IEC 61157

Edition 2.1 2013-01
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

Critères normalisés de déclaration des émissions acoustiques des appareils de diagnostic médical à ultrasons

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IEC 61157:2007+AMD1:2013 CSV(en-fr)

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ICS 11.040.50, 17.140.50

ISBN 978-2-8322-0634-8

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

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IEC 61157 edition 2.1 contains 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.

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

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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.

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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

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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*

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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.

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

3.2
acoustic pulse waveform
temporal waveform of the instantaneous acoustic pressure at a specified position in an acoustic field and displayed over a period sufficiently long to include all significant acoustic information in a single pulse or tone-burst, or in one or more cycles in a continuous wave

NOTE ~~1~~ Temporal waveform is a representation (e.g. oscilloscope presentation or equation) of the **instantaneous acoustic pressure**.

~~NOTE 2 Definition adapted from IEC 60469-1.~~

[SOURCE: IEC 62127-1:2007, definition 3.1]

3.3
acoustic repetition period
arp
pulse repetition period for non-automatic scanning systems and the **scan repetition period** for automatic scanning systems, equal to the time interval between corresponding points of consecutive cycles for continuous wave systems

NOTE The **acoustic repetition period** is expressed in seconds (s).

[IEC 62127-1, definition 3.2]

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3.4
acoustic frequency
acoustic-working frequency
frequency of an acoustic signal based on the observation of the output of a **hydrophone** placed in an acoustic field at the position corresponding to the **spatial-peak temporal-peak acoustic pressure**

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NOTE 1 The signal is analysed using either the **zero-crossing acoustic-working frequency** technique or a spectrum analysis method. Acoustic-working frequencies are defined in 3.4.1 and 3.4.2.

NOTE 2 In a number of cases, the present definition is not very helpful or convenient, especially for **broadband transducers**. In that case, a full description of the frequency spectrum should be given in order to enable any frequency-dependent correction to the signal.

NOTE 3 **Acoustic frequency** is expressed in hertz (Hz).

3.4.1
zero-crossing acoustic-working frequency
f_{awf}
number, *n*, of consecutive half-cycles (irrespective of polarity) divided by twice the time between the commencement of the first half-cycle and the end of the *n*-th half-cycle

NOTE 1 None of the *n* consecutive half-cycles should show evidence of phase change.

NOTE 2 The measurement should be performed at terminals in the receiver, that are as close as possible to the receiving transducer (**hydrophone**) and, in all cases, before rectification.

NOTE 3 This frequency is determined according to the procedure specified in IEC/TR 60854.

NOTE 4 This frequency is intended for continuous-wave systems only.

[SOURCE: IEC 62127-1:2007/Amendment 1:—, definition 3.3.1]

3.4.2
arithmetic-mean acoustic-working frequency
***f*awf**
arithmetic mean of the most widely separated frequencies f_1 and f_2, within the range of three times f_1, at which the magnitude of the acoustic pressure spectrum is 3 dB below the peak magnitude

NOTE 1 This frequency is intended for pulse-wave systems only.

NOTE 2 It is assumed that $f_1 < f_2$.

NOTE 3 If f_2 is not found within the range $< 3f_1$, f_2 is to be understood as the lowest frequency above this range at which the spectrum magnitude is -3 dB from the peak magnitude.

[SOURCE: IEC 62127-1, definition 3.3.2]

3.5
bandwidth
BW
difference in the most widely separated frequencies f_1 and f_2 at which the magnitude of the acoustic pressure spectrum becomes 3 dB below the peak magnitude, at a specified point in the acoustic field

NOTE Bandwidth is expressed in hertz (Hz).

[SOURCE: IEC 62127-1:2007, definition 3.6]

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3.6
beam area
~~***A*b*~~ ***A*b,6*, ***A*b,20***
area in a specified plane perpendicular to the **beam axis** consisting of all points at which the **pulse-pressure-squared integral** is greater than a specified fraction of the maximum value of the **pulse-pressure-squared integral** in that plane

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NOTE 1 If the position of the plane is not specified, it is the plane passing through the point corresponding to the ~~**spatial-peak temporal-peak acoustic pressure**~~ maximum value of the **pulse-pressure-squared integral** in the whole acoustic field.

NOTE 2 In a number of cases, the term **pulse-pressure-squared integral** is replaced everywhere in the above definition by any linearly related quantity, for example:

a) in the case of a continuous wave signal the term **pulse-pressure-squared integral** is replaced by mean square acoustic pressure as defined in IEC 61689;

b) in cases where signal synchronisation with the scanframe is not available the term **pulse-pressure-squared integral** may be replaced by **temporal average intensity.**

NOTE 3 Some specified ~~levels~~ fractions are 0,25 and 0,01 for the −6 dB and −20 dB beam areas, respectively.

NOTE 4 Beam area is expressed in square metres ~~squared~~ (m^2).

3.7
beam axis
straight line that passes through the **beam centrepoints** of two planes perpendicular to the line which connects the point of maximal **pulse-pressure-squared integral** with the centre of the **external transducer aperture**

NOTE 1 The location of the first plane is the location of the plane containing the maximum **pulse-pressure-squared integral** or, alternatively, is one containing a single main lobe which is in the focal Fraunhofer zone. The location of the second plane is as far as is practicable from the first plane and parallel to the first with the same two orthogonal scan lines (*x* and *y* axes) used for the first plane.

NOTE 2 In a number of cases, the term **pulse-pressure-squared integral** is replaced in the above definition by any linearly related quantity, for example:

a) in the case of a continuous wave signal the term **pulse-pressure-squared integral** is replaced by mean square acoustic pressure as defined in IEC 61689;

b) in cases where signal synchronisation with the scanframe is not available, the term **pulse-pressure-squared integral** may be replaced by **temporal average intensity**.

[IEC 62127-1,definition 3.8 modified]

3.8
beam centrepoint
position determined by the intersection of two lines passing through the **beamwidth midpoints** of two orthogonal planes, *xz* and *yz*

3.9
beamwidth midpoint
linear average of the location of the centres of **beamwidths** in a plane

NOTE The average is taken over as many **beamwidth** levels given in Table K.1 of IEC 62127-1 as signal level permits.

3.10
beamwidth
w_6, w_{12}, w_{20}
greatest distance between two points on a specified axis perpendicular to the **beam axis** where the **pulse-pressure-squared integral** falls below its maximum on the specified axis by a specified amount

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NOTE 1 In a number of cases, the term **pulse-pressure-squared integral** is replaced in the above definition by any linearly related quantity, for example:

a) in the case of a continuous wave signal the term **pulse-pressure-squared integral** is replaced by mean square acoustic pressure as defined in IEC 61689,

b) in cases where signal synchronisation with the scanframe is not available the term **pulse-pressure-squared integral** may be replaced by **temporal average intensity**.

NOTE 2 Commonly used **beamwidths** are specified at –6 dB, –12 dB and –20 dB levels below the maximum. The decibel calculation implies taking 10 times the logarithm of the ratios of the integrals.

NOTE 3 **Beamwidth** is expressed in metres (m).

[SOURCE: IEC 62127-1:2007, definition 3.11]

3.11
central scan line
for automatic scanning systems, the **ultrasonic scan line** closest to the symmetry axis of the **scan plane**

3.12
external transducer aperture
part of the surface of the **ultrasonic transducer** or **ultrasonic transducer element group** assembly that emits ultrasonic radiation into the propagation medium

NOTE This surface is either directly in contact with the patient or is in contact with a water or liquid path to the patient (see IEC 62127-1, Figure 1).

[IEC 62127-1,definition 3.27 modified]

3.13
instantaneous acoustic pressure
p(t)
pressure minus the ambient pressure at a particular instant in time and at a particular point in an acoustic field (see also IEV 801-21-19)

NOTE **Instantaneous acoustic pressure** is expressed in pascals (Pa).

3.14
instantaneous intensity
I(t)
acoustic energy transmitted per unit time in the direction of acoustic wave propagation per unit area normal to this direction at a particular instant in time and at a particular point in an acoustic field

NOTE 1 **Instantaneous intensity** is the product of **instantaneous acoustic pressure** and particle velocity. It is difficult to measure intensity in the ultrasound frequency range. For the measurement purposes referred to in this International Standard~~, and if it is reasonable to assume **far field** conditions,~~ and under conditions of sufficient distance from the **external transducer aperture** (at least one transducer diameter, or an equivalent transducer dimension in the case of a non-circular transducer) the **instantaneous intensity**~~, *I* is approximated as~~ can be approximated by the **derived instantaneous intensity.**

$$I(t) = \frac{p(t)^2}{\rho c} \quad (1)$$

~~where~~

~~$p(t)$ is the **instantaneous acoustic pressure**;~~

~~ρ is the density of the medium;~~

~~c is the velocity of sound in the medium.~~

NOTE 2 **Instantaneous intensity** is expressed in watts per square metre ~~squared~~ (W/m^2).

3.15
medical diagnostic ultrasonic equipment (or system)
combination of the **ultrasound instrument console** and the **transducer assembly** making up a complete diagnostic system

3.16
nominal frequency
the ultrasonic frequency of operation of an ultrasonic transducer or ultrasonic transducer element group quoted by the designer or manufacturer

[IEC 60854, definition 3.7 modified]

3.17
operating mode

3.17.1
combined-operating mode
mode of operation of a **system** that combines more than one **discrete-operating mode**s

NOTE Examples of **combined-operating mode**s 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.

[IEC 62127-1, definition 3.39.1]

3.17.2
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), continuous wave Doppler (cwD), pulsed Doppler (D), static flow-mapping (sD) and real-time flow-mapping Doppler (rD) using only one type of acoustic pulse.

[IEC 62127-1, definition 3.39.2]

3.17.3
inclusive mode
combined-operating mode having acoustic output levels (p_r and I_{spta}) less than those corresponding to a specified **discrete-operating mode**

[IEC 62127-1, definition 3.39.3]

3.17.4
non-scanning mode
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

[IEC 62127-1, definition 3.39.4]

3.17.5
scanning mode
mode of operation of a **system** that involves a sequence of ultrasonic pulses which give rise to **ultrasonic scan lines** that do not follow the same acoustic path

NOTE The sequence of pulses is not necessarily made up of identical pulses. For instance, the use of sequential multiple focal-zones is considered a scanning mode.

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[IEC 62127-1, definition 3.39.5]

3.18
output beam area
A_{ob}
area of the ultrasonic beam derived from the −12 dB beam area at the **external transducer aperture**

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NOTE 1 For reasons of measurement accuracy, the –12 dB **output beam area** may be derived from measurements at a distance chosen to be as close as possible to the face of the transducer, and, if possible, no more than 1 mm from the face.

NOTE 2 For contact transducers, this area can be taken as the geometrical area of the **ultrasonic transducer** or **ultrasonic transducer element group**.

NOTE 3 The **output beam area** is expressed in square metres ~~squared~~ (m^2).

[IEC 62127-1, definition 3.40]

3.19
output beam dimensions
X_{ob}, Y_{ob}
dimensions of the ultrasonic beam (–12 dB **beamwidth**) in specified directions perpendicular to each other and in a direction normal to the **beam axis** and at the **external transducer aperture**

NOTE 1 For reasons of measurement accuracy, the –12 dB **output beam dimensions** may be derived from measurements at a distance chosen to be as close as possible to the face of the transducer, and, if possible, no more than 1 mm from the face.

NOTE 2 For contact transducers, these dimensions can be taken as the geometrical dimensions of the **ultrasonic transducer** or **ultrasonic transducer element group**.

NOTE 3 **Output beam dimensions** are expressed in metres (m)

[IEC 62127-1, definition 3.41]

3.20
output beam intensity
***I*$_{ob}$**
temporal-average power output divided by the **output beam area**

NOTE **Output beam intensity** is expressed in watts per square metre ~~squared~~ (W/m^2).

[IEC 62127-1, definition 3.42]

3.21
patient entry plane
plane perpendicular to the **beam axis,** or the axis of symmetry of the **scan plane** for an automatic scanner, which passes through the point on the said axis at which the ultrasound enters the patient

NOTE See Figure C.1.

3.22
peak-rarefactional acoustic pressure
***p*$_-$ (or *p*$_r$)**
maximum of the modulus of the negative **instantaneous acoustic pressure** in an acoustic field or in a specified plane during an **acoustic repetition period**

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NOTE 1 **Peak-rarefactional acoustic pressure** is expressed as a positive number.

NOTE 2 **Peak-rarefactional acoustic pressure** is expressed in pascals (Pa).

NOTE 3 The definition of **peak-rarefactional acoustic pressure** also applies to peak-negative acoustic pressure which is also in use in literature.

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NOTE 4 See Figure C.4.

[IEC 62127-1, definition 3.44]

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3.23
pulse-pressure-squared integral
ppsi
time integral of the square of the **instantaneous acoustic pressure** at a particular point in an acoustic field integrated over the **acoustic pulse waveform**

NOTE The **pulse-pressure-squared integral** is expressed in pascal squared seconds (Pa^{2}s).

[IEC 62127-1, definition 3.50]

3.24
pulse repetition period
prp
time interval between equivalent points on successive pulses or tone-bursts

NOTE 1 This applies to single element non-automatic scanning systems and automatic scanning systems. See also IEC 60469-1:1987, 5.3.2.1.

NOTE 2 The **pulse repetition period** is expressed in seconds (s).

[IEC 62127-1, definition 3.51]