



# SLOVENSKI STANDARD

## SIST EN 60601-2-62:2015

01-september-2015

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**Medicinska električna oprema - 2-62. del: Posebne zahteve za osnovno varnost in bistvene lastnosti visokointenzivnih terapevtskih ultrazvočnih (HITU) naprav**

Medical electrical equipment - Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment

Medizinische elektrische Geräte - Teil 2-62: Besondere Anforderungen an die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von hochintensiven therapeutischen Ultraschallsystemen (HITU-Systemen)

Appareils électromédicaux - Partie 2-62: Exigences particulières pour la sécurité de base et les performances essentielles des systèmes à ultrasons thérapeutiques de haute intensité (HITU)

**Ta slovenski standard je istoveten z: EN 60601-2-62:2015**

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**ICS:**

11.040.60      Terapevtska oprema      Therapy equipment

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EUROPEAN STANDARD

EN 60601-2-62

NORME EUROPÉENNE

EUROPÄISCHE NORM

May 2015

ICS 11.040.01; 17.140.50

English Version

Medical electrical equipment - Part 2-62: Particular requirements  
for the basic safety and essential performance of high intensity  
therapeutic ultrasound (HITU) equipment  
(IEC 60601-2-62:2013)

Appareils électromédicaux - Partie 2-62: Exigences  
particulières pour la sécurité de base et les performances  
essentiels des appareils ultrasonores thérapeutiques de  
haute intensité (HITU)  
(IEC 60601-2-62:2013)

Medizinische elektrische Geräte - Teil 2-62: Besondere  
Anforderungen an die Sicherheit einschließlich der  
wesentlichen Leistungsmerkmale von hochintensiven  
therapeutischen Ultraschallsystemen (HITU-Systemen)  
(IEC 60601-2-62:2013)

This European Standard was approved by CENELEC on 2015-04-14. 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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.



European Committee for Electrotechnical Standardization  
Comité Européen de Normalisation Electrotechnique  
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

**EN 60601-2-62:2015****Foreword**

The text of document 62D/1069/FDIS, future IEC 60601-2-62, prepared by SC 62D "Electromedical equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-62:2015.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2016-01-14
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-04-14

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, which is an integral part of this document.

## iTeh STANDARD PREVIEW

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### Endorsement notice

The text of the International Standard IEC 60601-2-62:2013 was approved by CENELEC as a European Standard without any modification [EN 60601-2-62:2015](https://standards.iteh.ai/catalog/standards/sist/207e2195-58ea-40cb-8844-30a303090000/iec-60601-2-62-2015)

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

IEC 60601-2-5	NOTE	Harmonized as EN 60601-2-5.
IEC 60601-2-36	NOTE	Harmonized as EN 60601-2-36.
IEC 60529	NOTE	Harmonized as EN 60529.
IEC 61161	NOTE	Harmonized as EN 61161.
IEC 61828	NOTE	Harmonized as EN 61828.
IEC 62464-1	NOTE	Harmonized as EN 62464-1.
IEC 62555	NOTE	Harmonized as EN 62555.

## Annex ZA (normative)

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

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When 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.cenelec.eu](http://www.cenelec.eu)

#### **Annex ZA of EN 60601-1:2006 applies except as follows:**

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<b>Replacement:</b>				
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2 + corr. March	2007 <sup>1)</sup> 2010 <sup>1)</sup>
<b>Addition:</b>				
IEC 61689	2013	Ultrasonics - Physiotherapy systems - Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz	EN 61689	2013
IEC/TS 61949	-	Ultrasonics - Field characterization - In situ exposure estimation in finite- amplitude ultrasonic beams	CLC/TS 61949	-
IEC 62127-1	-	Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz	EN 62127-1	-
IEC 62127-2	-	Ultrasonics - Hydrophones - Part 2: Calibration for ultrasonic fields up to 40 MHz	EN 62127-2	-
IEC 62359	-	Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields	EN 62359	-
IEC 62555	-	Ultrasonics - Power measurement - High intensity therapeutic ultrasound (HITU) transducers and systems	EN 62555	-
IEC/TS 62556	-	Ultrasonics - Field characterization - Specification and measurement of field parameters for high intensity therapeutic ultrasound (HITU) transducers and systems	-	-

<sup>1)</sup> Superseded by EN 60601-1-2:2014 (IEC 60601-1-2:2014): DOW = 2018-12-31.

EN 60601-2-62:2015

**Annex ZZ**  
(informative)**Coverage of Essential Requirements of EU 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 given in Annex I of EU Directive 93/42/EEC of 14 June 1993 concerning medical devices.

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

**WARNING:** Other requirements and other EU Directives can be applied to the products falling within the scope of this standard.

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IEC 60601-2-62

Edition 1.0 2013-07

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE



**Medical electrical equipment –**  
**Part 2-62: Particular requirements for the basic safety and essential performance**  
**of high intensity therapeutic ultrasound (HITU) equipment**

[SIST EN 60601-2-62:2015](#)

**Appareils électromédicaux –**  
**Partie 2-62: Exigences particulières pour la sécurité de base et les performances**  
**essentiels des appareils ultrasonores thérapeutiques de haute intensité (HITU)**

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COMMISSION

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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

## MEDICAL ELECTRICAL EQUIPMENT –

**Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) 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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- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 60601-2-62 has been prepared by IEC subcommittee 62D: [Therapy equipment] Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice. It has been prepared in close co-operation with TC 87 (Ultrasonics).

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/1069/FDIS	62D/1076/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, 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 THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: 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 particular 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.

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 publication will remain unchanged until the stability 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.

**IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.**

## INTRODUCTION

In this particular standard, safety requirements additional to those in the general standard are specified for HIGH INTENSITY THERAPEUTIC ULTRASOUND (HITU) EQUIPMENT.

This particular standard takes into account IEC 62555 and IEC/TS 62556.

The requirements are followed by specifications for the relevant tests.

A rationale for the more important requirements, where appropriate, is given in Annex AA. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of the particular standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However this annex does not form part of the requirements of this standard.

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## MEDICAL ELECTRICAL EQUIPMENT –

### Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment

#### 201.1 Scope, object and related standards

Clause 1 of the general standard<sup>1)</sup> applies, except as follows:

##### 201.1.1 Scope

*Addition:*

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of HIGH INTENSITY THERAPEUTIC ULTRASOUND EQUIPMENT as defined in 201.3.218, hereafter referred to as ME EQUIPMENT.

This International Standard adds or replaces clauses listed in the IEC 60601-1 that are specific for HIGH INTENSITY THERAPEUTIC ULTRASOUND 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 the general standard.

NOTE 1 See also 4.2 of the general standard.

NOTE 2 As, in HITU fields, the acoustic waveform is expected to be extremely distorted due to non-linear propagation effects, the ultrasonic measurements are to be made under quasi linear conditions and then extrapolated following procedures given in IEC/TS 62556. See also IEC/TS 61949

This standard can also be applied to:

- therapeutic equipment for thrombolysis through exposure to high-intensity therapeutic ultrasound;
- therapeutic equipment for the treatment of occluding feeding vessels through exposure to high-intensity focused ultrasound;
- equipment intended to be used for relieving cancer pain due to bone metastases.

This particular standard does not apply to:

- ULTRASOUND EQUIPMENT intended to be used for physiotherapy (use: IEC 60601-2-5 [1]<sup>2)</sup> and IEC 61689);
- ULTRASOUND EQUIPMENT intended to be used for lithotripsy (use: IEC 60601-2-36 [2]);
- ULTRASOUND EQUIPMENT intended to be used for dedicated hyperthermia devices;
- ULTRASOUND EQUIPMENT intended to be used for phacoemulsification.

<sup>1)</sup> The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

<sup>2)</sup> Numbers in square brackets refer to the Bibliography.

### 201.1.2 Object

#### *Replacement:*

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for HIGH INTENSITY THERAPEUTIC ULTRASOUND (HITU) EQUIPMENT [as defined in 201.3.218.]

### 201.1.3 Collateral standards

#### *Addition:*

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2:2007 applies as modified in Clause 202. 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 the general standard and collateral standards 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 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. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 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. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables 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 clause or subclause in this particular standard, the 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:

NOTE Informative references [3,4,5,6,7,8,9,10 ] are listed in the bibliography beginning on page 61.

*Replacement:*

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

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*Addition:*

IEC 61689:2013, *Ultrasonics – Physiotherapy systems – Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz*

<https://standards.iteh.ai/catalog/standards/sist/207e2195-58ea-40cb-8844-36ca3091e349/sist-en-60601-2-62-2015>

IEC/TS 61949, *Ultrasonics – Field characterization – In-situ exposure estimation in finite amplitude ultrasonic beams*

IEC 62127-1, *Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz*

IEC 62127-2, *Ultrasonics – Hydrophones – Part 2: Calibration for ultrasonic fields up to 40 MHz*

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

IEC 62555<sup>3)</sup>, *Ultrasonics – Power measurement – High intensity therapeutic ultrasound (HITU) transducers and systems*

IEC/TS 62556<sup>4)</sup>, *Ultrasonics – Field characterization – Specification and measurement of field parameters for high intensity therapeutic ultrasound (HITU) transducers and systems*

## 201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1, IEC 62359, IEC 62127-1 and IEC 61689, as well as the following additional terms and definitions apply:

<sup>3)</sup> To be published.

<sup>4)</sup> To be published.