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Standards

Irish Standard  
I.S. EN 61689:2013

# Ultrasonics - Physiotherapy systems - Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz (IEC 61689:2013 (EQV))

## I.S. EN 61689:2013

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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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Comité Européen de Normalisation Electrotechnique  
Europäisches Komitee für Elektrotechnische Normung

**Management Centre: Avenue Marnix 17, B - 1000 Brussels**

## 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- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2016-04-02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/cm<sup>2</sup> 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.

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.

NOTE The following print types are used:

- Requirements: in Arial 10 point
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- Symbols and formulae: *Times New Roman + Italic*
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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.

## 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.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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 + A1	2007 2008 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

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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<sup>2</sup> 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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– 5 –

- 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.

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- Words in **bold** in the text are defined in Clause 3
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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

- 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

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