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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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CONTENTS

FOREWORD 4
INTRODUCTION 6
1 Scope and object 7
1.1 Scope 7
1.2 Object 7
2 Recommendations 7
2.1 Summary of all recommendations prepared by SC 62A/WG 14 7
2.2 Recommendation sheets 10
2.2.1 Separation: Reliability of component impedance 10
2.2.2 Separation: Non-complying creepage distance and air clearances 12
2.2.3 Mains supply transformers: Overload test 13
2.2.4 Mains supply transformers: Short circuit and overload tests 14
2.2.5 Creepage distance and air clearances: Values 15
2.2.6 Dielectric strength 16
2.2.7 Failure of components: Evidence of reliability 17
2.2.8 ENCLOSURES and protective covers 18
2.2.9 INTERNALLY POWERED EQUIPMENT: 110 % of the maximum supply voltage 19
2.2.10 Creepage distances and air clearances: Values under 1 mm 20
2.2.11 Separation: Secondary circuit impedance limit LEAKAGE CURRENT 21
2.2.12 ENCLOSURES and PROTECTIVE COVERS: Lampholder/switching device 22
2.2.13 Fixing, prevention of maladjustment: Torque test 23
2.2.14 Batteries not intended to be changed by OPERATOR: Lithium batteries 24
2.2.15 Excessive temperatures: Ambient temperatures 25
2.2.16 Continuous LEAKAGE CURRENTS: Different SUPPLY MAINS 26
2.2.17 ENCLOSURE and protective covers: EQUIPMENT in ambulances 27
2.2.18 Dielectric strength: Voltages appearing from external sources 28
2.2.19 Testing switch mode power supply units (SMPSU) 29
2.2.20 Failure of an electrical component: Time periodicity for detection 30
2.2.21 Environmental conditions: Compliance paragraph 31
2.2.22 Limitation of voltage and/or energy: Capacitance 32
2.2.23 LEAKAGE CURRENTS: Presence of 45 kΩ resistor in Figure 21 33
2.2.24 Humidity preconditioning treatment: Exception from requirement 34
2.2.25 Dielectric strength: EQUIPMENT containing floating circuits 35
2.2.26 General requirements for tests: Measurement uncertainty 36
2.2.27 CREEPAGE DISTANCES and AIR CLEARANCES: Interpolated values 37
2.2.28 Overheating: Change of load resistance 38
2.2.29 Mains operated EQUIPMENT with additional power source: Integrity of external protective earth 39
2.2.30 Rechargeable batteries: No OPERATOR/USER maintenance 40
2.2.31 Isolation from the SUPPLY MAINS: Symbol for single pole switch 41
2.2.32 Sequence of testing: Clause 52 before Clause 19 42
2.2.33 SINGLE FAULT CONDITION: ENCLOSURE LEAKAGE CURRENT from INTERNALLY POWERED EQUIPMENT 43
2.2.34 Marking on the outside of EQUIPMENT: Type and rating of fuses 44
2.2.35 Excessive temperatures: APPLIED PARTS not intended to supply heat 45
2.2.36 Mains supply transformers: Use of PTCs as protective devices 46

2.2.37 Components and general assembly: Reliability of components 47
2.2.38 Definition of APPLIED PART: EQUIPMENT worn by PATIENTS 48
2.2.39 Construction: Triple insulated winding wire 49
2.2.40 CREEPAGE DISTANCES and AIR CLEARANCES: Dielectric strength test versus CREEPAGE DISTANCES and AIR CLEARANCES 50
2.2.41 CREEPAGE DISTANCES and AIR CLEARANCES: Dielectric strength test versus CREEPAGE DISTANCES and AIR CLEARANCES – POWER SUPPLY CORDS 51
2.2.42 ACCOMPANYING DOCUMENTS: on CD-ROM or electronic file format 52
2.2.43 INTERNAL ELECTRICAL POWER SOURCE: Requirements for lithium batteries 53
2.2.44 Dielectric strength: Differences between B-d and B-e 54
2.2.45 Excessive temperatures: Thermocouple instead of resistance method 55
2.2.46 Mains fuses and OVER-CURRENT RELEASES: Fuses in CLASS II EQUIPMENT 56
2.2.47 Plug in power supply 57
2.2.48 Connecting cords between EQUIPMENT parts: Other applications 58
2.2.49 MULTIPLE PORTABLE SOCKET-OUTLET 59
2.2.50 Separation, DEFIBRILLATION-PROOF APPLIED PART: multiple APPLIED PARTS 60
2.2.51 Separation, APPLIED PART: Hand held flexible shafts 61
2.2.52 Protective earthing: No-load voltage of 6 V maximum 62
2.2.53 Foot-operated control devices: Protection against entry of liquids 63
2.2.54 Mains supply transformers 64
2.2.55 Dielectric strength: Reliability of components to bridge A-a_2 and B-a 65
2.2.56 Dielectric strength: A-e in switch mode power supply units (SMPSU) 66
2.2.57 Dielectric strength: Connection of 12 V dc negative side to ENCLOSURE 67
2.2.58 Dielectric strength: Voltages appearing on SIP/SOP 68
2.2.59 APPLIED PART: EQUIPMENT without APPLIED PART 69
2.2.60 Scope: Other than MEDICAL ELECTRICAL EQUIPMENT in contact with the body of a person 70
2.2.61 Markings: AC symbol 71
2.2.62 Interruption of power supply: Characteristics of interruption 72
2.2.63 Reference voltage: Different reference voltages in the same circuit 73
Bibliography 74
Index of Terms 76

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

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The main task of IEC technical committees is to prepare International Standards. However, a technical committee may propose the publication of a technical report when it has collected data of a different kind from that which is normally published as an International Standard, for example "state of the art".

IEC 62296, which is a technical report, has been prepared by subcommittee 62A: *Common aspects of electrical equipment used in medical practice*, of IEC technical committee 62: *Electrical equipment in medical practice*.

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

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

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

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

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

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

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

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

INTRODUCTION

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

> **IMPORTANT NOTE:** Per the 62A decision at Sydney (see RM3755/SC62A, August 1994), the 62A Secretary is circulating this recommendation, prepared by 62A/WG14, regarding problems of interpretation or application of IEC 60601-1 to all P-Member NC's.

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

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

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

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

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

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

1 Scope and object

1.1 Scope

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

This technical report is primarily intended to be used by:

– manufacturers of MEDICAL ELECTRICAL EQUIPMENT;

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

– those developing subsequent editions of IEC 60601-1.

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