On the development of a method to measure the surface temperature of ultrasonic diagnostic transducers.

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Abstract. A project to develop improved and practical procedures to measure the surface temperature of diagnostic ultrasound transducers under normal use conditions has been carried out. The approach taken in the project was first to produce tissue mimicking material and an experimental measurement set-up that could lead to reasonably accurate and reproducible values of surface temperature rise. The relative influence of different tissue layers close to the surface has been modelled. Measurement results obtained using different types of thermocouples and using an infrared camera system were compared. Typical transducer surface temperature rises on a layered physical model were compared to those obtained on human skin (forearm).

The difference between the average temperature rises on a 1.5 mm silicone layer on a soft tissue mimic and on the human forearm was not more than 7%. However, the variation between transducers introduces an uncertainty around 23% (95% confidence) of the temperature rise ratio. If the output beam dimension is accounted for as a (weak) factor of influence, the uncertainty is reduced to 19%. For endocavity transducers there does not seem to be a strong argument for potting the transducer in a tissue model.

An example set-up for the measurement of externally used transducers has been implemented in the IEC 60601-2-37 1st Amendment. The material developed can be ordered from TNO.

1. Introduction
In the draft IEC standard 601-2-37 in section 42.3 a measurement method to measure the surface temperature of diagnostic ultrasound transducers has been proposed. Much comment was given to the measurement procedure to obtain the surface temperature. Difficulties identified were: firstly, it was difficult to obtain measurement uncertainties better than 1 ºC and secondly, it will not be easy to implement the method in the manufacturer surrounding and, finally, an adequate physical model description was missing. Supported by a consortium of manufacturers, TNO-PG has started a project to develop adequate methods [1].

2. How to define: Normal Use
The ultrasonic transducer surface heating depends on the tissue in contact with the surface and its surrounding tissue. A number of human and artificial tissues are described in [2]. This tissue as seen from the transducer surface can roughly be grouped into five categories:
A: a thin layer of skin followed by soft tissue,
B: soft tissue all around,
C: a thin layer of skin followed by bone tissue (close to the surface) and further soft tissue,
D: soft tissue all around and bone tissue (close to the surface),
E: a fluid filled mass (the eye).
The importance to include skin and bone in the model follows from practical measurements supported by numerical modelling. Model E has not been examined, model D only partly.

3. Numerical tissue modelling
A numerical model has been developed, based on the one-dimensional bio heat transfer equation [3] using the monopole "point-source" solution as presented in [4, 5]. The model takes into account heating by ultrasound and direct heating through the transducer surface. Ultrasound and thermal parameters of transducer front (surface + backing) and model materials are defined in Table 1. The model material can consist of up to 3 layers, apart from the transducer material. Perfusion time $\tau$ in the model was related to the blood perfusion rate $w$ [6].

| Material                  | Speed of sound $c$ (m s$^{-1}$) | Density $\rho$ (kg m$^{-3}$) | Attenuation coefficient $\alpha$ at 3 MHz (dB cm$^{-1}$) | Acoustic impedance $Z$ ($10^6$ kg m$^{-2}$ s$^{-1}$) | Spec. Heat capacity $C$ (J kg$^{-1}$ K$^{-1}$) | Thermal Conductivity $\kappa$ (W m$^{-1}$ K$^{-1}$) | Thermal Diffusivity $D$ (10$^{-6}$ m$^2$ s$^{-1}$) |
|---------------------------|---------------------------------|------------------------------|------------------------------------------------------------|-------------------------------------------------|-----------------------------------------------|-----------------------------------------------|-----------------------------------------------|
| Bone (avg)                | 3000                            | 1600                         | 15 -                                                       | 5.5                                             | 1300                                          | 0.55-0.58                                      | 0.28                                          |
| PE (LD)                   | 2320                            | 900                          | 7.4                                                       | 2.01                                            | 1844                                          | 0.35-0.47                                      | 0.21-0.28                                     |
| Soft tissue (avg)         | 1575                            | 1055                         | 0.6 – 2.24                                                | 1.66                                            | 3550                                          | 0.525                                         | 0.14                                          |
| Soft tissue mimic         | 1540                            | 1050                         | 1.5                                                       | 1.6                                             | 3800                                          | 0.58                                          | 0.15                                          |
| Skin                      | 1615                            | 1090                         | 2.3 – 4.7                                                 | 1.76                                            | 3430                                          | 0.335                                         | 0.09                                          |
| Silicon rubber (avg)      | 1021                            | 1243                         | 5.5                                                       | 1.3                                             | 2400                                          | 0.25                                          | 0.08                                          |
| Transducer front          | 1200                            |                              |                                                            |                                                 |                                               |                                               |                                               |

An ultrasound beam in a 2-dimensional matrix is defined ($z$ and $r$; cylindrical symmetry). Between 0 and 5 mm from the transducer face the beams changes gradually from a fully rectangular beam to a fully Gaussian beam. Local heating of tissue by ultrasound follows from absorption in the material, under the assumption of linear behaviour of ultrasound. Direct heating of the transducer material follows from the transducer efficiency, total power, and transducer material specific heat capacity and size. These local heat sources (in Wm$^{-3}$) are defined in the same matrix as the ultrasound beam, extended by the transducer material matrix. For each point in this matrix the temperature rise due to heat conduction from other points to this point is calculated (see Figure 1).

![Figure 1](image1.png)

**Figure 1.** The calculation procedure to come from a pressure distribution through the bio-heat transfer function using the monopole "point-source" solution to the distribution of temperature rise.

This theoretical model is mainly used to predict the suitability of physical models that differ from those on which temperature measurements have been carried out. Another model has been used to estimate the relative importance of the different tissue layers for the temperature rise of the transducer surface. It is modelled with and without a 1.5 mm and 0.5 mm thick skin surface, with or
without bone close to the surface and a moderate \( (\tau=150 \text{ s}) \), or high \( (\tau=250 \text{ s}) \) perfusion. In these cases the transducer efficiency was set to 40 % and the focus has been set very far \((2000 \text{ mm})\). The calculations were performed for a 5 MHz and 2 MHz source with a beam diameter of 15 mm.

From the theoretical modelling it follows that the surface temperature rise is significantly higher using a skin layer than using soft tissue only.

4. Physical tissue modelling

The soft tissue test object material that has been used mainly consisted of agar, water and glycerol, with some powder additions to get a proper ultrasonic attenuation and scattering. See for the acoustic and thermal properties Table 1. The recipe is given in [7]. The advantage of this material is that it mimics the acoustic and thermal properties of soft tissue very well. It can also easily be produced in different forms. The disadvantage is that the material has to be stored in a water-glycerol fluid as the properties will change because of drying out in air and diffusion with a surrounding liquid.

Silicone rubber has been used to mimic skin. Low density PE (polyethylene) has been used to mimic bone. See for the acoustic and thermal properties Table 1.

Figure 2. Four different types of tissue model set-up. A: soft-tissue model, B: soft-tissue model with a transducer potted in gel, C: soft-tissue model to hold a curved transducer, D: soft-tissue model with a bone mimic at the surface. The bottom of all models is placed on a proper acoustic absorber.

Figure 3. Infra-red image of the interior of a soft-tissue mimic with bone at 16 mm depth.

In the project several set-ups are used, see Figure 2. For some measurements a set-up has been used where the tissue mimicking material could be opened to measure the temperature distribution in the mimic by means of an infrared camera. The advantage of this model is that not only the temperature at the surface can be measured but also at the same time the heat developed in a plane along the acoustic axis. With this model also the influence of bone near the surface has been investigated, see Figure 3. For the five models used a 10x16x4 mm bone mimic was at a depth of
respectively 0, 3.7, 9.3, 16 and 50 mm. Results are shown in Figure 4. They clearly show that the transducer surface temperature will considerably rise when bone is within 10 mm from the surface.

The need to use potting has been investigated for externally as well as for endo-cavity transducers. Figure 5 shows a block of tissue mimicking material (10x10x10 cm) with a hole to put in the transducer. The free space in the hole is filled with acoustic coupling gel. The transducer is fully potted from 80 mm from the front surface. The figure also shows a half potted transducer: potted in the scan direction. The simplest way of potting however is to put the transducer in a container filled with acoustic coupling gel. One of the difficulties in all the “potted” measurements is aligning the “hot spot” to the centre of the thermocouple.

![Figure 5. Schematic set-up on the left shows how endocavity transducers were potted, on the right respectively fully potted, only the top is potted covered with gel and potted in gel. In all models the transducer surface is acoustically coupled to soft tissue mimicking material.](image)

The results presented in Figure 6 show that there is not much difference when using the different potting set-ups. The average temperature rise of these different ways of potting is 4.6 °C with a variation of 0.3 °C. Here the results using a complete potting with tissue mimicking material were very close to that using the gel potting set-up (difference only 0.2 °C).

![Figure 6. Results of temperature measurements of a 6 MHz endo-cavity transducer in fully potted half potted or a gel potted situation as identified in Figure 5.](image)

5. Size of a thermocouple

The use of an infrared camera has shown to be very practical. It gives at one glance an overview of the size of the heated spot, see Figure 7. More often thermocouples are used to measure the surface temperature. Positioning is then most important if the transducer is energised for less then one minute.

In the present survey the region where the temperature was 0.5 °C lower than the maximum temperature after 3 minutes ultrasound, ranged from 1 mm to 10 mm, see Figure 7. For all transducers the equilibrium temperature, within 0.2 °C, was reached within 5 minutes.

Although the heat distribution curves from the IR measurements in Figure 7 show a maximum allowable size of 0.7 mm, care should be taken to use thermocouples of this size as there may be an unacceptable heat transfer into the leads. Figure 8 shows typical results using a 0.013 mm, a 0.15 mm and a 1 mm thick type. In a comparison with the infra-red camera readings the 0.013 mm and 0.15 mm thermocouple showed good agreement, this is not the case for the 1 mm thermocouple.

To minimise effects due to ultrasound the size should be small compared to the wavelength.
6. Measurements at 37°C

Measurements are performed to investigate the need for an environment of 37 °C for “externally” used and endo-cavity transducers. The set-up consists of a temperature controlled water bath, in which the soft tissue mimic is fixed. The surface is just (0.5 mm) above the water level. Temperature of the water: 37.0 °C, temperature of the water surface: 35.6 °C, temperature of the surface of the tissue mimic: 31.2 °C. These temperatures show the inappropriateness of the method described in clause 42.3 of the IEC 60601-2-37 standard concerning the simulated use conditions at a surface temperature of 37 °C. It implies that the internal temperature of a test object has to be about 43 °C.

A comparison of measurements in two modes carried out at 21 °C and 37 °C is shown in Table 2. The thermocouple (Tc) has been attached to the transducer using foil, IR shows the temperature rise as measured with the infrared camera.

Table 2. Temperature rise of an endocavity transducer

| Scan mode              | Potted at 21 °C | Potted at 37 °C |
|------------------------|----------------|----------------|
| IR+ foil               | 2.5            | 2.6            |
| Tc + foil              | 2.5            | 2.5            |
| Colour Flow Mapping    | 4.6            | 4.5            |
| Tc + foil              | 4.6            | 4.6            |

7. Diagnostic transducers on human tissue (forearm)

From the numerical modelling it already followed that a model to represent “normal use” for externally used transducers should contain a layer of skin. Measurements have been carried out on such a model and on practical tissue parts of some volunteers. As a start the transducer surface temperature rise was measured on the forearms of 13 volunteers, see Figure 9. Later, after the range was known, this number could be reduced to 3 volunteers.

For the measurements a small thin film thermocouple (12 µm) has been used and the correctness of its position was checked afterwards with the infra-red image. Ultrasound is switched on at a specified setting during 3 to 5 minutes. 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:

$$\Delta T = \Delta T_{eq} \left(1 - e^{-\left(t + \delta\right)/\beta}\right)$$

In this expression, $t$ is the time after switching on, $\Delta T_{eq}$ is the equilibrium temperature rise (after infinite time), $\delta$ 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 $\beta$ is the $1/e$-time for this exponential behaviour.

A range of linear, curvilinear, externally applied and endocavity diagnostic transducers has been investigated. Modes comprised B, PW Doppler, Colour flow and combination modes, with powers...
ranging from 9 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 area from 15 mm\(^2\) to 330 mm\(^2\).

The equilibrium temperature rises on the human forearm range from 3.5°C to 17°C, and in air from 5.5°C to 34°C. The average ratio \(\Delta T_{\text{air}} / \Delta T_{\text{tissue}}\) was 1.71 with a standard deviation of 12 %, see Figure 10. This could be used to convert measured temperature rise in air to that on the skin of the human forearm. This ratio increases somewhat with increasing Output Beam Area. If this relation is used too the standard deviation of the differences is 9%. Relations with intensity and power are investigated too, but no relation has been found.

8. Evaluation
A complete understanding of the work carried out, the results achieved and the conclusions drawn has been given in [7]. A few main conclusions are given here.

The ultrasonic power and the output beam area is not found to be related to \(\Delta T_{\text{air}} / \Delta T_{\text{mimic}}\).

In any model to represent “normal use” for externally used transducers, a layer of skin should be mimicked. Results show reasonable agreement between 1 to 1.5 mm of silicone rubber on a soft tissue mimic and the forearm.

For the internally used transducers measured 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. Coupling gel on a tissue mimic pots adequate.

The size of a thermocouple is important. It is easy to fix a thermocouple by using thin foil, although there is a tendency that the temperature rise is somewhat higher.

An example set-up has been implemented in the IEC 60601-2-37 1\(^{st}\) Amendment. The references [1 and 7] and the soft tissue mimic material can be ordered from TNO.

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