IEC 61689

Edition 4.0 2022-03
REDLINE VERSION

INTERNATIONAL STANDARD

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

colour inside

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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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

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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e) Annex D has been considerably shortened and reference to a now withdrawn regulatory document has been removed.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. The main document types developed by IEC are described in greater detail at 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 in the data related to the specific document. At this date, the document will be

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- withdrawn,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

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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~~

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

~~NOTE SI units (see ISO/IEC Directives – Part 2:2011, Annex I b) are used in the Notes to entry below certain parameter definitions for defining certain parameters, such as beam areas and intensities. It may be convenient to use decimal multiples or submultiples in practice but care should be taken in using decimal prefixes in combination with units when using and calculating numerical data. For example, beam area may be specified in cm^2 and intensities in W/cm^2 or mW/cm^2.~~

3.1
absolute maximum rated output power
sum of the **rated output power**, the 95 % confidence overall uncertainty in the **rated output power**, and the maximum increase in the **rated output power** for a ±10 % variation in the rated value of the mains voltage

Note 1 to entry: The possibility of variation in the **rated output power** resulting from ±10 % variation in the rated value of the mains voltage should be checked by using a variable output transformer between the mains voltage supply and the **ultrasonic physiotherapy equipment**. See Clause A.2 for further guidance.

Note 2 to entry: **Absolute maximum rated output power** is expressed in watts (W).

3.2
active area coefficient
Q
quotient of the **active area gradient**, m, and the **beam cross-sectional area** at 0,3 cm from the face of the **treatment head**, $A_{\mathrm{BCS}}(0{,}3\ \mathrm{cm})$

Note 1 to entry: **Active area coefficient** is expressed in units of one per metre (m^{-1}).

3.3
active area gradient
m

~~gradient of the line connecting the **beam cross-sectional area** at 0,3 cm from the face of the **treatment head**, A_{BCS}(0,3), and the **beam cross-sectional area** at the position of the last axial maximum acoustic pressure, $A_{\mathrm{BCS}}(z_{\mathrm{N}})$, versus distance~~

ratio of the difference of the **beam cross-sectional area** at z_N, $A_{\mathrm{BCS}}(z_N)$, and the **beam cross-sectional area** at 0,3 cm from the face of the **treatment head**, $A_{\mathrm{BCS}}(0{,}3\ \mathrm{cm})$, divided by the difference of the respective distances

$$m = \frac{A_{\mathrm{BCS}}(z_N) - A_{\mathrm{BCS}}(0{,}3\ \mathrm{cm})}{z_N - 0{,}3\ \mathrm{cm}} \tag{1}$$

where

A_{BCS} is the **beam cross-sectional area**;

z_N is the distance from the face of the **treatment head** to the last maximum of the **RMS acoustic pressure** on the **beam alignment axis**

Note 1 to entry: **Active area gradient** is expressed in metres (m).

[SOURCE: IEC 61689:2013, 3.3, modified – The calculation scheme of the gradient was added to the definition, and the formula was added.]

3.4
absolute maximum beam non-uniformity ratio
beam non-uniformity ratio plus the 95 % confidence overall uncertainty in the **beam non-uniformity ratio**

3.5
absolute maximum effective intensity
value of the **effective intensity** corresponding to the **absolute maximum rated output power** and the **absolute minimum effective radiating area** from the **equipment**

3.6
absolute minimum effective radiating area
effective radiating area minus the 95 % confidence overall uncertainty in the **effective radiating area**

3.7
acoustic-working frequency
acoustic frequency
f_{awf}
frequency of an acoustic signal based on the observation of the output of a **hydrophone** placed in an acoustic field at the position corresponding to the **spatial-peak temporal-peak acoustic pressure**

Note 1 to entry: The signal is analysed using either the **zero-crossing acoustic-working frequency** technique or a spectrum analysis method. Acoustic-working frequencies are defined in 3.7.1 and 3.7.2.

Note 2 to entry: In a number of cases the present definition is not very helpful or convenient, especially for broadband **transducers**. In that case a full description of the frequency spectrum should be given in order to enable any frequency-dependent correction to the signal.

Note 3 to entry: **Acoustic frequency** is expressed in hertz (Hz).

[SOURCE: IEC 62127-1:2007 ~~Amendment 1:2013~~, 3.3]

3.7.1
arithmetic-mean acoustic-working frequency
f_{awf}
arithmetic mean of the most widely separated frequencies f_1 and f_2, within the range of three times f_1, at which the magnitude of the acoustic pressure spectrum is 3 dB below the peak magnitude

Note 1 to entry: This frequency definition usually is intended for ~~pulse-wave~~ systems that produce short pulses containing only a few cycles, but it could be used for tone bursts.

Note 2 to entry: It is assumed that $f_1 < f_2$.

Note 3 to entry: If f_2 is not found within the range $< 3f_1$, f_2 is to be understood as the lowest frequency above this range at which the spectrum magnitude is 3 dB below the peak magnitude.

[SOURCE: IEC 62127-1:2007 and IEC 62127-1:2007/AMD1:2013, 3.3.2, modified – Note ~~3~~ 1 to entry has been ~~added~~ modified.]

3.7.2
zero-crossing acoustic-working frequency
f_{awf}
number, n, of consecutive half-cycles (irrespective of polarity) divided by twice the time between the commencement of the first half-cycle and the end of the n-th half-cycle

Note 1 to entry: None of the n consecutive half-cycles should show evidence of phase change.

Note 2 to entry: The measurement should be performed at terminals in the receiver that are as close as possible to the receiving transducer (**hydrophone**) and, in all cases, before rectification.

Note 3 to entry: This frequency is determined in accordance with the procedure specified in IEC TR 60854.

Note 4 to entry: This frequency is intended for **continuous wave** or quasi-continuous-wave (e.g. tone-burst) systems only.

[SOURCE: IEC 62127-1:2007/AMD1:2013, 3.3.1, modified – In Note 4 to entry, "or quasi-continuous-wave (e.g. tone-burst)" has been added.]

3.8
acoustic pulse waveform
temporal waveform of the **instantaneous acoustic pressure** at a specified position in an acoustic field and displayed over a period sufficiently long to include all significant acoustic information in a single pulse or tone-burst, or one or more cycles in a **continuous wave**

Note 1 to entry: Temporal waveform is a representation (e.g. oscilloscope presentation or equation) of the **instantaneous acoustic pressure**.

[SOURCE: IEC 62127-1:2007 and IEC 62127-1:2007/AMD1:2013, 3.1~~, modified – deletion of NOTE 2~~]

3.9
acoustic repetition period
arp
pulse repetition period equal to the time interval between corresponding points of consecutive cycles for **continuous wave** systems

Note 1 to entry: **Acoustic repetition period** is expressed in seconds (s).

[SOURCE: IEC 62127-1:2007~~ Amendment 1:2013~~, 3.2, modified – The definition~~ cited above is~~ has been made more specific for non-scanning systems.]

3.10
amplitude modulated wave
wave in which the ratio ~~$p_p / \sqrt{2} p_{rms}$~~ $p_{tp}/(\sqrt{2}p_{RMS})$ at any point in the **far field** on the **beam alignment axis** is greater than 1,05, where ~~p_p~~ p_{tp} is the **temporal-peak acoustic pressure** and ~~p_{rms}~~ p_{RMS} is the **RMS acoustic pressure**

3.11
attachment head
accessory intended to be attached to the **treatment head** for the purpose of modifying the ultrasonic beam characteristics

[SOURCE: IEC 60601-2-5:2009, 201-3-202]

3.12
beam alignment axis
~~straight line joining two points of **spatial-peak temporal-peak acoustic pressure** on two plane surfaces parallel to the faces of the **treatment head**. One plane is at a distance of approximately $A_{ERN}/(\pi\lambda)$ where A_{ERN} is the nominal value of the **effective radiating area** of the **treatment head** and λ is the wavelength of the **ultrasound** corresponding to the nominal value of the **acoustic-working frequency**. The second plane surface is at a distance of either $2A_{ERN}/(\pi\lambda)$ or $A_{ERN}/(3\pi\lambda)$, whichever is the more appropriate. For the purposes of alignment, this line may be projected to the face of the **treatment head**~~

~~Note 1 to entry: If the nominal value of the **effective radiating area** is unknown, then another suitable area may be used to define the **beam alignment axis** such as the area of the active element of the **ultrasonic transducer**.~~

straight line joining two points of **maximum RMS acoustic pressure** on two plane surfaces parallel to the faces of the **treatment head** at specific distances

Note 1 to entry: One plane is at a distance of approximately a^2/λ where a is the geometrical radius of the active element of the **treatment head**. The second plane surface is at a distance of either $2a^2/\lambda$ or $a^2/(3\lambda)$, whichever is the more appropriate. For the purposes of alignment, this line may be projected to the face of the **treatment head**.

Note 2 to entry: As the **beam alignment axis** is used purely for the purposes of alignment, the definitions of specific distances may be relaxed slightly to reflect the constraints of the measurement system employed. For example, some **treatment heads** will have ~~$A_{ERN}/(\pi\lambda)$~~ a^2/λ considerably greater than 12 cm, in which case a maximum distance of 12 cm may be used to define the first plane. General guidelines for determining the **beam alignment axis** are given in 7.3.

3.13
beam cross-sectional area
A_{BCS}
minimum area in a specified plane perpendicular to the **beam alignment axis** for which the sum of the **mean square acoustic pressure** is 75 % of the **total mean square acoustic pressure**

Note 1 to entry: **Beam cross-sectional area** is expressed in units of square metre (m^2).

Note 2 to entry: The rationale supporting the definition is described in Annex D.

3.14
beam maximum intensity
product of the **beam non-uniformity ratio** and **effective intensity**

Note 1 to entry: **Beam maximum intensity** is expressed in units of watt per square metre (W/m^2).

3.15
beam non-uniformity ratio
R_{BN}
ratio of the square of the **maximum RMS acoustic pressure** to the spatial average of the square of the **RMS acoustic pressure**, where the spatial average is taken over the **effective radiating area**~~. **Beam non-uniformity ratio** is given by:~~

$$\cancel{R_{BN} = \frac{p^2_{max}\, A_{ER}}{pms_t\, A_o} \qquad (1)}$$

$$R_{BN} = \frac{p^2_{max,RMS}\, A_{ER}}{pms_t\, A_0} \qquad (2)$$

where

$p_{max,RMS}$ is the **maximum RMS acoustic pressure**;

A_{ER} is the **effective radiating area**;

pms_t is the **total mean square acoustic pressure**;

A_0 is the unit area for the raster scan.

3.16
beam type
descriptive classification of the ultrasonic beam

Note 1 to entry: There are three beam types: **collimated** (3.18), **convergent** (3.19) and **divergent** (3.20).