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INTERNATIONAL STANDARD

colour inside

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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

FOREWORD

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6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
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This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

International standard IEC 60601-1-11 has been prepared by a joint working group of IEC subcommittee 62A: Common aspects of electrical equipment used in medical practice of IEC technical committee 62: Electrical equipment in medical practice and ISO subcommittee SC3: Lung ventilators and related devices, of ISO technical committee 121: Anaesthetic and respiratory equipment.

It is published as a double logo standard.

This second edition constitutes a collateral standard to IEC 60601-1 (third edition, including Amendment 1): *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance,* hereafter referred to as the general standard.

This second edition cancels and replaces the first edition of IEC 60601-1-11, published in 2010, and constitutes a technical revision.

The most significant changes with respect to the previous edition include the following modifications:

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– redrafting of subclauses that altered instead of adding to the general standard or other collateral standards; and
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– requirements and definitions: roman type;
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– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this collateral standard, the term

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

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

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

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

Clauses, subclauses and definitions for which a rationale is provided in informative Annex A are marked with an asterisk (*).

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NOTE The attention of Member Bodies and 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 ISO or IEC 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.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

Medical practice is increasingly using MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS for monitoring, treatment or diagnosis of PATIENTS in the HOME HEALTHCARE ENVIRONMENT (see 3.1). The safety of MEDICAL ELECTRICAL EQUIPMENT in this uncontrolled environment with regard to the electrical installation and its related safety and protection means is a cause for concern.

The potential lack of training of the LAY OPERATOR and possibly of those supervising the use of the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM and their level of education need to be addressed in the development of the ACCOMPANYING DOCUMENTS and in the relevant marking on the equipment itself so that this material can be understood. This collateral standard gives special guidance on how this should be addressed in the instructions for use.

This collateral standard was developed with contributions from clinicians, engineers and regulators. The terminology, requirements, general recommendations and guidance of this collateral standard are intended to be useful for MANUFACTURERS of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS and for technical committees responsible for the development of particular standards.

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

1 Scope, object and related standards

1.1 * Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS~~, hereafter referred to as ME EQUIPMENT and ME SYSTEMS, which are intended by their MANUFACTURER~~ for use in the HOME HEALTHCARE ENVIRONMENT, as defined in 3.1, and specified by the MANUFACTURER in the instructions for use. This International Standard applies regardless of whether the ME EQUIPMENT or ME SYSTEM is intended for use by a LAY OPERATOR or by trained healthcare personnel.

~~NOTE 1~~ The HOME HEALTHCARE ENVIRONMENT ~~ME EQUIPMENT and ME SYSTEMS can also be intended for use in other environments, for example, in a professional healthcare facility~~ includes:

– the dwelling place in which a PATIENT lives;
– other places where PATIENTS are present both indoors and outdoors, excluding professional healthcare facility environments where OPERATORS with medical training are continually available when PATIENTS are present.

This International Standard does not apply to ME EQUIPMENT and ME SYSTEMS intended solely for use in the EMERGENCY MEDICAL SERVICES ENVIRONMENT, covered by IEC 60601-1-12 or solely for use in professional healthcare facilities covered by IEC 60601-1 without the additions of IEC 60601-1-12 or this collateral standard. Nonetheless, ME EQUIPMENT or ME SYSTEMS can be intended for multiple use environments, and as such, if also intended for use in the HOME HEALTHCARE ENVIRONMENT, are within the scope of this standard.

EXAMPLE ME EQUIPMENT or ME SYSTEMS intended for both the HOME HEALTHCARE ENVIRONMENT and the professional healthcare facility environment.

NOTE ~~2~~ HOME HEALTHCARE ENVIRONMENT ME EQUIPMENT and ME SYSTEMS can frequently be used in locations with unreliable electrical sources and poor electrical grounding.

1.2 Object

The object of this collateral standard is to specify general requirements that are in addition to those of the general standard and to serve as the basis for particular standards.

1.3 Related standards

1.3.1 IEC 60601-1

For ME EQUIPMENT and ME SYSTEMS, this collateral standard complements IEC 60601-1.

When referring to IEC 60601-1 or to this collateral standard, either individually or in combination, the following conventions are used:

– "the general standard" designates IEC 60601-1 alone;

– "this collateral standard" designates IEC 60601-1-11 alone;

– "this standard" designates the combination of the general standard and this collateral standard.

1.3.2 Particular standards

A requirement in a particular standard takes priority over the corresponding requirement in this collateral standard.

2 Normative references

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

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

NOTE 2 Informative references are listed in the bibliography on page 61.

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IEC 60068-2-27:2008, *Environmental testing – Part 2-27: Tests – Test Ea and guidance: Shock*

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IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)*
~~Amendment 1 (1999)~~ ~~1)~~
IEC 60529:1989/AMD1:1999
IEC 60529:1989/AMD2:2013 2)

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012 3)

IEC 60601-1-2:~~2007~~ 2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic ~~compatibility~~ disturbances –Requirements and tests*

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
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IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
IEC 60601-1-8:2006/AMD1:2012 [5)]

IEC 60601-1-12:2014, *Medical electrical equipment – Part 1-2: 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 62366:2007, *Medical devices – Application of usability engineering to medical devices*
IEC 62366:2007/AMD1:2014 [6)]

ISO 7000, *Graphical symbols for use on equipment — Registered symbols.* Available from: http://www.graphical-symbols.info/equipment

ISO 7010:2011, *Graphical symbols – Safety colours and safety signs – Registered safety signs*
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ISO 7010:2011/AMD2:2012
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IEC 60601-1-11

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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Appareils électromédicaux –
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IEC 60601-1-11:2015-01(en-fr)

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IEC 60529:1989/AMD2:2013 [1)]

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012 [2)]

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

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
IEC 60601-1-6:2010/AMD1:2013) [3)]

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1) There exists a consolidated edition 2.2 (2013) including IEC 60529:1989 and its Amendment 1 (1999) and Amendment 2 (2013).

2) There exists a consolidated edition 3.1(2012) including IEC 60601-1:2005 and its Amendment 1 (2012).

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ISO 7010:2011/AMD3:2012
ISO 7010:2011/AMD4:2013
ISO 7010:2011/AMD5:2014

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

5) There exists a consolidated edition 2.1 (2014) including IEC 62366:2007 and Amendment 1 (2014).

SOMMAIRE

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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APPAREILS ÉLECTROMÉDICAUX –

Partie 1-11: Exigences générales pour la sécurité de base et les performances essentielles – Norme Collatérale: Exigences pour les appareils électromédicaux et les systèmes électromédicaux utilisés dans l'environnement des soins à domicile

AVANT-PROPOS

1) La Commission Electrotechnique Internationale (IEC) est une organisation mondiale de normalisation composée de l'ensemble des comités électrotechniques nationaux (Comités nationaux de l'IEC). L'IEC a pour objet de favoriser la coopération internationale pour toutes les questions de normalisation dans les domaines de l'électricité et de l'électronique. A cet effet, l'IEC – entre autres activités – publie des Normes internationales, des Spécifications techniques, des Rapports techniques, des Spécifications accessibles au public (PAS) et des Guides (ci-après dénommés "Publication(s) de l'IEC"). Leur élaboration est confiée à des comités d'études, aux travaux desquels tout Comité national intéressé par le sujet traité peut participer. Les organisations internationales, gouvernementales et non gouvernementales, en liaison avec l'IEC, participent également aux travaux. L'IEC collabore étroitement avec l'Organisation Internationale de Normalisation (ISO), selon des conditions fixées par accord entre les deux organisations.
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8) L'attention est attirée sur les références normatives citées dans cette publication. L'utilisation de publications référencées est obligatoire pour une application correcte de la présente publication.
9) L'attention est attirée sur le fait que certains des éléments de la présente Publication de l'IEC peuvent faire l'objet de droits de brevet. L'IEC ne saurait être tenue pour responsable de ne pas avoir identifié de tels droits de brevets et de ne pas avoir signalé leur existence.

La Norme Internationale IEC 60601-1-11 a été établie par le groupe de travail mixte du sous-comité 62A de l'IEC: Aspects généraux des équipements électriques utilisés en pratique médicale, du comité d'études 62 de l'IEC: Équipements électriques dans la pratique médicale, et du sous-comité SC3 de l'ISO: Ventilateurs pulmonaires et équipements connexes, du comité technique 121 de l'ISO: Matériel d'anesthésie et de réanimation respiratoire.

La présente publication est une norme double logo.

Cette deuxième édition constitue une norme collatérale de l'IEC 60601-1 (troisième édition, y compris l'Amendement 1): *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles,* désignée ci-après par norme générale.

Cette deuxième édition annule et remplace la première édition de l'IEC 60601-1-11, parue en 2010. Cette édition constitue une révision technique.

Les modifications majeures par rapport à l'édition précédente sont les suivantes:

- correction de la méthode d'essai pour le contrôle de l'humidité relative à des températures supérieures à 35 °C;
- reformulation des paragraphes qui modifient plus qu'ils ne complètent la norme générale ou d'autres normes collatérales; et
- harmonisation avec les modifications apportées aux amendements de la norme générale et aux autres normes collatérales.

Le texte de cette norme collatérale est issu des documents suivants:

FDIS	Rapport de vote
62A/959/FDIS	62A/978/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cette norme collatérale. A l'ISO, la norme a été approuvée par 17 membres P sur 17 ayant voté.

Cette publication a été rédigée selon les Directives ISO/IEC, Partie 2.

Dans la série des publications IEC 60601, les normes collatérales spécifient les exigences générales de sécurité applicables à:

– un sous-groupe d'APPAREILS ELECTROMEDICAUX (par exemple, les appareils de radiologie); ou

– une caractéristique spécifique commune à tous les APPAREILS ELECTROMEDICAUX, non traitée complètement dans la norme générale (par exemple, les SYSTEMES D'ALARME).

Dans la présente norme collatérale, les caractères d'imprimerie suivants sont utilisés:

– exigences et définitions: caractères romains;

– *modalités d'essais: caractères italiques;*

– les indications de nature informative apparaissant hors des tableaux, telles que les notes, les exemples et les références: petits caractères. Le texte normatif à l'intérieur des tableaux est également en petits caractères;

– TERMES DEFINIS A L'ARTICLE 3 DE LA NORME GENERALE, DANS LA PRESENTE NORME COLLATERALE OU COMME NOTES: PETITES MAJUSCULES.

Concernant la structure de la présente norme collatérale, le terme

– "article" désigne l'une des divisions numérotées dans la table des matières, avec toutes ses subdivisions (par exemple, l'Article 7 inclut les paragraphes 7.1, 7.2, etc.);

– "paragraphe" désigne une subdivision numérotée d'un article (par exemple, 7.1, 7.2 et 7.3.1 sont tous des paragraphes appartenant à l'Article 7).

Les références à des articles dans la présente norme, sont précédées du mot "Article" suivi du numéro de l'article concerné. Dans la présente norme collatérale, les références aux paragraphes utilisent uniquement le numéro du paragraphe concerné.

Dans la présente norme, la conjonction "ou" est utilisée avec la valeur d'un "ou inclusif ", ainsi un énoncé est vrai si une combinaison des conditions quelle qu'elle soit est vraie.

Les formes verbales utilisées dans la présente norme sont conformes à l'usage donné à l'Annexe H des Directives ISO/IEC, Partie 2. Pour les besoins de la présente norme, l'auxiliaire:

– “devoir” mis au présent de l’indicatif signifie que la satisfaction à une exigence ou à un essai est impérative pour la conformité à la présente norme;
– “il convient” signifie que la satisfaction à une exigence ou à un essai est recommandée mais n’est pas obligatoire pour la conformité à la présente norme;
– “pouvoir” mis au présent de l’indicatif est utilisé pour décrire un moyen admissible pour satisfaire à une exigence ou à un essai.

Les articles, paragraphes et définitions pour lesquels une justification est fournie à l’Annexe A informative sont marqués d’un astérisque (*).

Une liste de toutes les parties de la série IEC 60601, publiées sous le titre général: *Appareils électromédicaux*, peut être consultée sur le site web de l'IEC.

Le comité a décidé que le contenu de cette publication ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous "http://webstore.iec.ch" dans les données relatives à la publication recherchée. A cette date, la publication sera

- reconduite,
- supprimée,
- remplacée par une édition révisée, ou
- amendée.

NOTE L'attention des Comités Nationaux et des Organismes Membres est attirée sur le fait que les fabricants d'appareils et les organismes d'essai peuvent avoir besoin d'une période transitoire après la publication d'une nouvelle publication IEC ou ISO, ou d'une publication amendée ou révisée, pour fabriquer des produits conformes aux nouvelles exigences et pour adapter leurs équipements aux nouveaux essais ou aux essais révisés. Le comité recommande que le contenu de cette publication soit entériné au niveau national au plus tôt 3 ans après la date de publication.

IMPORTANT – Le logo *"colour inside"* qui se trouve sur la page de couverture de cette publication indique qu'elle contient des couleurs qui sont considérées comme utiles à une bonne compréhension de son contenu. Les utilisateurs devraient, par conséquent, imprimer cette publication en utilisant une imprimante couleur.

INTRODUCTION

La pratique médicale utilise de plus en plus des APPAREILS ELECTROMEDICAUX et des SYSTEMES ELECTROMEDICAUX pour la surveillance, le traitement ou le diagnostic des PATIENTS dans l'ENVIRONNEMENT DES SOINS A DOMICILE (voir 3.1). La sécurité des APPAREILS ELECTROMEDICAUX dans cet environnement non surveillé en ce qui concerne l'installation électrique et la sécurité et les moyens de protection qui lui sont associés constituent un motif de préoccupation.

L'éventuel manque de formation de l'OPERATEUR NON SPECIALISTE et de ceux qui surveillent l'utilisation de l'APPAREIL ELECTROMEDICAL ou du SYSTEME ELECTROMEDICAL et leur niveau de compétence nécessitent d'être pris en compte dans la mise au point des DOCUMENTS D'ACCOMPAGNEMENT et le marquage pertinent sur l'appareil lui-même, de sorte que cela puisse être compris. La présente norme collatérale donne des lignes directrices spéciales sur la façon dont il convient de traiter ceci dans les instructions d'utilisation.

La présente norme collatérale a été élaborée grâce aux contributions de médecins cliniciens, d'ingénieurs et d'autorités de tutelle. La terminologie, les exigences, les recommandations générales et les lignes directrices contenues dans la présente norme collatérale ont pour objectif d'être utiles aux FABRICANTS d'APPAREILS ELECTROMEDICAUX et de SYSTEMES ELECTROMEDICAUX et aux comités techniques responsables de l'élaboration des normes particulières.

APPAREILS ÉLECTROMÉDICAUX –

Partie 1-11: Exigences générales pour la sécurité de base et les performances essentielles – Norme Collatérale: Exigences pour les appareils électromédicaux et les systèmes électromédicaux utilisés dans l'environnement des soins à domicile

1 Domaine d'application, objet et normes connexes

1.1 * Domaine d'application

La présente Norme Internationale s'applique à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES des APPAREILS ÉLECTROMÉDICAUX et des SYSTEMES ÉLECTROMÉDICAUX, destinés à être utilisés dans l'ENVIRONNEMENT DES SOINS A DOMICILE, selon la définition donnée en 3.1, et spécifiés par le FABRICANT dans les instructions d'utilisation. La présente Norme internationale s'applique sans distinguer si l'APPAREIL EM ou le SYSTEME EM est prévu pour être utilisé par un OPERATEUR NON SPECIALISTE ou par du personnel de santé qualifié.

L'ENVIRONNEMENT DES SOINS A DOMICILE comprend:

– l'habitation dans laquelle un PATIENT vit;
– d'autres environnements où des PATIENTS sont présents à l'intérieur comme à l'extérieur, à l'exclusion des environnements des établissements de soins où des OPERATEURS ayant une formation médicale sont disponibles de façon continue lorsque des PATIENTS sont présents.

La présente Norme Internationale ne s'applique pas aux APPAREILS EM et aux SYSTEMES EM destinés seulement à une utilisation dans l'ENVIRONNEMENT DES SERVICES MEDICAUX D'URGENCE couvert par l'IEC 60601-1-12 ou seulement à une utilisation dans des établissements de soins couverts par l'IEC 60601-1 sans les additions de l'IEC 60601-1-12 ou de la présente norme collatérale. Néanmoins, les APPAREILS EM ou les SYSTEMES EM peuvent être prévus pour de multiples environnements d'utilisation et de ce fait, s'ils sont également destinés à être utilisés dans l'ENVIRONNEMENT DES SOINS A DOMICILE, ils relèvent du domaine d'application de la présente norme.

EXEMPLE Les APPAREILS EM et les SYSTEMES EM destinés à être utilisés dans l'ENVIRONNEMENT DES SOINS A DOMICILE et dans l'environnement des établissements de soins.

NOTE Les APPAREILS EM et les SYSTEMES EM pour l'ENVIRONNEMENT DES SOINS A DOMICILE peuvent souvent être utilisés dans des emplacements où se trouvent des sources électriques non fiables et une mise à la terre électrique insuffisante.

1.2 Objet

La présente norme collatérale est destinée à spécifier des exigences générales qui viennent s'ajouter à celles de la norme générale et à servir de base pour les normes particulières.

1.3 Normes connexes

1.3.1 IEC 60601-1

Pour les APPAREILS EM et les SYSTEMES EM, la présente norme collatérale complète l'IEC 60601-1.

Lorsqu'il est fait référence à l'IEC 60601-1 ou à la présente norme collatérale, soit individuellement soit en combinaison, les conventions suivantes sont utilisées:

- "la norme générale" désigne l'IEC 60601-1 seule;
- "la présente norme collatérale" désigne l'IEC 60601-1-11 seule;
- "la présente norme" désigne la combinaison de la norme générale et de la présente norme collatérale.

1.3.2 Normes particulières

Une exigence d'une norme particulière prévaut sur l'exigence correspondante de la présente norme collatérale.

2 Références normatives

Les documents suivants sont cités en référence de manière normative, en intégralité ou en partie, dans le présent document et sont indispensables pour son application. Pour les références datées, seule l'édition citée s'applique. Pour les références non datées, la dernière édition du document de référence s'applique (y compris les éventuels amendements).

NOTE 1 La manière dont ces documents de référence sont cités dans les exigences normatives détermine dans quelle mesure elles s'appliquent (en totalité ou en partie).

NOTE 2 Une liste de références informatives est donnée dans la bibliographie à la page 122.

CISPR 11:2009, *Appareils industriels, scientifiques et médicaux – Caractéristiques de perturbations radioélectriques – Limites et méthodes de mesure*

IEC 60068-2-27:2008, *Essais d'environnement – Partie 2-27: Essais – Essai Ea et guide: Chocs*

IEC 60068-2-31:2008, *Essais d'environnement – Partie 2-31: Essais – Essai Ec: Choc lié à des manutentions brutales, essai destiné en premier lieu aux matériels*

IEC 60068-2-64:2008, *Essais d'environnement – Partie 2-64: Essais – Essai Fh: Vibrations aléatoires à large bande et guide*

IEC 60529:1989, *Degrés de protection procurés par les enveloppes (Code IP)*
IEC 60529:1989/AMD1:1999
IEC 60529:1989/AMD2:2013 [1)]

IEC 60601-1:2005, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*
IEC 60601-1:2005/AMD1:2012 [2)]

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 60601-1-6:2010, *Appareils électromédicaux – Partie 1-6: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Aptitude à l'utilisation*
IEC 60601-1-6:2010/AMD1:2013) [3)]

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1) Il existe une édition consolidée 2.2 (2013) incluant l'IEC 60529:1989 et son Amendement 1 (1999) et l'Amendement 2 (2013).

2) Il existe une édition consolidée 3.1(2012) incluant l'IEC 60601-1:2005 et son Amendement 1 (2012).

3) Il existe une édition consolidée 3.1 (2013) incluant l'IEC 60601-1-6:2010 et l'Amendement 1 (2013).

IEC 60601-1-8:2006, *Appareils électromédicaux – Partie 1-8: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Exigences générales, essais et guide pour les systèmes d'alarme des appareils et des systèmes électromédicaux*
IEC 60601-1-8:2006/AMD1:2012 [4)]

IEC 60601-1-12:2014 , *Appareils électromédicaux – Partie 1-2: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Exigences pour les appareils électromédicaux et les systèmes électromédicaux destinés à être utilisés dans l'environnement des services médicaux d'urgence*

IEC 62366:2007, *Dispositifs médicaux – Application de l'ingénierie de l'aptitude à l'utilisation aux dispositifs médicaux*
IEC 62366:2007/AMD1:2014 [5)]

ISO 7000, *Symboles graphiques utilisables sur le matériel — Symboles enregistrés.*
Disponible à l'adresse: http://www.graphical-symbols.info/equipment

ISO 7010:2011, *Symboles graphiques – Couleurs de sécurité et signaux de sécurité – Signaux de sécurité enregistrés*
ISO 7010:2011/AMD1:2012
ISO 7010:2011/AMD2:2012
ISO 7010:2011/AMD3:2012
ISO 7010:2011/AMD4:2013
ISO 7010:2011/AMD5:2014

ISO 15223-1:2012, *Dispositifs médicaux – Symboles à utiliser avec les étiquettes, l'étiquetage et les informations à fournir relatifs aux dispositifs médicaux – Partie 1: Exigences générales*

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4) Il existe une édition consolidée 2.1 (2012) incluant l'IEC 60601-1-8:2006 et l'Amendement 1 (2012).

5) Il existe une édition consolidée 2.1 (2014) incluant l'IEC 62366:2007 et l'Amendement 1 (2014).