IEC 63009

Edition 1.0 2019-07

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Ultrasonics – Physiotherapy systems – Field specifications and methods of measurement in the frequency range 20 kHz to 500 kHz

Ultrasons – Systèmes de physiothérapie – Spécifications des champs et méthodes de mesure dans la plage de fréquences de 20 kHz à 500 kHz

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CONTENTS

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ULTRASONICS – PHYSIOTHERAPY SYSTEMS – FIELD SPECIFICATIONS AND METHODS OF MEASUREMENT IN THE FREQUENCY RANGE 20 kHz TO 500 kHz

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

CDV	Report on voting
87/705/CDV	87/714A/RVC

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

- Terms defined in Clause 3: **bold type**
- Compliance clauses: *Arial Italic*
- Symbols of quantities: *Times New Roman + Italic*

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- withdrawn,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

INTRODUCTION

Ultrasound is used in medicine for the purposes of physiotherapy. Such equipment consists of a generator of electrical energy and usually a hand-held **treatment head**, often referred to as an applicator. The **treatment head** contains a transducer 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 20 kHz TO 500 kHz

1 Scope

This International Standard is applicable to **ultrasonic equipment** designed for physiotherapy containing an **ultrasonic transducer** generating ultrasound in the frequency range 20 kHz to 500 kHz.

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**;
- 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**.

The therapeutic value and methods of use of **ultrasonic physiotherapy equipment** are not within the scope of this document.

Excluded equipment includes, but is not limited to:

- equipment in which ultrasound waves are intended to destroy conglomerates (for example stones in the kidneys or the bladder) or tissue of any type;
- equipment in which a tool is driven by ultrasound (for example surgical scalpels, phacoemulsifiers, dental scalers or intracorporeal lithotripters);
- equipment in which ultrasound waves are intended to sensitize tissue to further therapies (for example radiation or chemotherapy);
- equipment in which ultrasound waves are intended to treat cancerous (i.e., malignant) or pre-cancerous tissue, or benign masses, such as High Intensity Focused Ultrasound (HIFU) or High Intensity Therapeutic Ultrasound (HITU).

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 60565, *Underwater acoustics – Hydrophones – Calibration in the frequency range 0,01 Hz to 1 MHz*

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

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

IEC 62127-2, *Ultrasonics – Hydrophones – Part 2: Calibration for ultrasonic fields up to 40 MHz*

3 Terms and definitions

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

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

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).

[SOURCE: IEC 61689:2013, 3.1]

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**, $A_{\text{BCS}}(0,3)$

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

[SOURCE: IEC 61689:2013, 3.2]

3.3
active area gradient
m
ratio of the difference of the **beam cross-sectional area** at z_N, $A_{\text{BCS}}(z_N)$, and the **beam cross-sectional area** at 0,3 cm from the face of the **treatment head**, $A_{\text{BCS}}(0,3)$, divided by the difference of the respective distances

$$m = \frac{[A_{\text{BCS}}(z_N) - A_{\text{BCS}}(0,3)]}{(z_N - 0,3)} \quad (1)$$

where

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

z_N is the distance of the last axial maximum of the RMS acoustic pressure from the face of the **treatment head**;

Note 1 to entry: If z_N < 0,3 cm then A_{BCS} at a^2/λ or $2a$, whichever is greater, should be used instead of $A_{\text{BCS}}(z_N)$, where a is the geometrical radius of the active element of the **treatment head**.

Note 2 to entry: **Active area gradient** is expressed in metres (m).

[SOURCE: IEC 61689:2013, 3.3, modified – by defining the term "gradient" within the definition and adding the equation to calculate the gradient.]

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

[SOURCE: IEC 61689:2013, 3.4]

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

[SOURCE: IEC 61689:2013, 3.5]

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

[SOURCE: IEC 61689:2013, 3.6]

3.7
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** or 0,3 cm, whichever is greater

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-working frequency** is expressed in hertz (Hz).

[SOURCE: IEC 61689:2013, 3.7, modified – by adding a minimum measurement distance for low frequencies for which the distance to the **spatial-peak temporal-peak acoustic pressure** may be too close to the transducer to allow for hydrophone measurements.]

3.7.1
arithmetic-mean acoustic-working frequency
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 61689:2013, 3.7.1]

3.7.2
zero-crossing acoustic-working frequency
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 [1][1].

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

[SOURCE: IEC 61689:2013, 3.7.2]

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 61689:2013, 3.8]

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 61689:2013, 3.9]

3.10
amplitude modulated wave
wave in which the ratio $p_{tp}/\sqrt{2}p_{RMS}$ at a distance on the **beam alignment axis** of either a^2/λ or $2a$, whichever is the more appropriate, is greater than 1,05, where p_{tp} is the **temporal-peak acoustic pressure** and p_{RMS} is the **RMS acoustic pressure**

[SOURCE: IEC 61689:2013, 3.10, modified – to allow for low frequencies for which the distance a^2/λ may be too close to the transducer to allow hydrophone measurements.]

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]

———————
[1] Numbers in square brackets refer to the Bibliography.

3.12
beam alignment axis
straight line joining two points of **maximum RMS acoustic pressure** on two plane surfaces parallel to the face 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^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.

[SOURCE: IEC 61689:2013, 3.12, modified – The details of the plane surfaces have been moved to a note to entry.]

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 metre squared (m^2).

[SOURCE: IEC 61689:2013, 3.13, modified – Note 2 to entry has been removed.]

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 metre squared (W/m^2).

[SOURCE: IEC 61689:2013, 3.14]

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**

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

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.

[SOURCE: IEC 61689:2013, 3.15, modified – The symbol used for the maximum RMS acoustic pressure has been modified.]

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

[SOURCE: IEC 61689:2013, 3.16]

3.17
continuous wave
wave in which the ratio $p_{tp}/\sqrt{2}p_{RMS}$, at a distance on the **beam alignment axis** of either a^2/λ or $2a$, whichever is the more appropriate, is less than or equal to 1,05, where p_{tp} is the **temporal-peak acoustic pressure** and p_{RMS} is the **RMS acoustic pressure**

[SOURCE: IEC 61689:2013, 3.17, modified – Measurement distance is specified differently to account for lower frequencies.]

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

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

[SOURCE: IEC 61689:2013, 3.18]

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

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

[SOURCE: IEC 61689:2013, 3.19]

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

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

[SOURCE: IEC 61689:2013, 3.20]

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

[SOURCE: IEC 61689:2013, 3.21]

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 units of watt per metre squared (W/m^2).

[SOURCE: IEC 61689:2013, 3.22]

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:

$$F_{ac} = 1{,}333 \quad (3)$$

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 IEC 61689 [2] and in references [3] and [4].

Note 2 to entry: **Effective radiating area** is expressed in units of metre squared (m^2).

[SOURCE: IEC 61689:2013, 3.23]

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 units of volt per pascal (V/Pa).

[SOURCE: IEC 61689:2013, 3.24]

3.25
hydrophone
transducer that produces electrical signals in response to waterborne acoustic signals

[SOURCE: IEC 60050-801:1994, 801-32-26][5]

3.26
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 pascals (Pa).

[SOURCE: IEC 60050-802:2011, 802-01-03, modified – Note 1 to entry has been added.][6]

3.27
maximum RMS acoustic pressure
$p_{max,RMS}$
maximum value over the entire acoustic field of the **RMS acoustic pressure**

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

[SOURCE: IEC 61689:2013, 3.28, modified – removed measurement criteria from definition ("detected by a hydrophone").]