

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

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| ingliskeelset teksti. | standard EN 61828:2001. |
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EUROPEAN STANDARD

EN 61828

NORME EUROPÉENNE

EUROPÄISCHE NORM

October 2001

English version

Ultrasonics -Focusing transducers -Definitions and measurement methods for the transmitted fields

(IEC 61828:2001)

Ultrasons -

ICS 17

Transducteurs focaliseurs Définitions et méthodes de mes ıre des champs transmis (CEI 61828:2001)

Ultraschall -Fokusierende Wandler -Definitionen und Messverfahren für die erzeugten Felder (IEC 61828:2001)

This European Standard was approved by CENELEC on 2001-09-01. 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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



TT 000 European Committee for Electrotechnical Standardization Comité Européen de Normalisation Electrotechnique Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

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Foreword

The text of document 87/196/FDIS, future edition 1 of IEC 61828, prepared by IEC TC 87, Ultrasonics, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 61828 on 2001-09-01.

The following dates were fixed:

| — | latest date by which the EN has to be implemented | | |
|---|---|-------|------------|
| | at national level by publication of an identical | | |
| | national standard or by endorsement | (dop) | 2002-06-01 |
| | | | |
| _ | latest date by which the national standards conflicting | | |
| | with the EN have to be withdrawn | (dow) | 2004-09-01 |

Annexes designated "normative" are part of the body of the standard. Annexes designated "informative" are given for information only. In this standard, annex ZA is normative and annexes A, B and C are informative. Annex ZA has been added by CENELEC.

C Endorsement notice

The text of the International Standard IEC 61828:2001 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 61161:1992 NOTE: Harmonized as EN 61161:1994 (not modified).

IEC 62092:2001 NOTE: Harmonized as EN 62092:2001 (not modified).

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Annex ZA

(normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references, the latest edition of the publication referred to applies (including amendments).

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

| <u>Year</u> | Title | <u>EN/HD</u> | Year |
|-------------|--|--|---|
| 1994 | International Electrotechnical Vocabulary (IEV) - Chapter 801: Acoustics and electroacoustics | - | - |
| 1991 | Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz | EN 61102 | 1993 |
| 1992 | Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment | EN 61157 | 1994 |
| 1996 | Ultrasonics - Physiotherapy systems - Performance requirements and methods of measurement in the frequency range 0,5 MHz to 5 MHz | EN 61689 | 1996 |
| | 1994 1991 1992 | 1994 International Electrotechnical Vocabulary (IEV) - Chapter 801: Acoustics and electroacoustics 1991 Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz 1992 Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment 1996 Ultrasonics - Physiotherapy systems - Performance requirements and methods of measurement in the frequency range 0,5 MHz to 5 MHz | 1994 International Electrotechnical Vocabulary (IEV) - Chapter 801: Acoustics and electroacoustics 1991 Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz 1992 Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment 1996 Ultrasonics - Physiotherapy systems - Performance requirements and methods of measurement in the frequency range |



Publication numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series. For example, IEC 34-1 is now referred to as IEC 60034-1.

Consolidated editions

The IEC is now publishing consolidated versions of its publications. For example, edition numbers 1.0, 1.1 and 1.2 refer, respectively, to the base publication, the base publication incorporating amendment 1 and the base publication incorporating amendments 1 and 2.

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Catalogue of IEC publications

The on-line catalogue on the IEC web site (<u>www.iec.ch/catlg-e.htm</u>) enables you to search by a variety of criteria including text searches, technical committees and date of publication. On-line information is also available on recently issued publications, withdrawn and replaced publications, as well as corrigenda.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION



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

FOREWORD

- 1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The 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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- 6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The 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.

The text of this standard is based on the following document

| FDIS | Report on voting |
|-------------|------------------|
| 87/196/FDIS | 87/204/RVD |
| | |

Full information on the voting for the approval of this 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 3.

Annexes A, B and C are for information only.

The committee has decided that the contents of this publication will remain unchanged until 2005. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

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. Present terminology for focusing transducers is inadequate for communicating precisely the characteristics of the focused fields of the wide variety of transducers and transducer array types and focusing means in common usage.

This International Standard 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 standard, based on measurement istics beam axis Print is a preview of the second s 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 are given for focusing transducers.

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



This International Standard

- provides definitions for the transmitted field characteristics of focusing 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 characteristics of focusing transducers;
- specifies beam axis alignment methods appropriate for focusing transducers.

This International Standard 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 may 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 radiated 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. The standard 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 standard incorporates definitions from other related standards¹ where possible, and supplies new, more specific terminology, both for defining focusing characteristics and for providing a basis for measurement of these characteristics.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

IEC 60050(801):1994, International Electrotechnical Vocabulary (IEV) – Chapter 801: Acoustics and electroacoustics

IEC 61102:1991, Measurement and characterization of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz

¹ Specifically, IEC 61102 and IEC 61157 (see clause 2).