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(JEITA)

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

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Foreword

This translation has been made based on the original Japanese Industrial Standard revised by the Minister of Health, Labour and Welfare and the Minister of Economy, Trade and Industry, through deliberations at the Japanese Industrial Standards Committee as the result of proposal for revision of Japanese Industrial Standard submitted by Japan Electronics and Information Technology Industries Association (JEITA) with the draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law applicable to the case of revision by the provision of Article 14.

Consequently JIS T 0601-1 : 1999 has been revised and replaced with this Standard.

This JIS document is protected by the Copyright Law.

Attention is drawn to the possibility that some parts of this Standard may conflict with patent rights, applications for a patent after opening to the public, or utility model rights. The relevant Ministers and the Japanese Industrial Standards Committee are not responsible for identifying any of such patent rights, applications for a patent after opening to the public and utility model rights.

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

Introduction

This Japanese Industrial Standard has been prepared based on the third edition of IEC 60601-1 published in 2005 with some modifications of the technical contents in order to reflect the actual conditions in Japan.

The portions with continuous sidelines or dotted underlines in this Standard are the matters in which the contents of the corresponding International Standard have been modified. A list of modifications with explanations is given in Annex JC.

As for the portions with an asterisk (*) in clauses and subclauses, etc. of this Standard, the explanation of the grounds are given in Annex A.

In this Standard, the capital letters in the text mean terms defined in clause 3 of this Standard. If not indicated in capital letters, the terms defined in the Standard mentioned above are interpreted in context without applying the definition.

1 Scope, object and related standards

1.1 * Scope

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

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

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

NOTE 1 See also 4.2.

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

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

NOTE 2 The International Standards corresponding to this Standard and the symbol of degree of correspondence are as follows.

IEC 60601-1: 2005 *Medical electrical equipment—Part 1: General requirements for basic safety and essential performance* (MOD)

In addition, symbols, which denote the degree of correspondence in the contents between the relevant International Standard and JIS are IDT (identical), MOD (modified), and NEQ (not equivalent) according to ISO/IEC Guide 21-1.

Moreover, JIS T 0601-1: 1999 may be applied until May 31st, 2017.

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 this Standard, collateral standards specify general requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE of ME EQUIPMENT 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 its publication, establishment or revision and shall apply together with this Standard.

NOTE 1 When evaluating compliance with this Standard, it is permissible to independently assess compliance with the collateral standards.

NOTE 2 When declaring compliance with this Standard, 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 parts 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. In Japan, Japanese Industrial Standards corresponding to them needs to be also consulted.

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 this Standard 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. In Japan, Japanese Industrial Standards corresponding to them needs to be also consulted.

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

2 *Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. For standards with the year indication, only the edition of the indicated year shall apply and the revisions (including amendments) made thereafter shall not apply. For those without the indication of the year, the most recent edition (including amendments) shall apply.

Additional collateral standards of this Standard, which are issued subsequent to publication or revision of this Standard, become normative at the date of their publication or revision and shall be considered as being included among the normative references below (see 1.3).

NOTE : Informative references are listed in the Bibliography on the end of this Standard.

JIS B 7761-3 *Hand-transmitted vibration—Part 3: General requirements for measurement and evaluation*

NOTE : Corresponding International Standard : ISO 5349-1 *Mechanical vibration—Measurement and evaluation of human exposure to hand-transmitted vibration—Part 1: General requirements* (IDT)

JIS B 9707 *Safety of machinery—Safety distances to prevent danger zones being reached by the upper limbs*

NOTE : Corresponding International Standard : ISO 13852 *Safety of machinery—Safety distances to prevent danger zones being reached by the upper limbs* (IDT)

JIS B 9711 *Safety of machinery—Minimum gaps to avoid crushing of parts of the human body*

NOTE : Corresponding International Standard : ISO 13854 *Safety of machinery—Minimum gaps to avoid crushing of parts of the human body* (IDT)

In IEC 60601-1:2005, ISO 13852 *Safety of machinery—Safety distances to prevent danger zones being reached by the upper limbs* is taken as a normative reference. However, this Standard specifies the distance to prevent danger zones being reached by the upper limbs, the palm and fingers, but does not specify the minimum gap to avoid crushing of these parts.

JIS C 0445 *Identification of equipment terminals and of terminations of certain designated conductors, including general rules for an alphanumeric system*

NOTE : Corresponding International Standard : 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* (IDT)

JIS C 0447 *Man-machine interface (MMI)—Actuating principles*

NOTE : Corresponding International Standard : IEC 60447 *Basic and safety principles for man-machine interface, marking and identification—Actuating principle* (IDT)

JIS C 0920:2003 *Degrees of protection provided by enclosures (IP Code)*

NOTE 1 Corresponding International Standard : IEC 60529:2001 *Degrees of protection provided by enclosures (IP Code)* (IDT)

NOTE 2 In IEC 60601-1:2005, IEC 60529:1989 and Amendment 1:1999 are taken as a normative reference. However, presently, Edition 2.1 published in 2001 is available, and then the Japanese Industrial Standard corresponding to it is taken as a normative reference herein.

JIS C 1509-1 *Electroacoustics—Sound level meters—Part 1: Specifications*

NOTE : Corresponding International Standard : IEC 61672-1 *Electroacoustics—Sound level meters—Part 1: Specifications* (IDT)

JIS C 1509-2 *Electroacoustics—Sound level meters—Part 2: Pattern evaluation tests*

NOTE : Corresponding International Standard : IEC 61672-2 *Electroacoustics—Sound level meters—Part 2: Pattern evaluation tests* (IDT)

JIS C 2134 *Method for the determination of the proof and the comparative tracking indices of solid insulating materials*

NOTE : Corresponding International Standard : IEC 60112 *Method for the determination of the proof and the comparative tracking indices of solid insulating materials* (IDT)

JIS C 3301:2000 *Rubber insulated flexible cords*

NOTE : Corresponding International Standard : IEC 60245-4:1994 *Rubber insulated cables of rated voltages up to and including 450/750 V—Part 4: Cords and flexible cables*, Amendment 1:1997 (NEQ)

JIS C 3306:2000 *Polyvinyl chloride insulated flexible cords*

NOTE : Corresponding International Standard : IEC 60227-5:1997 *Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V—Part 5: Flexible cables (cords)* (NEQ)

JIS C 4003 *Electrical insulation—Thermal evaluation and designation*

NOTE : Corresponding International Standard : IEC 60085 *Electrical insulation—Thermal evaluation and designation* (MOD)

JIS C 5101-14:2009 *Fixed capacitors for use in electronic equipment—Part 14: Sectional specification: Fixed capacitors for electromagnetic interference suppression and connection to the supply mains*

NOTE : Corresponding International Standard : 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* (IDT)

JIS C 6065:2007 *Audio, video and similar electronic apparatus—Safety requirements*

NOTE : Corresponding International Standard : IEC 60065:2001 *Audio, video and similar electronic apparatus—Safety requirements* (MOD)

JIS C 6802:2005 *Safety of laser products*

NOTE : Corresponding International Standard : IEC 60825-1:1993 *Safety of laser products—Part 1: Equipment classification, requirements and user's guide*, Amendment 1:1997 and Amendment 2 :2001 (IDT)

JIS C 6965 *Mechanical safety of cathode ray tubes*

NOTE : Corresponding International Standard : IEC 61965 *Mechanical safety of cathode ray tubes* (IDT)

JIS C 8282-1 *Plugs and socket-outlets for household and similar purposes—Part 1: General requirements*

NOTE : Corresponding International Standard : IEC 60884-1 *Plugs and socket-outlets for household and similar purposes—Part 1: General requirements* (MOD)

JIS C 8303 *Plugs and receptacles for domestic and similar general use*

NOTE : Corresponding International Standard : Not specified. The said standard is adopted as a normative reference corresponding to IEC 60083 *Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC* adopted as a reference in IEC 60601-1:2005. See also JIS T 1021 [55].

JIS C 60068-2-2:1995 *Environmental testing—Part 2-2 : Tests—Test B: Dry heat*

NOTE : Corresponding International Standard : IEC 60068-2-2:1974 *Environmental testing—Part 2: Tests. Tests B: Dry heat*, Amendment 1:1993 and Amendment 2:1994 (IDT)

JIS C 60079-0 *Explosive atmospheres—Part 0: Equipment—General requirements*

NOTE : Corresponding International Standard : IEC 60079-0 *Electrical apparatus for explosive gas atmospheres—Part 0: General requirements* (IDT)

JIS C 60079-2 *Electrical apparatus for explosive gas atmospheres—Part 2: Pressurized enclosure “p”*

NOTE : Corresponding International Standard : IEC 60079-2 *Electrical apparatus for explosive gas atmospheres—Part 2: Pressurized enclosures “p”* (IDT)

JIS C 60079-6 *Electrical apparatus for explosive gas atmospheres—Part 6: Oil immersion “o”*

NOTE : Corresponding International Standard : IEC 60079-6 *Electrical apparatus for explosive gas atmospheres—Part 6: Oil-immersion “o”* (IDT)

JIS C 60364-4-41 *Low-voltage electrical installations—Part 4-41: Protection for safety—Protection against electric shock*

NOTE : Corresponding International Standard : IEC 60364-4-41 *Electrical installations of buildings—Part 4-41: Protection for safety—Protection against electric shock* (IDT)

JIS C 60664-1:2009 *Insulation coordination for equipment within low-voltage systems—Part 1: Principles, requirements and tests*

NOTE 1 Corresponding International Standard : IEC 60664-1:2007 *Insulation coordination for equipment within low-voltage systems—Part 1: Principles, requirements and tests* (IDT)

NOTE 2 In IEC 60601-1:2005, IEC 60664-1:1992, Amendment 1:2000 and Amendment 2:2002 are taken as a normative reference. However, there are no JIS corresponding to this International Standard, and then the said standard mentioned above corresponding to the latest International Standard is taken as a normative reference.

JIS C 60695-11-10 *Fire hazard testing—Part 11-10: Test flames—50 W horizontal and vertical flame test methods*

NOTE : Corresponding International Standard : IEC 60695-11-10 *Fire hazard testing—Part 11-10: Test flames—50 W horizontal and vertical flame test methods* (IDT)

JIS T 0307 *Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied*

NOTE : Corresponding International Standard : ISO 15223 *Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied* (IDT)

JIS T 0601-1-3 *Medical electrical equipment—Part 1-3: General requirements for basic safety and essential performance—Collateral Standard: Radiation protection in diagnostic X-ray equipment*

NOTE : Corresponding International Standard : 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* (IDT)

JIS T 14971:2003 *Medical devices—Application of risk management to medical devices*

NOTE : Corresponding International Standard : ISO 14971:2000 *Medical devices—Application of risk management to medical devices* (IDT)

JIS Z 8202 series *Quantities and units*

NOTE : Corresponding International Standard to JIS Z 8202 series mentioned above : ISO 31 (all parts) *Quantities and units* (IDT)

JIS Z 8203 *SI units and recommendations for the use of their multiples and of certain other units*

NOTE : Corresponding International Standard : ISO 1000 *SI units and recommendations for the use of their multiples and of certain other units* (IDT)

JIS Z 8736-1 *Acoustics—Determination of sound power levels of noise sources using sound intensity—Part 1: Measurement at discrete points*

NOTE : Corresponding International Standard : **ISO 9614-1** *Acoustics—Determination of sound power levels of noise sources using sound intensity—Part 1: Measurement at discrete points* (IDT)

JIS Z 9101:2005 *Safety colours and safety signs—Design principles for safety signs in workplaces and public areas*

NOTE : Corresponding International Standard : **ISO 3864-1:2002** *Graphical symbols—Safety colours and safety signs—Part 1: Design principles for safety signs in workplaces and public areas* (IDT)

ISO 780 *Packaging—Pictorial marking for handling of goods*

NOTE : Corresponding Japanese Industrial Standard : **JIS Z 0150** *Packaging—Pictorial marking for handling of goods* (MOD)

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

NOTE : Corresponding Japanese Industrial Standard : **JIS K 6271** *Rubber, vulcanized or thermoplastic—Determination of volume and surface resistivity* (MOD)

ISO 2878 *Rubber—Antistatic and conductive products—Determination of electrical resistance*

ISO 2882 *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 7000-DB:2004 *Graphical symbols for use on equipment—Index and synopsis*

NOTE : “DB” means to the **ISO-IEC** Online Database.

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

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

NOTE : Corresponding Japanese Industrial Standard : **JIS T 0993-1** *Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process* (MOD) However, in JIS, only Part 1 and Part 7 (*Ethylene oxide sterilization residuals*) of this standard series has been established.

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

NOTE : Corresponding Japanese Industrial Standard : At this time, JIS corresponding to the said standard and the corresponding International Standard are as follows.

JIS T 0816-1:2010 *Sterilization of health care products—moist heat—Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 17665-1:2006 *Sterilization of health care products—Moist heat—Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (IDT)*

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

NOTE : Corresponding Japanese Industrial Standard : At this time, **JIS** corresponding to the said standard and the corresponding International Standard are as follows.

JIS T 0801-1:2010 *Sterilization of health care products—Ethylene oxide—Part 1: Requirements for development, validation and routine control of a sterilization process for medical device*

ISO 11135-1:2007 *Sterilization of health care products—Ethylene oxide—Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (IDT)*

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

NOTE : Corresponding Japanese Industrial Standard : At this time, **JIS** corresponding to the said standard and the corresponding International Standard are as follows.

JIS T 0806-1:2010 *Sterilization of health care products—Radiation—Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1:2006 *Sterilization of health care products—Radiation—Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (IDT)*

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

NOTE : Corresponding Japanese Industrial Standard : **JIS K 6250** *Rubber—General procedures for preparing and conditioning test pieces for physical test methods (MOD)*

IEC 60079-5 *Explosive gas atmospheres—Part 5: Equipment protection by powder filling “q”*

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

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

NOTE : Corresponding Japanese Industrial Standard : **JIS C 8513** *Safety of primary lithium batteries (MOD)*

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

NOTE : Corresponding Japanese Industrial Standard : **JIS C 6575-1** *Miniature fuses—Part 1: Definitions of miniature fuses and general requirements for miniature fuse-links* (MOD)

IEC 60227-1:1993 *Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V—Part 1: General requirements*, Amendment 1:1995 and Amendment 2:1998

NOTE : Corresponding Japanese Industrial Standard : **JIS C 3662-1:2009** *Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V—Part 1: General requirements* (MOD)

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

NOTE : Corresponding Japanese Industrial Standard : **JIS C 3663-1:2007** *Rubber insulated cables—Rated voltages up to and including 450/750 V —Part 1: General requirements* (MOD)

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*

NOTE : Corresponding Japanese Industrial Standard : **JIS C 8283-1** *Appliance couplers for household and similar general purposes—Part 1: General requirements* (MOD)

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

NOTE : Corresponding Japanese Industrial Standard : **JIS C 9335-1:2003** *Household and similar electrical appliances—Safety—Part 1: General requirements* (MOD)

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

NOTE : DB (Database) means the system available on ISO-IEC online.

IEC 60601-1-2 *Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic compatibility—Requirements and tests*

NOTE 1 The existing corresponding Japanese Industrial Standard “**JIS T 0601-1-2:2012** *Medical electrical equipment—Part 1-2: General requirements for safety—Electromagnetic compatibility—Requirements and tests*” is JIS corresponding to IEC 60601-1-2:2001 and Amendment 1:2004.

NOTE 2 At this time, in other countries, IEC 60601-1-2 Ed2.1:2004 and IEC 60601-1-2 Ed3:2007 corresponding to the “construction” of IEC 60601-1:2005 with the same contents are used.

IEC 60601-1-6 *Medical electrical equipment—Part 1-6: General requirements for basic safety and essential performance—Collateral standard: Usability*

NOTE : IEC 62336 may be applied as the corresponding International Standard.

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

NOTE : Corresponding Japanese Industrial Standard : Presently, in process of preparing the draft.

IEC 60730-1:1999 *Automatic electrical controls for household and similar use—Part 1: General requirements*, Amendment 1:2003 and Amendment 2:2007

NOTE : Corresponding Japanese Industrial Standard : JIS C 9730-1:2010 *Automatic electrical controls for household and similar use—Part 1: General requirements* (MOD)

IEC 60851-3:1996 *Winding wires—Test methods—Part 3: Mechanical properties*, Amendment 1:1997 and Amendment 2:2003

IEC 60851-5:1996 *Winding wires—Test methods—Part 5: Electrical properties*, Amendment 1:1997 and Amendment 2:2004

IEC 60851-6:1996 *Winding wires—Test methods—Part 6: Thermal properties and* Amendment 1:1997

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

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*

NOTE : Corresponding Japanese Industrial Standard : JIS C 6950-1:2009 *Information technology equipment—Safety—Part 1: General requirements* (MOD)

IEC 61058-1:2000 *Switches for appliances—Part 1: General requirements and* Amendment 1:2001

NOTE : Corresponding Japanese Industrial Standard : JIS C 4526-1:2005 *Switches for appliances—Part 1: General requirements* (MOD)

IEC 61558-1:1997 *Safety of power transformers, power supply units and similar products—Part 1: General requirements and tests and* Amendment 1:1998

NOTE : While the corresponding Japanese Industrial Standard has not been established, JIS C 61558-1:2008 *Safety of power transformers, power supplies, reactors and similar products—Part 1: General requirements and tests* (MOD) is available as the JIS corresponding to IEC 61558-1:2005.

IEC 61558-2-1 *Safety of power transformers, power supplies, reactors and similar products—Part 2-1: Particular requirements and tests for separating transformers and power supplies incorporating separating transformers for general applications*

NOTE : Corresponding Japanese Industrial Standard : JIS C 61558-2-1 *Safety of power transformers, power supplies, reactors and similar products—Part 2-1: Particular requirements and tests for separating transformers and power supplies incorporating separating transformers for general applications* (MOD)

3 *Terms and definitions

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

NOTE 1 Where the terms “voltage” and “current” are used in this Standard, 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 in Annex JA.

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 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, 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 : See JIS C 60664-1, definition 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.

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 1 BASIC INSULATION provides one MEANS OF PROTECTION.

NOTE 2 IEV means International Electrotechnical Vocabulary.

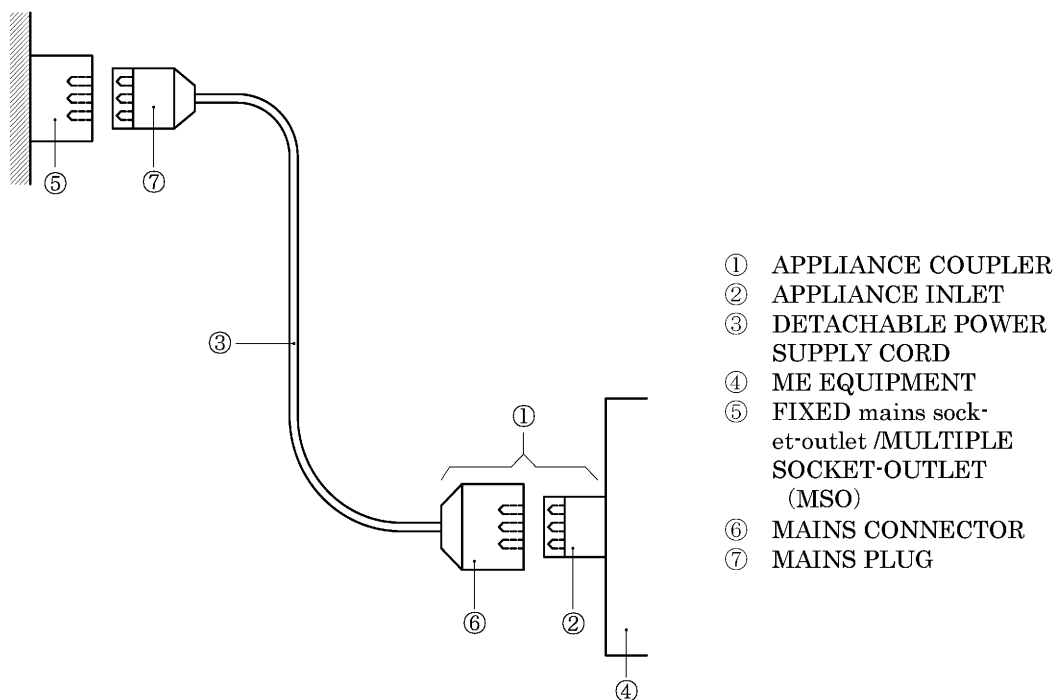


Figure 1 Detachable mains connection
(see definitions)

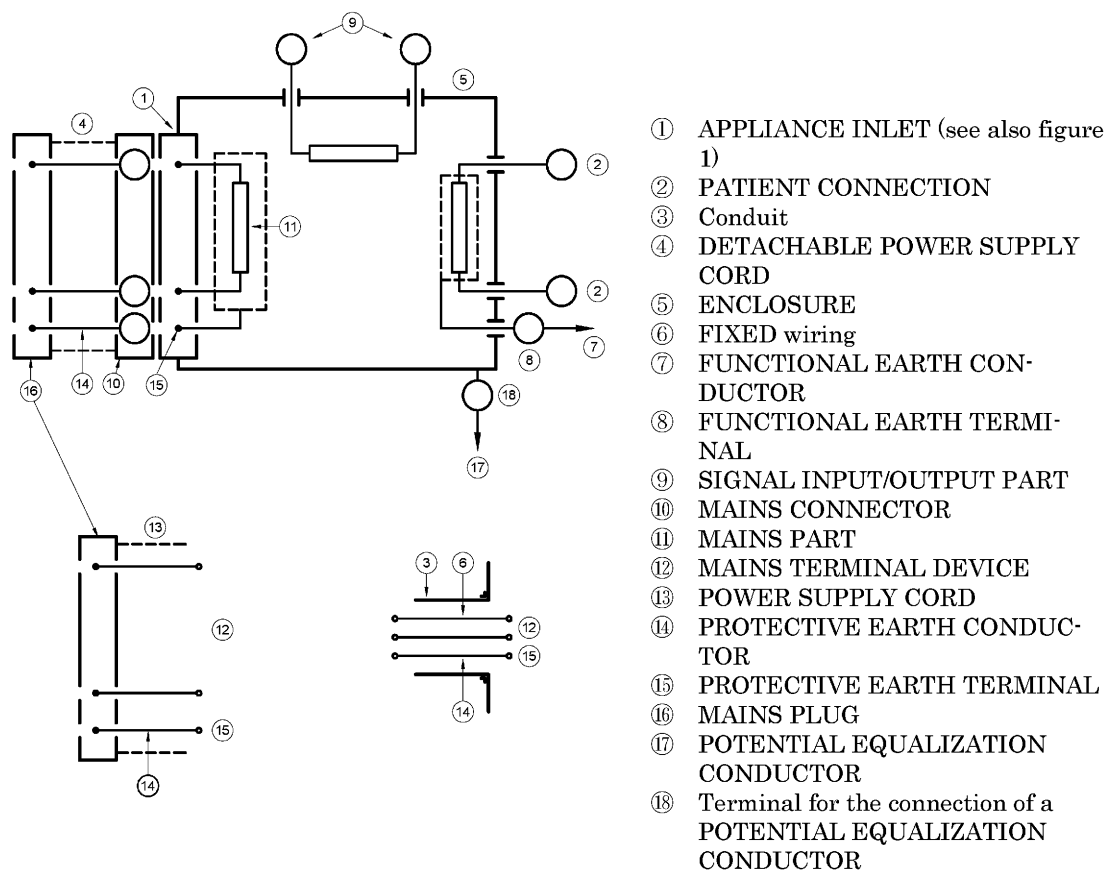


Figure 2 Example of the defined terminals and conductors
(see definitions)

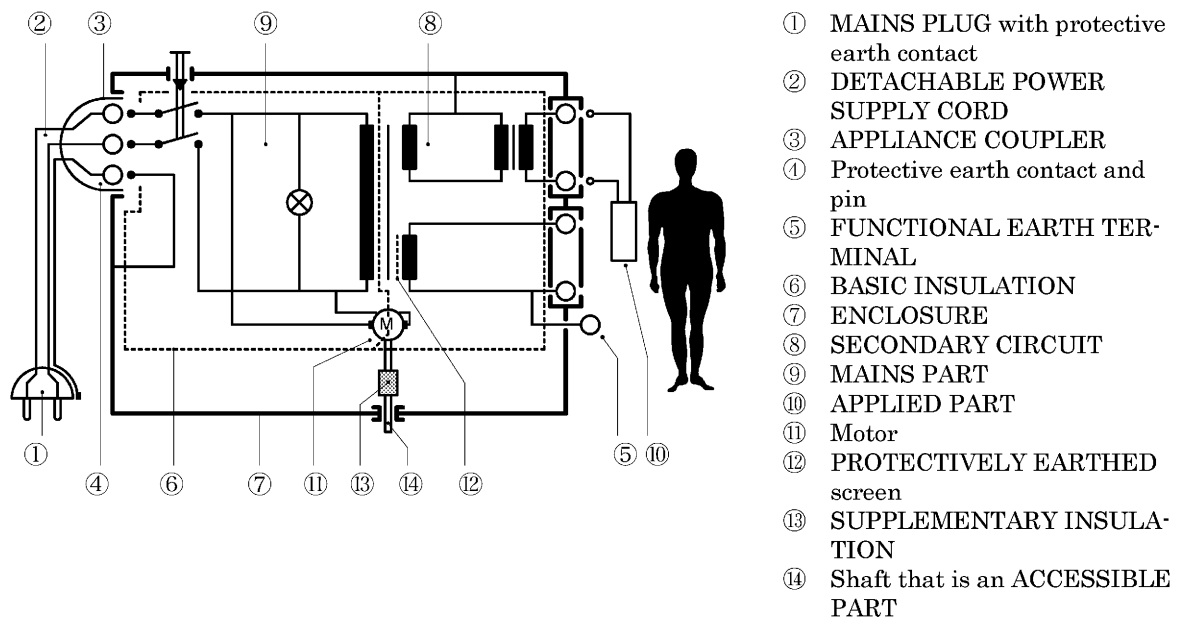


Figure 3 Example of a CLASS I ME EQUIPMENT
(see definitions)

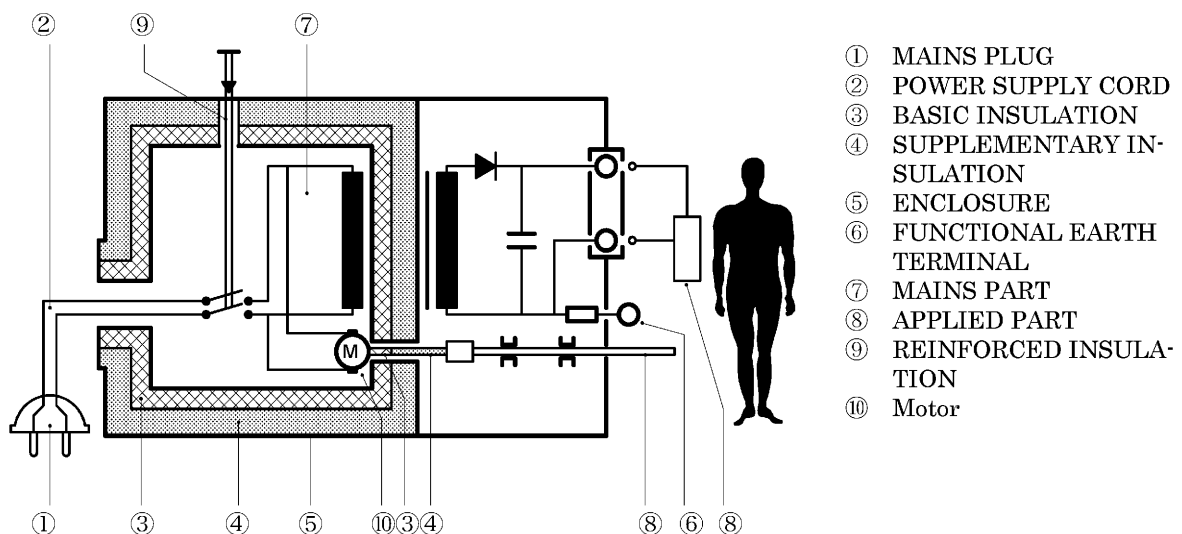


Figure 4 Example of a metal-enclosed CLASS II ME EQUIPMENT
(see definitions)

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

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

(JIS T 14971:2003, definition 2.2, modified)

3.39 HAZARD

potential source of HARM

(JIS T 14971:2003, 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

(JIS T 14971:2003, definition 2.5, modified)

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 : Some other form of energy includes chemical, mechanical, solar, or nuclear, etc.

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, and JIS T 1021.

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 any of the following:

- design, manufacture, packaging, or labelling of ME EQUIPMENT,
- assembling an ME SYSTEM,
- 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 **JIS Q 13485** defines “labelling” as follows.

It means 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 or 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 above.

NOTE 4 Adapted from **JIS T 14971:2003**, 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

NOTE : The requirement of this Standard specifies that the MECHANICAL HAZARD shall not occur. Moreover, the term, definition and its verbiage deviate from the principle of RISK MANAGEMENT. However, this Standard adopts the term and definition specified in the International Standard as is, because at this time it is difficult to revise them in terms of harmonizing this Standard with the International Standard.

Also, if the “MECHANICAL HAZARD” specified in this Standard is replaced with any one of “technical HAZARD”, “mechanical HAZARDOUS SITUATION”, “HARM” or “unacceptable RISK” in the text, it is possible to understand what to be meant in the text.

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 HAZARDOUS SITUATION or HARM 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

(JIS T 14971:2003, 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

(JIS T 14971:2003, definition 2.9)

3.89 PROCESS

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

(JIS T 14971:2003, 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

(JIS T 14971:2003, 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

(JIS T 14971:2003, 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

(JIS T 14971:2003, definition 2.13)

3.103 RISK ANALYSIS

systematic use of available information to identify HAZARDS and to estimate the RISK
(JIS T 14971:2003, definition 2.14)

3.104 RISK ASSESSMENT

overall PROCESS comprising a RISK ANALYSIS and a RISK EVALUATION
(JIS T 14971:2003, 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
(JIS T 14971:2003, 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
(JIS T 14971:2003, definition 2.17)

3.107 RISK MANAGEMENT

systematic application of management policies, PROCEDURES and practices to the tasks of analyzing, evaluating and controlling RISK
(JIS T 14971:2003, 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
(JIS T 14971:2003, 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 (HARM) of a HAZARD

(JIS T 14971:2003, 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 : A SUPPLY MAINS 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 JIS T 0601-1: 1999. 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 may be 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 19 in table D.1, or, when applicable, with symbol 25 in table D.1 (see 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 20 in table D.1 or, when applicable, with symbol 26 in table D.1 (see 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 21 in table D.1 or, when applicable, with symbol 27 in table D.1 (see 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, definition 3.11)

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, definition 3.12)

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.

(JIS T 14971:2003, 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, 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 JIS T 14971 shall be performed.

In applying JIS T 14971:

- The term “medical device” shall assume the same meaning as ME EQUIPMENT or ME SYSTEM.
- The term “fault conditions” referred to in JIS T 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 HAZARDOUS SITUATION 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 HAZARDOUS SITUATION are and the tests that need to be done to show that the identified HAZARDOUS SITUATION 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 SYSTEM are subject to specific requirements of this Standard (see 1.1).

NOTE 6 For the term, “HAZARDOUS SITUATION” used at the three positions in NOTE 2 mentioned above, the corresponding International Standard uses “HAZARD” instead. However, the usage of the term is obviously incorrect. This NOTE 2 describes the important concept about RISK MANAGEMENT, and the incorrect usage is not considered to be a simple mistake. Therefore, this Standard replaces “HAZARD” with “HAZARDOUS SITUATION” with dotted underlines. There are a number of similar mistakes throughout this Standard. These mistakes are also given dotted underlines without any NOTES.

(Test)

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, the functions determined above 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.

(Test)

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.

(Test)

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.

(Test)

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.

(Test)

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 JIS T 14971 that meet the SINGLE FAULT CONDITION criteria;
- c) so likely, so unpredictable or undetectable that they (multiple SINGLE FAULT CONDITIONS) 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.

(Test)

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 JIS, 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 **JIS**, **IEC** or **ISO** standard, the requirements of this Standard have to be applied.

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

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

(Test)

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.

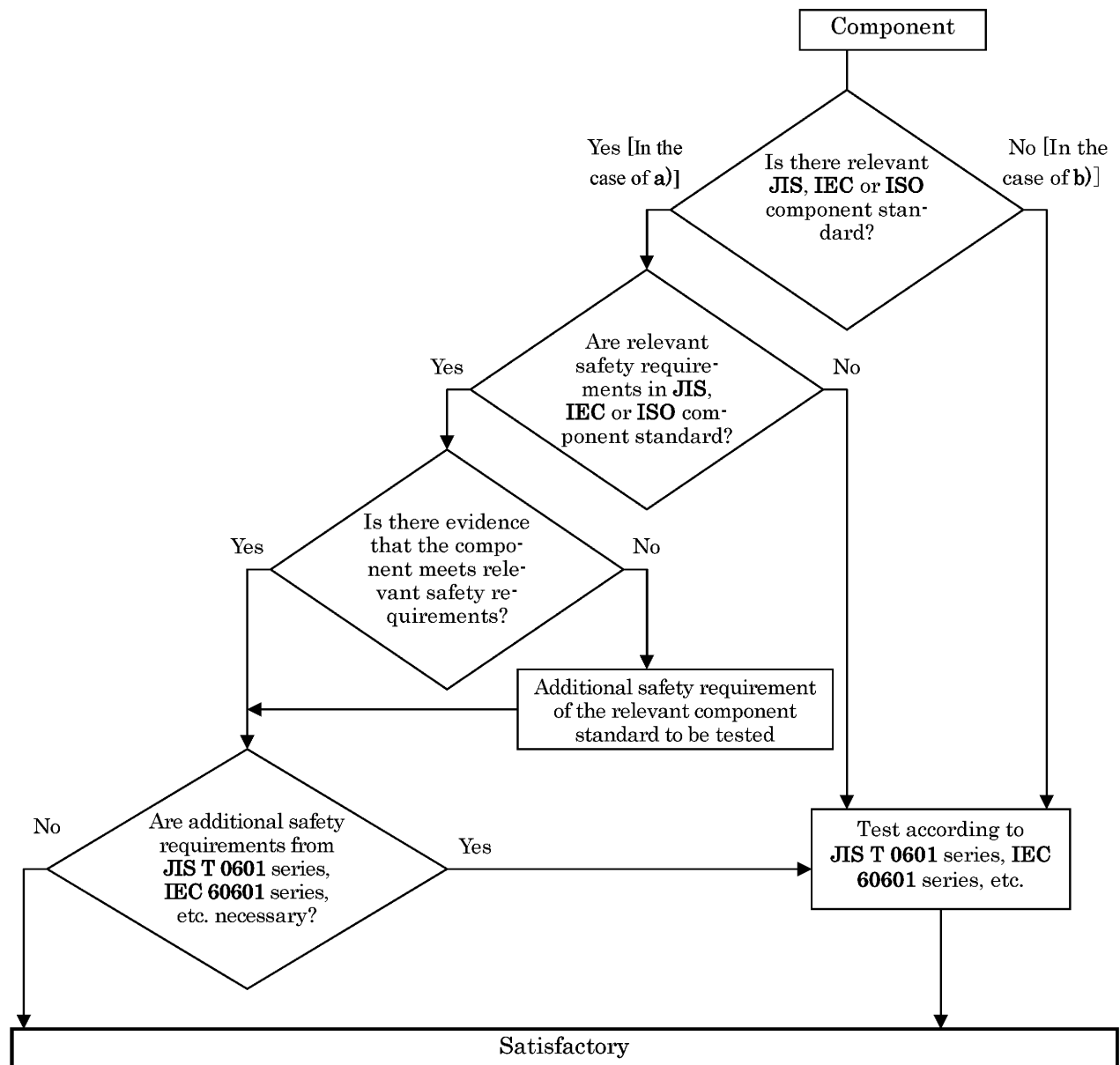


Figure 5 Schematic flow chart for component qualification
(see 4.8)

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.

(Test)

Compliance is checked by inspection of the RISK MANAGEMENT FILE and the selection criteria for the COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS.

4.10 *Power supply

4.10.1 Source of power for ME EQUIPMENT

ME EQUIPMENT shall be suitable for connection to a SUPPLY MAINS, be specified for connection to a separate power supply (e.g. a power supply of other equipment) or be powered by an INTERNAL ELECTRICAL POWER SOURCE. Alternatively, a combination of these sources may be used.

(Test)

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

4.10.2 SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

For ME EQUIPMENT intended to be connected to SUPPLY MAINS, the following RATED voltages shall not be exceeded:

- 250 V for HAND-HELD ME EQUIPMENT;
- 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input ≤ 4 kVA; or
- 500 V for all other ME EQUIPMENT and ME SYSTEMS.

SUPPLY MAINS in this Standard shall be assumed to have the following characteristics:

- overvoltage category II for SUPPLY-MAINS transients unless a higher category is specified by the MANUFACTURER;
- no voltage in excess of 110 % or lower than 90 % of the NOMINAL voltage between any of the conductors of the system or between any of these conductors and earth (see 7.9.3.1);

NOTE 1 IEC 60601-1-2 contains requirements and tests for voltage dips, short interruptions and voltage variations on the SUPPLY MAINS (see 1.3).

- voltages that are practically sinusoidal and forming a practically symmetrical supply system in case of polyphase supply;

- a frequency of ≤ 1 kHz;
- a frequency deviation of ≤ 1 Hz from the NOMINAL frequency up to 100 Hz and ≤ 1 % from the NOMINAL frequency from 100 Hz to 1 kHz;
- the protective measures as described in JIS C 60364-4-41;

NOTE 2 If ME EQUIPMENT or an ME SYSTEM is intended to be operated from a SUPPLY MAINS with characteristics different from the SUPPLY MAINS described in this subclause, additional safety measures could be necessary.

- a d.c. voltage (as measured by a moving coil meter or equivalent method) having a peak-to-peak ripple not exceeding 10 % of the average value.

Where peak-to-peak ripple exceeds 10 % of the average value, the peak voltage has to be applied.

4.11 Power input

The steady-state measured input of the ME EQUIPMENT or ME SYSTEM at RATED voltage and at operating settings indicated in the instructions for use shall not exceed the marked rating (power input) by more than 10 % (see 7.2.7).

(Test)

Compliance is checked by inspection and by the following tests.

- The ME EQUIPMENT or ME SYSTEM is operated as specified in the instructions for use until the input has reached a stable value. Input is measured and compared with markings and the contents of the technical description.
- ME EQUIPMENT or an ME SYSTEM marked with one or more RATED voltage ranges is tested at both upper and lower limits of the range, unless each marking of RATED input is related to the mean value of the relevant voltage range, in which case the test is performed at a voltage equal to the mean value of that range.
- The steady state current is measured with a true r.m.s. reading instrument.

Power input, if expressed in volt-amperes, is either measured with a volt-ampere meter or determined as the product of the steady state current (measured as described above) and the supply voltage.

A supplier certification may be used in place of the above measurement as the basis for steady state current or power input specification.

5 *General requirements for testing ME EQUIPMENT

5.1 *TYPE TESTS

The tests described in this Standard are TYPE TESTS. The tests to be performed are determined taking into consideration the requirements of clause 4, in particular 4.2.

A test need not be performed if analysis shows that the condition being tested has been adequately evaluated by other tests or methods.

The results of the RISK ANALYSIS are used to determine which combination(s) of simultaneous faults are to be tested.

NOTE : The test results might necessitate a revision of the RISK ANALYSIS.

5.2 *Number of samples

TYPE TESTS are performed on a representative sample of the item being tested.

NOTE : Multiple samples can be utilized simultaneously if the validity of the results is not significantly affected.

5.3 Ambient temperature, humidity and atmospheric pressure

The ambient temperature, humidity and atmospheric pressure shall be as follows.

- a) After the ME EQUIPMENT to be tested has been set up for NORMAL USE (according to 5.7), tests are performed within the range of environmental conditions indicated in the technical description (see 7.9.3.1).
- b) ME EQUIPMENT is shielded from other influences (for example, draughts), that might affect the validity of the tests.
- c) In cases where ambient temperatures cannot be maintained, the test conditions are to be consequently modified and results adjusted accordingly.

5.4 Other conditions

The other conditions shall be as follows.

- a) Unless otherwise specified in this Standard, ME EQUIPMENT is to be tested under the least favourable working conditions as specified in the instructions for use that are identified during RISK ANALYSIS.
- b) ME EQUIPMENT having operating values that can be adjusted or controlled by anyone other than SERVICE PERSONNEL shall be adjusted as part of the tests to values least favourable for the relevant test, but in accordance with the instructions for use.
- c) If the test results are influenced by the inlet pressure and flow or chemical composition of a cooling liquid, the test is performed within the limits for these characteristics as prescribed in the technical description.
- d) Where cooling water is required, potable water is used.

5.5 Supply voltages, type of current, nature of supply and frequency

The supply voltages, type of current, nature of supply and frequency shall be as follows.

- a) Where test results are influenced by deviations of the supply voltage from its RATED value, the effect of such deviations is taken into account.

The supply voltage during tests is according to 4.10 or according to that marked on the ME EQUIPMENT (see 7.2.6), whichever is least favourable.

- b) ME EQUIPMENT having a MAINS PART intended for connection to a.c. SUPPLY MAINS is only tested with a.c. at RATED frequency (if marked) ± 1 Hz up to and

including 100 Hz and ± 1 % above 100 Hz. ME EQUIPMENT marked with a RATED frequency range is tested at the least favourable frequency within that range.

- c) ME EQUIPMENT designed for more than one RATED voltage, or for both a.c. and d.c., is tested in conditions (described in 5.4) related to the least favourable voltage and nature of supply, for example, number of phases (except for single-phase supply) and type of current. It could be necessary to perform some tests more than once in order to establish which supply configuration is least favourable.
- d) ME EQUIPMENT having a MAINS PART intended for connection to d.c. SUPPLY MAINS is only tested with d.c. When performing the tests, the possible influence of polarity on the operation of the ME EQUIPMENT is taken into consideration, according to the instructions for use (see also 8.2.2).
- e) ME EQUIPMENT for which alternative ACCESSORIES or components specified in the ACCOMPANYING DOCUMENTS (see 7.9.2.14 and 7.9.3.2) are available is tested with those ACCESSORIES or components that give the least favourable conditions.
- f) If the instructions for use specify that ME EQUIPMENT is intended to receive its power from a separate power supply, it is connected to such a power supply (see 7.2.5 and 8.2.1).

NOTE : In this Standard, what referred to JIS T 0601-1: 1999 as a “specified power supply” is expressed as “another part”, and is now considered either as another part of the same ME EQUIPMENT or as another equipment in an ME SYSTEM.

5.6 Repairs and modifications

In the event of the necessity for repairs or modifications after a failure or a probability of future failure during the sequence of tests, the testing laboratory and the supplier of the ME EQUIPMENT for the test can agree, either upon the presentation of a new sample on which all tests influencing the result are performed again or, preferably, upon making all the necessary repairs or modifications after which only relevant tests are repeated.

5.7 *Humidity preconditioning treatment

Prior to the tests of 8.7.4 and 8.8.3, all ME EQUIPMENT or its parts shall be subjected to a humidity preconditioning treatment.

ME EQUIPMENT or its parts shall be set up complete (or where necessary partially). Covers used during transport and storage are detached.

This treatment is applied only to those ME EQUIPMENT parts which are influenced by the climatic conditions that are simulated by the test.

Parts that can be detached without the use of a TOOL are detached but are treated simultaneously with the major part.

ACCESS COVERS that can be opened or detached without the use of a TOOL are opened and detached.

The humidity preconditioning treatment is performed in a humidity cabinet containing air with a relative humidity of $93 \% \pm 3 \%$. The temperature of the air in the cabinet, at all places where ME EQUIPMENT can be located, is maintained within 2°C of any convenient value T in the range of $+ 20^{\circ}\text{C}$ to $+ 32^{\circ}\text{C}$. Before being placed in the humidity cabinet, ME EQUIPMENT shall be brought to a temperature between T and $T + 4^{\circ}\text{C}$, and kept at this temperature for at least 4 h before the humidity treatment.

ME EQUIPMENT and its parts is kept in the humidity cabinet for 48 h.

Where the RISK MANAGEMENT PROCESS suggests that the ME EQUIPMENT can be exposed to high humidity for extended periods (such as ME EQUIPMENT intended for out-door use), the period is extended appropriately.

After the treatment, the ME EQUIPMENT is reassembled, if necessary.

5.8 Sequence of tests

Unless stated otherwise, the tests in this Standard are sequenced in such a way that the results of any test do not influence the results of a subsequent test.

NOTE : It is recommended that all tests be performed in the sequence given in Annex B.

5.9 *Determination of APPLIED PARTS and ACCESSIBLE PARTS

5.9.1 APPLIED PARTS

APPLIED PARTS are identified by inspection and by reference to the ACCOMPANYING DOCUMENTS (see 4.6).

5.9.2 ACCESSIBLE PARTS

5.9.2.1 *Test finger

Parts of ME EQUIPMENT that are to be regarded as ACCESSIBLE PARTS are identified by inspection and where necessary by test. In case of doubt, accessibility is determined by a test with the standard test finger shown in figure 6, applied in a bent or straight position:

- for all positions of ME EQUIPMENT when operated as in NORMAL USE,
- even after opening of ACCESS COVERS and removal of parts, including lamps, fuses and fuseholders, without the use of a TOOL or according to the instructions for use.

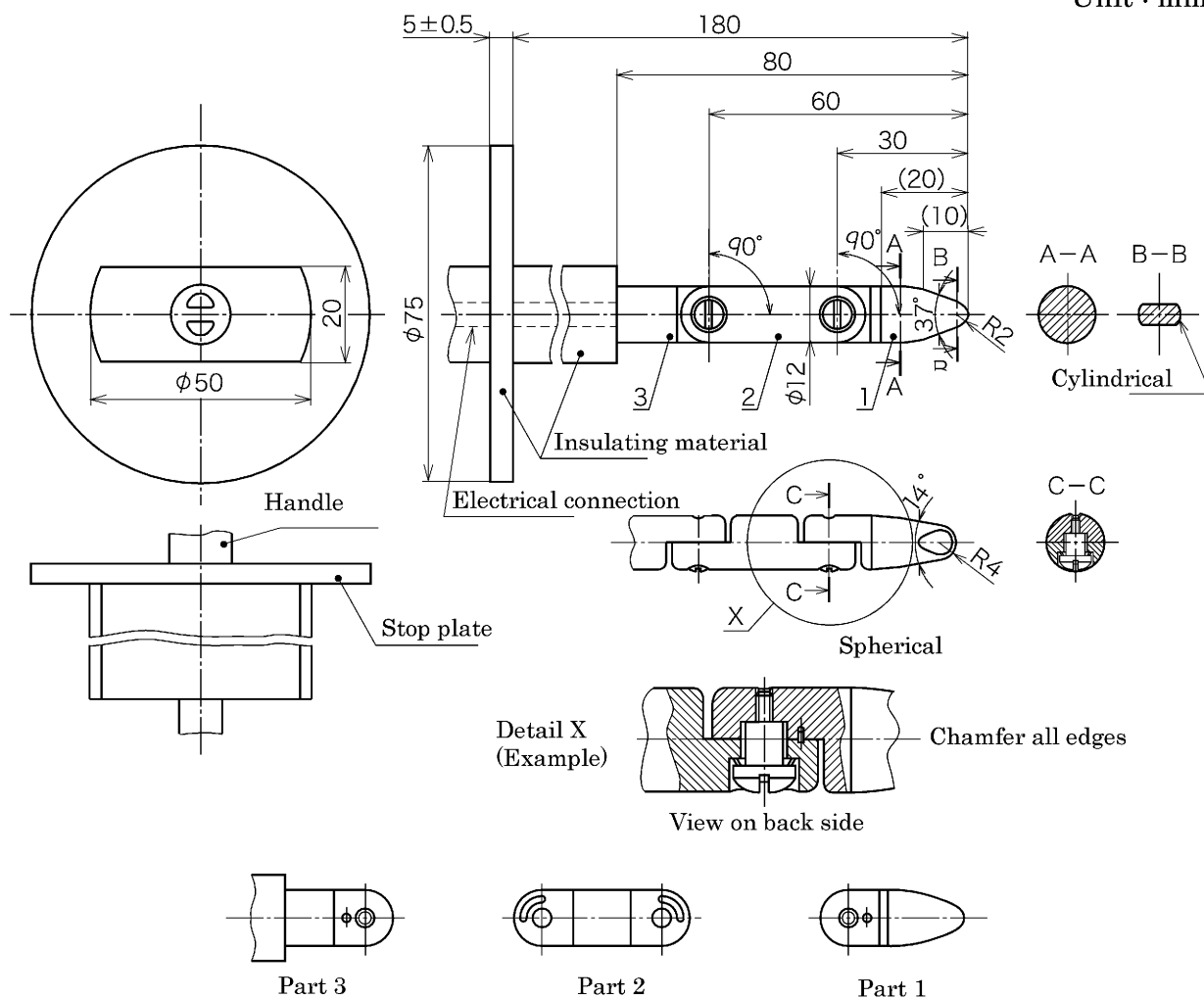
(Test)

The standard test finger is applied without appreciable force in every possible position, except that ME EQUIPMENT intended to be used on the floor and having a mass in any operational condition exceeding 45 kg is not tilted. ME EQUIPMENT which, according to the technical description, is intended for mounting into a cabinet, is tested in its final mounting position.

Openings preventing the entry of the standard test finger of figure 6 are mechanically tested by means of a straight unjointed test finger of the same dimensions, which

is applied with a force of 30 N. If this finger enters, the test with the standard test finger of figure 6 is repeated, the finger being pushed through the opening if necessary.

Unit : mm



Tolerances on dimensions without specific tolerances:

- 14° and 37° angles: $\pm 15'$
- on radii: ± 0.1 mm
- on linear dimensions:
 - ≤ 15 mm: $\begin{matrix} 0 \\ -0.1 \end{matrix}$ mm
 - > 15 mm ≤ 25 mm: ± 0.1 mm
 - > 25 mm: ± 0.3 mm

Material of finger: heat-treated steel, for example.

Both joints of this finger can be bent through an angle of $90^{\circ +10^{\circ}}_0$ but in one and the same direction only.

NOTE 1 Using the pin and groove solution is only one of the possible approaches in order to limit the bending angle to 90°. For this reason, dimensions and tolerances of these details are not given in the drawing. The actual design must insure a 90° bending angle with a 0° to +10° tolerance.

NOTE 2 Dimensions in parentheses are for information only.

NOTE 3 The test finger is taken from IEC 60950-1, figure 2A. That test finger is based on IEC 61032, figure 2, test probe B. In some cases, the tolerances are different.

Figure 6 Standard test finger
(see 5.9.2.1)