BS EN 61161:2013



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Ultrasonics — Power measurement — Radiation force balances and performance requirements

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This British Standard is the UK implementation of EN 61161:2013. It is identical to IEC 61161:2013. It supersedes BS EN 61161:2007, which will be withdrawn on 6 March 2016.

The UK participation in its preparation was entrusted to Technical Committee EPL/87, Ultrasonics.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Foreword

The text of document 87/520/FDIS, future edition 3 of IEC 61161, prepared by IEC/TC 87 "Ultrasonics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 61161:2013.

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) | 2013-12-06 |
|---|---|-------|------------|
| • | latest date by which the national standards conflicting with the document have to be withdrawn | (dow) | 2016-03-06 |

This document supersedes EN 61161:2007.

EN 61161:2013 includes the following significant technical changes with respect to EN 61161:2007:

- whereas the second edition tacitly dealt with circular transducers only, the present edition as far as possible deals with both circular and rectangular transducers, Including a number of symbols for rectangular transducers;
- attention is paid to focused cases and the influence of scanning has been added;
- the method of calibrating the radiation force balance now depends on whether the set-up is used as a primary or as secondary measurement tool;
- Annex B (basic formulae) has been updated and in Annex C the buoyancy change method is mentioned (see also future EN 62555).

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.

Endorsement notice

The text of the International Standard IEC 61161:2013 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 | Harmonised as EN 60601-2-5. |
|----------------|------|---|
| IEC 61157 | NOTE | Harmonised as EN 61157. |
| IEC 61846:1998 | NOTE | Harmonised as EN 61846:1998 (not modified). |
| IEC 62127-1 | NOTE | Harmonised as EN 62127-1. |
| IEC 62127-2 | NOTE | Harmonised as EN 62127-2. |
| IEC 62127-3 | NOTE | Harmonised as EN 62127-3. |
| IEC 62555 1) | NOTE | Harmonised as EN 62555 ¹⁾ . |

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 | <u>Year</u> | Title | <u>EN/HD</u> | <u>Year</u> |
|-------------|-------------|---|--------------|-------------|
| IEC 61689 | - | Ultrasonics - Physiotherapy systems - Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz | | - |

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INTRODUCTION

A number of measuring methods exist for the determination of the total emitted power of ultrasonic transducers ([1], [2], [3]¹, see also Annex C). The purpose of this International Standard is to establish standard methods of measurement of ultrasonic power in liquids in the lower megahertz frequency range based on the measurement of the radiation force using a gravimetric balance. The great advantage of radiation force measurements is that a value for the total radiated power is obtained without the need to integrate field data over the cross-section of the radiated sound beam. 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.

Basic safety requirements for ultrasonic physiotherapy devices are identified in IEC 60601-2-5 and make reference to IEC 61689, which specifies the need for acoustic power measurements with an uncertainty better than \pm 15 % at a level of confidence of 95 %. Considering the usual degradation of accuracy in the practical application of this standard, reference measurement methods need to be established with uncertainties better than \pm 7 %. Ultrasonic diagnostic device declaration requirements including acoustic power are specified in other IEC standards, as for example in IEC 61157.

The measurement of acoustic power accurately and repeatably using a radiation force balance as defined in this standard is influenced by a number of practical problems. As a guide to the user, additional information is provided in Annex A using the same section and clause numbering as the main body.

¹ Numbers in square brackets refer to the Bibliography.

1 Scope

This International Standard

- specifies a method of determining the total emitted acoustic power of ultrasonic transducers based on the use of a radiation force balance;
- establishes general principles for the use of radiation force balances in which an obstacle (target) intercepts the sound field to be measured;
- establishes limitations of the radiation force method related to cavitation and temperature rise;
- establishes quantitative limitations of the radiation force method in relation to diverging and focused beams;
- provides information on estimating the acoustic power for diverging and focused beams using the radiation force method;
- provides information on assessment of overall measurement uncertainties.

This International Standard is applicable to:

- the measurement of ultrasonic power up to 1 W based on the use of a radiation force balance in the frequency range from 0,5 MHz to 25 MHz;
- the measurement of ultrasonic power up to 20 W based on the use of a radiation force balance in the frequency range 0,75 MHz to 5 MHz;
- the measurement of total ultrasonic power in well-collimated, diverging and focused ultrasonic fields;
- the use of radiation force balances of the gravimetric type or force feedback type.

(See also Clause A.1)

NOTE 1 A focused beam is converging in the pre-focal range and diverging beyond focus.

NOTE 2 Ultrasonic power measurement in the high intensity therapeutic ultrasound (HITU) range, i.e. beyond 1 W or 20 W, respectively, is dealt with in the future IEC 62555.

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 61689, Ultrasonics – Physiotherapy systems – Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz

3 Terms and definitions

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