

Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment

The European Standard EN 61157:1994 has the status of a
British Standard

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National foreword

This British Standard has been prepared under the direction of the Electrotechnical Sector Board and is the English language version of EN 61157:1994 *Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment*, published by the European Committee for Electrotechnical Standardization (CENELEC). It is identical with IEC 1157:1992, published by the International Electrotechnical Commission (IEC).

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 20, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

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English version

Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment

(IEC 1157:1992)

Critères pour la déclaration des émissions
acoustiques des appareils de diagnostic
médical à ultrasons
(CEI 1157:1992)

Anforderung für die Deklaration der
akustischen Ausgangsgrößen von
medizinisch-diagnostischen Ultraschallgeräten
(IEC 1157:1992)

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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, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CENELEC

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

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Foreword

The CENELEC questionnaire procedure, performed for finding out whether or not the International Standard IEC 1157:1992 could be accepted without textual changes, has shown that no common modifications were necessary for the acceptance as European Standard.

The reference document was submitted to the CENELEC members for formal vote and was approved by CENELEC as EN 61157 on 8 March 1994.

The following dates were fixed:

- latest date of publication of an identical national standard (dop) 1995-03-15
- latest date of withdrawal of conflicting national standards (dow) 1995-03-15

Annexes designated “normative” are part of the body of the standard. Annexes designated “informative” are given only for information. In this standard, Annex A and Annex ZA are normative and Annex B and Annex C are informative.

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Introduction

This International Standard specifies the requirements for the declaration by manufacturers of the acoustic output of medical diagnostic ultrasonic equipment. The numerical values for specification purposes represent the maximum output levels for a given discrete- or combined-operating mode and are derived from measurements made in water.

Equipment which generates low acoustic output levels is exempt from the full declaration requirements of this International Standard.

1 Scope

This International Standard is applicable to medical diagnostic ultrasonic equipment.

It establishes requirements for the declaration of the acoustic output information:

- to be presented in technical data sheets supplied to prospective purchasers of equipment by manufacturers;
- to be declared in the accompanying literature/manual supplied by manufacturers;
- as background information to be made available on request to interested parties by manufacturers.

It also gives exemption conditions for equipment generating low acoustic output levels.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and 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. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 469-1:1987, *Pulse techniques and apparatus. Part 1: Pulse terms and definitions.*

IEC 854:1986, *Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment.*

IEC 1102:1991, *Measurement and characterization of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz.*

IEC 1161:1992, *Ultrasonic power measurement in liquids in the frequency range 0,5 MHz to 25 MHz.*

3 Definitions and symbols

For the purpose of this International Standard, the following definitions apply.

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

3.1

accompanying literature

operating and instruction manual provided by the **manufacturer** with each piece of **medical diagnostic ultrasonic equipment**

3.2

acoustic initialization fraction

ratio of the **peak-negative acoustic pressure** when a **system** is in **initialization mode** to the maximum value of the **peak-negative acoustic pressure** for any **system** settings of a specified mode of operation. This ratio is determined from measurements made at the position which yields the maximum **pulse-pressure-squared integral** (or maximum mean square acoustic pressure for continuous wave [cw] **systems**). The ratio is usually expressed as a percentage

NOTE The mode of operation of a **system** in **initialization mode** may be different from the specified mode of operation.

3.3

acoustic output freeze

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

3.4

acoustic power-up fraction

ratio of the **peak-negative acoustic pressure** when the **system** is in **power-up mode** to the maximum value of the **peak-negative acoustic pressure** for any **system** settings of a specified mode of operation. This ratio is determined from measurements made at the position which yields the maximum **pulse-pressure-squared integral** (or maximum mean square acoustic pressure for continuous wave [cw] **systems**). The ratio is usually expressed as a percentage

NOTE The mode of operation of a **system** in **power-up mode** may be different from the specified mode of operation.

3.5

bandwidth

difference in the frequencies f_1 and f_2 at which the amplitude of the spectrum of the acoustic pressure first becomes 3 dB lower than the peak amplitude

3.6**combined-operating mode**

mode of operation of a **system** which combines more than one **discrete-operating mode**

NOTE Examples of **combined-operating modes** are real-time B-mode combined with M-mode (B+M), real-time B-mode combined with pulsed Doppler (B+D), colour M-mode (cM), real-time B-mode combined with M-mode and pulsed Doppler (B+M+D), real-time B-mode combined with real-time flow-mapping Doppler (B+rD), i.e. flow-mapping in which different types of acoustic pulses are used to generate the Doppler information and the imaging information

3.7**discrete-operating mode**

mode of operation of **medical diagnostic ultrasonic equipment** in which the purpose of the excitation of the ultrasonic transducer or ultrasonic transducer element group is to utilize only one diagnostic methodology

NOTE Examples of **discrete-operating modes** are A-mode (A), M-mode (M), static B-mode (sB), real-time B-mode (B), acoustic wave Doppler (cwD), pulsed Doppler (D), static flow-mapping (sD) and real-time flow-mapping Doppler (rD) using only one type of acoustic pulse.

3.8**inclusive mode**

combined-operating mode having acoustic output levels (p_- and I_{spta}) less than those corresponding to a specified **discrete-operating mode**

3.9**initialization mode**

a defined state of a **system** corresponding to the mode of operation and **system** settings when a new patient procedure is initiated

3.10**manufacturer**

a company that makes, markets or distributes **medical diagnostic ultrasonic equipment**

3.11**medical diagnostic ultrasonic equipment (or system)**

combination of the **ultrasound instrument console** and the **transducer assembly** making up a complete diagnostic **system**

3.12**non-scanning mode**

a mode of operation of a **system** that involves a sequence of ultrasonic pulses which give rise to **ultrasonic scan lines** that follow the same acoustic path

NOTE The sequence of pulses is not necessarily made up of identical pulses, such as in multiple focal-zone **systems**.

3.13**output beam area**

area of the ultrasonic beam derived from the **output beam dimensions**

Unit: centimetre squared, cm^2 .

3.14**output beam dimensions**

dimensions of the ultrasonic beam (**– 6 dB pulse beam-width**) in a specified direction normal to the **beam alignment axis** and at the **transducer output face**

Unit: millimetre, mm.

3.15**output beam intensity**

temporal-average power output divided by the **output beam area**

Symbol: I_{ob}

Unit: milliwatt per centimetre squared, mW/cm^2 .

3.16**patient entry plane**

plane perpendicular to the **beam alignment axis**, or the axis of symmetry of the **scan plane** for an automatic scanner, which passes through the point on said axis at which the ultrasound enters the patient

see Figure 1

3.17**power-up mode**

a defined state of a **system** corresponding to the mode of operation and **system** settings automatically established when power to the **system** is first turned on. If the defined state is user dependent, **power-up mode** is referred to as “not applicable” (abbreviated n/a)

NOTE The defined state would normally be one of the **discrete-** or **combined-operating modes**.

3.18**pulse beam-width**

distance between two points, on a specified surface and in a specified direction passing through the point of the maximum **pulse-pressure-squared integral** (ppsi) in that surface, at which the ppsi is a specified fraction of the maximum value of the ppsi in the surface. The two points are farthest from and on opposite sides of the point of maximum ppsi. If the position of the specified surface is not given, then it passes through the point of spatial-peak temporal-peak acoustic pressure in the whole acoustic field

the specified levels are 0,25 and 0,01 for the **– 6 dB** and **– 20 dB pulse beam-widths** respectively