



ANSI/AAMI ES60601-1:2005

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

(IEC 60601-1:2005, MOD.)

The Objectives and Uses of AAMI Standards and Recommended Practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a fume of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards health care professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization, processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decisionmaking.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing device and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the Manager for Technical Development. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News*. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News*.

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

Developed by
Association for the Advancement of Medical Instrumentation

Approved 9 February 2006
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.

Keywords: equipment, electrical 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 five 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

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Road, Suite 220
Arlington, VA 22201-4795

© 2006 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

This publication is subject to copyright claims of IEC, ANSI, and AAMI. No part of this publication may be reproduced or transmitted 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. Violators 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 AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795. Phone: (703) 525-4890; Fax: (703) 525-1067. Printed in the United States of America

ISBN 1-57020-246-X

Contents

	Page
Glossary of equivalent standards	xi
Committee representation	xiii
Background of AAMI adoption of IEC 60601-1:2005	xiv
AAMI deviations from IEC 60601-1:2005.....	xv
Foreword	xvii
Introduction	xix
1 Scope, object, and related standards	1
1.1 Scope	1
1.2 Object	1
1.3 Collateral standards	1
1.4 Particular standards	1
2 Normative references	2
3 Terminology and definitions	4
4 General requirements	15
4.1 Conditions for application to ME EQUIPMENT OR ME SYSTEMS	15
4.2 RISK MANAGEMENT PROCESS for ME EQUIPMENT OR ME SYSTEMS	15
4.3 ESSENTIAL PERFORMANCE	16
4.4 EXPECTED SERVICE LIFE	16
4.5 Equivalent safety for ME EQUIPMENT OR ME SYSTEM	16
4.6 ME EQUIPMENT OR ME SYSTEM parts that contact the patient	16
4.7 SINGLE FAULT CONDITION for ME EQUIPMENT	16
4.8 Components of ME EQUIPMENT	17
4.9 Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT	18
4.10 Power supply	18
4.11 Power input	19
5 General requirements for testing ME EQUIPMENT	19
5.1 TYPE TESTS	19
5.2 Number of samples	20
5.3 Ambient temperature, humidity, atmospheric pressure	20
5.4 Other conditions	20
5.5 Supply voltage, type of current, nature of supply, frequency	20
5.6 Repairs and modifications	20
5.7 Humidity preconditioning treatment	21
5.8 Sequence of tests	21
5.9 Determination of APPLIED PARTS and ACCESSIBLE PARTS	21
6 Classification of ME EQUIPMENT and ME SYSTEMS	23
6.1 General	23
6.2 Protection against electric shock	23
6.3 Protection against harmful ingress of water or particulate matter	24
6.4 Method(s) of sterilization	24
6.5 Suitability for use in an OXYGEN RICH ENVIRONMENT	24
6.6 Mode of operation	24
7 ME EQUIPMENT identification, marking, and documents	24
7.1 General	24

7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts	25
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts	28
7.4	Marking of controls and instruments	29
7.5	Safety signs	30
7.6	Symbols	31
7.7	Colors of the insulation of conductors	31
7.8	Indicator lights and controls	32
7.9	ACCOMPANYING DOCUMENTS	32
8	Protection against electrical HAZARDS from ME EQUIPMENT	37
8.1	Fundamental rule of protection against electric shock	37
8.2	Requirements related to power sources	38
8.3	Classification of APPLIED PARTS	38
8.4	Limitation of voltage, current, or energy	38
8.5	Separation of parts	41
8.6	Protective earthing, functional earthing, and potential equalization of ME EQUIPMENT	47
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	48
8.8	Insulation	64
8.9	CREEPAGE DISTANCES and AIR CLEARANCES	70
8.10	Components and wiring	82
8.11	MAINS PARTS, components, and layout	84
9	Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	89
9.1	MECHANICAL HAZARDS of ME EQUIPMENT	89
9.2	HAZARDS associated with moving parts	89
9.3	HAZARD associated with surfaces, corners, and edges	93
9.4	Instability HAZARDS	93
9.5	Expelled parts HAZARD	97
9.6	Acoustic energy (including infra- and ultrasound) and vibration	97
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure	98
9.8	HAZARDS associated with support systems	100
10	Protection against unwanted and excessive radiation HAZARDS	104
10.1	X-Radiation	104
10.2	Alpha, beta, gamma, neutron, and other particle radiation	105
10.3	Microwave radiation	105
10.4	Lasers and light emitting diodes	105
10.5	Other visible electromagnetic radiation	105
10.6	Infrared radiation	105
10.7	Ultraviolet radiation	105
11	Protection against excessive temperatures and other HAZARDS	106
11.1	Excessive temperatures in ME EQUIPMENT	106
11.2	Fire prevention	109
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT	114
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anesthetics	116
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents	116
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization, and compatibility with substances used with the ME EQUIPMENT	116
11.7	Biocompatibility of ME EQUIPMENT and ME SYSTEMS	117
11.8	Interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT	118
12	Accuracy of controls and instruments and protection against hazardous outputs	118
12.1	Accuracy of controls and instruments	118
12.2	USABILITY	118
12.3	Alarm systems	118
12.4	Protection against hazardous output	118
13	HAZARDOUS SITUATIONS and fault conditions	119
13.1	Specific HAZARDOUS SITUATIONS	120

13.2	SINGLE FAULT CONDITIONS	120
14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS	124
14.1	General	124
14.2	Documentation	125
14.3	RISK MANAGEMENT plan	125
14.4	PEMS DEVELOPMENT LIFE-CYCLE	125
14.5	Problem resolution	125
14.6	RISK MANAGEMENT PROCESS	126
14.7	Requirement specification	126
14.8	Architecture	126
14.9	Design and implementation	127
14.10	VERIFICATION	127
14.11	PEMS VALIDATION	127
14.12	Modification	128
14.13	Connection of PEMS by NETWORK/DATA COUPLING to other equipment	128
15	Construction of ME EQUIPMENT	128
15.1	Arrangements of controls and indicators of ME EQUIPMENT	128
15.2	Serviceability	128
15.3	Mechanical strength	129
15.4	ME EQUIPMENT components and general assembly	132
15.5	MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5	136
16	ME SYSTEMS	138
16.1	General requirements for the ME SYSTEMS	138
16.2	ACCOMPANYING DOCUMENTS of an ME SYSTEM	139
16.3	Power supply	140
16.4	ENCLOSURES	140
16.5	SEPARATION DEVICES	140
16.6	LEAKAGE CURRENTS	140
16.7	Protection against MECHANICAL HAZARDS	141
16.8	Interruption of the power supply to parts of an ME SYSTEM	141
16.9	ME SYSTEM connections and wiring	141
17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	143
Annexes		
A	General guidance and rationale	144
B	Sequence of testing	225
C	Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS	228
D	Symbols on marking	231
E	Examples of the connection of the measuring device (MD) for measurement of the PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT	238
F	Suitable measuring supply circuits	241
G	Protection against HAZARDS of ignition of flammable anesthetic mixtures	244
H	PEMS structure, PEMS DEVELOPMENT LIFE-CYCLE, and documentation	257
I	ME SYSTEMS aspects	269
J	Survey of insulation paths	274
K	Simplified PATIENT LEAKAGE CURRENT diagrams	277
L	Insulated winding wires for use without interleaved insulation	280

Bibliography	282
Index	285
Index of abbreviations and acronyms	299

Figures

1 Detachable mains connection	5
2 Example of the defined terminals and conductors	6
3 Example of a CLASS I ME EQUIPMENT	6
4 Example of a metal-enclosed CLASS II ME EQUIPMENT	7
5 Schematic flow chart for component qualification	7
6 Standard test finger	20
7 Test hook	23
8 Test pin	39
9 Application of test voltage to bridged PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS ..	45
10 Application of test voltage to individual PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS ..	46
11 Application of test voltage to test the delivered defibrillation energy	47
12 Example of a measuring device and its frequency characteristics	50
13 Measuring circuit for the EARTH LEAKAGE CURRENT of CLASS I equipment, with or without APPLIED PART	53
14 Measuring circuit for the TOUCH CURRENT	54
15 Measuring circuit for the PATIENT LEAKAGE CURRENT from the PATIENT CONNECTION to earth	55
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)	56
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	57
18 Measuring circuit for the PATIENT LEAKAGE CURRENT from PATIENT CONNECTION(s) to earth 70 caused by an external voltage on a metal ACCESSIBLE PART that is not PROTECTIVELY EARTHED	58
19 Measuring circuit for the PATIENT AUXILIARY CURRENT	59
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	60
21 Ball-pressure test apparatus	70
22 CREEPAGE DISTANCE AND AIR CLEARANCE—Example 1	80
23 CREEPAGE DISTANCE AND AIR CLEARANCE—Example 2	80
24 CREEPAGE DISTANCE AND AIR CLEARANCE—Example 3	80
25 CREEPAGE DISTANCE AND AIR CLEARANCE—Example 4	81
26 CREEPAGE DISTANCE AND AIR CLEARANCE—Example 5	81
27 CREEPAGE DISTANCE AND AIR CLEARANCE—Example 6	81
28 CREEPAGE DISTANCE AND AIR CLEARANCE—Example 7	81
29 CREEPAGE DISTANCE AND AIR CLEARANCE—Example 8	82

30	CREEPAGE DISTANCE AND AIR CLEARANCE—Example 9	82
31	CREEPAGE DISTANCE AND AIR CLEARANCE—Example 10	82
32	Ratio between HYDRAULIC TEST PRESSURE and MAXIMUM PERMISSIBLE WORKING PRESSURE	99
33	Human body test mass	103
34	Spark ignition test apparatus	111
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	111
36	Maximum allowable voltage U as a function of the capacitance C measured in a capacitive circuit used in an OXYGEN RICH ENVIRONMENT	112
37	Maximum allowable current I as a function of the inductance L measured in an inductive circuit in an OXYGEN RICH ENVIRONMENT	112
38	Baffle	115
39	Area of the bottom of an ENCLOSURE as specified in 11.3 (b) (1)	116
A.1	Identification of ME EQUIPMENT, APPLIED PARTS, and PATIENT CONNECTIONS in an ECG monitor	149
A.2	Example of the insulation of an F-TYPE APPLIED PART with the insulation incorporated in the ME EQUIPMENT	150
A.3	Identification of ME EQUIPMENT, APPLIED PARTS, and PATIENT CONNECTIONS in a PATIENT monitor with invasive pressure monitoring facility	150
A.4	Identification of ME EQUIPMENT, APPLIED PARTS, and PATIENT CONNECTIONS in a multifunction PATIENT monitor with invasive pressure monitoring facilities	151
A.5	Identification of APPLIED PARTS and PATIENT CONNECTIONS in an X-ray ME SYSTEM	152
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	153
A.7	Identification of ME EQUIPMENT OF ME SYSTEM, APPLIED PARTS, and PATIENT CONNECTIONS in a personal computer with an ECG module	154
A.8	Pictorial representation of the relationship of HAZARD, sequence of events, HAZARDOUS SITUATION, and HARM	156
A.9	Example of PATIENT ENVIRONMENT	160
A.10	Floating circuit	171
A.11	Interruption of a power-carrying conductor between ME EQUIPMENT parts in separate ENCLOSURES	173
A.12	Identification of MEANS OF PATIENT PROTECTION and MEANS OF OPERATOR PROTECTION	176
A.13	Allowable protective earth impedance where the fault current is limited	181
A.14	Probability of ventricular fibrillation	186
A.15	ME EQUIPMENT with multiple PATIENT CONNECTIONS	189
A.16	Instability test conditions	199
A.17	Example of determining TENSILE SAFETY FACTOR using Table 21	203
A.18	Example of determining design and test loads	204
A.19	Example of human body mass distribution	204

E.1	TYPE B APPLIED PART	238
E.2	TYPE BF APPLIED PART	238
E.3	TYPE CF APPLIED PART	239
E.4	PATIENT AUXILIARY CURRENT	239
E.5	Loading of the PATIENT CONNECTIONS if specified by the MANUFACTURER	240
F.1	Measuring supply circuit with one side of the SUPPLY MAINS at approximately earth potential	241
F.2	Measuring supply circuit with SUPPLY MAINS approximately symmetrical to earth potential	241
F.3	Measuring supply circuit for polyphase ME EQUIPMENT specified for connection to a polyphase SUPPLY MAINS	242
F.4	Measuring supply circuit for single-phase ME EQUIPMENT specified for connection to a polyphase SUPPLY MAINS	242
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	243
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 vapor with air	249
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 vapor with air	250
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 vapor with air	250
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 vapor with oxygen	252
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 vapor with oxygen	255
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 vapor with oxygen	255
G.7	Test apparatus	256
H.1	Examples of PEMS/PESS structures	258
H.2	A PEMS DEVELOPMENT LIFE-CYCLE MODEL	259
H.3	PEMS documentation requirements from clause 14 and ISO 14971:2000	263
H.4	Example of potential parameters required to be specified for NETWORK/DATA COUPLING	268
I.1	Example of the construction of a MULTIPLE SOCKET-OUTLET	272
I.2	Examples of application of MULTIPLE SOCKET-OUTLETS	273
J.1	Insulation—Example 1	274
J.2	Insulation—Example 2	274
J.3	Insulation—Example 3	275
J.4	Insulation—Example 4	275
J.5	Insulation—Example 5	275
J.6	Insulation—Example 6	276
J.7	Insulation—Example 7	276
K.1	ME EQUIPMENT with an ENCLOSURE made of insulating material	277

K.2	ME EQUIPMENT with an F-TYPE APPLIED PART	277
K.3	ME EQUIPMENT with an APPLIED PART and a SIGNAL INPUT/OUTPUT PART	278
K.4	ME EQUIPMENT with a PATIENT CONNECTION of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED	278
K.5	ME EQUIPMENT with a PATIENT CONNECTION of a TYPE BF APPLIED PART that is not PROTECTIVELY EARTHED	279

Tables

1	Units outside the SI units system that may be used on ME EQUIPMENT	30
2	Colors of indicator lights and their meaning for ME EQUIPMENT	32
3	Allowable values of PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL CONDITION and SINGLE FAULT CONDITION	51
4	Allowable values of PATIENT LEAKAGE CURRENTS under the special test conditions identified in 8.7.4.7	52
5	Legends of symbols for Figure 9 to Figure 11, Figure 13 to Figure 20, Annex E, and Annex F	61
6	Test voltages for solid insulation forming a MEANS OF PROTECTION	67
7	Test voltages for MEANS OF OPERATOR PROTECTION	68
8	Multiplication factors for AIR CLEARANCES for altitudes up to 5,000 m	71
9	Material group classification	71
10	MAINS TRANSIENT VOLTAGE	72
11	Minimum CREEPAGE DISTANCES and AIR CLEARANCES between parts of opposite polarity of the MAINS PART	74
12	Minimum CREEPAGE DISTANCES and AIR CLEARANCES providing MEANS OF PATIENT PROTECTION	74
13	Minimum AIR CLEARANCES providing MEANS OF OPERATOR PROTECTION from the MAINS PART	75
14	Additional AIR CLEARANCES for insulation in MAINS PARTS with PEAK WORKING VOLTAGES exceeding the peak value of the NOMINAL MAINS VOLTAGE	76
15	Minimum AIR CLEARANCES for MEANS OF OPERATOR PROTECTION in SECONDARY CIRCUITS	77
16	Minimum CREEPAGE DISTANCES providing MEANS OF OPERATOR PROTECTION	78
17	NOMINAL cross-sectional area of conductors of a POWER SUPPLY CORD	85
18	Testing of cord anchorages	86
19	MECHANICAL HAZARDS covered by this clause	89
20	Acceptable gaps	90
21	Determination of TENSILE SAFETY FACTOR	101
22	Allowable maximum temperatures of parts	106
23	Allowable maximum temperatures for ME EQUIPMENT parts that are likely to be touched	107
24	Allowable maximum temperatures for skin contact with ME EQUIPMENT APPLIED PARTS	107
25	Acceptable perforation of the bottom of an ENCLOSURE	115
26	Temperature limits of motor windings	122

27	Maximum motor winding steady-state temperature	124
28	Mechanical strength test applicability	129
29	Drop height	130
30	Test torques for rotating controls.	134
31	Maximum allowable temperatures of transformer windings under overload and short-circuit conditions at 25 °C (± 5 °C) ambient temperature	136
32	Test current for transformers	137
A.1	Values of AIR CLEARANCE and CREEPAGE DISTANCE derived from Table 7 of IEC 61010-1:2001 and Table 12	192
A.2	CREEPAGE DISTANCES to avoid failure due to tracking from IEC 60664-1:2002	193
A.3	Instability test conditions	199
A.4	Allowable time exposure for level of acceleration.	200
A.5	Guidance on surface temperatures for ME EQUIPMENT that creates low temperatures (cools) for therapeutic purposes or as part of its operation	207
C.1	Marking on the outside of ME EQUIPMENT, ME SYSTEMS, or their parts	228
C.2	Marking on the inside of ME EQUIPMENT, ME SYSTEMS, or their parts	229
C.3	Marking of controls and instruments	229
C.4	ACCOMPANYING DOCUMENTS, General	229
C.5	ACCOMPANYING DOCUMENTS, Instructions for use.	230
C.6	ACCOMPANYING DOCUMENTS, Technical description	230
D.1	General symbols	232
D.2	Safety signs.	236
D.3	General codes	237
G.1	Gas-tightness of cord inlets.	252
H.1	NETWORK/DATA COUPLING classification	266
I.1	Some examples of ME SYSTEMS for illustration.	270
L.1	Mandrel diameter	280
L.2	Oven temperature	281

Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard.

NOTE—Documents are sorted by international designation.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1-2:2001	ANSI/AAMI/IEC 60601-1-2:2001	Identical
IEC 60601-2-04:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 and Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:1998	Major technical variations
IEC TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	Identical
ISO 5840:1996	ANSI/AAMI/ISO 5840:1996	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993/(R)2001	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002	ANSI/AAMI/ISO 10993-4:2002	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995/(R)2001	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	Identical
ISO 10993-8:2000	ANSI/AAMI/ISO 10993-8:2000	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999	Identical
ISO 10993-10:2002	ANSI/AAMI BE78:2002	Minor technical variations
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
ISO 10993-12:2002	ANSI/AAMI/ISO 10993-12:2002	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical
ISO 11134:1994	ANSI/AAMI/ISO 11134:1993	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137:1995 and Amdt 1:2001	ANSI/AAMI/ISO 11137:1994 and A1:2002	Identical
ISO 11138-1:1994	ANSI/AAMI ST59:1999	Major technical variations
ISO 11138-2:1994	ANSI/AAMI ST21:1999	Major technical variations

International designation	U.S. designation	Equivalency
ISO 11138-3:1995	ANSI/AAMI ST19:1999	Major technical variations
ISO TS 11139:2001	ANSI/AAMI/ISO 11139:2002	Identical
ISO 11140-1:1995 and Technical Corrigendum 1:1998	ANSI/AAMI ST60:1996	Major technical variations
ISO 11607:2003	ANSI/AAMI/ISO 11607:2000	Identical
ISO 11737-1:1995	ANSI/AAMI/ISO 11737-1:1995	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO TR 13409:1996	AAMI/ISO TIR13409:1996	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161:2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO 14969:1999	ANSI/AAMI/ISO 14969:1999	Identical
ISO 14971:2000 and A1:2003	ANSI/AAMI/ISO 14971:2000 and A1:2003	Identical
ISO 15223:2000	ANSI/AAMI/ISO 15223:2000	Identical
ISO 15223/A1:2002	ANSI/AAMI/ISO 15223:2000/A1:2001	Identical
ISO 15225:2000	ANSI/AAMI/ISO 15225:2000	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO TS 15843:2000	ANSI/AAMI/ISO TIR15843:2000	Identical
ISO TR 15844:1998	AAMI/ISO TIR15844:1998	Identical
ISO TR 16142:1999	ANSI/AAMI/ISO TIR16142:2000	Identical
ISO 25539-1:2003	ANSI/AAMI/ISO 25539-1:2003	Identical

Committee representation

Association for the Advancement of Medical Instrumentation

Electrical Safety Committee

This standard was developed by the AAMI Electrical Safety Committee. Committee approval of the standard does not necessarily imply that all committee members voted for its approval.

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

<i>Cochairs:</i>	Bernie Liebler Mike Schmidt
<i>Members:</i>	Stuart Albert, Ormond Beach, FL Shane Alesi, Respironics Thomas Anderson, GE Healthcare Alan S. Berson, Bioresearch Funding Group, Novato, CA Steve Cantwell, Spacelabs Medical Inc. Yadin David, Texas Childrens Hospital, Houston, TX Arthur Eddy, Jr., Conmed Corporation Jeffrey Eggleston, Tyco Healthcare/Valleylab Kenneth Gettman, National Electrical Manufacturers Association (NEMA) Joshua Kim, Welch Allyn Inc. Bernie Liebler, Advanced Medical Technology Association (AdvaMed) Alan Lipschultz, Christiana Care Health Services, Newark, DE Robert Malkin, University of Memphis, Memphis, TN Francis P. Mokris, Steris Corporation Robert Mosenkis, Citech Joe Murnane, Underwriters Laboratories Inc. David Osborn, Philips Medical Systems Craig Root, Hospira Inc. Michael W. Schmidt, Strategic Device Compliance Services, Cincinnati, OH James D. Stewardson, Brighton, CO Joshua Tsitlik, Washington Hospital Center, Columbia, MD Richard J. Wessels, Guidant Corporation Allen K. Wong, Abbott Laboratories
<i>Alternates:</i>	Joseph Basta, Spacelabs Medical Inc. Mark Graber, GE Healthcare Michael Jaffe, Respironics Richard Markle, Philips Medical Systems Harvey Rudolph, Underwriters Laboratories Inc. Victor Selig, Steris Corporation James Shults, Hospira Inc. Mark C. Simmons, Welch Allyn Inc. Amelia M. Slaughter, Tyco Helathcare/Valleylab Richard Stein, Guidant Corporation Stephen Vastagh, National Electrical Manufacturers Association (NEMA)

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 AAMI adoption of IEC 60601-1:2005

As indicated in the foreword to the main body of this document (page x), the International Electrotechnical Commission (IEC) is a worldwide organization of national electrotechnical committees. 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 Technical Subcommittee 62A, Common aspects of electrical equipment used in medical practice.

U.S. participation in this IEC SC is organized through the U.S. National Committee (USNC) and the U.S. Technical Advisory Group for IEC/SC 62A, administered by the Advanced Medical Technology Association (AdvaMed).

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 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.

AAMI (and ANSI) have adopted other international standards. See the Glossary of Equivalent Standards for a list of international standards adopted by AAMI which gives the corresponding U.S. designation and the level of equivalency with the international standard.

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 come to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795

AAMI deviations from IEC 60601-1:2005

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".

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.

8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

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:

To reflect agreement with the NEC, add the following requirement 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.

8.11.3 POWER SUPPLY CORDS

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.

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.

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). This edition constitutes a technical revision. This edition has been significantly restructured. Requirements in the electrical section have been furthered 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 A.3.

The text of this standard is based on the following documents:

FDIS	Report on voting
62A/505A/FDIS	62A/512/RVD

Full information on the voting for the approval of this standard 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.

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 H 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 this publication will remain unchanged until the maintenance result date¹ 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.

¹ The National Committees are requested to note that for this publication the maintenance result date is 2010.

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 favor 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 ESSENTIAL 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 [13] 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 a RISK MANAGEMENT PROCESS complying with ISO 14971 in place (see 0).

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.

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—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. This standard does not apply to the implantable parts of active implantable medical devices covered by the ISO 14708 series.

1.2 Object

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

1.3 * Collateral standards

In the IEC 60601 series, collateral standards specify general requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE applicable to:

- a subgroup of ME EQUIPMENT (e.g., radiological equipment);
- a specific characteristic of all ME EQUIPMENT not fully addressed in this standard.

Applicable collateral standards become normative at the date of their publication and shall apply together with this standard.

NOTE 1—When evaluating compliance with IEC 60601-1, it is permissible to independently assess compliance with the collateral standards.

NOTE 2—When declaring compliance with IEC 60601-1, the declarer should specifically list the collateral standards that have been applied. This allows the reader of the declaration to understand which collateral standards were part of the evaluation.

NOTE 3—Members of IEC maintain a register of valid International Standards. Users of this standard should consult this register to determine which collateral standards have been published.

If a collateral standard applies to ME EQUIPMENT for which a particular standard exists, then the particular standard takes priority over the collateral standard.

1.4 * Particular standards

In the IEC 60601 series, particular standards may modify, replace, or delete requirements contained in this standard as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.