EESTI STANDARD EVS-EN 60601-2-37:2003

Elektrilised meditsiiniseadmed. Osa 2-37: Erinõuded ultraheli meditsiinilise diagnostika- ja seireseadmestiku ohutusele

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

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN 60601-2-37:2003 sisaldab Euroopa standardi EN 60601-2-37:2001 ingliskeelset teksti. Käesolev dokument on jõustatud 15.01.2003 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 60601-2-37:2003 consists of the English text of the European standard EN 60601-2-37:2001. This document is endorsed on 15.01.2003 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: Establishes particular requirements for the safety of ultrasonic diagnostic equipment and those aspects thereof which are directly related to safety. Does not cover ultrasonic therapeutic equipment; however, equipment used for the imaging of body structures by ultrasound in conjunction with therapeutic modalities is covered.	**Scope:** Establishes particular requirements for the safety of ultrasonic diagnostic equipment and those aspects thereof which are directly related to safety. Does not cover ultrasonic therapeutic equipment; however, equipment used for the imaging of body structures by ultrasound in conjunction with therapeutic modalities is covered.

ICS 11.040.55, 17.140.50

Võtmesõnad: electrical medical e, medicine, protective devic, radiology, radiology apparatus, radiology apparatus (medical), safety, safety requirements, specification (approval), specifications, testing, therapy equipment, ultrasonic devices, ultrasonic medical apparatus

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

NORME EUROPÉENNE

EUROPÄISCHE NORM October 2001

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)

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)

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)

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 E

Foreword

The text of document 62B/428/FDIS, future edition 1 of IEC 60601-2-37, 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 EN 60601-2-37 on 2001-09-25.

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) 2002-07-01

– latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2004-10-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annexes AA and DD are normative and annexes BB, CC, EE, FF, GG and HH are informative.

In this standard, the following print types are used:

– requirements, compliance with which can be tested, and definitions: roman type;

– explanations, advice, notes, general statements and exceptions: smaller roman type;

– *test specifications and headings of subclauses: italic type;*

– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD, IN THIS STANDARD OR IN OTHER IEC STANDARDS REFERENCED IN ANNEX AA: SMALL CAPITALS.

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Endorsement notice

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

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INTERNATIONAL STANDARD

IEC 60601-2-37

Edition 1.1

2004-10

Edition 1:2001 consolidated with amendment 1:2004

Medical electrical equipment –

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

Reference number
IEC 60601-2-37:2001+A1:2004(E)

Publication numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series. For example, IEC 34-1 is now referred to as IEC 60034-1.

Consolidated editions

The IEC is now publishing consolidated versions of its publications. For example, edition numbers 1.0, 1.1 and 1.2 refer, respectively, to the base publication, the base publication incorporating amendment 1 and the base publication incorporating amendments 1 and 2.

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Medical electrical equipment –

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

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Международная Электротехническая Комиссия

PRICE CODE CL

For price, see current catalogue

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

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 60601-2-37 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This consolidated version of IEC 60601-2-37 is based on the first edition (2001) [documents 62B/428/FDIS and 62B/440/RVD] and its amendment 1 (2004) [documents 62B/524/FDIS and 62B/542/RVD].

It bears the edition number 1.1.

A vertical line in the margin shows where the base publication has been modified by amendment 1.

Annexes AA and DD form an integral part of this Particular Standard.

Annexes BB, CC, EE, FF, GG and HH are for information only.

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

– requirements, compliance with which can be tested, and definitions: in roman type

– notes, explanations, advice, introductions, general statements, exceptions, and references: in smaller type

– *test specifications: in italic type*

– TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 AND IEC 60601-1: IN SMALL CAPITALS.

The committee has decided that the contents of the base publication and its amendments 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.

A bilingual version of this standard may be issued at a later date.

INTRODUCTION

In this Particular Standard, safety requirements additional to those in the General Standard are specified for ULTRASONIC DIAGNOSTIC EQUIPMENT.

Guidance and a rationale for the requirements of this Particular Standard are given below.

Knowledge of the reasons for these requirements will not only facilitate the proper application of this Particular Standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology.

General guidance and rationale

The approach and philosophy used in drafting this particular standard for safety of ULTRASONIC DIAGNOSTIC EQUIPMENT are consistent with those in current standards in the IEC 60601-2 series that apply to other diagnostic modalities, such as X-ray equipment and magnetic resonance systems.

In each case, the safety standard is intended to require increasing sophistication of output display indicators and/or controls with increasing energy levels in the interrogating field of diagnosis. Thus, for all such diagnostic modalities, it is the responsibility of the OPERATOR to understand the risk of the output of the equipment, and to act appropriately in order to obtain the needed diagnostic information with the minimum risk to the PATIENT.

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.

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

MEDICAL ELECTRICAL EQUIPMENT –

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

SECTION ONE: GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

*1.1 Scope

Addition:

This Particular Standard specifies particular safety requirements for ULTRASONIC DIAGNOSTIC EQUIPMENT as defined in 2.1.145.

This standard does not cover ultrasonic therapeutic equipment; however, equipment used for the imaging of body structures by ultrasound in conjunction with therapeutic modalities is covered.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of ULTRASONIC DIAGNOSTIC EQUIPMENT and those aspects thereof which are directly related to safety.

1.3 Particular Standards

Addition:

This Particular Standard amends and supplements a set of IEC publications, hereinafter referred to as the “General Standard”, consisting of

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

IEC 60601-1-2:2001, *Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1-4: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems* and its Amendment 1 (1999)

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words: