SLOVENSKI STANDARD

SIST EN 61689:2008

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Nadomeġļa:

SIST EN 61689:2002

Ultrazvok - Fizioterapevtski sistemi - Specifikacije polja in merilne metode v frekvenļnem obmoļju od 0,5 MHz do 5 MHz (IEC 61689:2007)

Ultrasonics - Physiotherapy systems - Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz (IEC 61689:2007)

Ultraschall - Physiotherapiesysteme - Feldspezifikationen und Messverfahren im Frequenzbereich von 0,5 MHz bis 5 MHz (IEC 61689:2007)

Ultrasons - Systemes de physiothérapie - Spécifications des champs et méthodes de mesure dans la gamme de fréquences de 0,5 MHz à 5 MHz (IEC 61689:2007)

Ta slovenski standard je istoveten z: **EN 61689:2007**

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61689

November 2007

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Supersedes EN 61689:1996

English version

Ultrasonics - Physiotherapy systems - Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz
(IEC 61689:2007)

Ultrasons -
Systèmes de physiothérapie -
Spécifications des champs et méthodes de mesure dans la gamme de fréquences de 0,5 MHz à 5 MHz
(CEI 61689:2007)

Ultraschall -
Physiotherapiesysteme -
Feldspezifikationen und Messverfahren im Frequenzbereich von 0,5 MHz bis 5 MHz
(IEC 61689:2007)

This European Standard was approved by CENELEC on 2007-10-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

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Foreword

The text of document 87/351/CDV, future edition 2 of IEC 61689, prepared by IEC TC 87, Ultrasonics, was submitted to the IEC-CENELEC parallel Unique Acceptance Procedure and was approved by CENELEC as EN 61689 on 2007-10-01.

This European Standard supersedes EN 61689:1996.

EN 61689:2007 is a result of maintenance on this standard and the referenced standards EN 61161:2007 and EN 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.

This standard is to be used in conjunction with EN 60601-2-5.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2008-07-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2010-10-01

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.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 61689:2007 was approved by CENELEC as a European Standard without any modification.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

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 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	– [1)]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006 [2)]
IEC 60601-2-5	2000	Medical electrical equipment - Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment	EN 60601-2-5	2000
IEC 61161	2006	Ultrasonics - Power measurement - Radiation force balances and performance requirements	EN 61161	2007
IEC 62127-1	2007	Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz using hydrophones	EN 62127-1	2007
IEC 62127-3	2007	Ultrasonics - Hydrophones - Part 3: Properties of hydrophones for ultrasonic fields up to 40 MHz	EN 62127-3	2007

[1)] Undated reference.

[2)] Valid edition at date of issue.

IEC 61689

Edition 2.0 2007-08

INTERNATIONAL STANDARD

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

ULTRASONICS – PHYSIOTHERAPY SYSTEMS – FIELD SPECIFICATIONS AND METHODS OF MEASUREMENT IN THE FREQUENCY RANGE 0,5 MHz TO 5 MHz

FOREWORD

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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).