Nederlandse

Wijzigingsblad

norm

NEN-EN-IEC 60601-2-37/A1 (en)

Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment (IEC 60601-2-37:2001/A1:2004,IDT)

januari 2005
ICS 11.040.55; 17.140.50

Als Nederlands wijzigingsblad is aanvaard:
- EN 60601-2-37:2001/A1:2005,IDT
- IEC 60601-2-37:2001/A1:2004,IDT

Normcommissie 301 062 "Medische elektrische toestellen"

NEN

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EUROPEAN STANDARD **EN 60601-2-37/A1**

NORME EUROPÉENNE

EUROPÄISCHE NORM February 2005

ICS 11.040.55; 17.140.50

English version

Medical electrical equipment
Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
(IEC 60601-2-37:2001/A1:2004)

Appareils électromédicaux
Partie 2-37: Règles particulières de sécurité pour les appareils de diagnostic et de surveillance médicaux à ultrasons
(CEI 60601-2-37:2001/A1:2004)

Medizinische elektrische Geräte
Teil 2-37: Besondere Festlegungen für die Sicherheit von Ultraschall-Geräten für die medizinische Diagnose und Überwachung
(IEC 60601-2-37:2001/A1:2004)

This amendment A1 modifies the European Standard EN 60601-2-37:2001; it was approved by CENELEC on 2004-12-07. 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, 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

Ref. No. EN 60601-2-37:2001/A1:2005 E

Foreword

The text of document 62B/524/FDIS, future amendment 1 to IEC 60601-2-37:2001, prepared by SC 62B, Diagnostic imaging equipment, of 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 60601-2-37:2001 on 2004-12-07.

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) 2005-09-01

– latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 2008-01-01

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Endorsement notice

The text of amendment 1:2004 to the International Standard IEC 60601-2-37:2001was approved by CENELEC as an amendment to the European Standard without any modification.

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INTERNATIONAL STANDARD

IEC 60601-2-37

2001

AMENDMENT 1
2004-08

Amendment 1

Medical electrical equipment –

Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment

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FOREWORD

This amendment has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62B/524/FDIS	62B/542/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.

The committee has decided that the contents of this amendment and the base 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.

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INTRODUCTION

Replace the last three paragraphs and the note of the existing text by the following new paragraphs:

It should be noted that although UD-3 Rev.1, 1998[1] was developed as a national standard, it has since been referenced by numerous countries worldwide and by all internationally operating manufacturers and test houses; regulatory authorities also follow the standard, as it has become a *de facto* international standard. The material taken from UD-3 Rev.1, 1998 forms only a part of this Particular Standard.

This standard contains normative measurement methodologies. These clauses may be replaced in a future revision by reference to an appropriate future measurement standard.

This standard does not cover ultrasonic therapeutic equipment. Equipment used for the imaging and diagnosis of body structures by ultrasound in conjunction with other medical procedure is covered.

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1 Scope and object

1.3 Particular Standards

[1] See reference [19] in the Bibliography.

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