IEC 61157

Edition 2.0 2013-01

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

PRICE CODE
CODE PRIX H

ICS 11.040.50, 17.140.50

ISBN 978-2-83220-586-0

FOREWORD

This amendment has been prepared by IEC technical committee 87: Ultrasonics.

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

FDIS	Report on voting
87/517/FDIS	87/523/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

The committee has decided that the contents of this amendment and the base publication 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- withdrawn,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.

2 Normative references

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 – 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 62127-1:2007, *Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz*
Amendment 1:2013

Add the following new reference:

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

3 Terms, definitions and symbols

Replace in definitions 3.14, 3.20, 3.31 *and* 3.32 *"*expressed in watts per metre squared*" by "*expressed in watts per square metre*"*

Replace in definitions 3.6 *and* 3.18 "expressed in metres squared" by "expressed in square metres"

3.2
acoustic pulse waveform

Remove the numbering from Note 1 and replace existing Note 2 by the following:

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

3.4.1
zero-crossing acoustic-working frequency
f_{awf}
Replace the existing text of the definition by the following:

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}
Add the following new note and source reference to the existing definition:

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

Add, after the note, the following:

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

3.6
beam area

Replace the symbol by: "$\boldsymbol{A}_{b,6}$, $\boldsymbol{A}_{b,20}$"

Replace the existing text of Note 1 by the following:

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

*Replace, in Note 3, the word "*levels*" by "*fractions*".*

3.10
beamwidth

Add, after Note 3, the following source reference:

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

3.14
instantaneous intensity

Replace the existing text of Note 1 by the following:

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 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** can be approximated by the **derived instantaneous intensity.**

3.43
ultrasonic transducer element group dimensions

*Replace, in the definition, the term "***ultrasonic transducer** element group*" by "***ultrasonic transducer element group***" (bold font for the entire term).*

Add the following new definitions:

3.44
derived instantaneous intensity

quotient of squared **instantaneous acoustic pressure** and characteristic acoustic impedance of the medium at a particular instant in time at a particular point in an acoustic field

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

where:

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

ρ is the density of the medium;

c is the speed of sound in the medium.

NOTE 1 For measurement purposes referred to in this International Standard, the **derived instantaneous intensity** is an approximation of the **instantaneous intensity**.

NOTE 2 Increased uncertainty should be taken into account for measurements very close to the transducer.

NOTE 3 **Derived instantaneous intensity** is expressed in watts per square metre (W/m^2).

[SOURCE: IEC 62127-1:2007/Amendment 1:—, definition 3.78]

3.45
number of pulses per ultrasonic scan line
n_{pps}
the number of acoustic pulses travelling along a particular **ultrasonic scan line**

NOTE 1 Here **ultrasonic scan line** refers to the path of acoustic pulses on a particular **beam axis** in scanning and non-scanning modes.

NOTE 2 This number can be used in the calculation of any ultrasound temporal average value from **hydrophone** measurements.

NOTE 3 The following shows an example of the **number of pulses per ultrasonic scanline** and the **number of ultrasonic scanlines** (shows the end of a frame):

1 2 3 4; 1 2 3 4; 1 2 3 4... n_{pps} =1; n_{sl} = 4
1 1 2 2 3 3 4 4; 1 1 2 2 3 3 4 4; ... n_{pps} =2; n_{sl} = 4
1 1 1 1 2 2 2 2 3 3 3 3 4 4 4 4; 1 1 1 1 2 2 2 2 3 3 3 3 4 4 4 4; ... n_{pps} = 4; n_{sl} = 4
1 1 2 2 3 3 4 4 1 1 2 2 3 3 4 4; 1 1 2 2 3 3 4 4 1 1 2 2 3 3 4 4; ... n_{pps} = 4; n_{sl} = 4 (within one frame the pulses down each line may not occur contiguously)
Within one frame, all scan lines may not have the same npps value.
An example is: 1 2 2 3 3 4; 1 2 2 3 3 4; ... avg n_{pps} =1,5; max n_{pps} = 2; n_{sl}= 4

3.46
number of ultrasonic scanlines
***n*sl**
the quantity of **ultrasonic scanlines** that are excited during one **scan repetition period**

NOTE This number can be used in the calculation of any ultrasound temporal average value from **hydrophone** measurements.

Table 1 – List of symbols

Add the following new symbols:

n_{pps}	**number of pulses per ultrasonic scan line**	
n_{sl}	**number of ultrasonic scan lines** per image for spatial distribution	
$p(t)$	**instantaneous acoustic pressure**	IEC 62127-1
w_6	-6 *dB* **beamwidth**	IEC 62127-1
w_{20}	-20 dB **beamwidth**	IEC 62127-1
$A_{b,6}$ $A_{b,20}$	**beam area** corresponding to -6 dB **beam area** and -20 dB **beam area**	IEC 62127-1
$I(t)$	**instantaneous intensity**	IEC 62127-1
BW	**bandwidth**	IEC 62127-1
z_p	distance from the **transducer output face** to the point of maximum **pulse-pressure-squared integral**	IEC 62127-1

4 Requirements

4.2 Requirements for the reporting of acoustic output information

4.2.2 Detailed operating mode data sheets information format

Replace existing item h) by the following:

h) **Pulse repetition rate** (*prr*) for non-scanning modes. For scanning modes list the **scan repetition rate** (*srr*) and the **number of ultrasonic scan lines** (n_{sl}). In case there is more than 1 pulse per **ultrasonic scan line,** list the **pulse repetition rate** (*prr*) and the **number of pulses per ultrasonic scan line** (n_{pps}).

4.2.5 Dataset for low acoustic output equipment

Replace the last sentence of the second paragraph by the following:

Table A.1 need not be completed.

5 Compliance statement

5.1 General

Replace the existing text of items a) and b) of the second paragraph as follows:

a) the arithmetic mean determined from measurements on a group of *n* nominally identical systems, each with the acoustic output settings yielding the maximum output, where $n \geq 3$

and

b) the overall uncertainty of the value determined under a).

This overall uncertainty shall be calculated using an appropriate measure (with 95 % confidence, for 95 % of the population) of the statistical variation and the measurement uncertainty (at a level of confidence of 95 %).

Replace the existing third paragraph with the following text:

The tolerance interval is to be understood in accordance with ISO 16269-6. More guidance on assessment of uncertainties is given in IEC 62127-1, Annex I.

Measurement uncertainty involves many components (see IEC 62127-1, Annex I). It shall be an assessment of the contributions of all uncertainties (these referring to measurements made on one system). The measurement uncertainty shall be calculated as expanded uncertainty corresponding to a level of confidence of 95 %. The method of combining the uncertainty contributions specified by the ISO/IEC Guide 98-3, *Guide to the expression of uncertainty in measurement,* shall be followed.

NOTE "Tolerance interval" refers to the production scatter and "uncertainty" refers to the measurement method.

5.2 Maximum probable values

*Replace, in lettered item a) in the first paragraph, "*as referred to in 4.2" *by "*as referred to in 4.2, where $n \geq 3$*":*

Annex A – Presentation of acoustic output information

Table A.1 – An example of reporting of the acoustic output of a 3,5 MHz scan-head for a phased-array sector scanner in accordance with this standard

Replace existing Table A.1 (including the captions above the table) with the following:

Manufacturer: ZZZ

Acoustic output information for the ZZZ phased-array sector scanner
3,5 MHz general-purpose scan-head, type ZZZ

Parameter	**Mode**			
	B	**M**	**D_p**	**D_I**
System settings [a,b] Standard used: IEC 61157 Ed2 + A1	Focus F1 Output 0dB	Focus N Output 0dB	SVL = 1 mm RGD = 150 mm	SVL = 10 mm RGD = 100 mm
p_r (MPa)	2,2 ± 0,2	2,2 ± 0,2	1,8 ± 0,2	0,5 ± 0,05
I_{Ispta} (mW/cm²)	5,0 ± 1,0	180 ± 40	500 ± 100	900 ± 200
I_{ob} (mW/cm²)	0,7 ± 0,15	0,5 ± 0,1	2,1± 0,4 [c]	2,1 ± 0,4 [c]
Power output (mW)	2,1 ± 0,4	1,3 ± 0,3	6,0 ± 1,2 [c]	6,0 ± 1,2 [c]
Output beam dimensions (∅) (mm)	19	19	19	19
z_p (mm)	50 ± 1	50 ± 1	42 ± 1	44 ± 1
w_{12} (∥) (mm)	1,2 ± 0,05	1,2 ± 0,05	1,3 ± 0,05	1,4 ± 0,05
(⊥) (mm)	1,4 ± 0,05	1,4 ± 0,05	1,2 ± 0,05	1,4 ± 0,05
f_{awf} (MHz)	3,6 ± 0,2	3,6 ± 0,2	3,0 ± 0,2	3,0 ± 0,2
prr (kHz)	2 ± 0,05	0,8 ± 0,08	3,1 ± 0,3	6,0 ± 0,06
srr (Hz)	10 ± 0,5	–	–	–
n_{pps}	3	–	–	–
n_{sl}	128	–	–	–
z_{tt} (mm)	7	7	7	7
z_{ts} (mm)	..... contact			
Acoustic output freeze	Yes	Yes	Yes	Yes
Inclusive modes	–	B+M	B+D	B+D

a RGD – Range-gated depth
SVL – Sample volume length

b System settings – Focus F1, Output 0 dB, SVL = 10 mm, RGD = 100 mm

c Controllable by the user in 3 dB steps

NOTE The given overall uncertainty in the results may not be regarded as typical values or required limits but is inserted here only to provide an example for an appropriate reporting style. See Clause 5.1 for their meaning.

Annex C – Rationale

*Replace, in the fourth paragraph, the term "*beamwidth*" by "***beamwidth***".*

*Replace, in the fifth paragraph, first sentence, the term "*non-linear*" by "*nonlinear*".*

Bibliography

Replace the existing text of the bibliography with the following:

Related IEC documents

IEC/TR 60854:1986, *Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment*

IEC 61689, *Ultrasonics – Physiotherapy systems – Performance requirements and methods of measurement in the frequency range 0,5 MHz to 5 MHz*