SLOVENSKI STANDARD

SIST EN 60601-2-37:2002/A2:2006

01-marec-2006

Medicinska elektriļ na oprema - 2-37.del: Posebne varnostne zahteve za ultrazvoļ no medicinsko diagnostiļ no in nadzorovalno opremo (IEC 60601-2-37:2001/A2:2005)

Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment (IEC 60601-2-37:2001/A2:2005)

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/A2:2005)

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/A2:2005)

Ta slovenski standard je istoveten z: **EN 60601-2-37:2001/A2:2005**

ICS:

11.040.55

17.140.50

SIST EN 60601-2-37:2002/A2:2006 **en**

EUROPEAN STANDARD **EN 60601-2-37/A2**

NORME EUROPÉENNE

EUROPÄISCHE NORM December 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/A2:2005)

Appareils électromédicaux
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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/A2:2005)

This amendment A2 modifies the European Standard EN 60601-2-37:2001; it was approved by CENELEC on 2005-12-01. 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, 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

Foreword

The text of document 62B/591/FDIS, future amendment 2 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 A2 to EN 60601-2-37:2001 on 2005-12-01.

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) 2006-09-01
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 2008-12-01

Endorsement notice

The text of amendment 2:2005 to the International Standard IEC 60601-2-37:2001 was approved by CENELEC as an amendment to the European Standard without any modification.

INTERNATIONAL STANDARD

IEC 60601-2-37

2001

AMENDMENT 2
2005-11

Amendment 2

Medical electrical equipment –

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

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE C

For price, see current catalogue

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/591/FDIS	62B/598/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 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.

Page 8

1.3.101 Related international standards

Add, to the existing list, the following new standard.

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

Page 19

6.8.2 INSTRUCTIONS FOR USE

aa) *Add, on page 20, to the existing list of items, the following new item:*

14) declaration of output limits as selected according to Clause 35.4. For MULTI-PURPOSE ULTRASONIC EQUIPMENT the output limits shall be declared for each application.

Page 22

35 Acoustical energy (including ultrasonic)

Add the following subclause:

35.4. Acoustic output shall be limited based on RISK ASSESSMENT and RISK MANAGEMENT following ISO 14971 using the safety-related parameters defined in this standard and other relevant information such as clinical experience.

NOTE For guidance on the relevance of the safety-related parameters defined in this standard, see Annex HH.

When applicable, the MANUFACTURER shall address the risks associated with ultrasound acoustic output in the RISK MANAGEMENT process.

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Annex BB – Guidance and rationale for particular subclauses

Concerning 35 Acoustical energy (including ultrasonic)

Add the following paragraphs:

While this Particular Standard places no upper limits on permitted levels of acoustic output, all EQUIPMENT is limited for technical reasons, compliance with local regulatory requirements, or reasons resulting from the MANUFACTURER'S RISK MANAGEMENT. On the one hand the MANUFACTURERS should continuously track the scientific discussions on safety of ultrasonic fields for diagnostic ultrasound, on the other hand the USERS should know about the – possibly application-dependent – limits of their EQUIPMENT as selected by the MANUFACTURER.

Compliance with subclause 35.4 may be checked by inspection of the relevant documentation of the results of the RISK MANAGEMENT process provided by the MANUFACTURER, including relevant information such as clinical experience.