Irish Standard
I.S. EN 61157:2007

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

I.S. EN 61157:2007

Incorporating amendments/corrigenda issued since publication:

EN 61157:2007/A1:2013

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard – national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation - recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

This document replaces:	*This document is based on:*	*Published:*
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I.S. EN 61157:2007

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61157/A1

March 2013

ICS 11.040.50; 17.140.50

English version

Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment
(IEC 61157:2007/A1:2013)

Critères normalisés de déclaration des émissions acoustiques des appareils de diagnostic médical à ultrasons (CEI 61157:2007/A1:2013)

Normverfahren für die Angabe der akustischen Ausgangsgrößen von medizinischen Ultraschalldiagnostikgeräten (IEC 61157:2007/A1:2013)

This amendment A1 modifies the European Standard EN 61157:2007; it was approved by CENELEC on 2013-03-04. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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 amendment 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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

CENELEC

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

Management Centre: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 61157:2007/A1:2013 E

Foreword

The text of document 87/517/FDIS, future amendment 1 to edition 2 of IEC 61157, prepared by IEC/TC 87 "Ultrasonics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 61157:2007/A1:2013.

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)	2013-12-04
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2016-03-04

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

Endorsement notice

The text of the International Standard IEC 61157:2007/A1:2013 was approved by CENELEC as a European Standard without any modification.

In the Bibliography of EN 61157:2007, **replace** the existing text with the following:

IEC 61689	NOTE	Harmonised as EN 61689.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

***Replacements** and **addition** to Annex ZA of EN 61157:2007.*

Publication	Year	Title	EN/HD	Year
***Replace** the dated references to IEC 60050-801:1994, ISO 16269-6:2005 and ISO/IEC Guide 98:1994 by the following undated references:*				
IEC 60050-801	-	International Electrotechnical Vocabulary (IEV) - Chapter 801: Acoustics and electroacoustics	-	-
ISO 16269-6	-	Statistical interpretation of data - Part 6: Determination of statistical tolerance intervals	-	-
ISO/IEC Guide 98-3	-	Uncertainty of measurement - Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)	-	-
***Replace** the existing reference to IEC 62127-1 with the following:*				
IEC 62127-1 + corr. August + A1	2007 2008 2013	Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz	EN 62127-1 + A1	2007 2013
***Add** the following new reference:*				
IEC 60050-802	-	International Electrotechnical Vocabulary - Part 802: Ultrasonics	-	-

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I.S. EN 61157:2007

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61157

November 2007

ICS 11.040.50; 11.140.50

Supersedes EN 61157:1994

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)

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

Ref. No. EN 61157:2007 E

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.

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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.

Publication	Year	Title	EN/HD	Year
IEC 60050-801	1994	International Electrotechnical Vocabulary (IEV) - Chapter 801: Acoustics and electroacoustics	–	–
IEC 61161	– [1)]	Ultrasonics - Power measurement - Radiation force balances and performance requirements	EN 61161	2007 [2)]
IEC 62127-1	– [1)]	Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz	EN 62127-1	2007 [2)]
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)	–	–

[1)] Undated reference.

[2)] Valid edition at date of issue.

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CONTENTS

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.
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This consolidated version of IEC 61157 consists of the second edition (2007) [documents 87/356/CDV and 87/374/RVC], its amendment 1 (2013) [documents 87/517/FDIS and 87/523/RVD] and its corrigendum of August 2008. It bears the edition number 2.1.

The technical content is therefore identical to the base edition and its amendment and has been prepared for user convenience. A vertical line in the margin shows where the base publication has been modified by amendment 1. Additions and deletions are displayed in red, with deletions being struck through.

International Standard IEC 61157 has been prepared by IEC technical committee 87: Ultrasonics.

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.

This bilingual version (2012-06) corresponds to the monolingual English version, published in 2007-08.

The French version of this standard has not been voted upon.

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 the base publication and its amendments 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 publication using a colour printer.

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 60050-802, *International Electrotechnical Vocabulary – Chapter 802: Ultrasonics*

IEC 61161, *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

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)*~~

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

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.