SLOVENSKI STANDARD
SIST EN 60601-1-4:1998/A1:2002

01-februar-2002

Medicinska električna oprema - 1. del: Splošne varnostne zahteve - 4. spremljevalni standard: Programirljivi električni medicinski sistemi - Dopolnilo A1 (IEC 60601-1-4:1998)

Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems (IEC 60601-1-4:1998)

Medizinische elektrische Geräte - Teil 1-4: Allgemeine Festlegungen für die Sicherheit - Ergänzungsnorm: Programmierbare elektrische medizinische Systeme (IEC 60601-1-4:1998)

Appareils électromédicaux - Partie 1-4: Règles générales de sécurité - Norme collatérale: Systèmes électromédicaux programmables (CEI 60601-1-4:1998)

Ta slovenski standard je istoveten z: EN 60601-1-4:1996/A1:1999

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general
35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

SIST EN 60601-1-4:1998/A1:2002 en

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-4/A1

December 1999

ICS 11.040.01

English version

Medical electrical equipment
Part 1-4: General requirements for safety
Collateral standard: Programmable electrical medical systems
(IEC 60601-1-4:1996/A1:1999)

Appareils électromédicaux
Partie 1-4: Règles générales de sécurité
Norme collatérale: Systèmes électromédicaux programmables
(CEI 60601-1-4:1996/A1:1999)

Medizinische elektrische Geräte
Teil 1-4: Allgemeine Festlegungen für die Sicherheit
Ergänzungsnorm: Programmierbare elektrische medizinische Systeme
(IEC 60601-1-4:1996/A1:1999)

This amendment A1 modifies the European Standard EN 60601-1-4:1996; it was approved by CENELEC on 1999-12-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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 amendment 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, 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

Foreword

The text of document 62/114/FDIS, future amendment 1 to IEC 60601-1-4, prepared by IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as amendment A1 to EN 60601-1-4:1996 on 1999-12-01.

The following dates were fixed:

- latest date by which the amendment has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2000-09-01
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 2002-12-01

Endorsement notice

The text of amendment 1:1999 to the International Standard IEC 60601-1-4:1996 was approved by CENELEC as an amendment to the European Standard without any modification.

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
60601-1-4

1996

AMENDEMENT 1
AMENDMENT 1
1999-10

Amendement 1

Appareils électromédicaux –

Partie 1-4:
Règles générales de sécurité – Norme collatérale: Systèmes électromédicaux programmables

Amendment 1

Medical electrical equipment –

Part 1-4:
General requirements for safety – Collateral standard: Programmable electrical medical systems

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

CODE PRIX
PRICE CODE H

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FOREWORD

This amendment has been prepared by IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report of voting
62/114/FDIS	62/120/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.

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CONTENTS

Replace title of annex DDD by the following:

Page 9

INTRODUCTION

Replace the third dash by the following:

– methods by which SAFETY is assured;

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2.201.12 SAFETY INTEGRITY:

Replace this definition by the following:

2.201.12 Not used.

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6 Identification, marking and documents

6.8 ACCOMPANYING DOCUMENTS

Replace 6.8.201 by the following:

6.8.201 All relevant information regarding significant RESIDUAL RISK including descriptions of the HAZARDS and any actions by the OPERATOR or the USER necessary to avoid/mitigate them shall be placed in both the INSTRUCTIONS FOR USE and the RISK MANAGEMENT FILE.

Add the following new subclause 6.8.202:

6.8.202 ACCOMPANYING DOCUMENTS for the PEMS shall identify, as a minimum, the MANUFACTURER and a unique identifier such as revision level and date of release/issue.

NOTE Information pertaining to any specific EQUIPMENT that software is intended to be used in conjunction with, and a means by which the MANUFACTURER can be contacted, can be located on the package or in the INSTRUCTIONS FOR USE so that it is available to the USER independently of the software operation.

52 Abnormal operation and fault conditions

52.201.3c)

Replace 52.201.3 c) by the following:

c) reference to the SAFETY measures, used to eliminate or control the RISK of the HAZARD;

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Figure 201

Amend the box "VALIDATION methods and results 52.210.6" *to* "VALIDATION methods and results 52.210.7".

Amend the box "VERIFICATION plan 52.210.2" *to* "VALIDATION plan 52.210.2".

Amend, within the lower right-hand corner of the figure, the text "VERIFICATION methods and results 52.209.3" *to* "Methods, techniques and results of the VERIFICATION 52.209.4".

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52.203 DEVELOPMENT LIFE-CYCLE

Add the following new subclause 52.203.6:

52.203.6 Where appropriate, a defined system for problem resolution within and between all phases and tasks of the DEVELOPMENT LIFE CYCLE shall be developed and maintained as part of the RISK MANAGEMENT FILE. Depending upon the problem, the system may have the following characteristics:

– be defined as a part of the DEVELOPMENT LIFE-CYCLE;
– allow the reporting of potential or existing SAFETY and/or performance problems;
– include an assessment of each problem for associated RISKS;
– identify the criteria (SAFETY and/or performance) that have to be met for the issue to be closed;
– identify the action to be taken to resolve each problem;
– identify VALIDATION methods for each action;
– identify the steps taken for VERIFICATION of continuing compliance.

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52.204.3.1 HAZARD ANALYSIS

Replace on page 23, in subclause 52.204.3.1.5, the first dash by the following:

– human factors including ergonomic limitations;

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52.204.4 RISK control

Add, in subclause 52.204.4.3, the following new sentence:

The likelihood that the means for RISK reduction will perform correctly shall be specified quantitatively or qualitatively; see annex CCC.

52.206 Requirement specification

Replace 52.206.3 by the following new subclause 52.206.3:

52.206.3 The requirement specification shall include the information necessary to assure that RISK control measures satisfactorily reduce the identified RISKS.

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52.207 Architecture

Replace 52.207.3 by the following new subclause 52.207.3:

52.207.3 Where appropriate, the architecture specification of a PEMS and its subsystems shall address the RISK CONTROL requirements by reducing the corresponding likelihood of the HAZARD or by reducing the SEVERITY of the HAZARD or both.

Add the following new subclauses 52.207.4 and 52.207.5:

52.207.4 Where appropriate, to reduce the likelihood of the HAZARD, the architecture specification shall make use of:

a) highly reliable components;

b) fail-safe functions;

c) redundancy;

d) diversity;

e) defensive design;

f) limits on potentially hazardous effects, for example by restricting the available output power and/or by introducing means to limit the travel of actuators.

52.207.5 The architecture specification shall take the following into consideration:

a) allocation of RISK control measures to subsystems and components of the PEMS;

NOTE Subsystems and components include sensors, actuators, PESS and interfaces.

b) failure modes of components and their effects;

c) common cause failures;

d) systematic failures;

e) test interval, test duration and diagnostic coverage;

f) maintainability;

g) protection from human intentional or unintentional causes.

52.208 Design and implementation

Replace 52.208.2 by the following new subclause 52.208.2:

52.208.2 Descriptive data regarding the design environment shall be included in the RISK MANAGEMENT FILE.

NOTE See annex DDD for examples of design environment elements.

52.209 VERIFICATION

Replace 52.209.2 by the following new subclause 52.208.2:

52.209.2 A VERIFICATION plan shall be produced to show how the SAFETY requirements for each DEVELOPMENT LIFE-CYCLE phase will be verified. The plan shall include

a) the selection and documentation of VERIFICATION strategies, activities and techniques;

b) the selection and utilization of VERIFICATION tools;

c) coverage criteria for VERIFICATION.

NOTE Examples of methods and techniques are

– walkthroughs and inspections;
– static/dynamic analyses;
– white/black box testing.

Delete former subclause 52.209.3 and add the following new subclauses 52.209.3 and 52.209.4:

52.209.3 The VERIFICATION shall be performed according to the VERIFICATION plan. The results of the VERIFICATION activities shall be documented, analyzed and assessed.

52.209.4 A reference to the methods, techniques and results of the VERIFICATION shall be included in the RISK MANAGEMENT SUMMARY.

52.210 VALIDATION

Replace 52.210.1 by the following:

VALIDATION of the SAFETY of PEMS under the conditions of the intended use shall be carried out.