SLOVENSKI STANDARD
SIST EN 62555:2014

01-junij-2014

Ultrazvok - Merjenje moči - Merjenje izhodne moči visokointenzivnih terapevtskih ultrazvočnih (HITU) pretvornikov in sistemov (IEC 62555:2013)

Ultrasonics - Power measurement - Output power measurement for high intensity therapeutic ultrasound (HITU) transducers and systems

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Ultrasons - Mesurage de puissance - Transducteurs et systèmes ultrasonores thérapeutiques de haute intensité (HITU)

Ta slovenski standard je istoveten z: **EN 62555:2014**

ICS:

17.140.50	Elektroakustika	Electroacoustics

SIST EN 62555:2014 **en**

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)

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• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2016-12-24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

NORME INTERNATIONALE

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

Ultrasons – Mesurage de puissance – Transducteurs et systèmes ultrasonores thérapeutiques de haute intensité (HITU)

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

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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*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
acoustical efficiency
η_a
ratio of the acoustic **output power** from an **ultrasonic transducer** to the **transducer electrical power**

Note 1 to entry: **Acoustical efficiency** is unitless.

3.2
acoustic streaming
bulk fluid motion initiated by a sound field

[SOURCE: IEC 61161:2013, 3.1]

3.3
buoyancy sensitivity
S
ratio of the increase in the buoyancy force on an **expansion target** to the amount of absorbed energy in the absence of thermal losses

Note 1 to entry: This ratio may be temperature dependent.

Note 2 to entry: The **buoyancy sensitivity** for a fluid filled expansion target immersed in water is most conveniently and most accurately determined by calibration using electrical heating (see 7.2.9). It can also be calculated from the product of the **expansion ratio**, the density of the water and the acceleration due to gravity but, in practice, this leads to higher uncertainties.

Note 3 to entry: Since most sensitive balances display weight in grams or milligrams, the **buoyancy sensitivity** is often more conveniently expressed as mass-equivalent **buoyancy sensitivity** in terms of a mass-equivalent unit, such as mg J^{-1}.

Note 4 to entry: **Buoyancy sensitivity** is expressed in Newton per Joule, N J^{-1}.

3.4
expansion ratio
R_V
ratio of the increase in volume of the liquid inside an **expansion target** to the amount of absorbed energy in the absence of thermal losses

Note 1 to entry: Subject to certain assumptions, the **expansion sensitivity** for a fluid-filled **expansion target** can be calculated from the ratio of the volume expansivity of the fluid to its volumetric heat capacity. The ratio may be temperature dependent.

Note 2 to entry: **Expansion ratio** is expressed in cubic metre per Joule, m^3 J^{-1}.

3.5
expansion target
a liquid-filled device specially designed to intercept and absorb substantially all of the ultrasonic field and to undergo thermal expansion

3.6
free field
sound field in a homogeneous isotropic medium whose boundaries exert a negligible effect on the sound waves

[SOURCE: IEC 60050-801:1994, 801-23-28, modified – the term no longer contains “sound”]

3.7
high intensity therapeutic ultrasound (HITU) equipment
equipment for the generation and application of ultrasound to a patient for therapeutic purposes with the intention to destroy, disrupt or denature living tissues or non-tissue elements (for example, liquids, bubbles or micro-capsules) and which aims notably at making