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TECHNICAL REPORT

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

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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CONTENTS

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*.

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

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

Enquiry draft	Report on voting
62A/621/DTR	62A/632/RVC

Full information on the voting for the approval of this technical report can be found in the report on voting indicated in the above table.

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

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

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- withdrawn;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

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

INTRODUCTION

At the Sydney meeting in August 1994, IEC subcommittee (SC) 62A established a procedure under which working group (WG) 14 would develop recommendations regarding problems of interpretation or application of IEC 60601-1. WG 14 is made up of experts with particular expertise in testing according to the requirements of IEC 60601-1. Many of the experts on WG 14 are employed by test houses with a long history of applying IEC 60601-1 to MEDICAL ELECTRICAL EQUIPMENT. While the National Committee members of SC 62A nominate these experts, their recommendations were not to be formally adopted through any official voting procedure. To reinforce this process, the Subcommittee specifically directed that the following note appear on every page of the resulting informational circular:

> **IMPORTANT NOTE:** Per the 62A decision at Sydney (see RM3755/SC62A, August 1994), the 62A Secretary is circulating this recommendation, prepared by 62A/WG14, regarding problems of interpretation or application of IEC 60601-1 to all P-Member NC's.
>
> This recommendation/interpretation is the result of considerations by a group of nominated experts and has not been formally adopted through any NC voting procedure. Distribution is only for information.

The plan approved in Sydney called for the 62A Secretary to circulate these recommendations to the member National Committees via an informational (INF) document.

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

At the November 2000 meeting of SC 62A in Tokyo, the subcommittee discussed ways and means for achieving a wider distribution of the WG 14 recommendations. At the conclusion of this discussion, the subcommittee instructed the Secretariat to develop a technical report (TR) based on the published recommendations of WG 14. This technical report is intended to convey the results of WG 14's work to interested parties such as manufacturers and test houses while retaining the informative nature of the material.

This technical report may be amended from time to time as WG 14 prepares additional recommendations.

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

1 Scope and object

1.1 Scope

This technical report contains a series of recommendations developed by an expert working group of IEC subcommittee 62A in response to questions of interpretation of the second edition of IEC 60601-1.

This technical report is primarily intended to be used by:

– manufacturers of MEDICAL ELECTRICAL EQUIPMENT;

– test houses and others responsible for assessment of compliance with IEC 60601-1:1988, and

– those developing subsequent editions of IEC 60601-1.

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

1.2 Object

The object of this technical report is to make the recommendations/interpretations developed by the experts in IEC/SC 62A/WG 14 available to those interested in the application of the second edition of IEC 60601-1.

The reader is reminded that, although a majority of the National Committee members of IEC/SC 62A have approved publication of this technical report, the contents remain the opinion of the expert members of WG 14. These recommendations/interpretations are the result of considerations by this group of nominated experts and have not been formally adopted through any National Committee voting procedure. Distribution is only for information.

2 Recommendations

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

2.2 Recommendation sheets

2.2.1 Separation: Reliability of component impedance

IEC/SC 62A/WG14 Recommendation No. 1

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

Requirement, clause no.	17 Separation a) APPLIED PARTS shall be electrically separated from LIVE parts of EQUIPMENT in NORMAL CONDITION and in SINGLE FAULT CONDITION (see 3.6), in such a way that allowable LEAKAGE CURRENTS (see Clause 19) are not exceeded. g) ACCESSIBLE PARTS not being an APPLIED PART shall be electrically separated from LIVE parts of EQUIPMENT in NORMAL CONDITION and in SINGLE FAULT CONDITION (see 3.6) in such a way that allowable LEAKAGE CURRENTS are not exceeded (see Clause 19). This requirement may be fulfilled by one of the following methods: 17 a 5) Impedances of components prevent the flow to the APPLIED PART of a PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT exceeding the allowable values. 17 g 5) Impedances of components prevent the flow to the ACCESSIBLE PART of an ENCLOSURE LEAKAGE CURRENT exceeding the allowable value.
Test clause no.	Compliance with items a) and g) of Clause 17 is checked by inspection and measurement. If the CREEPAGE DISTANCE and/or AIR CLEARANCE between the APPLIED PART (ACCESSIBLE PARTS) and LIVE parts does not comply with the requirements of 57.10, such CREEPAGE DISTANCE and/or AIR CLEARANCE shall be short circuited. The LEAKAGE CURRENTS are measured as described in 19.4 and shall not exceed the limits for NORMAL CONDITION given in Table IV.
Source/Problem	SC 62A/WG 14(Canada)1 Component impedance is generally unreliable. Can components certified to IEC 60384-14 etc. be considered as high integrity? Is the impedance of a component sufficient? Does investigation of the product require further review of AIR CLEARANCE and CREEPAGE DISTANCE for such a component? Does this subclause mean that further component review is not required? SC 62A/WG 14(Canada)2 Assume mains to floating APPLIED PART does not comply with AIR CLEARANCE and CREEPAGE DISTANCE requirements. Mains to floating APPLIED PART isolation is short circuited. SC 62A/WG 14(Canada)4 If secondary circuit impedances limit the LEAKAGE CURRENT, is further investigation of secondary circuits required? (Refer to 52.5).
Discussion/comment	The problem is two-fold. Separation between LIVE PARTS and APPLIED PARTS/ACCESSIBLE PARTS is dependent on components (protective impedances) and/or AIR CLEARANCES and CREEPAGE DISTANCES. Subclause 52.5.9 requires that failure of components shall be investigated and especially those components which provide protective means. Subclause 17 requires compliance with the spacings, but if these spacings are inadequate, they shall be short circuited and LEAKAGE CURRENTS monitored. Referring to Canada 2, we assume that it refers to inadequate spacings which need to be short circuited. Up to now there are no requirements for components to be considered high integrity, but there are requirements for Y1 and Y2 capacitors.

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

2.2.2 Separation: Non-complying creepage distance and air clearances

IEC/SC 62A/WG14 Recommendation No. 2

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

Recommendation deleted: text implemented in recommendation No. 1	

2.2.3 Mains supply transformers: Overload test

IEC/SC 62A/WG14 Recommendation No. 3

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

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

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.

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.

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.

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).

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.

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.

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	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. The requirement is in line with IEC 60664-1 for pollution degree 2. It seems in IEC 60601-1 the assumption was made that EQUIPMENT would only be used in an environment equal to pollution degree 2 of IEC 60664-1.
WG 14 recommendation	AIR CLEARANCES less than 1 mm can not be used to meet the requirements for BASIC INSULATION.

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

Recommendation deleted: text implemented in recommendation No. 1	

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.	16d) 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" 16e) 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	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.

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.	56.10b) 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	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 56.10b). The adequacy of the mechanical stops, wherever located, is covered by 56.10b). 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.

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.	6.2d) 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	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	Requirements for associated circuits to the lithium battery are included in subclause 13.2.2 of IEC 61010-1:2001.
WG 14 recommendation	Although 6.8.3 addresses it in general, it is recommended that particular attention be drawn to this in the technical description.

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 ºC.
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	The manufacturer could specify higher ambient temperatures than 25 ºC. 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 ºC.
WG 14 recommendation	Table Xa gives the permissible temperature of materials for an ambient temperature of 40 ºC. Table Xb gives the permissible temperature of materials for an ambient temperature of 25 ºC. Tests will be conducted at ambient temperatures in the range 10 ºC to 40 ºC. The measured temperature obtained shall be corrected for an ambient temperature of either 40 ºC (Xa) or 25 ºC (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 ºC and the results of corrections.

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

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	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.

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	Some EQUIPMENT, designed for use in ambulances and operated from the vehicle d.c. supply, connects 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 BASIC INSULATION (for parts of opposite polarity) and DOUBLE INSULATION (between the supply and the ENCLOSURE).

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	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. See also Recommendation 58.

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 SMPSUs
Test clause no.	7.1, 15b, 19, 20, 42, 52.5.1, 52.5.9, 57
Source/Problem	SMPSU are not addressed in IEC 60601-1:1988 (see Appendix A, 57.9). Reference voltage in SMPSU can be measured in different manners. Specificity of SMPSU leads to difficulties when applying requirements of IEC 60601-1:1998.
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 has 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.
WG 14 recommendation	7.1 According to 6.1.j (power factor is often lower than 0.9). 15.b Item 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 such as optical isolators) 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 bullet. 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 leads 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 are no safety hazards in the event of short circuit in the windings of the transformer, taking into account that there are no dielectric strength tests 5 times the voltage: 57.9.2). 57.10 By using reference voltage measured or evaluated at Clause 20.

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) Refer also to 4.1.
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. Refer also to 4.1.

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 60601-1:1988: 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.

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".
WG 14 recommendation	To measure the capacitance between lines and ENCLOSURE and between lines.

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 a resistor in series, a fuse could be used or gradually ramping the applied voltage to required test value.

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 60601-1:1988 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	Requirements of 4.10 apply to all EQUIPMENT even when specified for use in a controlled environment However, attention is drawn to the exception noted in the 3rd paragraph of 4.10: *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.*

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.

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 60601-1:1988)

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 ISO/IEC 17025 and guidance in IECEE-CTL Guide 001.

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 not be 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. The AIR CLEARANCE can only be interpolated if the reference voltage is 2 800 V or more.

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 60127-1 and IEC 60241 as protective devices, are loaded for 30 min and 1 h 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.

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 EARTH CONDUCTOR 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."

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.

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.

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 asterisks (*) and the second sentence in C1, “The sequence of tests marked by an * is mandatory”.

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 is 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 is 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)."

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.

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 no ambient temperature is specified by the manufacturer, a maximum of 40 °C ambient shall be used. The limit of 41 °C on APPLIED PARTS of EQUIPMENT not intended to supply heat to a PATIENT must be applied in NORMAL CONDITION and SINGLE FAULT CONDITION. An exception would be where there is a medical justification for a higher limit/temperature rise. This requirement should also be addressed in particular standards.

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 see any reason why a PTC may not be used. Consideration should be given to Clause 49.1. 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. A positive temperature coefficient resistive device (PTC) is to be left in the circuit for the short circuit test until ultimate results. For the overload test the maximum loading not resulting in the PTC switching to its high resistance mode is to be used until ultimate results are known. They shall be in accordance with international or national standards which address the reliability of these components, e.g. as specified in 2.5 of IEC 60950-1:20051.

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	WG 14 strongly recommends that components in the MAINS PART and in APPLIED PARTS should comply with recognised component standards, consistent with their use. WG 14 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. As a minimum, components have to comply with IEC 60601-1 requirements.

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. 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 (e.g. by using a pouch). The ENCLOSURE is therefore not considered as an APPLIED PART and temperature measurements should be done on the external surface of the carrying case. Temperature limits are the same as for an APPLIED PART.

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 2.10.5.12 of IEC 60950-1:2005 requires such winding wire meet the requirements of its Annex U. Can we follow a similar practice for equipment evaluated to IEC 60601-1:1988?
WG 14 recommendation	Requirements of Annex U of IEC 60950-1:2005 can be applied, but precautions should be taken concerning possible mechanical damages to the wires. All other requirements of 57.9 shall be applied.

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, provided 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. The values of CREEPAGE DISTANCES in Table XVI are very conservative. If conformal coating withstands tests in IEC 60664-3, there are no CREEPAGE DISTANCES and conformal coating can be treated as a solid insulating material.

2.2.41 CREEPAGE DISTANCES and AIR CLEARANCES: Dielectric strength test versus CREEPAGE DISTANCES and AIR CLEARANCES – POWER SUPPLY CORDS

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 60320-1, WG14 sees no possibility of applying additional requirements. Up to now this was the first case which was brought to the knowledge of WG14.
WG 14 recommendation	If the APPLIANCE COUPLER is not according to IEC 60320-1, apply the tests according to 57.4.

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 shall be readable on a hard copy or as marking. A risk analysis will indicate which information needs to be provided as hard copy or as markings (e.g. emergency or critical care procedures).

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 60950-1 has requirements for lithium batteries. 6.2 d), 56.7 and 52.5.9 in IEC 60601-1:1988 already cover the requirements of 1.7.13 in IEC 60950-1:2005.
WG 14 recommendation	The requirements of 6.2 d), 52.5.9 and 56.7 in IEC 60601-1:1988 have to be applied to lithium batteries.

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 PART 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 PART. *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. If there is a voltage in the F-TYPE APPLIED PART, values for B-d and B-e are specified and the higher values are applied and tested.

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 of Table Xa and Table Xb to be reduced by 10°C if temperature determined by thermocouples (like Table 4B of IEC 60950-1:2005)?
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.

2.2.46 Mains fuses and OVER-CURRENT RELEASES: Fuses in CLASS II EQUIPMENT

IEC/SC 62A/WG 14 Recommendation No. 46

Problem raised in: WG14/London/3; 62A/WG14(Norway)4/97

Requirement, clause no.	57.6 Mains fuses and OVER-CURRENT RELEASES
Test clause no.	
Source/Problem	Some test houses do not require fuses in the supply leads for CLASS II appliances if the whole supply circuit is double-insulated, i.e. double insulation also between phases. This is not strictly in accordance with the requirements in the standard.
Discussion/ comment	The standard currently requires CLASS II EQUIPMENT to be fitted with fuses or OVER-CURRENT RELEASES in at least one supply lead. The intention was to prevent interruption of the SUPPLY MAINS in the event of a line to neutral short circuit. If DOUBLE INSULATION or REINFORCED INSULATION exists between all parts of opposite polarity within the MAINS PART, then this likelihood is reduced to zero, unless mains transformer secondary circuit faults create primary fault currents likely to trip installation over-current protection.
WG 14 recommendation	If testing of the EQUIPMENT shows that DOUBLE INSULATION or REINFORCED INSULATION is indeed present between all parts of opposite polarity within the MAINS PART, then the omission of fuses or OVER-CURRENT RELEASES would be acceptable. NOTE These insulation requirements must be continued up to and within any component, including any isolation component, e.g. mains transformer, which should also satisfy the requirements of 57.9. Y1 line capacitors according to IEC 60384-14 are acceptable in the MAINS PART. The effect in high powered EQUIPMENT, of short circuit fault conditions in secondary circuits shall be considered before eliminating fuses or OVER-CURRENT RELEASE.

2.2.47 Plug in power supply

IEC/SC 62A/WG 14 Recommendation No. 47

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

Requirement, clause no.	Plug-in power supply 6.3 a), 16 e), 56.8, 57.6, 57.8 b)
Test clause no.	
Source/Problem	Many pieces of MEDICAL ELECTRICAL EQUIPMENT have an INTERNAL ELECTRICAL POWER SOURCE. A connection to mains supply is mainly only necessary for charging the INTERNAL ELECTRICAL POWER SOURCE. But for this purpose small power supplies are sufficient which are not integrated in the EQUIPMENT housing. Non-MEDICAL ELECTRICAL EQUIPMENT has used so-called plug-in power supplies for a long time. Can this type of power supply also be used for EQUIPMENT? UK comment: A number of other standards allow small "plug-top" power supplies to be protected with only THERMAL CUT-OUTS or other devices (e.g. PTCs). Is this adequate protection or should all such PSUs for use with medical products additionally have one or more fuses in the mains circuit?
Discussion/comment	During the discussion at least four areas were discovered, where a deviation from requirements of IEC 60601-1:1988 is possible: 1) PTCs and THERMAL CUT-OUTS instead of mains fuses and/or OVER-CURRENT RELEASES (57.6) and internal wiring according to 57.8 b); 2) indication if the equipment is energised (6.3 a), 56.8); 3) accessibility of the secondary side (16 e)); 4) dimensions and weight when the power supply is integrated in the housing of the plug.
WG 14 recommendation	1) Apply Recommendation No. 36 if only the transformer in the plug-in power supply is connected to the mains supply. In the MAINS PART the cross-sectional area can be less than the minimum required for the POWER SUPPLY CORD (57.3 c)), if there is DOUBLE INSULATION or REINFORCED INSULATION between the opposite polarity. The other requirements of 57.6 apply. 2) WG14 recognizes that the plug-in power supply in itself cannot be considered as an EQUIPMENT according to IEC 60601-1:1988. The EQUIPMENT is the combination of the power supply and the unit it supplies and as a whole must meet IEC 60601-1. This means the plug-in power supply also has to fulfil requirements of IEC 60601-1:1988. 3) By using item a) 5) and e) 1) of Clause 16, Recommendation No. 8 can be expanded to all types of connectors. It should be recognized that there may be SAFETY HAZARDS related to the energy levels associated with accessible parts. This should be addressed in the risk analysis. 4) When the power supply is integrated in the housing of a plug, constructional details shall be in accordance with relevant national standards or International Standards. Dimensions of plugs and sockets are specified in national standards or International Standards (e.g. Clause 13 of IEC 60884-1). All other requirements of IEC 60601-1:1988 apply.

2.2.48 Connecting cords between EQUIPMENT parts: Other applications

IEC/SC 62A/WG 14 Recommendation No. 48

Problem raised in: SC 62A/WG14(Hungary)1

Requirement, clause no.	59.1 f) Applicable requirements Connecting cords between EQUIPMENT parts…shall be considered as belonging to the EQUIPMENT and not be subject to requirements for wiring of electrical installations (in hospitals or otherwise).
Test clause no.	
Source/Problem	A telephone/patient-entertainment/signalising/monitoring system is intended to be installed in a hospital. Possible terminal devices are as follows: – telephone hand pieces (for patients, doctors and nurses); – push-button for alarming the nursing personnel (by the patient); – large-surface „push-button“ for alarming lavatory, bath-room, etc.; – headphones for patients listening to the radio; – loudspeaker situated under the pillow of patient; – optically operating infusion (drop) monitoring device (moulded with artificial resign) situated on the drop-chamber of either a non-electrically or an electrically operated infusion-device. Placing of terminal devices is prohibited in „emphasized medically used rooms“ (operating theatre, intensive wardrooms, etc.) by the manufacturer. Central unit (incl. SMPSU of it) is situated somewhere in a central room of the hospital. The system covers numerous rooms of the hospital, the overall cable length may be several thousand meters.
Discussion/comment	The system described can neither be considered as MEDICAL ELECTRICAL EQUIPMENT nor as a MEDICAL ELECTRICAL SYSTEM. If a MEDICAL ELECTRICAL EQUIPMENT is connected to it, it becomes a MEDICAL ELECTRICAL SYSTEM according to IEC 60601-1-1. Attention is drawn to the fact that in some countries nurse calls are seen as medical equipment.
WG 14 recommendation	The system described should be treated as information technology equipment (ITE) and WG14 recommends that these should have relevant standards prepared by TC 74 and TC 92. We are of the opinion that these systems and other non-MEDICAL ELECTRICAL EQUIPMENT in the PATIENT environment should be covered in a guidance document such as IEC 60930.

2.2.49 MULTIPLE PORTABLE SOCKET-OUTLET

IEC/SC 62A/WG 14 Recommendation No. 49

Problem raised in: SC 62A/WG 14(Melville)6 item 7

Requirement, clause no.	IEC 60601-1-1:2000, 57.2.201 MULTIPLE PORTABLE SOCKET-OUTLET
Test clause no.	
Source/Problem	Detachable power supply cords, and adapters for detachable power supply cords, are becoming available providing two or more mains connectors, thus enabling two or more pieces of equipment to be supplied from a single mains plug.
Discussion/comment	The use of such cords or adapters creates a SYSTEM as described in 2.201 of IEC 60601-1-1:2001 similar to a MULTIPLE PORTABLE SOCKET-OUTLET.
WG 14 recommendation	If such cords or adapters are equipped with multiple mains connectors, then they should be treated as MULTIPLE PORTABLE SOCKET-OUTLET as defined in 2.204 of IEC 60601-1-1:2001 and should comply with the relevant requirements of the standard, in particular 57.2.201.

2.2.50 Separation, DEFIBRILLATION-PROOF APPLIED PART: multiple APPLIED PARTS

IEC/SC 62A/WG 14 Recommendation No. 50

Problem raised in: SC 62A/WG 14(Melville)3 and (Melville)6 item 8

Requirement, clause no.	17 h) Separation, DEFIBRILLATION-PROOF APPLIED PARTS
Test clause no.	17 h)
Source/Problem	Multi-parameter monitoring systems exist in which a number of physiological functions are monitored by multiple APPLIED PARTS sharing a common PATIENT CIRCUIT, i.e. not having individual isolation barriers. Since these physiological functions have different sets of APPLIED PARTS, should, in the differential-mode test, the test voltage be applied to all APPLIED PARTS, or can only one set of APPLIED PARTS be designated as defibrillation-proof?
Discussion/comment	Where multiple APPLIED PARTS share a common PATIENT CIRCUIT and are not separated by the CREEPAGE DISTANCE and AIR CLEARANCE specified in 57.10a) 4th dash. All these APPLIED PARTS must be included in the classification as DEFIBRILLATION-PROOF APPLIED PARTS. Each of these APPLIED PARTS should be subject to the test impulse with all other APPLIED PARTS connected to earth.
WG 14 recommendation	APPLIED PARTS may only be separately classified as DEFIBRILLATION-PROOF APPLIED PARTS if they are electrically separated from other APPLIED PARTS. If there are other APPLIED PARTS separated from the APPLIED PART under test and designated for connection to another (second) PATIENT e.g. in sleep study laboratories, these other APPLIED PARTS should be monitored as unearthed ACCESSIBLE PARTS during the tests illustrated in Figures 50 and 51. In 57.10 a) 4th dash, DEFIBRILLATION-PROOF APPLIED PARTS should be taken as including all parts of that PATIENT CIRCUIT. EQUIPMENT with more than one function on the same PATIENT CIRCUIT in an APPLIED PART shall be safe during defibrillation via one of the following methods: 1) An insulation barrier (basic insulation based on a reference voltage equal mains voltage or 250 V for internally powered equipment) will be inserted between the different functions. 2) The output connectors of unused applied parts directly at the patient monitor contain pins recessed by 4,0 mm when measured against the standard test finger. 3) The testing according to 17 h) (Common-mode test) of the general standard does not lead to more than 1 V when measured with a foil at the unused applied part output connector directly at the patient monitor.

2.2.51 Separation, APPLIED PART: Hand held flexible shafts

IEC/SC 62A/WG 14 Recommendation No. 51

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

Requirement, clause no.	17 Separation, 17 c) APPLIED PART
Test clause no.	17
Source/Problem	Hand-held flexible shaft-driven APPLIED PARTS may have parts of the flexible shaft which are accessible and not connected to protective earth. This particularly applies to the termination of the flexible shaft which is normally of metal for durability and strength.
Discussion/comment	17 c) requires that APPLIED PARTS may not have a CONDUCTIVE CONNECTION to accessible metal parts which are not PROTECTIVELY EARTHED. Hand-held flexible shafts are deemed likely to come into contact with the OPERATOR or PATIENT during NORMAL USE. If that is the normal situation, then it seems reasonable to treat the whole of the flexible shaft as an APPLIED PART.
WG 14 recommendation	Hand-held flexible shafts driving an APPLIED PART, e.g. a surgical or dental drill, may be considered part of the APPLIED PART and therefore the requirements of item c) of Clause 17 will not apply to the ACCESSIBLE PART of that flexible shaft.

2.2.52 Protective earthing: No-load voltage of 6 V maximum

IEC/SC 62A/WG 14 Recommendation No. 52

Problem raised in: SC 62A/WG 14(Melville)6 item 11 and (London)10 and 17

Requirement, clause no.	18 f) Protective earthing
Test clause no.	18 f) A current of 25 A or 1,5 times the rated current of the EQUIPMENT, whichever is greater (± 10 %), from current source with a frequency of 50 Hz or 60 Hz with a no-load voltage not exceeding 6 V is passed for 5 s to 10 s through the PROTECTIVE EARTH TERMINAL or the protective earth contact in the APPLIANCE INLET or the protective earth pin in the MAINS PLUG and each accessible metal part which could become LIVE in case of failure in BASIC INSULATION. The voltage drop between the parts described is measured and the impedance determined from the current and voltage drop. It shall not exceed the values indicated in this subclause.
Source/Problem	EQUIPMENT for example having a rated current of 30 A requires a test current of 1,5 × 30 A. With a maximum impedance of 0,2 Ω, the voltage drop has to be 9 V (0,2 Ω × 45 A = 9 V). This is in contradiction to the required no-load voltage of 6 V maximum.
Discussion/comment	A circuit to the PROTECTIVE EARTH TERMINAL may have zones of higher impedance, for example due to oxidation of materials. Voltages higher than 6 V prevent detection of such zones because of their ability to flash through. In this case, the impedance shall be determined first, using a voltage not exceeding 6 V. Using low voltages and low currents has a great impact on the accuracy of the measurement of low impedances. Impedances in the range of 0,1 Ω and 0,2 Ω then require a sophisticated measuring device. The relation between rated current of the EQUIPMENT and measuring current is in order to check cross-sectional areas of protective earth connections. If parts of the construction or printed circuit boards are used for protective earth connections, the cross-sectional areas and the ability of carrying short circuit currents are in doubt.
WG 14 recommendation	Measuring the protective earth connection has in fact two reasons. It is to determine impedance and cross-sectional area of protective earth connections. For a measuring current of 25 A, both can be done with one measurement. Requiring a measuring current of more than 25 A, it shall be split up into two measurements. In this case, the impedance shall be determined first, using a voltage not exceeding 6 V. If a cross-sectional area of the protective earth connections cannot be determined as equal to the one for the phase by measurement of the area, then measurement with current shall be from a source with a higher voltage than 6 V.

2.2.53 Foot-operated control devices: Protection against entry of liquids

IEC/SC 62A/WG 14 Recommendation No. 53

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

Requirement, clause no.	56.11 d) second dash – The electrical switching parts of foot-operated control devices of EQUIPMENT, specified by the manufacturer for use in operating rooms, shall be IPX8 according to IEC 60529.
Test clause no.	56.11 d)
Source/Problem	Operating rooms are not defined in IEC 60601-1:1988. Can every room where a medical intervention is carried out be seen as an operating room? If yes, most of the rooms in a hospital meet this definition. This means nearly every foot-operated control device has to be IPX8.
Discussion/comment	Foot-operated control devices have to be at least IPX1 according to IEC 60529 (56.11 d) first dash). Every foot-operated control device has a basic protection against entry of liquids. This is necessary because liquids for example used to clean the floor can affect insulations of electrical parts. Only those devices where due to the medical treatment the likelihood of an increased quantity of liquids can occur shall be taken into account for IPX8. To combine the requirement for IPX8 with the type of room increases the amount of foot-operated control devices falling under this requirement unnecessarily.
WG 14 recommendation	Change the requirement to read as follows: The electrical switching parts (including the electrical circuit remote from the connection/connector to the EQUIPMENT) of foot-operated control devices of EQUIPMENT, specified by the manufacturer for use in areas where there is a high probability of liquids on the floor (e.g. rooms for urological procedures etc.), shall be IPX8 according to IEC 60529.

2.2.54 Mains supply transformers

IEC/SC 62A/WG 14 Recommendation No. 54

Problem raised in: SC 62A/WG 14(London)4 and (Melville)6 item 3

Requirement, clause no.	57.9, Mains supply transformers
Test clause no.	57.9.1, 57.9.2 and 57.9.4
Source/Problem	'Mains supply transformer' is a not defined term according to IEC 60601-1:1988. Nevertheless the meaning of the term 'mains' is fixed in conjunction with other definitions like MAINS PART, MAINS CONNECTOR etc, and describes parts which are in a circuit with a direct connection to the electrical source or electrical installation of a building. Transformers in EQUIPMENT are also very often located in electrical circuits which cannot be seen as 'mains supply'. What are the requirements for this types of transformers?
Discussion/comment	The requirements in 57.9 were established at a time when no standard for transformers existed. EQUIPMENT had mainly a transformer in the mains circuit. Transformers, not being mains supply transformers also have to fulfil requirements according to IEC 60601-1:1988 if their construction is not according to an IEC standard for transformers. Thickness of insulation material is not required in IEC 60601-1:1988 except in 57.9.4 for mains transformers.
WG 14 recommendation	Following requirements shall be applied on transformers (except mains supply transformers and transformers according to an IEC standard). 1) Overheating, short circuit and overload: Failure of components in the secondary side of the transformer is considered according to 52.5.9. Resulting temperatures within the values listed in Table 19 if insulation between primary and secondary is an isolation barrier according to Clause 20. 2) Dielectric strength: Values according to Clause 20 apply. Insulation between turns and layers of transformer windings need not be tested according to 57.9.2 if in the respective circuits no overvoltages are measured. 3) Construction: CREEPAGE DISTANCES and AIR CLEARANCES according to 57.10. Requirements for the thickness of insulation material can be derived either from 57.9.4 or from the IEC 61558 series. All other requirements of IEC 60601-1:1988 apply.

2.2.55 Dielectric strength: Reliability of components to bridge A-a_2 and B-a

IEC/SC 62A/WG 14 Recommendation No. 55

Problem raised in: SC 62A/WG 14(Melville)6 item 1

Requirement, clause no.	20.2, A-a_2, B-a
Test clause no.	20.4
Source/Problem	Components between primary and secondary: DOUBLE INSULATION and REINFORCED INSULATION are defined in 2.3.4 and 2.3.7. Relevant requirements are in Clause 20 (Dielectric strength) and 57.10 (CREEPAGE DISTANCES and AIR CLEARANCES). Sometimes it is technically necessary to bridge these insulations by components (e.g. opto-couplers, capacitors). What are the requirements for these components?
Discussion/comment	Most of the components used to bridge DOUBLE INSULATION or REINFORCED INSULATION withstand relevant dielectric strength tests. As dielectric strength is a type test, no evidence is given concerning reliability of the components. Reliability of components is important to prevent breakdown of insulations during lifetime of EQUIPMENT. Just a few of the standards addressing requirements for components relate to reliability. Only components on the basis of such standards can be used to bridge DOUBLE INSULATION or REINFORCED INSULATION.
WG 14 recommendation	Two Y1 capacitors according to IEC 60384-14 in series with the same ratings can be used to bridge a DOUBLE INSULATION or REINFORCED INSULATION. In addition each of these capacitors shall be rated for the total voltage across the pair.

2.2.56 Dielectric strength: A-e in switch mode power supply units (SMPSU)

IEC/SC 62A/WG 14 Recommendation No. 56

Problem raised in 62A/WG14(Melville)25

Requirement, clause no.	20 Dielectric strength 20.1 General requirements for all types of equipment A-e Between LIVE parts not being parts of SIGNAL INPUT PARTS (SIP) or SIGNAL OUTPUT PARTS (SOP) and SIGNAL INPUT PARTS or SIGNAL OUTPUT PARTS not PROTECTIVELY EARTHED..... No separate investigation is needed if the voltages appearing on the SIGNAL INPUT PART and/or SIGNAL OUTPUT PART in NORMAL CONDITION and SINGLE FAULT CONDITION do not exceed SAFETY EXTRA-LOW VOLTAGE.
Test clause no.	20.4
Source/problem	There are two separate problems with this requirement particularly when applied to EQUIPMENT using switching mode power supply units (SMPSU): The reference to voltages not exceeding SAFETY EXTRA-LOW VOLTAGE is unclear. Does this apply to the voltage of the LIVE parts under investigation, or to the voltages which appear in the SIP/SOP in NORMAL CONDITION and SINGLE FAULT CONDITION? EQUIPMENT using SMPSU is likely to have interference suppression capacitors from parts of the MAINS PART to PROTECTIVELY EARTHED parts. These components would normally be rated at the maximum supply voltage and would need to satisfy the requirements for BASIC INSULATION. Insulation between the MAINS PART and unearthed parts of SIP/SOP must satisfy one of the methods in Items g) 1-5 of Clause 17. Most commonly for SPSUs this would be provided within the transformer(s), in the form of REINFORCED INSULATION, separating the MAINS PART from the secondary circuits. Application of the test voltage for REINFORCED INSULATION between an unearthed SIP/SOP and the MAINS PART will result in overstressing the BASIC INSULATION elements of the MAINS PART, since the SIP/SOP is also likely to have a conductive path to earth.
Discussion/comment	The reference to SAFETY EXTRA-LOW VOLTAGE is presumed to apply to the voltage limits i.e. < 25 V a.c. rms or < 60 V d.c., rather than to the isolation of the supply. The exemption is taken to apply to SINGLE FAULT CONDITIONS existing in the EQUIPMENT rather than fault conditions in EQUIPMENT connected to the SIP/SOP. In EQUIPMENT using SMPSU, secondary circuits are usually earthed referenced, as may be the SIP/SOPs. Application of a test voltage for REINFORCED INSULATION will therefore subject all basic insulation elements in the MAINS PART to this voltage.
WG14 recommendation	1) Treat the reference to SAFETY EXTRA-LOW VOLTAGE as referring to the voltage i.e. <25 V a.c. rms or <60 V d.c. and not to the character of the supply. 2) a) Consider only the effect of SINGLE FAULT CONDITIONS in the EQUIPMENT. This will cover breakdowns of BASIC INSULATION and component failures between LIVE parts and SIP/SOP. b) Identify insulation separating parts which are LIVE exceeding SELV from SIP/SOP and ensure that it complies with one of Items g) 1-5 of Clause 17. Test this insulation with the relevant test voltage. c) Ensure that the requirements of 20.4 g) are met. This may require disconnection of the separating part(s) for test purposes, or testing a separate representative sample of the component(s)

2.2.57 Dielectric strength: Connection of 12 V dc negative side to ENCLOSURE

IEC SC62A WG14 recommendation No. 57

Problem raised in: BSI 94/50141094.01.27 HCC/64

Requirement, clause no.	16 ENCLOSURES and PROTECTIVE COVERS a) EQUIPMENT shall be so constructed and enclosed that there is protection against contact with LIVE parts, ... 19.2 SINGLE FAULT CONDITIONS a) The EARTH LEAKAGE CURRENT, the ENCLOSURE LEAKAGE CURRENT, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT shall be measured …… 20.1 General requirements for all types of EQUIPMENT A-a_1 Between LIVE parts and accessible metal parts which are PROTECTIVELY EARTHED.
Test clause no.	16, 19.4, 20.4
Source/problem	Connection of a 12 V d.c. mains negative side to the ENCLOSURE. Isolation between MAINS PART and ACCESSIBLE PART.
Discussion/comment	10.2.2 address only a.c. power supplies, should include d.c. too, see also 2.12.10,14.1b. In addition, test with reverse mains as described in 19.1 b), 19.2 a) will lead to a non-compliance of ENCLOSURE LEAKAGE CURRENT.
WG14 recommendation	Connection of either side of d.c. mains to accessible metal parts of THE ENCLOSURE is not permitted by 14.1 b), at least BASIC INSULATION is required for a CLASS I EQUIPMENT. Alternatively other constructions preventing this kind of hazard are allowed.

2.2.58 Dielectric strength: Voltages appearing on SIP/SOP

IEC SC62A WG14 recommendation No. 58

Problem raised in: BSI Interpretation I/64-68/158

Requirement, clause no.	20.1 General requirements for all types of EQUIPMENT A-k Between, in turn, a SIGNAL INPUT PART, a SIGNAL OUTPUT PART and ACCESSIBLE PARTS not PROTECTIVELY EARTHED. 20.1 a) The voltages appearing on the SIGNAL INPUT PART or SIGNAL OUTPUT PARTS in NORMAL USE do not exceed SAFETY EXTRA-LOW VOLTAGE. 20.3 Values of test voltages 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 as specified by the manufacturer, whichever is the greater.
Test clause no.	20.4
Source/problem	It is not clear from the wording of this subclause what the reference voltage for test A-k should be. If it is the normal WORKING VOLTAGE of the SIGNAL INPUT PART or the SIGNAL OUTPUT PART and that is less than 50 V, the test voltage is only 500 V, which would barely ensure its suitability to withstand externally applied MAINS VOLTAGE. If on the other hand the reference voltage is MAINS VOLTAGE, then the test voltage is 4 kV, which seems excessive for insulation which is only subject to mains voltage in SINGLE FAULT CONDITION.
Discussion/comment	The requirement of DOUBLE INSULATION for 20.1 A-k corresponds to a reference voltage equal to the WORKING VOLTAGE in NORMAL USE. However, for EQUIPMENT with SIP/SOP not designated to be only connected to equipment (medical or non-medical) in compliance with IEC 60601-1-1, where the hazard of an external voltage higher than the WORKING VOLTAGE in the SIP/SOP exists, the insulation should be according to this external voltage. This external voltage will be in most cases MAINS VOLTAGE.
WG14 recommendation	Insulation should be BASIC INSULATION for 250 V. There should be a hint in the instruction for use to inform the USER that he has responsibility in sense of IEC 60601-1-1 for the MEDICAL ELECTRICAL SYSTEM when he connects equipment to the SIP/SOP of EQUIPMENT. See also Recommendation 18.

2.2.59 APPLIED PART: EQUIPMENT without APPLIED PART

IEC SC62A WG14 recommendation No. 59

Problem raised in: SC62A/WG14(Oslo)10

Requirement, clause no.	2.1.5 APPLIED PART A part of the EQUIPMENT which is in NORMAL USE: – necessarily comes into physical contact with the PATIENT for the EQUIPMENT to perform its function; or – can be brought into contact with the PATIENT; or – needs to be touched by the PATIENT. 5.2 According to the degree of protection against electric shock: – APPLIED PART OF TYPE B – APPLIED PART OF TYPE BF – APPLIED PART OF TYPE CF
Test clause no.	2.1.5, 5.2, 19
Source/problem	A lot of EQUIPMENT has no APPLIED PART (e. g. equipment for radiation). Which requirements apply?
Discussion/comment	MEDICAL ELECTRICAL EQUIPMENT without an APPLIED PART should not be classified in accordance with the degrees of protection against electric shock. However, the definition of APPLIED PART includes also parts which can be brought into contact with the PATIENT in NORMAL USE. In this case these parts are to be treated as APPLIED PARTS.
WG14 recommendation	Apply the relevant requirements of TYPE B APPLIED PARTS to an EQUIPMENT without an APPLIED PART, except the requirements for an APPLIED PART.

2.2.60 Scope: Other than MEDICAL ELECTRICAL EQUIPMENT in contact with the body of a person

IEC SC62A WG14 recommendation No. 60

Problem raised in: SC62A/WG14(Munich)3

Requirement, clause no.	1.1 This standard applies to MEDICAL ELECTRICAL EQUIPMENT 2.2.15 MEDICAL ELECTRICAL EQUIPMENT: electrical equipment...which is determined to be for diagnosis, treatment or observation of a PATIENT under medical supervision
Test clause no.	
Source/problem	It is not clear if equipment which is in physical contact with a person to perform its function or equipment which is used for diagnosis and is not in physical contact with a person needs to be covered by the standard for MEDICAL ELECTRICAL EQUIPMENT or by another safety standard.
Discussion/comment	– The term 'under medical supervision' is not defined. – There are situations where a person is in physical contact with an equipment for treatment other than medical (e.g. cosmetic treatment, personal hygiene equipment). – There are also situations where a person is not in physical contact with an equipment and the equipment is being used for diagnostic purposes (e.g. psychological equipment). – The risks are practically the same as for a person undergoing medical treatment. – In the case where there is no physical connection to the person (e.g. UV equipment) for treatment reasons or we are dealing with the operator of the equipment, any other appropriate safety standard could be used. – A higher degree of safety is obtained by applying IEC 60601-1 for all types of equipment having a physical connection to the body of a person.
WG14 recommendation	Where EQUIPMENT/SYSTEM is for a body treatment other than medical (e.g. cosmetic treatment), IEC 60601-1 may be used when no other standard exists. In this case the instruction for use shall clearly indicate that the EQUIPMENT/SYSTEM is not for medical purposes. For all other EQUIPMENT/SYSTEMS for medical purposes IEC 60601-1 is mandatory.

2.2.61 Markings: AC symbol

IEC SC62A WG14 recommendation No. 61

Problem raised in: SC62A/WG14(Munich)4

Requirement, clause no.	6.1 Markings on the outside of equipment 6.1 g) Type of supply and type of current 6.4 The symbols used must be in accordance with Annex D
Test clause no.	6.1, 6.4
Source/problem	Instead of the symbol for alternating current (Table DI, 1) often the term “a.c.” is used.
Discussion/comment	The problem was discussed when the third Edition of IEC 60601-1 was drafted. The term “a.c.” was not seen as an alternative. The solution from the 3rd edition can also be taken without any restrictions for the 2nd edition.
WG14 recommendation	For alternating current, the rated frequency in Hertz is sufficient to identify the type of current. Only “a.c.” is not sufficient.

2.2.62 Interruption of power supply: Characteristics of interruption

IEC SC62A WG14 recommendation No. 62

Problem raised in: SC62A/WG14(Oslo)11

Requirement, clause no.	49 Interruption of the power supply 49.2 EQUIPMENT shall be so designed that an interruption and restoration of the power supply shall not result in a SAFETY HAZARD other than interruption of its intended function. *Compliance is checked by interruption and restoration of relevant power supplies.* 4.7 *b) EQUIPMENT for a.c. only shall be tested with a.c. at RATED frequency (if marked) ± I Hz between 0 Hz and 100 Hz and ± 1 % above 100 Hz.*
Test clause no.	7, 19, 42, 49, 52,
Source/problem	The above requirement does not describe the characteristics of the interruption and restoration of the power supply. One example of a specific situation is found in hospitals where IEC 60364-7-710 (*Electrical installations of buildings – Part 7-710: Requirements for special installations or locations – Medical locations)* applies. In this case, within 15 s after switching over from the common power supply to the power supply for safety services, no deviations higher than 5 Hz from the rated frequency and 10 % from the rated voltage of the safety power supply may occur.
Discussion/comment	In the example above, in an interval of 15 s the frequency can deviate from the RATED frequency of the EQUIPMENT of much more than stated in the test conditions. There may not only be a deviation in the frequency but also in the duration of the interruption of the power supply or in the voltage level. According to 49.2 the EQUIPMENT has to be safe during the interruption and the following restoration of the power supply independent of frequency, voltage level or duration of interruption. Safety does not only mean physical safety of the equipment but also functional safety. IEC 60601-1-2 covers these aspects.
WG14 recommendation	The requirements in subclause 36.202.7 of IEC 60601-1-2:2001 should be applied. NOTE These requirements also appear in subclause 6.2.7 of IEC 60601-1-2:2007.

2.2.63 Reference voltage: Different reference voltages in the same circuit

IEC SC62A WG14 recommendation No. 63

Problem raised in: SC62A/WG14(Tel Aviv)20

Requirement, clause no.	20.3 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…… 57.10 57.10 a) The value of the reference voltage (*U*) is as given in subclause 20.3.
Test clause no.	20.3, 57.10
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 Subclause 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. Within an SMPSU, different components like switching transformer, opto-couplers and other single components might bridge the insulation barrier. If reference voltages will be measured at those components it often leads to different reference voltages. To apply the higher reference voltage for the whole barrier would lead to unnecessary higher test values (e.g. CREEPAGE DISTANCES) at locations where actually these reference voltages do not exist. For example, on the terminals of a transformer a voltage of 270 V rms is measured. On the pins of an opto-coupler in the same isolation barrier a voltage of 230 V rms is measured. Which reference voltage should be applied for the opto-coupler?
Discussion/comment	The voltage measured on a single component is the reference voltage to define dielectric strength, CREEPAGE DISTANCES and AIR CLEARANCES for the component under test.
WG14 recommendation	The standard defines minimum requirements. It is permitted to apply different reference voltages on different components which are part of the same isolation barrier. However the reference shall never be less than the highest voltage existing within each side of the concerned isolation barrier.

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Index of Terms

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