SLOVENSKI STANDARD

SIST EN 61157:2002

prva izdaja
september 2002

Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment (IEC 61157:1992)

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SIST EN 61157:2002
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ICS 17.140.50; 11.040.50

Referenčna številka
SIST EN 61157:2002(en)

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EUROPEAN STANDARD EN 61157

NORME EUROPEENNE

EUROPÄISCHE NORM August 1994

UDC 615.849:616-073.755:534.321.9

Descriptors: Ultrasound, medical electrical equipment, diagnosis, acoustic output

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)

This European Standard was approved by CENELEC on 1994-03-08. 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, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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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 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, annexes A and ZA are normative and annexes B and C are informative.

ENDORSEMENT NOTICE

The text of the International Standard IEC 1157:1992 was approved by CENELEC as a European Standard without any modification.

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ANNEX ZA (normative)

OTHER INTERNATIONAL PUBLICATIONS QUOTED IN THIS STANDARD WITH THE REFERENCES OF THE RELEVANT 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.

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

IEC Publication	Date	Title	EN/HD	Date
469-1	1987	Pulse techniques and apparatus Part 1: Pulse terms and definitions	-	-
854	1986	Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment	-	-
1102	1991	Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz	EN 61102	1993
1161	1992	Ultrasonic power measurement in liquids in the frequency range 0,5 MHz to 25 MHz	EN 61161	1994

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NORME INTERNATIONALE
INTERNATIONAL STANDARD

CEI
IEC
1157

Première édition
First edition
1992-07

Critères pour la déclaration des émissions acoustiques des appareils de diagnostic médical à ultrasons

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

CODE PRIX
PRICE CODE V

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

REQUIREMENTS FOR THE DECLARATION OF THE ACOUSTIC OUTPUT OF MEDICAL DIAGNOSTIC ULTRASONIC EQUIPMENT

FOREWORD

1) The formal decisions or agreements of the IEC on technical matters, prepared by Technical Committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.

2) They have the form of recommendations for international use and they are accepted by the National Committees in that sense.

3) In order to promote international unification, the IEC expresses the wish that all National Committees should adopt the text of the IEC recommendation for their national rules in so far as national conditions will permit. Any divergence between the IEC recommendation and the corresponding national rules should, as far as possible, be clearly indicated in the latter.

This International Standard has been prepared by IEC Technical Committee No. 87: Ultrasonics.

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

DIS	Report on Voting
87(CO)11	87(CO)19

Full information on the voting for the approval of this standard can be found in the Voting Report indicated in the above table.

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Annex A forms an integral part of this International Standard.

Annexes B and C are for information only.

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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.

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.

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REQUIREMENTS FOR THE DECLARATION OF THE ACOUSTIC OUTPUT OF MEDICAL DIAGNOSTIC ULTRASONIC EQUIPMENT

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.*

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

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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.

Figures 1 to 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.

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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.

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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.**