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Standards

Irish Standard
I.S. EN IEC 63009:2019

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

I.S. EN IEC 63009:2019

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National Foreword

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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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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.

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- 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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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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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

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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

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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.

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

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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*

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