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BSI Standards Publication

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

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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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# EN 61689

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English version

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

(IEC 61689:2013)

Ultrasons -
Systèmes de physiothérapie -
Spécifications des champs et méthodes de mesure dans la gamme de fréquences de 0,5 MHz à 5 MHz
(CEI 61689:2013)

Ultraschall -
Physiotherapiesysteme -
Feldspezifikation und Messverfahren im Frequenzbereich von 0,5 MHz bis 5 MHz
(IEC 61689:2013)

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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## Foreword

The text of document 87/522/FDIS, future edition 3 of IEC 61689, prepared by IEC TC 87 "Ultrasonics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 61689:2013.

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) | 2014-01-02 |
| • latest date by which the national standards conflicting with the document have to be withdrawn | (dow) | 2016-04-02 |

This document supersedes EN 61689:2007.

EN 61689:2013 includes the following significant technical changes with respect to EN 61689:2007:

- restriction introduced of 0,2 W/cm² effective intensity during hydrophone measurements for treatment heads with $ka \leq 20$, to limit the likelihood of cavitation;
- a change in the factor $F_{ac}$, to determine the **effective radiating area**, from 1,354 to 1,333;
- change to SI units for terms and definitions;
- closer alignment and re-ordered, updated definitions in line with standards in EN 62127 series;
- minor arithmetical errors corrected in data analysis;
- inconsistencies and errors in symbol usage removed throughout;
- large number of editorial and formal corrections made;
- changes introduced to references in the bibliography.

This standard should be read in conjunction with EN 60601-2-5, which, as indicated in its preface, will itself be revised in order to be compatible with this standard.

NOTE The following print types are used:
- Requirements: in Arial 10 point
- Notes: in Arial 8 point
- Words in **bold** in the text are defined in Clause 3
- Symbols and formulae: *Times New Roman + Italic*
- Compliance clauses : *in Arial Italic*

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## Endorsement notice

The text of the International Standard IEC 61689:2013 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 61828 | NOTE | Harmonized as EN 61828. |
| IEC 62127-2 | NOTE | Harmonized as EN 62127-2. |
| IEC 62127-3 | NOTE | Harmonized as EN 62127-3. |

# 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 60601-1 | - | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance | EN 60601-1 | - |
| IEC 60601-2-5 | - | Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment | EN 60601-2-5 | - |
| IEC 61161 | 2013 | Ultrasonics - Power measurement - Radiation force balances and performance requirements | EN 61161 | 2013 |
| IEC 62127-1<br>+ corr. August<br>+ A1 | 2007<br>2008<br>2013 | Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz | EN 62127-1<br><br>+ A1 | 2007<br><br>2013 |

# CONTENTS

INTRODUCTION ..... 6
1 Scope ..... 7
2 Normative references ..... 7
3 Terms and definitions ..... 8
4 List of symbols ..... 16
5 Ultrasonic field specifications ..... 18
6 Conditions of measurement and test equipment used ..... 19
6.1 General ..... 19
6.2 Test vessel ..... 19
6.3 Hydrophone ..... 20
6.4 rms or peak signal measurement ..... 20
7 Type testing reference procedures and measurements ..... 20
7.1 General ..... 20
7.2 Rated output power ..... 21
7.3 Hydrophone measurements ..... 21
7.4 Effective radiating area ..... 22
7.5 Reference type testing parameters ..... 23
7.6 Acceptance criteria for reference type testing ..... 24
8 Routine measurement procedure ..... 24
8.1 General ..... 24
8.2 Rated output power ..... 24
8.3 Effective radiating area ..... 25
8.4 Beam non-uniformity ratio ..... 25
8.5 Effective intensity ..... 25
8.6 Acceptance criteria for routine testing ..... 25
9 Sampling and uncertainty determination ..... 26
9.1 Reference type testing measurements ..... 26
9.2 Routine measurements ..... 26
9.3 Uncertainty determination ..... 26
Annex A (informative) Guidance for performance and safety ..... 27
Annex B (normative) Raster scan measurement and analysis procedures ..... 31
Annex C (normative) Diametrical or line scan measurement and analysis procedures ..... 33
Annex D (informative) Rationale concerning the beam cross-sectional area definition ..... 36
Annex E (informative) Factor used to convert the beam cross-sectional area ($A_{BCS}$) at the face of the treatment head to the effective radiating area ($A_{ER}$) ..... 41
Annex F (informative) Determining acoustic power through radiation force measurements ..... 43
Annex G (informative) Validity of low-power measurements of the beam cross-sectional area ($A_{BCS}$) ..... 45
Annex H (informative) Influence of hydrophone effective diameter ..... 46
Annex I (informative) Effective radiating area measurement using a radiation force balance and absorbing apertures ..... 48

Annex J (informative) Guidance on uncertainty determination ..... 58
Bibliography ..... 60

Figure A.1 – Normalized, time-averaged values of acoustic intensity (unbroken line) and of one of its plane-wave approximations (broken line), existing on the axis of a circular piston source of $ka$ = 30, versus the normalized distance $s_n$, where $s_n = \lambda z/a^2$ ..... 30
Figure A.2 – Histogram of $R_{BN}$ values for 37 treatment heads of various diameter and frequency ..... 30
Figure D.1 – Iso-pressure lines of a typical physiotherapy treatment head of small geometrical area ($ka$ = 17) ..... 38
Figure D.2 – Plot of beam cross-sectional area against different limit values for a small range of values in distance along the beam alignment axis, $z$ ..... 38
Figure D.3 – Normalized values of beam cross-sectional area for IEC and FDA limit values for five transducers of different $ka$ values ..... 39
Figure D.4 – Range of values of the beam cross-sectional area ($A_{BCS}$) with distance from the face of the treatment head ..... 40
Figure D.5 – Range of values of the normalized beam cross-sectional area ($A_{BCS}$) with transducer $ka$ ..... 40
Figure E.1 – Conversion factor $F_{ac}$ as a function of the $ka$ product for $ka$ product between 40 and 160 ..... 42
Figure I.1 – Schematic representation of aperture measurement set-up ..... 49
Figure I.2 – Measured power as a function of aperture diameter for commercially-available 1 MHz physiotherapy treatment heads ..... 53
Figure I.3 – Cumulative sum of annular power contributions, previously sorted in descending order of intensity contribution, plotted against the cumulative sum of their respective annular areas ..... 56

Table C.1 – Constitution of the transformed array [$B$] used for the analysis of half-line scans ..... 34
Table F.1 – Necessary target size, expressed as the minimum target radius $b$, as a function of the ultrasonic frequency, $f$, the effective radius of the treatment head, $a_1$, and the target distance, $z$, calculated according to A.5.3 of IEC 61161: 2013 (see [6]) ..... 44
Table G.1 – Variation of the beam cross-sectional area ($A_{BCS}(z)$) with the indicated output power from two transducers ..... 45
Table H.1 – Comparison of measurements of the beam cross-sectional area ($A_{BCS}(z)$) made using hydrophones of geometrical active element radii 0,3 mm, 0,5 mm and 2,0 mm ..... 47
Table I.1 – Aperture measurement check sheet ..... 52
Table I.2 – Annular power contributions ..... 54
Table I.3 – Annular intensity contributions ..... 54
Table I.4 – Annular intensity contributions, sorted in descending order ..... 55
Table I.5 – Annular power contributions, sorted in descending order of intensity contribution ..... 55
Table I.6 – Cumulative sum of annular power contributions, previously sorted in descending order of intensity contribution, and the cumulative sum of their respective annular areas ..... 56

# INTRODUCTION

**Ultrasound** at low megahertz frequencies is widely used in medicine for the purposes of physiotherapy. Such equipment consists of a generator of high frequency electrical energy and usually a hand-held **treatment head**, often referred to as an applicator. The **treatment head** contains a transducer, usually a disk of piezoelectric material, for converting the electrical energy to **ultrasound** and is often designed for contact with the human body.

# ULTRASONICS – PHYSIOTHERAPY SYSTEMS – FIELD SPECIFICATIONS AND METHODS OF MEASUREMENT IN THE FREQUENCY RANGE 0,5 MHz TO 5 MHz

## 1 Scope

This International Standard is applicable to **ultrasonic equipment** designed for physiotherapy containing an **ultrasonic transducer** generating continuous or quasi-**continuous wave** ultrasound in the frequency range 0,5 MHz to 5 MHz.

This standard only relates to **ultrasonic physiotherapy equipment** employing a single plane non-focusing circular transducer per **treatment head**, producing static beams perpendicular to the face of the **treatment head.**

This standard specifies:

- methods of measurement and characterization of the output of **ultrasonic physiotherapy equipment** based on reference testing methods;
- characteristics to be specified by manufacturers of **ultrasonic physiotherapy equipment** based on reference testing methods;
- guidelines for safety of the ultrasonic field generated by **ultrasonic physiotherapy equipment**;
- methods of measurement and characterization of the output of **ultrasonic physiotherapy equipment** based on routine testing methods;
- acceptance criteria for aspects of the output of **ultrasonic physiotherapy equipment** based on routine testing methods.

Therapeutic value and methods of use of **ultrasonic physiotherapy equipment** are not covered by the scope of this standard.

## 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 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-2-5, *Medical electrical equipment – Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment*

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

IEC 62127-1: *2007*, *Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz*
Amendment 1: *2013*