

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

**Appareils électromédicaux –
Partie 1: Exigences générales pour la sécurité de base et les performances
essentielles**



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**MEDICAL ELECTRICAL EQUIPMENT –
Part 1: General requirements for basic safety
and essential performance**

INTERPRETATION SHEET 1

This interpretation sheet has been prepared by SC 62A: Common aspects of electrical equipment used in medical practice

The text of this interpretation sheet is based on the following documents:

ISH	Report on voting
62A/599/ISH	62A/613/RVD

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

Subclause 1.1

This subclause is clarified by the following:

IEC 60601-1 does not apply to medical gas pipeline systems covered by ISO 7396-1, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*.

NOTE Subclause 6.3 of ISO 7396-1 applies the requirement of IEC 60601-1-8 to certain monitoring and alarm signals.

This clarification will remain valid until a new version of IEC 60601-1 is published.

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MEDICAL ELECTRICAL EQUIPMENT –

Part 1: General requirements for basic safety and essential performance

INTERPRETATION SHEET 2

This interpretation sheet has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this interpretation sheet is based on the following documents:

ISH	Report on voting
62A/634/ISH	62A/640/RVD

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Subclause 11.3

This subclause is clarified by the following:

As stated in the rationale for this subclause, fire ENCLOSURES are intended to be used only where there is a significant likelihood of fire due to the presence of a source of ignition (as described in the subclause) *and* a *significant* source of fuel. Most materials used in the construction of ME EQUIPMENT are not considered to be such a source of fuel unless they are in the presence of an OXYGEN RICH ENVIRONMENT. MANUFACTURERS should determine, through analyses documented in the RISK MANAGEMENT FILE, whether the ME EQUIPMENT contains combustible materials (fuel) in sufficient quantities to support combustion in conjunction with ignition sources (capable of releasing greater than 900 J).

Subclause 13.1.2

This subclause is clarified by the following:

As stated in subclause 4.7, it is the MANUFACTURER'S RISK ANALYSIS that determines which components are subject to failure testing based on the associated RISK. Where the associated RISK of fire exceeds the MANUFACTURER'S criteria for RISK acceptability, the MANUFACTURER'S simulation analysis (such as FMEAs) should be accepted in lieu of physical testing. As also stated in 4.7, component reliability and ratings are to be considered in such failure simulation analyses. Common electronic components that have a history of use without causing equipment fires should not be considered a likely source of ignition.

Where the subclause identifies "emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities;" as a hazardous situation, this refers to emissions from *the ENCLOSURE* not from components themselves. Where it identifies "exceeding the allowable values for 'other components and materials' identified in Table 22 times 1,5 minus 12,5 °C", this applies only where doing so would result in an unacceptable RISK (as identified in the MANUFACTURER'S RISK ANALYSIS according to 4.7). Typically, this would be cases where

ESSENTIAL PERFORMANCE would not be maintained or where greater than 900 J of energy would be released in the presence of flammable materials that could sustain combustion.

The first exemption to fault analysis or testing identified in subclause 13.1.2 (“The construction or the supply circuit limits the power dissipation in SINGLE FAULT CONDITION to less than 15 W or the energy dissipation to less than 900 J.”) is intended to apply where the component design itself (“The construction”) or fusing (or other current limiting devices) in the supply circuit (“or the supply circuit”) assure the energy released during failures will not exceed the limits. For most common signal level components rated for operation below 5 Watts, the energy released by short-circuiting of outputs will not exceed the 900 J limit.

This clarification will remain valid until a new version of IEC 60601-1 is published.

**MEDICAL ELECTRICAL EQUIPMENT –
Part 1: General requirements for basic safety and essential performance**

INTERPRETATION SHEET 3

This interpretation sheet has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this interpretation sheet is based on the following documents:

ISH	Report on voting
62A/858/ISH	62A/875/RVD

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

Subclause 13.1.2 fourth dash (Emissions, deformation of ENCLOSURE or exceeding maximum temperature)

This subclause states the following:

The following HAZARDOUS SITUATIONS shall not occur:

-
- temperatures of ME EQUIPMENT parts that are not APPLIED PARTS but are likely to be touched, exceeding the allowable values in Table 23 when measured and adjusted as described in 11.1.3;

This is clarified by the following:

The above requirement is regarded as fulfilled in accordance with Subclause 4.5 for temperatures at the surfaces of the enclosure, if the following conditions are fulfilled:

- The maximum allowed temperature on OPERATOR accessible surfaces in SINGLE FAULT CONDITION is 105 °C; and
- the instructions for use contain a warning that, under some SINGLE FAULT CONDITIONS, the temperature of: (*indicate the surface of concern*) could get hot and there is a possible RISK of a burn if touched, and
- if the RISK ANALYSIS demonstrates a need for a warning symbol on the ENCLOSURE, safety sign ISO 7010-W018 () shall be used on or adjacent to the hot spot on the ENCLOSURE; and
- the RISK ASSESSMENT demonstrates that the temperature attained in the SINGLE FAULT CONDITION is acceptable, and
- the RISK ASSESSMENT demonstrates that applying the alternative RISK CONTROL measures in this Interpretation Sheet results in a RESIDUAL RISK that is comparable to the RESIDUAL RISK resulting from applying the requirement of the standard.

NOTE 1 This Interpretation Sheet is intended to be used with both Edition 3.0 and Edition 3.1 of IEC 60601-1.

NOTE 2 An example of an analysis that demonstrates an adequately low probability of occurrence of HARM is shown below.

Example RISK ASSESSMENT:

The sum failure rate for parts that could increase the surface temperature of parts of the enclosure of XYZ device touchable only by the OPERATOR to values above those of Table 23 calculates to be 60 FIT (1 FIT = $1\text{E-}9/\text{h}$) according to the standard MIL-HDBK-217F where FIT stands for "failure in time". In case of such failures, the device would emit an odour and would no longer function properly. It is estimated, that only in one of 3 cases the device would not be switched off immediately and the hot surface would be resulting in a burn.

The resulting overall probability of such HARM where adequate warning is provided in the instructions for use in combination with warning sign ISO 7010 W018 would be: probability = $1/3 * 60 \text{ FIT} = 2 \text{ E-}8/\text{h}$ = approx. 0,0002 per year.

In this example, the WXW Company's RISK acceptance criteria require that a HARM of that severity must have a probability of less than 0,0003 per year for the associated RISK to be considered acceptable. Based on that RISK acceptance criterion, the RISK associated with overtemperature of the ENCLOSURE caused by single faults in the circuitry is acceptable.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 1: General requirements for basic safety
and essential performance**

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International Standard IEC 60601-1 has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

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

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

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

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

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

In this standard the following print types are used:

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

In referring to the structure of this standard, the term

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

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

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

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

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

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

The committee has decided that the contents of this publication will remain unchanged until the maintenance result 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.

The contents of the corrigenda of December 2006 and 2007 and the Interpretations sheets of April 2008, January 2009 and May 2013 have been included in this copy.

INTRODUCTION

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

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

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

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

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

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

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

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

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

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

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

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

1) Figures in square brackets refer to the Bibliography.

MEDICAL ELECTRICAL EQUIPMENT –

Part 1: General requirements for basic safety and essential performance

1 Scope, object and related standards

1.1 * Scope

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

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

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

NOTE See also 4.2.

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

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

1.2 Object

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

1.3 * Collateral standards

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

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

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

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

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

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

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

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

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

1.4 * Particular standards

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

NOTE Members of IEC and ISO maintain registers of valid International Standards. Users of this standard should consult these registers to determine which particular standards have been published.

A requirement of a particular standard takes priority over this standard.

2 * Normative references

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

ATTENTION: Additional collateral standards of the IEC 60601 series, which are issued subsequent to publication of this standard, become normative at the date of their publication and shall be considered as being included among the normative references below. See 1.3.

NOTE Informative references are listed in the Bibliography on page 372.

IEC 60065:2001, *Audio, video and similar electronic apparatus – Safety requirements*

IEC 60068-2-2:1974, *Environmental testing – Part 2: Tests. Tests B: Dry heat*
Amendment 1 (1993)
Amendment 2 (1994)

IEC 60079-0, *Electrical apparatus for explosive gas atmospheres – Part 0: General requirements*

IEC 60079-2, *Electrical apparatus for explosive gas atmospheres – Part 2: Pressurized enclosures “p”*

IEC 60079-5, *Electrical apparatus for explosive gas atmospheres – Part 5: Powder filling “q”*

IEC 60079-6, *Electrical apparatus for explosive gas atmospheres – Part 6: Oil-immersion “o”*

IEC 60083, *Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC*

IEC 60085, *Electrical insulation – Thermal classification*

IEC 60086-4, *Primary batteries – Part 4: Safety of lithium batteries*

IEC 60112, *Method for the determination of the proof and the comparative tracking indices of solid insulating materials*

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

IEC 60227-1:1993, *Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V – Part 1: General requirements*⁴⁾

Amendment 1 (1995)

Amendment 2 (1998)

IEC 60245-1:2003, *Rubber insulated cables – Rated voltages up to and including 450/750 V – Part 1: General requirements*

IEC 60252-1, *AC motor capacitors – Part 1: General – Performance, testing and rating – Safety requirements – Guide for installation and operation*

IEC 60320-1, *Appliance couplers for household and similar general purposes – Part 1: General requirements*

IEC 60335-1:2001, *Household and similar electrical appliances – Safety – Part 1: General requirements*

IEC 60364-4-41, *Electrical installations of buildings – Part 4-41: Protection for safety – Protection against electric shock*

IEC 60384-14:2005, *Fixed capacitors for use in electronic equipment – Part 14: Sectional specification: Fixed capacitors for electromagnetic interference suppression and connection to the supply mains*

IEC 60417-DB:2002, *Graphical symbols for use on equipment*⁵⁾

IEC 60445, *Basic and safety principles for man-machine interface, marking and identification – Identification of equipment terminals and of terminations of certain designated conductors, including general rules for an alphanumeric system*

IEC 60447, *Basic and safety principles for man-machine interface, marking and identification – Actuating principles*

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)*⁶⁾
Amendment 1 (1999)

4) There exists a consolidated edition 2.2 including IEC 60227-1:1993 and its Amendment 1 (1995) and Amendment 2 (1998).

5) "DB" refers to the joint ISO-IEC on-line database.

6) There exists a consolidated version 2.1, including IEC 60529:1989 and its Amendment 1 (1999).

IEC 60601-1-2, *Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-3, *Medical electrical equipment – Part 1: General requirements for safety – 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment*

IEC 60601-1-6, *Medical electrical equipment – Part 1-6: General requirements for safety – Collateral standard: Usability*

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

IEC 60664-1:1992, *Insulation coordination for equipment within low-voltage systems – Part 1: Principles, requirements and tests* ⁷⁾
Amendment 1 (2000)
Amendment 2 (2002)

IEC 60695-11-10, *Fire hazard testing – Part 11-10: Test flames – 50 W horizontal and vertical flame test methods*

IEC 60730-1:1999, *Automatic electrical controls for household and similar use – Part 1: General requirements* ⁸⁾
Amendment 1 (2003)

IEC 60825-1:1993, *Safety of laser products – Part 1: Equipment classification, requirements and user's guide* ⁹⁾
Amendment 1 (1997)
Amendment 2 (2001)

IEC 60851-3:1996, *Winding wires – Test methods – Part 3: Mechanical properties* ¹⁰⁾
Amendment 1 (1997)
Amendment 2 (2003)

IEC 60851-5:1996, *Winding wires – Test methods – Part 5: Electrical properties* ¹¹⁾
Amendment 1 (1997)
Amendment 2 (2004)

IEC 60851-6:1996, *Winding wires – Test methods – Part 6: Thermal properties*
Amendment 1 (1997)

IEC 60878:2003, *Graphical symbols for electrical equipment in medical practice*

⁷⁾ There exists a consolidated edition 1.2 including IEC 60664-1:1992 and its Amendment 1 (2000) and Amendment 2 (2002).

⁸⁾ There exists a consolidated edition 3.1, including IEC 60730-1:1999 and its Amendment 1 (2003)

⁹⁾ There exists a consolidated edition 1.2, including IEC 60825-1:1993 and its Amendment 1 (1997) and Amendment 2 (2001).

¹⁰⁾ There exists a consolidated edition 2.1, including IEC 60851-3:1996 and its Amendment 1 (1997).

¹¹⁾ There exists a consolidated edition 3.2, including IEC 60851-5:1996 and its Amendment 1 (1997) and Amendment 2 (2004).

IEC 60884-1, *Plugs and socket-outlets for household and similar purposes - Part 1: General requirements*

IEC 60950-1:2001, *Information technology equipment – Safety – Part 1: General requirements*

IEC 61058-1:2000, *Switches for appliances – Part 1: General requirements* ¹²⁾
Amendment 1 (2001)

IEC 61558-1:1997, *Safety of power transformers, power supply units and similar – Part 1: General requirements and tests* ¹³⁾
Amendment 1 (1998)

IEC 61558-2-1, *Safety transformers, power supply units and similar – Part 2: Particular requirements for separating transformers for general use*

IEC 61672-1, *Electroacoustics – Sound level meters – Part 1: Specifications*

IEC 61672-2, *Electroacoustics – Sound level meters – Part 2: Pattern evaluation tests*

IEC 61965, *Mechanical safety of cathode ray tubes*

ISO 31 (all parts), *Quantities and units*

ISO 780, *Packaging – Pictorial marking for handling of goods*

ISO 1000, *SI units and recommendations for the use of their multiples and of certain other units*

ISO 1853, *Conducting and dissipative rubbers, vulcanized or thermoplastic – Measurement of resistivity*

ISO 2878, *Rubber, vulcanized – Antistatic and conductive products – Determination of electrical resistance*

ISO 2882 ¹⁴⁾, *Rubber, vulcanized – Antistatic and conductive products for hospital use – Electrical resistance limits*

ISO 3746, *Acoustics – Determination of sound power levels of noise sources using sound pressure – Survey method using an enveloping measurement surface over a reflecting plane*

ISO 3864-1:2002, *Graphical symbols – Safety colours and safety signs – Part 1: Design principles for safety signs in workplaces and public areas*

¹²⁾ There exists a consolidated edition 3.1, including IEC 61058-1:2000 and its Amendment 1 (2001)

¹³⁾ There exists a consolidated edition 1.1, including IEC 61558-1:1997 and its Amendment 1 (1998).

¹⁴⁾ ISO 2882 was withdrawn on 1 February 2005 and no replacement standard has been identified.

ISO 5349-1, *Mechanical vibration – Measurement and evaluation of human exposure to hand-transmitted vibration – Part 1: General requirements*

ISO 7000-DB:2004 ¹⁵⁾, *Graphical symbols for use on equipment – Collection of symbols*

ISO 7010:2003, *Graphical symbols – Safety colours and safety signs – Safety signs used in workplaces and public areas*

ISO 9614-1, *Acoustics – Determination of sound power levels of noise sources using sound intensity – Measurement at discrete points*

ISO 10993 (all parts), *Biological evaluation of medical devices*

ISO 11134, *Sterilization of health care products – Requirements for validation and routine control – Industrial moist heat sterilization*

ISO 11135, *Medical devices – Validation and routine control of ethylene oxide sterilization*

ISO 11137, *Sterilization of health care products – Requirements for validation and routine control – Radiation sterilization*

ISO 13852, *Safety of machinery – Safety distances to prevent danger zones being reached by the upper limbs*

ISO 14971:2000, *Medical devices – Application of risk management to medical devices*

ISO 15223, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied*

ISO 23529, *Rubber – General procedures for preparing and conditioning test pieces for physical test methods*

3 * Terminology and definitions

For the purposes of this document, the following terms and definitions apply.

NOTE 1 Where the terms “voltage” and “current” are used in this document, they mean the r.m.s. values of an alternating, direct or composite voltage or current unless stated otherwise.

NOTE 2 The term “electrical equipment” is used to mean ME EQUIPMENT (see 3.63) or other electrical equipment. This standard also uses the term “equipment” to mean ME EQUIPMENT or other electrical or non-electrical equipment in the context of an ME SYSTEM (see 3.64).

NOTE 3 An index is found beginning on page 375.

¹⁵⁾ “DB” refers to the joint ISO-IEC on-line database.

3.1**ACCESS COVER**

part of an ENCLOSURE or GUARD providing the possibility of access to electrical equipment parts for the purpose of adjustment, inspection, replacement or repair

3.2**ACCESSIBLE PART**

part of electrical equipment other than an APPLIED PART that can be touched by means of the standard test finger

NOTE See also 5.9.2.1.

3.3**ACCESSORY**

additional part for use with equipment in order to:

- achieve the INTENDED USE,
- adapt it to some special use,
- facilitate its use,
- enhance its performance, or
- enable its functions to be integrated with those of other equipment

[IEC 60788:2004, rm-83-06 modified]

3.4**ACCOMPANYING DOCUMENT**

document accompanying ME EQUIPMENT, an ME SYSTEM, equipment or an ACCESSORY and containing information for the RESPONSIBLE ORGANIZATION or OPERATOR, particularly regarding BASIC SAFETY and ESSENTIAL PERFORMANCE

3.5**AIR CLEARANCE**

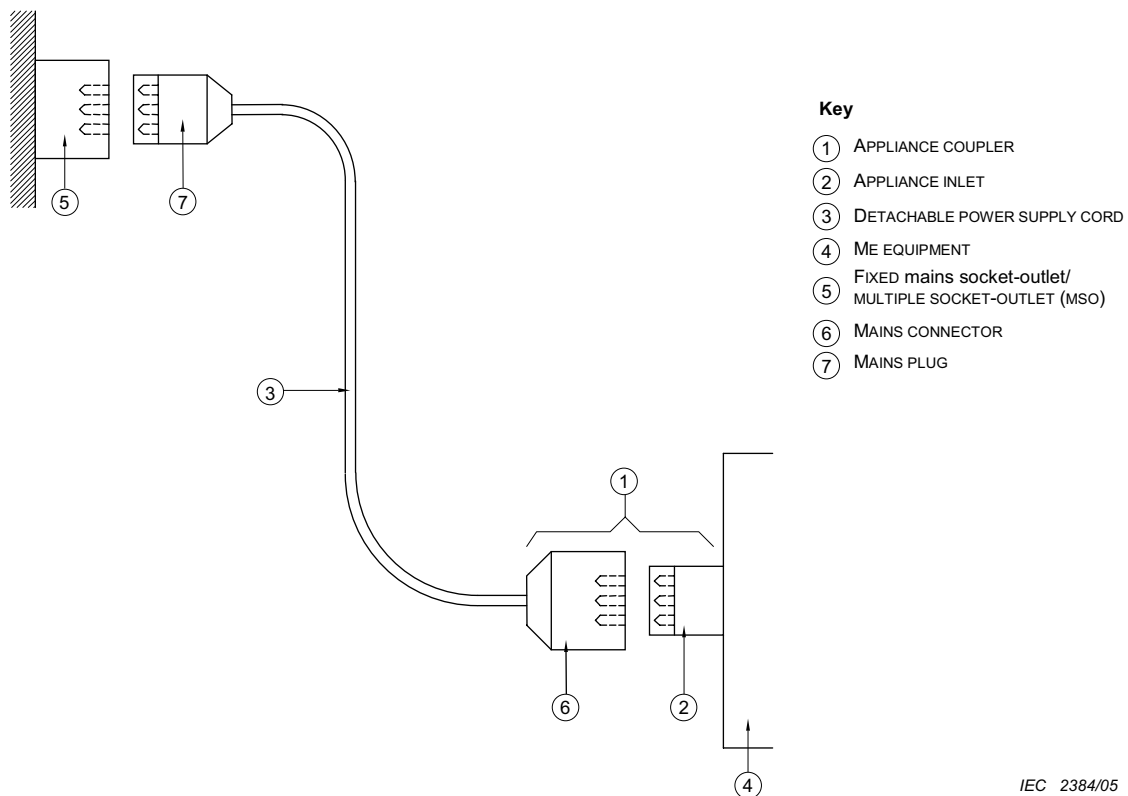
shortest path in air between two conductive parts

NOTE Adapted from IEC 60664-1, definition 1.3.2.

3.6**APPLIANCE COUPLER**

means enabling the connection of a flexible cord to electrical equipment without the use of a TOOL, consisting of two parts: a MAINS CONNECTOR and an APPLIANCE INLET

NOTE See Figure 1.



IEC 2384/05

Figure 1 – Detachable mains connection
(see definitions)

3.7

APPLIANCE INLET

part of an APPLIANCE COUPLER either integrated in or FIXED to electrical equipment

NOTE See Figure 1 and Figure 2.

3.8

*** APPLIED PART**

part of ME EQUIPMENT that in NORMAL USE necessarily comes into physical contact with the PATIENT for ME EQUIPMENT or an ME SYSTEM to perform its function

NOTE 1 See Figure 3, Figure 4 and Figure A.1 to Figure A.7 (inclusive).

NOTE 2 See also 4.6 regarding the treatment of parts that do not fall within the definition of APPLIED PARTS but need to be treated as APPLIED PARTS as a result of applying the RISK MANAGEMENT PROCESS.

NOTE 3 See also 3.78 for the definition of the associated term PATIENT CONNECTION.

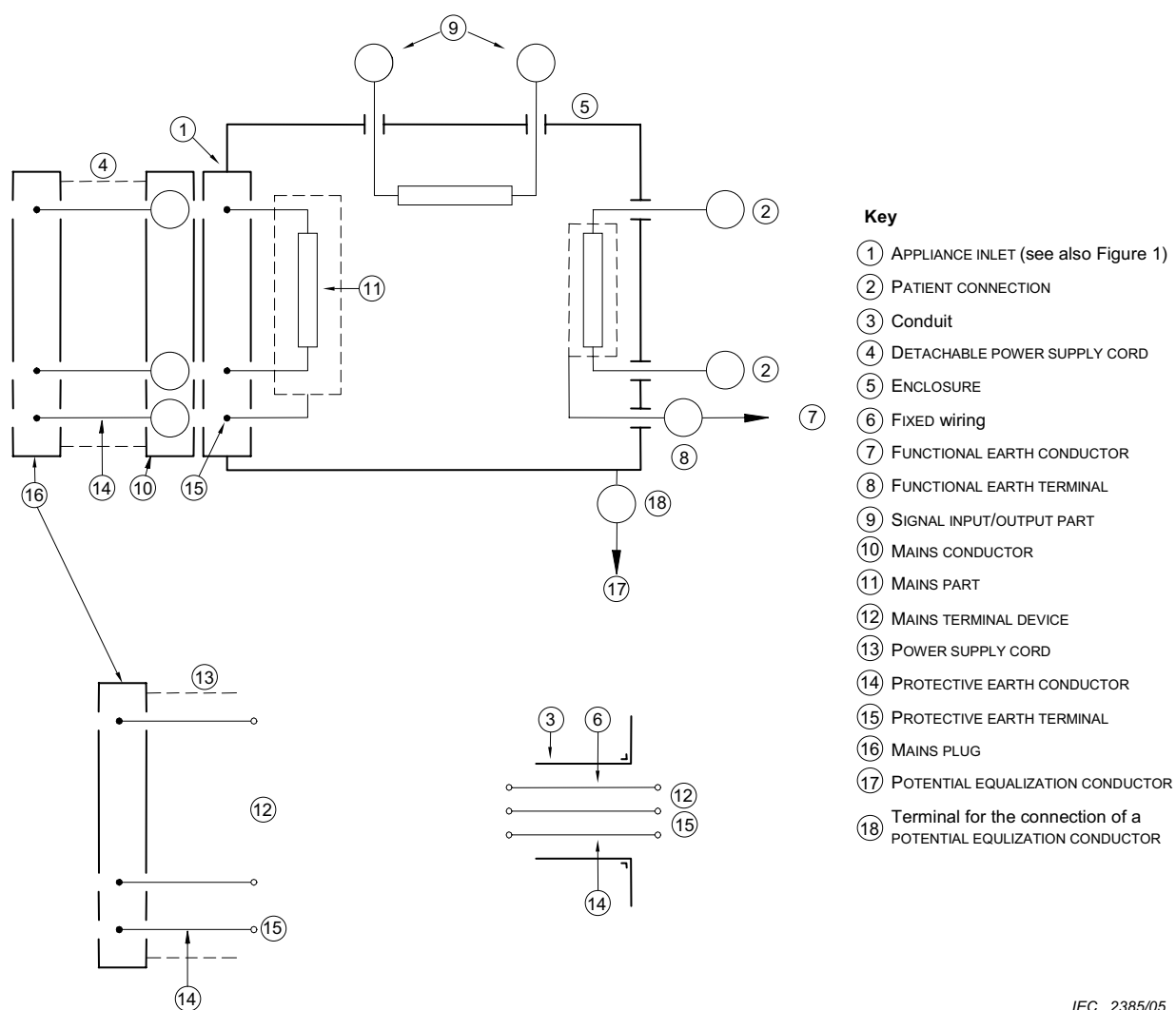
3.9

*** BASIC INSULATION**

insulation providing basic protection against electric shock

[IEV 826-12-14, modified]

NOTE BASIC INSULATION provides one MEANS OF PROTECTION.



IEC 2385/05

Figure 2 – Example of the defined terminals and conductors
(see definitions)

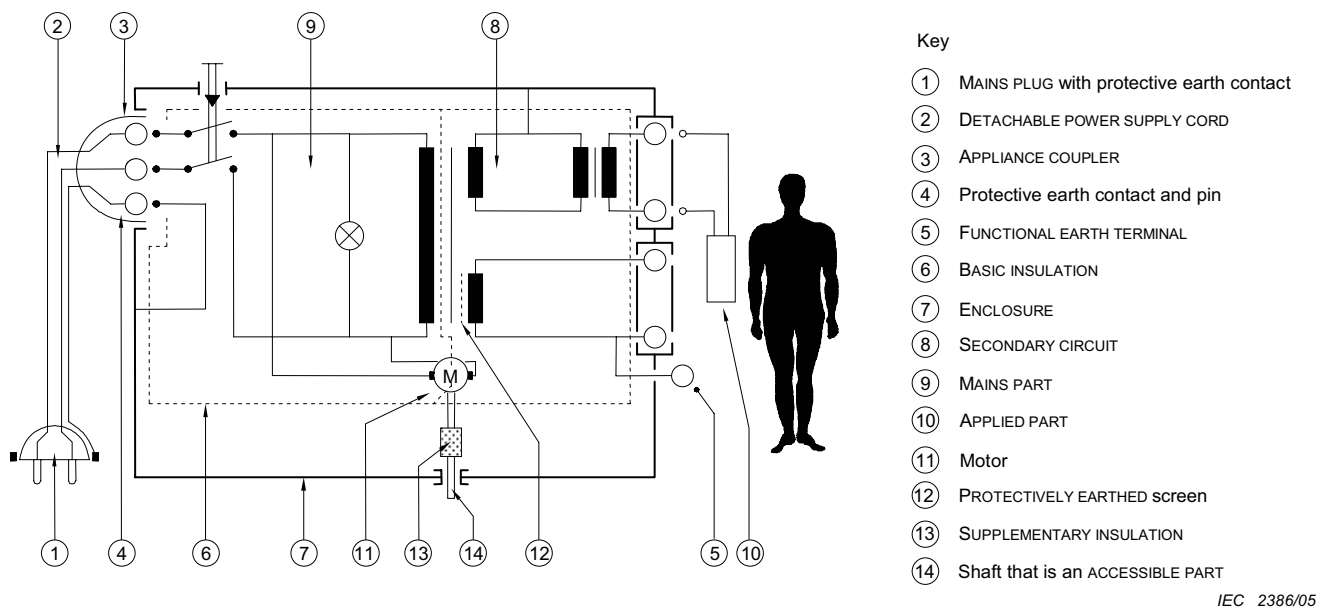


Figure 3 – Example of a CLASS I ME EQUIPMENT
(see definitions)

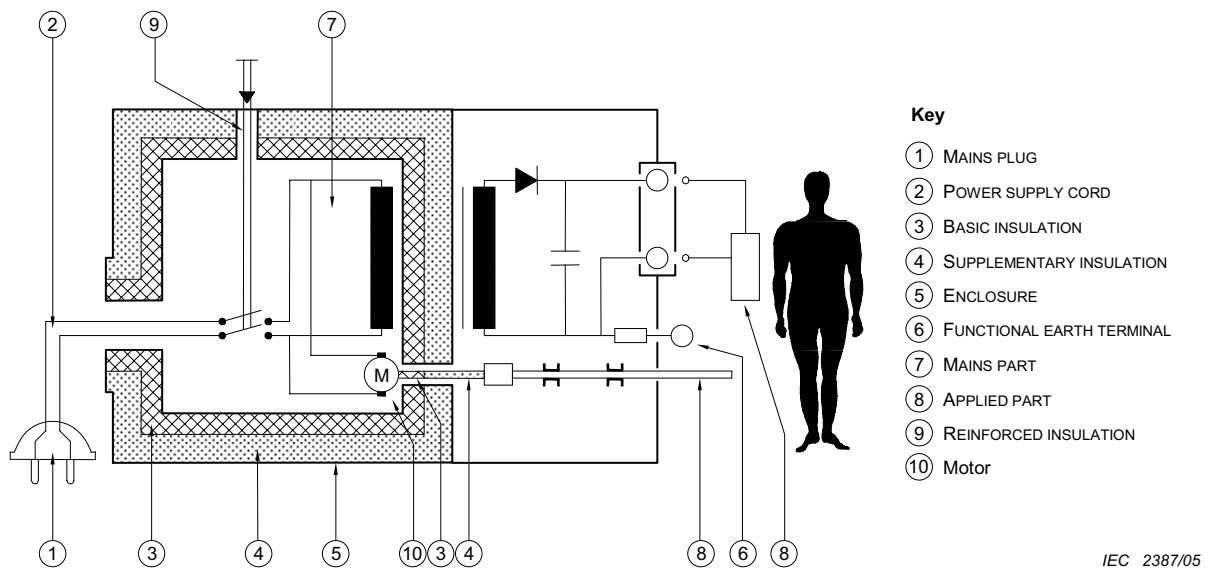


Figure 4 – Example of a metal-enclosed CLASS II ME EQUIPMENT
(see definitions)

3.10*** BASIC SAFETY**

freedom from unacceptable RISK directly caused by physical HAZARDS when ME EQUIPMENT is used under NORMAL CONDITION and SINGLE FAULT CONDITION

3.11**CATEGORY AP**

rating for ME EQUIPMENT or an ME EQUIPMENT part complying with specified requirements on construction, marking and documentation in order to avoid sources of ignition in a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR

3.12**CATEGORY APG**

rating for ME EQUIPMENT or an ME EQUIPMENT part complying with specified requirements on construction, marking and documentation in order to avoid sources of ignition in a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE

3.13**CLASS I**

term referring to electrical equipment in which protection against electric shock does not rely on BASIC INSULATION only, but which includes an additional safety precaution in that means are provided for ACCESSIBLE PARTS of metal or internal parts of metal to be PROTECTIVELY EARTHED

NOTE See Figure 3.

3.14**CLASS II**

term referring to electrical equipment in which protection against electric shock does not rely on BASIC INSULATION only, but in which additional safety precautions such as DOUBLE INSULATION or REINFORCED INSULATION are provided, there being no provision for protective earthing or reliance upon installation conditions

NOTE 1 See Figure 4.

NOTE 2 CLASS II equipment can be provided with a FUNCTIONAL EARTH TERMINAL or a FUNCTIONAL EARTH CONDUCTOR. See also 8.6.8 and 8.6.9.

3.15**CLEARLY LEGIBLE**

capable of being read by a person with normal vision

NOTE See also 7.1.2.

3.16**COLD CONDITION**

condition obtained if electrical equipment is de-energized for a sufficiently long time to attain the ambient temperature

3.17*** COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS**

component where one or more characteristics ensure that its function is fault-free in relation to the safety requirements of this standard during the EXPECTED SERVICE LIFE of the ME EQUIPMENT in NORMAL USE and reasonably foreseeable misuse

3.18

* CONTINUOUS OPERATION

operation in NORMAL USE for an unlimited period of time without the specified limits of temperature being exceeded

3.19

CREEPAGE DISTANCE

shortest distance along the surface of the insulating material between two conductive parts

[IEV 151-15-50, modified]

3.20

* DEFIBRILLATION-PROOF APPLIED PART

APPLIED PART that is protected against the effects of a discharge of a cardiac defibrillator to the PATIENT

3.21

* DETACHABLE POWER SUPPLY CORD

flexible cord intended to be connected to electrical equipment by means of a suitable APPLIANCE COUPLER for mains supply purposes

NOTE See Figure 1, Figure 2 and Figure 3.

3.22

* DIRECT CARDIAC APPLICATION

use of APPLIED PART that can come in direct contact with the PATIENT'S heart

3.23

* DOUBLE INSULATION

insulation comprising both BASIC INSULATION and SUPPLEMENTARY INSULATION

[IEV 195-06-08]

NOTE DOUBLE INSULATION provides two MEANS OF PROTECTION.

3.24

* DUTY CYCLE

maximum activation (on) time followed by minimum deactivation (off) time necessary for the safe operation of the ME EQUIPMENT

3.25

EARTH LEAKAGE CURRENT

current flowing from the MAINS PART through or across the insulation into the PROTECTIVE EARTH CONDUCTOR

3.26

* ENCLOSURE

exterior surface of electrical equipment or parts thereof

NOTE For the purpose of testing to this standard, metal foil, with specified dimensions, applied in contact with parts of the exterior surface made of material with low conductivity or made of insulating material is considered a part of the ENCLOSURE (see Figure 2, Figure 3 and Figure 4).

3.27

* ESSENTIAL PERFORMANCE

performance necessary to achieve freedom from unacceptable RISK

NOTE ESSENTIAL PERFORMANCE is most easily understood by considering whether its absence or degradation would result in an unacceptable RISK.

3.28**EXPECTED SERVICE LIFE**

maximum period of useful life as defined by the MANUFACTURER

3.29**F-TYPE ISOLATED (FLOATING) APPLIED PART** (herein F-TYPE APPLIED PART)

APPLIED PART in which the PATIENT CONNECTIONS are isolated from other parts of the ME EQUIPMENT to such a degree that no current higher than the allowable PATIENT LEAKAGE CURRENT flows if an unintended voltage originating from an external source is connected to the PATIENT, and thereby applied between the PATIENT CONNECTION and earth

NOTE F-TYPE APPLIED PARTS are either TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS.

3.30**FIXED**

term meaning fastened or otherwise secured at a specific location either permanently or so that it can only be detached by means of a TOOL

EXAMPLE 1 Permanently affixed by welding, etc.

EXAMPLE 2 Affixed by means of fasteners (screws, nuts, etc.) making removal/opening impossible without using a TOOL.

3.31**FLAMMABLE ANAESTHETIC MIXTURE WITH AIR**

mixture of a flammable anaesthetic vapour with air in such a concentration that ignition can occur under specified conditions

3.32**FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE**

mixture of a flammable anaesthetic vapour with oxygen or with nitrous oxide in such a concentration that ignition can occur under specified conditions

3.33*** FUNCTIONAL CONNECTION**

connection, electrical or otherwise, including those intended to transfer signals, data, power or substances

NOTE Connection to a FIXED SUPPLY MAINS socket-outlet, whether single or multiple, is not considered to result in a FUNCTIONAL CONNECTION.

3.34**FUNCTIONAL EARTH CONDUCTOR**

conductor to be connected to a FUNCTIONAL EARTH TERMINAL

NOTE See Figure 2.

3.35*** FUNCTIONAL EARTH TERMINAL**

terminal, directly connected to a circuit or to a screening part, that is intended to be earthed for functional purposes

NOTE See Figure 2, Figure 3 and Figure 4.

3.36**GUARD**

part of equipment specifically used to provide protection by means of a physical barrier

NOTE Depending on its construction, a GUARD can be called a casing, cover, screen, door, enclosing guard, etc. A GUARD can act:

- alone; it is then only effective when it is in place;
- in conjunction with an interlocking device with or without guard locking; in this case, protection is ensured whatever the position of the GUARD.

3.37

HAND-HELD

term referring to electrical equipment intended to be supported by the hand during NORMAL USE

3.38

*** HARM**

physical injury or damage to the health of people or animals, or damage to property or the environment

[ISO 14971:2000, definition 2.2, modified]

3.39

HAZARD

potential source of HARM

[ISO 14971:2000, definition 2.3]

3.40

*** HAZARDOUS SITUATION**

circumstance in which people, property, or the environment are exposed to one or more HAZARD(S)

[ISO/IEC Guide 51:1999, definition 3.6]

3.41

HIGH VOLTAGE

voltage over 1 000 V a.c. or over 1 500 V d.c. or over 1 500 V peak value

3.42

HYDRAULIC TEST PRESSURE

pressure applied to test a vessel or part of it

NOTE See 9.7.5.

3.43

INSULATION CO-ORDINATION

mutual correlation of insulation characteristics of electrical equipment taking into account the expected micro-environment and other influencing stresses

3.44

*** INTENDED USE**

INTENDED PURPOSE

use of a product, PROCESS or service in accordance with the specifications, instructions and information provided by the MANUFACTURER

[ISO 14971:2000, definition 2.5]

NOTE INTENDED USE should not be confused with NORMAL USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, service, transport, etc. as well.

3.45**INTERNAL ELECTRICAL POWER SOURCE**

electrical power source for operating equipment that is a part of the equipment and which produces electrical current from some other form of energy

EXAMPLE Chemical, mechanical, solar, or nuclear

NOTE An INTERNAL ELECTRICAL POWER SOURCE can be inside the principal part of equipment, attached to the outside, or contained in a separate ENCLOSURE.

3.46**INTERNALLY POWERED**

term referring to electrical equipment that is able to operate from an INTERNAL ELECTRICAL POWER SOURCE

3.47**LEAKAGE CURRENT**

current that is not functional

NOTE The following LEAKAGE CURRENTS are defined: EARTH LEAKAGE CURRENT, TOUCH CURRENT and PATIENT LEAKAGE CURRENT.

3.48**MAINS CONNECTOR**

part of an APPLIANCE COUPLER integral with or intended to be attached to a flexible cord that is intended to be connected to the SUPPLY MAINS

NOTE A MAINS CONNECTOR is intended to be inserted into the APPLIANCE INLET of electrical equipment (see Figure 1 and Figure 2).

3.49*** MAINS PART**

electrical circuit that is intended to be connected to the SUPPLY MAINS

NOTE 1 The MAINS PART includes all conductive parts that are not separated from the SUPPLY MAINS by at least one MEANS OF PROTECTION.

NOTE 2 For the purpose of this definition, the PROTECTIVE EARTH CONDUCTOR is not regarded as a part of the MAINS PART (see Figure 2 and Figure 3).

3.50*** MAINS PLUG**

part, integral with or intended to be attached to a POWER SUPPLY CORD of electrical equipment, to be inserted into a mains socket-outlet

NOTE 1 See Figure 1.

NOTE 2 See also IEC 60083 and IEC 60309-1 [8].

3.51**MAINS SUPPLY TRANSFORMER**

static piece of equipment with two or more windings which, by electro-magnetic induction, transforms an alternating voltage and current from a SUPPLY MAINS into a voltage and current usually of different values at the same frequency

3.52**MAINS TERMINAL DEVICE**

TERMINAL DEVICE by which the electrical connection to the SUPPLY MAINS is made

NOTE See Figure 2.

3.53

MAINS TRANSIENT VOLTAGE

highest peak voltage expected at the power input to the electrical equipment, arising from external transients on the SUPPLY MAINS

3.54

MAINS VOLTAGE

voltage of a SUPPLY MAINS between two line conductors of a polyphase system or voltage between the line conductor and the neutral conductor of a single-phase system

3.55

MANUFACTURER

natural or legal person with responsibility for the design, manufacture, packaging, or labelling of ME EQUIPMENT, assembling an ME SYSTEM, or adapting ME EQUIPMENT or an ME SYSTEM, regardless of whether these operations are performed by that person or on that person's behalf by a third party

NOTE 1 ISO 13485 [30] defines "labelling" as written, printed or graphic matter

- affixed to a medical device or any of its containers or wrappers, or
- accompanying a medical device,

related to identification, technical description, and use of the medical device, but excluding shipping documents. In this standard, that material is described as markings and ACCOMPANYING DOCUMENTS.

NOTE 2 "Adapting" includes making substantial modifications to ME EQUIPMENT or an ME SYSTEM already in use.

NOTE 3 In some jurisdictions, the RESPONSIBLE ORGANIZATION can be considered a MANUFACTURER when involved in the activities described.

NOTE 4 Adapted from ISO 14971:2000, definition 2.6.

3.56

*** MAXIMUM MAINS VOLTAGE**

voltage used for test purposes related to the voltage of the SUPPLY MAINS and connected to certain ME EQUIPMENT parts

NOTE The value for MAXIMUM MAINS VOLTAGE is determined according to 8.5.3.

3.57

*** MAXIMUM PERMISSIBLE WORKING PRESSURE**

maximum pressure permitted on a component according to a declaration of the manufacturer of such component

3.58

*** MEANS OF OPERATOR PROTECTION**

MOOP

MEANS OF PROTECTION for reducing the RISK due to electric shock to persons other than the PATIENT

3.59

*** MEANS OF PATIENT PROTECTION**

MOPP

MEANS OF PROTECTION for reducing the RISK due to electric shock to the PATIENT

3.60*** MEANS OF PROTECTION****MOP**

means for reducing the RISK due to electric shock in accordance with the requirements of this standard

NOTE MEANS OF PROTECTION include insulation, AIR CLEARANCES, CREEPAGE DISTANCES, impedances, and PROTECTIVE EARTH CONNECTIONS.

3.61**MECHANICAL HAZARD**

HAZARD connected with or produced by physical force

3.62**MECHANICAL PROTECTIVE DEVICE**

device that eliminates or reduces mechanical RISK to an acceptable level and which operates in the case of SINGLE FAULT CONDITION

3.63*** MEDICAL ELECTRICAL EQUIPMENT****ME EQUIPMENT**

electrical equipment having an APPLIED PART or transferring energy to or from the PATIENT or detecting such energy transfer to or from the PATIENT and which is:

- a) provided with not more than one connection to a particular SUPPLY MAINS; and
- b) intended by its MANUFACTURER to be used:
 - 1) in the diagnosis, treatment, or monitoring of a PATIENT; or
 - 2) for compensation or alleviation of disease, injury or disability

NOTE 1 ME EQUIPMENT includes those ACCESSORIES as defined by the MANUFACTURER that are necessary to enable the NORMAL USE of the ME EQUIPMENT.

NOTE 2 Not all electrical equipment used in medical practice falls within this definition (e.g. some in vitro diagnostic equipment).

NOTE 3 The implantable parts of active implantable medical devices can fall within this definition, but they are excluded from the scope of this standard by appropriate wording in Clause 1.

NOTE 4 This standard uses the term "electrical equipment" to mean ME EQUIPMENT or other electrical equipment.

NOTE 5 See also 4.10.1, 8.2.1 and 16.3.

3.64*** MEDICAL ELECTRICAL SYSTEM****ME SYSTEM**

combination, as specified by its MANUFACTURER, of items of equipment, at least one of which is ME EQUIPMENT to be inter-connected by FUNCTIONAL CONNECTION or by use of a MULTIPLE SOCKET-OUTLET

NOTE Equipment, when mentioned in this standard, should be taken to include ME EQUIPMENT.

3.65**MOBILE**

term referring to TRANSPORTABLE equipment intended to be moved from one location to another while supported by its own wheels or equivalent means

3.66

* **MODEL OR TYPE REFERENCE**

combination of figures, letters or both used to identify a particular model of equipment or ACCESSORY

3.67

* **MULTIPLE SOCKET-OUTLET**

MSO

one or more socket-outlets intended to be connected to, or integral with, flexible cables or cords or ME EQUIPMENT for SUPPLY MAINS or equivalent voltage

NOTE A MULTIPLE SOCKET-OUTLET can be a separate item or an integral part of equipment.

3.68

* **NETWORK/DATA COUPLING**

any means to transmit or receive information to or from other equipment in accordance with the MANUFACTURER'S specifications

3.69

NOMINAL (value)

value quoted for reference purposes that is subject to agreed tolerances

EXAMPLE NOMINAL MAINS VOLTAGE or NOMINAL diameter of a screw

3.70

NORMAL CONDITION

condition in which all means provided for protection against HAZARDS are intact

3.71

NORMAL USE

operation, including routine inspection and adjustments by any OPERATOR, and stand-by, according to the instructions for use

NOTE NORMAL USE should not be confused with INTENDED USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, service, transport, etc. as well.

3.72

OBJECTIVE EVIDENCE

information which can be proven true, based on facts obtained through observation, measurement, test or other means

[ISO 14971:2000, definition 2.8]

3.73

* **OPERATOR**

person handling equipment

NOTE See also 3.101.

3.74

OVER-CURRENT RELEASE

protective device that causes a circuit to open, with or without time-delay, when the current in the device exceeds a predetermined value

[IEV 441-16-33, modified]

3.75*** OXYGEN RICH ENVIRONMENT**

environment in which the concentration of oxygen is:

- a) greater than 25 % for ambient pressures up to 110 kPa; or
- b) the partial pressure of oxygen is greater than 27,5 kPa at ambient pressures exceeding 110 kPa

3.76**PATIENT**

living being (person or animal) undergoing a medical, surgical or dental procedure

3.77*** PATIENT AUXILIARY CURRENT**

current flowing in the PATIENT in NORMAL USE between any PATIENT CONNECTION and all other PATIENT CONNECTIONS and not intended to produce a physiological effect

3.78*** PATIENT CONNECTION**

individual point on the APPLIED PART through which current can flow between the PATIENT and the ME EQUIPMENT in NORMAL CONDITION or SINGLE FAULT CONDITION

3.79*** PATIENT ENVIRONMENT**

any volume in which intentional or unintentional contact can occur between a PATIENT and parts of the ME EQUIPMENT or ME SYSTEM or between a PATIENT and other persons touching parts of the ME EQUIPMENT or ME SYSTEM

3.80**PATIENT LEAKAGE CURRENT**

current:

- flowing from the PATIENT CONNECTIONS via the PATIENT to earth; or
- originating from the unintended appearance of a voltage from an external source on the PATIENT and flowing from the PATIENT via the PATIENT CONNECTIONS of an F-TYPE APPLIED PART to earth

3.81*** PEAK WORKING VOLTAGE**

highest peak or d.c. value of a WORKING VOLTAGE, including repetitive peak impulses generated in the electrical equipment, but not including external transients

[IEC 60950-1:2001, definition 1.2.9.7, modified]

3.82**PEMS DEVELOPMENT LIFE-CYCLE**

necessary activities occurring during a period of time that starts at the concept phase of a project and finishes when the PEMS VALIDATION is complete

NOTE See also 3.90.

3.83

PEMS VALIDATION

PROCESS of evaluating a PEMS or a component of a PEMS during or at the end of the development PROCESS, to determine whether it satisfies the requirements for its INTENDED USE

NOTE See also 3.90.

3.84

PERMANENTLY INSTALLED

term meaning electrically connected to the SUPPLY MAINS by means of a permanent connection that can only be detached by the use of a TOOL

3.85

PORTABLE

term referring to TRANSPORTABLE equipment intended to be moved from one location to another while being carried by one or more persons

3.86

POTENTIAL EQUALIZATION CONDUCTOR

conductor other than a PROTECTIVE EARTH CONDUCTOR or a neutral conductor, providing a direct connection between electrical equipment and the potential equalization busbar of the electrical installation

NOTE See Figure 2.

3.87

POWER SUPPLY CORD

flexible cord, FIXED to or assembled with electrical equipment for connection to SUPPLY MAINS

NOTE See Figure 1 to Figure 4 (inclusive).

3.88

PROCEDURE

specific way to perform an activity

[ISO 14971:2000, definition 2.9]

3.89

PROCESS

set of inter-related resources and activities which transform inputs into outputs

[ISO 14971:2000, definition 2.10]

3.90

PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM

PEMS

ME EQUIPMENT or an ME SYSTEM containing one or more PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS)

3.91

PROGRAMMABLE ELECTRONIC SUBSYSTEM

PESS

system based on one or more central processing units, including their software and interfaces

3.92**PROPERLY INSTALLED**

installed in accordance with the ACCOMPANYING DOCUMENTS

3.93**PROTECTIVE EARTH CONDUCTOR**

conductor to be connected between the PROTECTIVE EARTH TERMINAL and an external protective earthing system

NOTE See Figure 2.

3.94**PROTECTIVE EARTH CONNECTION**

connection to the PROTECTIVE EARTH TERMINAL provided for protective purposes and complying with the requirements of this standard

3.95**PROTECTIVE EARTH TERMINAL**

terminal connected to conductive parts of CLASS I equipment for safety purposes. This terminal is intended to be connected to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR

NOTE See Figure 2.

3.96**PROTECTIVELY EARTHED**

connected to the PROTECTIVE EARTH TERMINAL for protective purposes by means complying with the requirements of this standard

3.97**RATED (value)**

term referring to a value assigned by the MANUFACTURER for a specified operating condition

3.98**RECORD**

document which furnishes OBJECTIVE EVIDENCE of activities performed or results achieved [ISO 14971:2000, definition 2.11]

3.99*** REINFORCED INSULATION**

single insulation system that provides two MEANS OF PROTECTION

3.100**RESIDUAL RISK**

RISK remaining after protective measures have been taken

[ISO 14971:2000, definition 2.12]

3.101**RESPONSIBLE ORGANIZATION**

entity accountable for the use and maintenance of an ME EQUIPMENT or an ME SYSTEM

NOTE 1 The accountable entity can be, for example, a hospital, an individual clinician or a layperson. In home use applications, the PATIENT, OPERATOR and RESPONSIBLE ORGANIZATION can be one and the same person.

NOTE 2 Education and training is included in “use.”

3.102

RISK

combination of the probability of occurrence of HARM and the SEVERITY of that HARM

[ISO 14971:2000, definition 2.13]

3.103

RISK ANALYSIS

systematic use of available information to identify HAZARDS and to estimate the RISK

[ISO 14971:2000, definition 2.14]

3.104

RISK ASSESSMENT

overall PROCESS comprising a RISK ANALYSIS and a RISK EVALUATION

[ISO 14971:2000, definition 2.15]

3.105

RISK CONTROL

PROCESS through which decisions are reached and protective measures are implemented for reducing RISKS to, or maintaining RISKS within, specified levels

[ISO 14971:2000, definition 2.16]

3.106

RISK EVALUATION

judgement, on the basis of RISK ANALYSIS, of whether a RISK which is acceptable has been achieved in a given context based on the current values of society

[ISO 14971:2000, definition 2.17]

3.107

RISK MANAGEMENT

systematic application of management policies, PROCEDURES and practices to the tasks of analyzing, evaluating and controlling RISK

[ISO 14971:2000, definition 2.18]

3.108

RISK MANAGEMENT FILE

set of RECORDS and other documents, not necessarily contiguous, that are produced by a RISK MANAGEMENT PROCESS

[ISO 14971:2000, definition 2.19]

NOTE All safety related information including MANUFACTURER'S calculations, test results, etc. is considered to be part of the RISK MANAGEMENT FILE. See also 4.2.

3.109

SAFE WORKING LOAD

maximum external mechanical load (mass) on equipment or an equipment part that is permitted in NORMAL USE

3.110

*** SECONDARY CIRCUIT**

circuit which is separated from the MAINS PART by at least one MEANS OF PROTECTION and derives its power from a transformer, converter or equivalent isolation device, or from an INTERNAL ELECTRICAL POWER SOURCE

NOTE See also 8.9.1.12.

3.111**SELF-RESETTING THERMAL CUT-OUT**

THERMAL CUT-OUT that automatically restores the current after the relevant part of electrical equipment has cooled

3.112*** SEPARATION DEVICE**

component or arrangement of components with input parts and output parts that, for safety reasons, prevents a transfer of unwanted voltage or current between parts of an ME SYSTEM

3.113**SERVICE PERSONNEL**

individuals or entity accountable to the RESPONSIBLE ORGANIZATION that install, assemble, maintain or repair ME EQUIPMENT, ME SYSTEMS or equipment

3.114**SEVERITY**

measure of the possible consequences of a HAZARD

[ISO 14971:2000, definition 2.21]

3.115*** SIGNAL INPUT/OUTPUT PART****SIP/SOP**

part of ME EQUIPMENT, not being an APPLIED PART, intended to deliver or receive signals to or from other electrical equipment, for example, for display, recording or data processing

NOTE See Figure 2.

3.116**SINGLE FAULT CONDITION**

condition in which a single means for reducing a RISK is defective or a single abnormal condition is present

NOTE See 4.7 and 13.2.

3.117**SINGLE FAULT SAFE**

characteristic of ME EQUIPMENT or its parts whereby it remains free of unacceptable RISK during its EXPECTED SERVICE LIFE under SINGLE FAULT CONDITIONS

NOTE See 4.7.

3.118**STATIONARY**

term referring to equipment that is not intended to be moved from one place to another

3.119**SUPPLEMENTARY INSULATION**

independent insulation applied in addition to BASIC INSULATION in order to provide protection against electric shock in the event of a failure of BASIC INSULATION

[IEV 826-12-15, modified]

NOTE SUPPLEMENTARY INSULATION provides one MEANS OF PROTECTION.

3.120

*** SUPPLY MAINS**

source of electrical energy not forming part of ME EQUIPMENT or ME SYSTEM

NOTE This also includes battery systems and converter systems in ambulances and the like.

3.121

TENSILE SAFETY FACTOR

ratio between TENSILE STRENGTH and the stress corresponding to the TOTAL LOAD

3.122

TENSILE STRENGTH

maximum tensile stress a test piece will withstand before rupturing

3.123

TERMINAL DEVICE

part of electrical equipment by which electrical connection is made

NOTE A TERMINAL DEVICE can contain several individual contacts.

3.124

THERMAL CUT-OUT

device that, during an abnormal condition, limits the temperature of electrical equipment or of part of it, by automatically opening the circuit or by reducing the current, and that is so constructed that its setting cannot be altered except by qualified SERVICE PERSONNEL

3.125

THERMAL STABILITY

condition under which the temperature of an object does not increase by more than 2 °C over a period of 1 h

3.126

THERMOSTAT

temperature sensing control that is intended to keep a temperature within a specific range or above/below a preset value

3.127

TOOL

extra-corporeal object that can be used to secure or release fasteners or to make adjustments

NOTE Coins and keys are considered TOOLS within the context of this standard.

3.128

TOTAL LOAD

maximum total loading of a part including the maximum SAFE WORKING LOAD, where applicable, and the static and dynamic forces occurring in NORMAL USE

NOTE 1 Examples of dynamic forces include forces caused by acceleration or deceleration of masses.

NOTE 2 Where a load is divided over several parallel supporting parts and the distribution over these parts is not determined unequivocally, the least favourable possibility is to be considered.

3.129**TOUCH CURRENT**

LEAKAGE CURRENT flowing from the ENCLOSURE or from parts thereof, excluding PATIENT CONNECTIONS, accessible to any OPERATOR or PATIENT in NORMAL USE, through an external path other than the PROTECTIVE EARTH CONDUCTOR, to earth or to another part of the ENCLOSURE

NOTE The meaning of this term is the same as that of “enclosure leakage current” in the first and second editions of this standard. The term has been changed to align with IEC 60950-1 and to reflect the fact that the measurement now applies also to parts that are normally PROTECTIVELY EARTHED.

3.130**TRANSPORTABLE**

term referring to equipment that is intended to be moved from one place to another whether or not connected to a supply and without an appreciable restriction of range

EXAMPLE MOBILE equipment and PORTABLE equipment.

3.131**TRAPPING ZONE**

accessible location on or within the ME EQUIPMENT, ME SYSTEM or in the equipment environment where a human body or a part of the human body is exposed to a trapping, crushing, shearing, impact, cutting, entanglement, drawing in, stabbing or abrasion HAZARD

3.132*** TYPE B APPLIED PART**

APPLIED PART complying with the specified requirements of this standard to provide protection against electric shock, particularly regarding allowable PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT

NOTE 1 A TYPE B APPLIED PART is marked with symbol IEC 60417-5840 (DB:2002-10) (see Table D.1, symbol 19) or, when applicable, with symbol IEC 60417-5841 (DB:2002-10) (see Table D.1, symbol 25). See also 3.20.

NOTE 2 TYPE B APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.

NOTE 3 See also 4.6 regarding the treatment of parts that do not fall within the definition of APPLIED PARTS but need to be considered as APPLIED PARTS as a result of applying the RISK MANAGEMENT PROCESS.

3.133*** TYPE BF APPLIED PART**

F-TYPE APPLIED PART complying with the specified requirements of this standard to provide a higher degree of protection against electric shock than that provided by TYPE B APPLIED PARTS

NOTE 1 A TYPE BF APPLIED PART is marked with symbol IEC 60417-5333 (DB:2002-10) (see Table D.1, symbol 20) or, when applicable, with symbol 60417-5334 (DB:2002-10) (see Table D.1, symbol 26). See also 3.20.

NOTE 2 TYPE BF APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.

NOTE 3 See also 4.6 regarding the treatment of parts that do not fall within the definition of APPLIED PARTS but need to be considered as APPLIED PARTS as a result of applying the RISK MANAGEMENT PROCESS.

3.134*** TYPE CF APPLIED PART**

F-TYPE APPLIED PART complying with the specified requirements of this standard to provide a higher degree of protection against electric shock than that provided by TYPE BF APPLIED PARTS

NOTE 1 A TYPE CF APPLIED PART is marked with symbol IEC 60417-5335 (DB:2002-10) (see Table D.1, symbol 21) or, when applicable, with symbol 60417-5336 (DB:2002-10) (see Table D.1, symbol 27). See also 3.20.

NOTE 2 See also 4.6 regarding the treatment of parts that do not fall within the definition of APPLIED PARTS but need to be considered as APPLIED PARTS as a result of applying the RISK MANAGEMENT PROCESS.

3.135

TYPE TEST

test on a representative sample of the equipment with the objective of determining if the equipment, as designed and manufactured, can meet the requirements of this standard

3.136

USABILITY

characteristic that establishes effectiveness, efficiency and OPERATOR learnability and satisfaction

[IEC 60601-1-6:2004, definition 2.211]

3.137

USABILITY ENGINEERING

application of knowledge about human behaviour, abilities, limitations, and other characteristics to the design of tools, machines, equipment, devices, systems, tasks, jobs, and environments to achieve adequate USABILITY

[IEC 60601-1-6:2004, definition 2.212]

3.138

VERIFICATION

confirmation by examination and provision of OBJECTIVE EVIDENCE that specified requirements have been fulfilled

NOTE In design and development, VERIFICATION concerns the PROCESS of examining the result of a given activity to determine conformity with the stated requirements for that activity.

[ISO 14971:2000, definition 2.22]

3.139

*** WORKING VOLTAGE**

highest voltage to which the insulation or the component under consideration is, or can be, subjected when the electrical equipment is operating under conditions of NORMAL USE

[IEC 60950-1:2001, definition 1.2.9.6]

4 General requirements

4.1 * Conditions for application to ME EQUIPMENT or ME SYSTEMS

Unless otherwise specified, the requirements of this standard shall apply in NORMAL USE and reasonably foreseeable misuse.

When applying this standard to ME EQUIPMENT or ME SYSTEMS intended for the compensation or alleviation of disease, injury or disability, the definitions and requirements that use the term PATIENT shall be considered as applying to the person for whom the ME EQUIPMENT or ME SYSTEM is intended.

4.2 * RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

A RISK MANAGEMENT PROCESS complying with ISO 14971 shall be performed.

In applying ISO 14971:

- The term “medical device” shall assume the same meaning as ME EQUIPMENT or ME SYSTEM.

- The term “fault conditions” referred to in ISO 14971 shall include, but shall not be limited to, SINGLE FAULT CONDITIONS identified in this standard.
- The policy for determining acceptable RISK and the acceptability of the RESIDUAL RISK(S) shall be established by the MANUFACTURER.
- Where this standard or any of its collateral or particular standards specify verifiable requirements addressing particular RISKS, and these requirements are complied with, the RESIDUAL RISKS addressed by these requirements shall be presumed to be acceptable unless there is OBJECTIVE EVIDENCE to the contrary.

NOTE 1 This standard specifies requirements that are generally applicable to RISKS associated with ME EQUIPMENT or ME SYSTEMS, and is intended to serve as a tool during the RISK MANAGEMENT PROCESS. The RISK MANAGEMENT PROCESS should identify not only those HAZARDS addressed by this standard, but all HAZARDS, their associated RISKS and RISK CONTROL measures.

NOTE 2 Conditions or faults that can give rise to HAZARDS are identified in the clauses of this standard. In these cases, it will often be necessary to carry out a RISK MANAGEMENT PROCESS to determine what the actual HAZARDS are and the tests that need to be done to show that the identified HAZARDS do not arise in the specified circumstances.

NOTE 3 It is recognized that the MANUFACTURER might not be able to follow all the PROCESSES identified in this standard for each constituent component of the ME EQUIPMENT or ME SYSTEM, such as proprietary components, subsystems of non-medical origin, and legacy devices. In this case, the MANUFACTURER should take special account of the need for additional RISK CONTROL measures.

NOTE 4 Where requirements of this standard refer to freedom from unacceptable RISK, acceptability or unacceptability of this RISK is determined by the MANUFACTURER in accordance with the MANUFACTURER'S policy for determining acceptable RISK.

NOTE 5 Not all the RISKS associated with ME EQUIPMENT and ME SYSTEMS are subject to specific requirements of this standard (see 1.1).

Compliance is checked by inspection of the RISK MANAGEMENT FILE. The requirements of this clause and all requirements of this standard referring to inspection of the RISK MANAGEMENT FILE are considered to be satisfied if the MANUFACTURER has:

- *established a RISK MANAGEMENT PROCESS;*
- *established acceptable levels of RISK; and*
- *demonstrated that the RESIDUAL RISK(S) is acceptable (in accordance with the policy for determining acceptable RISK).*

4.3 * ESSENTIAL PERFORMANCE

The MANUFACTURER shall identify which functions of the ME EQUIPMENT and ME SYSTEMS are ESSENTIAL PERFORMANCE. Where this standard specifies that ESSENTIAL PERFORMANCE is to be maintained following a particular test, these functions shall be used and compliance shall be checked by inspection, and if necessary, by functional test.

NOTE Where requirements of this standard refer to ESSENTIAL PERFORMANCE, that ESSENTIAL PERFORMANCE is determined by the MANUFACTURER in accordance with the MANUFACTURER'S policy for RISK acceptability.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

4.4 * EXPECTED SERVICE LIFE

The MANUFACTURER shall state the EXPECTED SERVICE LIFE of the ME EQUIPMENT or ME SYSTEM in the RISK MANAGEMENT FILE.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

4.5 * Equivalent safety for ME EQUIPMENT or ME SYSTEMS

Where this standard specifies requirements addressing particular RISKS, alternative means of addressing these RISKS are acceptable provided that the MANUFACTURER can justify that the RESIDUAL RISKS that result from applying the alternative means are equal to or less than the RESIDUAL RISKS that result from applying the requirements of this standard.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

4.6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT

The RISK MANAGEMENT PROCESS shall include an assessment of whether parts that can come into contact with the PATIENT but fall outside of the definition of APPLIED PARTS shall be subject to the requirements for APPLIED PARTS. If the RISK MANAGEMENT PROCESS determines that such parts are subject to the requirements for APPLIED PARTS, then all the relevant requirements and tests of this standard shall apply, except that 7.2.10 does not apply to such parts.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

4.7 * SINGLE FAULT CONDITION for ME EQUIPMENT

ME EQUIPMENT shall be so designed and manufactured that it remains SINGLE FAULT SAFE, or the RISK remains acceptable as determined through application of 4.2.

NOTE 1 The NORMAL CONDITIONS identified in 8.1 a) are taken into consideration during evaluation of compliance with any requirement of this standard that they might affect.

ME EQUIPMENT is considered SINGLE FAULT SAFE if:

- a) it employs a single means for reducing a RISK that has a negligible probability of failure (e.g. REINFORCED INSULATION, suspended masses without MECHANICAL PROTECTIVE DEVICES employing a TENSILE SAFETY FACTOR of 8X, COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS), or
- b) a SINGLE FAULT CONDITION occurs, but:
 - the initial fault will be detected during the EXPECTED SERVICE LIFE of the ME EQUIPMENT and before a second means for reducing a RISK fails (e.g. suspended masses with MECHANICAL PROTECTIVE DEVICES); or
 - the probability that the second means of reducing the RISK will fail during the EXPECTED SERVICE LIFE of the ME EQUIPMENT is negligible.

Where a SINGLE FAULT CONDITION causes another SINGLE FAULT CONDITION, the two failures are considered as one SINGLE FAULT CONDITION.

During any test under SINGLE FAULT CONDITION, only one fault at a time shall be applied.

NOTE 2 Faults are generally divided into 3 probability categories:

- a) so remote that they can be ignored. The RISKS arising from these faults are considered acceptable;
- b) probable enough that they need to be considered, but improbable enough that they need only be considered one at a time (single fault). Faults of this category include all those identified as SINGLE FAULT CONDITIONS in this standard, and any other faults identified in applying ISO 14971 that meet the SINGLE FAULT CONDITION criteria;
- c) so likely, so unpredictable or undetectable that they are considered to be a NORMAL CONDITION and need to be considered individually and collectively.

The results of the RISK ANALYSIS shall be used to determine which failures shall be tested. The failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those mentioned in 13.1, shall be simulated, physically or theoretically. The evaluation of whether a component is subject to failure simulation shall take into account the RISK associated with the failure of the component during the EXPECTED SERVICE LIFE of the ME EQUIPMENT. This evaluation shall be accomplished by applying the principles of RISK MANAGEMENT. The evaluation shall take into account issues such as reliability, TENSILE SAFETY FACTORS and rating of components. Additionally, during the simulation of SINGLE FAULT CONDITIONS, component failures that are highly probable or undetectable shall be simulated.

NOTE 3 See also Note 2 in 4.2.

This requirement and relevant tests shall not be applied to failures of DOUBLE or REINFORCED INSULATION or COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS.

Compliance is determined by applying the specific requirements and tests associated with the SINGLE FAULT CONDITIONS identified in 13.2, and tests for the failures identified from evaluation of the results of the RISK ANALYSIS. Compliance is confirmed if the introduction of any of the SINGLE FAULT CONDITIONS described in 13.2, one at a time, does not lead directly to the HAZARDOUS SITUATIONS described in 13.1, or any other outcome that results in an unacceptable RISK.

4.8 Components of ME EQUIPMENT

All components, including wiring, the failure of which could result in a HAZARDOUS SITUATION shall be used in accordance with their specified ratings unless a specific exception is made in this standard or through the RISK MANAGEMENT PROCESS. The reliability of components that are used as MEANS OF PROTECTION shall be assessed for the conditions of use in the ME EQUIPMENT. They shall comply with one of the following (see also 4.5):

- a) the applicable safety requirements of a relevant IEC or ISO standard;

NOTE 1 For the components, it is not necessary to carry out identical or equivalent tests already performed to check compliance with the component standard.

- b) where there is no relevant IEC or ISO standard, the requirements of this standard have to be applied.

NOTE 2 If there are neither requirements in this standard nor in an IEC or ISO standard, any other applicable source (e.g. standards for other types of devices, national standards) could be used to demonstrate compliance with the RISK MANAGEMENT PROCESS.

See Figure 5 for a schematic flow chart for a) and b).

Compliance is checked by inspection and, where necessary, by test. The tests of this standard for motors (see 13.2.8 and 13.2.13.3) and transformers (see 15.5.3) are considered to be comprehensive and together with the evaluation of the motor or transformer insulation system according to Table 22 represent all testing required by this standard. ME SYSTEM components that provide isolation from non-ME EQUIPMENT are evaluated to Clause 16.

4.9 * Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT

A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS shall be used when a fault in a particular component can generate an unacceptable RISK. COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS shall be selected and evaluated consistent with their conditions of use and reasonably foreseeable misuse during the EXPECTED SERVICE LIFE of the ME EQUIPMENT.