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INTERNATIONAL STANDARD

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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

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International Standard IEC 61157 has been prepared by IEC technical committee 87: Ultrasonics.

This second edition cancels and replaces the first edition published in 1992. This edition constitutes a minor revision.

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.

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

Enquiry draft	Report on voting
87/356/CDV	87/374/RVC

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

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 this publication will remain unchanged until the maintenance result 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- withdrawn,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.

A bilingual version of this publication may be issued at a later date.

The contents of the corrigendum of August 2008 have been included in this copy.

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.

IEC 60050-801:1994 *International Electrotechnical Vocabulary – Chapter 801: Acoustics and electroacoustics*

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

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

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)*

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.

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

[IEC 62127-1, definition 3.2]

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**

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}
this is determined according to the procedure specified in IEC/TR 60854

NOTE This frequency is intended for continuous wave systems only.

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 $f_1 < f_2$.

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).

3.6
beam area
A_b
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

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** 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 are 0,25 and 0,01 for the −6 dB and −20 dB beam areas, respectively.

NOTE 4 Beam area is expressed in 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

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 **beamwidth**s 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).

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 standard, and if it is reasonable to assume **far field** conditions, the **instantaneous intensity**, *I* is approximated as

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

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 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