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

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COMMISSION

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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

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e) Annex D has been considerably shortened and reference to a now withdrawn regulatory document has been removed.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

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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.

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~~:2013~~, *Ultrasonics – Power measurement – Radiation force balances and performance requirements*

IEC 62127-1~~:2007~~, *Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields~~ up to 40 MHz~~*
~~Amendment 1:2013~~

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Edition 4.0 2022-03

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

IEC 61689:2022-03(en-fr)

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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*

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COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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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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L'IEC 61689 a été établie par le comité d'études 87 de l'IEC: Ultrasons. Il s'agit d'une Norme internationale.

Cette quatrième édition annule et remplace la troisième édition parue en 2013. Cette édition constitue une révision technique.

Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente.

a) L'exigence relative à la teneur en oxygène de l'eau est spécifiée en 6.1.
b) Les anciennes recommandations spécifiées en 6.2 ont été modifiées pour constituer des exigences.
c) Plusieurs définitions de l'Article 3 ont été actualisées conformément à d'autres documents qui relèvent du CE 87.

d) L'ancienne Annexe A informative a été modifiée en annexe normative, et contient désormais des informations détaillées sur la méthode selon laquelle la conformité aux exigences de l'IEC 60601-2-5 est vérifiée.

e) L'Annexe D a été raccourcie de manière importante et la référence à un document réglementaire désormais supprimé a été retirée.

Le texte de cette Norme internationale est issu des documents suivants:

Projet	Rapport de vote
87/784/FDIS	87/789/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à son approbation.

La langue employée pour l'élaboration de cette Norme internationale est l'anglais.

Le présent document a été rédigé selon les Directives ISO/IEC, Partie 2, il a été développé selon les Directives ISO/IEC, Partie 1 et les Directives ISO/IEC, Supplément IEC, disponibles sous www.iec.ch/members_experts/refdocs. Les principaux types de documents développés par l'IEC sont décrits plus en détail sous www.iec.ch/standardsdev/publications.

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INTRODUCTION

Les **ultrasons** aux fréquences de quelques mégahertz sont largement utilisés en médecine pour les besoins de la physiothérapie. Ces appareils comportent un générateur de courant électrique à haute fréquence et généralement un **transducteur** tenu à la main, souvent appelé applicateur. Ce **transducteur** se compose d'un transducteur, généralement un disque en matériau piézoélectrique, qui convertit l'énergie électrique en **ultrasons** et est souvent conçu pour être en contact avec le corps humain.

ULTRASONS – SYSTÈMES DE PHYSIOTHÉRAPIE – SPÉCIFICATIONS DES CHAMPS ET MÉTHODES DE MESURE DANS LA PLAGE DE FRÉQUENCES DE 0,5 MHz À 5 MHz

1 Domaine d'application

Le présent document est applicable aux appareils à ultrasons, conçus pour la physiothérapie, qui comprennent un **transducteur ultrasonique** fournissant des **ultrasons** à onde entretenue ou quasi entretenue (par exemple, salve d'impulsions) dans la plage de fréquences de 0,5 MHz à 5 MHz. Le présent document ne traite que des **appareils à ultrasons pour physiothérapie** qui emploient un seul transducteur circulaire plan sans focalisation par transducteur, produisant des faisceaux statiques perpendiculaires à la face de ce même **transducteur**.

Le présent document spécifie:

- les méthodes de mesure et la caractérisation de la sortie des **appareils à ultrasons pour physiothérapie**, qui reposent sur des méthodes d'essai de référence;
- les caractéristiques à spécifier par les fabricants des **appareils à ultrasons pour physiothérapie** qui reposent sur des méthodes d'essai de référence;
- les lignes directrices de sécurité du champ ultrasonique créé par les **appareils à ultrasons pour physiothérapie**;
- les méthodes de mesure et la caractérisation de la sortie des **appareils à ultrasons pour physiothérapie**, qui reposent sur des méthodes d'essai individuel de série;
- les critères d'aptitude relatifs aux aspects de la sortie des **appareils à ultrasons pour physiothérapie**, qui reposent sur des méthodes d'essai individuel de série.

La valeur thérapeutique et les modes d'utilisation des **appareils à ultrasons pour physiothérapie** n'entrent pas dans le domaine d'application du présent document.

Les **appareils à ultrasons pour physiothérapie** qui utilisent des **ultrasons** dont la plage de fréquences est comprise entre 20 kHz et 500 kHz sont couverts par l'IEC 63009.

2 Références normatives

Les documents suivants sont cités dans le texte de sorte qu'ils constituent, pour tout ou partie de leur contenu, des exigences du présent document. Pour les références datées, seule l'édition citée s'applique. Pour les références non datées, la dernière édition du document de référence s'applique (y compris les éventuels amendements).

IEC 60601-1, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*

IEC 60601-2-5, *Appareils électromédicaux – Partie 2-5: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à ultrasons pour physiothérapie*

IEC 61161, *Ultrasons – Mesurage de puissance – Balances de forces de rayonnement et exigences de fonctionnement*

IEC 62127-1, *Ultrasons – Hydrophones – Partie 1: Mesurage et caractérisation des champs ultrasoniques médicaux jusqu'à 40 MHz*