Technical Information Report

ANSI/AAMI/IEC TIR62296:2009

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

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An ANSI Technical Report prepared by AAMI

ANSI/AAMI/IEC TIR62296:2009
(Revision of ANSI/AAMI/IEC TIR62296:2003)

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

Approved 17 March 2009 by
Association for the Advancement of Medical Instrumentation

Approved 5 April 2009 by
American National Standards Institute, Inc.

Abstract: 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 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.

Keywords: electromedical equipment, interpretations, safety, testing

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International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1:2005	ANSI/AAMI ES60601-1:2005	Major technical variations
IEC 60601-1-2:2007	ANSI/AAMI/IEC 60601-1-2:2007	Identical
IEC 60601-2-2:2009	ANSI/AAMI/IEC 60601-2-2:2009	Identical
IEC 60601-2-4:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:2009	ANSI/AAMI/IEC 60601-2-19:2009	Identical
IEC 60601-2-20:2009	ANSI/AAMI/IEC 60601-2-20:2009	Identical
IEC 60601-2-21:2009	ANSI/AAMI/IEC 60601-2-21:2009	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004	Major technical variations
IEC 60601-2-47:2001	ANSI/AAMI EC38:2007	Major technical variations
IEC 60601-2-50:2009	ANSI/AAMI/IEC 60601-2-50:2009	Identical
IEC 80601-2-58:2008	ANSI/AAMI/IEC 80601-2-58:2008	Identical
IEC/TR 60878:2009	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2009	ANSI/AAMI/IEC TIR62296:2009	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 8637:2004	ANSI/AAMI RD16:2007	Major technical variations
ISO 8638:2004	ANSI/AAMI RD17:2007	Major technical variations
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002 and Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002/(R)2009 and Amendment 1:2006/(R)2009	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007	Identical
ISO 10993-7:2008	ANSI/AAMI/ISO 10993-7:2008	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999/(R)2005	Identical
ISO 10993-10:2002 and Amendment 1:2006	ANSI/AAMI BE78:2002/(R)2008 ANSI/AAMI BE78:2002/A1:2006/(R)2008	Minor technical variations Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006	Identical
ISO 10993-12:2007	ANSI/AAMI/ISO 10993-12:2007	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001/(R)2006	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000/(R)2006	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2009	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002/(R)2008	Identical
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical

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International designation	U.S. designation	Equivalency
ISO/TS 11135-2:2008	ANSI/AAMI/ISO TIR11135-2:2008	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006	Identical
ISO 11137-2:2006 (2006-08-01 corrected version)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006	Identical
ISO 11138-1: 2006	ANSI/AAMI/ISO 11138-1:2006	Identical
ISO 11138-2: 2006	ANSI/AAMI/ISO 11138-2:2006	Identical
ISO 11138-3: 2006	ANSI/AAMI/ISO 11138-3:2006	Identical
ISO 11138-4: 2006	ANSI/AAMI/ISO 11138-4:2006	Identical
ISO 11138-5: 2006	ANSI/AAMI/ISO 11138-5:2006	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005	Identical
ISO 11140-3:2007	ANSI/AAMI/ISO 11140-3:2007	Identical
ISO 11140-4:2007	ANSI/AAMI/ISO 11140-4:2007	Identical
ISO 11140-5:2007	ANSI/AAMI/ISO 11140-5:2007	Identical
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006	Identical
ISO 11737-1: 2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO 13408-1:2008	ANSI/AAMI/ISO 13408-1:2008	Identical
ISO 13408-2:2003	ANSI/AAMI/ISO 13408-2:2003	Identical
ISO 13408-3:2006	ANSI/AAMI/ISO 13408-3:2006	Identical
ISO 13408-4:2005	ANSI/AAMI/ISO 13408-4:2005	Identical
ISO 13408-5:2006	ANSI/AAMI/ISO 13408-5:2006	Identical
ISO 13408-6:2006	ANSI/AAMI/ISO 13408-6:2006	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003/(R)2008	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003/(R)2008	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998/(R)2008	Identical
ISO 14161:2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2007	ANSI/AAMI/ISO 14971:2007	Identical
ISO 15223-1:2007 and A1:2008	ANSI/AAMI/ISO 15223-1:2007 and A1:2008	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO 15882:2008	ANSI/AAMI/ISO 15882:2008	Identical
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2005	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006	Identical
ISO/TS 19218:2005	ANSI/AAMI/ISO 19218:2005	Identical
ISO 22442-1:2007	ANSI/AAMI/ISO 22442-1:2007	Identical
ISO 22442-2:2007	ANSI/AAMI/ISO 22442-2:2007	Identical
ISO 22442-3:2007	ANSI/AAMI/ISO 22442-3:2007	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003 and A1:2005	Identical
ISO 25539-2:2008	ANSI/AAMI/ISO 25539-2:2008	Identical
ISO 81060-1:2007	ANSI/AAMI/ISO 81060-1:2007	Identical

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Committee representation

Association for the Advancement of Medical Instrumentation

Electrical Safety Committee

The adoption of IEC Technical Report 62296:2009 as an AAMI Technical Information Report and ANSI Technical Report was initiated by the AAMI Electrical Safety Committee and the U.S. Technical Advisory Group for IEC/SC 62A. Committee approval of the technical report does not necessarily imply that all committee members and reviewers voted for its approval.

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Background of ANSI/AAMI adoption of IEC/TR 62296:2009

The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The United States is one of the IEC members that took an active role in the development of this technical report.

International Technical Report IEC/TR 62296 was developed by Working Group (WG) 14, *Testing to general safety standard 60601-1*, of Subcommittee (SC) 62A, *Common aspects of electrical equipment used in medical practice*.

U.S. participation in IEC/SC 62A/WG 14 is organized through the U.S. Technical Advisory Group for IEC/SC 62A, administered by the Advanced Medical Technology Association (AdvaMed) on behalf of the United States National Committee, which is a committee of the American National Standards Institute (ANSI). AAMI administers the International Secretariat for IEC/SC 62A on behalf of the United States, and U.S. experts made a considerable contribution to this technical report.

This second edition cancels and replaces the first edition published in 2003. It constitutes a technical revision. This edition includes seven new recommendations (See Recommendations 57 through 63 on pages "62 to 68").

AAMI encourages its committees to harmonize their work with international documents as much as possible. The AAMI Electrical Safety Committee, together with the U.S. Technical Advisory Group for IEC/SC 62A, reviewed IEC/TR 62296 to formulate the U.S. position and comments while the document was being developed. This close collaboration helped gain widespread U.S. consensus on the document. As the U.S. Technical Advisory Group for IEC/SC 62A, AdvaMed granted AAMI permission to consider adoption of IEC/TR 62296:2009 as a revised AAMI TIR. Following AAMI procedures, the AAMI Electrical Safety Committee voted to adopt the IEC Technical Report as written.

The concepts incorporated into this technical report should not be considered inflexible or static. This technical information report, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data comes to light.

Suggestions for improving this technical information report are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—Beginning with the IEC foreword on page “x”, ANSI/AAMI/IEC TIR62296:2009, *Considerations of unaddressed safety aspects in the second edition of IEC 60601-1 and proposals for new requirements* is identical to IEC/TR 62296:2009.

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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 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.
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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.

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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.

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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.

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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.

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2 Recommendations

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6.1 n)	**034**	Marking on the outside of EQUIPMENT: Type and rating of fuses	39
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6.8.1	**042**	ACCOMPANYING DOCUMENTS: On CD-ROM or electronic file format	47
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10	**021**	Environmental conditions: Compliance paragraph	26
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16	**008**	ENCLOSURES and protective covers: Accessibility of SIP/SOPs	12
16	**017**	ENCLOSURE and protective covers: EQUIPMENT in ambulances	21
16 d)	**012**	ENCLOSURES and PROTECTIVE COVERS: Lampholder/switching device	16
17 a)	**002**	Separation: Non-complying CREEPAGE DISTANCES and AIR CLEARANCES (Recommendation deleted: text implemented in recommendation No. 1)	6
17 a)+g) 5)	**001**	Separation: Reliability of component impedance	4
17 c)	**051**	Separation, APPLIED PART: Hand-held flexible shafts	56
17 g)	**011**	Separation: secondary circuit impedance limit LEAKAGE CURRENT (Recommendation deleted: text implemented in recommendation No. 1)	15
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18 f)	**052**	Protective earthing: No-load voltage of 6 V maximum	57
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19.4 h 7) / 8)	**009**	Internally powered equipment: 110 % of the maximum supply voltage	13
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20.1 A-e	**056**	Dielectric strength: A-e in switch mode power supply units (SMPSU)	61
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Subclause of the 2nd edition of IEC 60601-1	Recom-mendation number	Contents	Page
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20.2 B-e	**025**	Dielectric strength: EQUIPMENT containing floating circuits	30
20.3	**063**	Reference voltage: Different reference voltages in the same circuit	68
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49	**062**	Interruption of power supply: Characteristics of interruption	67
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56.1 b)	**037**	Components and general assembly: reliability of components	42
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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.

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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.

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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	
	(Table Intentionally Blank)

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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.	57.9.1b) 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.

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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	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? Insufficient transformer winding crossover insulation and secondary circuit CREEPAGE DISTANCES and AIR CLEARANCES causes transformer winding to short circuit and exceed allowable temperatures.
Discussion/comment	Inspection of the transformer arrangements will be necessary to determine the likelihood of a short circuit before the over-current protection.
WG 14 recommendation	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. (N.B. Similar recommendations can be made for batteries and their protective devices.) 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.

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2.2.5 Creepage distance and air clearances: Values

IEC/SC 62A/WG14 Recommendation No. 5

Problem raised in: SC 62A/WG 14(Canada)10

Requirement, clause no.	57.10a) CREEPAGE DISTANCES and AIR CLEARANCES: Values
Test clause no.	
Source/Problem	There appears no specific means of investigating opto-couplers, multi-layer printed circuit boards, d.c. to d.c. converters and secondary transformers for CREEPAGE DISTANCES and AIR CLEARANCES. Can we apply distance through insulation concepts?
Discussion/comment	At present the concept of distance through insulation (e.g. in an opto-coupler or between a multilayer printed circuit board) is not applied.
WG 14 recommendation	There is no additional recommendation to the already required dielectric strength test.

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2.2.6 Dielectric strength

IEC/SC 62A/WG14 Recommendation No. 6

Problem raised in: Fax from M.M. Stuchi (IMQ)

Requirement, clause no.	20 Dielectric strength. 20.1 A-a1) Between LIVE parts and accessible metal parts which are protectively earthed. The insulation shall be BASIC INSULATION.
Test clause no.	
Source/Problem	This requirement would appear to apply also to intermediate circuits which may or may not remain LIVE after interruption of the PROTECTIVE EARTH CONDUCTOR. Should A-a1) be applied also in those cases where the intermediate circuit ceases to be LIVE after interruption of the PROTECTIVE EARTH CONDUCTOR?
Discussion/comment	Insulation requirements are intended to provide protection for circuits which could be hazardous in SINGLE FAULT CONDITION.
WG 14 recommendation	Requirements for BASIC INSULATION A-a1) should be applied only to those intermediate circuits which may be hazardous in SINGLE FAULT CONDITION. ACCESSIBLE PARTS including APPLIED PARTS have to be separated from certain internal LIVE parts. In general two separate MEANS OF PROTECTION are necessary, one to provide separation in NORMAL CONDITION and a second to maintain safety in SINGLE FAULT CONDITION, and LEAKAGE CURRENTS (and possibly also voltages and energies) have to be below acceptable limits.

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2.2.7 Failure of components: Evidence of reliability

IEC/SC 62A/WG14 Recommendation No. 7

Problem raised in: SC 62A/WG 14(Sweden)13

Requirement, clause no.	52.5 The following SINGLE FAULT CONDITIONS are the subject of specific requirements and tests. 52.5.9 *Failure of components*: Failure of one component at a time, which failure could cause a SAFETY HAZARD as mentioned in 52.4, is simulated. This requirement and relevant tests shall not be applied to failures of DOUBLE or REINFORCED INSULATION. Rationale 57.7: Interference suppressors may be connected on the SUPPLY MAINS side of an EQUIPMENT mains switch or on the SUPPLY MAINS side of any mains fuse or OVER-CURRENT RELEASE.
Test clause no.	
Source/Problem	The Rationale to 57.7 is in contradiction with the requirement in 52.5.9. For instance, any capacitor connected on the SUPPLY MAINS side of mains fuses would, in the case of short-circuit fault, imply that the safety depends on safety devices external to the EQUIPMENT in which the capacitor is mounted. What shall be required of components connected on the SUPPLY MAINS side of any mains fuse or OVER-CURRENT RELEASE? For instance, shall capacitors complying with IEC 60384-14 be accepted?
Discussion/comment	Amendment 2 answers the capacitor problem, however it does not deal with other components, e.g. discharge resistors.
WG 14 recommendation	For these components, compliance with a relevant IEC standard should be sought. If no suitable standard exists, examination of characteristics and evidence of reliability should be researched as 3.4 suggests (equivalent degree of safety).

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2.2.8 ENCLOSURES and protective covers

IEC/SC 62A/WG 14 Recommendation No. 8

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

Requirement, clause no.	16 ENCLOSURES and protective covers
Test clause no.	
Source/Problem	In practice, many standard SIP/SOPs are constructed so that LIVE parts of the SIP/SOPs are accessible with the standard test finger or, alternatively, the AIR CLEARANCES and/or CREEPAGE DISTANCES between these live parts and the standard test finger are too short. This means that these LIVE parts of SIP/SOPs are to be considered as part of the ENCLOSURE and therefore the corresponding ENCLOSURE LEAKAGE CURRENT shall be measured. As a consequence, many existing standard SIP/SOPs fail to comply with the standard. Should, for instance, concession be granted for SIP/SOPs with accessible LIVE parts with a voltage (to earth) not exceeding 25 V a.c. or 60 V d.c.?
Discussion/comment	For the operator, access to parts at potentials not exceeding 25 V a.c. or 60 V d.c. is considered not to present a hazard, provided that simultaneous contact between operator and patient is avoided. Probability of simultaneous contact between patient and SIP/SOPs is considered very low during treatment.
WG 14 recommendation	SIP/SOPs with OPERATOR accessible LIVE parts and which are SAFETY EXTRA-LOW VOLTAGE (SELV) shall be accepted, if the instructions for use instruct the OPERATOR not to touch such parts and the PATIENT simultaneously.

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