

SLOVENSKI STANDARD SIST EN 60601-1-2:2015

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Medicinska električna oprema - 1-2. del: Splošne zahteve za osnovno varnost in bistvene tehnične lastnosti - Spremljevalni standard: Elektromagnetne motnje -Zahteve in preskušanje

Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances -

Requirements and tests Teh STANDARD PREVIEW (standards.iteh.ai)

SIST EN 60601-1-2:2015

Appareils électromédicaux de Partie 1-2: Exigences générales pour la sécurité de base et les performances essentielles - Norme collaterale. Perturbation électromagnétique -Exigences et essais

Ta slovenski standard je istoveten z: EN 60601-1-2:2015

ICS:

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| 11.040.01 | Medicinska oprema na splošno | Medical equipment in general |
|-----------|---|--|
| 33.100.01 | Elektromagnetna združljivost na splošno | Electromagnetic compatibility in general |

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<u>SIST EN 60601-1-2:2015</u> https://standards.iteh.ai/catalog/standards/sist/67520ca4-41ae-4cde-be81-43217d2c65e9/sist-en-60601-1-2-2015

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Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2:2014)

Appareils électromédicaux - Partie 1-2: Exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale: Perturbations électromagnétiques - Exigences et essais (IEC 60601-1-2:2014)

Medizinische elektrische Geräte - Teil 1-2: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: Elektromagnetische Störgrößen - Anforderungen und Prüfungen (IEC 60601-1-2:2014)

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CENELEC Management Centre has the same status as the official versions. 43217d2c65c9/sist-en-60601-1-2-2015

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European Committee for Electrotechnical Standardization Comité Européen de Normalisation Electrotechnique Europäisches Komitee für Elektrotechnische Normung

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European foreword

The text of document 62A/916/FDIS, future edition 4 of IEC 60601-1-2, prepared by SC 62A, "Common aspects of electrical equipment used in medical practice", of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-1-2:2015.

The following dates are fixed:

| • | latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement | (dop) | 2016-03-18 |
|---|---|-------|------------|
| • | latest date by which the national standards conflicting with the document have to be withdrawn | (dow) | 2018-12-31 |

This document supersedes EN 60601-1-2:2007.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

iTeh STEndorsement notice VIEW

The text of the International Standard JEC 60601-1-2:2014 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated: https://standards.iten.ai/catalog/standards/sist/67520ca4-41ae-4cde-be81-43217d2c65e9/sist-en-60601-1-2-2015

| IEC 60601-1-2:2007 | NOTE | Harmonized as EN 60601-1-2:2007 (not modified) |
|---------------------|------|--|
| IEC 60601-2-27:2011 | NOTE | Harmonized as EN 60601-2-27:2006 (not modified) |
| IEC 60601-2-44:2009 | NOTE | Harmonized as EN 60601-2-44:2009 (not modified) |
| IEC 61000-3-11:2000 | NOTE | Harmonized as EN 61000-3-11:2000 (not modified) |
| IEC 61000-3-12:2011 | NOTE | Harmonized as EN 61000-3-12:2011 (not modified) |
| IEC 61000-3-12:2011 | NOTE | Harmonized as EN 61000-3-12:2011 (not modified) |
| IEC 60601-6-1:2005 | NOTE | Harmonized as EN 60601-6-1:2007 (not modified) |
| IEC 60601-6-2:2005 | NOTE | Harmonized as EN 60601-6-2:2005 (not modified) |
| IEC 61496-1:2008 | NOTE | Harmonized as EN 61496-1:2008 (not modified) |
| CISPR 16-1-1:2010 | NOTE | Harmonized as EN 55016-1-1:2010 (not modified) |
| CISPR 16-2-3:2010 | NOTE | Harmonized as EN 55016-2-3:2010 (not modified) |
| CISPR 24:2010 | NOTE | Harmonized as EN 55024:2010 (not modified) |
| CISPR 25:2008 | NOTE | Harmonized as EN 55025:2008 (not modified) |
| ISO 17025:2005 | NOTE | Harmonized as EN ISO/IEC 17025:2005 (not modified) |

Annex ZA

(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. However, for any use of this standard "within the meaning of Annex ZZ", the user must always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When the IEC or ISO standard is referred to in the IEC text standard, this must be understood as a normative reference to the parallel EN standard, as outlined below, including the foreword and the Annexes ZZ.

NOTE 1 The way in which referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

| Dublication | iTe | h STANDARD PREVIE | | Voor |
|----------------|----------------------|--|----------------------|------|
| IEC 60417 | Data | Graphical symbols for use on equipment | IEC 60417 | 2004 |
| | base | available from http://www.graphical- | | |
| IEC 60601-1 | 2005 https://star | Medical electrical equipment ²⁰¹⁵ Part 1: General requirements for basic safety and essential performance ⁰¹⁻¹⁻²⁻²⁰¹⁵ | EN 60601-1 -be81- | 2006 |
| A1 | 2012 | | A1 | 2013 |
| IEC 60601-1-8 | 2006 | Medical electrical equipment | EN 60601-1-8 | 2007 |
| | | 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 | + corr. March | 2010 |
| A1 | 2013 | 2 | A1 | 2013 |
| IEC 60601-1-11 | 2010 | Medical electrical equipment Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment | EN 60601-1-11 | 2010 |
| IEC 60601-1-12 | 2014 | Medical electrical equipment Part 1-12: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment | | |
| IEC 60601-2-2 | 2010 | Medical electrical equipment Part 2-2: Particular requirements for the basic safety and essential performance of high | | |

NOTE 2 When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

EN 60601-1-2:2015

| Publication | <u>Year</u> | <u>Title</u> frequency surgical equipment and high | EN/HD and IEC/ISO | <u>Year</u> |
|----------------|----------------------|--|--------------------------|----------------------|
| IEC 60601-2-3 | 2012 | frequency surgical accessories Medical electrical equipment – Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment | | |
| IEC 61000-3-2 | 2005 | Electromagnetic compatibility (EMC) - Part 3- 2: Limits - Limits for harmonic current emissions (equipment input current <= 16 A per phase) | EN 61000-3-2 | 2006 |
| A1 A2 | 2008 2009 | | +A1 +A2 | 2009 2009 |
| IEC 61000-3-3 | 2013 | Electromagnetic compatibility (EMC) - Part 3- 3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low- voltage supply systems, for equipment with rated current <= 16 A per phase and not subject to conditional connection | EN 61000-3-3 | 2013 |
| IEC 61000-4-2 | 2008 | Electromagnetic compatibility (EMC) - Part 4- 2: Testing and measuring techniques - Electrostatic discharge immunity test | EN 61000-4-2 | 2009 |
| IEC 61000-4-3 | 2006 | Electromagnetic compatibility (EMC) - Part 4- 3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic | EN 61000-4-3 | 2006 |
| A1 | 2007 | field immunity test | +A1 | 2008 |
| A2 | 2010 | (standards.iten.al) | +IS1 +A2 | 2009 2010 |
| IEC 61000-4-4 | 2012 https://star | Electromagnetic compatibility (EMC) - Part 4- 4: Testing and measurement techniques - Electrical fast transient/burst immunity test | EN 61000-4-4 -be81- | 2012 |
| IEC 61000-4-5 | 2005 | Electromagnetic compatibility (EMC) - Part 4- 5: Testing and measurement techniques - Surge immunity test | EN 61000-4-5 | 2006 |
| IEC 61000-4-6 | 2013 | Electromagnetic compatibility (EMC) - Part 4- 6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields | | |
| IEC 61000-4-8 | 2009 | Electromagnetic compatibility (EMC) - Part 4- 8: Testing and measurement techniques - Power frequency magnetic field immunity test | EN 61000-4-8 | 2010 |
| IEC 61000-4-11 | 2004 | Electromagnetic compatibility (EMC) - Part 4- 11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests | EN 61000-4-11 | 2004 |
| CISPR 11 | 2009 | Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement | EN 55011 (mod) | 2009 |
| A1 | 2010 | | | |
| CISPR 14-1 | 2005 | Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: Emission | EN 55014-1 +A1 +A2 | 2006 2009 2011 |
| CISPR 16-1-2 | 2003 | Specification for radio disturbance and immunity measuring apparatus and methods - Part 1-2: Radio disturbance and immunity | EN 55016-1-2 | 2004 |

| Publication | <u>Year</u> | <u>Title</u> measuring apparatus - Ancillary equipment - Conducted disturbances | EN/HD and IEC/ISO | <u>Year</u> |
|-------------|-------------|--|-------------------|-------------|
| A1 | 2004 | | +A1 | 2005 |
| A2 | 2006 | | +A2 | 2006 |
| CISPR 32 | 2012 | Electromagnetic compatibility of multimedia equipment – Emission requirements | EN 55032 | 2012 |
| ISO 7137 | 1995 | Aircraft – Environmental conditions and test procedures for airborne equipment | | |
| ISO 7637-2 | 2011 | Road vehicles – Electrical disturbances from conduction and coupling – Part 2: Electrical transient conduction along supply lines only | | |
| ISO 14971 | 2007 | Medical devices – Application of risk management to medical devices | EN ISO 14971 | 2012 |

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EN 60601-1-2:2015

Application of Annexes of the EN 60601 series

The Annex ZZ of EN 60601-1:2006+A1:2013 applies.

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Annex ZZ

(informative)

Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association to provide a means of conforming to the Essential Requirements given in Annex I of EU Directive 93/42/EEC.

General Guidance:

Once this standard will be cited in the Official Journal of the European Union under that Directive, compliance with the clauses of this standard given in Table ZZ.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements (ERs) of that Directive and associated EFTA regulations.

NOTE 1 The standard's scope is limited to the specific uses, environments, contexts, objective situations specifically indicated. It cannot provide for presumption of conformity in other conditions. Some clauses or subclauses may be not applicable due to the specific type of equipment under consideration.

NOTE 2 Only prescriptions contained in the normative parts of the text are relevant to the presumption of conformity of this standard. Informative parts may, however, support users to interpret such prescriptions correctly.

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NOTE 3 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC. This means that risks have to be reduced "as far as possible", "to be lowest possible level", "minimized" or "removed", according to the wording of the corresponding essential requirement which must be interpreted and applied in such a way as to take account of technology and practice existing at the time of design and of technical and economical considerations compatible with a high level of protection of health and safety.

NOTE 4 The manufacturer's policy for determining acceptable risk must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the directive.

NOTE 5 For all parts of this standard that a) refer in their clauses to specific national legislation possibly exempting manufacturers from the thorough application of relevant provisions of this standard or b) link the completion of a relevant process/prescription to any discretional choice/power of manufacturers, the user of the standard should check that such clauses are in compliance with Directive 93/42/EEC.

NOTE 6 This Annex ZZ is based on Normative References according to Annex ZA, replacing the references in the core text.

NOTE 7 According to the scope of this standard the coverage in Table ZZ.1 only applies to protection of ME equipment and ME systems against electromagnetic disturbances. This European Standard lists in Table ZZ.1 only the essential requirements covered.

WARNING: Other requirements and other EU Directives and Regulations may be applicable to the product(s) falling within the scope of this standard.

Table ZZ.1: Relationship between Essential Requirements of Directive 93/42/EEC, and Clauses and Subclauses of this standard

| No. | Essential Requirements | Coverage EN 60601-1-2 | | | |
|--------|---|---|--|--|--|
| Ι. | GENERAL REQUIREMENTS | | | | |
| 1. | General Guidance notes 1-7 shall be observed | | | | |
| 1 | The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. This shall include: | If the manufacturer follows this standard in his design and manufacturing process, this European Standard gives a valuable set of technical requirements to assist in fulfilling this ER with regard to EMC- aspects of the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons (refer to clauses 4 to 9 of this collateral standard) without covering the risk benefit balancing. | | | |
| | iTeh STANDARD PH | REVIEW | | | |
| | - reducing, as far as possible, the risk of use teh error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and 43217d2c65e9/sist-en-60601-1-2 | Covered in respect to 7.1 Protection of radio services and other equipment, 7.2 Protection of the public mains network, and -8.9 Immunity test levels | | | |
| 2. | General Guidance notes 1-7 shall be observed | | | | |
| 2 | The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: | 1 st paragraph: Covered under the condition that 2nd paragraph (including the following 3 bullets) is taken into account. 2 nd paragraph (including the following 3 bullets): Not covered. | | | |
| | eliminate or reduce risks as far as possible (inherently safe design and construction), | | | | |
| | where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, | | | | |
| | inform users of the residual risks due to any shortcomings of the protection measures adopted. | | | | |
| П. | REQUIREMENTS FOR DESIGN AND CONSTRUCT | ION | | | |
| Genera | I Guidance notes 1-7 shall be observed | | | | |
| 9.2 | Devices must be designed and manufactured in such a way as to remove or minimize as far as is | | | | |

| No. | Essential Requirements | Coverage EN 60601-1-2 |
|--------|--|--|
| | possible: | |
| | the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features; | |
| | risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration; | Covered in respect to electromagnetic disturbances, see 8.9 Immunity test levels. |
| | the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; | Covered in respect to electromagnetic disturbances, see 7.1 Protection of radio services and other equipment, 7.2 Protection of the public mains network. |
| | risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism. | |
| 11 | Protection against radiation | General Guidance note 1-7 shall be observed |
| 11.1 | General iTeh STANDARD PI | REVIEW |
| 11.1.1 | Devices shall be designed and manufactured in the such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, specified levels for therapeutic and diagnostic purposes. | Covered in respect to electromagnetic disturbances, see 7.1 Protection of radio services and other equipment. Oca4-41ae-4cde-be81- -2015 |
| 12 | Requirements for medical devices connected to or equipped with an energy source | General Guidance notes 1-7 shall be observed |
| 12.5 | Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment. | Covered in respect to electromagnetic disturbances, see 7.1 Protection of radio services and other equipment. |
| 13 | Information supplied by the manufacturer | General Guidance notes 1-7 shall be observed |
| 13.5 | Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components. | Covered in respect to aspects related to accessories, components and subassemblies contained in 5.2.1.1 d) and e) |

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INTERNATIONAL STANDARD

NORME INTERNATIONALE



Medical electrical equipment ANDARD PREVIEW Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

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Appareils électromédicauxenai/catalog/standards/sist/67520ca4-41ae-4cde-be81-

Partie 1-2: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Perturbations électromagnétiques – Exigences et essais

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CONTENTS

| CON | TENTS. | | | 2 |
|--------------------------------------|----------|---------------|---|-----|
| FOF | REWORD | | | 6 |
| INT | RODUCT | ION | | 9 |
| 1 Scope object and related standards | | | elated standards | 11 |
| • | 1 1 | | | 11 |
| | 1.1 | Object | | 11 |
| | 1.2 | Delated et | andarde | 11 |
| | 1.5 | | | 11 |
| | | 132 | Particular standards | 11 |
| 2 | Normativ | ve referenci | ۲ articular standards | 11 |
| 2 | Torme a | nd dofinitio | nc | 12 |
| 3 | | | | 13 |
| 4 | General | requiremer | NTS | 17 |
| | 4.1 | RISK MANAG | GEMENT PROCESS for ME EQUIPMENT and ME SYSTEMS | 17 |
| | 4.2 | * Non-ME E | QUIPMENT used in an ME SYSTEM | 17 |
| | 4.3 | General te | st conditions | 17 |
| | | 4.3.1 | * Configurations | 17 |
| | | 4.3.2 | Artificial hand | 18 |
| | | 4.3.3 | * Power input voltages and frequencies | 18 |
| 5 | Me equi | PMENT and I | ME SYSTEMS identification, marking and documents | 20 |
| | 5.1 | Additional | requirements for marking on the outside of ME EQUIPMENT and | |
| | | | IS that are specified for use only in a shielded location SPECIAL | 20 |
| | 52 | | <u>8151-EN 60601-1-222015</u> MINÓDODIMENTÓDOCIANÓS (sist/67520c24_412e_4cde_be81_ | 20 |
| | 5.2 | 5 2 1 | Instructions the bisisten-60601-1-2-2015 | 20 |
| | | 522 | | 20 |
| 6 | Docume | ntation of th | he tests | 23 |
| 0 | 6 1 | Conorol | | 20 |
| | 0.1 | Tost plan | | 23 |
| | 0.Z | Test plan. | • | 23 |
| 7 | | | L | 23 |
| ' | | | efissions requirements for me equipment and me statems | 20 |
| | 7.1 | Protection | of radio services and other equipment | 23 |
| | | 7.1.1 | General | 23 |
| | | 7.1.2 | Operating modes | 23 |
| | | 7.1.3 | * Subovetere | 24 |
| | | 7.1.4 | Subsystems | 24 |
| | | 7.1.J | shielded location SPECIAL ENVIRONMENT | 24 |
| | | 7.1.6 | ME EQUIPMENT and ME SYSTEMS that include radio equipment | .24 |
| | | 7.1.7 | * ME EQUIPMENT whose main functions are performed by | |
| | | | motors and switching or regulating devices | 25 |
| | | 7.1.8 | ME EQUIPMENT and ME SYSTEMS containing X-ray generators | 25 |
| | | 7.1.9 | PATIENT physiological simulation | 25 |
| | | 7.1.10 | Artificial hand | 25 |
| | | 7.1.11 | PATIENT-coupled cables | 25 |
| | | 7.1.12 | PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE | _ |
| | | | ME SYSTEMS | 25 |
| | 7.2 | Protection | of the PUBLIC MAINS NETWORK | 26 |

| 606 | 01-1-2 © | IEC:2014 – 3 – | |
|--------------|-------------------|---|----------|
| | | 7.2.1 * Harmonic distortion | 26 |
| | | 7.2.2 * Voltage fluctuations and flicker | 26 |
| | 7.3 | EMISSIONS requirements summary | 26 |
| 8 | Electror | magnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS | 27 |
| | 8.1 | * General | 27 |
| | 8.2 | PATIENT physiological simulation | 30 |
| | 8.3 | Termination of PATIENT-COUPLED parts | 30 |
| | 8.4 | HAND-HELD ME EQUIPMENT and parts intended to be HAND-HELD | 30 |
| | 8.5 | * Subsystems | 31 |
| | 8.6 | PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS | 31 |
| | 8.7 | * Operating modes | 31 |
| | 0.0 9.0 | * IMMUNUTY TEST LEVELS | 3Z |
| | 0.9 8 10 | * IMMUNITY to provimity fields from RF wireless communications | 52 |
| | 0.10 | equipment | 39 |
| 9 | * Test re | eport | 41 |
| Ann | nex A (inf | ormative) General guidance and rationale | 43 |
| | A.1 | Safety and performance | 43 |
| | A.2 | Testing of normally non-observable functions | 43 |
| | A.3 | Rationale for particular clauses and subclauses | 43 |
| Ann | nex B (inf | ormative) Guide to marking and labelling requirements for ME EQUIPMENT | |
| and | ME SYST | ems (standards.iteh.ai) | 57 |
| | B.1 | Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts | 57 |
| | B.Z | ACCOMPANYING DOCUMENTS, Instructions for use | 5/ |
| Δnn | D.J Nev C (inf | ACCOMPANYING DOCOMENTS SECTION ACCOMPANYING SECTION | 57 50 |
| | | | 50 |
| | C.2 | Separation into groups | 59 |
| | C.3 | Division into classes | 60 |
| Ann | nex D (inf | ormative) Guidance in the application of IEC 60601-1-2 to particular | |
| star | ndards | · · · · · · · · · · · · · · · · · · · | 61 |
| | D.1 | General | 61 |
| | D.2 | Recommended modifications | 61 |
| | | D.2.1 Testing requirements | 61 |
| | | D.2.2 ACCOMPANYING DOCUMENTS | 61 |
| A n n | D.3 | Cautions | 61 |
| ENV | | TS | 63 |
| | E.1 | General | 63 |
| | E.2 | Summary of method for E.1 a) | 66 |
| | E.3 | Summary of method for E.1 b), c) and d) | 66 |
| | E.4 | Determination of EM DISTURBANCE level reduction | 66 |
| | E.5 | Assessment of EM DISTURBANCE sources | 66 |
| | E.6 | Reasonably foreseeable maximum EM DISTURBANCE levels | 67 |
| | E.7 | Determination of IMMUNITY TEST LEVELS | 67 |
| | E.8 | KF radiators in SPECIAL ENVIRONMENTS | 67 |
| ٨٣٣ | | Examples of mitigations and special conditions | 68 |
| with | n regard t | OFFICE PRISE MANAGEMENT OF BASIC SAFETY AND ESSENTIAL PERFORMANCE | 69 |