# IEC 61689

Edition 3.0 2013-02

# INTERNATIONAL STANDARD

# NORME INTERNATIONALE

**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 gamme de fréquences de 0,5 MHz à 5 MHz**

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

This third edition cancels and replaces the second edition published in 2007. It constitutes a technical revision.

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

- restriction introduced of 0,2 W/cm$^2$ 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 IEC 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 IEC 60601-2-5, which, as indicated in its preface, will itself be revised in order to be compatible with this standard.

The text of this standard is based on the following documents:

| FDIS | Report on voting |
|---|---|
| 87/522/FDIS | 87/529/RVD |

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table. This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

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 publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication 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 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*

## 3 Terms and definitions

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

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 watt (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**, $A_{BCS}(0,3)$



Note 1 to entry: **Active area coefficient** is expressed in 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, $A_{BCS}(z_N)$, versus distance

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

**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 frequency**
acoustic-working 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, definition 3.3]

**3.7.1**
**arithmetic-mean acoustic-working frequency**
$f_{\mathrm{awf}}$
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 is intended for pulse-wave systems only.

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 Amendment 1:2013 definition 3.3.2, modified – Note 3 to entry has been added]



**3.7.2**
**zero-crossing acoustic-working frequency**
$f_{\mathrm{awf}}$
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 according to the procedure specified in IEC/TR 60854.

Note 4 to entry: This frequency is intended for **continuous-wave** systems only.

[SOURCE: IEC 62127-1:2007 Amendment 1:2013 to, definition 3.3.1,]

**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 Amendment 1:2013, definition 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 second (s).

[SOURCE: IEC 62127-1:2007 Amendment 1:2013, definition 3.2, modified – the definition cited above is more specific for non-scanning systems]

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



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 $A_{ERN}/(\pi\lambda)$ 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 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 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:

$$R_{BN} = \frac{p_{max}^2 \, A_{ER}}{pms_t \, A_o} \tag{1}$$

where

$p_{max}$ is the **maximum r.m.s. acoustic pressure**;

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

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

$A_o$ is the unit area for the raster scan.

**3.16**
**beam type**
descriptive classification for the ultrasonic beam in one of three types: **collimated, convergent or divergent**

**3.17**
**continuous wave**
wave in which the ratio $p_p/\sqrt{2}p_{rms}$, at any point in the **far field** on the **beam alignment axis**, is less than or equal to 1,05, where $p_p$ is the **temporal-peak acoustic pressure** and $p_{rms}$ is the **rms acoustic pressure**

**3.18**
**collimated**
beam for which the **active area coefficient**, $Q$, obeys the following inequality:

$– 0,05 \text{ cm}^{-1} \leq Q \leq 0,1 \text{ cm}^{-1}$



**3.19**
**convergent**
beam for which the **active area coefficient**, $Q$, obeys the following inequality:

$Q < – 0,05 \text{ cm}^{-1}$



**3.20**
**divergent**
beam for which the **active area coefficient**, $Q$, obeys the following inequality:

$Q > 0,1 \text{ cm}^{-1}$

**3.21**
**duty factor**
ratio of the **pulse duration** to the **pulse repetition period**

**3.22**
**effective intensity**
$I_e$
intensity given by $I_e = P/A_{ER}$ where $P$ is the **output power** and $A_{ER}$ is the **effective radiating area**

Note 1 to entry: **Effective intensity** is expressed in watt per square metre (W/m$^2$).

**3.23**
**effective radiating area**
$A_{ER}$
**beam cross-sectional area** determined at a distance of 0,3 cm from the front of the **treatment head**, $A_{BCS}(0,3)$, multiplied by a dimensionless factor, $F_{ac}$, given by:

$$F_{ac} = 1{,}333 \qquad (2)$$

Note 1 to entry: The conversion factor $F_{ac}$ is used here in order to derive the area close to the **treatment head** which contains 100 % of the **total mean square acoustic pressure**. The origin of the value of $F_{ac}$ is described in Annex E, in references [1][1] and [2] in Annex K.

Note 2 to entry: **Effective radiating area** is expressed in square metre ($m^2$).

**3.24**
**end-of-cable loaded sensitivity**
end-of-cable loaded sensitivity of a hydrophone
end-of-cable loaded sensitivity of a hydrophone-assembly
$M_L(f)$
ratio of the instantaneous voltage at the end of any integral cable or output connector of a **hydrophone** or **hydrophone-assembly**, when connected to a specified **electric load impedance**, to the **instantaneous acoustic pressure** in the undisturbed free field of a plane wave in the position of the reference centre of the **hydrophone** if the **hydrophone** were removed

Note 1 to entry: **End-of-cable loaded sensitivity** is expressed in volt per pascal (V/Pa).

[SOURCE: IEC 62127-3:2007, definition 3.5]

**3.25**
**far field**
region of the field where $z \geq z_T$ aligned along the beam axis for planar non-focusing transducers



Note 1 to entry: In the **far field**, the sound pressure appears to be spherically divergent from a point on or near the radiating surface. Hence the pressure produced by the sound source is approximately inversely proportional to the distance from the source.



Note 2 to entry: The term "**far field**" is used in this standard only in connection with non-focusing source transducers. For focusing transducers a different terminology for the various parts of the transmitted field applies (see IEC 61828).

Note 3 to entry: For the purposes of this standard, the **far field** starts at a distance where $z_T = A_{ERN}/(\pi\lambda)$ where $A_{ERN}$ is the nominal value of the **effective radiating area** of the **treatment head** and $\lambda$ is the wavelength of the **ultrasound** corresponding to the **acoustic working frequency**. This differs from the NOTE in IEC 62127-1 Amendment 1:2013.

[SOURCE: IEC 62127-1:2007 Amendment 1:2013, definition 3.28, modified – The above definition has replaced the Note 3 to entry]

**3.26**
**hydrophone**
transducer that produces electrical signals in response to waterborne acoustic signals

[SOURCE: IEC 60050-801:1994, definition 801-32-26]

**3.27**
**instantaneous acoustic pressure**
$p(t)$
pressure minus the ambient pressure at a particular instant in time and at a particular point in an acoustic field

Note 1 to entry: **Instantaneous acoustic pressure** is expressed in pascal (Pa).

[SOURCE: IEC 60050-802:2011, definition 802-01-03, modified – only grammatical, plus addition of the Note 1 to entry

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1 Numbers in square brackets refer to the Bibliography.

**3.28**
**maximum rms acoustic pressure**
$p_{max}$
maximum value of the **rms acoustic pressure** detected by a **hydrophone** over the entire acoustic field

Note 1 to entry: **Maximum rms acoustic pressure** is expressed in pascal (Pa).

**3.29**
**mean square acoustic pressure**
mean square of the **instantaneous acoustic pressure** at a particular point in the acoustic field. The mean is taken over an integral number of **acoustic repetition periods**

Note 1 to entry: In practice, the mean value is often derived from rms measurements.

Note 2 to entry: **Mean square acoustic pressure** is expressed in pascal squared ($Pa^2$).

**3.30**
**modulation waveform**
temporal envelope waveform of the **amplitude modulated wave** at the point of **peak rms acoustic pressure** on the **beam alignment axis** and displayed over a period sufficiently long to include all significant acoustic information in the **amplitude modulated wave**

**3.31**
**output power**
$P$
time-average ultrasonic power emitted by a **treatment head** of **ultrasonic physiotherapy equipment** into an approximately free field under specified conditions in a specified medium, preferably in water



Note 1 to entry: **Output power** is expressed in watt (W).

[IEC 61161: 2013, definition 3.3, modified – **treatment head** of **ultrasonic physiotherapy equipment** instead of **ultrasonic transducer**]

**3.32**
**peak rms acoustic pressure**
maximum value of the **rms acoustic pressure** over a specified region, line or plane in an acoustic field

Note 1 to entry: **Peak rms acoustic pressure** is expressed in pascal (Pa).

**3.33**
**pulse duration**
time interval beginning at the first time the pressure amplitude exceeds a reference value and ending at the last time the pressure amplitude returns to that value. The reference value is equal to the sum of the minimum value of the pressure amplitude and 10 % of the difference between the maximum and minimum value of the pressure amplitude

Note 1 to entry: This definition differs from that in IEC 62127-1 Amendment 1:2013, from which it is derived, to account for incomplete modulation.

Note 2 to entry: **Pulse duration** is expressed in second (s).

**3.34**
**pulse repetition period**
*prp*
time interval between equivalent points on successive pulses or tone-bursts

Note 1 to entry: **Pulse repetition period** is expressed in second (s).