SLOVENSKI STANDARD

SIST EN 60601-1-6:2005

januar 2005

Medicinska električna oprema – 1-6. del: Splošne varnostne zahteve – Kolateralni standard: Uporabnost

(istoveten EN 60601-1-6:2004)

Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability

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ICS 11.040.01

Referenčna številka
SIST EN 60601-1-6:2005(en)

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EUROPEAN STANDARD **EN 60601-1-6**

NORME EUROPÉENNE

EUROPÄISCHE NORM November 2004

ICS 11.040

English version

Medical electrical equipment
Part 1-6: General requirements for safety – Collateral standard: Usability
(IEC 60601-1-6:2004)

Appareils électromédicaux
Partie 1-6: Règles générales de sécurité - Norme collatérale: Aptitude à l'utilisation
(CEI 60601-1-6:2004)

Medizinische elektrische Geräte
Teil 1-6: Allgemeine Festlegungen für die Sicherheit – Ergänzungsnorm: Gebrauchstauglichkeit
(IEC 60601-1-6:2004)

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This European Standard was approved by CENELEC on 2004-09-01. 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.

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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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

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Ref. No. EN 60601-1-6:2004 E

Foreword

The text of document 62A/452/FDIS, future edition 1 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 2004-09-01.

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) 2005-06-01

– latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2007-09-01

This European Standard is a collateral standard to EN 60601-1:1990, hereinafter referred to as the general standard.

In the 60601 series of publications, collateral standards specify general requirements for safety applicable to
– a group 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. electromagnetic compatibility).

The numbering of sections, clauses and subclauses of this collateral standard corresponds with that of the general standard.

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Clauses, subclauses, tables and figures which are additional to those of the general standard are numbered starting from 201; additional annexes are lettered AAA, BBB, etc., and additional items aaa), bbb), etc.

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In this collateral standard, the following print types are used:
– requirements and definitions: roman type;
– notes, examples, explanations, advice, introductions, general statements and references: smaller roman type;
– *test specifications: italic type;*
– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTED IN THE INDEX OF DEFINED TERMS: SMALL CAPITALS.

The requirements are followed by specifications for the relevant tests.

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

Annex ZA has been added by CENELEC.

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Endorsement notice

The text of the International Standard IEC 60601-1-6:2004 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 standard indicated:

ISO 9000	NOTE	Harmonized as EN ISO 9000:2000 (not modified)
ISO 9001	NOTE	Harmonized as EN ISO 9001:2000 (not modified)
ISO 9241-11	NOTE	Harmonized as EN ISO 9241-11:1998 (not modified)
ISO 13485	NOTE	Harmonized as EN ISO 13485:2003 (not modified)

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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 Where 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	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + Corr. Juli	1990 1994
A1	1991		A1 + Corr. Juli	1993 1994
A2 + corr. June	1995 1995		A2 A13	1995 1996
IEC 60601-1-8	2003	Medical electrical equipment Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	EN 60601-1-8	2004
ISO 14971	2000	Medical devices - Application of risk management to medical devices	EN ISO 14971 + corr. February	2000 2002
A1	2003		A1	2003

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NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
60601-1-6

Première édition
First edition
2004-06

Appareils électromédicaux –

Partie 1-6:
Règles générales de sécurité –
Norme collatérale: Aptitude à l'utilisation

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Medical electrical equipment –

Part 1-6: General requirements for safety – Collateral Standard: Usability

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International Electrotechnical Commission
Международная Электротехническая Комиссия

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 1-6: General requirements for safety – 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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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 first edition constitutes a Collateral Standard to IEC 60601-1:1998, *Medical electrical equipment – Part 1: General requirements for safety*, hereinafter referred to as the General Standard.

The text of this Collateral Standard is based on the following documents:

FDIS	Report of voting
62A/452/FDIS	62A/458/RVD

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

In the 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. electromagnetic compatibility).

The numbering of sections, clauses and subclauses of this Collateral Standard corresponds with that of the General Standard.

Clauses, subclauses, tables and figures which are additional to those of the General Standard are numbered starting from 201; additional annexes are lettered AAA, BBB, etc., and additional items aaa), bbb), etc.

In this Collateral Standard, the following print types are used:

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– requirements and definitions: roman type;

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The requirements are followed by specifications for the relevant tests.

Clause and subclauses for which a rationale is provided in informative Annex AAA are marked with an asterisk (*).

The committee has decided that the contents of this publication will remain unchanged until the maintenance result 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.

INTRODUCTION

Medical practice is increasingly using MEDICAL ELECTRICAL EQUIPMENT for observation and treatment of PATIENTS. USE ERRORS caused by inadequate MEDICAL ELECTRICAL EQUIPMENT USABILITY have become an increasing cause for concern. The USABILITY ENGINEERING PROCESS is intended to achieve reasonable USABILITY, which in turn is intended to minimise USE ERRORS and to minimise use associated RISKS. Some, but not all, forms of incorrect use are amenable to control by the manufacturer. The USABILITY ENGINEERING PROCESS is part of the PROCESS of RISK CONTROL.

This Collateral Standard describes a USABILITY ENGINEERING PROCESS, and provides guidance on how to implement and execute the PROCESS to provide MEDICAL ELECTRICAL EQUIPMENT SAFETY. It is intended to be useful not only for manufacturers of MEDICAL ELECTRICAL EQUIPMENT, but also for technical committees responsible for the preparation of particular standards.

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MEDICAL ELECTRICAL EQUIPMENT –

Part 1-6: General requirements for safety – Collateral Standard: Usability

SECTION ONE – GENERAL

1 Scope and object

1.201 Scope

This Collateral Standard specifies requirements for a PROCESS to analyse, design, verify and validate the USABILITY, as it relates to SAFETY of MEDICAL ELECTRICAL EQUIPMENT, hereinafter referred to as EQUIPMENT. This standard addresses NORMAL USE and USE ERRORS but excludes ABNORMAL USE.

1.202 Relationship to other standards

1.202.1 IEC 60601-1

This Collateral Standard complements IEC 60601-1.

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

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– “the General Standard” designates IEC 60601-1 alone;
– “this Collateral Standard” designates IEC 60601-1-6 alone;
– “this Standard” designates the combination of the General Standard and this Collateral Standard.

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1.202.2 Particular Standards

A requirement in a Particular Standard takes priority over the corresponding requirement in this Collateral Standard.

1.202.3 Normative references

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.

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*
Amendment 1 (1991)
Amendment 2 (1995)

IEC 60601-1-8:2003, *Medical electrical equipment – Part 1-8: General requirements for safety – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

ISO 14971:2000, *Medical devices – Application of risk management to medical devices*
Amendment 1 (2003)

2 Terminology and definitions

For the purpose of this collateral standard, the terms and definitions given in Clause 2 of IEC 60601-1:1988, as amended by the other collateral standards, Clause 3 of ISO 14971:2000 and the following apply.

NOTE An Index of all defined terms used in this collateral standard is found at the end of the document.

2.201
ABNORMAL USE
intended act or intended omission of an act by the USER or OPERATOR of EQUIPMENT as a result of conduct that is beyond any reasonable means of RISK CONTROL by the manufacturer

NOTE 1 See also Annex BBB. Examples are given in Annex CCC.

NOTE 2 It is possible for the PATIENT to be the OPERATOR, e.g. when EQUIPMENT is used in the PATIENT'S home.

NOTE 3 ABNORMAL USE is not considered REASONABLY FORESEABLE MISUSE.

2.202
EFFECTIVENESS
accuracy and completeness with which OPERATORS achieve specified goals

[ISO 9241-11:1998, definition 3.2, modified]

2.203
EFFICIENCY
resources expended in relation to the accuracy and completeness with which OPERATORS achieve goals

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[ISO 9241-11:1998, definition 3.3 modified]

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2.204
*** OPERATOR-EQUIPMENT INTERFACE**
means by which the OPERATOR and the EQUIPMENT communicate

[ANSI/AAMI/HE 74:2001, definition 3.24 modified]

NOTE The ACCOMPANYING DOCUMENTS are considered part of the EQUIPMENT and the OPERATOR-EQUIPMENT INTERFACE.

2.205
OPERATOR PROFILE
summary of the mental, physical and demographic traits of the intended OPERATOR population, as well as any special characteristics that can have a bearing on design decisions, such as occupational skills and job requirements

2.206
*** PRIMARY OPERATING FUNCTION**
function that involves OPERATOR interaction that is either frequently used or related to the SAFETY of the EQUIPMENT in NORMAL USE

2.207
*** REASONABLY FORESEEABLE MISUSE**
use by the OPERATOR in a way not intended by the manufacturer but which can result from readily predictable human behaviour

[ISO/IEC Guide 51:1999, definition 3.14, modified]

NOTE 1 REASONABLY FORESEEABLE MISUSE is an intended action.

NOTE 2 Use refers to a product, PROCESS or service.

NOTE 3 Slips, lapses, mistakes and ABNORMAL USE can also be reasonably foreseeable, but are not considered REASONABLY FORESEEABLE MISUSE.

NOTE 4 See also Annex BBB.

2.208
TRAINING
application-specific OPERATOR-oriented instruction or exercises required for the safe and effective use of the EQUIPMENT

2.209
USE ERROR
act or omission of an act that has a different EQUIPMENT response than intended by the manufacturer or expected by the OPERATOR

NOTE 1 USE ERROR includes slips, lapses, mistakes, and REASONABLY FORESEEABLE MISUSE.

NOTE 2 See also Annex BBB and DDD.1.3.

NOTE 3 The physiological response of the PATIENT is not considered part of USE ERROR.

2.210
USE SCENARIO
sequence of events and tasks used to specify and test the USABILITY of the EQUIPMENT

2.211
*** USABILITY**
Characteristic that establishes EFFECTIVENESS, EFFICIENCY and OPERATOR learnability and satisfaction

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2.212
USABILITY ENGINEERING
application of knowledge about human behaviour, abilities, limitations, and other characteristics to the design of tools, machines, EQUIPMENT, devices, systems, tasks, jobs, and environments to achieve adequate USABILITY

2.213
*** USABILITY ENGINEERING FILE**
set of RECORDS and other documents that are produced by USABILITY ENGINEERING activities

2.214
USABILITY SPECIFICATION
documentation defining the OPERATOR-EQUIPMENT INTERFACE requirements related to USABILITY

2.215
VALIDATION
confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

NOTE 1 The term “validated” is used to designate the corresponding status.

NOTE 2 The use conditions for VALIDATION can be real or simulated.

[ISO 9000:2000, definition 3.8.5]