

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE



**Medical electrical equipment –**

**Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment**

**Appareils électromédicaux –**

**Partie 2-62: Exigences particulières pour la sécurité de base et les performances essentielles des appareils ultrasonores thérapeutiques de haute intensité (HITU)**



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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

**MEDICAL ELECTRICAL EQUIPMENT –****Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment**

## FOREWORD

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International standard IEC 60601-2-62 has been prepared by IEC subcommittee 62D: [Therapy equipment] Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice. It has been prepared in close co-operation with TC 87 (Ultrasonics).

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

|               |                  |
|---------------|------------------|
| FDIS          | Report on voting |
| 62D/1069/FDIS | 62D/1076/RVD     |

Full information on the voting for the approval of this particular 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.

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (\*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this 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

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- withdrawn,
- replaced by a revised edition, or
- amended.

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## INTRODUCTION

In this particular standard, safety requirements additional to those in the general standard are specified for HIGH INTENSITY THERAPEUTIC ULTRASOUND (HITU) EQUIPMENT.

This particular standard takes into account IEC 62555 and IEC/TS 62556.

The requirements are followed by specifications for the relevant tests.

A rationale for the more important requirements, where appropriate, is given in Annex AA. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of the particular standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However this annex does not form part of the requirements of this standard.

## MEDICAL ELECTRICAL EQUIPMENT –

### Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment

#### 201.1 Scope, object and related standards

Clause 1 of the general standard<sup>1)</sup> applies, except as follows:

##### 201.1.1 Scope

*Addition:*

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of HIGH INTENSITY THERAPEUTIC ULTRASOUND EQUIPMENT as defined in 201.3.218, hereafter referred to as ME EQUIPMENT.

This International Standard adds or replaces clauses listed in the IEC 60601-1 that are specific for HIGH INTENSITY THERAPEUTIC ULTRASOUND EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE 1 See also 4.2 of the general standard.

NOTE 2 As, in HITU fields, the acoustic waveform is expected to be extremely distorted due to non-linear propagation effects, the ultrasonic measurements are to be made under quasi linear conditions and then extrapolated following procedures given in IEC/TS 62556. See also IEC/TS 61949

This standard can also be applied to:

- therapeutic equipment for thrombolysis through exposure to high-intensity therapeutic ultrasound;
- therapeutic equipment for the treatment of occluding feeding vessels through exposure to high-intensity focused ultrasound;
- equipment intended to be used for relieving cancer pain due to bone metastases.

This particular standard does not apply to:

- ULTRASOUND EQUIPMENT intended to be used for physiotherapy (use: IEC 60601-2-5 [1]<sup>2)</sup> and IEC 61689);
- ULTRASOUND EQUIPMENT intended to be used for lithotripsy (use: IEC 60601-2-36 [2]);
- ULTRASOUND EQUIPMENT intended to be used for dedicated hyperthermia devices;
- ULTRASOUND EQUIPMENT intended to be used for phacoemulsification.

<sup>1)</sup> The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

<sup>2)</sup> Numbers in square brackets refer to the Bibliography.

### 201.1.2 Object

#### *Replacement:*

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for HIGH INTENSITY THERAPEUTIC ULTRASOUND (HITU) EQUIPMENT [as defined in 201.3.218.]

### 201.1.3 Collateral standards

#### *Addition:*

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2:2007 applies as modified in Clause 202. All other published collateral standards in the IEC 60601-1 series apply as published.

### 201.1.4 Particular standards

#### *Replacement:*

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this particular standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term “this standard” is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

## 201.2 Normative references

Clause 2 of the general standard applies, except as follows:

NOTE Informative references [3,4,5,6,7,8,9,10] are listed in the bibliography beginning on page 61.

### *Replacement:*

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

### *Addition:*

IEC 61689:2013, *Ultrasonics – Physiotherapy systems – Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz*

IEC/TS 61949, *Ultrasonics – Field characterization – In-situ exposure estimation in finite amplitude ultrasonic beams*

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

IEC 62127-2, *Ultrasonics – Hydrophones – Part 2: Calibration for ultrasonic fields up to 40 MHz*

IEC 62359, *Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields*

IEC 62555<sup>3)</sup>, *Ultrasonics – Power measurement – High intensity therapeutic ultrasound (HITU) transducers and systems*

IEC/TS 62556<sup>4)</sup>, *Ultrasonics – Field characterization – Specification and measurement of field parameters for high intensity therapeutic ultrasound (HITU) transducers and systems*

## 201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1, IEC 62359, IEC 62127-1 and IEC 61689, as well as the following additional terms and definitions apply:

---

3) To be published.

4) To be published.

NOTE 1 An index of defined terms is found after the Bibliography.

NOTE 2 A list of symbols used in this particular standard is found in Table 201.101

### 201.3.201

#### 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 to entry: This frequency is intended for pulse-wave equipment only.

Note 2 to entry: It is assumed that  $f_1 < f_2$ .

Note 3 to entry: 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 3dB below the peak magnitude.

Note 4 to entry: See IEC 62127-1 for methods of determining the ARITHMETIC-MEAN ACOUSTIC-WORKING FREQUENCY.

[SOURCE: IEC 62127-1:2007 + Am1:2013, 3.3.2, modified – a note to entry has been added.]

### 201.3.202

#### BEAM AREA

$A_{b6}, A_{b20}$

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 to entry: 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.

Note 2 to entry: In a number of cases, the term PULSE-PRESSURE-SQUARED INTEGRAL is replaced everywhere in the above definition by any linearly related quantity, e.g.:

- 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 to entry: Some specified fractions are 0,25 and 0,01 for the -6 dB and -20 dB beam areas, respectively.

Note 4 to entry: Beam area is expressed in square metres (m<sup>2</sup>).

[SOURCE: IEC 62127-1:2007 + Am1:2013, 3.7, modified – the symbol has been changed]

### 201.3.203

#### 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 TRANSDUCER OUTPUT FACE

Note 1 to entry: 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 to entry: In a number of cases, the term PULSE-PRESSURE-SQUARED INTEGRAL is replaced in the above definition by any linearly related quantity, e.g.:

- 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.

[SOURCE: IEC 62127-1: 2007, 3.8, modified – EXTERNAL TRANSDUCER APERTURE replaced by TRANSDUCER OUTPUT FACE in the definition].

### 201.3.204

#### BEAM CENTREPOINT

position determined by the intersection of two lines passing through the BEAM WIDTH MIDPOINTS of two orthogonal planes, xz and yz

[SOURCE: IEC 61828:2001, 4.2.13]

### 201.3.205

#### \*BEAM WIDTH AT FOCUS

#### BEAM WIDTH AT BEAM MAXIMUM

$w_{6m}$

greatest distance between two points on a specified axis, perpendicular to the BEAM AXIS and at  $z_{spta}$  where the PULSE-PRESSURE-SQUARED INTEGRAL falls below its maximum on the specified axis by 6 dB

Note 1 to entry: In a number of cases, the term PULSE-PRESSURE-SQUARED INTEGRAL is replaced in the above definition by any linearly related quantity, e.g.: 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,

Note 2 to entry: BEAM WIDTH AT FOCUS or BEAM WIDTH AT BEAM MAXIMUM is expressed in metres (m).

[SOURCE: IEC 62127-1: 2007, 3.11, modified – here it concerns the -6dB beamwidth as defined in IEC62127-1]

### 201.3.206

#### BEAMWIDTH MIDPOINT

linear average of the location of the centres of BEAMWIDTHS in a plane

Note 1 to entry: The average is taken over as many BEAMWIDTH levels given in Table B.2 in IEC 61828 as signal level permits.

[SOURCE: IEC 61828:2001, 4.2.17, modified – the second sentence of the definition has been transformed into a note to entry.].

### 201.3.207

#### DISTANCE $z_{spta}$

$z_{spta}$

distance along the BEAM AXIS between the plane containing the SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY and the TRANSDUCER OUTPUT FACE

Note 1 to entry: In practice DISTANCE  $z_{spta}$  is equal to the distance where the maximum PULSE-PRESSURE SQUARED INTEGRAL occurs. In a number of cases, the term PULSE-PRESSURE-SQUARED INTEGRAL is replaced by any linearly related quantity, e.g.: 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,

Note 2 to entry: The DISTANCE  $z_{spta}$  is expressed in metres (m).

[SOURCE: IEC 62127-1: 2007, 3.18, modified – EXTERNAL TRANSDUCER APERTURE has been replaced by TRANSDUCER OUTPUT FACE in the definition and the first note to entry has been expanded.]

### 201.3.208

#### DISTANCE $z_{slpta}$

$z_{slpta}$

distance along the BEAM AXIS between the plane containing the SIDE-LOBE PEAK TEMPORAL-AVERAGE INTENSITY and the TRANSDUCER OUTPUT FACE

Note 1 to entry: The DISTANCE  $z_{slpta}$  is expressed in metres (m).

[SOURCE: IEC/TS 62556:----, 3.19 SOURCE APERTURE PLANE has been replaced by TRANSDUCER OUTPUT FACE]

### 201.3.209

#### DISTANCE $z_E$

#### $z_E$

distance along the BEAM AXIS between the PATIENT ENTRY PLANE and the TRANSDUCER OUTPUT FACE

Note 1 to entry: The DISTANCE  $z_E$  is expressed in metres (m).

[SOURCE: IEC/TS 62556:----, 3.14, modified – EXTERNAL TRANSDUCER APERTURE PLANE has been replaced by TRANSDUCER OUTPUT FACE.]

### 201.3.210

#### DISTANCE $z_r$

#### $z_r$

distance along the BEAM AXIS between the plane containing the PEAK-RAREFACTIONAL ACOUSTIC PRESSURE and the TRANSDUCER OUTPUT FACE

Note 1 to entry: The DISTANCE  $z_r$  is expressed in metres (m).

[SOURCE: IEC 62127-1: 2007, 3.15, modified – EXTERNAL TRANSDUCER APERTURE has been replaced by TRANSDUCER OUTPUT FACE]

### 201.3.211

#### DISTANCE $z_T$

#### TRANSITION DISTANCE

#### $z_T$

for a given LONGITUDINAL PLANE, the TRANSITION DISTANCE is defined based on the transducer design (when known) or from measurement:

- from design: the TRANSITION DISTANCE is the equivalent area of the ultrasonic TRANSDUCER APERTURE WIDTH divided by  $\pi$  times the EFFECTIVE WAVELENGTH,  $\lambda$ ;
- for measurements, the TRANSITION DISTANCE is the equivalent area of the TRANSDUCER APERTURE WIDTH divided by  $\pi$  times the EFFECTIVE WAVELENGTH.

Note 1 to entry: Using method a), an unapodized ULTRASONIC TRANSDUCER with circular symmetry about the BEAM AXIS, the equivalent area is  $\pi a^2$ , where  $a$  is the radius. Therefore the TRANSITION DISTANCE is  $z_T = a^2/\lambda$ . For the first example of a square ULTRASONIC TRANSDUCER, the equivalent area is  $(L_{TA})^2$ , where  $L_{TA}$  is the TRANSDUCER APERTURE WIDTH in the LONGITUDINAL PLANE. Therefore, the TRANSITION DISTANCE for both orthogonal LONGITUDINAL PLANES containing the sides or TRANSDUCER APERTURE WIDTHS, is  $z_T = (L_{TA})^2 / (\pi\lambda)$ . For the second example, for a rectangular ULTRASONIC TRANSDUCER with TRANSDUCER APERTURE WIDTHS  $L_{TA1}$  and  $L_{TA2}$ , the equivalent area for the first linear transducer aperture width for the purpose of calculating the TRANSITION DISTANCE for the associated LONGITUDINAL PLANE is  $(L_{TA1})^2$ , where  $L_{TA1}$  is the TRANSDUCER APERTURE WIDTH in this LONGITUDINAL PLANE. Therefore, the TRANSITION DISTANCE for this plane is  $z_{T1} = (L_{TA1})^2 / (\pi\lambda)$ . For the orthogonal LONGITUDINAL PLANE that contains the other TRANSDUCER APERTURE WIDTH,  $L_{TA2}$ , the equivalent area for the other for the purpose of calculating the transition distance for the associated LONGITUDINAL PLANE is  $(L_{TA2})^2$ , where  $L_{TA2}$  is the TRANSDUCER APERTURE WIDTH in this LONGITUDINAL PLANE. Therefore, the TRANSITION DISTANCE for this plane is  $z_{T2} = (L_{TA2})^2 / (\pi\lambda)$ .

Note 2 to entry: Using method b) for measurements in a longitudinal plane, the TRANSDUCER APERTURE WIDTH,  $L_{SA}$ , in the same plane is used in  $z_T = (L_{SA})^2 / (\pi\lambda)$ .

Note 3 to entry: TRANSITION DISTANCE is expressed in metres (m).

[SOURCE: IEC 62127-1:2007, Am1:2013, 3.88, modified – in Note 2 to entry, SOURCE APERTURE WIDTH has been replaced by TRANSDUCER APERTURE WIDTH. ]

### 201.3.212

#### ENTRY POWER

#### $P_E(z_E)$

time-average ultrasonic power measured under approximate free field conditions at the DISTANCE  $z_E$  of the PATIENT ENTRY PLANE in a specified medium, preferably in water

Note 1 to entry: For measurement purposes the PATIENT ENTRY PLANE is the position along the BEAM AXIS where ultrasound in normal use enters the PATIENT

Note 2 to entry: ENTRY POWER is expressed in watt (W),

Note 3 to entry: OUTPUT POWER is defined in 201.3.223.

### 201.3.213

#### ENTRY EFFECTIVE INTENSITY

$I_{\text{Eeff}}$   
intensity given by  $I_{\text{Eeff}} = P_{\text{E}}/A_{\text{EB}}$  where  $P_{\text{E}}$  is the ENTRY POWER and  $A_{\text{EB}}$  is the ENTRY BEAM AREA

Note 1 to entry: ENTRY EFFECTIVE INTENSITY is expressed in watts per square metre ( $\text{W/m}^2$ )

### 201.3.214

#### ENTRY BEAM AREA

$A_{\text{EB}}$   
area of the ultrasonic beam equal to the -12 dB BEAM AREA at the PATIENT ENTRY PLANE

Note 1 to entry: For reasons of measurement accuracy, the -12 dB ENTRY BEAM AREA may be derived from measurements at a distance chosen to be as close as possible to the face of the transducer or PATIENT ENTRY PLANE, if different, and, if possible, no more than 1 mm from the face or PATIENT ENTRY PLANE, if different,

Note 2 to entry: For contact transducers, this area can be taken as the geometrical area of the ULTRASONIC TRANSDUCER or ULTRASONIC TRANSDUCER ELEMENT GROUP,

Note 3 to entry: The ENTRY BEAM AREA is expressed in square metres ( $\text{m}^2$ ).

### 201.3.215

#### \*FOCAL DEPTH

#### BEAM MAXIMUM DEPTH

$L_6$   
greatest distance between two points on the BEAM AXIS where the PULSE-PRESSURE-SQUARED INTEGRAL falls below its maximum on the BEAM AXIS by 6 dB

Note 1 to entry: In a number of cases, the term PULSE-PRESSURE-SQUARED INTEGRAL is replaced in the above definition by any linearly related quantity, e.g.: 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,

Note 2 to entry: FOCAL DEPTH or BEAM MAXIMUM DEPTH is expressed in metres (m).

[SOURCE: IEC/TS 62556:----, 3.15, modified – the term, the definition and the notes to entry have all been modified.]

### 201.3.216

#### \*FOCAL POINT

#### BEAM MAXIMUM POINT

position on the BEAM AXIS where the maximum PULSE-PRESSURE-SQUARED INTEGRAL is measured

Note 1 to entry: In a number of cases, the term PULSE-PRESSURE-SQUARED INTEGRAL is replaced in the above definition by any linearly related quantity, e.g.: 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.

[SOURCE: IEC/TS 62556:----, 3.12]

### 201.3.217

#### \*FOCAL VOLUME

#### BEAM MAXIMUM VOLUME

$V_{\text{foc}}$   
volume in a specified space consisting of all points at which the PULSE-PRESSURE-SQUARED INTEGRAL is greater than - 6 dB of the PULSE-PRESSURE-SQUARED INTEGRAL value in the FOCAL POINT or BEAM MAXIMUM POINT

Note 1 to entry: In a number of cases, the term PULSE-PRESSURE-SQUARED INTEGRAL is replaced in the above definition by any linearly related quantity, e.g.: 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,

Note 2 to entry: FOCAL VOLUME or BEAM MAXIMUM VOLUME is expressed in cubic metres (m<sup>3</sup>).

[SOURCE: IEC/TS 62556:----, 3.13]

### 201.3.218

#### \* HIGH INTENSITY THERAPEUTIC ULTRASOUND (HITU) EQUIPMENT (hereinafter referred to as ME EQUIPMENT)

EQUIPMENT for the generation and application of ultrasound to a PATIENT for therapeutic purposes with the intention to destroy, disrupt or denature living tissues or non-tissue elements (for example liquids, bubbles, micro-capsules) and which aims notably at making treatments through actions of ultrasound having mechanical, thermal or more generally physical, chemical or biochemical effects

Note 1 to entry: Essentially HITU Equipment comprises a generator of electric high-frequency power and a transducer for converting this to ULTRASOUND. In a lot of cases this equipment also includes a targeting and monitoring device,

Note 2 to entry: HITU Equipment may as a side effect induce hyperthermia, however it should not be confused with this technique, which heats much less rapidly and to much lower therapeutic temperatures (in general 42 °C to 50 °C and thermal equivalent times of 0,2 min to 120 min). HITU Equipment typically causes temperature rises in excess of 55°C and for much shorter times, alternatively, HITU may also induce bioeffects by non-thermal mechanisms.

Note 3 to entry: This definition does not apply to: ULTRASOUND EQUIPMENT used for physiotherapy, ULTRASOUND EQUIPMENT used for lithotripsy or ULTRASOUND EQUIPMENT used for dedicated hyperthermia.

Note 4 to entry: See Annex AA for a few examples of equipment for which this standard should be used.

### 201.3.219

#### INVASIVE TRANSDUCER ASSEMBLY

a transducer which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body

### 201.3.220

#### LOCALIZATION DEVICE

device used to determine the position of the REGION OF INTEREST in (three-dimensional) space.

Note 1 to entry: Localization devices are e.g. a MRI or ultrasound imaging system.

### 201.3.221

#### LONGITUDINAL PLANE

the plane defined by the BEAM AXIS and a specified orthogonal axis

### 201.3.222

#### \*ORTHOGONAL BEAM WIDTH AT FOCUS

#### ORTHOGONAL BEAM WIDTH AT BEAM MAXIMUM

$w_{60}$

greatest distance between two points on a specified axis, perpendicular to the BEAM AXIS and at  $z_{spta}$  where the PULSE-PRESSURE-SQUARED INTEGRAL falls below its maximum on the specified axis by 6 dB in the direction perpendicular to the direction of the BEAM WIDTH AT FOCUS or BEAM WIDTH AT BEAM MAXIMUM

Note 1 to entry: In a number of cases, the term PULSE-PRESSURE-SQUARED INTEGRAL is replaced in the above definition by any linearly related quantity, e.g.: 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,

Note 2 to entry: ORTHOGONAL BEAM WIDTH AT FOCUS or ORTHOGONAL BEAM WIDTH AT BEAM MAXIMUM is expressed in metres (m).

**201.3.223****OUTPUT POWER** $P$ 

time-average ultrasonic power emitted by an ULTRASONIC TRANSDUCER into an approximately free field under specified conditions in a specified medium, preferably in water

Note 1 to entry: OUTPUT POWER is expressed in watt (W),

Note 2 to entry: See IEC 62555 for methods of determining the OUTPUT POWER.

[SOURCE: IEC 61161: 2013, 3.3]

**201.3.224****PATIENT ENTRY PLANE**

plane perpendicular to the BEAM AXIS, which passes through the point on the BEAM AXIS at which the ultrasound enters the PATIENT

Note 1 to entry: See figure 1.

[SOURCE: IEC 61157: 2007, 3.21, modified: axis of symmetry of the scan plane deleted ]

**201.3.225****PEAK-COMPRESSIONAL ACOUSTIC PRESSURE** $p_c$  (or  $p_+$ )

maximum positive INSTANTANEOUS ACOUSTIC PRESSURE in an acoustic field or in a specified plane during an ACOUSTIC REPETITION PERIOD

Note 1 to entry: PEAK-COMPRESSIONAL ACOUSTIC PRESSURE is expressed in pascals (Pa),

Note 2 to entry: The definition of PEAK-COMPRESSIONAL ACOUSTIC PRESSURE also applies to peak-positive acoustic pressure, an equivalent term which is also in use in literature.

[SOURCE: IEC 62127-1: 2007, 3.45]

**201.3.226****PEAK-RAREFACTIONAL ACOUSTIC PRESSURE** $p_r$  (or  $p_-$ )

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 to entry: PEAK-RAREFACTIONAL ACOUSTIC PRESSURE is expressed as a positive number,

Note 2 to entry: PEAK-RAREFACTIONAL ACOUSTIC PRESSURE is expressed in pascals (Pa),

Note 3 to entry: The definition of PEAK-RAREFACTIONAL ACOUSTIC PRESSURE also applies to peak-negative acoustic pressure which is also in use in literature.

[SOURCE: IEC 62127-1: 2007, 3.44]

**201.3.227****PHYSIOLOGICAL SIMULATION FREQUENCY**

fundamental frequency of a signal, electrical or non-electrical, used to simulate a physiological parameter such that the ME EQUIPMENT or ME SYSTEM will operate in a manner consistent with use on a PATIENT

[SOURCE: IEC 60601-1-2, 3.22]

**201.3.228****POSITIONING DEVICE**

device which aligns the part(s) of the ultrasonic beam associated with the intended therapeutic effect with the TARGET LOCATION

Note 1 to entry: A POSITIONING DEVICE usually comprises a device that positions, either by mechanical, manual or electronic means.

### 201.3.229

#### PRE-FOCAL PEAK TEMPORAL-AVERAGE INTENSITY

$I_{\text{pfpta}}$

the largest local maximum of the TEMPORAL-AVERAGE INTENSITY on the BEAM AXIS which is not within the - 6 dB FOCAL VOLUME or BEAM MAXIMUM VOLUME and is located between the TRANSDUCER OUTPUT FACE and the FOCAL VOLUME or BEAM MAXIMUM VOLUME

Note 1 to entry: Pre-focal peak temporal-average intensity is expressed in watts per square metre (W/m<sup>2</sup>).

[SOURCE: IEC/TS 62556:---, 3.64, modified – SOURCE APERTURE PLANE has been replaced by TRANSDUCER OUTPUT FACE ]

### 201.3.230

#### RATIO PEAK TO TEMPORAL AVERAGE INTENSITY

$R_{\text{Ipta}}$

the RATIO PEAK TO TEMPORAL AVERAGE INTENSITY is given by:

$$R_{\text{Ipta}} = \frac{I_{\text{w},\Delta t/s}(t)}{I_{\text{spta}}}$$

where

$I_{\text{w},\Delta t/s}(t)$  is the TIME-WINDOW-AVERAGE INTENSITY;

$I_{\text{spta}}$  is the SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY.

Both  $I_{\text{w},\Delta t/s}(t)$  and  $I_{\text{spta}}$  are measured at a specified point on the BEAM AXIS

Note 1 to entry: Determination in a distorted signal should be avoided, e.g. by measuring following the guidelines given in IEC/TS 62556.

### 201.3.231

#### REGION OF INTEREST

localized part of an image, which is of particular interest at a given time

[SOURCE: IEC 62464-1, 3.1.23]

### 201.3.232

#### SIDE-LOBE PEAK TEMPORAL-AVERAGE INTENSITY

$I_{\text{slpta}}$

maximum value of the TEMPORAL AVERAGE INTENSITY measured at a local maximum which is not within the - 6 dB FOCAL VOLUME (for focusing transducers) or BEAM MAXIMUM VOLUME (for non-focusing transducers)

Note 1 to entry: Annex DD provides useful information to determine regions of HITU fields,

Note 2 to entry: Several options on how to determine the SIDE-LOBE PEAK TEMPORAL-AVERAGE INTENSITY are given in the IEC/TS 62556,

Note 3 to entry: SIDE-LOBE PEAK TEMPORAL-AVERAGE INTENSITY is expressed in watts per square metre (W/m<sup>2</sup>).

[SOURCE: IEC/TS 62556:---, 3.79, modified – two notes to entry have been added.]

### 201.3.233

#### SIDE-WALL OF A TREATMENT HEAD

the APPLIED PART of the TREATMENT HEAD excluding the TRANSDUCER OUTPUT FACE

**201.3.234****SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY** **$I_{\text{spta}}$** 

maximum value of the TEMPORAL-AVERAGE INTENSITY in an acoustic field or in a specified plane

Note 1 to entry: SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY is expressed in watts per square metre ( $\text{W}/\text{m}^2$ ).

[SOURCE: IEC 62127-1: 2007, 3.62, modified – a note to entry has been deleted.]

**201.3.235****SPATIAL-PEAK PULSE-AVERAGE INTENSITY** **$I_{\text{sppa}}$** 

maximum value of the PULSE-AVERAGE INTENSITY in an acoustic field or in a specified plane

Note 1 to entry: SPATIAL-PEAK PULSE-AVERAGE INTENSITY is expressed in watts per square metre ( $\text{W}/\text{m}^2$ ).

[SOURCE: IEC 62127-1: 2007, 3.60]

**201.3.236****TARGET LOCATION**

location in the patient where the therapeutic effect is intended

**201.3.237****TARGET MARKER**

marker, on the imaging display, which is used to indicate the TARGET LOCATION

**201.3.238****TEMPORAL-AVERAGE INTENSITY** **$I_{\text{ta}}$** 

time-average of the INSTANTANEOUS INTENSITY at a particular point in an acoustic field

Note 1 to entry: The time-average is taken normally over an integral number of ACOUSTIC REPETITION PERIODS, if not it should be specified,

Note 2 to entry: TEMPORAL-AVERAGE INTENSITY is expressed in watts per square metre ( $\text{W}/\text{m}^2$ ).

[SOURCE: IEC 62127-1:2007, 3.65]

**201.3.239****TEMPORAL-MAXIMUM OUTPUT POWER** **$P_{\text{tm}}$** 

in the case of a pulsed wave mode, the TEMPORAL-MAXIMUM OUTPUT POWER is the maximum value of the OUTPUT POWER during a specified time and given by:

$$P_{\text{tm}} = R_{\text{Ipta}} \cdot P \quad (3)$$

where

 $P$  is the actual OUTPUT POWER in the pulse wave mode;

Note 1 to entry: TEMPORAL-MAXIMUM OUTPUT POWER is expressed in watt (W).

[SOURCE: IEC 61689:2013, 3.39, modified – the definition is different including an editorial change in the formula]

**201.3.240****TEMPORAL-PEAK ACOUSTIC PRESSURE** **$p_{\text{tp}}$** 

maximum value of the modulus of the INSTANTANEOUS ACOUSTIC PRESSURE at a particular point in an acoustic field

Note 1 to entry: TEMPORAL-PEAK ACOUSTIC PRESSURE is expressed in pascals (Pa).

[SOURCE: IEC 62127-1:2007,3.67]

### 201.3.241

#### TIME-WINDOW-AVERAGE INTENSITY

$I_{w,\Delta t/s}(t)$

the time-varying value of the INSTANTANEOUS INTENSITY averaged over a window of duration  $\Delta t$ , given by:

$$I_{w,\Delta t/s}(t) = \frac{1}{\Delta t} \int_{t-\Delta t/2}^{t+\Delta t/2} I(t') dt' \quad (25)$$

where:

$I(t)$  is the INSTANTANEOUS INTENSITY;

$\Delta t/s$  is the numerical value of the moving time window width in seconds

$t'$  is the variable of integration

Note 1 to entry: The time varying TIME-WINDOW-AVERAGE INTENSITY for a time window width of 20 s, for instance, is denoted by  $I_{w,20}(t)$

[SOURCE: IEC 62127-1:2007, Am1:2013, 3.86]

### 201.3.242

#### THERMALLY EQUIVALENT TIME

$t_{43}$

the duration of exposure at a constant temperature of 43 °C required to produce the magnitude of a thermally induced bio-effect, i.e., an "iso-effect", as is produced by an exposure of duration  $t_f$  at a different temperature  $T$  that may vary in time.

The THERMALLY EQUIVALENT TIME ( $t_{43}$ ) is defined mathematically as:

$$t_{43}(T_0, t_f) = \int_0^{t_f} R^{k(T(t)-T_0)} dt$$

where:

$t_{43}$  = THERMALLY EQUIVALENT TIME

$k$  =  $(1\text{ }^{\circ}\text{C})^{-1}$ , a constant to render the exponent dimensionless

$T_0$  = reference temperature of 43 °C

$T(t)$  = temperature (which may vary in time) producing the bioeffect

$t$  = time

$t_f$  = time required to produce the bioeffect at temperature  $T$

$R$  = 4,0 if  $T \leq 43\text{ }^{\circ}\text{C}$

$R$  = 2,0 if  $T > 43\text{ }^{\circ}\text{C}$

Note 1 to entry: See Annex D

### 201.3.243

#### 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 to entry: The TRANSDUCER ASSEMBLY is usually separable from the ultrasound instrument console.

[SOURCE: IEC 62127-1, 3.69]

**201.3.244****TRANSDUCER APERTURE PLANE**

the closest possible measurement plane to the external transducer aperture, that is perpendicular to the BEAM AXIS

[SOURCE: IEC 61828, 4.2.72, modified – the definition is different.]

**201.3.245****TRANSDUCER APERTURE WIDTH**

$L_{TA}$

full width of the TRANSDUCER APERTURE along a specified axis orthogonal to the BEAM AXIS of the unsteered beam

Note 1 to entry: See Figure 2,

Note 2 to entry: TRANSDUCER APERTURE WIDTH is expressed in metres (m).

[SOURCE: IEC 61828:2001, 4.2.74]

**201.3.246****TREATMENT HEAD**

assembly comprising an ULTRASONIC TRANSDUCER and associated parts for local application of ULTRASOUND to the PATIENT

Note 1 to entry: A TREATMENT HEAD is also referred to as an applicator.

[SOURCE: IEC 60601-2-5, 201.3.214]

**201.3.247****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 1 to entry: See Figure 201.101.

[SOURCE: IEC 61157:2007, 3.34]

**201.3.248****ULTRASOUND**

acoustic oscillation whose frequency is above the high-frequency limit of audible sound (about 20 kHz)

[SOURCE: IEC 60050-802:2011, 802-01-01]

**201.3.249****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

[SOURCE: IEC 62127-1:2007, 3.73]

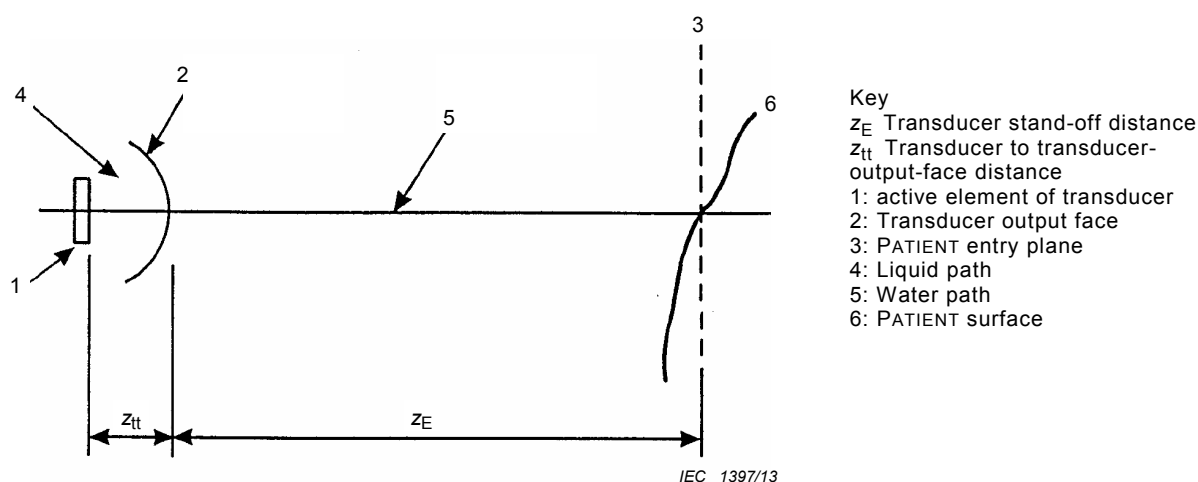


**Figure 201.101 – Schematic diagram showing the relationship between the various defined surfaces and distances for an ULTRASONIC TRANSDUCER with water stand-off distance when applied to a PATIENT [IEC 61157:2007]**

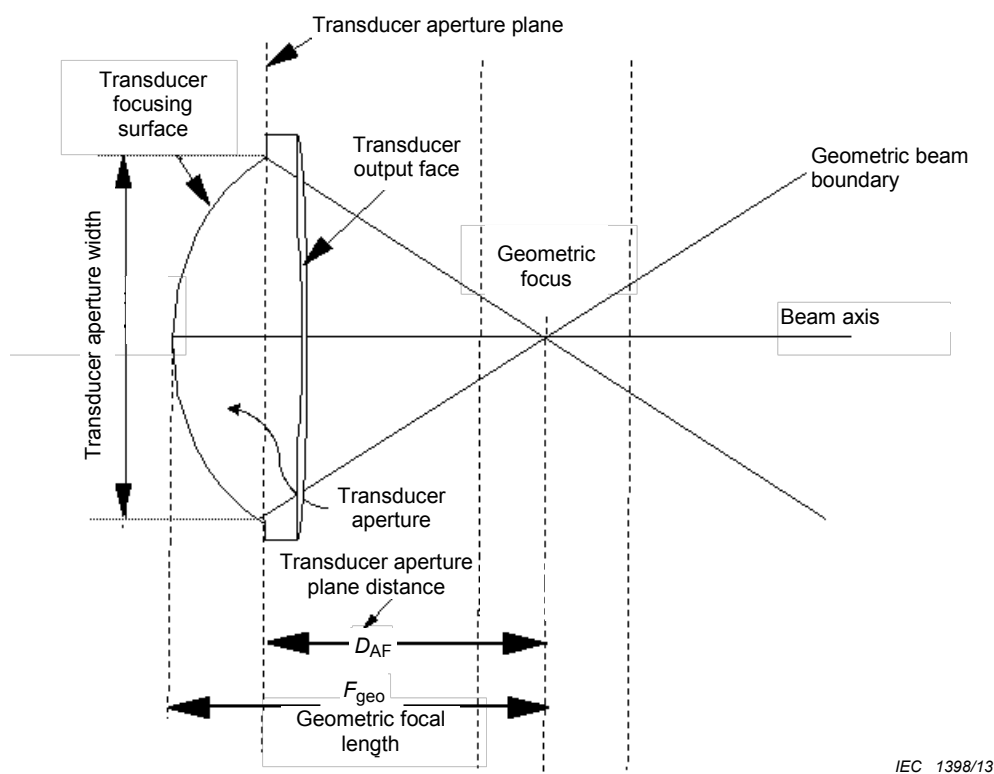


**Figure 201.102 – Parameters for describing a focusing transducer of a known geometry**

**Table 201.101 – List of symbols & abbreviations**

| Symbol                | Term                                                                        | Reference             |
|-----------------------|-----------------------------------------------------------------------------|-----------------------|
| $A_{b6}, A_{b20}$     | = BEAM AREA, corresponding to -6 dB beam area and -20 dB beam area          | IEC 62127-1, 3.7      |
| $A_6$                 | = -6 dB BEAM AREA                                                           | IEC 62127-1, 3.7      |
| $A_{EB}$              | = ENTRY BEAM AREA                                                           | IEC 60601-2-62        |
| $A_{SAeff}$           | = TRANSDUCER APERTURE PLANE                                                 | IEC 61828             |
| $d_{eq}$              | = EQUIVALENT BEAM DIAMETER                                                  | IEC 62359, 3.22       |
| $f_{awf}$             | = ACOUSTIC WORKING FREQUENCY                                                | IEC 62127-1, 3.3.2    |
| <i>HITU</i>           | = HIGH INTENSITY THERAPEUTIC ULTRASOUND                                     | IEC/TS 62556          |
| $I_{Eff}$             | = ENTRY EFFECTIVE INTENSITY                                                 | IEC 60601-2-62        |
| $I_{pfpta}$           | = PRE-FOCAL PEAK TEMPORAL-AVERAGE INTENSITY                                 | IEC/TS62556           |
| $I_{slpta}$           | = SIDE-LOBE PEAK TEMPORAL-AVERAGE INTENSITY                                 | IEC/TS 62556          |
| $I_{sppa}$            | = SPATIAL-PEAK PULSE-AVERAGE INTENSITY                                      | IEC 62127-1, 3.60     |
| $I_{ta}$              | = TEMPORAL-AVERAGE INTENSITY                                                | IEC 62127-1, 3.65     |
| $I_{spta}$            | = SPATIAL-PEAK, TEMPORAL-AVERAGE INTENSITY                                  | IEC 62127-1, 3.62     |
| $I_{w,\Delta t/s}(t)$ | = TIME-WINDOW-AVERAGE INTENSITY                                             | IEC 62127-1 Am1, 3.86 |
| $L_6$                 | = FOCAL DEPTH, BEAM MAXIMUM DEPTH                                           | IEC 60601-2-62        |
| $L_{TA}$              | = TRANSDUCER APERTURE WIDTH                                                 | IEC 61828             |
| $P$                   | = OUTPUT POWER                                                              | IEC 61161, 3.3        |
| $P_{tm}$              | = TEMPORAL MAXIMUM OUTPUT POWER                                             | IEC 61689, 3.33       |
| $P_E$                 | = ENTRY POWER                                                               | IEC 60601-2-62        |
| $p_+$                 | = PEAK-COMPRESSSIONAL ACOUSTIC PRESSURE                                     | IEC 62127-1, 3.45     |
| $p_-$                 | = PEAK-RAREFACTIONAL ACOUSTIC PRESSURE                                      | IEC 62127-1, 3.44     |
| $p_{tp}$              | = TEMPORAL PEAK ACOUSTIC PRESSURE                                           | IEC 62127-1, 3.67     |
| $R_{lpta}$            | = RATIO PEAK TO TEMPORAL AVERAGE INTENSITY                                  | IEC 60601-2-62        |
| $t_{43}$              | = THERMALLY EQUIVALENT TIME                                                 | IEC 60601-2-62        |
| $V_{foc}$             | = FOCAL VOLUME, BEAM MAXIMUM VOLUME                                         | IEC/TS 62556          |
| $w_{6m}$              | = BEAM WIDTH AT FOCUS<br>= BEAM WIDTH AT BEAM MAXIMUM                       | IEC 60601-2-62        |
| $w_{6o}$              | = ORTHOGONAL BEAM WIDTH AT FOCUS<br>= ORTHOGONAL BEAM WIDTH AT BEAM MAXIMUM | IEC 60601-2-62        |
| $z_E$                 | = DISTANCE $z_E$                                                            | IEC/TS 62556          |
| $z_r$                 | = DISTANCE $z_r$                                                            | IEC 62127-1, 3.15     |
| $z_{spta}$            | = DISTANCE $z_{spta}$                                                       | IEC 62127-1, 3.18     |
| $z_{slpta}$           | = DISTANCE $z_{slpta}$                                                      | IEC/TS 62556          |
| $z_T$                 | = DISTANCE $z_T$                                                            | IEC/TS 62556          |

## 201.4 General requirements

Clause 4 of the general standard applies, except as follows:

*Addition:*

In the case of combined EQUIPMENT (e.g. EQUIPMENT provided with a function or an APPLIED PART for imaging the target area) such EQUIPMENT shall also comply with any particular standard specifying safety requirements for the imaging function.

### 201.4.3 ESSENTIAL PERFORMANCE

*Addition:*

#### 201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements

Table 201.102 lists the requirements to avoid unacceptable risk identified to characterize the ESSENTIAL PERFORMANCE of HIGH INTENSITY THERAPEUTIC ULTRASOUND EQUIPMENT and the subclauses in which the requirements are found.

**Table 201.102 – Distributed ESSENTIAL PERFORMANCE requirements**

| Requirement                                                                                                           | Subclause  |
|-----------------------------------------------------------------------------------------------------------------------|------------|
| Free from the display of incorrect numerical values associated with the therapy to be performed. <sup>a</sup>         | 201.12.1   |
| Free from the production of unwanted ultrasound output.                                                               | 201.10.102 |
| Free from the production of excessive ultrasound output.                                                              | 201.12.4   |
| Free from the reflection of excessive ultrasonic power at the transducer-PATIENT interface due to inadequate coupling | 201.12.4   |
| Free from the unwanted targeting of tissue regions away from the intended target region                               | 201.12.4   |
| Free from the production of unwanted thermal or mechanical tissue damage in or distal to the REGION OF INTEREST.      | 201.12.4   |
| <sup>a</sup> "Incorrect" in the sense that the displayed value is different from what is produced or intended.        |            |

NOTE Annex CC provides guidance on HITU specific risks.

### 201.4.11 POWER INPUT

*Addition:*

This clause of the general standard applies with EQUIPMENT operated at maximum OUTPUT POWER.

#### 201.4.101 \*Ultrasound measurements

All ultrasonic measurements demanded for in this standard shall be based on degassed water measurements.

NOTE See for degassing methods and levels IEC/TR 62781 and Annex AA

As, in HITU fields, the acoustic waveform is expected to be extremely distorted due to nonlinear propagation effects, the ultrasonic measurements are to be made under quasi linear conditions and then extrapolated following procedures given in IEC/TS 62556 and IEC/TS 61949.

### 201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

#### 201.5.1 \* Type Tests

*Addition:*

NOTE 101 See Annex AA.

## 201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

## 201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

*Addition:*

### 201.7.4.101 \* Device type specific markings

The generator of an EQUIPMENT shall additionally be provided with the following markings:

- a display relevant to the planned treatment shall be clearly visible from the OPERATOR'S position.

Relevant displays may include one or more of the following:

- a) the expected or measured temperature rise in the FOCAL POINT or BEAM MAXIMUM POINT during the treatment;
- b) the ENTRY POWER at the treatment setting;
- c) the ENTRY EFFECTIVE INTENSITY during the treatment;
- d) an indication in case cavitation occurs;
- e) a display of the level of the reflected ultrasonic power;
- f) an indication of the THERMALLY EQUIVALENT TIME.

*Determination of the ENTRY POWER shall follow guidance given in IEC 62555.*

*The expected temperature rise can be estimated using appropriate computational models or can be measured using physical models and techniques like MR thermometry, thermal sensors, infra-red imaging or ultrasound.*

*Indications of occurring cavitation can be based on the observation of the drive voltage, the ultrasonic echo information or any other tool like MRI information.*

Any of the methods used to obtain the displayed information shall be based on validated literature. (See Annex AA)

- for ME EQUIPMENT which allows the OPERATOR to directly vary the output levels, the effect of adjusting the control which varies the output level shall be clearly indicated. The indication of the effect shall be of the nature of an active display;
- an indication of whether HITU ULTRASOUND power is on or off;
- an indication in case the transducer to PATIENT coupling is inadequate for efficacy and safety.

### 201.7.9.2 Instructions for use

#### 201.7.9.2.1 \* General

*Addition:*

The instructions for use shall additionally contain, but not be limited to, the following:

- The ultrasound field distribution(s). This should contain axial beam scan(s) of TEMPORAL-AVERAGE INTENSITY  $I_{TA}(x=0,y=0,z)$ , information about the BEAM WIDTH AT FOCUS and ORTHOGONAL BEAM WIDTH AT FOCUS or BEAM WIDTH AT BEAM MAXIMUM and ORTHOGONAL BEAM WIDTH AT BEAM MAXIMUM and 3D information about the FOCAL VOLUME or BEAM MAXIMUM VOLUME.

If complex beam patterns exist, including electronically phased, multiple depth, multi-beam, multi-foci, overlapping or intersecting beams, and/or any herein unspecified beam patterns, manufacturer should specify and characterize, via a risk based assessment, all clinically relevant or clinically utilized beam patterns with appropriate standards, and, if necessary, define effective parameters of depth, beam cross section, etc., where applicable, analogous to the existing standards.

NOTE 1 For the measurement of the field distribution see IEC/TS 62556 and Annex DD

- The targeting accuracy of the ultrasound therapeutic. Factors affecting the accuracy in clinical use shall be discussed.

NOTE 2 For the determination of the targeting accuracy see Annex BB

- A description of the POSITIONING DEVICE and how it is used to effect registration of the therapy delivery aspects of the equipment.
- A description of the monitoring method for treatment delivery and how failure of the monitoring equipment would affect treatment protocol.
- If temperature is measured during treatment, a discussion of the accuracy of a display related to temperature rise in the tissue due to the ultrasonic energy radiated.
- Information to the OPERATOR on the effect of the ultrasound treatment and its possible adverse effects (e.g. unintended tissue heating, skin damage and fistula formation). See also Annex CC.
- Information to the OPERATOR about which part(s) on the human body is not suitable for ultrasound treatment, for example, identifying tissues where ultrasound has difficulties in passing through like air pockets or bone.
- If the THERMALLY EQUIVALENT TIME is displayed, information on how that may be used during the treatment and for which tissue type it is determined.

The value of the THERMALLY EQUIVALENT TIME depends on the tissue for which it is determined, so the THERMALLY EQUIVALENT TIME should be specified for the type of tissue treated. This should be based on in-vivo tissue studies to account for differences in tissue properties.

- Instructions regarding the process to maintain adequate transducer to PATIENT coupling.

#### 201.7.9.2.2 Warning and safety notices

*Addition:*

The instructions for use shall provide:

- A list of conditions for which ULTRASOUND treatment is contraindicated.
- Advice on the type of electrical installation to which the EQUIPMENT may be safely connected, including the connection of any POTENTIAL EQUALIZATION CONDUCTOR.
- The procedures necessary for safe operation, drawing attention to the safety hazards that may occur as a result of an inadequate electrical installation when the APPLIED PART of the EQUIPMENT is a TYPE B APPLIED PART.
- Descriptions of any display or means relevant to ultrasound output by which the OPERATOR may modify the operation of the EQUIPMENT. This shall include information on the effects of HITU EQUIPMENT acoustic output levels on living tissue. These descriptions shall be in a special section on the subjects listed.
- The address the MANUFACTURER gives on the RISKS of heating of unintended tissue, e.g. particularly bone, the nervous system and organs containing gases, due to ultrasonic energy.
- The address the MANUFACTURER gives on the RISKS associated with bubble formation all along the acoustical path, notably at the surface of the transducer, at the transducer-tissue interface and in the REGION OF INTEREST.

NOTE For both, the risks associated with heating and with cavitation effects the bibliography lists some literature: [11, 12, 13, 14, 15, 16, 17].

- Advice drawing the USER's attention to the need for care when handling the TRANSDUCER, since rough handling may adversely affect its characteristics. Also the advice that a mechanical shock on the transducer has to lead to a checking by the manufacturer of the conformity of the transducers on all the parameters related to its essential performance. The manufacturer needs to identify the types of mechanical shocks relevant.
- A recommendation calling the OPERATOR's attention to the need for regular testing and periodic maintenance. The inspection should include searching for any cracks in the TRANSDUCER ASSEMBLY and TRANSDUCER OUTPUT FACE.

NOTE Inspection and testing of the transducer assembly is not a trivial operation but requires skilled personnel and dedicated equipment. Moreover, a periodic checking is expected to improve the reproducibility of the measured parameters in a fixed and controlled environment (known tolerances, calibrated equipment...). The manufacturer has to address this subject.

- A recommendation calling the OPERATOR's attention regarding how to act when unintended reflected ultrasonic power is observed.
- Description of the schedule and measurements to be performed within the scope of a regular performance check.
- Instructions regarding the avoidance of unintended control settings and acoustic output levels. This includes the effect the control settings have when they were unintentionally changed.
- A statement of intended use(s).

## **201.8 Protection against electrical HAZARDS from ME EQUIPMENT**

Clause 8 of the general standard applies, except as follows:

### **201.8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS**

#### **201.8.7.1 General requirements**

*Addition:*

- aa) For testing, the APPLIED PART that covers the TRANSDUCER ASSEMBLY shall be soaked in a 0,9 % saline solution.

As part of a single fault condition the measurement should also be performed without the membrane (if used) that covers the TRANSDUCER ASSEMBLY.

#### **201.8.8.3 Dielectric strength**

*Addition:*

- aa) For testing, the APPLIED PART that covers the TRANSDUCER ASSEMBLY shall be soaked in a 0,9 % saline solution.

As part of a single fault condition the measurement should also be performed without the membrane (if used) that covers the TRANSDUCER ASSEMBLY. The membrane does not need to be removed in case it is assured that the high voltage can under no circumstances reach the transducer.

## **201.9 Protection against mechanical hazards of ME EQUIPMENT and ME SYSTEMS**

Clause 9 of the general standard applies.

## **201.10 Protection against unwanted and excessive radiation HAZARDS**

Clause 10 of the general standard applies, except as follows:

*Addition:*

#### **201.10.101 \* Ultrasonic energy**

The MANUFACTURER shall address the RISKS associated with ultrasonic energy in the RISK MANAGEMENT PROCESS as described in the text of this standard.

NOTE 1 The risk is not only associated with heat but can also result from mechanical and other effects induced by ULTRASOUND.

NOTE 2 The risk is also associated with insonating unintended regions of tissue.

*Compliance is checked by inspection of the RISK MANAGEMENT FILE. See also Annex CC for guidance on subjects that should be addressed.*

#### **201.10.102 \* Unwanted ultrasound radiation on hand-held transducers**

The SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY of unwanted ULTRASOUND radiation from the handle of a TREATMENT HEAD intended for hand-held use, shall be less than 100 mW/cm<sup>2</sup>, when measured as described below.

*Compliance shall be checked by the following test:*

*The front face of the TREATMENT HEAD is immersed in degassed water at a temperature of 22 °C ± 3 °C. The EQUIPMENT is operated at the maximum PATIENT ENTRY POWER specified for the TREATMENT HEAD. The unwanted ULTRASOUND radiation is measured by scanning, by hand, the SIDE WALL OF THE TREATMENT HEAD by means of a calibrated hydrophone coupled to the side walls using a coupling gel.*

*The SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY shall be calculated using the approximation:*

$$I_{\text{spta}} = \frac{p_{\text{max}}^2}{\rho c} \quad (1)$$

where:

$p_{\text{max}}$  is the maximum r.m.s. acoustic pressure;

$\rho$  is the density of the coupling gel. For simplicity the density of water can be used;

$c$  is the velocity of sound in the medium. For simplicity the velocity of sound in water can be used.

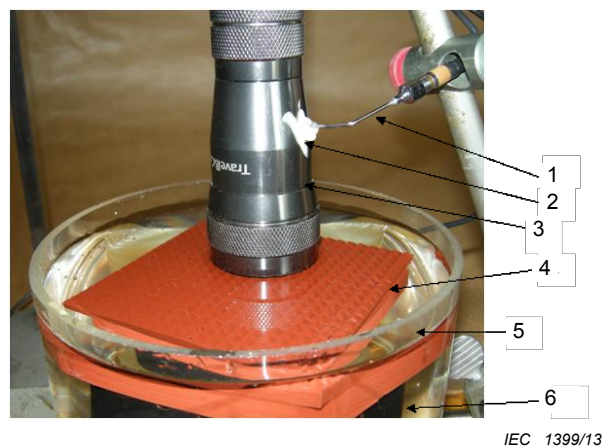
NOTE 1 SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY is expressed in watts per square metre (W/m<sup>2</sup>).

*The hydrophone used shall have an active element of diameter ≤ 1 mm.*

*The hydrophone used shall be calibrated following IEC 62127-2.*

NOTE 2 Neither the principle of this method nor the arrangement used allow an exact determination of the intensity value, however the value as measured does give an indication of the energy available at the sides of the treatment head.

NOTE 3 For requirements concerning PATIENT ENTRY POWER and intensity distribution, see Clause 201.12.

**Key:**

- |                          |                                  |
|--------------------------|----------------------------------|
| 1: hydrophone            | 4: absorbing material            |
| 2: coupling gel          | 5: water level in the water tank |
| 3: transducer under test | 6: water tank                    |

**Figure 201.103 – Example set-up for the measurement of the unwanted ultrasound radiation on the side-wall (the handle) of the transducer**

### 201.10.103 Unintended heating of tissue

The MANUFACTURER shall address the RISKS of unintended heating of tissue particularly bone, nerves, lungs and gastrointestinal (GI), and eye, due to ultrasonic energy.

Effects on human tissue in terms of THERMALLY EQUIVALENT TIME as related to the following subjects shall be discussed in the USER MANUAL and shall be addressed in the RISK MANAGEMENT FILE (see also Annex DD):

- total ENTRY POWER at clinical settings, including distance  $z_E$
- ENTRY EFFECTIVE INTENSITY at clinical settings, including distance  $z_E$
- the SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY at clinical settings
- the DISTANCE  $z_{spta}$
- the SPATIAL-PEAK PULSE-AVERAGE INTENSITY at clinical settings
- the BEAM WIDTH AT FOCUS and ORTHOGONAL BEAM WIDTH AT FOCUS or BEAM WIDTH AT BEAM MAXIMUM and ORTHOGONAL BEAM WIDTH AT BEAM MAXIMUM
- the FOCAL DEPTH or BEAM MAXIMUM DEPTH
- the SIDE-LOBE PEAK TEMPORAL-AVERAGE INTENSITY and its position relative to the position of the maximum PULSE-PRESSURE SQUARED INTEGRAL on the BEAM AXIS
- the DISTANCE  $z_{slpta}$
- the PRE-FOCAL PEAK TEMPORAL-AVERAGE INTENSITY and its position on the BEAM-AXIS
- the -6 dB BEAM AREA at  $z = z_{spta}$

### 201.10.104 Unintended cavitation effects on tissue

The MANUFACTURER shall address the RISKS of unintended cavitation effects on tissue particularly lungs and gastrointestinal (GI), and eye, due to ultrasonic energy.

Effects on human tissue related to the following subjects shall be discussed in the USER MANUAL shall be addressed in the RISK MANAGEMENT FILE:

- total ENTRY POWER at clinical settings, including distance  $z_E$

- TEMPORAL-MAXIMUM OUTPUT POWER,  $P_{tm}$
- RATIO PEAK TO TEMPORAL AVERAGE INTENSITY,  $R_{lpta}$
- TIME-WINDOW-AVERAGE INTENSITY,  $I_{w,\Delta t/s}(t)$
- ENTRY EFFECTIVE INTENSITY at clinical settings, including distance  $z_E$
- the PEAK RAREFACTIONAL ACOUSTIC PRESSURE at clinical settings
- the DISTANCE  $z_r$
- high temperature effects (e.g. gaseous effects created by excess heat)

## **201.11 Protection against excessive temperatures and other HAZARDS**

Clause 11 of the general standard applies, except as follows:

### **201.11.6.5 \* Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS**

*Addition:*

**201.11.6.5.101** The TREATMENT HEAD of EQUIPMENT intended for hand-held use shall be rated IPX7 according to IEC 60529.

*Compliance shall be checked by testing the TREATMENT HEAD including the inlet of the connecting cord according to IEC 60529.*

Parts of the TRANSDUCER ASSEMBLIES not intended to be immersed during NORMAL USE may be temporarily protected for the purposes of the test.

## **201.12 Accuracy of controls and instruments and protection against hazardous outputs**

Clause 12 of the general standard applies, except as follows:

### **201.12.1 Accuracy of controls and instruments**

*Addition:*

#### **201.12.1.101 PATIENT ENTRY POWER**

The accuracy of the data and controls specific to the PATIENT ENTRY POWER shall be specified in the technical description.

For the estimation of uncertainties the ISO Guide to the expression of uncertainty in measurement should be used [18].

#### **201.12.1.102 Targeting accuracy**

The accuracy of the data and controls specific to targeting shall be specified in the technical description.

For the estimation of uncertainties the ISO Guide to the expression of uncertainty in measurement should be used [18].

#### **201.12.1.103 Accuracy of THERMALLY EQUIVALENT TIME**

If the THERMALLY EQUIVALENT TIME is displayed, the uncertainty of the determination of the THERMALLY EQUIVALENT TIME shall be given in the technical description.

If the THERMALLY EQUIVALENT TIME is displayed, its source, whether measured or estimated from settings and models, shall be given in the technical description.

The value of the THERMALLY EQUIVALENT TIME depends on the tissue for which it is determined, so the THERMALLY EQUIVALENT TIME should be specified for the type of tissue treated. This should be based on in-vivo tissue studies to account for differences in tissue properties.

For the estimation of uncertainties the ISO Guide to the expression of uncertainty in measurement should be used.

#### **201.12.4 Protection against hazardous output**

##### **201.12.4.4 Incorrect output**

*Addition:*

###### **201.12.4.4.101 Output control**

The ENTRY POWER or the ENTRY EFFECTIVE INTENSITY relative to the control setting shall be given.

*Compliance is checked following procedures described in IEC 62555*

The ME shall be equipped with an emergency button that will switch off the ultrasound drive voltage when activated by hand, even if an automatic stop function is built into the device. Any other HAZARDS associated with activation of the emergency button shall be covered in the RISK MANAGEMENT PROCESS

###### **201.12.4.4.102 Targeting accuracy**

Instructions about the use of the LOCALIZATION DEVICE to localize the target tissue shall be given, which accounts for the 3D structure of the target and the surrounding tissues.

The uncertainty of the POSITIONING DEVICE to position the maximum PULSE-PRESSURE SQUARED INTEGRAL on the BEAM AXIS of the ultrasonic beam to the TARGET LOCATION shall be given.

###### **201.12.4.4.103 \* Unintended output levels**

The level of the SIDE-LOBE PEAK TEMPORAL-AVERAGE INTENSITY shall be given, based on measurements and/or modelling. Its position relative to the maximum in the FOCAL VOLUME or BEAM MAXIMUM VOLUME shall be given.

It shall be demonstrated, through the RISK ASSESSMENT PROCESS, that the risk of possible tissue damage that occurs during insonification outside the target area is acceptable.

NOTE 1 For information on the demonstration that minimal tissue damage occurs see Annex DD

*Compliance is checked following procedures described in IEC/TS 62556*

The level of PRE-FOCAL PEAK TEMPORAL-AVERAGE INTENSITY shall be given, based on measurements and modelling. Its position relative to the maximum in the FOCAL VOLUME or BEAM MAXIMUM VOLUME shall be given.

It shall be demonstrated, through the RISK ASSESSMENT PROCESS, that possible tissue damage that occurs during insonification outside the target area is acceptable.

NOTE 2 For information on the demonstration that minimal tissue damage occurs see Annex DD

*Compliance is checked following procedures described in IEC/TS 62556*

If a critical structure outside the TARGET LOCATION is insonated the temperature rise at the location of the critical structure shall be limited to values that are acceptable according to RISK ASSESSMENT.

The acceptable risk of collateral tissue damage should be weighed against the achievable benefit of the therapy.

*Compliance can be checked using methods described in Annex CC*

## **201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT**

*Addition:*

### **201.13.101**

For insonated tissue outside the TARGET LOCATION, the temperature rise and THERMALLY EQUIVALENT TIME shall be limited to values that are acceptable according to RISK ASSESSMENT.

## **201.14 Programmable ELECTRICAL MEDICAL SYSTEMS (PEMS)**

Clause 14 of the general standard applies

## **201.15 Construction of ME EQUIPMENT**

Clause 15 of the general standard applies

## **201.16 ME systems**

Clause 16 of the general standard applies

## **201.17 \* Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS**

Clause 17 of the general standard applies except as follows:

*Addition:*

HIGH INTENSITY THERAPEUTIC ULTRASOUND EQUIPMENT shall comply with the requirements of IEC 60601-1-2:2007 as modified in Clause 202.

## **202 Electromagnetic compatibility – Requirements and tests**

IEC 60601-1-2:2007 applies, except as follows:

### **202.6 Electromagnetic compatibility**

#### **202.6.1 Emissions**

##### **202.6.1.1 Protection of radio services**

###### **202.6.1.1.1 Requirements**

*Replacement:*

HIGH INTENSITY THERAPEUTIC ULTRASOUND EQUIPMENT shall be classified as Group 1 and class A or class B, in accordance with CISPR 11, as per their intended use, with the exceptions and clarifications specified in a), and b) below, specified by the MANUFACTURER in the INSTRUCTIONS FOR USE. Guidance for classification according CISPR 11 is reported in Annex EE.

- a) ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location
- For ME EQUIPMENT and ME SYSTEMS that are specified for use only in a shielded location, the electromagnetic radiation disturbance limits of CISPR 11 may be increased, when tests are performed on a test site, by an amount up to the applicable specified value of minimum RF shielding effectiveness, provided the minimum RF shielding effectiveness specification meets the requirements specified in 5.2.2.3 b).
  - For ME EQUIPMENT and ME SYSTEMS that are specified for use only in a shielded location, the mains terminal disturbance voltage limits of CISPR 11 may be increased, when tests are performed on a test site, by an amount up to the applicable specified value of minimum RF filter attenuation for all cables that exit the shielded location, provided the minimum RF filter attenuation specification meets the requirements specified in 5.2.2.3 b).
- b) ME EQUIPMENT and ME SYSTEMS that include radio equipment ME EQUIPMENT and ME SYSTEMS that include radio equipment and have been tested and found to comply with applicable national radio regulations are exempt from testing to CISPR ELECTROMAGNETIC DISTURBANCE requirements, provided the EMISSIONS limits of the applicable national radio regulations are less than or equal to the corresponding applicable CISPR ELECTROMAGNETIC DISTURBANCE limits. ME EQUIPMENT and ME SYSTEMS that include RF transmitters are exempt from the EMISSIONS requirements of this particular standard in the dedicated transmission band of the transmitter. Otherwise, and for ME EQUIPMENT and ME SYSTEMS intended only for countries with no national radio regulations, the EMISSIONS requirements of this particular standard shall apply.

- **Documentation of the test**

The documentation of the test shall include the test methods used to verify compliance with the requirements of this subclause and justification for any allowances of this particular standard used. This documentation shall include a description of the ME EQUIPMENT or ME SYSTEM under test, test equipment and test set-up, settings and mode(s) of the ME EQUIPMENT or ME SYSTEM, cable layout, and all PATIENT physiological, ACCESSORY, and subsystem simulators used.

#### **202.6.1.1.2 Tests**

*Addition to item a):*

A water bath may be used to prevent damage to the HITU device. Care should be taken to minimize the conductive and shielding effects of this vessel. See Annex FF for more information.

#### **202.6.2 IMMUNITY**

##### **202.6.2.1 General**

##### **202.6.2.1.10 \*Compliance criteria**

*Amendment:*

*The eighth through the eleventh dashes are replaced by the following:*

- the disturbance shall not produce noise on a waveform or artifacts or distortion in an image or error of a displayed numerical value which may be attributed to a physiological effect and which may alter the treatment;
- the disturbance shall not produce an error in a display or incorrect numerical values associated with the treatment to be performed;
- the disturbance shall not produce unintended or excessive ultrasound output;
- the disturbance shall not produce TRANSDUCER ASSEMBLY surface temperature exceeding the limits specified in 11.1.2 of the general standard;

- the disturbance shall not produce unintended or uncontrolled change in targeting position.

### **202.6.2.3 Radiated RF electromagnetic fields**

#### **202.6.2.3.2 Tests**

*Addition to item c)\*:*

In a case where the ME may use both slow and fast physiological signals, according to the intended use, the ME shall be tested using a 2 Hz or 1 000 Hz modulation frequency whichever represents the worst-case condition. The modulation frequency adopted shall be disclosed in the test report.

*Addition to item f):*

A water bath may be used to prevent damage to the HITU device during operation. It may be necessary for this water bath to be within the test area. Care should be taken to minimize the conductive and shielding effects of this vessel. See Annex FF for more information.

#### **202.6.2.4 Tests**

*Addition:*

A saline bath may be used to prevent damage to the HITU device during operation but allowing conduction to the copper foil hand. See Annex FF for more information.

### **202.6.2.5 PATIENT-COUPLED ME EQUIPMENT and ME SYSTEMS**

*Addition:*

A water bath may be used to prevent damage to the HITU device. Care should be taken to minimize the conductive and shielding effects of this vessel. See Annex FF for more information.

### **202.6.2.6 Conducted disturbances, induced by RF fields**

#### **202.6.2.6.2 Tests**

*Replacement of item c):*

- c) The cable(s) that connects the APPLIED PART to the ME, including the TRANSDUCER ASSEMBLY cable, shall be tested using a current clamp. All PATIENT-coupled cables including the TRANSDUCER ASSEMBLY cable may be tested simultaneously using a single current clamp.

The TRANSDUCER ASSEMBLY of the EQUIPMENT shall be terminated during the test as specified below. In all cases, no intentional decoupling device shall be used between the injection point and the PATIENT coupling point.

- For PATIENT coupling points that have conductive contact to the PATIENT, terminal M of the RC element (see CISPR 16-1-2) shall be connected directly to the conductive PATIENT connection, and the other terminal of the RC element shall be connected to the ground reference plane. If normal operation of the EQUIPMENT cannot be verified with terminal M of the artificial hand connected to the coupling point, a PATIENT simulator may be used between terminal M of the artificial hand and the PATIENT coupling point or points.
- TRANSDUCER ASSEMBLY shall be terminated with the artificial hand and RC element specified in CISPR 16-1-2. The metal foil of the artificial hand shall be sized and placed to simulate the approximate area of PATIENT and OPERATOR coupling in NORMAL USE.

- For EQUIPMENT that have multiple PATIENT coupling points intended to be connected to a single PATIENT, each artificial hand shall be tied to a single common connection and this common connection shall be connected to terminal M of the RC element, as specified in CISPR 16-2.

If the PATIENT coupling point is the transducer or applicator face, then TRANSDUCER ASSEMBLY shall be terminated with the artificial hand and RC element specified in CISPR 16-1-2. The metal foil of the artificial hand shall be sized and placed to simulate the approximate area of PATIENT and OPERATOR coupling in NORMAL USE. A saline bath may be used to prevent damage to the HITU device during operation but allowing conduction to the copper foil hand See Annex FF for more information.

#### **202.6.2.7 Voltage dips, short interruptions and voltage variations on power supply input lines**

##### **202.6.2.7.1 Requirements**

*Replacement of item a):*

- EQUIPMENT shall comply with the requirements of 6.2.1.10 of IEC 60601-1-2 as modified by clause 202.6.2.1.10 of this standard at the IMMUNITY TEST LEVELS specified in Table 10 of IEC 60601-1-2. Deviation from the requirements of 6.2.1.10 of IEC 60601-1-2 is allowed at the IMMUNITY TEST LEVELS specified in Table 10 of IEC 60601-1-2, provided the EQUIPMENT remains safe, experiences no component failures and is restorable to the pre-test state with OPERATOR intervention. Determination of compliance is based upon performance of the EQUIPMENT during and after application of the test sequence. EQUIPMENT for which the RATED input current exceeds 16 A per phase are exempt from the testing specified in Table 10 of IEC 60601-1-2.

#### **202.6.2.8 Magnetic fields**

##### **202.6.2.8.1 Power frequency magnetic fields**

###### **202.6.2.8.1.1 Requirements**

*Replacement:*

ME EQUIPMENT and ME SYSTEMS shall comply with the requirements of 6.2.1.10 of IEC 60601-1-2 as modified by clause 202.1.10 of this standard at an IMMUNITY TEST LEVEL of 3 A/m.

*Check compliance by application of the tests in 6.2.8.1.2 of IEC 60601-1-2. Evaluate the response of the ME EQUIPMENT or ME SYSTEM during and after these tests in accordance with 6.2.1.10 of IEC 60601-1-2 as modified by 202.1.10 of this standard.*

###### **202.6.2.8.1.2 Tests**

*Addition:*

A water bath may be used to prevent damage to the HITU device during operation. It may be necessary for this water bath to be within the test area. Care should be taken to minimize shielding effects of this vessel. See Annex FF for more information.

## **Annexes**

The annexes of the general standard apply except as follows.

## Annex AA (informative)

### Particular guidance and rationale

#### AA.1 General guidance

This annex provides a concise rationale for the important requirements of this standard and is intended for those who are familiar with the subject of this standard but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for the proper application of this standard. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate any revision of this standard necessitated by these developments.

#### AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclause in this particular standard, with clause and subclause numbers parallel to those in the body of the document.

##### **Definition 201.3.205, 201.3.215, 201.3.216, 201.3.217 and 201.3.222**

In the listed definitions there is a distinction made between the use of the term “focal” or “focus” and “beam maximum”. The term in which “focal” or “focus” is used is reserved for deliberately focussed ultrasonic beams as described in IEC 61828. “Beam maximum” is used for all non-focussing ultrasonic beams.

##### **Definition 201.3.218 HIGH INTENSITY THERAPEUTIC ULTRASOUND (HITU) EQUIPMENT**

HIGH INTENSITY THERAPEUTIC ULTRASOUND (HITU) is a precise medical procedure using high levels of ultrasound intensity (e.g.  $I_{\text{spta}} > 100 \text{ Wcm}^{-2}$ ) or ultrasound pressures (e.g.  $p_{-} > 3 \text{ MPa}$  but this is frequency dependent) to destroy or disrupt tissue or non-tissue elements (for example liquids, bubbles, micro-capsules). Although HITU is a modality of therapeutic ultrasound, which induces hyperthermia, it should not be confused with the hyperthermia technique, which heats much less rapidly and to much lower therapeutic temperatures (in general 42 °C to 50 °C and THERMALLY EQUIVALENT TIMES of 0,2 min to 120 min) as compared with HITU induced temperatures in excess of 55°C and much shorter times and also ultrasound-induced bioeffects by means other than heat.

The intended use of HIGH INTENSITY THERAPEUTIC ULTRASOUND EQUIPMENT can be divided into two groups based on primary mode of action:

- a) Equipment that is intended to produce heat in a specific local human tissue area.
- b) Equipment that is intended to produce mechanical effects in human tissue or a non-tissue element (excluding devices like pressure pulse lithotripsy, general pain relief devices, dedicated hyperthermia, etc.). Mechanical effects include cavitation, streaming, and radiation force.

Examples of HITU EQUIPMENT based on physical mechanism of action, clinical approach, clinical application, and image monitoring methods are:

| Application     | Mechanism  | Approach       | Monitoring         |
|-----------------|------------|----------------|--------------------|
| Prostate        | Thermal    | Transrectal    | Ultrasound         |
| Face, Neck Skin | Thermal    | Extracorporeal | Ultrasound         |
| Abdominal Fat   | Thermal    | Extracorporeal | None               |
| Abdominal Fat   | Cavitation | Extracorporeal | Ultrasound, A-Mode |

| Application         | Mechanism  | Approach                       | Monitoring                      |
|---------------------|------------|--------------------------------|---------------------------------|
| Abdominal Fat       | Cavitation | Extracorporeal, dual unfocused | None                            |
| Oncology            | Thermal    | Extracorporeal                 | Ultrasound                      |
| Thyroid             | Thermal    | Extracorporeal                 | Ultrasound                      |
| Oncology            | Thermal    | Extracorporeal                 | Ultrasound & magnetic resonance |
| Oncology            | Thermal    | Extracorporeal                 | Magnetic resonance              |
| Oncology, Brain     | Thermal    | Extracorporeal                 | Magnetic resonance              |
| Thrombolysis        | Mechanical | Intravascular, non-focused     | None                            |
| Atrial Fibrillation | Thermal    | Epicardial                     | None                            |
| Prostate            | Thermal    | Transurethral, unfocused       | Magnetic resonance              |
| Prostate            | Cavitation | Transurethral                  | Ultrasound                      |

#### Subclause 201.4.101 Ultrasound measurements

Ultrasound measurements at output levels used in HITU equipment are affected by cavitation effects in the water. So there is a demand for high quality and purity of the water used as medium. IEC/TR 62781 describes methods to treat water so it can be used in this type of measurements.

As, in HITU fields, the acoustic waveform is expected to be extremely distorted due to nonlinear propagation effects, the ultrasonic measurements are to be made under quasi linear conditions and then extrapolated following procedures given in IEC/TS 62556 and IEC/TS 61949.

#### Subclause 201.5.1 Type Tests

The testing during manufacture (see rationale in 5.1 of the general standard) should include verification of the ENTRY POWER according to the test method referred to in 201.12.4.4.101 and a test for water tightness of the TREATMENT HEAD as specified in 201.11.6.5.

#### Subclause 201.7.4.101 Device type specific markings

Presently the standard requires to determine the intended therapeutic effect on human tissue. It does not yet specify measurement methods. However, scientific literature, presents methods to estimate the effects.

References for temperature are: [19,20,21,22,23,24,25]. References related to cavitation effects are [17,26,27]. References for OUTPUT POWER measurements are: [9,28,29,30]

A proper coupling of the transducer to the PATIENT is very important for an effective energy transfer. Air bubbles in the interface could result in local temperature rise of the skin or de-focusing of the ultrasonic beam. Several methods are known to detect inefficient methods, one of them is the observation of the change of the transducer impedance.

#### Subclause 201.7.9.2.1 General

A proper coupling of the transducer to the PATIENT is very important for an effective energy transfer. Air bubbles in the interface could result in local temperature rise of the skin or de-focusing of the ultrasonic beam. The instruction manual has to contain a section that clearly describes methods to maintain proper coupling and what to do when coupling is inadequate.

### **Subclause 201.8.1 Fundamental rule of protection against electric shock**

In combined EQUIPMENT, in which the imaging part uses ultrasound, this particular standard is applicable only to the HITU part. However, see also Subclause 201.4.

### **Subclause 201.10.101 Ultrasonic energy**

This particular standard places the responsibility for guiding the user on the safe use of ULTRASOUND on the MANUFACTURER based on risk analysis.

### **Subclause 201.10.102 Unwanted ultrasound radiation on hand-held transducers**

The figure of 100 mW/cm<sup>2</sup> incorporates a reasonable safety factor due to the low efficiency of coupling to the OPERATOR's hand, in NORMAL USE, in comparison with the test conditions. If the OPERATOR's fingers were wet or covered in gel, then temperature rises of a few degrees Celsius could occur. In practice, this is an unlikely situation but remains an important issue for the OPERATOR.  $I_{spta}$  is the most effective parameter related to heat into the finger joints. Although it could be argued that a pressure level would be more adequate, there is no limit level known. The value of 100 mW/cm<sup>2</sup> is based on information for diagnostic equipment where no specification of  $I_{spta}$  needs to be given when this value is below 100 mW/cm<sup>2</sup>.

Neither the principle of this method nor the arrangement used allow an exact determination of the intensity value, however the value as measured does give an indication of the energy available at the sides of the treatment head.

### **Subclause 201.11.6.5 Ingress of liquids**

Water tightness of the ULTRASONIC TRANSDUCER ASSEMBLY (including any incorporated cover sheet) is necessary to prevent the ingress of oils or creams used for coupling of the ULTRASONIC TRANSDUCER face to the PATIENT'S skin, or other tissues or organs, during treatment.

### **Subclause 201.12.4.4.103 Unintended output levels**

In IEC 60601-2-37 the temperature rise of the surface of transducers for internal use is accepted to be no more than 6 °C. In addition to the average internal body temperature of 37 °C a tissue temperature of 43 °C will be reached. Above this temperature there is a real risk of tissue damage. This should be taken into account when analysing the risk of unintended output levels.

## **Clause 201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS**

ME EQUIPMENT is categorized as class A (under 60601-1-2) when the environment for the intended use as defined by the MANUFACTURER is in a hospital or a similar environment. For the extension of the intended use into a residential environment the ULTRASONIC DIAGNOSTIC EQUIPMENT has to be categorized as class B.

For further details see Annex EE.

ME EQUIPMENT subject to this particular standard, is classified in Group 1 (under 60601-1-2), since the device must intentionally generate radio frequency energy and transmit it through a shielded external cable (up to 2 m or longer in length) to a TRANSDUCER ASSEMBLY at the end of the cable.

For INVASIVE TRANSDUCER ASSEMBLIES, radiated and conducted emissions per IEC 60601-1-2 should be performed both with and without the transducer active to ensure compliance when the transducer is outside the body and not activated, and secondly, when the transducer is inside the body and activated. The condition "inside the body and activated" should be simulated using a phantom having the same attenuation as human tissue in the frequency pass band of the transducer. The phantom should only be used while making radiated and/or

conducted emission measurements in the frequency pass band of the transducer unless the phantoms frequency characteristics are known over the entire frequency range of the testing.

#### **Subclause 202.6.2.1.10 Compliance criteria**

There are many HITU devices which, in addition to transmitting ultrasound energy, also receive ultrasound energy for such things as control, targeting and monitoring. There is common agreement that it is not possible to require that nothing happens when an electromagnetic disturbance is applied to ME EQUIPMENT which is intended to acquire signals in the  $\mu\text{V}$  range by means of a transducer whose cable length is more than 2 m.

The sense of the requirement is that under the test conditions specified in 6.2.1.10 of IEC 60601-1-2, the ME EQUIPMENT has to be able to provide the ESSENTIAL PERFORMANCE and remain safe.

Examples of conformance to the compliance criteria:

- ME EQUIPMENT displays an image that may have regular dots, dashes or lines produced by the disturbance, but in a way that is recognizable as other than physiologic and that would not affect treatment;
- ME EQUIPMENT displays an image which may include noise signals, but in a way that is recognizable as other than physiologic and that would not affect treatment.

#### **Subclause 202.6.2.3.2 c)**

Table 9 of IEC 60601-1-2 lists a 2 Hz modulation frequency when the intended use of the device is “control, monitor or measure a physiological parameter” and 1 000 Hz modulation frequency for “all other” intended use. It is possible that the ME may utilize both slow physiological parameters for example tissue elasticity over time to measure thermal dose or fast physiological motion such as blood flow in a wound closure system.

## **Annex BB** (informative)

### **Targeting**

#### **BB.1 General**

Presently two methods of locating the target for the HITU treatment are used. One is based on magnetic resonance (MR) imaging; the other is based on ultrasound imaging.

Ultrasound or other imaging may not be necessary for targeting if the focus is fixed, the treatment depth is superficial, and the tissue being treated is not critical, for example, the cellular necrosis of abdominal fat.

Ultrasound or other imaging may not be necessary for targeting if the device is intended for superficial tissue destruction in the entire region from the FOCAL POINT or BEAM MAXIMUM POINT back to the PATIENT ENTRY PLANE.

#### **BB.2 Targeting accuracy in MR guided HITU**

Targeting accuracy in MR guided HITU is based on the following stages:

##### **a) Target localization and treatment planning**

MR images are taken to locate the target tissue and surrounding organs. Registration of the transducer to the MR images is achieved via the MR images or via micro coils, or other fiducial markers (e.g., water-filled shaped small cavities), attached to the transducer. The absolute accuracy of registration required, depends on the Field Of View of the MRI and the ultrasound beam dimensions in the FOCAL POINT or BEAM MAXIMUM POINT.

##### **b) Safety control of treatment**

During sonications, thermally sensitive MR images are acquired, or other beam focus images (e.g., ARFI images of tissue displacement mapping the pattern associated with the focal intensity distribution) are acquired, to allow adjustments of the FOCAL POINT or BEAM MAXIMUM POINT locations to compensate for tissue aberrations or equipment misalignment.

The first verification of sonication energy should be sufficient to allow either thermal spot imaging of the focus or tissue displacement pattern imaging of the focus (e.g., using ARFI), but at energies low enough to avoid damage to tissue. For treating sonications the energy need to be calibrated to achieve the required temperature rise. The imaging resolution should be chosen high enough not to add position uncertainty in imaging the thermal spot.

##### **c) Efficacy control of treatment**

During sonications thermally sensitive MR images are acquired, so that the energy of sonication can be controlled for the ablation of the tissue at the target. Acceptable uncertainty of the temperature determination is 5 °C.

#### **BB.3 Targeting accuracy in ULTRASOUND guided HITU**

Ultrasound imaging can use multiple "modes" to visualize the effects of the interaction (thermal or mechanical) of the therapeutic beam focus with the tissue. These modes can be used for either beam targeting, or monitoring the tissue effects produce during therapeutic energy deposition (dosing).

**For Targeting:** Normal pulse-echo imaging: B-mode ("normal" grey-scale), can track reflections from tissue scatterers or reflectors (e.g., gas-bubbles from heating), the Ultrasound

focus can push with ultrasound radiation force. In so doing the focus can produce focal effects that can be imaged by ultrasound, in effect to image the focus. The focus, for example, can move fluid (e.g., in blood or fluid-filled tissue cavities) in a localized area, (thus the focus can be localized by tracking the fluid motion with color or power Doppler). Alternatively, the focal radiation force can push on tissues at the focus and produce local tissue displacements, in approximate proportion to intensity (and thus acoustic radiation force impulse (ARFI) imaging, which images this displacement, can be used to map the focal intensity, or in effect, image the focus).

**For monitoring tissue during therapy:** a variety of acoustic modes (signal processing of ultrasound parameters, which can be mapped into images) can be used to evaluate the energy deposition effects (mechanical and thermal) on tissue.

These include:

- a) **Acoustic thermometry** (multi-parametric processing of reflected sound that can be associated with temperatures),
- b) **ARFI** (which can map tissue stiffness changes created by thermal viscosity changes and thermal denaturing of tissue proteins),
- c) **Tissue harmonic imaging (THI)**; a dynamic variation of ARFI whereby vibrational motion is induced in tissues by acoustic radiation force (e.g., pulsed at a characteristic PRF), and then ultrasound is used to monitor the vibrational tissue motion amplitude and phase difference from the source of acoustic pushes (which vary also with tissue temperature and changes in tissue properties occurring from dosing),
- d) **Shear wave elastography** imaging (a variation of ARFI whereby the acoustic push pulses create local tissue displacements that, in turn, create a shear wave normal to the push (whose velocity and amplitudes are a function of tissue stiffness and viscosity; and thus can be used to create images which can be used to monitor the tissue effects of dosing).

Targeting accuracy in ULTRASOUND guided HITU is based on the following stages:

#### A) Target localization

If targeting is required, in the case of using 2D ultrasound imaging, the FOCAL POINT or BEAM MAXIMUM POINT, or position of maximum PULSE-PRESSURE SQUARED INTEGRAL, has to be located in the plane of the ULTRASOUND images and localized on the images with a targeting marker. If multiple foci can exist simultaneously in the image plane, such that their maximum PULSE-PRESSURE SQUARED INTEGRALS are within  $\pm 3$  dB, then multiple markers should be displayed at the positions of such foci. The spatial tolerance between any such FOCAL POINT or BEAM MAXIMUM POINT and its associated marker shall be no more than 5 mm.

In the case of using 3D or "Volume" ultrasound imaging (using spatially registered imaging and therapy transducers, to enable coordinate transformations between their respective frames of reference), the same targeting principles apply, only the FOCAL POINT or BEAM MAXIMUM POINT, or position of maximum PULSE-PRESSURE SQUARED INTEGRAL, is to be located in the 3D volume of the ULTRASOUND images and localized on the images with a targeting marker placed in the three dimensional image volume. Appropriate visualization tools on the ultrasound system display should be made available to the operator (e.g., multi-planar windowed views, for example axial, sagittal and coronal views, in analogy to MR image displays) to enable the determination of the targeting spatial tolerance. In this case, the spatial tolerance between the FOCAL POINT or BEAM MAXIMUM POINT and its associated marker shall be measured such that the absolute value of the separation distance between the marker and FOCAL POINT or BEAM MAXIMUM POINT shall be (taking into account all Cartesian components of the separation distance in 3D space) less than the lesser of 5 mm or 5 % of the range from the FOCAL POINT or BEAM MAXIMUM POINT to the center of the aperture.