A “user-friendly” phantom to conduct Quality Controls on MRgFUS device

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Abstract. Magnetic Resonance guided Focused Ultrasound Surgery (MRgFUS) is a hybrid technique which uses Magnetic Resonance (MR) to obtain morphological information of the examined anatomical district and Focused Ultrasound Surgery (FUS) to ablate the body region under investigation by using MR as guidance. To ensure patients’ safety is necessary to establish periodic Quality Controls (QCs) providing a complete evaluation of system status. QCs cannot be done directly on patients, for this reason, dedicated phantoms are used to guarantee the maintenance of quality over equipment lifetime. Several phantoms are available on the market, which are distributed by manufacturers and specific to the medical equipment, resulting in closed systems. In this study, we idealized, developed and created a prototype of a completely “user-friendly” phantom, to conduct QCs on FUS devices. It consists of an empty cylinder of polymethylmethacrylate (PMMA), that can be filled with different fluids and various inserts, available for the Medical Physicists, to perform test measurements on different parameters (size of FUS spot, precision of FUS spot, linearity of FUS power, linearity of electric power, evaluation of target temperature). The obtained results demonstrated that the novel phantom represents a useful and adaptable device that could be used during FUS QCs evaluations.

1. Introduction
In the last decade different medical imaging hybrid techniques were developed and used in many clinical fields, including oncology, neurology, cardiology, neuroscience. In this context, Magnetic Resonance guided Focused Ultrasound (MRgFUS) represents an important new perspective in the field of imaging/therapy, combining MR to obtain morphological information and FUS for tissue ablation. On one side, MR utilizes powerful static magnetic fields and Radiofrequency signal to obtain information from organs inside the human body and to construct the images [1,2]. On the other side, FUS uses ultrasound (US), generated by a transducer embedded in the Magnetic Resonance Imaging (MRI) device (head coil or table). The energy of the focused US beam causes significant increase in
temperature of the targeted tissues, producing coagulation and necrosis [3], and, at the same time, MR images are used as guidance during the procedure and as temperature feedback [4]. This hybrid technique has been proposed for possible applications in the treatment of breast cancer [5], prostate cancer [6], uterine fibroids [7], and in mediated thalamotomy of the ventral intermediate nucleus (VIM) [8].

In order to maintain or enhance the quality of the radiological device and to ensure safe, for patients and health care staff, it is necessary to establish adequate quality-assurance (QA) procedures to identify and correct all problems that may lead to reduction of the diagnosis area in advance. [9].

In this context, Quality Controls (QCs) play a fundamental role, allowing a complete evaluation of the system status [10-12]. As can be reasonably understood, QCs cannot be done directly on patients, but they are performed by using dedicated phantoms, usually mimicking human tissues. For FUS systems, several phantoms are available, built using different materials, such as PMMA, water, Agar gel, etc., to simulate the different constituents of the human body [13-15]. The main limitation of these phantoms, commercially available, is that they are "closed" system. As a matter of fact, they are developed to analyze only few parameters, and if a complete QCs program is needed, to the use of more than one phantom is required. In addition, in many cases, the manufacturer of the device provides the phantoms together with the diagnostic equipment they are dedicated to, in order to test the functioning of the set-up according to dedicated protocols, often developed by the same companies for each machine and usually directly managed by the equipment software.

In order to overcome the aforementioned limitation, in this study we developed and built a "user-friendly" phantom to conduct a complete QCs program on MRgFUS equipment. The novel phantom was built in PMMA material, it has the shape of a cylinder, hollow inside so as to be filled with materials and inserts chosen by the medical physicist. By using this novel dedicated phantom, we are able to perform test measurements on different parameters (size of FUS spot, precision of FUS spot, linearity of FUS power, linearity of electric power, evaluation of target temperature). The reliability of this innovative phantom was evaluated during the acceptance test of a MRgFUS device. In all cases, the results obtained using the proposed new phantom were reliable and promising, confirming the flexibility of the method, its simplicity and reproducibility as an efficient tool for quick inspections, as discussed in detail in the following sections.

2. Materials and Methods

2.1. The used set-up

The QCs measurements, conducted by using the prototype of the developed phantom, were successfully performed on a 1.5 T MR scanner (Optima 450 W GE Medical Systems, Waukesha, WI) equipped with the ExAblate® 2000 (InSightec Inc., Haifa, Israel), for FUS treatments. The measurements were conducted by using the FUS transducer mounted on the MR table containing a high power phased array transducer (120 mm diameter, 211 elements, central frequency 1.1 MHz). The images were acquired setting a T2-weighted fast spin–echo in coronal, axial and sagittal planes, on MR scanner, and transferred to the ExAblate® FUS workstation.

2.2. The novel phantom

The developed phantom consists of an empty cylinder of 14.5 cm diameter and 15.5 cm height. The lateral surface, having a thickness of 0.5 mm, is realized in polymethylmetacrylate (PMMA). This choice of material and thickness is motivated by the fact that this configuration is able to simulate the cranial theca. The base surface is made
with an easily interchangeable module, depending on the tests to be carried out. The material used in our case is a PMMA sheet with a thickness of 0.05 mm. This choice was made to facilitate the coupling of the ultrasonic transducer with the phantom. The cylinder can be filled with various liquids, solids or gel, chosen by the medical physicist according to the parameters to be tested. The novel phantom is coupled with movable inserts. They consist of holders, always in PMMA, designed to sustain instrumentation or small Teflon pieces (1.0 mm x 1.0 mm and 1.0 mm x 2.0 mm) in order to simulate microcalcifications, mounted on nylon wire of 0.01 mm thickness. In figure 1, the developed phantom and the movable inserts are depicted.

![Figure 1. Upper view (a) and lateral view with movable inserts (b) of the developed phantom.](image)

Since during treatment several sonication parameters can be manually adjusted, when performing QCs it becomes necessary to evaluate, for each parameter, the correspondence between nominal value and measured one. In particular, the novel developed phantom allows the testing of the parameters reported in table 1, and better detailed in the following subsections.

| Parameter                                      |
|-----------------------------------------------|
| Precision of the FUS spot                     |
| Dimension of the FUS spot                     |
| Linearity of the mass vs. electric and FUS output power |
| Evaluation of the target temperature          |

During all measurements, the phantom was placed on the MRgFUS bed, and demineralized water was placed in the interface between the bottom of the phantom and the bed in order to provide an acoustic path for the ultrasound beam.

### 2.3. Precision of the FUS spot

FUS precision spot was evaluated conducting two different experiments. In the first one, the phantom was filled with a piece of white meat and demineralized water. Four wood pointers were positioned in different places on the target. A series of four identical sonication were performed, and the corresponding images were acquired by MR scanner and stored for image analysis. In the second test, the micro-calcifications insert were used and the phantom was filled with demineralized water. On the nylon wires of the insert were positioned, in different position, five meat pieces (10 mm x 10 mm x 10 mm) and a series of five identical sonication were executed and centred on the meat targets. The images were acquired, stored and analysed by using MR scanner.
2.4. Dimension of the FUS spot
Dimensions of sonication spots are a function of several sonication parameters, which can influence the success of the treatment. The novel phantom was filled with a piece of white meat and demineralized water. Five identical sonication were performed at 85 W output power, 18 seconds and at 5 mm scan slice thickness. The images were acquired and stored by MR scanner for post evaluation. The dimensions of the sonication spot (length and diameter) were evaluated by using the MR software available at the console and by using ad-hoc software, previously validated by authors [16], and developed in LabView environment. The DICOM images were used as standard for acquired pictures [17]. Statistical analysis was used The one way ANOVA was used to confirm the validity of the obtained results, comparing different and independent datasets of the same variable to assume whether they are generated by the same distribution.

2.5. Linearity of the mass vs. electric and FUS output power
Linearity refers to the ability of the amplifier to produce signals that are accurate copies of the input, generally at increased power levels [19-21].

The test consisted of measurements intended to assess the pressure of the ultrasounds, which can be linked to the intensity of the same. A precision balance (PCD - KERN & SOHN GmbH, Stuttgart, Germany) with a sensitivity of 0.1 g was used, positioned at a height of 16 cm, resting on the dedicated support, inserted inside the phantom, which was previously filled with physiological solution. It was assumed that the mass, as measured by balance and due to the FUS pressure, increases with increasing the output power of the transducer. The phantom was filled with demineralized water, to increase the coupling between the transducer and the phantom itself. Seven different values of Acoustic power were set and the corresponding value of mass was measured by balance. The Pearson’s correlation was used to validate the linearity of measurements.

2.6. Target Temperature
In this study, the target temperature was evaluated by using two different probes, i.e., a contact thermometer (HI83141 – Hanna Instruments) and a thermal camera (FLIR T440), and the obtained results were compared with the temperature value as given by the MR scanner. The measurements were conducted in two steps. In the first one, the phantom was filled with meat and demineralized water and placed inside the gantry, six sonication of 10 s each and at different set power input were executed, and the corresponding temperature gradients were evaluated by MR scanner. In this step, due to the high magnetic field inside the gantry, the thermal camera and the contact thermometer cannot be used. For this reason, it was necessary the second step. The phantom was always positioned on the bed coupled with the FUS transducer and the same sonication, used in the step one, were repeated with the phantom out of the gantry. The thermal camera was positioned at 50 cm from the target, while the contact thermometer was placed on the target, in correspondence of the FUS spot. The One-way ANOVA was used to assess whether a significant difference existed between dataset obtained following different procedures.

3. Results
In the following, the results of the measurements conducted during the acceptance test of MRgFUS device are reported. All the parameters were acquired and measured by using the novel developed phantom.

3.1. Precision of the FUS spot
In the first test, the matching between FUS spot and wood pointers was evaluated using the MR software and the maximum spot-pointers distance turned out to be ± 0.3 mm, where the positive (negative) sign indicates a distance greater (smaller) than the specific length.

In the second one, always by using the MR software, it was verified that all small targets were centred by the FUS spot.

In all cases a good agreement was achieved.

3.2. Dimension of the FUS spot
The diameter and the length dimensions of the FUS spot were measured by using coronal and sagittal plane images respectively. In figure 2 we show the MR images acquired along the sagittal, axial and coronal scan planes.

![Figure 2. MR images acquired along (a) sagittal, (b) axial, and (c) coronal scan plane. The user defined Region of Interest (ROI) are indicated by yellow rectangles.](image)

In table 2 the measurements results are reported.

| Dimension | Nominal value (mm) | MR software (mm) | LabView (mm) |
|-----------|--------------------|------------------|--------------|
| Diameter  | 3.0                | 3.20 ± 0.30      | 3.14 ± 0.30  |
| Length    | 6.0                | 6.48 ± 0.25      | 6.55 ± 0.30  |

3.3. Linearity of mass vs. Electric and FUS output power
From the control console it was possible to modify the electric power, with consequent variation of the FUS output power, and the corresponding mass was measured. Figure 3 shows the trend of the mass as a function, respectively, of electric power and FUS output power.
Figure 3. Plot of the mass as a function of the electric (a) and FUS output (b) power.

As can be seen, a linear fit faithfully reproduces the experimental data, being characterized by $r^2 \sim 0.996$ in both cases.

3.4. Target temperature

The current gold standard for real-time monitoring during sonication is accomplished using the known linear dependence of proton resonance frequency as a function of temperature [21, 22], during QCs it is important to evaluate the correctness of the parameter under investigation. In figure 4 the trend of temperature gradient as a function of sonication power, as obtained by using the contact thermometer (black line), thermal camera (red line) and MR scanner (blue line), is reported.

Figure 4. Temperature gradient as a function of sonication power, as obtained by contact thermometer (black line), thermal camera (red line) and MR scanner (blue line).

The one-way analysis of variance (ANOVA) was used to assess whether a significant difference existed between data set obtained following different procedures. According to it, the calculated F value is 0.02232, significantly smaller than the tabulated value ($p = 0.9779$ at $p = 0.05$ confidence level). Therefore, there is no statistically significant difference among the results obtained by the three methodologies.
4. Discussion
In this study we have described a novel phantom, completely “user-friendly”, used to perform QCs on FUS devices. The phantom was designed to be used on bed and head FUS transducer, embedded on MRI scanners. We tested the novel phantom evaluating different parameters; in particular, in our measurements we have considered the size of FUS spot, the precision of FUS spot, the linearity of FUS power, the linearity of electric power and the temperature variation of the target. All measurements were made by using the FUS transducer embedded on the MRI bed, as it can emit ultrasound both inside and outside the gantry. If we had used the head transducer, it would have been able to work only inside the gantry. In fact, usually the use of head transducer makes it possible to work only inside the gantry, where, however, because of the high static magnetic field, the use of electronic instrumentation employed for QCs is forbidden.

A key challenge in designing a FUS phantom was the need of coupling the FUS transducer with the phantom. The PMMA material was chosen to simulate typical anatomical body regions for quality assurance [23] and different thicknesses are used to mimicking different body regions (greater thickness for the head, less for the abdomen). The achieved results showed the validity of this novel phantom; in fact, all the measurements related to the observed parameters reproduced the experimental data.

5. Conclusions
The use of MRgFUS for imaging/therapy treatmets represents the culmination of scientific progress and clinical research on the application of FUS to human body. Understanding of flow physics is important to execute detailed healthcare product development; theoretical (Computational Fluid Dynamics) [24] and experimental evaluation are necessary to yield quantitative results. This progress includes improved technology to provide controlled levels of ultrasonic energy that can be focused to a target noninvasively and guided by MR imaging. To ensure patients’ safety is necessary to establish periodic Quality Controls (QCs) providing a complete evaluation of system status.

In the present work, a novel, completely "user-friendly" phantom was developed and used to conduct acceptance tests on MRgFUS equipment, with the final aim of providing an adaptable, reliable and robust procedure to perform a complete QCs program. The realized phantom is totally suited to the needs of the Expert in Medical Physics, responsible, in accordance with current legislation, for QCs, who can use it to evaluate the parameters representative of the state of the device.

The obtained results look very encouraging, so much so that the evaluated parameters allowed to draw up a complete QCs protocol for the used equipment, which represents the baseline for future evaluations.

The proposed FUS phantom has yielded exciting early results and serves as a prototype. Future implementations of the phantom may include new inserts mimicking other body organs.

Considering the importance of the new hybrid methodology and its prospects for applications to different targets of the human body, it is our intention to implement the developed prototype, to have always a single "user-friendly" phantom to be used for conducting QCs measurements.

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