# IEC/TR 62799

Edition 1.0 2013-09

# TECHNICAL REPORT

## Models for evaluation of thermal hazard in medical diagnostic ultrasonic fields



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## FOREWORD

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IEC 62799, which is a technical report, has been prepared by IEC technical committee 87: Ultrasonics.

The text of this technical report is based on the following documents:

| Enquiry draft | Report on voting |
|---|---|
| 87/510/DTR | 87/537/RVC |

Full information on the voting for the approval of this technical report 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.

Terms appearing in bold print in the text are defined in Clause 3 of this technical report.

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

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- withdrawn,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

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

# MODELS FOR EVALUATION OF THERMAL HAZARD IN MEDICAL DIAGNOSTIC ULTRASONIC FIELDS

## 1 Scope

This technical report provides background information for users of IEC 62359 to understand the relative merits of several of the potential replacements for the thermal index (TI) as described in IEC 60601-2-37 and IEC 62359.

The report discusses:

– parameters related to thermal aspects of diagnostic ultrasonic fields;

– methods for the determination of an exposure parameter relating to temperature rise in theoretical tissue-equivalent models, resulting from absorption of ultrasound.

The report is intended to be used by:

– those involved in the development and maintenance of IEC 62359;

– manufacturers of medical electrical equipment for risk assessment;

– health care regulatory authorities, test houses and other organizations responsible for implementing standards for medical electrical equipment.



## 2 Normative references



The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-2-37:2007, *Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment*

IEC 62127-1:2007, *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 62359:2010, *Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields*

## 3 Terms and definitions

For the purposes of this technical report, the terms and definitions given in IEC 60601-2-37, IEC 62127-1, IEC 62127-2 and IEC 62359, some of which are repeated below for convenience, and the following terms and definitions apply.

**3.1**
**acoustic absorption coefficient**
$\mu$
quantity intended to account for loss of ultrasonic energy to tissue at a specified point by mechanisms other than scattering

Note 1 to entry: **Acoustic absorption coefficient** is expressed in nepers per centimetre (Np $cm^{-1}$).

Note 2 to entry: The **acoustic absorption coefficient** must be less than or equal to the **acoustic attenuation coefficient**.

**3.2**
**acoustic attenuation coefficient**
$\alpha$
quantity intended to account for reduction of energy of an acoustic wave by all mechanisms involving interaction of the wave and all matter between the source and a specified point

Note 1 to entry: **Acoustic attenuation coefficient** is expressed in nepers per centimetre (Np $cm^{-1}$).

Note 2 to entry: The **acoustic attenuation coefficient** must be greater than or equal to the **acoustic absorption coefficient**.

Note 3 to entry: The **acoustic attenuation coefficient** does not account for geometric attenuation.

**3.3**
**acoustic working frequency**
$f_{awf}$
frequency of an acoustic signal based on the observation of the output of a hydrophone placed in an acoustic field at the position corresponding to the spatial-peak temporal-peak acoustic pressure

Note 1 to entry: The signal is analysed using either the **zero-crossing acoustic-working frequency** technique or a spectrum analysis technique. Acoustic working frequencies are defined in 3.3.1 and 3.3.2.



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



Note 3 to entry: **Acoustic working frequency** is expressed in hertz (Hz).



SOURCE: IEC 62127-1:2007, 3.3.

**3.3.1**
**zero-crossing acoustic working frequency**
number, $n$, of consecutive half-cycles (irrespective of polarity) divided by twice the time between the commencement of the first half-cycle and the end of the $n$-th half-cycle

Note 1 to entry: Any half-cycle in which the waveform shows evidence of phase change shall not be counted.

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

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

Note 4 to entry: This frequency is intended for continuous wave systems only.

**3.3.2**
**arithmetic-mean acoustic working frequency**
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 systems 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 $< 3 f_1$, $f_2$ is to be understood as the lowest frequency above this range at which the spectrum magnitude is -3dB from the peak magnitude.

**3.4**
**non-scanning mode**
mode of operation of a system that involves a sequence of ultrasonic pulses which give rise to ultrasonic scan lines that follow the same acoustic path

SOURCE: IEC 62127-1:2007, 3.39.4.

**3.5**
**peak-rarefactional acoustic pressure**
$p_-$; $p_r$
maximum of the modulus of the negative instantaneous acoustic pressure in an acoustic field or in a specified plane during an acoustic repetition period

Note 1 to entry: **Peak-rarefactional acoustic pressure** is expressed as a positive value.

Note 2 to entry: **Peak-rarefactional acoustic pressure** is expressed in pascal (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 62127-1:12007, 3.44.

**3.6**
**safe use time**
$SUT$
maximum duration of exposure in a region at a particular output level that would be no more hazardous than scanning at a specified **threshold exposure**



Note 1 to entry: **Safe use time** is expressed in seconds (s).



**3.7**
**scanning mode**
mode of operation of a system that involves a sequence of ultrasonic pulses which give rise to ultrasonic scan lines that do not follow the same acoustic path

Note 1 to entry: The sequence of pulses is not necessarily made up of identical pulses. For instance, the use of sequential multiple focal-zones is considered a scanning mode.

SOURCE: IEC 62127-1:2007, 3.39.5.

**3.8**
**temperature rise**
$\Delta T$
difference between the instantaneous temperature and the normal physiological temperature of the subject

Note 1 to entry: **Temperature rise** is expressed in degrees Celsius ( °C).

Note 2 to entry: **Temperature rise** may be either positive or negative.

**3.9**
**thermally equivalent time**
$t_{43}$
at a constant temperature of 43 °C, duration of exposure required to produce the same magnitude of a thermally induced bio-effect, i.e., an "iso-effect", as is produced by an exposure of duration $t'$ at a different temperature $T$ that may vary in time

The thermally equivalent time ($t_{43}$) is defined mathematically as:

$$t_{43} = \int_0^{t'} R^{[T(t)-43°C]/C_T}\, dt$$

where:

$C_T$ = 1 °C, a constant to render the exponent dimensionless;

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

$t$ = time;

$t'$ = time required to produce the bioeffect at temperature $T$;

$R$ = thermal normalization constant, equal to 4,0 if $T \leq 43$ °C;

$R$ = thermal normalization constant, equal to 2,0 if $T > 43$ °C

Note 1 to entry: In the scientific and medical literature, **thermally equivalent time** is commonly called “thermal dose”.

Note 2 to entry: The general expression for **thermally equivalent time** is $t_1/t_2 = R^{(T_2-T_1)/1°C}$, where $R$ is the thermal normalization constant. Because $R$ varies with both temperature and species, as well as among different tissues within the same species, it must be determined empirically. For simplicity, the values for $R$ are usually fixed at $R = 2$ for $T > 43$ °C and $R = 4$ for $T \leq 43$ °C. More generally, $T1$ is a constant reference temperature, and $T2$ is a function of time.

Note 3 to entry: When quantifying exposure to most forms of radiation, the general term 'dose' is usually expressed in units of absorbed energy (in joules) or specific energy (e.g., J/ kg) rather than in units of time. Although there is a growing preference within IEC to use the more precise term ‘**thermally equivalent time**’, this new term has not yet been carefully evaluated or widely accepted.

Note 4 to entry: The SI unit of **thermally equivalent time** is second (s).

**3.10**
**thermally equivalent time displayed**
*TETD*



exposure duration required to obtain a **thermally equivalent time** sufficient to induce harm in a specified fraction of exposed subjects at a specified point as estimated using a specified model



Note 1 to entry: **Thermally equivalent time displayed** is expressed in seconds (s).

**3.11**
**thermally equivalent time index**
**thermal dose index**
*TETI*

ratio of the **thermally equivalent time** calculated assuming that $T(t) = (TI + 37) \times 1$ °C and $R = 4$ to a **thermally equivalent time** below which the risk of an adverse thermal effect is very low.

The simplest form of the thermally equivalent time index ($TETI$) is given by the following expression:

$$TETI = \frac{(4)^{TI} \cdot t}{N},$$

where:

$TI$ = **thermal index;**

$t$ = exposure duration;

$N$ = a normalizing factor

Note 1 to entry: The normalizing factor is the **thermally equivalent time** below which the risk of an adverse thermal effect is very low.

Note 2 to entry: **Thermally equivalent time index** is non-dimensional.

**3.12**
**thermal index**
*TI*
ratio of attenuated acoustic power at a specified point to the attenuated acoustic power required to raise the temperature at that point in a specific model by 1 °C

SOURCE: IEC 62359, 3.56.

**3.13**
**thermal load**
*TL*
**Thermally equivalent time** calculated assuming a constant temperature equal to the value estimated at the **safe use time**, a duration equal to the **safe use time**, R = 4, minus the **safe use time**

Note 1 to entry: **Thermal load** is expressed in seconds (s).

**3.14**
**threshold exposure**
exposure to ultrasound which produces a specified constant **temperature rise**, $\Delta T$, that is maintained for a specified duration, $t$

Note 1 to entry: A **threshold exposure** has a **thermally equivalent time**. For example, if a subject having a normal physiologic temperature of 37 °C experiences an increase in temperature to 41 °C for 4 min, then $\Delta T$ = 4 °C and $dt$ = 4 min, and the **thermally equivalent time** is 4 min × $4^4$ = 1 024 min = 61 440 s.



**3.15**
**threshold temperature rise**
$\Delta T_{thr}$
minimum temperature increase above normal physiologic level required to induce harm in the exposed tissue



Note 1 to entry: **Threshold temperature rise** is expressed in degrees Celsius ( °C).

**3.16**
**time to threshold**
*TT*
exposure duration required to raise the temperature at a specified point by the **threshold temperature rise**

Note 1 to entry: **Time to threshold** is expressed in seconds (s).

## 4 Background

### 4.1 General

The safety of diagnostic ultrasound is currently assessed and communicated to the user under international standards IEC 62359 and IEC 60601-2-37, respectively. Although originally adopted in 2005 and 2003, these standards are based on work first published in 1992 as the so-called Output Display Standard (ODS), a joint effort of the American Institute of Ultrasound in Medicine and the (US) National Electrical Manufacturers Association [1][1)]. Much has been learned in the intervening fifteen years, and several reviews of the relevant literature, both general [2]-[4] and specific [5], [6] have appeared since that time. Therefore it is considered prudent to report on such aspects of this information as relate directly to IEC 60601-2-37.

1) Numbers in square brackets refer to the Bibliography.

It is well known that there are two broad categories of mechanisms whereby ultrasound may adversely affect biological material, nonthermal (or mechanical) and thermal. As it passes through tissue, diagnostic ultrasound necessarily induces a mechanical strain. This strain is highest in proximity to gas or vapour bubbles, and therefore mechanical damage is most likely to be induced where they are located. Ultrasound is also absorbed as it propagates, and the absorbed energy produces an increase in temperature of the tissue. Depending on the magnitude and duration of the increase, thermal damage to the tissue (or organism) may result. The goal of this report is to examine various means of quantifying the potential for tissue heating to damage biological tissue, and to suggest approaches for enhancing the safety of diagnostic ultrasound.

### 4.2 Limitations of the existing standard

International standard IEC 62359 quantifies the likelihood that any tissue heating produced by diagnostic ultrasound will harm a patient by requiring the calculation of a quantity called the **thermal index** (*TI*) and the display of this calculated value on the video screen of the equipment console. The calculation is based on one of several simplified thermal models described in the standard. The models currently defined include those for soft tissue (*TIS*), bone at the focus (*TIB*) and bone near the tissue surface, as for cranial bone, hence (*TIC*), as well as encompassing both **scanning** and **non-scanning** imaging **modes** [7]. The calculated value will depend on factors such as transmitted energy, imaging mode, beam shape, focal depth, waveform and duty factor, but rather than displaying a specific physical parameter, the *TI* indicates combinations of output settings that are more likely than others to produce an adverse thermal effect [8].



The general form of the *TI* is simply the ratio of the instantaneous value of a power parameter defined by the standard to the value of the same parameter required to produce a steady-state temperature rise of 1 °C in the exposed tissue. Although it is tempting to consider the value of the *TI* to be the actual *in situ* temperature rise, this is not the case. Because the models underlying the *TI* were made sufficiently simple to be implemented in real time with the limited computational power available in 1992, the *TI* provides only a relative indication of the maximum possible temperature rise at a specific point along the axis of the acoustic beam. Thus values of the *TI* obtained for different imaging consoles, or even with different transducers used with the same console, cannot be compared.

Several additional inaccuracies or limitations of the *TI* have been identified. Some of these were known or suspected at the time the ODS was developed [1], although their full significance was not always completely appreciated. A number of factors directly affecting the computational and display algorithms for the *TI* are discussed in the following subclauses. Other factors, those primarily affecting the measurement of the physical quantities required for specific calculations, are not addressed in this report.

#### 4.2.1 Linear display

As currently defined, the *TI* displayed onscreen is linearly proportional to the absorbed power or equivalently, to the *in situ* intensity or temperature. In contrast, the **thermally equivalent time** (also 'thermal dose', see Note 1 to entry of 3.9), a well known empirical relationship between the temperature $T$ of a biological system and the time $t$ needed for that temperature to induce a deleterious effect, has an exponential form. Specifically, for any two temperatures, $T_1$ and $T_2$, and the corresponding exposure times $t_1$ and $t_2$, required to produce the same level of effect, this general relation holds: $t_1/t_2 = R^{(T_2-T_1)/1°C}$, where $R$ is the thermal normalization constant. Hence, it is experimentally determined that the rate of induction, or risk, of a thermal effect increases exponentially with temperature. There is thus a fundamental discrepancy between the displayed value of the *TI* and its stated goal of quantifying thermal risk from exposure to diagnostic ultrasound. A potential solution to this problem is suggested in 4.1.