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Models for evaluation of thermal hazard in medical diagnostic ultrasonic fields

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TECHNICAL REPORT

Models for evaluation of thermal hazard in medical diagnostic ultrasonic fields

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COMMISSION

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CONTENTS

FOREWORD 4
1 Scope 6
2 Normative references 6
3 Terms and definitions 6
4 Background 10
4.1 General 10
4.2 Limitations of the existing standard 11
4.2.1 Linear display 11
4.2.2 Equilibrium temperature 12
4.2.3 Tissue parameters 12
4.2.4 Transducer self-heating 12
4.2.5 Safety limits 12
5 Options for improvement of the existing standard 13
5.1 General 13
5.2 Exponential display of the current *TI* 13
5.2.1 Theory 13
5.2.2 Illustrative results for the new thermal index display 15
5.2.3 Advantages of the new display 15
5.2.4 Shortcomings of the new display 16
5.3 Replacement of the *TI* with the thermally equivalent time index (*TETI*) 16
5.3.1 Theory 16
5.3.2 Illustrative results for the *TETI* 20
5.3.3 Advantages of the *TETI* 22
5.3.4 Shortcomings of the *TETI* 22
5.4 Replacement of the *TI* with the time to threshold (*TT*) 23
5.4.1 Theory 23
5.4.2 Illustrative results for the *TT* 24
5.4.3 Advantages of the *TT* 27
5.4.4 Shortcomings of the *TT* 27
5.5 Replacement of the *TI* with the safe use time (*SUT*) 28
5.5.1 Theory 28
5.5.2 Illustrative results for the *SUT* 30
5.5.3 Advantages of the *SUT* 33
5.5.4 Shortcomings of the *SUT* 33
5.6 Replacement of the *TI* with the thermally equivalent time displayed (*TETD*) 34
5.6.1 Theory 34
5.6.2 Illustrative results for the *TETD* 35
5.6.3 Advantages of the *TETD* 38
5.6.4 Shortcomings of the *TETD* 39
6 Summary 40
7 Recommendations 41
7.1 General 41
7.2 Thermally equivalent time index 41
7.3 Other models 41
Bibliography 42

AVA Documents
Document Sharing Hub
Full document details: PD IEC/TR 62799:2013

Figure 1 – Comparison of the values of thermal index that would be displayed under the proposed definition, TI_{new}, with that displayed currently, TI_{cur} 15
Figure 2 –Expanded view of the comparison of Figure 1 for smaller values of TI_{cur} 15
Figure 3 – Thermal-equivalent core temperature elevations *vs* time 18
Figure 4 – Temperature-time curve (solid line) that represents a conservative boundary for non-foetal exposure durations, particularly for exposure durations of less than 5 s 19
Figure 5 – Thermally equivalent time index (solid curves) vs foetal exposure duration for TI = 1, 2, 3 and 4 21
Figure 6 – Temperature rise for distance ($z_0 > 3$ cm) for four models as a function of US exposure time 25
Figure 7 – Relation between TT (time to threshold) and power parameters that give a temperature rise of ΔT_{thr} = 4 °C 26
Figure 8 – The ratio of temperature rise to acoustic absorption coefficient, $\Delta T/\mu$, vs exposure duration for the non-scanning soft tissue model with P_a = 100 mW. 27
Figure 9 – A typical example of temperature rise due to diagnostic ultrasound 29
Figure 10 – Values of temperature rise as a function of insonation time 31
Figure 11 – The thermal load as a function of time and f-number 32
Figure 12 – A comparison of thermally equivalent times (t_{43}) for the temperature profiles shown in Figure 6 36
Figure 13 – Probability of birth defect or kidney necrosis as a function of thermally equivalent time (t_{43}) 37
Figure 14 – Probabilities of kidney necrosis estimated for the thermally equivalent times (t_{43}) shown in Figure 12 38
Figure 15 – Probabilities of birth defect estimated for the thermally equivalent times (t_{43}) shown in Figure 12 39

Table 1 – Thermally equivalent time thresholds for chronic damage in various tissues, t_{43}; see [21]. 20
Table 2 – Foetal exposure durations for a thermally equivalent time index value of 1 22
Table 3 – Non-foetal exposure durations for a thermally equivalent time index value of 1 22
Table 4 – SUT values when including and ignoring the contribution of temperatures lower than ΔT_{max} for the four exposure conditions and the corresponding values of ΔT_{max} 32
Table 5 – Values of W, W_a, and ΔT_{max} for the case of SUT = 500 s. 33
Table 6 – Comparison of significant characteristics of the possible replacements for the TI. 40

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Document Sharing Hub
Full document details: PD IEC/TR 62799:2013

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MODELS FOR EVALUATION OF THERMAL HAZARD IN MEDICAL DIAGNOSTIC ULTRASONIC FIELDS

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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.

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

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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
μ
quantity intended to account for loss of ultrasonic energy to tissue at a specified point by mechanisms other than scattering

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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
α
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.

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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
ΔT
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:

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

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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) × 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.

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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**, ΔT, 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 ΔT = 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
ΔT_{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.

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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.

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4.2.2 Equilibrium temperature

As currently defined, the *TI*-value displayed onscreen is based on the steady-state temperature rise calculated for very long duration exposures from a stationary transducer. There are two difficulties here. First, the time needed to reach the steady state depends strongly on exposure parameters, e.g., the width of the acoustic beam, as well as various physiological factors, e.g., the perfusion rate. Clinical users are generally ignorant of the acoustic field they are using and can only guess at the relevant physiology. Second, in most clinical situations the transducer is moved frequently, and a particular imaging mode may be used for only a few tens of seconds before a different mode is selected. The AIUM suggests considering such motion as an additional safety margin protecting the patient [9], with the size of the margin depending on the time needed to reach the steady-state temperature rise. Most clinical users will not be able to estimate the magnitude of the safety margin, and in fact may not even be aware of its existence. Potential solutions to this problem are suggested in 5.3 and 5.4.

4.2.3 Tissue parameters

The choice of the tissue **acoustic attenuation** and **absorption coefficients** are critical to accurate modelling of the expected tissue temperature rise. The amount of heat deposited is proportional to the product of the local time-average intensity and the absorption coefficient, and the local intensity decreases exponentially with the product of the attenuation coefficient and the distance from the source transducer. As currently implemented, the algorithms for the *TI* assume homogeneous tissue with the slopes of both coefficients equal to 0,3 dB cm^{-1} MHz^{-1}. Of course, real tissues are not homogeneous and usually have higher values for both their **acoustic attenuation** and **absorption coefficients** [10]. This model, homogeneous tissue model H.3, was chosen as a reasonable worst case with regard to patient safety because it tends to overestimate **temperature rise** in most cases. However, by artificially limiting transducer output, this combination of factors may reduce the clinical utility of diagnostic ultrasound in many cases, particularly those involving hard-to-image patients.

4.2.4 Transducer self-heating

Because the transducer elements comprising an imaging probe are not 100% efficient at converting electrical to acoustic energy, heat is produced within the transducer itself. Whenever the energized probe is in contact with the patient, a portion of this heat will be conducted into the adjacent tissues. As currently implemented, the *TI* considers only heating produced by absorption of the acoustic beam, i.e., it does not include a correction for transducer self-heating. This seems reasonable for transcutaneous applications because the temperature rise due to surface heating will be small except within a depth of tissue on the order of the perfusion length, 3 mm to 5 mm [2]. For some intra-cavity applications, and especially in the presence of bone, however, the perfusion length may be significantly larger, and transducer self-heating may heat deeper tissues [11] – [13]. At present, the problem is dealt with by restricting the maximum measured surface temperature of the transducer to a level considered safe for patient contact, 43 °C (IEC 60601-2-37).

4.2.5 Safety limits

As currently implemented, no limit is placed on the value of the *TI* that may be employed in diagnostic imaging. This may be reasonable given the nature of the computational algorithms and the fact that almost any reasonably attainable temperature elevation can be sustained without harm if the duration is short enough, but it leaves the clinical user without guidance as to what should be considered “reasonable”. The options suggested in 5.3 and 5.4 automatically incorporate a solution to this problem.

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5 Options for improvement of the existing standard

5.1 General

Potential solutions to at least some of the limitations of the *TI* discussed above are available in the literature. For example, the nonlinear relation between temperature elevation and potential risk was pointed out in [14], which suggested replacing the current linear display with an exponential display based on the form of the **thermally equivalent time**. The fact that the risk of a thermally induced adverse effect depends on both the magnitude and duration of the increase in temperature was considered in [15], which proposed an improvement to the *TI*, the **thermally equivalent time index** (*TETI*), to account for both factors. The reliance of the *TI* on equilibrium temperature rise has been investigated in greater detail [8]. It was proposed to replace the current *TI* with a new parameter called the **time to threshold** (*TT*), which displays the estimated duration of imaging required for the **temperature rise** to reach the **threshold temperature rise** for an adverse biological effect. A similar approach was investigated in [16], which proposed a different parameter, the **safe use time** (*SUT*), to compare a simplified estimate of the **thermally equivalent time** to a threshold for an adverse effect in terms of **thermally equivalent time** rather than temperature rise. These four options are discussed first, followed by a fifth that has not yet been published.

A note on nomenclature: In this document, the widely accepted term “thermal dose” is replaced by the more descriptive term “**thermally equivalent time**”, except when referring to the published literature. The definition of “**thermally equivalent time**” is also more precise in that the reference temperature is fixed at 43 °C.

5.2 Exponential display of the current *TI*

5.2.1 Theory

It is well known that there is a relationship between an elevation above normal physiological temperature and the time needed to induce a deleterious effect in a biological system [2], [3], [17], [18]. Simply put, the higher the temperature rise, the shorter the time needed to produce the effect. For any two exposures at two different temperatures, the ratio of the minimum time t_1 required for the lower temperature T_1 to produce an effect, to the time t_2 required for the higher temperature T_2 to produce the same effect increased by a constant multiple for each degree of temperature difference [19], [20]. For example, if the temperature difference $T_2 - T_1$ = 1 °C, then $t_1/t_2 = R$, while if $T_2 - T_1$ = 2 °C, then $t_1/t_2 = R^2$, etc., where R is the thermal normalization constant. In general, $t_1/t_2 = R^{(T_2-T_1)/1°C}$, and the time calculated using this approach to quantify thermal exposures is termed the **thermally equivalent time**. Empirical values of R vary among species, tissues and biological endpoints. They are also temperature-dependent, with $R \approx 2$ for $T > 43$ °C, increasing by a factor of 2 to 3 for $T < 43$ °C. For simplicity, the values for R are usually fixed at $R = 2$ for $T > 43$ °C and $R = 4$ for $T < 43$ °C [20], [21].

The equation for **thermally equivalent time** is based on a thermodynamic or “Arrhenius-type” analysis that has been empirically validated for a number of biological endpoints [20], [22]. The underlying principle is that the thermal damage to a biological system, Ω, which occurs regardless of the temperature of the system, may be modelled as a first-order chemical rate equation. From the Eyring equation for reaction rates in condensed or mixed-phase materials [23], [24], it is possible to show that [25]:

$$\frac{d\Omega}{dt} = k = A \exp\left[\frac{-E_a}{R_g T(t)}\right] \tag{1}$$

where A is an arbitrary constant proportional to the change in entropy, E_a is the activation energy for the damage process, R_g is the gas constant, and T is the absolute temperature (i.e., temperature in units of kelvin) at time t. Equation (1) assumes that the rate, k, at which

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