

ELEKTRILISED MEDITSIINISEADMED. OSA 2-62:
ERINÕUDED KÕRGINTENSIIVSE
ULTRAHELIRAVISEADME (HITU) ESMASELE
OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-2-62:2015 sisaldab Euroopa standardi EN 60601-2-62:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-2-62:2015 consists of the English text of the European standard EN 60601-2-62:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
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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
essentielles 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)

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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

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document have to be withdrawn

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.

Endorsement notice

The text of the International Standard IEC 60601-2-62:2013 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 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

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>
Replacement:				
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 ¹⁾ 2010 ¹⁾
Addition:				
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	-	-

¹⁾ Superseded by EN 60601-1-2:2014 (IEC 60601-1-2:2014): DOW = 2018-12-31.

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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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.

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 standard¹⁾ 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]²⁾ 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.

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

²⁾ Numbers in square brackets refer to the Bibliography.