

INTERNATIONAL STANDARD



**Medical electrical equipment –
Part 1: General requirements for basic safety and essential performance**

This is a preview. [Click here to purchase the full publication.](#)



THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2012 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester.

If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

Useful links:

IEC publications search - www.iec.ch/searchpub

The advanced search enables you to find IEC publications by a variety of criteria (reference number, text, technical committee,...).

It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished

Stay up to date on all new IEC publications. Just Published details all new publications released. Available on-line and also once a month by email.

Electropedia - www.electropedia.org

The world's leading online dictionary of electronic and electrical terms containing more than 30 000 terms and definitions in English and French, with equivalent terms in additional languages. Also known as the International Electrotechnical Vocabulary (IEV) on-line.

Customer Service Centre - webstore.iec.ch/csc

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: csc@iec.ch.



IEC 60601-1

Edition 3.1 2012-08

INTERNATIONAL STANDARD



**Medical electrical equipment –
Part 1: General requirements for basic safety and essential performance**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

PRICE CODE **CW**

ICS 11.040

ISBN 978-2-8322-0331-6

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

© Registered trademark of

[This is a preview. Click here to purchase the full publication.](#)

CONTENTS

FOREWORD.....	11
INTRODUCTION.....	14
1 Scope, object and related standards.....	17
1.1 * Scope	17
1.2 Object	17
1.3 * Collateral standards	17
1.4 * Particular standards	18
2 * Normative references	18
3 * Terminology and definitions	18
4 General requirements	42
4.1 * Conditions for application to ME EQUIPMENT or ME SYSTEMS.....	42
4.2 * RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS	43
4.3 * ESSENTIAL PERFORMANCE	43
4.4 * EXPECTED SERVICE LIFE	46
4.5 * Equivalent safety for ME EQUIPMENT or ME SYSTEMS * Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS	47
4.6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT	47
4.7 * SINGLE FAULT CONDITION for ME EQUIPMENT.....	47
4.8 * Components of ME EQUIPMENT	48
4.9 * Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT	49
4.10 * Power supply	50
4.11 Power input	50
5 * General requirements for testing ME EQUIPMENT	51
5.1 * TYPE TESTS.....	51
5.2 * Number of samples	51
5.3 Ambient temperature, humidity, atmospheric pressure.....	51
5.4 Other conditions	51
5.5 Supply voltages, type of current, nature of supply, frequency	52
5.6 Repairs and modifications	52
5.7 * Humidity preconditioning treatment	53
5.8 Sequence of tests	53
5.9 * Determination of APPLIED PARTS and ACCESSIBLE PARTS	53
6 * Classification of ME EQUIPMENT and ME SYSTEMS	57
6.1 General	57
6.2 * Protection against electric shock.....	57
6.3 * Protection against harmful ingress of water or particulate matter	57
6.4 Method(s) of sterilization	57
6.5 Suitability for use in an OXYGEN RICH ENVIRONMENT	57
6.6 * Mode of operation	57

7	ME EQUIPMENT identification, marking and documents	58
7.1	General	58
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts	59
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts	64
7.4	Marking of controls and instruments	65
7.5	Safety signs	67
7.6	Symbols	67
7.7	Colours of the insulation of conductors	68
7.8	* Indicator lights and controls	68
7.9	ACCOMPANYING DOCUMENTS	69
8	* Protection against electrical HAZARDS from ME EQUIPMENT	75
8.1	Fundamental rule of protection against electric shock	75
8.2	Requirements related to power sources	76
8.3	Classification of APPLIED PARTS	77
8.4	Limitation of voltage, current or energy	77
8.5	Separation of parts	80
8.6	* Protective earthing, functional earthing and potential equalization of ME EQUIPMENT	90
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	93
8.8	Insulation	115
8.9	* CREEPAGE DISTANCES and AIR CLEARANCES	121
8.10	Components and wiring	138
8.11	MAINS PARTS, components and layout	140
9	* Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	146
9.1	MECHANICAL HAZARDS of ME EQUIPMENT	146
9.2	* MECHANICAL HAZARDS associated with moving parts	146
9.3	* MECHANICAL HAZARD associated with surfaces, corners and edges	152
9.4	* Instability HAZARDS	152
9.5	* Expelled parts HAZARD	157
9.6	Acoustic energy (including infra- and ultrasound) and vibration	158
9.7	* Pressure vessels and parts subject to pneumatic and hydraulic pressure	159
9.8	* MECHANICAL HAZARDS associated with support systems	162
10	* Protection against unwanted and excessive radiation HAZARDS	168
10.1	X-Radiation	168
10.2	Alpha, beta, gamma, neutron and other particle radiation	169
10.3	Microwave radiation	169
10.4	* Lasers and light emitting diodes (LEDs)	169
10.5	Other visible electromagnetic radiation	170
10.6	Infrared radiation	170
10.7	Ultraviolet radiation	170
11	* Protection against excessive temperatures and other HAZARDS	170
11.1	* Excessive temperatures in ME EQUIPMENT	170
11.2	* Fire prevention	175
11.3	* Constructional requirements for fire ENCLOSURES of ME EQUIPMENT	180

11.4	* ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics	181
11.5	* ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents	182
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT	182
11.7	Biocompatibility of ME EQUIPMENT and ME SYSTEMS	184
11.8	* Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	184
12	* Accuracy of controls and instruments and protection against hazardous outputs	184
12.1	Accuracy of controls and instruments	184
12.2	USABILITY of ME EQUIPMENT	184
12.3	ALARM SYSTEMS	184
12.4	Protection against hazardous output.....	185
13	* HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	186
13.1	Specific HAZARDOUS SITUATIONS	186
13.2	SINGLE FAULT CONDITIONS	187
14	* PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	192
14.1	* General.....	192
14.2	* Documentation.....	193
14.3	* RISK MANAGEMENT plan	193
14.4	* PEMS DEVELOPMENT LIFE-CYCLE	193
14.5	* Problem resolution	194
14.6	RISK MANAGEMENT PROCESS.....	194
14.7	* Requirement specification	195
14.8	* Architecture	195
14.9	* Design and implementation	195
14.10	* VERIFICATION	195
14.11	* PEMS VALIDATION	196
14.12	* Modification	196
14.13	* Connection of PEMS by NETWORK/DATA COUPLING to other equipment * PEMS intended to be incorporated into an IT-NETWORK	196
15	Construction of ME EQUIPMENT	197
15.1	* Arrangements of controls and indicators of ME EQUIPMENT	198
15.2	* Serviceability	198
15.3	Mechanical strength	198
15.4	ME EQUIPMENT components and general assembly.....	202
15.5	* MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5	207
16	* ME SYSTEMS	211
16.1	* General requirements for the ME SYSTEMS	211
16.2	* ACCOMPANYING DOCUMENTS of an ME SYSTEM	212
16.3	* Power supply	213
16.4	ENCLOSURES	213
16.5	* SEPARATION DEVICES.....	213
16.6	* LEAKAGE CURRENTS.....	214
16.7	* Protection against MECHANICAL HAZARDS	215

16.8	Interruption of the power supply to parts of an ME SYSTEM	215
16.9	ME SYSTEM connections and wiring	215
17	* Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	217
Annex A (informative) General guidance and rationale.....		218
Annex B (informative) Sequence of testing		331
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS		335
Annex D (informative) Symbols on marking.....		338
Annex E (informative) Examples of the connection of the measuring device (MD) for measurement of the PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT		347
Annex F (informative) Suitable measuring supply circuits.....		349
Annex G (normative) Protection against HAZARDS of ignition of flammable anaesthetic mixtures.....		352
Annex H (informative) PEMS structure, PEMS DEVELOPMENT LIFE-CYCLE and documentation		367
Annex I (informative) ME SYSTEMS aspects.....		380
Annex J (informative) Survey of insulation paths.....		386
Annex K (informative) Simplified PATIENT LEAKAGE CURRENT diagrams		389
Annex L (normative) Insulated winding wires for use without interleaved insulation.....		392
Annex M (normative) Reduction of pollution degrees		395
Bibliography.....		396
INDEX OF ABBREVIATIONS AND ACRONYMS		400
INDEX		402
Figure 1 – Detachable mains connection.....		23
Figure 2 – Example of the defined terminals and conductors.....		25
Figure 3 – Example of a CLASS I ME EQUIPMENT.....		26
Figure 4 – Example of a metal-enclosed CLASS II ME EQUIPMENT		26
Figure 5 – Schematic flow chart for component qualification		49
Figure 6 – Standard test finger.....		55
Figure 7 – Test hook.....		56
Figure 8 – Test pin.....		79
Figure 9 – Application of test voltage to bridged PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS.....		86
Figure 10 – Application of test voltage to individual PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS.....		88
Figure 11 – Application of test voltage to test the delivered defibrillation energy		90
Figure 12 – Example of a measuring device and its frequency characteristics.....		95
Figure 13 – Measuring circuit for the EARTH LEAKAGE CURRENT of CLASS I ME equipment, with or without APPLIED PART		98

Figure 14 – Measuring circuit for the TOUCH CURRENT	100
Figure 15 – Measuring circuit for the PATIENT LEAKAGE CURRENT from the PATIENT CONNECTION to earth	102
Figure 16 – Measuring circuit for the PATIENT LEAKAGE CURRENT via the PATIENT CONNECTION(S) of an F-TYPE APPLIED PART to earth caused by an external voltage on the PATIENT CONNECTION(S)	104
Figure 17 – Measuring circuit for the PATIENT LEAKAGE CURRENT from PATIENT CONNECTION(S) to earth caused by an external voltage on a SIGNAL INPUT/OUTPUT PART	106
Figure 18 – Measuring circuit for the PATIENT LEAKAGE CURRENT from PATIENT CONNECTION(S) to earth caused by an external voltage on a metal ACCESSIBLE PART that is not PROTECTIVELY EARTHED	108
Figure 19 – Measuring circuit for the PATIENT AUXILIARY CURRENT	109
Figure 20 – Measuring circuit for the total PATIENT LEAKAGE CURRENT with all PATIENT CONNECTIONS of all APPLIED PARTS of the same type (TYPE B APPLIED PARTS, TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS) connected together	110
Figure 21 – Ball-pressure test apparatus	121
Figure 22 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 1	134
Figure 23 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 2	134
Figure 24 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 3	134
Figure 25 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 4	135
Figure 26 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 5	135
Figure 27 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 6	135
Figure 28 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 7	136
Figure 29 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 8	136
Figure 30 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 9	137
Figure 31 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 10	138
Figure 32 – Ratio between HYDRAULIC TEST PRESSURE and MAXIMUM PERMISSIBLE WORKING PRESSURE	161
Figure 33 – Human body test mass Body upper-carriage module	167
Figure 34 – Spark ignition test apparatus	176
Figure 35 – Maximum allowable current I as a function of the maximum allowable voltage U measured in a purely resistive circuit in an OXYGEN RICH ENVIRONMENT	177
Figure 36 – Maximum allowable voltage U as a function of the capacitance C measured in a capacitive circuit used in an OXYGEN RICH ENVIRONMENT	177
Figure 37 – Maximum allowable current I as a function of the inductance L measured in an inductive circuit in an OXYGEN RICH ENVIRONMENT	178
Figure 38 – Baffle	181
Figure 39 – Area of the bottom of an ENCLOSURE as specified in 11.3 b) 1)	181
Figure A.1 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in an ECG monitor	224
Figure A.2 – Example of the insulation of an F-TYPE APPLIED PART with the insulation incorporated in the ME EQUIPMENT	224
Figure A.3 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a PATIENT monitor with invasive pressure monitoring facility	225
Figure A.4 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a multifunction PATIENT monitor with invasive pressure monitoring facilities	226

Figure A.5 – Identification of APPLIED PARTS and PATIENT CONNECTIONS in an X-ray ME SYSTEM	227
Figure A.6 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a transcutaneous electronic nerve stimulator (TENS) intended to be worn on the PATIENT'S belt and connected to electrodes applied to the PATIENT'S upper arm.....	227
Figure A.7 – Identification of ME EQUIPMENT or ME SYSTEM, APPLIED PARTS and PATIENT CONNECTIONS in a personal computer with an ECG module	228
Figure A.8 – Pictorial representation of the relationship of HAZARD, sequence of events, HAZARDOUS SITUATION and HARM	231
Figure A.9 – Example of PATIENT ENVIRONMENT.....	237
Figure A.10 – Floating circuit	256
Figure A.11 – Interruption of a power-carrying conductor between ME EQUIPMENT parts in separate ENCLOSURES.....	258
Figure A.12 – Identification of MEANS OF PATIENT PROTECTION and MEANS OF OPERATOR PROTECTION.....	263
Figure A.13 – Allowable protective earth impedance where the fault current is limited	270
Figure A.14 – Probability of ventricular fibrillation	276
Figure A.15 – Example of a measuring circuit for the PATIENT LEAKAGE CURRENT from a PATIENT CONNECTION to earth for ME EQUIPMENT with multiple PATIENT CONNECTIONS	281
Figure A.16 – Instability test conditions.....	292
Figure A.17 – Example of determining TENSILE SAFETY FACTOR using Table 21	299
Figure A.18 – Example of determining design and test loads	300
Figure A.19 – Example of human body mass distribution	300
Figure A.20 – Relationship of the terms used to describe equipment, ACCESSORIES or equipment parts.....	234
Figure A.21 – Example of ME EQUIPMENT having two different functions on one common APPLIED PART circuit.....	268
Figure A.22 – Maximum allowable temperature for surfaces and APPLIED PARTS at higher altitudes	305
Figure A.23 – Example of the needed MEANS OF OPERATOR PROTECTION between the terminals of an INTERNAL ELECTRICAL POWER SOURCE and a subsequent protective device.....	323
Figure E.1 – TYPE B APPLIED PART.....	347
Figure E.2 – TYPE BF APPLIED PART	347
Figure E.3 – TYPE CF APPLIED PART	348
Figure E.4 – PATIENT AUXILIARY CURRENT	348
Figure E.5 – Loading of the PATIENT CONNECTIONS if specified by the MANUFACTURER	348
Figure F.1 – Measuring supply circuit with one side of the SUPPLY MAINS at approximately earth potential.....	349
Figure F.2 – Measuring supply circuit with SUPPLY MAINS approximately symmetrical to earth potential.....	349
Figure F.3 – Measuring supply circuit for polyphase ME EQUIPMENT specified for connection to a polyphase SUPPLY MAINS.....	350
Figure F.4 – Measuring supply circuit for single-phase ME EQUIPMENT specified for connection to a polyphase SUPPLY MAINS.....	350
Figure F.5 – Measuring supply circuit for ME EQUIPMENT having a separate power supply unit or intended to receive its power from another equipment in an ME SYSTEM.....	351

Figure G.1– Maximum allowable current I_{ZR} as a function of the maximum allowable voltage U_{ZR} measured in a purely resistive circuit with the most flammable mixture of ether vapour with air	358
Figure G.2 – Maximum allowable voltage U_{ZC} as a function of the capacitance C_{max} measured in a capacitive circuit with the most flammable mixture of ether vapour with air	359
Figure G.3 – Maximum allowable current I_{ZL} as a function of the inductance L_{max} measured in an inductive circuit with the most flammable mixture of ether vapour with air ..	359
Figure G.4 – Maximum allowable current I_{ZR} as a function of the maximum allowable voltage U_{ZR} measured in a purely resistive circuit with the most flammable mixture of ether vapour with oxygen	363
Figure G.5 – Maximum allowable voltage U_{ZC} as a function of the capacitance C_{max} measured in a capacitive circuit with the most flammable mixture of ether vapour with oxygen.....	364
Figure G.6 – Maximum allowable current I_{ZL} as a function of the inductance L_{max} measured in an inductive circuit with the most flammable mixture of ether vapour with oxygen.....	364
Figure G.7 – Test apparatus	364
Figure H.1 – Examples of PEMS/ PESS structures	368
Figure H.2 – A PEMS DEVELOPMENT LIFE-CYCLE model	369
Figure H.3 – PEMS documentation requirements from Clause 14 and ISO 14971:2000 Not used	373
Figure H.4 – Example of potential parameters required to be specified for NETWORK/DATA COUPLING an IT-NETWORK	379
Figure I.1 – Example of the construction of a MULTIPLE SOCKET-OUTLET (MSO).....	384
Figure I.2 – Examples of application of MULTIPLE SOCKET-OUTLETS (MSO)	385
Figure J.1 – Insulation example 1	386
Figure J.2 – Insulation example 2	386
Figure J.3 – Insulation example 3	386
Figure J.4 – Insulation example 4	387
Figure J.5 – Insulation example 5	387
Figure J.6 – Insulation example 6	388
Figure J.7 – Insulation example 7	388
Figure K.1 – ME EQUIPMENT with an ENCLOSURE made of insulating material.....	389
Figure K.2 – ME EQUIPMENT with an F-TYPE APPLIED PART	389
Figure K.3 – ME EQUIPMENT with an APPLIED PART and a SIGNAL INPUT/OUTPUT PART	390
Figure K.4 – ME EQUIPMENT with a PATIENT CONNECTION of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED	390
Figure K.5 – ME EQUIPMENT with a PATIENT CONNECTION of a TYPE BF APPLIED PART that is not PROTECTIVELY EARTHED	391
Table 1 – Units outside the SI units system that may be used on me equipment	66
Table 2 – Colours of indicator lights and their meaning for me equipment.....	69
Table 3 – * Allowable values of patient leakage currents and patient auxiliary currents under normal condition and single fault condition.....	96
Table 4 – * Allowable values of patient leakage currents under the special test conditions identified in 8.7.4.7	97

Table 5 – Legends of symbols for Figure 9 to Figure 11, Figure 13 to Figure 20, Figure A.15, Annex E and Annex F	111
Table 6 – Test voltages for solid insulation forming a means of protection	118
Table 7 – Test voltages for means of operator protection	119
Table 8 – Multiplication factors for air clearances for altitudes up to 5 000 m	122
Table 9 – Material group classification	122
Table 10 – Mains transient voltage	124
Table 11 – Minimum creepage distances and air clearances between parts of opposite polarity of the mains part Not used	125
Table 12 – Minimum creepage distances and air clearances providing means of patient protection	126
Table 13 – Minimum air clearances providing means of operator protection from the mains part.....	127
Table 14 – Additional air clearances for insulation in mains parts with peak working voltages exceeding the peak value of the nominal mains voltage a	128
Table 15 – Minimum air clearances for means of operator protection in secondary circuits.....	129
Table 16 – Minimum Creepage distances providing means of operator protection	130
Table 17 – Nominal cross-sectional area of conductors of a power supply cord	142
Table 18 – Testing of cord anchorages	143
Table 19 – Mechanical hazards covered by this clause	146
Table 20 – Acceptable gaps.....	148
Table 21 – Determination of tensile safety factor	163
Table 22 – Allowable maximum temperatures of parts.....	171
Table 23 – Allowable maximum temperatures for me equipment parts that are likely to be touched.....	171
Table 24 – Allowable maximum temperatures for skin contact with me equipment applied parts.....	172
Table 25 – Acceptable perforation of the bottom of an enclosure	180
Table 26 – * Temperature limits of motor windings.....	190
Table 27 – Maximum motor winding steady-state temperature	192
Table 28 – Mechanical strength test applicability	199
Table 29 – Drop height	200
Table 30 – Test torques for rotating controls.....	206
Table 31 – Maximum allowable temperatures of transformer windings under overload and short-circuit conditions at 25 °C (± 5 °C) ambient temperature	208
Table 32 – Test current for transformers	209
Table 33 – Test conditions for overtravel end stop test	151
Table A.1 – Values of air clearance and creepage distance derived from Table 7 of IEC 61010-1:2001 and Table 12	284
Table A.2 – Creepage distances to avoid failure due to tracking from IEC 60664-1	285
Table A.3 – Instability test conditions.....	292
Table A.4 – Allowable time exposure for level of acceleration	295