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## REDLINE VERSION

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### **Ultraljud – Ultraljudsterapiapparater – Prestandafordringar och mätmetoder i frekvensområdet 0,5 MHz till 5 MHz**

*Ultrasonics –*

*Physiotherapy systems –*

*Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz*

En så kallad "Redline version" (RLV) innehåller både den fastställda IEC-standardens och en ändringsmarkerad standard. Alla tillägg och borttagningar sedan den tidigare utgåvan är markerade med färg. Med en RLV sparar du mycket tid när du ska identifiera och bedöma aktuella ändringar i standarden. SEK Svensk Elstandard kan bara ge ut en RLV i de fall den finns tillgänglig från IEC.

# INTERNATIONAL STANDARD



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

INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

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ICS 11.040.60

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## CONTENTS

FOREWORD .....	5
INTRODUCTION .....	7
1 Scope .....	8
2 Normative references .....	8
3 Terms and definitions .....	9
4 Symbols .....	19
5 Ultrasonic field specifications .....	20
6 Conditions of measurement and test equipment used .....	21
6.1 General .....	21
6.2 Test vessel .....	21
6.3 Hydrophone .....	22
6.4 RMS- <del>or</del> peak signal measurement .....	23
7 Type testing reference procedures and measurements .....	24
7.1 General .....	24
7.2 Rated output power .....	24
7.3 Hydrophone measurements .....	24
7.4 Effective radiating area .....	25
7.4.1 Effective radiating area measurements .....	25
7.4.2 Hydrophone positioning .....	26
7.4.3 Beam cross-sectional area determination .....	26
7.4.4 Active area gradient determination .....	26
7.4.5 Beam type determination .....	26
7.4.6 Effective radiating area calculation .....	26
7.4.7 Beam non-uniformity ratio calculation .....	26
7.4.8 Testing requirements .....	27
7.5 Reference type testing parameters .....	27
7.6 Acceptance criteria for reference type testing .....	28
8 Routine measurement procedure .....	28
8.1 General .....	28
8.2 Rated output power .....	28
8.3 Effective radiating area .....	28
8.4 Beam non-uniformity ratio .....	29
8.5 Effective intensity .....	29
8.6 Acceptance criteria for routine testing .....	29
9 Sampling and uncertainty determination .....	30
9.1 Reference type testing measurements .....	30
9.2 Routine measurements .....	30
9.3 Uncertainty determination .....	30
Annex A ( <del>informative</del> normative) Guidance for performance and safety .....	31
A.1 General .....	31
A.2 Rated output power .....	31
A.3 Effective intensity .....	31
A.4 Beam non-uniformity ratio .....	31
A.4.1 General .....	31

A.4.2	Rationale behind using a limiting value for the beam non-uniformity ratio ( $R_{BN}$ ) .....	31
Annex B (normative)	Raster scan measurement and analysis procedures .....	36
B.1	General.....	36
B.2	Requirements for raster scans .....	36
B.3	Requirements for analysis of raster scan data.....	37
B.3.1	General .....	37
B.3.2	Total mean square acoustic pressure .....	37
B.3.3	Calculation of the beam cross-sectional area, $A_{BCS}$ .....	37
Annex C (normative)	Diametrical or line scan measurement and analysis procedures.....	39
C.1	General.....	39
C.2	Requirements for line scans.....	39
C.3	Analysis of <del>line</del> scans .....	39
Annex D (informative)	Rationale concerning the beam cross-sectional area definition.....	43
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 ( $A_{ER}$ ).....	48
Annex F (informative)	Determining acoustic power through radiation force measurements .....	50
Annex G (informative)	Validity of low-power measurements of the beam cross-sectional area ( $A_{BCS}$ ).....	52
Annex H (informative)	Influence of hydrophone effective diameter .....	53
Annex I (informative)	Effective radiating area measurements using a radiation force balance and absorbing apertures .....	55
I.1	General.....	55
I.2	Concept of aperture method.....	55
I.3	Requirements for the aperture method .....	56
I.3.1	Radiation force balance .....	56
I.3.2	Apertures.....	56
I.4	Measurement procedure for determining the effective radiating area.....	57
I.5	Analysis of raw data to derive the effective radiating area.....	58
I.6	Implementation of the aperture technique .....	64
I.7	Relationship of results to reference testing method .....	65
Annex J (informative)	Guidance on uncertainty determination .....	66
Annex K (informative)	Examples of pulse duration and pulse repetition period of amplitude modulated waves .....	68
Bibliography	.....	70

Figure A.1 – Normalized, time-averaged values of acoustic intensity (solid line) and of one of its plane-wave approximations (broken line), existing on the axis of a circular piston source of  $ka = 30$ , plotted against the normalized distance  $s_n$ , where  $s_n = \lambda z/a^2$ ..... 34

Figure A.2 – Histogram of  $R_{BN}$  values for 37 treatment heads of various diameters and frequencies..... 35

~~Figure D.1 – Iso-pressure lines of a typical physiotherapy treatment head of small geometrical area ( $ka = 17$ ) .....~~

~~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,  $z$ .....~~

<del>Figure D.3 – Normalized values of beam cross-sectional area for IEC and FDA limit values for five transducers of different <math>ka</math> values</del>	<del>.....</del>
<del>Figure D.4 – Range of values of the beam cross-sectional area (<math>A_{BCS}</math>) with distance from the face of the treatment head</del>	<del>.....</del>
<del>Figure D.5 – Range of values of the normalized beam cross-sectional area (<math>A_{BCS}</math>) with transducer <math>ka</math></del>	<del>.....</del>
Figure E.1 – Conversion factor $F_{ac}$ as a function of the $ka$ product for $ka$ product between 40 and 160	49
Figure I.1 – Schematic representation of aperture measurement set-up	56
Figure I.2 – Measured power as a function of aperture diameter for commercially available 1 MHz physiotherapy treatment heads	60
Figure I.3 – Cumulative sum of annular power contributions, previously sorted in descending order of intensity contributions, plotted against the cumulative sum of their respective annular areas	64
Figure K.1 – Example 1: Tone-burst (i.e. rectangular modulation waveform)	68
Figure K.2 – Example 2: Half-wave modulation with no filtering of the AC mains voltage	68
Figure K.3 – Example 3: Full-wave modulation with no filtering of the AC mains voltage	68
Figure K.4 – Example 4: Half-wave modulation with filtering of the AC mains voltage; filtering insufficient to define the wave as continuous wave (3.17)	69
Figure K.5 – Example 5: Full-wave modulation with filtering of the AC mains voltage; filtering insufficient to define the wave as continuous wave (3.17)	69
Table C.1 – Constitution of the transformed array [B] used for the analysis of half-line scans	41
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 in accordance with A.5.3.1 of IEC 61161:2013 (see [8])	51
Table G.1 – Variation of the beam cross-sectional area $A_{BCS}(z)$ with the indicated output power from two transducers	52
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	54
Table I.1 – Aperture measurement check sheet	59
Table I.2 – Annular power contributions	61
Table I.3 – Annular intensity contributions	61
Table I.4 – Annular intensity contributions, sorted in descending order	62
Table I.5 – Annular power contributions, sorted in descending order of intensity contribution	62
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	63

## INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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**This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition IEC 61689:2013. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.**

IEC 61689 has been prepared by IEC technical committee 87: Ultrasonics. It is an International Standard.

This fourth edition cancels and replaces the third edition published in 2013. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition.

- a) The requirement on water oxygen content is specified in 6.1.
- b) Former recommendations in 6.2 have been changed to become requirements.
- c) Several definitions in Clause 3 have been updated in line with other TC 87 documents.
- d) The formerly informative Annex A has been changed to become normative, and now contains details on how conformance with IEC 60601-2-5 requirements is checked.
- e) Annex D has been considerably shortened and reference to a now withdrawn regulatory document has been removed.

The text of this International Standard is based on the following documents:

Draft	Report on voting
87/784/FDIS	87/789/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at [www.iec.ch/members\\_experts/refdocs](http://www.iec.ch/members_experts/refdocs). The main document types developed by IEC are described in greater detail at [www.iec.ch/standardsdev/publications](http://www.iec.ch/standardsdev/publications).

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*

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under [webstore.iec.ch](http://webstore.iec.ch) in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

**IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.**

## 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 disc 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 document is applicable to ultrasonic equipment designed for physiotherapy containing an **ultrasonic transducer** generating continuous or quasi-continuous (e.g. tone burst) wave **ultrasound** in the frequency range 0,5 MHz to 5 MHz. This document 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 document 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 within the scope of this document.

**Ultrasonic physiotherapy equipment** using **ultrasound** in the frequency range from 20 kHz to 500 kHz is dealt with in IEC 63009.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. 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~~

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## **Ultraljud – Ultraljudsterapiapparater – Prestandafordringar och mätmetoder i frekvensområdet 0,5 MHz till 5 MHz**

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

Som svensk standard gäller europastandarden EN IEC 61689:2022. Den svenska standarden innehåller den officiella engelska språkversionen av EN IEC 61689:2022.

### **Nationellt förord**

Europastandarden EN IEC 61689:2022

består av:

- **europastandardens ikraftsättningsdokument**, utarbetat inom CENELEC
- **IEC 61689, Fourth edition, 2022 - Ultrasonics - Physiotherapy systems - Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz**

utarbetad inom International Electrotechnical Commission, IEC.

Tidigare fastställd svensk standard SS-EN 61689, utgåva 3, 2013, gäller ej fr o m 2025-04-12.

### *Standarder underlättar utvecklingen och höjer elsäkerheten*

Det finns många fördelar med att ha gemensamma tekniska regler för bl a mätning, säkerhet och provning och för utförande, skötsel och dokumentation av elprodukter och elanläggningar.

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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 61689:2022)**

Ultrasons - Systèmes de physiothérapie - Spécifications  
des champs et méthodes de mesure dans la plage de  
fréquences de 0,5 MHz à 5 MHz  
(IEC 61689:2022)

Ultraschall - Physiotherapiesysteme - Feldspezifikation und  
Messverfahren im Frequenzbereich von 0,5 MHz bis 5 MHz  
(IEC 61689:2022)

This European Standard was approved by CENELEC on 2022-04-12. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.



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

**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

## **European foreword**

The text of document 87/784/FDIS, future edition 4 of IEC 61689, prepared by IEC/TC 87 "Ultrasonics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 61689:2022.

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) 2023-01-12
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2025-04-12

This document supersedes EN 61689:2013 and all of its amendments and corrigenda (if any).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

## **Endorsement notice**

The text of the International Standard IEC 61689:2022 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 IEC 61828
IEC 62127-2	NOTE	Harmonized as EN 62127-2
IEC 62127-3	NOTE	Harmonized as EN 62127-3
IEC 62555	NOTE	Harmonized as EN 62555
IEC 63009	NOTE	Harmonized as EN IEC 63009

## Annex ZA (normative)

### Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: [www.cenelec.eu](http://www.cenelec.eu).

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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	-	Ultrasonics - Power measurement - Radiation force balances and performance requirements	EN 61161	-
IEC 62127-1	-	Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields	-	-

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE

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

**Ultrasons – Systèmes de physiothérapie – Spécifications des champs  
et méthodes de mesure dans la plage de fréquences de 0,5 MHz à 5 MHz**

INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

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## CONTENTS

FOREWORD .....	5
INTRODUCTION .....	7
1 Scope .....	8
2 Normative references .....	8
3 Terms and definitions .....	9
4 Symbols .....	18
5 Ultrasonic field specifications .....	19
6 Conditions of measurement and test equipment used .....	20
6.1 General .....	20
6.2 Test vessel .....	20
6.3 Hydrophone .....	21
6.4 RMS peak signal measurement .....	22
7 Type testing reference procedures and measurements .....	22
7.1 General .....	22
7.2 Rated output power .....	23
7.3 Hydrophone measurements .....	23
7.4 Effective radiating area .....	24
7.4.1 Effective radiating area measurements .....	24
7.4.2 Hydrophone positioning .....	24
7.4.3 Beam cross-sectional area determination .....	24
7.4.4 Active area gradient determination .....	24
7.4.5 Beam type determination .....	25
7.4.6 Effective radiating area calculation .....	25
7.4.7 Beam non-uniformity ratio calculation .....	25
7.4.8 Testing requirements .....	25
7.5 Reference type testing parameters .....	26
7.6 Acceptance criteria for reference type testing .....	26
8 Routine measurement procedure .....	27
8.1 General .....	27
8.2 Rated output power .....	27
8.3 Effective radiating area .....	27
8.4 Beam non-uniformity ratio .....	27
8.5 Effective intensity .....	28
8.6 Acceptance criteria for routine testing .....	28
9 Sampling and uncertainty determination .....	28
9.1 Reference type testing measurements .....	28
9.2 Routine measurements .....	28
9.3 Uncertainty determination .....	29
Annex A (normative) Guidance for performance and safety .....	30
A.1 General .....	30
A.2 Rated output power .....	30
A.3 Effective intensity .....	30
A.4 Beam non-uniformity ratio .....	30
A.4.1 General .....	30



A.4.2	Rationale behind using a limiting value for the beam non-uniformity ratio ( $R_{BN}$ ) .....	30
Annex B (normative)	Raster scan measurement and analysis procedures .....	35
B.1	General.....	35
B.2	Requirements for raster scans .....	35
B.3	Requirements for analysis of raster scan data.....	36
B.3.1	General .....	36
B.3.2	Total mean square acoustic pressure .....	36
B.3.3	Calculation of the beam cross-sectional area, $A_{BCS}$ .....	36
Annex C (normative)	Diametrical or line scan measurement and analysis procedures.....	37
C.1	General.....	37
C.2	Requirements for line scans .....	37
C.3	Analysis of scans .....	37
Annex D (informative)	Rationale concerning the beam cross-sectional area definition.....	41
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 ( $A_{ER}$ ).....	42
Annex F (informative)	Determining acoustic power through radiation force measurements .....	44
Annex G (informative)	Validity of low-power measurements of the beam cross-sectional area ( $A_{BCS}$ ).....	46
Annex H (informative)	Influence of hydrophone effective diameter .....	47
Annex I (informative)	Effective radiating area measurements using a radiation force balance and absorbing apertures .....	49
I.1	General.....	49
I.2	Concept of aperture method.....	49
I.3	Requirements for the aperture method .....	50
I.3.1	Radiation force balance .....	50
I.3.2	Apertures.....	50
I.4	Measurement procedure for determining the effective radiating area.....	51
I.5	Analysis of raw data to derive the effective radiating area .....	52
I.6	Implementation of the aperture technique .....	58
I.7	Relationship of results to reference testing method .....	59
Annex J (informative)	Guidance on uncertainty determination .....	60
Annex K (informative)	Examples of pulse duration and pulse repetition period of amplitude modulated waves .....	62
Bibliography	.....	64

Figure A.1 – Normalized, time-averaged values of acoustic intensity (solid line) and of one of its plane-wave approximations (broken line), existing on the axis of a circular piston source of  $ka = 30$ , plotted against the normalized distance  $s_n$ , where  $s_n = \lambda z/a^2$ ..... 33

Figure A.2 – Histogram of  $R_{BN}$  values for 37 treatment heads of various diameters and frequencies..... 34

Figure E.1 – Conversion factor  $F_{ac}$  as a function of the  $ka$  product for  $ka$  product between 40 and 160 ..... 43

Figure I.1 – Schematic representation of aperture measurement set-up ..... 50

Figure I.2 – Measured power as a function of aperture diameter for commercially available 1 MHz physiotherapy treatment heads ..... 54

Figure I.3 – Cumulative sum of annular power contributions, previously sorted in descending order of intensity contributions, plotted against the cumulative sum of their respective annular areas.....	58
Figure K.1 – Example 1: Tone-burst (i.e. rectangular modulation waveform) .....	62
Figure K.2 – Example 2: Half-wave modulation with no filtering of the AC mains voltage.....	62
Figure K.3 – Example 3: Full-wave modulation with no filtering of the AC mains voltage .....	62
Figure K.4 – Example 4: Half-wave modulation with filtering of the AC mains voltage; filtering insufficient to define the wave as continuous wave (3.17).....	63
Figure K.5 – Example 5: Full-wave modulation with filtering of the AC mains voltage; filtering insufficient to define the wave as continuous wave (3.17).....	63
Table C.1 – Constitution of the transformed array [B] used for the analysis of half-line scans.....	39
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 in accordance with A.5.3.1 of IEC 61161:2013 (see [8]) .....	45
Table G.1 – Variation of the beam cross-sectional area $A_{BCS}(z)$ with the indicated output power from two transducers .....	46
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 .....	48
Table I.1 – Aperture measurement check sheet .....	53
Table I.2 – Annular power contributions .....	55
Table I.3 – Annular intensity contributions.....	55
Table I.4 – Annular intensity contributions, sorted in descending order .....	56
Table I.5 – Annular power contributions, sorted in descending order of intensity contribution.....	56
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.....	57

## INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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IEC 61689 has been prepared by IEC technical committee 87: Ultrasonics. It is an International Standard.

This fourth edition cancels and replaces the third edition published in 2013. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition.

- a) The requirement on water oxygen content is specified in 6.1.
- b) Former recommendations in 6.2 have been changed to become requirements.
- c) Several definitions in Clause 3 have been updated in line with other TC 87 documents.
- d) The formerly informative Annex A has been changed to become normative, and now contains details on how conformance with IEC 60601-2-5 requirements is checked.
- e) Annex D has been considerably shortened and reference to a now withdrawn regulatory document has been removed.

The text of this International Standard is based on the following documents:

Draft	Report on voting
87/784/FDIS	87/789/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at [www.iec.ch/members\\_experts/refdocs](http://www.iec.ch/members_experts/refdocs). The main document types developed by IEC are described in greater detail at [www.iec.ch/standardsdev/publications](http://www.iec.ch/standardsdev/publications).

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*
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The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under [webstore.iec.ch](http://webstore.iec.ch) in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

## 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 disc 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 document is applicable to ultrasonic equipment designed for physiotherapy containing an **ultrasonic transducer** generating continuous or quasi-continuous (e.g. tone burst) wave **ultrasound** in the frequency range 0,5 MHz to 5 MHz. This document 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 document 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 within the scope of this document.

**Ultrasonic physiotherapy equipment** using **ultrasound** in the frequency range from 20 kHz to 500 kHz is dealt with in IEC 63009.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. 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, *Ultrasonics – Power measurement – Radiation force balances and performance requirements*

IEC 62127-1, *Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields*