SVENSK STANDARD SS-EN IEC 61689

Utgåva 4

2022-05-18

REDLINE VERSION

Ultraljud – Ultraljudsterapiapparater – Prestandafordringar och mätmetoder i frekvensområdet 0,5 MHz till 5 MHz

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

En så kallad ”Redline version” (RLV) innehåller både den fastställda IEC-standarden och en ändringsmarkerad standard. Alla tillägg och borttagningar sedan den tidigare utgåvan är markerade med färg. Med en RLV sparar du mycket tid när du ska identifiera och bedöma aktuella ändringar i standarden. SEK Svensk Elstandard kan bara ge ut en RLV i de fall den finns tillgänglig från IEC.

IEC 61689

Edition 4.0 2022-03
REDLINE VERSION

INTERNATIONAL STANDARD

colour inside

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.60

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CONTENTS

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ULTRASONICS – PHYSIOTHERAPY SYSTEMS – FIELD SPECIFICATIONS AND METHODS OF MEASUREMENT IN THE FREQUENCY RANGE 0,5 MHz TO 5 MHz

FOREWORD

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This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition IEC 61689:2013. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

IEC 61689 has been prepared by IEC technical committee 87: Ultrasonics. It is an International Standard.

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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.
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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e) Annex D has been considerably shortened and reference to a now withdrawn regulatory document has been removed.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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- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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~~

SVENSK STANDARD SS-EN IEC 61689

Fastställd	Utgåva	Sida	Ansvarig kommitté
2022-05-18	4	1 (1+67)	SEK TK 62

Ultraljud – Ultraljudsterapiapparater – Prestandafordringar och mätmetoder i frekvensområdet 0,5 MHz till 5 MHz

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

Som svensk standard gäller europastandarden EN IEC 61689:2022. Den svenska standarden innehåller den officiella engelska språkversionen av EN IEC 61689:2022.

Nationellt förord

Europastandarden EN IEC 61689:2022

består av:

– **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
– **IEC 61689, Fourth edition, 2022 - Ultrasonics - Physiotherapy systems - Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz**

utarbetad inom International Electrotechnical Commission, IEC.

Tidigare fastställd svensk standard SS-EN 61689, utgåva 3, 2013, gäller ej fr o m 2025-04-12.

ICS 11.040.60

Denna standard är fastställd av SEK Svensk Elstandard,
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E-post: sek@elstandard.se. Internet: www.elstandard.se

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 61689

April 2022

ICS 11.040.60

Supersedes EN 61689:2013

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 Messverfahren im Frequenzbereich von 0,5 MHz bis 5 MHz (IEC 61689:2022)

This European Standard was approved by CENELEC on 2022-04-12. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN IEC 61689:2022 E

SEK Svensk Elstandard

SS-EN IEC 61689, utg 4:2022

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

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Endorsement notice

The text of the International Standard IEC 61689:2022 was approved by CENELEC as a European Standard without any modification.

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

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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.

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	-	-

IEC 61689

Edition 4.0 2022-03

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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