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TECHNICAL REPORT

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

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IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland
Email: inmail@iec.ch
Web: www.iec.ch

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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

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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 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*.

This second edition cancels and replaces the first edition published in 2003. It constitutes a technical revision. This edition includes seven new recommendations: Recommendations 57 through 63. As the third edition of IEC 60601-1 has been published, some of the recommendations in this edition have been changed to align with requirements in IEC 60601-1:2005.

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

Enquiry draft	Report on voting
62A/621/DTR	62A/632/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 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- withdrawn;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.

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 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.

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 60601-1:1988, 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. As the third edition of IEC 60601-1 has been published, some of the recommendations in the second edition of IEC/TR 62296 have been changed to align with requirements in IEC 60601-1:2005. Seven additional recommendations have been developed by IEC/SC 62A/WG 14 and are included in this edition of IEC/TR 62296. They are recommendations 57 through 63.

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 have 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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2.2 Recommendation sheets

2.2.1 Separation: Reliability of component impedance

IEC/SC 62A/WG14 Recommendation No. 1

Problem raised in: SC 62A/WG 14(Canada)1, 2 and 4

Requirement, clause no.	17 Separation 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. 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). This requirement may be fulfilled by one of the following methods: 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. 17 g 5) Impedances of components prevent the flow to the ACCESSIBLE PART of an ENCLOSURE LEAKAGE CURRENT exceeding the allowable value.
Test clause no.	Compliance with items a) and g) of Clause 17 is checked by inspection and measurement. If the CREEPAGE DISTANCE and/or AIR CLEARANCE between the APPLIED PART (ACCESSIBLE PARTS) and LIVE parts does not comply with the requirements of 57.10, such CREEPAGE DISTANCE and/or AIR CLEARANCE shall be short circuited. The LEAKAGE CURRENTS are measured as described in 19.4 and shall not exceed the limits for NORMAL CONDITION given in Table IV.
Source/Problem	SC 62A/WG 14(Canada)1 Component impedance is generally unreliable. Can components certified to IEC 60384-14 etc. be considered as 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? SC 62A/WG 14(Canada)2 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. SC 62A/WG 14(Canada)4 If secondary circuit impedances limit the LEAKAGE CURRENT, is further investigation of secondary circuits required? (Refer to 52.5).
Discussion/comment	The problem is two-fold. Separation between LIVE PARTS and APPLIED PARTS/ACCESSIBLE PARTS is dependent on components (protective impedances) and/or AIR CLEARANCES and CREEPAGE DISTANCES. Subclause 52.5.9 requires that failure of components shall be investigated and especially those components which provide protective means. Subclause 17 requires compliance with the spacings, but if these spacings are inadequate, they shall be short circuited and LEAKAGE CURRENTS monitored. Referring to Canada 2, we assume that it refers to inadequate spacings which need to be short circuited. Up to now there are no requirements for components to be considered high integrity, but there are requirements for Y1 and Y2 capacitors.

WG 14 recommendation	If a capacitor (protective impedance) is used, the following applies: – One Y1 capacitor complying with IEC 60384-14 is considered equivalent to one MEANS OF PROTECTION provided that it will pass the dielectric strength test for DOUBLE or REINFORCED INSULATION. Where two capacitors are used in series, they shall each be RATED for the total WORKING VOLTAGE across the pair and shall have the same NOMINAL capacitance. – Two Y2 capacitors complying with IEC 60384-14 in series are considered equivalent to ONE MEANS OF PROTECTION provided that each will pass the dielectric strength test for BASIC INSULATION. Where two capacitors are used in series, they shall each be RATED for the total WORKING VOLTAGE across the pair and shall have the same NOMINAL capacitance. According to the standard, DOUBLE INSULATION is not to be short circuited. DOUBLE INSULATION consists of BASIC INSULATION and SUPPLEMENTARY INSULATION, each of which can be short circuited. Where spacings for DOUBLE INSULATION are inadequate, these spacings effectively reduce to either BASIC INSULATION or SUPPLEMENTARY INSULATION. In this case, the whole of the spacing needs to be short circuited. This is considered to be a SINGLE FAULT CONDITION. Where the spacings are less than BASIC INSULATION the short circuit of these is considered a NORMAL CONDITION. LEAKAGE CURRENT measurements are carried out after applying the above short circuits. The secondary circuits and any protective means limiting LEAKAGE CURRENTS must be investigated under SINGLE FAULT CONDITION. See also Recommendation No. 20.

2.2.2 Separation: Non-complying creepage distance and air clearances

IEC/SC 62A/WG14 Recommendation No. 2

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

Recommendation deleted: text implemented in recommendation No. 1	

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.	57.9.1b) Mains supply transformers: Overload test
Test clause no.	
Source/Problem	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.