
Irish Standard
I.S. EN 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 (EQV))

# I.S. EN 60601-1-6:2010

*Incorporating amendments/corrigenda issued since publication:*

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I.S. xxx: Irish Standard – national specification based on the consensus of an expert panel and subject to public consultation.

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SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

| *This document replaces:* | *This document is based on:* | *Published:* |
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**I.S. EN 60601-1-6:2010**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN 60601-1-6

April 2010

ICS 11.040

Supersedes EN 60601-1-6:2007

English version

# Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

(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 (CEI 60601-1-6:2010)

Medizinische elektrische Geräte - Teil 1-6: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: Gebrauchstauglichkeit (IEC 60601-1-6:2010)

This European Standard was approved by CENELEC on 2010-04-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat 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 Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

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

**Central Secretariat: Avenue Marnix 17, B - 1000 Brussels**



Ref. No. EN 60601-1-6:2010 E

## Foreword

The text of document 62A/682/FDIS, future edition 3 of IEC 60601-1-6, 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 was approved by CENELEC as EN 60601-1-6 on 2010-04-01.

This standard supersedes EN 60601-1-6:2007.

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

The following dates were fixed:

| | | |
|---|---|---|
| – latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement | (dop) | 2011-01-01 |
| – latest date by which the national standards conflicting with the EN have to be withdrawn | (dow) | 2013-04-01 |

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directives 93/42/EEC and 90/385/EEC. See Annex ZZ.

Annexes ZA and ZZ have been added by CENELEC.

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## Endorsement notice

The text of the International Standard IEC 60601-1-6:2010 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:

| | | |
|---|---|---|
| [1] | ISO 9241-2:1992 | NOTE Harmonized as EN 29241:1993 (not modified). |
| [2] | ISO 9241-11:1998 | NOTE Harmonized as EN ISO 9241-11:1998 (not modified). |
| [3] | ISO 9241-20:2008 | NOTE Harmonized as EN ISO 9241-20:2009 (not modified). |
| [4] | ISO 9241-110:2006 | NOTE Harmonized as EN ISO 9241-110:2006 (not modified). |
| [5] | ISO 9241-171:2008 | NOTE Harmonized as EN ISO 9241-171:2008 (not modified). |
| [7] | ISO 9241-300:2008 | NOTE Harmonized as EN ISO 9241-300:2008 (not modified). |
| [8] | ISO 9241-302:2008 | NOTE Harmonized as EN ISO 9241-302:2008 (not modified). |
| [9] | ISO 9241-303:2008 | NOTE Harmonized as EN ISO 9241-303:2008 (not modified). |
| [10] | ISO 9241-304:2008 | NOTE Harmonized as EN ISO 9241-304:2008 (not modified). |
| [11] | ISO 9241-305:2008 | NOTE Harmonized as EN ISO 9241-305:2008 (not modified). |
| [12] | ISO 9241-307:2008 | NOTE Harmonized as EN ISO 9241-307:2008 (not modified). |
| [13] | ISO 9241-400:2007 | NOTE Harmonized as EN ISO 9241-400:2007 (not modified). |
| [14] | ISO 9241-410:2008 | NOTE Harmonized as EN ISO 9241-410:2008 (not modified). |
| [16] | ISO 13407:1999 | NOTE Harmonized as EN ISO 13407:1999 (not modified). |

# Annex ZA
(normative)

## Normative references to international publications with their corresponding European publications

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

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

| Publication | Year | Title | EN/HD | Year |
|---|---|---|---|---|
| IEC 60601-1 | 2005 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance | EN 60601-1 | 2006 |
| 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 | EN 60601-1-8 | 2007 |
| IEC 62366 | 2007 | Medical devices - Application of usability engineering to medical devices | EN 62366 | 2008 |
| ISO 14971 | 2007 | Medical devices - Application of risk management to medical devices | EN ISO 14971 | 2009 |

# Annex ZZ
(informative)

## Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC as well as Annex I of the EC Directive 90/385/EEC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive(s) concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

# CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

# MEDICAL ELECTRICAL EQUIPMENT –

# Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

## FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-1-6 has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

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

This document cancels and replaces the second edition of IEC 60601-1-6 which has been technically revised. To allow for equipment manufacturers and testing organizations to make products and to equip themselves for conducting revised tests in accordance with this third edition, it is recommended by SC 62A that the content of this document not be adopted for mandatory implementation earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

This edition of IEC 60601-1-6 was revised to align with the USABILITY ENGINEERING PROCESS in IEC 62366.

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

| FDIS | Report on voting |
|---|---|
| 62A/682/FDIS | 62A/689/RVD |

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

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

In the IEC 60601 series of publications, collateral standards specify general requirements for safety applicable to:

– a subgroup of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment); or
– a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the general standard (e.g. alarm systems).

In this collateral standard, the following print types are used:

– Requirements and definitions: roman type.
– *Test specifications or instructions to modify requirements in IEC 62366: italic type.*
– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 4 includes subclauses 4.1, 4.2, etc.);
– “subclause” means a numbered subdivision of a clause (e.g. 4.1 and 4.2 are all subclauses of Clause 4).

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

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

The verbal forms used in this standard conform to usage described in Annex 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 (*).