

ELEKTRILISED MEDITSIINISEADMED. OSA 2-37:
ERINÕUDED MEDITSIINILISTE ULTRAHELI
DIAGNOSTIKA- JA JÄLGIMISSEADMETE ESMASELE
OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE

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>See Eesti standard EVS-EN IEC 60601-2-37:2024 sisaldab Euroopa standardi EN IEC 60601-2-37:2024 ingliskeelset teksti.</p> <p>Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 29.11.2024.</p> <p>Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.</p>	<p>This Estonian standard EVS-EN IEC 60601-2-37:2024 consists of the English text of the European standard EN IEC 60601-2-37:2024.</p> <p>This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.</p> <p>Date of Availability of the European standard is 29.11.2024.</p> <p>The standard is available from the Estonian Centre for Standardisation and Accreditation.</p>
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ICS 11.040.55; 17.140.50

Supersedes EN 60601-2-37:2008; EN 60601-2-37:2008/A11:2011; EN 60601-2-37:2008/A1:2015

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 60601-2-37:2024)

Appareils électromédicaux - Partie 2-37: Exigences
particulières pour la sécurité de base et les performances
essentielle des appareils de diagnostic et de surveillance
médicaux à ultrasons
(IEC 60601-2-37:2024)

Medizinische elektrische Geräte - Teil 2-37: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von Ultraschallgeräten für
die medizinische Diagnose und Überwachung
(IEC 60601-2-37:2024)

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Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

The text of document 62B/1318/CDV, future edition 3 of IEC 60601-2-37, prepared by SC 62B "Medical imaging equipment, software, and systems" of IEC/TC 62 "Medical equipment, software, and systems" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60601-2-37:2024.

The following dates are fixed:

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The text of the International Standard IEC 60601-2-37:2024 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standard indicated:

IEC 61157:2007	NOTE	Approved as EN 61157:2007 (not modified)
IEC 61157:2007/A1:2013	NOTE	Approved as EN 61157:2007/A1:2013 (not modified)
IEC 60601-1-11:2015	NOTE	Approved as EN 60601-1-11:2015 (not modified)
IEC 60601-1-11:2015/A1:2020	NOTE	Approved as EN 60601-1-11:2015/A1:2021 (not modified)

INTERNATIONAL STANDARD

NORME INTERNATIONALE



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

**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**



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IEC Secretariat
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

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INTERNATIONAL STANDARD

NORME INTERNATIONALE



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

**Appareils électromédicaux –
Partie 2-37: Exigences particulières pour la sécurité de base et les performances
essentielle des appareils de diagnostic et de surveillance médicaux à ultrasons**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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INTERNATIONALE

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CONTENTS

FOREWORD.....	4
INTRODUCTION.....	7
201.1 Scope, object and related standards	8
201.2 Normative references.....	10
201.3 Terms and definitions.....	10
201.4 General requirements	17
201.5 General requirements for testing ME EQUIPMENT	18
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	18
201.7 ME EQUIPMENT identification, marking and documents	18
201.8 Protection against electrical HAZARDS from ME EQUIPMENT	23
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	23
201.10 Protection against unwanted and excessive radiation HAZARDS	23
201.11 Protection against excessive temperatures and other HAZARDS	24
201.12 Accuracy of controls and instruments and protection against hazardous outputs	29
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	31
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	31
201.15 Construction of ME EQUIPMENT	31
201.16 ME SYSTEMS.....	31
201.17 *Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	31
202 ELECTROMAGNETIC DISTURBANCES – Requirements and tests.....	31
212 Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment (EMS)	33
Annexes	34
Annex AA (informative) Particular guidance and rationale.....	35
Annex BB (informative) Guidance in classification according to CISPR 11	43
Annex CC (informative) Guidance to the MANUFACTURER on the interpretation of <i>Tl</i> and <i>Ml</i> to be used to inform the OPERATOR.....	44
Annex DD (informative) Example set-up to measure surface temperature of externally applied TRANSDUCER ASSEMBLIES	48
Annex EE (informative) Acoustic output table intended for third parties.....	51
Bibliography.....	54
Index of defined terms	58
Figure AA.1 – Method a) for an external probe.....	38
Figure AA.2 – Method b) for an external probe.....	39
Figure AA.3 – Method b) for an external probe.....	39
Figure DD.1 – Set-up of an example test object to measure the surface temperature of externally applied transducers	50
Table 201.101 – List of symbols.....	16
Table 201.102 – Distributed essential performance requirements	18

Table 201.103 – Acoustic output reporting table	22
Table 201.104 – Overview of the tests noted under 201.11.1.3	28
Table CC.1 – Relative importance of maintaining low exposure indices in various scanning situations	46
Table DD.1 – Acoustic and thermal properties of tissues and materials.....	48
Table DD.2 – Weight % pure components	49
Table EE.1 – Example of acoustic output table for third parties.....	52

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

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IEC 60601-2-37 has been prepared by subcommittee 62B: Medical imaging equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

This third edition cancels and replaces the second edition published in 2007 and Amendment 1:2015. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

- a) technical and editorial changes resulting from the amended general standard IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and its collateral standards IEC 60601-1-xx,

- b) technical and editorial changes as a result of maintenance to normative references;
- c) technical and editorial changes resulting from relevant developments in TC 87 Ultrasonics standards. In particular, Clause 201.11 about protection against excessive temperatures and other hazards has been fully revised.

The text of this International Standard is based on the following documents:

Draft	Report on voting
62B/1318/CDV	62B/1348/RVC

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

In this document, the following print types are used:

- requirements and definitions: roman type.
- *test specifications: 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this document are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

- "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
- "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.

A list of all parts of the IEC 60601 series, published under the general title: *Medical electrical equipment*, can be found on the IEC website

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

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INTRODUCTION

In this document, safety requirements additional to those in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 are specified for ULTRASONIC DIAGNOSTIC EQUIPMENT.

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

Knowledge of the reasons for these requirements will not only facilitate the proper application of this document 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 document for safety of ULTRASONIC DIAGNOSTIC EQUIPMENT are consistent with those in standards of 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 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.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.1.1 *Scope

Replacement:

This document 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 document are not covered by specific requirements in this document except in 201.7.2.13.

This document 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 document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ULTRASONIC DIAGNOSTIC EQUIPMENT as defined in 201.3.217.

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and Clause 201.2 of this document.

IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-12:2014 and IEC 60601-1-12:2014/AMD1:2020 apply as modified in Clause 202 and Clause 212 respectively. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

The numbering of sections, clauses and subclauses of this document corresponds to that of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) 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 document addresses the content of Clause 6 of the IEC 60601-1-2 collateral standard, 203.4 in this document addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is replaced completely by this document.

"*Addition*" means that the text of this document is additional to the requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard.

"*Amendment*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.154, additional definitions in this document are numbered beginning from 201.3.201. 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 document" is used to make reference to the IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, any applicable collateral standards and this document taken together.

Where there is no corresponding section, clause or subclause in this document, the section, clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies except as follows:

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-1-12:2014, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*
IEC 60601-1-12:2014/AMD1:2020

IEC 60601-2-18:2009, *Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment*

IEC 62127-1:2022, *Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields*

IEC 62359:2010, *Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields*
IEC 62359:2010/AMD1:2017

CISPR 11:2024, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and in IEC 62359 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at <https://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

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

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