

STN	Ultrazvuk Fyzioterapeutické systémy Špecifikácie poľa a metódy merania vo frekvenčnom rozsahu od 20 kHz do 500 kHz	STN EN IEC 63009 34 0899
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Ultrasonics - Physiotherapy systems - Field specifications and methods of measurement in the frequency range 20 kHz to 500 kHz

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 01/20

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EUROPEAN STANDARD

EN IEC 63009

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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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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
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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

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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.

<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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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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**IEC 63009**

Edition 1.0 2019-07

INTERNATIONAL STANDARD

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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**

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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.

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- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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.

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*

IEC 62127-1, *Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz*

IEC 62127-2, *Ultrasonics – Hydrophones – Part 2: Calibration for ultrasonic fields up to 40 MHz*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN