**Ultrasonics - Power measurement - High intensity** d Constitution Sensible of the therapeutic ultrasound (HITU) transducers and systems



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## **EUROPEAN STANDARD**

## EN 62555

## NORME EUROPÉENNE EUROPÄISCHE NORM

April 2014

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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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#### **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	(dop)	2014-10-25
	publication of an identical national standard or by endorsement		
•	latest date by which the national standards conflicting with the	(dow)	2016-12-24
	document have to be withdrawn		

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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.

applies.				
<u>Publication</u>	<u>Year</u>	<u>Title</u>	EN/HD	<u>Year</u>
IEC 61161	2013	Ultrasonics - Power measurement - Radiation force balances and performance requirement		2013
IEC/TR 62781		Ultrasonics - Conditioning of water for ultrasonic measurements		

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#### 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.