

**Standard means for the reporting of the  
acoustic output of medical diagnostic  
ultrasonic equipment**

Standard means for the reporting of the acoustic  
output of medical diagnostic ultrasonic equipment

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN 61157:2007 sisaldab Euroopa standardi EN 61157:2007 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 17.12.2007 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN 61157:2007 consists of the English text of the European standard EN 61157:2007.</p> <p>This document is endorsed on 17.12.2007 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
--	---

<p><b>Käsitlusala:</b></p> <p>This International Standard is applicable to medical diagnostic ultrasonic equipment. - It provide a set of traceable acoustic parameters describing the acoustic fields - It defines a standard means and format for the reporting of the acoustic output information. - It also describes a reduced dataset recommended for equipment generating low acoustic output levels.</p>	<p><b>Scope:</b></p> <p>This International Standard is applicable to medical diagnostic ultrasonic equipment. - It provide a set of traceable acoustic parameters describing the acoustic fields - It defines a standard means and format for the reporting of the acoustic output information. - It also describes a reduced dataset recommended for equipment generating low acoustic output levels.</p>
--	--

**ICS** 11.040.50, 17.140.50

**Võtmesõnad:** acoustic properties, diagnostic equipm, electrical appliances, measurement, medical equipment, medical technology, medicine, output quantities, specification (approval), specifications, testing, ultrasonic devices, ultrasonic medic, ultrasonic medical apparatus

English version

**Standard means for the reporting of the acoustic output  
of medical diagnostic ultrasonic equipment  
(IEC 61157:2007)**

Moyens normalisés pour la déclaration  
des émissions acoustiques des appareils  
de diagnostic médical à ultrasons  
(CEI 61157:2007)

Normverfahren für die Angabe  
der akustischen Ausgangsgrößen  
von medizinischen  
Ultraschalldiagnostikgeräten  
(IEC 61157:2007)

This European Standard was approved by CENELEC on 2007-10-01. 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, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

**CENELEC**

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

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

## Foreword

The text of document 87/356/CDV, future edition 2 of IEC 61157, prepared by IEC TC 87, Ultrasonics, was submitted to the IEC-CENELEC parallel Unique Acceptance Procedure and was approved by CENELEC as EN 61157 on 2007-10-01.

This European Standard supersedes EN 61157:1994.

The changes with respect to EN 61157:1994 are listed below:

- maintenance on this standard and the referenced standards EN 61161 and EN 62127-1;
- a clause on compliance has been added.

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) 2008-07-01
- latest date by which the national standards conflicting  
with the EN have to be withdrawn (dow) 2010-10-01

NOTE The following print types are used:

- Requirements: in roman type
- *Test specifications: in italic type*
- Notes: in small roman type
- Words in **bold** in the text are defined in Clause 3.

Annex ZA has been added by CENELEC.

---

## Endorsement notice

The text of the International Standard IEC 61157:2007 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 61689	NOTE	Harmonized as EN 61689:2007 (not modified).
IEC 61828	NOTE	Harmonized as EN 61828:2001 (not modified).

---

## Annex ZA (normative)

### Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application 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 When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60050-801	1994	International Electrotechnical Vocabulary (IEV) - Chapter 801: Acoustics and electroacoustics	–	–
IEC 61161	– <sup>1)</sup>	Ultrasonics - Power measurement - Radiation force balances and performance requirements	EN 61161	2007 <sup>2)</sup>
IEC 62127-1	– <sup>1)</sup>	Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz	EN 62127-1	2007 <sup>2)</sup>
ISO 16269-6	2005	Statistical interpretation of data - Part 6: Determination of statistical tolerance intervals	–	–
ISO/IEC Guide 98	1995	Guide to the expression of uncertainty in measurement (GUM)	–	–

<sup>1)</sup> Undated reference.

<sup>2)</sup> Valid edition at date of issue.

# INTERNATIONAL STANDARD

**Standard means for the reporting of the acoustic output of medical diagnostic  
ultrasonic equipment**



## THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2007 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester.

If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

IEC Central Office  
3, rue de Varembe  
CH-1211 Geneva 20  
Switzerland  
Email: [inmail@iec.ch](mailto:inmail@iec.ch)  
Web: [www.iec.ch](http://www.iec.ch)

### About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

### About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

- Catalogue of IEC publications: [www.iec.ch/searchpub](http://www.iec.ch/searchpub)

The IEC on-line Catalogue enables you to search by a variety of criteria (reference number, text, technical committee,...). It also gives information on projects, withdrawn and replaced publications.

- IEC Just Published: [www.iec.ch/online\\_news/justpub](http://www.iec.ch/online_news/justpub)

Stay up to date on all new IEC publications. Just Published details twice a month all new publications released. Available on-line and also by email.

- Electropedia: [www.electropedia.org](http://www.electropedia.org)

The world's leading online dictionary of electronic and electrical terms containing more than 20 000 terms and definitions in English and French, with equivalent terms in additional languages. Also known as the International Electrotechnical Vocabulary online.

- Customer Service Centre: [www.iec.ch/webstore/custserv](http://www.iec.ch/webstore/custserv)

If you wish to give us your feedback on this publication or need further assistance, please visit the Customer Service Centre FAQ or contact us:

Email: [csc@iec.ch](mailto:csc@iec.ch)  
Tel.: +41 22 919 02 11  
Fax: +41 22 919 03 00



IEC 61157

Edition 2.0 2007-08

# INTERNATIONAL STANDARD

---

**Standard means for the reporting of the acoustic output of medical diagnostic  
ultrasonic equipment**

INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

PRICE CODE

**V**

---

ICS 11.040.50; 11.140.50

ISBN 2-8318-9257-0



## CONTENTS

FOREWORD.....	3
INTRODUCTION.....	5
1 Scope.....	6
2 Normative references .....	6
3 Terms, definitions and symbols .....	6
4 Requirements.....	16
4.1 General.....	16
4.2 Requirements for the reporting of acoustic output information .....	17
4.2.1 Technical data sheets information format .....	17
4.2.2 Detailed operating mode data sheets information format .....	18
4.2.3 Background information.....	19
4.2.4 Diagnostic fields in the absence of scan-frame synchronization .....	20
4.2.5 Dataset for low acoustic output equipment.....	20
5 Compliance statement.....	21
5.1 General.....	21
5.2 Maximum probable values .....	21
5.3 Sampling.....	21
6 Test methods .....	22
7 Presentation of results.....	22
Annex A (normative) Presentation of acoustic output information.....	23
Annex B (informative) Reporting requirements for extensive systems .....	25
Annex C (informative) Rationale .....	26
Index of defined terms .....	30
Bibliography.....	32
Figure C.1 – Schematic diagram showing the relationship between the various defined surfaces and distances for a mechanical sector scanner with water stand-off distance when applied to a patient.....	27
Figure C.2 – Schematic diagram showing the relationship between the various defined parameters and distances for a mechanical sector scanner during the measurement of acoustic output.....	27
Figure C.3 – Schematic diagram showing various defined parameters associated with the distribution of the scan lines in a linear array scanner and mechanically-scanned sector scanner.....	28
Figure C.4 – Schematic diagram illustrating the peak-rarefactional acoustic pressure during an acoustic pulse.....	29
Table 1 – List of symbols .....	15
Table A.1 – An example of reporting of the acoustic output of a 3,5 MHz scan-head for a phased-array sector scanner in accordance with this standard.....	24

## INTERNATIONAL ELECTROTECHNICAL COMMISSION

# STANDARD MEANS FOR THE REPORTING OF THE ACOUSTIC OUTPUT OF MEDICAL DIAGNOSTIC ULTRASONIC EQUIPMENT

## 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 provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with an IEC Publication.
- 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 61157 has been prepared by IEC technical committee 87: Ultrasonics.

This second edition cancels and replaces the first edition published in 1992. This edition constitutes a minor revision.

The changes with respect to the previous edition are listed below:

- maintenance on this standard and the referenced standards IEC 61161 and IEC 62127-1.
- a clause on compliance has been added.

The text of this standard is based on the following documents:

Enquiry draft	Report on voting
87/356/CDV	87/374/RVC

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 2.

NOTE The following print types are used:

- Requirements: in roman type
- *Test specifications: in italic type*
- Notes: in small roman type
- Words in **bold** in the text are defined in Clause 3.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result 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.

A bilingual version of this publication may be issued at a later date.

## INTRODUCTION

This International Standard specifies a standard means and format for the reporting of the acoustic output of medical diagnostic ultrasonic equipment. The numerical values for reporting purposes represent the average values for the maximum output conditions for a given discrete- or combined-operating mode and are derived from measurements made in water.

Intensity parameters are specified in this standard, but these are regarded as derived quantities that are meaningful only under certain assumptions related to the ultrasonic field being measured.

# STANDARD MEANS FOR THE REPORTING OF THE ACOUSTIC OUTPUT OF MEDICAL DIAGNOSTIC ULTRASONIC EQUIPMENT

## 1 Scope

This International Standard is applicable to medical diagnostic ultrasonic equipment.

- It provides a set of traceable acoustic parameters describing the acoustic fields.
- It defines a standard means and format for the reporting of the acoustic output information.
- It also describes a reduced dataset recommended for equipment generating low acoustic output levels.

NOTE The information tabulated in this standard format can be used for

- a) exposure planning for biological effects studies;
- b) exposure data for prospective epidemiological studies conducted using exposure conditions similar to those reported in this standard. In the absence of actual exposure data for retrospective epidemiological studies, the information tabulated in this standard format might also be used with cautionary comment.

## 2 Normative references

The following referenced documents are indispensable for the application 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 60050-801:1994 *International Electrotechnical Vocabulary – Chapter 801: Acoustics and electroacoustics*

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 up to 40 MHz*

ISO 16269-6:2005, *Statistical interpretation of data – Part 6: Determination of statistical tolerance intervals*

ISO/IEC Guide 98:1995, *Guide to the expression of uncertainty in measurement (GUM)*

## 3 Terms, definitions and symbols

For the purposes of this document, the terms and definitions given in IEC 62127-1, IEC 61161, the Index of defined terms at the end of this standard and the following definitions apply.

Figures C.1 to C.4 illustrate some of the defined parameters given below.

### 3.1

#### acoustic output freeze

condition of a system for which the acoustic output is disabled when there is no active updating of ultrasonic echo information