the third edition of IEC 60601-1 and applicable collateral standards.

NOTE There might be other acceptable solutions which are not reflected in this document. The reader is reminded that, although a majority of the National Committee members of IEC/SC 62A have approved publication of this document, the contents remain the opinion of the expert members having participated in the drafting of the document. 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 are referred to in the text in such a way that some or all of their content constitutes requirements 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.

NOTE For improved reading and easy understanding of the recommendation section of each issue, the referenced standards are written as follows:

a) Written IEC 60601-1:2005, meant only Edition 3.0 from 2005.

b) Written IEC 60601-1:2005/AMD1:2012, meant only Amendment 1:2012.

c) Written IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, meant Edition 3.0 and Amendment 1:2012 combined.

d) Written IEC 60601-1 (in undated form), meant IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 (in the year 2018 the latest edition of IEC 60601-1).

If an edition is not explicitly specified, all editions referenced in this normative references clause applies.

IEC 60332-1-2, *Tests on electric and optical fibre cables under fire conditions – Part 1-2: Test for vertical flame propagation for a single insulated wire or cable – Procedure for 1 kW pre-mixed flame*

IEC 60332-2-2, *Tests on electric and optical fibre cables under fire conditions – Part 2-2: Test for vertical flame propagation for a single small insulated wire or cable – Procedure for diffusion flame*

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)*
IEC 60529:1989/AMD1:1999
IEC 60529:1989/AMD2:2013

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

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*

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*[1]

IEC 60601-1-11:2015, *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*

IEC 60601-1-12:2014, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

IEC 60747-5-5:2007, *Semiconductor devices – Discrete devices – Part 5-5: Optoelectronic devices – Photocouplers*

IEC 60950-1:2005, *Information technology equipment – Safety – Part 1: General requirements*

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*[2]

IEC 62304:2006, *Medical device software – Software life cycle processes*
IEC 62304:2006/AMD1:2015

ISO 8820-3:2010, *Road vehicles – Fuse-links – Part 3: Fuse-links with tabs (blade type) Type C (medium), Type E (high current) and Type F (miniature)*

_____

[1] This publication was withdrawn and replaced by IEC 60601-1-11:2015.

[2] This publication was withdrawn and replaced by IEC 62366-1:2015.

ISO 14971:2000, *Medical devices – Application of risk management to medical devices*[3]

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

UL 1642:2012, *Standard for lithium batteries*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-11:2010, IEC 60601-1-11:2015 and IEC 60601-1-12:2014 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

4 Recommendations

4.1 Template used for recommendations prepared by SC 62A

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

Recommendation number	NNN [a]
Clause(s) number (only) [b]	
Source/problem [c]	
Discussion/comment [d]	
Submitter proposed recommendation [e]	
Recommendation [f]	

[a] The numbering of the recommendations in the Technical Report starts with 101 instead of just 1 to ensure that these recommendations will not accidentally be confused with previously issued 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. In case of a collateral standard, please specify: IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-11:2010, IEC 60601-1-11:2015 and IEC 60601-1-12:2014.

[c] A description of the problem as submitted to SC 62A.

[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 SC 62A.

[3] This publication was withdrawn and replaced by ISO 14971:2007.

4.2 Recommendation sheets

4.2.101 Total PATIENT LEAKAGE CURRENT of a ME SYSTEM

Recommendation number	101
Clause(s) number (only)	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	–
SC 62A 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. SC 62A 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 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 8.7.4.7 h) separately for each individual ME EQUIPMENT belonging to the ME SYSTEM? SC 62A 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 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, but SC 62A 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.

4.2.102 Pollution degree for MOPP

Recommendation number	102
Clause(s) number (only)	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.
SC 62A recommendation	It is recommended to use Table 12 for MOPP for pollution degrees 1, 2 and 3. NOTE Pollution degree 4 is not allowed.

4.2.103 Transients on DC mains

Recommendation number	103
Clause(s) number (only)	8.9, 8.9.1.1
Source/problem	Transients on DC mains (e.g. ambulance power source).
Discussion/comment	The tables are based on AC mains transients. What about ME EQUIPMENT that operates from a DC mains such as an ambulance?
Submitter proposed recommendation	Apply Tables 12 through 16 as provided for ME EQUIPMENT connected to the DC mains.
SC 62A recommendation	It is recommended to apply Tables 12 through 16 for ME EQUIPMENT connected to the DC mains. Examples: a) pure external battery power: no MAINS TRANSIENT VOLTAGE exists; b) if the external DC power is derived out of an AC MAINS VOLTAGE (e.g. 230 V AC), use the concept already described in IEC 60601-1; c) if the external DC power is locally generated by a local generator (i.e. not derived out of MAINS VOLTAGE 230 V AC), for example by a generator of the ambulance, then use transient level Table 10, line 50 V RMS for primary DC circuit.