



BSI Standards Publication

Medical electrical equipment

Part 4-3: Guidance and interpretation —
Considerations of unaddressed safety aspects
in the third edition of IEC 60601-1 and
proposals for new requirements

National foreword

This Published Document is the UK implementation of IEC/TR 60601-4-3:2015.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/1, Common aspects of Electrical Equipment used in Medical Practice.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2015.

Published by BSI Standards Limited 2015

ISBN 978 0 580 85664 8

ICS 11.040

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 30 April 2015.

Amendments/corrigenda issued since publication

Date	Text affected
------	---------------

TECHNICAL REPORT

**Medical electrical equipment –
Part 4-3: Guidance and interpretation – Considerations of unaddressed safety
aspects in the third edition of IEC 60601-1 and proposals for new requirements**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040

ISBN 978-2-8322-2613-1

Warning! Make sure that you obtained this publication from an authorized distributor.

CONTENTS

FOREWORD.....	5
INTRODUCTION.....	7
1 Scope and object.....	8
1.1 Scope.....	8
1.2 Object.....	8
2 Normative references.....	8
3 Recommendations.....	9
3.1 Template used for recommendations prepared by SC 62A/WG 14.....	9
3.2 Recommendation sheets.....	10
3.2.101 Total PATIENT LEAKAGE CURRENT of a ME SYSTEM.....	10
3.2.102 Pollution degree for MOPP.....	10
3.2.103 Transients on d.c. mains.....	11
3.2.104 Altitude factor for DEFIBRILLATION-PROOF APPLIED PARTS.....	12
3.2.105 Defibrillation energy protection for MOOP / MOPP.....	13
3.2.106 Overvoltage categories III and IV.....	13
3.2.107 Pollution degree related to different micro/macro environments.....	13
3.2.108 Warnings versus ALARM SIGNALS.....	14
3.2.109 Single Y1 capacitor for MOPP.....	14
3.2.110 WORKING VOLTAGE > 14 140 V peak.....	15
3.2.111 CREEPAGE DISTANCE and AIR CLEARANCE for dental equipment.....	15
3.2.112 Short circuiting of one constituent part of DOUBLE INSULATION.....	16
3.2.113 Instability in transport position.....	16
3.2.114 When to conduct leakage current tests after humidity preconditioning treatment.....	17
3.2.115 DEFIBRILLATION-PROOF TYPE I APPLIED PARTS.....	17
3.2.116 Instability excluding transport position.....	18
3.2.117 DIELECTRIC STRENGTH of two serial MOPP barrier parts.....	18
3.2.118 Overheating transformer.....	19
3.2.119 Test equipment for recurrent tests according to IEC 62353 testing used within IEC 60601-1 type approval testing.....	20
3.2.120 Tolerances of apparatus.....	22
3.2.121 FUNCTIONAL EARTH CONDUCTOR and ESSENTIAL PERFORMANCE.....	23
3.2.122 A.c. motors.....	24
3.2.123 Operational insulation.....	25
3.2.124 WORKING VOLTAGE measurement.....	25
3.2.125 Defibrillation test.....	26
3.2.126 Oil containers for moving parts.....	27
3.2.127 PERMANENTLY INSTALLED ME EQUIPMENT in the HOME HEALTHCARE ENVIRONMENT.....	27
3.2.128 Polystyrene plate for LEAKAGE CURRENT tests.....	30
3.2.129 Push buttons.....	31
3.2.130 Temperature limit at the ENCLOSURE in SINGLE FAULT CONDITION.....	31
3.2.131 Optic coupler requirements.....	33
3.2.132 Eye-verification of tester before legibility test.....	35
3.2.133 End stops to prevent overtravel.....	36
3.2.134 MOPP barrier with low WORKING VOLTAGE r.m.s. and high WORKING VOLTAGE peak.....	37

3.2.135	Labeling: spare parts vs. detachable parts vs. ACCESSORIES	38
3.2.136	Protective earth impedance of ME SYSTEM >200 mΩ	41
3.2.137	Ball pressure test	42
3.2.138	Magnesium alloy ENCLOSURE	43
3.2.139	Instability with initial movement	44
3.2.140	Ball pressure test	45
3.2.141	DIELECTRIC STRENGTH test values	47
3.2.142	SECONDARY CIRCUITS	48
3.2.143	LEAKAGE CURRENTS in SINGLE FAULT CONDITION and during component faults	48
3.2.144	Impedance of a PROTECTIVE EARTH CONDUCTOR within a DETACHABLE POWER SUPPLY CORD	49
3.2.145	Time delay of the 100 VA limit	50
3.2.146	Test voltage multiplied by factor 1,6	51
3.2.147	Overflow, spillage,	51
3.2.148	DIELECTRIC STRENGTH test of transformers without accessible parts	52
3.2.149	Expected voltage on SIP/SOPS	52
3.2.150	Flammability rating for transformer bobbin	53
3.2.151	COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS	54
3.2.152	Peak and r.m.s. WORKING VOLTAGES	55
3.2.153	Critical components	56
3.2.154	LEAKAGE CURRENT test for ME EQUIPMENT with multiple APPLIED PARTS	56
3.2.155	DIELECTRIC STRENGTH test value for extended and spirally wrapped multi-layer wires	57
3.2.156	DIELECTRIC STRENGTH test after thermal cycling test	57
3.2.157	Required MOOP values higher than MOPP values	58
3.2.158	Optocouplers	58
3.2.159	Impact test	59
3.2.160	Spillage test in NORMAL CONDITION and in SINGLE FAULT CONDITION	60
3.2.161	TYPE B APPLIED PARTS connected to ACCESSIBLE PARTS	61
3.2.162	Current/power labeling	62
3.2.163	Separate power supply part of ME EQUIPMENT or ME SYSTEM	62
3.2.164	Specification of the allowed power supply	63
3.2.165	Main components for opposite polarity on the secondary side or battery pole to pole barrier	64
3.2.166	Keep dry and umbrella symbol	65
3.2.167	MOBILE and STATIONARY ME EQUIPMENT with wheels	66
3.2.168	Varistors installed in the MAINS PART	67
3.2.169	Using Y2 capacitors for MOPP	67
3.2.170	Overtravel end stops – specification of the speed	68
3.2.171	CREEPAGE DISTANCE and AIR CLEARANCE between input and output of fuse contacts	69
3.2.172	Examples of SINGLE FAULT CONDITION	69
3.2.173	Examples of ME SYSTEMS	70
3.2.174	Cross sectional area of POWER SUPPLY CORD for rated input current > 63 A	70
3.2.175	Biocompatibility for quasi APPLIED PARTS	71
3.2.176	Floating reference earth	71
3.2.177	SINGLE FAULT CONDITION in OXYGEN RICH ENVIRONMENT	72
3.2.178	Laser requirements	74

3.2.179	Flammability rating of insulated wires	74
3.2.180	Infrared lamps	75
3.2.181	Identification of internal fuses	76
3.2.182	Chargers for ME EQUIPMENT used at home	77
3.2.183	CLASS II ME EQUIPMENT with FUNCTIONAL EARTH CONDUCTOR	78
3.2.184	Symbol D2-2 on MSO	78
3.2.185	PATIENT leads connectors	79
3.2.186	Rationale for IP2X	80
3.2.187	Battery – limited power	80
3.2.188	TYPE B APPLIED PART separated from ACCESSIBLE PARTS.....	81
3.2.189	Protective earth test >25A	81
3.2.190	Reference to IEC 62304:2006.....	82
3.2.191	The SIP/SOP pin to earth TOUCH CURRENT.....	82
3.2.192	Overbalancing	84
3.2.193	MAINS VOLTAGE on APPLIED PART.....	85
Annex A (informative) Overview of the recommendations developed by IEC/SC 62A/WG 14		86
Bibliography.....		91
Table A.1 – Cross-reference of recommendations by subclause of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 (1 of 5).....		86

Currently in preview, click buy full version.

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 4-3: Guidance and interpretation – Considerations
of unaddressed safety aspects in the third edition of IEC 60601-1
and proposals for new requirements**

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, accept to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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 TR 60601-4-3, which is a technical report, has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

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

Enquiry draft	Report on voting
62A/951/DTR	62A/973A/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.

Terms used throughout this technical report that have been defined in Clause 3 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD 1:2012 are printed in SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC website 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 laboratories 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/WG 14, regarding problems of interpretation or application of IEC 60601-1 to all P-Member NCs.

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

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 laboratories while retaining the informative nature of the material.

This first edition of IEC TR 60601-4-3 contains 93 recommendations, numbered 101 to 193. All these recommendations are based upon IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012.

The numbering starts with 101 instead of just 1 to ensure that these WG 14 recommendations (101 to 193) will not accidentally be confused with previous issued WG 14 recommendations 1 to 63, which are based on the second edition of IEC 60601-1 and published in IEC TR 62296.

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

MEDICAL ELECTRICAL EQUIPMENT

Part 4-3: Guidance and interpretation – Considerations of unaddressed safety aspects in the third 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 third edition of IEC 60601-1.

This technical report is primarily intended to be used by:

- MANUFACTURERS of MEDICAL ELECTRICAL EQUIPMENT;
- test laboratories and others responsible for assessment of compliance with IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 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. Similarly it is expected that these recommendations within IEC 60601-4-3 will be considered when preparing a future revision of IEC 60601-1.

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 third 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 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments), applies.

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-1:2005/AMD1:2012

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

IEC 60601-1-8:2006/AMD1:2012

IEC 60601-1-11:2010, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*