SLOVENSKI STANDARD
SIST EN IEC 61689:2022

01-junij-2022

Nadomešča:
SIST EN 61689:2013

Ultrazvok - Fizioterapevtski sistemi - Specifikacije polja in merilne metode v frekvenčnem območju od 0,5 MHz do 5 MHz (IEC 61689:2022)

Ultrasonics - Physiotherapy systems - Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz (IEC 61689:2022)

Ultraschall - Physiotherapiesysteme - Feldspezifikation und Messverfahren im Frequenzbereich von 0,5 MHz bis 5 MHz (IEC 61689:2022)

Ultrasons - Systèmes de physiothérapie - Spécifications des champs et méthodes de mesure dans la gamme de fréquences de 0,5 MHz à 5 MHz (IEC 61689:2022)

Ta slovenski standard je istoveten z: **EN IEC 61689:2022**

ICS:

11.040.60	Terapevtska oprema	Therapy equipment

SIST EN IEC 61689:2022 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 61689

April 2022

ICS 11.040.60

Supersedes EN 61689:2013

English Version

Ultrasonics - Physiotherapy systems - Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz (IEC 61689:2022)

Ultrasons - Systèmes de physiothérapie - Spécifications des champs et méthodes de mesure dans la plage de fréquences de 0,5 MHz à 5 MHz
(IEC 61689:2022)

Ultraschall - Physiotherapiesysteme - Feldspezifikation und Messverfahren im Frequenzbereich von 0,5 MHz bis 5 MHz
(IEC 61689:2022)

This European Standard was approved by CENELEC on 2022-04-12. 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.

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CENELEC

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN IEC 61689:2022 E

European foreword

The text of document 87/784/FDIS, future edition 4 of IEC 61689, prepared by IEC/TC 87 "Ultrasonics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 61689:2022.

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)	2023-01-12
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2025-04-12

This document supersedes EN 61689:2013 and all of its amendments and corrigenda (if any).

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

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 61689:2022 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 IEC 61828
IEC 62127-2	NOTE	Harmonized as EN 62127-2
IEC 62127-3	NOTE	Harmonized as EN 62127-3
IEC 62555	NOTE	Harmonized as EN 62555
IEC 63009	NOTE	Harmonized as EN IEC 63009

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

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	-	Ultrasonics - Power measurement - Radiation force balances and performance requirements	EN 61161	-
IEC 62127-1	-	Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields	-	-

IEC 61689

Edition 4.0 2022-03

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

Ultrasons – Systèmes de physiothérapie – Spécifications des champs et méthodes de mesure dans la plage de fréquences de 0,5 MHz à 5 MHz

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

This fourth edition cancels and replaces the third edition published in 2013. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition.

a) The requirement on water oxygen content is specified in 6.1.

b) Former recommendations in 6.2 have been changed to become requirements.

c) Several definitions in Clause 3 have been updated in line with other TC 87 documents.

d) The formerly informative Annex A has been changed to become normative, and now contains details on how conformance with IEC 60601-2-5 requirements is checked.

e) Annex D has been considerably shortened and reference to a now withdrawn regulatory document has been removed.

The text of this International Standard is based on the following documents:

Draft	Report on voting
87/784/FDIS	87/789/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

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*

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document 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 disc 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 document is applicable to ultrasonic equipment designed for physiotherapy containing an **ultrasonic transducer** generating continuous or quasi-continuous (e.g. tone burst) wave **ultrasound** in the frequency range 0,5 MHz to 5 MHz. This document 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 document 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 within the scope of this document.

Ultrasonic physiotherapy equipment using **ultrasound** in the frequency range from 20 kHz to 500 kHz is dealt with in IEC 63009.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 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, *Ultrasonics – Power measurement – Radiation force balances and performance requirements*

IEC 62127-1, *Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

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 watts (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**, $A_{\mathrm{BCS}}(0{,}3\ \mathrm{cm})$

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

3.3
active area gradient
m
ratio of the difference of the **beam cross-sectional area** at z_N, $A_{\mathrm{BCS}}(z_N)$, and the **beam cross-sectional area** at 0,3 cm from the face of the **treatment head**, $A_{\mathrm{BCS}}(0{,}3\ \mathrm{cm})$, divided by the difference of the respective distances

$$m = \frac{A_{\mathrm{BCS}}(z_N) - A_{\mathrm{BCS}}(0{,}3\ \mathrm{cm})}{z_N - 0{,}3\ \mathrm{cm}} \tag{1}$$

where

A_{BCS} is the **beam cross-sectional area**;

z_N is the distance from the face of the **treatment head** to the last maximum of the **RMS acoustic pressure** on the **beam alignment axis**

Note 1 to entry: **Active area gradient** is expressed in metres (m).

[SOURCE: IEC 61689:2013, 3.3, modified – The calculation scheme of the gradient was added to the definition, and the formula was added.]

3.4
absolute maximum beam non-uniformity ratio
beam non-uniformity ratio plus the 95 % confidence overall uncertainty in the **beam non-uniformity ratio**