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Assessment of the likely thermal index values for pulsed Doppler ultrasonic equipment - Stage I: calculation based on manufacturers' data

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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 has initiated a project to be carried out at NPL which aims to assess the likely thermal hazard from commercial pulsed Doppler diagnostic ultrasound equipment. The project is in three stages and will assess the thermal hazard by published prediction algorithms, by experimental methods and by improved theoretical methods.

This report covers Stage I, which uses published methods to calculate Thermal Indices from acoustic data supplied by manufacturers. Results are given for 11 different scanners from eight manufacturers. Eight prediction algorithms are used.

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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), 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, 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 The output levels and potential for thermal hazard need 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 UK equipment. 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 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, aims to meet all of 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 will predict the likely thermal hazard using agreed theoretical algorithms and acoustic output data supplied by manufacturers, Stage II will verify those predictions by making controlled measurements of the acoustic output and temperature rise for a range of scanners; and Stage III will predict the temperature rise for realistic clinical conditions using layered tissue models. All of this work will result in publications that will be 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 Stage I of the project. The aims of Stage I are described in detail in Section 2, together with the acoustic data which is required to calculate thermal indices, and the method of carrying out the calculations. Communication with manufacturers is documented in Section 3: this is an important part of the report since it deals with a number of objections and observations raised during the course of the work. Results are tabulated alphabetically by manufacturer in Section 4 and there is a brief discussion and summary in Section 5.

2. AIMS OF STAGE I

In February 1994, a letter from NPL to potential participants in the project summarised the overall aim of Stage I as follows:

> **To estimate the maximum temperature rise which could occur during diagnostic examination with pulsed Doppler ultrasound using published prediction methods.**

The following statement regarding the methodology was made:

> The calculations will be carried out according to the methods published by NCRP and AIUM/NEMA for different clinical conditions (soft tissue, obstetric, bone etc..) and, wherever possible, will use acoustic output information supplied by manufacturers. Where manufacturers are not able to supply precisely the data specified by NCRP or AIUM/NEMA, best estimates of the missing values will be made (for instance, the entry beam dimensions could be approximated from the transducer dimensions).

The deliverables expected from Stage I were described as:

> The estimated temperature rise attributed to each scanner/transducer combination will be published and a spreadsheet will be produced which will allow similar calculations to be carried out on future systems.

Two sets of prediction methods have been published. The National Council on Radiation Protection and Measurements (NCRP, 1992) have a range of algorithms to cover different exposure conditions: homogenous soft tissue path, obstetric examination, and the case of ultrasound incident on bone are considered. The American Institute of Ultrasound in Medicine and the National Electrical Manufacturers Association (AIUM/NEMA, 1992) have a different set of algorithms: homogeneous soft tissue and incidence on bone are included, but obstetric or other specific examination types are not explicitly mentioned. The philosophies behind the two sets are somewhat different: NCRP algorithms are intended to be 'reasonable worst case' values, whereas the AIUM approach is to give a 'typical' value. One would therefore expect that the NCRP values would be higher than the AIUM values. The 'Thermal Indices' which appear on some scanners are calculated according to the AIUM/NEMA algorithms.

To calculate the thermal indices according to the NCRP and AIUM/NEMA schemes, values are required for various acoustical parameters. The important parameters are, in approximate order of **decreasing** importance:

1=	acoustic frequency
1=	spatial-peak temporal-average intensity
3	total power
4	focal beamwidth
5	focal distance
6	radiating aperture area

Mathematically, the two most important parameters are total radiated power and acoustic frequency; without these none of the formulae can be calculated. However, the parameter that is most widely available from manufacturers is spatial-peak temporal-average intensity, I_{spta},

and, for unscanned pulsed Doppler beams, the spreadsheet can estimate total power from I_{spta} and focal beamwidth, the beamwidth being estimated from the acoustic frequency if necessary. Consequently, some estimate of the temperature rise can be gained as long the acoustic frequency and I_{spta} are known.

3. COMMUNICATION WITH MANUFACTURERS/SUPPLIERS

Due to the complexity of the data required for the calculations and its commercial sensitivity, it was important to establish good communications with manufacturers and their representative bodies such as the UK Ultrasound Manufacturers' and Suppliers' Association (UMSA) and the US National Electrical Manufacturers' Association (NEMA).

Initially, the Regulatory Affairs managers or chairmen of all known suppliers of pulsed Doppler ultrasound equipment in the UK were contacted to request their cooperation and to ask for relevant acoustic output information for their equipment (see Appendices A and B). Some suppliers were able to provide us with information almost immediately (or at least agreed to provide it as soon as it was available). Other suppliers were more reluctant, either because of concerns over how the acoustic data and the results of the Stage I calculations were to be presented or, simply, because they could not readily obtain the data in the form we requested it.

There followed three series of communications. The first series was involved with clarifying the acoustic data we had received and chasing up suppliers who had expressed a desire to be involved but could not immediately provide the information. Often the UK suppliers needed to contact the manufacturing arm (generally in the USA or Japan) or to put NPL in touch with them; sometimes our request was not explicit enough or the data which was available did not fit in with our request.

No communications detailing acoustic information specific to a manufacturer is given in this report, but a secondary request sent by NPL can be found in Appendix C. It can be seen from these that the data requested changed slightly during the project; the reason for this is that, as the project progressed, it became clear that different manufacturers carried out different measurements of their equipment and, consequently, different acoustic parameters were available from each. Many manufacturers are now carrying out measurements to the AIUM Output Display Standard (AIUM/NEMA, 1992) and are able to supply this information along with their own calculated values of Thermal Indices (TI's). At the beginning of the project, we did not anticipate that this data would be widely available and tried to formulate our requests in the most general way so that an estimate could be made of TI's, almost regardless of what format the manufacturers' data was in. The software to calculate TI values was also written with this in mind.

The second series of communications involved responding to concerns about the use to which the manufacturers' data would be put and the validity of our procedures. Although these were often discussed individually with manufacturers and suppliers, the most comprehensive coverage is given in a series of letters between NEMA and DoH (see Appendix D). In addition, RC Preston and A Shaw from NPL gave a presention to the Ultrasound Imaging Section of NEMA at their meeting in San Francisco, March 1995.

Before compilation of these results, each manufacturer received copies of all calculations and results relating to their own equipment. All comments and corrections received were incorporated in to a preliminary version of this report which was circulated on a restricted basis (NPL report CIRA(RES)008 - *Assessment of the likely thermal index values for pulsed Doppler ultrasonic equipment - Stage I: calculation based on manufacturers' data*, dated

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4. THERMAL INDEX RESULTS

The following Tables 1 to 8 give the TI results for all the scanner/probe combinations for which we received data from manufacturers. No attempt has been made in Stage I to obtain equipment for independent measurement. Similarly, no attempt has been made obtain information for all scanners and/or probes from each manufacturer. The intention was to obtain information for a wide (but not necessarily complete) range of equipment used in the UK. The distribution of results is summarised in Figure 1.

It is often the case that a particular manufacturer will produce a number of different scanners based on the same platform but aimed at different medical specialities or with extra modes (for instance, colour-flow) available. In these cases, it may be possible to use a particular transducer on more than one scanner and for it to generate the same acoustic output and, therefore, the same TI values. However, this cannot be guaranteed and no such assumption is made in this report: it is quite possible for even minor software upgrades to significantly affect acoustic output.

All values were calculated using ***NPL_4-0.xls***, an Excel workbook which contains a calculation worksheet functionally identical Version 1.0 of ***Dopticalc***; a sample ***Dopticalc*** spreadsheet is given in Appendix F and the method used to carry out the calculations is described in Appendix G.

Each table contains 11 columns. The first three give the scanner type, transducer type and, as far as they were declared, the operating conditions which were relevant to the supplied acoustic output values. The next five columns give the results for each of five models described by NCRP: homogeneous soft tissue; first, second and third trimester obstetric; and bone. The final three columns give the results for each of the three AIUM/NEMA thermal indices: soft tissue, bone and transcranial. When two or more sets of values are given for the same scanner/transducer combination (generally indicated by (1) or (2) after the transducer type, or by a comment in the 'Operating conditions' column), this means that measurements were reported for different operating conditions. This happens typically when the TIS and TIB are maximum for different operating conditions, or where acoustic data is reported in different formats: for instance, according to IEC1157 and to FDA510(k).

4.1 INTERPRETING THE RESULTS

Each TI value given is simply the result of applying a particular calculation to a particular set of acoustic data. When interpreting the results given in this report, the following cautions should be kept in mind.

a. Results have, of necessity, been based on estimated values for acoustical parameters when the parameters ideally required for a particular thermal prediction model are not available.

b. NCRP models are intended to represent the 'reasonable worst-case' whereas AIUM models are intended to be 'typical'. NCRP models would therefore be expected to produce higher values than the equivalent AIUM models.

c. There is no AIUM equivalent of the NCRP foetal models.

d. Not all equipment is intended for foetal examination. If the manufacturer specifies that the equipment is not to be used for obstetric examination, the NCRP models F1, F2 and F3 will not be relevant.

e. Some output settings on some equipment are not intended for obstetric examination. If the equipment is used as specified by the manufacturer, the TI values for NCRP models F1, F2 and F3 may be overestimates.

f. The AIUM model TIC is relevant for equipment which is specified as being for transcranial examinations. The TIC model is also relevant to any other examination in which bone is close to the transducer, even when the transducer is not specified for transcranial use.

Table 1 Thermal Index values for Aloka SSD-2000.

Aloka									
Scanner	Probe	Operating conditions	NCRP H4	NCRP F1	NCRP F2	NCRP F3	NCRP B	TIS	TIB	TIC
SSD-2000 Ver.8	UST-979-3.5	Pulsed Doppler Mode, Focus F3, Velocity range = 10kHz, Sample gate: depth =4.2cm, size = 0.1cm, Power 100%	1.7	1.1	5.8	6.9	4.9	0.9	2.1	1.8
SSD-2000 Ver.8	UST-990-5	Pulsed Doppler Mode, Focus F2, Velocity range = 5kHz, Sample gate: depth =1.7cm, size = 0.1cm, Power 100%	2.0	0.9	4.3	5.3	3.4	1.5	2.7	1.8
SSD-2000 Ver.8	UST-984P-5	Pulsed Doppler Mode, Focus F5, Velocity range = 5kHz, Sample gate: depth =3cm, size = 0.1cm, Power 100%	0.9	0.3	1.5	1.9	1.2	0.5	1.2	0.9
SSD-2000 Ver.8	UST-670P-5	Pulsed Doppler Mode, Focus F3, Velocity range = 5kHz, Sample gate: depth =1.5cm, size = 1.0cm, Power 100%	1.6	0.2	0.6	0.8	0.5	0.3	1.2	0.9
SSD-2000 Ver.8	UST-5524-5	Pulsed Doppler Mode, Focus F1, Velocity range = 5kHz, Sample gate: depth =0.2cm, size = 0.1cm, Power 100%	1.2	0.3	1.8	2.2	1.4	0.5	1.8	0.8
SSD-2000 Ver.8	UST-5524-7.5	Pulsed Doppler Mode, Focus F4, Velocity range = 5kHz, Sample gate: depth =3.5cm, size = 1.0cm, Power 100%	1.2	0.4	1.7	2.2	1.3	0.8	1.4	1.0
SSD-2000 Ver.8	UST-5710-7.5	Pulsed Doppler Mode, Focus F2, Velocity range = 5kHz, Sample gate: depth =1.4cm, size = 0.1cm, Power 100%	1.2	0.3	1.2	1.7	0.9	0.6	1.8	0.8

NOTES

This table must be read in conjunction with cautions a) to f) on page 9.

Table 2 Thermal Index values for ATL Ultramark 9 HDI and HDI 3000.

		ATL							
Scanner	Probe	Operating conditions	NCRP H4	NCRP F1	NCRP F2	NCRP F3	NCRP B	TIS	TIB	TIC
HDI3000	P3-2	Pulsed Doppler, 2D+Pulsed Doppler - TIB values	2.1	1.1	7.1	8.0	6.4	n/a	n/a	2.3
HDI3000	P3-2	Pulsed Doppler, 2D+Pulsed Doppler - TIC values	n/a	1.3	8.6	9.7	7.6	n/a	n/a	2.4
HDI3000	P3-2	Doppler, IEC values, system settings which yield maximum peak negative pressure	1.5	0.8	5.2	5.9	4.7	0.8	3.2	
HDI3000	P3-2	Doppler, IEC values, system settings which yield maximum intensity (SPTA)	1.4	0.9	5.9	6.6	5.3	0.8		
HDI3000	P7-4	PW & 2D+PW, TIB values	2.9		3.6	4.5	2.8	1.5	n/a	2.3
HDI3000	P7-4	PW & 2D+PW, TIC values	n/a	1.5	7.9	9.9	6.3	2.2	n/a	2.8
HDI3000	P7-4	Doppler, IEC values, system settings which yield maximum intensity (SPTA)	0.6	0.3	1.3	1.6	1.0	0.4	1.3	
HDI3000	P7-4	Doppler, IEC values, system settings which yield maximum peak negative pressure		0.5	2.0	2.6	1.6	1.0	1.5	1.3
HDI3000	L7-4	Pulsed Doppler, 2D+Pulsed Doppler, TIS Aaptr<=1 values	n/a	1.0	5.6	7.0	4.4	1.6	n/a	2.0
HDI3000	L7-4	Pulsed Doppler, 2D+Pulsed Doppler - TIB values	3.3	0.4	2.4	3.0	1.9	0.6	n/a	1.5
HDI3000	L7-4	Doppler, IEC values, system settings which yield maximum intensity (SPTA)			2.6	3.2	2.0	0.8		
HDI3000	L7-4	Doppler, IEC values, system settings which yield maximum peak negative pressure	0.9	0.2	1.3	1.6	1.0	0.4		0.6
HDI3000	L10-5	Pulsed Doppler, 2D+Pulsed Doppler - TIS Aaptr<=1 values	n/a	1.4	7.3	10.3	5.2	2.9	n/a	2.5
HDI3000	L10-5	Pulsed Doppler, 2D+Pulsed Doppler - TIB values		1.0	2.8	4.0	2.0	2.9	n/a	2.5
HDI3000	L10-5	Doppler, IEC values, system settings which yield maximum intensity (SPTA)		0.4	2.0	2.8	1.4	0.8	2.1	0.9
HDI3000	L10-5	Doppler, IEC values, system settings which yield maximum peak negative pressure		0.2	1.0		0.7	0.6		0.7
HDI3000	C3 5/76R	Pulsed Doppler, 2D+Pulsed Doppler - TIS Aaptr>=1 values	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
HDI3000	C3 5/76R	Pulsed Doppler, 2D+Pulsed Doppler - TIB values	0.8	0.6	3.5		2.9	n/a	n/a	
HDI3000	C3 5/76R	Doppler, IEC values, system settings which yield maximum intensity (SPTA)		0.8		5.5	3.9	0.7		
HDI3000	C3 5/76R	Doppler, IEC values, system settings which yield maximum peak negative pressure		0.6	2.7	3.1	2.2		1.0	0.9
HDI3000	C4-2	Pulsed Doppler, 2D+Pulsed Doppler - TIS Aaptr>=1 values	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
HDI3000	C4-2	Pulsed Doppler, 2D+Pulsed Doppler - TIB values			3.2	3.7	2.8	n/a	n/a	
HDI3000	C4-2	Doppler, IEC values, system settings which yield maximum peak negative pressure		0.5		2.8	2.1	0.5		
HDI3000	C4-2	Doppler, IEC values, system settings which yield maximum intensity (SPTA)			5.1	5.9	4.4			
HDI3000	C7-4	Pulsed Doppler, 2D+Pulsed Doppler - TIB values	3.0	0.6	2.6		2.1		n/a	
HDI3000	C7-4	Doppler, IEC values, system settings which yield maximum peak negative pressure			3.1	3.9	2.5	0.8	1.6	
HDI3000	C7-4	Doppler, IEC values, system settings which yield maximum intensity (SPTA)	2.2	1.3	5.9	7.5	4.7	1.2	2.4	2.1
HDI3000	C9-5	Pulsed Doppler, 2D+Pulsed Doppler - TIB values	4.3	0.6	1.8	2.4		1.5	n/a	2.4
HDI3000	C9-5	Doppler, IEC values, system settings which yield maximum peak negative pressure			4.0	5.1	3.2			
HDI3000	C9-5	Doppler, IEC values, system settings which yield maximum intensity (SPTA)	3.6	1.0	4.2	5.6	3.1	2.1	2.8	3.2

ATL

Scanner	Probe	Operating conditions	NCRP H4	NCRP F1	NCRP F2	NCRP F3	NCRP B	TIS	TIB	TIC
HDI3000	C51VT	Pulsed Doppler, 2D+Pulsed Doppler - TIB values	3.0	0.3	1.7	2.1	1.4	0.5	n/a	1.7
HDI3000	C51VT	Doppler, IEC values, system settings which yield maximum peak negative pressure.	0.9	0.2	1.0	1.2	0.8			0.7
HDI3000	C51VT	Doppler, IEC values, system settings which yield maximum intensity (SPTA).	1.1	0.4	1.7	2.2	1.4	0.6	1.3	1.0
HDI3000	CL10-5	Pulsed Doppler, 2D+Pulsed Doppler - TIB values.	0.7	0.1	0.2	0.3	0.2		n/a	0.3
HDI3000	CL10-5	Doppler, IEC values, system settings which yield maximum peak negative pressure.	0.8	0.1	0.7	1.0	0.5	0.2	0.8	0.4
HDI3000	CL10-5	Doppler, IEC values, system settings which yield maximum intensity (SPTA).	0.9	0.1	0.7	1.0	0.5	0.2	1.2	
HDI3000	D2TCD	Pulsed Doppler - TIS Aaprt>=1 values.	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
HDI3000	D2TCD	Pulsed Doppler - TIB values	1.8	0.8	5.2	5.8	4.6	n/a	n/a	2.3
HDI3000	D2TCD	Pulsed Doppler - TIC values	1.2	0.8	5.5	6.2	4.9	n/a	n/a	2.3
HDI3000	D2TCD	Doppler, IEC values, system settings which yield maximum intensity (SPTA)	1.8	1.0	6.4	7.2	5.7			2.1
HDI3000	D2TCD	Doppler, IEC values, system settings which yield maximum peak negative pressure.	0.3	0.2	1.2	1.4	1.1	0.2	0.8	
HDI3000	P5-3	Pulsed Doppler, 2D+Pulsed Doppler - TIS Aaprt>=1 values	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
HDI3000	P5-3	Pulsed Doppler, 2D+Pulsed Doppler - TIB values	7.3	1.0	4.3	5.1	3.6		n/a	
HDI3000	P5-3	Doppler, IEC values, system settings which yield maximum intensity (SPTA)	2.4	1.5	7.3		6.1	1.4	3.8	2.5
HDI3000	P5-3	Doppler, IEC values, system settings which yield maximum peak negative pressure	2.0			5.9	4.1	1.1	2.7	2.0
HDI3000	MPT7-4	Pulsed Doppler, 2D+Pulsed Doppler - TIS Aaprt<=1 values	n/a			3.4	2.2	0.8	n/a	
HDI3000	MPT7-4	Pulsed Doppler, 2D+Pulsed Doppler - TIB values	3.2	0.4		2.2	1.4	0.7	n/a	1.9
HDI3000	MPT7-4	Doppler IEC values, system settings which yield maximum peak negative pressure		0.2			0.7	0.4	1.2	
HDI3000	MPT7-4	Doppler IEC values, system settings which yield maximum intensity (SPTA)		0.5			1.9	0.8		

ATL

Scanner	Probe	Operating conditions	NCRP H4	NCRP F1	NCRP F2	NCRP F3	NCRP B	TIS	TIB	TIC
Ultramark 9 HDI	L10-5	Pulsed Doppler	0.6	0.2	1.0	1.4	0.7	0.3	1.0	0.4
Ultramark 9 HDI	C7-4	Pulsed Doppler	1.3	0.6	2.9	3.7	2.3	0.9	2.4	1.2
Ultramark 9 HDI	L7-4	Pulsed Doppler	1.5	0.6	3.1	3.9	2.5	0.8	2.3	1.3
Ultramark 9 HDI	C4-2	Pulsed Doppler	1.6	0.9	6.0	7.0	5.2	0.7	3.3	1.4
Ultramark 9 HDI	P3-2	Pulsed Doppler	1.7	1.2	8.3	9.4	7.4	1.0	4.0	2.2
Ultramark 9 HDI	A6-3	Pulsed Doppler	n/a	0.4	2.3	2.9	1.8	n/a	2.3	n/a

NOTES

This table must be read in conjunction with cautions a) to f) on page 9.

Table 3 Thermal Index values for B&K 3535

B & K Medical									
Scanner	Probe	Operating conditions	NCRP H4	NCRP F1	NCRP F2	NCRP F3	NCRP B	TIS	TIB	TIC
3535	8542	Fractional bandwidth=30%. , Beam angle to rotating axis=60 drgrees.	0.3	0.3	2.4	2.9	- -	0.2	0.9	0.3
3535	8543	Fractional bandwidth=30%. , Beam angle to rotating axis=60 drgrees.	0.5	0.3	1.7	2.3	1.3	0.2		
3535	8544	Fractional bandwidth=30%. , Beam angle to rotating axis=60 drgrees.		0.2		1.9		0.3		0.3
3535	8545	Fractional bandwidth=30%. , Beam angle to rotating axis=60 degrees.	0.4		0.7		0.5	0.3	0.7	0.2
3535	8553 (3.5 MHz)	Fractional bandwidth=65%. , Beam angle to rotating axis=60 degrees. Ispta value for medium setting		3.9	22.1	27.0		3.4	4.3	6.2
3535	8553 (4.3 MHz)	Fractional bandwidth=65%. , Beam angle to rotating axis=60 degrees. Ispta value for medium setting	6.3	3.0	16.2	20.7	12.6			
3535	8553 (5.0 MHz)	Fractional bandwidth=65%. , Beam angle to rotating axis=60 degrees. Ispta value for medium setting.	7.7	3.4	17.0	22.7	12.7	3.1	3.0	
3535	8554	Fractional bandwidth=30% , Beam angle to rotating axis=90 degrees.		0.3	1.5	2.2				

NOTES

This table must be read in conjunction with cautions a) to f) on page 9.

The values provided for total acoustic power for probes 8553 (3.5 MHz), 8553 (4.3 MHz) and 8553 (5.0 MHz) were absolute maximum values for B+M+Doppler operation. The scanner settings which produce these power levels may not be the same settings which produce the I_{spta} values quoted by the manufacturer. Total acoustic power values were not provided for probes 8542, 8543, 8544 or 8554; for these probes, power was estimated from I_{spta} and beamwidth.

Table 4 Thermal Index values for Hewlett Packard Sonos 1000.

Hewlett Packard									
Scanner	Probe	Operating conditions	NCRP H4	NCRP F1	NCRP F2	NCRP F3	NCRP B	TIS	TIB	TIC
Sonos 1000	21202A(1)	TIS values. Scan depth=24cm; doppler freq=2MHz; gate depth=23.8cm; gate length=0.28cm; scale=max; transmit=max	2.3	1.0	5.0	5.6	4.4	1.3	2.5	2.5
Sonos 1000	21202A(2)	TIB values. Scan depth=2cm; doppler freq=2MHz; gate depth=1.9cm; gate length=0.28cm; scale=max; transmit=max	2.5	0.7	3.8	4.3	3.4	1.0	3.0	2.7
Sonos 1000	21210B	Scan depth=24cm; doppler freq=5MHz; gate depth=3.7cm; gate length=0.12cm; scale=min; transmit=max	1.2	0.5	1.8	2.4	1.4	0.5	1.1	0.8
Sonos 1000	21211B(1)	TIS values. Scan depth=24cm; doppler freq=5MHz; gate depth=23.8cm; gate length=0.12cm; scale=max; transmit=max	1.8	0.4	1.3	1.7	1.0	1.0	1.1	1.3
Sonos 1000	21211B(2)	TIB values. Scan depth=24cm; doppler freq=5MHz; gate depth=23.8cm; gate length=0.19cm; scale=min; transmit=max	1.2	0.3	1.3	1.7	1.0	0.5	1.5	0.7
Sonos 1000	21242A	Scan depth=24cm; doppler freq=2.7MHz; gate depth=10.9cm; gate length=0.22cm; scale=min; transmit=max	2.0	1.4	7.1	8.3	6.0	1.2	2.5	2.2
Sonos 1000	21246A	Scan depth=24cm; doppler freq=3.7MHz; gate depth=3.0cm; gate length=0.16cm; scale=min; transmit=max	1.6	0.6	2.8	3.4	2.2	0.6	2.2	1.0
Sonos 1000	21255A(1)	TIS values. Scan depth=24cm; doppler freq=3.7MHz; gate depth=23.8cm; gate length=0.25cm; scale=min; transmit=max	3.0	0.7	2.6	3.2	2.1	0.9	2.6	1.6
Sonos 1000	21255A(2)	TIB values. Scan depth=24cm; doppler freq=3.7MHz; gate depth=6.2cm; gate length=0.25cm; scale=min; transmit=max	3.1	0.7	3.2	3.9	2.6	1.3	2.8	2.1
Sonos 1000	21255B	Scan depth=24cm; doppler freq=3.7MHz; gate depth=23.9cm; gate length=0.25cm; scale=max; transmit=max	3.8	0.8	2.9	3.6	2.4	1.6	3.4	2.7
Sonos 1000	21275A	Scan depth=24cm; doppler freq=5.5MHz; gate depth=0.9cm; gate length=0.16cm; scale=min; transmit=max	1.1	0.2	0.9	1.3	0.7	0.5	1.1	0.5

NOTES

This table must be read in conjunction with cautions a) to f) on page 9.

Table 5 Thermal Index values for IGE Logiq 500.

IGE									
Scanner	Probe	Operating conditions	NCRP H4	NCRP F1	NCRP F2	NCRP F3	NCRP B	TIS	TIB	TIC
Logiq 500	S316	Pulsed Doppler mode	1.8	0.9	3.4	4.1	2.8	1.2	2.6	2.5
Logiq 500	L739	Pulsed Doppler mode	1.2	0.3	1.6	2.1	1.2	0.7	1.6	0.6
Logiq 500	C551	Pulsed Doppler mode	1.4	0.5	1.5	2.1	1.2	0.8	1.3	1.3
Logiq 500	C551	Pulsed Doppler mode	1.2	0.5	2.3	2.7	1.9	0.6	2.0	1.2

NOTES

This table must be read in conjunction with cautions a) to f) on page 9.

Table 6 Thermal Index values for Kretz Combison 530.

Kretz Technic									
Scanner	Probe	Operating conditions	NCRP H4	NCRP F1	NCRP F2	NCRP F3	NCRP B	TIS	TIB	TIC
Combison 530	EW5/7	Power setting 6. Focus NEAR,7MHz. Gatewidth 1mm. PRF 31.8kHz.	0.4	0.1	0.5	0.7	0.3	0.2	0.6	0.2
Combison 530	VW7/10	Power setting 13. Focus FAR, 7 MHz. Gatewidth 1mm. PRF 13.8 kHz.	0.7	0.2	0.9	1.3	0.6	0.4	1.0	0.5
Combison 530	ICA6 5B	Focal zone 5, gatewidth = 1mm, prf = 13.89kHz, power setting = 19	4.5	1.0	3.1	4.5	2.1	3.0	2.6	3.4
Combison 530	AWP3.5	Focus zone 5. Power setting 20. Gatewidth 2.5mm. PRF 3.2kHz.	4.9	1.5	5.1	6.2	4.2	2.3	4.6	3.9
Combison 530	ACA3.5	Power setting 19. Focal zone 5. Gatewidth 2.5mm. PRF 5.23kHz.	3.0	1.5	6.0	7.2	4.9	1.3	2.5	2.6
Combison 530	EW5/7	Power setting 13. Focus: FAR,5MHz. Gatewidth 2.5mm. PRF 26kHz.	1.5	0.7	3.5	4.5	2.7	1.1	2.0	1.2
Combison 530	ACA5	Power setting 20. Focal zone 5. Gatewidth 1mm. PRF 8.55kHz.	6.2	2.1	6.5	8.4	5.0	2.7	3.8	4.3
Combison 530	VW7/10 NEAR	Power setting 13. Focus = NEAR, 10MHz. Gatewidth 1mm. PRF 13.8 kHz.	0.5	0.0	0.3	0.5	0.2	0.2	0.6	0.2

NOTES

This table must be read in conjunction with cautions a) to f) on page 9.

Table 7 Thermal Index values for Philips P700.

Philips									
Scanner	Probe	Operating conditions	NCRP H4	NCRP F1	NCRP F2	NCRP F3	NCRP B	TIS	TIB	TIC
P700	LA3510		0.8	0.3	1.9	2.3	1.6	0.5	1.4	0.8
P700	CA3550		0.4	0.2	1.0	1.2	0.8	0.2	0.8	0.4
P700	CA5040		0.9	0.5	2.6	3.3	2.1	0.6	1.4	0.8
P700	CA5025		1.1	0.4	1.5	2.0	1.1	0.7	0.9	0.7
P700	LA 5030A		0.5	0.1	0.6	0.8	0.4	0.2	0.8	0.4
P700	CA 6511-ER		0.1	0.0	0.1	0.1	0.1	0.0	0.1	0.1
P700	CA 6514-EV		0.1	0.0	0.1	0.1	0.1	0.0	0.1	0.0
P700	LA 7530		0.4	0.1	0.6	0.8	0.4	0.2	0.6	0.5
P700	LA 7530A		0.7	0.2	0.8	1.1	0.6	0.3	1.0	0.6

NOTES

This table must be read in conjunction with cautions a) to f) on page 9

Table 8 Thermal Index values for Toshiba SSA-270, SSA-250A and SSH-140A.

Toshiba									
Scanner	Probe	(	NCRP H4	NCRP F1	NCRP F2	NCRP F3	NCRP B	TIS	TIB	TIC
SSA-270A	PLF-503ST	focus 3 , PWR = 16	0.2	0.1	0.6	0.7	0.4	0.1	0.7	-
SSA-270A	PSF-25KT	focus 5, PWR = 15	0.2	0.1	0.6	0.7	0.6	0.1	0.6	
SSA-270A	PSF-37DT	focus 4 PWR = 16	0.2	0.2	0.9	1.0	0.7	0.1	0.6	
SSA-270A	PSF-50FT	focus 2 PWR = 16	0.2	0.1	0.4	0.5	0.3	0.1	0.3	
SSA-270A	PVF-357MT	focus 2, PWR = 16	0.1	0.0	0.3	0.3	0.2	0.1	0.2	
SSA-270A	PVF-621VT	focus 4, PWR = 16	0.1	0.1	0.3	0.4	0.2	0.1	0.2	
SSA-270A	PVF-738F (and 738H)	focus 4 , PWR = 16	0.2	0.1	0.2	0.3	0.2	0.1	0.3	
SSA-270A	PVF- 745V	focus 4, PWR = 16	0.1	0.0	0.2	0.3	0.2	0.1	0.2	0.1
SSA-250A	PVF-738F	Focus 4, PWR = 16	0.3	0.1	0.3	0.4	0.2	0.1	0.3	0.2
SSA-250A	PVF-745V	focus 4, PWR = 16	0.2	0.1	0.3	0.4	0.2	0.1	0.3	0.2
SSH-140A	PLF-308P	Focus 3, PWR = 16	0.1	0.0	0.2	0.2	0.2	0.0	0.2	0.1
SSH-140A	PLF-503NT	Focus 4, PWR= 16	0.4	0.1	0.7	0.9	0.6	0.2	1.2	0.3
SSH-140A	PSF-25LT	Focus 5, PWR = 16	0.2	0.1	0.6	0.7	0.6	0.1	0.6	0.2
SSH-140A	PSF-37FT	focus 6, PWR = 16	0.4	0.2	1.1	1.3	0.9	0.2	0.8	0.3
SSH-140A	PSF-50FT	Focus 2, PWR = 16	0.1	0.0	0.3	0.3	0.2	0.1	0.3	0.1
SSH-140A	PSH-70LT	Focus 8, PWR = 16	0.2	0.1	0.3	0.4	0.2	0.1	0.4	0.2
SSH-140A	PVF-375MT	focus 4, PWR = 16	0.1	0.0	0.3	0.3	0.2	0.0	0.2	0.1
SSH-140A	PVF-575MT	Focus 4, PWR = 16	0.1	0.0	0.2	0.2	0.1	0.0	0.1	0.1
SSH-140A	PVF-621VT	Focus 5, PWR = 16	0.2	0.0	0.2	0.3	0.2	0.1	0.2	0.1
SSH-140A	PVF-738F	Focus 6, PWR = 16	0.2	0.1	0.2	0.3	0.2	0.1	0.2	0.1
SSH-140A	PVF-738H	Focus 6, PWR = 16	0.2	0.1	0.2	0.3	0.2	0.1	0.2	0.1
SSH-140A	PVF-745V	Focus 4, PWR = 16	0.2	0.1	0.3	0.4	0.3	0.1	0.3	0.2

NOTES

This table must be read in conjunction with cautions a) to f) on page 9.

5. SUMMARY AND DISCUSSION

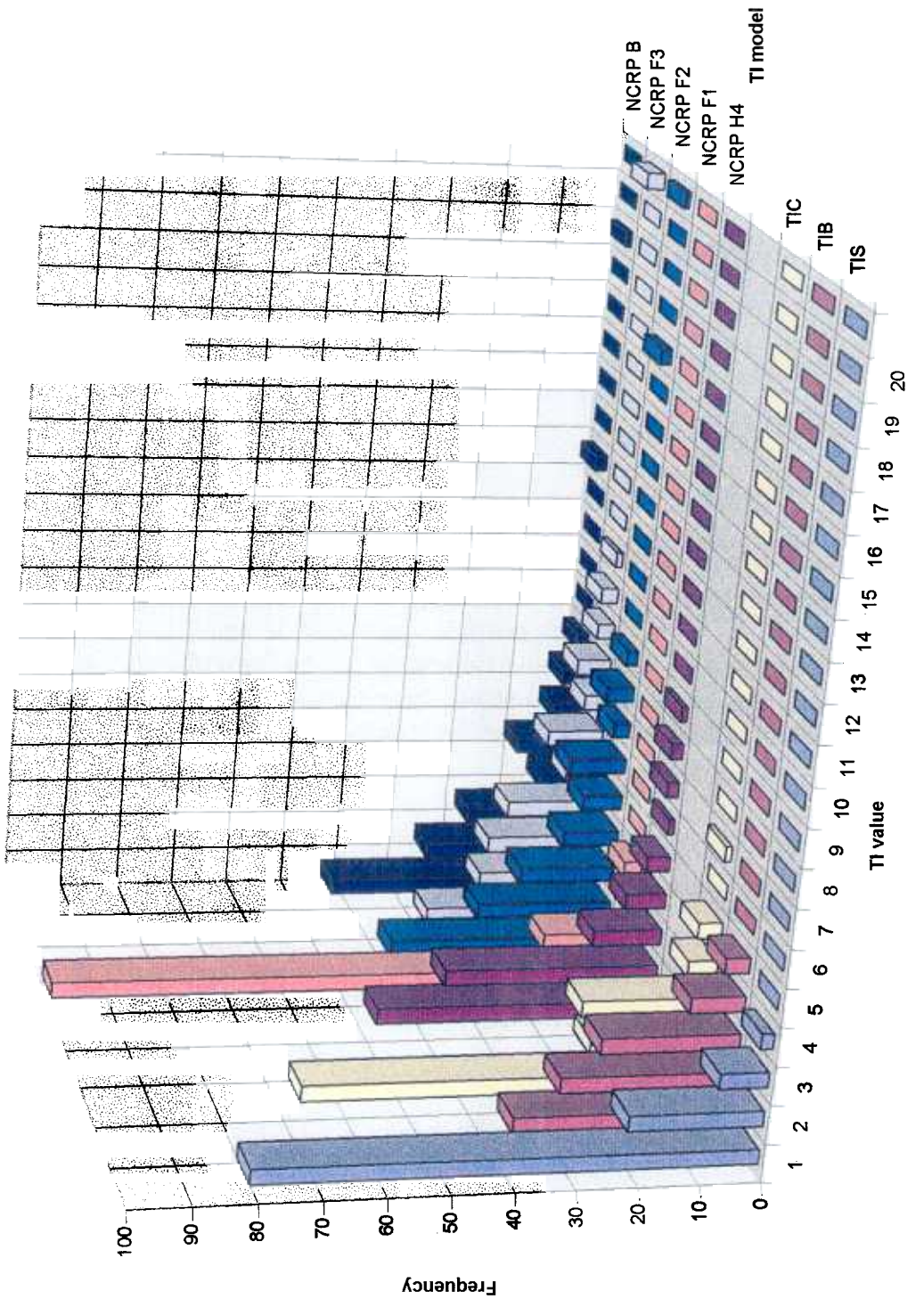
A spreadsheet has been written which calculates Thermal Indices according to methods based on those published by AIUM/NEMA and NCRP. Acoustic output data has been obtained from manufacturers and entered in the calculation spreadsheet; the results of the calculations are given in Section 4 by manufacturer and scanner/probe combination. The results from all these calculations have been aggregated and the distribution of Thermal Index values is given in Figure 1 by Thermal Index model. Note that, if information is available for more than one set of operating conditions, the results for all conditions are included in the overall distribution.

The distribution of the Thermal Index values for each prediction model (*ie* the number of occurrences of TI values in the range indicated) is summarised below.

T I	NCRP H4	NCRP F1	NCRP F2	NCRP F3	NCRP B	TIS	TIB	TIC
< 1.0	48	100	39	29	43	82	36	66
1.0 - 1.5	23	15	10	13	19	13	21	12
1.5 - 3.0	26	2	31	26	26	16	31	31
3.0 - 5.0	11	3	17	22	17	2	13	9
5.0 - 10.0	6	0	20	26	11	0	0	1
> 10	0	0	3	4	3	0	0	0

Bearing in mind the cautions given in Section 4.1, it does not seem appropriate to attempt to draw any conclusions from the outcome of Stage I. This report has, therefore, merely presented the results as objectively as possible. In Stages II and III, experimental and improved theoretical methods will be used to assess the thermal hazard from pulsed Doppler equipment. It will then be possible to compare the results from the new methods with the Thermal Index values calculated using the methods described in this report.

Figure 1 The distribution of calculated Thermal Index values for each thermal prediction model (*ie* the number of occurrences of results between *n-1* and *n*, where *n* is the indicated TI value).



6. 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.

7. REFERENCES

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ROYAL COLLEGE OF OBSTETRICIANS AND GYNAECOLOGISTS (1984) *Report of the RCOG working party on routine ultrasound exaination in pregnancy*, Press release, London.

ROYAL COLLEGE OF RADIOGRAPHERS (1985) Press release, London.

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APPENDIX A.

Letter of support from DoH

0902am1

Skipton House 80 London Road London SE1 6LW Telephone 071 972 2000
Direct line 071 972 5645
FAX 071 972 5670

9 February 1994

Dear

Research on temperature rise from pulsed Doppler ultrasound equipment

You will be aware that interest has been expressed in national, international, and both public and professional forums, in the safety of medical ultrasound. Extraordinary claims have been made, in particular, that large temperature rises can be induced in human tissue exposed to diagnostic Doppler systems.

The Department of Health wishes to assemble reliable data and authoritative models on which to base its guidance to users, and to use these findings to inform the development of European and international standards for medical equipment. We have therefore commissioned Dr R C Preston, of the National Physical Laboratory, to undertake a program of research that includes a survey of equipment currently in use and on the market in the United Kingdom.

It will clearly benefit all concerned if the study covers the widest possible selection of equipment, and its findings will be most reliable if the majority is loaned in known good condition by its suppliers rather than taken "as found" from clinical service.

May I therefore ask you to respond helpfully to Dr Preston's detailed request, which this letter accompanies. Please contact me if you have any questions.

Yours faithfully

Dr A M Calverd

APPENDIX B.

First call for data

NPL

Mr Richard Kirby
Chairman
Ultrasound Manufacturers'
and Suppliers' Association
PO Box 66
Stevenage
Herts SG1 SS

National Physical Laborato

Teddington
Middlesex
United Kingdom
TW11 0LW

Switchboard
081-977 3222

Telex 262344 NPL G
Fax 081-943 2155
Local fax 081 943 6161

Direct line 081-943-6154
Our ref NPR 3/6/9
Your ref
Date 14 February 1994

Dear Mr Kirby,

I am writing to you in your capacity as Chairman of the Ultrasound Manufacturers' and Suppliers Association in order to let you know about, and hopefully gain your support for, a project being undertaken by NPL on behalf of the UK Department of Health.

Enclosed is a copy of a letter and associated material that I am sending to companies who either manufacture or market pulsed Doppler diagnostic ultrasonic equipment in the UK. As you will see, the letter specifically requests acoustic output information and seeks their support in the later stages of the project during which we will need access to some systems. Accompanying my letter is one from the Department of Health which provides some background and justification for the project.

For information, I enclose a list of all those companies to whom the letter has been sent. I would be interested to know whether there are any other companies to whom you think that it should be sent.

I hope that you will see the benefit of the project and can see your way to giving it your support. If you would like to discuss the project, please do not hesitate to contact me or Adam Shaw (Tel: 081 943 6581). Alternatively, you might like to visit us here at NPL where we could discuss matters in greater depth.

Looking forward to hearing from you.

Yours sincerely,

Dr Roy C Preston
Division of Radiation Science and Acoustics

NPL

Manufacturer's
Name and address

National Physical Laborator

Teddington
Middlesex
United Kingdom
TW11 0LW

Switchboard
081-977 3222
Telex 262344 NPL G
Fax 081-943 2155
Local fax 081 943 6161

Direct line 081-943-6154
Our ref NPR 3/6/9
Your ref
Date 14 February 1994

Dear Sir,

I am writing to the Ultrasound Equipment Manufacturers' and Suppliers' Association and to all companies who either manufacture or market pulsed Doppler diagnostic ultrasonic equipment in the UK in order hopefully to gain their assistance and support for a project being undertaken by NPL on behalf of the UK Department of Health (see the accompanying letter from DoH).

The main objective of the project is to establish the thermal hazard from pulsed Doppler diagnostic equipment currently on the UK market. The Project Outline is attached but briefly the project involves three main stages. The first is to predict the temperature rise using existing published prediction methods, preferably based on acoustic output information provided by manufacturers. The second stage is to select a range of systems including those which appear to have the potential for producing significant heating and, with the assistance of the manufacturer, to undertake at NPL more detailed acoustic output measurements in order to allow better estimates of temperature rise to be made. This stage will also involve the measurement of temperature rise based on thermal test objects simulating the models used in the published test methods. The final stage will be to determine the temperature rise based on improved theoretical methods and also based on tissue models more closely approximating clinical situations.

It is important to realise that the intention is to publish the results of the calculations and measurements. In fact, the aim will be to name the particular product and probe assessed. Prior to any publication, manufacturers/marketing companies will be given the opportunity of commenting on and discussing the results. We would therefore prefer that this project is undertaken in full cooperation and assistance of manufacturers and marketing companies. To achieve this, it is important that adequate liaison is set up between NPL and the companies at an early stage.

On the assumption that your company is prepared to cooperate in this important project, we would therefore ask each company:

* To provide, for each ultrasound system/probe combination that has the capability

of generating pulsed Doppler beams, as much of the acoustic output information specified on the accompanying sheet as is possible. We need to receive this information within six weeks of the date of this letter. This information will allow us to undertake the calculations according to the published test methods of NCRP and AIUM/NEMA.

* To be prepared to supply on short-term loan to NPL those systems which are selected for further evaluation. The intention is to select carefully the probe/systems so that the group is representative of most manufacturers. It is therefore expected that there will be no more than three or four probe/system combinations from any one manufacturer (which could mean for a manufacturer just one system with one to four probes). In order that we will be able to schedule the tests, we would appreciate knowing how much time you need in order to organise the loan, especially if this is strongly dependent on the system under consideration. We would not require access before July/August 1994.

I would appreciate knowing in writing within ten days of the date of this letter whether your company is prepared to collaborate with this project.

Please do not hesitate to contact me or Adam Shaw (Tel: 081 943 6581, Fax: 081 943 6161) if you have any queries. We look forward to hearing from you soon.

Yours sincerely,

Dr Roy C Preston
Division of Radiation Science and Acoustics

Project Outline

Stage I

To estimate the maximum temperature rise which could occur during diagnostic examination with pulsed Doppler ultrasound using published prediction methods.

The calculations will be carried out according to the methods published by NCRP[1] and AIUM/NEMA[2] for different clinical conditions (soft tissue, obstetric, bone etc..) and, wherever possible, will use acoustic output information supplied by manufacturers. Where manufacturers are not able to supply precisely the data specified by NCRP or AIUM/NEMA, best estimates of the missing values will be made (for instance, the entry beam dimensions could be approximated from the transducer dimensions).
The estimated temperature rise attributed to each scanner/transducer combination will be published and a spreadsheet will be produced which will allow similar calculations to be carried out on future systems.
The acoustic parameters which are needed for the NCRP[1] and AIUM/NEMA[2] models are specified on page 2, and manufacturers are asked to supply as much of this information as they can.

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[1] and AIUM/NEMA[2] models. (Note: the thermal test objects have been developed as part on 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.

Requirements for Stage I

In order carry out the calculations specified by NCRP[1] and AIUM/NEMA[2], the following parameters are required for each scanner/transducer combination operating in pulsed Doppler mode under the conditions that give the maximum acoustic power output. [NB If the parameters are not known under the conditions which give maximum acoustic power, please supply values corresponding to the maximum derated temporal-average intensity.]

Output power

Spatial-peak temporal-average derated intensity

Position of spatial-peak temporal-average derated intensity

Centre frequency of acoustic pulse

-6dB beam-area (or dimensions) at position of maximum free-field temporal-average intensity

(ie focal area or dimensions)

Active aperture area (or dimensions) of the transducer (ie output beam-area or dimensions)

In addition, to comply fully with the NCRP[1] and AIUM/NEMA[2] soft tissue models, the following information would be desirable:

Axial variation of intensity (either free-field or derated)

Radius of curvature of transducer (if appropriate)

Please also send us any marketing literature relating scanners and/or transducers which can be used for pulsed Doppler examinations.

If any particular parameter is not available, please try to give us any other information which might help us produce an accurate estimate for that parameter.

1. NCRP, 1992. "Exposure criteria for medical diagnostic ultrasound: I. Criteria based on thermal mechanisms", Report No. 113, National Council on Radiation Protection and Measurements, Bethesda, MD-20814, USA.
2. AIUM/NEMA 1992. "Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment", UD3-1992, American Institute of Ultrasound in Medicine/National Electrical Manufacturers' Association, USA.

APPENDIX C

Second call for data

Project Outline

Stage I

To estimate the maximum temperature rise which could occur during diagnostic examination with pulsed Doppler ultrasound using published prediction methods.

The calculations will be carried out according to the methods published by NCRP[1] and AIUM/NEMA[2] for different clinical conditions (soft tissue, obstetric, bone etc..) and, wherever possible, will use acoustic output information supplied by manufacturers. Where manufacturers are not able to supply precisely the data specified by NCRP or AIUM/NEMA, best estimates of the missing values will be made (for instance, the entry beam dimensions could be approximated from the transducer dimensions).
The estimated temperature rise attributed to each scanner/transducer combination will be published and a spreadsheet will be produced which will allow similar calculations to be carried out on future systems.
The acoustic parameters which are needed for the NCRP[1] and AIUM/NEMA[2] models are specified on page 4, and manufacturers are asked to supply as much of this information as they can.

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[1] and AIUM/NEMA[2] models. (Note: the thermal test objects have been developed as part on 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.

Requirements for NPL project on Thermal Indices

In order carry out the calculations specified by NCRP[1] and AIUM/NEMA[2], the following parameters are required for each scanner/transducer combination operating in pulsed Doppler mode. **The conditions under which these parameters should be measured is described in the notes and flowchart below. Please contact me (tel: +44 (0)181 943 6581; fax: +44 (0)181 943 6161) if you think that the information you have available does not meet our requirements.**

Please supply values for as many of the following parameters as possible. *If any particular parameter is not available, please try to give us any other information which might help us produce an accurate estimate for that parameter.*

Scanner control settings
Output power
Spatial-peak temporal-average derated intensity
Position of spatial-peak temporal-average derated intensity
Centre frequency of acoustic pulse
-6dB beam-area (or dimensions) at position of maximum free-field temporal-average intensity (ie focal area or dimensions)
Active aperture area (or dimensions) of the transducer (ie output beam-area or dimensions)
Axial variation of intensity (either free-field or derated)
Radius of curvature of transducer (if appropriate)

<u>Notes</u>

During the course of our work on this project, it has become apparent that different manufacturers carry out measurements according to different standards and, consequently, the acoustical parameters which are known differs from one manufacturer to another.

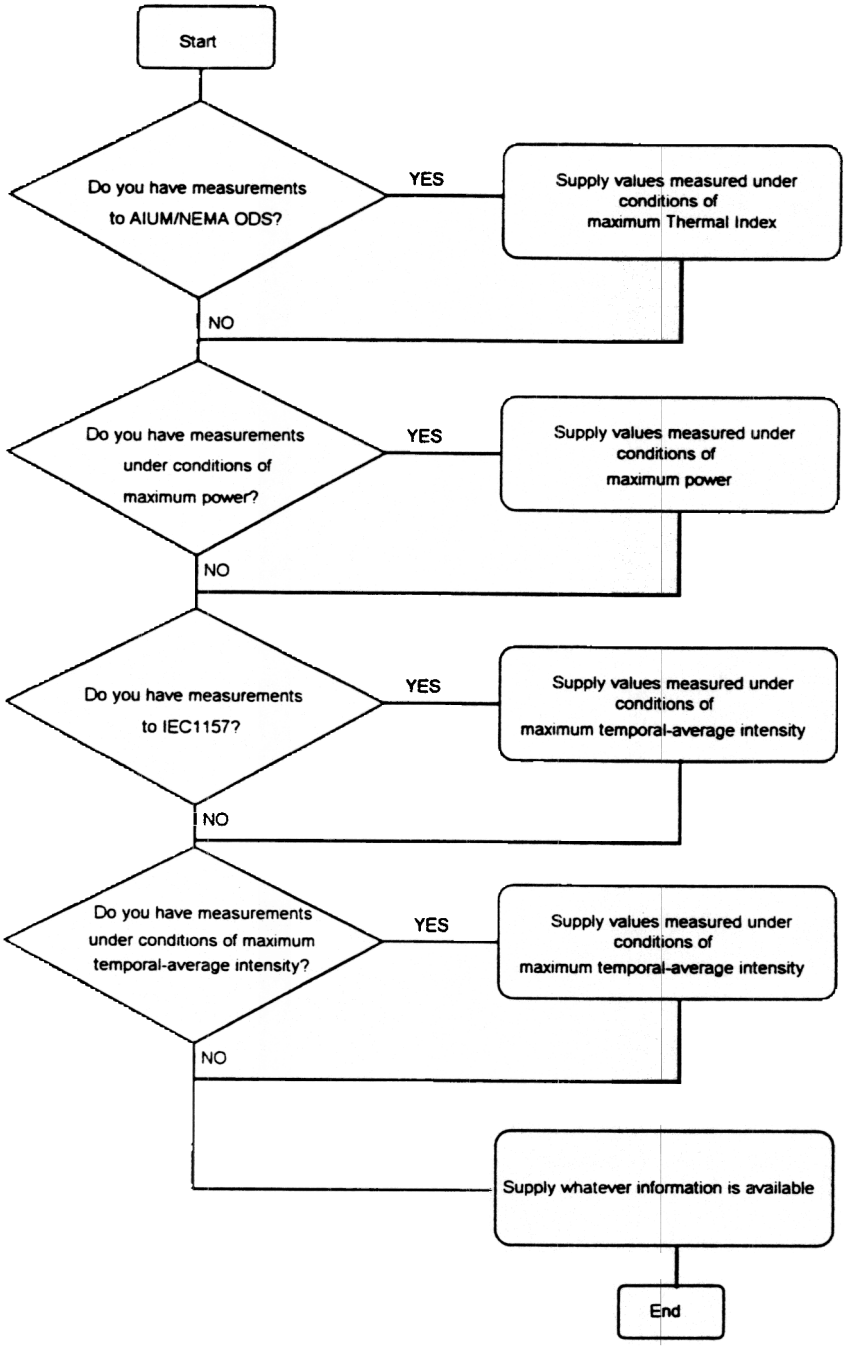
The AIUM/NEMA Output Display Standard requires acoustic parameters which have been measured under those conditions which produce the maximum Thermal Index. (*In this context, 'conditions' means a particular combination of scanner control settings.)* At the start of our project, we did not expect that values measured under maximum Thermal Index conditions would be available. Since we did not want to ask manufacturers to carry out a great deal of extra work, we requested data measured *either* under conditions which give the maximum radiated acoustic power *or* under conditions which give the maximum spatial-peak temporal-average intensity. However, from the acoustic information we have received so far, it is clear that some manufacturers have already been carrying out measurements according to the Output Display Standard.

If your company has already carried out measurements to the ODS, please supply us with the acoustic values you have used to calculate the Thermal Indices and with any other acoustic measurements you have made (*eg* under conditions of maximum power or maximum I_{spta}).

If you have not carried out measurements to the ODS, please supply us with results under conditions which give maximum power or maximum I_{spta} for the scanner/probe combinations concerned. (*If you have carried out measurements to IEC1157, the values you have measured will be those for maximum* I_{spta}). If you have made measurements under both conditions,

please supply both sets data.

Adam Shaw
Division Radiation Science and Acoustics
National Physical Laboratory
23 february 1995



Selection of measurement conditions for acoustic data to be supplied for NPL project on Thermal Indices.

1 NCRP, 1992. "Exposure criteria for medical diagnostic ultrasound: I. Criteria based on thermal mechanisms", Report No. 113, National Council on Radiation Protection and Measurements, Bethesda, MD-20814, USA.

2. AIUM/NEMA 1992. "Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment", UD3-1992, American Institute of Ultrasound in Medicine/National Electrical Manufacturers' Association, USA.

APPENDIX D.

Correspondence between NPL, DoH and NEMA

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Diagnostic Imaging and Therapy Systems Divisio

May 31, 1994

Dr. Roy C. Preston
National Physical Laboratory
Division of Radiation Sciences and Acoustics
Teddington, Middlesex
TW 11 OLW, England, UNITED KINGDOM

Dear Dr. Preston:

The National Physical Laboratory project to establish the thermal hazard of Pulsed Doppler ultrasound diagnostic equipment was discussed recently at a meeting of the NEMA Ultrasound Imaging Section, Technical Committee. At that time, several members expressed concern about the use of non-standard methods and non-standard test objects to predict thermal rise in human tissue, and how the final project results will be published. NEMA wishes to inform you of these concerns and requests clarification regarding certain aspects of the project.

The Committee feels very strongly that the test methodologies and test objects used in this project must mimic biologically relevant conditions such as those assumed in the NCRP and AIUM/NEMA models. Otherwise, results will not accurately predict true thermal rise in tissue and may misrepresent any potential thermal hazard of diagnostic ultrasound equipment. NEMA would like to know more details about your proposed test methodology and test object specifications and construction, particularly those aspects relating to tissue perfusion, acoustic attenuation and thermal conductivity.

Given that you intend to name specific manufacturers' equipment in your report, NEMA is especially concerned about how the final results will be published. In particular:

Will the resulting predictions and measurement data be presented as realistic in-vivo temperature rise? If so, will any test reports establishing the validity (and limitations) of the methods and test objects developed in this study be published prior to publication of the final results?

NEMA members appreciate the opportunity to comment on and discuss the results of this study prior to publication. Will manufacturers be provided with interim progress reports prior to final publication? At what point in the publication

process will manufacturers be allowed to comment on and discuss results? Will manufacturers' comments be incorporated into the report, and if so, how will these comments be presented?

Please be assured that NEMA supports the development of more accurate methods and models for predicting thermal rise in tissue, including the development and improvement of thermal test objects. At the same time, however, these methods and models must be relevant to actual in-vivo conditions.

We look forward to your response to our questions regarding the technical aspects and publishing plans of your project. Please feel free to contact us if you have any questions.

Sincerely,

Charles Grossman (RE)

Charles Grossman,
Chairman
NEMA Ultrasound Imaging Section,
Technical Committee

cc: Ultrasound Imaging Section
members

NPL

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Mr Charles Grossman
Chairman, NEMA Ultrasound Imaging Section
Technical Committee
National Electrical Manufacturers Association
2101 L Street, N.W. Suite 300
Washington, D.C. 20037
U.S.A.

ct line 081-943-6154
Our ref NPR 3/6/9B
our ref
Date 7 June 1994

Dear Mr Grossman,

Thank you for your letter dated 31 May 1994 referring to the NPL pulsed Doppler ultrasound project. Your Technical Committee have raised important points and we appreciate the interest being taken in this project. Before dealing with the specific points raised, I would like to explain our position in relation to this project.

The project is one which is being undertaken by The National Physical Laboratory on behalf of the UK Department of Health (DoH). Therefore, although NPL will have a significant say in how the results will be disseminated, ultimately it is the responsibility of the DoH. I am therefore not in a position to give absolute assurances about how the results will be published and how much opportunity will be given to manufacturers to comment on the results and to have their comments reflected in the proposed publication. I do however believe that this is an important aspect of the project and I will do my best to ensure that manufacturers are kept informed and their comments are taken on board. It is essential for manufacturers to realise however that NPL is contractually obligated to deliver results to DoH which means that if manufacturers are to register their comments for inclusion they will have to respond quite quickly. This aspect concerns me because I originally requested data for Stage I in mid-February and to date some major manufacturers have yet to provide this information. Maybe the reason for the current delay is with the concerns that you indicate in your letter, and it is for this reason that I am responding quickly to your letter. I am therefore hoping that manufacturers will respond more rapidly now and also at later stages of the project when their comments may be important. At later stages, we will do our best to give manufacturers as much time as possible but it is difficult to be precise at this stage but a response within four to six weeks would be expected.

Dealing with your specific points

Details about the proposed test methodology

It should be noted that NPL is the UK National Standards Laboratory and has an on-going programme for the development of measurement standards in medical

ultrasonics. This programme includes, amongst other things, the development of improved methods for theoretical prediction of ultrasonic heating and the development of improved methods for experimentally determining temperature rise. Some of the output of this work feeds into the international standards through participation in IEC activities. Given these responsibilities, the processes of systematic study and validation play an important role in NPL's work.

Looking at the project, Stage I involves the determination of temperature rises based on methods published by NCRP and AIUM/NEMA (ODS). Manufacturers have been requested to provide values for a set of acoustical parameters necessary to enable the calculation of the temperature rises for different clinical conditions, defined in the NCRP and ODS documents. These results will be the first set to be published. We will take care to liaise with manufacturers to enable our results to be seen and for manufacturers to comment on them. As already indicated, time scales are important and the longer the delay in providing information, the less time there will be for these important later interactive phases.

Stage II will involve selecting a subset of the transducer/systems identified in Stage I and, with the collaboration of manufacturers, making more detailed acoustic output measurements. The main purpose of these measurements will be to determine the actual intensity distributions within the beams, an aspect which has been identified as being important for reliable assessment of temperature rises (see the attached paper by Adam Shaw which is to be published in 'Physics in Medicine and Biology' and the paper by Bacon and Shaw). This information will be used to confirm, or otherwise, the predictions obtained in Stage I and also to enable predictions to be made using more complete theoretical models. For instance, a number of different methods of predicting temperature rise are now established at NPL including the use of finite-element calculations. Note that so far all work is based on theoretical predictions of temperature rise using measured acoustical data.

Stage II and Stage III will also involve making temperature measurements using thermal test objects closely simulating the NCRP and ODS models. These thermal test objects are more refined versions of that illustrated in Figure 1 of the published paper by Bacon and Shaw (copy attached) but with a number of significant differences. First, attenuating medium will be employed in the propagation path in order to simulate the model being matched (NCRP or ODS). Second, the thermal sensor test object will be based on an encapsulated version to ensure reproducibility. The thermal sensors used are thin film thermocouples which have been shown to provide reliable measurements of temperature rise, overcoming problems of viscous heating and thermal conduction problems experienced with wire thermocouples.

As far as the properties of the tissue mimicking materials are concerned, at the region of the thermal sensor, attenuation of the soft tissue mimicking material will be close to 0.44 dB cm^{-1} MHz^{-1} and thermal conductivity close to 0.5 W K^{-1} m^{-1}. For the soft tissue thermal test object, the thermal sensor will be sandwiched

between layers of gel. Small corrections based on theoretical analysis will be made to account for deviations between the thermal test object configuration and that of an ideal test object.

Perfusion is not taken into account in the measurements but will be considered as a correction to the measured values in a way similar to that used in the paper by Bacon and Shaw (further details to be published). Essentially, this correction is based on knowledge of the time history of the heating curve measured in an unperfused test object. The only input parameter is the perfusion constant and this will be assumed to be the same as that of the model being simulated (1000 s in the case of NCRP and equivalent to 750 s for the ODS). It should be noted that the importance of perfusion depends on the situation being considered. Perfusion plays a less important role for narrow focused beams, for short exposure times and when tissue/bone interfaces are being considered.

Stage III will also include work to mimic more closely clinical situations. The models used by NCRP were worst case and those used for the ODS were reasonable worst case, both being very simplified models. We have undertaken in the UK, also partly supported by our Department of Health, a project at St George's Hospital to establish a set of layered models derived from extensive analysis of clinical scans for critical clinical applications of ultrasound (initial results are published in UMB, vol. 19, pp 319-329, 1993, further publication by the St George's group is in press). One of the objectives of the current DoH Doppler project is to see how results using these more realistic models compare with those of the ODS. This will involve both theoretical and experimental simulations. For this stage of the project, publication will be in the form of a research paper and therefore there will be no attempt to give results related to particular manufacturers equipment.

In conclusion, an overriding consideration in the Department of Health project is therefore to obtain information based on:

* Comprehensive data on ultrasonic field quantities from manufacturers;
* Comprehensive measurements of acoustic field quantities;
* Improved theoretical calculations taking into account actual intensity distributions in the beams;
  Experimental measurements using test objects which closely simulate the models being studied and incorporating corrections for perfusion (and other artifacts) based on theoretical estimates.

This work is expected to be published (in consultation with manufacturers).

The last stage, which would <u>not</u> be correlated with particular equipment, would involve:

* Improved models based on layered models derived from the analysis of

clinical scans.

Presentation of results as *in vivo* temperature rises?

None of the results will be presented on the basis that they represent *in vivo* temperature rises. Relating the results to actual *in vivo* temperature rises requires further work which we hope will be undertaken as a follow-up to this project. The limitations of the models (NCRP and ODS as well as the more refined models) will be pointed out in the publication.

Provision of results prior to publication

As already indicated, the intention is to provide manufacturers with results prior to them being finalised and presented for publication. We expect to liaise with manufacturers during the measurement process (Note: To be undertaken on only a few systems) and hope to be able to reconcile any problems before finalising the results. If, once the results are finalised, manufacturers want to record specific comments, we will endeavour to include these comments in the publication. In this case, the manufacturer will have the opportunity to see the text prior to it being finalised.

I hope that these comments and the enclosed copies of related documents reassure your members that the purpose of the project is to establish reference data based on standardised and well-defined test methods.

With your assistance, I look forward to receiving full cooperation from manufacturers, and the execution of a successful project.

Yours sincerely,

Dr Roy C Preston
Division of Radiation Science and Acoustics

National Electrical Manufacturers Associa
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Fax (202) 457-8

Dr. A.M. Calverd
Department of Health of the U.K.
Skipton House
80 London Road
Elephant and Castle
London SE1 6LW
UNITED KINGDOM

August 2, 1994

Dear Dr. Calverd:

I am the Industry Manager at the National Electrical Manufacturers Association (NEMA) with responsibility for the Ultrasound Imaging Section. NEMA is the largest U.S. trade association representing and serving America's electroindustries. The Ultrasound Imaging Section, is comprised of 19 ultrasound equipment manufacturers, and thus represents over 90% of the diagnostic ultrasound industry. This letter seeks to share with you some of our concerns on the NPL/DHS project to model thermal risk in tissue due to ultrasound exposure.

NEMA has noted with great interest the proposed NPL project to establish the thermal hazard of Pulsed Doppler ultrasound diagnostic equipment. We support the development of more accurate methods and models for predicting thermal rise in tissue, including the development and improvement of thermal test objects. The Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment which NEMA developed in a joint effort of the U.S. Food and Drug Administration, American Institute of Ultrasound in Medicine, and other international ultrasound-related clinical societies, reflects the industry's staunch commitment to ultrasound safety, particularly with respect to thermal and cavitational bioeffects.

NEMA members will wish to cooperate with any project which they believe will improve our understanding of ultrasound equipment and the effects of ultrasound on the human body. However, before we can undertake to give our full cooperation to the NPL, we would like to have our concerns about some aspects of this project understood and satisfactorily answered.

Firstly, we are concerned about the methodology of the calculations and measurements. Will any reports establishing the validity (and limitations) of the methods and test objects developed in this study be released prior to the publication of results? Will NEMA have an opportunity to review and comment on these methods?

Secondly, we would like assurances that manufacturers will be kept in touch with the progress of the project and will see interim reports and results on which they will be able to comment.

Thirdly, we are concerned about the way in which the

results of this project will be represented to ultrasound system users and the public. Will NEMA be able to comment on the presentation? Will manufacturers be able to comment on results relating to their equipment, and will their comments be included in the publications?

We have had helpful correspondence with Dr. Preston on these issues but while he has gone some way to offer reassurance, he has made it clear that control of the project and decisions about publications rest with the Department of Health.

We are therefore seeking answers from you to these questions. We feel that it is absolutely essential that these concerns be discussed and satisfactorily resolved. Care must be taken that the public not be unduly alarmed by the publication of test results derived from nonvalidated test methods. It would be a great disservice to this lifesaving technology to assign a significance to results that do not represent actual in-vivo scanning conditions.

Dr. Preston has stated that none of the results will be presented on the basis that they represent in-vivo temperature rises. We would be grateful for your confirmation that this will be the case and that the possible relationship of the results to the real clinical situation will be sensitively discussed. Dr. Preston has also indicated that he will try to include manufacturers' comments in the publications but appears to be unable to give a firm promise.

It would clearly help to avoid a protracted correspondence if a face-to-face discussion could be held to resolve these issues. If you will agree to hold a meeting for this purpose, we would propose (for reasons of convenience) that NEMA be represented by a U.K. resident, Mr. Gordon Higson. Mr. Higson is a former Director of Scientific and Technical Services in the Department of Health and is currently Chairman of Medical Technology Consultants Europe Ltd. He is fully conversant with the issues and is known to Dr. Preston. In the hope and expectation that you will agree to a meeting, I will ask Mr. Higson to phone you in a few days time.

If you have any further questions, please do not hesitate to contact me. I can be reached at (202) 457 - 8484, or by fax at (202) 457 - 8411.

The NEMA Ultrasound Imaging Section looks forward to your clarification of these issues and hopes that we can work together for the advancement of the safe use of diagnostic ultrasound.

Sincerely,

Richard Eaton,
Industry Manager

cc: Ultrasound Imaging Section members

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Richard Eaton
Industry Manager
NEMA
2101 L Street
NW Suite 300
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USA

18 August 1994

Dear Mr Eaton

Thank you for your letter of 2 August concerning the DH/NPL investigation of the temperature rise from diagnostic ultrasound equipment. In response to your specific questions, I can give you the following assurances:

Test methods

Dr Preston wrote to Mr Grossman on 7 June 1994, giving details. I understand that the methods for Stage I are those that are already published by AIUM/NEMA and NCRP. Stage II test methods are those which are being developed as part of the UK National Measurement System, based on published procedures, and on those which are being discussed through the International Electrotechnical Commission (IEC), in which I believe your members are actively involved. NPL is the UK's national standards laboratory: part of its remit is the establishment of validated test methods. The entire procedure will be subject to peer scrutiny through open publication, a policy consistent with current practice at NPL and embodied in DH research contracts.

Progress/interim reports etc

Manufacturers will be informed of results and will be asked to comment and advise, particularly where findings are anomalous or unexpected. DH requires this undertaking, which is consistent with our own practice. However, you will appreciate that the project must keep to schedule and that manufacturers are expected to respond quickly.
Dr Preston is concerned that he replied to NEMA's original letter within 10 days but, two months later, his assurances are still being questioned. You further raised a concern that Dr Preston did not provide a commitment to include all manufacturers' comments in any publication. As is the normal DH practice, he expects to be able to resolve any anomalies and discrepancies before publication. We do, however, expect a timely response to any questions raised, and I see little purpose in suppressing a repeatable finding merely because it is unexpected and unexplained at the time of writing.

Relation to in-vivo temperature rises

Again, this has been dealt with by Dr Preston. We have not commissioned the measurement of in-vivo temperature rises, and we do not intend to misrepresent any experimental data. Limitations of the models will be pointed out in the publication. As you assert that the technology is lifesaving, and as we have not contracted NPL to investigate biological effects or clinical outcomes, I do not see how any public alarm could arise from the publication or circulation of Dr Preston's findings.

Both Dr Preston and I are aware of the need for sensitivity in the presentation of the information. Objectivity is essential, as is a discussion of the limitations of the test methods. We would be pleased to receive any guidance that you may have on the interpretation of test results, during the course of this important project.

Having given the assurances that you are seeking from DH, I would be pleased if you could give me a date by which your companies will provide Dr Preston with the requested acoustic output information. Mr Higson called me a few days ago, and I was able to tell him that a number of NEMA members had in fact been very prompt and helpful in complying with Dr Preston's requests. I pointed out that it is in the interests of all suppliers to ensure that the equipment that NPL receive for testing is in new condition or properly serviced, and accompanied by authoritative data from the manufacturer.

Yours sincerely

Dr A M Calverd

National Electrical Manufacturers Assoc
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Diagnostic Imaging and Therapy Systems Di

September 16, 1994

Dr. A.M. Calverd
Department of Health of the U.K.
Skipton House
80 London Road
Elephant and Castle
London SE1 6LW
UNITED KINGDOM

Dear Dr. Calverd:

Thank you for your letter of August 18, 1994 which came in response to our questions in our letter of August 2. While you have addressed some of the issues we have raised involving the NPL project, we have not yet received assurances on several issues, for which we are requesting clarification.

We are still unsure whether the Stage I calculations will use the actual AIUM/NEMA and NCRP methods, or will use methods based on them. Moreover, NEMA is not certain whether the methods used in the Stage II calculations using thermal test objects for making temperature measurements, will be made known to the NEMA members before or after the NPL report has been published. Your statement that the entire procedure will be subject to peer scrutiny through open publication leaves us unsure on this point. Since the results will be used to predict temperature rises, validity of the measurements is critical. NEMA would very much wish to be informed of the test methods to be used at an early stage, before publication.

Your response to our request that the manufacturers be kept in touch with the process is not as clear as we had hoped. We would be grateful if you could confirm that manufacturers will in all cases be informed of results and be asked to offer comments. We recognize your need for timely responses, and will urge that our members reply promptly with their comments.

NEMA appreciates your interest in our thoughts on the interpretation of results. We would like to know your views as to how the presentation of results will be handled. Mr. Higson will be attending the NPL meeting on October 19, and perhaps you and Dr. Preston will have an opportunity then to discuss this issue with him at that time.

Meanwhile, I will bring your request for responses from NEMA before the Ultrasound Imaging Section membership, at our

meeting on September 20. While I will endeavor to present your requests to the Ultrasound Imaging Section in a prompt manner, you should be aware that NEMA, as an association, cannot command its members to undertake action on this project. The decision to participate rests wholly within each manufacturer's discretion.

If you have any further questions, please do not hesitate to contact me at (202) 457 - 8484, or by telefax at (202) 457 - 8411.

We look forward to hearing from you.

Sincerely,

Richard Eaton,
Industry Manager

cc: Gordon Higson
Ultrasound Imaging Section members

NPL

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Mr Richard Eaton
Chairman, NEMA Ultrasound Imaging Section
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Direct line +44 181 943 6154
Our ref NPR 3/6/9B
Your ref
Date 30 September 1994

Dear Mr Eaton,

Alan Calverd passed on to me a copy of a letter dated September 16th that you recently sent to him regarding the Doppler ultrasound heating project that we are undertaking at NPL on behalf of the UK Department of Health. He thought it best for me to reply to some of your remaining technical concerns.

Stage I calculations

The aim here is to use the methods specified in the AIUM/NEMA ODS or the NCRP to determine the thermal indices. However, as we are asking manufacturers to provide the raw acoustical data, we cannot be sure that they have derived this using the methods specified in these two documents. By asking manufacturers to supply a set of acoustical parameters - our Stage I specification request - the intention was to ensure that the correct acoustical parameters are provided by manufacturers. So, the aim of the project for Stage I is purely to undertake the determination of the thermal indices using the algorithms specified in the AIUM/NEMA ODS and the NCRP report but based on acoustical data provided by manufacturers. From the data already provided by some manufacturers, we have also received their estimates of thermal indices which allows a useful cross-check.

Stage II and III

The first part of Stage II will be to model temperature rise from actual intensity profile data and to make measurements using thermal test objects. For instance, we will measure the actual intensity profiles, both laterally and axially, and then apply improved methods of predicting temperature rise. These procedures will be similar to the work already published by Adam Shaw (see accompanying publication) and also include predictions based on finite element calculations. As far as measurements are concerned, these will be based on thermal test objects which are a further development of the work of Bacon and Shaw (copy of paper enclosed) and will follow the work being developed within IEC. In answer your specific question, more detailed results of our work on validating thermal test object test methods will be made available to manufacturers collaborating with us on this project before any results are published.

NPL

Notification of results prior to publication
For Stage I, each manufacturer who provides us with data will be provided with the results for their systems before they are published. They will be given time to respond as indicated previously. For Stage II and III, in cases where manufacturers have provided systems for more detailed evaluation, we would provide each company with results for their particular systems, again before publication. At all stages we would endeavour to deal with any concerns and queries before final compilation for publication. All those who cooperated in providing Stage I data, even if their systems did not proceed to Stage II and II, will be provided with a copy of the final report.

In conclusion, our aim is to keep manufacturers informed of the results prior to any publication. However, as pointed out previously, when we provide results to manufacturers before publication, we will have to limit the response time available to be within 4/6 weeks and we will endeavour to resolve problems prior to publication.

A number of NEMA members have already provided us with very useful acoustic data. I hope that those members who have not yet made up their minds will recognise the advantages of supplying pristine equipment and of being able to comment on results at an early stage and will co-operate with our project.

I hope that I have provided the assurance that you and your members are seeking and hope that this will allow the project to proceed more rapidly.

Yours sincerely,

Dr Roy C Preston
Division of Radiation Science and Acoustics

Copy: Dr A Calverd, DoH
Mr Gordon Higson, MTC Europe

National Electrical Manufacturers Associat
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Diagnostic Imaging and Therapy Systems Divis

March 15, 1995

Dr. Adam Shaw and Dr. Roy Preston:
National Physical Laboratory
Division of Radiation Science and Acoustics
Queens Road
Teddington, Middlesex
UNITED KINGDOM TW11 OLW

Dear Adam Shaw and Roy Preston:

Thank you for your telefax of March 15, 1995.

Since the Ultrasound Imaging Section has a very full agenda, we would like to have you come to our meeting at about 2:15 p.m., to discuss the NPL Project. In this way, we can address these issues early in the meeting, and resume the NEMA meeting thereafter.

The meeting will be held in Pacific 4B in the Marriott Hotel. The hotel is located at 55 Fourth Street in downtown San Francisco.

If you have any questions, please feel free to call me.

I look forward to our meeting on Tuesday, March 28

Sincerely,

Richard Eaton,
Industry Manager

APPENDIX E.

Comments by manufacturers on preliminary report of September 1996.

No comments relating to the general presentation of the preliminary report were returned. Specific technical comments relating to the tables of results were received from Aloka and B&K and are reproduced in this Appendix along with NPL responses to the comments. Tables 1 and 3 have been modified from the preliminary report in the light of these comments. The comments from Aloka included several additional pages which contained acoustic output data and thermal index values; these pages have not been reproduced.

Comment for NPL report "Assessment of the likely thermal index values for pulsed Doppler ultrasonic equipment-Stage I: calculation based on manufacturers' data"

'96/11/18 Miwa.Naito and Toshiyuki.Matsunaka

We re-calculated all thermal index values using data which were provided by Aloka, and we found that some results of our calculation were different from those of NPL.
The values of NCRP ΔT_F1, ΔT_B, NEMA TIS and TIB of NPL are very close to those of Aloka. **On the other hand, the values of NCRP ΔT_H4, ΔT_F2, ΔT_F3, NEMA TIC of NPL are not consistent with Aloka's results.**

We send you our calculation results which are different from those of NPL with "*" on Table 1 and excel calculation sheets for each probe. **Please check them. We hope the report to be published will be corrected.**

1. NCRP ΔT_F2 and ΔT_F3 value

With reference to Eq.5.25, we suggest it should be worked well with d in the Eq.5.23 better than actual 6dB beam diameter, d6. Even if using d6 value, we think something wrong for NPL's results of ΔT_F2 and ΔT_F3.

We calculate ΔT_Fs using d and d6 each.
The results of ΔT_F1 using d6 are very consistent with the results of NPL But the results of ΔT_F2 and ΔT_F3 of NPL are extremely high.
Although we don't know other manufacturer's raw data, we think their results of ΔT_F2 and ΔT_F3 derived by NPL will be not correct. For example, NPL derived results as follows, in the cases of ATL, HDI 3000, P3-2 on Table 2, the ratio; ΔT_F1/ΔT_F2=1.1/7.1=0.15, and ΔT_F2/ΔT_F3 =7.1/8.0=0.89.
Those of ratio do not coincide with each other.

However the ratio (ΔT_F1/ΔT_F2) must be equal to (ΔT_F2/ΔT_F3), the reason is as follows,

From Eq.10.1(NCRP 113 p.169), Wdeg is

$$Wdeg=(W^*\_deg)*10^{(Af/10)}$$ f is frequency
$$Wdeg\_F1=(W^*\_deg)*10^{(A1*f/10)}$$ A1 is 1.0 dB/MHz
$$Wdeg\_F2=(W^*\_deg)*10^{(A2*f/10)}$$ A2 is 0.75 dB/MHz
$$Wdeg\_F3=(W^*\_deg)*10^{(A3*f/10)}$$ A3 is 0.5 dB/MHz

$$\Delta T=W0/Wdeg$$ W0 is total power

$$\Delta T\_F1/\Delta T\_F2=10^{\{-(A1-A2)*f/10\}}=10^{(-0.025f)}$$
$$\Delta T\_F2/\Delta T\_F3=10^{\{-(A2-A3)*f/10\}}=10^{(-0.025f)}$$

Please check your excel calculation sheet.

In the calculation of ΔT_Fs, W*_deg defined by Eq.5.25 must be used. But in the cases of ΔT_F2 and ΔT_F3, we guess NPL reffers to W*_deg for ΔT_B defined by Eq.5.14 instead of W*_deg for ΔT_Fs.

$$W^*\_deg=(101/f)/(1-0.321n(d))$$ Eq.5.25 for ΔT_Fs
$$W^*\_deg=4*d6$$ Eq.5.14 for ΔT_B

Our Ref: AN0601
Your Ref:

Dr T Matsunaka
Aloka
3-7-19 Imai
Ohme-Shi
Tokyo 198
JAPAN

Dear Dr Matsunaka 23 January 1997

Thermal index project for UK Department of Health

Thank you very much for commenting on our report CIRA(RES)008 - *Assessment of the likely thermal index values for pulsed Doppler ultrasonic equipment - Stage I: calculation based on manufacturers' data.* You have clearly put a great deal of effort in to checking our calculations for your equipment. I will reproduce pages 1 and 2 of your comments in our final report along with this letter; I will not reproduce the other pages, since they contain acoustic output values which you may not want published. I will answer each of your four itemised comments in turn.

1. NCRP ΔT_F2 and ΔT_F3 values

In calculating the values for NCRP_F2 and NCRP_F3 in our tables, we have followed the flow-chart given on page 160 of NCRP report 113 (Chapter 10. Conclusions and Recommendations). According to this flow-chart, the first trimester foetal model assumes a soft tissue target at the focus of the beam, whereas the second and third trimester models assume that the target tissue is bone (this is because bone mineralisation, and acoustic absorption, increases with gestational age). This means that the ratio of NCRP_F1:NCRP_F2 should be different to the ratio of NCRP_F2:NCRP_F3 and also that the NCRP_F2 and NCRP_F3 values will be high.

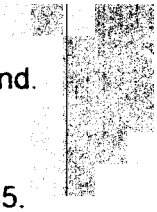
2. Radius of curvature

This was a common misunderstanding (see next paragraph). We have removed these values from our data sheets.

3. NCRP ΔT_H4 value

Strictly, your procedure for calculating NCRP_H4 is correct. However, the concept of a radius of curvature of the acoustic wavefront only really applies to a focussed bowl transducer. Generally, if a value for radius of curvature was supplied by a

dr. Shaw,



s nice to speak with you during the TC87 meeting in Charlottenlund.

eived the NPL report from Bjørn Fortling in our UK office.

e seems to be some misunderstandings in the table for B&K 3535.

probe combinations with 1850 are not possible. I beleive, 1850 (a motor
or transducers 8523,30,31,33,39)should be deleted, at least the
onal bandwith seems correct for 8542,43,44 and 45. There is no
ng axis then, the 60 degrees are simply the sector angle of a curved
. This is also valid for 8553 and 54.

nder, how you derive the high numbers(NCRP F2,F3,B) for 8553. It is
similar to 8543 (without 1850, I assume), also in terms of Ispta and
er. Actually,8543 has the highest Ispta and power numbers but gives low
R F2 etc.??

se indicate the user guide version(s) from which you used the acoustic data.

looking forward to solve these problems. Please feel free to contact
or further information.

s Sincerely

Brænder

Ultrasound Systems
dtoften 9, DK 2820 Gentofte, Denmark

Our Ref: AN0601
Your Ref:

Dr V Braender
B&K Ultrasound Systems
Sandtoften 9
DK2820 Gentofte
DENMARK

Dear Dr Braender 23 January 1997

Thermal index project for UK Department of Health

Thank you very much for commenting on our report CIRA(RES)008 - *Assessment of the likely thermal index values for pulsed Doppler ultrasonic equipment - Stage I: calculation based on manufacturers' data.* I will reproduce your Email in the final version of our report along with this letter. You have made two comments which I will address below.

Firstly, my apologies for the incorrect numbering of some of your transducers; we have corrected this on our data sheets.

Secondly, we have discussed the high values for NCRP F2, F3 and B by 'phone and agreed that these values may be due to some inconsistencies in the acoustic data provided since the data is drawn from different tables in your user manuals and may not all apply to the same combination of scanner settings. I have added some additional comments to our table of results for your equipment.

I will send you a copy of the final report shortly. Many thanks for all your help.

Yours sincerely

Adam Shaw
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fax: +44 (0)181 943 6161
Email: AS@npl.co.uk

APPENDIX F.

Example spreadsheet

IPL spreadsheet for calculation of Thermal and Mechanical Indices from manufacturers' acoustic data.
Part of DoH project: Thermal Hazard from Doppler Ultrasound .

nter as much information as possible in the double lined region. Thermal and mechanical indices are calculated in column B from row 20 onwards.

Manufacturer:	Any company	Nominal values	Scanned or unscanned?	Unscanned	
			Nominal frequency (MHz)	7.00	MHz
Platform type:	Topnotch		Transducer diameter (mm) -	20.00	mm
Platform description:	Panacea		Transducer diameter (mm) -	10.00	mm
			Rectangular or circular?	Rectangular	
Transducer type:	A1plus		Radius of curvature (mm)		
Transducer description:	hyper phased		Nominal focal distance (mm)	20.00	mm
Operating conditions:	Other notes:				
	...				

Comments: Sample worksheet only

Predicted Thermal Indices

TCRP homogeneous	0.59
TCRP 1st trimester obstetric	0.14
TCRP 2nd trimester obstetric	0.74
TCRP 3rd trimester obstetric	1.07
TCRP bone	0.51
TAIUM soft tissue T.I.	0.32
TAIUM bone T.I.	0.87
TAIUM cranial T.I.	0.38

Warnings and Cautions

Free-field focal diameter used

Caution: position of free-field focus only is given

Measured values	Parameter	Free-field	Derated	Used	Units	Source
Essential data	Centre frequency (MHz)	6.40		6.40	MHz	Free field centre frequency
	Radiating diameter (mm) - X	6.16		6.16	mm	Free-field radiating diameter
	Radiating diameter (mm) - Y			6.16	mm	Free-field radiating diameter
	Focal distance (cm)	2.08		2.08	cm	Caution: position of free-field focus only is given
	Focal diameter (mm) - X	1.17		1.17	mm	Free-field focal diameter used
	Focal diameter (mm) - Y	1.17		1.17	mm	Free-field focal diameter used
	SPTA intensity (mW/cm2)			1,146.24	mW/cm2	Ispta calculated from derated Ispta
	Power (mW)	10.50		10.50	mW	Radiated power measured
Non-essential data	Pulse repetition rate (Hz)	13,800		13,800	Hz	
	SPPA intensity (mW/cm2)		64,000	160,524	mW/cm2	
	Positive pressure (MPa)			#N/A		
	Negative pressure (MPa)	1.50		1.50	MPa	

Axial variation	Distance (cm)	0.60	0.70	0.80	1.05	1.20	1.60	1.80	1.90	2.00	2.20	3.00
	Free-field intensity (mW/cm2)											
	Derated intensity (mW/cm2)	120.00	130.00	110.00	40.00	80.00	310.00	400.00	420.00	430.00	380.00	170.00
(derived)	Derated power (mW)	8.05	7.71	7.37	6.60	6.18	5.18	4.74	4.53	4.34	3.97	2.79
(derived)	Used intensity (mW/cm2)	120	130	110	40	80	310	400	420	430	380	170
(derived)	Derated (Power*Intensity)	966	1,002	811	264	494	1,605	1,895	1,904	1,865	1,509	474
(derived)	(Derated P or I) x (z>Zbp)	0.00	0.00	0.00	6.60	6.18	5.18	4.74	4.53	4.34	3.97	2.79

Secondary values

Aperture area (cm2)	0.38
Break point distance (cm)	1.04
Z_B.3 (cm)	1.90

Predicted Mechanical Index

TAIUM M.I.	0.24

Warnings and Cautions

AIUM model A	#N/A
AIUM model B	0.20
AIUM model C	0.32
AIUM model D	0.87
AIUM model E	0.38

APPENDIX G.

Guidance for use of spreadsheet

Note: this is an extract.

Page numbers and references to Appendices and Sections do NOT refer to parts of this current report.

2.3 ENTERING DATA

A sample spreadsheet is given in Appendix A.

The spreadsheet is divided into a number of main areas: a description of the equipment, nominal values describing the transducer, operating conditions and other notes, measured acoustic parameters, variation of intensity with distance from the transducer, and Thermal and Mechanical Indices. The main difficulty that will be encountered is that the information given by the manufacturer is often in a different form to that present on the spreadsheet. This section should provide some help in deciding how to enter the most appropriate values into the spreadsheet.

There is no need to fill in all the data cells in the spreadsheet. Any values which are not known should simply be left blank or as 'NA#' (meaning 'Not Available'). The calculation cells will attempt to give a best estimate of any important parameters which are not known. The most important data cells are those which describe the scanner/transducer combination and the outlined cells in the Measured Values section. The latter allow thermal indices to be calculated; the former allow calculated thermal indices to be associated with particular equipment. It is important to describe the equipment and operating conditions as fully as possible to maintain traceabilty.

In the instructions that follow, cells are referred to by their column and row numbers: *eg* B8 is the cell in column B on row 8.

2.3.1 Equipment

Manufacturer
The name of the manufacturer should be inserted in B8 (eg.Hewlett Packard, ATL).

Platform Type
The model name or number of the platform, also referred to as the 'system' or 'scanner', should be inserted in B10.

Platform Description
Enter any other information which may identify the platform in B11 (eg. the platform may be designated for cardiovascular use, or software update may be included).

Transducer Type
This may also be referred to as the 'probe' and should be inserted in B13. There may be initially some confusion as to which is the 'Platform Type' and which is the 'Transducer Type'. Typically, many different transducers can be used with each platform. It may also be possible for the same transducer to be used with several platforms.

Transducer Description
This should include what sort of transducer it is eg. phased array, linear array, and should be inserted in B14.

2.3.2 Nominal Values

These are approximate values which the manufacturer has provided to describe the transducer. In the event that a measured value is not available for a particular acoustical parameter, the corresponding nominal value may allow an estimate of thermal or mechanical indices to be made.

As values are entered or calculated for any acoustic parameter, the magnitude of the entered number is automatically checked to see if it falls within the range expected. If it does not, a series of question marks are appended to the required units in the column immediately to the right of the number. If the question marks appear, check carefully that the correct units have been used: common confusions are W cm^{-2} or W m^{-2} in place of mW cm^{-2} and cm in place of mm, or *vice versa*. The question marks are simply to alert the user and do not prevent any calculations being carried out; if the number has been entered correctly, ignore the question marks.

Scanned or unscanned
Enter 'Unscanned' for pulsed Doppler or M-mode or 'scanned' for B-mode and colour flow Doppler in E8. The default value is 'Unscanned'.

Nominal frequency
The frequency given by the manufacturer, possibly as part of the transducer type number, to indicate approximately the acoustic frequency of the transducer. This should be placed in E9.

Transducer diameter
The width or diameter of the body of the transducer parallel to the scan plane and perpendicular to the scan plane should be placed in E10 and E11 respectively. Sometimes the transducer area will be given instead; in this case, the square root of this area should be entered in both E10 and E11. If the transducer is circular, however, the diameter may be calculated exactly from $d = (4\ A\ /\ \pi)^{1/2}$. Some confusion may arise between 'Transducer Diameter' and 'Radiating Diameter' (see later).

Rectangular or circular
The shape of radiating face of the transducer should be inserted in E12. This information may be given along with the transducer type or description by the manufacturer. The default is 'Rectangular'.

Radius of curvature
The radius of curvature should be inserted in E13. This is the concave curvature of the wavefronts emitted by the probe, *not* the (generally convex) curvature of the actual probe,

and is related to the focal length. Generally, this information will only be available for mechanical sector scanning transducers.

Nominal focal depth
This may also be referred to as the mechanical focus and is an approximate value for the focal length which may be given along with the transducer type or description by the manufacturer. This should be entered in E14.

2.3.3 Notes

Operating Conditions
The measured values obtained by the manufacturer correspond to particular operating conditions ie. settings of scanner controls. These conditions include power settings, gatewidths, whether conditions were set to obtain maximum thermal indices or not, pulse repetition rate or frequency (PRR or PRF) etc. Any information which may be relevant should be entered in A17.

After entering the information, ensure that the full contents of the cell are displayed by placing the cursor in the grey border between rows '17' and '18' and dragging down the cursor while holding down the left button of the mouse .

Other notes
Any other useful information provided by the manufacturer which does not have its own specific box should be inserted in B17. Also, any values which are estimated and not supplied directly by the manufacturer should be explained here.

Other notes or observations which may be useful can be entered into any unused cells on the worksheet.

2.3.4 Measured values

The values appearing in this section are those of important acoustical parameters for the platform/transducer combination in question and should have been measured under the operating conditions described in 2.3.3. These values are used in the calculation cells to estimate thermal indices. This section is split into two parts; one including data which is essential for the calculation of thermal indices, and the other including non-essential data which may be supplied for completeness. Each part has two columns of data cells - for free-field and derated values - the cell with the more pronounced border in each case being the value which is more directly required by the NCRP or AIUM/NEMA formulae. There is no need to enter a value in both columns. If the manufacturer supplies a free-field value for intensity or pressure, enter it in the free-field column; if a derated value is given, enter it in the derated column. The third column, headed 'Used' contains calculation cells and must not be altered.

Free-field values are those obtained in water, whilst derated values may also be referred to

as 'in situ' values. Some manufacturers may indicate that a value is derated by the use of a subscript eg. $SPTA_{.3}$ indicates I_{spta} derated by 0.3 dB cm^{-1} MHz^{-1}.

The question often arises as to whether a given value is derated or not - some judgement must be used in these cases. For instance, if most of the values have been derated, but one parameter is unspecified, it is probably derated too. Generally, when a value is derated the derating constant (0.3 dB cm^{-1} MHz^{-1}) will be quoted.

As values are entered or calculated for any acoustic parameter, the magnitude of the number is automatically checked to see if it falls within the range expected. If it does not, a series of question marks are appended to the required units in the column immediately to the right of the 'Used' column. If the question marks appear, check carefully that the correct units have been used: common confusions are W cm^{-2} or W m^{-2} in place of mW cm^2 and cm in place of mm, or *vice versa.*

The source of the numbers in the 'Used' column will be reflected by any advice given in red in the second column to the right. Check that the comments here correspond with your own expectations.

ESSENTIAL DATA

Centre frequency

This should be placed in E20(free-field) or F20(derated). If it is not clear which cell to place it in, it is most likely to be a free-field value.

Radiating diameter

The diameter of the radiating area of the transducer parallel to the scan plane and perpendicular to the scan plane should be inserted in E21 and E22 respectively, as the values will be the same in the free-field as in the derated case. The 'Radiating diameters' may also be referred to as the 'entrance azimuth' and 'entrance elevation'. If only the radiating area is given, the diameters may be estimated by taking the square root of the area for a rectangular aperture, or $\sqrt{4 \times \text{Area} / \pi}$ for a circular transducer.

Note: the 'transducer diameters' described earlier give the dimensions of the body of the probe, whereas the 'radiating diameters' give the dimensions of the active region of the transducer face which is generating the ultrasound.

Focal distance

This is the distance from the transducer face at which the I_{spta} is a maximum. The direction of propagation of the ultrasound is normally defined as being in the z-direction, so the focal distance may often be described as 'z-I_{spta}max' or similar. The free-field Ispta reaches a maximum at further from the transducer than the derated Ispta so it is important whether the value given refers to the free-field or derated maximum and to enter the value in the correct column.

Focal Diameters
These give the -6dB diameter of the beam parallel and perpendicular to the scan plane at the focal distance. If the beam area is given, the focal diameters may be estimated by taking the square root of the beam area. A default value of 5 wavelengths is taken if a measured beamwidth or area is not known.

SPTA intensity
This is the spatial-peak temporal-average intensity and is the maximum time-averaged intensity in the beam; it occurs at a distance from the transducer equal to the focal distance. Take care to enter the value in the correct column. Generally, if the position of the free-field focus is given, I_{spta} will also be free-field, and if the position of the derated focus is given, I_{spta} will also be derated. However, it is possible that the free-field I_{spta} measured at the position of the derated focus will be given; in which case the I_{spta} should be placed in the free-field column and the focal distance placed in the derated column.

Power
This is the total acoustic energy generated by the scanner per second, and will normally be a free-field value. It should be placed in E27. Sometimes a derated power measured at the focus may be given. In this case, enter the value in F27.

NON-ESSENTIAL DATA

Pulse repetition rate
This is the number of pulses emitted by the transducer per second - sometimes referred to as the Pulse Repetition Frequency (abbreviated to PRR or PRF).

SPPA Intensity
This is the spatial-peak pulse-average intensity, and is the average intensity over the duration of a single pulse.

Positive Pressure
The maximum positive pressure (either free-field or derated) in the field. If only the value at the focus is known, use this instead.

Negative Pressure
The maximum negative pressure in the field (see Positive Pressure above). This parameter, whilst not needed to calculate thermal indices, is essential to calculate the AIUM Mechanical Index.

2.3.5 Axial variation

This section of the spreadsheet should include axial information on the beam which should allow a graph of free-field or derated intensity against distance from the transducer to be drawn in the spreadsheet. If the information is available, perhaps in the form of a graph supplied by the manufacturer, include sufficient points to give a good representation of the axial intensity profile.

The first three rows contain data cells. The following four rows contain calculation cells; these are described in Section 4 and must not be altered.

If it is necessary to include intensity values at more than 11 distances, select all the cells in the last column and move them to the right pressing the right mouse button and selecting **Insert**.

Distance
Enter the distance from the transducer at which each intensity value was measured.

Free-field intensity
Enter the free-field temporal-average intensity measured at each of the distances specified above.

Derated intensity
Enter the derated temporal-average intensity measured at each of the distances specified above.

2.3.6 Predicted thermal indices

All the calculations are for unscanned ultrasound beams. The details of the thermal index calculations are given in Section 3.4. Advice in interpreting the answers is given in Section 2.3.

NCRP
The NCRP figures are calculated according to the simpler Category I algorithms described in Section 10.7 of NCRP Report 113 on the assumption that the ratio of the beam dimensions in the two perpendicular directions does no exceed 5. For more details refer to the following NCRP sections:

Homogeneous	NCRP Section 10.7.2
Obstetric	NCRP Section 10.7.3
Bone	NCRP Section 10.7.6

AIUM/NEMA
The AIUM/NEMA figures are calculated according to the formulae given in Tables 2-1 and 2-2 of the publication. For more details refer to the following sections:

Soft tissue	AIUM/NEMA Sections 6.2.6, A5.1.2 and A5.1.3
Bone at focus	AIUM/NEMA Sections 6.2.5 and A5.1.4
Bone at surface	AIUM/NEMA Sections 6.2.7 and A5.1.5

2.3.7 Predicted mechanical index

This calculation is provided for interest when peak negative acoustic pressure is known. The mechanical index (M.I.) is beginning to appear on some scanners, and is related to the possibility of cavitation occurring. For more details refer to AIUM/NEMA Sections 6.2.4

and B3.

2.3.8 Warnings and cautions

Two sets of warnings and cautions are presented in red text on the spreadsheet. The first group is to the right of the input data cells in the Measured Values region, with an additional warning below the Axial Variation region. This group confirms the source of the numbers which are calculated in the column labelled 'Used'; the use of the word 'Caution' indicates that the corresponding used value does not come from the measured value ideally required by the thermal index calculations. The use of the word 'Warning' indicates that a lack of measured data has required an approximation to be carried out which could introduce significant errors in the assessment of thermal index. The reason for the caution or warning is also given.

The second set of warnings and cautions are presented, also in red, below the calculated thermal and mechanical indices to remind the user of the spreadsheet of possible sources of uncertainty. This set is broadly similar to the first set described above.

2.3 INTERPRETING THE ANSWERS

NCRP

The NCRP formulae aim to give **reasonable worst case** estimates of the likely temperature rise under certain standard conditions. They are largely based on a solution to the bio-heat transfer equation proposed by Nyborg (1988). The solution assumes a simplified distribution of intensity which can be calculated from the transducer size, radius of curvature, acoustic frequency and total power; the solution also assumes that bloodflow in the heated region produces cooling which can be modelled by the perfusion term proposed by Pennes (1948) (*ie* the cooling term in Equation 1 is $-c_v T/\tau$, where τ is the time constant for perfusion - τ is given a value of 1000 seconds). The NCRP report contains tables of results which give detailed estimates of the power needed to produce a temperature rise of 1 °C; the formulae on the spreadsheet are simplified upper estimates given by NCRP of the thermal index based on those tables.

AIUM/NEMA

The AIUM/NEMA thermal formulae are intended to give **typical**, rather than worst case, estimates of the likely temperature rise under standard conditions. Their derivation is not so well explained as for the NCRP formulae, although the thermal formulae are largely based on the work by Nyborg and colleagues for NCRP. Perfusion is slightly faster than that assumed by NCRP: AIUM/NEMA have calculated a perfusion length of 1 cm (*ie* bloodflow prevents any heated region affecting the temperature at distances greater than 1 cm), roughly corresponding to a 750 s perfusion time constant.

Even calculating the thermal or mechanical indices according to the standard formulae

requires care. Any errors in the values for the acoustic parameters will inevitably be reflected in inaccurate assessments of the indices. For instance, if a nominal value of 3 MHz for acoustic frequency is taken from the manufacturer's description of a transducer and it turns out that the true frequency for the Doppler waveform is 2.25 MHz (which could well be the case), the predicted thermal index will be in error by (3-2.25)/3 = 25% for the NCRP soft tissue model. Or, if the aperture area is asssumed to be 1.1 cm^2 from nominal dimensions, when the true value is 0.9 cm^2 could increase the AIUM/NEMA soft tissue thermal index by more than 60% for a 5 MHz waveform; this is because AIUM/NEMA model B applies for aperture areas greater than 1 cm^2 and model C applies for smaller apertures. The warnings and cautions listed in the spreadsheet are therefore very important and should be noted.

The lesson is that even small changes in the measured acoustic output or the way information is presented, can lead to large changes in the calculated thermal index for a piece of equipment. A factor of 1.5 or even 2 could easily be accounted for in this way, so there is no need to be unduly concerned if one piece of equipment gives a thermal index of 0.9 and another gives a thermal index of 1.1. The value of the mechanical index is less sensitive to small changes in the measured output.

Further Reading

AIUM/NEMA (1992). 'Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment', UD3-1992, (American Institute of Ultrasound in Medicine/National Electrical Manufacturers' Association).

NCRP (1992). 'Exposure criteria for medical diagnostic ultrasound: I. criteria based on thermal mechanisms', NCRP report 113, (National Council on Radiation Protection and Measurement, USA).

NYBORG, W L (1988). 'Solutions of the bio-heat transfer equation', Physics in Medicine and Biology, **33**, no 7, pp 785-92.

PENNES, H H (1948). 'Analysis of tissue and arterial blood temperatures in the resting human forearm', Journal of Applied Physiology, **1**, no 2, pp 93-122.