BS EN IEC 61689:2022



BSI Standards Publication

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

bsi.

# National foreword

This British Standard is the UK implementation of EN IEC 61689:2022. It is identical to IEC 61689:2022. It supersedes BS EN 61689:2013, which will be withdrawn on 28 October 2022.

The UK participation in its preparation was entrusted to Technical Committee EPL/87, Ultrasonics.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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# 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)

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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.

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- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2025-04-12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

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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 | - | - |

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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:

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- 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*