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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

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NATIONAL FOREWORD

See Eesti standard EVS-EN 61689:2013 sisaldab Euroopa standardi EN 61689:2013 ingliskeelset teksti.	This Estonian standard EVS-EN 61689:2013 consists of the English text of the European standard EN 61689:2013.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 19.04.2013.	Date of Availability of the European standard is 19.04.2013.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.60

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61689

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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)

This European Standard was approved by CENELEC on 2013-04-02. 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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

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

CENELEC

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

Management Centre: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 61689:2013 E

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.

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
- Notes: in Arial 8 point
- Words in **bold** in the text are defined in Clause 3
- Symbols and formulae: *Times New Roman + Italic*
- Compliance clauses : *in Arial Italic*

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

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.

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 + 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

CONTENTS

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*