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Assessment of the likely thermal index values for pulsed Doppler ultrasonic equipment - Stages II and III: experimental assessment of scanner/transducer combinations

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ABSTRACT

There is currently considerable international concern about the possible adverse effects on tissue due to the thermal effects of ultrasound. Although no-one has yet shown deleterious effects with current devices in patients, studies have shown that significant temperature rises can occur.

To address these concerns, the UK Department of Health initiated a project at the National Physical Laboratory to assess the likely thermal hazard from commercial pulsed Doppler diagnostic ultrasound equipment. The three stage project was to assess the thermal hazard by means of published prediction algorithms, by experimental methods and by improved theoretical methods.

This report covers Stages II and III, in which measurements of acoustic output and temperature rise were made on ultrasound scanners; the acoustic measurements were used to predict the temperature rise and thermal index by different methods and these predictions were compared with the temperature rise measured in thermal test objects. A summary of Stage I, which used published methods to calculate thermal indices from acoustic data supplied by manufacturers, is given in NPL Report CIRA(EXT)018 *Assessment of the likely thermal index values for pulsed Doppler ultrasonic equipment - Stage I: calculation based on manufacturers' data* which is available from The Acoustics Library at NPL.

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1 BACKGROUND TO PROJECT

There is currently considerable international concern about the possible effects on tissue due to the thermal effects of ultrasound. Although no-one has yet shown deleterious effects with current devices in patients, studies have shown that significant temperature rises can occur. Many national and international bodies are now active in this area, including the World Federation for Ultrasound in Medicine (WFUMB, 1992 and 1997), the European Federation of Societies for Ultrasound in Medicine (EFSUMB, 1996) the International Electrotechnical Commission (IEC, 1992), the National Council for Radiation Protection (NCRP, 1992), the American Institute for Ultrasound in Medicine (AIUM/NEMA, 1992) along with the United States Food and Drug Administration (FDA, 1985). In the UK, concern has also been expressed by the Royal College of Obstetrics and Gynaecology (RCOG, 1984), the Royal College of Radiologists (RCR, 1985) and the British Medical Ultrasound Society (BMUS, 1988).

The above bodies are preparing several basic kinds of output: regulations, standards (covering output labelling, measurement and safety), safety recommendations and reports. A consensus is being sought over what types of field might produce significant temperature rises under appropriate circumstances. At present, however, the extent to which current commercial equipment has the potential for hazard is not completely clear. In the UK, there have been several safety recommendations made by professional bodies and some reports, but none of these has yet addressed in depth the problem of ultrasonic heating from the most recent equipment.

The above concerns gain added weight with the advent of the EC Medical Devices Directive (EC, 1993). Through the route of compliance with published international standards, this will require, amongst other things, the temperature rise to be known under conditions which are representative of clinical examination. In the case of ultrasound, it is expected that the required standards will be provided by the IEC. NPL is involved in the development and validation work which is needed before an agreed standard can be produced. As part of this process, it is necessary to use thermal test-objects to measure the temperature rise produced by current commercial equipment.

There are, therefore, a number of requirements for factual information on the thermal effects of ultrasound specifically to meet UK needs, as outlined below.

1. Knowledge of the output levels is the starting point for one route to determining the potential for thermal hazard and this route needs to be assessed for pulsed Doppler equipment marketed in the UK. Some information on output levels is already available, and needs to be processed in an appropriate manner. Some, however, would have to be acquired separately, to take account of recent developments. In this way, it would be possible to make an objective evaluation of the potential for hazard with equipment in UK service. Once available, it is crucial that this information be communicated appropriately to those responsible for the clinical use of ultrasound.

2. There needs to be experimental verification of the predicted temperature rises for commercial equipment. The existing work is largely theoretical, and it is not clear how it relates to the true heating. Furthermore, previous experimental work is subject to

2 AIMS OF STAGES II AND III

The prime purpose of the project was not to survey the maximum temperature rise caused by exposure to pulsed Doppler ultrasound but rather to compare different methods for arriving at an estimated temperature rise. The original letter to potential project participants in 1994 summarised the aims of Stages II and III as follows:

> **Stage II**
>
> **To carry out detailed measurements at NPL on a subset of the scanner/transducer combinations studied in Stage I, in order to produce more realistic estimates of the likely temperature rise.**
>
> The criterion for selecting the subset depends on the outcome of Stage I, but the intention is to include devices from a wide range of manufacturers whilst concentrating on those combinations which appear to be capable of generating the highest temperature rise.
>
> These new estimates will come both from calculations based on the measured intensity distribution, and from direct measurement of temperature increase in thermal test objects which mimic the conditions underlying the NCRP and AIUM/NEMA models. (Note: the thermal test objects have been developed as part of NPL's measurement standards programme) These estimates will also be published.
>
> **Stage III**
>
> **To carry out measurements of the temperature rise produced by a small number of scanner/transducer combinations in thermal test objects which more realistically mimic the properties of the tissue exposed during particular clinical examinations.**
>
> To minimise the disturbance to manufacturers, these measurements will be carried out at the same time as the Stage II measurements. The aim is to use two or three test objects which mimic critical clinical applications of Doppler ultrasound. Experimental measurements and improved theoretical predictions will be undertaken and the results compared with those obtained in Stages I and II. These results will be published.

Inevitably, in a project of this duration in such a rapidly developing field as diagnostic ultrasound, the details of the work have had to be modified from the original expectations. In particular, the equipment which was available for loan from manufacturers was limited due to commercial pressures and it was not possible to choose all the systems that might have been desired. Instead, the decision was made to obtain the most recent scanners with two or three transducers each. The transducers were generally standard linear or phased array and were intended to be ones which were widely used and covered a reasonable frequency range. No attempt was made to select preferentially transducers which were expected to produce the highest thermal index. This decision also meant that the systems used in Stages II and III were not merely a subset of equipment covered in Stage I but also included new devices. Additionally, two older systems were measured.

4 ASSESSMENT METHODS

The experimental assessment of each scanner/transducer combination consisted of the following steps:

- ❑ Identify scanner settings which produce maximum free-field spatial-peak temporal-average intensity (I_{spta}).
- ❑ Characterise ultrasound field at free-field focus, derated focus and transducer face.
- ❑ Map ultrasound field in three dimensions from transducer face to beyond the free-field focus.
- ❑ Calculate thermal index (TI) values from measured field parameters.
- ❑ Using measured intensity maps, predict temperature rise expected in soft tissue and bone thermal test objects .
- ❑ Measure temperature rise in soft tissue and bone thermal test objects .

More detail is given on each of these stages in the following subsections.

4. IDENTIFICATION OF SETTINGS FOR MAXIMUM INTENSITY

The acoustic output of each scanner/transducer combination was measured using the NPL Ultrasound Beam Calibrator (or UBC) (Preston, 1988; Shaw and Preston, 1996) fitted with a membrane hydrophone of 21 active elements, each 0.4 mm in diameter and spaced 0.6 mm between centres. The system automatically assesses changes in beam shape and in pulse amplitude, duration and repetition rate; I_{spta} is calculated and displayed in realtime allowing instant assessment of the effect of changing scanner settings.

The hydrophone was placed at different distances from the transducer in a water-filled test-tank and the scanner settings which produced the maximum I_{spta} in pulsed Doppler mode at each distance were recorded. The settings which produced the global maximum were used as the basis for subsequent measurements. In modern scanners with power management systems, there are generally many output settings which generate similar levels of I_{spta}. Random measurement variation means, therefore, that it is not possible to be sure that we have identified the absolute maximum intensity achievable.

The maximum intensity approach is not entirely consistent with the US FDA track 3 requirements based on the AIUM/NEMA Output Display Standard, which asks for the settings which produce the maximum thermal index. It is quite possible, for instance, that a broader beam of lower intensity would result in a larger temperature rise or thermal index than the beam defined by the settings which produce the maximum free-field intensity.

4.2 MEASUREMENT OF ACOUSTIC OUTPUT

For the selected scanner settings, the positions of maximum free-field I_{spta} and maximum derated I_{spta} were located and measurements made using the UBC at both positions. Measurements were made with the hydrophone array aligned parallel to the scan-plane direction of the transducer and also at 30°, 60° and 90° to the scan plane to allow for the

4.5 PREDICTION OF TEMPERATURE RISE

In principle, the temperature rise in a patient can be calculated if the geometry of the tissue path and the properties of the different tissue types in the path are known. The temperature rise at any point can be calculated from the bio-heat transfer equation (BHTE):

$$\textbf{(1)} \qquad c_v \frac{\mathrm{d}\, T(\vec{r})}{\mathrm{d}\, t} = \nabla \cdot (K \nabla T(\vec{r})) + q_v(\vec{r}) + C(\vec{r})$$

where $\vec{r}$ is the positional vector, T is the temperature, K is the thermal conductivity, c_v is the volumetric heat capacity, q_v is the absorbed power per unit volume (normally assumed to be proportional to the product of the temporal-average intensity and the absorption coefficient of the medium) and C is a term (generally called the perfusion term) which results from blood flow in the heated region. The BHTE describes the energy balance within an incremental tissue volume and can be solved by appropriate techniques if the form of the perfusion term is known. The most widely quoted perfusion term is that due to Pennes (1948), which has the form $C(\vec{r}) = T / \tau$ where τ is known as the perfusion time constant; it is this form which is assumed in the Output Display Standard with a perfusion time constant of 720 seconds.

To calculate the expected temperature rise in the thermal test objects, the perfusion term is ignored and the solution given by Nyborg (1988) is applied, leading to:

$$\textbf{(2)} \qquad T(s,t) = \frac{q_v(\underline{r})}{8\pi K s} \operatorname{erfc}(R)\ \mathrm{d}V$$

where $T(s, t)$ is the temperature increase at a distance s from the incremental heat source of volume $\mathrm{d}V$ after time t, K is the thermal conductivity,

$$R = \left(\frac{s}{4\kappa t} \right)^{1/2}$$

and κ is the thermal diffusivity.

The temperature rise resulting from a continuum of heat sources can be calculated by first estimating the *in situ* intensity, I_{is} from the measured free-field intensity, and then assuming that

$$q_v(\underline{r}) = 2\alpha(\underline{r}) I_{is}(\underline{r})$$

where $\alpha(\underline{r})$ is the local absorption coefficient, and integrating equation (2) over the entire heated volume. The free-field intensity is derived from a weighted mean of the four scans along the beam-axis. This is essentially the method used by Shaw (1994).

The temperature rise was predicted for two types of thermal test objects (homogeneous soft tissue mimic and layered soft tissue and bone mimics) placed at a range of distances from the transducer. Two cases are considered for each test object: the worst-case, $\Delta T_{\text{pred wc}}$, in which the path from the transducer to the test object is non-attenuating, and the derated-case, $\Delta T_{\text{pred att}}$, in which a derating factor of 0.3 dB/cm/MHz is applied over the intervening path. The uncertainty in the predicted value has contributions from measurement of the local intensity, incomplete sampling of the intensity distribution, nonlinear propagation effects and knowledge of the acoustic and thermal properties of the test object. The overall uncertainty in the predicted value is estimated to be ±35% at the 95% confidence level. Results are given in Section 5.

path. Since the attenuators were only available in discrete thicknesses, a small correction was applied to ensure that the final values, $\Delta T_{meas\text{-}att}$, corresponded to having a total attenuation between the transducer and the sensor (or the soft tissue/bone interface) of 0.3 dB/cm/MHz in agreement with the ODS. For both sets of measurements, contributions to the uncertainty in the temperature arise from the calibration of the thermocouple, location of the beam-axis and repeatability. The overall uncertainty is estimated to be ±12% at the 95% confidence level.

the influence of transducer heating. Clearly, for $\Delta T_{meas\text{-}cont}$, transducer heating will influence the final temperature rise (see Section 6.2).

Figures in normal text in Table 1 refer to soft tissue target tissue, underlined figures refer to bone target tissue near the surface and figures in italics refer to bone target tissue at depth. Columns three to six are different methods for estimating a temperature rise or thermal index under derated or attenuated conditions. All four columns are intended to be directly comparable and so measurements in which the test object was close enough for there to have been significant heat conducted directly from the transducer have not been considered.

The final two columns are not directly comparable with the preceding four. $\Delta T_{meas\text{-}wc}$ is under worst-case conditions with no additional attenuation and $\Delta T_{meas\text{-}cont}$ includes the influence of probe heating on the temperature increase.

These results are analysed and discussed more fully in Section 6 and there is a technical summary of the analysis in Section 7 which contains a breakdown of the results into different temperature categories: < 1.5°C, 1.5-4°C, 4-8°C and > 8°C. These categories were chosen on the basis recommendations by the World Federation of Ultrasound in Medicine and Biology (WFUMB 1997) that:

"A diagnostic exposure that produces a maximum in situ temperature rise of 1.5°C above normal physiological levels (37°C) may be used clinically without reservation on thermal grounds."

and

"A diagnostic exposure that elevates embryonic and fetal in situ temperature above 41°C (4°C above normal temperature) for 5 minutes or more should be considered potentially hazardous."

Most of the scanners were current or very recent systems obtained direct from the UK suppliers. The Acuson 128 was obtained from a supplier of used equipment and was approximately nine years old. The HP77020 is a scanner which belongs to NPL and was approximately 8 years old.

Scanner/ transducer combination	Target tissue	TI_{disp}	TI_{ODS}	max $\Delta T_{pred\text{-}att}$ (°C)	max $\Delta T_{meas\text{-}att}$ (°C)	max $\Delta T_{meas\text{-}wc}$ (°C)	$\Delta T_{meas\text{-}cont}$ (°C)
ATL HDI 3000							
9) C4-2	soft tissue	1.30	1.01	0.78	0.78	1.57	1.22
	bone	*2.80*	*3.82*	*3.26*	*3.69*	*8.69*	N/A
	cranial	-	2.28	2.08	N/A	N/A	3.72
10) C7-4	soft tissue	1.10	0.83	0.80	0.81	1.34	1.78
	bone	*1.90*	*2.04*	*1.91*	*2.99*	*5.45*	*N/A*
	cranial	-	1.79	1.91	N/A	N/A	4.47
11) L10-5	soft tissue	1.10	0.82	0.65	0.79	0.96	1.06
	bone	*1.50*	*1.81*	*1.22*	*1.57*	*2.18*	*N/A*
	cranial	-	1.09	1.11	N/A	N/A	2.24
HP 77020 AC							
12) 21200B	soft tissue	-	0.39	0.28	0.35	0.70	0.71
	bone	-	*1.98*	*1.60*	*1.77*	*3.30*	N/A
	cranial	-	0.81	1.21	N/A	N/A	1.63
12a) 21200B (M-mode)	soft tissue	-	0.22	0.09	0.07	0.11	0.38
	bone	-	*0.45*	*0.33*	*0.49*	*0.56*	N/A
	cranial	-	0.48	0.33	N/A	N/A	0.98
12b) 21200B (Colour flow)	soft tissue	-	0.51	0.29	0.40	0.40	0.80
	bone	-	*1.08*	*1.03*	*1.35*	*1.42*	*N/A*
	cranial	-	1.13	1.03	N/A	N/A	1.68
13) 21211A	soft tissue	-	0.53	0.56	0.48	0.58	1.02
	bone	-	*1.21*	*1.24*	*1.00*	*1.36*	N/A
	cranial	-	0.49	1.24	N/A	N/A	2.13
HP Sonos 2500							
14) 21243A	soft tissue	0.90	0.66	0.54	0.50	1.17	-
	bone	*2.40*	*1.99*	*1.81*	*1.89*	*5.48*	N/A
	cranial						

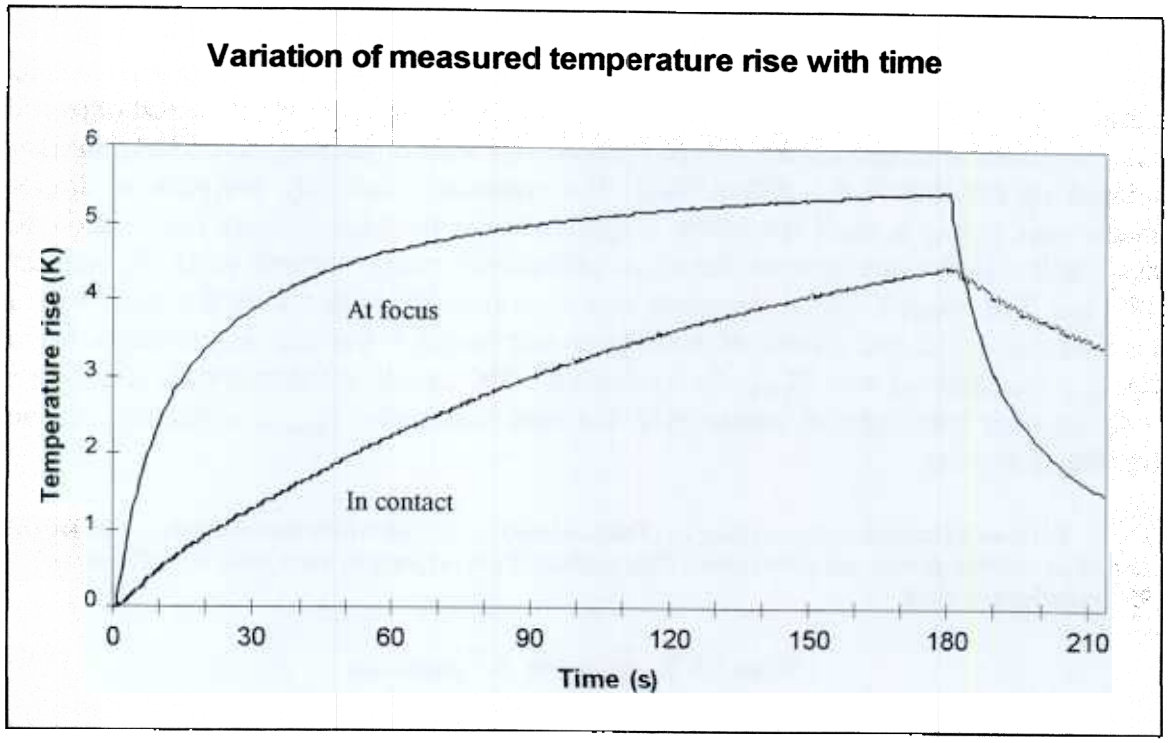
6 ANALYSIS AND DISCUSSION

The use of thermal test objects to measure temperature rise under standardised conditions is a radical departure both from calculation of thermal indices (TIs) and from more detailed predictions of temperature rise. All calculated results are derived at least in part, from measurements made with hydrophones which sense the acoustic pressure field. Calculation of a TI or temperature rise is based on the assumption that there is a well known and constant relationship between the voltage generated by the hydrophone and the local ultrasonic intensity. The phrases "intensity" and "intensity distribution" used widely in this report actually refer to intensity values and distributions derived from the square of the *rms* acoustic pressure as measured with the UBC hydrophone. In reality, intensity is not always proportional to pressure squared and, more importantly, effects such as directional response, frequency response and spatial-averaging of local pressure and phase variations in the acoustic wave may result in substantial and unpredictable variations in the relationship between the measured hydrophone signal and the true local pressure. A well chosen tissue substitute, on the other hand, will respond to the ultrasound in a similar way to tissue irrespective of the direction, shape and frequency content of the incident ultrasound field. Test objects, therefore, offer a completely independent way of assessing the heating potential of ultrasound fields and the relationship between the measured temperature rise and calculation based methods provides some interesting observations.

It is clear from the following analysis that, whereas calculations for most scanners agree reasonably well with measured temperature rise, the agreement for the Aloka scanner is much poorer. Both the acoustic and thermal measurement systems were carefully checked at the time of assessing the Aloka and appeared to be functioning properly. The most likely explanation seems to be that the wavefront generated by the Aloka exhibits rapid spatial variation of phase or amplitude over the dimensions of the measuring hydrophone (0.4 mm diameter). This phenomenon of spatial-averaging is well known and is normally considered to be significant on the axis of a tightly focussed beam, since the pressure amplitude naturally falls off rapidly when moving away from the beam-axis (Zeqiri and Bond 1992). In principle, however a similar effect can be observed at any part of the field where variations occur on the scale of the measuring device. If this is the correct explanation, any hydrophone based measurement system with a sensor diameter of 0.4 mm or larger (and the majority of hydrophones in use are 0.5 mm diameter) would introduce similar errors when deriving values for acoustical parameters such as I_{spta} and power. Interestingly, the use of a radiation force balance to measure power would not be subject to the same errors and, as can be seen in Section 6.8, UBC values for power are much lower than the corresponding radiation force values for the Aloka. For other systems, the agreement in power is much closer which tends to give weight to the proposed explanation. The hypothesis could be checked by performing measurements with a smaller hydrophone (ideally 0.1 mm diameter) but it has not been possible to gain access to the Aloka scanner for a second time to make these new measurements.

The statistical analysis of the results in this report (*ie* calculation of means and standard deviations) do not include the Aloka scanner unless specifically indicated. Note that this omission will bias the quoted mean value and will generally reduce the standard deviation of the results. If the Aloka is actually representative of a significant number of scanners, the Aloka results should be included, which would

Fig 3. Representative measured heating curves with a bone test object at the focus and in contact with the transducer.



formulae, the predictions are based on the absorbed ultrasound energy only and ignore any contribution from self-heating of the transducer due to electrical inefficiency. When the sensor is close to the transducer, self-heating has a major influence on the temperature rise although it can be ignored at greater distance, as evidenced from Section 6.1. It is instructive to compare the typical variation of temperature with time at the focus and at the surface. Figure 3 shows typical measured temperature-time curves. Notice that at the focus, where the beam is narrow and there is no self-heating effect, the temperature is approaching equilibrium and so longer heating times would result in only a modest increase in final temperature. At the surface, however, the temperature is still increasing at a substantial rate and so longer heating times would result in much higher temperatures. After three minutes, the measured value is already typically twice the value predicted when ignoring self-heating; for exposures where there is prolonged contact with the transducer (as would be relevant for some transcranial probes amongst others), the measured value may be four or more times higher than expected. The formulae used to calculate TI_{ODS} values do not account for transducer heating. It is clear from the comparison of $\Delta T_{pred\text{-}wc}$ and $\Delta T_{meas\text{-}cont}$ above that transducer heating is important and will be more important for longer heating times. Whilst test objects offer the ability to include this effect, it is difficult to see how ODS or other prediction methods could be modified to account for it since the importance of transducer heating will depend on the electrical efficiency, the size and the thermal properties of the transducer.

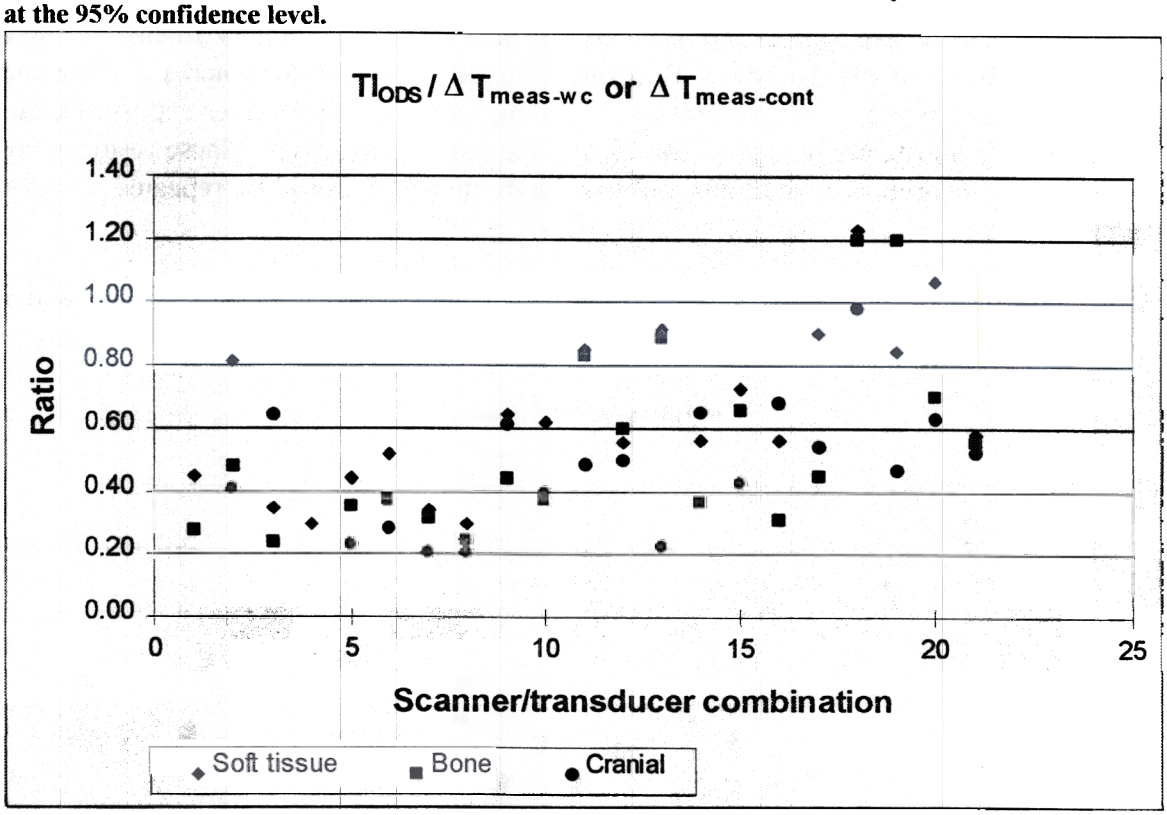
6.3 COMPARISON OF TI_{ODS} AND ATTENUATED MEASURED TEMPERATURE RISE

To make test object measurements which are intended to be analogous to the ODS calculations, it is necessary to take account of the attenuation required between the transducer and the point of interest in the test object. The method used here involves

6.4 COMPARISON OF TI_{ODS} AND WORST-CASE MEASURED TEMPERATURE RISE

Worst-case measurements of temperature rise, $\Delta T_{meas\text{-}wc}$, are made with no extra attenuation between the transducer and the test object. The attenuation between the transducer and the thermal sensor (in the case of the soft tissue test object) or the tissue/bone interface (in the case of the bone test object) does not vary with distance but depends only on the thickness of the overlying tissue mimicking material; this fixed attenuation is around 0.35 dB/MHz. The most commonly quoted fixed attenuation models are those given by NCRP for 2nd and 3rd trimester obstetric exposure in which the attenuation is slightly higher at 0.75 and 0.5 dB/MHz respectively.

Fig 5. Ratio of TI calculated according to ODS methods to worst case temperature rise measured wit thermal test objects without additional attenuation. The estimated uncertainty in each ratio is ±28% at the 95% confidence level.

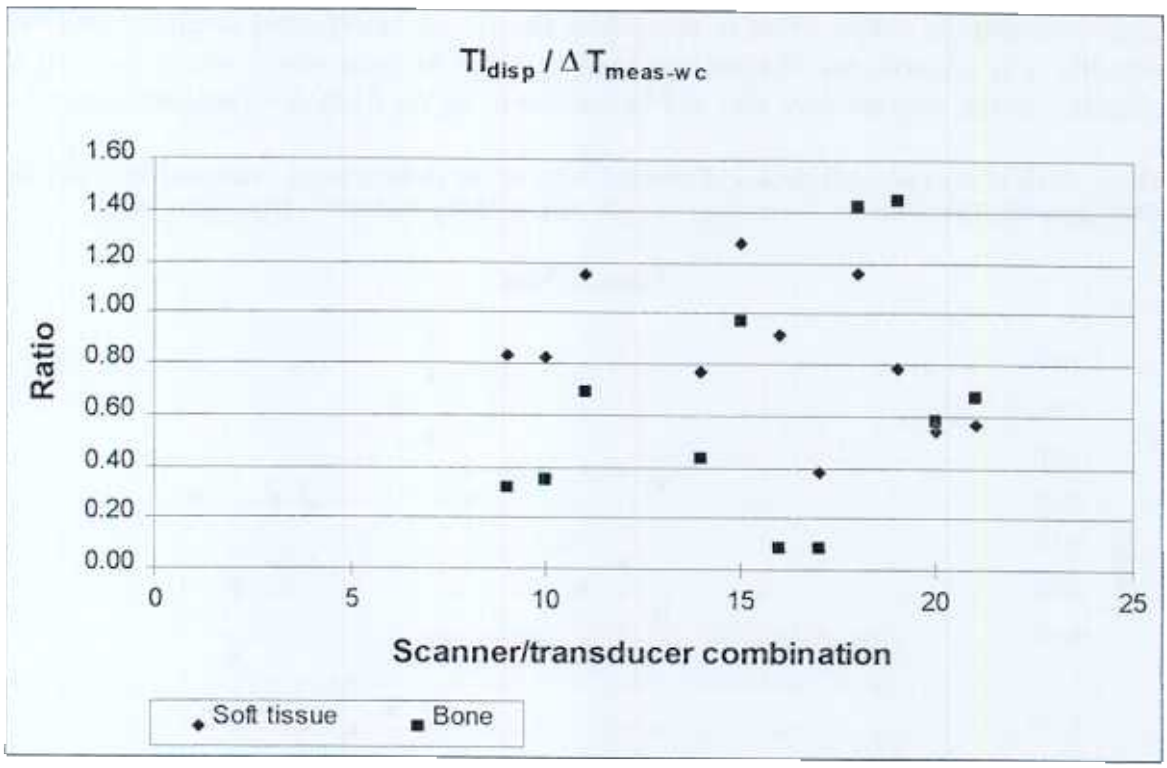


The distance at which the maximum worst-case temperature rise occurred was the same as the location of maximum I_{spta} for all the pulsed Doppler transducers. The ratio of TI_{ODS} to either the maximum observed $\Delta T_{meas\text{-}wc}$ or $\Delta T_{meas\text{-}cont}$ is given in Figure 5 as appropriate. In almost all cases the ratio is smaller than one ($\mu = 0.73$, $\sigma = 0.23$ for TIS; $\mu = 0.60$, $\sigma = 0.30$ for TIB; $\mu = 0.55$, $\sigma = 0.17$ for TIC) indicating that TI cannot be used as an indicator of worst-case temperature rise; in some cases the measured value was more than three times greater than TI_{ODS}. Again, measurements made in contact with the transducer are only used for the transcranial simulation.

Of course, the ODS models are not intended to be worst-case and the test object implementation may not be representative of the worst-case clinical conditions. It is instructive to look at the ratios of the worst-case measured maximum to the attenuated

patient is exposed would generally be the on-screen display of TIS and TIB; it is relevant, therefore to compare this number with the maximum worst-case measured temperature rise. Figure 7 shows the ratio of TI_{disp} to $\Delta T_{meas\text{-}wc}$ and it can be seen that the on-screen value is generally lower than the measured maximum ($\mu = 0.84$, $\sigma = 0.28$ for TIS; $\mu = 0.64$, $\sigma = 0.47$ for TIB) and in two cases the on-screen value is more than 10 times smaller than the measured value. When considering patient exposure, therefore, it appears from these results that the on-screen value should definitely not be taken as an absolute upper limit. Moreover, the spread of results makes it very difficult to interpret the on-screen display in terms of patient safety at all.

Fig 7. Ratio of the on-screen display of TI as implemented by manufacturers to the maximum measured worst case temperature rise. The estimated uncertainty in each ratio is ±12% at the 95% confidence level.



Of course, the value of TI_{disp} is not necessarily intended to be an upper limit for temperature rise; it is intended to be an implementation of the Output Display Standard and so it is also relevant to examine the agreement of TI_{disp} with the calculated TI values, TI_{ODS}, and this is done in Figure 8. The TI_{disp} values come either from a look-up table in the scanner software or from an algorithm relating the engineering set-up of the scanner to the expected TI. Each manufacturer implements their own technique and may or may not include safety margins for measurement uncertainty and device variation. The estimated uncertainty in the NPL values of TI_{ODS} is ±25% at the 95% confidence level and so the perfect on-screen implementation would generate values within ±25% of the NPL values. Figure 7 shows the ratio of the TI_{disp} to TI_{ODS} and demonstrates that the spread is substantially greater than ±25% and also that the on-screen value is almost equally likely to be smaller or bigger than it should be ($\mu = 1.14$, $\sigma = 0.42$ for TIS; $\mu = 0.92$, $\sigma = 0.40$ for TIB).

Table 2. Comparison of 'on-screen' TI values displayed for settings which produced maximum I_{spta} and the maximum displayed TI observed for any settings.

Scanner/transducer	At maximum I_{spta}			Observed maximum		
	TIS	TIB	TIC	TIS	TIB	TIC
ATL HDI 3000 + C4-2	1.3	2.8	-	1.4	3.7	-
ATL HDI 3000 + C7-4	1.1	1.9	-	1.7	2.9	-
ATL HDI 3000 + L10-5	1.1	1.5	-	3.8	4.0	-
IGE Logiq 500 + C551	0.6	<0.4	-	2.0	<0.4	-
Toshiba Eccocee + PLF805ST	0.4	1.6	0.6	0.6	1.8	0.8
Toshiba Eccocee + PVE382M	0.6	3.0	1.2	0.6	3.0	1.2
Toshiba Eccocee + PVF375MT	0.4	2.0	0.8	0.8	3.2	1.4

For the Toshiba and HP77020 systems, the conditions which produce the maximum output power as measured with a radiation force balance were also searched for. For the Toshiba Eccocee with PVF-375MT, the output power for the conditions which gave maximum I_{spta} was only 50% of the maximum power observed for all pulsed Doppler operating conditions; with the PLF805ST the power was 72% of the observed maximum. For the HP77020 with 21200B the power was also 72% of the observed maximum but with the 21211A transducer, the settings for maximum I_{spta} were the same as those which produced the observed maximum power.

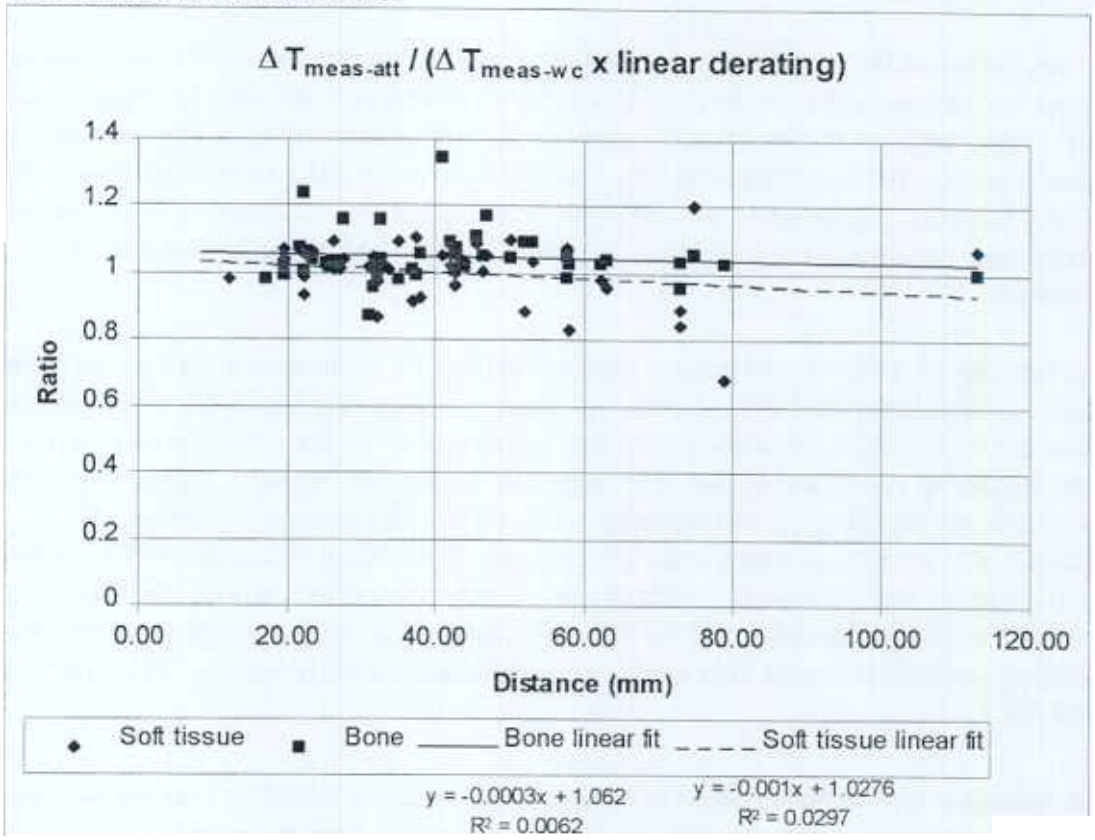
6.7 PERFUSION

The ODS TI algorithms are intended to be relevant to the steady state temperature rise achieved in a perfused medium; the test object measurements and the detailed temperature predictions are both for three minutes heating in non-perfused media. Clearly, a longer heating time would be expected to result in a greater temperature increase while perfusion would tend to reduce the increase. It is relevant, therefore, to consider the relative importance of these two effects. Shaw *et al.* (1996) have shown that introducing Pennes-type perfusion (Pennes 1948) with a perfusion time of 720 seconds (as assumed by the ODS algorithms) makes only a modest change to the temperature increase expected in the absence of perfusion for a heating time of three minutes. For ultrasound beams with a radius up to 5 mm, the perfused temperature rise would be less than 10% lower than the unperfused value. However, they have also shown that the unperfused three minute temperature rise will in general underestimate the steady state perfused temperature rise by between 7% for beams of 0.5 mm and 25% for beams of 5 mm radius. It might therefore be considered that both test object measurements and detailed predictions are actually slightly lower than they would be if all the ODS assumptions were included.

6.8 MEASUREMENT OF TOTAL POWER

The values for the calculated thermal index reported used here are derived using the output power measured with the UBC (see Section 4.4). However, power was also measured with a radiation force balance and, for comparison, TI_{ODS} figures were also

Fig 9. Comparison of attenuated measured temperature rise with the worst-case measured rise multiplied by the appropriate linear derating factor. The estimated uncertainty in each ratio is ±15% at the 95% confidence level.



- The on-screen TI values should not be regarded as an upper limit to the possible temperature rise. The displayed value of TIB varied from only 9% to 144% of the measured worst-case maximum for the same field.(See Section 6.5.)

- Current ODS thermal index formulae ignore the effects of energy dissipation within the transducer itself; this leads to an underestimate of the temperature rise measured close to the transducer by a factor of two. This factor would be larger for exposure times in excess of three minutes. (See Section 6.2.)

- The temperature near the focus of the ultrasound field increases rapidly after the start of insonation. Typically, the temperature reaches 50% of its final value after less than 20 seconds insonation. (See temperature histories in Appendix C.)

- The temperature rise measured under worst-case conditions is typically twice the temperature rise measured under the attenuation conditions assumed by the ODS formulae, although factors in excess of five were observed. (See Section 6.4.)

- On average, there is reasonable agreement between the calculated thermal index and the measured temperature rise under attenuated conditions for soft tissue and bone; however, there is a substantial random variation in the results. (See Section 6.3)

- It is unlikely that introducing perfusion would significantly affect either predicted or measured values for temperature rise unless a very rapid perfusion rate was used. Using the combination of perfusion and longer heating times assumed in the ODS may even increase the expected temperature rise slightly. (See Section 6.7.)

- For unscanned fields, the maximum worst-case temperature rise occurs at the location of the maximum I_{spta} for both soft tissue and bone test objects. For many scanned fields, it is likely that the maximum temperature rise will occur closer to the transducer. (See Section 6.4)

- The temperature rise measured with the test objects show very good agreement with theoretical expectations. They appear to work equally well over the range 2 MHz to 6 MHz and for all field geometries and they are inherently sensitive to the influence of transducer heating. (See Sections 6.1 and 6.2.)

which are recommended for safe clinical ultrasound examinations. It has also shown that the on-screen information available to sonographers is representative of average rather than maximum heating potential and should, therefore, not be taken as an indication of patient safety.

9 ACKNOWLEDGEMENTS

The authors gratefully acknowledge the support of the UK Department of Health in funding this project and the manufacturers and suppliers who have contributed to it.

10 REFERENCES

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NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS

APPENDIX A: MANUFACTURERS' COMMENTS (1)

Request by NPL for comments on provisional results and replies from manufacturers.

(There were also a number of verbal responses which are not included here.)

National Physical Laboratory | Queens Road | Teddington | Middlesex | United Kingdom | TW11 0LW
Telephone 0181-977 3222 (Switchboard) | NPL Helpline: 0181-943 6880 | Facsimile 0181-943 6458

NPL
National Physical Laboratory

Our Ref: AN0601
Your Ref:

Name
Address

Dear Name

15 September 1997

THERMAL INDICES AND TEMPERATURE RISE FOR PULSED DOPPLER ULTRASOUND

You will recall that we have been involved in a project for the UK Department of Health which involves making measurements and predictions of the temperature rise produced by commercial pulsed Doppler ultrasound systems under standardised conditions. You were kind enough to contribute to the project by lending us one of your scanners.

This project is now approaching its conclusion and, before compiling the final report, we would like you to have the opportunity to comment on the results for your scanner. Accordingly, I enclose a description of the measurements carried out and a summary of the results for your scanner which will be included in the published summary report. Please let me have any comments by Friday 12th December at the latest. I also enclose some example printouts and results sheets which we would like to include either in a fuller report or as an appendix to the summary report. Do you have any objection to this additional material appearing?

The issues of output levels and thermal index currently have a very high profile. You might, therefore, like to know that we are able to carry out any aspect of the assessments described in the report (ie output measurement, field mapping, prediction of temperature rise and measurement of temperature rise) for any individual manufacturer. Should you wish to pursue this possibility, please contact me. You can also talk to me on the NPL stand at BMUS this year where we will be demonstrating the equipment used for temperature measurement.

Yours sincerely

Adam Shaw
Centre for Mechanical and Acoustical Metrology
tel: +44 (0)181 943 6581
fax: +44 (0)181 943 6161
Email: AS@npl.co.uk

KeyMed (Medical & Industrial Equipment) Ltd
KeyMed House, Stock Road
Southend-on-Sea, Essex SS2 5QH, UK
Telephone: + 44 (0)1702 616333 (52 lines)
Facsimile: + 44 (0)1702 465677, Telex: 995283

Specialised Services to Medicine & Industry

LD028.SAM/ksm

28 November 1997

For the personal attention of:

Dr A Shaw
Centre for Mechanical and
Acoustical Metrology
National Physical Laboratory
1 Queens Road
Teddington
Middlesex
TW11 OLW

Dear Adam

Thank you very much for your recent letter and report. As you say, it has been impossible for us to arrange to bring a scanner in for you to check - blame the intense seasonal activity within the NHS!

Frankly, I am not in a position to be able to comment on your findings. I will forward your letter with a covering note to my contacts in Aloka and trust that Dr Matsunaka may be able to come back to you directly with his views. We would, of course, try to comply with any requests to check your hypothesis, but please understand this is unlikely to be possible in the short term.

Hopefully, we may be able to meet at BMUS, but if not, I will contact you again shortly.

Yours sincerely

DOUGLAS OGG
Senior Products Specialist

ISO 9001 Registered

24 November 1997

Mr Adam Shaw
National Physical Laboratory
Teddington
Middlesex
TW11 0LW

Dear Mr Shaw

Thank you for your letter dated 14 November including information on the thermal indices and temperature rise for pulsed Doppler ultrasound. As you know John Abbott is coming over from the States and I believe he is meeting you and a few others, Francis Duck, etc. He is also attending BMUS, with this in mind it would be the ideal opportunity to get together to discuss your findings. I look forward to seeing you there.

Kind regards

Yours sincerely

Bill

W E Dundon
Managing Director

WED/db

PS: Have you sent these results to ATL in Seattle?

Arden Press House
Pixmore Avenue
Letchworth. Hertfordshire SG6 1LH
Sales: (01462) 679371 Service: (01462) 678437
Fax: (01462) 670899

UK reg. no. 1534102
Barclays Bank plc. 5/6 High Street
Hitchin. Herts. SG5 1BJ

To: Mr. Adam Shaw
Centre for Mechanical and Acoustical Metrology
National Physical Laboratory

From: Charlie Grossman
Manufacturing Development Engineer
Acoustic Output Measurement Laboratory
Hewlett-Packard Medical Products Group

Subject: Comments On NPL Doppler Ultrasound Thermal Rise Study - Stage II/III Results

Dear Adam:

I've reviewed the results package you sent me and here are my comments:

RESULTS SUMMARY:

1) On-screen TI's are consistently higher than ODS TI's measured by NPL. I performed measurements for the indicated system setups in our lab and found our measured values for acoustic power and intensity were somewhat higher than your measured values. Consequently, TI's calculated from our data are much closer to the displayed values. Differences can be attributed to transducer acoustic output variability (we did measure different transducers). Our displayed values are for "typical" devices. Incidentally, axial scan profiles were very similar to what we measured. Z1 and Zb.3 distances were very virtually identical.

2) I was pleased to see the good correlation between your ODS TI calculated data and the NPL Predicted (derated) and NPL Measured (derated)values.

3) Regarding NPL measured (worst case) and NPL measured (surface) values:

I'm not suprised that the measured surface values are higher than those predicted by the ODS. ODS equations do not take into account conductive heating. This is a known "defect" in the ODS equations.

The worst case values should be presented as truly worst case and their relevance to actual insitu values should be pointed out in the final report. Comparison to the NCRP model values would also be helpful, since these predicted values are based on more relevant tissue models.

APPENDIX MATERIAL:

Regarding the inclusion of example results and printouts, Hewlett-Packard Company regards the some of this data to be proprietary and therefore requests that you NOT include the following types of data in the final report:

UBC screen dumps
UBC printout
Thermal Index spread sheets
Intensity maps including contour and profile plots

TOSHIBA

TOSHIBA MEDICAL SYSTEMS LIMITED UNITED KINGDOM

MANOR COURT, MANOR ROYAL, CRAWLEY, WEST SUSSEX RH10 2PY
TELEPHONE: (01293) 560772 FAX: (01293) 560791
REGISTERED IN ENGLAND NO. 983579 REGISTERED OFFICE: AS ABOVE

Mr. Adam Shaw,
Centre for Mechanical and Acoustical Metrology
National Physical Laboratory,
1 Queens Road,
Teddington
Middlesex TW11 OLW

Our ref. DS:RC:***L-1773*** Date 4 December 1997

Dear Mr. Shaw,

Thermal Indices and Temperature Rise
for Pulsed Doppler Ultrasound

Your letter addressed to Mr. M. J. Naylor, our Managing Director, has been passed to me for response.

We have read the Report in some detail and have no actual comment to make on your findings, except that we are in agreement with the overall view. We are, therefore, happy for this Report to be published, in it's present outline.

We hope this is helpful and forward our best wishes.

Yours sincerely,
For TOSHIBA MEDICAL SYSTEMS LIMITED

David Sayer
ACTING MANAGER - ULTRASOUND PRODUCTS

cc Mr. M. J. Naylor
Mr. D. Hoogmoed

APPENDIX B: MANUFACTURERS' COMMENTS (2)

Request by NPL for comments on preliminary' Restricted - commercial' report and replies from manufacturers.

National Physical Laboratory | Queens Road | Teddington | Middlesex | United Kingdom | TW11 0LW
Telephone 0181-977 3222 (Switchboard) | NPL Helpline: 0181-943 6880 | Facsimile 0181-943 6458

NPL
National Physical Laboratory

Our Ref: AN0601
Your Ref:

Manufacturer's name
Manufacturer's address

Dear Manufacturer's name 27 January 1998

THERMAL INDICES AND TEMPERATURE RISE FOR PULSED DOPPLER ULTRASOUND

You will recall that we have been involved in a project for the UK Department of Health which involves making measurements and predictions of the temperature rise produced by commercial pulsed Doppler ultrasound systems under standardised conditions. You were kind enough to contribute to the project by lending us one of your scanners and by commenting on our preliminary results

Our project has now been completed and the final report sent to Department of Health. I enclose a copy of this final report for your information. Currently, this report is of "Restricted - commercial" status and is not generally available. However, we intend to re-issue it and publicise it as an "Open" report at the beginning of March. If you have any comments on the project or its findings which you would like to have included in the "Open" report, please send them to me **before 28 February 1998.**

Many thanks for your help during this important project.

Yours sincerely

Adam Shaw
Centre for Mechanical and Acoustical Metrology
tel: +44 (0)181 943 6581
fax: +44 (0)181 943 6161
Email: AS@npl.co.uk

From: Charles Grossman
Development Engineer
Acoustic Measurement Laboratory
Hewlett-Packard Co.
Medical Products Group
Imaging Systems Division

To: Mr. Adam Shaw
Centre for Mechanical and Acoustical Metrology
National Physical Laboratory
Teddington
Middlesex
United Kingdom

Sub: Comments on Thermal Index Value Study - Final Report

Dear Mr. Shaw:

Thank you for the opportunity to comment on this report. The Hewlett-Packard Company Imaging Systems Division has a long term interest in understanding the nature and degree of bioeffects induced by diagnostic ultrasound equipment. We sponsored research on transcranial heating (Wu et al, Ultrasound in Medicine and Biology, 21:561 (1995)) that compared temperature rises in a transcranial phantom to Output Display Standard indices.

While we generally agree with the results of this study, it is our opinion that the conclusions reached in the final paragraph of Section 8 are somewhat overstated and may not be entirely justified.

First of all, we question the statement that the project has produced substantial evidence of heating that could exceed safe levels. While some evidence of high heating levels is presented, the small number of scanner/transducer combinations evaluated does not justify the term "substantial". Indeed, the second paragraph of Section 8 cautions not to draw too definite conclusions based on the limited study sample size. Furthermore, the worst case values presented appear to be derived from a thermal phantom with a direct water path to the target, since none of the measured attenuated temperature rises exceeded 4 degrees Centigrade. In virtually all clinical situations, there is some intervening attenuative tissue between the transducer and the target tissue. As pointed out in your conclusions, further work is needed to clarify the relationships between these measurements and in vivo temperature rises. Also, in actual clinical situations, the sonographer has the option of minimizing exam time as a way to reduce thermal effects. Therefore, worst case temperature rise, by it self, may not necessarily imply an unsafe condition.

Secondly, while we agree that the onscreen information quite often represents average heating potential, we take issue with the statement that these values should not be taken as an indication of patient safety. In the majority of instances, the display does provide indication of heating potential. In our opinion, use of this display, in conjunction with the setting of output levels per the ALARA (As Low As Reasonably Achievable) principle, will assist the operator in making informed patient risk/benefit decisions.

Best Regards,

Charles Grossman

NPL

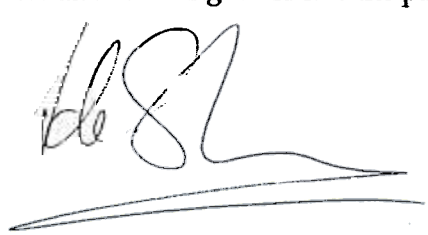
trimester. These figures are much closer to the attenuation used for the worst-case measurements at NPL.

This does not, of course, "prove" that temperature rises in excess of 4°C actually do occur but it is certainly evidence that they may occur and that investigations of *in vivo* temperature increase are required. I would like to emphasise your point that the temperature rises observed would not necessarily be unsafe if they occurred *in vivo* because the operator, when reliably informed of the possibility, would be able to take steps to reduce the temperature.

This leads on to your second point that you take issue with the statement in the report that the on-screen display of TI is "..representative of average rather than maximum heating potential and should, therefore, not be taken as an indication of patient safety." As you say, the TI can be used in conjunction with the ALARA and, in general, taking steps to reduce the displayed TI value will reduce the hazard to the patient. However, it is difficult to use the display to make an informed assessment of risk (and hence to carry out a risk/benefit analysis) for three main reasons. Firstly, we have shown that agreement between the ODS TI value and the temperature rise under attenuated conditions varies from field to field and so a TI indication of 2 for one field configuration may actually produce a higher temperature rise than an indication of 3 for a different field. Secondly, the displayed TI values in some cases were significantly different from the values calculated according to the ODS formulae from measurements made at NPL. And thirdly, as discussed earlier, exposure through low attenuation tissue regions will generally produce greater temperature rises. Overall, there is good evidence to suggest that, for one or more of these reasons, the maximum temperature rise in the ultrasound field could exceed the displayed TI value in a substantial fraction of examinations (especially obstetric examinations) and taking steps to reduce the displayed TI value will not necessarily reduce the maximum temperature rise.

A true safety indicator would need to provide the operator with a "reasonable worst-case" indication of patient safety so that the maximum temperature rise would exceed the indicated value in a small percentage of cases (perhaps 2.5% as suggested by WFUMB, 1997). This would allow the knowledgeable operator to assess the potential risk with reference to national or international guidelines and would give confidence that any steps taken to reduce the indicated value were also reducing the risk to the patient.

Yours sincerely



Adam Shaw

References

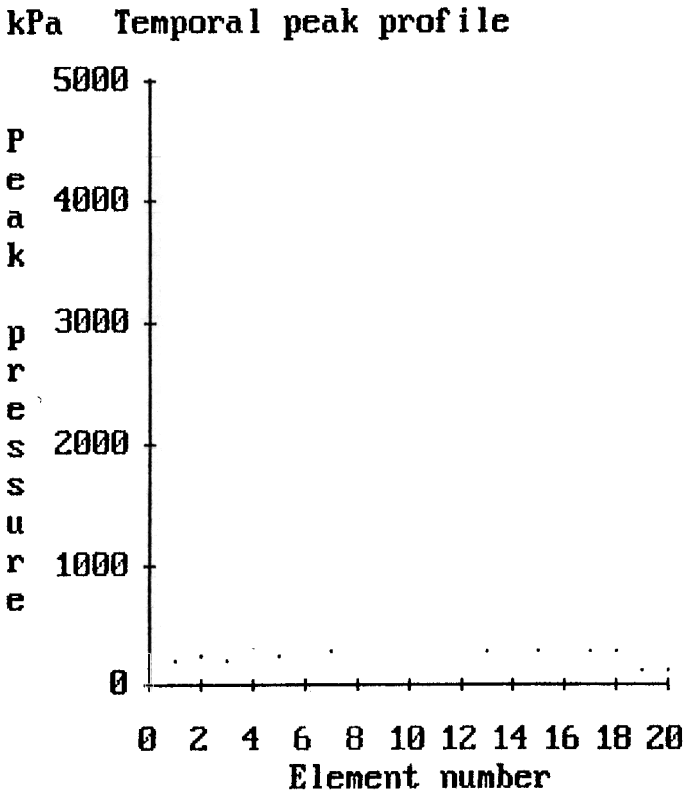
Carson PL, Rubin JM and Chiang EH (1989). *Fetal depth and ultrasound path lengths through overlying tissues.* Ultrasound Med. Biol., **15**, p629-39.

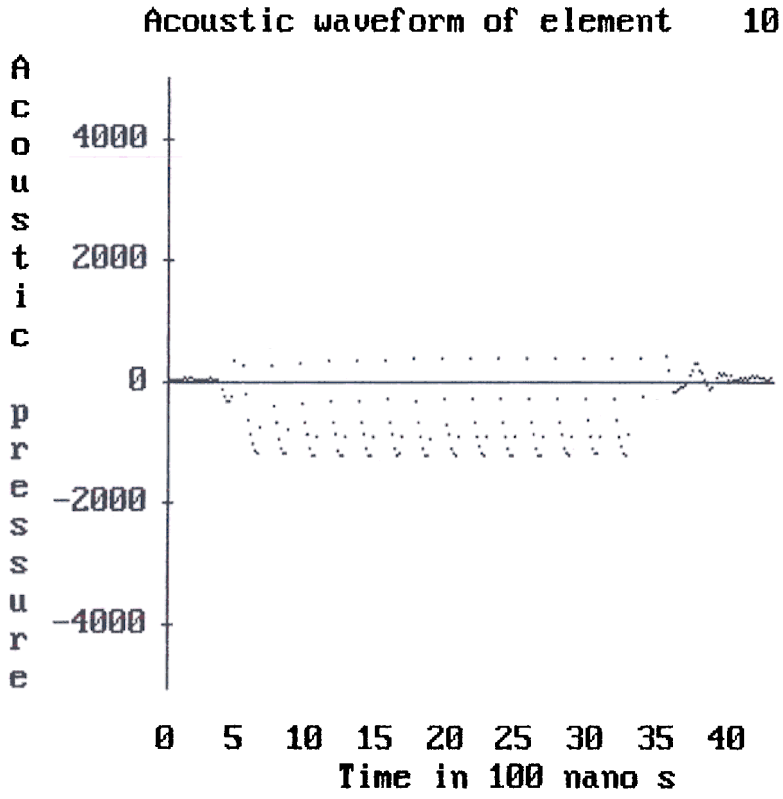
See Section 10 of NPL Report (CMAM 12) for other references.

APPENDIX C: EXAMPLE MEASUREMENT DATA

Example data generated for Acuson 128 with S519 transducer

Scanner settings
Xmtr power: <500
Gate depth: 55 mm
Velocity scale: -0.6 - +0.6m s^{-1}
Gate: 30 mm





Non-automatic scanner option Clock frq = 60 MHz Gain = 6 dB psi = 2167
Peak pos pres @ cent (+) = 2897 kPa Max peak pos pres @ cent (+) = 3054 kPa
prr = 8282 Hz
I(ta) = 2610 I.3 = 525 I.6 = 106 mW/cm2 Freq = 4.95 MHz

X: -0.8 Y: 0.0 Depth: 47.0 (mm)
04 Apr 1997 10:06

NPL ULTRASOUND BEAM CALIBRATION SYSTEM

Current date and time: 4/4/97 10:10

Identification NMP ACUSON 128, TRANSDUCER S519

Other information:
Position of maximum Ispta
Scan plane perpendicular to array

Pulse repetition rate: 8281.57 Hz

Depth: 47.0 mm (0%) X: 0.6 mm Y: 1.5 mm

Nominal frequency: 5.0 MHz

p_+	2.94 MPa (6%)
p_-	-1.29 MPa (1%)
-6dB Beam width	2.16 mm (1%)
Pulse duration	2.80 μs (1%)
I_{spta}	2.60 W cm^{-2} (1%)
Total power	118. mW (1%)

Acoustic Parameters

p_{spp}	1.29 MPa (1%)	p_{sp}	197. kPa (1%)	p_{sap}	945. kPa (1%)	p_{sa}	144. kPa (1%)
I_{sptp}	549. W cm^{-2} (11%)	I_{sppa}	112. W cm^{-2} (2%)	I_{sapa}	62.9 W cm^{-2} (1%)	I_{sata}	1.46 W cm^{-2} (1%)
I_m	164. W cm^{-2} (8%)	f_{AWF}	4.95 MHz (1%)	$\sqrt{p_i}$ (psi)	2163. Pa s$^{\frac{1}{2}}$	Pressure correction N/A	
Ita-scan	N/A	Ita-meter N/A					

F.D.A. Derated Values

I_{spta}	523. mW cm^{-2}	I_{sppa}	22.5 W cm^{-2}	I_m	33.1 W cm^{-2}

System Parameters

Software Version V8.1a (standard)

Serial Number	106079601	Hydrophone spacing	0.6 mm	Hydrophone diameter	0.4 mm		
Digitization rate	60.0 MHz	Points/waveform	256	Amplifier gain	6.00 dB	Sensitivity	50.0 mV/MPa
Duplicate factor	1	Trigger factor	4	Number of averages	5	Temperature	25.0 °C

95% confidence RANDOM uncertainties are given.

WARNING: Spatial(beam)-average and power values are calculated on the assumption of a cylindrically-symmetrical beam.

Document to generate interpolated intensity distribution from measured UBC data sets.
The interpolated grid is specified by maximum and minimum z distances, z step size and radial oversam factor.
Standard values for z_{min}, $z_{incremental}$ and radial_oversampling are 0mm, 1mm and 5 respectively. z_{max} depends on the focal length of the transducer.

Include various subroutines for data manipulation.

Include:C:\SHARED\DOH\INTERP1E.MCD

Define the axial dimensions of the grid, bearing in mind the range of measured distances.

$z_{min} := 0 \cdot mm$

$z_{max} := 80 \cdot mm$

$z_{increment} := 1 \cdot mm$

$min\_measured\_depth = 3 \cdot mm$

$max\_measured\_depth = 70 \cdot mm$

Specify radial oversampling factor $radial\_oversampling := 5$ to increase resolution.

giving a mesh size of: $\frac{spacing}{radial\_oversampling} = 0.12 \cdot mm$

Perform interpolation:

$$Results\_array := UBC\_interpolate\left(Measured\_UBC\_data, z_{min}, z_{max}, \frac{z_{increment}}{m}, radial\_oversampling\right)$$

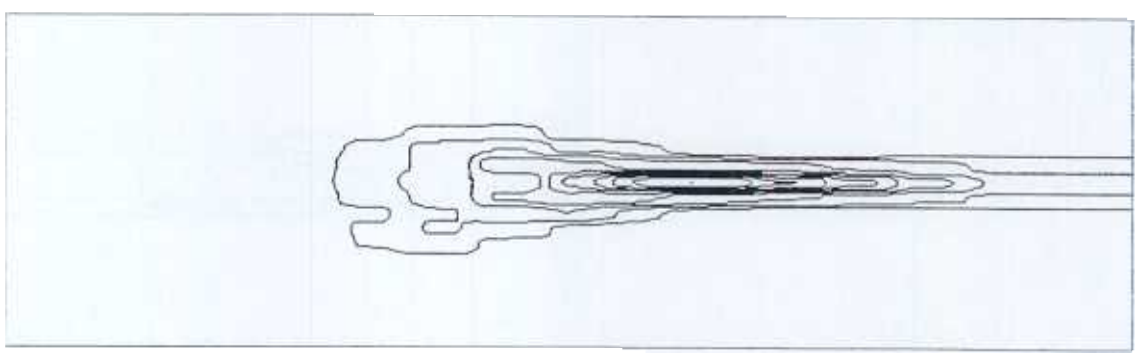
Insert filenames for UBC measured data file and for saving interpolated matrix

$Measured\_UBC\_data := READPRN(aacus519\_prn)$

$WRITEPRN(aacus519\_mat) := Results\_array$

$min(Depth) = 0 \cdot mm$

$max(Depth) = 80 \cdot mm$



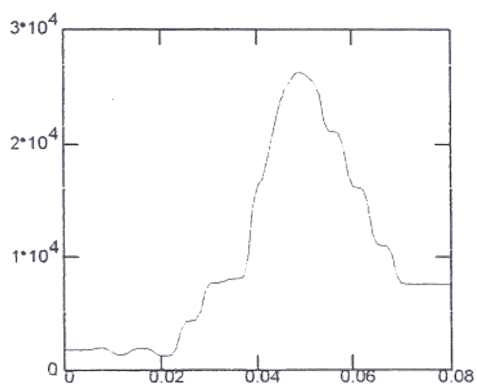
Interpolated_intensity

Check that measured and interpolated intensities are within acceptable agreement.

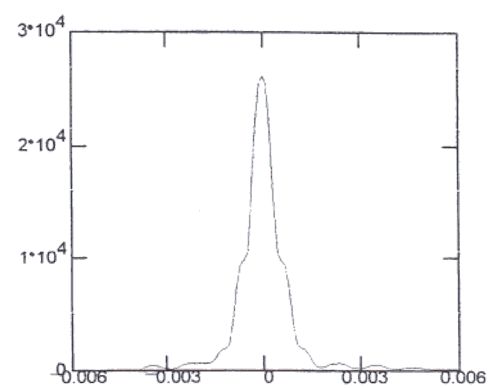
$max\_measured\_intensity = 2.64 \cdot 10^3 \cdot \frac{mW}{cm^2}$

$max(Interpolated\_intensity) = 2.624 \cdot 10^3 \cdot \frac{mW}{cm^2}$

Axial profile



Radial profile at depth, $Z := 48 \cdot mm$



Adam Shaw, Ultrasonics, NPL

Document to calculate temperature rise in TTO using a summation of weighted intensities within the TMM region of the TTO.
This method is not susceptible to the convergence errors associated with the numerical integral method and is faster.

Enter names of intensity files to be used. Transducer must be a matrix with column headings of axial distance and row headings of radial distanc. If the acoustic frequency is not in the 0,0 location, enter a value where shown.

$$Transducer := \frac{1}{6}\cdot\begin{bmatrix} READPRN(aacus519_{mat}) + READPRN(bacus519_{mat}) \cdots \\ +2\cdot(READPRN(cacus519_{mat}) + READPRN(dacus519_{mat})) \end{bmatrix}^T \qquad Freq := 4.94\cdot MHz$$

Include TTO descriptor file:

Include:C:\SHARED\THERMAL\SUMTEMPS\TTO9619.MCD

Perfusion time: $\tau := 720\cdot sec$

Modify TTO descriptor if necessary (sensor position in TTO is 0 mm):

Include subroutine file:

Include:C:\SHARED\THERMAL\SUMTEMPS\SUMSUB1.MCD $\quad pre\_sensor\_compensation := e^{2\cdot atten(face_1)\cdot Freq}$

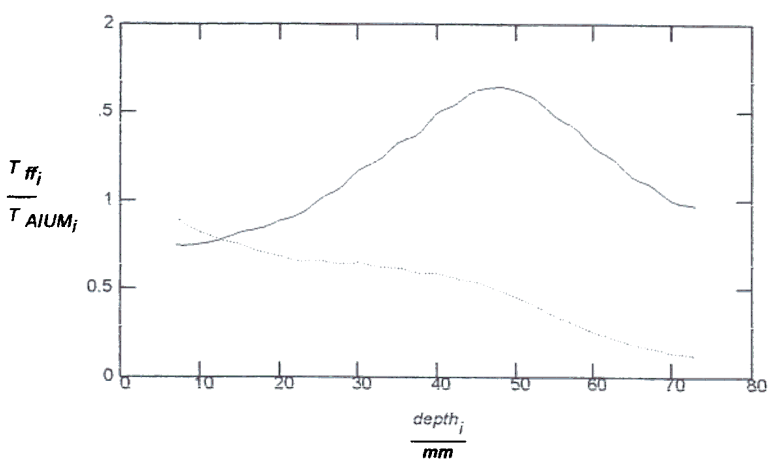
Call calculation subroutine T_vs_Z(model, Freq, Transducer, exposure time, conductivity, diffusivity, perfusion time), where model is either "unperf", "perf_t" or "perf_ss" for unperfused, perfused(after time t) and perfused(steady state) respectively.

$$Results := T\_vs\_Z(unperf, Freq, Transducer, 180\cdot sec, k, \kappa, \tau) \qquad depth := Results^{<0>}\cdot m \qquad T_{ff} := Results^{<1>}\cdot K$$

and derate according to desired model (generally 0.3 dB/cm/MHz)

$$T_{AIUM} := \overline{(T_{ff}\, pre\_sensor\_compensation\cdot derating(AIUM, Freq, depth)}$$

$i := 0..length(depth)$



$max(T_{ff}) = 1.645\cdot K$

$max(T_{AIUM}) = 0.9\cdot K$

$dB \equiv 1$

$$face = \begin{bmatrix} -6.9 \\ 0 \\ 6.9 \\ 6.9 \\ 6.9 \end{bmatrix}\cdot mm \qquad absorb = \begin{bmatrix} 1\cdot 10^{-4} \\ 0.063 \\ 0.063 \\ 0.063 \\ 0.063 \end{bmatrix}\cdot\frac{Np}{cm\cdot MHz} \qquad k = 0.518\cdot\frac{watt}{m\cdot K} \qquad c_V = 3.9\cdot\frac{joule}{mL\cdot K}$$

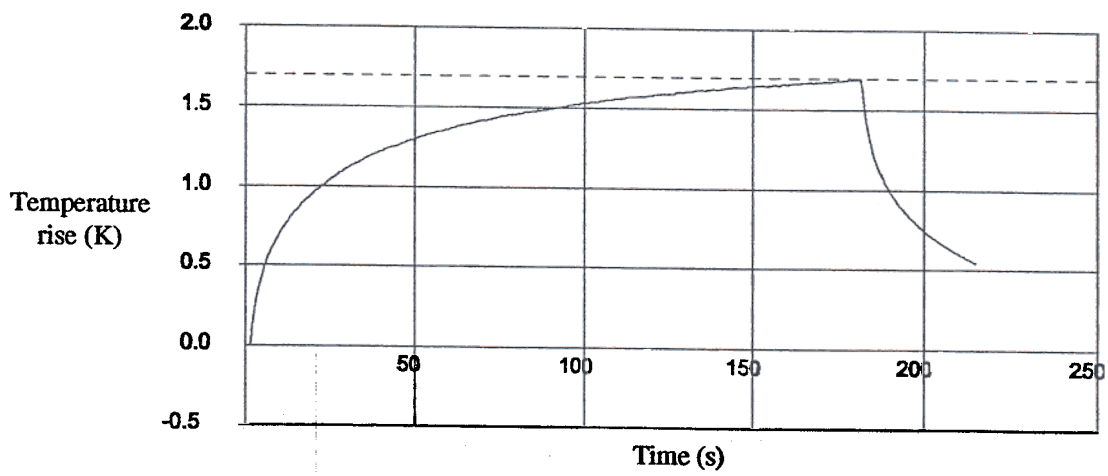
$pre\_sensor\_compensation =$ 1.582 equivalent to $\frac{10\cdot log(pre\_sensor\_compensation)}{Freq} = \cdot\frac{dB}{MHz}$ 0.375

Measurement Description

Scanner:	Acuson 128
Transducer:	S519
Sensor:	TTO 96/19 Soft tissue
Measurement:	S519 47mm
Maximum value:	**1.70 K**

Measurement Parameters

Position (z-axis):	47 mm
Heating Time:	180 seconds
Cooling Time:	30 seconds
Sampling Rate:	2 Hz

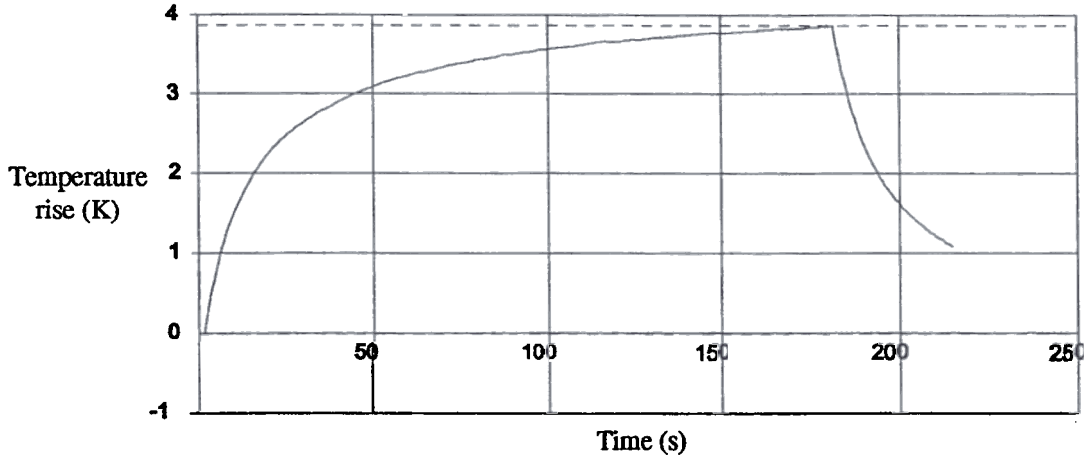


Measurement Description

Scanner:	Acuson 128
Transducer:	S519
Sensor:	TTO 97/029 Soft tissue/bone
Measurement:	B S519 47A
Maximum value:	**3.86 K**

Measurement Parameters

Position (z-axis):	47 mm
Heating Time:	180 seconds
Cooling Time:	30 seconds
Sampling Rate:	2 Hz



APPENDIX D: TABULATION OF RESULTS

The figures in bold on the same line as the name of each scanner and transducer are for the quantities described at the top of each column. The figures in normal type on the lines below each scanner name give measured temperature values at the separation indicated in the "Distance" column. For each type of test object, the reported values are (left to right): $\Delta T_{meas\text{-}wc}$, $\Delta T_{meas\text{-}wc}$ x linear derating factor, the temperature rise measured with attenuators in the beam, and $\Delta T_{meas\text{-}att}$ (where a correction has been applied to the previous column in order to compensate for any discrepancy between the actual attenuation used and the required amount). See Section 4.6 for more details.

				On-screen		OOS TI			NPL Predictions (K)								Soft tissue measurements (K)				Bone measurements (K)			
Ref #	Scanner	Transducer	Freq (MHz)	TIS	TIB	TIS	TIB	TIC	Worst-case soft tissue max	Worst-case bone max	Attenuated soft tissue max	Attenuated bone max	Soft tissue in contact	Bone in contact		Distance (mm)	Max worst-case	Max derated	Contact	Max attenuated	Max worst-case	Max derated	Contact	Max attenuated
1	Aucson 128	L312	2.52			0.91	2.45	1.47	2.07	9.14	0.40	1.58	0.37	1.17			2.02	0.35	0.00	0.40	8.76	1.59	0.00	1.59
			2.52													contact		0.00		0.00		0.00		0.00
			2.52													12.00	0.35	0.35	0.35	0.35	1.68	1.59	1.68	1.59
			2.52													37.00	0.52	0.34	0.33	0.31	2.47	1.52	1.73	1.53
			2.52													75.00	0.98	0.33	0.43	0.40	4.68	1.48	1.81	1.57
			2.52													113.00	2.02	0.35	0.34	0.38	8.76	1.43	1.37	1.43
2	Aucson 128	S519	4.94			1.38	1.88	1.40	1.95	4.40	0.90	1.88	0.75	1.88			1.70	0.75	1.73	0.75	3.92	1.88	3.42	1.88
			4.94													contact	1.73	0.00	1.73	0.00	3.42	0.00	3.42	0.00
			4.94													14.00	0.79	0.75	0.79	0.75	2.21	1.86	2.21	1.86
			4.94													44.00	1.59	0.54	0.47	0.56	3.92	1.19	1.14	1.21
			4.94													47.00	1.70	0.52	0.61	0.55	3.92	1.07	1.31	1.26
3	Aucson 128	V328	3.48			1.03	2.44	1.74	2.51	9.13	0.64	1.93	0.54	1.51			2.98	0.67	0.00	0.67	10.10	2.24	2.71	2.43
			3.48													contact		0.00		0.00	2.71	0.00	2.71	0.00
			3.48													12.00	0.68	0.67	0.68	0.67	2.14	1.99	2.14	1.99
			3.48													45.50	1.29	0.58	0.58	0.64	5.25	2.18	2.41	2.43
			3.48													62.25	2.03	0.61	0.64	0.60	8.04	2.24	2.30	2.30
			3.48													79.00	2.98	0.60	0.38	0.41	10.10	1.88	1.95	1.93
4	Aloka SSD2000	UST-5524-7.5	5.02			0.32	0.80	0.52	Insufficient information								1.09	0.61	0.00	0.61	0.00	0.00	0.00	0.00
	(Aloka settings)		5.02													contact		0.00		0.00		0.00		0.00
			5.02													16.00	0.69	0.61	0.69	0.61	0.00	0.00	0.00	0.00
			5.02													30.00	1.09	0.59	1.09	0.59	0.00	0.00	0.00	0.00
5	Aloka SSD2000	UST-994P-5	3.78			0.40	1.19	0.85	0.34	1.09	0.38	1.06	0.37	1.06			0.91	0.64	0.90	0.64	3.38	2.26	3.62	2.26
	(Aloka settings)		3.78													contact	0.90	0.00	0.90	0.00	3.62	0.00	3.62	0.00
			3.78													15.00	0.56	0.52	0.56	0.52	2.64	2.26	2.64	2.26
			3.78													24.00	0.86	0.64	0.86	0.64	3.25	2.20	3.25	2.20
			3.78													31.00	0.91	0.56	0.91	0.56	3.38	1.90	3.38	1.90
6	Aloka SSD2000	UST-994P-5	3.78			0.55	1.38	1.05	0.46	1.49	0.34	0.98	0.30	0.92			1.06	0.79	1.45	0.79	3.67	2.19	3.69	2.19
	(NPL settings)		3.78													contact	1.45	0.00	1.45	0.00	3.69	0.00	3.69	0.00
			3.78													15.00	0.84	0.79	0.84	0.79	2.56	2.19	2.56	2.19
			3.78													23.00	0.93	0.71	0.93	0.71	3.14	2.18	3.14	2.18
			3.78													30.00	1.06	0.67	1.06	0.67	3.67	2.12	3.67	2.12
7	Aloka SSD2000	UST-990-5	3.73			0.66	1.82	0.94	0.55	1.81	0.47	1.29	0.40	1.29			1.95	0.96	1.97	0.96	5.82	3.02	4.50	3.02
	(Aloka settings)		3.73													contact	1.97	0.00	1.97	0.00	4.50	0.00	4.50	0.00
			3.73													15.00	0.94	0.88	0.94	0.88	3.53	3.02	3.53	3.02
			3.73													35.00	1.68	0.94	1.68	0.94	5.68	2.91	5.68	2.91
			3.73													39.00	1.67	0.84	1.67	0.84	5.44	2.51	5.44	2.51
			3.73													40.00	1.95	0.96	1.96	0.96	5.82	2.82	5.82	2.82
8	Aloka SSD2000	UST-990-5	3.73			0.57	1.91	1.17	0.90	2.90	0.60	1.72	0.52	1.53			1.93	1.07	0.00	1.07	7.72	3.48	5.69	3.48
	(NPL settings)		3.73													contact		0.00		0.00	5.69	0.00	5.69	0.00
			3.73													15.00	1.14	1.07	1.14	1.07	4.06	3.48	4.06	3.48
			3.73													40.00	1.86	0.91	1.85	0.91	7.39	3.32	7.39	3.32
			3.73													43.00	1.93	0.88	1.93	0.88	7.72	3.21	7.72	3.21

Ref #	Scanner	Transducer	Freq (MHz)	On-screen		ODS TI			NPL Predictions (K)							Distance (mm)	Soft tissue measurements (K)				Bone measurements (K)			
				TIS	TIB	TIS	TIB	TIC	Worst case soft tissue max	Worst case bone max	Attenuated soft tissue max	Attenuated bone max	Soft tissue in contact	Bone in contact			Max worst case	Max derated	Contact	Max attenuated	Max worst case	Max derated	Contact	Max attenuated
16	IGE Logiq 500 MD	C364	3.28	1.00	0.40	0.81	1.41	1.40	1.22	4.59	0.48	1.43	0.44	1.35			1.09	0.51	0.69	0.51	4.59	1.78	2.05	1.78
			3.28													contact	0.69	0.00	0.69	0.00	2.05	0.00	2.05	0.00
			3.28													12.00	0.50	0.51	0.50	0.51	1.90	1.78	1.90	1.78
			3.28													42.50	0.73	0.37	0.38	0.37	3.39	1.59	1.56	1.88
			3.28													57.75	0.90	0.32	0.33	0.35	4.10	1.36	1.48	1.43
			3.28													73.00	1.09	0.28	0.23	0.25	4.59	1.08	1.12	1.11
17	IGE Logiq 500 MD	C551	4.92	0.60	0.40	1.42	2.10	1.70	1.61	4.28	0.98	1.99	0.80	1.99			1.57	0.91	1.44	0.91	4.09	2.46	3.15	2.46
			4.92													contact	1.44	0.00	1.44	0.00	3.15	0.00	3.15	0.00
			4.92													11.50	0.88	0.91	0.69	0.91	2.68	2.46	2.68	2.46
			4.92													26.25	1.13	0.71	0.80	0.72	3.68	2.05		0.00
			4.92													33.65	1.37	0.67	0.68	0.68	4.31	1.88		0.00
			4.92													41.00	1.57	0.60	0.62	0.63	4.69	1.58	2.38	2.12
18	IGE Logiq 500 MD	LA39	6.58	0.80	2.00	0.85	1.69	1.54	0.70	1.40	0.78	1.26	0.58	1.15			0.69	0.65	0.75	0.65	1.41	1.21	1.57	1.21
			6.58													contact	0.75	0.00	0.75	0.00	1.57	0.00	1.57	0.00
			6.58													12.00	0.64	0.65	0.64	0.65	1.39	1.21	1.39	1.21
			6.58													22.00	0.67	0.44	0.41	0.43	1.41	0.78	0.88	0.79
			6.58													32.00	0.69	0.28	0.23	0.25	1.37	0.48	0.52	0.47
19	Toshiba Esaote	PLF-805ST	5.08	0.40	1.80	0.43	1.33	0.70	0.52	1.34	0.44	0.94	0.37	0.93			0.51	0.39	0.69	0.39	1.11	0.91	1.51	0.91
			5.08													contact	0.69	0.00	0.69	0.00	1.51	0.00	1.51	0.00
			5.08													8.40	0.64	0.74		0.00		0.00		0.00
			5.08													12.00	0.38	0.39	0.39	0.39	1.01	0.91	1.01	0.91
			5.08													17.00	0.40	0.34		0.00	1.06	0.80	0.72	0.79
			5.08													18.00	0.47	0.39		0.00		0.00		0.00
			5.08													19.50	0.46	0.36	0.34	0.38	1.06	0.73	0.75	0.75
			5.08													22.00	0.51	0.37	0.33	0.34	1.11	0.70	0.95	0.87
20	Toshiba Esaote	PVE-382M	3.06	0.60	3.00	1.18	3.57	2.08	1.23	4.93	0.73	2.65	0.55	1.92			1.11	0.66	0.00	0.69	5.12	2.83	3.30	2.94
			3.06													contact		0.00		0.00	3.30	0.00	3.30	0.00
			3.06													12.00	0.56	0.57	0.56	0.57	2.62	2.46	2.62	2.46
			3.06													25.00	0.60	0.61	0.65	0.62	3.84	2.74	2.68	2.82
			3.06													31.50	0.98	0.66	0.66	0.69	4.71	2.93	2.90	2.81
			3.06													38.00	1.11	0.65	0.66	0.60	5.12	2.77	2.95	2.94
21	Toshiba Esaote	PVF-375MT	3.10	0.40	2.00	0.41	1.83	0.76	0.77	3.08	0.37	1.31	0.31	0.93			0.71	0.32	0.54	0.33	2.95	1.32	1.45	1.44
			3.10													contact	0.54	0.00	0.54	0.00	1.45	0.00	1.45	0.00
			3.10													12.00	0.29	0.29	0.29	0.29	1.15	1.06	1.15	1.06
			3.10													20.80	0.33	0.28		0.00	1.42	1.10		0.00
			3.10													32.00	0.45	0.30	0.28	0.29	1.93	1.18	1.24	1.18
			3.10													40.00	0.57	0.32		0.00	2.14	1.31		0.00
			3.10													42.00	0.60	0.32	0.33	0.33	2.67	1.32	1.33	1.44
			3.10													52.00	0.71	0.30	0.27	0.27	2.95	1.17	1.17	1.28

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large errors due to the methods used and so needs to be re-assessed in the light of more controlled measurements.

3. The UK needs to develop an independent view in this field so as to support its position in the development of IEC standards, which would then be applied in the UK. Indeed, as an active participant in the relevant IEC committees, the UK has already committed itself to provide a substantive input to this work. NPL is already involved in several aspects of the basic scientific research required to underpin this activity, but a need remains to test the developing systems on commercial equipment.

This project, funded by the DoH, was intended to meet these requirements and make the information available in the scientific literature in a form that will be of practical use to those involved in ultrasound scanning. It is divided into three stages: Stage I provides estimates of the likely thermal hazard using agreed theoretical algorithms and acoustic output data supplied by manufacturers, Stage II attempts to verify those predictions by making controlled measurements of the acoustic output and temperature rise for a range of scanners; and Stage III provides predictions of the temperature rise for realistic clinical conditions using layered tissue models. The results of this work will be made widely available to inform clinicians and others who have to make decisions about the safe use of ultrasound. Overall, the project will ensure the provision of validated test methods for use in IEC standards and so will provide a vital link in implementing the EC Medical Devices Directive for diagnostic ultrasound equipment.

This report covers Stages II and III of the project. The aims are described in detail in Section 2, communication with manufacturers is documented in Section 3, the measurements and calculations carried out on each system are described in Section 4, and the main results are tabulated in Section 5. The results are analysed and discussed at length in Section 6 with a brief technical summary of the findings following in Section 7. The overall conclusions from Stages II and III relating to the implications for the assessment of thermal hazard and patient exposure are drawn out in Section 8. Appendices reproduce the comments provided by manufacturers prior to publication of this report, and provide examples of the type of data obtained during the acoustic and thermal assessments and a fuller tabulation of results

3 COMMUNICATION WITH MANUFACTURERS/SUPPLIERS

As agreed during communications documented by Shaw, Preston and Bond (1997), preliminary results were sent to manufacturers for comment. The following list contains the contact addresses for UK manufacturers and suppliers of diagnostic ultrasound equipment who have either supplied equipment for or commented on the results of Stages II and III of this project. The letter sent requesting comments initial results of measurements and calculations can be found in Appendix A along with any relevant comments which were returned. A 'Restricted - commercial' version of this report was sent to manufacturers for comment prior to publication of the current 'Open' version. Details of this correspondence are given in Appendix B.

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non-circular geometry of the field. The main parameters measured were peak-positive pressure, peak-negative pressure, I_{spta}, total power and -6dB beamwidth. UBC printouts parallel and perpendicular to the scan-plane for an example transducer are given in Appendix C. Measurements are traceable to the NPL Primary Standard Interferometer and typical overall uncertainties at the 95% confidence level are estimated to be ±12% for peak-positive pressure, ±9% for peak-negative pressure, ±18% for I_{spta}, ±22% for total power in the focal plane and ±7% for -6dB beamwidth. The power in the focal plane is expected to underestimate the total radiated power due to the effects of absorption in the water path and non-linear shock-loss; the systematic bias is estimated to be -5% for a typical transducer. In addition, the -6dB beamwidth was measured parallel and perpendicular to the scan-plane close to the transducer surface (with an estimated uncertainty of ±10%). The total power was also measured independently using a radiation force balance fitted with a right-angled convex conical target. The balance was calibrated against the NPL Primary Standard Radiation Force Balance using an unfocused transducer as a transfer standard giving an uncertainty in the calibration of ±7%. For measurements of the focused fields generated by Doppler transducers, there is expected to be a systematic overestimate of the true power. There is no recognised standard method for evaluating this bias but simple estimates suggest that it is around +10% for a typical transducer.

4.3 MAPPING OF INTENSITY DISTRIBUTION

A series of scans were made placing the hydrophone at different distances from the transducer to map the temporal-average intensity distribution across the beam as a function of distance with an estimated uncertainty at the 95% confidence level of ±18%. The measured values were automatically written to an ASCII file by the UBC software so that they could be analysed later. Scans were made with the hydrophone array aligned parallel to the scan-plane direction of the transducer and also at 30°, 60° and 90° to the scan plane to allow for the non-circular geometry of the field. For each scan, the measured values were interpolated to generate a regular grid of intensity values in which the matrix elements were typically spaced 0.12 mm radially and 1 mm axially. To minimise possible artefacts, a nearest neighbour interpolation technique was used with a modest degree of smoothing to make the interpolated distribution more continuous. Example contour plots parallel and perpendicular to the scan-plane are given in Appendix C.

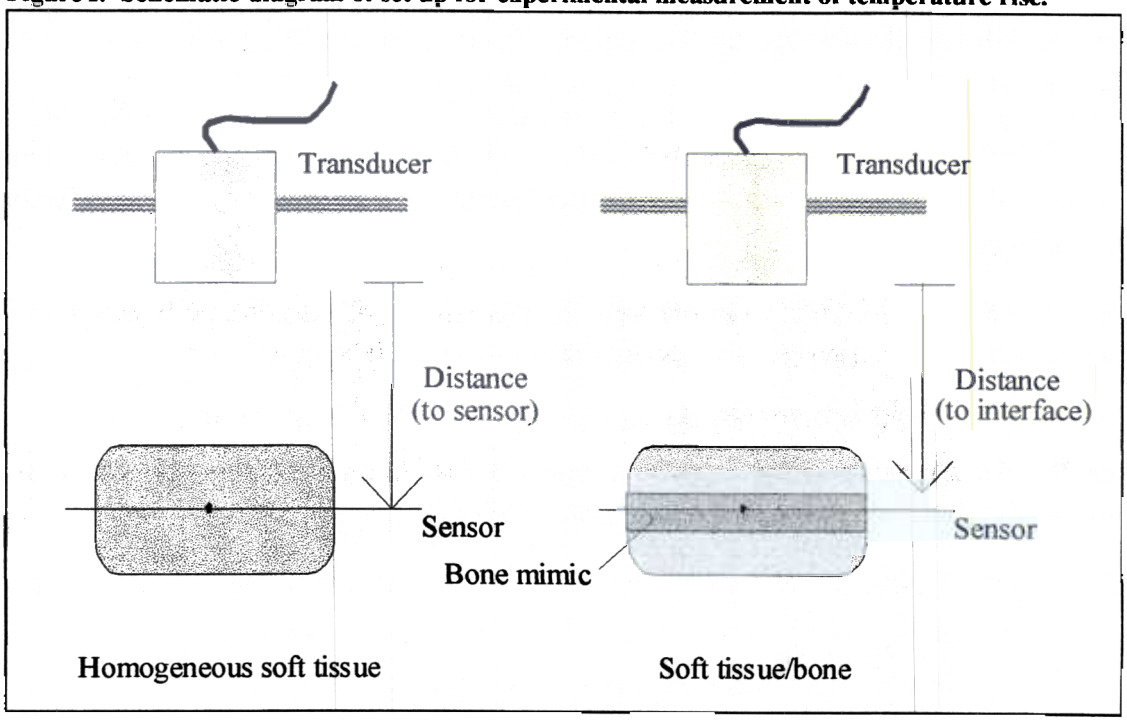
4.4 CALCULATION OF THERMAL INDEX VALUES

Thermal index values, TI_{ODS}, were calculated for the AIUM/NEMA soft tissue, bone and cranial models (TIS, TIB and TIC) from the UBC data described in 4.2 and 4.3; the Excel spreadsheet written during Stage I of this project (Shaw, Preston & Bond, 1997) was used. The values for total power which are used are those derived from the UBC measurements; these are used in preference to the force balance measurements since the anticipated bias is smaller as is explained in Section 4.2. The estimated uncertainty TI values is ±25% at the 95% confidence level. An Excel printout for the example scanner/transducer combination is given in Appendix C.

4.6 MEASUREMENT OF TEMPERATURE RISE

Temperature rise was measured using thermal test objects. Each test object consists of a thermal sensor sandwiched between layers of tissue mimicking material (Bacon and Shaw, 1993). The assembly was enclosed for protection and ease of handling; the output of the thermal sensor was connected *via* a low-noise pre-amp to a digital voltmeter. The test object was mounted in a stepper-motor positioning system in a test tank below the transducer. Data acquisition and movement of the test object was controlled by a PC, allowing the test object to be scanned through the field to locate the centre of the beam at any defined distance.

Figure 1. Schematic diagram of set up for experimental measurement of temperature rise.



Generally, the temperature rise was measured at five positions within the ultrasound field: (i) at the free-field focus; (ii) approximately 10-12 mm from the transducer, (iii) midway between (i) and (ii); (iv) midway between (i) and (iii); and (v) in contact with the transducer surface. Position (i) was chosen to give the maximum worst-case temperature rise; position (ii) was chosen as being close to the transducer surface but with sufficient water gap between the transducer and the surface of the test object to prevent significant heating by conduction from the transducer itself; positions (iii) and (iv) are intermediate points; and position (v) was chosen to assess the total temperature increase, $\Delta T_{meas\text{-}cont}$, caused by both absorption within the test object and conduction from the transducer. For some systems, different or fewer points were chosen. Again, examples of the measured variation of temperature with time can be found in Appendix C.

Worst-case measurements, $\Delta T_{meas\text{-}wc}$, were made with no additional attenuation between the transducer and the test object. For the soft tissue test object, this meant that the total attenuation between the transducer and the thermal sensor was approximately 0.35 dB/MHz; for the bone test object, the attenuation between the transducer and the soft tissue/bone interface was approximately 0.25 dB/MHz. Attenuated measurements were made by inserting acoustical attenuators (Preston *et al.* 1991*a* and *b*) in the propagation

5 RESULTS

A total of 23 fields covering a frequency range of 2.2 MHz to 6.6 MHz were measured from 19 transducers on seven different scanners. Generally, only one field was measured from each of the transducers with the exception of two transducers on the Aloka SSD2000 and one on the HP 77020. The two Aloka transducers were assessed under the operating conditions which the manufacturers quoted as giving the maximum thermal index as well as the operating conditions which were identified as producing the maximum I_{spta}. The HP transducer was assessed in M-mode and colour-flow operation under conditions of maximum I_{spta} in addition to pulsed Doppler mode. The M-mode and colour-flow results are given in this Section, but are not included in any of the later graphs or statistical analyses.

Appendix D gives a fuller tabulation of on-screen values, calculated TI's, temperature predictions and temperature measurements. However, to make the information more comprehensible, the key results relating to comparison of different methods for estimating temperature rise for each scanner are summarised in the Table 1 below.

Due to the large number of different measured or derived quantities and the complex relation of each quantity to the others, it is important to establish a clear nomenclature. The following terms are used:

TI_{disp} - the dimensionless quantity displayed on the scanner video monitor.

TI_{ODS} - the dimensionless quantity calculated by NPL from measured acoustic data according to methods defined in the AIUM/NEMA Output Display Standard.

$\Delta T_{pred\text{-}wc}$ - the "worst-case" temperature rise predicted to occur in a test object by NPL based on the measured intensity distribution. For worst-case values there is assumed to be no attenuation between the transducer and the surface of the test object

$\Delta T_{pred\text{-}att}$ - the "attenuated" temperature rise predicted to occur in a test object by NPL based on the measured intensity distribution. For attenuated values, the total attenuation between the transducer and the sensor (or the soft tissue/bone interface in the case of the bone test object) is assumed to be 0.3 dB/cm/MHz.

$\Delta T_{meas\text{-}wc}$ - the "worst-case" temperature rise measured in a test object by NPL. For worst-case values, there are no attenuators between the transducer and the surface of the test object.

$\Delta T_{meas\text{-}att}$ - the "attenuated" temperature rise measured in a test object by NPL. For attenuated values, the total attenuation between the transducer and the sensor (or the soft tissue/bone interface in the case of the bone test object) is 0.3 dB/cm/MHz.

$\Delta T_{meas\text{-}cont}$ - the "contact" temperature rise measured in a test object by NPL. For contact values, the surface of the test object is in contact with or very close to the transducer face. Consequently, there will be a contribution to the temperature rise from energy dissipated within the transducer itself.

Predictions and measurements are made for a range of separation between the transducer and the test object. For $\Delta T_{meas\text{-}wc}$ and $\Delta T_{meas\text{-}att}$, there was a gap of at least 5 mm to minimise

Table 1. Summary results table. See text for description of column entries.

Scanner/ transducer combination	Target tissue	TI_{disp}	TI_{ODS}	max $\Delta T_{pred\text{-}att}$ (°C)	max $\Delta T_{meas\text{-}att}$ (°C)	max $\Delta T_{meas\text{-}wc}$ (°C)	$\Delta T_{meas\text{-}cont}$ (°C)
Acuson 128							
1) L312	soft tissue	-	0.91	0.40	0.40	2.02	-
	bone	-	*2.45*	*1.55*	*1.59*	*8.76*	N/A
	cranial	-	1.47	1.17	N/A	N/A	-
2) S519	soft tissue	-	1.38	0.90	0.75	1.70	1.73
	bone	-	*1.88*	*1.86*	*1.86*	*3.92*	N/A
	cranial	-	1.40	1.86	N/A	N/A	3.42
3) V328	soft tissue	-	1.03	0.64	0.67	2.96	-
	bone	-	*2.44*	*1.93*	*2.43*	*10.10*	*N/A*
	cranial	-	1.74	1.51	N/A	N/A	2.71
Aloka SSD-2000							
4) UST-5524-7.5	soft tissue	-	0.32	-	0.61	1.09	-
(Aloka settings)	*bone*	-	*0.80*	-	-	-	*N/A*
	cranial	-	0.53	-	N/A	N/A	-
5) UST-984P-5	soft tissue	-	0.40	0.38	0.64	0.91	0.90
(Aloka settings)	*bone*	-	*1.19*	*1.05*	*2.26*	*3.38*	N/A
	cranial	-	0.85	1.05	N/A	N/A	3.62
6) UST-984P-5	soft tissue	-	0.55	0.34	0.79	1.06	1.45
(NPL settings)	*bone*	-	*1.36*	*0.98*	*2.19*	*3.67*	N/A
	cranial	-	1.05	0.92	N/A	N/A	3.69
7) UST-990-5	soft tissue	-	0.66	0.47	0.96	1.95	1.97
(Aloka settings)	*bone*	-	*1.82*	*1.29*	*3.02*	*5.82*	N/A
	cranial	-	0.94	1.29	N/A	N/A	4.50
8) UST-990-5	soft tissue	-	0.57	0.60	1.07	1.93	-
(NPL settings)	*bone*	-	*1.91*	*1.72*	*3.48*	*7.72*	N/A
	cranial	-	1.17	1.53	N/A	N/A	5.69

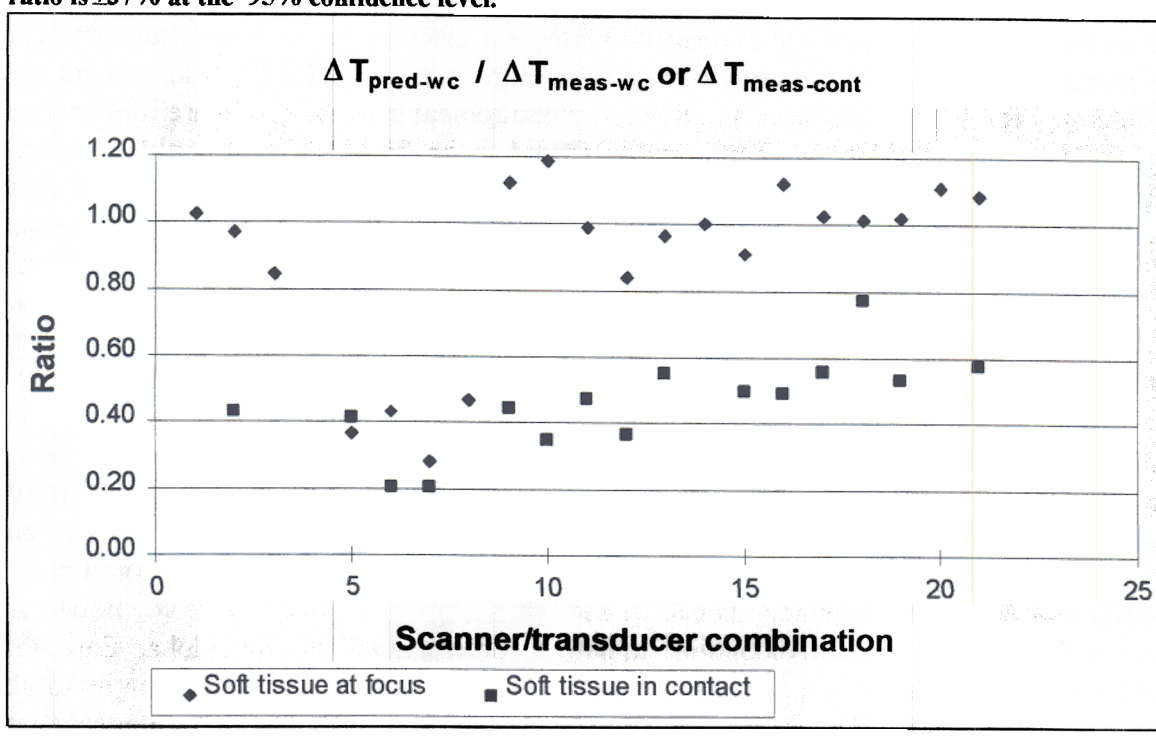
Scanner/ transducer combination	Target tissue	TI_{disp}	TI_{ODS}	max $\Delta T_{pred\text{-}att}$ (°C)	max $\Delta T_{meas\text{-}att}$ (°C)	max $\Delta T_{meas\text{-}wc}$ (°C)	$\Delta T_{meas\text{-}cont}$ (°C)
		-	1.64	1.82	N/A	N/A	2.52
15) 21275A	soft tissue	1.30	0.74	0.71	0.69	1.02	1.17
	bone	*2.10*	*1.42*	*1.89*	*1.47*	*2.17*	N/A
	cranial	-	1.01	1.39	N/A	N/A	2.37
IGE Logiq 500 MD							
16) C364	soft tissue	1.00	0.61	0.48	0.51	1.09	0.89
	bone	*<0.4*	*1.41*	*1.43*	*1.78*	*4.59*	*N/A*
	cranial	-	1.40	1.35	N/A	N/A	2.05
17) C551	soft tissue	0.60	1.42	0.98	0.91	1.57	1.44
	bone	*<0.4*	*2.10*	*1.99*	*2.46*	*4.69*	N/A
	cranial	-	1.70	1.99	N/A	N/A	3.15
18) LA39	soft tissue	0.80	0.85	0.76	0.65	0.69	0.75
	bone	*2.00*	*1.69*	*1.26*	*1.21*	*1.41*	N/A
	cranial	-	1.54	1.15	N/A	N/A	1.57
Toshiba Eccocee							
19) PLF-805ST	soft tissue	0.40	0.43	0.44	0.39	0.51	0.69
	bone	*1.60*	*1.33*	*0.94*	*0.91*	*1.11*	N/A
	cranial	0.6	0.70	0.93	N/A	N/A	1.51
20) PVE-382M	soft tissue	0.60	1.18	0.73	0.69	1.11	–
	bone	*3.00*	*3.57*	*2.65*	*2.94*	*5.12*	*N/A*
	cranial	1.2	2.08	1.92	N/A	N/A	3.30
21) PVF-375MT	soft tissue	0.40	0.41	0.37	0.33	0.71	0.54
	bone	*2.00*	*1.63*	*1.31*	*1.44*	*2.95*	N/A
	cranial	–	0.76	0.93	N/A	N/A	1.45

have important implications in deriving relationships and correlations between different calculated and measured quantities. The M-mode and colour-flow results for HP77020 are also generally omitted.

6.1 VALIDITY OF MEASURED TEMPERATURE RISE

It is worthwhile establishing the validity of the thermal test object technique by comparing the measured temperature rise at a given position in the field with predictions based on the measured intensity distributions at the point where the test object is put (at least, intensity derived from the measured local pressure) and the acoustic and thermal properties of the test objects. Figure 2 shows the ratio of $\Delta T_{pred\text{-}wc}$ to $\Delta T_{meas\text{-}wc}$ for all the systems examined with the soft tissue test object at the focus; it also shows the ratio of $\Delta T_{pred\text{-}wc}$ for the test object in contact with the transducer to $\Delta T_{meas\text{-}cont}$. The results at the focus are relevant for confirming the validity of the test object technique and show that, with the exception of the Aloka results (#4 - #8), the ratio is close to one ($\mu = 1.01$, $\sigma = 0.10$), which is very good agreement considering the uncertainties involved in making the predictions and knowing the properties of the test objects. This confirms that the test objects are performing as expected.

Fig 2. Ratio of predicted worst case temperature rise to measured worst case temperature for soft tissue test object at the focus and in contact with the transducer. The estimated uncertainty in each ratio is ±37% at the 95% confidence level.

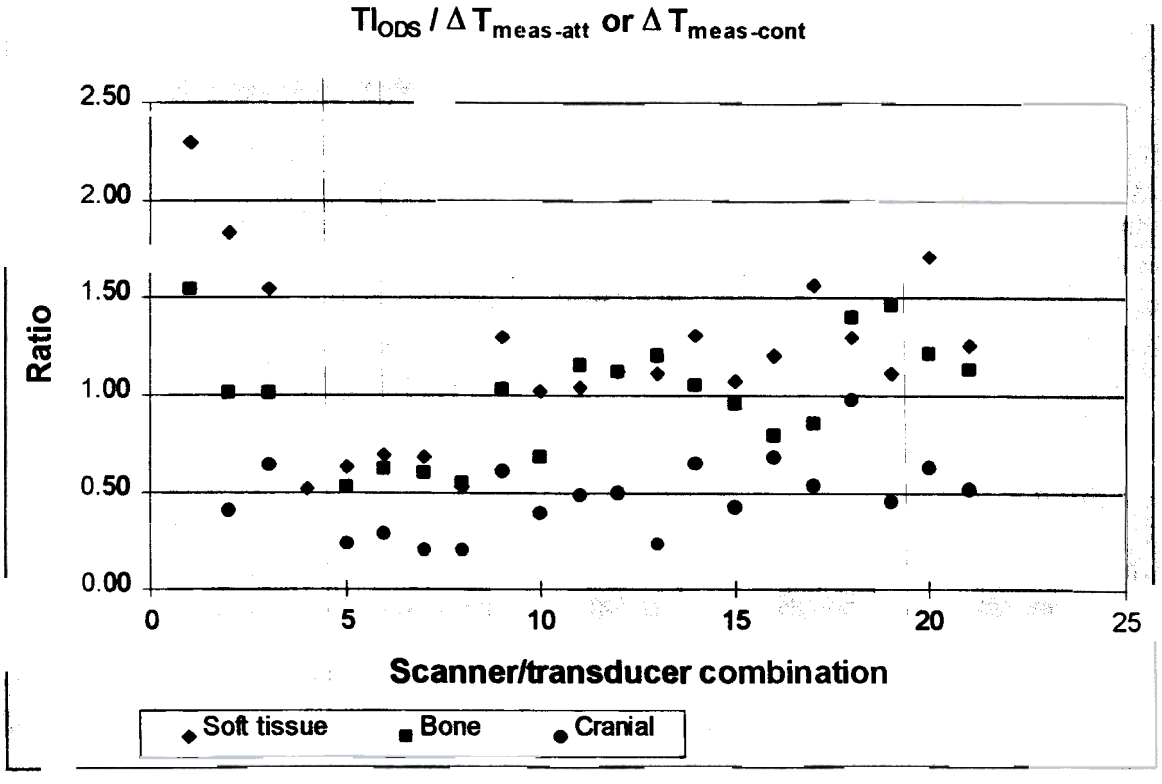


6.2 TRANSDUCER HEATING

Figure 2 also shows the ratio of $\Delta T_{pred\text{-}wc}$ for the test object in contact with the transducer to $\Delta T_{meas\text{-}cont}$. Here, the predicted value is generally around half the measured value ($\mu = 0.50$, $\sigma = 0.11$). The reason for this difference is due to the fact that, as for the ODS

inserting polyethylene attenuators into the beam between the transducer and the test object (Preston et al 1991*a* and *b*). Two attenuators are generally used, one at the face of the transducer and one close to the surface of the test object. The intention is to have approximately the same attenuation at each location and ensure that the total attenuation between the transducer and the thermal sensor (in the case of the soft tissue test object) or the tissue/bone interface (in the case of the bone test object) including any overlying tissue mimicking material is 0.3 dB/cm/MHz. The attenuators are only available in discrete thicknesses and so a small correction is applied to the final temperature rise to allow for any residual difference between the actual attenuation and the desired value. To replicate TIS and TIB models, the temperature rise measured in contact with the transducer is ignored (to avoid the effects of transducer self-heating) and the maximum value of $\Delta T_{meas\text{-}att}$ is compared with TI_{ODS}. To replicate the TIC model, the temperature is measured with the bone test object in contact with the transducer and $\Delta T_{meas\text{-}cont}$ inevitably includes transducer heating.

Fig 4. Ratio of TI calculated according to ODS methods to temperature rise measured with thermal test objects through acoustic attenuators. The estimated uncertainty in each ratio is ±28% at the 95% confidence level.

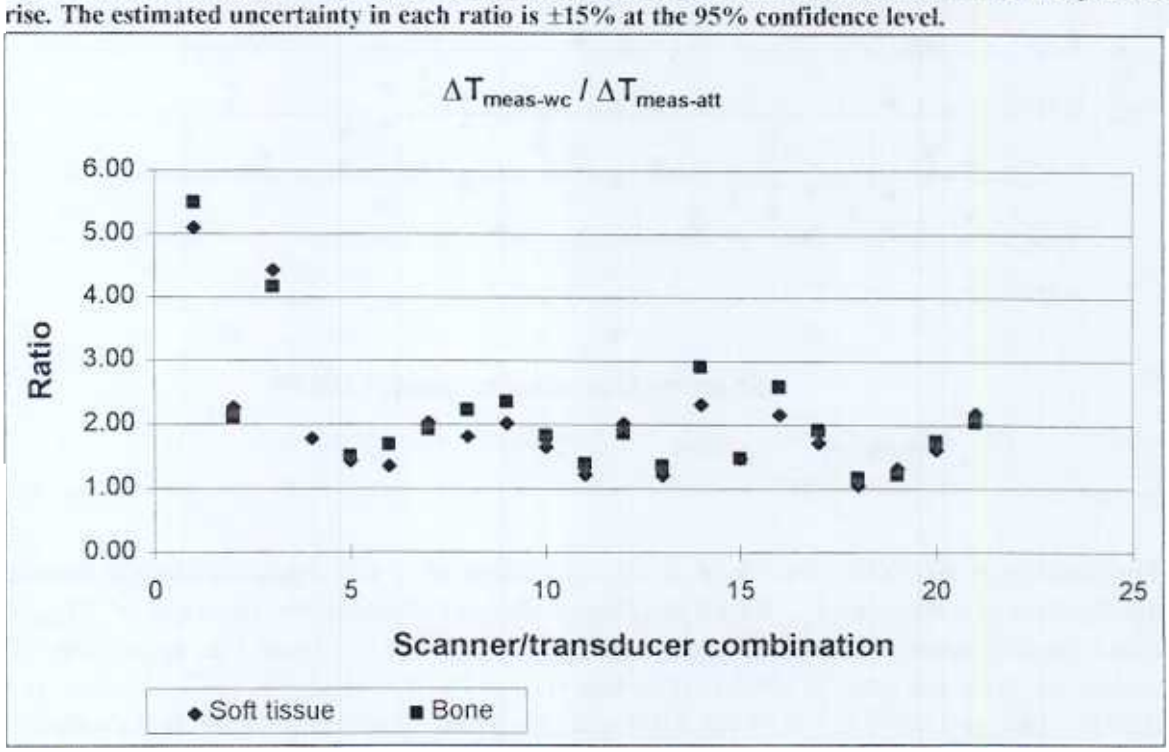


The ratio of TI_{ODS} to either the maximum observed $\Delta T_{meas\text{-}att}$ or $\Delta T_{meas\text{-}cont}$ are given in Figure 4 as appropriate. All ODS TIS values are higher than the equivalent measured values (μ = 1.36, σ = 0.35), indicating that TIS is generally a slightly conservative estimate of the three minute temperature rise away from the transducer face. ODS TIB, values are mostly within ± 50% of the test object value (μ = 1.10, σ = 0.23) and so seem to be reasonable, but not conservative, estimates of the temperature measured. The ODS TIC values are mostly around half of the measured values (μ = 0.55, σ = 0.17), since transducer self-heating is not considered in the ODS calculations.

measured maximum given in Figure 6; the worst-case values are typically twice the attenuated values, although there is a wide spread in the results ($\mu = 2.11$, $\sigma = 1.12$ for soft tissue; $\mu = 2.22$, $\sigma = 1.15$ for bone). The fact that differences of a factor of up to five are observed depending on the chosen variation of attenuation with distance, clearly demonstrates the importance of deciding on the appropriate tissue model.

The location of the maximum worst-case temperature rise in the M-mode field studied for transducer 21200B on the HP77020 scanner was also the same as the location of maximum I_{spta}, but this was not the case for the colour-flow field. For the colour-flow field, I_{spta} reached a maximum of 93 mW cm^{-2} at 55 mm where the worst-case three minute measured temperature was 0.19°C in the soft tissue test object and 0.83°C in bone. The maximum value of $\Delta T_{meas\text{-}wc}$ observed was 0.40°C in soft tissue and 1.42°C in bone; in both test objects this occurred at 12 mm where I_{spta} was approximately 47 mW cm^{-2} Clearly, in this scanned field, a large region of lower intensity is produced by the overlap between adjacent colour-flow imaging lines close to the transducer and this results in a higher temperature rise than is produced by the small region of higher intensity which occurs at the focus of a single colour-flow line. The rate of temperature increase at the end of three minutes heating was also greater at 12 mm, indicating that longer exposure times would result in substantially higher temperature increases at this point. These results were confirmed by theoretical predictions and it is likely that they would be repeated in other scanned fields.

Fig 6. Ratio of maximum worst case measured temperature rise to maximum attenuated temperature rise. The estimated uncertainty in each ratio is ±15% at the 95% confidence level.



6.5 COMPARISON OF ON-SCREEN TI VALUES WITH MEASURED TEMPERATURE RISE AND TI_{ODS}

The only information available to the clinician relevant to the thermal hazard to which the

6.6 ALTERNATIVE OPERATING CONDITIONS

The purpose of the project was to compare the results obtained when assessing a particular field configuration using a number of different methods. The scanner settings selected for assessment at NPL were those which appeared to give the maximum I_{spta}. These are not necessarily the same settings which would produce the maximum values for TIS, TIB or TIC (as is required by FDA Track 3), or which would produce the maximum measured temperature rise (either worst case or derated) or the maximum output power. Additionally, power management algorithms on many systems mean that there may be many different scanner operating conditions which produce similar spatial-peak temporal-average intensities. For all of these reasons, it should be assumed that higher values of TI_{ODS} or measured temperature rise could have been obtained from different operating conditions and the values given in this report should not be regarded as global maxima. Equally, it is possible that the settings used may not be ones which would be used in clinical practice; nevertheless, they can be reached using the front panel scanner controls.

Fig 8. Ratio of the on-screen display of thermal index to the thermal index calculated according to ODS methods. The estimated uncertainty in each ratio is ±25% at the 95% confidence level.

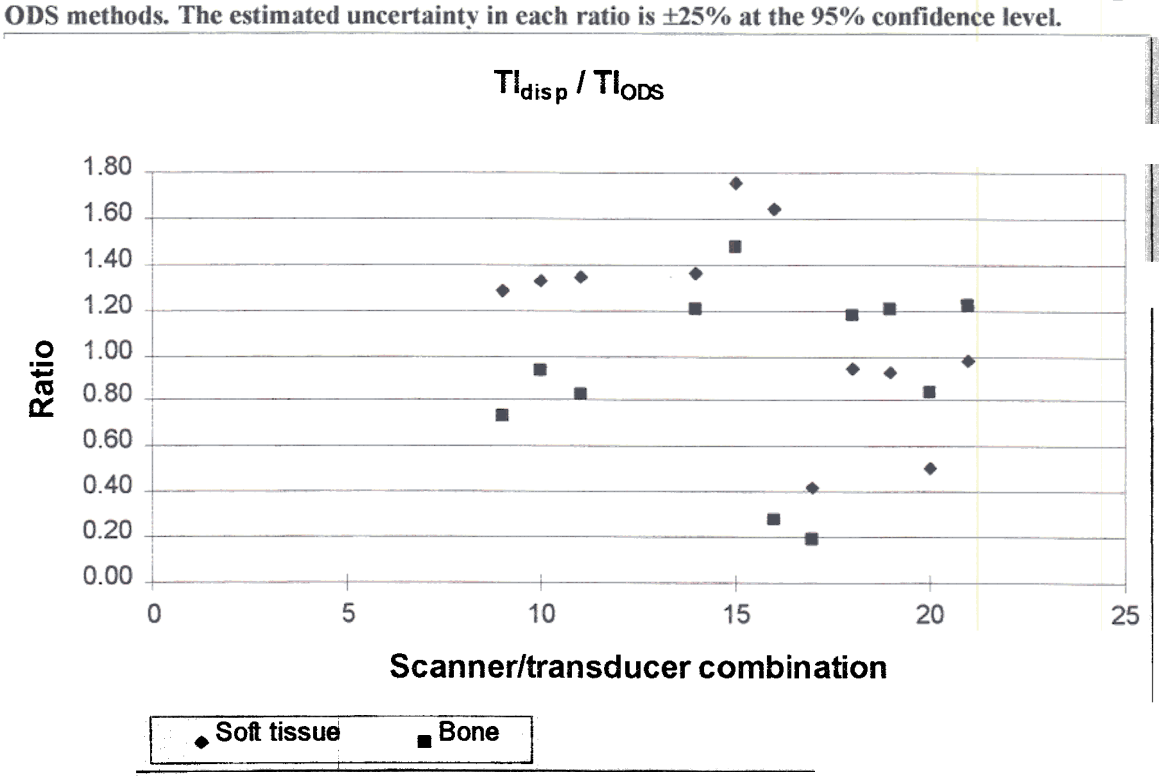


Table 2 gives the on-screen TI values for the conditions of maximum I_{spta} and the maximum on-screen values observed during the initial exploration of the scanners' output. This information is only available for a limited number of systems but it is clear from the table that manufacturers often expect that settings other than those which produce the maximum I_{spta} will produce the highest values for TIS, TIB and TIC and, presumably, for temperature also.

calculated using these radiation force balance values. The results using the radiation force balance figures were 15% higher on average than when using the UBC figures for TIS and TIC ($\mu = 1.15$, $\sigma = 0.15$) and 7% higher for TIB ($\mu = 1.07$, $\sigma = 0.07$) if the Aloka results are ignored. These results are consistent with the expected uncertainties reported in Section 4.3. For the Aloka, the mean ratio was 2.05 for TIS and TIC, and 1.42 for TIB.

6.9 NONLINEAR EFFECTS

The phenomenon of nonlinear propagation is well known in medical ultrasound (see *eg* Carstensen *et al.* 1980; Bacon 1984; Baker and Humphrey 1992) and it has been suggested that it is important in determining the temperature increase in a medium exposed to diagnostic ultrasound (Bacon and Carstensen 1990). There is little evidence from the measurements reported here that nonlinear enhancement has a significant influence on the measured temperature rise. If nonlinear enhancement was a major influence, there should be a difference between $\Delta T_{pred\text{-}wc}$ and $\Delta T_{meas\text{-}wc}$ since the prediction method used takes no account of the presence of higher frequency harmonics in the acoustic wave incident on the test object. Section 6.1 shows, however, that there is rather good agreement. It is possible that the absence of significant nonlinear enhancement is because the degree of distortion present in these fields did not reach the levels required since the value of the nonlinear propagation parameter, σ_m, (Bacon 1984; IEC1102) was less than 2.5 for all cases.

Nonlinear propagation, however, was very plainly evident and can be seen in the pressure waveform of the example system given in Appendix C. When measurements of $\Delta T_{meas\text{-}att}$ were made using a single attenuator, it was found that the measured temperature rise depended upon how far from the transducer the attenuator was placed. This agrees with the findings in Preston *et al.* (1991a,b) and is the reason for using the "two attenuator" method instead of a single attenuator. Using the two attenuator technique, there is little difference between applying a linear derating factor to $\Delta T_{meas\text{-}wc}$ and the measured values of $\Delta T_{meas\text{-}att}$: Figure 9 plots the ratio of these quantities as a function of the distance from transducer to test object. It shows that the ratio is close to one for both types of test object (for soft tissue, $\mu = 1.01$, $\sigma = 0.09$; for bone, $\mu = 1.05$, $\sigma = 0.08$) although there is some indication of a slight downward trend with distance for the soft tissue test object, this is almost entirely due to the single point at 79 mm.

7 TECHNICAL SUMMARY OF RESULTS

Due to the length of the preceding analysis section and the number of quantities which are measured, calculated and compared, it is useful to summarise the key findings. These findings relate only to the equipment assessed in this report and it is not possible to extrapolate precise relationships from this small sample of an extremely large population of pulsed Doppler equipment. Nevertheless, the equipment is representative of the population and the findings can be taken as indicative of what might be expected from a larger sample.

- The number of systems generating thermal indices or temperature rise of different values is summarised in Table 3 below. In almost all cases, the values for soft tissue are below 1.5°C although, in contact with the transducer or under worst case conditions, some measured values are higher. For bone, the values are naturally higher with 75% of systems giving $\Delta T_{meas\text{-}att}$ in the range 1.5°C - 4°C. The worst-case values, $\Delta T_{meas\text{-}wc}$, exceeded 4°C in 50% of cases, with the highest values being in excess of 8°C. When the transducer was in contact with the bone mimicking test object, the measured temperature rise exceeded 1.5°C in 88% of cases. It is also possible that different operating conditions would have produced significantly greater heating. (See Sections 5 and 6.6.)

Table 3. Number of systems falling into each range for each method of estimating temperature rise.

Tissue type	TI or ΔT (°C	TI_{disp}	TI_{ODS}	max $\Delta T_{pred\text{-}att}$ (°C)	max $\Delta T_{meas\text{-}att}$ (°C)	max $\Delta T_{meas\text{-}wc}$ (°C)	$\Delta T_{meas\text{-}cont}$ (°C)
Soft tissue	< 1.5	11	21	20			12
	1.5 - 4	0	0	0			3
		0	0	0	0		0
		0	0	0	0		0
	< 1.5	2	7	9			n/a
		9		11	15		n/a
				0	0		
		0		0	0		
Cranial	< 1.5		14	12	n/a	n/a	2
	1.5 - 4		7	8	n/a	n/a	13
	4 - 8		0	0	n/a	n/a	3
	> 8		0	0	n/a	n/a	0

8 CONCLUSIONS

This report covers Stages II and III of a project whose purpose was to provide information on thermal hazard by comparing different methods for deriving thermal index and temperature rise values for fields from a range of clinical pulsed Doppler ultrasound systems. The front panel controls of the systems were adjusted to produce the maximum spatial-peak temporal-average intensity, detailed measurements made of the resulting acoustic field and, when available, the on-screen TI values was noted. Soft tissue, bone and cranial thermal indices were calculated from the acoustical measurements and more detailed predictions were made of the temperature rise that would be expected to result from exposing soft tissue and bone mimicking thermal test objects to the same fields. The actual temperature rise produced in these test objects was then measured experimentally. A total of 21 Doppler and two other fields were studied.

The measurements reported here represent a very small subset of the many hundreds of scanner/transducer combinations available and it would be unwise to draw too definite conclusions. Nevertheless, a number of general observations can be made.

- It appears unlikely that a temperature rise above 1.5°C will occur in soft tissue in the absence of bone or other strongly absorbing material. Under attenuated conditions the measured temperature rise was below 1.5°C in a soft tissue mimicking test object for all of the systems studied; even under worst-case conditions, the maximum temperature rise measured was less than 3°C. However, it is possible that prolonged exposure may result in higher temperature rises within 1cm of the transducer face.
- When the ultrasound beam impinges on bone or other strongly absorbing material (even if that material is not the subject of the examination), the temperature rise may be much higher. Under attenuated conditions, a temperature rise of between 1.5°C and 4°C was measured in a bone mimicking test object for 75% of the systems studied. Under worst-case conditions, 50% of the systems gave temperature rises in excess of 4°C and 15% in excess of 8°C.
- The temperature rise generally occurs very rapidly. The temperature rise at the focus of the ultrasound beam typically reached 50% of its final value within 20 seconds.
- On average, the TIS and TIB formulae, when correctly applied, show reasonable agreement with the temperature rise measured under attenuated conditions. For any individual field, however, the TI value may be substantially lower or higher than the measured temperature rise.
- The values of TIS and TIB displayed on the scanner should not be taken as the absolute maximum possible temperature rise. The worst-case temperature rise may be three times higher than the displayed value.

The question of whether these temperature rises actually occur during real clinical examinations has not been addressed and it is clear that further work is required to establish *in vivo* temperature rises. There is also a need to establish more reliable methods for estimating temperature rise than the current thermal index displays offer, particularly if this information is to be used by the sonographer to make an informed risk assessment.

Overall, this project has produced substantial evidence that the temperature rise from some Doppler ultrasound fields, at least in the presence of bone, may exceed the levels

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Subject: followup on your measurements

To: AS@npl.co.uk
From: Douglas worth
Date: 11/12/97 15:12:15
CC:
Subject: followup on your measurements

Adam,

We have been able to reproduce most of your measurements on our measurement equipment and have found very good agreement. The differences for the L312 and V328 part were less than 1dB. For the s519, the differences were on between 1 and 2 dB for the intensity parameters (I measured higher).

Given the variation in transducers and measurement uncertainity I still feel these are acceptable results.

Also, as a confirmation to you, the operating conditions that you had selected to measure, were very close to the maximum output operating conditions that we had found when these devices were originally measured.

Thank you again for the opportunity to review the data before publication.

I will try to call you tomorrow around 2:30pm (your time, 6:30am my time) to confirm receipt of this message.

Doug

ACUSON

ALOKA

FACSIMILE COVER SHEET

DATE: January 19, '98

PAGE: 1 of 3

To: Dr. Adam Shaw

From: T. Matsunaka

Dear Dr. Adam Shaw;
Center for Ionising Radiation and Acoustics
National Physical Laboratory

Comments on temperature rise

I am very sorry for my late response to your request.
We cheked your data and found that there was acceptable difference between the acoustic power measured by ALOKA and that by NPL, and that the predicted value of temperature rise based on the data masured by the radiation force balance method agreed almost with the measured value. Watching the -6dB beamwidth of two transducers; UST-990-5 and UST-5524-7.5 at the focus F7, we were awared of large differance between the focal length of acoustic lens and that of the scan plane of the transducer (see attached figure 1 and figure 2). Furthermore, the position of muximum acoustic intensity depends on the focus position of acoustic lens.
Well, you calculated the thermal index value from the data measured at 30 degree, 60 degree and 90 degree to the scan plane direction of the transducer and by interpolation between the data mesured at four directions apart from 30 degree. We doubut that such method can be also applied to the case of non-symmetric beam profiles. We guess that the case of non-symmetric beam profile will lead lower temperature rise than actual temperature, and that the beam profiles of other manufactures' transducers will fairly be symmetrical.
Finally, the focus position for PWD-mode on the SSD-2000 is set up with the position of sample gate of B/D-mode. The focus condition selected at B-mode is erased at PWD-mode. So, we guess that the focus condition of UST-5524-7.5 was not at the focus position F4, actually at focus position F7.

Best regards,

T. Matsunaka

Toshiyuki Matsunaka ,Ph.D.
Director of Transducer Engineering Department

〒198 東京都青梅市今井三丁目7-19 アロカ(株)東京事業所

Adam

Please find below the comments from Charlie Grossman on the results of NPL's study.

Best regards

Liz

_____ Forward Header _____

Subject: NPL Doppler Study Comments
Author: CHARLIE GROSSMAN at HP-Andover,om3
Date: 11/12/97 15:11

Hello Liz,

Below, please find my comments on the results of NPL's Stage II/III Pulse Doppler Ultrasound Thermal Rise Study. Please forward to Adam Shaw at NPL.

Best Regards,

Charlie Grossman

Please feel free to contact me if you have any questions regarding these comments.

Youre Truly,

Charlie Grossman

KeyMed (Medical & Industrial Equipment) Ltd
KeyMed House, Stock Road
Southend-on-Sea, Essex SS2 5QH, UK
Telephone: + 44 (0)1702 616333 (52 lines)
Facsimile: + 44 (0)1702 465677, Telex: 995283

Specialised Services to Medicine & Industry

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2 February 1998

For the personal attention of:

Dr A Shaw
Centre for Mechanical and Acoustical
Metrology
National Physical Laboratory
1 Queens Road
Teddington
Middlesex
TW11 OLW

Dear Adam

THERMAL INDICES AND TEMPERATURE RISE FOR PULSED DOPPLER ULTRASOUND

Many thanks for your letter of 27 January with which was enclosed a copy of the final report sent to the Department of Health.

I was pleased to note that Dr Matsunaka from Aloka Tokyo had provided comments for inclusion in the report and trust a copy has been sent to him. I am sure he will be in touch if Aloka feels it has anything further to say on the project or its findings.

As always, it was a pleasure to assist you and your colleagues.

Yours sincerely

DOUGLAS OGG
Senior Products Specialist

National Physical Laboratory | Queens Road | Teddington | Middlesex | United Kingdom | TW11 0LW
Telephone 0181-977 3222 (Switchboard) | NPL Helpline: 0181-943 6880 | Facsimile 0181-943 6458

Our Ref: AN0601
Your Ref:

NPL
National Physical Laboratory

Dr Charles Grossman
Acoustics Measurement Laboratory
Hewlett-Packard Co.
3000 Minuteman Road
Andover
Massachusetts 01810-1099
USA

Direct Line 0181-943 6581
Direct Fax 0181 943 6161
Date 16 March 1998

Dear Dr Grossman

Assessment of likely thermal index values

Thank you for providing comments on our report. You have raised two main points which I would like to respond to. I would like to stress first, however, that ultrasound has so far been rightly considered a "safe" diagnostic modality. To continue to justify this confidence, it is important to have reliable, validated methods of assessing any hazard it does pose so that new techniques and new technology can be properly evaluated in terms of risk to the patient. Of course any risk which is demonstrated has to be compared with the benefit to the patient and with the risks of using alternative diagnostic techniques or, indeed, of doing nothing.

Your first point is to question our conclusions that the project has produced substantial evidence of heating that could exceed safe levels. The precise words used in the report were "Overall, this project has produced substantial evidence that the temperature rise from some Doppler fields, at least in the presence of bone, may exceed the levels which are recommended for safe clinical ultrasound examinations". The recommended level to which we refer is a temperature increase of 4°C for a period of up to 5 minutes (WFUMB, 1997). We found that, in ten out of the twenty systems which were evaluated with the bone-mimicking test objects, the temperature rise exceeded 4°C within the 3 minute exposure time used when there was a fixed attenuation of approximately 0.3 dB MHz^{-1} between the transducer and the test object.

You are quite right that, with greater attenuation in the intervening propagation path, the temperature rise would be lower; our attenuated measurements, which were made to mimic the 0.3 dB cm^{-1} MHz^{-1} assumed in the Output Display Standard (AIUM/NEMA, 1992) confirm this. However, the justification for our conclusion is that the particular case of an obstetric examination of the fetus through the bladder and amnion is one where following the AIUM/NEMA assumptions can lead to a large underestimate of the likely temperature rise produced at the surface of the fetus. The most widely quoted models for obstetric examinations are those due to Carson (1989) and recommended by NCRP (1992) in which the attenuation is fixed at 0.75 dB MHz^{-1} during the 2nd trimester and 0.5 dB MHz^{-1} during the 3rd

DESCRIPTION OF EXAMPLE RESULTS AND PRINTOUTS

UBC measurements at position of maximum I_{spta} in water

UBC screen dump
Left hand graph shows peak-positive pressure profile through the beam in the direction of the scan-plane: the dots correspond to measurements 0.6mm apart. Right hand graph shows pressure/time waveform. The value for psi is the square root of the pulse-pressure-squared integral in units of Pa $s^{1/2}$; I(ta) and I.3 are free-field and derated temporal-average intensity on the beam axis.

UBC printout
Measured acoustic parameters in specified orientation to the scan-plane. Figure for total power assumes that beam is circularly symmetrical: measurements were made in 4 orientations to derive a more accurate assessment; a power balance was also used. Figures in brackets are 95% confidence random uncertainties for consecutive measurements; overall uncertainties are of the order of 9% for p- and 18% for I_{spta}

Thermal Index spreadsheet

Acoustic parameters used for calculating thermal index values. Refer to report on Stage I for further details.

Intensity maps parallel and perpendicular to the scan-plane

Contour plot
Lines of equal intensity are drawn at 10%, 20%....90% of I_{spta} . The transducer is at the left of the plot and the maximum illustrated depth is indicated above the top right corner of the plot. The height of the plot corresponds to 12.48mm. The measured value of I_{spta} is given below the plot.

Profile plots
Variation of intensity along the beam axis and also across the beam at the indicated depth. The stepped nature of the graphs results from the fact that measurements are made at discreet points and intermediate points are derived by nearest neighbour interpolation and a small amount of smoothing.

Temperature predictions

Graph
The two curves on each printout show the predicted temperature rise in K (equivalent to °C) as a function of distance from the transducer The solid curve is the worst case, the dotted curve is the derated case. Printouts are given for soft tissue and for bone test objects.

Temperature measurements on the beam axis

Description
Amongst other information, scanner/transducer, thermal test object type and position are given. The entry for sensor and z-position are the most important as this defines which type of test object was used and how far either the sensor or the soft tissue/bone interface was from the transducer. Contact is made at 7mm distance.

Graph
Shows temperature rise in K versus time during 180 seconds heating and 30 seconds cooling.

NPL ULTRASOUND BEAM CALIBRATION SYSTEM

Current date and time: 4/4/97 10:09

Identification: NMP ACUSON 128, TRANSDUCER S519

Other information:
Position of maximum Ispta
Scan plane parallel to array

Pulse repetition rate: 8281.57 Hz

Depth: 47.0 mm (0%) X: -0.8 mm Y: 0.0 mm

Nominal frequency: 5.0 MHz

p_+	2.94 MPa (7%)
p_-	-1.33 MPa (3%)
-6dB Beam width	1.43 mm (1%)
Pulse duration	2.78 μs (2%)
I_{spta}	2.61 W cm^{-2} (1%)
Total power	53.5 mW (1%)

Acoustic Parameters

P_{spp}	1.30 MPa (1%)	P_{sp}	197. kPa (1%)	P_{sap}	921. kPa (1%)	P_{sa}	141. kPa (1%)
I_{sptp}	511. W cm^{-2} (14%)	I_{sppa}	113. W cm^{-2} (2%)	I_{sapa}	60.9 W cm^{-2} (1%)	I_{sata}	1.42 W cm^{-2} (1%)
I_m	170. W cm^{-2} (10%)	f_{AWF}	4.94 MHz (1%)	$\sqrt{p_i}$ (psi)	2168. Pa s^{½}	Pressure correction	N/A
Ita-scan	N/A	Ita-meter	N/A				

F.D.A. Derated Values

I_{spta}	525. mW cm^{-2}	I_{sppa}	22.8 W cm^{-2}	34.3 W cm^{-2}

System Parameters

Software Version	V8.1a (standard)						
Serial Number	106079601	Hydrophone spacing	0.6 mm	Hydrophone diameter	0.4 mm		
Digitization rate	60.0 MHz	Points/waveform	256	Amplifier gain	6.00 dB	Sensitivity	50.0 mV/MPa
Duplicate factor	1	Trigger factor	4	Number of averages	5	Temperature	25.0 °C

95% confidence RANDOM uncertainties are given

WARNING: Spatial(beam)-average and power values are calculated on the assumption of a cylindrically-symmetrical beam.

Worksheet for calculation of Thermal and Mechanical Indices from manufacturers' acoustic data.

Part of DoH Thermal Hazard from Doppler Ultrasound Project.

Version 2.1
Originated by Adam Shaw - 24/1/96

Manufacturer:	Acuson	Nominal values	Scanned or unscanned?	unscanned	
			Nominal frequency (MHz)	5.00	MHz
Platform type:	128		Transducer diameter (mm) - X	19.00	mm
Platform description:	unknown		Transducer diameter (mm) - Y	10.00	mm
			Rectangular or circular?	rectangular	
Transducer type:	S519		Radius of curvature (mm)	#N/A	
Transducer description:	unknown		Nominal focal distance (mm)	#N/A	
Operating conditions:	Other notes:				
Scale: -0.6 to 0.6, Gate: 30mm, Gate depth: 55 mm, XMTR Power: <500	Measured power using (BECA)				

Predicted Thermal Indices

NCRP homogeneous	1.62
NCRP 1st trimester obstetric	0.75
NCRP 2nd trimester obstetric	3.55
NCRP 3rd trimester obstetric	4.73
NCRP bone	2.67
AIUM soft tissue T.I.	1.38
AIUM bone T.I.	1.88
AIUM cranial T.I.	1.40

Warnings and Cautions

Free-field focal diameter used

Derated focal distance used

Measured values	Parameter	Free-field	Derated	Used	Units	Source
Essential data	Centre frequency (MHz)	4.95	#N/A	4.95	MHz	Free field centre frequency
	Radiating diameter (mm) - X	6.90	#N/A	6.90	mm	Free-field radiating diameter
	Radiating diameter (mm) - Y	12.50	#N/A	12.50	mm	Free-field radiating diameter
	Focal distance (cm)	5.50	4.40	4.40	cm	Derated focal distance used
	Focal diameter (mm) - X	1.43	1.66	1.43	mm	Free-field focal diameter used
	Focal diameter (mm) - Y	2.16	2.00	2.16	mm	Free-field focal diameter used
	SPTA intensity (mW/cm2)	2620.00	561.00	2,525.59	mW/cm2	Ispta calculated from derated ispta
	Power (mW)	58.75	#N/A	58.75	mW	Radiated power measured
Non-essential data	Pulse repetition rate (Hz)	8,282	#N/A	8,282	Hz	
	SPPA intensity (mW/cm2)	113000	#N/A	113,000	mW/cm2	
	Positive pressure (MPa)	3	#N/A	3.00	MPa	
	Negative pressure (MPa)	1.33	#N/A	1.33	MPa	

Insert or delete columns as appropriate within this table to describe axial variation of intensity.

Axial variation	Distance (cm)	0.30	1.00	1.50	2.50	3.00	3.50	4.00	4.40	4.70	5.00	5.50
	Free-field intensity (mW/cm2)	184.00	140.00	226.00	438.00	773.00	1250.00	1640.00	2410.00	2640.00	2540.00	2110.00
	Derated intensity (mW/cm2)	#N/A	#N/A	#N/A	#N/A	#N/A	#N/A	#N/A	#N/A	#N/A	#N/A	#N/A
(derived)	Derated power (mW)	53.02	41.74	35.18	24.99	21.06	17.75	14.96	13.05	11.78	10.63	8.96
(derived)	Used intensity (mW/cm2)	166	99	135	188	277	378	418	535	529	460	322
(derived)	Derated (Power*Intensity)	8,805	4,151	4,760	4,656	5,837	6,705	6,250	6,986	6,233	4,885	2,883
(derived)	(Derated P or I) x (z>Zbp)	0.00	0.00	0.00	24.99	21.06	17.75	14.96	13.05	11.78	10.63	8.96

Predicted Mechanical Index

AIUM M.I. 0.13

Warnings and Cautions

Secondary values	
Aperture area (cm2)	0.86
Break point distance (cm)	1.57
Z_B.3 (cm)	0.30
AIUM model A	#N/A
AIUM model B	0.59
AIUM model C	1.38
AIUM model D	1.88
AIUM model E	1.40

Document to generate interpolated intensity distribution from measured UBC data sets.
The interpolated grid is specified by maximum and minimum z distances, z step size and radial oversam factor.
Standard values for z_{min}, $z_{incremental}$ and radial_oversampling are 0mm, 1mm and 5 respectively. z_{max} depends on the focal length of the transducer.

Include various subroutines for data manipulation.

Include:C:\SHARED\DOH\INTERP1E.MCD

Define the axial dimensions of the grid, bearing in mind the range of measured distances.

$z_{min} := 0 \cdot mm$

$z_{max} := 80 \cdot mm$

$z_{increment} := 1 \cdot mm$

$min\_measured\_depth = 3 \cdot mm$

$max\_measured\_depth = 70 \cdot mm$

Specify radial oversampling factor to increase resolution. $radial\_oversampling := 5$

giving a mesh size of: $\frac{spacing}{radial\_oversampling} = 0.12 \cdot mm$

Perform interpolation:

$$Results\_array := UBC\_interpolate\left(Measured\_UBC\_data, z_{min}, z_{max}, \frac{z_{increment}}{m}, radial\_oversampling\right)$$

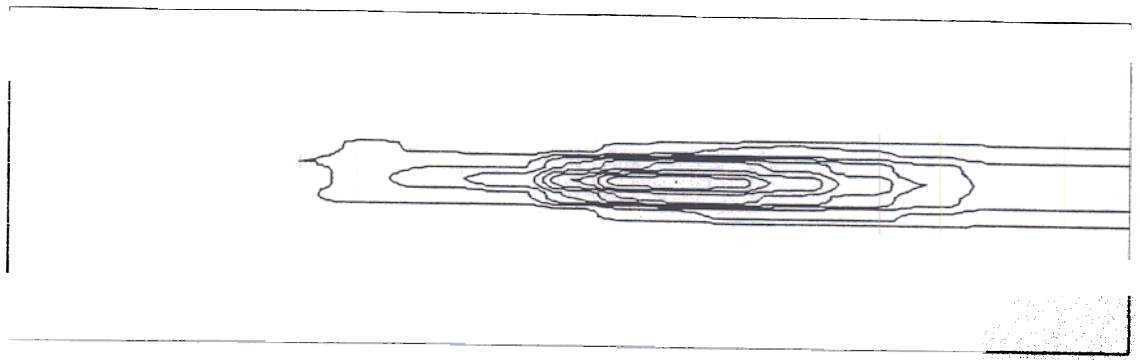
Insert filenames for UBC measured data file and for saving interpolated matrix

$Measured\_UBC\_data := READPRN(bacus519\ prn)$

$WRITEPRN(bacus519\ mat) := Results\_array$

$min(Depth) = 0 \cdot mm$

$max(Depth) = 80 \cdot mm$



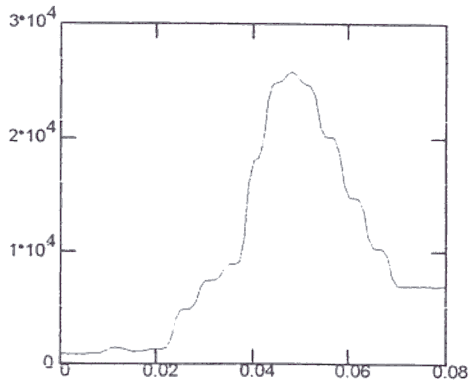
$Interpolated\_intensity$

Check that measured and interpolated intensities are within acceptable agreement.

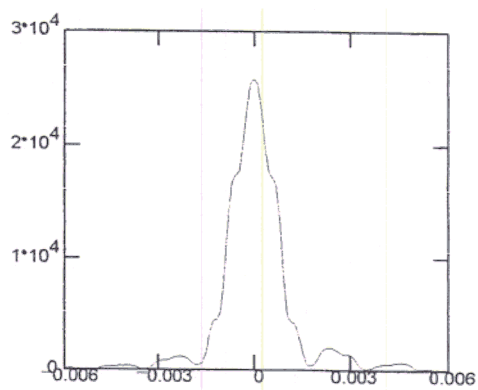
$max\_measured\_intensity = 2.582 \cdot 10^3 \cdot \frac{mW}{cm^2}$

$max(Interpolated\_intensity) = 2.575 \cdot 10^3 \cdot \frac{mW}{cm^2}$

Axial profile



Radial profile at depth, $Z := 48 \cdot mm$



Adam Shaw, Ultrasonics, NPL

Document to calculate temperature rise in TTO using a summation of weighted intensities within the TMM region of the TTO.
This method is not susceptible to the convergence errors associated with the numerical integral method and is faster.

Enter names of intensity files to be used. Transducer must be a matrix with column headings of axial distance and row headings of radial distanc. If the acoustic frequency is not in the 0.0 location, enter a value where shown.

$$Transducer := \frac{1}{6}\cdot\begin{bmatrix} READPRN(aacus519_{mat}) + READPRN(bacus519_{mat}) \cdots \\ +2\cdot\left(READPRN(cacus519_{mat}) + READPRN(dacus519_{mat})\right) \end{bmatrix}^T \qquad Freq := 4.94\cdot MHz$$

Include TTO descriptor file:

Include:C:\SHARED\THERMAL\SUMTEMPS\Tto9729.mcd

Perfusion time: $\tau := 720\cdot sec$

Modify TTO descriptor if necessary (sensor position in TTO is 0 mm):

Include subroutine file:

Include:C:\SHARED\THERMAL\SUMTEMPS\SUMSUB1.MCD $pre\_sensor\_compensation := e^{2\cdot atten(face_1)\cdot Freq}$

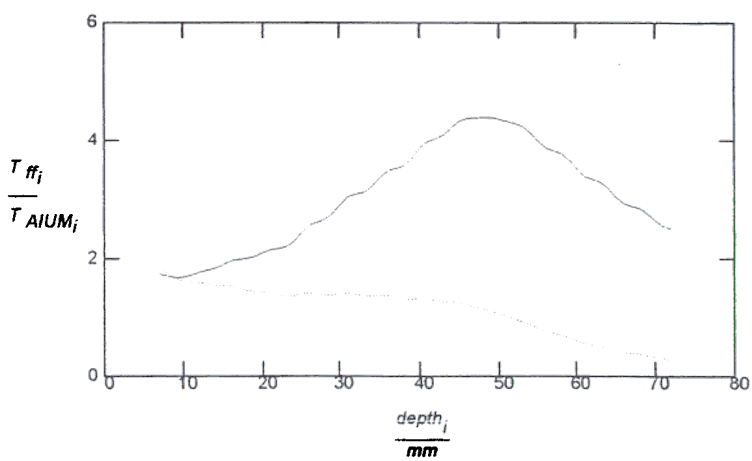
Call calculation subroutine T_vs_Z(model, Freq, Transducer, exposure time, conductivity, diffusivity, perfusion time), where model is either "unperf", "perf_t" or "perf_ss" for unperfused, perfused(after time t) and perfused(steady state) respectively.

$$Results := T\_vs\_Z(unperf, Freq, Transducer, 180\cdot sec, k, \kappa, \tau) \qquad depth := Results^{\langle 0\rangle}\cdot m \qquad T_{ff} := Results^{\langle 1\rangle}\cdot K$$

and derate according to desired model (generally 0.3 dB/cm/MHz)

$$T_{AIUM} := \overrightarrow{\left(T_{ff}\, pre\_sensor\_compensation\cdot derating(AIUM, Freq, depth)\right)}$$

$= 0..length(depth) - 1$



$max(T_{ff}) = 4.402\cdot K$

$max(T_{AIUM}) = 1.858\cdot K$

$dB \equiv 1$

$$face = \begin{bmatrix} -6.5 \\ -2 \\ 0 \\ 3 \\ 7.5 \end{bmatrix}\cdot mm \qquad absorb = \begin{bmatrix} 1\cdot 10^{-4} \\ 0.068 \\ 0.94 \\ 0.94 \\ 0.068 \end{bmatrix}\cdot\frac{Np}{cm\cdot MHz} \qquad k_{eff} = 0.505\cdot\frac{watt}{m\cdot K} \qquad c_V = 3.08\cdot\frac{joule}{mL\cdot K}$$

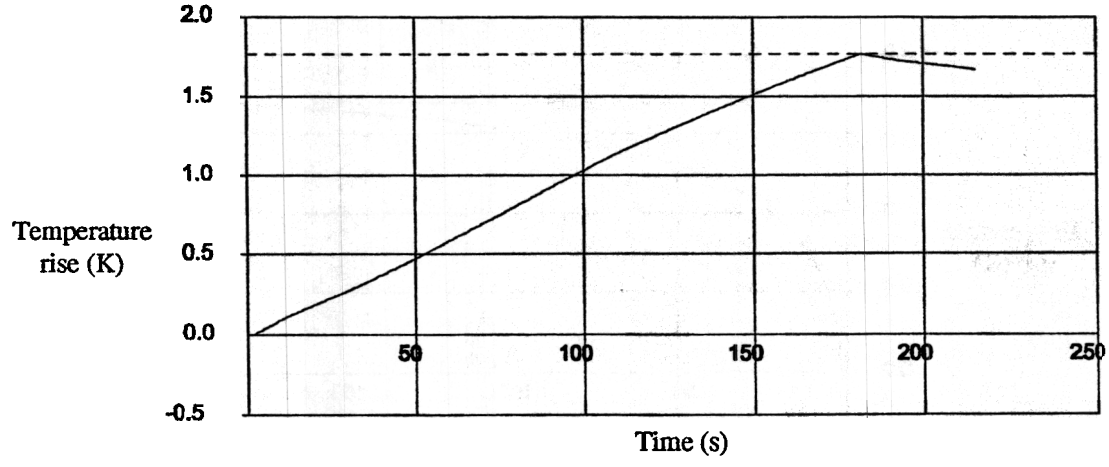
$pre\_sensor\_compensation = 1.351$ equivalent to $\frac{10\cdot log(pre\_sensor\_compensation)}{Freq} = 0.264\cdot\frac{dB}{MHz}$

Measurement Description

Scanner:	Acuson 128
Transducer:	S519
Sensor:	TTO 96/19 Soft tissue
Measurement:	S519 7mm
Maximum value:	**1.77 K**

Measurement Parameters

Position (z-axis):	7 mm
Heating Time:	180 seconds
Cooling Time:	30 seconds
Sampling Rate:	2 Hz

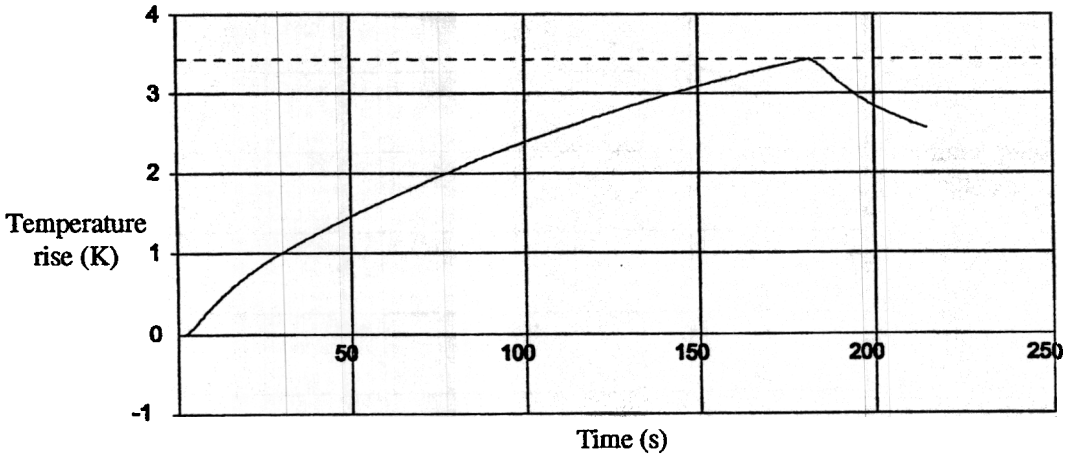


Measurement Description

Scanner:	Acuson 128
Transducer:	S519
Sensor:	TTO 97/029 Soft tissue/bone
Measurement:	B S519 7A
Maximum value:	**3.43 K**

Measurement Parameters

Position (z-axis):	7 mm
Heating Time:	180 seconds
Cooling Time:	30 seconds
Sampling Rate:	2 Hz



Ref #	Scanner	Transducer	Freq (MHz)	On-screen TIS	On-screen TIB	ODS TI TIS	ODS TI TIB	ODS TI TIC	NPL Predictions (K) Worst-case soft tissue max	Worst-case bone max	Attenuated soft tissue max	Attenuated bone max	Soft tissue in contact	Bone in contact	Distance (mm)	Soft tissue measurements (K) Max worst-case	Max derated	Contact	Max attenuated	Bone measurements (K) Max worst-case	Max derated	Contact	Max attenuated
9	ATL HDI 3000	C4-2	2.48	1.30	2.80	1.01	3.12	2.28	1.76	7.09	0.78	3.26	0.54	2.08		1.57	0.78	1.22	0.78	8.69	3.52	3.72	3.69
			2.48												contact	1.22	0.00	1.22	0.00	3.72	0.00	3.72	0.00
			2.48												12.00	0.77	0.78	0.77	0.78	3.17	3.01	3.17	3.01
			2.48												37.50	0.86	0.56	0.58	0.62	5.10	3.13	3.09	
			2.48												50.25	1.21	0.63	0.71	0.70	7.14	3.52	3.81	3.69
			2.48												63.00	1.57	0.66	0.67	0.63	8.69	3.49	3.63	3.58
10	ATL HDI 3000	C7-4	4.01	1.10	1.90	0.83	2.04	1.79	1.59	5.07	0.80	1.91	0.62	1.91		1.34	0.81	1.78	0.81	5.45	2.99	4.47	2.99
			4.01												contact	1.78	0.00	1.78	0.00	4.47	0.00	4.47	0.00
			4.01												12.00	0.80	0.81	0.80	0.81	3.25	2.99	3.25	2.99
			4.01												35.00	0.95	0.51	0.58	0.56	4.04	1.97	1.78	1.93
			4.01												46.50	1.16	0.45	0.42	0.45	4.75	1.68	1.80	1.77
			4.01												58.00	1.34	0.38	0.30	0.32	5.45	1.40	1.51	1.44
11	ATL HDI 3000	L10-5	5.93	1.10	1.50	0.82	1.81	1.09	0.95	2.12	0.65	1.22	0.50	1.11		0.96	0.79	1.06	0.79	2.18	1.57	2.24	1.57
			5.93												contact	1.06	0.00	1.06	0.00	2.24	0.00	2.24	0.00
			5.93												12.00	0.77	0.79	0.77	0.79	1.78	1.57	1.78	1.57
			5.93												19.50	0.77	0.58	0.52	0.60	1.94	1.26	1.25	1.25
			5.93												23.25	0.86	0.57	0.61	0.60	2.11	1.18	1.43	1.23
			5.93												27.00	0.96	0.53	0.63	0.53	2.18	1.04	1.06	1.06
12	HP 77020	21200B	2.41			0.39	1.96	0.81	0.59	3.40	0.28	1.60	0.26	1.21		0.70	0.33	0.71	0.35	3.30	1.64	1.63	1.77
			2.41												contact	0.71	0.00	0.71	0.00	1.63	0.00	1.63	0.00
			2.41												12.00	0.32	0.31	0.32	0.30	1.37	1.23	1.37	1.23
			2.41												32.50	0.39	0.26	0.28	0.27	2.31	1.48	1.49	1.54
			2.41												42.75	0.56	0.32	0.32	0.33	3.05	1.64	1.78	1.77
			2.41												53.00	0.70	0.33	0.33	0.35	3.30	1.50	1.64	1.64
12a	HP 77020 (M-mode)	21200B	2.18			0.22	0.45	0.48	0.11	0.53	0.09	0.33	0.09	0.33		0.11	0.07	0.38	0.07	0.56	0.49	0.98	0.49
			2.18												contact	0.38	0.00	0.38	0.00	0.98	0.00	0.98	0.00
			2.18												12.00	0.07	0.07	0.07	0.07	0.51	0.49	0.51	0.49
			2.18												33.50	0.08	0.06	0.08	0.06	0.45	0.31	0.45	0.31
			2.18												44.25	0.11	0.07	0.11	0.07	0.52	0.31	0.52	0.31
			2.18												55.00	0.11	0.06	0.11	0.06	0.56	0.28	0.56	0.28
12b	HP 77020 (Colour-flow)	21200B	2.40			0.51	1.08	1.13	0.29	1.15	0.29	1.03	0.29	1.03		0.40	0.40	0.80	0.40	1.42	1.28	1.68	1.28
			2.40												contact	0.80	0.00	0.80	0.00	1.68	0.00	1.68	0.00
			2.40												12.00	0.40	0.40	0.40	0.40	1.42	1.28	1.42	1.28
			2.40												33.50	0.25	0.18	0.25	0.18	1.22	0.77	1.22	0.77
			2.40												44.25	0.22	0.13	0.22	0.13	1.05	0.55	1.05	0.55
			2.40												55.00	0.19	0.09	0.19	0.09	0.84	0.37	0.84	0.37
13	HP 77020	21211A	4.96			0.53	1.21	0.49	0.56	1.49	0.58	1.24	0.56	1.24		0.58	0.48	1.02	0.48	1.38	1.00	2.13	1.00
			4.96												contact	1.02	0.00	1.02	0.00	2.13	0.00	2.13	0.00
			4.96												12.00	0.47	0.48	0.47	0.48	1.25	1.00	1.25	1.00
			4.96												22.25	0.53	0.38	0.39	0.40	1.34	0.76	0.76	0.81
			4.96												27.40	0.56	0.34	0.31	0.35	1.36	0.64	0.77	0.75
			4.96												32.50	0.58	0.29	0.29	0.30	1.32	0.53	0.57	0.61
14	HP Sonos 2500	21243A	2.74	0.90	2.40	0.66	1.99	1.64	1.17	4.95	0.54	1.82	0.49	1.81		1.17	0.50	0.00	0.50	5.48	1.89	2.52	1.89
			2.74												contact		0.00		0.00	2.52	0.00	2.52	0.00
			2.74												12.00	0.50	0.50	0.50	0.50	2.00	1.89	2.00	1.89
			2.74												42.50	0.70	0.40	0.39	0.38	3.37	1.79	1.70	1.81
			2.74												57.75	0.91	0.39	0.40	0.42	4.40	1.75	1.77	1.72
			2.74												73.00	1.17	0.37	0.33	0.31	5.48	1.63	1.57	1.56
15	HP Sonos 2500	21275A	5.45	1.30	2.10	0.74	1.42	1.01	0.93	2.61	0.71	1.89	0.58	1.39		1.02	0.69	1.17	0.69	2.17	1.47	2.37	1.47
			5.45												contact	1.17	0.00	1.17	0.00	2.37	0.00	2.37	0.00
			5.45												12.00	0.68	0.69	0.68	0.69	1.65	1.47	1.65	1.47
			5.45												21.50	0.82	0.58	0.59	0.62	1.93	1.21	1.40	1.30
			5.45												26.25	0.92	0.55	0.68	0.60	2.07	1.08	1.07	
			5.45												31.00	1.02	0.51	0.62	0.52	2.17	0.95	0.86	0.83

NPL REPORT CMAM 1

REPORT

Assessment of the likely thermal index values for pulsed Doppler ultrasonic equipment - Stages II and III: experimental assessment of scanner/transducer combinations

A Shaw, N M Pay and R C Preston

March 1998

NPL
National Physical Laboratory