IEC/TR 62348

Edition 2.0 2012-12

TECHNICAL REPORT

colour inside

Assessment of the impact of the most significant changes in Amendment 1 to IEC 60601-1:2005 and mapping of the clauses of IEC 60601-1:2005 to the previous edition

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

ASSESSMENT OF THE IMPACT OF THE MOST SIGNIFICANT CHANGES IN AMENDMENT 1 TO IEC 60601-1:2005 AND MAPPING OF THE CLAUSES OF IEC 60601-1:2005 TO THE PREVIOUS EDITION

FOREWORD

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IEC 62348, which is a technical report, has been prepared by subcommittee 62A; Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 2006. The second edition retains the mapping that traces the requirements of IEC 60601-1:2005 and its Amendment A1:2012 (Edition 3.1) from their source in the documents that relate to IEC 60601-1:1998 and its amendments (Edition 2.2). See Clause 7. The second edition adds an assessment of the impact of the most significant changes in Amendment 1:2012 (Clauses 4, 5 and 6).

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

Enquiry draft	Report on voting
62A/831/DTR	62A/841/RVC

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

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

The committee has decided that the contents of this publication will remain unchanged until the 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- withdrawn,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.

A bilingual version of this Technical Report may be issued at a later date.

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 document using a colour printer.

INTRODUCTION

The first edition of this technical report was created by the Secretariat of SC 62A to assist users of IEC 60601-1 by providing a tool to trace requirements between IEC 60601-1:2005 and their source in the documents that form the basis of the third edition; principally the second edition as amended.

At the Auckland meeting in 2008, IEC Technical Committee (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 issues reported to the Secretariat of IEC Subcommittee (SC) 62A 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.

Since the Auckland meeting, the Secretariat of SC 62A has received 73 additional issues from National Committees or other interested parties for a total of 182 identified issues with the 2005 edition. Amendment 1 to IEC 60601-1:2005 is intended to address those issues.

The amendment process has resulted in 496 separate changes. Each change was assessed by the experts developing the amendment for its potential impact on users of the standard. Most of the changes are editorial corrections or clarifications and were assessed as having minimal or no impact on the application of the standard. Others were assessed as having moderate or significant impact because they represent a technical change, or they impact a wide range of users, or both.

The second edition of this technical report was prepared by the Secretariat of IEC/SC 62A to summarize those changes that were assessed during the development process as having a moderate to significant impact on users of IEC 60601-1.

The tables from the first edition of this technical report were retained in the second edition because there are counties that have not fully transitioned to the third edition of IEC 60601-1. Therefore, the original contents of IEC/TR 62348 remain useful in those countries.

Table 6 has been updated to include new subclauses added in Amendment 1:2012 (highlighted in blue).

ASSESSMENT OF THE IMPACT OF THE MOST SIGNIFICANT CHANGES IN AMENDMENT 1 TO IEC 60601-1:2005 AND MAPPING OF THE CLAUSES OF IEC 60601-1:2005 TO THE PREVIOUS EDITION

1 Scope

This technical report provides a tool to assist users of IEC 60601-1:2005 to assess the impact of the most significant changes in Amendment 1:2012.

This technical report also provides a tool to assist users of IEC 60601-1 to trace requirements between the third edition and their source in the documents that form the basis of the third edition; principally the second edition as amended.

This report is intended to be used by:

– those who must align standards based on the second edition of IEC 60601-1 with the third edition as amended;
– manufacturers of medical electrical equipment or medical electrical systems;
– health care regulatory authorities, test houses and other organizations responsible for implementing standards for medical electrical equipment and medical electrical systems.

2 Normative references

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

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 + A1:2012 apply.

4 Assessment of the changes in Amendment 1:2012

Amendment 1 contains 496 separate changes. During the development of the amendment, each change was assessed by the experts involved for its potential impact on users of the standard. Most of the changes are editorial corrections or clarifications and were assessed and having minimal or no impact on the application of the standard.

However, 83 of the changes were assessed as having a moderate to significant impact on the users of the standard. This assessment is based on the likelihood that some alterations to the design documentation, testing, the product itself or its accompanying documents will be required because of the change to a requirement in the amendment.

The changes have been divided into two groups:

– those assessed as having a significant impact (Table 1), and

– those assessed as having a moderate impact (Table 2).

Because any assessment is somewhat subjective, users of the standard are encouraged to review the contents of the amendment and determine its impact on the sections that are relevant to their products.

Table 1 – Amendment 1 changes assessed as having the potential for a significant impact

Clause of IEC 60601-1	Clause Title	Impact many users	Impact particular users	Section of this document
4.2	RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS	X		5.3
4.3	Essential performance	X		5.4
4.5	Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS	X		5.5
4.6	ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT	X		5.6
5.1	TYPE TESTS	X		5.8
5.5 a)	Supply voltages, type of current, nature of supply, frequency	X		5.9
5.7	Humidity preconditioning treatment	X		5.10
7.2.1	Minimum requirements for marking on ME EQUIPMENT and on interchangeable parts	X		5.13
7.2.4	ACCESSORIES	X		5.13
7.2.5	ME EQUIPMENT intended to receive power from other equipment		X	6.1
7.2.21	Mass of MOBILE ME EQUIPMENT		X	6.4
7.9.1	General	X		5.17
7.9.3.1	General	X		5.20
8.5.5.1 a)	Defibrillation protection		X	6.7
8.5.5.2	Energy reduction test		X	6.8
8.7.3	Allowable values	X		5.24
8.8.1	General	X		5.26
9.2.3.1	Unintended movement		X	6.14
9.4.2.3 a)	Instability from horizontal and vertical forces		X	6.16
9.4.2.4.3	Movement over a threshold		X	6.17
9.4.3.2 b)	Instability excluding transport position		X	6.20
10.3	Microwave radiation		X	6.27
11.8	Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	X		5.31
13.1.2	Emissions, deformation of ENCLOSURE or exceeding maximum temperature		X	5.32
15.5.3	Construction of transformers used to provide separation as required by 8.5	X		5.42

Table 2 – Amendment 1 changes assessed as having the potential for a moderate impact *(1 of 2)*

Clause of IEC 60601-1	Clause Title	Impact many users	Impact particular users	Section of this document
2	Normative references	X		5.1
3.28	EXPECTED SERVICE LIFE	X		5.2
4.11	Power input	X		5.7
5.9.2.3	Actuating mechanisms	X		5.11
7.1.2	Legibility of markings	X		5.12
7.3.4	Fuses, THERMAL CUT-OUTS and OVER-CURRENT RELEASES	X		5.14
7.2.17	Protective packaging		X	6.2
7.2.18	External pressure source		X	6.3
7.4.2	Control devices	X		5.15
7.5	Safety signs	X		5.16
7.9.2.1	General		X	6.5
7.9.2.15	Environmental protection	X		5.18
7.9.2.17	ME EQUIPMENT emitting radiation		X	6.6
7.9.2.18	ME EQUIPMENT and ACCESSORIES supplied sterile		X	6.2
7.9.2.19	Unique version identifier	X		5.19
7.9.3.1	General	X		5.19
8.1 b)	Fundamental rule of protection against electric shock	X		5.21
8.5.1.2	MEANS OF PATIENT PROTECTION (MOPP)	X		5.22
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)	X		5.22
8.6.4	Impedance and current-carrying capability	X		5.23
8.7.1 b)	General requirements		X	6.9
8.7.4.5	Measurement of the EARTH LEAKAGE CURRENT and current in functional earth connection	X		5.25
Table 16	Minimum CREEPAGE DISTANCES providing MEANS OF OPERATOR PROTECTION	X		5.27
8.9.4	Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES	X		5.28
8.11.1	Isolation from the SUPPLY MAINS		X	6.10
9.2.2.4.4	Other RISK CONTROL measures		X	6.11
9.2.2.5	Continuous activation		X	6.12
9.2.2.6	Speed of movement(s)		X	6.13
9.2.3.2	Overtravel end stops		X	6.15
9.4.3.1 c)	Instability in transport position		X	6.18
9.4.3.2 a)	Instability excluding transport position		X	6.19
9.6.1	General		X	6.21
9.6.2.1	Audible acoustic energy		X	6.22
9.8.3.2	Static forces due to loading from persons		X	6.23
9.8.3.3	Dynamic forces due to loading from persons		X	6.24
10.1.1	ME EQUIPMENT not intended to produce diagnostic or therapeutic X-radiation		X	6.25

Table 2 *(2 of 2)*

Subclause of IEC 60601-1	Clause Title	Impact many users	Impact particular users	Section of this document
10.1.2	ME EQUIPMENT intended to produce diagnostic or therapeutic X-radiation		X	6.26
10.4	Lasers		X	6.28
11.1.2.2	APPLIED PARTS not intended to supply heat to a PATIENT		X	6.29
11.6.2	Overflow in ME EQUIPMENT		X	6.30
11.6.3	Spillage on ME EQUIPMENT and ME SYSTEMS	X		5.29
11.6.6	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS	X		5.30
12.4.5.2	Diagnostic X-ray equipment		X	6.31
14.1	General	X		5.33
14.9	Design and implementation	X		5.34
14.11	PEMS VALIDATION	X		5.35
14.13	PEMS intended to be incorporated into an IT-NETWORK		X	6.32
15.3.1	General	X		5.36
15.3.5	Rough handling test		X	6.33
15.4.2.1 d)	Application		X	6.34
14.4.3.5	Excessive current and voltage protection		X	6.35
15.4.6.1 b)	Fixing, prevention of maladjustment	X		5.37
15.4.6.2	Limitation of movement	X		5.38
15.4.7.3	Entry of liquids		X	6.36
15.5.1.1	Transformers	X		5.39
15.5.1.3	Overload test	X		5.40
15.5.2	Dielectric strength	X		5.41
16.3	Power supply		X	6.37
16.6.4.1	General conditions for ME SYSTEMS		X	6.38
16.8	Interruption of the power supply to parts of an ME SYSTEM		X	5.31
16.9.2.1 d)	MULTIPLE SOCKET-OUTLET		X	6.39
16.9.2.2	PROTECTIVE EARTH CONNECTIONS in ME SYSTEMS		X	6.40
Annex A, 4.8	Components of ME EQUIPMENT	X		5.43

The following clauses break down the changes into two groups based on the breadth of their anticipated impact.

– The first group are those changes that are anticipated to impact many, if not most, of the users of IEC 60601-1 (Clause 5). An example would be the change to the requirements for humidity preconditions testing to align with the IEC Certified Testing Laboratories (CTL) decision to harmonize basic environmental testing conditions for electrical products. Because of the impact on existing test protocols, the impact was assessed as significant.

– The second group are those changes that should impact only some of the users of IEC 60601-1 depending on the nature of the equipment to which they are applying the standard (Clause 6). Examples are the requirements that are applied only to sterile ME EQUIPMENT or ME EQUIPMENT parts or to MOBILE ME EQUIPMENT.

5 Changes impacting many users of the standard

5.1 **Updated normative references** (Clause 2) [Moderate impact]

A number of the standards that are referenced in the 3rd edition have been revised or have been withdrawn and replaced by different documents (e.g., ISO 14971-1:2000 has been replaced by ISO 14971:2007). These normative references have been updated to reflect current editions.

5.2 **Definition and rationale for EXPECTED SERVICE LIFE** (Definition 3.28 and rationale for 4.4) [Moderate impact]

The application of the term EXPECTED SERVICE LIFE has lead to a misunderstanding in some quarters. To address the misunderstanding, the definition and the rationale have been expanded.

5.3 **Restructuring of RISK MANAGEMENT** (Subclause 4.2) [Significant impact]

Subclause 4.2 and its rationale have been significantly modified and expanded. The subclause describes in greater detail the RISK MANAGEMENT PROCESS to be employed in complying with IEC 60601-1.

Subclause 4.2.1 introduces the concepts and the purposes of RISK MANAGEMENT within the framework of a TYPE TEST or design assurance standard. The subclause includes a reminder that, "*verification of compliance with the RISK MANAGEMENT requirements of this standard can be accomplished by examination of the RECORDS and other documentation required by this standard and assessment of the processes cited in this standard and does not require auditing of the RISK MANAGEMENT PROCESS*."

Subclause 4.2.2 is the heart of the subclause and sets out the basic PROCESS requirements, which remain in compliance with ISO 14971 except for the requirements related to product and post-production monitoring and periodic reviews of the suitability of the RISK MANAGEMENT PROCESS.

Subclause 4.2.3 details how the requirements of this standard are to be applied when evaluating RISK. There are four scenarios described. They are:

a) where IEC 60601-1 or its collateral or particular standards specify requirements addressing particular HAZARDS or HAZARDOUS SITUATIONS, together with specific acceptance criteria;

b) where IEC 60601-1 or its collateral or particular standards specify requirements addressing particular HAZARDS or HAZARDOUS SITUATIONS but do not provide specific acceptance criteria;

c) where IEC 60601-1 or its collateral or particular standards identify particular HAZARDS or HAZARDOUS SITUATIONS that have to be investigated without providing specific technical requirements; and

d) where HAZARDS or HAZARDOUS SITUATIONS are identified for the particular ME EQUIPMENT or ME SYSTEM but are not specifically addressed in this IEC 60601-1 or its collateral or particular standards.

5.4 **Application of ESSENTIAL PERFORMANCE** (Subclause 4.3) [Significant impact]

The definition of ESSENTIAL PERFORMANCE has been modified from:

> performance necessary to achieve freedom from unacceptable risk

in the 3rd edition to:

performance of a clinical function, other than that related to BASIC SAFETY, where loss or degradation beyond the limits specified by the MANUFACTURER results in an unacceptable RISK

Subclause 4.3 has been revised and extended to discuss the process the MANUFACTURER can use to determine the ESSENTIAL PERFORMANCE of ME EQUIPMENT or an ME SYSTEM. The fundamental goal was not to change the intent of the concept but make it easier to understand and apply. The definition and the process in 4.3 have been changed to focus on clinical functions and to try an exclude "performance" related to BASIC SAFETY, e.g., the performance of insulation. However, remember, regardless of whether we are speaking of BASIC SAFETY or ESSENTIAL PERFORMANCE, both must be managed.

The rationale for Subclause 4.3 has also been updated.

5.5 Revision to the concept of equivalent safety (Subclause 4.5) [Significant impact]

Recognizing that demonstrating "equivalent safety" can be difficult because many of the requirements in IEC 60601-1 do not provide sufficient detail regarding the level of RESIDUAL RISK, this subclause has been modified to allow alternative RISK CONTROL measures or test methods when it can be demonstrated that that the RESIDUAL RISK resulting from application of the alternative RISK CONTROL measure or test method remains acceptable and is comparable to the RESIDUAL RISK that results from applying the requirements of this standard. The RESIDUAL RISK must satisfy the MANUFACTURER'S RISK acceptance criteria and must be comparable to that remaining after applying the requirements of the standard. The MANUFACTURER can demonstrate this by applying:

– scientific data,
– clinical opinion,
– comparative studies, or
– a combination of all three methods.

5.6 Requirements for parts that contact the PATIENT (Subclause 4.6) [Significant impact]

The requirement for such parts was moved from 8.3 d). The RISK MANAGEMENT PROCESS is still required to assess the parts that fall outside of the definition of APPLIED PARTS that need to be subject to the requirements for APPLIED PARTS. However, the revision to 4.6 clarifies that applicable requirements of the collateral standards also apply to these parts.

5.7 Steady-state measurement of input of the ME EQUIPMENT or ME SYSTEM (Subclause 4.11) [Moderate impact]

The provision in the IEC 60601-1:2005 that allowed a supplier certification to be used in place of the power input measurements required by 4.11 has been replaced by a note that supplier information can be used to supplement those measurements.

5.8 Simultaneous fault testing (Subclause 5.1) [Moderate impact]

Subclause 5.1 was modified to clarify the requirement that the combination of simultaneous independent faults that could result in a HAZARDOUS SITUATION be documented in the RISK MANAGEMENT FILE. The original text of IEC 60601-1:2005 required that the results of the RISK ANALYSIS be used to determine which combination(s) of simultaneous faults were to be tested. Since the RISK ANALYSIS is documented in the RISK MANAGEMENT FILE, this is not a new requirement. When testing is necessary to demonstrate that BASIC SAFETY and ESSENTIAL PERFORMANCE are maintained under such simultaneous independent faults, the related testing may be limited to worst case situations. Because of the potential for additional documentation, this was judged to be of moderate impact.

5.9 SUPPLY MAINS test characteristics (Subclause 5.5 a)) [Significant impact]

The requirement in 5.5 a) was modified to include other characteristics of the SUPPLY MAINS other than just supply voltage. As this could involve additional testing, the impact was assessed as significant.

5.10 Humidity preconditioning (Subclause 5.7) [Significant impact]

The requirements for humidity preconditions testing have been aligned with the IEC Certified Testing Laboratories (CTL) decision to harmonize basic environmental testing conditions for electrical products. The minimum time for soaking ME EQUIPMENT enclosures with an IPX0 rating is set to 48 h and for higher IP rating to 168 h. Because of the impact on existing test protocols, the impact was assessed as significant.

5.11 Actuating mechanisms (Subclause 5.9.2.3) [Moderate impact]

The reference to RISK MANAGEMENT was removed. Any conductive parts of actuating mechanisms are not to be considered ACCESSIBLE PARTS if removal of the handles, knobs, etc. requires the use of a TOOL.

5.12 Legibility of markings (Subclause 7.1.2) [Moderate impact]

The test procedure for legibility of markings has been modified so the test is run from the intended OPERATOR position, or, if that is not specified, a distance of 1 m. Also, the description of the visual acuity of the observer is extended to include a near-vision specification.

5.13 Identification of ME EQUIPMENT, parts and ACCESSORIES (Subclauses 7.2.1 and 7.2.4) [Significant impact]

The requirements for Identification of ME EQUIPMENT and ACCESSORIES have been expanded to include several new items. These include:

– contact information of the MANUFACTURER (for example, this could be a mailing address, a web site, or a telephone number);

– a serial number or lot or batch identifier; and

– the date of manufacture or use by date, if applicable.

The serial number, lot or batch identifier, and the date of manufacture may be provided in a human readable code or through automatic identification technology such as barcodes or RFID.

Detachable components of the ME EQUIPMENT shall be marked with:

– the name or trademark of the MANUFACTURER; and

– a MODEL OR TYPE REFERENCE;

unless misidentification does not result in an unacceptable RISK.

5.14 Marking of fuses, THERMAL CUT-OUTS and OVER-CURRENT RELEASES (Subclause 7.3.4) [Moderate impact]

The requirements for marking of these protective devices have been clarified and an allowance to use the nomenclature described in IEC 60127-1 has been added.

5.15 Marking of stand-by control (Subclause 7.4.2) [Moderate impact]

The switch marking commonly used in IT equipment ( ) to indicate a control that activates a stand-by mode is now permitted on ME EQUIPMENT.

5.16 Use of safety signs (Subclause 7.5) [Moderate impact]

The requirements have been modified to clarify:

a) that the general warning sign () is not required when a safety sign with an established meaning is appropriately used; and

b) that when supplementary text is placed together with safety signs, the supplementary text shall be in a language that is acceptable to the intended OPERATOR.

5.17 General requirements for ACCOMPANYING DOCUMENTS (Subclause 7.9.1) [Significant impact]

The general requirements have been revised to replace the "address" of the MANUFACTURER with contact information for the MANUFACTURER. This aligns with the changes made to Subclauses 7.2.1 and 7.2.4). The contact information could include information beyond the postal address such as a Web site address or telephone number(s).

The requirement to use RISK MANAGEMENT to determine what information needs to be provided as hard copy or marking if the ACCOMPANYING DOCUMENTS are provided electronically has been eliminated. The USABILITY ENGINEERING PROCESS in Subclause 12.2 must consider which information also needs to be provided as hard copy or as markings on the ME EQUIPMENT.

5.18 Disposal of waste (Subclause 7.9.2.15) [Moderate impact]

The requirement to identify the RISKS associated with the disposal of waste products and the ME EQUIPMENT and ACCESSORIES at the end of life has been replaced with a simpler requirement. The MANUFACTURER must provide advice on proper disposal.

5.19 Unique version identification (Subclauses 7.9.2.19 and 7.9.3.1) [Moderate impact]

The instructions for use must contain a unique version identifier such as its date of issue. If the technical description is provided as a separate document, then it must also contain a unique version identifier.

5.20 Disclosure of ESSENTIAL PERFORMANCE (Subclause 7.9.3.1) [Significant impact]

The technical description needs to contain information pertaining to ESSENTIAL PERFORMANCE and the absence or degradation thereof and any necessary recurrent ESSENTIAL PERFORMANCE and BASIC SAFETY testing including details of the means, methods and recommended frequency.

5.21 Change to the fundamental rule of protection against electric shock (Subclause 8.1 b)) [Moderate impact]

The reference to RISK MANAGEMENT has been removed from the dash dealing with interruption of power-carrying conductor between parts of a separate ENCLOSURE. This can be done by a plain engineering calculation and is not a RISK MANAGEMENT issue.

The dash dealing with unintended movement was simplified because the issue is dealt with in Subclause 8.10.1.

5.22 Use of Y capacitors as a MEANS OF PROTECTION (Subclauses 8.5.1.2 and 8.5.1.3) [Moderate impact]

The requirements allowing use of Y capacitors as a MEANS OF PROTECTION have been substantially revised to clarify when Y1 or Y2 capacitors can be used as either a MEANS OF PATIENT or MEANS OF OPERATOR PROTECTION.

5.23 **Requirements for impedance and current-carrying capabilities** (Subclause 8.6.4) [Moderate impact]

In those cases where DETACHABLE POWER SUPPLY CORD is neither supplied nor specified by the MANUFACTURER, testing shall be done with a 3 m long cord of appropriate cross-sectional area based on 8.11.3.3 and Table 17. This may involve some retesting of equipment.

In addition, provision is made for using a d.c. current when making earth impedance measurements. This should facilitiate testing as IEC 60950-1 allows either a.c. or d.c. to be used and has done for some years without problem.

5.24 **Allowable values** of **LEAKAGE CURRENTS that can flow in a FUNCTIONAL EARTH CONDUCTOR** (Subclause 8.7.3) [Substantial impact]

A new requirement has been added for the LEAKAGE CURRENT that can flow in a FUNCTIONAL EARTH CONDUCTOR in non-PERMANENTLY INSTALLED ME EQUIPMENT. The maximum current allowed is 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION.

5.25 **Measurement of the EARTH LEAKAGE CURRENT and current in functional earth connection** (Subclause 8.7.4.5) [Moderate impact]

The requirement for measuring EARTH LEAKAGE CURRENT for CLASS II ME EQUIPMENT with a functional earth connection has been clarified. This equipment is tested as if it were CLASS I ME EQUIPMENT.

5.26 **Clarification of the insulation to be tested** (Subclause 8.8.1) [Significant impact]

The requirement has been clarified. Only insulation that is relied upon as a MEANS OF PROTECTION, including REINFORCED INSULATION is to be subjected to the insulation testing in Subclauses 8.8. This change also allowed for the deletion of Table 11, *Minimum CREEPAGE DISTANCES and AIR CLEARANCES between parts of opposite polarity of the MAINS PART*. The removal of Table 11 does not mean that the requirements for minimum CREEPAGE DISTANCES and AIR CLEARANCES between parts of opposite polarity of the MAINS PART have been eliminated. These CREEPAGE DISTANCE and AIR CLEARANCE requirements are defined in 8.9.1.1, which refers to the tables for MEANS OF OPERATOR PROTECTION.

5.27 **Spacing for one MEANS OF OPERATOR PROTECTION for a WORKING VOLTAGE of 25 V r.m.s.** (Table 16) [Moderate impact]

A slightly smaller CREEPAGE DISTANCE providing a MEANS OF OPERATOR PROTECTION was added to Table 16 for a WORKING VOLTAGE of 25 V r.m.s or d.c. This change may benefit some MANUFACTURERS by allowing slightly smaller CREEPAGE DISTANCES at WORKING VOLTAGES under 25 V r.m.s or d.c.

5.28 **Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES** (Subclause 8.9.4) [Moderate impact]

The minimum spacing for CREEPAGE DISTANCE can now be adjusted depending on the pollution degree associated with the intended environment of use. As the majority of applications are for pollution degree 2, it is unlikely that this proposed change will affect many existing products.

5.29 **Spillage on ME EQUIPMENT and ME SYSTEMS** (Subclause 11.6.3) [Moderate impact]

The requirement was modified to use RISK MANAGEMENT to identify use environments where spillage on the ME EQUIPMENT or ME SYSTEM would be likely to occur. Once the liquid is applied, BASIC SAFETY and ESSENTIAL PERFORMANCE are to be maintained in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION.

5.30 Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS (Subclause 11.6.6) [Moderate impact]

The requirement was clarified that it is the effect of number of cleaning/disinfection cycles stated in the instructions for use that is evaluated. Following these PROCESSES, there is to be no loss of BASIC SAFETY and ESSENTIAL PERFORMANCE.

5.31 Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT or ME SYSTEM (Subclauses 11.8 and 16.8) [Significant impact]

Subclauses 11.8 and 16.8 were modified to require that following interruption and restoration of the power supply to ME EQUIPMENT or all or part of an ME SYSTEM, BASIC SAFETY and ESSENTIAL PERFORMANCE need to be maintained. This replaced the requirement that the interruption and restoration of power supply must not result in an unacceptable RISK.

5.32 Emissions, deformation of ENCLOSURE or exceeding maximum temperature (Subclause 13.1.2) [Significant impact]

The additions to this subclause will significantly reduce the situations where a fire ENCLOSURE may be required. The original text was unclear and the new text allows the use of the most conservative values combined with construction restrictions in, IEC 60950-1 for limited energy circuits.

5.33 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) (Subclause 14.1) [Moderate impact]

IEC 60601-1:2005 already required a development process for all PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS) including software. It also has informative references to IEC 62304 for information on software. IEC 62304 was under development when the FDIS of IEC 60601-1:2005 was circulated for ballot.

If IEC 62304 was used for software development to meet the requirements of IEC 60601-1, there will be no additional cost. IEC 62304 does provide additional detailed software requirements beyond the requirements of Clause 14, and if IEC 60601-1:2005 was implemented without considering these additional requirements, a moderate amount of effort will be necessary to bring an existing process into compliance with the additional requirements included by referencing IEC 62304.

5.34 Design and implementation (Subclause 14.9) [Moderate impact]

The reference to the RISK MANAGEMENT FILE WAS removed and replaced with “shall be documented. This is consistent with the way the documentation requirements are written in IEC 62304.

5.35 PEMS VALIDATION (Subclause 14.11) [Moderate impact]

A new requirement was introduced regarding documentation of the methods used for PEMS VALIDATION.

5.36 Mechanical strength (Subclause 15.3.1) [Moderate impact]

The reference to unacceptable risk was replaced by a requirement that ME EQUIPMENT or its parts shall have adequate mechanical strength and shall not result in loss of BASIC SAFETY or ESSENTIAL PERFORMANCE due to moulding stress or when subjected to mechanical stress caused by pushing, impact, dropping, and rough handling.

A new major row was inserted in Table 28 to deal with push, impact, drop and moulding stress relief.

5.37 Actuating parts of controls of ME EQUIPMENT (Subclause 15.4.6.1 b) [Moderate impact]

The portion of the requirement that limited its applicability to controls, the adjustment of which can result in a HAZARDOUS SITUATION for the PATIENT or OPERATOR while ME EQUIPMENT is in use has been removed. The requirement now applies to all controls that indicate any scale, which includes “on” or “off” position, scale markings or other indications of position.

5.38 Limitation of movement (Subclause 15.4.6.2) [Moderate impact]

The requirement to provide stops of adequate mechanical strength to prevent an unexpected change from maximum to minimum, or vice-versa, of the controlled parameter has been extended to all rotating or movable parts of controls. The limitation that the requirement be applied only when an unexpected change could produce a HAZARDOUS SITUATION has been removed.

In addition, when an axial pull is likely to be applied in NORMAL USE there is to be no unexpected change of the controlled parameter.

5.39 Transformers (Subclause 15.5.1.1) [Moderate impact]

The wording of Subclause 15.5.1.1 in IEC 60601-1:2005 might be understood to say that only one MEANS OF OPERATOR PROTECTION is required between opposite polarity of the secondary output contacts in the area between secondary windings and the subsequent protection component (e.g. the fuse). If this would be true, the device would not be SINGLE FAULT SAFE as required by Subclause 4.7. This change clarifies that requirement.

5.40 Overload test (Subclause 15.5.1.3) [Moderate impact]

A permissive requirement was added to allow that the overload test may be applied after rectification. This may be advantageous in some situations.

5.41 Dielectric strength (Subclause 15.5.2) [Moderate impact]

A new requirement was added to clarify how to deal with dielectric strength testing of insulation in transformers other than mains transformers. For transformers operating at frequencies above 1 KHz, the insulation is tested according to the requirement in 8.8.3.

5.42 Construction of transformers used to provide separation as required by 8.5 (Subclause 15.5.3) [Significant impact]

IEC 60601-1:2005 cited the requirements for transformers in Subclause 5.12 or IEC 61558-1:1997. That standard was modified during the development of 60601-1 making it obsolete and referring the user to IEC 61558-2-15. IEC 61558-2-15 is for transformers between 3 and 10 kVA. These requirements are not appropriate for most transformers in ME EQUIPMENT. New text was added containing specific requirements that are based on the principles of the second edition of IEC 60601-1. With reference to spacing and dielectric strength, the requirements of the third edition are employed. Where only MEANS OF OPERATOR PROTECTION is required, transformers constructed for use in IEC 60950-1 equipment should be considered acceptable.

5.43 Resistors bridging a MEANS OF PROTECTION (Rationale for Subclause 4.8) [Moderate impact]

During the development of Amendment 1, it was observed that the third edition still does not offer a means of providing requirements for resistors that are bridging safety insulation (MOP). Often product design engineers are not sure what is required. As a step forward, the experts in Maintenance Team 28 developed this guidance.

6 Changes impacting particular users of the standard

6.1 ME EQUIPMENT intended to receive power from other equipment (Subclause 7.2.5) [Significant impact]

For ME EQUIPMENT intended to receive power from other equipment where compliance with this standard is dependent on that other equipment, the marking requirement is expanded. The MANUFACTURER must:

a) place the name or trademark of the manufacturer of the other electrical equipment with a MODEL OR TYPE REFERENCE of the specified other equipment adjacent to the relevant connection point; or

b) place a safety sign ( ) adjacent to the connection point and include the required information in the instructions for use; or

c) use a special connector style that is not commonly available on the market and listing of the required details in the instructions for use.

The change also eliminated any reference to RISK MANAGEMENT, so the MANUFACTURER is obligated to use one of these RISK CONTROL measures.

6.2 ME EQUIPMENT or ACCESSORIES supplied sterile (Subclauses 7.2.17 and 7.9.2.18) [Moderate impact]

For ME EQUIPMENT or ACCESSORIES supplied sterile, the marking and instructions for use must indicate the method of sterilization.

The instructions for use must include the necessary instructions in the event of damage to the sterile packaging, and where appropriate, details of the appropriate methods of re-sterilization.

6.3 ME EQUIPMENT supplied from an external pressure source (Subclause 7.2.18) [Moderate impact]

In addition to the maximum supply pressure, ME EQUIPMENT that depends on an external pressure source is now required to label each input connector with the RATED flow rate if a certain flow rate is required to maintain BASIC SAFETY or ESSENTIAL PERFORMANCE.

6.4 Mass of MOBILE ME EQUIPMENT (Subclause 7.2.21) [Significant impact]

MOBILE ME EQUIPMENT is to be marked with its mass including its SAFE WORKING LOAD in kilograms.

6.5 General requirements for the instructions for use when the PATIENT is an OPERATOR (Subclause 7.9.2.1) [Moderate impact]

Where the PATIENT is an intended OPERATOR, the instructions for use are to indicate:

– the PATIENT is an intended OPERATOR;
– a warning against servicing and maintenance while the ME EQUIPMENT is in use;
– which functions the PATIENT can safely use and, where applicable, which functions the PATIENT cannot safely use; and
– which maintenance the PATIENT can perform (e.g. changing batteries).

6.6 ME EQUIPMENT emitting radiation (Subclause 7.9.2.17) [Moderate impact]

When ME EQUIPMENT emits radiation for medical purposes, the instructions for use are to disclose the nature, type, intensity and distribution of this radiation.

6.7 ME EQUIPMENT with DEFIBRILLATION-PROOF APPLIED PARTS (Subclause 8.5.5.1 a)) [Significant impact]

The test requirement was modified to require the measurement of stray voltage during the defibrillation test at any unused or disconnected connections of the APPLIED PART under test or any function of the same APPLIED PART. There is a distinct danger of electric shock to an OPERATOR in the case of an APPLIED PART with multiple functions, where one or more of those functions is unused or is disconnected during defibrillation. There are two distinct situations to be considered:

a) The unused connection is located at the main body of the ME EQUIPMENT (i.e. directly at the ENCLOSURE) where the likelihood of being touched by a second OPERATOR during defibrillation is deemed to be high; and

b) An adapter cable is connected to the main body of the ME EQUIPMENT where the likelihood of a second OPERATOR touching any pins at the remote end of the cable during defibrillation is deemed to be low.

The rationale for 8.5.5.1 attempts to clarify how the requirement should be applied in these two situations.

Note 1 in subclause 8.5.5.1 IEC 60601-1:2005 emphasized that the MANUFACTURER needed to consider the possibility of an OPERATOR receiving a shock from such parts should be considered in the RISK MANAGEMENT PROCESS due to the high RISK of a 4 kV electric shock.

This change could have an impact on the testing previously done by MANUFACTURERS of ME EQUIPMENT with such APPLIED PARTS. ME EQUIPMENT that is completely BODY-WORN (e.g. a Holter monitor) is exempt from this requirement.

6.8 Energy reduction test for ME EQUIPMENT with DEFIBRILLATION-PROOF APPLIED PARTS (Subclause 8.5.5.2) [Significant impact]

The test requirements have been modified to more clearly specify how the test voltage is applied to each PATIENT CONNECTION of the APPLIED PART under test. The test is now repeated with the polarity of the test voltage reversed. This change may require retesting of some DEFIBRILLATION-PROOF APPLIED PARTS.

6.9 Measurement of LEAKAGE CURRENT for sterile equipment (Subclause 8.7.1 b)) [Moderate impact]

The general conditions for the measurement of LEAKAGE CURRENT have been extended to require that, when applicable, these measurements be made following any required sterilization PROCEDURES.

6.10 Isolation of PERMANENTLY INSTALLED ME EQUIPMENT from the SUPPLY MAINS (Subclause 8.11.1) [Moderate impact]

A new requirement was added that means needs to be provided to isolate PERMANENTLY INSTALLED ME EQUIPMENT from the SUPPLY MAINS. When appropriate, the means for isolating the equipment form the supply mains needs to be capable of being locked in the off position. The actuator of a SUPPLY MAINS switch needs to comply with IEC 60447.

6.11 Protective measures (Subclause 9.2.2.4.4) [Moderate impact]

The term “protective measures” was changed to “RISK CONTROL measures” and the compliance paragraph was changed from checking the RISK MANAGEMENT FILE TO examination of the construction and circuits, and conducting any applicable tests including, if necessary, tests under SINGLE FAULT CONDITION.

6.12 Continuous activation (Subclause 9.2.2.5) [Moderate impact]

The compliance paragraph was changed from checking the RISK MANAGEMENT FILE to examination of the construction and circuits, and conducting any applicable tests including, if necessary, tests under SINGLE FAULT CONDITION.

6.13 Speed of movement(s) (Subclause 9.2.2.6) [Moderate impact]

The compliance paragraph was changed from checking the RISK MANAGEMENT FILE to inspection of the overtravel (stopping distance) calculations and evaluation and any functional tests.

6.14 Unintended movement (Subclause 9.2.3.1) [Significant impact]

Inspection of the RISK MANAGEMENT FILE has been replaced by inspection of the USABILITY ENGINEERING FILE when the control limiting unintended movement is part of a PRIMARY OPERATING FUNCTION.

6.15 Overtravel end stops (subclause 9.2.3.2) [Moderate impact]

The use of RISK MANAGEMENT was replaced by a specific test procedure based on UL 187.

6.16 Overbalancing from horizontal and vertical forces (Subclause 9.4.2.3 a)) [Significant impact]

In the test procedure, the lateral force to be applied to the ME EQUIPMENT has been reduced from 25 % of the weight of the unit to 15 % of the weight. The maximum force to be applied has been reduced from 220 N to 150 N.

6.17 Movement over a threshold (Subclause 9.4.2.4.3) [Significant impact]

The height of the threshold barrier was reduced from 20 mm to 10 mm. The compliance measure was changed from assessment of unacceptable RISK to maintenance of BASIC SAFETY and ESSENTIAL PERFORMANCE.

6.18 Instability of MOBILE ME EQUIPMENT in transport position (Subclause 9.4.3.1 c)) [Moderate impact]

MOBILE ME EQUIPMENT is to be provided with wheel locks or with a braking system to prevent unwanted movement on an incline of 10° when in its transport position.

6.19 Instability of MOBILE ME EQUIPMENT on an incline surface and in other than transport position (Subclause 9.4.3.2 a)) [Moderate impact]

MOBILE ME EQUIPMENT is to be provided with wheel locks or with a braking system to prevent unwanted movement on an incline of 5° when in any position excluding transport position.

6.20 Instability of MOBILE ME EQUIPMENT from lateral forces in other than transport position (Subclause 9.4.3.2 b)) [Significant impact]

In the test procedure, the lateral force to be applied to the ME EQUIPMENT has been reduced from 25 % of the weight of the unit to 15 % of the weight. The maximum force to be applied has been reduced from 220 N to 150 N.

6.21 Acoustic energy and vibration (Subclause 9.6.1) [Moderate impact]

This change reduces but does not entirely eliminate the reference to RISK MANAGEMENT in this subclause. Compliance with the general requirement is demonstrated by the tests in Subclauses 9.6.2 and 9.6.3. Reference is made to RISK MANAGEMENT only “when necessary”.

6.22 Audible acoustic energy measurements (Subclause 9.6.2.1) [Moderate impact]

This new requirement allows ME EQUIPMENT that is too large to fit in a test room to be tested in place.

6.23 Static forces due to loading from persons (Subclause 9.8.3.2) [Moderate impact]

In paragraphs a) and b), the requirement that any deflection that could result in an unacceptable RISK would constitute a failure was replaced by a firm requirement that any permanent deflection from normal of greater than 5° would constitute a failure. In additions, BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained.

6.24 Dynamic forces due to loading from persons (Subclause 9.8.3.3) [Moderate impact]

The requirement that the dynamic forces resulting from sitting down, standing up, or other movements of the PATIENT are not to result in an unacceptable RISK was modified to require that BASIC SAFETY and ESSENTIAL PERFORMANCE are to be maintained after a dynamic load is applied.

6.25 ME EQUIPMENT not intended to produce diagnostic or therapeutic X-radiation (Subclause 10.1.1) [Moderate impact]

The second paragraph contains a new requirement if the INTENDED USE of the ME EQUIPMENT requires it to be in permanent proximity to a PATIENT. If this is the case, then the resulting annual exposure should be made acceptable taking into account the irradiated body part and national regulations and/or international recommendations.

6.26 ME EQUIPMENT intended to produce diagnostic or therapeutic X-radiation (Subclause 10.1.2) [Moderate impact]

Any unintended X-radiation from ME EQUIPMENT designed to produce diagnostic or therapeutic X-radiation is to be reduced as far as possible by application of applicable particular and collateral standards, or in the absence of these standards by application of RISK MANAGEMENT PROCESS.

6.27 Microwave radiation (Subclause 10.3) [Significant impact]

The general requirement to apply RISK MANAGEMENT to unintended microwave radiation was replaced by specific requirement and a test procedure. However, a MANUFACTURER is allowed to present calculations to support a claim of compliance. Therefore, the test is only required if calculations are insufficient to demonstrate compliance.

6.28 Lasers and light-emitting diodes (LEDs) (Subclause 10.4) [Moderate impact]

LEDs are no longer covered by IEC 60825-1. This subclause is restricted to equipment that produces or amplifies electromagnetic radiation in the wavelength range from 180 nm to 1 mm. There is no requirement for LEDs in the general standard. There is an IEC standard (IEC 62471) that could be used to evaluate the safety of LED light sources. However, the testing in that standard is extensive and does not appear to be relevant to typical LEDs used in ME EQUIPMENT.

6.29 APPLIED PARTS not intended to supply heat to a PATIENT (Subclause 11.1.2.2) [Moderate impact]

For APPLIED PARTS that can exceed 41 °C, the disclosure requirements in this subclause have been extended to include the conditions for safe contact, e.g. duration or condition of the PATIENT.

6.30 Overflow in ME EQUIPMENT (Subclause 11.6.2) [Moderate impact]

A more severe test has been added unless the fill level is marked on the ME EQUIPMENT. Having the fill level in the instructions was not judged sufficient. Therefore, the reference to the instructions for use was removed. MOBILE ME EQUIPMENT exceeding 45 kg is required to pass over the threshold in Subclause 9.4.2.4.3 without overflowing.

6.31 Diagnostic X-ray equipment (Subclause 12.4.5.2) [Moderate impact]

The general requirement for RISK MANAGEMENT was replaced by a direct reference to IEC 60601-1-3.

6.32 PEMS intended to be incorporated into an IT-NETWORK (Subclause 14.13) [Moderate impact]

The requirements of this subclause were aligned with both the terminology and the contents of the documentation for medical device MANUFACTURERS included in IEC 80001-1. It does not add any additional requirements, but provides additional detail about what should be included in the documentation required by this subclause. The requirement in 14.13 e) was limited to safety aspects as other aspects are out of scope of IEC 60601-1. Compliance paragraphs were added to the subclause.

6.33 Rough handling test (Subclause 15.3.5) [Moderate impact]

The speed of motor-driven MOBILE ME EQUIPMENT in this series of tests was increased from 0,4 m/s to 0,80 m/s. The 0,8 m/s speed together with the severity of the obstacles chosen, are considered to represent worst case reasonably foreseeable misuse levels of stress/shock energies.

6.34 Application of temperature and overload control devices (Subclause 15.4.2.1 d)) [Moderate impact]

A requirement was added that operation of a THERMAL CUT-OUT or OVER-CURRENT RELEASE is not to result in the loss of ESSENTIAL PERFORMANCE or any of the HAZARDOUS SITUATIONS described in Subclause 13.1.

6.35 Excessive current and voltage protection (Subclause 15.4.3.5) [Moderate impact]

A new requirement was added that the short circuit test between the positive pole and the negative pole of an INTERNAL ELECTRICAL POWER SOURCE in the area between the INTERNAL ELECTRICAL POWER SOURCE output contacts and the subsequent protection device may be omitted if two MEANS OF OPERATOR PROTECTION are provided.

6.36 Entry of liquids for foot-operated control devices (Subclause 15.4.7.3) [Moderate impact]

The reference to the RISK MANAGEMENT PROCESS has been removed from this requirement. Foot operated control devices used in areas such as emergency rooms or operating theatres where liquids are likely to be present at floor level and that contain electrical circuits shall be classified at least IPX6 according to IEC 60529.

6.37 ME SYSTEM power supply (Subclause 16.3) [Moderate impact]

A new requirement was added to this subclause dealing with an ME SYSTEM that is intended to receive its power from an isolated power supply (IPS) or an uninterruptible power supply (UPS) and can draw high inrush currents when switched on.

6.38 General measurement conditions for ME SYSTEMS (Subclause 16.6.4.1) [Moderate impact]

The phrase "of any MULTIPLE SOCKET OUTLET" was deleted from this requirement because it presupposes a particular design arrangement for the ME SYSTEM. It is possible, for example, to distribute mains power and PE connections to various items in a ME SYSTEM by wiring short DETACHABLE POWER SUPPLY CORDS back to a suitable fixed, enclosed MAINS TERMINAL DEVICE, thus not using an MSO.

6.39 An MSO combined with a separating transformer (Subclause 16.9.2.1 d)) [Moderate impact]

If an MSO is combined with a separating transformer, then the transformer is to meet the requirements of IEC 60601-1. Alternatively, the requirements of IEC 61558-2-1 may be applied, except that the requirements of maximum RATED output power of 1 kVA and degree of protection IPX4 do not apply.

6.40 Impedance of protective earth connections in ME SYSTEMS (Subclause 16.9.2.2) [Moderate impact]

The impedance between the protective earth pin in the MAINS PLUG and any part of the ME SYSTEM that is PROTECTIVELY EARTHED is limited to 200 mΩ.

7 Mapping

7.1 Mapping to the second edition of IEC 60601-1

The first column in Table 3 lists in numerical sequence the elements of the second edition of IEC 60601-1 as amended [1]. The first few words of the title or paragraph text are provided to assist in locating the element in the second edition. The second column gives the clause and title where that element has been addressed in IEC 60601-1:2005.

Elements that were deleted because they were not used in the second edition are marked as “Not used, Deleted.” Elements that were deleted during the preparation of IEC 60601-1:2005 are marked simply as “Deleted.”

Table 3 – Mapping between the elements of the second edition of IEC 60601-1 as amended and IEC 60601-1:2005 *(1 of 35)*

IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
SECTION 1 – GENERAL, Heading Deleted			
1	“Scope and object”	1	Scope, object and related standards
1.1	“Scope”	1.1	Scope
1.2	“Object”	1.2	Object
1.3	“Particular Standards”	1.4	Particular Standards
1.4	Not used, Deleted		
1.5	“Collateral Standards”	1.3	Collateral Standards

Table 3 *(2 of 35)*

IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
2	"Terminology and definitions"	3	Terminology and definitions
2.1	'Equipment parts, auxiliaries and accessories", Deleted		
2.1.1	"Access cover"	3.1	ACCESS COVER
2.1.2	"Accessible metal part", Deleted		
2.1.3	"Accessory"	3.3	ACCESSORY
2.1.4	"Accompanying document"	3.4	ACCOMPANYING DOCUMENT
2.1.5	"Applied part"	3.8	APPLIED PART
2.1.6	"Enclosure"	3.26	ENCLOSURE
2.1.7	"F-type isolated (floating) applied part"	3.29	F-TYPE ISOLATED (floating) APPLIED PART
2.1.8	Not used, Deleted		
2.1.9	"Internal electrical power source	3.45	INTERNAL ELECTRICAL POWER SOURCE
2.1.10	"Live", Deleted		
2.1.11	Not used, Deleted		
2.1.12	"Mains part"	3.49	MAINS PART
2.1.13	Not used, Deleted		
2.1.14	Not used, Deleted		
2.1.15	"Patient circuit", Deleted		
2.1.16	Not used, Deleted		
2.1.17	"Protective cover", Deleted		
2.1.18	"Signal input part"	3.115	SIGNAL INPUT/OUTPUT PART
2.1.19	"Signal output part"		
2.1.20	Not used, Deleted		
2.1.21	"Supply equipment", Deleted		
2.1.22	"Accessible part"	3.2	ACCESSIBLE PART
2.1.23	"Patient connection"	3.78	PATIENT CONNECTION
2.1.24	"Type B applied part"	3.132	TYPE B APPLIED PART
2.1.25	"Type BF applied part"	3.133	TYPE BF APPLIED PART
2.1.26	"Type CF applied part"	3.134	TYPE CF APPLIED PART
2.1.27	"Defibrillation-proof applied part"	3.20	DEFIBRILLATION-PROOF APPLIED PART
2.2	"Equipment types", Deleted		
2.2.1	Not used, Deleted		
2.2.2	"Category AP equipment"	3.11	CATEGORY AP
2.2.3	"Category APG equipment"	3.12	CATEGORY APG
2.2.4	"Class I equipment"	3.13	CLASS I
2.2.5	"Class II equipment"	3.14	CLASS II

Table 3 *(3 of 35)*

IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
2.2.6	Not used, Deleted		
2.2.7	"Direct cardiac application"	3.22	DIRECT CARDIAC APPLICATION
2.2.8	Not used, Deleted		
2.2.9	Not used, Deleted		
2.2.10	Not used, Deleted		
2.2.11	"Equipment", Deleted		
2.2.12	"Fixed equipment"	3.30	FIXED
2.2.13	"Hand-held equipment"	3.37	HAND-HELD
2.2.14	Not used, Deleted		
2.2.15	"Medical electrical equipment"	3.63	MEDICAL ELECTRICAL EQUIPMENT (ME EQUIPMENT)
2.2.16	"Mobile equipment"	3.65	MOBILE
2.2.17	"Permanently installed equipment"	3.84	PERMANENTLY INSTALLED
2.2.18	"Portable equipment"	3.85	PORTABLE
2.2.19	Not used, Deleted		
2.2.20	Not used, Deleted		
2.2.21	"Stationary equipment"	3.118	STATIONARY
2.2.22	Not used, Deleted		
2.2.23	"Transportable equipment"	3.130	TRANSPORTABLE
2.2.24	Not used, Deleted		
2.2.25	Not used, Deleted		
2.2.26	Not used, Deleted		
2.2.27	Not used, Deleted		
2.2.28	Not used, Deleted		
2.2.29	"Internally powered equipment"	3.46	INTERNALLY POWERED
2.3	"Insulation", Deleted		
2.3.1	"Air clearance"	3.5	AIR CLEARANCE
2.3.2	"Basic insulation"	3.9	BASIC INSULATION
2.3.3	"Creepage distance"	3.19	CREEPAGE DISTANCE
2.3.4	"Double insulation"	3.23	DOUBLE INSULATION
2.3.5	Not used, Deleted		
2.3.6	Not used, Deleted		
2.3.7	"Reinforced insulation"	3.99	REINFORCED INSULATION
2.3.8	"Supplementary insulation"	3.119	SUPPLEMENTARY INSULATION
2.4	"Voltages", Deleted		
2.4.1	"High voltage"	3.41	HIGH VOLTAGE

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
2.4.2	“Mains voltage”	3.54	MAINS VOLTAGE
2.4.3	‘Safety extra-low voltage (SELV)”, Deleted		
2.5	“Currents”, Deleted		
2.5.1	“Earth leakage current”	3.25	EARTH LEAKAGE CURRENT
2.5.2	“Enclosure leakage current”	3.129	TOUCH CURRENT
2.5.3	“Leakage current”	3.47	LEAKAGE CURRENT
2.5.4	“Patient auxiliary current”	3.77	PATIENT AUXILIARY CURRENT
2.5.5	Not used, Deleted		
2.5.6	“Patient leakage current”	3.80	PATIENT LEAKAGE CURRENT
2.6	“Earth terminals and conductors”, Deleted		
2.6.1	Not used, Deleted		
2.6.2	Not used, Deleted		
2.6.3	“Functional earth conductor”	3.34	FUNCTIONAL EARTH CONDUCTOR
2.6.4	“Functional earth terminal”	3.35	FUNCTIONAL EARTH TERMINAL
2.6.5	Not used, Deleted		
2.6.6	“Potential equalization conductor”	3.86	POTENTIAL EQUALIZATION CONDUCTOR
2.6.7	“Protective earth conductor”	3.93	PROTECTIVE EARTH CONDUCTOR
2.6.8	“Protective earth terminal”	3.95	PROTECTIVE EARTH TERMINAL
2.6.9	“Protectively earthed”	3.96	PROTECTIVELY EARTHED
2.7	“Electrical connection (devices)”, Deleted		
2.7.1	“Appliance coupler”	3.6	APPLIANCE COUPLER
2.7.2	“Appliance inlet”	3.7	APPLIANCE INLET
2.7.3	Not used, Deleted		
2.7.4	“Auxiliary mains socket-outlet”, merged with Multiple portable socket-outlet	3.67	MULTIPLE SOCKET-OUTLET
2.7.5	“Conductive connection” Deleted		
2.7.6	“Detachable power supply cord”	3.21	DETACHABLE POWER SUPPLY CORD
2.7.7	“External terminal device”, Deleted		
2.7.8	“Fixed mains socket-outlet”, Deleted		
2.7.9	“Interconnection terminal device”, Deleted		
2.7.10	“Mains connector”	3.48	MAINS CONNECTOR
2.7.11	“Mains plug”	3.50	MAINS PLUG
2.7.12	“Mains terminal device”	3.52	MAINS TERMINAL DEVICE
2.7.13	Not used, Deleted		

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
2.7.14	Not used, Deleted		
2.7.15	Not used, Deleted		
2.7.16	“Terminal device”	3.123	TERMINAL DEVICE
2.7.17	“Power supply cord”	3.87	POWER SUPPLY CORD
2.8	“Transformers”, Deleted		
2.8.1	Not used, Deleted		
2.8.2	Not used, Deleted		
2.8.3	“Safety extra-low voltage transformer”, Deleted		
2.8.4	Not used, Deleted		
2.8.5	Not used, Deleted		
2.8.6	Not used, Deleted		
2.9	“Controls and limiting devices”, Deleted		
2.9.1	“Adjustable setting”, Deleted		
2.9.2	Not used, Deleted		
2.9.3	Not used, Deleted		
2.9.4	“Fixed setting”, Deleted		
2.9.5	Not used, Deleted		
2.9.6	Not used, Deleted		
2.9.7	“Over-current release”	3.74	OVER-CURRENT RELEASE
2.9.8	Not used, Deleted		
2.9.9	Not used, Deleted		
2.9.10	“Self-resetting thermal cut-out”	3.111	SELF-RESETTING THERMAL CUT-OUT
2.9.11	Not used, Deleted		
2.9.12	“Thermal cut-out”	3.124	THERMAL CUT-OUT
2.9.13	“Thermostat”	3.126	THERMOSTAT
2.10	“Operation of equipment”, Deleted		
2.10.1	“Cold condition”	3.16	COLD CONDITION
2.10.2	“Continuous operation”	3.18	CONTINUOUS OPERATION
2.10.3	“Continuous operation with intermittent loading”, Deleted		
2.10.4	“Continuous operation with short-term loading”, Deleted		
2.10.5	“Duty cycle”	3.24	DUTY CYCLE
2.10.6	“Intermittent operation”, Deleted		
2.10.7	“Normal condition”	3.70	NORMAL CONDITION
2.10.8	“Normal use”	3.71	NORMAL USE

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
2.10.9	"Properly installed"	3.92	PROPERLY INSTALLED
2.10.10	"Short-time operation", Deleted		
2.10.11	"Single fault condition"	3.116	SINGLE FAULT CONDITION
2.11	"Mechanical safety", Deleted		
2.11.1	"Hydraulic test pressure"	3.42	HYDRAULIC TEST PRESSURE
2.11.2	"Maximum permissible working pressure"	3.57	MAXIMUM PERMISSIBLE WORKING PRESSURE
2.11.3	"Minimum breaking load", Deleted		
2.11.4	"Pressure", Deleted		
2.11.5	"Safe working load (Mechanical)"	3.109	SAFE WORKING LOAD
2.11.6	"Safety device"	3.62	MECHANICAL PROTECTIVE DEVICE
2.11.7	"Static load", Deleted		
2.11.8	"Safety factor"	3.121	TENSILE SAFETY FACTOR
2.11.9	"Total load"	3.128	TOTAL LOAD
2.12	"Miscellaneous", Deleted		
2.12.1	Not used, Deleted		
2.12.2	"Model or type reference (type number)"	3.66	MODEL OR TYPE REFERENCE (type number)
2.12.3	"Nominal (value)"	3.69	NOMINAL (value)
2.12.4	"Patient"	3.76	PATIENT
2.12.5	Not used, Deleted		
2.12.6	Not used, Deleted		
2.12.7	Not used, Deleted		
2.12.8	"Rated (value)"	3.97	RATED (value)
2.12.9	"Serial number", Deleted		
2.12.10	"Supply mains"	3.120	SUPPLY MAINS
2.12.11	Not used, Deleted		
2.12.12	"Tool"	3.127	TOOL
2.12.13	"User"	3.101	RESPONSIBLE ORGANIZATION
2.12.14	"Emergency trolley", Deleted		
2.12.15	"Flammable anaesthetic mixture with air"	3.31	FLAMMABLE ANAESTHETIC MIXTURE WITH AIR
2.12.16	"Flammable anaesthetic mixture with oxygen or nitrous oxide"	3.32	FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE
2.12.17	"Operator"	3.73	OPERATOR
2.12.18	"Safety hazard"	3.10	BASIC SAFETY
		3.39	HAZARD
3	"General requirements"	4	General requirements

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
3.1	"EQUIPMENT shall…."	4.1	Conditions for application to ME EQUIPMENT or ME SYSTEMS
3.2	Not used, Deleted		
3.3	Not used, Deleted		
3.4	"Equipment or parts thereof…."	4.5	Equivalent safety for ME EQUIPMENT and ME SYSTEMS
3.5	Not used, Deleted		
3.6	"The following…."	4.7	SINGLE FAULT CONDITION for ME EQUIPMENT
3.6 a)	"a) Interruption of a PROTECTIVE EARTH CONDUCTOR"	8.1 b)	Indent 4 "– open-circuit of any one PROTECTIVE EARTH CONDUCTOR…."
3.6 b)	"b) Interruption of one supply conductor"	8.1 b)	Indent 5 "– Interruption of one supply conductor
3.6 c)	"c) appearance of an external voltage on an F-TYPE…."	8.7.4.7 d)	
3.6 d)	"d) appearance of an external voltage on SIGNAL….",	8.1 a)	Indent 1 "– the presence on any SIGNAL INPUT/OUTPUT PART of any voltage…."
3.6 e)	"leakage of the…."	11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics
3.6 f)	"f) leakage of liquid"	13.2.6	Leakage of liquid
3.6 g)	"g) failure of an electrical component…."	4.7	SINGLE FAULT CONDITION for ME EQUIPMENT
3.6 h)	"h) failure of mechanical parts…."	13.2.12	Failure of mechanical parts that might cause a MECHANICAL HAZARD
3.6 j)	"j) failure of temperature limiting devices	13.2.5	Failure of temperature limiting devices
3.7	'The following phenomena are…."	4.9	Use of HIGH-INTEGRITY COMPONENTS in ME EQUIPMENT
3.7 a)	"a) total electrical breakdown…."	4.7	SINGLE FAULT CONDITION for ME EQUIPMENT
3.7 b)	"b) electrical breakdown of a…."		
3.7 c)	"c) interruption of a fixed and…."	8.1 b)	Indent 4 "– open circuit of any one PROTECTIVE EARTH CONDUCTOR…."
3.8	'Earthing of a patient…."	8.7.4.7 b)	
3.9	"Unless otherwise specified….", Deleted		
4	"General requirements for tests"	5	General requirements for tests for ME EQUIPMENT
4.1	"Tests"	5.1	TYPE TESTS
4.2	"Repetition of tests	Annex A, Subclause 5.1	
4.3	"Number of samples"	5.2	Number of samples
4.4	"Components"	4.8	Components of ME EQUIPMENT

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
4.5	"Ambient temperature, ..."	5.3	Ambient temperature, humidity, atmospheric pressure
4.5 a)	"a) After the...."	5.3 a)	
4.5 b)	"b) Equipment shall...."	5.3 b)	
4.5 c)	"c) In cases where"	5.3 c)	
4.6	"Other conditions"	5.4	Other conditions
4.6 a)	"a) Unless otherwise...."	5.4 a)	
4.6 b)	"b) Equipment having...."	5.4 b)	
4.6 c)	"c) If the test results...."	5.4 c)	
4.6 d)	"During any test...."	4.7	NORMAL CONDITION and SINGLE FAULT CONDITION for ME EQUIPMENT
4.6 e)	"e) Where cooling water...."	5.4 d)	
4.7	"Supply and test voltages, type of current...."	5.5	Supply voltages, type of current, nature of supply, frequency
4.7 a)	"a) Where test results...."	5.5 a)	
4.7 a):	Third paragraph, "Any test voltage...."	8.8.3 a)	
4.7 b)	"b) Equipment for a.c. ...."	5.5 b)	
4.7 c)	"c) Equipment designed...."	5.5 c)	
4.7 d)	"d) Equipment for d.c. ...."	5.5 d)	
4.7 e)	"e) Unless otherwise...."	5.5 d)	
4.7 f)	"f) Equipment for which...."	5.5 e)	
4.7 g)	"g) Equipment intended...."	5.5 f)	
4.7 h)	"h) Measurement of voltages....", Deleted		
4.8	"Preconditioning", Deleted		
4.9	"Repairs and modifications"	5.6	Repairs and modifications
4.10	"Humidity preconditioning treatment"	5.7	Humidity preconditioning treatment
4.11	"Sequence"	5.8	Sequence of tests
5	"Classification"	6	Classification of ME EQUIPMENT and ME SYSTEMS
5.1	"According to the type...."	6.2	Protection against electric shock
5.1 a)	"a) Equipment energized...."		
5.1 b)	"b) Internally powered...."		
5.2	"According to the degree of protection against electric shock...."		
5.3	"According to the degree of protection against harmful...."	6.3	Protection against harmful ingress of water or particulate matter
5.4	"According to the method(s)...."	6.4	Method(s) of sterilization

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
5.5	"According to the degree of safety…."	11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics
5.6	"According to the mode…."	6.6	Mode of operation
5.7	Not used, Deleted		
5.8	Not used, Deleted		
6	"Identification, marking and documents"	7	ME EQUIPMENT identification, marking and documents
6	Indent 1 "– Permanently affixed:"	7.1.3	Durability of markings
6	Indent 2 "– Clearly legible:"	7.1.2	Legibility of markings
6	Indent 3 "– Major part:"	7.2.6	Connection to the SUPPLY MAINS
6.1	"Marking on the outside of equipment or equipment parts"	7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts
6.1 a)	"a) Mains operated equipment"	7.2.1	Minimum requirements for marking on ME EQUIPMENT and on interchangeable parts
6.1 b)	"b) Internally powered equipment", Deleted		
6.1 c)	"c) equipment supplied from…."	7.2.5	ME EQUIPMENT intended to receive power from another equipment
6.1 d)	"d) Minimum requirements…."	7.2.1	Minimum requirements for marking on ME EQUIPMENT and on interchangeable parts
6.1 e)	"e) Indication of origin"	7.2.2	Identification
6.1 f)	"f) Model or type reference"		
6.1 g)	"g) Connection to the supply"	7.2.6	Connection to the SUPPLY MAINS
6.1 h)	"h) Supply frequency"		
6.1 j)	"Power input"	7.2.7	Electrical input power from the SUPPLY MAINS
6.1 k)	"k) Mains power output"	7.2.8.1	Mains power output
6.1 l)	"Classification", Deleted heading		
6.1 l)	Indent 1 "– The symbol for…."	7.2.6	Connection to the SUPPLY MAINS
6.1 l)	Indent 2 "– The symbol, using…."	7.2.9	IP classification
6.1 l)	Indent 3 "– A symbol indicating…."	7.2.10	APPLIED PARTS
6.1 m)	"m) Mode of operation"	7.2.11	Mode of operation
6.1 n)	"n) Fuses"	7.2.12	Fuses
6.1 p)	"p) Output"	7.2.8.2	Other power sources
6.1 q)	"q) Physiological effects…."	7.2.13	Physiological effects (safety signs and warning statements)
6.1 r)	"r) Category AP/APG equipment"	Annex G.3.1	CATEGORY APG marking
		Annex G.3.2	CATEGORY AP marking
6.1 s)	"s) High voltage terminal devices"	7.2.14	HIGH VOLTAGE TERMINAL DEVICES

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
6.1 t)	"t) Cooling conditions"	7.2.15	Cooling conditions
6.1 u)	"u) Mechanical stability"	7.2.16	Mechanical stability
6.1 v)	"v) Protective packaging"	7.2.17	Protective packaging
6.1 w)	Not used, Deleted		
6.1 x)	Not used, Deleted		
6.1 y)	"y) Earth terminals"	7.2.19	FUNCTIONAL EARTH TERMINALS
6.1 z)	"z) Removable protective means"	7.2.20	Removable protective means
6.1	Compliance "For determination of durability…."	7.1.3 b)	
6.1	Compliance "Markings shall be clearly legible…."	7.1.3 a)	
6.1	Compliance "When evaluating durability…."	7.1.3	
6.2	"Marking on the inside of EQUIPMENT or EQUIPMENT parts"	7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts
6.2 a)	"a) Marking on the inside…."	7.1.2	Legibility of markings
6.2 a)	"a) Marking on the inside…."	7.1.3	Durability of markings
6.2 b)	"b) The maximum power…."	7.3.1	Heating elements or lampholders
6.2 c)	"c) The presence of…."	7.3.2	HIGH VOLTAGE parts
6.2 d)	"d) The type of battery…."	7.3.3	Batteries
6.2 e)	"e) Fuses accessible only…."	7.3.4	Fuses, THERMAL CUT-OUTS and OVER-CURRENT RELEASES
6.2 f)	"f) Protective earth terminals…."	7.3.5	PROTECTIVE EARTH TERMINALS
6.2 g)	"g) Functional earth terminals…."	7.3.6	FUNCTIONAL EARTH TERMINALS
6.2 h)	"h) Terminals which are…."	7.3.7	Supply terminals
6.2 j)	"j) Markings required in…."		
6.2 k)	"k) The correct method…."		
6.2 l)	"l) If any point…."	7.3.8	Temperature of supply terminals
6.2 m)	Not used, Deleted		
6.2 n)	"n) Capacitors and/or…."	8.4.4	Internal capacitive circuits
6.3	Marking of controls and instruments	7.4	Marking of controls and instruments
6.3 a)	"a) A mains switch…."	7.4.1	Power switches
6.3 b)	"b) Different positions of…."	7.4.2	Control devices
6.3 c)	"c) If in NORMAL USE…."		
6.3 d)	Not used, Deleted		
6.3 e)	Not used, Deleted		
6.3 f)	"f) The functions of operator controls and indicators….", Deleted		
6.3 g)	"g) Numeric indications of…."	7.4.3	Units of measure

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
6.4	"Symbols"	7.6	Symbols
6.4 a)	"a) Symbols used for marking…."	7.6.2	Symbols from Annex D
6.4 b)	"b) Symbols used for controls…."	7.6.3	Symbols for controls and performance
6.5	Colours of the insulation of conductors	7.7	Colours of the insulation of conductors
6.5 a)	"a) A protective earth conductor…."	7.7.1	PROTECTIVE EARTH CONDUCTOR
6.5 b)	"b) Any insulation on…."	7.7.2	PROTECTIVE EARTH CONNECTIONS
6.5 c)	"c) Identification by green…."	7.7.3	Green and yellow insulation
6.5 d)	"d) Conductors in POWER…."	7.7.4	Neutral conductor
6.5 e)	"e) Colours of conductors…."	7.7.5	POWER SUPPLY CORD conductors
6.5 f)	"f) Where a multi-conductor…."	7.7.2	PROTECTIVE EARTH CONNECTIONS
6.6	"Identification of medical gas cylinders and connections", Deleted		
6.6 a)	"a) Identification of the….", Deleted		
6.6 b)	"b) The point of connection….", Deleted		
6.7	Indicator lights and push-buttons	7.8	Indicator lights and controls
6.7 a)	"a) Colours of indicator…."	7.8.1	Colours of indicator lights
6.7 b)	"b) Colours of unilluminated…."	7.8.2	Colours of controls
6.7 c)	Not used, Deleted		
6.7 d)	Not used, Deleted		
6.8	"ACCOMPANYING DOCUMENTS"	7.9	ACCOMPANYING DOCUMENTS
6.8.1	General	7.9.1	General
6.8.2	"Instructions for use"	7.9.2	Instructions for use
6.8.2 a)	"General information", Heading Deleted		
6.8.2 a)	Indent 1 "– Instructions for use shall state…."	7.9.2.1	General
6.8.2 a)	Indent 2 "– Instructions for use shall contain…."	7.9.2.9	Operating instructions
6.8.2 a)	Indent 3 "– Instructions for use shall provide…."	7.9.2.2	Warnings and safety notices
6.8.2 a)	Indent 4 "– Instructions for use shall include…."	7.9.2.14	ACCESSORIES, supplementary equipment, used material
6.8.2 a)	Indent 5 "– Instructions for use shall instruct…."	7.9.2.13	Maintenance
6.8.2 a)	Indent 6 "– The meaning of figures, symbols…."	7.9.2.9	Operating instructions
6.8.2 b)	"b) Responsibility of the manufacturer", Not used, Deleted		

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
6.8.2 c)	"c) SIGNAL INPUT and…."	7.9.2.5	ME EQUIPMENT description
6.8.2 d)	"d) Cleaning, disinfection and…."	7.9.2.12	Cleaning, disinfection and sterilization
6.8.2 e)	"e) Mains operated EQUIPMENT…."	7.9.2.4	Electrical power source
6.8.2 f)	"f) Removal of primary batteries"		
6.8.2 g)	"g) Rechargeable batteries"	7.9.2.13	Maintenance
6.8.2 h)	"h) EQUIPMENT with a…."	7.9.2.14	ACCESSORIES, supplementary equipment, used material
6.8.2 j)	"Environmental protection"	7.9.2.15	Environmental protection
6.8.3	"Technical description"	7.9.3	Technical description
6.8.3 a)	"a) General"	7.9.3.1	General
6.8.3 b)	"b) Replacement of fuses…."	7.9.3.2	Replacement of fuses, POWER SUPPLY CORDS and other parts
6.8.3 c)	"c) Circuit diagrams, components…."	7.9.3.3	Circuit diagrams, component part lists, etc.
6.8.3 d)	"d) Environmental conditions for transport and…."	7.9.3.1	General
6.8.4	Not used, Deleted		
6.8.5	Not used, Deleted		
7	"Power input"	4.11	Power input
7.1	"The steady state current or power input…."		
7.1 a)	"a) for equipment with a power input….", Deleted		
7.1 b)	"b) for other equipment:"	4.11	Power input
7.1,	Indent 1 "– Equipment shall be operated…."	4.11,	Indent 1
7.1,	Indent 2 "– For equipment marked…."	4.11,	Indent 2
7.1,	Indent 3 "– The steady state current shall be measured…."	4.11,	Indent 3
7.2	Not used, Deleted		
SECTION TWO – ENVIRONMENTAL CONDITIONS, Heading Deleted			
8	Not used, Deleted		
9	Not used, Deleted		
10	"Environmental conditions", Deleted		
10.1	"Transport and storage"	7.9.3.1,	Indent 2
10.2	"Environment"	Annex A, 7.9.3.1	
10.2.1	"Environment", Deleted		

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
10.2.1 a)	"a) An ambient temperature range…."	Annex A, 7.9.3.1 a)	
10.2.1 b)	"b) A relative humidity range…."	Annex A, 7.9.3.1 b)	
10.2.1 c)	"c) An atmospheric pressure range…."	Annex A, 7.9.3.1 c)	
10.2.1 d)	"d) A temperature of the water…."	Annex A, 7.9.3.1 d)	
10.2.2	Power supply	4.10	Power supply
10.2.2 a)	"a) Equipment shall be suitable…."	4.10.2	SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS
10.2.2 b)	"b) An internal electrical…."	7.9.2.4	Electrical power source
11	Not used, Deleted		
12	Not used, Deleted		
SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS		8	Protection against electrical HAZARDS from ME EQUIPMENT
13	"General"	8.1	Fundamental rule of protection against electric shock
14	"Requirements related to classification"	8.2	Requirements related to power sources
14.1	"Class I equipment", Deleted		
14.1 a)	"a) Class I equipment may have….", Deleted		
14.1 b)	"b) If the isolation of the mains part….", Deleted		
14.2.	"Class II equipment", Deleted		
14.2 a)	"a) Class II equipment shall be….", Deleted		
14.2 a).1	"1) insulation-enclosed Class II equipment….", Deleted		
14.2 a).2	"2) metal-enclosed Class II equipment….", Deleted		
14.2 a).3	"3) Equipment which is a combination….", Deleted		
14.2 b)	"b) If equipment is fitted….", Deleted		
14.2 c)	"c) Class II equipment may…."	3.14	CLASS II, Note 2
14.3	Not used, Deleted		
14.4	"Class I and class II equipment", Deleted heading		
14.4 a)	"a) In addition to basic insulation….", Deleted		
14.4 b)	"b) In EQUIPMENT specified…."	8.2.2	Connection to an external d.c. power source

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
14.5	"Internally powered equipment", Deleted		
14.5 a)	Not used, Deleted		
14.5 b)	"b) Internally powered equipment intended…."	6,2	Protection against electric shock
14.6	Types B, BF and CF equipment	8.3	Classification of APPLIED PARTS
14.6 a)	Not used, Deleted		
14.6 b)	Not used, Deleted		
14.6 c)	"c) Applied parts which are specified…."	8.3 a)	
14.6 d)	Not used, Deleted		
14.7	Not used, Deleted		
15	"Limitation of voltage and/or energy"	8.4	Limitation of voltage, current or energy
15 a)	Not used, Deleted		
15 b)	"b) Equipment intended to…."	8.4.3	ME EQUIPMENT intended to be connected to a power source by a plug
15 c)	"c) Live parts of capacitors…."	8.4.4	Internal capacitive circuits
16	"Enclosures and protective covers"	5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS
16 a)	"a) Equipment shall be so constructed…."	5.9.2.1	Test finger
16 a) 1)	"1) It does not apply…."	8.4.1	PATIENT CONNECTIONS intended to deliver current
16 a) 2)	"2) Varnishing, enamelling, …."	8.5.1.1	General
16 a) 3)	Not used, Deleted		
16 a) 4)	Not used, Deleted		
16 a) 5)	"5) Where the occurrence of…."	8.4.2 c)	
16 a)	"Compliance with the requirements of 16 a)…."	5.9.2.1	Test finger
		5.9.2.2	Test hook
16 b)	"b) Any opening in…."	8.4.2 d)	
16 c)	"c) Conductive parts of actuating mechanisms…."	5.9.2.3	Actuating mechanisms
16 d)	"d) Parts within the enclosure…."	8.11.1 i)	
16 e)	"e) Enclosures protected against contact…."	8.4.2 e)	
16 e) 1)	"1) Enclosures or equipment parts…."	8.4.2 c)	
16 e) 2)	"2) Lampholders allowing access to…."	8.4.2 c)	
16 f)	"f) Openings for the adjustment…."	8.4.2 cd)	
16 g)	Not used, Deleted		

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
17	Separation	8.5	Separation of parts
17 a)	"a) Applied parts shall be…", Deleted		
17 a) 1)	"1) The applied part…."	Annex A, Subclause 8.5.1 1)	
17 a) 2)	"2) The applied part…."	Annex A, Subclause 8.5.1 2)	
17 a) 3)	"3) The applied part is not protectively earthed….", Deleted		
17 a) 4)	"4) The applied part…."	Annex A, Subclause 8.5.1 3)	
17 a) 5)	"5) Impedances of components preventing…."	Annex A, Subclause 8.5.1 4)	
17 b)	Not used, Deleted		
17 c)	"c) An applied part shall have no…."	8.5.2.2	TYPE B APPLIED PARTS
17 d)	"d) Hand-held flexible shafts…"	8.6.3	Protective earthing of moving parts
17 e)	Not used, Deleted		
17 f)	Not used, Deleted		
17 g)	"g) Accessible parts not being an….", Deleted		
17 g) 1)	"1) The accessible part is separated from live parts by basic…."	Annex A, Subclause 8.5.1 1)	
17 g) 2)	"2) The accessible part is separated from live parts by a protectively…"	Annex A, Subclause 8.5.1 2)	
17 g) 3)	"3) The accessible part is not protectively….", Deleted		
17 g) 4)	"4) The accessible part is separated from live parts by double…."	Annex A, Subclause 8.5.1 3)	
17 g) 5)	"5) Impedances of components…."	Annex A, Subclause 8.5.1 4)	
17 h)	"h) Arrangements used to…."	8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS
17 h),	Indent 1 "– During a discharge of…."	8.5.5.1 a)	
17 h),	Indent 2 "– After exposure to the…."	8.5.5.1 b)	
18	"Protective earthing, functional earthing and potential equalization"	8.6	Protective earthing, functional earthing and potential equalization of ME EQUIPMENT
18 a)	"a) Accessible parts of Class I equipment….", Deleted		
18 b)	"b) The protective earth terminal…."	8.6.2	PROTECTIVE EARTH TERMINAL
18 c)	Not used, Deleted		
18 d)	Not used, Deleted		
18 e)	"e) If equipment is provided with…."	8.6.7	POTENTIAL EQUALIZATION CONDUCTOR 83
18 f)	"f) For equipment without…."	8.6.4 a)	
18 g)	"g) The impedance of…."	8.6.4 b)	
18 h)	Not used, Deleted		

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
18 j)	Not used, Deleted		
18 k)	"k) Functional earth terminals…."	8.6.8	FUNCTIONAL EARTH TERMINAL
18 L)	"L) IF CLASS II EQUIPMENT…."	8.6.9	CLASS II ME EQUIPMENT
19	"Continuous leakage currents and patient auxiliary currents"	8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS
19.1	"General requirements"	8.7.1	General requirements
19.1 a)	"a) The electrical insulation providing…."	8.7.1 a)	
19.1 b)	"b) The specified values of…."	8.7.1 b)	
19.1 c)	"c) Equipment specified for connection to a SELV source…."	8.2.1	Connection to a separate power supply
19.1 c)	"Such EQUIPMENT and INTERNALLY POWERED EQUIPMENT….", Deleted		
19.1 D)	"THE MEASUREMENT OF THE….", DELETED		
19.1 e)	"e) The patient leakage current….	8.7.4.7 g)	
19.1 f)	"f) The patient auxiliary…."	8.7.4.8	Measurement of the PATIENT AUXILIARY CURRENT
19.1 g)	"g) Equipment with multiple…."	8.7.4.9	ME EQUIPMENT with multiple PATIENT CONNECTIONS
19.2	"Single fault conditions"	8.7.2	SINGLE FAULT CONDITIONS
19.2 a)	"a) The earth leakage current….", Deleted		
19.2 b)	"b) Additionally the patient leakage current…."	8.1 a),	Indent 1
19.2 b)	Indent 2 "– A voltage equal to 110% of the highest…."	8.5.2.1	F-TYPE APPLIED PARTS
19.2 c)	"c) Additionally the enclosure leakage current…."	8.1 a),	Indent 1
19.3	"Allowable values"	8.7.3	Allowable values
19.3 a)	"a) The allowable values of the continuous…."	8.7.3 a)	
		8.7.3 b)	
19.3 b)	"b) The allowable values stated…." (First paragraph, modified)	8.7.3 a)	
19.3 b)	"Additionally, regardless of waveform…." (Second paragraph)	8.7.3 e)	
19.3 c)	Not used, Deleted		
19.3 d)	Not used, Deleted		
19.3 e)	Not used, Deleted		
19.4	"Tests"	8.7.4	Measurements
19.4 a)	"a) General"	8.7.4.1	General

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
19.4 a) 1)	"1) The earth leakage current…."	8.7.4.1 a)	
19.4 a) 2)	"2) Equipment is connected…."	8.7.1 b)	
19.4 a) 3)	"3) Three-phase equipment which….", Deleted		
19.4 a) 4)	"4) Where examination of…."	8.7.4.1 b)	
19.4 a) 5)	Not used, Deleted		
19.4 b)	"b) Measuring supply circuit"	8.7.4.2	Measuring supply circuits
19.4 b) 1)	"1) Equipment specified for connection to a supply mains which….", Deleted		
19.4 b) 2)	"2) Equipment specified for connection to a supply mains of which….", Deleted		
19.4 b) 3)	"3) Polyphase or single phase….", Deleted		
19.4 b) 4)	"4) Equipment specified for use with a specified Class I….", Deleted		
19.4 b) 5)	"5) Equipment specified for use with a specified Class II….", Deleted		
19.4 c)	"c) Connection of the equipment…."	8.7.4.3	Connection to the measuring supply circuit
19.4 c) 1)	"1) Equipment provided with a…."	8.7.4.3 a)	
19.4 c) 2)	"2) Equipment provided with an…."	8.7.4.3 b)	
19.4 c) 3)	"3) Equipment specified to…."	8.7.4.3 c)	
19.4 d)	"Measuring arrangement"	8.7.4.3 d)	
19.4 d) 1)	"1) It is recommended…"	8.7.4.3 d).1	
19.4 d) 2)	"2) However, external parts…."	8.7.4.3 d).1	
19.4 e)	"e) Measuring device"	8.7.4.4	Measuring device (MD)
19.4 e) 1)	"1) The measuring device shall load…."	8.7.4.4 a)	
19.4 e) 2)	"2) The evaluation of current or…."	8.7.4.4 b)	
19.4 e) 3)	Not used, Deleted		
19.4 e) 4)	"4) The measuring instrument…."	8.7.4.4 c)	
19.4 f)	"f) Measurement of the earth leakage current"	8.7.4.5	Measurement of the EARTH LEAKAGE CURRENT
19.4 f) 1)	"1) Class I equipment…."	8.7.4.5 a)	
19.4 f) 2)	"2) Equipment specified for use with a specified Class I….", Deleted		
19.4 g)	"g) Measurement of the enclosure leakage current"	8.7.4.6	Measurement of the TOUCH CURRENT

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
19.4 g) 1)	"1) Class I equipment…."	8.7.4.6 a)	
19.4 g) 2)	"2) Class II equipment…."		
19.4 g) 3)	"3) Equipment specified for connection…."		
19.4 g) 4)	"4) Equipment, with or without an applied part…."		
19.4 g) 5)	"5) If equipment has an enclosure…."	8.7.4.6 b)	
19.4 g) 6)	"6) If applicable, the measurements….", Deleted		
19.4 h)	"h) Measurement of the patient leakage current…."	8.7.4.7	Measurement of the PATIENT LEAKAGE CURRENT
19.4 h) 1)	"1) Class I equipment with an applied part…."	8.7.4.7 a)	
19.4 h) 2)	"2) Class I equipment with an F-type…."	8.7.4.7 b)	
19.4 h) 3)	"3) CLASS i equipment with an applied part and a signal input…."	8.7.4.7 c)	
19.4 h) 4)	"4) CLASS ii Equipment…." (First paragraph)	8.7.4.7 a)	
		8.7.4.7 b)	
		8.7.4.7 c)	
19.4 h) 4)	The patient leakage current…." (Second paragraph)	8.7.4.7 b)	
19.4 h) 4)	In the case of CLASS II….", (Third paragraph)	8.7.4.7 a)	
19.4 h) 5)	"5) Equipment with an applied part…."	8.7.4.7 a)	
		8.7.4.7 b)	
		8.7.4.7 c)	
19.4 h) 6)	"6) Internally powered equipment is tested…."	8.7.4.7 a)	
19.4 h) 7)	"7) Internally powered equipment provided with an F-TYPE…."	8.7.4.7 b)	
19.4 h) 8)	"8) Internally powered equipment provided with an applied part…."	8.7.4.7 c)	
19.4 h) 9)	"9) An applied part consisting of…."	8.7.4.7 e)	
19.4 h) 10)	"10) If loading of the applied part…."	8.7.4.7 i)	
19.4 h) 11)	11) If applicable, the measurements….", Deleted		
19.4 j)	"j) Measurement of the PATIENT…."	8.7.4.8	Measurement of the PATIENT AUXILIARY CURRENT
19.4 j) 1)	"1) Class I equipment with an applied part…."		
19.4 j) 2)	"2) Class II equipment…."		
19.4 j) 3)	3) Equipment with an applied part…."		
19.4 j) 4)	4) Internally powered equipment…."		

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
20	"Dielectric strength"	8.8	Insulation
20.1	"General requirements for all types of equipment", Deleted		
20.1 A-k a)	"a) The voltage appearing....", Deleted		
20.1 A-k b)	"b) The leakage currents....", Deleted		
20.1 A-k c)	"c) The signal input parts or signal output parts are protectively....", Deleted		
20.1 A-k d)	"d) The signal input or signal output parts are....", Deleted		
20.2	"Requirements for equipment with an applied part", Deleted		
20.2 B-d	Between an F-TYPE APPLIED PART...."	8.5.2.1	F-TYPE APPLIED PARTS
20.3	"Values of test voltage (Part)	8.5.4	WORKING VOLTAGE
20.3	"Values of test voltage"	8.8.3	Dielectric strength
20.4	"Tests"		
20.4 a)	"a) The test voltage...."		
20.4 b)	"b) The test voltage shall...."	8.8.3 a)	
20.4 c)	Not used, Deleted		
20.4 d)	Not used, Deleted		
20.4 e)	Not used, Deleted		
20.4 f)	"f) During the test...."	8.8.3 b)	
20.4 g)	"g) Care is taken that the voltage...."	Annex A, Subclause 8.8.1	
20.4 h)	"h) Where metal foil...."	8.8.3 c)	
20.4 j)	"j) Power-consuming voltage-limiting devices....", Deleted		
20.4 k)	"k) With the exception...."	8.8.3 c)	
20.4 l)	"l) In the case of motors...."	8.5.4	WORKING VOLTAGE
SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS		9	Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS
21	"Mechanical strength"	9.1	MECHANICAL HAZARDS of ME EQUIPMENT
21 a)	"a) The rigidity of an enclosure...."	15.3.2	Push test
21 b)	"b) The strength of an enclosure...."	15.3.3	Impact test
21 c)	"c) Carrying handles or grips...."	9.4.4 c)	
21.1	Not used, Deleted		
21.2	Not used, Deleted		
21.3	"Equipment parts serving for support...."	9.8.3.1	General

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
21.4	Not used, Deleted		
21.5	"Equipment or equipment parts…."	15.3.4.1	HAND-HELD ME EQUIPMENT
22	"Moving parts"	9.2	HAZARDS associated with moving parts
22.1	Not used, Deleted		
22.2	"Moving parts which do not need…."	9.2.2	TRAPPING ZONE
22.2 a)	"a) In the case of transportable equipment….", Deleted		
22.2 b)	"b) In the case of stationary equipment….", Deleted		
22.3	"Cords (ropes), chains and bands….", Deleted		
22.4	"Movements of equipment…."	9.2.2.5 b)	
22.5	Not used, Deleted		
22.6	"Parts subject to mechanical…."	15.2	Serviceability
22.7	"– If an electrically produced…."	9.2.4	Emergency stopping devices
23	"Surfaces, corners and edges"	9.3	HAZARDS associated with surfaces, corners and edges
24	"Stability in normal USE"	9.4	Instability HAZARDS
24.1	"Equipment shall either…."	9.4.2.2	Instability excluding transport
24.2	Not used, Deleted		
24.3	"If equipment overbalances…."	9.4.2.2	Instability excluding transport
24.3	Indent 1 "– Equipment shall not overbalance…."		
24.3	Indent 2 "– Equipment shall carry a warning…."		
24.3	Indent 3 "– In the position specified for transport…."	9.4.2.1	Instability in transport position
24.3 a)	"a) Equipment is provided with all specified…."	9.4.2.2 a)	
24.3 b)	"b) If no special transport…."	9.4.2.2 e)	
24.3 c),	First paragraph "If a special transport position…."."	9.4.2.1	Instability in transport position
24.3 c),	Last paragraph "Furthermore, such equipment shall…."	9.4.2.2	Instability excluding transport
24.3 d)	"d) EQUIPMENT having containers…."	9.4.2.2 f)	
24.4	Not used, Deleted		
24.5	Not used, Deleted		
24.6	"Grips and other handling devices"	9.4.4	Grips and other handling devices
24.6 a)	"a) EQUIPMENT or EQUIPMENT parts…."	9.4.4 a)	
24.6 b)	"b) EQUIPMENT specified by the…."	9.4.4 b)	

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
25	"Expelled parts"	9.5	Expelled parts HAZARD
25.1	"Where expelled parts…."	9.5.1	Protective means
25.2	"A graphical display…."	9.5.2	Cathode ray tubes
26	"Vibration and noise"	9.6	Acoustic energy (including infra- and ultrasound) and vibration
27	Pneumatic and hydraulic power	9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure
28	Suspended masses	9.8	HAZARDS associated with support systems
28.1	"General"	9.8.1	General
28.2	Not used, Deleted		
28.3	"Suspension system with SAFETY DEVICES"	9.8.4	Systems with MECHANICAL PROTECTIVE DEVICES
28.4	"Suspension systems of metal….",	9.8.5	Systems without MECHANICAL PROTECTIVE DEVICES
28.4 1)	"1) The total load…."	9.8.1	General
28.4 2)	"2) Where it is unlikely…."		
28.4 3)	"3) Where impairment by wear…."	9.8.2	TENSILE SAFETY FACTOR
28.4 4)	"4) Where metal having a specific…."		
28.4 5)	"5) Sheaves, sprockets, bandwheels…."		
28.4	Compliance "*Compliance with the requirements of….*		
28.5	"Dynamic loads", Not used, Deleted		
28.6	Not used, Deleted		
SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION		10	Protection against unwanted and excessive radiation HAZARDS
	"General"	12.4.5.1	Limits
29	"X-radiation"	10.1	X-Radiation
29.1,	Indent 1 "– For diagnostic X-ray…."	12.4.5.2	Diagnostic X-ray equipment
29.1,	Indent 2 "– For radiotherapy equipment…."	12.4.5.3	Radiotherapy equipment
29.2	"For equipment not intended…."	10.1.1	ME EQUIPMENT not intended to produce diagnostic or therapeutic x-radiation
30	"Alpha, beta, gamma…."	10.2	Alpha, beta, gamma, neutron radiation and other particle radiation
31	"Microwave radiation"	10.3	Microwave radiation
32	"Light radiation…."	10.5	Other visual electromagnetic radiation
33	"Infra-red radiation"	10.6	Infrared radiation
34	"Ultraviolet radiation"	10.7	Ultraviolet radiation

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
35	"Acoustical energy (including ultra-sonics)"	9.6.2	Acoustic energy
36	"Electromagnetic compatibility"	17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS
SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES		Annex G	Protection against HAZARDS of ignition of flammable anaesthetic mixtures
37	"Location and basic requirements"	Annex G.2	Location and basic requirements
37.1	Not used, Deleted		
37.2	Not used, Deleted		
37.3	Not used, Deleted		
37.4	Not used, Deleted		
37.5	Flammable anaesthetic mixture with air	Annex G.2.2	FLAMMABLE ANAESTHETIC MIXTURE WITH AIR
37.6	"Flammable anaesthetic mixture with oxygen or nitrous oxide"	Annex G.2.3	FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE
37.7	"Equipment or parts thereof...."	Annex G.2.4	ME EQUIPMENT specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH AIR ...."
37.8	"Equipment or parts thereof...."	Annex G.2.5	ME EQUIPMENT specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE
38	"Marking, accompanying documents"	Annex G.3	Marking, ACCOMPANYING DOCUMENTS
38.1	Not used, Deleted		
38.2	"Category APG equipment should...."	Annex G.3.1	CATEGORY APG marking
38.3	Not used, Deleted		
38.4	"Category AP equipment should...."	Annex G.3.2	CATEGORY AP marking
38.5	"The marking according...."	Annex G.3.3	Placement of markings
38.6	"Accompanying documents shall...."	Annex G.3.4	ACCOMPANYING DOCUMENTS
38.7	"On equipment in which...."	Annex G.3.5	Markings when parts of ME EQUIPMENT are CATEGORY AP or CATEGORY APG
38.8	Not used, Deleted		
39	"Common requirements for...."	Annex G.4	Common requirements for CATEGORY AP and CATEGORY APG EQUIPMENT
39.1	"Electrical connections"	Annex G.4.1	Electrical connections
39.1 a)	"a) Creepage distances and air clearances...."	Annex G.4.1 a)	
39.1 b)	"b) Connections, except those...."	Annex G.4.1 b)	
39.1 c)	"c) Category AP equipment...."	Annex G.4.1 c)	
39.2	"Construction details"	Annex G.4.2	Construction details

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
39.2 a)	"a) Opening of an enclosure…."	Annex G.4.2 a)	
39.2 b)	"b) To avoid the likelihood…."	Annex G.4.2 b)	
39.2 c)	"c) Where basic insulation of electrical…."	Annex G.4.2 c)	
39.3	"Prevention of electrostatic charges"	Annex G.4.3	Prevention of electrostatic charges
39.3 a)	"a) Electrostatic charges shall be prevented…."	Annex G.4.3 a)	
39.3 b)	"b) The electrical resistance limits…."	Annex G.4.3 b)	
39.3 c) to j)	Not used, Deleted		
39.4	"Corona"	Annex G.4.4	Corona
40	"Requirements and tests for …."	Annex G.5	Requirements and tests for CATEGORY AP EQUIPMENT, parts and components thereof
40.1	"General"	Annex G.5.1	General
40.2	"Temperature limits"	Annex G.5.2	Temperature limits
40.3	"Low-energy circuits"	Annex G.5.3	Low-energy circuits
40.4	"External ventilation with…."	Annex G.5.4	External ventilation with internal overpressure
40.4 a)	"a) Flammable anaesthetic mixtures with air…."	Annex G.5.4 a)	
40.4 b)	"b) The overpressure inside the enclosure…."	Annex G.5.4 b)	
40.4 c)	"c) If the overpressure drops…."	Annex G.5.4 c)	
40.4 d)	"d) The external surface of the enclosure…."	Annex G.5.4 d)	
40.5	"Enclosures with restricted breathing	Annex G.5.5	ENCLOSURES with restricted breathing
40.5 a)	"a) Enclosures with restricted breathing…."	Annex G.5.5 a)	
40.5 b)	"b) If the required tightness…."	Annex G.5.5 b)	
40.5 c)	"c) If the enclosure contains inlets…."	Annex G.5.5 c)	
41	"Requirements and tests for category APG…."	Annex G.6	Requirements and tests for CATEGORY APG EQUIPMENT, parts and components thereof
41.1	"General"	Annex G.6.1	General
41.2	"Power supply"	Annex G.6.2	Power supply
41.3	"Temperatures and low-energy circuits"	Annex G.6.3	Temperatures and low-energy circuits
41.3 a)	"a) no sparks are produced….."	Annex G.6.3 a)	
41.3 b)	"b) A temperature limit of….."	Annex G.6.3 b)	
41.4	"Heating elements"	Annex G.6.4	Heating elements
41.5	"Humidifiers", Deleted		

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS		11	Protection against excessive temperatures and other HAZARDS
42	"Excessive temperatures"	11.1	Excessive temperatures in ME EQUIPMENT
42.1	"Equipment parts having a safety function…."	11.1.1	Maximum temperature during NORMAL USE
42.2	"Equipment parts and their environment….", Deleted		
42.3	"Applied parTS of equipment…."	11.1.2	Temperature of APPLIED PARTS
42.3 1)	"1) Positioning and cooling"	11.1.3 a)	
42.3 2)	"2) Supply"	11.1.3 b)	
42.3 3)	"3) Duty cycle"	11.1.3 c)	
42.3 4)	"4) Temperature measurements"	11.1.3 d)	
42.3 5)	"5) Test criteria"	11.1.3 e)	
42.4	Delete, Not used		
42.5	"Guards"	11.1.4	GUARDS
43	"Fire prevention"	11.2	Fire prevention
43.1	"Strength and rigidity"	11.2.1	Strength and rigidity required to prevent fire in ME EQUIPMENT
43.2	"Oxygen enriched atmospheres"	11.2.2	ME EQUIPMENT and ME SYSTEMS used in conjunction with OXYGEN RICH ENVIRONMENTS
44	"Overflow, spillage, leakage…."	11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT
44.1	"General"	11.6.1	General
44.2	"Overflow"	11.6.2	Overflow in ME EQUIPMENT
44.3	"Spillage"	11.6.3	Spillage on ME EQUIPMENT and ME SYSTEM
44.4	"Leakage"	13.2.6	Leakage of liquid
44.5	"Humidity", Deleted		
44.6	"Ingress of liquids"	11.6.5	Ingress of liquids and particulate matter into ME EQUIPMENT and ME SYSTEMS
44.7	"Cleaning, sterilization and disinfection"	11.6.6	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS
44.8	"Compatibility with substances…."	11.6.8	Compatibility with substances used with the ME EQUIPMENT
45	"Pressure vessels and …."	9.7.1	General

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
45.1	Not used, Deleted		
45.2	"If a pressure vessel...."	9.7.5	Pressure vessels
45.3	"the maximum PRESSURE...."	9.7.3	Maximum pressure
45.3 a)	"a) The rated maximum...."	9.7.3 a)	
45.3 b)	"b) The pressure setting...."	9.7.3 b)	
45.3 c)	"c) The maximum PRESSURE...."	9.7.3 c)	
45.4	Not used, Deleted		
45.5	Not used, Deleted		
45.6	Not used, Deleted		
45.7	Equipment shall incorporate..."	9.7.7	Pressure-relief device
45.7 a)	"a) It shall be connected...."	9.7.7 a)	
45.7 b)	"b) It shall be so...."	9.7.7 b)	
45.7 c)	"c) It shall not be...."	9.7.7 c)	
45.7 d)	"d) It shall have its...."	9.7.7 d)	
45.7 e)	"e) It shall have its...."	9.7.7 e)	
45.7 f)	"f) It shall be of...."	9.7.7 f)	
45.7 g)	"g) There shall be no...."	9.7.7 g)	
45.7 h)	"h) The minimum number...."	9.7.7 h)	
45.8	Not used, Deleted		
45.9	Not used, Deleted		
45.10	Not used, Deleted		
46	Not used, Deleted		
47	Not used, Deleted		
48	"Biocombatibility...."	11.7	Biocompatibility of ME EQUIPMENT and ME SYSTEMS
49	"Interruption of the power supply"	11.8	Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT
49.1	"Thermal cut-outs and...."	15.4.2.1 a)	
49.2	"Equipment shall be so...."	11.8	Interruption of the power supply to ME EQUIPMENT and ME SYSTEM
49.3	"Means shall be provided...."	9.2.5	Release of PATIENT
49.4	Not used, Deleted		
SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT		12	Accuracy of controls and instruments and protection against hazardous outputs
50	"Accuracy of operating data"	12.1	Accuracy of controls and instruments

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
50.1	Not used, Deleted		
50.2	Not used, Deleted		
51	"Protection against hazardous output"	12.4	Protection against hazardous output
51.1	"Intentional exceeding of safety limits"	12.4.1	Intentional exceeding of safety limits
51.2	"Indication of parameters relevant to safety"	12.4.2	Indication of parameters relevant to safety
51.3	Not used, Deleted		
51.4	"Accidental selection of…."	12.4.3	Accidental selection of excessive output values
51.5	"Incorrect output"	12.4.4	Incorrect output
SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS		13	Hazardous situations and fault conditions
52	"Abnormal operation and fault conditions"		
52.1	"Equipment shall be so designed…."	4.7	NORMAL CONDITION and SINGLE FAULT CONDITION for ME EQUIPMENT
52.2	Not used, Deleted		
52.3	Not used, Deleted		
52.4	"The following safety…."	13.1	Specific HAZARDOUS SITUATIONS
52.4.1	"– emission of flames…."	13.1.2	Emissions, deformation of ENCLOSURE or exceeding maximum temperature
52.4.2	"– Exceeding of the limits…"	13.1.3	Exceeding LEAKAGE CURRENT or voltage limits
52.4.3	"Starting, interrupting, or locking…."	13.1.4	Specific MECHANICAL HAZARDS
52.5	"The following single fault…."	13.2	SINGLE FAULT CONDITIONS
52.5.1	"Overloading of mains supply…."	13.2.3	Overloading of transformers in ME EQUIPMENT
52.5.2	"Failure of thermostats"	13.2.4	Failure of THERMOSTATS
52.5.3	"Short-circuiting of either…."	8.1 b) Indent 1	"– short circuit of any one insulation…."
52.5.4	"Interruption of the protective…."	8.1 b) Indent 4	"– open circuit of any one PROTECTIVE EARTH CONDUCTOR…."
52.5.5	"Impairment of cooling"	13.2.7	Impairment of cooling that could result in a HAZARD
52.5.6	"Locking of moving parts"	13.2.8	Locking of moving parts
52.5.7	"Interruption and short-circuiting…."	13.2.9	Interruption and short-circuiting of motor capacitors
52.5.8	"Additional tests for motor…."	13.2.10	Additional test criteria for motor operated ME EQUIPMENT

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
52.5.8 a)	"a) 30 s for…."	13.2.10 a)	
52.5.8 b)	"b) 5 min for other…."	13.2.10 b)	
52.5.8 c)	"c) for the maximum…."	13.2.10 c)	
52.5.8 d)	"d) as long as necessary…."	13.2.10 d)	
52.5.9	"Failure of components"	4.7	NORMAL CONDITION and SINGLE FAULT CONDITION for ME EQUIPMENT
52.5.10	"Overload"	13.2.13	Overload
52.5.10 a)	"a) Equipment with heating…."	13.2.13.2 a)	
52.5.10 a) 1)	"1) for thermostatically controlled…."	13.2.13.2 a) 1)	
52.5.10 a) 2)	"2) For equipment having…."	13.2.13.2 a) 2)	
52.5.10 a) 3)	"3) For other EQUIPMENT…."	13.2.13.2 a) 3)	
52.5.10 b)	"b) Equipment having motors…."	13.2.13.3 a)	
52.5.10 b) 1)	"1) for the motor part…."	13.2.13.3 a) 1)	
52.5.10 b) 2)	"2) for equipment containing…."	13.2.13.3 a) 2)	
52.5.10 b) 3)	"3) if more than…."	13.2.13.3 a) 3)	
52.5.10 c)	"c) Equipment having heating…."	13.2.13.2 b)	
52.5.10 d)	"d) Heating parts of…."	13.2.13.2 c)	
52.5.10 d) 1)	"1) as specified in…."		
52.5.10 d) 2)	"2) with the equipment…."		
52.5.10 d) 3)	"3) with a supply voltage…."		
52.5.10 d) 4)	"4) disabling any control…."	13.2.13.2 c) 1)	
52.5.10 d) 5)	"5) if the equipment…."	13.2.13.2 c) 2)	
52.5.10 e)	"e) Heating parts of…."	13.2.13.2 c)	
52.5.10 e) 1)	"1) as specified in…."		
52.5.10 e) 2)	"2) with the equipment…."		
52.5.10 e) 3)	"3) with a supply voltage…."		
52.5.10 e) 4)	"4) without any control….", Deleted		
52.5.10 e) 5)	"5) until steady thermal…."	13.2.13.2 c) 3)	
52.5.10 f)	"f) Motors are checked…."	13.2.13.3 b)	
52.5.10 f) 1)	"1) intended to be…."	13.2.13.3 b) 1)	
52.5.10 f) 2)	"2) liable to be…."	13.2.13.3 b) 2)	
52.5.10 g)	"g) Equipment rated for…."	13.2.13.4	ME EQUIPMENT RATED for non-CONTINUOUS OPERATION
52.5.10 h)	"h) Equipment with three-phase…."	13.2.13.3 c)	
53	"Environmental tests", Deleted		

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
SECTION TEN – CONSTRUCTIONAL REQUIREMENTS		15	Construction of ME EQUIPMENT
54	"General"	4.5	Equivalent safety for ME EQUIPMENT or ME SYSTEMS
54.1	"Arrangements of functions"	15.1	Arrangements of controls and indicators of ME EQUIPMENT
54.2	"Serviceability"	15.2	Serviceability
54.3	Not used, Deleted		
55	"Enclosures and covers"	15.3	Mechanical strength
55.1	"Materials"	15.3.1	General
55.2	"Mechanical strength"	15.3.7	Environmental influences
55.3	Not used, Deleted		
55.4	Not used, Deleted		
56, Some parts	"Components and general assembly"	8.10	Components and wiring
56, Some parts	"Components and general assembly"	15.4	ME EQUIPMENT components and general assembly
56.1	"General", Deleted		
56.1 a)	Not used, Deleted		
56.1 b)	"b) Marking of components"	4.8	Components of ME EQUIPMENT
56.1 c)	Not used, Deleted		
56.1 d)	"d) Component fixing"	8.10.1	Fixing of components
56.1 e)	Not used, Deleted		
56.1 f)	"f) Fixing of wiring"	8.10.2	Fixing of wiring
56.2	Not used, Deleted		
56.3	"Connections – General"	8.11.2	MULTIPLE SOCKET-OUTLETS
		8.11.4	MAINS TERMINAL DEVICES
56.3 a)	"Construction of connectors"	15.4.1	Construction of connectors
56.3 a)	Indent 1 "– Connectors shall comply with….", Deleted		
56.3 a)	Indent 2 "– Plugs for connection…."	15.4.1 a)	
56.3 a)	Indent 3 "– Medical gas connections…."	15.4.1 b)	
56.3 b)	"b) Connections between different…."	8.10.3	Connections between different parts of ME EQUIPMENT
Appendix A, 56.3 c)	"c) There are two…."	8.5.2.3	PATIENT leads
56.4	"Connections of capacitors", Deleted		
56.4	Indent 1 "– Capacitors shall not be connected….", Deleted		

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
56.4	Indent 2 "– Capacitors connected directly...."	8.5.1.2	"A Y1 capacitor complying with IEC 60348-14...."
		8.5.1.3	"A Y2 capacitor complying with IEC 60348-14...."
		Annex A, Subclause 8.5.1	
56.4	Indent 3 "– The enclosure of capacitors connected....", Deleted		
56.4	Indent 4 "– Capacitors or other...."	15.4.2.1 e)	
56.5	"Protective devices"	8.11.1 h)	
56.6	"Temperature and overload control devices"	15.4.2	Temperature and overload control devices
56.6 a)	"a) Application"	15.4.2.1	Application
56.6 a)	Indent 1 "– Thermal cutouts with a...."	15.4.2.1 b)	
56.6 a)	Indent 2 "– Thermal safety devices....", Deleted		
56.6 a)	Indent 3 "– Where a failure of a...."	15.4.2.1 c)	
56.6 a)	Indent 4 "– Where the consequent loss...."	15.4.2.1 d)	
56.6 a)	"Equipment which incorporates a fluid...."	15.4.2.1 g)	
56.6 b)	"b) Allowable temperature range"	15.4.2.2	Temperature settings
56.6 b)	Indent 1 "– Where means are provided...."		
56.6 b)	Indent 2 "– The operating temperature....", Deleted		
56.7	"Batteries"	15.4.3	Batteries
56.7 a)	"a) Housing"	15.4.3.1	Housing
56.7 b)	"b) Connection"	15.4.3.2	Connection
56.7 b) 1)	"1) Establishing whether there...."		
56.7 b) 2)	"2) Where such a possibility...."		
56.7 c)	"c) Battery state"	15.4.3.3	Protection against overcharging
56.8	"Indicators"	15.4.4	Indicators
56.9	"Pre-set controls"	15.4.5	Pre-set controls
56.10	"Actuating parts of controls"	15.4.6	Actuating parts of controls of ME EQUIPMENT
56.10 a)	"a) Protection against electric shock"	5.9.2.3	Actuating mechanisms
56.10 b)	"b) Fixing, prevention of maladjustment"	15.4.6.1	Fixing, prevention of maladjustment

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
56.10 b)	Indent 1 "– All activating parts shall…"	15.4.6.1 a)	
56.10 b)	Indent 2 "– Controls, the adjustment of which….""	15.4.6.1 b)	
56.10 b)	Indent 3 "– Incorrect connection of the indicating device…."	15.4.6.1 c)	
56.10 c)	"c Limitation of movement"	15.4.6.2	Limitation of movement
56.11,	Some parts "Cord-connected hand-held…."	8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices
56.11 a)	"a) Limitation of operating voltages"	8.10.4.1	Limitation of operating voltages
56.11, Some parts	"Cord-connected hand-held…."	15.4.7	Cord-connected HAND-HELD and foot-operated control devices
56.11 b)	"b) Mechanical strength"	15.4.7.1	Mechanical strength
56.11 b)	Indent 1 "– Hand-held control devices…."	15.4.7.1 a)	
56.11 b)	Indent 2 "– Foot-operated control devices…."	15.4.7.1 b)	
56.11 c)	"c) Inadvertent operation"	15.4.7.2	Accidental operation of ME EQUIPMENT
56.11 d)	"d) Entry of liquids"	15.4.7.3	Entry of liquids
56.11 d)	Indent 1 "– Foot-operated controls…."	15.4.7.3 a)	
56.11 d)	Indent 2 "– The electrical switching…."	15.4.7.3 b)	
56.11 e)	"e) Connection cords"	8.10.4.2	Connection cords
57	"Mains parts, components and layout"	8.11	MAINS PARTS, components and layout
57.1	"Isolation from the supply mains"	8.11.1	Isolation from the SUPPLY MAINS
57.1 a)	Heading deleted, text retained		
57.1 a)	Indent 1 "– Equipment shall have means to…."	8.11.1 a)	
57.1 a)	Indent 2 "– Means for isolation…."	8.11.1 b)	
57.1 b)	Not used, Deleted		
57.1 c)	Not used, Deleted		
57.1 d)	"d) Switches that are…."	8.11.1 c)	
57.1 e)	Not used, Deleted		
57.1 f)	"f) Mains switches shall…."	8.11.1 d)	
57.1 g)	"g) The directions of…."	8.11.1 e)	
57.1 h)	"h) In non-permanent installed equipment…."	8.11.1 f)	
57.1 j)	Not used, Deleted		
57.1 k)	Not used, Deleted		
57.1 l)	Not used, Deleted		

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
57.1 m)	"m) Fuses and semiconductors…."	8.11.1 g)	
57.2	"Mains connectors, appliance…."	8.11.2	MULTIPLE SOCKET-OUTLETS
57.2 a)	Not used, Deleted		
57.2 b)	Not used, Deleted		
57.2 c)	Not used, Deleted		
57.2 d)	Not used, Deleted		
57.2 e)	"e) Auxiliary mains socket outlets…."	8.11.2	MULTIPLE SOCKET-OUTLETS
57.2 f)	Not used, Deleted		
57.2 g)	"g) Except where a functional earth….", Deleted		
57.3	Power supply cords"	8.11.3	POWER SUPPLY CORDS
57.3 a)	"a) Application"	8.11.3.1	Application
57.3 b)	"b) Types"	8.11.3.2	Types
57.3 c)	"c) Cross-sectional area of…."	8.11.3.3	Cross-sectional area of POWER SUPPLY CORD conductors
57.3 d)	"d) Preparation of conductors"	8.10.2	Fixing of wiring
57.4	"Connection of power supply cords", Deleted		
57.4 a)	"a) Cord anchorages"	8.11.3.5	Cord anchorages
57.4 a)	Indent 1 "– Equipment and mains…."	8.11.3.5 a)	
57.4 a)	Indent 2 "–Cord anchorages of…."	8.11.3.5 b)	
57.4 a)	Indent 3 "–Cord anchorages of…."	8.11.3.5 c)	
57.4 a)	Indent 4 "– Screws, if any, which…."	8.11.3.5 d)	
57.4 a)	Indent 5 "– Conductors of the…."	8.11.3.5 e)	
57.4 a)	Last paragraph, "It shall not be possible…."	8.11.3.5 f)	
57.4 b)	"b) Cord guards"	8.11.3.6	Cord guards
57.4 c)	"c) Accessibility of the connection"	8.11.4.5	Accessibility of the connection
57.5	"Mains terminal devices…."	8.11.4	MAINS TERMINAL DEVICES
57.5 a)	"a) General requirements for mains…."	8.11.4.1	General requirements for MAINS TERMINAL DEVICES
57.5 b)	"b) Arrangement of MAINS…."	8.11.4.2	Arrangement of MAINS TERMINAL DEVICES
57.5 b)	Indent 1 "– For equipment with rewirable cords…."	8.11.4.2 a)	
57.5 b)	Indent 2 "– For details of protective…."	8.11.4.2 b)	
57.5 b)	Indent 3 "– For marking of mains…."	8.11.4.2 c)	
57.5 b)	Indent 4 "– Mains terminal devices shall not be…."	8.11.4.2 d)	
57.5 b)	Indent 5 "– Mains terminal devices shall be…."	8.11.4.2 e)	

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
57.5 c)	"c) Fixing of mains terminals"	8.11.4.3	Fixing of mains terminals
57.5 d)	"d) Connections to mains terminals"	8.11.4.4	Connections to mains terminals
57.5 d)	Indent 1 "– For equipment with rewirable…."		
57.5 d)	Indent 2 "– For further requirements…."		
57.5 e)	Not used, Deleted		
57.6	"Mains fuses and over-current releases"	8.11.5	Mains fuses and OVER-CURRENT RELEASES
57.7	Not used, Deleted		
57.8	"Wiring of the mains part"	8.11.6	Internal wiring of the MAINS PART
57.8 a)	"a) Insulation", Deleted		
57.8 b)	"Cross-section", Deleted heading	8.11.6	Internal wiring of the MAINS PART
57.8 b),	Indent 1 "– Internal wiring in a…."	8.11.6 a)	
57.8 b),	Indent 2 "– The cross-sectional area…."	8.11.6 b)	
57.9	"Mains supply transformers"	15.5	MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5
57.9.1	"Overheating"	15.5.1	Overheating
57.9.1 a)	"a) Short-circuit"	15.5.1.2	Short-circuit test
57.9.1 b)	"b) Overload"	15.5.1.3	Overload test
57.9.1 b)	Indent 1 "– under the conditions specified in…."	15.5.1.3 a)	
57.9.1 b)	Indent 2 "– the supply voltage being maintained….", Deleted		
57.9.1 b)	Indent 3 "– the tests are made on each winding…."	15.5.1.3 a)	
59.9.1 b)	Indent 4 "– the section or winding…."	15.5.1.3 b)	
57.9.2	"Dielectric strength"	15.5.2	Dielectric strength
57.9.2	Indent 1 "– Transformers not having…."	15.5.2 a)	
57.9.2	Indent 2 "– Transformers having any…."	15.5.2 b)	
57.9.2	Indent 3 "– Three-phase transformers may…."	15.5.2	Indent 1
57.9.2	Indent 4 "– The value of the test voltage…."	15.5.2	Indent 2
57.9.2	Indent 5 "– During the test, all windings…."	15.5.2	Indent 3
57.9.2	Indent 6 "– Initially not more than…."	15.5.2	Indent 4

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
57.9.2	Indent 7 "– Tests are not conducted at …."	15.5.2	Indent 5
57.9.2	Indent 8 "– During the test, no flashover…."	15.5.2. Compliance	
57.9.3	Not used, Deleted		
57.9.4	"Construction"	15.5.3	Construction of transformers used to provide separation as required by 8.5
57.9.4 a)	"a) The separation of primary and secondary….", Deleted		
57.9.4 b)	Not used, Deleted		
57.9.4 c)	"c) Means shall be provided….", Deleted		
57.9.4 d)	"d) If a protectively earthed….", Deleted		
57.9.4 e)	"e) In transformers with….", Deleted		
57.9.4 f)	"f) For transformers complying with….", Deleted		
57.9.4 g)	"g) The exit of the wires….", Deleted		
57.10	"Creepage distances and air clearances"	8.9	CREEPAGE DISTANCES and AIR CLEARANCES
57.10 a)	"a) Values"	8.9.1	Values
57.10 a)	Indent 1 "– Creepage distances and air clearances…."	8.9.1.1	General
57.10 a)	Indent 2 "– The value of the reference voltage…."	8.9.1.6	Interpolation
57.10 a)	Indent 3 "– For slot insulation….", Deleted		
57.10 a)	Indent 4 "– Between defibrillation-proof applied parts…."	8.9.1.15	CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS
57.10 b)	"b) Application"	8.9.2	Application
57.10 b)	Indent 1 "– For insulation in the…."	8.9.2 a)	
57.10 b)	Indent 2 "– The contribution of the…."	8.9.2 b)	
57.10 b)	Indent 3 "– When assessing creepage distances….", Deleted		
57.10 b)	Indent 4 "– Air clearance alone is…."	8.9.2 c)	
57.10 c)	Not used, Deleted		
57.10 d)	"d) Measurement of creepage…."	8.9.4	Measurement of CREEPAGE DISTANCES and AIR CLEARANCES
58	"Protective earthing – Terminals and connections"	8.6	Protective earthing, functional earthing and potential equalization of ME EQUIPMENT
58.1	"The clamping means…"	8.6.2	PROTECTIVE EARTH TERMINAL

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
58.2	"For internal protective earthing….", Deleted		
58.3	Not used, Deleted		
58.4	Not used, Deleted		
58.5	Not used, Deleted		
58.6	Not used, Deleted		
58.7	"Where and appliance…."	8.6.2	PROTECTIVE EARTH TERMINAL
58.8	"The protective earth…."		
58.9	"Protective earth connection"	8.6.6	Plugs and sockets
59	"Construction and layout", Deleted		
59.1	Internal wiring	8.10.2	Fixing of wiring
59.1 a)	"a) Mechanical protection"	8.10.5	Mechanical protection of wiring
59.1 a)	Indent 1 "– Cables and wiring shall…."	8.10.5 a)	
59.1 a)	Indent 2 "– Wiring having basic insulation only….", Deleted		
59.1 a)	Indent 3 "– EQUIPMENT shall be so designed…."	8.10.5 b)	
59.1 b)	"b) Bending"	8.10.6	Guiding rollers for insulated conductors
59.1 c)	"c) Insulation"	8.10.7	Insulation of internal wiring
59.1 c)	Indent 1 "– If insulating sleeving…."	8.10.7 a)	
59.1 c)	Indent 2 "– Inside equipment the sheath of a…."	8.10.7 b)	
59.1 c)	Indent 3 "– Insulating conductor which in…."	8.10.7 c)	
59.1 d)	"Materials"	15.4.8	Internal wiring of ME EQUIPMENT
59.1 e)	Not used, Deleted		
59.1 f)	"f) Applicable requirements"	3.63	MEDICAL ELECTRICAL EQUIPMENT (ME EQUIPMENT)
59.2	Insulation	8.8.4	Insulation other than wire insulation
59.2 a)	Not used, Deleted		
59.2 b)	"b) "Mechanical strength and…."	8.8.4.1	Mechanical strength and resistance to heat and fire
59.2 b) 1)	"1) For parts of the…."	8.8.4.1 a)	
59.2 b) 2)	"2) For parts of insulating…."	8.8.4.1 b)	
59.2 c)	"c) Protection"	8.8.4.2	Resistance to environmental stress
59.3	"Excessive current and voltage protection"	15.4.3.5	Excessive current and voltage protection
59.3 Indent 1	"– See Sub-clause 57.6"		
59.3 Indent 2	"– An internal electrical power source…."		

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IEC 60601-1 Second Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
59.3 Indent 3	"– Fuse elements replaceable without…."	8.4.2 c)	
59.3 Indent 4	"– Protective devices connected…."	8.5.2.1	F-TYPE APPLIED PARTS
59.4	"Oil containers"	15.4.9	Oil containers
59.4 Indent 1	"– Oil containers in portable…."	15.4.9 a)	
59.4 Indent 1	"– Oil containers in mobile…."	15.4.9 b)	
59.4 Indent 2	"– Partially sealed oil-filled…."	15.4.9 c)	
Figure 10 to Figure 14		Annex F	Suitable measuring supply circuits
Appendix A	"General guidance and rationale"	Annex A	General guidance and rationale
Appendix B	Not used, Deleted		
Appendix C	Sequence of testing	Annex B	Sequence of testing
Appendix D	"Symbols on marking"	Annex D	Symbols on marking
Appendix E	"Survey of insulation paths and test circuits"	Annex J	Survey of insulation paths
Appendix F	"Test apparatus for flammable mixtures"	Annex G.7	Test apparatus for flammable mixtures
Appendix G	"Impact-test apparatus", Deleted		
Appendix H	Not used, Deleted		
Appendix J	Not used, Deleted		
Appendix K	"Examples of the connection of the applied part for measurement of the patient leakage current"	Annex E	Examples of the connection of the measuring device (MD) for measurement of the PATIENT LEAKAGE CURRENT and PATIENT AUXILIART CURRENT
Appendix L	"Publications mentioned in this standard"	2	Normative references
		Bibliography	

7.2 Mapping to the second edition of IEC 60601-1-1

The first column in Table 4 lists in numerical sequence the elements of the second edition of IEC 60601-1-1 [3] that have been incorporated into the third edition. The first few words of the tile or paragraph text are provided to assist in locating the element in IEC 60601-1-1. The second column gives the clause and title where that element has been addressed in IEC 60601-1:2005.

Elements that were deleted during the preparation of IEC 60601-1:2005 are marked simply as "Deleted."

Table 4 – Mapping between the elements of the second edition of IEC 60601-1-1 and IEC 60601-1:2005 *(1 of 2)*

IEC 60601-1-1 Second Edition		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
2.201	"Medical electrical system"	3.64	MEDICAL ELECTRICAL SYSTEM (ME SYSTEM)
2.202	"Patient environment"	3.79	PATIENT ENVIRONMENT
2.203	"Separation device"	3.112	SEPARATION DEVICE
2.204	"Multiple portable socket-outlet"	3.67	MULTIPLE SOCKET-OUTLET
2.205	"Functional connection"	3.33	FUNCTIONAL CONNECTION
3.201	"General requirements for the system"	16.1	General requirements for the ME SYSTEMS
3.201.2,	"Non-medical electrical equipment"		
3.201.3	"Specified power supply", Deleted		
3.201.4	"System"	16.1	General requirements for the ME SYSTEMS
6.8.201	"Accompanying documents of a system"	16.2	ACCOMPANYING DOCUMENTS of an ME SYSTEM
6.8.201 a)	"a) The accompanying documents for each ...."	16.2 a)	
6.8.201 b)	"b) the equivalent documents for each...."	16.2 b)	
6.8.201 c)	"c) the following information...."	16.2 c)	
6.8.201 d)	"d) advice to...."	16.2 d)	
10.2.2.201	"Power supply"	16.3	Power supply
16.201	"Enclosures"	16.4	ENCLOSURES
17.201	"Electrical separation"	16.5	SEPARATION DEVICES
19	"Continuous leakage currents and..."	16.6	LEAKAGE CURRENTS
19.201	"Leakage currents", Deleted		
19.201.1	"Enclosure leakage current"	16.6.1	TOUCH CURRENT
19.201.2	"Patient leakage current"	16.6.3	PATIENT LEAKAGE CURRENT
19.201.3	"Connection of signal input parts...."	16.5	SEPARATION DEVICES
22.7.201	"Protective means"	16.7	Protection against MECHANICAL HAZARDS
49.201	"Interruption of the power supply"	16.8	Interruption of the power supply to parts of an ME SYSTEM
56.3.201	"Connections	16.9	ME SYSTEM connections and wiring
57	"Mains parts, components and layout"	16.9.2	MAINS PARTS, components and layout

Table 4 *(2 of 2)*

IEC 60601-1-1 Second Edition		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
57.2.201	"Multiple portable socket-outlet"	16.9.2.1	MULTIPLE SOCKET-OUTLET
57.10	"Creepage distance and...."	16.5	SEPARATION DEVICES
58.201	"Protective earth conductor"	16.9.2.2	PROTECTIVE EARTH CONNECTIONS in ME SYSTEMS
59.201	"Protection of wiring"	16.9.2.3	Protection of conductors
Annex BBB	Examples of combinations of...."	Annex I	ME SYSTEMS aspects
Annex EEE.1	"Multiple portable socket-outlet with separating transformer"	16.9.2.1 a)	
Annex EEE.1	"Multiple portable socket-outlet with separating transformer"	16.9.2.1 b)	
Annex EEE.1	"Multiple portable socket-outlet with separating transformer"	16.9.2.1 d)	
Annex EEE.2	"Multiple portable socket-outlet"	16.9.2.1 c)	
Annex FFF	"Examples of application of...."	Annex I	ME SYSTEMS aspects

7.3 Mapping to the first edition of IEC 60601-1-4, as amended

The first column in Table 5 lists in numerical sequence the elements of the first edition of IEC 60601-1-4, as amended [4], which have been incorporated into the third edition. The first few words of the tile or paragraph text are provided to assist in locating the element in IEC 60601-1-4.

Many of the requirements in IEC 60601-1-4 for risk management activities were incorporated into ISO 14971[11]. As a risk management process complying with ISO 14971 is now a normative requirement of IEC 60601-1, these requirements were no longer needed in the clause dealing with programmable electrical medical systems. The second column gives the clause and title where that element has been addressed in IEC 60601-1:2005 or in ISO 14971.

Elements that were deleted during the preparation of IEC 60601-1:2005 are marked simply as "Deleted."

Table 5 – Mapping between the elements of the first edition of IEC 60601-1-4 as amended and IEC 60601-1:2005 *(1 of 3)*

IEC 60601-1-4 First Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
2.201.1	“Development life-cycle”	3.82	PEMS DEVELOPMENT LIFE-CYCLE
2.201.10	“Safety”	3.10	BASIC SAFETY
2.201.14	“Validation”	3.83	PEMS VALIDATION
2.201.15	“Verification”	3.138	VERIFICATION
2.201.4	“Programmable electrical medical system (PEMS)”	3.90	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM (PEMS)
2.201.5	“Programmable electronic subsystem (PESS)”	3.91	PROGRAMMABLE ELECTRONIC SUBSYSTEM (PESS)
6.8.201	"All relevant information regarding significant residual risk...."	ISO 14971, 6.4	Residual risk evaluation
6.8.202	"Accompanying documents for the PEMS...."	7.2.2	Identification
		7.9.2.1	General
52.201	“Documentation”	14.2	Documentation
52.201.1	"Documentation produced from application...."		
52.201.2	"These documents herein referred to as the risk management fie...."		
52.201.3	"A risk management summary...."	ISO 14971, 8	Risk management report
52.202	“Risk management plan”	14.3	RISK MANAGEMENT Plan
52.202.1	'The manufacturer shall prepare....."	ISO 14971, 3.5	Risk management plan
52.202.2	"This plan shall include....."	ISO 14971, 3.5	Risk management plan
		14.3	RISK MANAGEMENT Plan
52.202.3	"If the plan changes...."	ISO 14971, 3.5	Risk management plan
52.203	“Development life-cycle”	14.4	PEMS DEVELOPMENT LIFE-CYCLE
52.203.1	"A development life-cycle shall be defined....."		
52.203.2	"The development life-cycle shall be divided...."		
52.203.3	"The development life-cycle shall include integral...."		
52.203.4	"The development life-cycle shall include documentation...."		
52.203.5	"Risk management activities shall apply...."		
52.203.6	"Where appropriate, a defined system for problem...."	14.5	Problem resolution
52.204	“Risk management process”	14.6	RISK MANAGEMENT PROCESS
52.204.1	"A risk management process shall...."	4.2	RISK MANAGEMENT PROCESS for ME EQUIPMENT and ME SYSTEMS
52.204.2	"The process shall be applied...."	ISO 14971, 1	Scope
52.204.3	"Risk analysis"	ISO 14971, 4	Risk analysis

Table 5 *(2 of 3)*

IEC 60601-1-4 First Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
52.204.3.1	“Hazard analysis”, Heading deleted		
52.204.3.1.1	“Hazard identification shall....”	ISO 14971, 3.5	Risk management plan
52.204.3.1.2	"Hazards shall be identified...."	ISO 14971, 4.1	Risk analysis process
52.204.3.1.3	"The hazards considered shall include...."	ISO 14971, 4.2	Intended use/intended purpose and identification of characteristics related to the safety of the medical device
52.204.3.1.4	"Reasonably foreseeable sequences of events...."	ISO 14971, 4.3	Identification of known and foreseeable hazards
52.204.3.1.5	"Initiating causes considered...."		
52.204.3.1.6	'Matters considered shall include....."	ISO 14971, Annex D	
		14.6.1	Identification of known and foreseeable HAZARDS
52.204.3.1.7	"Hazards identification methods...."	ISO 14971, 4.3	Identification of known and foreseeable hazards
52.204.3.1.8	"The methods used...."	ISO 14971, 3.6	Risk management file
52.204.3.1.9	"The results of the application...."		
52.204.3.1.10	"Each identified hazards...."	ISO 14971, 8	Risk management report
52.205.3.2	"Risk estimation"	ISO 14971, 4.4	Estimation of the risk(s) for each hazard
52.205.3.2.1	"For each identified hazard...."		
52.205.3.2.2	"The estimation of the risk...."		
52.205.3.2.3	"The severity level categorization		
52.205.3.2.4	"The likelihood estimation method...."		
52.205.3.2.5	"The estimated shall be recorded...."	ISO 14971, 8	Risk management report
52.204.4	“Risk control”	14.6.2	RISK CONTROL
52.204.4.1	"The risks shall be controlled...."	ISO 14971, 6.4	Residual risk evaluation
52.204.4.2	"A risk is acceptable...."		
52.204.4.3	"Methods of risk...."	ISO 14971, 6.2	Option analysis
52.204.4.4	"Risks control methods shall..."		
52.204.4.5	"The requirement(s) to control...."	ISO 14971, 8	Risk management report
52.204.4.6	"An evaluation of the effectiveness...."		
52.205	Qualification of personnel	ISO 14971, 3.4	Qualification of personnel
52.206	“Requirement specification”	14.7	Requirement specification
52.206.1	'For the PEMS and each...."		
52.206.2	"The requirement specification shall detail...."		
52.206.3	"The requirement specification shall include...."		

Table 5 *(3 of 3)*

IEC 60601-1-4 First Edition as amended		IEC 60601-1:2005	
Clause	**Title**	**Clause**	**Title**
52.207	"Architecture"	14.8	Architecture
52.207.1	"The architecture shall satisfy...."		
52.207.2	"For the PEMS and each...."		
52.207.3	"Where appropriate, the architecture specification...."		
52.207.4	"Where appropriate, to reduce...."		
52.207.5	"The architecture specification shall...."		
52.208	"Design and implementation"	14.9	Design and implementation
52.208.1	"Where appropriate, the design shall...."		
52.208.2	"Descriptive data regarding...."		
52.209	"Verification"	14.10	VERIFICATION
52.209.1	"Verification of the implementation...."		
52.209.2	"A verification plan shall...."		
52.209.3	"The verification shall be performed...."		
52.209.4	"A reference to the methods...."	ISO 14971, 8	Risk management report
52.210	"Validation"	14.11	PEMS VALIDATION
52.210.1	"Validation of the safety...."		
52.210.2	"A validation plan shall be produced...."		
52.210.3	'The validation shall be performed...."		
52.210.4	"The leader of the team...."		
52.210.5	"All professional relationships of the members...."		
52.210.6	No member of a design team...."		
52.210.7	"A reference to the methods and results...."		
52.211	"Modification"	14.12	Modification
52.211.1	"If any or all of a design...."		
52.211.2	All relevant documents...."	14.2	Documentation
52.212	"Assessment", Deleted		
Annex DDD	"Development life-cycle"	Annex H	PEMS structure, DEVELOPMENT LIFE-CYCLE and documentation
Annex EEE	"Example of PEMS/PESS structure"		

7.4 Mapping from IEC 60601-1:2005 + A1:2012

The first column in Table 6 lists in numerical sequence the elements of IEC 60601-1:2005 + A1:2012 along with the title. For each element, the second column gives the clause and the first few words of the tile or paragraph text of the source of the material. These sources include the second edition of IEC 60601-1 as amended [1], IEC 60601-1-1 [3], IEC 60601-1-4 as amended [4], as well as definitions from IEC 62366 [10], IEC 60950-1 [6], ISO 14971 [11] and ISO/IEC Guide 51 [12].

Elements that were added during the preparation of IEC 60601-1:2005+A1:2012 are marked as “New” and are highlighted in blue.

Table 6 – Mapping between the elements of IEC 60601-1:2005 + A1:2012 and other standards *(1 of 36)*

IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
1	Scope, object and related standards	1	“Scope and object”
1.1	Scope	1.1	“Scope”
1.2	Object	1.2	“Object”
1.3	Collateral Standards	1.5	“Collateral Standards”
1.4	Particular Standards	1.3	“Particular Standards”
2	Normative references	Appendix L	“Publications mentioned in this standard”
3	Terminology and definitions	2	“Terminology and definitions”
3.1	ACCESS COVER	2.1.1	“Access cover”
3.2	ACCESSIBLE PART	2.1.22	“Accessible part”
3.3	ACCESSORY	2.1.3	“Accessory”
3.4	ACCOMPANYING DOCUMENT	2.1.4	“Accompanying documents”
3.5	AIR CLEARANCE	2.3.1	“Air clearance”
3.6	APPLIANCE COUPLER	2.7.1	“Appliance coupler”
3.7	APPLIANCE INLET	2.7.2	“Appliance inlet”
3.8	APPLIED PART	2.1.5	“Applied part”
3.9	BASIC INSULATION	2.3.2	“Basic insulation”
3.10	BASIC SAFETY	60601-1-4, 2.201.10	"Safety"
		2.12.18	"Safety hazard"
3.11	CATEGORY AP	2.2.2	“Category AP equipment”
3.12	CATEGORY APG	2.2.3	“Category APG equipment”
3.13	CLASS I	2.2.4	“Class I equipment”
3.14	CLASS II	2.2.5	“Class II equipment”
3.14	CLASS II, Note 2	14.2 c)	“c) Class II equipment may….”
3.15	CLEARLY LEGIBLE		New
3.16	COLD CONDITION	2.10.1	“Cold condition”
3.17	COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS		New
3.18	CONTINUOUS OPERATION	2.10.2	“Continuous operation”
3.19	CREEPAGE DISTANCE	2.3.3	“Creepage distance”

Table 6 *(2 of 36)*

IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
3.20	DEFIBRILLATION-PROOF APPLIED PART	2.1.27	"Defibrillation-proof applied part"
3.21	DETACHABLE POWER SUPPLY CORD	2.7.6	"Detachable power supply cord"
3.22	DIRECT CARDIAC APPLICATION	2.2.7	"Direct cardiac application"
3.23	DOUBLE INSULATION	2.3.4	"Double insulation"
3.24	DUTY CYCLE	2.10.5	"Duty cycle"
3.25	EARTH LEAKAGE CURRENT	2.5.1	"Earth leakage current"
3.26	ENCLOSURE	2.1.6	"Enclosure"
3.27	ESSENTIAL PERFORMANCE		New
3.28	EXPECTED SERVICE LIFE		New
3.29	F-TYPE ISOLATED (floating) APPLIED PART	2.1.7	"F-type isolated (floating) applied part"
3.30	FIXED	2.2.12	"Fixed equipment"
3.31	FLAMMABLE ANAESTHETIC MIXTURE WITH AIR	2.12.15	"Flammable anaesthetic mixture with air"
3.32	FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE	2.12.16	"Flammable anaesthetic mixture with oxygen or nitrous oxide"
3.33	FUNCTIONAL CONNECTION	60601-1-1, 2.205	"Functional connection"
3.34	FUNCTIONAL EARTH CONDUCTOR	2.6.3	"Functional earth conductor"
3.35	FUNCTIONAL EARTH TERMINAL	2.6.4	"Functional earth terminal"
3.36	GUARD		New
3.37	HAND-HELD	2.2.13	"Hand-held equipment"
3.38	HARM	ISO 14971:2007	"Harm"
3.39	HAZARD	ISO 14971:2007 2.12.18	"Hazard" "Safety hazard"
3.40	HAZARDOUS SITUATION	ISO/IEC Guide 51	"hazardous situation"
3.41	HIGH VOLTAGE	2.4.1	"High voltage"
3.42	HYDRAULIC TEST PRESSURE	2.11.1	"Hydraulic test pressure"
3.43	INSULATION CO-ORDINATION		New
3.44	INTENDED USE	ISO 14971:2007	"Intended use/intended purpose"
3.45	INTERNAL ELECTRICAL POWER SOURCE	2.1.9	"Internal electrical power source
3.46	INTERNALLY POWERED	2.2.29	"Internally powered equipment"
3.47	LEAKAGE CURRENT	2.5.3	"Leakage current"
3.48	MAINS CONNECTOR	2.7.10	"Mains connector"
3.49	MAINS PART	2.1.12	"Mains part"
3.50	MAINS PLUG	2.7.11	"Mains plug"
3.51	MAINS SUPPLY TRANSFORMER		New
3.52	MAINS TERMINAL DEVICE	2.7.12	"Mains terminal device"
3.53	MAINS TRANSIENT VOLTAGE		New

Table 6 *(3 of 36)*

IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
3.54	MAINS VOLTAGE	2.4.2	"Mains voltage"
3.55	MANUFACTURER	ISO 14971:2007 (adapted) "Manufacturer"	
3.56	MAXIMUM MAINS VOLTAGE		New
3.57	MAXIMUM PERMISSIBLE WORKING PRESSURE	2.11.2	"Maximum permissible working pressure"
3.58	MEANS OF OPERATOR PROTECTION (MOUP)		New
3.59	MEANS OF PATIENT PROTECTION (MOPP)		New
3.60	MEANS OF PROTECTION (MOP)		New
3.61	MECHANICAL HAZARD		New
3.62	MECHANICAL PROTECTIVE DEVICE	2.11.6	"Safety device"
3.63	MEDICAL ELECTRICAL EQUIPMENT (ME EQUIPMENT)	2.2.15	"Medical electrical equipment"
		59.1 f)	"f) Applicable requirements"
3.64	MEDICAL ELECTRICAL SYSTEM (ME SYSTEM)	60601-1-1, 2.201 "Medical electrical system"	
3.65	MOBILE	2.2.16	"Mobile equipment"
3.66	MODEL OR TYPE REFERENCE (type number)	2.12.2	"Model or type reference (type number)"
3.67	MULTIPLE SOCKET-OUTLET	60601-1-1, 2.204 "Multiple portable socket-outlet"	
		2.7.4	"Auxiliary mains socket-outlet"
3.68	NETWORK/DATA COUPLING		New
3.69	NOMINAL (value)	2.12.3	"Nominal (value)"
3.70	NORMAL CONDITION	2.10.7	"Normal condition"
3.71	NORMAL USE	2.10.8	"Normal use"
3.72	OBJECTIVE EVIDENCE	ISO 14971:2007 "Objective evidence"	
3.73	OPERATOR	2.12.17	"Operator"
3.74	OVER-CURRENT RELEASE	2.9.7	"Over-current release"
3.75	OXYGEN RICH ENVIRONMENT		New
3.76	PATIENT	2.12.4	"Patient"
3.77	PATIENT AUXILIARY CURRENT	2.5.4	"Patient auxiliary current"
3.78	PATIENT CONNECTION	2.1.23	"Patient connection"
3.79	PATIENT ENVIRONMENT	60601-1-1, 2.202 "Patient environment"	
3.80	PATIENT LEAKAGE CURRENT	2.5.6	"Patient leakage current"
3.81	PEAK WORKING VOLTAGE	60950-1:2005 "Peak working voltage"	
3.82	PEMS DEVELOPMENT LIFE-CYCLE	60601-1-4, 2.201.5 "Development life-cycle"	
3.83	PEMS VALIDATION	60601-1-4, 2.201.14 "PEMS validation"	
3.84	PERMANENTLY INSTALLED	2.2.17	"Permanently installed equipment"
3.85	PORTABLE	2.2.18	"Portable equipment"
3.86	POTENTIAL EQUALIZATION CONDUCTOR	2.6.6	"Potential equalization conductor"

Table 6 *(4 of 36)*

IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
3.87	POWER SUPPLY CORD	2.7.17	"Power supply cord"
3.88	PROCEDURE	ISO 14971:2007	"Procedure"
3.89	PROCESS	ISO 14971:2007	"Process"
3.90	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM (PEMS)	60601-1-4, 2.201.4	"Programmable electrical medical system (PEMS)"
3.91	PROGRAMMABLE ELECTRONIC SUBSYSTEM (PESS)	60601-1-4, 2.201.5	"Programmable electronic subsystem (PESS)"
3.92	PROPERLY INSTALLED	2.10.9	"Properly installed"
3.93	PROTECTIVE EARTH CONDUCTOR	2.6.7	"Protective earth conductor"
3.94	PROTECTVE EARTH CONNECTION		New
3.95	PROTECTIVE EARTH TERMINAL	2.6.8	"Protective earth terminal"
3.96	PROTECTIVELY EARTHED	2.6.9	"Protectively earthed"
3.97	RATED (value)	2.12.8	"Rated (value)"
3.98	RECORD	ISO 14971:2007	"Record"
3.99	REINFORCED INSULATION	2.3.7	"Reinforced insulation"
3.100	RESIDUAL RISK	ISO 14971: 2007	"Residual risk"
3.101	RESPONSIBLE ORGANIZATION	2.12.13	"User"
3.102	RISK	ISO 14971:2007	"Risk"
3.103	RISK ANALYSIS	ISO 14971:2007	"Risk analysis"
3.104	RISK ASSESSMENT	ISO 14971:2007	"Risk assessment"
3.105	RISK CONTROL	ISO 14971:2007	"Risk control"
3.106	RISK EVALUATION	ISO 14971:2007	"Risk evaluation"
3.107	RISK MANAGEMENT	ISO 14971:2007	"Risk management"
3.108	RISK MANAGEMENT FILE	ISO 14971:2007	"Risk management file"
3.109	SAFE WORKING LOAD	2.11.5	"Safe working load (Mechanical)"
3.110	SECONDARY CIRCUIT		New
3.111	SELF-RESETTING THERMAL CUT-OUT	2.9.10	"Self-resetting thermal cut-out"
3.112	SEPARATION DEVICE	60601-1-1, 2.203, "Separation device"	
3.113	SERVICE PERSONNEL		New
3.114	SEVERITY	ISO 14971:2007	"Severity"
3.115	SIGNAL INPUT/OUTPUT PART	2.1.18	"Signal input part"
		2.1.19	"Signal output part"
3.116	SINGLE FAULT CONDITION	2.10.11	"Single fault condition"
3.117	SINGLE FAULT SAFE		New
3.118	STATIONARY	2.2.21	"Stationary equipment"
3.119	SUPPLEMENTARY INSULATION	2.3.8	"Supplementary insulation"

Table 6 *(5 of 36)*

IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
3.120	SUPPLY MAINS	2.12.10	"Supply mains"
3.121	TENSILE SAFETY FACTOR	2.11.8	"Safety factor"
3.122	TENSILE STRENGTH		New
3.123	TERMINAL DEVICE	2.7.16	"Terminal device"
3.124	THERMAL CUT-OUT	2.9.12	"Thermal cut-out"
3.125	THERMAL STABILITY		New
3.126	THERMOSTAT	2.9.13	"Thermostat"
3.127	TOOL	2.12.12	"Tool"
3.128	TOTAL LOAD	2.11.9	"Total load"
3.129	TOUCH CURRENT	2.5.2	"Enclosure leakage current"
3.130	TRANSPORTABLE	2.2.23	"Transportable equipment"
3.131	TRAPPING ZONE		New
3.132	TYPE B APPLIED PART	2.1.24	"Type B applied part"
3.133	TYPE BF APPLIED PART	2.1.25	"Type BF applied part"
3.134	TYPE CF APPLIED PART	2.1.26	"Type CF applied part"
3.135	TYPE TEST		New
3.136	USABILITY	IEC 62366:2007	"Usability"
3.127	USABILITY ENGINEERING	IEC 62366:2007	"Usability engineering"
3.138	VERIFICATION	ISO 14971:2007	"Verification"
3.139	WORKING VOLTAGE	IEC 60950-1:2005	"Working voltage"
3.140	AIR KERMA	IEC 60601-1-3:2008	"Air kerma"
3.141	ALARM CONDITION	IEC 60601-1-8 +A1, 3.1	"Alarm condition"
3.142	ALARM SIGNAL	IEC 60601-1-8, 3.9	"Alarm signal"
3.143	ALARM SYSTEM	IEC 60601-1-8, 3.11	"Alarm system"
3.144	BODY WORN	IEC 60601-1-11, 3.1	"Body worn"
3.145	IT-NETWORK (INFORMATION TECHNOLOGY NETWORK)	IEC 80001-1:2012, 2.12	"IT-network"
3.146	PRIMARY OPERATING FUNCTION	IEC 62366:2007	"Primary operating function"
3.147	USABILITY ENGINEERING FILE	IEC 62366:2007	"Usability engineering file"
4	General requirements	3	"General requirements"
4.1	Conditions for application to ME EQUIPMENT or ME SYSTEMS	3.1	"EQUIPMENT shall…."
4.2	RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS	IEC 60601-1-4, 52.204.1 "A risk management process shall…."	

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
4.2.1	Introduction to RISK MANAGEMENT		New
4.2.2	General requirement for RISK MANAGEMENT		New
4.2.3	Evaluating RISK		New
4.2.3.1	HAZARDS identified in the IEC 60601-series		New
4.2.3.1 a)			New
4.2.3.1 b)			New
4.2.3.1 c)			New
4.2.3.2	HAZARDS not identified in the IEC 60601-series		New
4.3	ESSENTIAL PERFORMANCE		New
4.4	EXPECTED SERVICE LIFE		New
4.5	Alternative RISK CONTROL measures or test methods	3.4	“Equipment or parts thereof….”
		54	“General”
4.6	ME EQUIPMENT or ME SYSTEMS parts that contact the PATIENT		New
4.7	SINGLE FAULT CONDITION for ME EQUIPMENT	3.6	“The following….”
		52.1	“Equipment shall be so designed….”
		4.6 d)	“During any test….”
		3.6 e)	“Leakage of the….”
		52.5.9	“Failure of components”
		3.6 g)	“g) failure of an electrical component….”
		3.7 a)	“a) total electrical breakdown….”
		3.7 b)	“b) electrical breakdown of a….”
4.7 a)			New
4.7 b)			New
4.8	Components of ME EQUIPMENT	4.4	“Components”
		56.1 b)	“b) Marking of components”
4.8 a)			New
4.8 b)			New
4.9	Use of HIGH-INTEGRITY COMPONENTS in ME EQUIPMENT	3.7	‘The following phenomena are….”
4.10	Power supply	10.2.2	Power supply
4.10.1	Source of power for ME EQUIPMENT		New
4.10.2	SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS	10.2.2 a)	“a) Equipment shall be suitable….”

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
4.11	Power input	7	"Power input"
		7.1	"The steady state current or power input...."
		7.1 b)	"b) for other equipment:"
4.11,	Indent 1	7.1, Indent 1 (a))	"– Equipment shall be operated...."
4.11,	Indent 2	7.1, Indent 2 (b))	"– For equipment marked...."
4.11,	Indent 3	7.1, Indent 3 (c))	"– The steady state current shall be measured...."
5	General requirements for testing ME EQUIPMENT	4	"General requirements for tests"
5.1	TYPE TESTS	4.1	"Tests"
5.2	Number of samples	4.3	"Number of samples"
5.3	Ambient temperature, humidity, atmospheric pressure	4.5	"Ambient temperature, ..."
5.3 a)		4.5 a)	"a) After the...."
5.3 b)		4.5 b)	"b) Equipment shall...."
5.3 c)		4.5 c)	"c) In cases where"
5.4	Other conditions	4.6	"Other conditions"
5.4 a)		4.6 a)	"a) Unless otherwise...."
5.4 b)		4.6 b)	"b) Equipment having...."
5.4 c)		4.6 c)	"c) If the test results...."
5.4 d)		4.6 e)	"e) Where cooling water...."
5.5	Supply voltages, type of current, nature of supply, frequency	4.7	"Supply and test voltages, type of current...."
5.5 a)		4.7 a)	"a) Where test results...."
5.5 b)		4.7 b)	"b) Equipment for a.c. ...."
5.5 c)		4.7 c)	"c) Equipment designed...."
5.5 d)		4.7 d)	"d) Equipment for d.c. ...."
5.5 d)		4.7 e)	"e) Unless otherwise...."
5.5 e)		4.7 f)	"f) Equipment for which...."
5.5 f)		4.7 g)	"g) Equipment intended...."
5.6	Repairs and modifications	4.9	"Repairs and modifications"
5.7	Humidity preconditioning treatment	4.10	"Humidity preconditioning treatment"
5.8	Sequence of tests	4.11	"Sequence"
5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS	16	"Enclosures and protective covers"
5.9.1	APPLIED PARTS		New
5.9.2	ACCESSIBLE PARTS		New

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
5.9.2.1	Test finger	16 a)	"a) Equipment shall be so constructed...."
		16 a)	"Compliance with the requirements of Subclause 16 a)...."
5.9.2.2	Test hook	16 a)	"Compliance with the requirements of Subclause 16 a)...."
5.9.2.3	Actuating mechanisms	16 c)	"c) Conductive parts of actuating mechanisms...."
		56.10 a)	"a) Protection against electric shock"
6	Classification of ME EQUIPMENT and ME SYSTEMS	5	"Classification"
6.1	General		New
6.2	Protection against electric shock	5.1	"According to the type...."
		5.1 a)	"a) Equipment energized...."
		5.1 b)	"b) Internally powered...."
		5.2	"According to the degree of protection against electric shock...."
		14.5 b)	"b) Internally powered equipment intended...."
6.3	Protection against harmful ingress of water or particulate matter	5.3	"According to the degree of protection against harmful...."
6.4	Method(s) of sterilization	5.4	"According to the method(s)...."
6.5	Suitability for use in an OXYGEN RICH ENVIRONMENT		New
6.6	Mode of operation	5.6	"According to the mode...."
7	ME EQUIPMENT identification, marking and documents	6	"Identification, marking and documents"
7.1	General		New
7.1.1	USABILITY of the identification, markings and documents		New
7.1.2	Legibility of markings	6	Indent 2 "– Clearly legible:"
		6.2 a)	"a) Marking on the inside...."
7.1.3	Durability of markings	6	Indent 1 "– Permanently affixed:
		6.2 a)	"a) Marking on the inside...."
		6.1 Compliance	"When evaluating durability...."
7.1.3 a)		6.1 Compliance	"Markings shall be clearly legible...."
7.1.3 b)		6.1 Compliance	"For determination of durability...."
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts	6.1	"Marking on the outside of equipment or equipment parts"
7.2.1	Minimum requirements for marking on ME EQUIPMENT and on interchangeable parts	6.1 a)	"a) Mains operated equipment"
		6.1 d)	"d) Minimum requirements...."
7.2.2	Identification	6.1 e)	"e) Indication of origin"
		6.1 f)	"f) Model or type reference"

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
7.2.3	Consult ACCOMPANYING DOCUMENTS		New
7.2.4	ACCESSORIES		New
7.2.5	ME EQUIPMENT intended to receive power from other equipment	6.1 c)	"c) Equipment supplied from…."
7.2.6	Connection to the SUPPLY MAINS	6.1 g)	"g) Connection to the supply"
		6.1 h)	"h) Supply frequency"
		6.1 l)	Indent 1 "– The symbol…."
		6	Indent 3 "– Major part:"
7.2.7	Electrical input power from the SUPPLY MAINS	6.1 j)	"Power input"
7.2.8	Output connectors		New
7.2.8.1	Mains power output	6.1 k)	"k) Mains power output"
7.2.8.2	Other power sources	6.1 p)	"p) Output"
7.2.9	IP classification	6.1 l)	Indent 2 "– A symbol, using…."
7.2.10	APPLIED PARTS	6.1 l)	Indent 3 "– A symbol indicating…."
7.2.11	Mode of operation	6.1 m)	"m) Mode of operation"
7.2.12	Fuses	6.1 n)	"n) Fuses"
7.2.13	Physiological effects (safety signs and warning statements)	6.1 q)	"q) Physiological effects…."
7.2.14	HIGH VOLTAGE TERMINAL DEVICES	6.1 s)	"s) HIGH VOLTAGE TERMINAL DEVICES"
7.2.15	Cooling conditions	6.1 t)	"t) Cooling conditions"
7.2.16	Mechanical stability	6.1 u)	"u) Mechanical stability"
7.2.17	Protective packaging	6.1 v)	"v) Protective packaging"
7.2.18	External pressure source		New
7.2.19	FUNCTIONAL EARTH TERMINALS	6.1 y)	"y) Earth terminals"
7.2.20	Removable protective means	6.1 z)	"z) Removable protective means"
7.2.21	Mass of MOBILE ME EQUIPMENT		New
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts	6.2	"Marking on the inside of EQUIPMENT or EQUIPMENT parts"
7.3.1	Heating elements or lampholders	6.2 b)	"b) The maximum power…."
7.3.2	HIGH VOLTAGE parts	6.2 c)	"c) The presence of…."
7.3.3	Batteries	6.2 d)	"d) The type of battery…."
7.3.4	Fuses, THERMAL CUT-OUTS and OVER-CURRENT RELEASES	6.2 e)	"e) Fuses accessible only…."
7.3.5	PROTECTIVE EARTH TERMINALS	6.2 f)	"f) Protective earth terminals…."
7.3.6	FUNCTIONAL EARTH TERMINALS	6.2 g)	"g) Functional earth terminals…."
7.3.7	Supply terminals	6.2 h)	"h) Terminals which are…."
		6.2 k)	"k) The correct method…."
		6.2 j)	"j) Markings required in…."

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
7.3.8	Temperature of supply terminals	6.2 l)	"l) If any point…."
7.4	Marking of controls and instruments	6.3	Marking of controls and instruments
7.4.1	Power switches	6.3 a)	"a) A mains switch…."
7.4.2	Control devices	6.3 b)	"b) Different positions of…."
		6.3 c)	"c) If in NORMAL USE…."
7.4.3	Units of measure	6.3 g)	"g) Numeric indications of…."
7.5	Safety signs		New
7.6	Symbols	6.4	"Symbols"
7.6.1	Explanation of symbols		New
7.6.2	Symbols from Annex D	6.4 a)	"a) Symbols used for marking…."
7.6.3	Symbols for controls and performance	6.4 b)	"b) Symbols used for controls…."
7.7	Colours of the insulation of conductors	6.5	Colours of the insulation of conductors
7.7.1	PROTECTIVE EARTH CONDUCTOR	6.5 a)	"a) A protective earth conductor…."
7.7.2	PROTECTIVE EARTH CONNECTIONS	6.5 b)	"b) Any insulation on…."
		6.5 f)	"f) Where a multi-conductor…."
7.7.3	Green and yellow insulation	6.5 c)	"c) Identification by green…."
7.7.4	Neutral conductor	6.5 d)	"d) Conductors in POWER…."
7.7.5	POWER SUPPLY CORD conductors	6.5 e)	"e) Colours of conductors…."
7.8	Indicator lights and controls	6.7	Indicator lights and push-buttons
7.8.1	Colours of indicator lights	6.7 a)	"a) Colours of indicator…."
7.8.2	Colours of controls	6.7 b)	"b) Colours of unilluminated…."
7.9	ACCOMPANYING DOCUMENTS	6.8	"ACCOMPANYING DOCUMENTS"
7.9.1	General	6.8.1	General
7.9.2	Instructions for use	6.8.2	"Instructions for use"
7.9.2.1	General	6.8.2 a)	Indent 1"– Instructions for use shall contain…."
7.9.2.2	Warning and safety notices		New
7.9.2.3	ME EQUIPMENT specified for connection to a separate power supply		New
7.9.2.4	Electrical power source	6.8.2 e)	"e) Mains operated EQUIPMENT…."
		6.8.2 f)	"f) Removal of primary batteries"
		10.2.2 b)	"b) An internal electrical…."
7.9.2.5	ME EQUIPMENT description	6.8.2 c)	"c) SIGNAL OUTPUT and SIGNAL INPUT PARTS"
7.9.2.6	Installation		New
7.9.2.7	Isolation from the SUPPLY MAINS		New
7.9.2.8	Start-up PROCEDURE		New

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
7.9.2.9	Operating instructions	6.8.2 a)	Indent 1"– Instructions for use shall contain…."
		6.8.2 a)	Indent 4"– The meaning of figures, symbols…."
7.9.2.10	Messages		New
7.9.2.11	Shutdown PROCEDURE		New
7.9.2.12	Cleaning, disinfection and sterilization	6.8.2 d)	"d) Cleaning, disinfection and…."
7.9.2.13	Maintenance	6.8.2 a)	Indent 3 "– Instructions for use shall instruct…."
		6.8.2 g)	"g) Rechargeable batteries"
7.9.2.14	ACCESSORIES, supplementary equipment, used material	6.8.2 a)	Indent 2"– Instructions for use shall include…."
		6.8.2 h)	"h) EQUIPMENT with a…."
7.9.2.15	Environmental protection	6.8.2 j)	"Environmental protection"
7.9.2.16	Reference to the technical description		New
7.9.2.17	ME EQUIPMENT emitting radiation		New
7.9.2.18	ME EQUIPMENT and ACCESSORIES supplied sterile		New
7.9.2.19	Unique version identifier		New
7.9.3	Technical description	6.8.3	"Technical description"
7.9.3.1	General	6.8.3 a)	"a) General"
		6.8.3 d)	"d) Restricted environmental conditions…."
7.9.3.1,	Indent 2	10.1	"Transport and storage"
		10.2	"Environment"
7.9.3.2	Replacement of fuses, POWER SUPPLY CORDS and other parts	6.8.3 b)	"b) Replacement of fuses…."
7.9.3.3	Circuit diagrams, component part lists, etc.	6.8.3 c)	"c) Circuit diagrams, components…."
7.9.3.4	Mains isolation		New
8	Protection against electrical HAZARDS from ME EQUIPMENT	Section 3	
8.1	Fundamental rule of protection against electric shock	13	General
8.1 a)			New
8.1 a)	Indent 1 "– the presence on any SIGNAL INPUT/OUTPUT PART of any voltage…."	3.6 d)	"d) appearance of an external voltage on signal…."
		19.2 b)	"b) Additionally the patient leakage current…."
		19.2 c)	"c) Additionally the enclosure leakage current…."
8.1 b)			New

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
8.1 b)	Indent 4 "– open-circuit of any one PROTECTIVE EARTH CONDUCTOR…."	3.6 a)	"a) Interruption of a PROTECTIVE EARTH CONDUCTOR"
		3.7 c)	"c) interruption of a fixed and…."
		52.5.4	"Interruption of the protective…."
8.1 b)	Indent 5 "–) Interruption of any one supply conductor…."	3.6 b)	"b) Interruption of one supply conductor"
8.2	Requirements related to power sources	14	"Requirements related to classification"
8.2.1	Connection to a separate power source	19.1 c)	"c) Equipment specified for connection to a SELV source…."
8.2.2	Connection to an external d.c. power source	14.4 b)	"b) In EQUIPMENT specified…."
8.3	Classification of APPLIED PARTS	14.6	Types B, BF and CF equipment
8.3 a)		14.6 c)	"c) Equipment or equipment parts…."
8.3 b)			New
8.3 c)			New
8.3 d)			Deleted
8.4	Limitation of voltage, current or energy	15	"Limitation of voltage and/or energy"
8.4.1	PATIENT CONNECTIONS intended to deliver current	16 a) 1)	"1) It does not apply…."
8.4.2	ACCESSIBLE PARTS and APPLIED PARTS		New
8.4.2 a)			New
8.4.2 b)			New
8.4.2 c)		16 a) 5)	"5) Where the occurrence of…."
		16 e) 1)	"1) Enclosures or equipment parts…."
		16 e) 2)	"2) Lampholders allowing access to…."
8.4.2 d)		16 b)	"b) Any opening in…."
		16 f)	"f) Openings for the adjustment…."
8.4.2 e)		16 e)	"e) Enclosures protecting against contact…."
8.4.3	ME EQUIPMENT intended to be connected to a power source by a plug	15 b)	"b) Equipment intended to…."
8.4.4	Internal capacitive circuits	15 c)	"c) Live parts of capacitors…."
		6.2 n)	"n) Capacitors and/or…."
8.5	Separation of parts	17	Separation
8.5.1	MEANS OF PROTECTION (MOP)		New
8.5.1.1	General	16 a) 2)	"2) Varnishing, enamelling, …."
8.5.1.2	MEANS OF PATIENT PROTECTION (MOPP)		New
8.5.1.2	"A Y capacitor (Y1 or Y2 only) complying with IEC 60348-14…."	56.4	Indent 2 "– Capacitors connected directly…."

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)		New
8.5.1.3	"A Y capacitor (Y1 or Y2) complying with IEC 60348-14…."	56.4	Indent 2 "– Capacitors connected directly…."
8.5.2	Separation of PATIENT CONNECTIONS		New
8.5.2.1	F-TYPE APPLIED PARTS	19.2 b)	Indent 2 "– A voltage equal to 110% of the highest rated mains voltage applied between any F-TYPE APPLIED PART…."
		20.2 B-d	Between an F-TYPE APPLIED PART…."
		59.3	Indent 4"– Protective devices connected…."
8.5.2.2	TYPE B APPLIED PARTS	17 c)	"c) An applied part shall have no…."
8.5.2.3	PATIENT leads or PATIENT cables	56.3 c)	"c) There are two…."
8.5.3	MAXIMUM MAINS VOLTAGE		New
8.5.4	WORKING VOLTAGE	20.3	"Values of test voltages (part)
		20.4 l)	"l) In the case of motors…."
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS	17 h)	"h) Arrangements used to…."
8.5.5.1	Defibrillation protection		
8.5.5.1 a)		17 h),	Indent 1"– during a discharge of…."
8.5.5.1 b)		17 h),	Indent 2"– after exposure to the…."
8.5.5.2	Energy reduction test		New
8.5.5.2 a)			New
8.5.5.2 b)			New
8.5.5.2 c)			New
8.5.5.2 d)			New
8.5.5.2 e)			New
8.6	Protective earthing, functional earthing and potential equalization of ME EQUIPMENT	18	"Protective earthing, functional earthing and potential equalization"
		58	"Protective earthing – Terminals and connections"
8.6.1	Applicability of requirements		New
8.6.2	PROTECTIVE EARTH TERMINAL	18 b)	"b) The protective earth terminal…."
		58.1	"The clamping means…"
		58.7	"Where an appliance…."
		58.8	"The protective earth…."
8.6.3	Protective earthing of moving parts	17 d)	"d) Hand-held flexible shafts…"
8.6.4	Impedance and current-carrying capability		New
8.6.4 a)		18 f)	"f) For equipment without…."
8.6.4 b)		18 g)	"g) The impedance of…."
8.6.5	Surface coatings		New

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
8.6.6	Plugs and sockets	58.9	"Protective earth connection"
8.6.7	POTENTIAL EQUALIZATION CONDUCTOR	18 e)	"e) If equipment is provided with…."
8.6.8	FUNCTIONAL EARTH TERMINAL	18 k)	"k) Functional earth terminals…."
8.6.9	CLASS II ME EQUIPMENT	18 l)	"l) If Class II equipment…."
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	19	"Continuous leakage currents and patient auxiliary currents"
8.7.1	General requirements	19.1	"General requirements"
8.7.1 a)		19.1 a)	"a) The electrical insulation providing…."
8.7.1 b)		19.1 b)	"b) The specified values of…."
		19.4 a) 2)	"2) Equipment is connected…."
8.7.2	SINGLE FAULT CONDITIONS	19.2	"Single fault conditions"
8.7.3	Allowable values	19.3	"Allowable values"
8.7.3 a)		19.3 a)	"a) The allowable values of the continuous…."
		19.3 b)	"b) The allowable values stated…." (first paragraph)
8.7.3 b)		19.3 a)	"a) The allowable values of the continuous…."
8.7.3 c)			New
8.7.3 d)			New
8.7.3 e)		19.3 b)	"Additionally, regardless of waveform…." (second paragraph)
8.7.3 f)			New
8.7.4	Measurements	19.4	"Tests"
8.7.4.1	General	19.4 a)	"a) General"
8.7.4.1 a)		19.4 a) 1)	"1) The earth leakage current…."
8.7.4.1 b)		19.4 a) 4)	"4) Where examination of…."
8.7.4.2	Measuring supply circuits	19.4 b)	"b) Measuring supply circuits"
8.7.4.3	Connection to the measuring supply circuit	19.4 c)	"c) Connection of the equipment…."
8.7.4.3 a)		19.4 c) 1)	"1) Equipment provided with a…."
8.7.4.3 b)		19.4 c) 2)	"2) Equipment provided with an…."
8.7.4.3 c)		19.4 c) 3)	"3) Equipment specified to…."
8.7.4.3 d)		19.4 d)	"Measuring arrangement"
8.7.4.3 d) 1)		19.4 d) 2)	"2) However, external parts…."
8.7.4.3 d) 1)		19.4 d) 1)	"1) It is recommended…"
8.7.4.3 d) 2)			New

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
8.7.4.4	Measuring device (MD)	19.4 e)	"e) Measuring device"
8.7.4.4 a)		19.4 e) 1)	"1) The measuring device shall load...."
8.7.4.4 b)		19.4 e) 2)	"2) The evaluation of current or...."
8.7.4.4 c)		19.4 e) 4)	"4) The measuring instrument...."
8.7.4.5	Measurement of the EARTH LEAKAGE CURRENT and current in functional earth connection	19.4 f)	"f) Measurement of the earth leakage current"
8.7.4.5 a)		19.4 f) 1)	"1) Class I equipment...."
8.7.4.5 b)			New
8.7.4.5 c)			New
8.7.4.6	Measurement of the TOUCH CURRENT	19.4 g)	"g) Measurement of the enclosure leakage current"
8.7.4.6 a)		19.4 g) 1)	"1) Class I equipment...."
		19.4 g) 2)	"2) Class II equipment...."
		19.4 g) 3)	"3) Equipment specified for connection...."
		19.4 g) 4)	"4) Equipment, with or without an applied part...."
8.7.4.6 b)		19.4 g) 5)	"5) If equipment has an enclosure...."
8.7.4.6 c)			New
8.7.4.7	Measurement of the PATIENT LEAKAGE CURRENT	19.4 h)	"h) Measurement of the patient...."
8.7.4.7 a)		19.4 h).1)	"1) Class I equipment with an applied part...."
		19.4 h) 4)	"4) Class II Equipment...." (first paragraph)
		19.4 h) 4)	In the case of Class II....", (third paragraph)
		19.4 h) 5)	"5) Equipment with an applied part...."
		19.4 h) 6)	"6) Internally powered equipment is tested...."
8.7.4.7 b)		19.4 h) 2)	"2) Class I equipment with an F-type...."
		9.4 h) 4)	The patient leakage current...." (Second paragraph)
		19.4 h) 7)	"7) Internally powered equipment provided with an F-TYPE...."
8.7.4.7 c)		19.4 h) 3)	"3) Class I equipment with an applied part and a signal input...."
		19.4 h) 4)	"4) Class II Equipment...." (first paragraph)
		9.4 h) 8)	"8) Internally powered equipment provided with an applied part...."
8.7.4.7 d)		3.6 c)	"c) appearance of an external voltage on an F-TYPE...."
8.7.4.7 e)		19.4 h) 9)	"9) An applied part consisting of...."

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
8.7.4.7 f)			New
8.7.4.7 g)		19.1 e)	“e) The patient leakage current....
8.7.4.7 h)			New
8.7.4.7 i)		19.4 h).10)	“10) If loading of the applied part....”
8.7.4.8	Measurement of the PATIENT AUXILIARY CURRENT	19.4 j)	“j) Measurement of the PATIENT....”
		19.4 j).1)	“1) Class I equipment with an applied part....”
		19.4 j) 2)	“2) Class II equipment....”
		19.4 j) 3)	3) Equipment with an applied part....”
		19.4 j) 4)	4) Internally powered equipment....”
		19.1 f)	“f) The patient auxiliary....”
8.7.4.9	ME EQUIPMENT with multiple PATIENT CONNECTIONS	19.1 g)	“g) Equipment with multiple....”
8.8	Insulation	20	“Dielectric strength”
8.8.1	General		New
8.8.2	Distance through solid insulation or use of thin sheet material		New
8.8.2 a)			New
8.8.2 b)			New
8.8.2 c)			New
8.8.2 d)			New
8.8.2 e)			New
8.8.3	Dielectric strength	20.3	“Values of test voltages”
		20.4	“Tests”
		20.4 a)	“a) The test voltage....”
8.8.3 a)		20.4 b)	“b) The test voltage shall....”
8.8.3 a)		4.7 a):	Third paragraph, “Any test voltage....”
8.8.3 b)		20.4 f)	“f) During the test....”
8.8.3 c)		20.4 h)	“h) Where metal foil....”
		20.4 k)	“k) With the exception....”
8.8.4	Insulation other than wire insulation	59.2	Insulation
8.8.4.1	Mechanical strength and resistance to heat	59.2 b)	“b) “Mechanical strength and....”
8.8.4.1 a)		59.2 b) 1)	“1) For parts of the....”
8.8.4.1 b)		59.2 b) 2)	“2) For parts of insulating....”
8.8.4.2	Resistance to environmental stress	59.2 c)	“c) Protection”
8.9	CREEPAGE DISTANCES and AIR CLEARANCES	57.10	“Creepage distances and air clearances”

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
8.9.1	Values	57.10 a)	"a) Values"
8.9.1.1	General	57.10 a)	Indent 1"– Creepage distances and air clearances…."
8.9.1.2	CREEPAGE DISTANCES and AIR CLEARANCES complying with IEC 60950-1		New
8.9.1.3	CREEPAGE DISTANCES across glass, mica, ceramic and similar materials		New
8.9.1.4	Minimum CREEPAGE DISTANCE		New
8.9.1.5	ME EQUIPMENT RATED for high altitudes		New
8.9.1.6	Interpolation	57.10 a)	Indent 2"– The value of the reference voltage…."
		57.10 a)	Indent 3"– For slot insulation…."
8.9.1.7	Material groups classification		New
8.9.1.8	Pollution degree classification		New
8.9.1.9	Overvoltage category classification		New
8.9.1.10	AIR CLEARANCE for MAINS PARTS		New
8.9.1.11	SUPPLY MAINS overvoltage		New
8.9.1.12	SECONDARY CIRCUITS		New
8.9.1.13	PEAK WORKING VOLTAGES above 1 400 V peak or d.c.		New
8.9.1.14	Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION		New
8.9.1.15	CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS	57.10 a)	Indent 4"– Between defibrillation-proof applied parts…."
8.9.2	Application	57.10 b)	"b) Application"
8.9.2 a)		57.10 b)	Indent 1"– For insulation in the…."
8.9.2 b)		57.10 b)	Indent 2"– The contribution to the…."
8.9.2 c)		57.10 b)	Indent 4"– Air clearance alone is…."
8.9.3	Spaces filled by insulating compound		New
8.9.3.1	General		New
8.9.3.2	Insulating compound forming solid insulation between conductive parts		New
8.9.3.3	Insulating compound forming a cemented joint with other insulating parts		New
8.9.3.4	Thermal cycling		New
8.9.4	Measurement of CREEPAGE DISTANCES and AIR CLEARANCES	57.10 d)	"d) Measurement of creepage…."
8.10	Components and wiring	56, Some parts "Components and general assembly"	
8.10.1	Fixing of components	56.1 d)	"d) Component fixing"

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
8.10.2	Fixing of wiring	56.1 f)	"f) Fixing of wiring"
		57.3 d)	"d) Preparation of conductors"
		59.1	Internal wiring
8.10.3	Connections between different parts of ME EQUIPMENT	56.3 b)	"b) Connection between different…."
8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices	56.11, Some parts	"Cord-connected hand-held…."
8.10.4.1	Limitation of operating voltages	56.11 a)	"a) Limitation of operating voltages"
8.10.4.2	Connection cords	56.11 e)	"e) Connection cords"
8.10.5	Mechanical protection of wiring	59.1 a)	"a) Mechanical protection"
8.10.5 a)		59.1 a)	Indent 1"– Cables and wiring shall…."
8.10.5 b)		59.1 a)	Indent 3"– EQUIPMENT shall be so designed…."
8.10.6	Guiding rollers for insulated conductors	59.1 b)	"b) Bending"
8.10.7	Insulation of internal wiring	59.1 c)	"c) Insulation"
8.10.7 a)		59.1 c)	Indent 1 "– If insulating sleeving…."
8.10.7 b)		59.1 c)	Indent 2 "– Inside equipment the sheath of a…."
8.10.7 c)		59.1 c)	Indent 3 "– Insulating conductors which in…."
8.11	MAINS PARTS, components and layout	57	"Mains parts, components and layout"
8.11.1	Isolation from the SUPPLY MAINS	57.1	"Isolation from the supply mains"
		57.1 a)	Heading deleted, text retained
8.11.1 a)		57.1 a)	Indent 1"– Equipment shall have means…."
8.11.1 b)		57.1 a)	Indent 2"– Means for isolation…."
8.11.1 c)		57.1 d)	"d) Switches that are…."
8.11.1 d)		57.1 f)	"f) Mains switches shall…."
8.11.1 e)		57.1 g)	"g) The directions of…."
8.11.1 f)		57.1 h)	"h) In non-permanently installed equipment…."
8.11.1 g)		57.1 m)	"m) Fuses and semiconductor…."
8.11.1 h)		56.5	"Protective devices"
8.11.1 i)		16 d)	"d) Parts within the enclosure…."
8.11.2	MULTIPLE SOCKET-OUTLETS	56.3	"Connections – General"
		57.2	"Mains connectors, appliance…."
		57.2 e)	"e) Auxiliary mains socket outlets…."

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
8.11.3	POWER SUPPLY CORDS	57.3	Power supply cords"
8.11.3.1	Application	57.3 a)	"a) Application"
8.11.3.2	Types	57.3 b)	"b) Types"
8.11.3.3	Cross-sectional area of POWER SUPPLY CORD conductors	57.3 c)	"c) Cross-sectional area of…."
8.11.3.4	APPLIANCE COUPLERS		New
8.11.3.5	Cord anchorage	57.4 a)	"a) Cord anchorages"
8.11.3.5 a)		57.4 a)	Indent 1"– Equipment and mains…."
8.11.3.5 b)		57.4 a)	Indent 2"–Cord anchorages of…."
8.11.3.5 c)		57.4 a)	Indent 3"–Cord anchorages of…."
8.11.3.5 d)		57.4 a)	Indent 4"– Screws, if any, which…."
8.11.3.5 e)		57.4 a)	Indent 5"– Conductors of the…."
8.11.3.5 f)		57.4 a)	Last paragraph, "It shall not be possible…."
8.11.3.6	Cord guards	57.4 b)	"b) Cord guards"
8.11.4	MAINS TERMINAL DEVICES	56.3	"Connections – General"
		57.5	"Mains terminal devices…."
8.11.4.1	General requirements for MAINS TERMINAL DEVICES	57.5 a)	"a) General requirements for mains…."
8.11.4.2	Arrangement of MAINS TERMINAL DEVICES	57.5 b)	"b) Arrangement of MAINS…."
8.11.4.2 a)		57.5 b)	Indent 1"– For equipment with rewirable cords…."
8.11.4.2 b)		57.5 b)	Indent 2"– For details of protective…."
8.11.4.2 c)		57.5 b)	Indent 3"– For marking of mains…."
8.11.4.2 d)		57.5 b)	Indent 4"– Mains terminal devices shall…."
8.11.4.2 e)		57.5 b)	Indent 5"– Mains terminal devices shall be…."
8.11.4.3	Fixing of mains terminals	57.5 c)	"c) Fixing of mains terminals"
8.11.4.4	Connections to mains terminals	57.5 d)	"d) Connections to mains terminals"
		57.5 d)	Indent 1"– For equipment with rewirable…."
		57.5 d)	Indent 2"– For further requirements…."
8.11.4.5	Accessibility of the connection	57.4 c)	"c) Accessibility of the connection"
8.11.5	Mains fuses and OVER-CURRENT RELEASES	57.6	"Mains fuses and over-current releases"
8.11.6	Internal wiring of the MAINS PART	57.8	"Wiring of the mains part"
		57.8 b)	"Cross-section", Deleted heading
8.11.6 a)		57.8 b),	Indent 1"– Internal wiring in a…."
8.11.6 b)		57.8 b),	Indent 2"– The cross-sectional area…."

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
9	Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	Section 4	
9.1	MECHANICAL HAZARDS of ME EQUIPMENT	21	"Mechanical strength"
9.2	MECHANICAL HAZARDS associated with moving parts	22	"Moving parts"
9.2.1	General		New
9.2.2	TRAPPING ZONE	22.2	"Moving parts which do not need…."
9.2.2.1	General		New
9.2.2.2	Gaps		New
9.2.2.3	Safe distances		New
9.2.2.4	GUARDS and other RISK CONTROL measures		New
9.2.2.4.1	Access to TRAPPING ZONES		New
9.2.2.4.2	FIXED GUARDS		New
9.2.2.4.3	Movable GUARDS		New
9.2.2.4.4	Other RISK CONTROL measures		New
9.2.2.5	Continuous activation		New
9.2.2.5 a)			New
9.2.2.5 b)		22.4	"Movements of equipment…."
9.2.2.5 c)			New
9.2.2.6	Speed of movement(s)		New
9.2.3	Other MECHANICAL HAZARDS associated with moving parts		New
9.2.3.1	Unintended movement		New
9.2.3.2	Overtravel end stops		New
9.2.4	Emergency stopping devices	22.7	"– If an electrically produced…."
9.2.4 a)			New
9.2.4 a)			New
9.2.4 c)			New
9.2.4 d)			New
9.2.4 e)			New
9.2.4. f)			New
9.2.4 g)			New
9.2.4 h)			New
9.2.4 i)			New
9.2.4 j)			New
9.2.4 k)			New
9.2.5	Release of PATIENT	49.3	"Means shall be provided…."

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
9.3	MECHANICAL HAZARDS associated with surfaces, corners and edges	23	"Surfaces, corners and edges"
9.4	Instability HAZARDS	24	"Stability in normal USE"
9.4.1	General		New
9.4.2	Instability – overbalance		New
9.4.2.1	Instability in transport position	24.3	Indent 3 "– In the position specified for transport...."
		24.3 c),	First paragraph, "If a special transport position....".”
9.4.2.2	Instability excluding transport position	24.1	"Equipment shall either...."
		24.3 c),	Last paragraph "Furthermore, such equipment shall...."
		24.3	"If equipment overbalances...."
		24.3	Indent 1"– Equipment shall not overbalance...."
		24.3	Indent 2"– Equipment shall carry a warning...."
9.4.2.2 a)		24.3 a)	"a) Equipment is provided with all specified...."
9.4.2.2 b)			New
9.4.2.2 c)			New
9.4.2.2 d)			New
9.4.2.2 e)		24.3 b)	"b) If no special transport...."
9.4.2.2 f)		24.3 d)	"d) EQUIPMENT having containers...."
9.4.2.2 g)			New
9.4.2.3	Instability from horizontal and vertical forces		New
9.4.2.3 a)			New
9.4.2.3 b)			New
9.4.2.4	Castors and wheels		New
9.4.2.4.1	General		New
9.4.2.4.2	Force for propulsion		New
9.4.2.4.3	Movement over a threshold		New
9.4.3	Instability from unwanted lateral movement (including sliding)		New
9.4.3.1	Instability in transport position		New
9.4.3.1 a)			New
9.4.3.1 b)			New
9.4.3.1 c)			New

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
9.4.3.2	Instability excluding transport position		New
9.4.3.2 a)			New
9.4.3.2 b)			New
9.4.4	Grips and other handling devices	24.6	"Grips and other handling devices"
9.4.4 a)		24.6 a)	"a) EQUIPMENT or EQUIPMENT parts…."
9.4.4 b)		24.6 b)	"b) EQUIPMENT specified by the…."
9.4.4 c)		21 c)	"c) Carrying handles or grips…."
9.5	Expelled parts HAZARD	25	"Expelled parts"
9.5.1	Protective means	25.1	"Where expelled parts…."
9.5.2	Cathode ray tubes	25.2	"A graphical display…."
9.6	Acoustic energy (including infra- and ultrasound) and vibration	26	"Vibration and noise"
9.6.1	General		New
9.6.2	Acoustic energy	35	"Acoustical energy (including ultra-sonics)"
9.6.2.1	Audible acoustic energy		New
9.6.2.1 a)			New
9.6.2.1 b)			New
9.6.2.1 c)			New
9.6.2.1 d)			New
9.6.2.1 e)			New
9.6.2.2	Infrasound and ultrasound energy		New
9.6.3	Hand-transmitted vibration		New
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure	27	Pneumatic and hydraulic power
9.7.1	General	45	"Pressure vessels and …."
9.7.2	Pneumatic and hydraulic parts		New
9.7.3	Maximum pressure	45.3	"the maximum PRESSURE…."
9.7.3 a)		45.3 a)	"a) The rated maximum…."
9.7.3 b)		45.3 b)	"b) The pressure setting…."
9.7.3 c)		45.3 c)	"c) The maximum PRESSURE…."
9.7.4.	Pressure rating of ME EQUIPMENT parts		New
9.7.5	Pressure vessels	45.2	"If a pressure vessel…."
9.7.6	Pressure-control device		New
9.7.7	Pressure-relief device	45.7	Equipment shall incorporate…"
9.7.7 a)		45.7 a)	"a) It shall be connected…."
9.7.7 b)		45.7 b)	"b) It shall be so…."

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
9.7.7 c)		45.7 c)	"c) It shall not be…."
9.7.7 d)		45.7 d)	"d) It shall have its…."
9.7.7 e)		45.7 e)	"e) It shall have its…."
9.7.7 f)		45.7 f)	"f) It shall be of…."
9.7.7 g)		45.7 g)	"g) There shall be no…."
9.7.7 h)		45.7 h)	"h) The minimum number…."
9.7.8	RATED maximum supply PRESSURE		New
9.8	MECHANICAL HAZARDS associated with support systems	28	Suspended masses
9.8.1	General	28.1	"General"
		28.4 1)	"1) The total load…."
		28.4 2)	"2) Where it is unlikely…."
9.8.2	TENSILE SAFETY FACTOR	28.4 3)	"3) Where impairment by wear…."
		28.4 4)	"4) Where metal having a specific…."
		28.4 5)	"5) Sheaves, sprockets, bandwheels…."
		28.4	Compliance "*Compliance with the requirements of….*
9.8.3	Strength of PATIENT or OPERATOR support, or suspension systems		New
9.8.3.1	General	21.3	"Equipment parts serving for support…."
9.8.3.2	Static forces due to loading from persons		New
9.8.3.2 a)			New
9.8.3.2 b)			New
9.8.3.3	Dynamic forces due to loading from persons		New
9.8.4	Systems with MECHANICAL PROTECTIVE DEVICES	28.3	"Suspension system with SAFETY DEVICES"
9.8.4.1	General		New
9.8.4.1 a)			New
9.8.4.1 b)			New
9.8.4.2	Use after activation of a MECHANICAL PROTECTIVE DEVICE		New
9.8.4.3	MECHANICAL PROTECTIVE DEVICE intended for single activation		New
9.8.5	Systems without MECHANICAL PROTECTIVE DEVICES	28.4	"Suspension systems of metal….",

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
10	Protection against unwanted and excessive radiation HAZARDS	Section 5	
10.1	X-Radiation	29	"X-radiation"
10.1.1	ME EQUIPMENT not intended to produce diagnostic or therapeutic x-radiation	29.2	"For equipment not intended…."
10.1.2	ME EQUIPMENT intended to produce diagnostic or therapeutic x-radiation		New
10.2	Alpha, beta, gamma, neutron radiation and other particle radiation	30	"Alpha, beta, gamma…."
10.3	Microwave radiation	31	"Microwave radiation"
10.4	Lasers		New
10.5	Other visual electromagnetic radiation	32	"Light radiation…."
10.6	Infrared radiation	33	"Infra-red radiation"
10.7	Ultraviolet radiation	34	"Ultraviolet radiation"
11	Protection against excessive temperatures and other HAZARDS	Section 7	
11.1	Excessive temperatures in ME EQUIPMENT	42	"Excessive temperatures"
11.1.1	Maximum temperature during NORMAL USE	42.1	"Equipment parts having a safety function…."
11.1.2	Temperature of APPLIED PARTS	42.3	"Applied parts of equipment…."
11.1.2.1	APPLIED PARTS intended to supply heat to a PATIENT		New
11.1.2.2	APPLIED PARTS not intended to supply heat to a PATIENT		New
11.1.3	Measurements		New
11.1.3 a)		42.3 1)	"1) Positioning and cooling"
11.1.3 b)		42.3 2)	"2) Supply"
11.1.3 c)		42.3 3)	"3) Duty cycle"
11.1.3 d)		42.3 4)	"4) Temperature measurement"
11.1.3 e)		42.3 5)	"5) Test criteria"
11.1.4	GUARDS	42.5	"Guards"
11.2	Fire prevention	43	"Fire prevention"
11.2.1	Strength and rigidity required to prevent fire in ME EQUIPMENT	43.1	"Strength and rigidity"
11.2.2	ME EQUIPMENT and ME SYSTEMS used in conjunction with OXYGEN RICH ENVIRONMENTS	43.2	"Oxygen enriched atmospheres"

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT		New
11.2.2.1 a)			New
11.2.2.1 b)			New
11.2.2.2	External exhaust outlets for OXYGEN RICH ENVIRONMENT		New
11.2.2.3	Electrical connections in OXYGEN RICH ENVIRONMENTS		New
11.2.3	SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS in conjunction with ME EQUIPMENT and ME SYSTEMS		New
11.3	Constructional requirements for fire-proof ENCLOSURES OF ME EQUIPMENT		New
11.3 a)			New
11.3 b)			New
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics	3.6 e)	"Leakage of the…."
		5.5	"According to the degree of safety…."
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents		New
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT	44	"Overflow, spillage, leakage…."
11.6.1	General	44.1	"General"
11.6.2	Overflow in ME EQUIPMENT	44.2	"Overflow"
11.6.3	Spillage on ME EQUIPMENT and ME SYSTEMS	44.3	"Spillage"
11.6.4	Leakage		New
11.6.5	Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS	44.6	"Ingress of liquids"
11.6.6	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS	44.7	"Cleaning, sterilization and disinfection"
11.6.7	Sterilization of ME EQUIPMENT and ME SYSTEMS		New
11.6.8	Compatibility with substances used with the ME EQUIPMENT	44.8	"Compatibility with substances…."
11.7	Biocompatibility of ME EQUIPMENT and ME SYSTEMS	48	"Materials in applied parts…."
11.8	Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	49	"Interruption of the power supply"
11.8	Interruption and restoration of the power supply to ME EQUIPMENT and ME SYSTEM	49.2	"Equipment shall be so…."

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
12	Accuracy of controls and instruments and protection against hazardous outputs	Section 8	
12.1	Accuracy of controls and instruments	50	"Accuracy of operating data"
12.2	Usability of ME EQUIPMENT		New
12.3	ALARM SYSTEMS		New
12.4	Protection against hazardous output	51	"Protection against hazardous output"
12.4.1	Intentional exceeding of safety limits	51.1	"Intentional exceeding of safety limits"
12.4.2	Indication relevant to safety	51.2	"Indication of parameters relevant to safety"
12.4.3	Accidental selection of excessive output values	51.4	"Accidental selection of…."
12.4.4	Incorrect output	51.5	"Incorrect output"
12.4.5	Diagnostic or therapeutic radiation		New
12.4.5.1	Limits	Section 5	"General"
12.4.5.2	Diagnostic X-ray equipment	29.1, Indent 1	"– For diagnostic X-ray…."
12.4.5.3	Radiotherapy equipment	29.1, Indent 2	"– For radiotherapy equipment…."
12.4.5.4	Other ME EQUIPMENT producing diagnostic or therapeutic radiation		New
12.4.6	Diagnostic or therapeutic acoustic pressure		New
13	HAZARDOUS SITUATIONS and FAULT CONDITIONS for ME EQUIPMENT	Section 9	
		52	"Abnormal operation and fault conditions"
13.1	Specific HAZARDOUS SITUATIONS	52.4	"The following safety…."
13.1.1	General		New
13.1.2	Emissions, deformation of ENCLOSURE or exceeding maximum temperature	52.4.1	"– emission of flames…."
13.1.3	Exceeding LEAKAGE CURRENT or voltage limits	52.4.2	"– Exceeding of the limits…"
13.1.4	Specific MECHANICAL HAZARDS	52.4.3	"Starting, interrupting, or locking…."
13.2	SINGLE FAULT CONDITIONS	52.5	"The following single fault…."
13.2.1	General		New
13.2.2	Electrical SINGLE FAULT CONDITION		New
13.2.3	Overloading of transformers in ME EQUIPMENT	52.5.1	"Overloading of mains supply…."
13.2.4	Failure of THERMOSTATS	52.5.2	"Failure of thermostats"
13.2.5	Failure of temperature limiting devices	3.6 j)	"j) failure of temperature limiting devices
13.2.6	Leakage of liquid	44.4	"Leakage"
		3.6 f)	"f) Leakage of liquid"

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
13.2.7	Impairment of cooling that could result in a HAZARDOUS SITUATION	52.5.5	"Impairment of cooling"
13.2.8	Locking of moving parts	52.5.6	"Locking of moving parts"
13.2.9	Interruption and short-circuiting of motor capacitors	52.5.7	"Interruption and short-circuiting…."
13.2.10	Additional test criteria for motor operated ME EQUIPMENT	52.5.8	"Additional tests for motor…."
13.2.10 a)		52.5.8 a)	"a) 30 s for…."
13.2.10 b)		52.5.8 b)	"b) 5 min for other…."
13.2.10 c)		52.5.8 c)	"c) for the maximum…."
13.2.10 d)		52.5.8 d)	"d) as long as necessary…."
13.2.11	Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS	New	
13.2.12	Failure of parts that might result in a MECHANICAL HAZARD	3.6 h)	"h) failure of mechanical parts…."
13.2.13	Overload	52.5.10	"Overload"
13.2.13.1	General overload test conditions	New	
13.2.13.2	ME EQUIPMENT with heating elements	New	
13.2.13.2 a)		52.5.10 a)	"a) Equipment with heating…."
13.2.13.2 a) 1)		52.5.10 a).1)	"1) for thermostatically controlled…."
13.2.13.2 a) 2)		52.5.10 a).2)	"2) For equipment having…."
13.2.13.2 a) 3)		52.5.10 a).3)	"3) For other EQUIPMENT…."
13.2.13.2 b)		52.5.10 c)	"c) Equipment having heating…."
13.2.13.2 c)		52.5.10 d)	"d) Heating parts of…."
		52.5.10 d) 1)	"1) as specified in…."
		52.5.10 d) 2)	"2) with the equipment…."
		52.5.10 d) 3)	"3) with a supply voltage…."
		52.5.10 e)	"e) Heating parts of…."
		52.5.10 e) 1)	"1) as specified in…."
		52.5.10 e) 2)	"2) with the equipment…."
		52.5.10 e) 3)	"3) with a supply voltage…."
13.2.13.2 c) 1)		52.5.10 d) 4)	"4) disabling any control…."
13.2.13.2 c) 2)		52.5.10 d) 5)	"5) if the equipment…."
13.2.13.2 c) 3)		52.5.10 e) 5)	"5) until steady thermal…."
13.2.13.3	ME EQUIPMENT with motors	New	

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
13.2.13.3 a)		52.5.10 b)	"b) Equipment having motors…."
13.2.13.3 a) 1)		52.5.10 b) 1)	"1) for the motor part…."
13.2.13.3 a) 2)		52.5.10 b) 2)	"2) for equipment containing…."
13.2.13.3 a) 3)		52.5.10 b) 3)	"3) if more than…."
13.2.13.3 b)		52.5.10 f)	"f) Motors are checked…."
13.2.13.3 b) 1)		52.5.10 f) 1)	"1) intended to be…."
13.2.13.3 b) 2)		52.5.10 f) 2)	"2) liable to be…."
13.2.13.3 c)		52.5.10 h)	"h) Equipment with three-phase…."
13.2.14.4	ME EQUIPMENT RATED for non-CONTINUOUS OPERATION	52.5.10 g)	"g) Equipment rated for…."
14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	New	
14.1	General	New	
14.2	Documentation	60601-1-4, 52.201	"Documentation"
14.3	RISK MANAGEMENT plan	60601-1-4, 52.202	"Risk management plan"
14.4	PEMS DEVELOPMENT LIFE-CYCLE	60601-1-4, 52.203	"Development life-cycle"
15.5	Problem resolution		New
14.6	RISK MANAGEMENT PROCESS	60601-1-4, 52.204	"Risk management process"
14.6.1	Identification of known and foreseeable HAZARDS	60601-1-4, 52.204.3.1	"Hazard identification shall…."
14.6.2	RISK CONTROL	60601-1-4, 52.204.4	"Risk control"
14.7	Requirement specification	60601-1-4, 52.206	"Requirement specification"
14.8	Architecture	60601-1-4, 52.207	"Architecture"
14.9	Design and implementation	60601-1-4, 52.208	"Design and implementation"
14.10	VERIFICATION	60601-1-4, 52.209	"Verification"
14.11	PEMS VALIDATION	60601-1-4, 52.210	"Validation"
14.12	Modification	60601-1-4, 52.211	"Modification"
14.13	PEMS intended to be incorporated into an IT-NETWORK	New	
14.13 a)		New	
14.13 b)		New	
14.13 c)		New	
14.13 d)		New	
14.13 e)		New	
14.13 f)		New	

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
15	Construction of ME EQUIPMENT	Section 10	
15.1	Arrangements of controls and indicators of ME EQUIPMENT	54.1	"Arrangements of functions"
15.2	Serviceability	54.2	"Serviceability"
		22.6	"Parts subject to mechanical…."
15.3	Mechanical strength	55	"Enclosures and covers"
15.3.1	General	55.1	"Material"
15.3.2	Push test	21 a)	"a) The rigidity of an enclosure…."
15.3.3	Impact test	21 b)	"b) The strength of an enclosure…."
15.3.4	Drop test		New
15.3.4.1	HAND-HELD ME EQUIPMENT	21.5	"Equipment or equipment parts…."
15.3.4.2	PORTABLE ME EQUIPMENT		New
15.3.5	Rough handling test		New
15.3.5 a)			New
15.3.5 b)			New
15.3.5 c)			New
15.3.6	Mould stress relief		New
15.3.7	Environmental influences	55.2	"Mechanical strength"
15.4	ME EQUIPMENT components and general assembly	56, Some parts	"Components and general assembly"
15.4.1	Construction of connectors	56.3 a)	"Construction of connectors"
15.4.1 a)		56.3 a)	Indent 2 "– Plugs for connection…."
15.4.1 b)		56.3 a)	Indent 3 "– Medical gas connections…."
15.4.2	Temperature and overload control devices	56.6	"Temperature and overload control devices"
15.4.2.1	Application	56.6 a)	"a) Application"
15.4.2.1 a)		49.1	"Thermal cut-outs and…."
15.4.2.1 b)		56.6 a)	Indent 1 "– Thermal cutouts with a…."
15.4.2.1 c)		56.6 a)	Indent 3 "– Where a failure of a…."
15.4.2.1 d)		56.6 a)	Indent 4 "– Where the consequent loss…."
15.4.2.1 e)		56.4	Indent 4 "– Capacitors or other…."
15.4.2.1 f)		56.6 a)	"Equipment which incorporates a fluid…."
15.4.2.1 g)			New
15.4.2.1 h)			New
15.4.2.2	Temperature settings	56.6 b)	"b) Allowable temperature range"
		56.6 b)	Indent 1 "– Where means are provided…."

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
15.4.3	Batteries	56.7	"Batteries"
15.4.3.1	Housing	56.7 a)	"a) Housing"
15.4.3.2	Connection	56.7 b)	"b) Connection"
		56.7 b).1)	"1) Establishing whether there...."
		56.7 b).2)	"2) Where such a possibility...."
15.4.3.3	Protection against overcharging	56.7 c)	"c) Battery state"
15.4.3.4	Lithium batteries		New
15.4.3.5	Excessive current and voltage protection	59.3	"Excessive current and voltage protection"
		59.3	Indent 1 "– See Sub-clause 57.6"
		59.3	Indent 2 "– An internal electrical power source...."
15.4.4	Indicators	56.8	"Indicators"
15.4.5	Pre-set controls	56.9	"Pre-set controls"
15.4.6	Actuating parts of controls of ME EQUIPMENT	56.10	"Actuating parts of controls"
15.4.6.1	Fixing, prevention of maladjustment	56.10 b)	"b) Fixing, prevention of maladjustment"
15.4.6.1 a)		56.10 b)	Indent 1 "– All activating parts shall..."
15.4.6.1 b)		56.10 b)	Indent 2 "– Controls, the adjustment of which....""
15.4.6.1 c)		56.10 b)	Indent 3 "– Incorrect connection of the indicating device...."
15.4.6.2	Limitation of movement	56.10 c)	"c Limitation of movement"
15.4.7	Cord-connected HAND-HELD and foot-operated control devices	56.11,	Some parts "Cord-connected hand-held...."
15.4.7.1	Mechanical strength	56.11 b)	"b) Mechanical strength"
15.4.7.1 a)		56.11 b)	Indent 1 "– Hand-held control devices...."
15.4.7.1 b)		56.11 b)	Indent 2 "– Foot-operated control devices...."
15.4.7.2	Accidental operation of ME EQUIPMENT	56.11 c)	"c) Inadvertent operation"
15.4.7.3	Entry of liquids	56.11 d)	"d) Entry of liquids"
15.4.7.3 a)		56.11 d)	Indent 1 "– Foot-operated control...."
15.4.7.3 b)		56.11 d)	Indent 2 "– The electrical switching...."
15.4.8	Internal wiring of ME EQUIPMENT	59.1 d)	"Materials"
15.4.9	Oil containers	59.4	"Oil containers"
15.4.9 a)		59.4	Indent 1 "– Oil containers in portable...."
15.4.9 b)		59.4	Indent 1 "– Oil containers in mobile...."
15.4.9 c)		59.4	Indent 2 "– Partially sealed oil-filled...."

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
15.5	MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5	57.9	"Mains supply transformers"
15.5.1	Overheating	57.9.1	"Overheating"
15.5.1.1	Transformers		New
15.5.1.2	Short-circuit test	57.9.1 a)	"a) Short-circuit"
15.5.1.3	Overload test	57.9.1 b)	b) Overload"
15.5.1.3 a)		57.9.1 b) Indent 1	"– under the conditions specified in…."
15.5.1.3 a)		57.9.1 b) Indent 3	"– the tests are made on each winding…."
15.5.1.3 b)		59.9.1 b) Indent 4	"– the section or winding…."
15.5.2	Dielectric strength	57.9.2	"Dielectric strength"
15.5.2 a)		57.9.2 Indent 1	"– Transformers not having…."
15.5.2 b)		57.9.2 Indent 2	"– Transformers having any…."
15.5.2 Indent 1		57.9.2 Indent 3	"– Three-phase transformers may…."
15.5.2 Indent 2		57.9.2 Indent 4	"– The value of the test voltage…."
15.5.2 Indent 3		57.9.2 Indent 5	"– During the test, all windings…."
15.5.2 Indent 4		57.9.2 Indent 6	"– Initially not more than…."
15.5.2 Indent 5		57.9.2 Indent 7	"– Tests are not conducted at …."
15.5.2, Compliance		57.9.2 Indent 8	"– During the test, no flashover…."
15.5.3	Construction of transformers used to provide separation as required by 8.5	57.9.4	"Construction"
16	ME SYSTEMS		New
16.1	General requirements for the ME SYSTEMS	60601-1-1, 3.201	"General requirements for the system"
		60601-1-1, 3.201.4	"System"
		60601-1-1, 3.201.2,	"Non-medical electrical equipment"
16.2	ACCOMPANYING DOCUMENTS of an ME SYSTEM	60601-1-1, 6.8.201	"Accompanying documents of a system"
16.2 a)		60601-1-1, 6.8.201 a)	"a) The accompanying documents for each …."
16.2 b)		60601-1-1, 6.8.201 b)	"b) the equivalent documents for each…."
16.2 c)		60601-1-1, 6.8.201 c)	"c) the following information…."
16.2 d)		60601-1-1, 6.8.201 d)	"d) advice to…."
16.3	Power supply	60601-1-1, 10.2.2.201	"Power supply"
16.4	ENCLOSURES	60601-1-1, 16.201	"Enclosures"

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
16.5	SEPARATION DEVICES	60601-1-1, 17.201	"Electrical separation"
		60601-1-1, 19.201.3	"Connection of signal input parts…."
		60601-1-1, 57.10	"Creepage distances and…."
16.6	LEAKAGE CURRENTS	60601-1-1, 19	"Continuous leakage currents and…"
16.6.1	TOUCH CURRENT	60601-1-1, 19.201.1	"Enclosure leakage current"
16.6.2	EARTH LEAKAGE CURRENT of MULTIPLE SOCKET-OUTLET		New
16.6.3	PATIENT LEAKAGE CURRENT	60601-1-1, 19.201.2	"Patient leakage current"
16.6.4	Measurements		New
16.6.4.1	General conditions for ME SYSTEMS		New
16.6.4.1 a)			New
16.6.4.1 b)			New
16.6.4.2	Connection of the ME SYSTEM to the measuring supply circuit		New
16.6.4.2 a)			New
16.6.4.2 b)			New
16.7	Protection against MECHANICAL HAZARDS	60601-1-1, 22.7.201	"Protective means"
16.8	Interruption of the power supply to parts of an ME SYSTEM	60601-1-1, 49.201	"Interruption of the power supply"
16.9	ME SYSTEM connections and wiring	60601-1-1, 56.3.201	"Connections
16.9.1	Connection terminals and connectors		New
16.9.2	MAINS PARTS, components and layout	60601-1-1, 57	"Mains parts, components and layout"
16.9.2.1	MULTIPLE SOCKET-OUTLET	60601-1-1, 57.2.201	"Multiple portable socket-outlet"
16.9.2.1 a)		60601-1-1,Annex EEE.1	"Multiple portable socket-outlet with separating transformer"
16.9.2.1 b)		60601-1-1,Annex EEE.1	"Multiple portable socket-outlet with separating transformer"
16.9.2.1 c)		60601-1-1, Annex EEE.2	"Multiple portable socket-outlet"
16.9.2.1 d)		60601-1-1,Annex EEE.1	"Multiple portable socket-outlet with separating transformer"
16.9.2.2	PROTECTIVE EARTH CONNECTIONS in ME SYSTEMS	60601-1-1, 58.201	"Protective earthing of SYSTEMS"
16.9.2.3	Protection of conductors	60601-1-1, 59.201	"Protection of wiring"
17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	36	"Electromagnetic compatibility"

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
Annex A	General guidance and rationale	Appendix A	"General guidance and rationale"
Annex A,	Subclause 5.1	4.2	"Repetition of tests
Annex A,	Subclause 7.9.3.1 a)	10.2.1 a)	"a) An ambient temperature range…."
Annex A,	Subclause 7.9.3.1 b)	10.2.1 b)	"b) A relative humidity range…."
Annex A,	Subclause 7.9.3.1 c)	10.2.1 c)	"c) An atmospheric pressure range…."
Annex A,	Subclause 7.9.3.1 d)	10.2.1 d)	"d) A temperature of the water…."
Annex A,	Subclause 8.5.1	56.4	Indent 2 "– Capacitors connected directly…."
Annex A,	Subclause 8.5.1 1)	17 a) 1)	"1) The applied part…."
		17g) 1)	"1) The accessible part….",
Annex A,	Subclause 8.5.1 2)	17 a) 2)	"2) The applied part…."
		17 g) 2)	"2) The accessible part…."
Annex A,	Subclause 8.5.1 3)	17 a) 4)	"4) The applied part…."
		17 g) 4)	"4) The accessible part…."
Annex A,	Subclause 8.5.1 4)	17 a).5)	"5) Impedances of components prevent…."
		17 g) 5)	"5) Impedances of components…."
Annex A,	Subclause 8.8.1	20.4 g)	"g) Care is taken that the voltage…."
Annex B	Sequence of testing	Appendix C	Sequence of testing
Annex C	Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS		New
Annex D	Symbols on marking	Appendix D	"Symbols on marking"
Annex E	Examples of the connection of the measuring device (MD) for measurement of the PATIENT LEAKAGE CURRENT and PATIENT AUXILIART CURRENT	Appendix K	"Examples of the connection of the applied part for measurement of the patient leakage current"
Annex F	Suitable measuring supply circuits	Figures 10 to Figure 14	
Annex G	Protection against HAZARDS of ignition of flammable anaesthetic mixtures	Section 6	
Annex G.1	Introduction		New
Annex G.1.1	Applicability		New
Annex G.1.2	Industrial equipment and components		New
Annex G.1.3	Requirements for ME EQUIPMENT		New
Annex G.2	Location and basic requirements	37	"Location and basic requirements"

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
Annex G.2.1	Parts of CATEGORY APG ME EQUIPMENT		New
Annex G.2.2	FLAMMABLE ANAESTHETIC MIXTURE WITH AIR	37.5	Flammable anaesthetic mixture with air
Annex G.2.3	FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE	37.6	"Flammable anaesthetic mixture with oxygen or nitrous oxide"
Annex G.2.4	ME EQUIPMENT specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH AIR	37.7	"Equipment or parts thereof…."
Annex G.2.5	ME EQUIPMENT specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE	37.8	"Equipment or parts thereof…."
Annex G.3	Marking, ACCOMPANYING DOCUMENTS	38	"Marking, accompanying documents"
Annex G.3.1	CATEGORY APG marking	6.1 r)	"r) Category AP/APG equipment"
		38.2	"Category APG equipment should…."
Annex G.3.2	CATEGORY AP marking	6.1 r)	"r) Category AP/APG equipment"
		38.4	"Category AP equipment should…."
Annex G.3.3	Placement of markings	38.5	"The marking according…."
Annex G.3.4	ACCOMPANYING DOCUMENTS	38.6	"Accompanying documents should…."
Annex G.3.5	Marking when parts of ME EQUIPMENT are CATEGORY AP or CATEGORY APG	38.7	"On equipment in which…."
Annex G.4	Common requirements for CATEGORY AP and CATEGORY APG EQUIPMENT	39	"Common requirements for…."
Annex G.4.1	Electrical connections	39.1	"Electrical connections"
Annex G.4.1 a)		39.1 a)	"a) Creepage distances and air clearances…."
Annex G.4.1 b)		39.1 b)	"b) Connections, except those…."
Annex G.4.1 c)		39.1 c)	"c) Category AP equipment…."
Annex G.4.2	Construction details	39.2	"Construction details"
Annex G.4.2 a)		39.2 a)	"a) Opening of an enclosure…."
Annex G.4.2 b)		39.2 b)	"b) To avoid the likelihood…."
Annex G.4.2 c)		39.2 c)	"c) Where basic insulation of electrical…."
Annex G.4.3	Prevention of electrostatic charges	39.3	"Prevention of electrostatic charges"
Annex G.4.3 a)		39.3 a)	"a) Electrostatic charges shall be prevented…."
Annex G.4.3 b)		39.3 b)	"b) The electrical resistance limits…."
Annex G.4.4	Corona	39.4	"Corona"
Annex G.5	Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components thereof	40	"Requirements and tests for …."

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
Annex G.5.1	General	40.1	"General"
Annex G.5.2	Temperature limits	40.2	"Temperature limits"
Annex G.5.3	Low-energy circuits	40.3	"Low-energy circuits"
Annex G.5.4	External ventilation with internal overpressure	40.4	"External ventilation with…."
Annex G.5.4 a)		40.4 a)	"a) Flammable anaesthetic mixtures with air…."
Annex G.5.4 b)		40.4 b)	"b) The overpressure inside the enclosure…."
Annex G.5.4 c)		40.4 c)	"c) If the overpressure drops…."
Annex G.5.4 d)		40.4 d)	"d) The external surface of the enclosure…."
Annex G.5.5	ENCLOSURES with restricted breathing	40.5	"Enclosures with restricted breathing
Annex G.5.5 a)		40.5 a)	"a) Enclosures with restricted breathing…."
Annex G.5.5 b)		40.5 b)	"b) If the required tightness…."
Annex G.5.5 c)		40.5 c)	"c) If the enclosure contains inlets…."
Annex G.6	Requirements and tests for CATEGORY APG EQUIPMENT, parts and components thereof	41	"Requirements and tests for category APG…."
Annex G.6.1	General	41.1	"General"
Annex G.6.2	Power supply	41.2	"Power supply"
Annex G.6.3	Temperatures and low-energy circuits	41.3	"Temperatures and low-energy circuits"
Annex G.6.3 a)		41.3 a)	"a) no sparks are produced….."
Annex G.6.3 b)		41.3 b)	"b) A temperature limit of….."
Annex G.6.4	Heating elements	41.4	"Heating elements"
Annex G.7	Test apparatus for flammable mixtures	Appendix F	"Test apparatus for flammable mixtures"
Annex H	PEMS structure, PEMS DEVELOPMENT LIFE-CYCLE and documentation	60601-1-4, Annex DDD	"Development life-cycle"
		60601-1-4, Annex EEE	"Example of PEMS/PESS structure"
Annex I	ME SYSTEMS aspects	60601-1-1, Annex BBB	"Examples of combinations of…."
		60601-1-1, Annex FFF	"Examples of application of…."
Annex J	Survey of insulation paths	Appendix E	"Survey of insulation paths and test circuits"

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IEC 60601-1:2005 + A1:2012		IEC 60601-1 Second edition as amended or other standards	
Clause	**Title**	**Clause**	**Title**
Annex K	Simplified PATIENT LEAKAGE CURRENT diagrams		New
Annex L	Insulated winding wires for use without interleaved insulation		New
Annex M	Reduction of pollution degrees		New
Bibliography		Appendix L	"Publications mentioned in this standard"
Index of abbreviations and acronyms			New
Index			New

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[1] IEC 60127-1:2006, *Miniature fuses – Part 1: Definitions for miniature fuses and general requirements for miniature fuse-links*

[2] IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*[1]
Amendment 1:1991
Amendment 2:1995

[3] IEC 60601-1-1:2000, *Medical electrical equipment – General requirements for safety – Collateral standard: Safety requirements for medical electrical systems*

[4] IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral standard: Programmable electrical medical systems*
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[5] IEC 60601-1-4, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral standard: Programmable electrical medical systems*

[6] IEC 60950-1:2005, *Information technology equipment – Safety – Part 1: General requirements*

[7] IEC 61558:2005, *Safety of power transformers, power supplies, reactors and similar products – Part 1: General requirements and tests*
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[8] IEC 61558-2-15:2011, *Safety of transformers, reactors, power supply units and combinations thereof – Part 2-15: Particular requirements and tests for isolating transformers for the supply of medical locations*

[9] IEC 62304:2006, *Medical device software – Software life cycle processes*

[10] IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices*

[11] ISO 14971:2007, *Medical devices – Application of risk management to medical devices*

[12] ISO/IEC Guide 51:1999, *Safety aspects – Guidelines for their inclusion in standards*

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1 Withdrawn. Replaced by the third edition: IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* and its Amendment 1:2012.

2 There exists a consolidated edition 1.1 (2000) including IEC 60601-1-4 (1996) and its Amendment 1 (1999).

3 There exists a consolidated edition 2.1 (2009) including IEC 61558 (2005) and its Amendment 1 (2009).

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