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

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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- withdrawn;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

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.	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 values.
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 and LIVE parts does not comply with the requirements of 57.10, such CREEPAGE DISTANCE and/or AIR CLEARANCE shall be short-circuited. 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.
Source/problem	SC 62A/WG 14(Canada)1 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?
Discussion/comment	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.
WG 14 recommendation	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.

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

Requirement, clause no.	17 a) 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. This requirement may be fulfilled by one of the following methods: 5) Impedances of components prevent the flow to the APPLIED PART of a PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT exceeding the allowable values
Test clause no.	Compliance with item a) of Clause 17 is checked by inspection and measurement. 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. 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.
Source/problem	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. If secondary circuit impedances limit the LEAKAGE CURRENT, is further investigation of secondary circuits required?
Discussion/comment	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.
WG 14 recommendation	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.

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.

2.2.3 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	SC 62A/WG 14(Canada)9 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.

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.

2.2.5 CREEPAGE DISTANCE and AIR CLEARANCES: Values

IEC/SC 62A/“ Recommendation No. 5.

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

Requirement, clause no.	57.10 a) CREEPAGE DISTANCES and AIR CLEARANCES: Values
Test clause no.	
Source/problem	SC 62A/WG 14(Canada)10 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. Could be addressed in the third edition.
WG 14 recommendation	No recommendation

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.

2.2.6 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	Fax from M.M. Stuchi (IMQ) 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. Refer also to SC 62A/WG 14(Sec)18, p 3 of 14 : proposal for definition of "LIVE", which clarifies the situation.

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.

2.2.7 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	SC 62A/WG 14(Sweden)13 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	SC 62A/WG 14(Sweden)14 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.

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.

2.2.9 INTERNALLY POWERED EQUIPMENT: 110 % of the maximum supply voltage

IEC/SC 62A/WG 14 Recommendation No. 9.

Problem raised in: SC 62A/WG 14(Sweden)15

Requirement, clause no.	19.4 h) Measurement of PATIENT LEAKAGE CURRENT
Test clause no.	19.4 h) 7) and 8) for INTERNALLY POWERED EQUIPMENT
Source/problem	Both these tests are required to be conducted at 250 V at the supply frequency.
Discussion/comment	SC 62A/WG 14(Sweden)15 Since some INTERNALLY POWERED EQUIPMENT is provided with a means of connection to a SUPPLY MAINS, should not these tests be carried out at more than 110 % of the maximum RATED supply voltage? Some INTERNALLY POWERED EQUIPMENT may be designated for use in areas with specific maximum supply voltages less than 230 V.
WG 14 recommendation	INTERNALLY POWERED EQUIPMENT provided with a means of connection to a supply mains shall be tested at 110 % of the maximum RATED supply voltage. INTERNALLY POWERED EQUIPMENT designated for use in areas with specific maximum supply voltages, e.g. North America, should also be tested at 110 % of the maximum supply voltage. If in doubt 230 V should be taken as the maximum supply voltage.

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.

2.2.10 CREEPAGE DISTANCES and AIR CLEARANCES: Values under 1 mm

IEC/SC 62A/WG 14 Recommendation No. 10.

Problem raised in: SC 62A/WG 14(Sweden)16

Requirement, clause no.	57.10. CREEPAGE DISTANCES and AIR CLEARANCES
Test clause no.	57.10 d)
Source/problem	SC 62A/WG 14(Sweden)16 For values of AIR CLEARANCE under 1 mm in Table XVI, it is difficult to apply rules to evaluate clearance and creepage according to Figures 39 to 47 since creepage = clearance.
Discussion/comment	Either Table XVI is wrong or the rules of measurement are wrong.
WG 14 recommendation	Await correction in 3rd edition of IEC 60601-1

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.

2.2.11 Separation: Secondary circuit impedance limit LEAKAGE CURRENT

IEC/SC 62A/WG 14 Recommendation No. 11.

Problem raised in: SC 62A/WG 14(Canada)4

Requirement, clause no.	17 g) Separation. 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 values.
Test clause no.	Compliance with item a) of Clause 17 is checked by inspection of the required separation in order to find out where an insulation failure might cause a SAFETY HAZARD. If the CREEPAGE DISTANCE and/or AIR CLEARANCE between an ACCESSIBLE PART and LIVE parts does not comply with the requirements of 57.10, such CREEPAGE DISTANCE and AIR CLEARANCE shall be short-circuited. The ENCLOSURE LEAKAGE CURRENT shall subsequently be 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)4 If secondary circuit impedances limit the leakage current, is further investigation of secondary circuits required? (Refer to 52.5.)
Discussion/comment	Any such components should be treated in the same way as any other component, i.e. subject to the requirements for correct rating, subject to simulated failure under SINGLE FAULT CONDITION and compliance with AIR CLEARANCE and CREEPAGE DISTANCE requirements.
WG 14 recommendation	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.

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.

2.2.12 ENCLOSURES and PROTECTIVE COVERS: Lampholder/switching device

IEC/SC 62A/WG 14 Recommendation No. 12.

Problem raised in: SC 62A/WG 14(Germany)1

Requirement, clause no.	16 d) ENCLOSURES and protective covers. Parts within the ENCLOSURE of EQUIPMENT with a circuit voltage exceeding 25 V a.c. or 60 V d.c. which cannot be disconnected from the supply by an external mains switch or a plug device that is accessible at all times (for example, in circuits for room lighting, remote control of the main switch etc.) shall be protected against contact even after opening of the ENCLOSURE (for example, for the purpose of maintenance) by additional coverings or, in the case of a spatially separated arrangement, shall be marked clearly as "LIVE" 16 e) ENCLOSURES protecting against contact with LIVE parts shall be removable only with the aid of a TOOL or, alternatively, an automatic device shall make these parts not LIVE, when the ENCLOSURE is opened or removed. Excluded are: 1)..... 2) Lampholders allowing access to LIVE parts after removal of the lamp.
Test clause no.	*Compliance is checked by inspection and:* – *by measurement of the effectiveness of an automatic switching off or discharging device;* – *by measurement of the voltage of LIVE parts accessible with the standard test finger of Figure 7.*
Source/problem	SC 62A/WG 14(Germany)1 a) What is the definition of a lampholder? b) What are the requirements for the automatic switching off device?
Discussion/comment	a) Since everybody is familiar with changing a "normal" lamp, and therefore these were excluded, this exclusion should only apply to standard lampholders i.e. Edison screw and bayonet cap. b) The automatic switching off device fulfils the function of an isolating means and should have the same requirements as a mains switch.
WG 14 recommendation	a) The exclusion for lampholders shall apply only to standard lampholders e.g. Edison screw and bayonet cap. b) The automatic switching off device shall comply with the requirements for isolation given in 57.1 a) and d). The automatic switching off device shall not be capable of manual resetting by the operator. Compliance should be checked by inspection and with the standard test finger of Figure 7.

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.

2.2.13 Fixing, prevention of maladjustment: Torque test

IEC/SC 62A/WG 14 Recommendation No. 13.

Problem raised in: SC 62A/WG 14(Australia)1

Requirement, clause no.	56.10 b) Fixing, prevention of maladjustment. 2nd dash: Controls.....shall be so secured that the indication of any scale always corresponds with the position of the control.
Test clause no.	*Compliance is checked by inspection and manual tests. For rotating controls, the torques as shown in Table XIII shall be applied between the control knob and the shaft for not less than 2 s in each direction alternately. The test shall be repeated 10 times.*
Source/problem	SC 62A/WG 14(Australia)1 a) The criteria is that the knob shall not rotate with respect to the shaft. This does not cover the possibility of internal damage to the controlling device e.g. potentiometer. b) The torque test values are too high. Maximum torque on a 10 mm diameter knob was found to be <0.5 Nm.
Discussion/comment	The adequacy of the knob/shaft mechanical link is covered by 56.10 b). The adequacy of the mechanical stops, wherever located, is covered by 56.10 c). This is intended to minimise the potential for internal damage by excessive torque.
WG 14 recommendation	WG 14 does not feel that the torque test values in Table XIII are excessive. This table should be re-examined in the 3rd edition of IEC 60601-1.

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2.2.14 Batteries not intended to be changed by OPERATOR: Lithium batteries

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

Problem raised in: SC 62A/WG 14(Israel)1

Requirement, clause no.	6.2 d) The type of battery and the mode of insertion, if applicable shall be marked (see item b) of 56.7). For batteries not intended to be changed by the OPERATOR and which can be changed only with the use of a TOOL, an identifying marking referring to information stated in the ACCOMPANYING DOCUMENTS is sufficient.
Test clause no.	*Compliance with the requirements of 6.2 is checked by application of the tests and criteria as described in 6.1, except for the rubbing test.*
Source/problem	SC 62A/WG 14(Israel)1 Lithium batteries are commonly used for memory backup. There is a risk of explosion if such batteries are soldered in position by an inadequately trained person.
Discussion/comment	Such a requirement is included in IEC 60950-1 and this could be included in the 3rd edition of IEC 60601-1.
WG 14 recommendation	Although 6.8.3 covers this in general, WG 14 recommends that particular attention be drawn to this in the technical description.

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2.2.15 Excessive temperatures: Ambient temperatures

IEC/SC 62A/WG 14 Recommendation No. 15.

Problem raised in: SC 62A/WG 14(Israel)1

Requirement, clause no.	42.2 EQUIPMENT parts and their environment shall not attain temperatures exceeding the values as given in Table Xb when the EQUIPMENT is operated during NORMAL USE and under NORMAL CONDITIONS at an ambient temperature of 25 °C.
Test clause no.	*Compliance with the requirements of 42.1 to 42.3 is checked by operation of EQUIPMENT and temperature measurement as follows:*
Source/problem	SC 62A/WG 14(Israel)1 The manufacturer could specify higher ambient temperatures than 25 °C. Should this influence the test conditions?
Discussion/comment	The tests for 42.2 are carried out at the prevailing ambient temperature, and the test results corrected to determine the temperature which would have been reached had the ambient temperature been 25 °C.
WG 14 recommendation	Table Xa gives the permissible temperature of materials for an ambient temperature of 40 °C. Table Xb gives the permissible temperature of materials for an ambient temperature of 25 °C. Tests will be conducted at ambient temperatures in the range 10 °C to 40 °C. The measured temperature obtained shall be corrected for an ambient temperature of either 40 °C (Xa) or 25 °C (Xb). These corrected temperatures are used for comparison with the allowed maximum values for materials in Tables Xa and Xb. The table below gives examples of tests carried out at 35 °C and the results of corrections.

Parts	Ambient °C	Measure value at ambient	Corrected value for 25 °C ambient	Corrected value at 40 °C ambient	Allowable values listed in
listed in Xa	35	130	—	135	Table Xa
listed in Xb	35	110	100	—	Table Xb

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2.2.16 Continuous LEAKAGE CURRENTS: Different SUPPLY MAINS

IEC/SC 62A/WG 14 Recommendation No. 16

Problem raised in: SC 62A/WG 12 (Israel)1

Requirement, clause no.	19.1 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS.
Test clause no.	19.1 e), f) and g), 19.2 a) and b)
Source/problem	Where an EQUIPMENT is capable of operating from different SUPPLY MAINS, e.g. a.c. mains supply or d.c mains supply, do the tests need to be repeated for each supply?
Discussion/comment	SC 62A/WG 12(Israel)1 An EQUIPMENT is defined in 2.2.15 as having only one connection to a particular SUPPLY MAINS. This means that connection should only be possible to one SUPPLY MAINS at any one time. However there may be situations where leakage currents could be worse with a particular modality of SUPPLY MAINS even though of lower voltage, e.g. with d.c. supply. The 2nd edition of IEC 60601-1 does not specifically address this.
WG 14 recommendation	If examination of the circuit arrangements suggests that there might be a problem, tests should be repeated for other SUPPLY MAINS modalities.

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2.2.17 ENCLOSURE and protective covers: EQUIPMENT in ambulances

IEC/SC 62A/WG 14 Recommendation No. 17.

Problem raised in: BSI document 94/501410

Requirement, clause no.	16 ENCLOSURES and protective covers. EQUIPMENT shall be so constructed and enclosed that there is adequate protection against contact with LIVE parts..... 20.1 A-a_1 Dielectric strength between LIVE parts and accessible metal parts. 19.2 SINGLE FAULT CONDITIONS.
Test clause no.	16, 20, 19.2
Source/problem	BSI document 94/501410 Some EQUIPMENT, designed for use in ambulances and operated from the vehicle d.c. supply, connect the negative side of the supply to the enclosure. Is this acceptable?
Discussion/comment	It could be argued that since a vehicle d.c. supply's negative pole is commonly connected to the vehicle chassis, this pole cannot become LIVE. However the possibility remains of the MAINS PLUG or MAINS CONNECTOR being incorrectly wired or connected, which would cause the EQUIPMENT ENCLOSURE to assume the full voltage of the SUPPLY MAINS. There is also the possibility of interruption of the negative pole of the supply, which would result in excessive ENCLOSURE LEAKAGE CURRENT. Although this could be prevented by a PROTECTIVE EARTH CONDUCTOR, which would then have to carry the continuous full load current, the WG does not think that this would be desirable.
WG 14 recommendation	Connection of the negative side of the d.c. mains to the ENCLOSURE should not be permitted. The insulation between all poles of the supply and the ENCLOSURE shall comply with 20.1 A-a_1 and A-a_2

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2.2.18 Dielectric strength: Voltages appearing from external sources

IEC/SC 62A/WG 14 Recommendation No. 18.

Problem raised in: BSI interpretation 64-68/158-159

Requirement, clause no.	Clause 20. Dielectric strength. 20.1. General requirements for all types of EQUIPMENT A-k ..... This insulation need not be investigated separately if at least one of the following conditions is satisfied: a) The voltages appearing on the SIGNAL INPUT PART or SIGNAL OUTPUT PART in NORMAL USE do not exceed SAFETY EXTRA-LOW VOLTAGE. b) The LEAKAGE CURRENTS do not exceed the allowable values in SINGLE FAULT CONDITION in the event of any single component failure in the SIGNAL INPUT PART or SIGNAL OUTPUT PART. d) The SIGNAL INPUT PARTS or SIGNAL OUTPUT PARTS are designated by the manufacturer for connection to EQUIPMENT in situations where no risk of external voltage exists (see IEC 60601-1-1).
Test clause no.	20.1
Source/problem	BSI interpretation 64-68/158-159 I) Does exemption a) refer to voltages arising within the EQUIPMENT, to voltages appearing from external sources, or both? ii) Does exemption b) refer to the SINGLE FAULT CONDITION of MAINS VOLTAGE on the SIP or SOP? Is insulation which ensures absence of excessive LEAKAGE CURRENTS not to be tested? iii) For exemption d) to apply, does the manufacturer have to restrict connection of the SIP and SOP to other MEDICAL ELECTRICAL EQUIPMENT or can connection to non-medical equipment be permitted, subject to some restrictions?
Discussion/comment	a) is intended to cover the working voltages on the SIP or SOP in NORMAL USE regardless of their origin. b) is intended to cover the SINGLE FAULT CONDITION caused by a component failure within the SIP or SOP in NORMAL USE. d) exemption does not allow connection to equipment, only EQUIPMENT, as defined, is covered.
WG 14 recommendation	i) a) applies only if the voltages within the SIP and SOP are less than SAFETY EXTRA-LOW VOLTAGE when connected to EQUIPMENT consistent with the instructions for use. ii) b) applies to a SINGLE FAULT CONDITION resulting from a single component failure within the SIP or SOP in NORMAL USE, i.e. connected as specified in the instructions for use. If such a SINGLE FAULT CONDITION does not produce excessive LEAKAGE CURRENTS then no additional insulation test is needed. iii) d) According to IEC 60601-1-1, this applies only if the manufacturer restricts connection of MEDICAL ELECTRICAL EQUIPMENT or non-MEDICAL ELECTRICAL EQUIPMENT which comply with relevant IEC and ISO safety standards to the SIP/SOPs.

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2.2.19 Testing switch mode power supply units (SMPSU)

IEC/SC 62A/WG 14 Recommendation No. 19

Problem raised in: 62A/WG14 (Piestany/Hagiwara)1

Requirement, clause no.	Testing switch mode power supply units (SMPSU)
Test clause no.	7.1, 15 b), 19, 20, 42, 52.5.1, 52.5.9, 57
Source/problem	SMPSU are not addressed in IEC 60601-1 (see Appendix A, 57.9). Reference voltage in SMPSU can be measured in different manners. Specifity of SMPSU leads to difficulties when applying requirements of 60601-1.
Discussion/comment	The following items have to be taken into account: 7.1 power input; 15 b) limitation of voltage and/or energy; 19 continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS, (For the time being, SMPSUs which use frequency higher than 1 MHz should not be used for EQUIPMENT which have a direct conductive connection to the heart); 20 dielectric strength; 42 excessive temperatures; 52.5.1 overloading of mains supply transformers; 52.5.9 failure of components 57.10 CREEPAGE DISTANCES and AIR CLEARANCES.

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WG 14 recommendation	7.1	According to 6.1 j) (power factor is often lower than 0,9).
	15 b)	Idem described but read only capacitor instead of interference suppression capacitor in “The test between lines shall not be performed if interference suppression capacitor....”.
	19	No recommendation, shall be addressed by relevant WG for next edition.
	20	Between components and between inputs and outputs of SMPSU. Reference voltage: mains voltage (even if testing value is more severe for components like optical isolator) or SMPSU being in normal use, by measurement of reference voltage (RMS) between components: transformers, optical isolators,... (in using a 2 channels differential oscilloscope : Ref. O V and neutral grounded to earth);
	42	Tested together with the equipment (depends on the load, fans, location, etc....).
	52.5.1	Test according to 57.9.1 b) fourth dash, fifth dot. The power supply is loaded on the output. If the SMPSU is protected against overload by an electronic device, the device is bridged during the test. The electronic device does not need to be bridged if every defect in the SMPSU can be discovered or lead to an inoperability.
	52.5.9	Tests like described. If not already covered by a component failure, a short-circuit shall be applied directly across the transformer secondary windings. (short-circuiting across the transformer secondary windings ensures there is no safety hazards in the event of short-circuit in the windings of the transformer, taking into account that there is no dielectric strength tests 5 times the voltage: 57.9.2)
	57.10	By using reference voltage measured or evaluated at Clause 20.

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2.2.20 Failure of an electrical component: Time periodicity for detection

IEC/SC 62A/WG 14 Recommendation No. 20

Problem raised in: 62A/WG14 (Milan)5

Requirement, clause no.	Condition in which a single means for protection against a SAFETY HAZARD in EQUIPMENT is defective or a single external abnormal condition is present. Failure of an electrical component which might cause a SAFETY HAZARD
Test clause no.	2.10.11, 3.6 f)
Source/problem	Shall a fault which remains undetected be considered as NORMAL CONDITION (NC) or SINGLE FAULT CONDITION (SFC)? If every fault is considered as SFC, regardless of whether it is detected or not, the consequence will be that there is no protection required against situations where an undetected first fault is followed by a second fault which may cause a SAFETY HAZARD.
Discussion/comment	See Annex A, rationale for subclause 3.6 item d) – a single fault is discovered and remedied by periodic inspection and maintenance which is prescribed in the instructions for use. Also autotest when switching on can check the protective device. A faulty condition becomes a SFC when detected. Reaction time after a SFC (when detected) should be also taken into account.
WG 14 recommendation	If a fault is not detected (for example by periodic inspection, maintenance, autotest, etc ...), it shall not be considered as a SINGLE FAULT CONDITION. Time periodicity for the detection of fault depends on risks analysis

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2.2.21 Environmental conditions: Compliance paragraph

IEC/SC 62A/WG 14 Recommendation No. 21

Problem raised in: 62A/WG14 (Milan)6

Requirement, clause no.	Environmental conditions
Test clause no.	10.1, 10.2
Source/problem	Compliance with the conditions of 10.2 is checked by application of the tests of this standard. 10.1 is no longer included in IEC 60601-1: in Amendment 2 replaced by "EQUIPMENT shall be capable, while...environmental conditions as stated by the manufacturer (see 6.8.3 d)".
Discussion/comment	Instead of "EQUIPMENT shall be capable ...", we should read something like : After packaging, transport and storage, the EQUIPMENT shall be in compliance with the standard. Subclause 10.1 does not contain any compliance paragraph, therefore we recommend that a compliance paragraph should be added and further work is needed.
WG 14 recommendation	EQUIPMENT shall comply with the requirements of this standard after being exposed to the environmental conditions as stated by the manufacturer. Compliance may be checked by testing and/or inspection of documentary evidence.

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2.2.22 Limitation of voltage and/or energy: Capacitance

IEC/SC 62A/WG 14 Recommendation No. 22

Problem raised in: 62A/WG14 (Milan)4

Requirement, clause no.	"The tests between lines and ENCLOSURE shall not be performed if interference suppression capacitors are used...." "The tests between lines shall not be performed if interference suppression capacitors are used...."
Test clause no.	15 b)
Source/problem	In most EQUIPMENT, interference suppression capacitors are not the only capacitance used.
Discussion/comment	Replace "interference suppression capacitor" by "the measured capacitance" for 3rd edition.
WG 14 recommendation	To measure the capacitance between lines and ENCLOSURE and between lines.

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2.2.23 LEAKAGE CURRENTS: Presence of 45 kΩ resistor in Figure 21

IEC/SC 62A/WG 14 Recommendation No. 23

Problem raised in: 62A/WG14 (Milan)4

Requirement, clause no.	In Figure 21, presence of a resistance of 45 kΩ resistor
Test clause no.	19
Source/problem	Because of the 45 kΩ resistor, the current is always limited to 5 mA, and the limit is 5 mA.
Discussion/comment	
WG 14 recommendation	For first edition, use the method of 2nd edition (use any resistance). For 2nd edition, instead of using any resistance, you may also use alteration of the voltage or fuses.

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2.2.24 Humidity preconditioning treatment: Exception from requirement

IEC/SC 62A/WG 14 Recommendation No. 24

Problem raised in: 62A(Sec)140A (USA)

Requirement, clause no.	4.10 Humidity preconditioning treatment
Test clause no.	4.10 (is a test clause)
Source/problem	Should this test be applied to EQUIPMENT which is permanently installed and operated only in a controlled temperature and humidity conditions as specified in the ACCOMPANYING DOCUMENTS.
Discussion/comment	Certain EQUIPMENT is permanently installed and operated in controlled temperature and humidity conditions. Nevertheless IEC 60601-1 requires equipment to comply with all the relevant parts of the standard when exposed to the environmental conditions specified in 10.2.1, even though the operating conditions may be restricted, as allowed in 6.8.3.
WG 14 recommendation	No exception can be made from the requirements of 4.10. However, attention is drawn to the 3rd paragraph: *The test shall be applied only to those EQUIPMENT parts likely to create a SAFETY HAZARD when influenced by the climatic conditions that are simulated by the test.*

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2.2.25 Dielectric strength: EQUIPMENT containing floating circuits

IEC/SC 62A/WG 14 Recommendation No. 25

Problem raised in: SC/62A(Sydney)8

Requirement, clause no.	20 Dielectric strength 20.2 Requirements for EQUIPMENT with an APPLIED PART. (B-e requirement).
Test clause no.	20.4
Source/problem	An EQUIPMENT may contain floating circuits which under the definition 2.1.10 would not be considered as LIVE, since contact with these parts could not result in excessive leakage currents to earth or to other ACCESSIBLE PARTS. There would therefore appear to be no requirements for safety separation between these circuits and ACCESSIBLE PART or APPLIED PARTS. But voltages within these circuits or in conjunction with other circuits may lead to currents exceeding the values given in Table IV.
Discussion/comment	There are two possibilities for solving this problem. One is to change the definition of LIVE and adopt the requirements for insulation accordingly. The second is to treat the separation of the isolated circuits as subject to failure. If one pole of the isolated circuit is short-circuited to earth (failure of insulation), then the other pole becomes LIVE and the adequacy of the separation of this LIVE part under these conditions may be assessed. If that separation is inadequate, then it should be short-circuited in turn to assess the separation on the other pole. Since for an isolated circuit there may be two separate protective insulations (on either pole), WG14 proposes that each of these can be BASIC INSULATION rather than BASIC and SUPPLEMENTARY INSULATION. Of course other combinations may be used, although if the insulation of one pole is less than BASIC INSULATION then the other pole must have DOUBLE INSULATION or REINFORCED INSULATION.
WG 14 recommendation	If the failure of insulation of such isolated circuits is likely to lead to a SAFETY HAZARD, such insulation should be short-circuited before determining whether a part is LIVE. This short-circuit should not be treated as a SINGLE FAULT CONDITION unless the insulation concerned satisfies the requirements for BASIC or SUPPLEMENTARY INSULATION necessary for the voltages within the isolated part. WG16 is to include this problem in discussing insulation requirements in the 3rd edition.

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2.2.26 General requirements for tests: Measurement uncertainty

IEC/SC 62A/WG 14 Recommendation No. 26

Problem raised in: Australian draft document Supplement 1. to AS 3200-1 (technically equivalent to IEC 60601-1)

Requirement, clause no.	All requiring measurements
Test clause no.	All requiring measurements
Source/problem	The Australian document proposes that measurement uncertainty should be stated in the standard for many physical and electrical parameters.
Discussion/comment	The WG decided that measurement uncertainty should not generally be part of any revision to the standard.
WG 14 recommendation	Test laboratories should deal with measurement uncertainty in line with the requirements of 5.4.6 of ISO/IEC 17205:1999.

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2.2.27 CREEPAGE DISTANCES and AIR CLEARANCES: Interpolated values

IEC/SC 62A/WG 14 Recommendation No. 27

Problem raised in: SC 62A/WG 14(Sweden)5

Requirement, clause no.	20 Dielectric strength 20.3 Values of test voltages 57.10 CREEPAGE DISTANCE and AIR CLEARANCES
Test clause no.	20. 57.10 d)
Source/problem	The reference voltage (*U*) as used in Table V is the voltage to which the relevant insulation is subjected in NORMAL USE and at RATED supply voltage or a voltage specified by the manufacturer, whichever is the greater. The value of the reference voltage (*U*) is as given in 20.3. In case the reference voltage has a value between those given in Table XVI, the higher of the two values shall be applied.
Discussion/comment	Assume the following case. An EQUIPMENT with functionally earthed secondary circuits or a floating accessible secondary SIGNAL INPUT PART or SIGNAL OUTPUT PART. Mains (primary) voltage 230 V and a nominal secondary voltage of 24 V, a very common application. Theoretically the voltage the insulation is subjected to will be the sum of the two voltages above. Hence it follows that the reference voltage will 254 V. The relevant dielectric strength test for A-e, see 20.1, will then be 4 016 V for DOUBLE INSULATION or REINFORCED INSULATION. The corresponding requirement for CREEPAGE DISTANCE and AIR CLEARANCES will, on the other hand be 12 mm and 7 mm respectively. Is it the intention of the standard that 20.3 and 57.10 are not aligned (continuity in Table V but discontinuity in Table XVI for reference voltages above 250 V) or is this a misinterpretation?
WG 14 recommendation	To avoid application of sudden increases in CREEPAGE DISTANCE and AIR CLEARANCE it is recommended that interpolated values between reference voltages in Table XVI be used to determine these values.

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2.2.28 Overheating: Change of load resistance

IEC/SC 62A/WG 14 Recommendation No. 28

Problem raised in: SC 62A/WG 14(Sweden)6

Requirement, clause no.	57.9 Mains supply transformers. 57.9.1 b) Overload Mains supply transformers including their protective devices, if any, are tested in conditions of normal operation: .... - the section or winding of the transformer under overload is loaded as follows: • Mains supply transformers having fuses in accordance with IEC 60127 and IEC 60241 as protective devices, are loaded for 30 minutes and 1 hr respectively, so that the test current in the fused circuit is in accordance with Table XX with the fuses replaced by links of negligible impedance.
Test clause no.	57.9.1 b)
Source/problem	Swedish comment: Practically the test is performed with the winding under overload connected to a resistor with the resistance value that yields the correct test current in accordance with Table XX. As the windings get heated during the test their resistance increases and one has to decrease the value of the load resistor to keep the current in the fused circuit in accordance with Table XX during the test. Since the decrease of current is a result of the increase in the winding's temperature, it seems to be an unrealistic fault condition to keep the current in the fused circuit unchanged instead of keeping the load resistance unchanged.
Discussion/comment	Canadian comment: Although the winding resistance increases requiring a decrease in the load resistance to maintain the test current, this would present a worst-case test. The overload test is based on the protective device characteristics. The test current must remain constant because it is not known what will happen in the abnormal conditions. The only known factor is the criteria for the protective device.
WG 14 recommendation	Endorse the Canadian comment. The test load current must be maintained at its original value

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2.2.29 Mains operated EQUIPMENT with additional power source: Integrity of external protective earth

IEC/SC 62A/WG 14 Recommendation No. 29

Problem raised in: SC 62A/WG 14(Sweden)7

Requirement, clause no.	6.8.2 Instructions for use. 6.8.2 e) Mains operated EQUIPMENT with additional power source. If CLASS I EQUIPMENT is specified for operation connected to a SUPPLY MAINS and alternatively using an INTERNAL ELECTRICAL POWER SOURCE, instructions for use shall contain a statement saying that where the integrity of the external protective conductor in the installation or its arrangement is in doubt, EQUIPMENT shall be operated from its INTERNAL ELECTRICAL POWER SOURCE.
Test clause no.	6.8
Source/problem	Swedish comment: The requirement seems to be a little unreasonable. Assume for example, an EQUIPMENT with an internal battery intended for back-up power in the event of a failure of the SUPPLY MAINS as a power source. Further, how can one say whether the external PROTECTIVE EARTH CONDUCTOR arrangement is in doubt or not?
Discussion/comment	This appears to be directed at EQUIPMENT used in the home, where the integrity of the protective earth may be less certain. The WG would be happy to see this subclause removed altogether. The recommendation is intended to draw an unskilled user's attention to the importance of protective earthing.
WG 14 Recommendation	The instructions for use shall include for CLASS I EQUIPMENT the following statement: "WARNING: THIS EQUIPMENT MUST ONLY BE CONNECTED TO A SUPPLY MAINS WITH PROTECTIVE EARTH."

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2.2.30 Rechargeable batteries: No OPERATOR/USER maintenance

IEC/SC 62A/WG 14 Recommendation No. 30

Problem raised in: SC 62A/WG 14(Sweden)8

Requirement, clause no.	6.8.2 Instructions for use. 6.8.2 g) Rechargeable batteries Instructions for use of EQUIPMENT containing rechargeable batteries shall contain instructions to ensure safe use and adequate maintenance.
Test clause no.	6.8
Source/problem	Swedish comment: The standard does not make any exceptions for rechargeable batteries permanently mounted in EQUIPMENT, not intended to be maintained by the operator. For example batteries that supply audible alarms. The requirement should only be applicable for batteries that are exclusively intended to be maintained by the OPERATOR and/or where risk of overcharging is present.
Discussion/comment	WG fully agrees with the Swedish comment.
WG 14 Recommendation	Where batteries are completely free of OPERATOR/USER maintenance, the instructions for use shall contain a statement to that effect.

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2.2.31 Isolation from the SUPPLY MAINS: Symbol for single pole switch

IEC/SC 62A/WG 14 Recommendation No. 31

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

Requirement, clause no.	57.1 Isolation from the SUPPLY MAINS 57.1 a) Isolation – EQUIPMENT shall have means to isolate its circuits electrically from the SUPPLY MAINS on all poles simultaneously. This isolation shall include each LIVE supply conductor, except that PERMANENTLY INSTALLED EQUIPMENT connected to a polyphase SUPPLY MAINS may be provided with a device which does not interrupt the neutral conductor, but only if local installation conditions are such that in NORMAL CONDITION the voltage on the neutral conductor can be expected not to exceed extra-low voltage. – Means for isolation shall either be incorporated in EQUIPMENT or, if external shall be specified in the ACCOMPANYING DOCUMENTS (see 6.8.3). 57.1 h) In non-PERMANENTLY INSTALLED EQUIPMENT a suitable plug device used to isolate EQUIPMENT from the SUPPLY MAINS shall be considered as complying with the requirements of 57.1 a). APPLIANCE COUPLERS and flexible cords with MAINS PLUGS are suitable plug devices.
Test clause no.	57.1
Source/problem	Swedish comment: Is single phase non-PERMANENTLY INSTALLED EQUIPMENT with a suitable plug device according to item h) of 57.1 allowed to incorporate a switch that isolates its circuits electrically from only one SUPPLY MAINS pole? How shall the different positions of the switch be indicated?
Discussion/comment	Yes, the Standard clearly permits such a switch. The use of symbols 15 and 16 is however prohibited for such functional switches.
WG 14 recommendation	Symbols used on functional switches shall not use symbols 15 and 16. Any symbol used must be reproduced and fully explained in the Instructions for use. Suitable symbols from IEC 60417 could be 5009, 5264 and 5265.

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2.2.32 Sequence of testing: Clause 52 before Clause 19

IEC/SC 62A/WG 14 Recommendation No. 32

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

Requirement, clause no.	Appendix C. Sequence of testing C.1 General: Tests should, if applicable, be carried out in the sequence indicated below, unless otherwise stated by Particular Standards. The sequence of the tests marked by an * is mandatory. See also 4.11. However, this does not preclude the possibility of conducting a test which preliminary inspection suggests might cause failure. 19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS.
Test clause no.	19.4 Tests 19.4 a) General 1) The EARTH LEAKAGE CURRENT, the ENCLOSURE LEAKAGE CURRENT, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT are measured: - after the EQUIPMENT has been brought to operating temperature in accordance with the requirements of Section Seven.
Source/problem	Swedish comment: The standard states that a test under abnormal operations and fault conditions, Clause 52, shall be performed before the measurements of LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS at operating temperature, even if the tests might cause failure. If those tests cause failures that make the EQUIPMENT unable to operate in NORMAL USE and NORMAL CONDITION, the measurement of LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS at operating temperatures will be impossible.
Discussion/comment	WG agrees with the Swedish comment.
WG 14 recommendation	In Appendix C ignore all * and the second sentence in C1, “The sequence of tests marked by an * is mandatory”.

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2.2.33 SINGLE FAULT CONDITION: ENCLOSURE LEAKAGE CURRENT from INTERNALLY POWERED EQUIPMENT

IEC/SC 62A/WG 14 Recommendation No. 33

Problem raised in: SC 62A/WG 14(Sweden)11

Requirement, clause no.	19. SINGLE FAULT CONDITIONS 19.2 c) Additionally the ENCLOSURE LEAKAGE CURRENT shall be measured with a voltage equal to 110 % of the highest RATED MAINS VOLTAGE applied between earth and any SIGNAL INPUT PART or SIGNAL OUTPUT PART.
Test clause no.	19.4 g) Measurement of the ENCLOSURE LEAKAGE CURRENT 3) EQUIPMENT specified for connection to an SELV-source and INTERNALLY POWERED EQUIPMENT are tested for ENCLOSURE LEAKAGE CURRENT flowing between different parts of the ENCLOSURE (measuring device applied as MD2 in Figure 18) Figure 18: Measuring circuit for ENCLOSURE LEAKAGE CURRENT.
Source/problem	Swedish comment: Since INTERNALLY POWERED EQUIPMENT has no reference to earth, the ENCLOSURE LEAKAGE CURRENT flowing between different parts of the ENCLOSURE will not be affected by an external voltage applied between earth and a SIGNAL INPUT PART or SIGNAL OUTPUT PART. Therefore, the ENCLOSURE LEAKAGE CURRENT for INTERNALLY POWERED EQUIPMENT caused by such a voltage, should be measured as for CLASS II EQUIPMENT with MD1 between the ENCLOSURE and earth according to Figure 18. Further, the external voltage to be applied should be specified in item g) 3) of 19.4, in a similar way as in item h) 8) of 19.4 and Figure 25 (Measurement of the PATIENT LEAKAGE CURRENT flowing from the APPLIED PART to earth, caused by an external voltage between earth and any SIGNAL INPUT PART or SIGNAL OUTPUT PART), except that supply frequency does not apply for EQUIPMENT with an internal battery.
Discussion/comment	WG agrees with Swedish comment.
WG 14 recommendation	Modify item g) 3) of 19.4 to read: ....."and INTERNALLY POWERED EQUIPMENT are tested for ENCLOSURE LEAKAGE CURRENT flowing between the ENCLOSURE and earth and also between different parts of the ENCLOSURE (measuring device applied as MD1 and MD2 in Figure 18)."

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2.2.34 Marking on the outside of EQUIPMENT: Type and rating of fuses

IEC/SC 62A/WG 14 Recommendation No. 34

Problem raised in: SC 62A/WG 14(Sweden)12

Requirement, clause no.	6.1. Marking on the outside of EQUIPMENT or EQUIPMENT parts 6.1 n). Fuses. The type and rating of fuses accessible from the outside of EQUIPMENT shall be marked adjacent to the fuse-holder.
Test clause no.	6.1
Source/problem	Swedish comment: Shall fuse-holders intended for fuses in accordance with EN 60127 (IEC 60127) be provided with adjacent complete marking according to the requirements in these standards or can, for example, the rated voltage be omitted? See Clause 6, Marking, of IEC 60127-1:1988 and IEC 60127-2:1989.
Discussion/comment	This requirement is interpreted as meaning that the marked 'rating' should include the rated current, voltage, fuse characteristic and high (H) or low (L) breaking capacity designation in accordance with the relevant fuse standard.
WG 14 recommendation	The marking shall be in accordance with the applicable fuse standard.

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2.2.35 Excessive temperatures: APPLIED PARTS not intended to supply heat

IEC/SC 62A/WG 14 Recommendation No. 35

Problem raised in: National comments

Requirement, clause no.	42 Excessive temperatures. 42.3. APPLIED PARTS of EQUIPMENT not intended to supply heat to a patient shall not have surface temperatures exceeding 41 °C
Test clause no.	42
Source/problem	UK comment: It is not clear at what ambient temperature the limit of 41 °C should be applied. The temperature range of 10 °C to 40 °C stated in 10.2 applies to Table Xa and would appear to apply in this instance. Is a 1 °C temperature difference correct or realistic?
Discussion/comment	It may be possible to consider a reduced maximum ambient temperature, say 35 °C, if that is stated by the manufacturer in the instructions for use.
WG 14 recommendation	When not otherwise specified by the manufacturer, the limit of 41 °C at an ambient temperature of 40 °C must be applied in NORMAL CONDITION or SINGLE FAULT CONDITION except were there is a medical justification for a higher limit/temperature rise. This requirement should be addressed in Particular Standards.

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2.2.36 Mains supply transformers: Use of PTCs as protective devices

IEC/SC 62A/WG 14 Recommendation No. 36

Problem raised in: SC 62A/WG 14/Milan/8

Requirement, clause no.	57.9 b) Mains supply transformers. Overload
Test clause no.	
Source/problem	Is it permitted to use a PTC as a protective device and what should be the overload test?
Discussion/comment	WG14 does not foresee any technical reason why not, however there is concern about the reliability of such devices.
WG 14 recommendation	Where a PTC is used as a protective device for a mains supply transformer, the requirements for THERMAL CUT-OUTS as required by 57.9 shall be applied. They shall be in accordance with international or national standards which address the reliability of these components, e.g. as specified in 2.11 of IEC 60950:1991 (Amendment 4:1996).

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2.2.37 Components and general assembly: Reliability of components

IEC/SC 62A/WG 14 Recommendation No. 37

Problem raised in: SC 62A/WG 14

Requirement, clause no.	56 Components and general assembly
Test clause no.	
Source/problem	56.1 b) requires that ratings of components shall not conflict with the conditions of use in EQUIPMENT. There are no requirements for components themselves to meet specific standards which include the control of reliability.
Discussion/comment	WG14 is concerned that components, particularly in the MAINS PART and in APPLIED PARTS, are not required to have any proof of their suitability.
WG 14 recommendation	WG14 strongly recommends that components in the MAINS PART and in APPLIED PARTS should comply with recognised component standards, consistent with their use. WG14 suggests the following hierarchy of acceptable standards: International standards (e.g. IEC, ISO etc.) National standards (e.g. BSI, DIN, UL etc.) Component manufacturer standards, covered by suitable quality control procedures. The manufacturer's tests and controls, supported by appropriate technical documentation.

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2.2.38 Definition of APPLIED PART: EQUIPMENT worn by PATIENTS

IEC/SC 62A/WG 14 Recommendation No. 38

Problem raised in: WG14/London/1 62A/WG14 (Canada)11

Requirement, clause no.	2.1.5 APPLIED PART (second dash) – can be brought into contact with the PATIENT; or
Test clause no.	2.1.5, 42
Source/problem	EQUIPMENT worn by the patient, such as an ambulatory ECG system or an ambulatory recorder, is now considered as an APPLIED PART in addition to the associated electrodes and cables. Subclause 42.3 does not allow surface temperature exceeding 41 °C for an APPLIED PART and, according to 3.1 EQUIPMENT, shall cause no safety hazard in NORMAL CONDITION and in SINGLE FAULT CONDITION. Very often the EQUIPMENT exceeds the temperature limit of 41 °C under the above testing conditions.
Discussion/comment	Since the special temperature limits have been set for PATIENT contact, would the patient clothing (if the manufacturer specifies that the EQUIPMENT should not be worn directly on the body) change the classification?
WG 14 recommendation	The instructions for use shall advise that the recorder is not to be worn in contact with the skin. The ENCLOSURE is therefore not considered as an APPLIED PART and should comply with "Equipment parts which may in normal use have a brief contact with a patient 50 °C" of Table Xa.

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2.2.39 Construction: Triple insulated winding wire

IEC/SC 62A/WG 14 Recommendation No. 39

Problem raised in: WG14/London/1, 62A/WG14 (Canada)12

Requirement, clause no.	57.9 Mains supply transformers 57.9.4 Construction
Test clause no.	Compliance with the requirements is checked by inspection
Source/problem	Many manufacturers are using a triple insulated winding wire on a transformer, where BASIC, DOUBLE , or REINFORCED INSULATION is required between the primary and the secondary windings
Discussion/comment	Subclause 2.9.4.4 of IEC 60950:1991 (Amendment 3:1995 and Amendment 4:1996), requires such winding wire to meet the requirements of its Annex U. Can we follow a similar practice for equipment evaluated to IEC 60601-1?
WG 14 recommendation	In principle WG 14 agrees, but precautions should be taken concerning possible mechanical damages to the wires. Other requirements of 57.9 shall be applied.

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2.2.40 CREEPAGE DISTANCES and AIR CLEARANCES: Dielectric strength test versus CREEPAGE DISTANCES and AIR CLEARANCES

IEC/SC 62A/WG 14 Recommendation No. 40

Problem raised in: WG14/London/1; 62A/WG14 (Canada)13

Requirement, clause no.	57.10 CREEPAGE DISTANCES and AIR CLEARANCES
Test clause no.	Compliance with item d) of 57.10 is checked by inspection and measurement.
Source/problem	In many instances, it is not possible to comply with CREEPAGE DISTANCES and AIR CLEARANCES without major redesign of the EQUIPMENT.
Discussion/comment	Would it be acceptable, in cases where the dielectric strength test is satisfactory, to accept reduced CREEPAGE DISTANCES on PCB, providing satisfactory conformal coating is applied and satisfactory thermal aging and thermal cycling tests are performed as specified in IEC 60950-1?
WG 14 recommendation	A necessary redesign is not a reason for reducing the CREEPAGE DISTANCES. But WG14 has the feeling that the values of CREEPAGE DISTANCES in Table XVI are very conservative. A reduction of CREEPAGE DISTANCES similar to those outlined in 57.9.4 f) first dash are acceptable after introducing conformal coating. By using the tests in 2.9.5 of IEC 60950:1991 [as amended], a reduction could be allowed of the CREEPAGE DISTANCES in Table XVI to the level in the preceding column. WG16 is requested to take into account the effects of conformal coatings in their discussions about insulation coordination

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2.2.41 Cord anchorages/ Cord guards: In mobile unit with APPLIANCE COUPLER

IEC/SC 62A/WG 14 Recommendation No. 41

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

Requirement, clause no.	57.4 Connection of POWER SUPPLY CORDS
Test clause no.	57.4 a) Cord anchorages: EQUIPMENT and MAINS CONNECTORS provided with POWER SUPPLY CORDS shall have cord-anchorages such that the conductors are relieved from strain, including twisting, where they are connected within the EQUIPMENT and within the MAINS CONNECTORS and the insulation of the conductors is protected from abrasion. 57.4 b) Cord guards: POWER SUPPLY CORDS of other than STATIONARY EQUIPMENT shall be protected against excessive bending at the inlet opening of EQUIPMENT by means of a cord guard of insulating material.
Source/problem	In a mobile unit (with power supply cord attached), due to an excessive amount of mobility of the EQUIPMENT, it is possible that it can damage internal parts of the APPLIANCE COUPLER which eventually could result in fire.
Discussion/comment	If the APPLIANCE COUPLER complies with IEC 60320, WG 14 sees no possibility of applying additional requirements. Up to now this was the first case which was brought to the knowledge of WG 14. If more cases arise with the same reasons for damages, WG 14 proposes for the third edition to restrict the use of appliance couplers to equipment with limited mobility.
WG 14 recommendation	If the APPLIANCE COUPLER is not according to IEC 60320, apply the tests according to 57.4.

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2.2.42 ACCOMPANYING DOCUMENTS: on CD-ROM or Electronic File Format

IEC/SC 62A/WG 14 Recommendation No. 42

Problem raised in: WG14/London/2; 62A/WG14 (Canada)15

Requirement, clause no.	6.8 ACCOMPANYING DOCUMENTS
Test clause no.	6.8.1
Source/problem	1) Is it a MUST that ACCOMPANYING DOCUMENTS shall be provided as hard copy? 2) What if ACCOMPANYING DOCUMENTS are provided either on CD-ROM or electronic file format?
Discussion/comment	
WG 14 recommendation	1) Agree that ACCOMPANYING DOCUMENTS may be in electronic format if acceptable to the USER. 2) WG 14 draws attention to the fact that at least that part concerned with SAFETY FACTORS shall be readable with the EQUIPMENT in NORMAL USE and without interrupting a clinical procedure. A risk analysis will indicate whether hard copy is necessary to cover emergency procedures, e.g. resulting from power failures.

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2.2.43 INTERNAL ELECTRICAL POWER SOURCE: Requirements for lithium batteries

IEC/SC 62A/WG 14 Recommendation No. 43

Problem raised in: WG14/London/3; 62A/WG14(Norway)1/97

Requirement, clause no.	56.7 Batteries
Test clause no.	
Source/problem	No specific requirements for lithium batteries
Discussion/comment	IEC 60950 has requirements for lithium batteries. 6.2 d), 56.7 and 52.5.9 in IEC 60601-1 cover already the requirements of 1.7.17 and 4.3.21 in IEC 60950:1991 [as amended].
WG 14 recommendation	The requirements of 6.2 d), 52.5.9 and 56.7 in IEC 60601-1 have to be applied to lithium batteries.

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2.2.44 Dielectric strength: Differences between B-d and B-e

IEC/SC 62A/WG 14 Recommendation No. 44

Problem raised in: WG14/London/3; 62A/WG14 (Norway)2/97

Requirement, clause no.	20.2 B-d and B-e
Test clause no.	
Source/problem	1) Different interpretations may occur about whether to use B-d or B-e to state the correct insulation level between an F-TYPE APPLIED PART and the ENCLOSURE. 2) B-e refers to "voltages stressing the insulation". What is a hazardous voltage stressing an insulation?
Discussion/comment	B-d insulation is required for F-TYPE APPLIED PARTS. B-e insulation is required for F-TYPE APPLIED PARTS containing internal voltages, with a reference voltage equal to the internal voltage. The second sentence in the statement in 20.3 concerning the reference voltage between an F-TYPE APPLIED PARTS and the ENCLOSURE, applies to B-d only and not to B-e.
WG 14 recommendation	B-d is always applicable for a F-TYPE APPLIED PARTS. *U* equals maximum RATED supply voltage; or, 250 V for INTERNALLY POWERED EQUIPMENT. BASIC INSULATION IS required. In addition B-e is also applicable if there is a voltage in the F-TYPE APPLIED PART. *U* equals the voltage stressing the insulation in NORMAL USE including earthing of any PATIENT connection.

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2.2.45 Excessive temperatures: Thermocouple instead of resistance method

IEC/SC 62A/WG 14 Recommendation No. 45

Problem raised in: WG14/London/3; 62A/WG14(Norway)3/97

Requirement, clause no.	42 Excessive temperature
Test clause no.	42
Source/problem	Use of thermocouple instead of resistance method? Allowable values Table Xa and Table Xb to be reduced by 10 °C if temperature determined by thermocouples (like 5.11 of IEC 60950:1991)?
Discussion/comment	Use of thermocouple may be acceptable (see 42.3.4 ".....unless the windings are non-uniform or severe complications are involved....")
WG 14 recommendation	The allowable maximum temperatures given in Table Xa and Table Xb apply, regardless of the test method. However, the systematic errors and uncertainties in any measurement must be considered when comparing the measured value to the required value.

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