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Influence of subcutaneous fat in surface heating of ultrasonic diagnostic transducers

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ABSTRACT

The transducers of diagnostic ultrasonic equipment generate undesired local heating at the applied part of the transducer surface. The assessment of this heating is fundamental in warranting patient safety. On the standard IEC 60601-2-37, methods have been established for the reliable measurement of heating, where three tissue models based on tissue-mimicking materials are recommended: soft tissue mimic only, bone mimic close to the surface of soft tissue, and skin mimic at the surface of soft tissue. In the present work, we compared the last-mentioned tissue model with a new one using a layer of porcine subcutaneous fat inserted between the soft tissue and skin-mimicking materials. We verify significant statistical differences between models, with the average temperature rise measured for the tests without subcutaneous fat at 6.7 °C ± 1.7 °C and for the ones with subcutaneous fat at 8.9 °C ± 1.8 °C ($k = 2$; $p = 0.95$). For each model, the procedure was performed 10 times in repeatability conditions of measurement. It has been suggested that the influence of subcutaneous fat for external transducers heating evaluation should be considered, as the presence of many millimeters of subcutaneous fat is a common condition in patients. Otherwise, the transducer surface heating and, therefore, the risk to the patient may be underestimated.

1. Introduction

Heating of ultrasonic transducer from the diagnostic equipment is an undesirable effect that is always present, and if the temperature rises excessively, tissues injuries may occur. A reliable evaluation of heating on applied parts of transducers (i.e. parts in contact with the patient) is a fundamental task on ensuring patient safety [1].

The heating generated by ultrasonic transducers can be explained by two mechanisms. One derives from the transducer inefficiencies on energy conversion, as only a small part of the electrical energy provided to the transducer is converted to acoustical energy, with the remainder dissipated as thermal energy [2]. Moreover, when acoustic waves propagate through a viscous medium, part of their energy is lost as heat, thus further increasing the local temperature. Being so, heating of a transducer surface is dependent on the acoustic and thermal properties of the tissue that it is in direct contact with, as well as of its surrounding tissues [3].

In the standard IEC 60601-2-37 [1], the basic conditions for a reliable ultrasonic transducer heating assessment are presented, and three possible measurement methods are proposed. In the first method, a test object near human temperatures is used to simulate human conditions. The applied part of the transducer must be coupled acoustically to the test object, which must be at initial temperatures of at least 33 °C (for external-use transducers) or 37 °C (for invasive-use transducers). To meet the requirements, the temperature at the transducer surface in these conditions shall not exceed 43 °C after 30 min of test. The second method is based on temperature rise measurements using also simulated conditions; however, the test objects shall be initially at temperatures between 20 °C and 33 °C. To meet the requirements with this procedure, the temperature rise shall not exceed 10 °C or 6 °C after 30 min of test for transducers intended for external or invasive use, respectively. The last method proposed in Ref. [1] is conducted in still air, without the employment of a test object. The initial temperature of the transducer surface must be the ambient temperature (23 °C ± 3 °C),

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and the temperature rise along the test shall not exceed 27 °C to meet the criteria.

The IEC 60601-2-37 also suggested three test object models for measurements implementation (based on tissue-mimicking materials): soft tissue all around, bone mimic close to the surface of soft tissue; and a thin layer of skin followed by soft tissue. Moreover, Hekkenberg and Bezemer [3–5] implemented four additional models: a thin layer of skin followed by bone tissue and further soft tissue; a thin layer of skin followed by a thin layer of soft tissue and a layer of bone; bone at the top followed by a layer of soft tissue; and a fluid-filled mass. To the best of our knowledge, there have been no more tissue models implemented in this sense.

The soft tissue-mimicking material (TMM) proposed in the IEC 60601-2-37 [1] has appropriated acoustical and thermal properties for matching that of human soft tissue, but has some faults in matching that of fatty soft tissues. In Table 1, these properties are presented (obtained from Ref. [1]), where considerable differences in some parameters for fatty tissue and TMM, as seen for the thermal conductivity, can be observed.

It is well known that subcutaneous fat has thermal insulation properties [6], which led us to think that considerable differences in the thermal field generated by ultrasonic transducers can be observed if mimicking materials with properties closer to fatty tissues are introduced into the test object. This is important for external applications of diagnostic ultrasound (as abdominal studies) because subcutaneous fat can reach thickness going from some millimeters to some centimeters, depending on a patient's characteristics [7]. If the presence of subcutaneous fat is ignored, the models cannot predict appropriately the thermal field produced by ultrasonic transducers, which may put the patients at risk.

Attempting to test our hypothesis, we implemented two test objects. One consisted of skin-mimicking material (SMM) followed by TMM. Another consisted of SMM followed by porcine subcutaneous fat and further TMM. The procedure employed for heating assessment followed the recommendations presented in Ref. [1], and the values obtained for both models were finally compared.

2. Materials and methods

2.1. Tissue models

The TMM was implemented based on the "recipe" presented in Ref. [1], and with appropriated dimensions for the transducer employed. Because the measurements were conducted with a convex transducer, a concave format was given at the top surface of the TMM.

The SMM consisted of a layer of room temperature vulcanizing (RTV) silicone with a thickness of 1.13 mm ± 0.19 mm, and their flexible characteristics allowed adaptation to the TMM surface.

To represent subcutaneous fat, porcine fat with a thickness of 15 mm ± 3 mm was used. This thickness was chosen because it is a typical value found in the abdomen of adult patients with body mass index within the healthy range [6]. The porcine fat was easily adapted to the TMM surface.

The coupling between TMM and SMM (Group 1), or between TMM, subcutaneous fat, and SMM (Group 2), was made by means of a conductive gel, avoiding the air presence. The assemblage for the test object corresponding to Group 2 measurements is presented in Fig. 1.

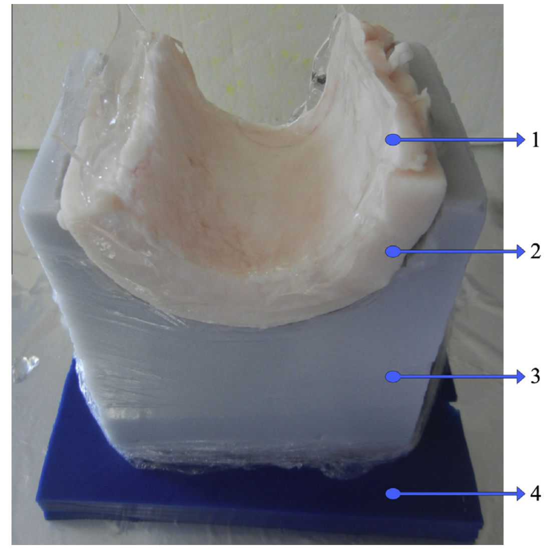

Fig. 1. Test object for transducer heating measurement, including subcutaneous fat (Group 2). (1) SMM; (2) porcine fat; (3) TMM; (4) acoustic absorber. The TMM was covered by a polymer lamina to avoid water evaporation during tests.

2.2. Temperature sensor

The temperature sensor used was an infrared (IR) camera (InfraCAMTM, FLIR Systems, Danderyd, Sweden) with an uncertainty stated by the manufacturer of ±2% in the temperature-measured values (Fig. 2). The use of an IR camera was preferred to thermocouples for two reasons: better localization of hot spots and to reduce influences of the sensor in the thermal field. The camera is also provided with the software ThermaCAM QuickReport (FLIR Systems, Danderyd, Sweden), which was used to read temperatures over the IR images acquired.

2.3. Ultrasound diagnostic equipment

The ultrasound diagnostic equipment used was from the Shantou Institute of Ultrasonic Instruments Co., Ltd. (CTS-5500V, SIUI, Guangdong, China). The measurements were made with the equipment operating on B-mode, and were configured to provide the maximum output power. The transducer consisted of a curvilinear array (C5F220, SIUI, Guangdong, China) working at a fundamental frequency of 5 MHz.

2.4. Measurement procedure

The first step consisted of coupling the test object components: the SMM to TMM for Group 1 measurements, and the fat layer to TMM and the SMM at top for Group 2. The TMM rests over an

Table 1
Acoustic and thermal properties of soft tissue, fatty tissue, and the TMM proposed in IEC 60601-2-37 [1].

Tissue/material	Velocity ($m\,s^{-1}$)	Density ($kg\,m^{-3}$)	Attenuation coefficient ($dB\,cm^{-1}\,MHz^{-1}$)	Acoustic impedance ($10^6\,kg\,m^{-2}\,s^{-1}$)	Specific heat capacity ($J\,kg^{-1}\,K^{-1}$)	Thermal conductivity ($W\,m^{-1}\,K^{-1}$)	Thermal diffusivity ($10^{-6}\,m^2\,s^{-1}$)
Soft tissue	1575	1055	0.6–2.24	1.66	3550	0.525	0.150
Fatty tissue	1465	985	0.4	1.44	3000	0.350	0.135
TMM	1540	1050	0.5	1.6	3800	0.58	0.15