

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

ICS 11.040.55; 17.140.50

National foreword

This British Standard is the UK implementation of EN 61157:2007+A1:2013. It is identical to IEC 61157:2007 incorporating amendment 1:2013. It supersedes BS EN 61157:2007 which will be withdrawn on 4 March 2016.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment 1 is indicated by A1 A1 .

The UK participation in its preparation was entrusted to Technical Committee EPL/87, Ultrasonics.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 December 2007

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Amendments/corrigenda issued since publication

Date	Comments
30 June 2013	Implementation of IEC amendment 1:2013 with CENELEC endorsement A1:2013: Annex ZA updated

**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.

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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.

Foreword to amendment A1

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.

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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.

A1 IEC 60050-801, *International Electrotechnical Vocabulary – Chapter 801: Acoustics and electroacoustics*

IEC 60050-802, *International Electrotechnical Vocabulary – Chapter 802: Ultrasonics* **A1**

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

A1 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, *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)* **A1**

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