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)

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

Useful links:

IEC publications search - www.iec.ch/searchpub

The advanced search enables you to find IEC publications by a variety of criteria (reference number, text, technical committee,…).
It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished

Stay up to date on all new IEC publications. Just Published details all new publications released. Available on-line and also once a month by email.

Electropedia - www.electropedia.org

The world's leading online dictionary of electronic and electrical terms containing more than 30 000 terms and definitions in English and French, with equivalent terms in additional languages. Also known as the International Electrotechnical Vocabulary (IEV) on-line.

Customer Service Centre - webstore.iec.ch/csc

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: csc@iec.ch.

A propos de la CEI

La Commission Electrotechnique Internationale (CEI) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications CEI

Le contenu technique des publications de la CEI est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

Liens utiles:

Recherche de publications CEI - www.iec.ch/searchpub

La recherche avancée vous permet de trouver des publications CEI en utilisant différents critères (numéro de référence, texte, comité d'études,…).
Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

Just Published CEI - webstore.iec.ch/justpublished

Restez informé sur les nouvelles publications de la CEI. Just Published détaille les nouvelles publications parues. Disponible en ligne et aussi une fois par mois par email.

Electropedia - www.electropedia.org

Le premier dictionnaire en ligne au monde de termes électroniques et électriques. Il contient plus de 30 000 termes et définitions en anglais et en français, ainsi que les termes équivalents dans les langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (VEI) en ligne.

Service Clients - webstore.iec.ch/csc

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: csc@iec.ch.

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)

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

PRICE CODE
CODE PRIX XA

ICS 17.140.50

ISBN 978-2-8322-1163-2

Warning! Make sure that you obtained this publication from an authorized distributor.
Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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.

2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.

3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.

4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.

5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.

6) All users should ensure that they have the latest edition of this publication.

7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.

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 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

treatments through actions of ultrasound having mechanical, thermal or more generally physical, chemical or biochemical effects

Note 1 to entry: Essentially **HITU equipment** comprises a generator of electric high-frequency power and a transducer for converting this to ultrasound. In a lot of cases this equipment also includes a targeting and monitoring device.

Note 2 to entry: HITU may as a side effect by its operation induce hyperthermia, however it should not be confused with this technique, which heats much less rapidly and to much lower therapeutic temperatures (in general 42 °C to 50 °C and thermal equivalent times of 0,2 min to 120 min). **HITU equipment** typically causes temperature rises in excess of 55 °C and for much shorter times: alternatively, HITU may also induce bioeffects by non-thermal mechanisms.

Note 3 to entry: This definition does not apply to: ultrasound equipment used for physiotherapy, ultrasound equipment used for lithotripsy or ultrasound equipment used for general pain relief.

[SOURCE: IEC 60601-2-62:2013, 201.3.218, modified – the Note 3 to entry refers to "general pain relief" instead of "dedicated hyperthermia".]

3.8
incident power
P_i
time-average ultrasonic power reaching a specified plane or surface after being emitted by an **ultrasonic transducer** into an approximately **free field,** under specified conditions and in a specified medium, preferably water

Note 1 to entry: **Incident power** is expressed in watt, W

3.9
multi-element transducer
a source of ultrasound comprising two or more spatially separated **ultrasonic transducers**

Note 1 to entry In this context, a single piezoelectric element in a phased array is considered to be an **ultrasonic transducer.**

3.10
nonlinear loss
loss of energy from an ultrasound beam due to the absorption of harmonic components which arise from nonlinear propagation effects

Note 1 to entry: In general, **nonlinear loss** does not occur uniformly throughout an ultrasound field but occurs preferentially where the pressure amplitude is greatest, resulting in a change in the relative distribution of ultrasound energy.

3.11
output power
P
time-average ultrasonic power emitted by an **ultrasonic transducer** into an approximately **free field** under specified conditions in a specified medium, preferably water

Note 1 to entry: **Output power** is expressed in watt, W

[SOURCE: IEC 61161:2013, 3.3]

3.12
radiation conductance
G
ratio of the acoustic **output power** and the squared r.m.s. transducer input voltage.

Note 1 to entry: It is used to characterize the electrical to acoustical transfer of **ultrasonic transducers**.

Note 2 to entry: The r.m.s. drive voltage is used (rather than, for instance, peak-to-peak drive voltage) because its value is less affected by distortion of the applied electrical signal.

Note 3 to entry: This term is not the same as the real part of transducer admittance.

Note 4 to entry: **Radiation conductance** is expressed in siemens, S

[SOURCE: IEC 61161:2013, 3.8, modified –two notes to entry relevant to HITU have been added]

3.13
radiation force
acoustic radiation force
F
time-average force acting on a body in a sound field and caused by the sound field, excluding the component due to **acoustic streaming**

Note 1 to entry: More generally: time-average force (excluding the component due to **acoustic streaming**) in a sound field, appearing at the boundary surface between two media of different acoustic properties

Note 2 to entry: **Radiation force** is expressed in Newton, N

[SOURCE; IEC 61161:2013, 3.4 modified – the second part of the original definition is presented as a note to entry, but without the phrase "or within a single attenuating medium"]

3.14
radiation force target
device specially designed to intercept substantially all of the ultrasonic field and to serve as the object which is acted upon by the **radiation force**

3.15
target
device specially designed to intercept substantially all of the ultrasonic field

3.16
transducer electrical power
P_{el}
rate at which time-average electrical energy is converted by an **ultrasonic transducer** into other forms of energy (typically into heat and the energy of the ultrasonic field)

Note 1 to entry: Electrical power which is reflected from the **ultrasonic transducer** is not part of the **transducer electrical power.**

Note 2 to entry: **Transducer electrical power** is expressed in Watt, W

3.17
ultrasonic transducer
device capable of converting electrical energy to mechanical energy within the ultrasonic frequency range and/or reciprocally of converting mechanical energy to electrical energy

Note 1 to entry: An **ultrasonic transducer** may include connected cables and components for electrical matching.

4 List of symbols

a	radius of a circular ultrasonic source transducer
b_x and b_y	half-dimensions of a rectangular **ultrasonic transducer** in x and y direction, respectively (so that $2b_x$ and $2b_y$ are the transducer's side lengths)
B	change in the buoyancy force acting on an **expansion target** immersed in a sound propagating medium (usually water)
c	speed of sound (usually in water)
d_x and d_y	geometrical focal lengths of a convergent ultrasonic transducer in the x-z and the y-z plane, respectively

d	geometrical focal length of a convergent **ultrasonic transducer, in the case that** $d_x = d_y = d$
C	the volumetric heat capacity
E	the volumetric expansion coefficient
F	**radiation force** on a **target** in the direction of the incident ultrasonic wave
g	acceleration due to gravity
G	**radiation conductance**
h_d	half the diagonal of a rectangular transducer, $h_\mathrm{d} = (b_x{}^2 + b_y{}^2)^{1/2}$
h_h	harmonic mean of b_x and b_y, $h_\mathrm{h} = 2 / (1/b_x + 1/b_y)$
k	circular wavenumber ($2\pi/\lambda$)
L	the fraction of **acoustic streaming** momentum recovered by a **target**
M	the time-varying weight of a **target** or **expansion target** as it is displayed by the supporting balance (often in mass-equivalent units)
P	**output power** of an **ultrasonic transducer**
P_el	the **transducer electrical power**
P_i	**incident power** on a **target** or **expansion target**
R_c	radius of curvature of a focused bowl transducer
R_V	the **expansion ratio** of an **expansion target**
s	normalized distance from an **ultrasonic transducer** ($s = z\lambda / a^2$)
S	the **buoyancy sensitivity** of an **expansion target**
t_0	the duration of insonation
z	distance between a **target** and the radiating surface of an **ultrasonic transducer** measured along the beam-axis
α	amplitude attenuation coefficient of plane waves in a medium (usually water)
β_x and β_y	focus (half-)angles of a convergent **ultrasonic transducer** in the x-z and the y-z plane, respectively; $\beta_x = \arctan(b_x/d_x)$, $\beta_y = \arctan(b_y/d_y)$ if the transducer is planar and the focal lengths are counted from the planar transducer surface
γ	focus (half-)angle of a circular convergent **ultrasonic transducer**; $\gamma = \arcsin(a/d)$ if the transducer is spherically curved and the focal length is counted from the "bottom" of the "bowl"; $\gamma = \arctan(a/d)$ if the focal length is counted from the plane defined by the rim of the active part of the "bowl" or if the transducer is planar
η_a	the **acoustic efficiency** of an **ultrasonic transducer**
θ	angle between the direction of the incident ultrasonic wave and the normal to the surface of a **target**
ϕ	angle between the direction of the incident ultrasonic wave and the sensitive axis (usually vertical) of a balance
λ	ultrasonic wavelength in the sound-propagating medium (usually water)
ρ	(mass) density of the sound-propagating medium (usually water).

NOTE The direction of the incident wave mentioned above under F and θ is understood to be the direction of the field axis, i.e., it is understood in a global sense rather than in a local sense.

5 Power measurement for HITU equipment

Measurement of **output power** is well established for collimated (and weakly convergent or weakly divergent) ultrasound fields at powers up to 20 W using the **radiation force** method [IEC 61161]. Clause 6 of this International Standard is based on IEC 61161:2013 but some changes are introduced to make it more appropriate for **HITU equipment** which in general is not collimated and has higher **output power**. IEC 61161 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. 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 (guidance is given in Annex E). Although the buoyancy change method determines the time-average power incident on the **target** during the insonation time, the **radiation force** method actually determines the turn-on and turn-off power. These two values may be different to each other, and the average of the two is not necessarily equal to the time-average power. In general, insonation time is adjusted as appropriate to the measuring device to account for device limitations.

6 Radiation force on a target

6.1 General

The **radiation force** balance shall consist of a **target** which is connected to a balance. The ultrasonic beam shall be directed vertically upwards or downwards or horizontally on the **target** and the **radiation force** exerted by the ultrasonic beam shall be measured by the balance. The incident ultrasonic power shall be determined from the difference between the force measured with and without ultrasonic radiation. Calibration of the balance can be carried out by means of small precision weights of known mass.

The **target** shall be chosen so as to closely approach one of the two extreme cases, i.e. perfect absorber or perfect reflector.

For a plane incident wave only, the acoustic **incident power** P_i from the **ultrasonic transducer** shall be calculated from the **radiation force** component F on the **target** in the propagation direction using Equation 1 or 2 as appropriate:

For a perfectly absorbing **target**:

$$P_i = cF \tag{1}$$

For a perfectly reflecting **target**:

$$P_i = cF / (2 \cos^2 \theta) \tag{2}$$

where

c is the speed of sound in the sound-propagating fluid (water);

θ is the angle between the propagation direction of the incident wave and the normal to the reflecting surface

NOTE 1 The direction of the incident wave mentioned above is understood to be the direction of the field axis, i.e., it is understood in a global sense rather than in a local sense.

The relationship between **radiation force** and **incident power** depends in principle on assumptions about the radiated field and its interaction with the **target** and the measurement tank. For any non-plane wave (e.g. convergent, divergent or arising from multiple simultaneous sources), the correct relationship between **radiation force** and **incident power** shall be determined. The uncertainty in the **incident power** due to the non-plane nature of the field shall be estimated.