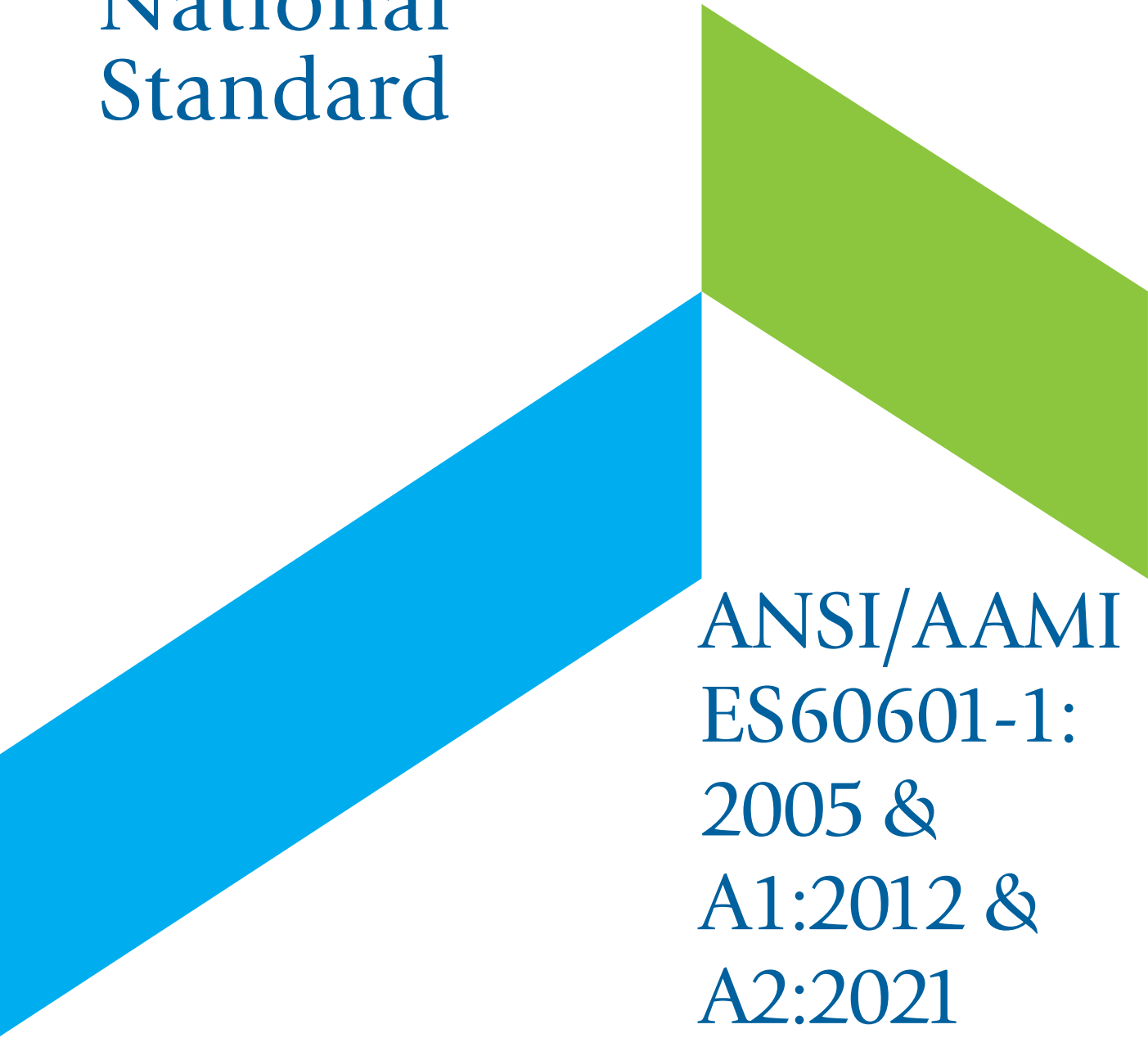


American
National
Standard



ANSI/AAMI
ES60601-1:
2005 &
A1:2012 &
A2:2021

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

Consolidated Text REDLINE VERSION

(IEC 60601-1:2005, MOD)

American National Standard

ANSI/AAMI ES60601-1:2005
and ANSI/AAMI ES60601-1:2005/A1:2012
and ANSI/AAMI ES60601-1:2005/A2:2021
(Consolidated text)

(IEC 60601-1:2005, MOD)

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

Approved 07 January 2022 by
AAMI

Approved 01 February 2022 by
American National Standards Institute, Inc.

Abstract: Baseline of requirements for the basic safety and essential performance of all medical electrical equipment used by or under the supervision of qualified personnel in the general medical and patient environment. Also contains certain requirements for reliable operation to ensure safety. This standard can also be applied to equipment used for compensation or alleviation of disease, injury, or disability. The second amendment addresses changes to terminology and references since the main document was finalized in 2005 and first amended in 2012.

Keywords: medical electrical equipment, medical electrical systems, safety, essential performance

AAMI Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than 5 years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI.

All AAMI standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

Published by

AAMI
901 N. Glebe Road, Suite 300
Arlington, VA 22203
www.aami.org

© 2022 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

This publication is subject to copyright claims of IEC and AAMI. No part of this publication may be reproduced or distributed in any form, including an electronic retrieval system, without the prior written permission of AAMI. All requests pertaining to this draft should be submitted to AAMI. It is illegal under federal law (17 U.S.C. § 101, *et seq.*) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violator's risk legal action, including civil and criminal penalties, and damages of \$100,000 per offense. For permission regarding the use of all or any part of this document, contact [Copyright Clearance Center](http://www.copyright.com).

Printed in the United States of America

ISBN 978-1-57020-851-5

Contents

Page

Committee representation	xi
Background of ANSI/AAMI adoption of IEC 60601-1:2005 as ES60601-1 and Amendments 1 and 2....	xiii
U.S. (AAMI) deviations from IEC 60601-1:2005	xv
Foreword	xviii
Introduction.....	xx
<u>INTRODUCTION TO AMENDMENT 1</u>	<u>xxi</u>
<u>INTRODUCTION TO AMENDMENT 2</u>	<u>xxii</u>
1 Scope, object and related standards.....	1
1.1 * Scope	1
1.2 Object	1
1.3 * Collateral standards	2
1.4 * Particular standards	2
2 * Normative references.....	2
3 * Terminology and definitions	7
4 General requirements.....	29
4.1 * Conditions for application to ME EQUIPMENT or ME SYSTEMS.....	29
4.2 * RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS	29
4.3 * ESSENTIAL PERFORMANCE	32
4.4 * EXPECTED SERVICE LIFE	33
4.5 * Equivalent safety for ME EQUIPMENT or ME SYSTEMS * <u>Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS</u>	33
4.6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT	33
4.7 * SINGLE FAULT CONDITION for ME EQUIPMENT	33
4.8 * Components of ME EQUIPMENT	34
4.9 * Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT	35
4.10 * Power supply	36
4.11 Power input.....	37
5 * General requirements for testing ME EQUIPMENT	38
5.1 * TYPE TESTS.....	38
5.2 * Number of samples	38
5.3 Ambient temperature, humidity, atmospheric pressure	38
5.4 Other conditions	38
5.5 Supply voltages, type of current, nature of supply, frequency	39
5.6 Repairs and modifications	39
5.7 * Humidity preconditioning treatment	39
5.8 Sequence of tests	40
5.9 * Determination of APPLIED PARTS and ACCESSIBLE PARTS	40
6 * Classification of ME EQUIPMENT and ME SYSTEMS	44
6.1 General.....	44
6.2 * Protection against electric shock	44
6.3 Protection against harmful ingress of water or particulate matter	44
6.4 Method(s) of sterilization	44
6.5 Suitability for use in an OXYGEN RICH ENVIRONMENT	44
6.6 * Mode of operation.....	44
7 ME EQUIPMENT identification, marking and documents	45

7.1	General.....	45
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.1)	46
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.2)	51
7.4	Marking of controls and instruments (see also Table C.3).....	52
7.5	Safety signs SAFETY SIGNS	54
7.6	Symbols.....	55
7.7	Colours of the insulation of conductors	55
7.8	* Indicator lights and controls	56
7.9	ACCOMPANYING DOCUMENTS	58
8	* Protection against electrical HAZARDS from ME EQUIPMENT	63
8.1	Fundamental rule of protection against electric shock	63
8.2	Requirements related to power sources	64
8.3	Classification of APPLIED PARTS.....	65
8.4	Limitation of voltage, current or energy	65
8.5	Separation of parts.....	68
8.6	* Protective earthing, functional earthing and potential equalization of ME EQUIPMENT	83
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS.....	85
8.8	Insulation	107
8.9	* CREEPAGE DISTANCES and AIR CLEARANCES.....	113
8.10	Components and wiring	131
8.11	MAINS PARTS, components and layout.....	133
9	* Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	139
9.1	MECHANICAL HAZARDS of ME EQUIPMENT	139
9.2	* MECHANICAL HAZARDS associated with moving parts	139
9.3	* MECHANICAL HAZARD associated with surfaces, corners and edges	145
9.4	* Instability HAZARDS	145
9.5	* Expelled parts HAZARD.....	150
9.6	Acoustic energy (including infra- and ultrasound) and vibration	150
9.7	* Pressure vessels and parts subject to pneumatic and hydraulic pressure	151
9.8	* MECHANICAL HAZARDS associated with support systems	155
10	* Protection against unwanted and excessive radiation HAZARDS.....	161
10.1	X-Radiation	161
10.2	Alpha, beta, gamma, neutron and other particle radiation	162
10.3	Microwave radiation	162
10.4	* Lasers and light emitting diodes (LEDs)	163
10.5	* Other visible electromagnetic radiation.....	163
10.6	* Infrared radiation	163
10.7	* Ultraviolet radiation	163
11	Protection against excessive temperatures and other HAZARDS	163
11.1	* Excessive temperatures in ME EQUIPMENT.....	163
11.2	* Fire prevention	168
11.3	* Constructional requirements for fire ENCLOSURES of ME EQUIPMENT	173
11.4	* ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics	176
11.5	* ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents ..	176
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT ..	176
11.7	Biocompatibility of ME EQUIPMENT and ME SYSTEMS.....	178

11.8	* Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	179
12	* Accuracy of controls and instruments and protection against hazardous outputs	179
12.1	Accuracy of controls and instruments.....	179
12.2	USABILITY <u>of ME EQUIPMENT</u>	179
12.3	ALARM SYSTEMS	179
12.4	Protection against hazardous output	179
13	* HAZARDOUS SITUATIONS and fault conditions <u>for ME EQUIPMENT</u>	181
13.1	Specific HAZARDOUS SITUATIONS	181
13.2	SINGLE FAULT CONDITIONS	183
14	* PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....	188
14.1	* General	188
14.2	* Documentation.....	189
14.3	* RISK MANAGEMENT plan	189
14.4	* PEMS DEVELOPMENT LIFE-CYCLE	189
14.5	* Problem resolution	189
14.6	RISK MANAGEMENT PROCESS	189
14.7	* Requirement specification	190
14.8	* Architecture	190
14.9	* Design and implementation	191
14.10	* VERIFICATION	191
14.11	* PEMS VALIDATION	191
14.12	* Modification	192
14.13	* Connection of PEMS by NETWORK/DATA COUPLING to other equipment * <u>PEMS intended to be incorporated into an IT-NETWORK</u>	192
15	Construction of ME EQUIPMENT	193
15.1	* Arrangements of controls and indicators of ME EQUIPMENT	193
15.2	* Serviceability	193
15.3	Mechanical strength	193
15.4	ME EQUIPMENT components and general assembly	197
15.5	* MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5.....	202
16	* ME SYSTEMS	206
16.1	* General requirements for the ME SYSTEMS	206
16.2	* ACCOMPANYING DOCUMENTS of an ME SYSTEM	207
16.3	* Power supply	208
16.4	ENCLOSURES	208
16.5	* SEPARATION DEVICES.....	208
16.6	* LEAKAGE CURRENTS	208
16.7	* Protection against MECHANICAL HAZARDS	209
16.8	Interruption of the power supply to parts of an ME SYSTEM.....	210
16.9	ME SYSTEM connections and wiring.....	210
17	* Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	212
	Annex A (informative) General guidance and rationale	213
	Annex B (informative) Sequence of testing	329
	Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS	333
	Annex D (informative) Symbols on marking (see Clause 7)	336

Annex E (informative) Examples of the connection of the measuring device (MD) for measurement of the PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT (see 8.7)	345
Annex F (informative) Suitable measuring supply circuits	348
Annex G (normative) Protection against HAZARDS of ignition of flammable anaesthetic mixtures	351
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	390
Annex L (normative) Insulated winding wires for use without interleaved insulation	393
<u>Annex M (normative) Reduction of pollution degrees</u>	<u>396</u>
Bibliography	397
INDEX OF ABBREVIATIONS AND ACRONYMS	402
INDEX	404

Figure 1 – Detachable mains connection	8
Figure 2 – Example of the defined terminals and conductors	9
Figure 3 – Example of a CLASS I ME EQUIPMENT	10
Figure 4 – Example of a metal-enclosed CLASS II ME EQUIPMENT	10
Figure 5 – Schematic flow chart for component qualification (see 4.8)	36
Figure 6 – Standard test finger (see 5.9.2.1)	41
Figure 7 – Test hook (see 5.9.2.2)	43
Figure 8 – Test pin (see 8.4.2 d)	67
Figure 9 – Application of test voltage to bridged PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS (see 8.5.5.1)	78
Figure 10 – Application of test voltage to individual PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS (see 8.5.5.1)	80
Figure 11 – Application of test voltage to test the delivered defibrillation energy	82
Figure 12 – Example of a measuring device and its frequency characteristics	87
Figure 13 – Measuring circuit for the EARTH LEAKAGE CURRENT of CLASS I ME EQUIPMENT, with or without APPLIED PART	90
Figure 14 – Measuring circuit for the TOUCH CURRENT	92
Figure 15 – Measuring circuit for the PATIENT LEAKAGE CURRENT from the PATIENT CONNECTION to earth	94
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)	96
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	98
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	100
Figure 19 – Measuring circuit for the PATIENT AUXILIARY CURRENT	101
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	102
Figure 21 – Ball-pressure test apparatus	113
Figure 22 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 1	126

Figure 23 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 2	126
Figure 24 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 3	126
Figure 25 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 4	127
Figure 26 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 5	127
Figure 27 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 6	128
Figure 28 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 7	128
Figure 29 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 8	129
Figure 30 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 9	130
Figure 31 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 10	131
Figure 32 – Ratio between HYDRAULIC TEST PRESSURE and MAXIMUM PERMISSIBLE WORKING <u>EQUIPMENT</u> PRESSURE	154
Figure 33 – Human body test mass (see 9.8.3.3) <u>Body upper-carriage module</u>	160
Figure 34 – Spark ignition test apparatus	169
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	170
Figure 36 – Maximum allowable voltage U as a function of the capacitance C measured in a capacitive circuit used in an OXYGEN RICH ENVIRONMENT	171
Figure 37 – Maximum allowable current I as a function of the inductance L measured in an inductive circuit in an OXYGEN RICH ENVIRONMENT	172
Figure 38 – Baffle	175
Figure 39 – Area of the bottom of an ENCLOSURE as specified in 11.3 b) 1)	176
<u>Figure 40 – Identification of MEANS OF PATIENT PROTECTION and MEANS OF OPERATOR PROTECTION</u>	<u>70</u>
<u>Figure 41 – WORKING VOLTAGE measurement</u>	<u>75</u>
Figure A.1 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in an ECG monitor	218
Figure A.2 – Example of the insulation of an F-TYPE APPLIED PART with the insulation incorporated in the ME EQUIPMENT	219
Figure A.3 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a PATIENT monitor with invasive pressure monitoring facility	220
Figure A.4 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a multifunction PATIENT monitor with invasive pressure monitoring facilities	221
Figure A.5 – Identification of APPLIED PARTS and PATIENT CONNECTIONS in an X-ray ME SYSTEM	222
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	223
Figure A.7 – Identification of ME EQUIPMENT or ME SYSTEM, APPLIED PARTS and PATIENT CONNECTIONS in a personal computer with an ECG module	224
Figure A.8 – Pictorial representation <u>Illustration</u> of the relationship of HAZARD, sequence of events, HAZARDOUS SITUATION and HARM	228
Figure A.9 – Example of PATIENT ENVIRONMENT	233
Figure A.10 – Floating circuit	252
Figure A.11 – Interruption of a power-carrying conductor between ME EQUIPMENT parts in separate ENCLOSURES	254
Figure A.12 – Identification of MEANS OF PATIENT PROTECTION and MEANS OF OPERATOR PROTECTION
Figure A.13 – Allowable protective earth impedance where the fault current is limited	270
Figure A.14 – Probability of ventricular fibrillation	275

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	280
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.....	299
Figure A.19 – Example of human body mass distribution	300
<u>Figure A.20 – Relationship of the terms used to describe equipment, ACCESSORIES or equipment parts.....</u>	<u>230</u>
<u>Figure A.21 – Example of ME EQUIPMENT having two different functions on one common APPLIED PART circuit</u>	<u>268</u>
<u>Figure A.22 – Maximum allowable temperature for surfaces and APPLIED PARTS at higher altitudes</u>	<u>304</u>
<u>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.....</u>	<u>321</u>
Figure A.24 – Example of Scenario 1.....	257
Figure A.25 – Example of Scenario 2.....	258
<u>Figure A.26 – Procedure for determination of AIR CLEARANCE requirements IEC TR 62368-2:2019 [77], 5.4.2.1 (modified).....</u>	<u>263</u>
Figure E.1 – TYPE B APPLIED PART	345
Figure E.2 – TYPE BF APPLIED PART	345
Figure E.3 – TYPE CF APPLIED PART	346
Figure E.4 – PATIENT AUXILIARY CURRENT.....	346
Figure E.5 – Loading of the PATIENT CONNECTIONS if specified by the MANUFACTURER.....	347
Figure F.1 – Measuring supply circuit with one side of the SUPPLY MAINS at approximately earth potential	348
Figure F.2 – Measuring supply circuit with SUPPLY MAINS approximately symmetrical to earth potential	348
Figure F.3 – Measuring supply circuit for polyphase ME EQUIPMENT specified for connection to a polyphase SUPPLY MAINS	349
Figure F.4 – Measuring supply circuit for single-phase ME EQUIPMENT specified for connection to a polyphase SUPPLY MAINS	349
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	350
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	357
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.....	358
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.....	358
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 .	362
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	363
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.....	366
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	387
Figure J.4 – Insulation example 4	388
Figure J.5 – Insulation example 5	388
Figure J.6 – Insulation example 6	389
Figure J.7 – Insulation example 7	389
Figure K.1 – ME EQUIPMENT with an ENCLOSURE made of insulating material	390
Figure K.2 – ME EQUIPMENT with an F-TYPE APPLIED PART	390
Figure K.3 – ME EQUIPMENT with an APPLIED PART and a SIGNAL INPUT/OUTPUT PART	391
Figure K.4 – ME EQUIPMENT with a PATIENT CONNECTION of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED	391
Figure K.5 – ME EQUIPMENT with a PATIENT CONNECTION of a TYPE BF APPLIED PART that is not PROTECTIVELY EARTHED	392
Table 1 – Units outside the SI units system that may be used on ME EQUIPMENT.....	54
Table 2 – Colours of indicator lights and their meanings <u>of indicator lights and alarm indicator lights</u> for ME EQUIPMENT	57
Table 3 – * Allowable values of PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL CONDITION and SINGLE FAULT CONDITION	88
Table 4 – * Allowable values of PATIENT LEAKAGE CURRENTS under the special test conditions identified in 8.7.4.7	89
Table 5 – Legends of symbols for Figure 9 to Figure 11, Figure 13 to Figure 20, Figure A.15, Annexes E and F	103
Table 6 – Test voltages for solid insulation forming a MEANS OF PROTECTION.....	110
Table 7 – Test voltages for MEANS OF OPERATOR PROTECTION	111
Table 8 – Multiplication factors for AIR CLEARANCES for altitudes up to 5 000 m	114
Table 9 – Material group classification.....	115
Table 10 – MAINS TRANSIENT VOLTAGE	116
Table 11 – Minimum CREEPAGE DISTANCES and AIR CLEARANCES between parts of opposite polarity of the MAINS PART <u>Not used</u>	117
Table 12 – Minimum CREEPAGE DISTANCES and AIR CLEARANCES providing MEANS OF PATIENT PROTECTION	118
Table 13 – Minimum AIR CLEARANCES providing MEANS OF OPERATOR PROTECTION from the MAINS PART..	119
Table 14 – Additional AIR CLEARANCES for insulation in MAINS PARTS with PEAK WORKING VOLTAGES exceeding the peak value of the NOMINAL MAINS VOLTAGE ^a	120
Table 15 – Minimum AIR CLEARANCES for MEANS OF OPERATOR PROTECTION in SECONDARY CIRCUITS	121
Table 16 – Minimum CREEPAGE DISTANCES providing MEANS OF OPERATOR PROTECTION ^a	122
Table 17 – NOMINAL cross-sectional area of conductors of a POWER SUPPLY CORD	135

Table 18 – Testing of cord anchorages	136
Table 19 – MECHANICAL HAZARDS covered by this clause	139
Table 20 – Acceptable gaps ^a	141
Table 21 – Determination of TENSILE SAFETY FACTOR	156
Table 22 – Allowable maximum temperatures of parts	164
Table 23 – Allowable maximum temperatures for ME EQUIPMENT parts <u>ACCESSIBLE PARTS</u> that are likely to be touched	164
Table 24 – Allowable maximum temperatures for skin contact with ME EQUIPMENT APPLIED PARTS	165
Table 25 – Acceptable perforation of the bottom of an ENCLOSURE	175
Table 26 – * Temperature limits of motor windings	185
Table 27 – Maximum motor winding steady-state temperature	187
Table 28 – Mechanical strength test applicability	194
Table 29 – Drop height	196
Table 30 – Test torques for rotating controls	201
Table 31 – Maximum allowable temperatures of transformer windings under overload and short- circuit conditions at 25 °C (± 5 °C) ambient temperature	203
Table 32 – Test current for transformers	204
<u>Table 33 – Test conditions for overtravel end stop test</u>	<u>144</u>
<u>Table 34 – Allowable maximum temperatures for ACCESSIBLE PARTS that are likely to be touched, but not intended to be touched to operate the ME EQUIPMENT</u>	<u>182</u>
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
Table A.5 – Guidance on surface temperatures for ME EQUIPMENT that creates low temperatures (cools) for therapeutic purposes or as part of its operation	304
<u>Table A.6 – Typical scenarios for the use of equipment complying with IEC 62368-1:2018 in ME EQUIPMENT</u>	<u>257</u>
Table C.1– Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts	333
Table C.2 – Marking on the inside of ME EQUIPMENT, ME SYSTEMS or their parts	334
Table C.3 – Marking of controls and instruments	334
Table C.4 – ACCOMPANYING DOCUMENTS, general	334
Table C.5 – ACCOMPANYING DOCUMENTS, instructions for use	335
Table D.1 – General symbols	337
Table D.2 – Safety signs <u>SAFETY SIGNS</u>	342
Table D.3 – General codes	344
Table G.1 – Gas-tightness of cord inlets	360
Table H.1 – NETWORK/DATA COUPLING classification <u>Not used</u>	377
Table I.1 – Some examples of ME SYSTEMS for illustration	382
Table L.1– Mandrel diameter	394
Table L.2 – Oven temperature	394
<u>Table M.1 – Reduction of the pollution degree of internal environment through the use of additional protection</u>	<u>396</u>

Committee representation

Association for the Advancement of Medical Instrumentation

Electrical Safety Committee

The adoption of Amendment 2 to IEC 60601-1:2005 as an American National Standard was initiated by the AAMI Electrical Safety Committee. AAMI Electrical Safety Committee provides input to the U.S. TAG for IEC/SC 62A which is the responsible group for providing the U.S. input to the relevant group in IEC. U.S. representatives from AAMI Electrical Safety Committee and the TAG played an active part in developing the IEC document.

At the time this document was published, the **AAMI Electrical Safety Committee** has the following members:

Cochairs: Jeffrey L. Eggleston
Alex Grob

Members: Alan S. Berson, Bioresearch Funding Group
Stephen Briol, Nonin Medical Inc
Michael Britko, Draeger Medical Systems Inc
Steve Cantwell, Spacelabs Healthcare
Gregory Chase, TUV Rheinland of North America Inc
Martin Joseph Crnkovich, Fresenius Medical Care
Rebecca K. Crossley, UPMC Montefiore
Roberto Del Cid, Arthrex Inc
Yadin David, Biomedical Engineering Consultants LLC
Jeffrey L. Eggleston, Medtronic - Boulder
Leonard Eisner, Eisner Safety Consultants
Hamed Ghods, FDA - CDRH
Johanna Goforth, Eurofins E&E North America (MET Labs)
David L. Green, Square One Industries LLC
Alex Grob, MECA - Medical Equipment Compliance Associates LLC
Pamela Gwynn, UL LLC
Nabeel Jadeed, Ethicon Endo-Surgery
James Kamke, Baxter Healthcare Corporation
Kevin Van Kammen, ICU Medical Inc
Bahram Kevin Kayvani, Medline Industries, Inc
Brian Killoran, Hillrom, Inc
Alan Lipschultz, HealthCare Technology Consulting LLC
Martin Masters, Boston Scientific Corporation
Enio Montenegro, Cadwell Laboratories Inc
Robert Moore, ResMed Ltd
Susumu Nozawa, Siemens Healthineers
Nate Osborn, Stryker Instruments Division
Robert David G. Osborn, Philips
Brodie C. Pedersen, Borderless Compliance LLC
Salman Raza, Razalution Bureau LLC
Peter Rech, Smiths Medical
Steven Rus, STERIS Corporation | Healthcare
Robert Steurer, Steurer Consulting Group
Mark Swanson, Quality and Regulatory Expert Partners
Matthew Trachtenberg, Becton Dickinson & Company
Daidi Zhong, Chongqing University

Alternates: David M. Deaven, GE Healthcare
Essam El-Nady, Amgen Inc
Matthew English, TUV Rheinland of North America Inc
Gabriel Frederito, Boston Scientific Corporation
Joshua Kim, Hillrom, Inc
Travis J. Lindahl, Stryker Instruments Division
Yaqing Liu, Intertek
Richard Markle, Philips

Avital Merl, Becton Dickinson & Company
Behnam Molavi, Spacelabs Healthcare
David McCall, STERIS Corporation | Healthcare
James Shults, ICU Medical Inc
Sandy Weininger, FDA - CDRH
John Zekic, ResMed Ltd
Nicole Zuk, Siemens Medical Systems - Malvern, PA

NOTE Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Background of ANSI/AAMI adoption of IEC 60601-1:2005 as ES60601-1 and Amendments 1 and 2

As indicated in the foreword to the main body of this document (page v), the International Electrotechnical Commission (IEC) is a worldwide federation of national standards bodies. The United States is one of the IEC members that took an active role in the development of this standard, which was developed by IEC/SC 62A to publish a second Amendment to IEC 60601-1, which updates references and other information to remain relevant and up to date.

U.S. participation in IEC is organized through the U.S. Technical Advisory Group, IEC/SC 62A, administered by the Association for the Advancement of Medical Instrumentation. Experts from the United States made a considerable contribution to this standard.

The U.S. adoption of IEC 60601-1:2005 was approved by the American National Standards Institute (ANSI) as a revision, with expanded scope, of AAMI ES1:1993, Safe current limits for electromedical apparatus, on 9 February 2006. The AAMI Electrical Safety Committee initiated the U.S. adoption of IEC 60601-1:2005. This edition of IEC 60601-1 has significant technical changes in the general requirements section (clause 4), electrical safety (clause 8), mechanical safety (clauses 9 and 15), and thermal/fire safety (clause 11).

The risk management philosophy introduced in clause 4.2 is the most significant change compared to ES1 and previous editions of IEC 60601-1. Manufacturers are now required to apply a risk management process in accordance with ISO 14971. For electrical safety under clause 8, this edition replaced the basic and double/reinforced insulations from the last edition with one or two "means of protection". The mechanical requirements contained in clauses 9 and 15 are far more extensive and detailed than in previous editions. Finally, clause 11 will also deal with flammability of materials used in the product in addition to requirements that address the temperature of components and surfaces that can be touched by users or patients.

AAMI encourages its committees to harmonize their work with International Standards in the area of safety and essential performance for medical electrical equipment. Upon review of IEC 60601-1:2005/A1:2012/A2:2020, the U.S. TAG for IEC/SC 62A and the AAMI Electrical Safety Committee decided to adopt the amendments verbatim, as Amendment 1 and Amendment 2 to ANSI/AAMI ES60601-1.

AAMI and ANSI procedures require that standards be reviewed and, if necessary, revised every five years to reflect technological advances that may have occurred since publication.

As used within the context of this document, "shall" indicates requirements strictly to be followed to conform to the recommended practice. "Should" indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited.

"May" is used to indicate that a course of action is permissible within the limits of the standard. "Can" is used as a statement of possibility and capability. Finally, "must" is used only to describe "unavoidable" situations, including those mandated by government regulation.

NOTE Users of this standard are advised that this document is an AAMI identical adoption of an IEC document and that the following international conventions have been carried over to the AAMI publication:

- British English spelling (e.g., colour instead of color);
- Use of SI units (e.g., metres instead of feet, Celsius instead of Fahrenheit, etc.);
- Decimal comma instead of a decimal point (e.g., 1 000,15 instead of 1,000.15).

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data comes to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

NOTE This background does not contain provisions of the American National Standard, *Medical electrical equipment—Part 1: General requirements for basic safety and essential performance*, but it does provide important information about the development and intended use of the document.

U.S. (AAMI) deviations from IEC 60601-1:2005

As part of an effort to harmonize standards throughout an increasing global industry, the AAMI Electrical Safety Committee voted to adopt IEC 60601-1 as ES60601-1. The AAMI Electrical Safety Committee also agreed that a number of U.S. deviations to the IEC standard would improve the document to be used in U.S. The deviations are only to the main IEC 60601-1 standard and not to the subsequent amendments.

Deviations are listed below. A rationale for each change has also been provided by the committee.

Please note that beginning with IEC Foreword, this document is identical to IEC 60601-1 with Amendments 1 and 2. The clauses where there are U.S. deviations are highlighted throughout the text and a hyperlink in the highlighted section will direct the reader back to this page which lists all of the deviations. Please pay particular attention to the deviations listed below as the deviations are not incorporated into the main text—just the hyperlink back to this page.

4 General requirements

4.8 Components of ME EQUIPMENT

Replacement:

Because ANSI (American National Standards Institute) has published more component standards that are relevant to ME EQUIPMENT than either IEC or ISO, replace 4.8 b) with the following paragraph:

- b) where there is no relevant IEC/ISO standard, the relevant ANSI standard shall be applied; if no relevant ANSI standard exists, the requirements of this standard shall be applied.

4.10.2 SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

Replacement:

To reflect agreement with the NEC, replace the reference to "500 V" with "600 V" in the second and third dashes.

Addition:

To reflect agreement with the NEC, in the text of the second-to-last dash of this sub-clause, add "and the NEC" after the reference to "IEC 60364-4-41".

6 * Classification of ME EQUIPMENT and ME SYSTEMS

6.6 Mode of operation

Addition:

To reflect agreement with NFPA 70, X-Ray systems shall be classified as long time operation (> 5 min) or momentary operation (< 5 sec).

7 ME EQUIPMENT identification, marking and documents

7.2.11 Mode of operation

Addition:

To reflect agreement with NFPA 70, X-Ray systems shall be marked as long time operation or momentary operation.

New Subclause:

7.2.22 Colors of medical gas cylinders

To reflect agreement with NFPA 99: Cylinders containing medical gases and their connection points shall be colored in accordance with the requirements of NFPA 99.

8 * Protection against electrical hazards from me equipment

8.2 Requirements related to power sources

Addition:

To reflect agreement with the NEC, add the following requirement to this clause:

All FIXED ME EQUIPMENT and PERMANENTLY INSTALLED ME EQUIPMENT shall be CLASS I ME EQUIPMENT.

8.6.1 Application of requirements

Addition:

To reflect agreement with NFPA 99, the enclosure of X-ray ME EQUIPMENT operating over 600 Vac, 850 Vdc MAINS VOLTAGE, or containing voltages up to 50 V peak and enclosed in protectively earthed enclosure as well as connections to X-ray tubes and other high voltage components that include high voltage shielded cables shall be PROTECTIVELY EARTHED.

To reflect agreement with NFPA 99, non-current carrying conductive parts of X-Ray ME EQUIPMENT likely to become energized shall be PROTECTIVELY EARTHED.

8.7.3 Allowable values

Deletion:

To reflect agreement with NFPA 99 which does not allow for allowance greater than the stated values, delete the second sentence and note to sub-clause 8.7.3 d) so that it reads:

- d) The allowable values of the EARTH LEAKAGE CURRENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION.

8.11 MAINS PARTS, components and layout

Addition:

a) To reflect agreement with the NEC, add the following requirements to this clause:

Permanently connected ME EQUIPMENT shall have provision for the connection of one of the wiring systems that is in accordance with the NEC.

Exception: Fixed and stationary X-ray ME EQUIPMENT supplied from a branch circuit rated at 30 A or less, and ME EQUIPMENT that is not strictly portable but obviously is intended to be stationary, may be acceptable if provided with a length of attached hard service flexible cord - such as Type S, or the equivalent, for supply connection.

The installation of connecting cords between EQUIPMENT parts shall meet the requirements of the NEC, as applicable. Cable used as external interconnection between units shall be as follows:

- 1) If exposed to abuse, the cable shall be Type SJT, SJTO, SJO, ST, SO, STO, or equivalent flexible cord or similar multiple-conductor appliance-wiring material such as computer cable.
- 2) If not exposed to abuse, the cable shall be as indicated in item 1) above or shall be:
 - i) Type SPT-2, SP-2, or SPE-2, or equivalent,
 - ii) Type SVr, SVRO, SVE, or equivalent flexible cord or similar multiple-conductor appliance wiring material, or
 - iii) An assembly of insulated wires each with a nominal insulation thickness of 0.8 mm (1/32 inch) or more, enclosed in acceptable insulating tubing having a nominal wall thickness of 0.8 mm (1/32 inch) or more.

Receptacles provided as part of ME EQUIPMENT or ME SYSTEMS for use in the patient care areas of pediatric wards, rooms, or areas shall be listed tamper resistant or shall employ a listed tamper resistant cover in accordance with the NEC.

b) For ME EQUIPMENT provided with NEMA configuration non-locking plug types 120 V/15 A, 125 V/20 A, 250 V/15 A, 250 V/20 A "Hospital Grade" mains plug shall be provided and the POWER SUPPLY CORD shall be marked.

8.11.3.2 Types

Addition:

To reflect agreement with the NEC, add the following requirement to this clause:

The flexible cord shall be of a type that is acceptable for the particular application. It shall be acceptable for use at a voltage not less than the rated voltage of the appliance and shall have an ampacity, as given in the NEC, not less than the current rating of the appliance.

8.11.3.3 Cross-sectional area of POWER SUPPLY CORDS

Addition:

To reflect agreement with NFPA 99, for X-Ray ME EQUIPMENT with an attachment plug, the current rating on a hospital grade plug should be 2X the maximum input current of the equipment.

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 provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with an IEC Publication.
- 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.

This consolidated version of the official IEC Standard and its amendments has been prepared for user convenience.

IEC 60601-1 edition 3.2 contains the third edition (2005-12) [documents 62A/505A/FDIS and 62A/512/RVD], its amendment 1 (2012-07) [documents 62A/805/FDIS and 62A/820/RVD] and its amendment 2 (2020-08) [documents 62A/1389/FDIS and 62A/1404/RVD].

This Consolidated version includes the contents of the corrigenda 1 (2006-12) and 2 (2007-12), the contents of the corrigendum to Amendment 1 (2014-07), as well as the interpretation sheets 1 (2008-04), 2 (2009-01), 3 (2013-05) and Interpretation Sheet 1 to Amendment 1 (2021-03).

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendments 1 and 2. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

International Standard IEC 60601-1 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 third edition cancels and replaces the second edition published in 1988, its Amendment 1 (1991) and Amendment 2 (1995), the second edition of IEC 60601-1-1 published in 2000 and the first edition of IEC 60601-1-4 published in 1996 and its Amendment 1 (1999). This edition constitutes a technical revision. This edition has been significantly restructured. Requirements in the electrical section have been further aligned with those for information technology equipment covered by IEC 60950-1 and a requirement for including a RISK MANAGEMENT PROCESS has been added. For an expanded description of this revision, see Annex A.3.

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

In this standard the following print types are used:

- Requirements and definitions: in roman type.
- *Test specifications: in italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS USED THROUGHOUT THIS STANDARD THAT HAVE BEEN DEFINED IN CLAUSE 3 AND ALSO GIVEN IN THE INDEX: IN SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex G of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

The committee has decided that the contents of the base publication and its amendments will remain unchanged until the stability 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.

NOTE The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The “colour inside” logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this publication using a colour printer.

Introduction

In 1976, IEC subcommittee 62A published the first edition of IEC/TR 60513, *Basic aspects of the safety philosophy for electrical equipment used in medical practice*. The first edition of IEC/TR 60513 provided the basis for developing:

- the first edition of IEC 60601-1 (the parent safety standard for MEDICAL ELECTRICAL EQUIPMENT);
- the IEC 60601-1-xx series of collateral standards for MEDICAL ELECTRICAL EQUIPMENT;
- the IEC 60601-2-xx series of particular standards for particular types of MEDICAL ELECTRICAL EQUIPMENT; and
- the IEC 60601-3-xx series of performance standards for particular types of MEDICAL ELECTRICAL EQUIPMENT.

Aware of the need and the urgency for a standard covering electrical equipment used in medical practice, the majority of National Committees voted in 1977 in favour of the first edition of IEC 60601-1, based on a draft that at the time represented a first approach to the problem. The extent of the scope, the complexity of the equipment concerned, and the specific nature of some of the protective measures and the corresponding tests for verifying them, required years of effort in order to prepare this first standard, which can now be said to have served as a universal reference since its publication.

However, the frequent application of the first edition revealed room for improvement. These improvements were all the more desirable in view of the considerable success that this standard has enjoyed since its publication.

The careful work of revision subsequently undertaken and continued over a number of years resulted in the publication of the second edition in 1988. This edition incorporated all the improvements that could be reasonably expected up to that time. Further developments remained under constant study. The second edition was amended in 1991 and then again in 1995.

The original IEC approach was to prepare separate BASIC SAFETY and performance standards for MEDICAL ELECTRICAL EQUIPMENT. This was a natural extension of the historical approach taken at the national and international level with other electrical equipment standards (e.g. those for domestic equipment), where BASIC SAFETY is regulated through mandatory standards but other performance specifications are regulated by market pressure. In this context, it has been said that, "The ability of an electric kettle to boil water is not critical to its safe use!"

It is now recognized that this is not the situation with many items of MEDICAL ELECTRICAL EQUIPMENT, and RESPONSIBLE ORGANIZATIONS have to depend on standards to ensure ESSENTIAL PERFORMANCE as well as BASIC SAFETY. Such areas include the accuracy with which the equipment controls the delivery of energy or therapeutic substances to the PATIENT, or processes and displays physiological data that will affect PATIENT management.

This recognition means that separating BASIC SAFETY and performance is somewhat inappropriate in addressing the HAZARDS that result from inadequate design of MEDICAL ELECTRICAL EQUIPMENT. Many particular standards in the IEC 60601-2-xx series address a range of ESSENTIAL PERFORMANCE requirements that cannot be directly evaluated by the RESPONSIBLE ORGANIZATION without applying such standards. (However, the current IEC 60601 series includes fewer requirements for ESSENTIAL PERFORMANCE than for BASIC SAFETY).

In anticipation of a third edition of IEC 60601-1, IEC subcommittee 62A prepared a second edition of IEC/TR 60513 [12]¹⁾ in 1994. It was intended that the second edition of IEC/TR 60513 would provide guidance for developing this edition of IEC 60601-1, and for the further development of the IEC 60601-1-xx and IEC 60601-2-xx series.

In order to achieve consistency in international standards, address present expectations in the health care community and align with developments in IEC 60601-2-xx, the second edition of IEC/TR 60513 includes two major new principles:

- the first change is that the concept of “SAFETY” has been broadened from the BASIC SAFETY considerations in the first and second editions of IEC 60601-1 to include ESSENTIAL PERFORMANCE matters, (e.g. the accuracy of physiological monitoring equipment). Application of this principle leads to the change of the title of this publication from “Medical electrical equipment, Part 1: General requirements for safety” in the second edition, to “Medical electrical equipment, Part 1: General requirements for basic safety and essential performance”;
- the second change is that, in specifying minimum safety requirements, provision is made for assessing the adequacy of the design PROCESS when this is the only practical method of assessing the safety of certain technologies such as programmable electronic systems. Application of this principle is one of the factors leading to introduction of a general requirement to carry out a RISK MANAGEMENT PROCESS. In parallel with the development of the third edition of IEC 60601-1, a joint project with ISO/TC 210 resulted in the publication of a general standard for RISK MANAGEMENT of medical devices. Compliance with this edition of IEC 60601-1 requires that the MANUFACTURER have in place a RISK MANAGEMENT PROCESS complying with parts of ISO 14971 (see 4.2).

This standard contains requirements concerning BASIC SAFETY and ESSENTIAL PERFORMANCE that are generally applicable to MEDICAL ELECTRICAL EQUIPMENT. For certain types of MEDICAL ELECTRICAL EQUIPMENT, these requirements are either supplemented or modified by the special requirements of a collateral or particular standard. Where particular standards exist, this standard should not be used alone.

Amendment 1 to this standard is intended to address:

- issues identified by National Committees and other interested parties since the publication of IEC 60601-1:2005;
- the way in which RISK MANAGEMENT has been introduced into IEC 60601-1:2005; and
- the way the concept of ESSENTIAL PERFORMANCE is used in IEC 60601-1:2005.

Throughout this document, there are many references to, and requirements incorporated from IEC 60950-1. Some of these requirements are derived from IEC 60950-1. For example, the requirements for spaces filled by insulating compound in 8.9.3. In other cases, the requirements are incorporated by a normative reference to IEC 60950-1:2005. For example, the requirements for solid insulation forming a MEANS OF OPERATOR PROTECTION in 8.5.1.3. The requirements incorporated by reference are primarily found in Clause 8 of this document, including many of the tables used to determine the requirements for MEANS OF PROTECTION, primarily MEANS OF OPERATOR PROTECTION and INSULATION CO-ORDINATION. The requirements incorporated by reference are addressed in Amendment 2. The derived requirements will be addressed during the development of the fourth edition of this document.

INTRODUCTION TO AMENDMENT 1

The third edition of IEC 60601-1 was published in 2005. At the time of publication, there were 94 National Committee comments on the 2nd CDV and the FDIS that were deferred to a future amendment/revision. Each of their deferred comments was captured in an Issue Sheet by the SC 62A secretariat. By the time of the Auckland meeting in April 2008, the Subcommittees had developed two Interpretation Sheets and the SC 62A secretariat has received an additional 15 issues from National Committees and other interested parties.

1) Figures in square brackets refer to the Bibliography.

At the Auckland meeting, IEC/TC 62 approved a project to develop the 1st amendment to IEC 60601-1:2005 based on the issues outstanding at the time. The TC approved developing the 1st amendment with a view to addressing outstanding issues, including but not limited to:

- those listed in 62A/593/DC and 62A/602/INF;
- the way in which risk management has been introduced into IEC 60601-1:2005; and
- the way the concept of essential performance is used in IEC 60601-1:2005.

Since the Auckland meeting, the secretariat has received 73 additional issues from National Committees or other interested parties for a total of 182 Issues Sheets. This amendment is intended to address those issues.

INTRODUCTION TO AMENDMENT 2

The third edition of IEC 60601-1 was published in 2005 and amended in 2012. Since the publication of IEC 60601-1:2005/AMD1:2012, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees and questions submitted to IEC/SC 62A/Working Group (WG) 14. At the November 2015 meeting of IEC/SC 62A in Kobe, Japan, the subcommittee initiated a process to identify high-priority issues that need to be considered in Amendment 2 and should not wait until the fourth edition of IEC 60601-1, which is presently targeted for publication sometime after 2024.

Those issues selected for inclusion on the final "short list" to be addressed in Amendment 2 were those approved by a 2/3 majority of the National Committees present and voting at the Frankfurt meeting of SC 62A. At the meeting held on 10 October 2016, 109 items were presented to the National Committees present. A total of 78 items received the required 2/3 majority of the National Committees present and voting and were included in the "short list" for consideration in preparing Amendment 2. All remaining issues have been placed on a "long list" for consideration in the fourth edition of IEC 60601-1.

The "short list" of issues was documented in the design specification for Amendment 2. The responsible expert groups were directed to consider each issue assigned to it in Clause 6 of the design specification and develop an appropriate solution for the identified problem. That final solution in this amendment can encompass any technical solution proposed by the author of the issue or it can involve a different solution developed by the expert group. The expert group can also have recommended that no change to the standard was justified by the problem statement.

Because this is an amendment to the 2005 edition of IEC 60601-1, the style in force at the time of publication of IEC 60601-1 has been applied to this amendment. The style specified in ISO/IEC Directives, Part 2:2018 has only been applied when implementing the new style guidance would not result in additional editorial changes. For example, notes to definitions are designated as "NOTE" rather than "Note to entry" in Clause 3.

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.

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

1 Scope, object and related standards

1.1 * Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1.

NOTE 1 See also 4.2.

~~This standard can also be applied to equipment used for compensation or alleviation of disease, injury or disability.~~

~~In vitro diagnostic equipment that does not fall within the definition of ME EQUIPMENT is covered by the IEC 61010 series ²⁾. This standard does not apply to the implantable parts of active implantable medical devices covered by ISO 14708-1 ³⁾.~~

The IEC 60601 series does not apply to:

- in vitro diagnostic equipment that does not fall within the definition of ME EQUIPMENT, which is covered by the IEC 61010 series [61];
- implantable parts of active implantable medical devices covered by the ISO 14708 series [69]; or
- medical gas pipeline systems covered by ISO 7396-1 [68].

NOTE 2 ISO 7396-1 applies the requirement of IEC 60601-1-8 to certain monitoring and ALARM SIGNALS.

1.2 Object

The object of this standard is to specify general requirements and to serve as the basis for particular standards.

²⁾ IEC 61010 (all parts), *Safety requirements for electrical equipment for measurement, control, and laboratory use*

³⁾ ISO 14708-1, *Implants for surgery—Active implantable medical devices—Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*