ICS 17.140.50 SLOVENSKÁ TECHNICKÁ NORMA November 2014

STN	**Ultrazvuk. Meranie výkonu. Meranie výstupného výkonu vysokointenzívnych terapeutických ultrazvukových (HITU) meničov a systémov.**	**STN EN 62555** 34 0876

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 10/14

Obsahuje: EN 62555:2014, IEC 62555:2013

119598

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 62555

April 2014

ICS 17.140.50

English version

Ultrasonics - Power measurement - High intensity therapeutic ultrasound (HITU) transducers and systems

(IEC 62555:2013)

Ultrasons -
Mesurage de puissance -
Transducteurs et systèmes ultrasonores thérapeutiques de haute intensité (HITU)
(CEI 62555:2013)

Ultraschall -
Leistungsmessung -
Messung der Ausgangsleistung für hochintensive, therapeutische Ultraschallwandler und -systeme
(IEC 62555:2013)

This European Standard was approved by CENELEC on 2013-12-24. 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.

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CENELEC

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

Ref. No. EN 62555:2014 E

Foreword

The text of document 87/538/FDIS, future edition 1 of IEC 62555, prepared by IEC TC 87 "Ultrasonics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 62555:2014.

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) 2014-10-25
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2016-12-24

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Endorsement notice

The text of the International Standard IEC 62555:2013 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 62127-2	NOTE	Harmonized as EN 62127-2
IEC 60601-2-62	NOTE	Harmonized as EN 60601-2-62

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 When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC 61161	2013	Ultrasonics - Power measurement - Radiation force balances and performance requirements	EN 61161	2013
IEC/TR 62781		Ultrasonics - Conditioning of water for ultrasonic measurements	-	-

IEC 62555

Edition 1.0 2013-11

INTERNATIONAL STANDARD

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ULTRASONICS – POWER MEASUREMENT – HIGH INTENSITY THERAPEUTIC ULTRASOUND (HITU) TRANSDUCERS AND SYSTEMS

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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International Standard IEC 62555 has been prepared by IEC technical committee 87: Ultrasonics

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

FDIS	Report on voting
87/538/FDIS	87/543/RVD

Full information on the voting for the approval of this 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.

NOTE The following print types are used:

- Requirements: roman type
- Notes: in small roman type

- Words in **bold** in the text are defined in Clause 3.
- The numbers in square brackets refer to references given in the Bibliography which follows Annex G.

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.

INTRODUCTION

In ultrasound fields at megahertz frequencies, output power is typically determined by measuring the force on a target using a radiation force balance [1],[2],[3]. However, the relationship between the radiation force and the output power is affected by the focusing or other geometrical aspects of the field, by the type and shape of the target, by the distance of the target from the transducer, by absorption (including 'shock-loss') in the water path, and by acoustic streaming currents. Whilst many of these effects are small for typical diagnostic or physiotherapy ultrasound fields, they cannot generally be ignored for HITU fields (particularly for those often referred to as high intensity focused ultrasound HIFU) [4]. Furthermore, in HITU, the quantity of interest is the power incident on the patient rather than the output power at the transducer face. Since it is common to have a water stand-off between the transducer and the patient, attenuation and shock-loss in the water path may be significant and will vary depending upon the chosen distance.

The purpose of this International Standard is to establish standard methods of measurement of ultrasonic power of HITU devices in liquids in the lower megahertz frequency range based on the measurement of the radiation force using a gravimetric balance, and calorimetry (based on the measurement of thermal expansion). This standard identifies the sources of errors and describes a systematic step-by-step procedure to assess overall measurement uncertainty as well as the precautions that should be undertaken and uncertainties that should be taken into account while performing power measurements. Practical guidance is given for the determination of acoustic power from the very wide range of transducer geometries used for HITU. Unlike radiation force approaches in IEC 61161 that deal with "time average power," other power measurement methods are described in this document.

The structure and content of parts of this International Standard are largely based on IEC 61161:2013 but there are differences that are summarised below. In this standard the prime measurand is considered to be the incident power, and not the output power. Output power is always the quantity of interest in IEC 61161, which specifies that measurements are made with the target placed close to the transducer. However, this may not always be possible for strongly convergent transducers and there are cases where it is more relevant to measure the incident power which reaches a specified surface at some substantial distance from the transducer (this surface may represent the skin surface of the patient, for instance). This extra distance may result in significant nonlinear loss in the water path even at low megahertz frequencies. Consequently, in this International Standard the prime measurand is considered to be the incident power, and not the output power. The incident power may of course be the basis for determining the output power using an appropriate model with its own uncertainties.

ULTRASONICS – POWER MEASUREMENT – HIGH INTENSITY THERAPEUTIC ULTRASOUND (HITU) TRANSDUCERS AND SYSTEMS

1 Scope

This International Standard

- establishes general principles relevant to **HITU** fields for the use of **radiation force** balances in which an obstacle (**target**) intercepts the sound field to be measured;
- specifies a calorimetric method of determining the total emitted acoustic power of **ultrasonic transducers** based on the measurement of thermal expansion of a fluid-filled target;
- specifies requirements related to the statement of electrical power characteristics of **ultrasonic transducers**;
- provides guidance related to the avoidance of acoustic cavitation during measurement;
- provides guidance related to the measurement of HITU transducers of different construction and geometry, including collimated, diverging and convergent transducers, and multi-element transducers;
- provides guidance on the choice of the most appropriate measurement method;
- provides information on assessment of overall measurement uncertainties.

This International Standard is applicable to the measurement of ultrasonic power generated by **HITU equipment** up to 500 W in the frequency range from 0,5 MHz to 5 MHz. **HITU equipment** may generate convergent, collimated or divergent fields.

For frequencies less than 500 kHz, no validations exist and the user should assess the uncertainties of the power measurement and measurement system at the frequencies of operation.

This International Standard does not apply to:

- ultrasound equipment used for physiotherapy, for lithotripsy for general pain relief.

2 Normative references

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.

IEC 61161:2013, *Ultrasonics – Power measurement – Radiation force balances and performance requirements*

IEC/TR 62781, *Ultrasonics – Conditioning of water for ultrasonic measurements*