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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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CONTENTS

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

This second edition cancels and replaces the first edition published in 1996 and constitutes a technical revision.

This second edition is a result of maintenance on this standard and the referenced standards IEC 61161 (2006) and IEC 62127-1. A relatively large technical change is the determination of the effective radiating area. This is now no longer based on the measurement of four areas but only on one. This change was needed to improve the accuracy of the determination of this parameter for small transducers. Be aware that this change may alter the value obtained for this and related parameters.

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

CDV	Report on voting
87/351/CDV	87/370/RVC

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.

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

NOTE The following print types are used:

– Requirements: in roman type
– *Test specifications: in italic type*
– Notes: in small roman type
– Words in **bold** in the text are defined in Clause 3.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result 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- withdrawn,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.

A bilingual version of this publication may be issued at a later date.

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** consists of 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 consisting of an **ultrasonic transducer** generating continuous or quasi-**continuous wave** ultrasonic energy in the frequency range 0,5 MHz to 5 MHz.

This standard only relates to **ultrasonic physiotherapy equipment** employing a single plane unfocused 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 referenced documents are indispensable for the application 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 60050-801:1994, *International Electrotechnical Vocabulary (IEV) – Chapter 801: Acoustics and electroacoustics*

IEC 60469-1:1987, *Pulse techniques and apparatus – Part 1: Pulse terms and definitions*

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

IEC 60601-2-5:2000, *Medical electrical equipment – Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment*

IEC 61161:2006, *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 using hydrophones*

IEC 62127-3:2007, *Ultrasonics – Hydrophones – Part 3: Properties of hydrophones for ultrasonic fields up to 40 MHz*

3 Terms and definitions

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

3.1
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 Temporal waveform is a representation (e.g. oscilloscope presentation or equation) of the **instantaneous acoustic pressure**.

NOTE 2 Definition adopted from IEC 60469-1.

3.2
acoustic repetition period
arp
pulse repetition period for non-automatic scanning systems and the **scan repetition period** for automatic scanning systems, equal to the time interval between corresponding points of consecutive cycles for continuous wave systems

NOTE 1 **Acoustic repetition period** is expressed in seconds (s).

NOTE 2 Definition adopted from IEC 62127-1.

3.3
acoustic frequency
acoustic-working frequency

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 The signal is analysed using either the **zero-crossing acoustic-working frequency** technique or a spectrum analysis method. Acoustic-working frequencies are defined in 3.3.1 and 3.3.2.

NOTE 2 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 Acoustic frequency is expressed in hertz (Hz).

NOTE 4 Definition adopted from IEC 62127-1.

3.3.1
zero-crossing acoustic-working frequency
f_{awf}
this is determined according to the procedure specified in IEC/TR 60854.

NOTE This frequency is intended for continuous wave systems only.

3.3.2
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 This frequency is intended for pulse-wave systems only.

NOTE 2 It is assumed that $f_1 < f_2$.

3.4
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 **r.m.s. acoustic pressure**

3.5
attachment head
accessory intended to be attached to the **treatment head** for the purpose of modifying the ultrasonic beam characteristics

NOTE Definition adopted from IEC 60601-2-5.

3.6
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 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 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 8.3.

3.7
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 **Beam cross-sectional area** is expressed in centimetre squared (cm^2).

3.8
beam maximum intensity
product of the beam non-uniformity ratio and effective intensity

NOTE **Beam maximum intensity** is expressed in watt per centimetre squared (W/cm^2).

3.9
beam non-uniformity ratio
***R*_BN**

ratio of the square of the **maximum r.m.s. acoustic pressure** to the spatial average of the square of the **r.m.s. 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.

3.10
absolute maximum beam non-uniformity ratio
beam non-uniformity ratio plus the 95 % confidence overall uncertainty in the beam non-uniformity ratio

3.11
beam type
descriptive classification for the ultrasonic beam in one of three types: **collimated, convergent or divergent**

3.12
collimated
beam for which the **active area coefficient**, Q, obeys the following inequality:

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

3.13
convergent
beam for which the **active area coefficient**, Q, obeys the following inequality:

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

3.14
divergent
beam for which the **active area coefficient**, Q, obeys the following inequality:

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

3.15
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 **r.m.s. acoustic pressure**

3.16
duty factor
ratio of the pulse duration to the pulse repetition period

NOTE Definition adopted from IEC 60469-1, 5.3.2.4.

3.17
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 **Effective intensity** is expressed in watt per centimetre squared (W/cm^2).

3.18
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

3.19
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:

$$F_{ac} = 1{,}354 \quad (2)$$

NOTE 1 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 and bibliographic references [3] and [4].

NOTE 2 Beam cross-sectional area is expressed in centimetre squared (cm^2).

3.20
absolute minimum effective radiating area
effective radiating area minus the 95 % confidence overall uncertainty in the **effective radiating area**

3.21
end-of-cable loaded sensitivity
end-of-cable loaded sensitivity of a hydrophone (or 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 **End-of-cable loaded sensitivity** is expressed in volts per pascal (V/Pa).

NOTE 2 Definition adopted from IEC 62127-3.

3.22
far field
acoustic (sound) field at distances from an **ultrasonic transducer** where the values of the **instantaneous acoustic pressure** and particle velocity are substantially in phase [see also IEC 60050-801, 801-03-30]

NOTE 1 Definition adopted from IEC 62127-1.

NOTE 2 For the purposes of this standard, the far field is at a distance greater than $A_{ERN}/(\pi\lambda)$ 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 acoustic working frequency. This differs from IEC 62127-1.

3.23
hydrophone
transducer that produces electrical signals in response to waterborne acoustic signals

NOTE Definition adopted from IEC 60050-801, 801-32-26 (1994).

3.24
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 (see also IEC 60050-801, 801-01-19)

NOTE 1 **Instantaneous acoustic pressure** is expressed in pascal (Pa).

NOTE 2 Definition adopted from IEC 60050-801, 801-21-19 (1994).

3.25
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 **Active area coefficient** is expressed in per centimetre (cm^{-1}).

3.26
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 **Active area gradient** is expressed in centimetre (cm).

3.27
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 In practice, the mean value is often derived from rms measurements.

NOTE 2 **Mean square acoustic pressure** is expressed in pascal squared (Pa^2).

3.28
total mean square acoustic pressure
pms_t
sum of the **mean square acoustic pressure** values, each with a specified incremental area, in a specified plane over specified limits of summation

NOTE **Total mean square acoustic pressure** is expressed in pascal squared (Pa^2).

3.29
modulation waveform
temporal envelope waveform of the **amplitude modulated wave** at the point of **peak r.m.s. 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**

3.30
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 Definition adopted from IEC 61161:2006.

NOTE 2 **Output power** is expressed in watt (W).