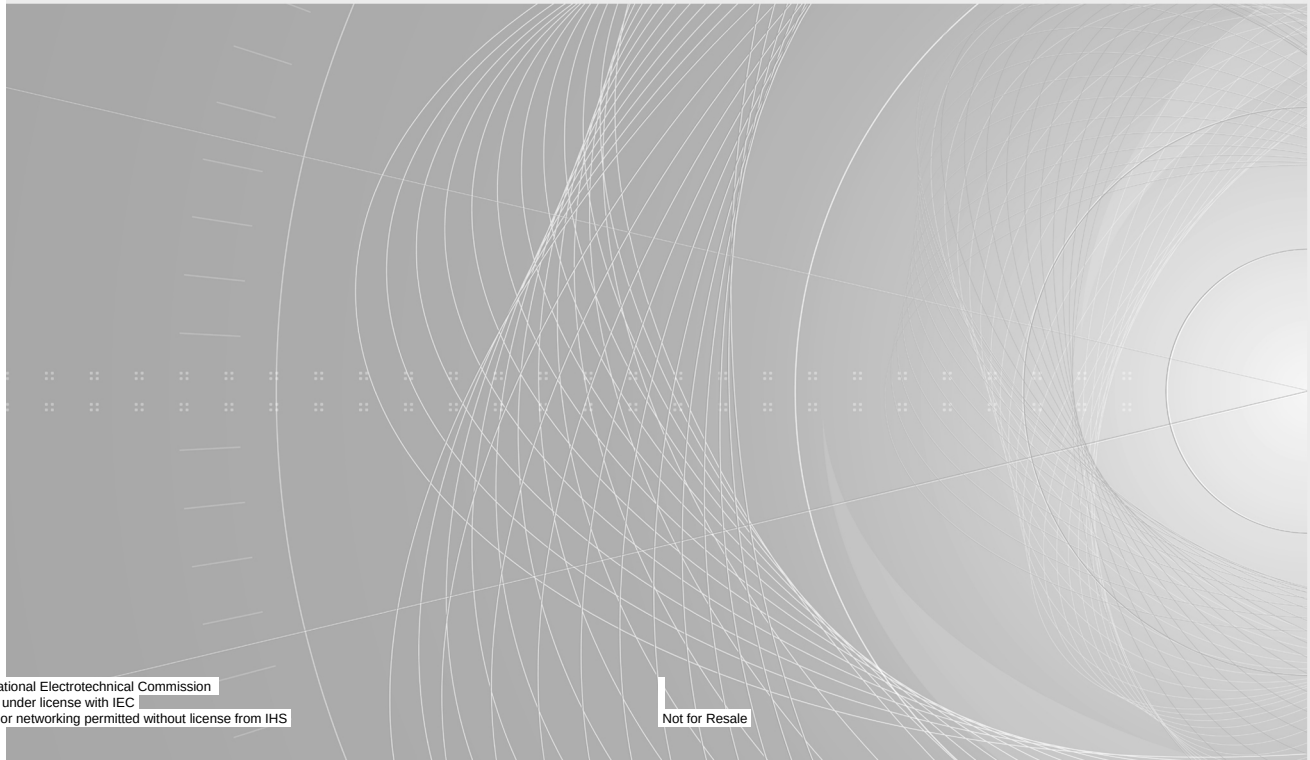
IEC 61157

Edition 2.0 2007-08

INTERNATIONAL STANDARD

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



IEC 61157:2007(E)

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

PRICE CODE V

ICS 11.040.50; 11.140.50

ISBN 2-8318-9257-0

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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- withdrawn,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.

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
$\boldsymbol{f_{awf}}$
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
$\boldsymbol{f_{awf}}$
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**.

[IEV 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 1 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

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

NOTE 1 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.

[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**

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 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 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**

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.

NOTE 4 See Figure C.4.

[IEC 62127-1, definition 3.44]

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

[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]

3.25
pulse repetition rate
prr
reciprocal of the **pulse repetition period**

NOTE 1 See also IEC 60469-1:1987, 5.3.2.2.

NOTE 2 The **pulse repetition rate** is expressed in hertz (Hz).

[IEC 62127-1, definition 3.51]

3.26
reference direction
for systems with scanning modes, the direction normal to the **beam axis** for an **ultrasonic scan line** and in the **scan plane**. For systems with only non-scanning modes, the direction normal to the **beam axis** and parallel to the direction of maximum −12 dB **beamwidth**

3.27
scan direction
for systems with scanning modes, the direction in the **scan plane** and perpendicular to a specified **ultrasonic scan line**

3.28
scan plane
for automatic scanning systems**,** a plane containing all the **ultrasonic scan lines.**

NOTE 1 See 62127-1, Figure 1.

NOTE 2 Some scanning systems have the ability to steer the ultrasound beam in two directions. In this case, there is no **scan plane** that meets this definition. However, it might be useful to consider a plane through the major-axis of symmetry of the ultrasound transducer and perpendicular to the transducer face (or another suitable plane) as being equivalent to the **scan plane**.

[IEC 62127-1, definition 3.56]

3.29
scan repetition period
srp
time interval between identical points on two successive frames, sectors or scans, applying to automatic scanning systems with a periodic scan sequence only

NOTE 1 In general, this standard assumes that an individual scan line repeats exactly after a number of acoustic pulses. In the case where an **ultrasonic transducer** or **ultrasonic transducer element group** radiates ultrasound without any sequence of repetition, it will not be possible to characterize a scanned mode in the way described in this standard. The approach described in Annex F of IEC 62127-1 can be useful when synchronization cannot be achieved.

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

[IEC 62127-1, definition 3.57]

3.30
scan repetition rate
srr
reciprocal of the scan repetition period

NOTE 1 The **scan repetition rate** is expressed in hertz (Hz).

[IEC 62127-1, definition 3.58]

3.31
spatial-peak temporal-average intensity
I_{spta}
maximum value of the **temporal-average intensity** in an acoustic field or in a specified plane

NOTE 1 For systems in **combined-operating mode,** the time interval over which the temporal average is taken is sufficient to include any period during which scanning may not be taking place.

NOTE 2 **Spatial-peak temporal-average intensity** is expressed in watts per metre squared (W/m^2).

[IEC 62127-1, definition 3.62]

3.32
temporal-average intensity
I_{ta}
time-average of the **instantaneous intensity** at a particular point in an acoustic field

NOTE 1 The time-average is taken normally over an integral number of **acoustic repetition periods**, if not, it should be specified.

NOTE 2 **Temporal-average intensity** is expressed in watts per metre squared (W/m^2).

[IEC 62127-1, definition 3.65]

3.33
transducer assembly
those parts of **medical diagnostic ultrasonic equipment** comprising the **ultrasonic transducer** and/or **ultrasonic transducer element group**, together with any integral components, such as an acoustic lens or integral stand-off

NOTE 1 The transducer assembly is usually separable from the ultrasound instrument console.

[IEC 62127-1, definition 3.69]

3.34
transducer output face
external surface of a **transducer assembly** which is either directly in contact with the patient or is in contact with a water or liquid path to the patient

NOTE See Figures C.1 and C.2.

3.35
transducer stand-off distance
z_{ts}
shortest distance between the **transducer output face** and the **patient entry plane**

NOTE 1 The term "contact" is used to connote direct contact between the **transducer output face** and the patient, with the **transducer stand-off distance** equal to zero.

NOTE 2 The transducer stand-off distance z_{ts} is expressed in metres (m).

NOTE 3 See Figure C.1.

3.36
transducer to transducer output face distance
z_{tt}
distance along the **beam axis** between the surface containing the active face of the **ultrasonic transducer** or **ultrasonic transducer element group** and the **transducer output face**

NOTE See Figures C.1 and C.2.

3.37
ultrasonic scan line
for scanning systems, the **beam axis** for a particular **ultrasonic transducer element group**, or for a particular excitation of an **ultrasonic transducer** or **ultrasonic transducer element group**

NOTE 1 Here, an ultrasonic scan line refers to the path of acoustic pulses and not to a line on an image on the display screen of a system.

NOTE 2 In general, this standard assumes that an individual scan line repeats exactly after a given number of acoustic pulses. In case an **ultrasonic transducer** or **ultrasonic transducer element group** radiates ultrasound without any sequence of repetition, it will not be possible to characterize a scanned mode in the way described in this standard. The approach described in Annex F of IEC 62127-1 can be useful when synchronization cannot be achieved.

NOTE 3 The case where a single excitation produces ultrasonic beams propagating along more than one **beam axis** is not considered.

[IEC 62127-1, definition 3.71]

3.38
ultrasonic scan line separation
s_s
for automatic scanning systems, the distance between the points of intersection of two consecutive **ultrasonic scan lines** of the same type and a specified line in the scan plane

NOTE 1 It is assumed here that consecutive ultrasonic scan lines are spatially adjacent; this is not true for all types of scanning equipment.

NOTE 2 The **ultrasonic scan line separation** is expressed in metres (m).

NOTE 3 See Figure C.3.

[IEC 62127-1, definition 3.72]

3.39
ultrasound instrument console
electronic unit to which the **transducer assembly** is attached

3.40
ultrasonic transducer
device capable of converting electrical energy to mechanical energy within the ultrasonic frequency range and/or reciprocally of converting mechanical energy to electrical energy

[IEC 62127-1, definition 3.73]

3.41
ultrasonic transducer element
element of an **ultrasonic transducer** that is excited in order to produce an acoustic signal

[IEC 62127-1, definition 3.74]

3.42
ultrasonic transducer element group
group of elements of an **ultrasonic transducer** which are excited together in order to produce an acoustic signal

[IEC 62127-1, definition 3.75]

3.43
ultrasonic transducer element group dimensions
dimensions of the surface of the group of elements of an **ultrasonic transducer** element group which includes the distance between the elements, hence representing the overall dimensions

NOTE 1 **Ultrasonic transducer element group dimensions** are expressed in metres (m).

NOTE 2 This direction is along the **central scan line** of a sector scan. When the **ultrasonic transducer** is symmetric, the **unsteered beam** may be chosen to be near the symmetry axis or a symmetry plane of the **ultrasonic transducer**.

[IEC 62127-1, definition 3.76]

Table 1 – List of symbols

Symbol	Term	Reference
arp	acoustic repetition period	IEC 62127-1
A_{ob}	output beam area	IEC 62127-1
f_{awf}	arithmetic-mean acoustic-working frequency	IEC 62127-1
$I_{ta}(z)$	temporal-average intensity	IEC 62127-1
$I_{spta}(z)$	spatial-peak temporal-average intensity	IEC 62127-1
I_{ob}	output beam intensity	IEC 62127-1
ppsi	pulse pressure squared integral	IEC 62127-1
p_r	peak-rarefactional acoustic pressure	IEC 62127-1
prp	pulse repetition period	IEC 62127-1
prr	pulse repetition rate	IEC 62127-1
srp	scan repetition period	IEC 62127-1
srr	scan repetition rate	IEC 62127-1
s_s	ultrasonic scan line separation	IEC 62127-1
X_{ob}, Y_{ob}	−12dB output beam dimensions	IEC 62127-1
z	axial distance from the source to a specified point	IEC 62127-1
z_{ts}	transducer stand-off distance	
z_{tt}	transducer to transducer output face distance	
w_{12}	−12 dB beamwidth	IEC 62127-1

4 Requirements

4.1 General

Statements of acoustic output shall be given in accordance with the specification given in Clause 7, 8.1 and 8.2 of IEC 62127-1 (see Clause 5 of this standard). The reporting of the information should be in accordance with the requirements of Clause 7 of this standard.

To simplify the tabulation of acoustical parameters, the following symbols may be used to indicate the various modes of operation of **medical diagnostic ultrasonic equipment:**

A	A-mode
B	Real-time B-mode
sB	Static B-mode
M	M-mode
D	Static pulsed Doppler mode
cwD	Continuous-wave Doppler mode (cw Doppler)
rD	Real-time flow-mapping Doppler mode (colour Doppler)
sD	Static flow-mapping Doppler mode
cM	Colour M-mode
B+M	B-mode combined with M-mode
B+D	B-mode combined with pulsed Doppler mode
B+rD	B-mode combined with real-time flow mapping Doppler mode
B+D+M	B-mode combined with pulsed Doppler mode and M-mode

Any **discrete-operating modes** or **combined-operating modes** other than those given above shall be identified by using similar notation; definitions shall be given where the meaning is not obvious by reference to the above list.

For all **discrete-operating modes**, the general requirements for reporting are:

- acoustic output information shall be given in accordance with 4.2;
- **inclusive modes** shall be stated (the **combined-operating modes** whose acoustic output parameters [p_r and I_{spta}] do not exceed the levels of this specified **discrete-operating mode**).

  NOTE The modes which make up the **combined-operating mode** do not necessarily include this specific **discrete-operating mode**.

For **combined-operating modes**, the general requirements for reporting are:

- acoustic output information shall be specified if the system can only operate in a **combined-operating mode;**
- acoustic output information shall be specified if the value of p_r or I_{spta} for any **combined-operating mode** is greater than the larger (or largest) of the corresponding values when the system is operating in the **discrete-operating modes;**
- if the acoustic output levels (p_r and I_{spta}) of a **combined-operating mode** are lower than the levels specified for a **discrete-operating mode** of a system**,** then the **combined-operating mode** shall be specified as an **inclusive mode** of the particular **discrete-operating mode,**

  NOTE When acoustic output information is specified for a **combined-operating mode**, it should be possible to achieve this by specifying the acoustic output of one or more dominant **discrete-operating modes**.

- a **combined-operating mode** is composed of a dominant **discrete-operating mode** if it consists of a sequence of acoustic pulses for which the acoustic output parameters (p_r and

I_{spta}) are determined by those pulses associated with one or more **discrete-operating mode**s which make up the **combined-operating mode.** In this case, the reporting of the acoustic output of the **combined-operating mode** shall be based on that for the dominant **discrete-operating mode**.

Some systems capable of operating only in **combined-operating modes** during clinical use may have internal test options which allow operation in **discrete-operating modes** for measurement purposes. For such systems**,** acoustic output information for the various types of acoustic pulses or **discrete-operating modes** can be determined. With the knowledge of the appropriate pulsing sequences for the **combined-operating modes,** it may be possible to make reliable estimates of the output of the **combined-operating modes.** This process of estimation may be applied in all cases where the output of **combined-operating modes** is to be determined.

A **discrete-** or **combined-operating mode** may consist of a sequence of acoustic pulses of different types used to generate one **ultrasonic scan line**, such as a system operating in multiple-focus mode. In this case, the acoustic pressure parameters shall be derived from the particular acoustic pulse in the sequence which yields the highest values of the acoustical output parameters. For instance, they would be determined from one particular focal-zone firing. However, I_{spta} would include contributions from all the focal zone firings and the overlap factors from neighbouring **ultrasonic scan lines**.

Two sets of acoustic pressure and derived intensity parameters may be necessary to specify the acoustic output of certain types of equipment if system settings yielding maximum acoustic pressure (p_r) differ from those settings which yield maximum derived intensities (I_{spta}). When two such sets of acoustic output parameters are necessary to specify the output of one operating mode in accordance with 4.2, a subscript shall be used to distinguish between the symbols used to denote the two sets of values. For example, in the case of some Doppler systems**,** symbol D_p would be used to refer to the parameters and settings which yield the maximum acoustic pressure parameters (p_r) whilst D_I would be used to denote those which yield the maximum intensity parameter (I_{spta}).

4.2 Requirements for the reporting of acoustic output information

Three standard formats for the distribution of acoustic output data are defined: technical data sheets, detailed operating mode data sheets, and background information.

4.2.1 Technical data sheets information format

The following format is defined for the reporting of information in the form of technical data sheets.

One set of values for the five parameters, a) to e) below, shall be given for each **transducer assembly** and **ultrasound instrument console**.

The maximum values of parameters a) to d) shall be chosen from the full information on all modes reported in accordance with 4.2.2. The reporting of data shall include reference to the mode which generates each of the reported maximum values.

a) Temporal-average power output. For scanning modes, this shall be the total power output of all the acoustic pulses. A statement shall be made as to whether the power output can be controlled by the user.

b) **Peak-rarefactional acoustic pressure** in the plane perpendicular to the **beam axis** containing the maximum **pulse-pressure-squared integral** (or maximum mean square acoustic pressure for continuous wave systems**)** in the whole ultrasonic field.

c) **Output beam intensity.**

d) **Spatial-peak temporal-average intensity** in the whole ultrasonic field.

e) **Nominal frequency.**

4.2.2 Detailed operating mode data sheets information format

The following format is defined for the presentation of detailed operating mode data sheets. Information shall be given only for all **discrete-operating modes** unless the system can operate only in **combined-operating modes**, in which case refer to 4.1.

The acoustical parameters a) to d) represent the maximum values for a particular **transducer assembly** and associated **ultrasound instrument console**. Where not specified, the rest of the parameters refer to the operating conditions which yield these maximum acoustic parameters.

NOTE See Annex A for an example of the reporting of the acoustic output information for an automatic scanning system.

The following information shall be reported.

a) Temporal-average power output. For scanning modes, this shall be the total power output of all the acoustic pulses.

b) **Peak-rarefactional acoustic pressure** (p_r) in the plane perpendicular to the **beam axis** containing the maximum **pulse-pressure-squared integral** (or maximum mean square acoustic pressure for continuous wave systems) in the whole ultrasonic field.

c) **Output beam intensity**, I_{ob}.

d) **Spatial-peak temporal-average intensity** (I_{spta}) in the whole ultrasonic field. For scanning modes, this shall be for the **central scan line** (including overlapping scan line contributions in accordance with IEC 62127-1).

e) **Ultrasound instrument console** settings (system settings) which yield the values specified in a) to d). If the system settings differ in a), b), c), or d) then the system settings shall be specified separately for the different parameters.

f) Distance (z_p) from the **transducer output face** to the point of maximum **pulse-pressure-squared integral** (or maximum mean square acoustic pressure for continuous wave systems).

   If the **spatial-peak temporal-average intensity** occurs at a position in the ultrasonic field other than the position corresponding to the maximum of the **pulse-pressure-squared integral** (or maximum mean square acoustic pressure for continuous wave systems), then the distance from the **transducer output face** to the point corresponding to the I_{spta} shall also be given.

   NOTE This can occur in multiple-focus and/or sector-scan systems.

g) **-12 dB beam-width** (w_{12}) at the point of maximum **pulse-pressure-squared integral** (or maximum mean square acoustic pressure for continuous wave systems). If the **beam-widths** in different directions differ by more than 10 % of the maximum **beam-width** then the **beam-widths** in two orthogonal directions shall be specified. These directions shall be parallel (||) and perpendicular (⊥) to the **reference direction**. For scanning modes, the **beam-widths** shall correspond to the **central scan line** only.

h) **Pulse repetition rate** (*prr*) for non-scanning modes or **pulse repetition rate** (*prr*) and **scan repetition rate** (*srr*) for scanning modes.

i) **Output beam dimensions**. Dimensions parallel (||) and perpendicular (⊥) to the **reference direction** shall be specified. For scanning modes, these shall refer to the **central scan line** only. In many cases, especially contact **systems,** these dimensions may be taken as the geometrical dimensions of the ultrasonic transducer or ultrasonic transducer element group.

j) **Arithmetic-mean acoustic-working frequency** (f_{awf}) measured by a hydrophone placed at the point of maximum **pulse-pressure-squared integral** (or maximum mean square acoustic pressure for continuous wave systems).

The following information should be reported.

k) **Acoustic output freeze**. If the system has **acoustic output freeze** then this shall be stated as "yes", otherwise it shall be stated as "no".

l) Transducer to transducer output face distance (z_{tt}), if appropriate.

m) Typical value for the **transducer stand-off distance** (z_{ts}). If the **transducer assembly** is normally used in contact with the patient then this shall be specified as a "contact" system.

If the system (front-panel) settings of the equipment (such as sample depth and sample volume length in Doppler systems) yielding the maximum acoustic pressure [b) above] differ from those which yield the maximum **spatial-peak temporal-average intensity** [d) above] then two groups of values for parameters b), d) to k) and m) shall be specified. One group shall contain the largest acoustic pressure p_r and system settings or system parameters whilst the second group shall contain the largest **spatial-peak temporal-average intensity** and the corresponding system settings or system parameters. However, each group shall give values for all the required parameters. This means that the reporting for the two groups of parameters would have the same entries for parameters a), c) and k) to m). This ensures that a set of numerical values for the acoustic parameters corresponding to a particular operating condition of the equipment are given; the set should be as complete as current understanding permits. For instance, one set of values would be given corresponding to the system settings which yield the maximum I_{spta}. Of these, the acoustic pressure would have a lower value than that of the second set which corresponds to the system settings which yield the maximum acoustic pressure.

As the system settings for the parameters a) and c) above may differ from those for the parameters b) or d), the maximum power and I_{ob} may be given, as shown in Table B.1. The corresponding system settings for the maximum power and I_{ob} may be given in a footnote or in a separate listing.

4.2.3 Background information

The following format is defined for the reporting of background information. Whenever background information is provided, the relevant information for each mode in accordance with 4.2.2 shall also be provided.

Where appropriate, the parameters refer to the operating conditions corresponding to the system settings which yield the maximum acoustic output levels referred to in 4.2.2. For automatic scanners which can operate only in a **combined-operating mode**, any information provided in accordance with 4.2.3.1 and 4.2.3.2 shall be for each of the various types of acoustic pulses associated with the **combined-operating mode**.

Where a mode consists of more than four different types of acoustic pulses, the background information shall be restricted to the four types of pulses which have the largest axial maximum **pulse-pressure-squared integral**.

4.2.3.1 All discrete-operating modes

The following information may be provided on request.

a) Axial plots of the variation of **peak-rarefactional acoustic pressure** (p_r) and **pulse-pressure-squared integral** (or mean square acoustic pressure for continuous wave systems) as a function of distance from the **transducer output face**. The axial plot shall extend from the **transducer output face** in a straight line collinear with the **beam axis** to a position approximately 1,3 times the distance from the **transducer output face** to the point of maximum **pulse-pressure squared integral** (maximum mean square acoustic pressure for continuous wave systems). The axial plot shall contain a minimum of five equally-spaced sample points and should include the point of maximum **pulse-pressure-squared integral** (or maximum mean square acoustic pressure for continuous wave systems).

NOTE The factor 1,3 is not critical and is chosen to ensure the axial plot extends beyond the maximum peak-positive acoustic pressure.

b) **Acoustic pulse waveform** at the point of maximum **pulse-pressure-squared integral** (or maximum mean square acoustic pressure for continuous wave systems) in the whole ultrasonic field.

c) **Bandwidth** of the **acoustic pulse waveform** measured by a hydrophone placed at the point of maximum **pulse-pressure-squared integral** (or maximum mean square acoustic pressure for continuous wave systems).

4.2.3.2 All scanning modes

The following information may be provided on request.

a) Number of **ultrasonic scan lines** during a **scan repetition period**.

b) **Ultrasonic scan line separation** at the point of maximum **pulse-pressure-squared integral**, measured in the **scan plane** in the **scan direction**.

c) Any other information necessary to specify the sequence of operation. For instance, the rate of rotation of the **scan plane**, if appropriate.

The following information should be provided on request.

d) Number of transducer excitations during a **scan repetition period**.

e) The pulse sequence during one **scan repetition period** for systems which can operate only in a **combined-operating mode**.

4.2.4 Diagnostic fields in the absence of scan-frame synchronization

The ultrasound fields generated by clinical imaging scanners have become increasingly complex as technology has advanced. Many parameters have been defined which attempt to describe the spatial and temporal variation of pressure and intensity in the ultrasound field. The definitions and the measurement procedures specified in the most widely-used national and international standards work well for **non-scanning mode** fields such as those used for pulsed Doppler or M-mode; however, it is becoming increasingly difficult to follow these standards for the enormously complicated pulse sequences generated in **scanning modes** such as colour-flow imaging.

A modified set of acoustic parameters which may be more appropriate to modern imaging equipment is specified in the informative Annex F of IEC 62127-1. In the table of results (see Clause 7) a note should be added in case measurements followed the methods of Annex F of IEC 62127-1. In this case, the methodology how to derive frequency from acquired raw data by digital oscilloscope with long time, typically 1 s, should be provided.

4.2.5 Dataset for low acoustic output equipment

A manufacturer may select an alternate data tabulation if the following conditions conform to:

For all operating modes for a particular combination of **transducer assembly** and **ultrasound instrument console**, the maximum probable values (see 5.2) of the **peak-rarefactional acoustic pressure, output beam intensity** and **spatial-peak temporal-average intensity** shall conform to the following three inequalities:

$p_r < 1$ MPa

$I_{ob} < 20$ mW/cm²

$I_{spta} < 100$ mW/cm²

For a **transducer assembly** and **ultrasound instrument console** which conforms to these three conditions, information reported in the technical data sheets shall include the maximum value of the **peak-rarefactional acoustic pressure**, the maximum value of the **output beam**

intensity, the maximum value of the **spatial-peak temporal-average intensity** and the **nominal frequency.** Table B.1 need not be completed.

5 Compliance statement

5.1 General

The acoustical parameters shall be chosen from those defined in this standard. To ensure traceability, the settings should be recorded of any controls on the equipment console which might affect the field generated.

For compliance with this standard, the following shall be stated for any parameter that is reported:

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;

and

b) the measurement uncertainty.

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 *Guide to the expression of uncertainty in measurement,* International Organisation for Standardization (ISO), Geneva, Switzerland, 1995, ISBN-92-67-10188-9, shall be followed.

5.2 Maximum probable values

A requirement of the type "shall conform to", for example in 4.2.5, means that the measurement uncertainty and tolerance interval shall be included when comparing against a limit. The maximum probable values shall be determined in accordance with the following procedure:

a) measurements shall be carried out on a group of *n* nominally identical systems, each with the acoustic output settings yielding the maximum output as referred to in 4.2;

b) the maximum probable value shall be calculated by linear summation of the upper tolerance limit of the one-sided tolerance interval (with 95 % confidence, for 95 % of the population) and the measurement uncertainty (at a level of confidence of 95 %).

The tolerance interval is to be understood in accordance with ISO 16269-6:2005. More guidance on assessment of uncertainties is given in IEC 62127-1, Annex I.

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

5.3 Sampling

For good manufacturing practice, measurements should be taken on a certain percentage of production but, exceptionally, could be taken on each manufactured unit.

For the purpose of determining the product variation of the reported parameters when full repeat measurements of all parameters are impractical, this variation may be estimated from partial repeat measurements (by repeating the measurement of a subset of the parameters).

Standard statistics on probability and confidence as given in ISO 16269-6:2005 shall apply.

6 Test methods

Acoustic output measurements should be undertaken using test methods based on the use of hydrophones in accordance with IEC 62127-1 and the use of radiation force balances for power measurements in accordance with IEC 61161.

7 Presentation of results

Information defined in 4.2.2 should be presented as follows:

- all information for a particular transducer should be presented on a single page;
- the name of the manufacturer should be given;
- the model and type number, together with any general description should be given;
- tabular information should be given with each column representing one operating mode (either a **discrete-** or **combined-operating mode**).

Additional acoustic output information can be supplied, such as spatial-peak pulse-average intensity (I_{sppa}) etc. In this case, extra rows should be provided in the tables.

The general format of the tabulations should follow the example given in Annex A.

Annex A
(normative)

Presentation of acoustic output information

For reasons of equality with related standards and improved measurement uncertainty the definition of the **output beam dimension** has changed compared to the previous version of the IEC 61157 standard. By this the value of the **output beam intensity** will change. To avoid misinterpretation by comparison of data reported in the past and in future, the standard used shall be clearly stated in the reporting tables as in Table A.1. The values reported are average values in accordance with 5.1.

This annex gives an example of the format for reporting the acoustic output of a 3,5 MHz phased-array sector scanner in accordance with this standard. The numbers included in Table A.1 are not taken from any particular system and are not, therefore, typical in any sense. The phased array can operate in B, M, B+M, D, B+D modes. Only the information for the three **discrete-operating modes**, B, M and D, is given. However, for the Doppler mode, two sets of data are given because the maximum **peak-rarefactional acoustic pressure**, p_r was found at different system settings from those which yielded the maximum value of I_{spta}. The Doppler information is therefore given in two columns headed D_p and D_I respectively in accordance with 4.1.

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

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**	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) (⊥) (mm)	1,2 ± 0,05 1,4 ± 0,05	1,2 ± 0,05 1,4 ± 0,05	1,3 ± 0,05 1,2 ± 0,05	1,4 ± 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)	–	0,8 ± 0,08	3,1 ± 0,3	6,0 ± 0,06
srr (Hz)	10 ± 0,5	––	–	
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 variation in the results may not be regarded as typical values or required limits but are inserted here only to provide an example for an appropriate reporting style. See 5.1 for their meaning.

Annex B
(informative)

Reporting requirements for extensive systems

The example given in Annex A would represent the typical reporting requirement for compliance with this standard in the case of a piece of **medical diagnostic ultrasonic equipment** capable of operating in three **discrete-operating modes** and at least two **combined-operating modes** and which can also generate a wide range of beam focusing for each scan line.

To provide further guidance on the reporting requirements of this standard for a system with many **ultrasonic transducers** and **combined-operating modes**, the following example is given.

Consider a system with 10 **ultrasonic transducers** all capable of operating in 11 or more modes. Four of the modes are the discrete B, M, rD and D-modes and the rest are **combined-operating modes.**

Assume that measurements had been made on all **ultrasonic transducers** and that for all modes the maximum values for p_r and I_{spta} and their respective system (front-panel) settings are known.

The need for reporting would be assessed as follows:

B — reporting is required as it is a **discrete-operating mode**. Two sets are required because p_r and I_{spta} correspond to different system settings;

M — reporting is required as it is a **discrete-operating mode**. One set of parameters is required because p_r and I_{spta} correspond to the same system settings;

D — reporting is required as it is a **discrete-operating mode**. Two sets of parameters are required because p_r and I_{spta} correspond to different system settings;

rD — reporting is required as it is a **discrete-operating mode** [Note that this is unusual as most colour-flow-mapping systems work in **combined-operating modes** as they utilize more than one diagnostic methodology]. Two sets of parameters are required because p_r and I_{spta} correspond to different system settings;

B+D
B+M
B+M+D
M+D
B+rD
M+rD
cM — reporting is only required if p_r for the particular **combined-operating mode** exceeds the largest value of p_r for the four **discrete-operating modes** or I_{spta} exceeds the largest value of I_{spta} for the four **discrete-operating modes**. In all these cases, the largest p_r occurs for the discrete B-mode and the largest I_{spta} occurs for the discrete D-mode. Therefore, none of these modes qualify for reporting. However, for B+M the values of p_r and I_{spta} are smaller than the corresponding values for the discrete M mode, hence B+M is an **inclusive mode** of M-mode and would be listed as such. Likewise, B+D, B+M+D and M+D are **inclusive modes** of D-mode. However, for modes B+rD, M+rD and cM, the values of p_r and I_{spta} are both smaller than the largest of the corresponding values for the four **discrete-operating modes**. In addition, the pair of values of p_r and I_{spta} for one of these three **combined-operating modes** is not both smaller than the corresponding values for any one of the four **discrete-operating modes**. Hence, modes B+rD, M+rD and cM do not satisfy the criterion for being **inclusive modes** and, as they also do not qualify for being reported as **combined-operating modes** in their own right, they are not reported at all.

For this system**,** the tabulation of data would therefore comprise seven columns for each probe (three double sets and one single), all data referring to **discrete-operating modes**. This could easily be accommodated on one page. For the example given above, 10 pages of data would be required for a system with all 10 **ultrasonic transducers**.

Annex C
(informative)

Rationale

There has been considerable discussion of the acoustic output levels of **medical diagnostic ultrasonic equipment** and the potentially harmful effects of the use of such equipment in medical practice.

The purpose of this standard is to provide a standard means for tabulating information on both the technical aspects of the characteristics of the ultrasonic field and to provide a set of traceable acoustic parameters. Information consists of three types. First, there is a small amount of information to be tabulated in the technical data sheets. Second, there is the information to be provided with each system consisting of a limited amount of information to describe the acoustic fields. Third, there is background information of a technical nature which provides basic data for the specialist.

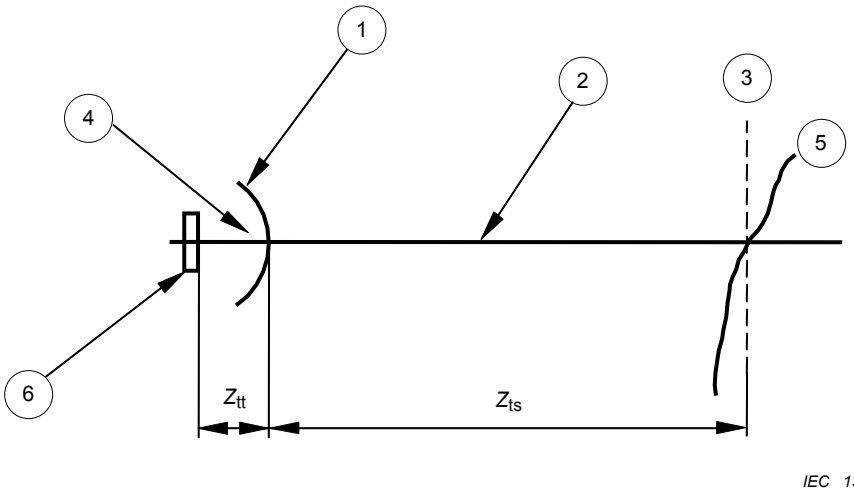
The information tabulated in this standard format can be used for a) exposure planning for biological effects studies, b) exposure data for prospective epidemiological studies conducted using exposure conditions similar to those reported in this standard. In the absence of actual exposure data for retrospective epidemiological studies, the information tabulated in this standard format might also be used with cautionary comment.

The reason for choosing the **peak-rarefactional acoustic pressure** is that it is most relevant for non-thermal effects of ultrasound whilst the total power, **output beam intensity** and **spatial-peak temporal-average intensity** together with beamwidth are most relevant for thermal effects

One of the major problems of characterizing ultrasonic fields propagating in water is associated with the distortion of the pulse waveform caused by finite amplitude (non-linear) effects. Consequently, the use of acoustical parameters measured in water combined with a linear attenuation model to predict ultrasonic exposure in tissue may be a serious error. Similarly, the acoustical parameters measured in water may suffer from errors due to "shock-loss". Consequently, care should be exercised in using acoustic output information. Nevertheless, until reliable and validated methods of measuring or predicting exposure in tissues are established, the measurement of ultrasonic fields in water is the only measurement method which can be regarded as a reference method.

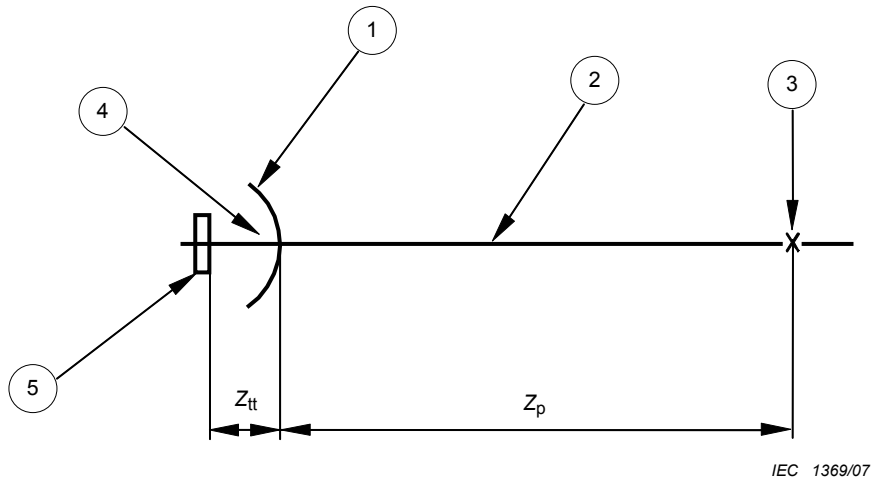
The philosophy of this standard is based on the derivation of acoustical parameters from axial plots of two acoustical parameters, **peak-rarefactional acoustic pressure** and **pulse-pressure-squared integral** (or mean square acoustic pressure for continuous wave systems**).** From these plots, the **peak-rarefactional acoustic pressure** at the axial position of the maximum of the **pulse-pressure-squared integral** is determined and used for the reporting requirements. The group of acoustical parameters chosen is intended to provide a full set of acoustical parameters from which others, not explicitly specified and given, may be derived with reasonable confidence. This process should give sufficient information on acoustic output to meet future requirements even though these requirements are not known at the time of preparation of this standard.

To avoid excessive and unnecessary documentation, the requirement of this standard is the reporting of the acoustic output information for the **discrete-operating modes** and the output for **combined-operating modes** only if their levels exceed those of any of the **discrete operating modes**, not necessarily those which make up the **combined-operating mode.**



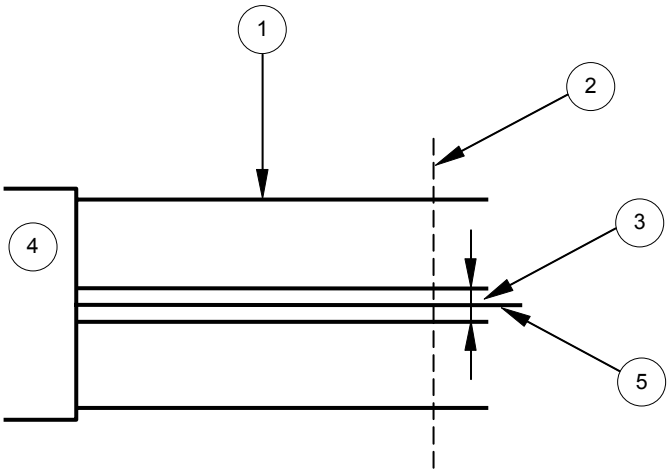
z_{ts} Transducer stand-off distance
z_{tt} Transducer to transducer output face distance
1: Transducer output face
2: Water path
3: Patient entry plane
4: Liquid path
5: Patient surface
6: Active element of transducer

Figure C.1 – Schematic diagram showing the relationship between the various defined surfaces and distances for a mechanical sector scanner with water stand-off distance when applied to a patient



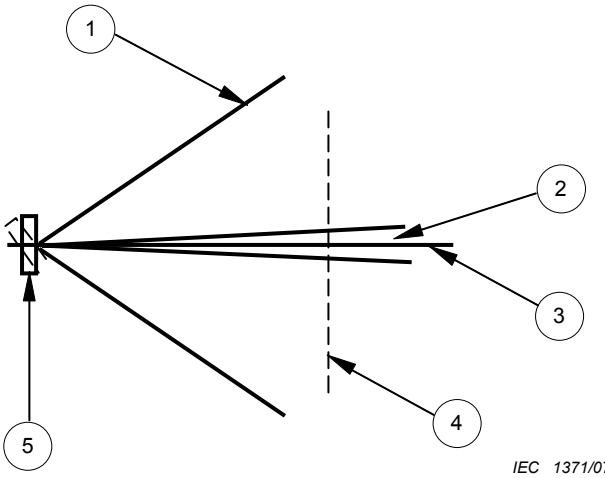
z_p Distance from the transducer output face to the point of maximum **pulse-pressure-squared integral**
z_{tt} Transducer to transducer output face distance
1: Transducer output face
2: Water path
3: Point of maximum **pulse-pressure-squared integral**
4: Liquid path
5: Active element of transducer

Figure C.2 – Schematic diagram showing the relationship between the various defined parameters and distances for a mechanical sector scanner during the measurement of acoustic output



1: ultrasonic scan line
2: specified plane (measurement plane)
3: ultrasonic scan line separation
4: linear array transducer
5: central scan line
6: scan direction

IEC 1370/07



1: ultrasonic scan line
2: ultrasonic scan line separation
3: central scan line
4: specified plane (measurement plane)
5: mechanical sector scanner

IEC 1371/07

Figure C.3 – Schematic diagram showing various defined parameters associated with the distribution of the scan lines in a linear array scanner and mechanically-scanned sector scanner

NOTE The specified plane refers to the plane, corresponding to the maximum **pulse-pressure-squared integral** (or maximum mean square acoustic pressure for continuous wave systems), in which measurements are made in accordance with IEC 62127-1.

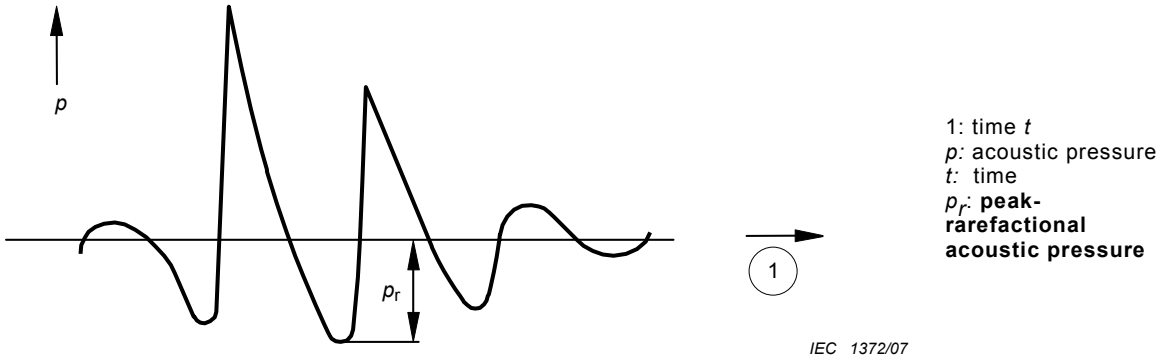


Figure C.4 – Schematic diagram illustrating the peak-rarefactional acoustic pressure during an acoustic pulse

Index of defined terms

Bibliography

IEC 60469-1, *Pulse techniques and apparatus – Part 1: Pulse terms and definitions*

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*

IEC 61828, *Ultrasonics – Focusing transducers – Definitions and measurement methods for the transmitted fields*

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