ICS 17.140.50 SLOVENSKÁ TECHNICKÁ NORMA Jún 2021

STN	**Ultrazvuk Prevodníky Definície a metódy merania týkajúce sa fokusovania prenosových polí**	**STN EN IEC 61828 35 6891**

Ultrasonics - Transducers - Definitions and measurement methods regarding focusing for the transmitted fields

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 05/21

Obsahuje: EN IEC 61828:2021, IEC 61828:2020

Oznámením tejto normy sa od 19.01.2024 ruší
STN EN 61828 (35 6891) z decembra 2002

132691

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 61828

February 2021

ICS 17.140.50

Supersedes EN 61828:2001 and all of its amendments and corrigenda (if any)

English Version

Ultrasonics - Transducers - Definitions and measurement methods regarding focusing for the transmitted fields (IEC 61828:2020)

Ultrasons - Transducteurs - Définitions et méthodes de mesure pour la focalisation des champs transmis (IEC 61828:2020)

Ultraschall - Fokussierende Wandler - Definitionen und Messverfahren mit Bezug auf die Fokussierung für die erzeugten Felder (IEC 61828:2020)

This European Standard was approved by CENELEC on 2021-01-19. 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

European foreword

The text of document 87/746/FDIS, future edition 2 of IEC 61828, prepared by IEC/TC 87 "Ultrasonics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 61828:2021.

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) 2021-10-19
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2024-01-19

This document supersedes EN 61828:2001 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.

Endorsement notice

The text of the International Standard IEC 61828:2020 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 62127-1:2007	NOTE	Harmonized as EN 62127-1:2007 (not modified)
IEC 60601-2-62:2013	NOTE	Harmonized as EN 60601-2-62:2015 (not modified)
IEC/TS 61949:2007	NOTE	Harmonized as CLC/TS 61949:2008 (not modified)

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 61161	-	Ultrasonics - Power measurement - Radiation force balances and performance requirements	EN 61161	-
IEC 61689	2013	Ultrasonics - Physiotherapy systems - Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz	EN 61689	2013
IEC 62127-3	2007	Ultrasonics - Hydrophones - Part 3: Properties of hydrophones for ultrasonic fields up to 40 MHz	EN 62127-3	2007
IEC 62555	-	Ultrasonics - Power measurement - High intensity therapeutic ultrasound (HITU) transducers and systems	EN 62555	-
IEC/TS 62556	2014	Ultrasonics - Field characterization - Specification and measurement of field parameters for high intensity therapeutic ultrasound (HITU) transducers and systems	-	-
ISO/IEC Guide 98-3	2008	Uncertainty of measurement - Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)	-	-

IEC 61828

Edition 2.0 2020-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

Ultrasonics – Transducers – Definitions and measurement methods regarding focusing for the transmitted fields

Ultrasons – Transducteurs – Définitions et méthodes de mesure pour la focalisation des champs transmis

IEC 61828:2020-12(en-fr)

IEC 61828

Edition 2.0 2020-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

Ultrasonics – Transducers – Definitions and measurement methods regarding focusing for the transmitted fields

Ultrasons – Transducteurs – Définitions et méthodes de mesure pour la focalisation des champs transmis

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 17.140.50 ISBN 978-2-8322-9019-4

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

ULTRASONICS –TRANSDUCERS – DEFINITIONS AND MEASUREMENT METHODS REGARDING FOCUSING FOR THE TRANSMITTED FIELDS

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.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 61828 has been prepared by IEC technical committee 87: Ultrasonics.

This second edition cancels and replaces the first edition published in 2001. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) Clause 6 on Measurement procedures has been replaced by Clause 6: "Acoustic field measurement: equipment" and Clause 7: "Measurement procedure" and related definitions.
b) Reorganization of definitions and measurement section to accommodate specific sets of measurements for focusing, nonlinearity, beam axis alignment, beam area, beam maximum, numerical projection, plane wave, high intensity therapeutic ultrasound, multiple sources, spatial impulse response and compound plane waves. Clause 3 has been moved to Annex B.
c) The normative references have been updated and the Bibliography has been expanded from 8 to 40 references.

d) Twelve figures have been updated and seven new figures (B.1, B.3, B.7, B.10, B.11, B.12, B.13, B.14) have been added to facilitate measurements and be consistent with measurement terminology.

e) New measurements have been added for time delays, arrays, plane waves and spatial impulse response.

f) Annex A has been expanded to provide general guidance on pulsed waves, system responses, focusing gains and minimum beamwidth estimation.

g) New annexes have been added:

- Annex B (informative) Rationale for focusing and nonfocusing definitions
- Annex E (informative) Uncertainties;
- Annex F (informative) Transducer and hydrophone positioning systems;
- Annex G (informative) Planar scanning of a hydrophone to determine acoustic output power;
- Annex H (informative) Properties of water;

In addition, Annex A was reorganized and new Clauses A.1, A.5 and A.6 were added.

h) Guidelines for remaining within the manufacturer's pressure and intensity hydrophone limits and the determination of the extent of nonlinearity in the field have been added.

The text of this International Standard is based on the following documents:

FDIS	Report on voting
87/746/FDIS	87/749/RVD

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

NOTE 1 The following print types are used:

– Requirements: in roman type.

– Notes: small roman type.

– Words in **bold** in the text are defined in Clause 3.

NOTE 2 There are some inconsistencies in font type for symbols and formulae between some of the normative references and this document. They will be resolved in a future revision of the normative references.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- 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

Focusing transducers are essential in medical applications for obtaining high-resolution images, Doppler and flow data and for concentrating ultrasonic energy at desired sites for therapy. This document provides specific definitions appropriate for describing the focused field from a theoretical viewpoint for transducers with known characteristics intended by design. Other specific definitions included in this document, based on measurement methods, provide a means of determining **focusing** properties, if any, of a transducer of unknown field characteristics. The measurement method and definitions provide criteria for determining if the transducer is focusing, as well as a means of describing the **focusing** properties of the field. **Beam axis** alignment methods and field characterization measurements are given for both **focusing** and **nonfocusing** transducers.

ULTRASONICS –TRANSDUCERS – DEFINITIONS AND MEASUREMENT METHODS REGARDING FOCUSING FOR THE TRANSMITTED FIELDS

1 Scope

This document

– provides definitions for the transmitted field characteristics of focusing and nonfocusing transducers for applications in medical ultrasound;
– relates these definitions to theoretical descriptions, design, and measurement of the transmitted fields of focusing transducers;
– gives measurement methods for obtaining defined field characteristics of focusing and nonfocusing transducers;
– specifies beam axis alignment methods appropriate for focusing and nonfocusing transducers.

This document relates to focusing ultrasonic transducers operating in the frequency range appropriate to medical ultrasound (0,5 MHz to 40 MHz) for both therapeutic and diagnostic applications. It shows how the characteristics of the transmitted field of transducers can be described from the point of view of design, as well as measured by someone with no prior knowledge of the construction details of a particular device. The transmitted ultrasound field for a specified excitation is measured by a hydrophone in either a standard test medium (for example, water) or in a given medium. This document applies only to media where the field behaviour is essentially like that in a fluid (i.e. where the influence of shear waves and elastic anisotropy is small), including soft tissues and tissue-mimicking gels. Any aspects of the field that affect their theoretical description or are important in design are also included. These definitions would have use in scientific communications, system design and description of the performance and safety of systems using these devices.

This document incorporates definitions from other related standards where possible, and supplies more specific terminology, both for defining focusing characteristics and for providing a basis for measurement of these characteristics.

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 61689:2013, *Ultrasonics – Physiotherapy systems – Field specifications and methods of measurement in the frequency range 0,5 MHz to 5MHz*

IEC 62127-3:2007, *Ultrasonics – Hydrophones – Part 3: Properties of hydrophones for ultrasonic fields up to 40 MHz*
IEC 62127-3:2007/AMD1:2013

IEC TS 62556:2014, *Ultrasonics – Field characterization – Specification and measurement of field parameters for high intensity therapeutic ultrasound (HITU) transducers and systems*

IEC 61161, *Ultrasonics – Power measurement – Radiation force balances and performance requirements*

IEC 62555, *Ultrasonics – Power measurement –High intensity therapeutic ultrasound (HITU) transducers and systems*

ISO/IEC Guide 98-3:2008, *Uncertainty of measurement – Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*