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TNO report

PG/TG/2003.134

Aspects concerning the measurement of surface temperature of ultrasonic diagnostic transducers, Part 2: on a human and artificial tissue

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Contents

1 Introduction

In the IEC standard 60601-2-37, Ed 1, (2001) in clause 42.3 a measurement method to measure the surface temperature of diagnostic ultrasound transducers has been described. During meetings of SC62B MT34 this standard has been discussed and much comment was given to the measurement procedure to obtain the surface temperature.

Funded by a consortium of manufacturers, TNO Prevention and Health, division Technology in Health Care (NL) has carried out research to identify the problems with the measurement of the surface temperature, and give direction to the development of simplified measurement methods. The results are presented in the TNO report PG/TG/2001.246, *"Aspects concerning the measurement of surface temperature of ultrasonic diagnostic transducers"*, (see ref [1]). The conclusions of the research gave guidance to, more focused, future work. The results of that work is presented in the present report. A consortium of four manufacturers supported the project financially.

1.1 Objective of the project

The goal of the project is:
- Redraft text for the clause 42.3 in the IEC 60601-2-37 standard,
- Setting up a measurement procedure to measure surface temperature of diagnostic probes that can be used in an (informative) annex in the IEC 60601-2-37 standard. This procedure should cover the conditions listed in the redrafted clause 42.3.

1.2 The consortium

As the problem identified is not a unique problem for a single manufacturer, a consortium of manufacturers supported the project. The manufacturers participating in the project are:

Manufacturer	Contact person
- EsaOte (IT) / Pie Medical (NL), Research & Product Development Via di Caciolle 15, I-50127, Florence, Italy	M. Polignano
- Siemens MED US OPE Henkestrasse 127 D-91052 Erlangen, Germany	H. Kaarmann
- Philips Medical Systems, (USA/NL) P.O.Box 3003 Bothell 98041-3003 WA, USA	J. Abbott
- General Electric Company PO Box 414; EA-54 Milwaukee WI 53201, USA USA	M. MacDonald

2 Activities in the project

The activities in the present project have been mainly based on the results of the previous project reported in TNO report PG/TG/2001.246 and comments from the maintenance team 62B MT34.

To reach the goal of the project the following work has been carried out:
- Determining typical transducer surface temperature rises on human skin (underarm).
- Specifying a representative physical model to measure transducer surface temperature rise.
- Investigating the possibility to predict temperature rise on the underarm from transducer surface heating in air and on the physical model.
- Supporting the validity of a physical model by theoretical calculations of surface temperature rise and investigating possible improvements.

2.1 Measurements in air

The cooling rate is an interesting figure to calculate the time needed for the surface temperature to decrease to an acceptable value. More measurements were needed to validate the assumptions from the previous project. This will also be of importance to be able to redraft part of the IEC 60601-2-37 standard.

2.2 Physical model that includes a skin mimic

A model to represent “normal use” for externally used transducers should contain a layer of skin. Measurements have been carried out using a model that includes a skin mimic and practical tissue parts of some volunteers.

2.3 Use of different thermocouples

As there was a discussion on the sizes of thermocouples in use at the different laboratories a comparison have been made between results obtained with at least three different types and the infrared camera.

2.4 Measurement set-up for endocavity transducers

With the results of the previous project it was justified that a simple way of potting, just to couple the transducer surface to tissue, is sufficient for curved externally used transducers. For endocavity transducers further potting is needed, but also easy to perform. As it was shown that there is no need for a heat sink, all measurements have been performed under laboratory conditions (20 °C ± 2 °C).

2.5 Simplification of the methods

The relationships as suggested in figure 19, 20 and 23 of the TNO report

PG/TG/2001.246 are very promising for a simplification once a transducer has been characterised. The relations have been investigated more thoroughly to improve the confidence. As stated earlier, some observations are based upon a limited number of measurements. To be statistically useful, the measurements have been extended to more units and device - setting combinations. Also I_{ob} needed to be known more precisely.
We have investigated the possibility to use just one tissue model to calculate the ratio of heat transfer in the “air” situation to that in the “normal use “situation.

3 Methods to predict surface temperature

3.1 Diagnostic transducers on human tissue (underarm)

As a start the transducer surface temperature was measured on the underarms of 13 volunteers. Later, after the spread was known, this number could be reduced to 3 volunteers. The procedure was as follows:

- A small K-type thinfilm thermocouple (12 µm) is placed on the surface of a fixed transducer (room temperature), in the middle of the area that will heat up after the transducer is switched on, see *Figure 1.* The thermocouple is covered by acoustic gel that is used for coupling with the arm. We have also performed a measurement where the transducer is heated up in air first, after that a human arm is placed toward that source and temperatures are recorded.
- The underarm is placed against the transducer without sliding (this is verified after the measurement), see *Figure 2.* The transducer is not switched on, but is allowed to heat up through heat transfer from the underarm (about 5 minutes)
- Ultrasound is switched on at a specified setting during more than 3 minutes, often 5 minutes. Local temperature at the middle of the transducer surface is recorded through the thermocouple.
- Ultrasound is switched off; the arm and transducer are allowed to cool for about 5 minutes. Temperature decrease is recorded.

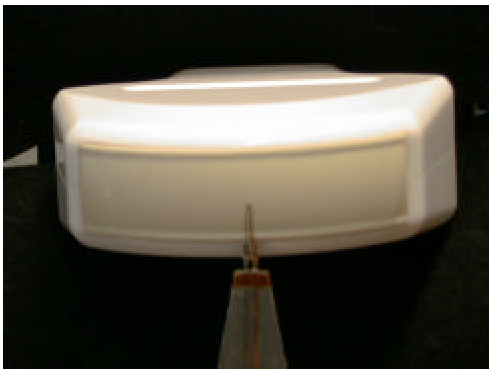


Figure 1. Position of the thin film thermocouple on a curved linear transducer.

Figure 2. Position on the underarm where the human tissue measurements are carried out.

The temperature rise is plotted as a function of time and the part of the curve above 100 s is fitted to a curve that satisfies the equation:

$$\Delta T = \Delta T_{eq}(1 - e^{-(t+d)/b})$$

In this expression, t is the time after switching on, ?T_{eq} is the equilibrium temperature rise (after infinite time), d is a time shift that is needed to account for the fact that directly after switching on, the temperature rise does not yet behave according to the same expression as for t > 100 s. The quantity ß is the 1/*e*-time for this exponential behaviour.

The relevant properties of two kinds of tissue are needed later in the theoretical model (see ref [2]). They are:

Skin:	Nonfatty tissue:
c = 1615 m s^{-1}	c = 1575 m s^{-1}
? = 1090 kg m^{-3}	? = 1055 kg m^{-3}
a = 3,0 dB cm^{-1} at 1 MHz (linear with f)	a = 0,6 dB cm^{-1} at 1 MHz (linear with $f^{1,2}$)
c_v = $3{,}7 \cdot 10^6$ J m^{-3} K^{-1}	c_v = $3{,}7 \cdot 10^6$ J m^{-3} K^{-1}
K = 0,34 W m^{-1} K^{-1}	K = 0,53 W m^{-1} K^{-1}
t = 8	t = 150 s

3.2 Diagnostic transducers on a physical model

The measurement process for temperature on the surface of a physical model is almost identical to that for the underarm. For these measurements the same curve fitting procedure is used. The only difference is the shorter time needed for the initial thermal equilibrium between transducer and test object, before heating.

Several physical models have been made, all based on a material with ultrasound parameters that represent those of soft tissue (previously developed for a flow Doppler test object). It is called Test Object Soft tissue (TOS). In the measurements a layer of silicone rubber is used on the TOS, with varying thicknesses, to simulate a skin layer, see *Figure 3*. The properties of TOS and silicone are:

TOS:	Silicone:
c = 1540 m s^{-1}	c = 1021 m s^{-1}
? = 1050 kg m^{-3}	? = 1243 kg m^{-3}
a = 0,5 dB cm^{-1} at 1 MHz (linear with f)	a = 1,8 dB cm^{-1} at 1 MHz (linear with f)
c_v = $4{,}0 \cdot 10^6$ J m^{-3} K^{-1}	c_v = $3{,}0 \cdot 10^6$ J m^{-3} K^{-1}
K = 0,58 W m^{-1} K^{-1}	K = 0,25 W m^{-1} K^{-1}

The temperature rise due to ultrasound and direct heating of diagnostic transducers was investigated. The aim was to find a suitable model, with appropriate silicone thickness that represents the human underarm with respect to temperature rise in the first few minutes. Longer heating times are not taken into account, since diagnostic transducers are generally not applied to one part of the skin for more than a few minutes.

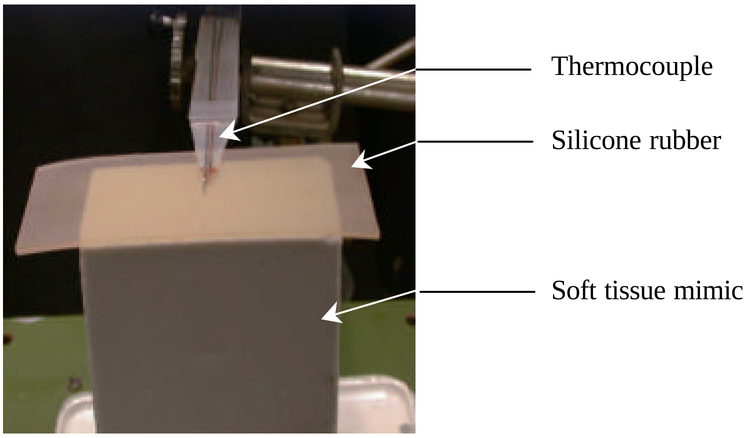


Figure 3. Set-up to measure the surface temperature of externally used transducers. This set-up intends to mimic also the skin.

3.2.1 *Measurement set-up for endocavity transducers*

From the previous project it followed that more investigations were needed to show the validity of simplifying the set-up for endocavity transducers. Additional to the work reported in the TNO report PG/TG/2001.246, different models were used. The first, see *Figure 4*a, is a block of tissue mimicking material TMM (10x10x10 cm) with a hole to put in the transducer. The space in the hole, after the transducer has been inserted, is filled with acoustic coupling gel. The transducer is fully potted from 80 mm from the front surface. *Figure 4*b shows a half potted transducer: potted in the scan direction. The simplest way of potting is to put the transducer in a container filled with acoustic coupling gel. The bottom of that container is the soft tissue mimic, see *Figure 4*c. Finally the whole testobject is placed on a proper acoustic absorbing material. One of the difficulties in all the “potted” measurements is aligning the “hot spot” to the centre of the thermocouple. Of course this would be simpler in a more rigid set-up.

a. **b.** **c.**

Figure 4. Several set-ups to measure the surface temperature of endocavity transducers. ***a****: fully potted,* ***b****: only the top is potted covered with gel,* ***c****: potted in gel. In all models the transducer surface is acoustically coupled to TOS.*

3.3 Diagnostic transducers in air

The most straightforward method to measure transducer surface temperature, is in air, with a thermocouple attached to the surface, see *Figure 5*. For a reasonably broad range of transducers, temperature rise measurements in air have been carried out with the aim to find possible relations of the results with temperature measurements on the physical model or the underarm. Parameters like ultrasound frequency, power or entrance beam dimensions could then determine the relation between air and non-air measurements. For air measurements the same curve fitting procedure is used.

Figure 5. A method to ensure that the thermocouple is in firm contact with the transducer surface, without affecting the accuracy of the measurement.

3.4 Diagnostic transducers as calculated in a theoretical description

A computer model has been built, based on the one-dimensional bio heat transfer equation. This model takes into account heating by ultrasound and direct heating through the transducer surface. The following steps are taken:

- Ultrasound and thermal parameters of transducer material (surface + backing) and model material are defined. The model material can consist of up to 3 layers, apart from the transducer material. Important ultrasound parameters are density ?, speed of sound *c*, and absorption a. Important thermal parameters are volumetric heat capacity c_v, heat conductivity *K*, and perfusion constant t.
- An ultrasound beam in a 2-dimensional matrix is defined (*z* and *r*; cylindrical symmetry). The beam can either be a measured pressure distribution or a combination of a modelled rectangular beam and a Gaussian beam. In the calculations or this report only the second (modelled) option is chosen. Between 0 and 5 mm from the transducer face the beams changes gradually from a fully rectangular beam to a fully Gaussian beam. The axial spacing d*z* is constant to reduce calculation time.
- Efficiency of the transducer is defined.
- Local heating of each point in the material matrix is calculated. Local heating by ultrasound follows from absorption in the material, under the assumption of linear

behaviour of ultrasound. Heating of the transducer material follows from the transducer efficiency, total power, and transducer material specific heat capacity and size.

- The bio heat transfer equation is used to calculate the temperature rise in each point of the 3-dimensional space, due to heating of all other points of the space. The assumption of cylindrical symmetry greatly reduces the calculation time. Heat transfer from the transducer surface to the material surface is automatically taken into account, since the transducer surface contains heat sources.
- For an ultrasound beam that has no cylindrical symmetry, a smaller symmetrical beam is modelled, and its temperature rises calculated. Copies of this beam are taken to be shifted with respect to the first beam, such that several small beams constitute the required non-symmetric beam. Temperature rises from the several (identical, shifted) small beams are added to obtain the temperature rise profile of the non-symmetric beam.
- Example for non-symmetric beam: a rectangular 4mm x 12mm beam can be split in three 4mm x 4mm beams, each with 1/3 of the original power and each shifted by 4 mm from the other. Each small beam has a 16 mm^2 area, so the radius of the cylinder is 2,3mm. The temperature rise profile is calculated. The result (taken as the centre beam of the three) is added to twice the 4mm shifted profile (left and right beams). So still use is made of cylindrical symmetry and symmetry in the odd number of beams (effect of left beam = effect of right beam).

The theoretical model is mainly used to predict the suitability of physical models that differ from those on which temperature measurements have been carried out.

4 Results

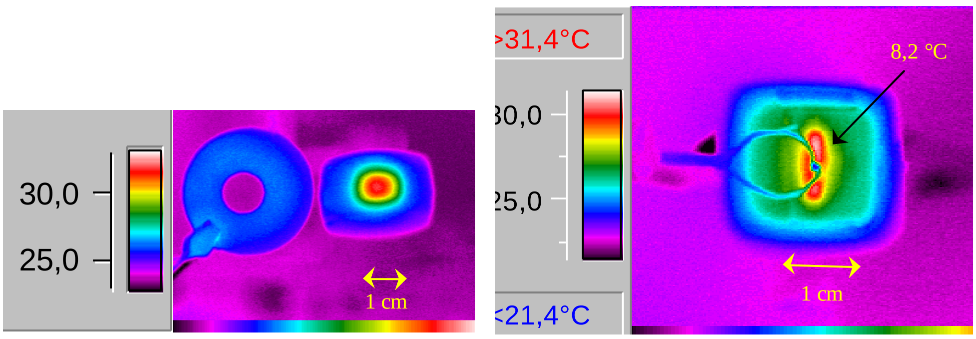
4.1 Introduction

In the figures presenting the temperature rise, the x-axis presents the time that has elapsed after ultrasound was switched on. Some of the abbreviations are used: “B” is B-mode, “C” is Colour flow mode, “D” is PW Doppler mode. The combination is used to identify simultaneous operation of these modes, in a number of cases the working frequency in MHz is also given. Shortcuts like “rhg”, “rab”, “gln”, “mpg”, “cjh” identify the volunteers. The measurement in a stable air surrounding is identified with “air” and “sil” identifies the use of a thin layer of silicone rubber, of which the thickness is also given. “TMM” is Tissue Mimicking Material, in this report it is the same as TOS (Test Object Soft tissue).

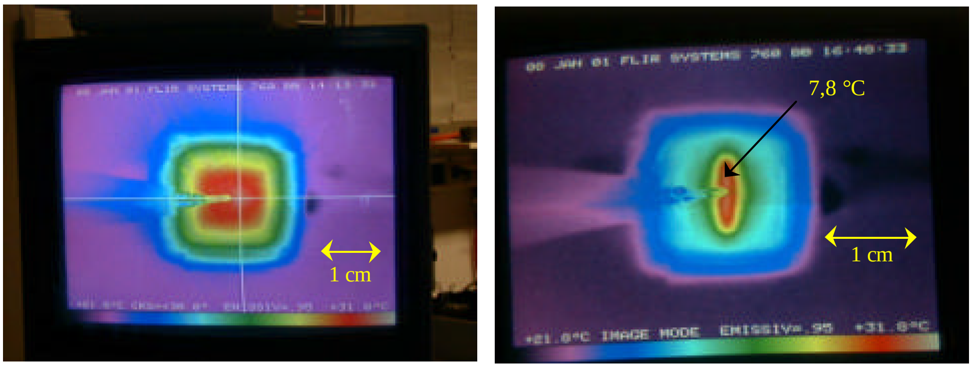
4.2 Importance of the size of the thermocouple

For various reasons the size and type of the thermocouple are important. First a large thermocouple will measure the average temperature in case of small heated spots. *Figure* 6b shows the image of the infrared camera where the thermocouple has the size of a 1 mm oval disc. *Figure* 6d shows the same image with a thin film, 12 µm thickness, thermocouple. A third thermocouple used is a 150 µm ball type. It will be clear that the heat developed on the thermocouple will also be a result of heat developed due to absorption of ultrasound in the thermocouple itself. This strongly depends on the thickness of the thermocouple. Also a thermocouple that does not have a flat surface but is more a ball type will easier transfer its heat to the surrounding air. This last effect can be seen in *Figure 7* were the result of measurements in air are shown. The thermocouples were connected to the transducer surface using thin household foil. The 1 mm thermocouple was pressed after 200 s towards the transducer surface with a small wooden stick. This gave a rise of the measurement of 1,2 °C. Also, the bad contact with the surface results in the somewhat disturbed curve for this thermocouple.

The measurement temperature rise, obtained with the infrared camera for the situations showed in *Figure* 6b and *Figure* 6d, is in average 8,0 °C. When comparing this with the results showed in *Figure 7*, the result obtained with the 12 µm thermocouple (7,6 °C at 300 s) is closest to the infrared camera result.



a. **b.**



c. **d.**

Figure 6. Typical thermal images obtained by an infrared camera system shows the distribution of heat on a transducers surface in different operation modes of the device, after 300 s. ***a****. is taken from an endocavity transducer during a PW Doppler,* ***b****. and* ***d****. are taken from a phased array transducer in a Colour flow mode and* ***c*** *is taken from the same transducer as* ***b****. and* ***d****. but in a PW Doppler mode. The image* ***b****. also shows the 1 mm thermocouple,* ***d****. shows the thin film thermocouple.*

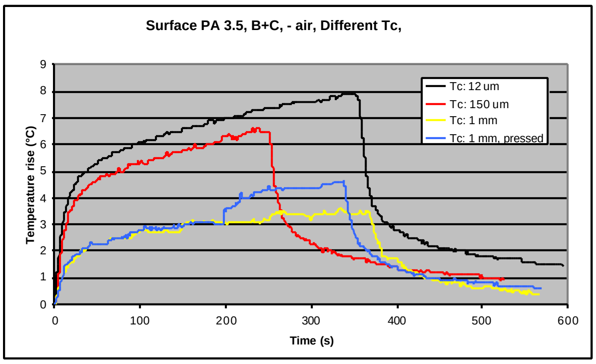
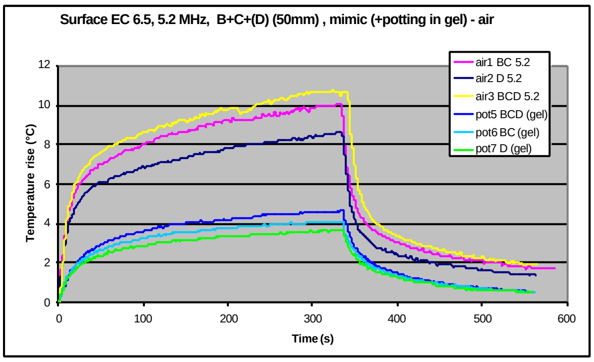


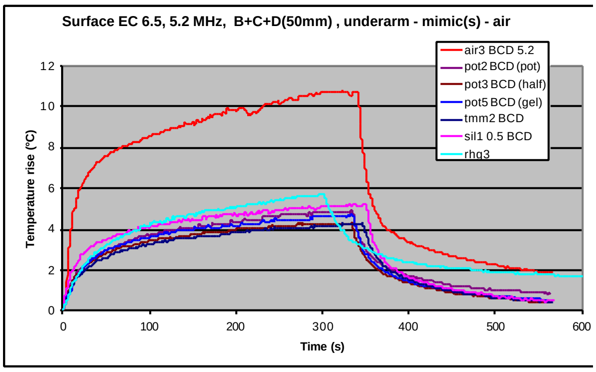
Figure 7. Measurement results, in air, using three different types of thermocouples. T_c stands for a thermocouple with the given thickness.

4.3 Results for endocavity transducers, different ways of potting

As discussed in the methods in section 3.2.1, various potting situations were investigated. In the previous project it has already been shown that an increased starting temperature of the mimicking material did not influence the surface temperature rise. Based on the few measurements performed it has also been assumed that simpler ways of potting could be possible. Results of an additional endocavity transducer now shows that that assumption was reasonable. *Figure 8* shows some results. In *Figure 8*a measurements were carried out for three different modes in air and potted in gel using the set-up from *Figure 4*c. Although the equilibrium temperature differs, the development of the heat looks the same for the three different modes. The results presented in *Figure 8*b show that there is not much difference when using the different potting set-ups. The average temperature rise of pot 2, 3 and 5 is 4,6 °C with a variation of 0,3 °C. Here the results using a complete potting with TMM were very close to that using the gel potting set-up (difference only 0,2 °C).



a.

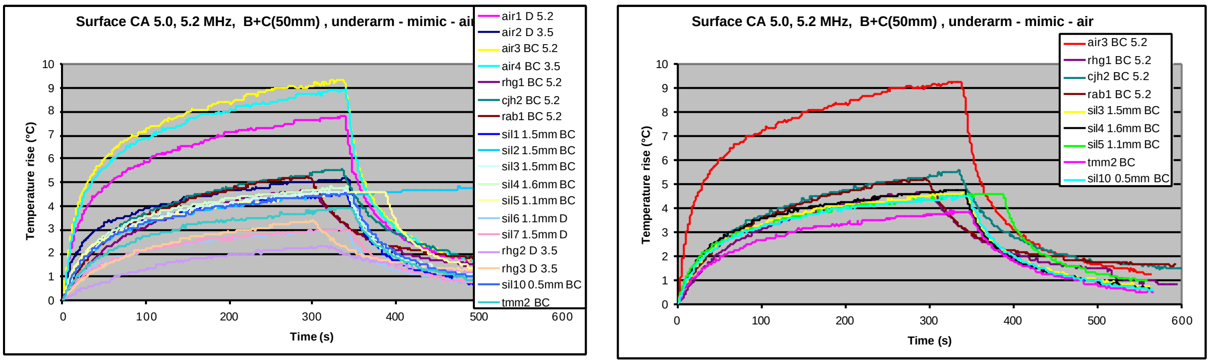


b.

Figure 8. Measurement results of an endocavity transducer working at a frequency of 5,2 MHz. ***a****. shows the effect of different modes (PW Doppler, Colour Flow and these both together).* ***b****. shows the effect of various potting methods measured in a simultaneous Colour Flow and PW Doppler mode .*

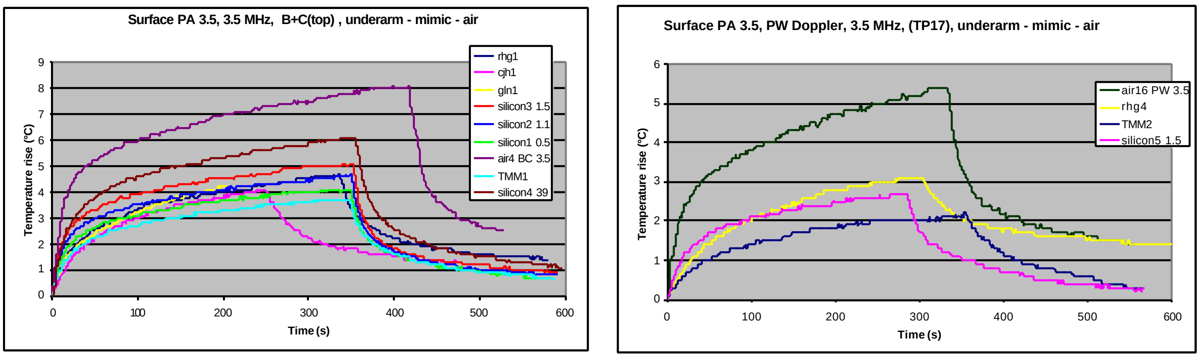
4.4 Some typical results

Typical measurement results of surface temperature rise on externally used transducers are visualised in *Figure 9*, *Figure 10*, *Figure 11* and *Figure 12*. Results like these are used for the determination of the relations discussed further in sections 4.5, 4.6 and 4.7. Measurements were undertaken in various modes of operation with several transducers, with various transmitting frequencies in air, on a number of human underarms, on tissue mimic comparable with soft tissue and on several situations mimicking soft tissue with skin. From the results it is very clear that the temperature rise on a human underarm is slower than in all other situations. Equally, the cooling down of the surface temperature in contact with a human underarm takes more time. The figures also clearly show that using only a soft tissue mimic (“tmm” in the graphs) is not enough: a surface layer mimicking the skin is needed to mimic the underarm situation properly. Although an endocavity transducer is not intended to be used as an external transducer, these transducers have been processed the same way as externally used transducers, see *Figure 11*. By doing this more information of the importance of various transducer constructions has been collected. The measurement of the surface temperature rise during a long period (30 minutes), see *Figure 12*, shows that the temperature rise does not approach the equilibrium according to a simple exponential function; in the first tens of seconds the rise is faster then later in the heating process. This point to the fact that there are at least two heat transfer processes involved (conduction in several directions and convection).



a. **b.**

*Figure 9. **a.** Results of a curved linear array transducer in various situations. **b.** A selection of measurement results all from one identical mode of operation but under various thermal load conditions.*



a **b**

*Figure 10. **a.** Results of a phased array in a selection of measurement results all from one identical mode of operation but under various thermal load conditions. **b.** Just one set of measurements of the same transducer in another mode of operation.*

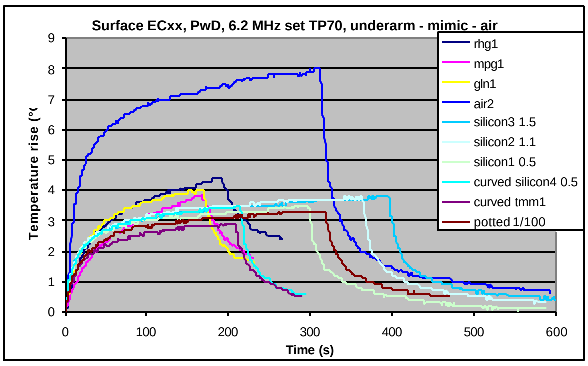


Figure 11. Results of a endocavity (array) transducer in a selection of measurement results all from one identical mode of operation but under various thermal load conditions. For all measurements, scan line 100 has been used here for the Doppler.

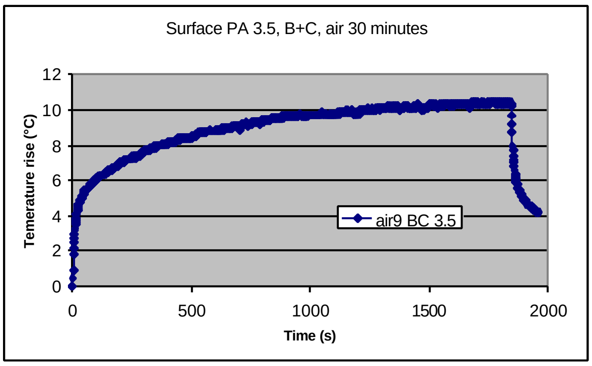


Figure 12. A typical presentation of the temperature rise during a very long time.

4.5 Relation between measurements in air and on human skin

A range of linear and curvilinear, externally applied and endocavity diagnostic transducers has been investigated. Modes comprised the B-mode, PW Doppler mode, Colour flow mode and combination modes, with powers ranging from 9 mW to 235 mW, output beam intensities from 1 mW/cm^2 to over 800 mW/cm^2, frequencies from 2,5 MHz to 7,0 MHz and output beam dimensions (OBD) from 15 mm^2 to 330 mm^2. Table 1 below gives the details of the results for measurements on the human underarm and in air after a long time of heating ('infinite').

Table 1. Relation between temperature rise in air and human tissue

Mode	Power (mW)	*f* (MHz)	OBD (mm^2)	? T_{eq}(air)	? T_{eq}(tissue)$^{1)}$	? T(air) / ? T(tissue)
PW Doppler	134	2,5	273	16,1	9,9 (15%)	1,63
	90,9	2,8	283	34,0	16,7 (16%)	2,04
PW Doppler	235	2,8	328	18,3	9,1 (10%)	2,01
	45,5	3,7	135	10,9	6,4$^{2)}$ (30%)	1,70
	18,3	5,5	62	8,3	6,8$^{2)}$ (9%)	1,22
PW Doppler$^{3)}$	8,9	6,2	37	8,3	5,0 (8%)	1,66
B + Colour	126	7,0	15	20,3	12,7 (9%)	1,60
B + Colour	58,8	3,5	50	8,9	5,4 (11%)	1,65
PW Doppler	60,9	3,5	188	6,4	3,5 (20%)	1,83
B + Colour	53,4	5,2	135	10,0	6,2 (17%)	1,61
PW Doppler	45,3	3,5	248	5,5	3,7 (x)	1,49
B + Colour + PWD$^{3)}$	25,3	5,2	281	11,0	6,8 (x)	1,62
				Average$^{4)}$:		**1,71**
				St.dev. (%)$^{4)}$:		**12**

1. Between brackets the full range of underarm relative temperature rises (min to max), if more than one underarm has been measured.
2. Heating period for tissue measurements was less than 200 seconds; curve fitting considerably less reliable.
3. Endocavity transducers, with a very curved font.
4. Transducers mentioned in 2) not included. Standard deviation is expressed relative to the average.

The equilibrium temperature rises on the human underarm range from 3,5°C to 17°C, and in air from 5,5°C to 34°C. These temperature rises are reached after a theoretically infinite time. These values were calculated using the expression given in the section "Methods". It was found that a good exponential fit can always be made to the temperature curve, and that the resulting equilibrium temperature rise cannot vary more than about 5% without obviously reducing the quality of the fit. The range of the temperature rises on the underarms is 10% to 20% for transducers for which reliable measurements have been carried out. It is estimated that this leads to an uncertainty of

6% to 12% (95% confidence). The temperature rise at t = 300 s is found to be at least 85% of the equilibrium temperature rise for all transducers and modes.

The average ratio ? T_{air} / ? T_{tissue} (see Table 1) could be used to convert measured temperature rise in air to that on the skin of the human underarm for any non-endocavity and non-invasive diagnostic transducer. The uncertainty in the skin temperature rises thus calculated, can be derived from the measurements reported in the table. The standard deviation of the measured temperature rises is given in the table; uncertainty could be defined as twice the standard deviation, 23% (95% confidence).

The ratio seems to increase somewhat with OBD, see *Figure 13* below.

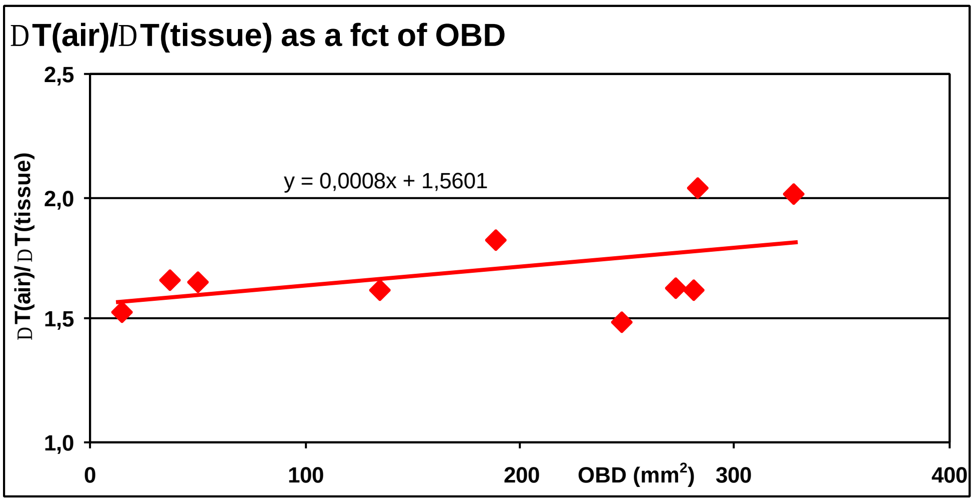


Figure 13. Relation between the ratio of the temperature rise in air to the temperature rise in human tissue (underarm) and the output beam dimension as defined in IEC.

Drawing a linear regression line through the data points, the average difference between the regression value and the data point can be calculated, including the standard deviation of the difference. The difference is defined as ? T_{air} / ? T_{tissue} at the data point minus the corresponding ratio on the regression line at the same OBD. The average difference is then zero by definition. If the difference is expressed as the relative deviation from the regression line (in %), the standard deviation of the differences is 9%. This is somewhat smaller than the 12% that was found if the influence of OBD is not taken into account. If this relation between OBD and the ratio is used, skin surface temperature rise can be predicted within 19% (95% confidence).

Other variables that may influence the ratio ? T_{air} / ? T_{tissue} are frequency f, output beam intensity I_{ob}, and variations with these parameters ($OBD^{½}$, log(OBD) and OBD/f). However, no other relations were found that could suitably be used to reduce the uncertainty with which underarm surface heating can be predicted from air surface heating results. Especially the lack of influence from I_{ob} is remarkable, since in the preceding project (TNO-report: PG/TG/2001.246, December 2001) a clear dependence was found. *Figure 114* displays the (lack of) influence of I_{ob} on ? T_{air} / ? T_{tissue}.

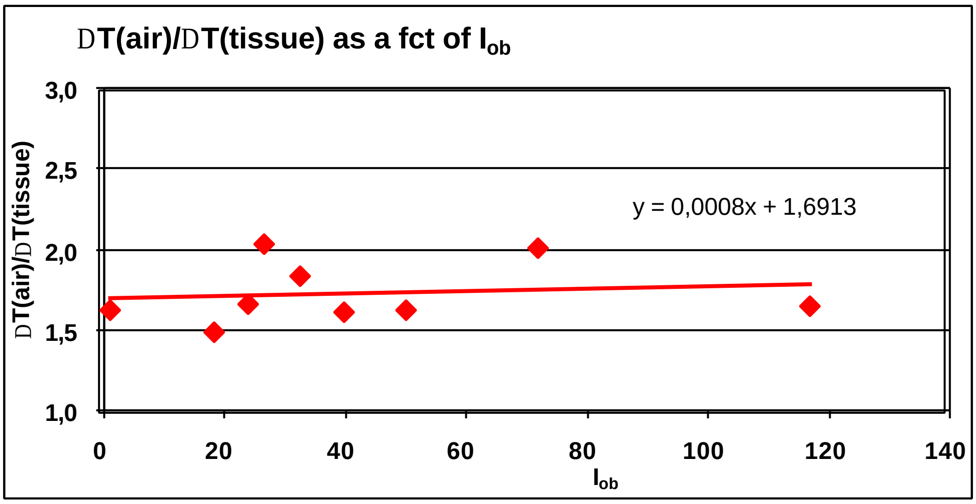


Figure 14. Relation between the ratio of the temperature rise in air to the temperature rise in human tissue (underarm) and the output beam intensity as defined in IEC.

Possible causes of this difference between results of the preceding and the current project are discussed in section 5.2.

4.5.1 Measurement in air next on a human arm

Figure 15 shows the results of a test which is close to practice. The transducer, in this case a 3,5 MHz curved linear array transducer, is heated up in air. After about 7,5 minutes the transducer is connected to a human underarm to start the investigation. This was finished 3 minutes later. There remained some coupling gel on the transducer surface, which was whipped away after 1,5 minute.

The transducer surface temperature at the start was 23,1 °C. The surface temperature of the human arm at the start was 31,0 °C. After some coupling gel was applied it was 28,3 °C.

The temperature drop after the transducer is connected to the tissue is very clear and the value of recovering after a few minutes is in agreement with the results presented in Figure 16. It is also very clear that the remaining coupling gel is cooling the surrounding of the thermocouple very much.

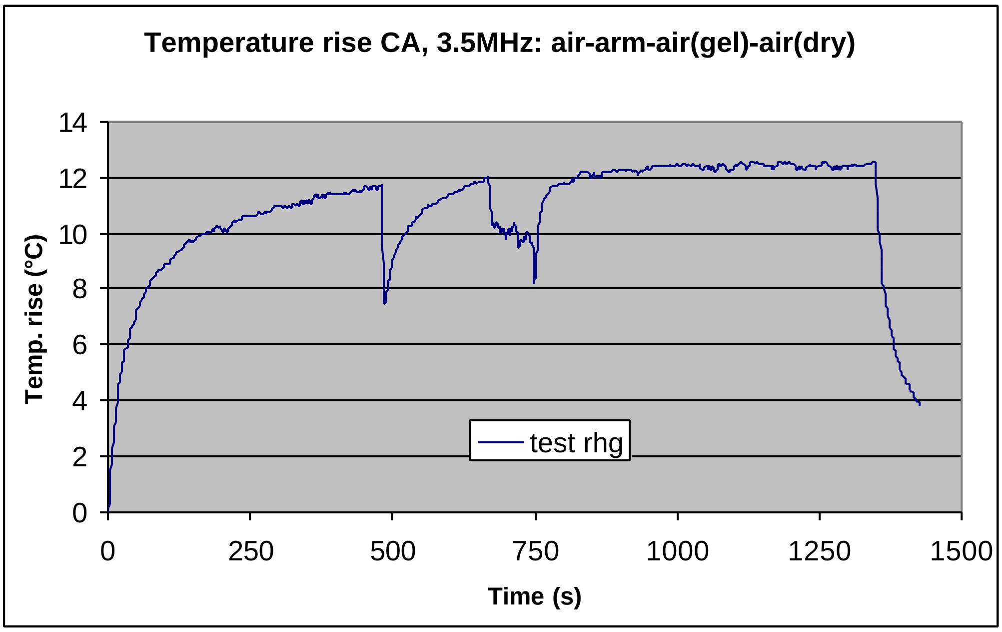


Figure 15. Temperature rise in air, after 8 minutes transducer connected to a human underarm for 3 minutes, disconnected leaving some coupling gel behind which has been removed after 1.5 minutes.

4.6 Relation between measurements on a physical model and on human skin

A physical model has been built with a soft tissue mimicking material as described in the “Methods” section and a silicone layer on top of that. Silicone thicknesses were 0,0 mm (so pure TOS), 0,5 mm, 1,1 mm and 1,5 mm. For the same transducers as for the human underarm, temperature rise measurements have been carried out and equilibrium temperature rises ?T_{eq} have been calculated through extrapolation using curve fitting. The results are given in Table 2 below.

Table 2. Relation between measurements on a physical model and on human skin

Mode	**? T_{eq} (tissue)**	**? T_{eq} (sil 0,0)**	**Ratio Sil./Tiss.**	**? T_{eq} (sil 0,5)**	**Ratio Sil./Tiss.**	**? T_{eq} (sil 1,1)**	**Ratio Sil./Tiss.**	**? T_{eq} (sil 1,5)**	**Ratio Sil./Tiss.**
PW Doppler	9,9			8,6	0,87	9,0	0,91	10,4	1,05
	16,7							18,2	1,09
PW Doppler	9,1			7,5	0,82	7,8	0,86	8,4	0,92
	6,4[1)]			6,8	1,06	7,0	1,09	7,0	1,09
	6,8[1)]			5,5	0,81	5,9	0,87	6,1	0,90
PW Doppler[2)]	5,0	3,0	0,60	3,6	0,72	3,9	0,78	3,9	0,78
B + Colour	13,3			12,6	0,95	13,9	1,05		
B + Colour	5,4	4,0	0,74	4,6	0,85	5,3	0,98	5,7	1,06
PW Doppler	3,5	2,3	0,66					2,9	0,83
B + Colour	6,2					4,9	0,79	5,0	0,81
PW Doppler	3,7	2,6	0,70					3,3	0,89
B+Colour+PWD[2)]	6,8	4,6	0,68	5,5	0,81				
		Average[3)]:	**0,68**	**Average[3)]:**	**0,84**	**Average[3)]:**	**0,89**	**Average[3)]:**	**0,93**
		Stdev(%)[3)]:	**8**	**Stdev(%)[3)]:**	**9**	**Stdev(%)[3)]:**	**12**	**Stdev(%)[3)]:**	**13**

1) Heating period for tissue measurements was less than 200 seconds; curve fitting considerably less reliable.
2) Endocavity transducer, with a very curved font
3) Transducers mentioned in 1) not included. Standard deviation is expressed relative to the average.

From the curve fitting results (the parameters ?T_{eq}, d and ß, (see section "Methods"), the temperature rises at t = 300 s and at t = 100 s are calculated for the underarm and for the test objects with the four silicone layers (including the 0,0 mm layer). The ratios and their averages and standard deviations are then calculated, see Table 3 and Table 4 below.

Table 3. Relation between measurements on a physical model and on human skin at 300s.

Mode	**? *T*(tissue) (300s)**	**? *T*(sil 0,0) (300s)**	**Ratio Sil./Tiss.**	**? *T*(sil 0,5) (300s)**	**Ratio Sil./Tiss.**	**? *T*(sil 1,1) (300s)**	**Ratio Sil./Tiss.**	**? *T*(sil 1,5) (300s)**	**Ratio Sil./Tiss.**
PW Doppler	9,1			8,0	0,88	8,6	0,94	9,5	1,04
	16,0							16,4	1,03
PW Doppler	8,4			7,0	0,84	7,3	0,88	7,9	0,94
	6,2			6,3	1,02	6,8	1,10	6,7	1,09
	6,4			5,2	0,81	5,5	0,87	5,7	0,90
PW Doppler[2)]	4,8	3,0	0,62	3,4	0,72	3,7	0,78	3,7	0,77
B + Colour	12,3			11,8	0,92	13,1	1,02		
B + Colour	4,5	3,6	0,80	4,0	0,89	4,5	0,99	4,9	1,10
PW Doppler	3,2	2,1	0,65					2,7	0,85
B + Colour	5,4					4,4	0,83	4,5	0,85
PW Doppler	3,3	2,4	0,73					3,0	0,89
B+Colour+PWD[2)]	5,7	4,2	0,74	5,1	0,89				
		Average[3)]:	**0,73**	**Average[3)]:**	**0,88**	**Average[3)]:**	**0,93**	**Average[3)]:**	**0,96**
		Stdev(%)[3)]:	**10**	**Stdev(%)[3)]:**	**3**	**Stdev(%)[3)]:**	**8**	**Stdev(%)[3)]:**	**10**

Table 4. Relation between measurements on a physical model and on human skin at 100s.

Mode	**? *T*(tissue) (100s)**	**? *T*(sil 0,0) (100s)**	**Ratio Sil./Tiss.**	**? *T*(sil 0,5) (100s)**	**Ratio Sil./Tiss.**	**? *T*(sil 1,1) (100s)**	**Ratio Sil./Tiss.**	**? *T*(sil 1,5) (100s)**	**Ratio Sil./Tiss.**
PW Doppler	6,1			5,7	0,93	6,2	1,02	6,8	1,12
	11,4							11,5	1,01
PW Doppler	6,0			5,2	0,88	5,5	0,92	5,9	0,99
	4,7			4,8	1,03	5,3	1,14	5,4	1,15
	4,5			4,1	0,91	4,5	1,01	4,7	1,04
PW Doppler[2)]	3,7	2,6	0,70	3,0	0,80	3,1	0,85	3,1	0,84
B + Colour	10,2			9,7	0,93	11,0	1,05		
B + Colour	3,3	2,7	0,82	3,1	0,94	3,5	1,05	3,9	1,18
PW Doppler	2,1	1,4	0,68					2,0	0,99
B + Colour	3,7					3,3	0,91	3,4	0,92
PW Doppler	2,2	1,7	0,77					2,1	0,97
B+Colour+PWD[2)]	4,2	3,3	0,78	4,2	0,99				
		Average[3)]:	**0,75**	**Average[3)]:**	**0,91**	**Average[3)]:**	**0,97**	**Average[3)]:**	**1,00**
		Stdev(%)[3)]:	**8**	**Stdev(%)[3)]:**	**7**	**Stdev(%)[3)]:**	**9**	**Stdev(%)[3)]:**	**11**

The surface temperature rise differences between a silicone layer on TOS and the human underarm are summarised in the following table for the three heating times (100 s, 300 s and infinity). The range of the temperature rise ratio is defined as the average ratio minus 2 standard deviations to average ratio plus 2 standard deviations (the 95% confidence interval). Table 5 summarises the results, which are also graphically presented in *Figure 16*. Keep in mind that each range reflects the variation between the transducers.

Table 5. Summary of fitted results at 100s, 300s and infinity

	? *T*(sil 0,0) / ? *T*(tiss)	**? *T*(sil 0,5) / ? *T*(tiss)**	**? *T*(sil 1,1) / ? *T*(tiss)**	**? *T*(sil 1,5) / ? *T*(tiss)**
At t = 100 s	Average: 0,75 Range: 0,63 - 0,87	Average: 0,91 Range: 0,78 – 1,04	Average: 0,97 Range: 0,79 – 1,14	Average: 1,00 Range: 0,79 – 1,21
At t = 300 s	Average: 0,71 Range: 0,57 – 0,85	Average: 0,86 Range: 0,72 – 1,00	Average: 0,91 Range: 0,72 – 1,09	Average: 0,93 Range: 0,71 – 1,16
At t = 8	Average: 0,68 Range: 0,57 – 0,78	Average: 0,84 Range: 0,69 – 0,99	Average: 0,89 Range: 0,68 – 1,11	Average: 0,93 Range: 0,68 – 1,17

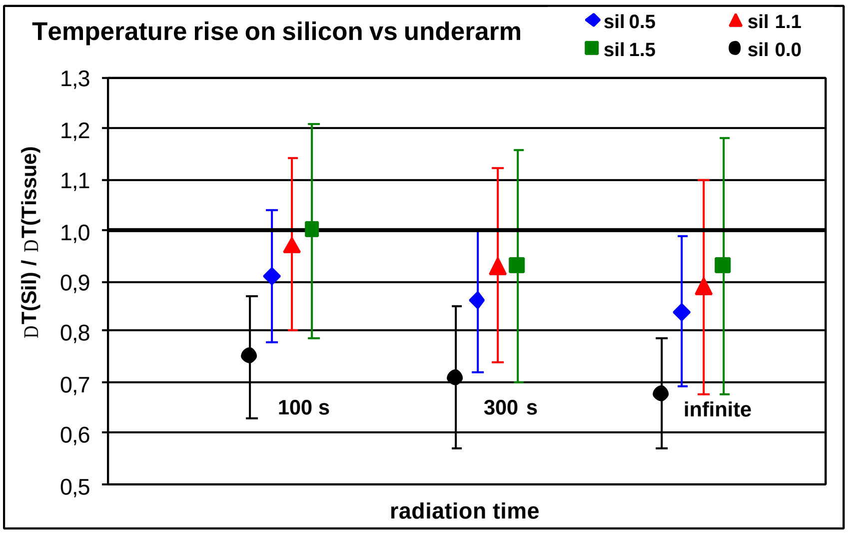


Figure 16. Summary of fitted results after heating during 100s, 300s and an infinite time.

One remark should be made here: the results are not based on a large number of transducers: 5 for 0,0 mm silicone, 6 for 0,5 mm silicone, 6 for 1,1 mm silicone and 8 for 1,5 mm silicone. A second remark is that variation in the temperature rises on tissue is not taken into account. For this a 6% to 12% uncertainty was estimated (95% confidence).

4.7 Comparison of temperature measurements supported by the theoretical model

The theoretical (computer)model has been applied to one situation, with which also temperature measurements on the underarm and on silicone layers on TOS were carried out: a PW Doppler ultrasound beam, power 75 mW, frequency 3,7 MHz, beam dimensions 4 x 14 mm^2, estimated transducer efficiency 0,4. Comparisons between the physical measurements and the theoretical calculations are made and the effect of using test object materials with different properties is investigated:

- Effect of different thicknesses of silicone on TOS and comparison with the underarm
- Effect of different *K*, c_v and a of TOS
- Effect of a different t of TOS, to investigate whether the lack of perfusion is a serious drawback

The relevant transducer backing properties used in the theoretical model are as follows:
$c_v = 3{,}0 \cdot 10^6$ J m^{-3} K^{-1}
$K = 0{,}25$ W m^{-1} K^{-1}
TOS and silicone properties are given in the section "Methods". The transducer front material is only a thin layer, and most of the (non-ultrasonic) heat production in the transducer takes place in the backing. Therefore the whole of the transducer is approximated by a material of a certain suitable thickness, with which the measured temperature rise is reasonably well modelled. A transducer thickness of 10 mm was found to be the most appropriate.

For the given particular transducer and settings, Table 6 gives the measured and modelled surface temperature rises after 300 s and 1800 s heating for TOS, silicone layers on TOS, and the human underarm. For the theoretical model, the arm is defined as 1,0 mm skin and further nonfatty tissue. The percentage increase in temperature rise for a one step thicker silicone layer is also given (between brackets).

Table 6. Measured and modelled surface temperature rises after 300 s and 1800 s heating

Material	**? *T*(°C) - Physically measured (300 s / 1800 s)**	**? *T*(°C) – Theoretically modelled (300 s / 1800 s)**
TOS	3,6 / 4,0	3,3 / 5,2
0,5 mm silicone on TOS	4,0 (11%) / 4,5 (13%)	4,0 (21%) / 6,0 (15%)
1,1 mm silicone on TOS	4,5 (13%) / 5,1 (13%)	4,4 (10%) / 6,5 (8%)
1,5 mm silicone on TOS	5,0 (11%) / 5,6 (10%)	4,6 (5%) / 6,8 (5%)
Silicone only	5,9 (18%) / 6,9 (23%)	5,3 (15%) / 7,9 (16%)
Underarm	4,5 / 5,2 (estimated)	4,3 / 6,1

It is observed that the theoretical model gives a reasonable estimate (within 10%) of the actual temperature rise after 300 s. For longer times (1800 s) it gives an overestimation of 15% to 35%, especially for the thin silicone layers (no silicone – 0,5 mm – 1,1 mm). This could be caused by using the wrong parameters for the transducer backing and by neglecting the increasing perfusion of skin if the temperature increases. See section 5.4 for further discussion.
The increase in temperature rise if a thicker silicone layer is used, is smaller in the theoretical model than for the measurements (apart from the first step, where the TOS temperature rise was too low in the theoretical model). See section 5.4 for further discussion on this.

It could be advantageous to use a homogeneous physical model without the need of separate layers. The theoretical model is used to estimate the suitability of using a TOS-material with somewhat different properties. The criterion is that temperature rise reasonably agrees with the physically measured values. The modelled materials are TOS and several variants:

TOS, but with: K = 0,25 W m^{-1} K^{-1} (was 0,58)
K = 0,4 W m^{-1} K^{-1}
K = 0,5 W m^{-1} K^{-1}
TOS, but with: c_v = $2{\cdot}10^6$ J m^{-3} K^{-1} (was $4{\cdot}10^6$)
TOS, but with: a = 6 dB cm^{-1} at 3,7 MHz (was 1,9 dB cm^{-1})
TOS, but with: a = 6 dB cm^{-1} <u>and</u> K = 0,25 W m^{-1} K^{-1}

Table 7 summarises the results.

Table 7. Modelled surface temperature rises after 300 s of heating with various models

Property change	**? *T* (°C) - Theoretically modelled (t = 300 s; aim: 4,5°C)**	**Remarks**
TOS	3,3	Too low
K = 0,25 W m^{-1} K^{-1}	3,6	Too low
K = 0,4 W m^{-1} K^{-1}	3,4	Too low
K = 0,5 W m^{-1} K^{-1}	3,3	Too low
c_v = $2{\cdot}10^6$ J m^{-3} K^{-1}	3,4	Too low
a = 6 dB cm^{-1}	4,0	Reasonable
a = 6 dB cm^{-1}; K = 0,25 W m^{-1} K^{-1}	4,8	Better

It is observed that changing heat conductivity K or volumetric heat capacity c_v does not have sufficient effect on ?T. It is the ultrasound absorption a that has to be increased considerably in order to obtain a temperature rise close to the measured value, preferably combined with decreasing K.

In mimicking materials like TOS and silicone, no perfusion can be modelled. The effect of (the absence of) perfusion (quantity t is the typical perfusion time) is investigated using the theoretical model. Two quite extreme situations have been modelled: no perfusion (t = 8) in all modelled materials and reasonably high perfusion (t = 100 s, representative for high perfusion in nonfatty tissue) in all modelled materials. Table 8 gives the results for heating during 300 s, in one case during 60 s.

Table 8. Effect of perfusion on modelled surface temperature rises.

Materials	**? *T*(°C; theoretical) (t = 100 s)**	**? *T*(°C; theoretical) (t = 8)**	**Difference (%)**
TOS with K = 0,4 W m^{-1} K^{-1}	3,2	3,4	7
1,1 mm silicone on TOS	3,8 (1,9 after 60 s)	4,4 (2,1 after 60 s)	15 (8)
1,0 mm skin on nonfatty tissue	4,0	4,5	13

Whether or not perfusion is modelled, is relatively unimportant, in view of the large difference in t. The maximum effect is observed in silicone on TOS (15% for 300 s heating) and decreases if heating time is lower.

5 Discussion

5.1 General

The curve fitting method that is used to extrapolate the measured temperatures to longer heating times, gives confidence that the extrapolated values are within 5% of the measured value if the transducer had been switched on for longer times. However, heating times of at least 200 s and preferably at least 250 s are needed to obtain a heating curve on which a reliable fit can be made. For this reason the two transducers for which heating was too short, were excluded from further analysis.

Endocavity transducers differ from external transducers in two fundamental ways:

- The transducers are intended to be used only inside the human body, not on the underarm.
- The transducers have a very different construction (e.g. smaller, strongly curved), which in the measurements may have led to ultrasound being emitted very close to (or even past) the edge of contact with the underarm. Also thermal transfer processes in the transducer itself are probably quite different from externally applied transducers.

In spite of these differences, it was observed that endocavity transducers behave reasonably similar to ‘normal’ transducers. In the analyses of the results they are treated as every other transducer.

5.2 Transducer surface temperature rise in air versus on the underarm

The measured temperature rise in air is on average 1,71 times higher than on the underarm (endocavity transducers included). The standard deviation of this ratio is 12%, based on the variation between the transducers. The corresponding type A expanded uncertainty at a 95% level of confidence is 23%. If also the variation in the underarm measurements is taken account of (expanded uncertainty 6% to 12%, take now 10%), the type A expanded uncertainty is 25%. With the variety of transducers and underarms that is used in this investigation, this is a very promising result. It opens the possibility (also for endocavity transducers) to calculate surface temperature rise on tissue from measurements in air, which would be quite practicable.
This result can be somewhat improved if the influence of the output beam dimensions (OBD) is taken into account. After linear regression of the ratio ?T_{air} / ?T_{tissue} as a function of OBD, the standard deviation of the deviation of the data points from the regression line, is 9%. This means that if the OBD is known and temperature rise in air is measured, the surface temperature rise on tissue can be predicted within 19% (95% confidence), and within 21% if variation in underarms is taken account of.

In the preceding project (TNO report PG/TG/2001.246, December 2001), it was found that the ratio ?T_{air} / ?T_{TOS} was 3,0 to 3,5, which is considerably higher than found in this second project for the ratio ?T_{air} / ?T_{skin}. The explanation for this difference is probably the fact that TOS has almost twice as high a heat conductivity than tissue (human skin). The temperature rise on TOS is therefore lower than on human skin, and the ratio ?T_{air} / ?T_{TOS} accordingly higher.

In the preceding project it was also found that I_{ob} had a considerable influence on the ratio ?T_{air} / ?T_{TOS}. In the second project, TOS is investigated to some extent, but not in relation to air measurements; the ratios ?T_{air} / ?T_{skin} and ?$T_{silicone1.5}$ / ?T_{skin} are used. The explanation for the absence of a significant dependence on I_{ob} is probably that skin and air are both bad heat conductors compared to TOS. The ratio ?T_{air} / ?T_{skin} will therefore be more difficult to influence than the ratio ?T_{air} / ?T_{TOS}: the ratio is less sensitive to precise heating processes, including I_{ob}. Especially at small I_{ob} the surface temperature on TOS cannot rise very high due to efficient heat conduction away from the 'hot spot'. This effect is less at larger I_{ob}. This I_{ob}-dependence of the ratio is basically caused by a good heat conductivity and therefore is not observed on materials that have lower conductivity (at least about factor 2): in this case skin.
In the preceding project it was also found that OBD had no observable influence on the ratio ?T_{air} / ?T_{TOS}. The explanation for this absence of influence could be that in the preceding project the OBD-values were all grouped around OBD = 50 mm^2, with two points almost coinciding at OBD = 250 mm^2. Such a distribution is not suitable for the determination of a dependence. In this second project the points are much more evenly distributed between 0 mm^2 and 330 mm^2 and indeed a weak dependence is found, although not significant at the 95% confidence level.

5.3 Transducer surface temperature rise on a layer of silicone on TOS versus on the underarm

The physical model with a silicone layer on TOS to mimic the situation on human skin, yields reasonable results, especially in the light of the variation between transducers:

- B-mode, PW Doppler mode, Colour flow mode and combination modes
- Linear (not curved), curved linear and endocavity transducers
- Powers from 9 mW to 235 mW
- Output beam intensities from 1 mW/cm^2 to over 800 mW/cm^2
- Frequencies from 2,5 MHz to 7,0 MHz
- Output beam dimensions from 15 mm^2 to 330 mm^2

Also temperature rises from the endocavity transducers, in spite of their different design, can be analysed together with those of the other transducers.
The equilibrium temperature rise ?$T_{eq,silicone}$ (averaged over the transducers) for all silicone thicknesses (0,5 – 1,5 mm), including pure TOS, deviates maximum 16% from ?T_{skin}. However, the variation between the transducers cannot be ignored: around 23% for 1,5 mm silicone on TOS and around 14% for 0,5 mm silicone on TOS.
For all heating times there is no recommended silicone layer thickness. A thickness of 1,5 mm silicone seems to be the most suitable for imitating the situation on human skin: the temperature rise (averaged over the transducers) deviates not more than 7% from the rise on skin, but the variation between transducers leads to an uncertainty around 23% (95% confidence). A 0,5 mm silicone layer mimics human skin and tissue more reproducibly (uncertainty around 14%), but less accurately (deviation up to 16%). One warning should be given on the reliability of the figures: the number of measurements

on 0,5 mm silicone is quite small (6). Therefore there is not a specific thickness recommended at this stage.
The pure TOS measurements clearly deviate from the tissue measurements (at least 25%), since TOS conducts the heat away from the transducer better than silicone. The variation between the transducers is smaller than for the silicone layer models (11% to 14%; 95% confidence). Therefore, pure TOS could be a suitable candidate for the physical model to mimic human skin and tissue, provided a correction factor is applied.

The results lead to the following conclusions:

- If the model is required to yield as closely as possible an absolute temperature rise on human skin on tissue, the 1,5 mm or possibly the 1,1 mm silicone layer seems to be the best model for the human underarm, for heating during 100 s or more. The difference between the average temperature rise on a 1,5 mm silicone layer on TOS and the human underarm is not more than 7%. However, the variation between transducers introduces an uncertainty around 23% (95% confidence) of the ratio, depending on the heating time.
- If reaching a representative absolute temperature rise is less important, but a model is required for which ?T_{silicone} / ?T_{tissue} is less sensitive to the kind of transducer (less variations), pure TOS and the 0,5 mm silicone layer on TOS are the best choice. The uncertainty is 11% to 15% of the ratio, depending on the heating time. The absolute temperature rise deviates more from that on the human underarm than for the other models, 9% to 16% for 0,5 mm silicone and 25% to 32% for pure TOS, depending on the heating time. Therefore, the introduction of a correction factor to account for this systematic deviation from the ‘human underarm’-case is needed if an absolute temperature rise is required, especially if pure TOS is used.
- If the primary interest is to have a suitable thermal mimic of skin and tissue after a long heating time (‘infinity’), the most *representative* choice is 1,5 mm silicone on TOS (deviation 7%; uncertainty 25%) but the most *reproducible* choice pure TOS (deviation 32%; uncertainty 11%). These results need further corroboration, since they are based on 5 to 8 transducers only.

It was found that the factor to be applied to convert silicone temperature rise to skin temperature rise, is less related to the person (underarm) than to the transducer type. This gives confidence in the possibility to generalise the method at a later stage.

From the ratios ?T_{silicone} / ?T_{skin} after 100 s, 300 s and infinite heating, a time dependence of the heating process is observed. The silicone layers first heat up about as fast as the underarm, but later the relative temperature rise on the underarm is larger than on silicone. The latter effect can be explained from the increased perfusion of the skin and tissue: this removes the heat, but also creates a higher ‘basic temperature’, since blood temperature is higher than skin temperature. No investigation into these complex processes has yet been carried out.

5.4 Effects of tissue or transducer properties on surface temperature rise as predicted with the theoretical model

The theoretical model has been applied to a number of situations to predict the effect of different material properties: silicone thickness on TOS, physical parameters of TOS, and especially perfusion in TOS.

5.4.1 Silicone thickness

For the silicone layers on TOS it is observed that the theoretical model gives a reasonable estimate (within 10%) of surface temperature rise after 300 s heating. After 1800 s, there is generally an overestimation of 15% to 35%. This points to the fact that in the theoretical model, heat conduction may not be taken high enough. Especially the transducer backing is an important source of uncertainty, since the material and its thickness are less well known and heat conduction of the backing to the cable has not (yet) been modelled. This could lead to too much heating of the backing, resulting in a higher modelled temperature rise, especially after longer times. Also in other modelled situations we have to take this into account.

The increase in temperature rise if a thicker silicone layer is used, is consistently somewhat smaller in the theoretical model than for the measurements (apart from the thinnest layer). There can be many reasons for this difference, such as deviations in theoretical transducer modelling, silicone modelling and TOS modelling. At this stage in the project it is too early to speculate about the causes.

5.4.2 Effect of physical parameters of pure TOS on surface temperature rise

It would be attractive to use one single material, without separate silicone layers, to simulate the situation on human skin and tissue (*in situ*). One of the requirements is that the surface temperature rise is not too far from the *in situ* situation. For TOS the surface temperature rise is 3,3°C for a specific transducer in a specific mode, while for the underarm it is 4,5°C. It was found that decrease of heat conductivity and decrease of volumetric heat capacity do not sufficiently increase the calculated temperature rise to bridge the gap between TOS and the *in situ* situation. This can only be done if acoustic absorption is considerably increased, up to the levels of at least silicone (so from 1,9 dB cm^{-1} to 6,0 dB cm^{-1} at 3,7 MHz). Moreover, heat conductivity should be decreased. Then the model is more resembling the skin–tissue situation: high absorption and low conductivity in the skin. Whether a model consisting of one single material with these physical properties can be made consistently, is an investigation that could, with regard to the amount of work, be defined as a project in itself.

5.4.3 Effect of perfusion

The theoretical model is applied to TOS with varying perfusion constants. It was found that after 300 s heating there is not much difference (maximum 15%) between the surface temperature rises obtained with reasonably high perfusion and without any perfusion in the materials (TOS, silicone on TOS and skin on tissue). Therefore, it is reasoned that the improvement of the physical model by adding perfusion to it, does not balance the difficulty to manufacture it. Moreover, the effect of higher perfusion (lower temperature rise) can partly be obtained by decreasing heat conductivity, decreasing volumetric heat capacity, or increasing absorption.

These results are valid for heating during 300 s, which is about the maximum that is clinically relevant. For shorter periods the effect of perfusion is less, as is observed for the silicone in TOS set-up.

6 Conclusions

- We believe that in any model to represent "normal use" for externally used transducers, a layer of skin should be mimicked. Results up till now show reasonable agreement between 1 to 1,5 mm of silicone rubber on a soft tissue mimic and the underarm. An example set-up for the measurement of externally used transducers is given in Appendix A and has been proposed to be implemented in the IEC 60601-2-37 1st Amendment.
- For the endocavity transducers there does not seem to be a strong argument for potting. A reason for potting could be the 2D or colour flow mode, but usually the power density at the surface is lower than in a mode like PW Doppler. Using coupling gel on a tissue mimic pots well enough.
- If a thermocouple is used for the measurement, it should be a very thin flat type. Most suitable are small thin film thermocouples, size in the order of 15 µm.

- Endocavity transducers have a construction that considerably differs from external transducers with regard to thermal properties. Also the endocavity transducers between themselves can vary considerably. However, the comparisons between model measurements (air or physical model) and *in situ* measurements (underarm, skin on tissue) reveal that endocavity transducers do not considerably differ from the other transducers in their results, so they are covered by the models described in this report.
- The surface temperature rise on the underarm due to heating by external transducers can be estimated based on air temperature rise measurement and applying a correction factor of 1,71. The type A uncertainty (95% confidence) of temperature rise using this method is 23%, including variation between underarms. If OBD is accounted for as a (weak) factor of influence, the uncertainty is reduced to 19%.
- Contrary to the preceding project, where the ratio ?T_{air} / ?T_{TOS} was investigated, the output beam intensity is found to have no effect on the ratio ?T_{air} / ?T_{tissue} or ?T_{silicone} / ?T_{tissue}. This is probably due to the difference in thermal properties of TOS (preceding project) and tissue (current project).
- The variation between the persons (underarms) is smaller than the variation between the transducers, as far as the conversion from ?T_{silicone} to ?T_{tissue} is concerned. This gives confidence in the possibility to generalise the method at a later stage.
- The use of one single TOS-like material to mimic skin on tissue (the human underarm) regarding absolute temperature rise, seems not to be feasible, unless a lot of effort is put into developing such a material, which should have increased frequency dependent absorption.

  If however a larger deviation from the underarm absolute temperature rise is allowed (which would necessitate the use of a correction factor), TOS seems to be a suitable candidate. However, this depends on further research.

Further activities

Further activities within or outside the project are recommended, at this stage regardless of the feasibility:

- The effect of perfusion in human skin and underlying tissue should be investigated and possibly theoretically modelled.
- More temperature measurements on silicone on TOS, or pure TOS, are necessary to better investigate suitable silicone thickness and the relation with temperature rise on the underarm. The possibility to reduce the variation between the ratios ?T_{silicone} / ? T_{tissue} for the various transducers should be investigated.
- Investigate the possibility to calculate surface temperature rise on skin (underarm) for heating times between, say, 0 s and 180 s, based on the measured values on silicone and in air for these heating times.
- The thermal properties of the transducer should be better modelled in the theoretical description, since this has a considerable effect on the thermal processes.

7 References

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8 Signature

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A Example set-up to measure surface temperature for externally applied transducers.

A.1 General

The test object set-up described below is a result of measurements presented in report PG/TG/2003.134 [ref. 4]. For at least 10 different transducers, the surface temperature of the transducers radiating into human underarms was compared with surface temperature rise on several models and set-ups described.

Basically the set-up consists of a piece of Soft Tissue Mimicking Material (TOS) covered by a slab of silicon rubber on which a (thin film) thermocouple is placed (see figure A.1). The TOS is placed on a piece of material that absorbs all acoustic energy.

The properties of the materials used will be those of silicon and TOS as listed in table A.1:

Table A.1 Acoustic and Thermal properties of some tissues

Tissue	Velocity c (m s^{-1})	Density r (kg m^{-3})	Attenuation coefficient a (dB cm^{-1}f^{-1})	Acoustic impedance Z (10^6 kg m^{-2} s^{-1})	Spec. Heat capacity C (J kg^{-1} K^{-1})	Thermal Conductivity k (W m^{-1} K^{-1})	Thermal Diffusivity D (10^{-6} m^2 s^{-1})	Source
Skin	1615	1090	2,3 – 4,7 3,5 [2)]	1,76	3430	0,335	0,09	[1]ICRU rep.61 1998 [2]Chivers 1978
Silicon	1021	1243	5,5	1,3		0,25		TNO / Dow Corning
Soft tissue	1575	1055	0,6 – 2,24 [5)]	1,66	3550	0,525	0,150	ICRU rep.61 1998
TOS	1540	1050	1,5	1,6	3800	0,58	0,15	[3]TNO (Soft Tissue Model)
Soft tissue Fatty	1465	985	0,4	1,44	3000	0,350	0,135	ICRU rep.61 1998
Cortical Bone	3635	1920	14/22	6,98	1300	0,79	0,32	ICRU rep.61 1998

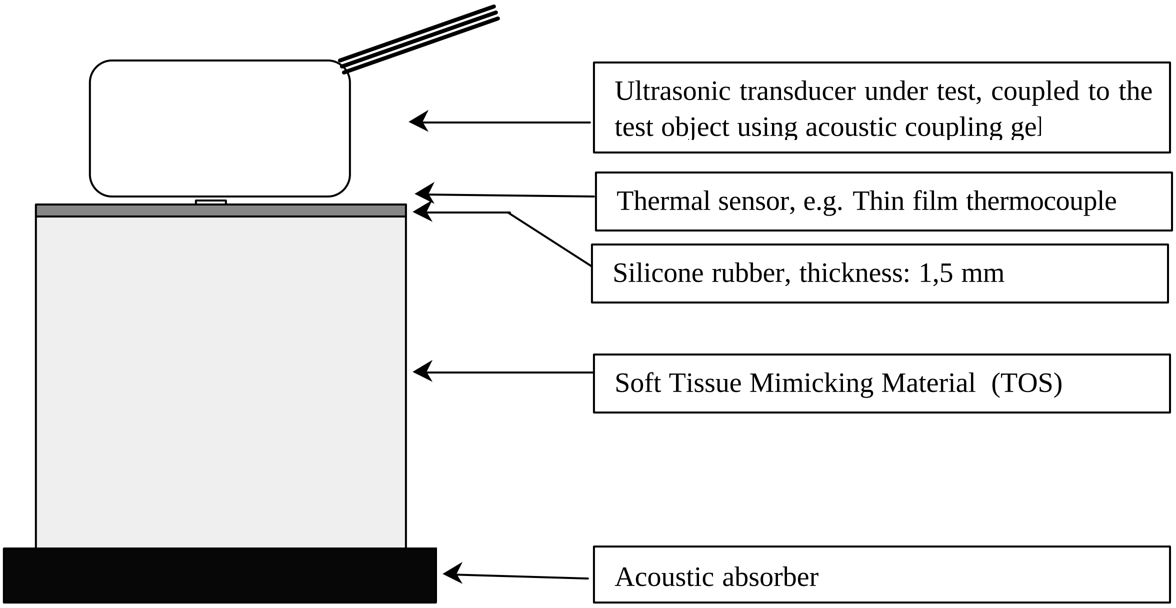

Figure A.1. Set-up of an example test object to measure the surface temperature of externally applied transducers.

A.2 Preparation of the Soft Tissue Mimicking material (TOS)

A mixture is made from the following materials (weight % pure components)

Table A.2 Weight % pure components

Component	Mass %
Glycerol	11,21
Water	82,95
Benzalkoniumchloride	0,47
Silicon Carbide (SiC)	0,53
Aluminium Oxide (Al_2O_3 (0.3 µm))	0,88
Aluminium Oxide (Al_2O_3 (3µm))	0,94
Agar	3,02
Sum	**100**

A.3 Recipe to prepare the Soft Tissue Mimicking Material (TOS) and the set-up

1. Mix all components listed in the table and degas at laboratory temperature.
2. Heat, while stirring, till 90 °C.
   To avoid evaporation and hence a change in components ratio, the substance should be covered during this process.
3. Cool the substance, while stirring as long as the viscosity allows, till about 47 °C.
   To avoid evaporation and hence a change in components ratio, the substance should be covered during this process.
4. Pour the substance quickly in a mould and let it further cool down while the mould is covered.

5. The TOS is now ready for use. To prepare the total measurements set-up the TOS should be covered with a slab of silicone rubber with a thickness of 1,5 mm. Take care that there is no air between the TOS and the silicon rubber.
   Although figure A.1 shows a set-up for a flat transducer surface, a curved surface is easily obtained by cutting the curvature in the TOS.
6. A (thin film) thermocouple is to be placed on top of the silicone rubber layer.
7. Finally the transducer under test has to be placed, coupled with acoustic coupling gel.

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[1] ICRU Report 61, Tissue substitutes, phantoms and computational modelling in medical ultrasound, International Commission on Radiation Units and measurements, June 1998, ISBN 0-913394-60-2.

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