



**Elektrilised meditsiiniseadmed. Osa 2-37:
Erinõuded ultraheli meditsiinilise diagnostika- ja
seireseadmete esmasele ohutusele ja olulistele
toimivusnäitajatele**

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN 60601-2-37:2008 sisaldab Euroopa standardi EN 60601-2-37:2008 ingliskeelset teksti.</p> <p>Standard on kinnitatud Eesti Standardikeskuse 20.02.2008 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 31.01.2008.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN 60601-2-37:2008 consists of the English text of the European standard EN 60601-2-37:2008.</p> <p>This standard is ratified with the order of Estonian Centre for Standardisation dated 20.02.2008 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.</p> <p>Date of Availability of the European standard text 31.01.2008.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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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

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Kui Teil on küsimusi standardite autorikaitse kohta, palun võtke ühendust Eesti Standardikeskusega:
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English version

**Medical electrical equipment -
Part 2-37: Particular requirements for the basic safety
and essential performance of ultrasonic medical diagnostic
and monitoring equipment
(IEC 60601-2-37:2007)**

Appareils électromédicaux -
Partie 2-37: Exigences particulières
pour la sécurité de base
et les performances essentielles
des appareils de diagnostic
et de surveillance médicaux à ultrasons
(CEI 60601-2-37:2007)

Medizinische elektrische Geräte -
Teil 2-37: Besondere Festlegungen für die
Sicherheit einschließlich der wesentlichen
Leistungsmerkmale von
Ultraschallgeräten für die medizinische
Diagnose und Überwachung
(IEC 60601-2-37:2007)

This European Standard was approved by CENELEC on 2007-10-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard 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 European Standard 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, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the 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/624/CDV, future edition 2 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 Unique Acceptance Procedure and was approved by CENELEC as EN 60601-2-37 on 2007-10-01.

This European Standard supersedes EN 60601-2-37:2001 + A1:2005 + A2:2005.

EN 60601-2-37:2008 combines EN 60601-2-37:2001 + A1:2005 + A2:2005 into a form compatible with the parent EN 60601-1:2006.

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) 2008-08-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2010-10-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC. See Annex ZZ.

In this standard, the following print types are used:

- requirements and definitions: in roman type;
- *test specifications: in italic type;*
- informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: IN SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes Subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-37:2007 was approved by CENELEC as a European Standard without any modification.

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Annex ZA
(normative)**Normative references to international publications
with their corresponding European publications**

Addition to Annex ZA of EN 60601-1:2006:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 62359	- ¹⁾	Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields	EN 62359	2005 ²⁾

¹⁾ Undated reference.

²⁾ Valid edition at date of issue.

Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

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INTRODUCTION

In this particular standard, safety requirements additional to those in the general standard are specified for ULTRASONIC DIAGNOSTIC EQUIPMENT.

A general guidance and rationale for the requirements of this particular standard are given in Annex AA.

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.

The approach and philosophy used in drafting this particular standard for safety of ULTRASONIC DIAGNOSTIC EQUIPMENT are consistent with those in standards of the IEC 60601-2-xx 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 ULTRASONIC DIAGNOSTIC EQUIPMENT, and to act appropriately in order to obtain the needed diagnostic information with the minimum risk to the PATIENT.

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MEDICAL ELECTRICAL EQUIPMENT –

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

The clauses and subclauses of the general standard apply except as follows:

201.1 Scope, object and related standards

Clause 1 of the general standard applies, except as follows:

201.1.1 *Scope

Addition:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ULTRASONIC DIAGNOSTIC EQUIPMENT as defined in 201.3.217, hereinafter referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of this standard.

NOTE See also subclause 4.2 of this standard.

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

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ULTRASONIC DIAGNOSTIC EQUIPMENT as defined in 201.3.217.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of sections, clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this particular standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.6 in this particular standard addresses the content of Clause 6 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding section, clause or subclause in this particular standard, the section, clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

Clause 2 of the general standard applies except as follows:

Addition:

IEC 62359, *Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields*

201.3 Terminology and definitions

For the purposes of this document, the terms and definitions given in the general standard and in IEC 62359, as well as the following additions apply:

NOTE 1 An index of defined terms is given after the Bibliography.

NOTE 2 A list of symbols used in this particular standard is found in Table 201.101.