



# SLOVENSKI STANDARD SIST EN IEC 63009:2020

01-januar-2020

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**Ultrazvok - Fizioterapevtski sistemi - Poljske specifikacije in merilne metode v frekvenčnem območju od 20 kHz do 500 kHz (IEC 63009:2019)**

Ultrasonics - Physiotherapy systems - Field specifications and methods of measurement in the frequency range 20 kHz to 500 kHz (IEC 63009:2019)

Ultraschall - Physiotherapiesysteme - Feldspezifikationen und Messmethoden im Frequenzbereich 20 kHz bis 500 kHz (IEC 63009:2019)

Ultrasons - Systèmes de physiothérapie - Specifications des champs et méthodes de mesure dans la plage de fréquences de 20 kHz à 500 kHz (IEC 63009:2019)

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**Ta slovenski standard je istoveten z: EN IEC 63009:2019**

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**ICS:**

11.040.60      Terapevtska oprema      Therapy equipment

**SIST EN IEC 63009:2020      en**

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EUROPEAN STANDARD

**EN IEC 63009**

NORME EUROPÉENNE

EUROPÄISCHE NORM

September 2019

ICS 17.140.50; 11.040.60

English Version

Ultrasonics - Physiotherapy systems - Field specifications and  
methods of measurement in the frequency range 20 kHz to 500  
kHz  
(IEC 63009:2019)

Ultrasons - Systèmes de physiothérapie - Spécifications  
des champs et méthodes de mesure dans la plage de  
fréquences de 20 kHz à 500 kHz  
(IEC 63009:2019)

Ultraschall - Physiotherapiesysteme - Feldspezifikationen  
und Messmethoden im Frequenzbereich 20 kHz bis 0,5  
MHz  
(IEC 63009:2019)

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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

**EN IEC 63009:2019 (E)****European foreword**

The text of document 87/705/CDV, future edition 1 of IEC 63009, prepared by IEC/TC 87 "Ultrasonics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 63009:2019.

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) 2020-05-15
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2022-08-15

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In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 61689:2013	NOTE	Harmonized as EN 61689:2013 (not modified)
IEC 61161	NOTE	Harmonized as EN 61161
IEC 62127-3	NOTE	Harmonized as EN 62127-3
IEC 62555	NOTE	Harmonized as EN 62555

## 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](http://www.cenelec.eu).

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60565	-	Underwater acoustics - Hydrophones - Calibration in the frequency range 0,01 Hz to 1 MHz	EN 60565	-
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 62127-1	-	Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz	EN 62127-1	-
IEC 62127-2	-	Ultrasonics - Hydrophones - Part 2: Calibration for ultrasonic fields up to 40 MHz	EN 62127-2	-

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IEC 63009

Edition 1.0 2019-07

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE

Ultrasonics – Physiotherapy systems – Field specifications and methods of measurement in the frequency range 20 kHz to 500 kHz

Ultrasons – Systèmes de physiothérapie – Spécifications des champs et méthodes de mesure dans la plage de fréquences de 20 kHz à 500 kHz

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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

**ULTRASONICS – PHYSIOTHERAPY SYSTEMS – FIELD SPECIFICATIONS  
AND METHODS OF MEASUREMENT IN THE FREQUENCY  
RANGE 20 kHz TO 500 kHz**

## 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 63009 has been prepared by technical committee 87: Ultrasonics.

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

CDV	Report on voting
87/705/CDV	87/714A/RVC

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

- Terms defined in Clause 3: **bold type**
- Compliance clauses: *Arial Italic*
- Symbols of quantities: *Times New Roman + Italic*

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "<http://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.

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## INTRODUCTION

**Ultrasound** is used in medicine for the purposes of physiotherapy. Such equipment consists of a generator of electrical energy and usually a hand-held **treatment head**, often referred to as an applicator. The **treatment head** contains a transducer 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 20 kHz TO 500 kHz

## 1 Scope

This International Standard is applicable to **ultrasonic equipment** designed for physiotherapy containing an **ultrasonic transducer** generating ultrasound in the frequency range 20 kHz to 500 kHz.

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**;
- 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**.

The therapeutic value and methods of use of **ultrasonic physiotherapy equipment** are not within the scope of this document.

Excluded equipment includes, but is not limited to:

- equipment in which ultrasound waves are intended to destroy conglomerates (for example stones in the kidneys or the bladder) or tissue of any type;
- equipment in which a tool is driven by ultrasound (for example surgical scalpels, phacoemulsifiers, dental scalers or intracorporeal lithotripters);
- equipment in which ultrasound waves are intended to sensitize tissue to further therapies (for example radiation or chemotherapy);
- equipment in which ultrasound waves are intended to treat cancerous (i.e., malignant) or pre-cancerous tissue, or benign masses, such as High Intensity Focused Ultrasound (HIFU) or High Intensity Therapeutic Ultrasound (HITU).

## 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 60565, *Underwater acoustics – Hydrophones – Calibration in the frequency range 0,01 Hz to 1 MHz*

IEC 60601-2-5, *Medical electrical equipment – Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment*