

TECHNICAL REPORT

IEC TR 62296

First edition
2003-03

Considerations of unaddressed safety aspects in the Second Edition of IEC 60601-1 and proposals for new requirements

*Etudes des aspects de sécurité non énoncés
dans la seconde édition de la CEI 60601-1
et propositions de nouvelles prescriptions*

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**CONSIDERATIONS OF UNADDRESSED SAFETY ASPECTS
IN THE SECOND EDITION OF IEC 60601-1 AND
PROPOSALS FOR NEW REQUIREMENTS**

FOREWORD

- 1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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IEC 62296, 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/398/CDV	62A/414/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.

The committee has decided that the contents of this publication will remain unchanged until 2005. At this date, the publication will be

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- withdrawn;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

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 houses 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/WG14, regarding problems of interpretation or application of IEC 60601-1 to all P-Member NC's.

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

The plan approved in Sydney called for the 62A Secretary to circulate these recommendations to the member National Committees via an informational (INF) document. At the time this Technical Report was prepared, three documents containing 56 recommendations had been circulated (documents 62A/221/INF, 62A/264/INF and 62A/284/INF).

While the quality of the technical work of WG 14 is widely recognized and applauded, the overall process has achieved less than originally hoped. The INF documents have not proved a particularly successful way of getting this information to those who could use it most. The WG 14 recommendations are largely unknown beyond the people actively involved in the work of SC 62A. Several alternatives have been explored. These include making the individual recommendation sheets available on the Internet either through the IEC Web Site, the web site of a participating National Committee, or the web site of an interested third party. However, concerns over intellectual property and control of distribution have proved extremely difficult to overcome.

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 houses while retaining the informative nature of the material.

This Technical Report may be amended from time to time as WG 14 prepares additional recommendations.

CONSIDERATIONS OF UNADDRESSED SAFETY ASPECTS IN THE SECOND 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 second edition of IEC 60601-1.

This Technical Report is primarily intended to be used by:

- manufacturers of MEDICAL ELECTRICAL EQUIPMENT;
- test houses and others responsible for assessment of compliance with IEC 60601-1, and
- those developing subsequent editions of IEC 60601-1.

The recommendations in the first edition of IEC/TR 62296 have been considered in preparing the third edition of IEC 60601-1. If and when additional recommendations are developed by IEC/SC 62A/WG 14 and published as amendments to this technical report, these will also be considered for incorporation into the third edition through the amendment/revision process.

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 Second 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 has not been formally adopted through any National Committee voting procedure. Distribution is only for information.

2 Recommendations

2.1 Summary of all recommendations prepared by SC 62A/WG 14

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Subclause of the 2 nd edition of IEC 60601-1	Recommendation number	Contents	Page
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Subclause of the 2 nd edition of IEC 60601-1	Recommendation number	Contents	Page
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^a This recommendation relates to a subclause of IEC 60601-1-1:2000.

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2.2 Recommendation sheets

2.2.1 Separation: Reliability of component impedance

IEC/SC 62A/WG 14 Recommendation No. 1

Problem raised in: SC 62A/WG 14(Canada)1 and 3

Requirement, clause no.	<p>17 Separation.</p> <p>a) APPLIED PARTS shall be electrically separated from LIVE parts of EQUIPMENT in NORMAL CONDITION and in SINGLE FAULT CONDITION (see 3.6), in such a way that allowable LEAKAGE CURRENTS (see Clause 19) are not exceeded.</p> <p>g) ACCESSIBLE PARTS not being an APPLIED PART shall be electrically separated from LIVE parts of EQUIPMENT in NORMAL CONDITION and in SINGLE FAULT CONDITION (see 3.6) in such a way that allowable LEAKAGE CURRENTS are not exceeded (see Clause 19).</p> <p>This requirement may be fulfilled by one of the following methods:</p> <p>17 a) 5) Impedances of components prevent the flow to the APPLIED PART of a PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT exceeding the allowable values.</p> <p>17 g) 5) Impedances of components prevent the flow to the ACCESSIBLE PART of an ENCLOSURE LEAKAGE CURRENT exceeding the allowable values.</p>
Test clause no.	<p>Compliance with items a) and g) of Clause 17 is checked by inspection and measurement.</p> <p>If the CREEPAGE DISTANCE and/or AIR CLEARANCE between the APPLIED PART and LIVE parts does not comply with the requirements of 57.10, such CREEPAGE DISTANCE and/or AIR CLEARANCE shall be short-circuited.</p> <p>The PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT are measured as described in 19.4 and shall not exceed the limits for NORMAL CONDITION given in Table IV.</p>
Source/problem	<p>SC 62A/WG 14(Canada)1</p> <p>Component impedance is generally unreliable. Components certified to IEC 60384-14 etc. can be considered of high integrity. Is the impedance of a component sufficient? Does investigation of the product require further review of AIR CLEARANCE and CREEPAGE DISTANCE for such a component? Does this subclause mean that further component review is not required?</p>
Discussion/comment	<p>Subclause 52.5.9 requires that failure of components shall be investigated and especially those components which provide protective means. Exempted are capacitors (X1 and X2) complying with IEC 60384-14 connected between parts of opposite polarity of the supply mains. The short-circuit of inadequate AIR CLEARANCE and CREEPAGE DISTANCE is a NORMAL CONDITION.</p>
WG 14 recommendation	<p>Secondary circuits providing protective means after short-circuiting of inadequate AIR CLEARANCE and CREEPAGE DISTANCE shall be investigated. Failure of components in these circuits shall be investigated as a SINGLE FAULT CONDITION.</p>

This recommendation/interpretation was prepared by 62A/WG 14 regarding problems of interpretation of the application of the 2nd edition of IEC 60601-1. This recommendation/interpretation is the result of consideration by this group of nominated experts and has not been formally adopted through any National Committee voting procedure. Publication is only for information.

2.2.2 Separation: Non-complying CREEPAGE DISTANCE and AIR CLEARANCES

IEC/SC 62A/WG 14 Recommendation No. 2

Problem raised in: SC 62A/WG 14(Canada)2

<p>Requirement, clause no.</p>	<p>17 a) Separation.</p> <p>a) APPLIED PARTS shall be electrically separated from LIVE parts of EQUIPMENT in NORMAL CONDITION and in SINGLE FAULT CONDITION (see 3.6), in such a way that allowable LEAKAGE CURRENTS (see Clause 19) are not exceeded.</p> <p>This requirement may be fulfilled by one of the following methods:</p> <p>5) Impedances of components prevent the flow to the APPLIED PART of a PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT exceeding the allowable values</p>
<p>Test clause no.</p>	<p>Compliance with item a) of Clause 17 is checked by inspection and measurement.</p> <p>If the CREEPAGE DISTANCE and/or AIR CLEARANCE between the APPLIED PART and LIVE parts does not comply with the requirements of 57.10, such CREEPAGE DISTANCE and/or AIR CLEARANCE shall be short-circuited.</p> <p>The PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT are measured as described in 19.4 and shall not exceed the limits for NORMAL CONDITION given in Table IV.</p>
<p>Source/problem</p>	<p>SC 62A/WG 14(Canada)2</p> <p>Assume mains to floating APPLIED PART does not comply with AIR CLEARANCE and CREEPAGE DISTANCE requirements. Mains to floating APPLIED PART isolation is short-circuited.</p> <p>If secondary circuit impedances limit the LEAKAGE CURRENT, is further investigation of secondary circuits required?</p>
<p>Discussion/comment</p>	<p>Since in this case the short-circuit of the AIR CLEARANCE and CREEPAGE DISTANCE is a NORMAL CONDITION, the remaining circuits and any protective means must be investigated under SINGLE FAULT CONDITION and for compliance with AIR CLEARANCE and CREEPAGE DISTANCE requirements. Since these remaining circuits are stressed to MAINS VOLTAGE under NORMAL CONDITION this must be taken into account.</p>
<p>WG 14 recommendation</p>	<p>Secondary circuits providing protective means after short-circuiting of inadequate AIR CLEARANCE and CREEPAGE DISTANCE shall be investigated. Failure of components in these circuits shall be investigated as a SINGLE FAULT CONDITION.</p>

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2.2.3 Mains supply transformers: Overload test**IEC/SC 62A/WG14 Recommendation No. 3.****Problem raised in: SC 62A/WG 14(Canada)8**

Requirement, clause no.	57.9.1 b) Mains supply transformers: Overload test
Test clause no.	
Source/problem	SC 62A/WG 14(Canada)8 Normal product investigation requires dielectric strength test after transformer overload test. Does the overload test alone verify that no SAFETY HAZARD exists?
Discussion/comment	
WG 14 recommendation	The overload test alone verifies that no SAFETY HAZARD exists, but if the integrity of the insulation is in doubt (regarding temperature limits), a repeated dielectric strength test should be carried out after the overload test.

This recommendation/interpretation was prepared by 62A/WG 14 regarding problems of interpretation of the application of the 2nd edition of IEC 60601-1. This recommendation/interpretation is the result of consideration by this group of nominated experts and has not been formally adopted through any National Committee voting procedure. Publication is only for information.

2.2.4 Mains supply transformers: Short circuit and overload tests

IEC/SC 62A/WG14 Recommendation No. 4.

Problem raised in: SC 62A/WG 14(Canada)9

Requirement, clause no.	57.9.1 Mains supply transformers: Short Circuit and Overload tests.
Test clause no.	
Source/problem	<p>SC 62A/WG 14(Canada)9</p> <p>Secondary circuit over-current protection is the first active component on the secondary side of a mains supply transformer. Is the overload test performed before or after the fuse?</p> <p>Insufficient transformer winding crossover insulation and secondary circuit CREEPAGE DISTANCES and AIR CLEARANCES causes transformer winding to short-circuit and exceed allowable temperatures.</p>
Discussion/comment	<p>Inspection of the transformer arrangements will be necessary to determine the likelihood of a short-circuit before the over-current protection.</p>
WG 14 recommendation	<p>If the possibility of a short-circuit exists before the secondary over-current protection device (e.g. failure of basic insulation between winding or detachment of the wiring) the short circuit test should be conducted at the exit of the wiring from the transformer.</p> <p>(N.B. Similar recommendations can be made for batteries and their protective devices)</p> <p>The overload test however shall always be conducted after any secondary over-current protection device providing that the conditions of 57.9.1. second dash are fulfilled.</p>

This recommendation/interpretation was prepared by 62A/WG 14 regarding problems of interpretation of the application of the 2nd edition of IEC 60601-1. This recommendation/interpretation is the result of consideration by this group of nominated experts and has not been formally adopted through any National Committee voting procedure. Publication is only for information.