Comparison of the Output Display Standard's TIS Estimates with Independently Determined Maximum Temperature Increase Calculations

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Abstract - The monopole-source solution [1] was used to calculate the three-dimensional complex acoustic pressure field for focused circular apertures (diameters: 1, 2, 4 cm) and transmit *f-numbers* (radius of curvature/diameter values: 0.7, 1, 1.3, 1.6, 2, 3, 4, 5) for various ultrasonic frequencies (1, 2, 3, 4, 5, 7, 9, 12 MHz) from which the three-dimensional temperature distribution was calculated using the bio-heat transfer equation in homogeneous, perfused media (attenuation = absorption = 0.3 dB/cm-MHz; perfusion length: 1.0 cm). For the 184 cases, the acoustic field was normalized to the derated spatial peak, temporal average intensity ($I_{SPTA.3}$) of 720 mW/cm^2, the maximum value allowed by the FDA 510(k) diagnostic ultrasound equipment approval process [2], from which the axial temperature increase profile and the maximum temperature increase (ΔT_{max}) were determined. Also, from the normalized acoustic field, the soft-tissue thermal index (*TIS*) was determined according to the procedures of the Output Display Standard [3] from the normalized acoustic field. In general, *TIS* and ΔT_{max} increase with increasing transmit *f-number* and *TIS* tracks ΔT_{max} which allows for As Low As Reasonably Achievable (ALARA) Principle implementation. TIS mostly underestimates ΔT_{max} (TIS $\leq \Delta T_{max}$) for *f-numbers* ≤ 1 and mostly overestimates ΔT_{max} (TIS $\geq \Delta T_{max}$) for f-numbers ≥ 2. For the lower transmit *f-numbers* ≤ 2, ΔT_{max} does not exceed a value of 0.30°C ($0.0060 \leq \Delta T_{max} \leq 0.30$°C for these 115 cases) and the maximum value of *TIS* does not exceed a value of 0.40 ($0.00010 \leq TIS \leq 0.40$ for these 115 cases). Therefore, for *f-numbers* ≤ 2, the *TIS* display would never be available to the system operator since the *TIS* value does not equal or exceed 1.0. For the higher transmit *f-numbers* ≥ 3, *TIS* is generally within a factor of 2 of ΔT_{max} for predicting ΔT_{max}. These results generally confirm the applicability of the *TIS* estimation procedure but question the FDA $I_{SPTA.3}$ intensity limit of 720 mW/cm^2.

I. Introduction

When the Food and Drug Administration initiated the regulation of diagnostic ultrasound equipment in the mid-1980s [4], it set application-specific intensity limits which manufactures could not exceed (Table 1). Note that for the Fetal Imaging and Other application, the spatial peak, temporal average intensity could not exceed 94 mW/cm^2. These limits were not based on safety considerations. Rather, they were based on the output of diagnostic ultrasound equipment at the time when the Medical Devices Amendments were enacted, in May, 1976.

Table 1: FDA's pre-amendments levels of diagnostic ultrasound devices

	Derated Intensity Values		
	I_{SPTA} (mW/cm^2)	I_{SPPA} (W/cm^2)	I_m (W/cm^2)
Cardiac	430	190	310
Peripheral Vessel	720	190	310
Ophthalmic	17	28	50
Fetal Imaging and Other*	94	190	310

* Abdominal, Intraoperative, Small Organ (breast, thyroid, testes), Neonatal Cephalic, Adult Cephalic

Diagnostic ultrasound manufacturers can still have their equipment approved through the

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application-specific limits listed in Table 1. However, now, manufacturers can also have their equipment approved under the provisions of the Output Display Standard [2,3,5] in which case the regulatory upper limits are based on the spatial peak, temporal average intensity, $I_{SPTA.3}$, of 720 mW/cm^2 and the Mechanical Index, *MI*, of 1.9. In doing so, provisions must be made available for the *TI* and *MI* to be displayed, since the ODS limits are greater than the application-specific intensity limits.

The purpose of the Output Display Standard [3] is to provide the capability for users of diagnostic ultrasound equipment to operate their systems at levels much higher than previously had been possible in order to have greater diagnostic capabilities. In doing so, the possibility exists for the potential to do harm to the patient. Therefore, two biophysical indices are provided so that the equipment operator has real-time information available to make appropriate clinical decisions, *viz.*, benefit *vs.* risk, and to implement the ALARA (As Low As Reasonable Achievable) principle [6].

This contribution is a detailed evaluation for only one of the indices, *viz.*, the unscanned soft-tissue thermal index (*TIS*). Table 2 describes all three thermal indices for the three different tissue models and two scan modes, that is, *TIS*, bone thermal index (*TIB*) and cranial-bone thermal index (*TIC*).

Table 2: Outline of the three Thermal Indices

	Scanned Mode	Unscanned Mode
Soft Tissue	TIS at Surface	TIS Small Aperture Large Aperture
Bone at Focus	TIS at Surface	TIB
Bone at Surface	TIC	TIC

II. Methods

The monopole-source solution for estimating tissue temperature temperature increases for focused ultrasound fields was used and has been described in detail [1]. Briefly, the monopole-source solution, which consists of two independent steps. The first step determines the three-dimensional distribution of the complex acoustic pressure field **p** generated by an ultrasonic source from the solution to the lossy Helmholtz equation given by [1]

$$\nabla^2\mathbf{p} + \mathbf{k}^2\mathbf{p} = 0 \qquad (1)$$

where k is the complex wave number $\mathbf{k} = k_o - j\alpha$, and where k_o and α are the wave number (ω/c) and amplitude absorption coefficient, respectively. For a very small and spherically symmetric acoustic source (a monopole source) with angular frequency ω in an unbounded fluid, the monopole-source solution to the lossy Helmholtz equation is

$$\begin{aligned}\mathbf{p} &= G\frac{\exp(-\mathbf{jkr})}{r} \\ &= G\frac{\exp(-\alpha r)\exp(-jk_o r)}{r}\end{aligned} \qquad (2)$$

where the constant G is called the monopole-pressure amplitude and r is the outgoing radial distance. The acoustic pressure spatial distribution is determined by summing the N acoustic monopoles from a source aperture at each spatial location and the value of G is determined at the axial distance z from a known temporal-average source power W_{SOURCE} (at z = 0). The absorption coefficient α in (2) is replaced by the attenuation coefficient A to account for the fact that the loss of amplitude as the wave propagates is quantified by the attenuation coefficient.

The second step uses the three-dimensional acoustic pressure field to determine the temperature increase at any point in the medium. The bio-heat transfer equation is used to combine the processes of ultrasonic absorption, tissue perfusion, and heat conduction, that is,

$$\frac{\partial T}{\partial t} = \kappa \nabla^2 T - \frac{\Delta T}{\tau} + \frac{q_v}{\rho c_p} \qquad (3)$$

where T is the ambient temperature level, κ is the thermal diffusivity, ΔT is the temperature elevation, τ is the perfusion time constant, c_p is the heat capacity per unit mass of the medium, $q_v = \frac{\alpha p_o^2}{\rho c}$ is the heat generated locally at a temporal-average rate per unit volume [7], $p_o^2 = \mathbf{p}\mathbf{p}^*$ is the square of the complex acoustic pressure amplitude at a specific field location, and ρc is the media's characteristic acoustic impedance (product of density, ρ, and propagation speed, c). A solution to (3) is used as the basis for the monopole-source solution to yield the steady-state temperature increase at a distance r from an monopole (infinitesimal) heat source of volume dv which is generating heat at a rate $q_v dv$, that is [8], and these are summed to yield the axial steady-state temperature increase,

$$\Delta T_{ss}(r) = \frac{2C}{r}\exp(-\frac{r}{L}) \qquad (4)$$

$$C = \frac{q_v dv}{8\pi K} = \frac{\alpha p_o^2 dv}{8\pi \rho c K} \qquad (5)$$

where K is the thermal conductivity coefficient and L is the perfusion length.

The steady-state temperature increase reported herein is in terms its the axial maximum value, $\Delta T_{\max}$.

This contribution is an evaluation only for the unscanned soft-tissue thermal index (*TIS*). For the *TIS*, it was assumed that the tissue is homogeneous (in terms of both acoustic and thermal properties) with attenuation coefficient A (also referred to as a derating factor) and absorption coefficient α of 0.3 dB/cm-MHz, density ρ of 1000 kg/m^3, propagation speed c of 1540 m/s, tissue perfusion L of 1.00 cm and tissue thermal conductivity K of 0.006 W/cm^2, all of which are the values used herein.

The basis for estimating temperature increase in the ODS is discussed in detail elsewhere [3,9,10]. For the homogeneous tissue case, estimating temperature increase considered the beam area relative to a perfusion length of 1 cm. The cross-sectional area defined by a perfusion length of 1 cm was approximated to 1 cm^2 (actually 0.79 cm^2) for convenience. If the beam area was less than 1 cm^2, then acoustic power was used to define the temperature increase, and if the beam area was greater than 1 cm^2, then the local acoustic intensity was used to define the temperature increase. Thus, separate calculations are used to estimate *TIS* at the appropriate location where the temperature increase is a maximum value. For a large aperture, $A_{aprt} > 1\text{cm}^2$,

$$TIS = \frac{\max\limits_{z_1 > z_{bp}} \left\{ \min\left\{ W_{.3}(z_1);\ I_{TA.3}(z_1)\text{x}1\text{cm}^2 \right\} \right\}}{\left(\frac{210}{f_c} \right)} \qquad (6)$$

where $W_{.3}(z_1)$ is the derated power at distance z_1, $I_{TA.3}(z_1)$ is the derated temporal-average intensity at distance z_1, f_c is the ultrasound center frequency, and z_1 is the axial distance greater than the axial break-point location in order to avoid inaccuracies introduced by attempting to measure intensities too close to the source surface, that is,

$$z_{bp} = 1.5\sqrt{\frac{4}{\pi}A_{aprt}} = 1.69\sqrt{A_{aprt}} \qquad (7)$$

For a small aperture, $A_{aprt} \le 1\text{cm}^2$,

$$TIS = \frac{W_o}{\left(\frac{210}{f_c} \right)} \qquad (8)$$

All computations were made on either a SUN SparcStation 2 or SUN SparcStation 20. 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 were verified previously [1] to yield reasonable asymptotic temperature increase values.

III. Results and Discussion

One hundred and eighty four cases have been investigated at 8 frequencies of 1, 2, 3, 4, 5, 7, 9 and 12 MHz; 3 source diameters of 1, 2 and 4 cm; and appropriate radii of curvature (*ROC*) to yield *f-numbers* (= *ROC/D*) of 0.7, 1.0, 1.3, 1.6, 2.0, 3.0, 4.0 and 5.0. The 4-cm source diameter was not evaluated at 12 MHz.

All results reported herein are based on the derated spatial peak, temporal average intensity $I_{SPTA.3}$ of 720 mW/cm^2, the current FDA limit [2], in order to provide a common reference andwhich is the worst-case exposure condition.

Table 3 lists the range (minimum-maximum) for *TIS* , ΔT_{max} and ΔT_{max} / *TIS* as a function of *f-number* (f#) for all 184 cases between 1 and 12 MHz, 23 cases for each f#.

Table 3

f#	*TIS*	ΔT_{max} (°C)	$\frac{\Delta T_{max}}{TIS}$
0.7	0.00010-0.025	0.0060-0.049	1.88-87.3
1.0	0.0026-0.082	0.014-0.095	1.10-7.59
1.3	0.010-0.15	0.025-0.15	0.65-2.86
1.6	0.026-0.24	0.038-0.20	0.49-2.03
2.0	0.078-0.40	0.058-0.30	0.35-1.92
3.0	0.25-3.60	0.18-6.68	0.30-1.86
4.0	0.33-5.79	0.23-6.51	0.24-2.78
5.0	0.36-7.83	0.25-6.31	0.29-3.20

The standard's display requirements do not require the display of *TIS* unless the diagnostic ultrasound equipment is capable of equaling or exceeding a *TIS* of 1. Therefore, based on the results shown in Table 3, the *TIS* would not have to be displayed until the *f-number* exceeded 2.0. Note that as long as the *f-number* ≤ 2.0, the maximum value of ΔT_{max} ≤ 0.30°C.

Figure 1 compares the one-to-one relationship between *TIS* and ΔT_{max} for all 184 cases as a function of *f-number*. For ΔT_{max} < 0.1°C, *TIS* generally underestimates (is less than) ΔT_{max}; whereas, for ΔT_{max} > 0.1°C, *TIS* generally overestimates (is greater than) ΔT_{max}. Therefore, Fig. 1 demonstrates that for *TIS* values greater than 0.4, *TIS* is a conservative estimate of ΔT_{max}, that is, *TIS* > ΔT_{max}.

IV. Acknowledgements

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V. References

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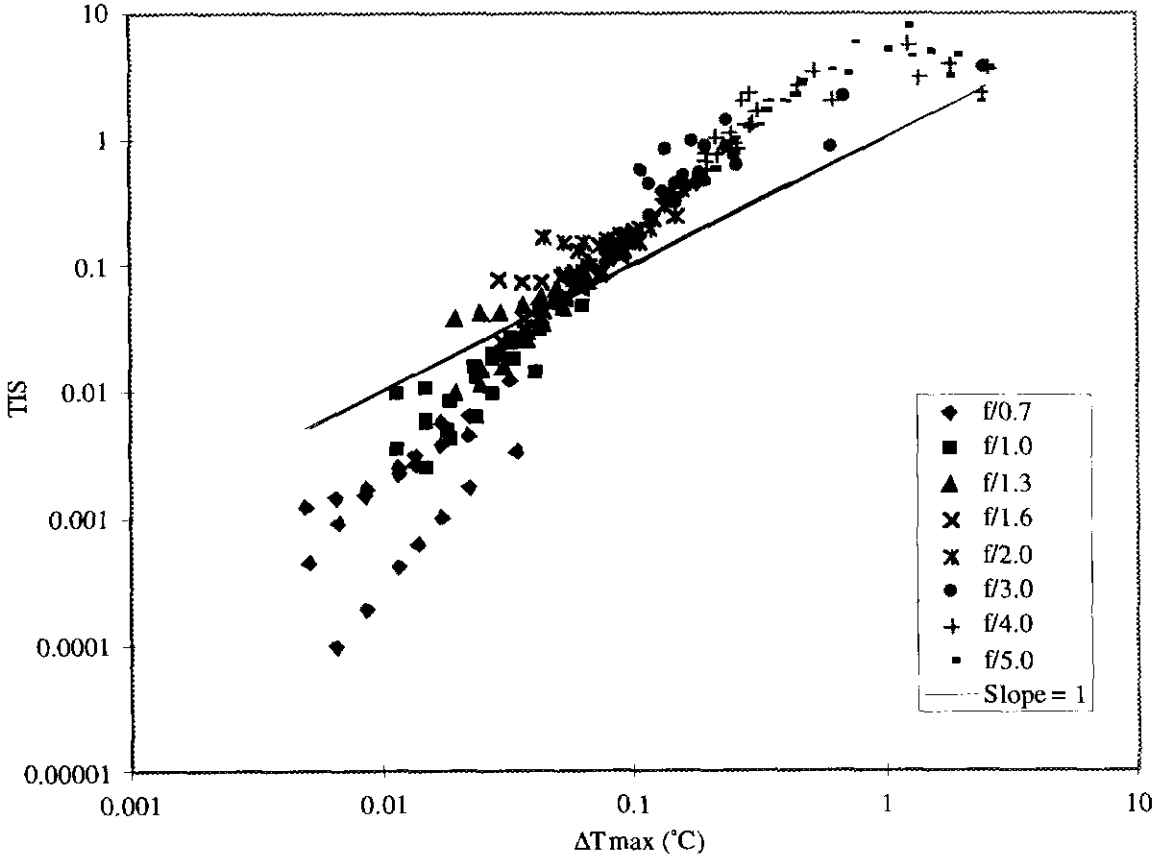

Figure 1