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**Medicinska električna oprema - 2-37. del: Posebne zahteve za osnovno varnost in bistvene lastnosti ultrazvočne medicinske diagnostične in nadzorovalne opreme (IEC 60601-2-37:2024)**

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)

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)

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 (IEC 60601-2-37:2024)

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**Ta slovenski standard je istoveten z: EN IEC 60601-2-37:2024**

**ICS:**

11.040.55	Diagnostična oprema	Diagnostic equipment
17.140.50	Elektroakustika	Electroacoustics

**SIST EN IEC 60601-2-37:2025**                      **en**



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NORME EUROPÉENNE  
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**EN IEC 60601-2-37**

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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  
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(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**

**EN IEC 60601-2-37:2024 (E)****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:

- latest date by which the document has to be implemented at national (dop) 2025-11-30 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2027-11-30 document have to be withdrawn

This document supersedes EN 60601-2-37:2008 and all of its amendments and corrigenda (if any).

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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)

## Annex ZA (normative)

### Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: [www.cencenelec.eu](http://www.cencenelec.eu).

Clause 2 of EN 60601-1:2006, EN 60601-1:2006/AC:2010, EN 60601-1:2006/A1:2013, EN 60601-1:2006/A1:2013/AC:2014, EN 60601-1:2006/A12:2014, EN 60601-1:2006/A2:2021, EN 60601-1:2006/AC:2022 and EN 60601-1:2006/A13:2024 is applicable, except as follows:

Add the following references:

Publication	Year	Title	EN/HD	Year
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ AC	2010
+ A1	2012		+ A1	2013
-	-		+ AC	2014
-	-		+ A12	2014
+ A2	2020		+ A2	2021
-	-		+ AC	2022
-	-		+ A13	2024
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	EN 60601-1-12	2015
+ A1	2020		+ A1	2020
IEC 60601-2-18	2009	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment	EN 60601-2-18	2015
IEC 62127-1	2022	Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields	EN IEC 62127-1	2022

**EN IEC 60601-2-37:2024 (E)**

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 62359	2010	Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields	EN 62359	2011
+ A1	2017		+ A1	2018
CISPR 11	2024	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement	EN 55011	— <sup>1</sup>

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<sup>1</sup> Under preparation. Stage at the time of publication: FprEN 55011:2023.



IEC 60601-2-37

Edition 3.0 2024-07

# 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**

<https://standards.iteh.ai/catalog/standards/sist/a2129bd0-5010-4e7b-9d94-cb04bb0dcd6d/sist-en-iec-60601-2-37-2025>

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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](http://www.iec.ch/members_experts/refdocs). The main document types developed by IEC are described in greater detail at [www.iec.ch/publications](http://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](https://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.

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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

#### 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.