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Temperature Elevation in an Instrumented Phantom Insonated by B-Mode Imaging, Pulse Doppler and Shear Wave Elastography

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1 **Temperature elevation in an instrumented phantom**
2 **insonated by B-mode imaging, Pulse-Doppler and Shear**
3 **Wave Elastography**

4
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27 **Abstract** — Diagnostic ultrasound is the gold standard for obstetric scanning and one of the
28 most important imaging techniques for perinatal and neonatal monitoring and diagnosis.
29 Ultrasound provides detailed real-time anatomical information, including blood flow
30 measurements and tissue elasticity. The latter is provided through various techniques
31 including Shear Wave Elastography (SWE). SWE is increasingly used in many areas of
32 medicine, especially in detection and diagnosis of breast, thyroid, and prostate cancers and
33 liver disease. More recently, SWE has found application in gynaecology and obstetrics. This
34 method mimics manual palpation, showing the elastic properties of soft biological tissues.
35 Despite its rising potential and expanding clinical interest in obstetrics and gynaecology (such
36 as for assessment of cervical ripening or organ development and structure during pregnancy),
37 its effects on and potential risks to the developing fetus remain unknown. Risks should be
38 evaluated before recommendations are made on the use of SWE by regulatory bodies.
39 **Because** ultrasound is known to produce thermal and mechanical effects, this study measured
40 the temperature increase caused by B-mode, Pulse-Doppler (PD) and SWE, using an
41 instrumented phantom with eleven embedded thermocouples. Experiments were performed
42 with an Aixplorer® diagnostic ultrasound system (Supersonic Imagine, Aix-en-Provence,
43 France). As expected, the largest heating was detected by the thermocouple closest to the
44 surface in contact with the transducer (2.9°C for SWE, 1.2°C for PD, 0.7°C for B-mode after
45 380-second excitation). Both conduction from the transducer face and direct heating due to
46 ultrasound waves contribute to temperature increase in the phantom with SWE showing a
47 larger temperature increase than PD and B-mode. This manuscript offers a methodological
48 approach and reference data for future safety studies, as well as initial recommendations about
49 SWE safety in obstetrics and gynaecology.

50

51 **Keywords:** Shear wave elastography; Ultrasound safety; Phantom; Thermocouple;
52 Temperature change; tissue mimic; thermal damage; Obstetrics; Gynaecology; Fetus

53

54 INTRODUCTION

55

56 Shear wave elastography (SWE) is a non-invasive diagnostic imaging technique used for
57 mapping the elastic properties of tissues (Parker et al. 2011). This modality is being
58 increasingly used in many areas of medicine, offering high-quality diagnostic examination, as
59 it increases specificity and improves diagnostic accuracy, as discussed below. SWE provides
60 the elastic properties of soft biological tissues, from the measurement of the speed of
61 propagation of ultrasound radiation induced shear waves. Ophir et al. developed a strain-
62 measuring compression elastography method (Ophir et al. 1991). Elastography was initially
63 developed by Wilson and Robinson (1982) with the aim of quantifying Young's modulus for
64 diagnostic purposes. Young's modulus quantifies the stiffness, defined as stress divided by
65 strain, of a solid material. Tissue elasticity can be explored either by studying its deformation
66 under the effect of constant pressure (*i.e.* the static method) or by studying the propagation of
67 a mechanical shear wave induced by an oscillating source (*i.e.* the dynamic method)
68 (Dickinson and Hill 1982). SWE represents an ultrasound-based approach to manual
69 palpation medical examination (Fink 2013). Modern scanners like that used in this study
70 generate the shear wave by producing a displacement in the tissue through a focused, high
71 intensity and short duration ultrasonic push.

72 SWE has already been demonstrated that elastography is useful for characterizing malignant
73 tumours in breast (Klotz et al. 2014), thyroid (Monpeyssen et al. 2013) and prostate (Dudea et
74 al. 2011), as well as lymph nodes structure (Alam et al. 2008), and localized (Menten et al.
75 2010; Sandulescu et al. 2012) or diffuse liver diseases (Kennedy et al. 2018).

76 The use of SWE has recently been extended to gynaecology diagnosis of uterine
77 disorders (Metin et al. 2016; Stoelinga et al. 2014; Thomas et al. 2007) and to obstetrics
78 (Ogawa et al. 2012) for cervix stiffness/ripening assessment (Duan et al. 2020; Egorov et al.
79 2020; Hernandez-Andrade et al. 2013; Pereira et al. 2014). Potential indications of SWE in
80 fetal and uterine imaging during pregnancy include placental examination (Akbas et al. 2019;
81 Kılıç et al. 2015; Cimsit et al. 2015) and fetal organ development and structure. In fact, SWE
82 has recently been explored to assess fetal brain (Diguisto et al. 2017), lung (Mottet et al.
83 2019) and liver (Zheng et al. 2016), outside regulatory indication scopes. In obstetrics, the
84 first use of this ultrasound technique was for the study of cervix (maturation, threats of
85 premature delivery). The measurement techniques involving direct application of deformation
86 (the only ones used until now) are not perfect, especially in terms of reproducibility.
87 Histological modifications of the placenta in certain pathologies of pregnancy (*i.e.* pre-
88 eclampsia) could have an observable effect in terms of tissue elasticity. In the same way, the
89 evolution linked to the maturation of certain organs could also be of clinical interest. The
90 examination of the fetal lungs (in particular in order to assess their spontaneous maturity or
91 after preventive treatment of hyaline membrane disease by corticosteroid therapy) and the
92 pre-implantation endometrium in assisted reproductive technology (ART) are typical
93 examples. Few researchers have addressed the teratogenic effects of fetal elastography, one
94 example was the discussion held between K. Preisand and G. Rus at the World Congress of
95 Fetal Medicine in 2016 (Massó et al. 2017): although no apparent histological changes
96 following ultrasound elastography have been reported, the absence all bioeffects could not be
97 excluded (Sugitani et al. 2013). One of the first studies using SWE to assess cervical ripening
98 in 2012 (Peralta et al. 2017), conducted in the lack of any regulatory framework, was the
99 subject of comments (Massó et al. 2017) highlighting the need for follow-up of children
100 exposed *in utero*. The potential teratogenic effects of elastography were subsequently

101 explored by a follow-up study of the children at 4 years of age, focusing on the results of a
102 neonatal hypoacusis screening test and medical records. The exposed population was
103 compared to the reference population using a contingency-table analysis to assess excess risk.
104 Hypoacusis was reported in a late premature case (36 weeks, 1860 g), and was attributable to
105 a Prader–Willi-like phenotype. No other case negative outcomes were observed, though a
106 larger sample size would be beneficial. Some *in vivo* experiments have also shown that the
107 threshold temperature increase for teratogenic effects induced by hyperthermia is estimated at
108 1.5°C for an exposure of 5 min (Abramowicz et al. 2008).

109 Considering the increasing number of publications on elastography, the World
110 Federation for Ultrasound in Medicine and Biology (WFUMB) first published guidelines for
111 its clinical use in August 2011. The initial consensus meeting was held in March 2013 and led
112 to the development of general guidelines for elastography (Shiina et al. 2015), and specifically
113 for imaging of breast (Barr et al. 2015), liver (Ferraioli et al. 2015), prostate (Barr et al. 2017)
114 and thyroid (Cosgrove et al. 2017). These guidelines did not distinguish between the different
115 elastography modes. The European Federation of Societies for Ultrasound in Medicine and
116 Biology (EFSUMB) later published guidelines and recommendations for the clinical use of
117 ultrasound elastography (Dietrich et al. 2017; Săftoiu et al. 2018). Neither updated
118 recommendation included obstetric application. The only British Medical Ultrasound Society
119 (BMUS) recommendations regarding obstetrics focus on the use of B-mode and Pulse-
120 Doppler (PD) imaging (BMUS Safety Group 2010). To date, SWE has not been approved by
121 the Food and Drug Administration (FDA) for clinical applications in obstetrics.

122 Ultrasound can lead to two main types of potentially damaging effects on biological
123 tissues, namely thermal and mechanical effects (Shankar and Pagel 2011). A developing fetus
124 could be particularly sensitive to the aforementioned effects (Issaoui et al. 2018).

125 Previous studies have measured the temperature increase due to ultrasonic push used
126 in SWE (Lui et al. 2014). A pre-clinic experimental approach is also required, and developing
127 experimental techniques to measure the temperature rise in biological tissue caused by
128 ultrasound is of great interest for a variety of diagnostic and therapeutic applications.

129 Previous (non-SWE) studies have been performed to assess whether the temperature
130 increase in soft tissue mimicking materials can exceed the aforementioned safety limits
131 (Miloro et al. 2017; Calvert et al. 2007; Clarke and terHaar 1997; Palmeri and Nightingale
132 2004; Skurczynski et al. 2009). Thermocouples are known to generate artifacts (Morris et al.
133 2008), the main source being the viscous heating. In the work, mitigating actions have been
134 taken to reduce the artifacts. Different techniques that involve the analysis of ultrasound
135 images have been developed (Alvarenga et al. 2017), but require a high level access to the
136 raw data of the ultrasound scanners.

137 The present study aims to compare SWE imaging with two diagnostic imaging modes
138 which are in routine clinical use for scanning of pregnant women (B-mode and pulsed
139 Doppler (PD)). For this purpose, heating patterns caused by the three modalities were
140 characterized in an instrumented phantom, composed of a well characterized Tissue
141 Mimicking Material (TMM) with 11 embedded fine-wire thermocouples. It is important to
142 note that a perspective of the study concerns the health risk of SWE for fetus in terms of
143 temperature rises. The experimental program was carried out with a view to assessing health
144 risks in order to meet a clinical objective in obstetrics in the future.

145

146 **MATERIALS AND METHODS**

147

148 *Instrumented Phantom*

149 An acousto-thermal phantom with embedded thermocouples was designed,
150 manufactured and used to measure the temperature increase due to diagnostic ultrasound
151 excitation. The phantom was developed at the National Physical Laboratory (NPL,
152 Teddington, UK). The tissue mimicking material (TMM) used in the phantom was the agar-
153 based gel described in the IEC 60601-2-37 (2007). The recipe, based on 3% w/w of agar,
154 includes glycerol to match the speed of sound of soft tissues, as well as additives (silicon
155 carbide and aluminium oxide) to adjust the attenuation and backscatter coefficients. A plastic
156 frame mould was 3D-printed at NPL, in order to cast a $136 \times 80 \times 80$ mm³ block of TMM (see
157 Fig. 1-a to 1-c). For use and storage, the phantom was kept in an aqueous solution of 11.9%
158 w/w glycerol in order to prevent dehydration and glycerol leaching out of the TMM.

159 The main acoustic properties of the TMM were measured at NPL using the finite
160 amplitude insertion substitution (FAIS) method described by Baêsson et al. (2019): attenuation
161 was almost linear with frequency (0.57 ± 0.05 dB·cm⁻¹·MHz⁻¹) and speed of sound was 1540
162 m·s⁻¹ $\pm 1\%$. Thermal properties, measured using a hand held device (TEMPOS, Meter Group,
163 Pullman, WA, USA), were: specific heat capacity of 3770 J·kg⁻¹·K⁻¹, thermal conductivity of
164 0.58 W·m⁻¹·K⁻¹ and thermal diffusivity of 0.15 mm²·s⁻¹, with a quoted measurement
165 uncertainty of 10%. The density of the TMM was 1070 ± 30 kg·m⁻³ (IEC 60601-2-37, 2007).
166 These values are comparable to those of soft tissues. In particular, the IT'IS Database of
167 Tissue Properties (Hagall et al. 2018) reports values of 3676 J·kg⁻¹·K⁻¹, 0.53 W·m⁻¹·K⁻¹ and
168 1105 kg·m⁻³ for the specific heat capacity, the thermal conductivity and the density of uterine
169 tissues, respectively, while the IEC 60601-2-37 (2007) reports 0.6 dB·cm⁻¹·MHz⁻¹ and 1575
170 m·s⁻¹ for acoustic attenuation and speed of sound in soft tissues.

171 Eleven 75 μ m diameter K-type insulated thermocouples from Omega Engineering
172 (5SRTC-TT-KI-40-1 M, Manchester, UK) were embedded into TMM gel at pre-determined
173 positions in the phantom using notches in the frame used to mold the gel. The carefully

174 designed wire matrix is shown in Fig. 1-d and 1-e. One of the 11 thermocouples (called ref in
175 the figure), was used during the tests as a reference to track environmental thermal
176 fluctuation. It was placed at the location ($x = 0$ mm, $y = 24$ mm, $z = 74$ mm) to be outside the
177 ultrasonic excitation, so that it can be reasonably assumed that it provides the externally
178 affected TMM reference conditions. The present study is based on measuring temperature
179 change due to ultrasound excitation at the locations of the ten other thermocouples whose
180 coordinates are given in Table 1. The position of the thermocouples was chosen based on the
181 results of a previous work (Issaoui et al. 2020) and assuming symmetry in the temperature
182 field with respect to the two symmetry planes of the transducer. To limit the number of
183 thermocouples and reduce the complexity of the instrument, it was decided to place all of
184 them in one quarter of the phantom. **Because** the imaging probe can be orientated however the
185 user prefers, this does not limit the flexible use of the phantom. Thermocouples Tc-1 to Tc-7
186 were designed to be located in the transducer imaging plane ($y = 0$ mm) with Tc-8*, Tc-9* and
187 Tc-10* outside this plane by either 10 or 13 mm (*: symbol referring to thermocouples located
188 out of the transducer plane).

189

190 *Experimental setup*

191 Preliminary tests were performed by three operators (MI, PM and IR) at the
192 Institute of Cancer Research, London (ICR) to check the locations and the proper functioning
193 of the TMM embedded thermocouples, and to validate the feasibility of using the
194 instrumented phantom with an Aixplorer® scanner. Subsequently, the core of the study was
195 carried out at the department of obstetrics and gynaecology of the University Hospital of
196 Clermont-Ferrand (CHU), France. The test campaign was performed by five operators (MI,
197 XB, BB, MG, DL). The echography system used was an Aixplorer® (Supersonic Imagine,
198 Aix-en-Provence, France), featuring B-mode, PD and SWE imaging modes. Only a curved

199 SC6-1 probe (Supersonic Imagine, Aix-en-Provence, France) featuring 192 piezoelectric
200 elements and a bandwidth of 1–6 MHz, typically used in obstetrics, was employed. The
201 transducer face has a thickness of 15 mm, a radius of curvature of 100 mm and a frontal area
202 of $73 \times 15 \text{ mm}^2$. The imaging transducer was clamped in placed in contact with the top surface
203 of the phantom as shown in Fig. 2-a. Acoustic gel was employed to couple the phantom to the
204 transducer. Figure 2-b shows a typical B-mode image of the thermocouple wires. Table 2
205 provides the ultrasound settings used for each of the three imaging modes. For each of them,
206 the “obstetric preset” option was chosen, and no other settings were changed during the tests.
207 Ultrasonic imaging exposures lasted 380 seconds. This is a typical duration of an obstetric B-
208 mode examination (Martin et al. 2015). Although not directly comparable to a clinical
209 scenario, for comparison purposes, it was decided to consider the same duration for all the
210 three modalities. Temperature measurements began twenty seconds before exposure and
211 lasted 30 min so that the return to thermal equilibrium could be monitored. Temperature data
212 from the thermocouples were recorded using a TC08 datalogger (PicoTech, St Neots, UK)
213 connected to a computer. Recording frequency was set to 1 Hz. The standard deviation of the
214 noise in temperature measurements was lower than 0.01°C (measurable for instance during
215 the first 20 seconds before ultrasound excitation in Fig. 3). Ultrasound induced temperature
216 changes were calculated by subtracting the reference thermocouple temperature to the value
217 of thermocouples Tc-1 to Tc-10* at every time. The variation of the temperature reading for
218 the reference thermocouple was always below 0.05°C during the 400 s of insonation.

219

RESULTS

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Figure 3 presents the temperature change measured by the ten thermocouples as a function of time for (a) B-mode, (b) Pulse-Doppler (PD) and (c) Shear Wave Elastography (SWE). The first vertical dashed line indicates ultrasound activation, at time $t = 20$ s. The second one corresponds to the end of exposure, at $t = 400$ s. Values are shown until $t = 750$ s in order to demonstrate initial cooling. Temperature increases at $t = 400$ s are shown in Figure 4 using circles with diameters proportional to the maximum temperature change measured for each mode, which always occurs for Tc-1). This representation gives a better visualization of the temperature distributions for each mode but does not allow comparison between imaging modes. Finally, Figure 5 compares the temporal temperature variations of the three thermocouples closest to the transducer (Tc-1, Tc-10* and Tc-7) for the three imaging modes. Some important features can be extrapolated from the graphs:

- the maximum temperature increase was about 0.7°C , 1.2°C and 2.9°C for B-mode, PD and SWE respectively. After validation of the device and numerous preliminary tests, experiments were repeated twice and good reproducibility of the results was observed for each ultrasound mode (the maximum temperature variations between repeats was measured to be lower than 0.1°C for all thermocouples). It is worth **noting** that the objective of the study was not to perform a statistical analysis of the results, but to compare three ultrasound modalities among which two are already in routine clinical use for scanning of pregnant women;
- as expected from previous works (Miloro et al. 2017; Issaoui et al. 2020), the highest temperature rises were observed for Tc-1, which was just under the transducer. Large temperature changes were also observed for Tc-10* (more than 50% of the peak

244 increase), which was superficially close to the transducer (4 mm below Tc-1) but
245 10 mm away in the out of plane direction (see Fig. 1-d and 1-e);

- 246 • The temperature change at Tc-3 is smaller than the temperature change at Tc-2 and
247 Tc-4, whatever the mode under consideration. In particular, Tc-4 readings at 400 s
248 were about 0.04°C, 0.2°C and 0.4°C for B-mode, PD and SWE respectively;
- 249 • heating was also clearly detected out of the transducer plane for PD and SWE (see Tc-
250 8* to Tc-10*).

251

252

DISCUSSION

253

254 An instrumented phantom was developed for the assessment of the temperature increase
255 during B-mode, PD and SWE ultrasound imaging. 10 thermocouples were used, and their
256 positioning was not limited to being on the transducer axis. To our best knowledge, the
257 present study is the first one to measure heating variations due to SWE with thermocouples
258 inside a phantom. As expected from previous studies, the largest temperature rises were
259 observed for the thermocouple which was just under the transducer. This is likely to be due to
260 the self heating of the transducer and the effects are visible also for thermocouples outside
261 the imaging plane (Tc-10). More in depth, direct absorption of ultrasound energy is expected
262 to play a more significant role. The role of absorption is highlighted on the results by an
263 immediate and measurable temperature rise from Tc-2 and Tc-7, more evident in SWE where
264 a higher signal-to-noise ratio was achieved. Due to the proximity of these thermocouples to
265 the transducer, heat transfer is likely to play a role in the temperature readings at the end of
266 the insonation.

267 Furthermore, the temperature increase for Tc-4 was higher than the one observed for
268 Tc-3 (which is closed to the transducer) for all the imaging modes. It is interesting to observe

269 that in SWE mode, Tc-4 is within the focus of the acoustic beam used for generation of the
270 shear waves. Similar observations were made on a sample without embedded thermocouples
271 using surface infrared thermography (Issaoui et al. 2020).

272 Future studies could advantageously couple embedded thermocouples and surface
273 thermographic measurements in order to reconstruct the three-dimensional thermal field in the
274 sample.

275 A limitation of our study is that it was performed on a phantom composed of soft
276 tissue mimicking material only. The BMUS guidelines for the safe use of diagnostic
277 ultrasound equipment (BMUS Safety Group 2010) suggests using the bone thermal index for
278 obstetric scans after the 10th week. Many other studies have shown that heating of bones is
279 much higher than that of soft tissues (Tabaru et al. 2012; Nitta et al. 2001). Further studies
280 should be performed on phantoms containing soft tissues and bone mimicking materials.

281 On the other hand, in clinical practice, other factors such as the almost continuous
282 movement of the transducer, freezing of the output and reviewing acquired data during the
283 examination, blood perfusion and the presence amniotic fluid could reduce the temperature
284 changes deeper in the tissue. The TMM used in the present study was selected to mimic the
285 average acoustic and thermal properties of soft tissues. However, real tissues are
286 inhomogeneous.

287 Thermocouples have been used in the past to measure temperature increases in tissue
288 mimicking materials despite well-known artifacts in the measurements, the most relevant
289 being the viscous heating. Precaution have been taken to minimize these artifacts. The
290 sensitive element of the selected thermocouple was 3.5 times be smaller than the shortest
291 wavelength (257 μm at 6 MHz), following the indications of the IEC committee (IEC 60601-
292 2-37, 2007). The thermocouples were positioned such that the wires were on a plane
293 perpendicular to the acoustic propagation axis (Suo et al. 2019). Furthermore, diagnostic

294 imaging modes are characterized by small duty cycles, thus reducing the effects of viscous
295 heating (Morris et al. 2008).

296 Despite the limitations, a clear trend was observed: temperature rise is faster and
297 higher for SWE than by PD and B-mode, with the last two modes already in use in obstetrics
298 for decades. Although all the measured values, including MI and TI, fall within the safety
299 guidelines of BMUS, these are in the category of time limits.

300 The temperature rise due to SWE was the highest: about 2.5 times greater than that
301 due to PD, and more than 4 times greater than that due to B-mode. These results also indicate,
302 consistently with previous works (Milorio et al. 2017) that TI is a poor indicator of the actual
303 temperature rise in tissues. If TI is not displayed, like for B-mode and PD, it indicates values
304 below 0.4. These are at least 4 times lower than the TI indicated for SWE, which is not in
305 agreement with the results of this work.

306 However, recently released EFSUMB guidelines (Kollman et al. 2019), recommend
307 that Pulsed Doppler ultrasound should not be used routinely in early pregnancy (before the
308 14th week) and when used driven by a clear clinical motivation, the displayed Thermal Index
309 should be less than or equal to 1.0, and exposure time should be kept as short as possible.
310 BMUS guidelines (BMUS Safety Group 2010) also suggest that Pulsed Doppler should not be
311 used without a risk-benefit analysis (and always monitoring the TI) on the head, brain or spine
312 of any fetus or neonate or the eye of a subject of any age.

313 Based on the existing guidelines, the results of this work suggest that the risks
314 associated with SWE are higher than those associated with B-mode and PD. More in general,
315 the results raise questions about the health risk associated with obstetric SWE, as well as
316 about the approach to be put in place and the standards to be considered when certifying this
317 technique for obstetrical use.

318

319

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324

325 **References**

- 326 Abramowicz JS, Barnett SB, Duck FA, Edmonds PD, Hynynen KH, Ziskin MC. Fetal
327 Thermal Effects of Diagnostic Ultrasound. *J Ultras Med* 2008;27:541–59.
- 328 Akbas M, Koyuncu FM, Artunç-Ulkumen B. Placental elasticity assessment by point shear
329 wave elastography in pregnancies with intrauterine growth restriction. *J Perinat Med*
330 2019;47:841–46.
- 331 Alam F, Naito K, Horiguchi J, Fukuda H, Tachikake T, Ito K. Accuracy of Sonographic
332 Elastography in the Differential Diagnosis of Enlarged Cervical Lymph Nodes:
333 Comparison with Conventional B-Mode Sonography. *Am J Roentgenol* 2008;191:604–
334 10.
- 335 Alvarenga AV, Wilkens V, Georg O, Costa-Félix RPB. Non-invasive estimation of
336 temperature during physiotherapeutic ultrasound application using the average gray-level
337 content of B-Mode Images: a metrological approach. *Ultrasound Med Biol*
338 2017;43:1938–52.
- 339 Baêsso RM, Costa-Felix RPB, Miloro P, Zeqiri B. Ultrasonic parameter measurement as a
340 means of assessing the quality of biodiesel production. *Fuel* 2019;241:155–63.
- 341 Barr RG, Nakashima K, Amy D, Cosgrove D, Farrokh A, Schafer F, Bamber JC, Jeffrey C,
342 Castera L, Choi BI, Chou YH, Dietrich CF, Ding H, Ferraioli G, Filice C, Friedrich-Rust
343 M, Hall TJ, Nightingale KR, Palmeri ML, Shiina T, Suzuki S, Sporea I, Wilson S, Kudo
344 M. WFUMB guidelines and recommendations for clinical use of ultrasound elastography:
345 Part 2: Breast. *Ultrasound Med Biol* 2015;41:1148–60.
- 346 Barr RG, Cosgrove D, Brock M, Cantisani V, Correias JM, Postema AW, Salomon G,
347 Tsutsumi M, Xu HX, Dietrich CF. WFUMB Guidelines and Recommendations on the
348 Clinical Use of Ultrasound Elastography: Part 5: Prostate. *Ultrasound Med Biol*
349 2017;43:27–48.

350 British Medical Ultrasound Society, Safety group of the. Guidelines for the safe use of
351 diagnostic ultrasound equipment, 2010. <https://doi.org/10.1258/ult.2010.100003>.

352 Calvert J, Duck F, Clift S, Azaimé H. Surface heating by transvaginal transducers. *Ultrasound*
353 *Obst Gyn* 2007;29:427–32.

354 Cimsit C, Yoldemir T, Akpınar İN. Shear wave elastography in placental dysfunction:
355 comparison of elasticity values in normal and preeclamptic pregnancies in the second
356 trimester. *J Ultras Med* 2015;34:151–9.

357 Clarke RL, terHaar GR. Temperature rise recorded during lesion formation by high-intensity
358 focused ultrasound. *Ultrasound Med Biol* 1997;23:299–306.

359 Cosgrove D, Barr R, Bojunga J, Cantisani V, Chammas MC, Dighe M, Vinayak S, Xu JM,
360 Dietrich CF. WFUMB Guidelines and Recommendations on the Clinical Use of
361 Ultrasound Elastography: Part 4. Thyroid. *Ultrasound Med Biol* 2017;43:4–26.

362 Dickinson RJ, Hill CR. Measurement of soft tissue motion using correlation between A-scans.
363 *Ultrasound Med Biol* 1982;8:263–71.

364 Dietrich CF, Bamber J, Berzigotti A, Bota S, Cantisani V, Castera L, Cosgrove D, Ferraioli G,
365 Friedrich-Rust M, Gilja OH, Goertz RS, Karlas T, de Knecht R, de Ledinghen V, Piscaglia
366 F, Procopet B, Saftoiu A, Sidhu PS, Sporea I, Thiele M. EFSUMB Guidelines and
367 Recommendations on the Clinical Use of Liver Ultrasound Elastography, *Ultraschall*
368 *Med* 2017;38:16–47.

369 Diguisto C, Simon EG, Callé S, Ternifi R, Remeniéras J-P, Hervé P, Herve P, Perrotin F.
370 Ultrasonic elastography exploration of the foetal brain: A case of atypical choroid plexus
371 papilloma. *J Obst Gyn* 2017;37:525–7.

372 Duan H; Chaemsaitong P; Ju X; Ho SYS; Sun Q; Tai YY; Leung TY, Poon LC. Shear-wave
373 sonoelastographic assessment of cervix in pregnancy. *Acta Obstet Gynecol Scand*
374 2020;doi: 10.1111/aogs.13874

375 Dudea SM, Giurgiu CR, Dumitriu D, Chiorean A, Ciurea A, Botar-Jid C, Coman I. Value of
376 ultrasound elastography in the diagnosis and management of prostate carcinoma. *Med*
377 *Ultrason* 2011;13:45–53.

378 Egorov V, Rosen T, van Raalte H, Kurtenoks V. Cervical Characterization with Tactile-
379 Ultrasound Probe. *Open J Obstet Gynecol* 2020;10:85–99.

380 Ferraioli G, Filice C, Castera L, Choi BI, Sporea I, Wilson SR, Cosgrove D, Dietrich CF,
381 Amy D, Bamber JC, Barr R, Chou YH, Ding H, Farrokh A, Friedrich-Rust M, Hall TJ,
382 Nakashima K, Nightingale KR, Palmeri ML, Schafer F, Shiina T, Suzuki S, Kudo M.

383 WFUMB Guidelines and Recommendations for Clinical Use of Ultrasound Elastography:
384 Part 3: Liver. *Ultrasound Med Biol* 2015;41:1161–79.

385 Fink M. Elastography: a new modality of ultrasound imaging. *Diagn Interv Imag*
386 2013;94:485.

387 Hasgall PA, Di Gennaro F, Baumgartner C, Neufeld E, Lloyd B, Gosselin MC, Payne D,
388 Klingenböck A, Kuster N. IT'IS Database for thermal and electromagnetic parameters of
389 biological tissues, Version 4.0, May 15, 2018. DOI: 10.13099/VIP21000-04-0

390 Hernandez-Andrade E, Hassan SS, Ahn H, Korzeniewski SJ, Yeo L, Chaiworapongsa T,
391 Romero R. Evaluation of cervical stiffness during pregnancy using semiquantitative
392 ultrasound elastography. *Ultrasound Obst Gyn* 2013;41:152–61.

393 Issaoui M, Debost-Legrand A, Skerl K, Chauveau B, Magnin B, Delabaere A, Boyer L,
394 Sauvant-Rochat MP, Lemery D. Shear wave elastography safety in fetus: A quantitative
395 health risk assessment. *Diagn Interv Imag* 2018;99:519–24.

396 Issaoui M, Balandraud X, Grédiac M, Blaysat B, Ouchchane L, Sauvant-Rochat M-P,
397 Delabaere A, Lemery D. Temperature rise caused by Shear Wave Elastography Pulse-
398 Doppler and B-mode in biological tissue: an infrared thermographic approach.
399 *Ultrasound Med Biol* 2020;46:325–35.

400 IEC (International Electrotechnical Commission). IEC 60601-2-37 Medical electrical
401 equipment - particular requirements for the safety of ultrasonic medical diagnostic and
402 monitoring equipment. Geneva: IEC, 2007.

403 Kennedy P, Wagner M, Castéra L, Hong CW, Johnson CL, Sirlin CB, Taouli B. Quantitative
404 Elastography Methods in Liver Disease: Current Evidence and Future Directions.
405 *Radiology* 2018;286:738–63.

406 Killingback AL, Newey VR, El-Brawany MA. Development of a thermal test object for the
407 measurement of ultrasound intracavity transducer self-heating. *Ultrasound Med Biol*
408 2008; 34: 2035–42.

409 Kılıç F, Kayadibi Y, Yüksel MA, Adaletli İ, Ustabaşoğlu FE, Öncül M, Madazli R, Yılmaz
410 MH, Mihmanli I, Kantarci F. Shear wave elastography of placenta: in vivo quantitation of
411 placental elasticity in preeclampsia. *Diagn Interv Radiol* 2015;21:202–7.

412 Klotz T, BouSSION V, Kwiatkowski F, Dieu-de Fraissinette V, Bailly-Glatre A, Lemery S,
413 Boyer L. Shear wave elastography contribution in ultrasound diagnosis management of
414 breast lesions. *Diagn Interv Radiol* 2014;95:813–24.

415 Kollmann C, Jenderka KV, Moran C M, Draghi F, Jimenez Diaz JF, Sande, R. EFSUMB
416 Clinical Safety Statement for Diagnostic Ultrasound - (2019 revision). *Ultraschall Med*
417 2019. DOI: 10.1055/a-1010-6018

418 Liu YB, Herman BA, Sonesson JE, Harris GR. Thermal safety simulations of transient
419 temperature rise during acoustic radiation force-based ultrasound elastography.
420 *Ultrasound Med Biol* 2014;40:1001–4.

421 Martin E, Shaw A, Lees C. Survey of current practice in clinical transvaginal ultrasound
422 scanning in the UK. *Ultrasound* 2015;23:138–48.

423 Massó P, Rus G, Molina FS. Safety of elastography in fetal medicine: preliminary study on
424 hypoacusis. *Ultrasound Obst Gyn* 2017;50:660–1.

425 Menten R, Leonard A, Clapuyt P, Vincke P, Nicolae A-C, Lebecque P. Transient
426 elastography in patients with cystic fibrosis. *Pediatr Radiol* 2010;40:1231–5.

427 Metin MR, Aydın H, Ünal Ö, Akçay Y, Duymuş M, Türkyılmaz E, Avcu S. Differentiation
428 between endometrial carcinoma and atypical endometrial hyperplasia with transvaginal
429 sonographic elastography. *Ultrasound Obst Gyn* 2016;97:425–31.

430 Miloro P, Martin E, Shaw A. Temperature elevation measured in a tissue-mimicking phantom
431 for transvaginal ultrasound at clinical settings. *Ultrasound* 2017;25:6–15.

432 Monpeyssen H, Tramalloni J, Poirée S, Hélénon O, Correas J-M. Elastography of the thyroid.
433 *Diagn Interv Radiol* 2013;94:535–44.

434 Mottet N, Metz J-P, Chaussy Y. Evolution of fetal lung stiffness during gestation in two
435 different congenital malformations. *J Obstet Gynaecol Re* 2019;45:931–4.

436 Nitta N, Ishiguro Y, Sasanuma H, Taniguchi N, Akiyama I. Experimental system for in-situ
437 measurement of temperature rise in animal tissue under exposure to acoustic radiation
438 force impulse. *J Med Ultrason* 2015;42:39–46.

439 Ogawa M, Nagao D, Mori K, Sato M, Sato A, Shimizu D, Terada Y. Elastography for
440 differentiation of subchorionic hematoma and placenta previa. *Ultrasound Obst Gyn*
441 2012;39:112–4.

442 Ophir J, Céspedes I, Ponnekanti H, Yazdi Y, Li X. Elastography: a quantitative method for
443 imaging the elasticity of biological tissues. *Ultrasonic Imaging* 1991;13:111–34.

444 Parker KJ, Doyley MM, Rubens DJ. Imaging the elastic properties of tissue: the 20 year
445 perspective. *Phys Med Biol*. 2011;56:1–29.

446 Peralta L, Molina FS, Melchor J, Gómez LF, Massó P, Florido J, Rus G. Transient
447 Elastography to Assess the Cervical Ripening during Pregnancy: A Preliminary Study.
448 *Ultraschall Med* 2017;38:395–402.

449 Palmeri ML, Nightingale KR. On the thermal effects associated with radiation force imaging
450 of soft tissue. *IEEE Trans Ultrason Ferroelectr Freq Control* 2004;51:551–65.

451 Pereira S, Frick AP, Poon LC, Zamprakou A, Nicolaidis KH. Successful induction of labor:
452 prediction by preinduction cervical length, angle of progression and cervical
453 elastography. *Ultrasound Obst Gyn* 2014;44:468–75.

454 Săftoiu A, Gilja OH, Sidhu PS, Dietrich CF, Cantisani V, Amy D, Bachmann-Nielsen M, Bob
455 F, Bojunga J, Brock M, Calliada F, Clevert DA, Correas JM, D'Onofrio M, Ewertsen C,
456 Farrokh A, Fodor D, Fusaroli P, Havre RF, Hocke M, Ignee A, Jenssen C, Klauser AS,
457 Kollmann C, Radzina M, Ramnarine KV, Sconfienza LM, Solomon C, Sporea I,
458 Stefanescu H, Tanter M, Vilmann P. The EFSUMB Guidelines and Recommendations
459 for the Clinical Practice of Elastography in Non-Hepatic Applications: Update 2018.
460 *Ultraschall Med* 2019;40:425–53.

461 Sandulescu L, Padureanu V, Dumitrescu C, Braia N, Streba CT, Gheonea DI, Cazacu S,
462 Ciurea T, Rogoveanu I, Saftoiu A. A Pilot Study of Real Time Elastography in the
463 Differentiation of Focal Liver Lesions. *Curr Health Sci J* 2012;38 :32–5.

464 Shankar H, Pagel PS. Potential Adverse Ultrasound-related Biological Effects A Critical
465 Review. *Anesthesiology* 2011;115:1109–24.

466 Shiina T, Nightingale KR, Palmeri ML, Hall TJ, Bamber JC, Barr RG, Castera L, Choi BI,
467 Chou YH, Cosgrove D, Dietrich CF, Ding H, Amy D, Farrokh A, Ferraioli G, Filice C,
468 Friedrich-Rust M, Nakashima K, Schafer F, Sporea I, Suzuki S, Wilson S, Kudo M.
469 WFUMB Guidelines and Recommendations for Clinical Use of Ultrasound Elastography:
470 Part 1: Basic Principles and Terminology. *Ultrasound Med Biol* 2015;41(5):1126–47.

471 Skurczynski MJ, Duck FA, Shipley JA, Bamber JC, Melodelima D. Evaluation of
472 experimental methods for assessing safety for ultrasound radiation force elastography. *Br*
473 *J Radiol* 2009;82:666–74.

474 Sugitani M, Fujita Y, Yumoto Y, Fukushima K, Takeuchi T, Shimokawa M, Kato K. A new
475 method for measurement of placental elasticity: acoustic radiation force impulse imaging.
476 *Placenta* 2013;34:1009–13.

477 Suo D, Clark A, Bonilla S, Keller S, Averkiou M. Controlled Bubble-Enhanced Heating With
478 Added Microbubbles. 19th International Symposium of ISTU, Barcelona, Spain, 2019,
479 13th–15th June, p. 96.

480 Stoelinga B, Hehenkamp WJK, Brölmann H a. M, Huirne J a. F. Real-time elastography for
481 assessment of uterine disorders. *Ultrasound Obst Gyn* 2014;43:218–26.

482 Tabaru M, Yoshikawa H, Azuma T, Asami R, Hashiba K. Experimental study on temperature
483 rise of acoustic radiation force elastography. *J Med Ultrason* 2012;39:137–46.
484 Wilson LS, Robinson DE. Ultrasonic measurement of small displacements and deformations
485 of tissues. *Ultrasonic Imaging* 1982;4:71–82.
486 Zheng X-Z, Wu J, Tan X-Y. A novel approach to assessing fetal tissue stiffness using virtual
487 touch tissue quantification. *Med Ultrason* 2016;18:70–4.
488

Figure Captions List

489

490

491 **Figure 1.** 3D-printed frame showing thermocouple placement: a) CAD drawing of the frame
492 showing notches used to control horizontal thermocouple placement; b) photograph of the
493 frame; c) front view of the frame with mounted thermocouples. The front and side walls of the
494 frame were removed in the photographs; d) schematic view of the thermocouple locations
495 (labelled 1 to 10 and ref) and definition of the x, y, z axis directions; e) same in top view, with
496 imaging plane highlighted.

497

498 **Figure 2.** a) Picture of the experimental setup showing the clamp arrangement used to hold
499 the imaging probe in a static position; b) B-mode image of the phantom showing
500 thermocouple wires.

501

502 **Figure 3.** Temperature change of the ten thermocouples as a function of time: a) for B-mode;
503 b) for PD; c) for SWE. For a better visualization of the lowest thermal responses, temperature
504 changes at 400 s can be seen in Fig. 4.

505

506 **Figure 4.** Temperature change for the three tested ultrasound imaging modes at 400 s
507 (corresponding to the end of the 380 s exposure duration). For each mode, the circle diameter
508 is proportional to the temperature change with the diameter for Tc-1 (maximum temperature
509 change) being set to be the same (normalized) for the three modes in order to reveal relative
510 temperature distributions within each mode.

511

512 **Figure 5.** Comparison of temperature changes for B-mode, PD and SWE imaging exposures
513 for thermocouple: a) Tc-1, b) Tc-10*, c) Tc-7.

Table 1. Coordinates (in mm) of the ten thermocouples used to track the temperature change due to ultrasound excitation. The origin of the coordinates system is shown in Fig. 1-d. An asterisk is used to specify the thermocouples located beyond the imaging plane (which is at $y = 0$ mm).

	Tc-1	Tc-2	Tc-3	Tc-4	Tc-5	Tc-6	Tc-7	Tc-8*	Tc-9*	Tc-10*
x	0	0	0	0	0	25	10	15	35	0
y	0	0	0	0	0	0	0	10	13	10
z	1	26	44	56	74	26	15	44	44	5

Table 2. Scanner settings for the three ultrasound modes used: B-mode, Pulse-Doppler (PD) and Shear Wave Elastography (SWE).

Parameters (OB-GYN GenOB preset)	B-mode	PD	SWE
Total depth	80 mm	22 mm	80 mm
B-mode focal zone	10 – 40 mm	22 mm	25 – 40 mm
Tissuetuner (Speed of sound used to transmit and receive beamforming)	1540 m/s	1540 m/s	1540 m/s
SWE Opt (Res, Std, Pen) for the optimization of elastography resolution and penetration	N/A	N/A	Standard
SWE box geometry	N/A	N/A	Top width: 43.9 mm Bottom width: 63.2 mm Height: 30.8 mm Top depth: 6.7 mm
MI (Mechanical Index)	1.2	1	1.5
TIb (Thermal Index bone)	0	0	1.6
TI_s (Thermal Index soft tissue)	0	0	1.4

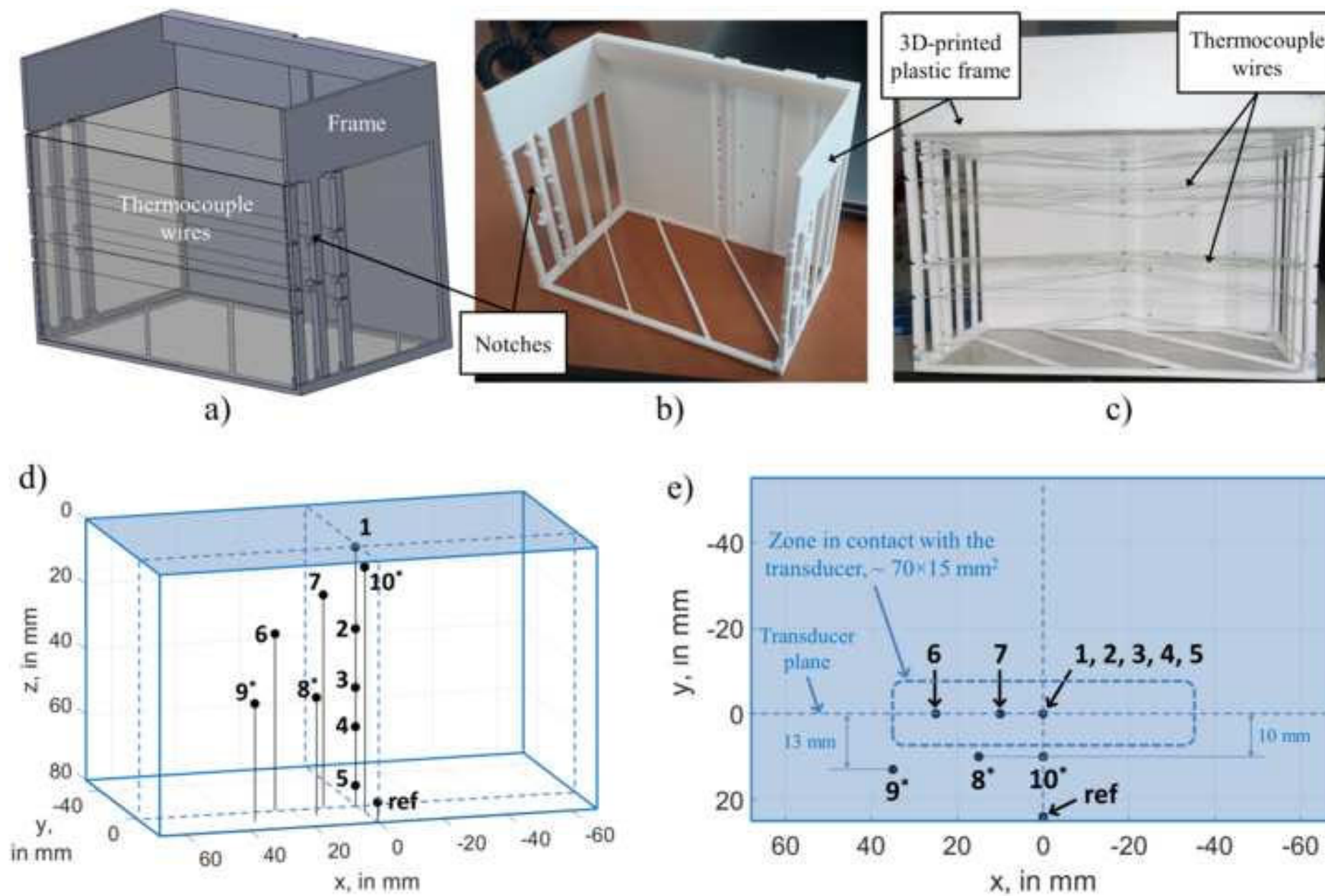


Figure 2

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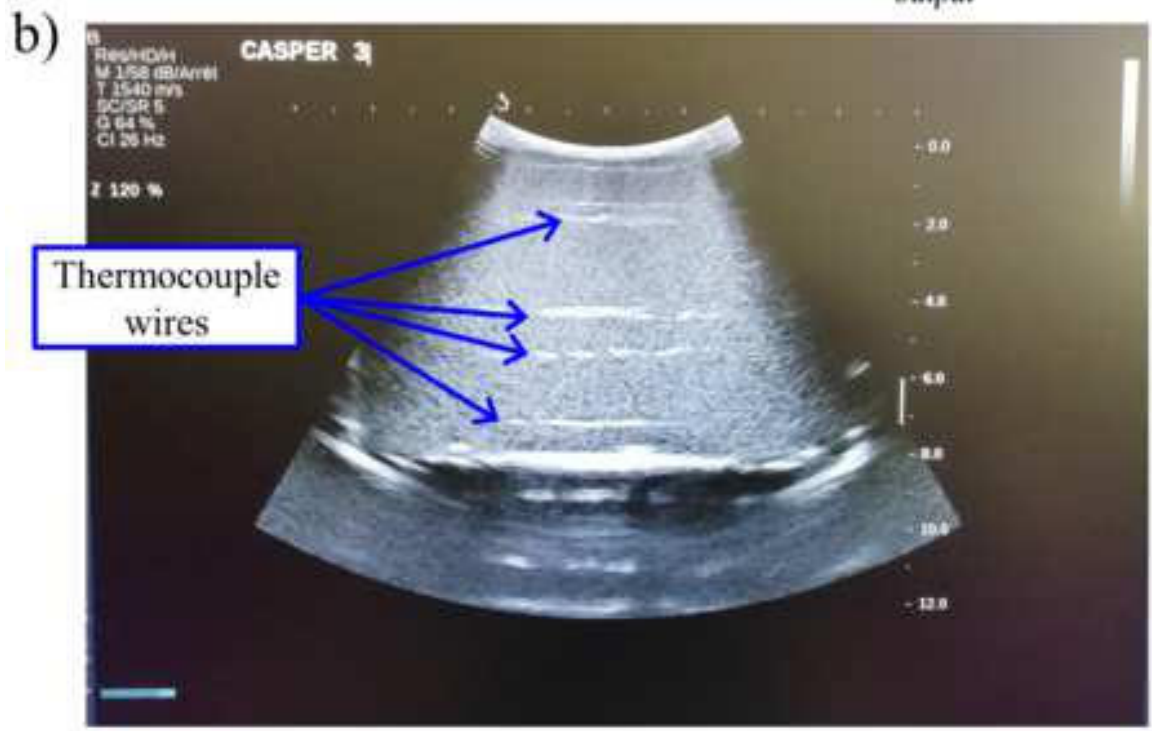
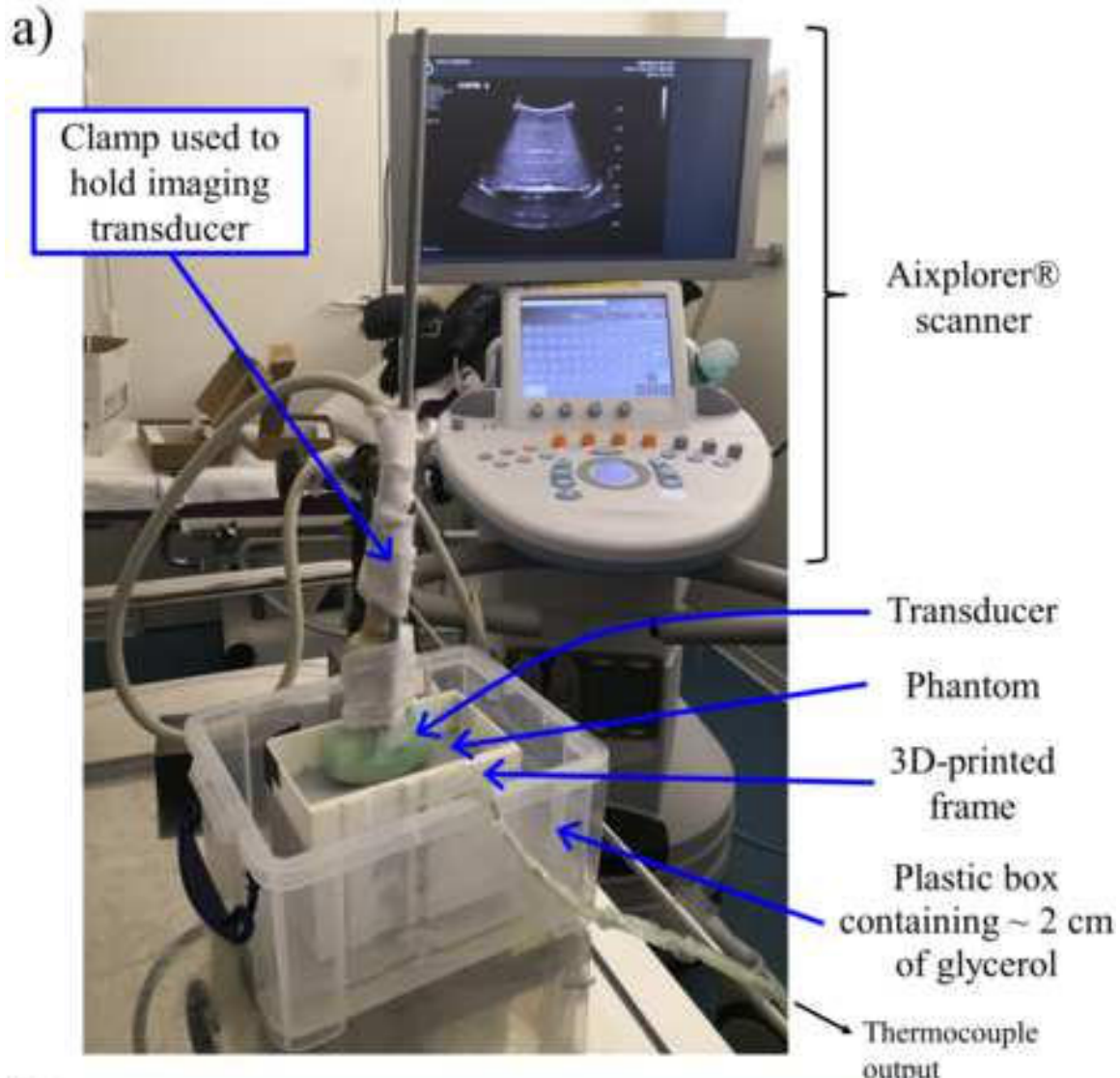


Figure 3

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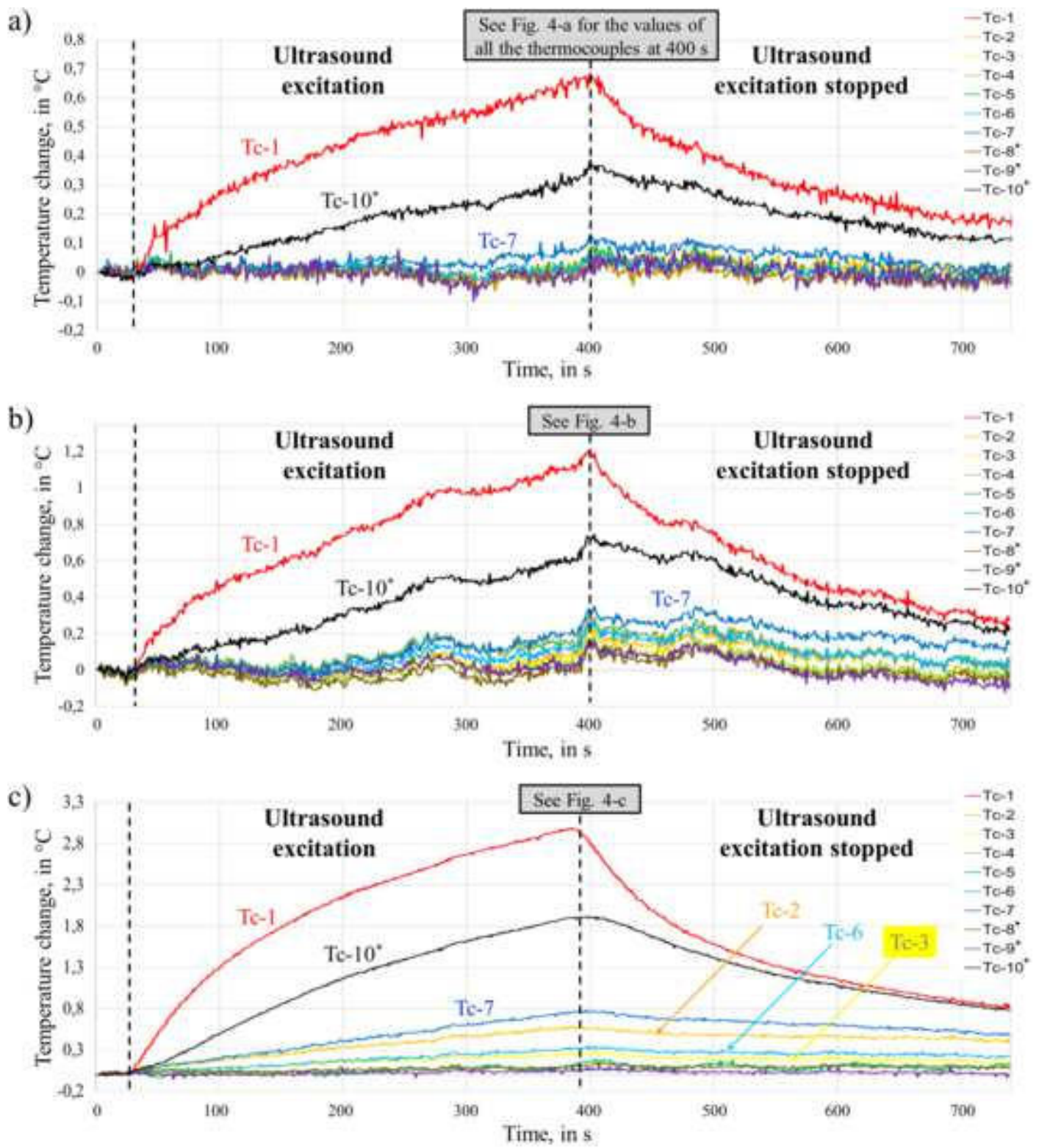


Figure 4

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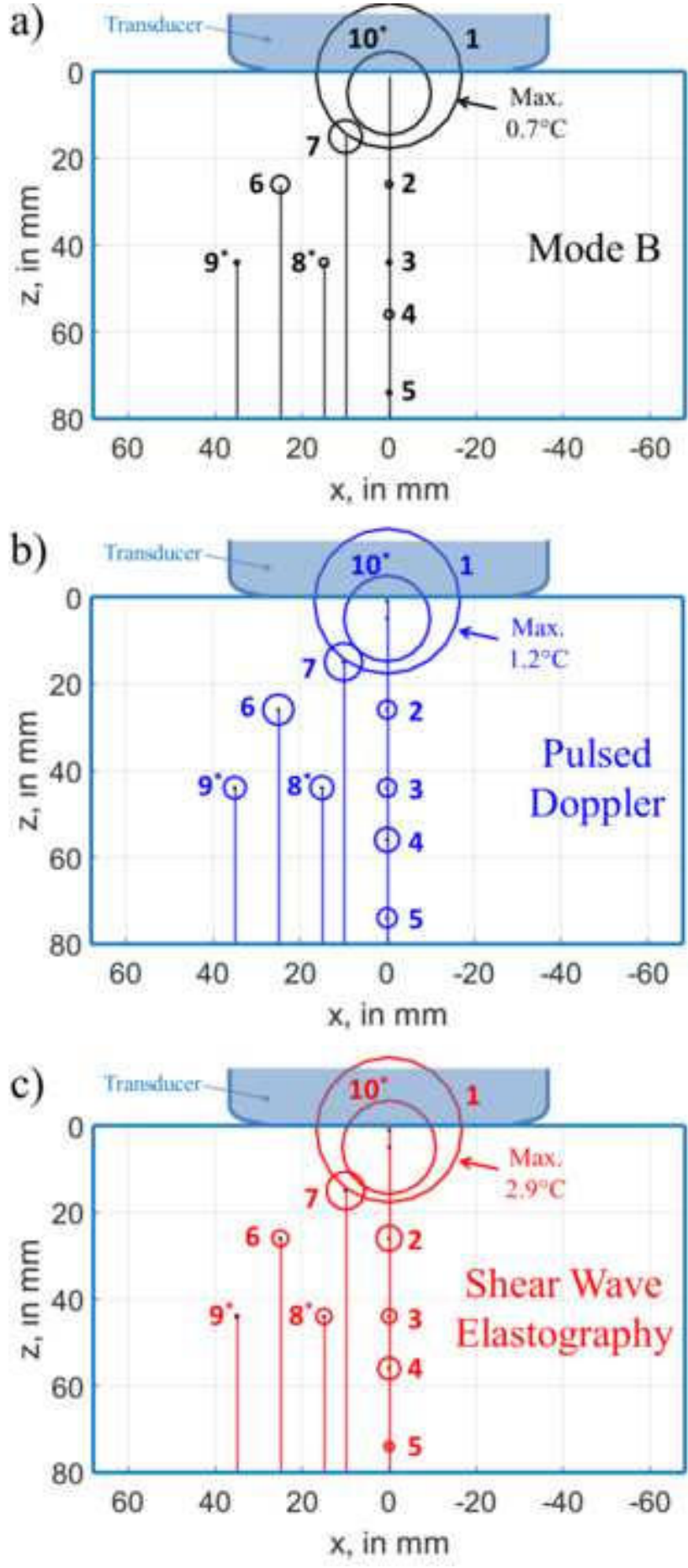


Figure 5

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