

● *Original Contribution*

## EVALUATION OF UNSCANNED-MODE SOFT-TISSUE THERMAL INDEX FOR RECTANGULAR SOURCES AND PROPOSED NEW INDICES

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**Abstract**—The monopole-source solution was used to calculate the three-dimensional complex acoustic pressure field for one-dimensional focused rectangular apertures in a medium having homogeneous acoustic and thermal properties. For each of six frequencies (1, 3, 5, 7, 9 and 12 MHz) and three focuses ( $f/1$ ,  $f/2$  and  $f/4$ ), 33 rectangular aperture cases were investigated, for a total of 594 cases. For these focused field geometries, the three-dimensional temperature distribution was calculated using the bioheat transfer equation in homogeneous perfused media (attenuation = absorption: 0.3 dB/cm-MHz; perfusion length: 1.0 cm). For each of the 594 cases, the acoustic field was normalized to the derated spatial-peak temporal-average intensity ( $I_{SPTA,3}$ ) of 720 mW/cm<sup>2</sup>, the maximum value condition allowed based on the U.S. Food and Drug Administration (FDA) regulatory limit for most diagnostic ultrasound (US) equipment. Using the normalized acoustic field, the axial temperature increase profiles and the maximum temperature increases ( $\Delta T_{max}$ ) were determined for each case. Also, from the normalized acoustic field, the unscanned-mode soft-tissue thermal index (TIS) for the rectangular sources was determined according to the procedures of the Standard for Real-Time Display of Thermal and Mechanical Indices on Diagnostic Ultrasound Equipment, commonly called the output display standard, ODS. The  $\Delta T_{max}$ : TIS ratio of the 594 cases yielded a mean value of 0.22, a median value of 0.16, a maximum value of 1.04 and a minimum value of 0.039. For all but one of the cases, TIS was greater than  $\Delta T_{max}$ . Also, two new unscanned-mode soft-tissue thermal indices (denoted TIS<sub>new(1)}</sub> and TIS<sub>new(2)}</sub>) were proposed. For new model 1, the  $\Delta T_{max}$ : TIS<sub>new(1)}</sub> ratio yielded a mean value of 1.02, a median value of 1.01, a maximum value of 1.83 and a minimum value of 0.44. For new model 2, the  $\Delta T_{max}$ : TIS<sub>new(2)}</sub> ratio yielded a mean value of 1.04, a median value of 0.99, a maximum value of 2.31 and a minimum value of 0.34. Further, both new models fit more closely to  $\Delta T_{max}$  than does the ODS-determined TIS and have the potential of being easier for manufacturers to implement because only the source power and frequency need to be measured. (E-mail: [wdo@uiuc.edu](mailto:wdo@uiuc.edu)) © 2004 World Federation for Ultrasound in Medicine & Biology.

**Key Words:** Thermal index, Rectangular sources, Output display standard.

### INTRODUCTION

In the mid-1980s, the U. S. Food and Drug Administration (FDA) initiated the regulatory process for diagnostic ultrasound equipment and set application-specific intensity limits that could not be exceeded (FDA 1985, 1987). These limits were not based on safety considerations. Rather, they were based on the output of diagnostic US systems that had been entered into interstate commerce prior to May 28, 1976, the date when the Medical Devices Amendments were enacted. In the early 1990s, the FDA implemented the Standard for Real-Time Display

of Thermal and Mechanical Indices on Diagnostic Ultrasound Equipment (commonly called the output display standard or ODS) (AIUM/NEMA 1992; FDA 1993, 1994, 1997). Although the ODS did not specify upper limits, the FDA implementation of the ODS stipulated regulatory upper limits of 720 mW/cm<sup>2</sup> for the derated (0.3 dB/cm-MHz) spatial-peak temporal-average intensity,  $I_{SPTA,3}$ , and 1.9 for the Mechanical Index (MI) for all but ophthalmological applications (FDA 1997). In the late 1990s, the Output Standard Display was revised (AIUM/NEMA 1998b) but the FDA regulatory upper limits were not changed.

The purpose of the ODS (AIUM/NEMA 1992) is to provide the capability for users of diagnostic US equipment to operate their systems at levels much higher than previously had been possible to provide greater diagnos-

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tic capabilities. In doing so, the possibility was hypothesized for harm to the patient because of the potential for higher output levels. Therefore, the ODS requires that two biophysical indices be provided so that the equipment operator has displayed information available to make appropriate clinical decisions (viz., benefit vs. risk) and to implement the ALARA (As Low As Reasonably Achievable) principle (NCRP 1990). The two biophysical indices are the Thermal Index and the Mechanical Index. The Thermal Index provides information about tissue temperature increase and the Mechanical Index provides information about the potential for cavitation. This contribution does not address the Mechanical Index.

The basic Thermal Index definition is (AIUM/NEMA 1998b):

$$TI = \frac{W_o}{W_{DEG}}, \quad (1)$$

where  $W_o$  is the source power of the diagnostic ultrasound system and  $W_{DEG}$  is the source power required to increase the tissue temperature by 1°C under very specific and conservative conditions. Three different Thermal Indices were developed to address three different tissue models and two different scan modes; that is, the soft-tissue Thermal Index TIS, the bone Thermal Index TIB and the cranial-bone Thermal Index TIC. The unscanned mode is typically used clinically for spectral Doppler and M-mode where the ultrasound beam remains stationary for a period of time. Also, the unscanned-mode soft-tissue Thermal Index, as well as TIB, are the only TI quantities that attempt to estimate temperature increase at locations other than at or near the source surface. The others estimate temperature increase at or near the source surface. This contribution is an evaluation only for the unscanned-mode soft-tissue Thermal Index for rectangular sources. In addition, two new unscanned-mode soft-tissue Thermal Indices for rectangular sources are proposed. An evaluation of the unscanned-mode soft-tissue Thermal Index for circular sources has previously been published (O'Brien and Ellis 1999).

## METHODOLOGY

As published previously, the monopole-source solution for estimating tissue temperature increase of a focused US field was used (Ellis and O'Brien 1996; O'Brien and Ellis 1999). Briefly, the monopole-source solution is not restricted to a specific aperture (source) or beam geometry. The monopole-source solution consists of three steps. The first step determines the three-dimensional distribution of the complex acoustic pressure field generated by an ultrasonic source from the solution to the

lossy Helmholtz equation. The second step uses the computed three-dimensional acoustic pressure field to determine the temperature increase at any point in the medium. The third step also used the same computed three-dimensional acoustic pressure field to determine the unscanned-mode soft-tissue Thermal Index.

For the unscanned-mode soft-tissue Thermal Index, it was assumed that the tissue is homogeneous (in terms of both acoustic and thermal properties). The attenuation coefficient (also referred to as a derating factor) and absorption coefficient are both 0.3 dB/cm-MHz, density is 1000 kg/m<sup>3</sup>, propagation speed is 1540 m/s, tissue perfusion length is 1 cm and tissue thermal conductivity is 0.006 W/cm<sup>2</sup>. These are the values used in the Output Display Standard (AIUM/NEMA 1998b) and the values used herein for the evaluation of the unscanned-mode soft-tissue Thermal Index for rectangular sources. They are also the values used to compute the maximum steady-state temperature increase.

The basis for the development of the unscanned-mode soft-tissue Thermal Index (TIS) computations for the small and large aperture cases is discussed in detail elsewhere (NCRP 1992; AIUM/NEMA 1998b; Abbott 1999). The TIS was computationally determined from the three-dimensional distribution of the complex acoustic pressure field for a derated  $I_{SPTA,3}$  of 720 mW/cm<sup>2</sup>. The two expressions for the TIS computations are based on the source aperture area. For a large aperture area:

$$TIS = \frac{\max_{z_1 > z_{bp}} \{ \min \{ W_{,3}(z_1); I_{TA,3}(z_1) \times 1 \text{ cm}^2 \} \}}{\left( \frac{210}{f_c} \right)} \quad \text{for } A_{\text{aprt}} > 1 \text{ cm}^2 \quad (2)$$

where  $W_{,3}(z_1)$  is the derated (0.3 dB/cm-MHz) power (in mW) at  $z_1$ ,  $I_{TA,3}(z_1)$  is the derated temporal-average intensity (in mW/cm<sup>2</sup>) at  $z_1$ ,  $f_c$  is the US center frequency (in MHz),  $A_{\text{aprt}}$  is the aperture (source) surface area (in cm<sup>2</sup>) and  $z_1$  is the axial distance greater than the axial breakpoint distance  $z_{bp}$  (both in cm). The breakpoint distance was introduced into the TIS determination in order to avoid measurement inaccuracies caused by measuring the US field too close to the source surface and is given by:

$$z_{bp} = 1.5 \sqrt{\frac{4}{\pi}} A_{\text{aprt}} = 1.69 \sqrt{A_{\text{aprt}}} \quad (3)$$

For a small aperture area:

$$TIS > = \frac{W_o}{\left( \frac{210}{f_c} \right)} \quad \text{for } A_{\text{aprt}} \leq 1 \text{ cm}^2. \quad (4)$$

The maximum steady-state temperature increase  $\Delta T_{\max}$  for a derated  $I_{\text{SPTA},3}$  of  $720 \text{ mW/cm}^2$  was computationally determined from the bioheat transfer equation being applied to the 3D distribution of the complex acoustic pressure field.

All results reported herein are based on the derated  $I_{\text{SPTA},3}$  of  $720 \text{ mW/cm}^2$ . This value provides a common reference as well as a worst-case exposure condition based on the FDA regulatory limit for most diagnostic ultrasound equipment approved under the ODS procedures (AIUM/NEMA 1998b).

All computations were made on one of four Athlons (AMD, Sunnyvale, CA), each having a 2-GHz processor and running Redhat Linux®. A monopole-source spacing on the transducer surface of  $\lambda/4$  and a field spacing of 0.01 cm were used for the monopole-source solution. These spatial quantities were verified previously (Ellis and O'Brien 1996; O'Brien and Ellis 1999) to yield convergent asymptotic temperature increase values.

### EVALUATION OF THE UNSCANNED-MODE SOFT-TISSUE THERMAL INDEX FOR RECTANGULAR SOURCES

A total of 594 cases have been investigated at six frequencies (1, 3, 5, 7, 9 and 12 MHz), 99 cases for each frequency. Figure 1 shows the dimensions of the 33 rectangular aperture cases investigated. The x-length direction of the aperture is the axis that is focused to an appropriate radius of curvature (ROC) to yield f-numbers (= ROC/x-length) of 1, 2 and 4. The y-length direction of the aperture is not focused. This selection of frequencies, aperture dimensions and transmit f-numbers was chosen to provide sufficient detail to evaluate TIS,  $\Delta T_{\max}$  and other exposure trends over the diagnostic ultrasound frequency range.

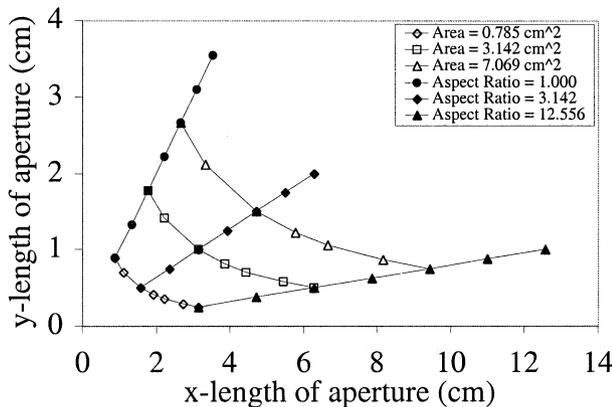


Fig. 1. Dimensions of the 33 rectangular aperture cases investigated. Area is the active aperture area and aspect ratio is (x – length: y – length).

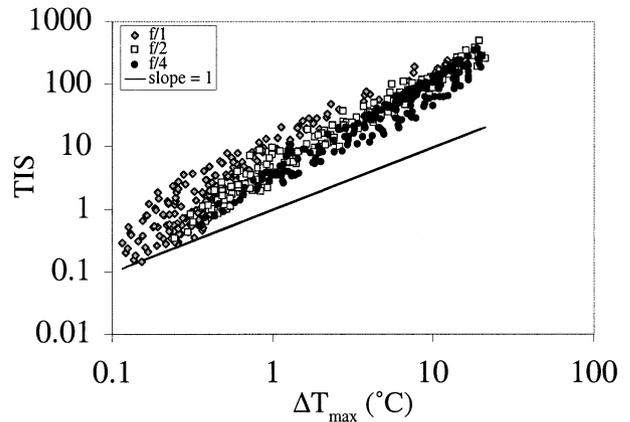


Fig. 2. Paired maximum steady-state temperature increase  $\Delta T_{\max}$  vs. unscanned-mode TIS for rectangular sources grouped by f-number under the condition that the derated  $I_{\text{SPTA},3}$  is  $720 \text{ mW/cm}^2$ .

Direct comparison of the 594  $\Delta T_{\max}$ -TIS pairs (Fig. 2) provides an understanding of how the maximum steady-state temperature increase  $\Delta T_{\max}$  tracks its matched unscanned-mode TIS value from the same computed acoustic pressure field. The  $\Delta T_{\max}$ : TIS ratio for each of the 594 cases was calculated and yielded a mean value of 0.22, a median value of 0.16, a maximum value of 1.04 and a minimum value of 0.039. For all but one of the cases, TIS was greater than  $\Delta T_{\max}$ .

A breakdown of  $\Delta T_{\max}$ : TIS as a function of  $\Delta T_{\max}$  range (Fig. 3) shows that, as  $\Delta T_{\max}$  increases, the mean,

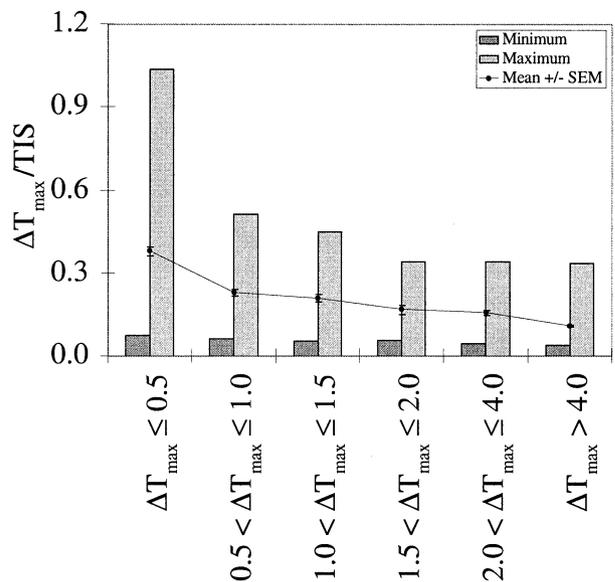


Fig. 3. The ratio  $\Delta T_{\max}$ : TIS grouped by maximum steady-state temperature increase  $\Delta T_{\max}$  ranges under the condition that the derated  $I_{\text{SPTA},3}$  is  $720 \text{ mW/cm}^2$ .

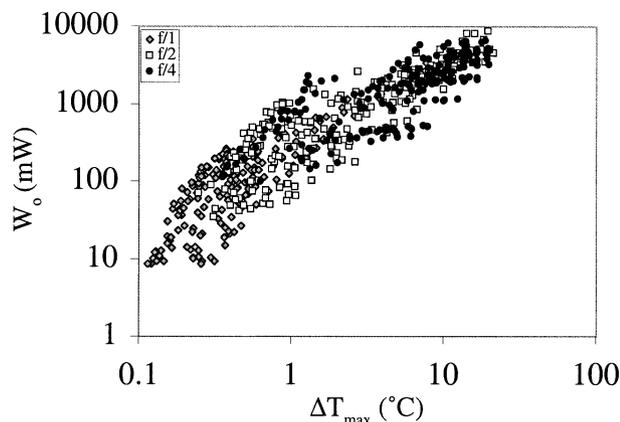


Fig. 4. Paired maximum steady-state temperature increase  $\Delta T_{max}$  vs. source power  $W_o$  grouped by f-number under the condition that the derated  $I_{SPTA,3}$  is  $720 \text{ mW/cm}^2$ .

maximum and minimum values of  $\Delta T_{max} : TIS$  progressively decrease. The  $\Delta T_{max} : TIS$  ratio for all cases is less than 0.51 when  $\Delta T_{max} > 0.5$ .

$\Delta T_{max}$  generally increases as the source power  $W_o$  increases (Fig. 4). There is a weak trend with f-number. The lower source powers, or  $\Delta T_{max}$  values, are associated with the f/1 focusing cases and the higher source powers are associated with the f/4 focusing cases.

As the frequency (Fig. 5) and aperture area (Fig. 6) individually increase, the mean, maximum and minimum values of  $\Delta T_{max} : TIS$  progressively decrease except for the maximum value of  $\Delta T_{max} : TIS$  when the aperture area is  $12.57 \text{ cm}^2$  (Fig. 6). Likewise, as the f-number (Fig. 7) increases, the mean and maximum values of  $\Delta T_{max} : TIS$  decrease, but the minimum value is lowest for the f/2 case. And, as a function of aspect ratio (AR) (x – length: y – length) (Fig. 8), mean, maximum and

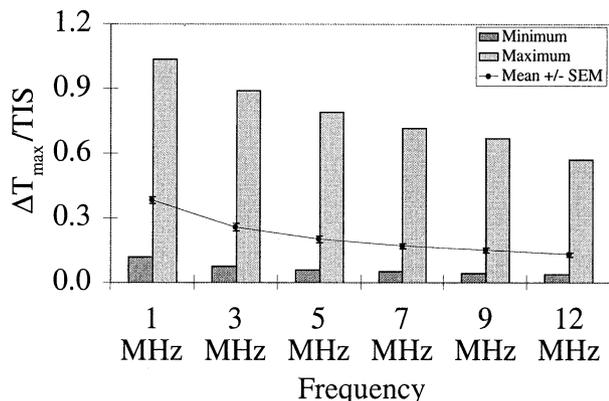


Fig. 5. The ratio  $\Delta T_{max} : TIS$  grouped by frequency under the condition that the derated  $I_{SPTA,3}$  is  $720 \text{ mW/cm}^2$ .

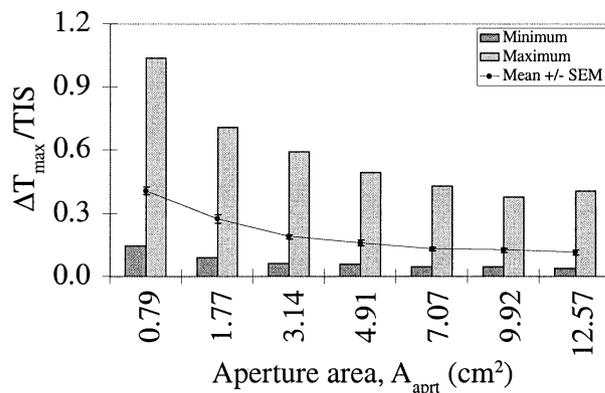


Fig. 6. The ratio  $\Delta T_{max} : TIS$  grouped by aperture area under the condition that the derated  $I_{SPTA,3}$  is  $720 \text{ mW/cm}^2$ .

minimum values of  $\Delta T_{max} : TIS$  peak at an AR of 1.57 and then progressively decrease as the AR increases for  $AR \geq 4.72$ .

The ODS process does not specify the location of the  $\Delta T_{max}$ . Figure 9 shows the relationship between  $\Delta T_{max}$  and its location (axial distance) for the three f-number cases. For the f/1, f/2 and f/4 cases, respectively, when  $\Delta T_{max} \geq 1$ , the greatest  $\Delta T_{max}$  locations are 0.92 cm, 2.34 cm and 14.94 cm. For the f/2 cases, with the 1-MHz and 3-MHz data excluded, when  $\Delta T_{max} \geq 1$ , the greatest  $\Delta T_{max}$  location is 1.24 cm. For the f/4 cases, with the 1-MHz data excluded, when  $\Delta T_{max} \geq 1$ , the greatest  $\Delta T_{max}$  location is 1.48 cm. Consistent with the TIS evaluation of the circular source (O'Brien and Ellis 1999), the location of  $\Delta T_{max}$  was always less than the geometric focus location (*i.e.*, ROC) for the rectangular source (Fig. 10). For the f/1, f/2 and f/4 cases, respectively, the ranges of the location of the  $\Delta T_{max} : ROC$  ratio are (0.040, 0.99), (0.019, 0.95) and (0.0095, 0.68).

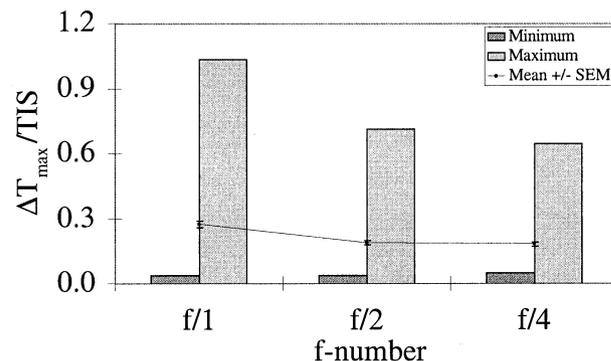


Fig. 7. The ratio  $\Delta T_{max} : TIS$  grouped by f-number under the condition that the derated  $I_{SPTA,3}$  is  $720 \text{ mW/cm}^2$ .

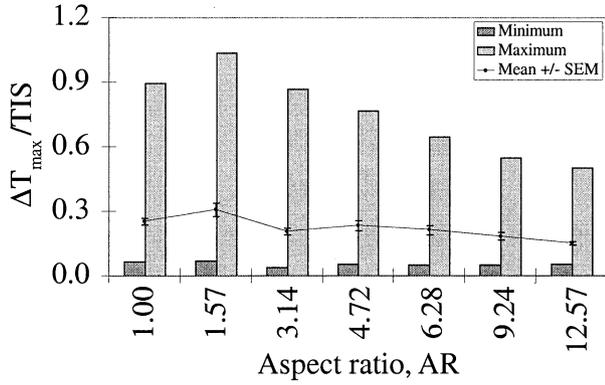


Fig. 8. The ratio  $\Delta T_{\max}$ : TIS grouped by aspect ratio under the condition that the derated  $I_{\text{SPTA},3}$  is  $720 \text{ mW/cm}^2$ .

### PROPOSED NEW UNSCANNED-MODE SOFT-TISSUE THERMAL INDEX FOR RECTANGULAR SOURCES

The measurement process detailed in the ODS (AIUM/NEMA 1998b) is time-consuming to implement. Therefore, a new concept for the unscanned-mode soft-tissue Thermal Index (TIS) for rectangular sources is proposed, that is:

$$\text{TIS}_{\text{new}} = A \cdot W_{dc}^B f_c^C A_{\text{aprt}}^D AR^E f\#^F, \quad (5)$$

where  $A$  is a constant,  $B$  is the source power exponent,  $C$  is the center frequency exponent,  $D$  is the aperture (source) surface area exponent,  $E$  is the AR ( $x$  – length:  $y$  – length) exponent and  $F$  is the  $f$ -number (ROC/ $x$ -length) exponent. For the following developments, the units for the indicated quantities are:  $W_o$  in mW,  $f_c$  in MHz,  $A_{\text{aprt}}$  in  $\text{cm}^2$ ,  $AR$  unitless (cm/cm) and  $f\#$  unitless (cm/cm). The model of interest is:

$$\Delta T_{\max} = A \cdot W_{dc}^B f_c^C A_{\text{aprt}}^D AR^E f\#^F, \quad (6)$$

where  $\Delta T_{\max}$  is the computed maximum steady-state temperature increase for a derated  $I_{\text{SPTA},3}$  of  $720 \text{ mW/cm}^2$ . It is hypothesized that each of these variables, in eqn (6), separately is proportional to  $\Delta T_{\max}$ , as shown in the previous section. The multiplicative model for  $\Delta T_{\max}$  in eqn (6) implies a linear regression model for the logarithm of  $\Delta T_{\max}$ . Expressed in logarithms (to the base 10) and including a random error term  $e$ , eqn (6) becomes:

$$\log \Delta T_{\max} = \log A + B \log W_o + C \log f_c + D \log A_{\text{aprt}} + E \log AR + F \log f\# + e. \quad (7)$$

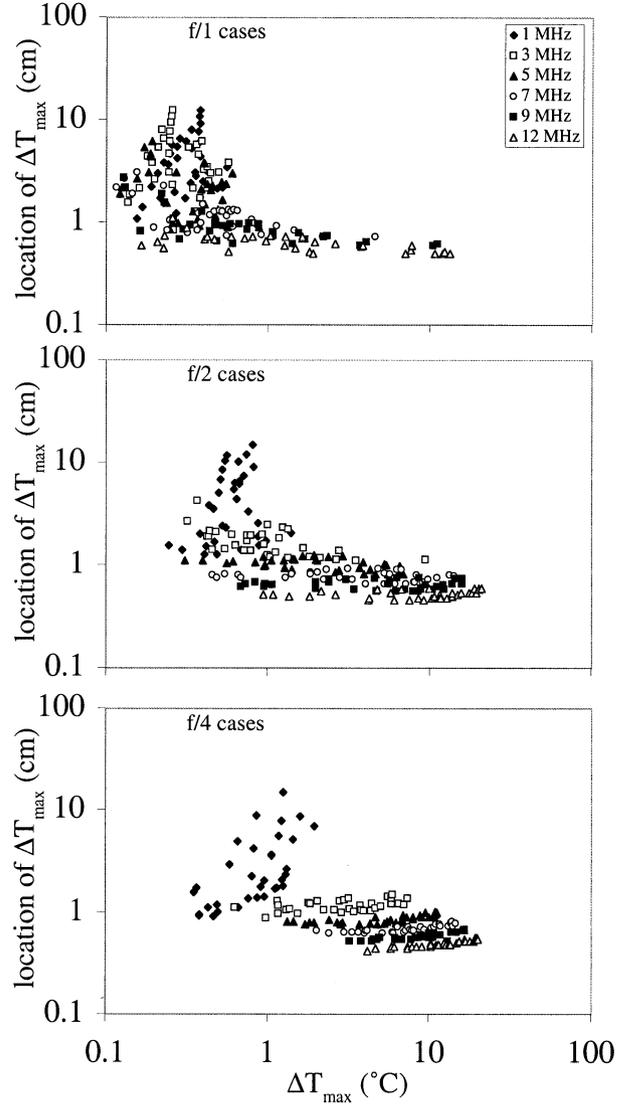


Fig. 9. Paired maximum steady-state temperature increase  $\Delta T_{\max}$  vs. location (axial distance) of  $\Delta T_{\max}$  grouped by  $f$ -number (top:  $f/1$ ; middle:  $f/2$ ; bottom:  $f/4$ ) and frequency under the condition that the derated  $I_{\text{SPTA},3}$  is  $720 \text{ mW/cm}^2$ .

The parameters  $\log(A)$ ,  $B$ ,  $C$ ,  $D$ ,  $E$  and  $F$  were estimated by the method of least squares, and the corresponding parameter estimates are listed in Table 1. The  $R^2$  value for eqn (7) is 0.98, with all the effects being statistically significant ( $p < 0.0001$ ). However, the estimated coefficients for  $\log AR$  and  $\log f\#$  were small in magnitude and, thus, the parameters  $E$  and  $F$  in eqn (7) were each set to zero, yielding a simpler second model (simplified model 1), that is:

$$\log \Delta T_{\max} = \log A + B \log W_o + C \log f_c + D \log A_{\text{aprt}} + e. \quad (8)$$

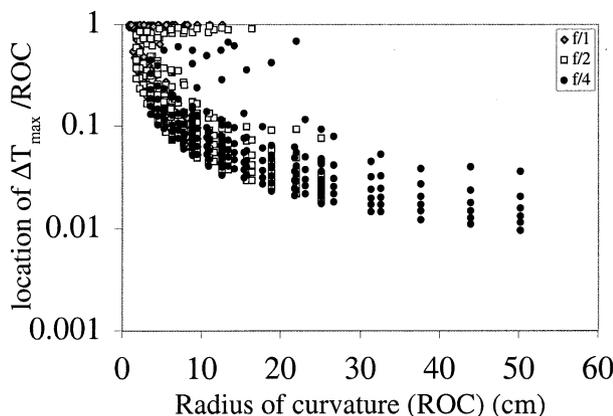


Fig. 10. Paired location of the geometric focus (ROC) vs. normalized location (axial distance) of  $\Delta T_{\max}$  (location of  $\Delta T_{\max}$ : ROC) grouped by f-number.

The parameter estimates for  $\log \Delta T_{\max}$  in simplified model 1, eqn (8), are listed in Table 2, and the corresponding  $R^2$  value is 0.97, with all the effects in simplified model 1 statistically significant ( $p < 0.0001$ ).

For simplified model 1, the estimated coefficient for  $\log A_{\text{aprt}}$  was small in magnitude relative to those for the other three effects. Thus, parameter  $D$  in eqn (8) was set to zero, yielding an even simpler model (simplified model 2), that is:

$$\log \Delta T_{\max} = \log A + B \log W_o + C \log f_c + e. \quad (9)$$

The parameter estimates for  $\log \Delta T_{\max}$  in simplified model 2, eqn (9), are listed in Table 3 and the  $R^2$  value is 0.94. Again, all the effects are statistically significant ( $p < 0.0001$ ).

The analysis of the full model, eqn (7), yields statistically significant  $p$  values for all of the parameters. However, the estimated coefficients for  $\log A_{\text{aprt}}$ ,  $\log AR$  and  $\log \#$  were small in magnitude. Note that  $R^2$  is 0.97 for simplified model 1, eqn (8), with  $E = F = 0$  and 0.94 for simplified model 2, eqn (9), with additionally  $D = 0$ , whereas  $R^2$  is 0.98 for the full model, eqn (7), an insufficient difference to justify the inclusion of two ( $E$  and  $F$ ;

Table 1. The parameter estimates and standard errors (SEs) for  $\log \Delta T_{\max}$  in the full model, eqn (7)

| Variable               | Parameter estimate | Standard error |
|------------------------|--------------------|----------------|
| $\log A$ (intercept)   | -2.126             | 0.0180         |
| $\log W_o$             | $B = 0.8192$       | 0.0121         |
| $\log f_c$             | $C = 0.5867$       | 0.0112         |
| $\log A_{\text{aprt}}$ | $D = -0.3064$      | 0.0162         |
| $\log AR$              | $E = -0.1209$      | 0.00966        |
| $\log \#$              | $F = 0.1380$       | 0.0265         |

Table 2. The parameter estimates and standard errors (SEs) for  $\log \Delta T_{\max}$  in the simplified model 1, eqn (8)

| Variable               | Parameter estimate | Standard error |
|------------------------|--------------------|----------------|
| $\log A$ (intercept)   | -2.228             | 0.0193         |
| $\log W_o$             | $B = 0.8483$       | 0.00845        |
| $\log f_c$             | $C = 0.5763$       | 0.0133         |
| $\log A_{\text{aprt}}$ | $D = -0.3331$      | 0.0147         |

simplified model 1) or three ( $D$ ,  $E$  and  $F$ ; simplified model 2) extra parameters. The large sample size ( $n = 594$ ) and the computational data source imply that the computations have the capacity to detect effects of small magnitude that have little effect on the calibration. Furthermore, the histograms of residuals and the scatter plots of observed values of  $\log \Delta T_{\max}$  vs. the predicted values for the two simplified models, eqns (8) and (9), show that both simplified models give adequate fits. The histograms displayed Gaussian patterns that suggested that the deviations from the model are reasonably modeled as random noise.

The constant and exponent estimates for simplified model 1 (Table 2) were, thus, used to yield the predicted  $\Delta T_{\max}$ , that is,  $TIS_{\text{new}(1)}$ , for all of the 594 rectangular aperture cases:

$$\hat{\Delta T}_{\max} = TIS_{\text{new}(1)} = \frac{W_o^{0.85} f_c^{0.58}}{169 \cdot A_{\text{aprt}}^{0.33}}. \quad (10)$$

Alternatively, the parameter estimates for simplified model 2 (Table 3) were used to yield the predicted  $\Delta T_{\max}$ , that is,  $TIS_{\text{new}(2)}$ :

$$\hat{\Delta T}_{\max} = TIS_{\text{new}(2)} = \frac{W_o^{0.73} f_c^{0.62}}{130}. \quad (11)$$

$TIS_{\text{new}(1)}$  and  $TIS_{\text{new}(2)}$  are shown graphically as a function of  $\Delta T_{\max}$  (Fig. 11).

The ratio  $\Delta T_{\max} : TIS_{\text{new}(1)}$  for each of the 594 cases was calculated and yielded a mean value of 1.02, a median value of 1.01, a maximum value of 1.83 and a minimum value of 0.44. The corresponding numbers for  $\Delta T_{\max} : TIS_{\text{new}(2)}$  were 1.04, 0.99, 2.31 and 0.34, respectively. A breakdown of  $\Delta T_{\max} : TIS_{\text{new}(1)}$  and  $\Delta T_{\max} :$

Table 3. The parameter estimates and standard errors (SEs) for  $\log \Delta T_{\max}$  in the simplified model 2, eqn (9)

| Variable             | Parameter estimate | Standard error |
|----------------------|--------------------|----------------|
| $\log A$ (intercept) | -2.114             | 0.0255         |
| $\log W_o$           | $B = 0.7269$       | 0.00895        |
| $\log f_c$           | $C = 0.6197$       | 0.0180         |

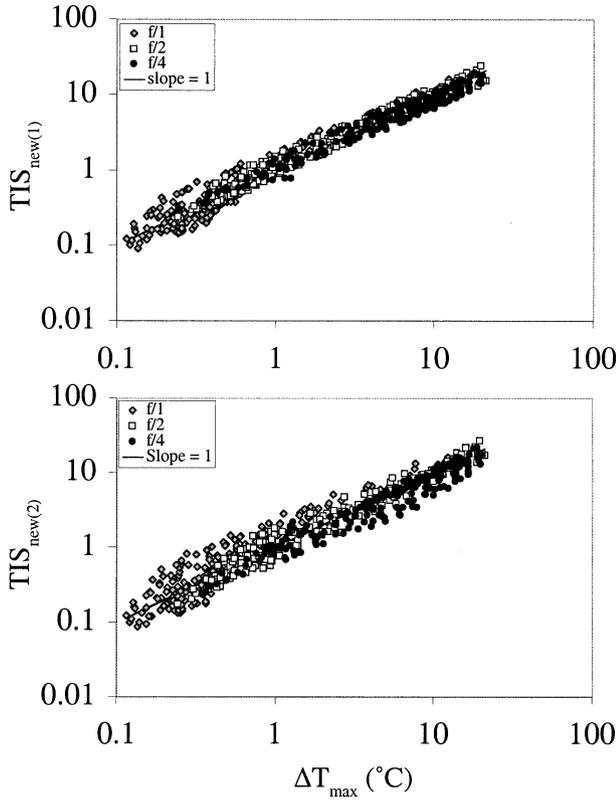


Fig. 11. Proposed unscanned-mode soft-tissue Thermal Indices  $TIS_{new(1)}$  and  $TIS_{new(2)}$  vs. paired maximum steady-state temperature increase  $\Delta T_{max}$  for rectangular sources grouped by  $f$ -number under the condition that the derated  $I_{SPTA,3}$  is  $720 \text{ mW/cm}^2$ .

$TIS_{new(2)}$  as a function of  $\Delta T_{max}$  range (Fig. 12) indicates that, as  $\Delta T_{max}$  increases, their mean, maximum and minimum values show no apparent trends or patterns.

A 95% confidence interval for an individual prediction can be obtained from:

$$\log \Delta \hat{T}_{max} \pm 1.96 \times SE(\log \Delta \hat{T}_{max}), \quad (12)$$

where  $\Delta \hat{T}_{max}$  represents either simplified model 1, eqn (10), or simplified model 2, eqn (11), and the associated standard error (SE) for  $\Delta \hat{T}_{max}$  is 0.1125 or 0.1539, respectively. For example, consider  $\Delta T_{max} = 12.687$  in the data set for which  $\log \Delta T_{max} = 1.103$ . For simplified model 1, eqn (10),  $\log \Delta \hat{T}_{max} = 0.967$ , then a 95% confidence interval for  $\log \Delta T_{max} = 1.103$  is  $0.967 \pm 1.96 \times 0.1125 = (0.7465, 1.1875)$  and a 95% confidence interval for  $\Delta T_{max} = 12.687$  is  $(10^{0.7465}, 10^{1.1875}) = (5.578, 15.399)$ ; for simplified model 2, eqn (11),  $\log \Delta \hat{T}_{max} = 1.073$  and a 95% confidence interval for  $\Delta T_{max} = 12.687$  is  $(10^{0.7714}, 10^{1.3746}) = (5.907, 23.692)$ . The 95% confidence intervals based on the two simpli-

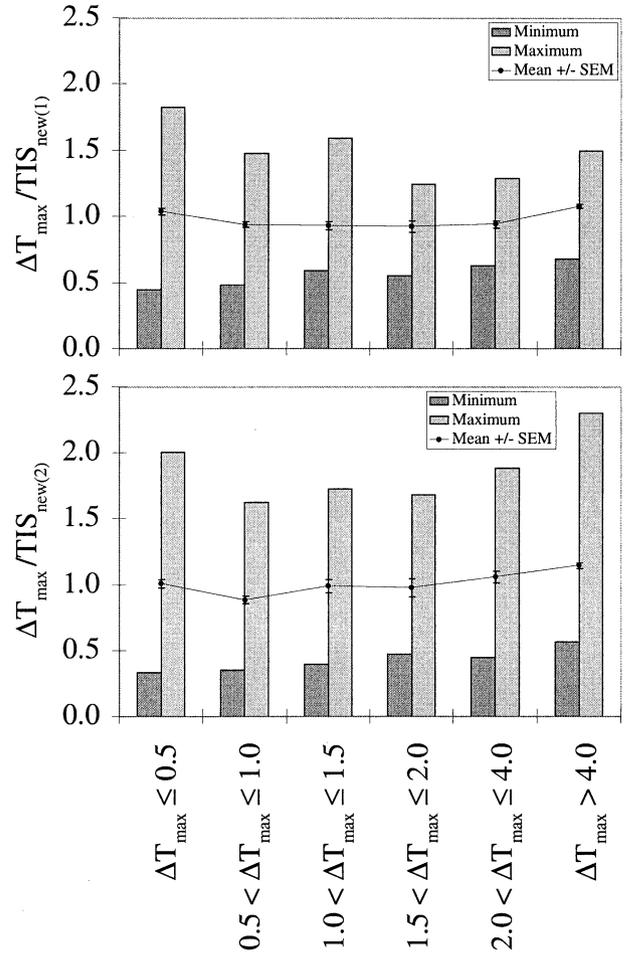


Fig. 12. The ratios  $\Delta T_{max} : TIS_{new(1)}$  and  $\Delta T_{max} : TIS_{new(2)}$  grouped by maximum steady-state temperature increase  $\Delta T_{max}$  ranges under the condition that the derated  $I_{SPTA,3}$  is  $720 \text{ mW/cm}^2$ .

fied models both contain the true data point, and the confidence interval from simplified model 1 has a narrower range than that of simplified model 2.

Based on the results above, the two new TIS models fit much more closely to  $\Delta T_{max}$  (Fig. 11) than does the ODS-determined TIS (Fig. 2). In particular, a common measure of predictive accuracy is the root-mean-squared error (RMSE). On the logarithmic scale, the RMSE of an estimator  $\Delta \hat{T}_{max}$  is given by:

$$RMSE(\log \Delta \hat{T}_{max}) = \sqrt{\frac{1}{n} \sum_{i=1}^n \log \left\{ \left( \frac{\Delta \hat{T}_{max,i}}{\Delta T_{max,i}} \right)^2 \right\}}, \quad (13)$$

where the subscript  $i$  denotes the  $i^{\text{th}}$  set of input conditions. The RMSE for the ODS-determined  $\log(TIS)$  was 0.830, compared with 0.112 for  $\log(TIS_{new(1)})$  and 0.154

for  $\log(\text{TIS}_{\text{new}(2)})$ , nearly an order of magnitude improvement for the new models.

Both simplified models support the idea that new unscanned-mode soft-tissue Thermal Indices,  $\text{TIS}_{\text{new}(1)}$  and  $\text{TIS}_{\text{new}(2)}$ , for rectangular sources are feasible and do not require the extensive US field measurements required by the ODS (AIUM/NEMA 1998b). In both simplified models, only the source power and frequency need to be measured; they can adequately be measured (AIUM/NEMA 1998b). The only difference between  $\text{TIS}_{\text{new}(1)}$  and  $\text{TIS}_{\text{new}(2)}$  is the degree of agreement with  $\Delta T_{\text{max}}$  that might be required.

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