

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

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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  
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## 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.

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IEC 61828	NOTE	Harmonized as EN IEC 61828
IEC 62127-2	NOTE	Harmonized as EN 62127-2
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IEC 62555	NOTE	Harmonized as EN 62555
IEC 63009	NOTE	Harmonized as EN IEC 63009

# 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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# INTERNATIONAL STANDARD

## NORME INTERNATIONALE

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- e) Annex D has been considerably shortened and reference to a now withdrawn regulatory document has been removed.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

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## 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.

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# 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*