

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1 AMENDEMENT 1

**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
essentiels**



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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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FOREWORD

This amendment 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 amendment is based on the following documents:

FDIS	Report on voting
62A/805/FDIS	62A/820/RVD

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

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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INTRODUCTION TO THE AMENDMENT

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

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

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

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

FOREWORD

Replace the paragraph beginning "This third edition cancels..." with the following:

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

Add the following note at the end of the Foreword:

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

INTRODUCTION

In the second dash of the existing ninth paragraph, replace the final sentence with:

Compliance with this edition of IEC 60601-1 requires that the MANUFACTURER have in place a RISK MANAGEMENT PROCESS complying with parts of ISO 14971 (see 4.2).

After the last paragraph of the introduction, insert the following new paragraph:

Amendment 1 to this standard is intended to address:

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

1 Scope, object and related standards

1.1 * Scope

Renumber the note as Note 1.

Delete the fourth paragraph.

Replace the fifth paragraph with:

The IEC 60601 series does not apply to:

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

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

1.3 * Collateral standards

Replace Note 3 with:

NOTE 3 Collateral standards in the IEC 60601 family are numbered IEC 60601-1-xx. The IEC maintains a catalogue of valid International Standards. Users of this standard should consult this catalogue at "<http://webstore.iec.ch>" to determine which collateral standards have been published.

1.4 * Particular standards

Replace the note with:

NOTE Particular standards in the IEC 60601 family that are developed by IEC committees are numbered IEC 60601-2-xx. In addition, particular standards developed by joint projects between ISO and IEC can be numbered either IEC 80601-2-xx or ISO 80601-2-xx depending on which committee administered the project. IEC and ISO maintain catalogues of valid International Standards. Users of this standard should consult these catalogues at "<http://webstore.iec.ch>" and "<http://www.iso.org/iso/store.htm>" to determine which particular standards have been published.

2 * Normative references

Update the following normative references:

IEC 60065:2001, *Audio, video and similar electronic apparatus – Safety requirements*¹⁾
Amendment 1:2005
Amendment 2:2010

IEC 60068-2-2:2007, *Environmental testing – Part 2-2: Tests – Test B: Dry heat*

IEC 60227-1:2007, *Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V – Part 1: General requirements*

IEC 60245-1:2003, *Rubber insulated cables – Rated voltages up to and including 450/750 V – Part 1: General requirements*²⁾
Amendment 1:2007

IEC 60335-1:2010, *Household and similar electrical appliances – Safety – Part 1: General requirements*

IEC 60417, *Graphical symbols for use on equipment*. Available from: <<http://www.graphical-symbols.info/equipment>>

IEC 60601-1-3, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance: Collateral standard: Radiation protection in diagnostic X-ray equipment*

IEC 60664-1:2007, *Insulation coordination for equipment within low-voltage systems – Part 1: Principles, requirements and tests*

IEC 60730-1:2010, *Automatic electrical controls for household and similar use – Part 1: General requirements*

IEC 60825-1:2007, *Safety of laser products – Part 1: Equipment classification and requirements*

1) There exists a consolidated edition 7.2 including IEC 60065:2001 and its Amendment 1 (2005) and Amendment 2 (2010).

2) There exists a consolidated edition 4.1 including IEC 60245-1:2003 and its Amendment 1 (2007).

IEC 60851-3:2009, *Winding wires – Test methods – Part 3: Mechanical properties*

IEC 60851-5:2008, *Winding wires – Test methods – Part 5: Electrical properties*

IEC 61058-1:2000, *Switches for appliances – Part 1: General requirements*³⁾

Amendment 1:2001

Amendment 2:2007

ISO 7010:2011, *Graphical symbols – Safety colours and safety signs –Registered safety signs*

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

Replace the existing references to ISO 11135, ISO 11137, ISO 13852 and ISO 15223 by the following:

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*

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*

ISO 13857:2008, *Safety of machinery – Safety distances to prevent hazard zones being reached by the upper and lower limbs*

ISO 15223-1:2012, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*

Delete the following normative references:

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

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

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

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

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

Add the following new normative references:

IEC 62133, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications*

IEC 62304:2006, *Medical device software – Software lifecycle processes*

³⁾ There exists a consolidated edition 3.2, including IEC 61058-1:2000 and its Amendment 1 (2001) and Amendment 2 (2007)

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*

ISO 80000-1:2009, *Quantities and units – Part 1: General*

3 * Terminology and definitions

Add a new Note 3 and renumber the existing Note 3 to Note 4:

NOTE 3 When the term "safety" is used in this document in roman or italic type, it does not mean "safety" as defined in ISO 14971, but rather is used to mean "the state of being protected from or guarded against hurt or injury; freedom from danger".

3.5

AIR CLEARANCE

Replace the existing note with the following:

NOTE Adapted from IEC 60664-1:2007, definition 3.2.

Figure 2 – Example of the defined terminals and conductors

In the key, replace "Ⓜ MAINS CONDUCTOR" by "Ⓜ MAINS CONNECTOR".

3.15

CLEARLY LEGIBLE

Add an asterisk before the term and replace the existing note by the following:

NOTE See the test in 7.1.2.

3.25

EARTH LEAKAGE CURRENT

Replace the existing definition with the following:

current flowing from the MAINS PART through or across the insulation into the PROTECTIVE EARTH CONDUCTOR or a functional earthed connection according to 8.6.9

3.27

*** ESSENTIAL PERFORMANCE**

Replace the existing definition with the following:

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

3.28

EXPECTED SERVICE LIFE

Replace the existing definition with the following:

time period specified by the MANUFACTURER during which the ME EQUIPMENT or ME SYSTEM is expected to remain safe for use (i.e. maintain BASIC SAFETY and ESSENTIAL PERFORMANCE)

NOTE Maintenance can be necessary during the EXPECTED SERVICE LIFE.

3.30

FIXED

Add the following note after the examples:

NOTE See the taxonomy in the rationale for definition 3.63.

3.37

HAND-HELD

Replace the existing definition with the following:

term referring to equipment that, once installed and placed into service, is intended to be supported by the hand

NOTE 1 Equipment can refer to ACCESSORIES or equipment parts.

NOTE 2 See the taxonomy in the rationale for definition 3.63.

3.38

HARM

Replace the source citation with the following:

[ISO 14971:2007, definition 2.2, modified]

3.39

HAZARD

Replace the existing source citation with the following:

[ISO 14971:2007, definition 2.3]

3.40

HAZARDOUS SITUATION

Replace the existing source citation with the following:

[ISO 14971:2007, definition 2.4]

3.43

INSULATION CO-ORDINATION

Add a note to the existing definition as follows:

NOTE This includes insulation types, CREEPAGE DISTANCES, AIR CLEARANCES, distance through insulation, coatings, encapsulation, environmental aspects, etc.

3.44

* INTENDED USE

INTENDED PURPOSE

Delete the asterisk in front of the term and replace the existing definition and note with the following:

use for which a product, PROCESS or service is intended according to the specifications, instructions and information provided by the MANUFACTURER

[ISO 14971:2007, 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, transport, etc. as well.

3.49

* MAINS PART

Replace the existing definition and the notes with the following:

part of electrical equipment forming a 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).

3.55

MANUFACTURER

Replace existing Note 4 with:

NOTE 4 Adapted from ISO 14971:2007, definition 2.8.

3.65

MOBILE

Replace the existing definition with the following:

term referring to TRANSPORTABLE equipment that, once installed and placed into service, is intended to be moved from one location to another while supported by its own wheels or equivalent means

NOTE See the taxonomy in the rationale for definition 3.63.

3.67

MULTIPLE SOCKET-OUTLET

MSO

In the existing definition, replace "cables or cords or ME EQUIPMENT for" with "cables, cords or ME EQUIPMENT providing".

3.71

NORMAL USE

In the existing note, delete the term "service" in the last line of the sentence.

3.72

OBJECTIVE EVIDENCE

Replace the existing definition with the following:

data supporting the existence or verity of something

NOTE Objective evidence can be obtained through observation, measurement, testing or other means.

[ISO 14971:2007, definition 2.10]

3.76

PATIENT

Add a note to the definition as follows:

NOTE A PATIENT can be an OPERATOR.

3.81

PEAK WORKING VOLTAGE

Replace the existing source citation with the following:

[IEC 60950-1:2005, definition 1.2.9.8, modified]

3.85

PORTABLE

Replace the existing definition with the following:

term referring to TRANSPORTABLE equipment that, once installed and placed into service, is intended to be moved from one location to another while being carried by one or more persons

NOTE 1 Equipment can refer to ACCESSORIES or equipment parts.

NOTE 2 See the taxonomy in the rationale for definition 3.63.

3.88

PROCEDURE

Replace the existing definition with the following:

specified way to carry out an activity or a PROCESS

[ISO 14971:2007, definition 2.12]

3.89

PROCESS

Replace the existing definition with the following:

set of interrelated or interacting activities which transforms inputs into outputs

[ISO 14971:2007, definition 2.13]

3.98

RECORD

Replace the existing definition with the following:

document stating results achieved or providing evidence of activities performed

[ISO 14971:2007, definition 2.14]

3.100

RESIDUAL RISK

Replace the existing definition with the following:

RISK remaining after RISK CONTROL measures have been taken

[ISO 14971:2007, definition 2.15]

3.102

RISK

Replace the existing source citation with the following:

[ISO 14971:2007, definition 2.16]

3.103

RISK ANALYSIS

Replace the existing source citation with the following:

[ISO 14971:2007, definition 2.17]

3.104

RISK ASSESSMENT

Replace the existing source citation with the following:

[ISO 14971:2007, definition 2.18]

3.105**RISK CONTROL**

Replace the existing definition with the following:

PROCESS in which decisions are made and measures implemented by which RISKS are reduced to, or maintained within, specified levels

[ISO 14971:2007, definition 2.19]

3.106**RISK EVALUATION**

Replace the existing definition with the following:

PROCESS of comparing the estimated RISK against given RISK criteria to determine the acceptability of the RISK

[ISO 14971:2007, definition 2.21]

3.107**RISK MANAGEMENT**

Replace the existing definition with the following:

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

[ISO 14971:2007, definition 2.22]

NOTE For the purposes of this standard, RISK MANAGEMENT does not include planning for or monitoring of production and post-production information; whereas this is required for compliance with ISO 14971 (see 4.2.2).

3.108**RISK MANAGEMENT FILE**

Replace the existing definition with the following:

set of RECORDS and other documents that are produced by RISK MANAGEMENT

[ISO 14971:2007, definition 2.23]

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.

3.114**SEVERITY**

Replace the existing source citation with the following:

[ISO 14971:2007, definition 2.25]

3.116**SINGLE FAULT CONDITION**

Replace the existing definition with the following:

condition of ME EQUIPMENT 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.

3.118**STATIONARY**

Replace the existing definition with the following:

term referring to equipment that, once installed and placed into service, is not intended to be moved from one place to another

NOTE See the taxonomy in the rationale for definition 3.63.

3.130

TRANSPORTABLE

Replace the existing definition with the following:

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

EXAMPLES MOBILE equipment, PORTABLE equipment and BODY-WORN equipment

NOTE See the taxonomy in the rationale for definition 3.63.

3.132

TYPE B APPLIED PART

Delete the reference to "DB" in two places in Note 1.

3.133

TYPE BF APPLIED PART

Delete the reference to "DB" in two places in Note 1.

3.134

TYPE CF APPLIED PART

Delete the reference to "DB" in two places in Note 1 and insert Note 3 as follows:

NOTE 3 See the rationale for the definition of DIRECT CARDIAC APPLICATION (3.22) concerning the applied parts that need to be TYPE CF APPLIED PARTS.

3.136

USABILITY

Replace the existing definition with the following:

characteristic of the OPERATOR interface that establishes effectiveness, efficiency, ease of OPERATOR learning and OPERATOR satisfaction

[IEC 62366:2007, definition 3.17, modified]

3.137

USABILITY ENGINEERING

Replace the existing definition with the following:

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

[IEC 62366:2007, definition 3.18]

3.138

VERIFICATION

Replace the existing definition with the following:

confirmation, through the provision of OBJECTIVE EVIDENCE, that specified requirements have been fulfilled

NOTE 1 The term "verified" is used to designate the corresponding status.

NOTE 2 Confirmation can comprise activities such as:

- performing alternative calculations;
- comparing a new design specification with a similar proven design specification;
- undertaking tests and demonstrations;
- reviewing documents prior to issue.

[ISO 14971:2007, definition 2.28]

3.139

WORKING VOLTAGE

Replace the existing source citation with the following:

[IEC 60950-1:2005, definition 1.2.9.6]

Add the following new definitions:

3.140

AIR KERMA

K

quotient of dE_{tr} by dm , where dE_{tr} is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass dm of air, thus

$$K = \frac{dE_{tr}}{dm}$$

Unit: J kg⁻¹

The special name for the unit of AIR KERMA is gray (Gy) (ICRU 60)

[IEC 60601-1-3:2008, definition 3.4]

3.141

ALARM CONDITION

state of the ALARM SYSTEM when it has determined that a potential or actual HAZARDOUS SITUATION exists for which OPERATOR awareness or response is required

NOTE 1 An ALARM CONDITION can be invalid, i.e. a false positive ALARM CONDITION.

NOTE 2 An ALARM CONDITION can be missed, i.e. a false negative ALARM CONDITION.

[IEC 60601-1-8:2006 / Amendment 1 (2012), definition 3.1]

3.142

ALARM SIGNAL

type of signal generated by the ALARM SYSTEM to indicate the presence (or occurrence) of an ALARM CONDITION

[IEC 60601-1-8:2006, definition 3.9]

3.143

ALARM SYSTEM

parts of ME EQUIPMENT or a ME SYSTEM that detect ALARM CONDITIONS and, as appropriate, generate ALARM SIGNALS

[IEC 60601-1-8:2006, definition 3.11]

3.144

BODY-WORN

term referring to TRANSPORTABLE equipment whose INTENDED USE includes operation while being worn by a PATIENT or attached to a PATIENT'S clothing

NOTE 1 TRANSPORTABLE equipment can be both BODY-WORN and HAND-HELD.

[IEC 60601-1-11:2010, definition 3.1]

NOTE 2 See the taxonomy in the rationale for definition 3.63.

3.145

IT-NETWORK

INFORMATION TECHNOLOGY NETWORK

a system or systems composed of communicating nodes and transmission links to provide physically linked or wireless transmission between two or more specified communication nodes

[IEC 80001-1:2010, definition 2.12]

3.146

PRIMARY OPERATING FUNCTION

function that involves OPERATOR interaction that is frequently used or related to the safety of the ME EQUIPMENT

[IEC 62366:2007, definition 3.14, modified]

3.147

USABILITY ENGINEERING FILE

set of RECORDS and other documents that are produced by the USABILITY ENGINEERING PROCESS

[IEC 62366:2007, definition 3.19]

4 General requirements

4.2 * RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

Replace the existing text of the subclause with the following:

4.2.1 Introduction to RISK MANAGEMENT

Subclause 4.2 specifies the RISK MANAGEMENT PROCESS that is required for compliance with this standard. This RISK MANAGEMENT PROCESS is intended to serve the following purposes:

- a) To identify whether the normative requirements specified in Clauses 5 to 17 of this standard, together with the requirements of applicable collateral and particular standards, address all the HAZARDS associated with the particular ME EQUIPMENT or ME SYSTEM under consideration.
- b) To identify the way in which some particular tests specified in this standard should be applied to a particular ME EQUIPMENT or ME SYSTEM.
- c) To identify whether particular HAZARDS or HAZARDOUS SITUATIONS for which this standard does not provide specific acceptance criteria result in any RISKS for a particular ME EQUIPMENT or ME SYSTEM, and, if so, to establish acceptable RISK levels and evaluate the RESIDUAL RISKS.
- d) To evaluate the acceptability of alternative RISK CONTROL strategies by comparing RESIDUAL RISK with that achieved by applying the full requirements of this standard.

Although the RISK MANAGEMENT PROCESS specified in this standard is required to comply with the relevant requirements of ISO 14971, it is not as extensive as and does not include all of the elements required for compliance with ISO 14971. For example, the RISK MANAGEMENT PROCESS required for compliance with this standard does not include the production and post-production monitoring required in ISO 14971. Furthermore, verification of compliance with the RISK MANAGEMENT requirements of this standard can be accomplished by examination of the

RECORDS and other documentation required by this standard and assessment of the processes cited in this standard and does not require auditing of the RISK MANAGEMENT PROCESS.

4.2.2 General requirement for RISK MANAGEMENT

A RISK MANAGEMENT PROCESS complying with ISO 14971 shall be performed. For compliance with this standard, all elements of the ISO 14971:2007 RISK MANAGEMENT PROCESS shall be applied except:

- the planning for and execution of production and post-production monitoring (subclause 3.1, fourth dash, subclause 3.4, item f), and Clause 9 of ISO 14971:2007), and
- periodic reviews of the suitability of the RISK MANAGEMENT PROCESS (subclause 3.2, fourth dash, of ISO 14971:2007).

When applying any of the requirements of ISO 14971:

- the term “medical device” shall assume the same meaning as ME EQUIPMENT or ME SYSTEM; and
- the term “fault conditions” referred to in ISO 14971 shall include, but shall not be limited to, SINGLE FAULT CONDITIONS identified in this standard.

NOTE 1 This standard specifies requirements that are generally applicable to RISKS associated with the ME EQUIPMENT or ME SYSTEMS. Those requirements are intended to facilitate the RISK MANAGEMENT PROCESS. The RISK MANAGEMENT PROCESS is aimed at identifying 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 SITUATIONS 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 SITUATIONS are and the tests that need to be done to show that the identified HAZARDOUS SITUATIONS 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 would need to 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 the ME EQUIPMENT or ME SYSTEM are subject to specific requirements of this standard (see 1.1).

Compliance is checked by:

- *inspection of the MANUFACTURER'S policy for determining criteria for RISK acceptability;*
- *inspection of the RISK MANAGEMENT plan for the particular ME EQUIPMENT or ME SYSTEM under consideration; and*
- *confirming the MANUFACTURER has prepared a RISK MANAGEMENT FILE containing the RISK MANAGEMENT RECORDS and other documentation required by this standard for the particular ME EQUIPMENT or ME SYSTEM under consideration.*

NOTE 6 It is helpful to keep an index containing references or pointers to the RISK MANAGEMENT RECORDS and other documentation required by this standard.

4.2.3 Evaluating RISK

4.2.3.1 HAZARDS identified in the IEC 60601-series

The requirements of this standard shall be applied in the following way when evaluating RISK:

- a) Where this standard or its collateral or particular standards specify requirements addressing particular HAZARDS or HAZARDOUS SITUATIONS, together with specific acceptance criteria, compliance with these requirements is presumed to establish that the RESIDUAL

RISKS have been reduced to acceptable levels unless there is OBJECTIVE EVIDENCE to the contrary.

EXAMPLE 1 Subclause 8.5.1.2, MEANS OF PATIENT PROTECTION (MOPP)

EXAMPLE 2 Subclause 9.4.2.1, Instability in transport position

Compliance is checked by satisfying the relevant requirements of this standard and its collateral and particular standards.

- b) Where this standard or its collateral or particular standards specify requirements addressing particular HAZARDS or HAZARDOUS SITUATIONS but do not provide specific acceptance criteria, the MANUFACTURER shall provide the acceptance criteria defined in the RISK MANAGEMENT plan. These acceptance criteria shall ensure that the RESIDUAL RISK is acceptable according to the criteria for RISK acceptability recorded in the RISK MANAGEMENT plan.

EXAMPLE 3 Subclause 9.8.3.3, Dynamic forces due to loading from persons

EXAMPLE 4 Subclause 11.6.3, Spillage on ME EQUIPMENT and ME SYSTEMS

Compliance is checked by confirming that the RECORDS in the RISK MANAGEMENT FILE demonstrate that, after applying the specific requirements of this standard, the acceptance criteria determined by the MANUFACTURER are satisfied. Only the relevant parts of the RISK MANAGEMENT FILE need to be reviewed, e.g. the MANUFACTURER'S calculations or test results, or the determination of RISK acceptability.

- c) Where this standard or its collateral or particular standards identify particular HAZARDS or HAZARDOUS SITUATIONS that have to be investigated without providing specific technical requirements:
- the MANUFACTURER shall determine whether such HAZARDS or HAZARDOUS SITUATIONS exist for the particular ME EQUIPMENT or ME SYSTEM, and
 - where such HAZARDS or HAZARDOUS SITUATIONS exist for the particular ME EQUIPMENT or ME SYSTEM, the MANUFACTURER shall evaluate and (if necessary) control these RISKS following the RISK MANAGEMENT PROCESS specified in 4.2.2.

EXAMPLE 5 Subclause 10.2, Alpha, beta, gamma, neutron and other particle radiation

Compliance is checked by confirming that the RECORDS in the RISK MANAGEMENT FILE demonstrate that the RESIDUAL RISK is acceptable using the criteria for RISK acceptability recorded in the RISK MANAGEMENT plan, i.e. no unacceptable RISK remains. Only the relevant parts of the RISK MANAGEMENT FILE need to be reviewed, e.g. the MANUFACTURER'S calculations or test results, or the determination of RISK acceptability.

NOTE When ME EQUIPMENT or an ME SYSTEM has been designed in such way that for a certain type of HAZARDS no HAZARDOUS SITUATION exists, no further RISK ASSESSMENT for that HAZARD is necessary. This can be verified by tests or inspections.

4.2.3.2 HAZARDS not identified in the IEC 60601 series

For HAZARDS or HAZARDOUS SITUATIONS that are identified for the particular ME EQUIPMENT or ME SYSTEM but are not specifically addressed in this standard or its collateral or particular standards, the MANUFACTURER shall address those HAZARDS in the RISK MANAGEMENT PROCESS as specified in 4.2.2.

EXAMPLE ME EQUIPMENT or an ME SYSTEM for which there are particular RISKS but no particular standard.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

4.3 * ESSENTIAL PERFORMANCE

Replace the existing text of the subclause with the following:

During RISK ANALYSIS, the MANUFACTURER shall identify the performance of the clinical function(s) of the ME EQUIPMENT or ME SYSTEM, other than that related to BASIC SAFETY, that is necessary to achieve its INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM.

The MANUFACTURER shall then specify performance limits between fully functional and total loss of the identified performance in both NORMAL CONDITION and SINGLE FAULT CONDITION.

The MANUFACTURER shall then evaluate the RISK from the loss or degradation of the identified performance beyond the limits specified by the MANUFACTURER. If the resulting RISK is unacceptable, then the identified performance constitutes an ESSENTIAL PERFORMANCE of the ME EQUIPMENT or ME SYSTEM.

The MANUFACTURER shall implement RISK CONTROL measures to reduce the RISK from the loss or degradation of the identified performance to an acceptable level.

NOTE 1 The performance of the RISK CONTROL measure might well become an aspect of the ESSENTIAL PERFORMANCE of the ME EQUIPMENT or ME SYSTEM. For example, the generation of the ALARM SIGNAL to indicate the interruption of the SUPPLY MAINS could be "essential" if an interruption of the SUPPLY MAINS could result in an unacceptable RISK if it went unattended.

The MANUFACTURER shall specify the methods used to verify the effectiveness of the RISK CONTROL measures. This shall include any assessment made to determine whether verification is needed.

NOTE 2 Following the principles of RISK MANAGEMENT, the MANUFACTURER is required to verify the effectiveness of each RISK CONTROL measure. This can involve demonstrating that the RISK CONTROL measure will operate in the presence of the conditions that result in the loss or degradation of the identified performance.

EXAMPLE 1 If ESSENTIAL PERFORMANCE is lost because of an interruption of the SUPPLY MAINS, an ALARM SYSTEM intended to notify the OPERATOR that the SUPPLY MAINS has been interrupted would need to have a backup power source so that the generation of the ALARM SIGNAL would not depend on the SUPPLY MAINS.

EXAMPLE 2 If the failure of a component results in the loss of ESSENTIAL PERFORMANCE, the design of the ME EQUIPMENT or ME SYSTEM would need to be such that the component failure does not compromise the effectiveness of any RISK CONTROL measures put in place to mitigate the RISK from the loss of the ESSENTIAL PERFORMANCE.

NOTE 3 Each collateral standard or particular standard in the IEC 60601 or the IEC/ISO 80601 series can list potential ESSENTIAL PERFORMANCES to guide the MANUFACTURER to identify particular ESSENTIAL PERFORMANCE in accordance with 4.3.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

Where this standard requires that ESSENTIAL PERFORMANCE is to be maintained following a particular test, compliance is checked by inspection and, if necessary, by functional test(s) that demonstrate the MANUFACTURER'S specified limits are maintained or the ME EQUIPMENT or ME SYSTEM transitions to a safe state as defined by the MANUFACTURER.

4.5 * Equivalent safety for ME EQUIPMENT or ME SYSTEMS

Replace the heading and the text of the subclause with the following:

4.5 * Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS

Where this standard specifies a particular RISK CONTROL measure or test method, an alternative RISK CONTROL measure or test method is acceptable, provided that the MANUFACTURER can demonstrate through scientific data or clinical opinion or comparative studies that the RESIDUAL RISK that results from applying the alternative RISK CONTROL measure or test method remains acceptable and is comparable to the RESIDUAL RISK that results from applying the requirements of this standard.

Comparative studies in this context mean studies comparing the effect of the alternative RISK CONTROL measure or test method with the RISK CONTROL measure or test method specified in this standard.

NOTE Alternative RISK CONTROL measures can allow for exceeding limits specified in this standard or in its collateral or particular standards if additional measures for compensation are provided.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

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

Replace the text of the subclause with the following:

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 need to be subject to the requirements for APPLIED PARTS. For the parts concerned, the requirements for TYPE B APPLIED PART shall be applied unless the assessment identifies a need for the requirements for a TYPE BF APPLIED PART or TYPE CF APPLIED PART to apply.

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 and of relevant collateral and particular standards shall apply, except that 7.2.10 does not apply to such parts.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

4.8 Components of ME EQUIPMENT

Add an asterisk to the title.

4.11 Power input

After the third dashed item, insert the following note:

NOTE 1 Technical details of a true r.m.s. meter can be found in IEC 62354 [66].

Replace the existing final paragraph with the following note:

NOTE 2 Supplier information can be used to supplement the above measurement as a power input specification.

5 * General requirements for testing ME EQUIPMENT

5.1 * Type tests

Replace the existing third paragraph and the note with the following:

The combination of simultaneous independent faults that could result in a HAZARDOUS SITUATION shall be documented in the RISK MANAGEMENT FILE (see also 4.7). When testing is necessary to demonstrate that BASIC SAFETY and ESSENTIAL PERFORMANCE are maintained under such simultaneous independent faults, the related testing may be limited to worst case situations.

NOTE 1 The test results might necessitate a revision of the RISK ANALYSIS.

NOTE 2 When considering use of tests described in this standard as routine tests, see Annex K of IEC/TR 62354 (production line tests) or see IEC 62353 (recurrent tests).

5.4 Other conditions

Replace existing list item a) with the following:

- a) Unless otherwise specified in this standard, ME EQUIPMENT is to be tested under the least favourable working conditions. The working conditions are specified in the ACCOMPANYING DOCUMENTS. The least favourable working conditions shall be documented for every test where they apply.

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

Replace existing list item a) with the following:

- a) Where test results are influenced by deviations of the characteristics of the SUPPLY MAINS from their RATED values, the effect of such deviations is taken into account.

The values used during testing are according to 4.10.2 or according to that marked on the ME EQUIPMENT (see 7.2.6), whichever is least favourable.

NOTE 1 For the RATED value(s) given on the ME EQUIPMENT, deviations of the SUPPLY MAINS as provided in 4.10.2 are only to be tested if the deviations have a negative impact on BASIC SAFETY or ESSENTIAL PERFORMANCE.

In the existing first sentence of list item b), delete the phrase "(if marked) ± 1 Hz up to and including 100 Hz and ± 1 % above 100 Hz".

Replace existing list item c) with the following:

- c) ME EQUIPMENT designed for more than one RATED voltage, for both a.c. and d.c., or for both external power and an INTERNAL ELECTRICAL POWER SOURCE, 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.

Renumber the note following list item f) as Note 2.

5.7 * Humidity preconditioning treatment

Replace the existing sixth, seventh and eighth paragraphs with the following:

The humidity preconditioning treatment is performed in a humidity cabinet containing air with a relative humidity of $93 \% \pm 3 \%$ where the ME EQUIPMENT or its parts under test are located. The humidity conditions at other locations in the chamber may vary by $\pm 6 \%$. The temperature of the air in the cabinet, at all places where ME EQUIPMENT or its parts can be located, shall be maintained within $2\text{ }^{\circ}\text{C}$ of any convenient value T in the range of $+20\text{ }^{\circ}\text{C}$ to $+30\text{ }^{\circ}\text{C}$. Before being placed in the humidity cabinet, ME EQUIPMENT or its parts are brought to a temperature between T and $T + 4\text{ }^{\circ}\text{C}$, and kept at this temperature for at least 4 h before the humidity treatment starts.

Keep ME EQUIPMENT and its parts, where the ENCLOSURE is classified as IPX0, in the humidity cabinet for 48 h.

Keep ME EQUIPMENT and its parts, where the ENCLOSURE is designed to provide higher ingress protection against liquids, in the humidity cabinet for 168 h.

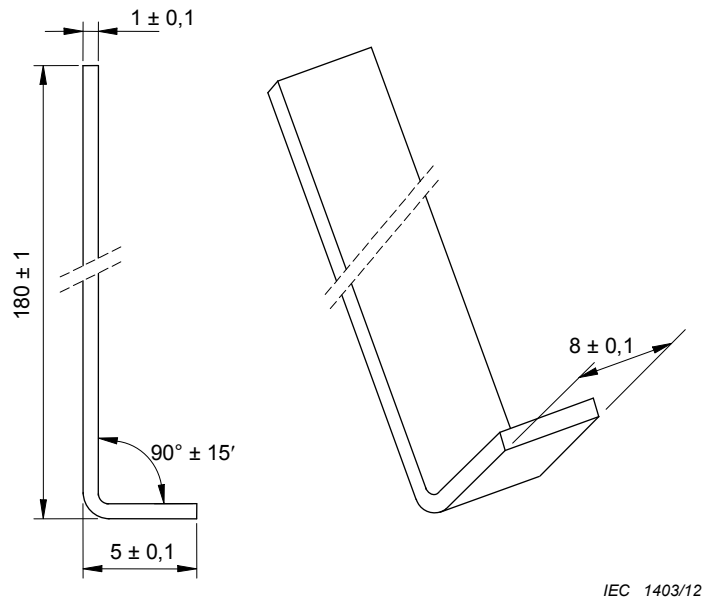
5.9 * Determination of APPLIED PARTS and ACCESSIBLE PARTS

5.9.2 ACCESSIBLE PARTS

5.9.2.2 Test hook

In the second paragraph, replace "Figure 7" by "Figure 6".

Replace existing Figure 7 with the following:



Material: steel

Figure 7 – Test hook
(see 5.9.2.2)

5.9.2.3 Actuating mechanisms

Replace the existing text of the subclause with the following:

Conductive parts of actuating mechanisms of electrical controls that are accessible after the removal of handles, knobs, levers and the like are regarded as ACCESSIBLE PARTS. Conductive parts of actuating mechanisms are not considered ACCESSIBLE PARTS if removal of handles, knobs, etc. requires the use of a TOOL.

Compliance is checked by tests according to 5.9.2.1 and 15.4.6.1.

7 ME EQUIPMENT identification, marking and documents

7.1 General

7.1.1 * USABILITY of the identification, marking and documents

Replace the existing text of the subclause with the following:

See 12.2.

7.1.2 * Legibility of markings

Replace the existing compliance paragraphs with the following:

Compliance for clear legibility is checked by the following test:

The ME EQUIPMENT or its part is positioned so that the viewpoint is the intended position of the OPERATOR. If the intended position of the OPERATOR is not specified and the position is not obvious, the viewpoint is at any point within the base of a cone subtended by an angle of 30 ° to the axis normal to the centre of the plane of the marking and at a distance of 1 m. The ambient illumination is the least favourable level in the range of 100 lx to 1 500 lx.

The observer has a visual acuity, corrected if necessary, of:

- 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20); and
 - is able to read N6 of the Jaeger test card;
- in normal room lighting conditions (approximately 500 lx).

The observer correctly reads the marking from the viewpoint.

7.1.3 * Durability of markings

In existing list item b), replace "methylated spirit" with "ethanol 96 %".

7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.1)

7.2.1 Minimum requirements for marking on ME EQUIPMENT and on interchangeable parts

Replace the existing last paragraph with the following and insert a note:

Any material, component, ACCESSORY or ME EQUIPMENT that is intended for a single use or its packaging shall be marked "Single Use Only", "Do Not Reuse" or with symbol ISO 7000-1051 (2004-01) (see Table D.1, symbol 28).

NOTE See also 7.9.2.12.

7.2.2 * Identification

Replace the existing first paragraph with the following:

ME EQUIPMENT shall be marked with:

- the name or trademark and contact information of the MANUFACTURER;
- a MODEL OR TYPE REFERENCE;
- a serial number or lot or batch identifier; and
- the date of manufacture or use by date, if applicable.

NOTE See ISO 15223-1 for symbols for MANUFACTURER, serial number, lot or batch, year of manufacture and use by date.

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

Detachable components of the ME EQUIPMENT shall be marked with:

- the name or trademark of the MANUFACTURER; and
- a MODEL OR TYPE REFERENCE;

unless misidentification does not result in an unacceptable RISK.

In the final sentence of the existing second paragraph, replace "does not need to be" with "need not be".

7.2.4 * ACCESSORIES

Replace the existing text of the subclause with the following:

ACCESSORIES shall be marked with:

- the name or trade-mark and contact information of their MANUFACTURER
- a MODEL OR TYPE REFERENCE;
- a serial number or lot or batch identifier; and
- the date of manufacture or use by date, if applicable.

NOTE See ISO 15223-1 for symbols for MANUFACTURER, serial number, lot or batch, year of manufacture and use by date.

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

Where no marking of the ACCESSORIES is practicable, these markings may be affixed to the individual packaging.

7.2.5 ME EQUIPMENT intended to receive power from other equipment

Replace the existing text of the subclause with the following:

If ME EQUIPMENT is intended to receive its power from other electrical equipment in an ME SYSTEM and compliance with the requirements of this standard is dependent on that other equipment, one of the following shall be provided:

- the name or trademark of the manufacturer of the other electrical equipment with a MODEL OR TYPE REFERENCE of the specified other equipment adjacent to the relevant connection point;
- placing safety sign ISO 7010-M002 (see Table D.2, safety sign 10) adjacent to the relevant connection point and listing of the required details in the instructions for use; or
- using a special connector style that is not commonly available on the market and listing of the required details in the instructions for use.

See also 7.9.2.3, 8.2.1 and 16.3.

7.2.6 Connection to the SUPPLY MAINS

In the existing second and fourth bullets, delete "DB:".

In the last line of the existing final paragraph, replace "supply connection terminals" with "SUPPLY MAINS connection".

7.2.7 Electrical input power from the SUPPLY MAINS

Replace the existing first paragraph with:

The RATED input from the SUPPLY MAINS shall be marked on the ME EQUIPMENT. The RATED input shall be given in:

- amperes or volt-amperes, or
- if the power factor exceeds 0,9, in amperes, volt-amperes or watts.

7.2.10 * APPLIED PARTS

In the existing second and third paragraphs, delete "DB:".

7.2.14 HIGH VOLTAGE TERMINAL DEVICES

In the existing paragraph, delete "DB:", and insert the following note at the end of the subclause.

NOTE CREEPAGE DISTANCES and AIR CLEARANCES between the high voltage contacts and the standard test finger are subject to the requirements in 8.9.

7.2.17 Protective packaging

In the existing second paragraph, replace "ISO 15223" with "ISO 15223-1".

Replace the existing fourth paragraph with the following

The packaging of ME EQUIPMENT or ACCESSORIES supplied sterile shall be marked as sterile and indicate the method of sterilization (see ISO 15223-1).

7.2.18 External pressure source

Replace the existing subclause with the following:

Adjacent to each input connector, the ME EQUIPMENT shall be marked with:

- the RATED maximum supply pressure from an external source, and
- the RATED flow rate if required to maintain BASIC SAFETY or ESSENTIAL PERFORMANCE.

7.2.19 FUNCTIONAL EARTH TERMINALS

In the existing paragraph, replace "(DB:2002-10)" with "(2006-08)".

Add a new subclause following 7.2.20:

7.2.21 * Mass of MOBILE ME EQUIPMENT

MOBILE ME EQUIPMENT shall be marked with its mass including its SAFE WORKING LOAD in kilograms. The marking shall be done in a way that it is obvious that it applies to the whole of the MOBILE ME EQUIPMENT when loaded with its SAFE WORKING LOAD and is separate and distinct from any markings related to maximum bin, shelf or drawer loading requirements.

7.3 Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.2)

7.3.2 * HIGH VOLTAGE parts

In the existing paragraph, delete "DB:".

7.3.4 * Fuses, THERMAL CUT-OUTS and OVER-CURRENT RELEASES

Replace the existing text of the subclause with the following:

Fuses and replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES that are accessible only by the use of a TOOL shall be identified either by specification (voltage, current, operating speed, size, breaking capacity) adjacent to the component, or by a reference to information in the ACCOMPANYING DOCUMENTS.

The nomenclature of IEC 60127-1 may be used.

7.3.5 PROTECTIVE EARTH TERMINALS

Add an asterisk before the subclause heading, and in the existing first paragraph replace "(DB:2002-10)" with "(2006-08)".

7.3.6 FUNCTIONAL EARTH TERMINALS

In the existing paragraph, replace "(DB:2002-10)" with "(2006-08)".

7.3.7 Supply terminals

In the existing first paragraph, replace "HAZARDOUS SITUATION" with "unacceptable RISK".

7.4 Marking of controls and instruments (see also Table C.3)

7.4.1 Power switches

Add an asterisk before the subclause heading and delete "DB:" in two places in the first dash and in one place in the fourth and seventh dashes.

7.4.2 Control devices

Add an asterisk before the subclause heading and delete "DB:" in two places in the first paragraph.

After the last dash of the existing second paragraph, insert the following:

A control device or switch that brings the ME EQUIPMENT into the "stand-by" condition may be indicated by use of symbol IEC 60417-5009 (2002-10) (see Table D.1, Symbol 29).

7.4.3 Units of measure

Replace the existing subclause heading as follows:

7.4.3 Units of measurement

In the existing first paragraph, replace "ISO 31" with "ISO 80000-1", and in the existing second paragraph, replace "ISO 1000" with "ISO 80000-1".

Table 1 – Units outside the SI units system that may be used on ME EQUIPMENT

In the existing footnote ^a in Table 1, replace "ISO 31" with "ISO 80000-1".

7.5 Safety signs

Add to the end of the existing first paragraph, the following:

If a safety sign with an established meaning is appropriately used, the use of the general warning sign ISO 7010:2003-W001 (see Table D.2, safety sign 2) is not required.

Add, immediately before the compliance statement:

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

NOTE 4 In some countries, more than one language is required.

7.6 Symbols

7.6.3 Symbols for controls and performance

In the existing note, append bibliography reference "[60]" to IEC 60878.

7.7 Colours of the insulation of conductors

7.7.3 Green and yellow insulation

After the existing second dash, insert the following:

NOTE In other safety standards such as IEC 60950-1, internal connections between conductive parts and the main protective earth are called protective bonding conductors.

7.9 ACCOMPANYING DOCUMENTS

7.9.1 * General (see also Table C.4)

Replace the existing first dash with the following:

- name or trade-name of the MANUFACTURER and contact information to which the RESPONSIBLE ORGANIZATION can refer;

Replace the existing third paragraph with the following:

ACCOMPANYING DOCUMENTS may be provided electronically, e.g. electronic file format on CD-ROM. If the ACCOMPANYING DOCUMENTS are provided electronically, the USABILITY ENGINEERING PROCESS shall include consideration of which information also needs to be provided as hard copy or as markings on the ME EQUIPMENT (see 12.2).

EXAMPLE Information to cover emergency operation

NOTE ACCOMPANYING DOCUMENTS provided electronically might not be acceptable in all jurisdictions.

Replace the existing compliance paragraph with the following:

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS, and, when provided electronically, as specified in IEC 60601-1-6.

7.9.2 Instructions for use (see also Table C.5)

7.9.2.1 * General

Replace the existing first paragraph with the following new text, renumbering subsequent notes in this subclause:

The instructions for use shall document:

- the use of the ME EQUIPMENT as intended by the MANUFACTURER;
- the frequently used functions;
- any known contraindication(s) to the use of the ME EQUIPMENT; and
- those parts of the ME EQUIPMENT that shall not be serviced or maintained while in use with a PATIENT.

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

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

NOTE 1 For ME EQUIPMENT where the INTENDED USE includes the PATIENT partially or fully operating the ME EQUIPMENT, the PATIENT becomes an OPERATOR.

NOTE 2 For ME EQUIPMENT where the PATIENT is allowed to perform restricted maintenance, the PATIENT becomes SERVICE PERSONNEL.

The instructions for use shall indicate:

- the name or trademark and address of the MANUFACTURER;
- the MODEL OR TYPE REFERENCE.

Insert after the last paragraph:

NOTE 5 In some countries, more than one language is required.

7.9.2.7 * Isolation from the SUPPLY MAINS

In the existing text of the subclause, replace "separable plug" with "MAINS PLUG or other separable plug".

7.9.2.14 ACCESSORIES, supplementary equipment, used material

In the existing second paragraph, replace "continuous service" with "continuous duty".

7.9.2.15 Environmental protection

Replace the existing text of the subclause with the following:

The instructions for use shall provide advice on the proper disposal of waste products, residues, etc. and of the ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE.

Insert the following new subclauses ahead of the overall compliance paragraph for subclause 7.9.2:

7.9.2.17 ME EQUIPMENT emitting radiation

For ME EQUIPMENT emitting radiation for medical purposes, when appropriate, the instructions for use shall indicate the nature, type, intensity and distribution of this radiation.

7.9.2.18 ME EQUIPMENT and ACCESSORIES supplied sterile

The instructions for use for ME EQUIPMENT or ACCESSORIES supplied sterile shall indicate that they have been sterilized and indicate the method of sterilization.

The instructions for use shall indicate the necessary instructions in the event of damage to the sterile packaging, and where appropriate, details of the appropriate methods of re-sterilization (see also 7.9.2.12).

7.9.2.19 * Unique version identifier

The instructions for use shall contain a unique version identifier such as its date of issue.

EXAMPLE Month and year.

7.9.3 Technical description (see also Table C.6)

7.9.3.1 * General

Add the following dashed item to the first paragraph:

- information pertaining to ESSENTIAL PERFORMANCE and any necessary recurrent ESSENTIAL PERFORMANCE and BASIC SAFETY testing including details of the means, methods and recommended frequency.

NOTE 2 This information is directly derived from the ESSENTIAL PERFORMANCE identified by the MANUFACTURER in 4.3.

Replace the existing dash immediately ahead of Note 2 with the following and renumber Note 2 to Note 3 and Note 3 to Note 4:

- a brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions and its significant physical and performance characteristics; and
- a unique version identifier such as its date of issue.

8 Protection against electrical HAZARDS from ME EQUIPMENT

8.1 Fundamental rule of protection against electric shock

In existing list item b), replace the sixth and seventh dashes as follows:

- interruption of any one power-carrying conductor between ME EQUIPMENT parts in separate ENCLOSURES, if this condition might cause permitted limits to be exceeded;
- unintended movement of a component (see 8.10.1);

8.2 Requirements related to power sources

8.2.2 Connection to an external d.c. power source

Replace the existing first paragraph and the note with the following:

If ME EQUIPMENT is specified for power supplied from an external d.c. power source, then a connection with the wrong polarity shall not lead to the HAZARDOUS SITUATIONS described in 13.1. The ME EQUIPMENT, when connection is subsequently made with the correct polarity, shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE.

Protective devices that can be reset by anyone without the use of a TOOL are acceptable provided the ME EQUIPMENT returns to NORMAL CONDITION on reset.

NOTE 1 See also 11.8.

NOTE 2 The external d.c. power source can be a SUPPLY MAINS or another item of electrical equipment. In the latter case, the combination is considered to be an ME SYSTEM as specified in 8.2.1.

8.3 Classification of APPLIED PARTS

In existing list item a), replace the existing note with the following:

NOTE See the rationale for the definition of DIRECT CARDIAC APPLICATION (3.22) concerning the APPLIED PARTS that need to be TYPE CF APPLIED PARTS. Other restrictions can apply for cardiac applications.

Delete existing list item d).

8.4 Limitation of voltage, current or energy

8.4.2 ACCESSIBLE PARTS including APPLIED PARTS

Replace the existing title and list item b) with the following:

8.4.2 ACCESSIBLE PARTS and APPLIED PARTS

- b) *. The LEAKAGE CURRENTS from, to or between ACCESSIBLE PARTS shall not exceed the limits for TOUCH CURRENT specified in 8.7.3 c) when measured as specified in 8.7.4.

In the second paragraph of existing list item c), replace "potential up to 2 V" with "potential of 2 V or more".

Replace the compliance paragraph in list item c) with the following:

Compliance is checked by inspection of the instructions for use and by measurement.

In existing list item d), replace the second dash with the following:

- internal parts that can be touched by a metal test rod with a diameter of $4 \begin{smallmatrix} 0 \\ -0,05 \end{smallmatrix}$ mm and a length of $100 \begin{smallmatrix} +0,5 \\ 0 \end{smallmatrix}$ mm, inserted through any opening in the top of an ENCLOSURE or through any opening provided for the adjustment of pre-set controls that can be adjusted by the RESPONSIBLE ORGANIZATION in NORMAL USE by using a TOOL.

8.4.3 * ME EQUIPMENT intended to be connected to a power source by a plug

In the existing sixth paragraph, replace "affect the test" with "affect the test significantly".

Add, after the sixth paragraph, the following note:

NOTE An example of a measuring arrangement that is considered acceptable is an oscilloscope and probe having an input impedance consisting of a resistance of $100 \text{ M}\Omega \pm 5 \text{ M}\Omega$ in parallel with an input capacitance of $20 \text{ pF} \pm 5 \text{ pF}$.

Add, after the last paragraph, the following new text:

Where appropriate, a d.c. input voltage equal to the peak of the RATED SUPPLY MAINS voltage may be used.

8.4.4 * Internal capacitive circuits

In the existing second paragraph, delete "DB:"

8.5 Separation of parts

8.5.1 * MEANS OF PROTECTION (MOP)

8.5.1.1 General

Replace the existing note with the following:

NOTE Coatings and other insulation that are intended as a MEANS OF PROTECTION and that comply with IEC 60950-1:2005 may be used as a MEANS OF OPERATOR PROTECTION but not automatically as a MEANS OF PATIENT PROTECTION. For MEANS OF PATIENT PROTECTION, considerations can arise as a result of the RISK MANAGEMENT PROCESS.

Add the following new final paragraph:

Compliance is checked by the test in 8.5.1.3.

8.5.1.2 MEANS OF PATIENT PROTECTION (MOPP)

Replace the existing title with the following:

8.5.1.2 * MEANS OF PATIENT PROTECTION (MOPP)

Replace the existing fourth paragraph with the following:

A Y capacitor (Y1 or Y2 only) complying with IEC 60384-14 is considered equivalent to one MEANS OF PATIENT PROTECTION. Where two capacitors are used in series, they shall be identical in type (either both Y1 or both Y2) and shall have the same NOMINAL capacitance. The capacitor(s) shall meet the dielectric strength for the type of protection for which they are being used (i.e. one or two MEANS OF PATIENT PROTECTION).

Where the working voltage across a barrier forming a MEANS OF PATIENT PROTECTION is less than 42,4 V peak a.c. or 60 V d.c., a single Y1 capacitor is acceptable for two MEANS OF PATIENT PROTECTION

Compliance is checked by the test in 8.5.1.3.

8.5.1.3 MEANS OF OPERATOR PROTECTION (MOOP)

Replace the existing fourth paragraph with the following:

A Y capacitor (Y1 or Y2 only) complying with IEC 60384-14 is considered equivalent to one MEANS OF OPERATOR PROTECTION. Where two capacitors are used in series, they shall be identical in type (either both Y1 or both Y2) and shall have the same NOMINAL capacitance. The capacitor(s) shall meet the dielectric strength for the type of protection for which they are being used (i.e. one or two MEANS OF OPERATOR PROTECTION). A Y1 capacitor can be used for two MEANS OF OPERATOR PROTECTION.

Replace the first paragraph of the compliance statement and the note with the following:

Compliance is checked by examination of the physical and electrical configuration of the ME EQUIPMENT to identify points at which insulation, CREEPAGE DISTANCES, AIR CLEARANCES, impedances of components or PROTECTIVE EARTH CONNECTIONS prevent ACCESSIBLE PARTS or APPLIED PARTS from exceeding the limits specified in 8.4.

NOTE Such points typically include insulation between parts different from earth potential and ACCESSIBLE PARTS or APPLIED PARTS but can also include, for example, insulation between a floating circuit and earth or other circuits. A survey of insulation paths is found in Annex J.

Replace the last paragraph of the compliance statement with:

The voltage, current or energy that can appear between any ACCESSIBLE PART or APPLIED PART and any other ACCESSIBLE PART, APPLIED PART or earth in NORMAL CONDITION and in SINGLE FAULT CONDITION is determined by inspection or calculation or, where necessary, by measurement in the relevant conditions.

8.5.2 Separation of PATIENT CONNECTIONS

8.5.2.3 * PATIENT leads

Replace the title, and in the existing first paragraph, replace the first sentence and the first dash with the following:

8.5.2.3 * PATIENT leads or PATIENT cables

Any connector for electrical connections on a PATIENT lead or PATIENT cable that:

- is at the end of the lead or cable that is remote from the PATIENT; and

Delete the full stop at the end of the second dash of the first paragraph.

8.5.5 DEFIBRILLATION-PROOF APPLIED PARTS

8.5.5.1 * Defibrillation protection

Delete the existing Note 1 and renumber the subsequent notes.

In existing list item a), delete the "or" at the end of the third dash, replace the full stop at the end of the fourth dash with "; or", and insert a fifth dash as follows:

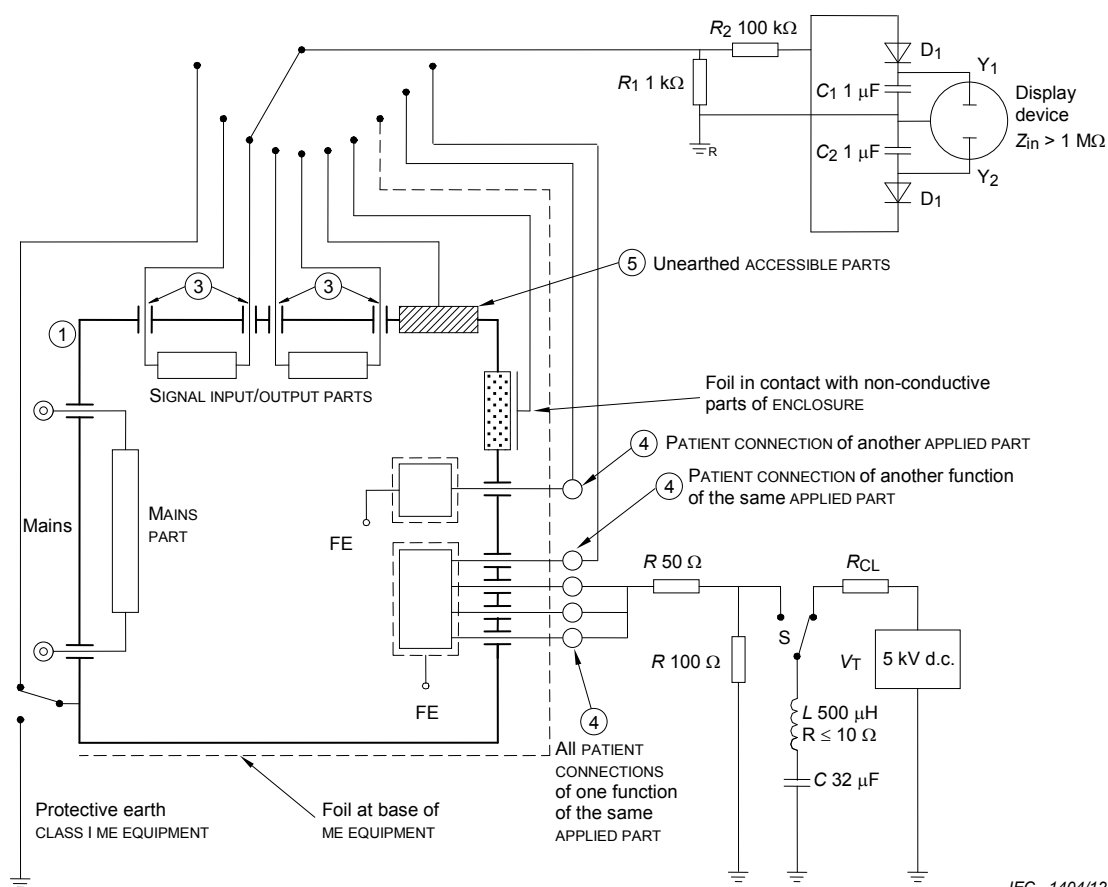
- any unused or disconnected connections of the APPLIED PART under test or any function of the same APPLIED PART. ME EQUIPMENT that is completely BODY-WORN (e.g. a Holter monitor) is exempt from this requirement.

- **Common-mode test**

Add the following sentence to the end of the first paragraph.

If an APPLIED PART has multiple functions, the test voltage is applied to all the PATIENT CONNECTIONS of one function at a time with the other functions disconnected.

Replace existing Figure 9 with the following:



IEC 1404/12

For legends, see Table 5.

Components

- V_T Test voltage
 S Switch for applying the test voltage
 R_1, R_2 Tolerance at $\pm 2\%$, not less than 2 kV
 R_{CL} Current limiting resistor
 D_1, D_2 Small signal silicon diodes
 Other components toleranced at $\pm 5\%$

Figure 9 – Application of test voltage to bridged PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS (see 8.5.5.1)

8.5.5.2 Energy reduction test

Replace the third sentence of the existing second compliance paragraph with the following:

The test voltage is applied to each PATIENT CONNECTION or APPLIED PART in turn with all the remaining PATIENT CONNECTIONS of the same APPLIED PART being connected to earth (differential mode). Other DEFIBRILLATION PROOF APPLIED PARTS, if any, are tested separately, in turn.

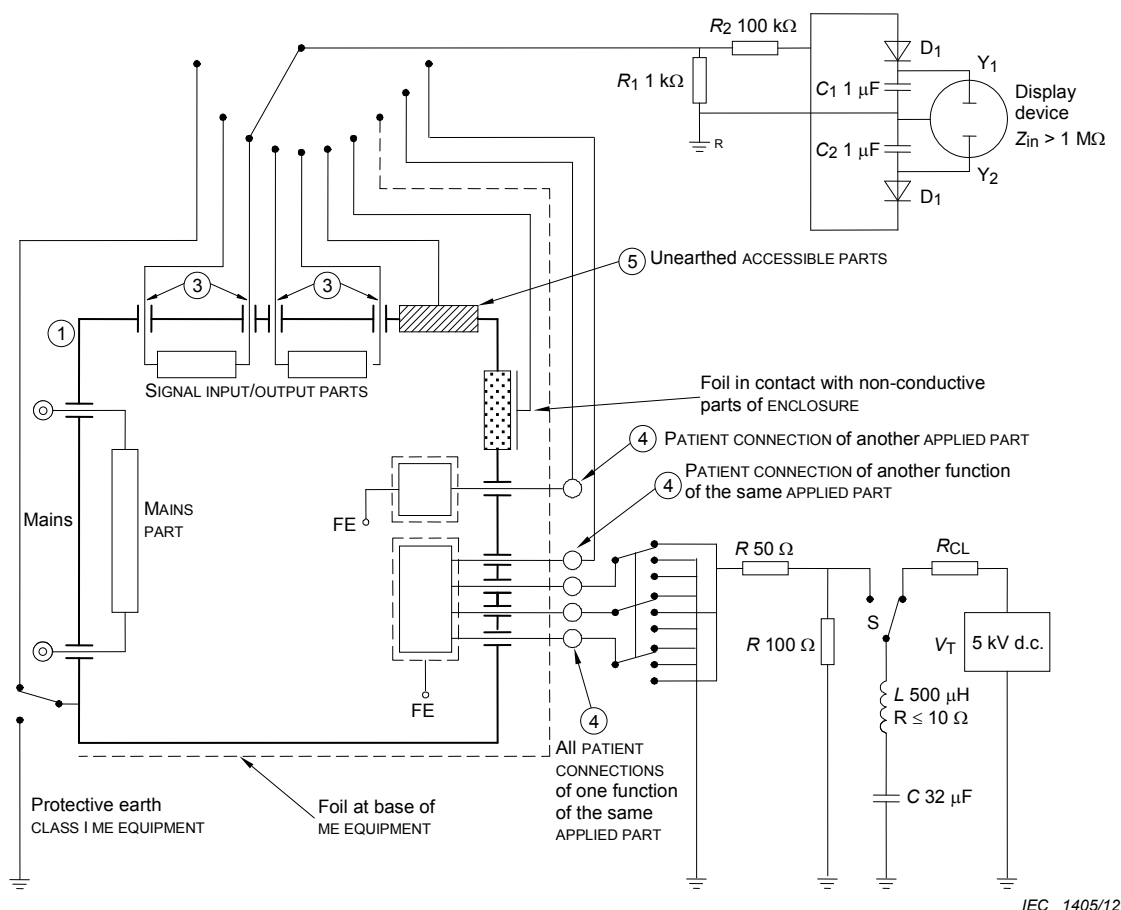
Replace the existing list item a) with the following:

- a) Connect the APPLIED PART or PATIENT CONNECTION to the test circuit. The parts described in 8.5.5.1 a) are connected to earth.

Insert a new list item f) as follows:

- f) Repeat the test with V_T reversed.

Move existing Figure 10 to immediately follow Figure 9 and replace it with the following:



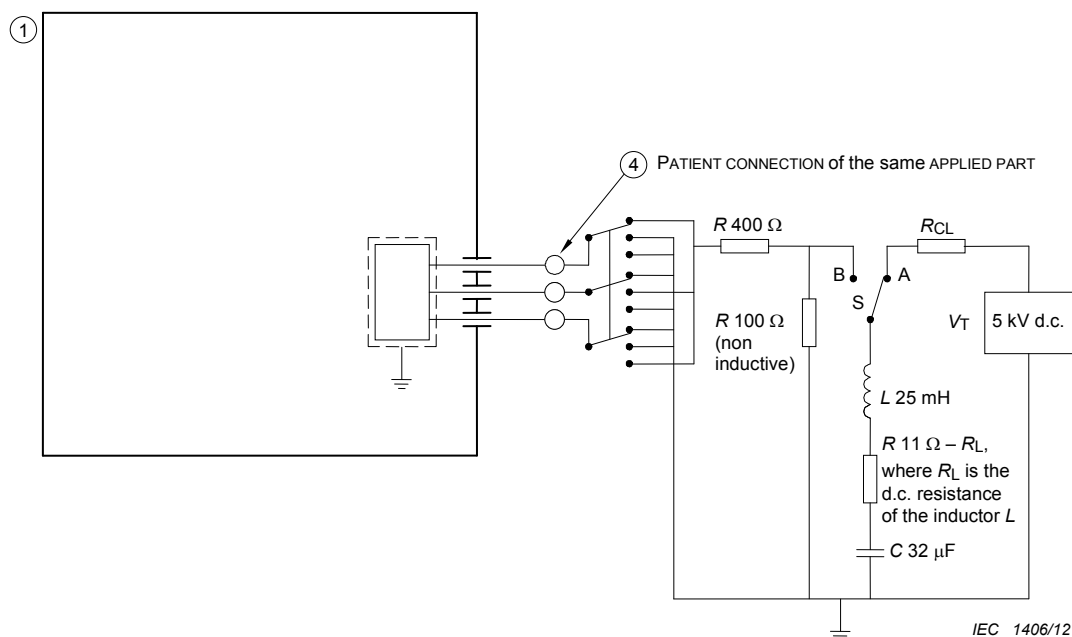
For legends, see Table 5.

Components

- V_T Test voltage
- S Switch for applying the test voltage
- R_1, R_2 Tolerance at $\pm 2\%$, not less than 2 k Ω
- R_{CL} Current limiting resistor
- D_1, D_2 Small signal silicon diodes
- Other components toleranced at $\pm 5\%$

Figure 10 – Application of test voltage to individual PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS
(see 8.5.5.1)

Replace the existing Figure 11 with the following:



For legends, see Table 5

Components

S Switch for applying the test voltage

A, B Switch positions

R_{CL} Current limiting resistor

Components toleranced at $\pm 5\%$

Figure 11 – Application of test voltage to test the delivered defibrillation energy
(see 8.5.5.2)

8.6 * Protective earthing, functional earthing and potential equalization of ME EQUIPMENT

8.6.4 Impedance and current-carrying capability

In existing list item a) immediately before the compliance statement, insert the following:

Additionally, the impedance between the protective earth pin in the MAINS PLUG of any DETACHABLE POWER SUPPLY CORD supplied or specified by the MANUFACTURER, when attached to the ME EQUIPMENT, and any part of the ME EQUIPMENT that is PROTECTIVELY EARTHED shall not exceed 200 mΩ, except as allowed by 8.6.4 b).

Where a DETACHABLE POWER SUPPLY CORD is neither supplied nor specified, testing shall be carried out using a 3 m long cord of appropriate cross sectional area based on 8.11.3.3 and Table 17.

In existing list item a) immediate after the second paragraph of the compliance statement, insert the following:

Alternatively, d.c. may be used for this test.

8.6.7 * POTENTIAL EQUALIZATION CONDUCTOR

Replace the existing second dash with the following:

- Accidental disconnection shall be avoided in NORMAL USE.

In the existing fifth dash, delete "DB:".

8.6.9 * CLASS II ME EQUIPMENT

At the end of the existing first paragraph, insert the following:

In such a case, the ACCOMPANYING DOCUMENTS shall state that the third conductor in the POWER SUPPLY CORD is only a functional earth.

Replace the existing second paragraph with the following:

The insulation between internal screens, including internal wiring connected to them and ACCESSIBLE PARTS, shall provide two MEANS OF PROTECTION.

8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

8.7.1 General requirements

After the first dash in existing list item b), insert the following:

- after any required sterilization PROCEDURE (see 11.6.7);

8.7.3 * Allowable values

Renumber the existing note in list item d) to Note 1 and insert Note 2 as follows:

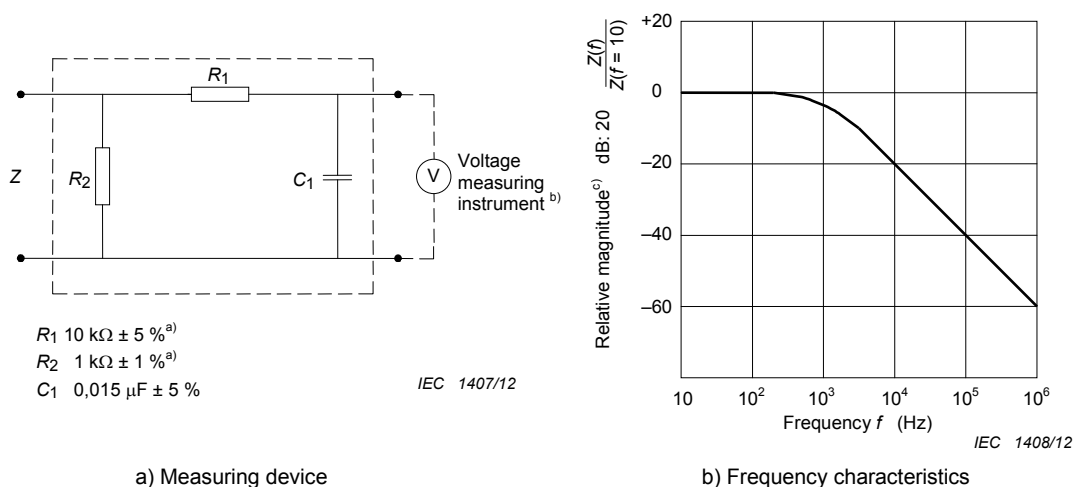
NOTE 2 The EARTH LEAKAGE CURRENT in NORMAL CONDITION can become TOUCH CURRENT in SINGLE FAULT CONDITION unless the ME EQUIPMENT is PERMANENTLY INSTALLED or the protective earth is not accessible from outside the ME EQUIPMENT.

Insert a new item f) as follows:

- f) *. The allowable values of LEAKAGE CURRENTS that can flow in a FUNCTIONAL EARTH CONDUCTOR in a non-PERMANENTLY INSTALLED ME EQUIPMENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION.

NOTE 3 Subclause 16.6.1 requires that when ME EQUIPMENT is included in an ME SYSTEM, the TOUCH CURRENTS from any part of the ME SYSTEM cannot exceed 100 µA in NORMAL CONDITION and 500 µA in SINGLE FAULT CONDITION.

Replace existing Figure 12 with the following:



NOTE The network and voltage measuring instrument above are replaced by the symbol  in the following figures.

a) Non-inductive components

b) Resistance $\geq$ 1 M Ω and capacitance $\leq$ 150 pF

c) $Z(f)$ is the transfer impedance of the network, i.e. V_{out}/I_{in} , for a current of frequency f .

Figure 12 – Example of a measuring device and its frequency characteristics
(see 8.7.3)

8.7.4 Measurements

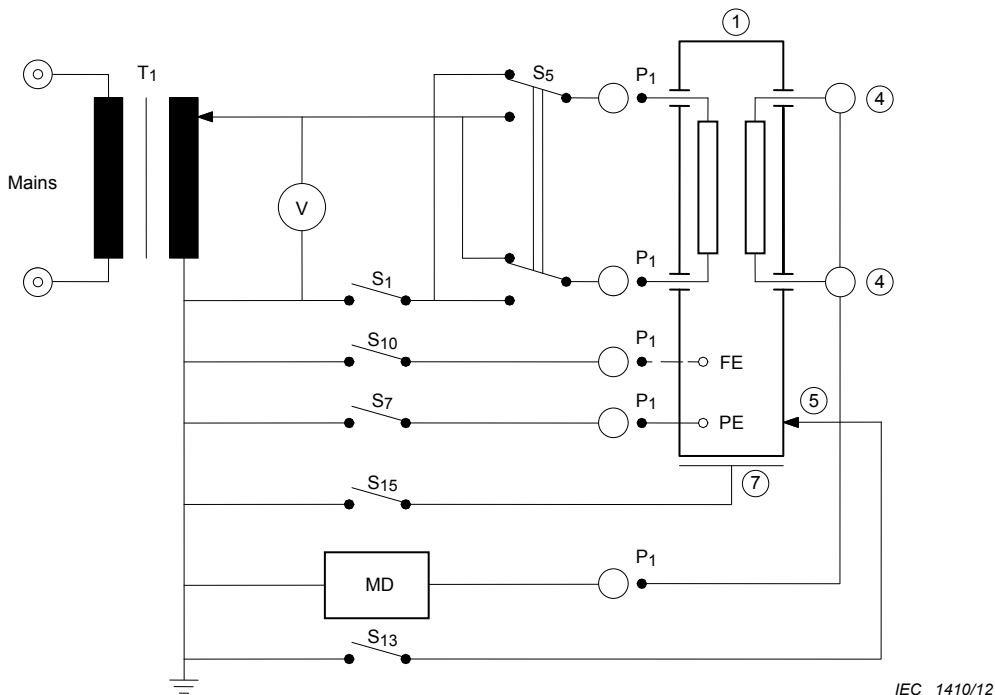
8.7.4.1 General

In existing list item b), replace "any HAZARDOUS SITUATION" with "any HAZARDOUS SITUATION described in 13.1".

Figure 13 – Measuring circuit for the EARTH LEAKAGE CURRENT of CLASS I ME EQUIPMENT, with or without APPLIED PART (see 8.7.4.5)

In the existing title of the figure, delete the word "the".

Replace existing Figure 15 with the following:



For legends, see Table 5.

Key

Measure (with S_7 closed if CLASS I ME EQUIPMENT)
under all possible combinations of positions of S_1 ,
 S_5 , S_{10} , S_{13} and S_{15} :

S_1 open is a SINGLE FAULT CONDITION.

CLASS I ME EQUIPMENT only:

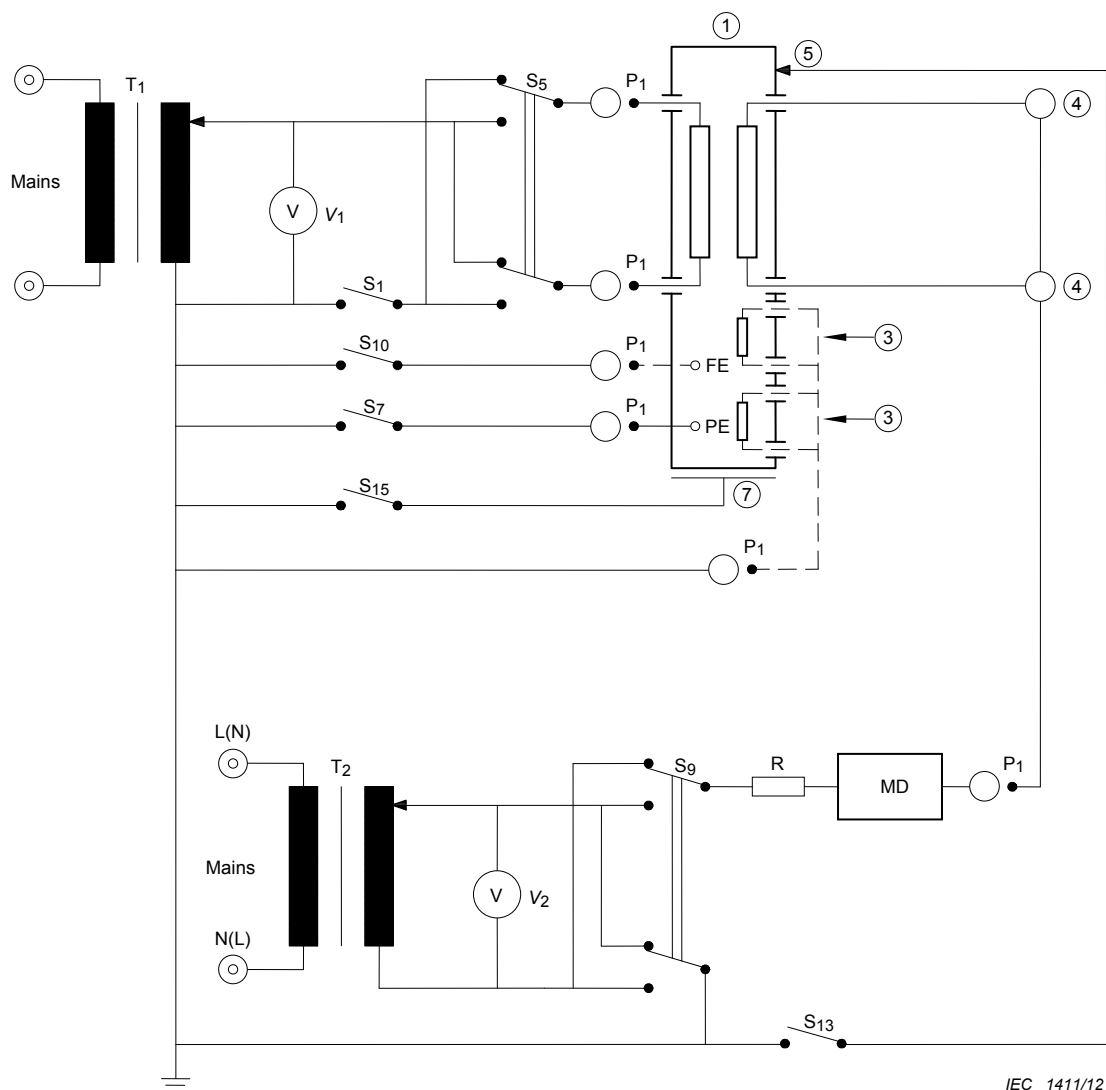
Measure with S_7 open (SINGLE FAULT CONDITION) and with S_1 closed under all possible combinations of S_5 , S_{10} , S_{13} and S_{15} .

For CLASS II ME EQUIPMENT, the PROTECTIVE EARTH CONNECTION and S_7 are not used.

Example with the measuring supply circuit of Figure F.1.

**Figure 15 – Measuring circuit for PATIENT LEAKAGE CURRENT from the
PATIENT CONNECTION to earth
(see 8.7.4.7 a))**

Replace existing Figure 16 with the following:



For legends, see Table 5.

Key

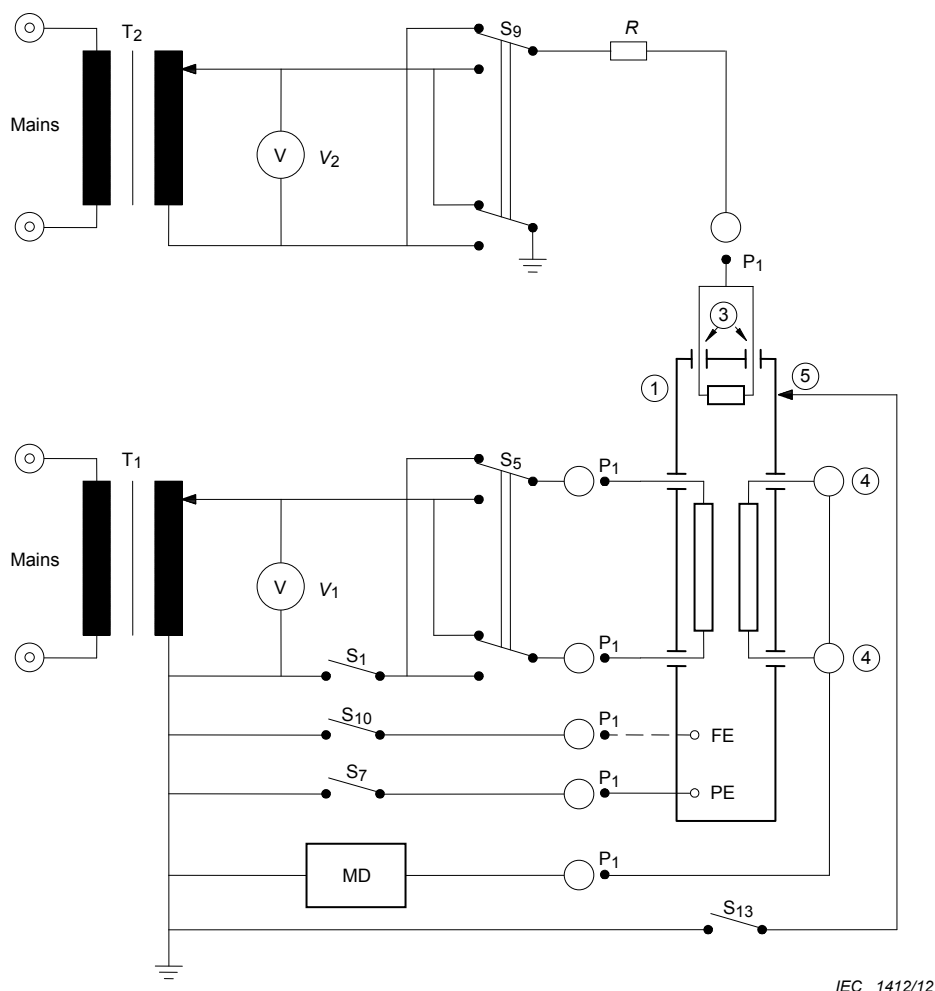
Measure (with S_7 closed, if CLASS I ME EQUIPMENT) WITH S_1 closed under all possible combinations of positions of S_5 , S_9 , S_{10} and S_{13} .

For CLASS II ME EQUIPMENT, the PROTECTIVE EARTH CONNECTION and S_7 are not used.

Example with the measuring supply circuit of Figure F.1.

Figure 16 – Measuring circuit for PATIENT LEAKAGE CURRENT via the PATIENT CONNECTION(S) of an F-TYPE APPLIED PART to earth caused by an external voltage on the PATIENT CONNECTION(S) (see 8.7.4.7 b))

Replace existing Figure 17 with the following:



For legends, see Table 5.

Key

Measure (with S_7 closed, if CLASS I ME EQUIPMENT) under all possible combinations of positions of S_1 , S_5 , S_9 , S_{10} and S_{13} (S_1 open is SINGLE FAULT CONDITION).

CLASS I ME EQUIPMENT only:

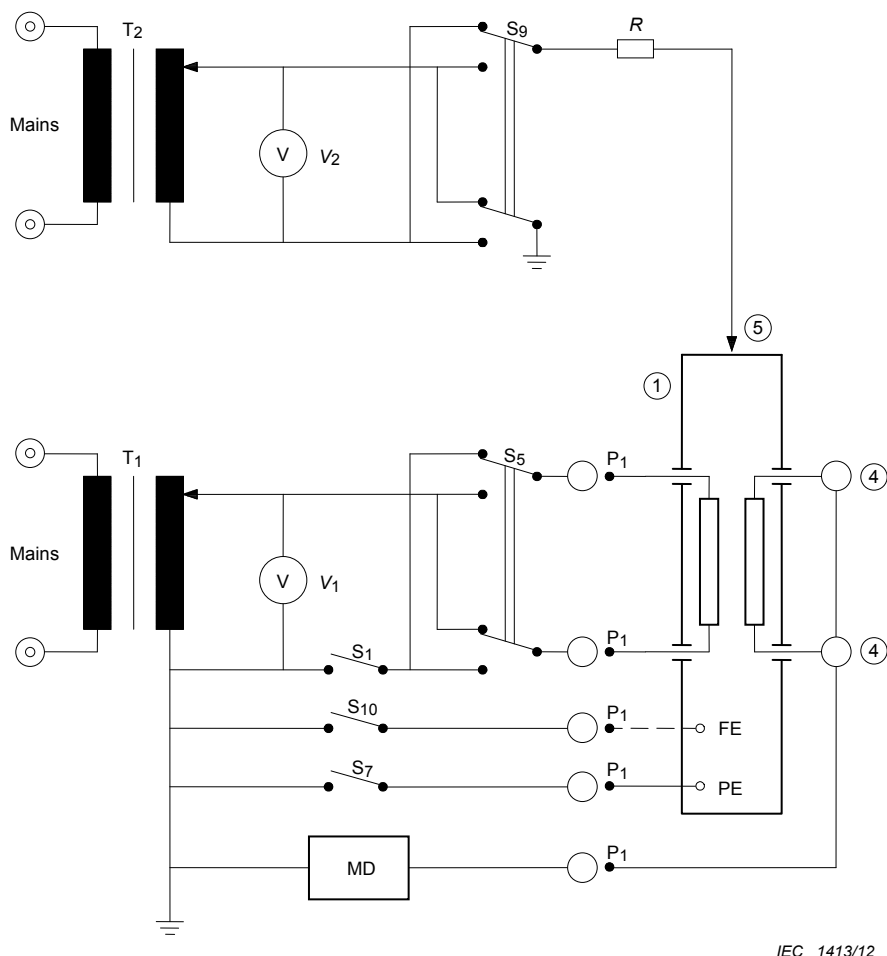
Measure with S_7 open (SINGLE FAULT CONDITION) and with S_1 closed under all possible combinations of S_5 , S_9 , S_{10} and S_{13} .

For CLASS II ME EQUIPMENT, the PROTECTIVE EARTH CONNECTION and S_T are not used.

Example with the measuring supply circuit of Figure F.1.

Figure 17 – Measuring circuit for PATIENT LEAKAGE CURRENT from PATIENT CONNECTION(S) to earth caused by an external voltage on a SIGNAL INPUT/OUTPUT PART
(see 8.7.4.7 c))

Replace existing Figure 18 with the following:



IEC 1413/12

For legends, see Table 5.

Key

Measure with S_1 closed (and with S_7 closed, if CLASS I ME EQUIPMENT) under all possible combinations of positions of S_5 , S_9 and S_{10}

For CLASS II ME EQUIPMENT, the PROTECTIVE EARTH CONNECTION and S_7 are not used.

Example with the measuring supply circuit of Figure F.1.

Figure 18 – Measuring circuit for PATIENT LEAKAGE CURRENT from PATIENT CONNECTION(S) to earth caused by an external voltage on a metal ACCESSIBLE PART that is not PROTECTIVELY EARTHED (see 8.7.4.7 d))

Figure 19 – Measuring circuit for the PATIENT AUXILIARY CURRENT (see 8.7.4.8)

In the existing title of the figure, delete the word "the".

Replace the existing second entry in the figure key with the following:

S_1 open is a SINGLE FAULT CONDITION.

Figure 20 – Measuring circuit for total PATIENT LEAKAGE CURRENT with all PATIENT CONNECTIONS of all APPLIED PARTS of the same type (TYPE B APPLIED PARTS, TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS) connected together(see 8.7.4.7 h))

Replace, in the current title of the figure, the phrase " "the total patient leakage current" with "total patient leakage current".

**Table 5 – Legends of symbols for Figure 9 to Figure 11, Figure 13 to Figure 20
Figure A.15, Annexes E and F**

In the existing legend (2), replace "(see 5.5 g) and" with "(See 5.5 f) and".

Replace the existing legend (5) with the following:

(5)	Metal ACCESSIBLE PART NOT PROTECTIVELY EARTHED In case of a non-conductive ENCLOSURE and PATIENT LEAKAGE CURRENT measurement, connection is replaced by a metal foil of maximum 20 cm × 10 cm in intimate contact with the ENCLOSURE or relevant parts of the ENCLOSURE and connected to the reference earth.
-----	--

After legend (6) insert the following new legend:

(7)	Metal plate under a non-conductive ENCLOSURE with dimensions at least equal to the plan projection of the ENCLOSURE connected to the reference earth
-----	--

Replace legend T_1 T_2 as follows

T_1, T_2	Single- or polyphase isolation transformers with sufficient power rating and adjustable output voltage (See also the rationale for 8.7.4.2 and 8.7.4.3.)
------------	--

Below legend S_{14} , insert the following new legend:

S_{15}	Switch for connecting to earth a metal plate under a non-conductive ENCLOSURE
----------	---

Replace legend R with the following:

R	Impedance to protect the circuitry and the person performing the test, but low enough to accept currents higher than the allowable values of the LEAKAGE CURRENT to be measured (optional)
-----	--

Replace legend $\frac{R}{=}$ with the following:

$\frac{1}{=}$	Reference earth (for LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT measurements and for testing of DEFIBRILLATION-PROOF APPLIED PARTS, not connected to protective earth of the SUPPLY MAINS)
---------------	---

8.7.4.5 * Measurement of the EARTH LEAKAGE CURRENT

Replace the title and the existing list item a) with the following:

8.7.4.5 * Measurement of the EARTH LEAKAGE CURRENT and current in functional earth connection

a) CLASS I ME EQUIPMENT is tested according to Figure 13. CLASS II ME EQUIPMENT with a functional earth connection according to 8.6.9 is tested as if it were CLASS I ME EQUIPMENT.

8.7.4.7 Measurement of the PATIENT LEAKAGE CURRENT

Replace existing list item g) with the following:

g) The PATIENT LEAKAGE CURRENT is measured (see also Annex E):

- for TYPE B APPLIED PARTS, from all PATIENT CONNECTIONS connected directly together.

- for TYPE BF APPLIED PARTS, from and to all PATIENT CONNECTIONS of a single function either connected directly together or loaded as in NORMAL USE.
- for TYPE CF APPLIED PARTS, from and to every PATIENT CONNECTION in turn.

In the existing second paragraph of list item g), replace "PATIENT leads and electrodes" with "PATIENT leads or PATIENT cables and electrodes".

8.8 Insulation

8.8.1 * General

Replace the first paragraph and its two dashes with:

Only insulation that is relied upon as a MEANS OF PROTECTION, including REINFORCED INSULATION, shall be subject to testing.

Table 6 – Test voltages for solid insulation forming a MEANS OF PROTECTION

Add the following new table notes:

NOTE 1 For a barrier according to:

- Figure J.6, use the column MEANS OF PATIENT PROTECTION – Protection from SECONDARY CIRCUITS – Two MOPP.
- 8.5.2.1 and Figure J.7, use the column MEANS OF PATIENT PROTECTION – Protection from MAINS PART – One MOPP.

NOTE 2 See the rationale for 8.8.3.

8.8.4 Insulation other than wire insulation

8.8.4.1 * Mechanical strength and resistance to heat

Replace the existing second paragraph with the following:

Compliance is checked by inspection of the ME EQUIPMENT and the design documentation, and, if necessary, inspection of the RISK MANAGEMENT FILE in conjunction with the following tests:

- resistance to moisture, etc. (see 11.6);
- dielectric strength (see 8.8.3);
- mechanical strength (see 15.3).

8.9 * CREEPAGE DISTANCES and AIR CLEARANCES

8.9.1 * Values

8.9.1.1 General

Replace the existing text of the subclause with the following:

CREEPAGE DISTANCES and AIR CLEARANCES of ME EQUIPMENT shall be equal to or greater than the values of:

- for insulation between parts of opposite polarity of the MAINS PART on the SUPPLY MAINS side of any mains fuse or OVER-CURRENT RELEASE, one MEANS OF OPERATOR PROTECTION in accordance with Table 13, Table 14 and Table 16; and
- for insulation providing at least a MEANS OF PROTECTION, in accordance with Table 12 to Table 16 (inclusive) except as specified in 8.9.1.2 to 8.9.1.15. See also 8.9.2 to 8.9.4.

8.9.1.2 CREEPAGE DISTANCES and AIR CLEARANCES complying with IEC 60950-1

In the existing text, replace "Table 11 to Table 16 (inclusive)" with "Table 12 to Table 16 (inclusive)".

8.9.1.4 Minimum CREEPAGE DISTANCE

In the existing text, replace "Table 11 to Table 16 (inclusive)" with "Table 12 to Table 16 (inclusive)".

8.9.1.6 * Interpolation

In the existing text, replace "Table 11 to Table 16 (inclusive)" with "Table 12 to Table 16 (inclusive)".

8.9.1.5 ME EQUIPMENT RATED for high altitudes

Table 8 – Multiplication factors for AIR CLEARANCES for altitudes up to 5 000 m

In existing table Note 3, replace "IEC 60664-1:1993 as amended" with "IEC 60664-1:2007".

8.9.1.8 Pollution degree classification

After the last paragraph of the subclause, insert the following:

Annex M specifies measures that may be used to reduce the pollution degree.

8.9.1.15 * CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS

In the existing note, delete "Table 11 and" and replace "the clearance is related" with "the AIR CLEARANCE is related".

Delete the existing Table 11 and replace the title with "Table 11 – Not used".

Table 14 – Additional AIR CLEARANCES for insulation in MAINS PARTS with PEAK WORKING VOLTAGES exceeding the peak value of the NOMINAL MAINS VOLTAGE ^a (see 8.9.1.10)

Add the following table note:

NOTE For voltage values above the PEAK WORKING VOLTAGE values given in the table, linear extrapolation is permitted.

Table 16 – Minimum CREEPAGE DISTANCES providing MEANS OF OPERATOR PROTECTION ^a

Replace existing Table 16 with the following:

WORKING VOLTAGE V r.m.s or d.c.	Spacing for one MEANS OF OPERATOR PROTECTION						
	Pollution degree 1	Pollution degree 2			Pollution degree 3		
	Material group	Material group			Material group		
	I, II, IIIa, IIIb	I	II	IIIa or IIIb	I	II	IIIa or IIIb
25	Use the AIR CLEARANCE from the appropriate table	0,5	0.5	0,5	1,3	1,3	1,3
50		0,6	0,9	1,2	1,5	1,7	1,9
100		0,7	1,0	1,4	1,8	2,0	2,2
125		0,8	1,1	1,5	1,9	2,1	2,4
150		0,8	1,1	1,6	2,0	2,2	2,5
200		1,0	1,4	2,0	2,5	2,8	3,2
250		1,3	1,8	2,5	3,2	3,6	4,0
300		1,6	2,2	3,2	4,0	4,5	5,0
400		2,0	2,8	4,0	5,0	5,6	6,3
600		3,2	4,5	6,3	8,0	9,6	10,0
800		4,0	5,6	8,0	10,0	11,0	12,5
1 000	5,0	7,1	10,0	12,5	14,0	16,0	
NOTE 1 Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION are obtained by doubling the values in this table.							
NOTE 2 A CREEPAGE DISTANCE cannot be less than the required air clearance. See 8.9.1.4.							
NOTE 3 For WORKING VOLTAGE values greater than 1 000 V, refer to Table A.2.							
^a CREEPAGE DISTANCES within this table apply to all situations.							

8.9.2 * Application

In existing list item a), replace "result in a HAZARDOUS SITUATION" with "result in a HAZARDOUS SITUATION described in 13.1".

8.9.4 * Measurement of CREEPAGE DISTANCES and AIR CLEARANCES

Replace the existing first paragraph with the following:

Compliance is checked by measurement taking into account the rules in Figure 22 to Figure 31 (inclusive). In each figure, the dashed line (— — —) represents AIR CLEARANCE and the shaded bar (▨) represents CREEPAGE DISTANCE.

The minimum spacing (X) for grooves transverse to the CREEPAGE DISTANCE in Figure 23 to Figure 25 and Figure 27 to Figure 31 (inclusive) that are considered a MEANS OF OPERATOR PROTECTION may be adjusted based on pollution degree if the minimum AIR CLEARANCE is 3 mm or more. The minimum width of the groove is:

- 0,25 mm for pollution degree 1
- 1,0 mm for pollution degree 2
- 1,5 mm for pollution degree 3

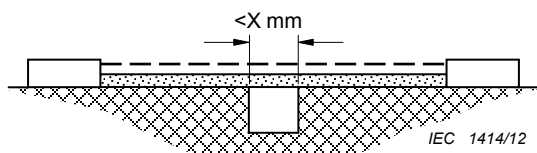
If the specified minimum AIR CLEARANCE is less than 3 mm, the minimum spacing (X) for grooves transverse to the CREEPAGE DISTANCE is the lesser of:

- the relevant value specified in the previous paragraph, or
- one third of the specified minimum AIR CLEARANCE.

The minimum spacing (X) for a groove transverse to a CREEPAGE DISTANCE that is considered a MEANS OF PATIENT PROTECTION is 1 mm for pollution degree 1 and pollution degree 2, and 1,5 mm for pollution degree 3.

In the existing seventh paragraph, replace "Table 11 to Table 16 (inclusive)" with "Table 12 to Table 16 (inclusive)".

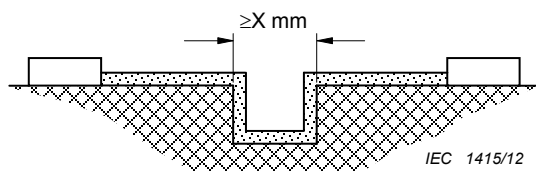
Replace existing Figures 23, 24 and 25 with the following:



Condition: Path under consideration includes a parallel- or converging-sided groove of any depth with a width less than X mm.

Rule: CREEPAGE DISTANCE and AIR CLEARANCE are measured directly across the groove as shown.

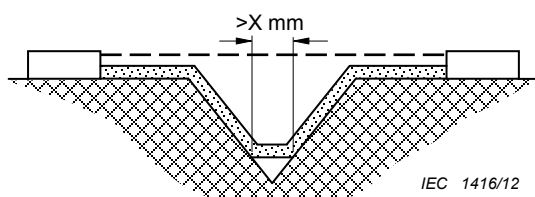
Figure 23 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 2



Condition: Path under consideration includes a parallel-sided groove of any depth and equal to or more than X mm.

Rule: AIR CLEARANCE is the "line of sight" distance. CREEPAGE DISTANCE path follows the contour of the groove.

Figure 24 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 3

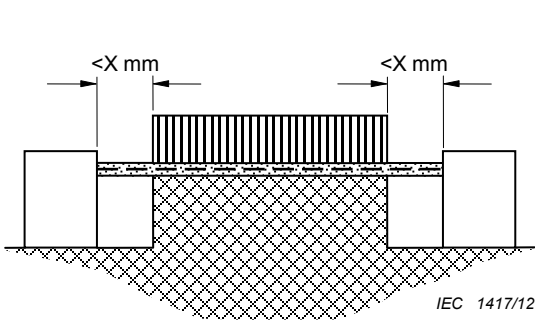


Condition: Path under consideration includes a V-shaped groove with a width greater than X mm and an internal angle of less than 80° .

Rule: AIR CLEARANCE is the "line of sight" distance. CREEPAGE DISTANCE path follows the contour of the groove but "short circuits" the bottom of the groove by an X mm link.

Figure 25 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 4

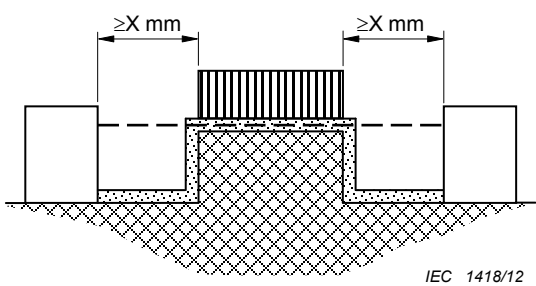
Replace existing Figures 27, 28, 29, 30 and 31 with the following:



Condition: Path under consideration includes an uncemented joint (see 8.9.3) with grooves less than $X \text{ mm}$ wide on each side.

Rule: CREEPAGE DISTANCE and AIR CLEARANCE path are the "line of sight" distance shown.

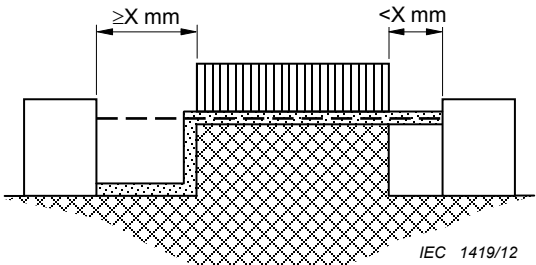
Figure 27 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 6



Condition: Path under consideration includes an uncemented joint (see 8.9.3) with grooves equal to or more than $X \text{ mm}$ wide on each side.

Rule: AIR CLEARANCE is the "line of sight" distance. CREEPAGE DISTANCE path follows the contour of the groove.

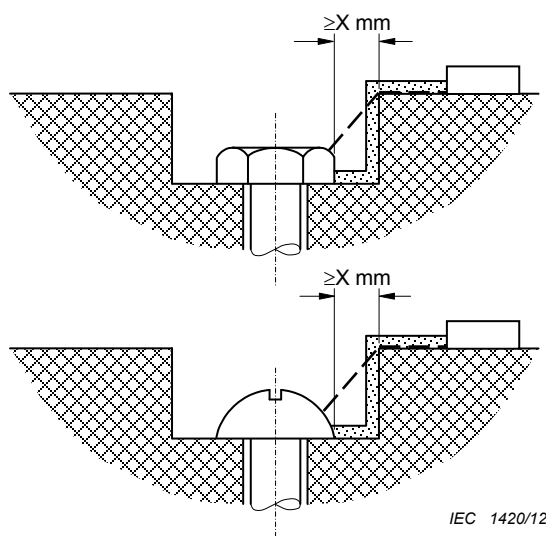
Figure 28 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 7



Condition: Path under consideration includes an uncemented joint (see 8.9.3) with a groove on one side less than $X \text{ mm}$ wide and the groove on the other side equal to or more than $X \text{ mm}$ wide.

Rule: AIR CLEARANCE and CREEPAGE DISTANCE are as shown.

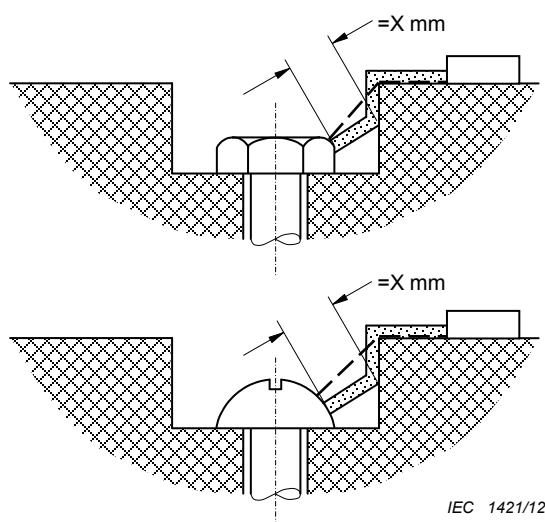
Figure 29 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 8



Condition: Gap between head of screw and wall of recess wide enough to be taken into account.

Rule: The AIR CLEARANCE is the shortest distance to any point on the head of the screw. CREEPAGE DISTANCE path follows the surface.

Figure 30 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 9



Condition: Gap between head of screw and wall of recess too narrow to be taken into account.

Rule: Measurement of CREEPAGE DISTANCE is from screw to wall at any point where the distance is equal to X mm. The AIR CLEARANCE is the shortest distance to any point on the head of the screw.

Figure 31 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 10

8.10 Components and wiring

8.10.2 * Fixing of wiring

In the existing first paragraph, replace "touching circuit points resulting in a HAZARDOUS SITUATION" with "touching parts resulting in a HAZARDOUS SITUATION described in 13.1".

In the existing third paragraph, replace "result in a HAZARDOUS SITUATION" with "result in a HAZARDOUS SITUATION described in 13.1".

Replace the compliance paragraph with the following:

Compliance is checked by inspection of the ME EQUIPMENT.

8.10.4 * Cord-connected HAND-HELD parts and cord-connected foot-operated control devices (see also 15.4.7)

8.10.4.2 Connection cords

Replace the existing first paragraph with the following:

The connection and anchorage at both ends of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT shall comply with the requirements specified for POWER SUPPLY CORDS in 8.11.3, if breaking free or shorting between the conductors could result in a HAZARDOUS SITUATION described in 13.1. This requirement also applies to other HAND-HELD parts if disturbance or breaking of one or more of the connections could result in a HAZARDOUS SITUATION described in 13.1.

8.10.5 * Mechanical protection of wiring

In existing list items a) and b), replace "could result in a HAZARDOUS SITUATION" with "could result in a HAZARDOUS SITUATION described in 13.1".

Replace the existing compliance paragraph with the following:

Compliance is checked by inspection and, where appropriate, by manual test.

8.11 MAINS PARTS, components and layout

8.11.1 Isolation from the SUPPLY MAINS

In existing list item a), after the second paragraph, insert the following:

For PERMANENTLY INSTALLED ME EQUIPMENT, the means provided to isolate its circuits electrically from the SUPPLY MAINS shall be capable of being locked in the off position if:

- reconnection would result in a HAZARDOUS SITUATION; or
- any OPERATOR including SERVICE PERSONNEL is unable to view the means of isolation from their intended position.

The locking mechanism may be in a SUPPLY MAINS switch provided by the RESPONSIBLE ORGANIZATION.

The requirements for the isolation device shall be specified in the ACCOMPANYING DOCUMENTS.

Replace existing list items e) and f) with the following:

- e) The actuator of a SUPPLY MAINS switch that is used to comply with 8.11.1 a) shall comply with IEC 60447.
- f) In non-PERMANENTLY INSTALLED ME EQUIPMENT that has no SUPPLY MAINS switch, a suitable plug device used to isolate ME EQUIPMENT from the SUPPLY MAINS shall be considered as complying with the requirements of 8.11.1 a). An APPLIANCE COUPLER or a flexible cord with a MAINS PLUG may be used.

8.11.5 Mains fuses and OVER-CURRENT RELEASES

Replace the existing final sentence of the second dash with the following:

The effect of short-circuit fault conditions in other circuits shall be VERIFIED before eliminating fuses or OVER-CURRENT RELEASES.

Replace the existing first paragraph following the note and the compliance paragraph with the following:

Justification for omission of fuses or OVER-CURRENT RELEASES shall be documented.

Compliance is checked by inspection of the ME EQUIPMENT and the MANUFACTURER'S documentation.

8.11.6 Internal wiring of the MAINS PART

Replace existing list item a) with the following:

- a) Internal wiring in a MAINS PART between the MAINS TERMINAL DEVICE or the APPLIANCE INLET and the protective devices shall have a cross-sectional area not less than the minimum required for the POWER SUPPLY CORD as specified in 8.11.3.3.

9 * Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

9.2 * HAZARDS associated with moving parts

Replace the existing title with the following:

9.2 * MECHANICAL HAZARDS associated with moving parts

9.2.1 * General

In the existing second paragraph, replace "protective measures" with "RISK CONTROL measures".

Replace the existing third paragraph with the following:

The RESIDUAL RISK associated with moving parts is considered acceptable if exposure is needed for the ME EQUIPMENT to perform its intended function, and RISK CONTROL measures have been implemented (e.g. warnings).

Renumber the note to Note 1 and insert the following:

NOTE 2 See ISO 14971:2007, subclauses 6.2 and 6.5.

9.2.2 Trapping zone

9.2.2.1 General

In the third dash of the existing first paragraph, replace "protective measures" with "other RISK CONTROL measures".

In the existing second paragraph, replace "protective measures" with "RISK CONTROL measures".

9.2.2.3 Safe distances

In the third line of the existing paragraph, replace "ISO 13852" with ISO 13857:2008".

9.2.2.4 * GUARDS and protective measures

Replace the existing title with the following:

9.2.2.4 * GUARDS and other RISK CONTROL measures

Table 20 – Acceptable gaps

In the existing table footnote ^a, replace "ISO 13852:1996" with "ISO 13857:2008".