National Standards Authority of Ireland

IRISH STANDARD

I.S. EN 60601-1-4:1998

ICS 11.040.01

National Standards
Authority of Ireland
Dublin 9
Ireland

Tel (01) 807 3800
Tel. (01) 807 3838

MEDICAL ELECTRICAL EQUIPMENT PART 1: GENERAL REQUIREMENTS FOR SAFETY 4. COLLATERAL STANDARD: PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (IEC 601-1-4:1996)

This Irish Standard was published under the authority of the National Standards Authority of Ireland and comes into effect on February 6, 1998

Price Code M

Údarás um Chaighdeáin Náisiúnta na hÉireann

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

Ref. No. EN 60601-1-4:1996/A1:1999 E

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

International Electrotechnical Commission 3, rue de Varembé Geneva, Switzerland
Telefax +41 22 919 0300 e-mail: inmail@iec.ch IEC web site http://www.iec.ch

Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

CODE PRIX
PRICE CODE H

Pour prix, voir catalogue en vigueur
For price, see current catalogue

AVANT-PROPOS

Le présent amendement a été établi par le comité d'études 62 de la CEI: Equipements électriques dans la pratique médicale.

Le texte de cet amendement est issu des documents suivants:

FDIS	Rapport de vote
62/114/FDIS	62/120/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cet amendement.

Page 2

SOMMAIRE

Remplacer le titre de l'annexe DDD par ce qui suit:

DDD CYCLE DE DÉVELOPPEMENT 48

Page 8

INTRODUCTION

Remplacer le troisième tiret par ce qui suit:

– méthodes assurant la SÉCURITÉ;

Page 14

2.201.12 SÉCURITÉ ABSOLUE:

Remplacer cette définition par ce qui suit:

2.201.12 Non utilisé.

Page 16

6 Identification, marquage et documentation

6.8 DOCUMENTS D'ACCOMPAGNEMENT

Remplacer 6.8.201 par ce qui suit:

6.8.201 Toutes les informations importantes relatives au RISQUE RÉSIDUEL significatif, informations comprenant la description des DANGERS et les actions à entreprendre par L'OPÉRATEUR ou L'UTILISATEUR pour les éviter/les réduire, doivent être reportées à la fois dans les INSTRUCTIONS D'UTILISATION et dans le FICHIER DE GESTION DES RISQUES.