SLOVENSKI STANDARD
SIST EN 61689:2013

01-julij-2013

Nadomešča:
SIST EN 61689:2008

Ultrazvok - Fizioterapevtski sistemi - Specifikacije polja in merilne metode v frekvenčnem območju od 0,5 MHz do 5 MHz

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

Ultraschall - Physiotherapiesysteme - Feldspezifikation und Messverfahren im Frequenzbereich von 0,5 MHz bis 5 MHz

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Ultrasons - Systèmes de physiothérapie - Spécifications de champ et méthodes de mesure dans la gamme de fréquences de 0,5 MHz à 5 MHz

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Ta slovenski standard je istoveten z: **EN 61689:2013**

ICS:

11.040.60	Terapevtska oprema	Therapy equipment

SIST EN 61689:2013 **en**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61689

April 2013

ICS 11.040.60

Supersedes EN 61689:2007

English version

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

(IEC 61689:2013)

Ultrasons - Systèmes de physiothérapie - Spécifications des champs et méthodes de mesure dans la gamme de fréquences de 0,5 MHz à 5 MHz (CEI 61689:2013)

Ultraschall - Physiotherapiesysteme - Feldspezifikation und Messverfahren im Frequenzbereich von 0,5 MHz bis 5 MHz (IEC 61689:2013)

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
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Foreword

The text of document 87/522/FDIS, future edition 3 of IEC 61689, prepared by IEC TC 87 "Ultrasonics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 61689:2013.

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)	2014-01-02
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2016-04-02

This document supersedes EN 61689:2007.

EN 61689:2013 includes the following significant technical changes with respect to EN 61689:2007:

- restriction introduced of 0,2 W/cm² 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 EN 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.

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

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- Notes: in Arial 8 point
- Words in **bold** in the text are defined in Clause 3
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- Compliance clauses : *in Arial Italic*

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Endorsement notice

The text of the International Standard IEC 61689:2013 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 61828.
IEC 62127-2	NOTE	Harmonized as EN 62127-2.
IEC 62127-3	NOTE	Harmonized as EN 62127-3.

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Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
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	2013	Ultrasonics - Power measurement - Radiation force balances and performance requirements	EN 61161	2013
IEC 62127-1 + corr. August 2008 + A1	2007 2013	Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz	EN 62127-1 + A1	2007 2013

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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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

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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;

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- 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
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- Compliance clauses : *in Arial Italic*

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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

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- 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 disk of piezoelectric material, for converting the electrical energy to **ultrasound** and is often designed for contact with the human body.

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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.

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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*

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

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

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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**

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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_{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]

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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

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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).