Evaluation of the safety standards and the potential efficacy of tumor exposure with the Therabionic device

Yijian Gong[1], Myles Capstick[1], Niels Kuster[1]

[1] IT'IS Foundation for Research on Information Technologies in Society (IT'IS) - ETH Zurich, Switzerland

Abstract — This study investigates dosimetrically a device from Theraboinic which claims to treat cancer using low level electromagnetic fields. The performance is assessed in terms of the SAR level and distribution inside the human body and the variability with device positioning and patient posture quantified. A numerical analysis is based on the Duke human model from the virtual family and results verified using measurements in a simple phantom. The device delivers whole body mean SAR in the range of only 0.2 to 1mW/kg, with a 1g peak spatial SAR between 150 and 350mW/kg.

INTRODUCTION

Nowadays, treatment of inoperable or metastatic solid tumors is still a major challenge. There is some evidence that cancer cells may be altered by very low levels of electromagnetic fields modulated at specific frequencies [1] [2]. This study investigates the Theraboinic Device which uses low level amplitude modulated electromagnetic fields. The basic treatment posture is shown in Figure 1. The purpose of this project was to determine the safety of the device and provide insights into potential efficacy of the approach to applying the treatment.

Figure 1: *Theraboinic device and basic treatment method [1]*

MATERIAL AND METHODS

The dosimetric assessment was performed using SEMCAD X and was based on an adult male numerical model Duke, from the virtual family [3]. SAR distribution, the organ specific SAR and the total power delivered were assessed, and compared with the experimental results for a similar but simplified scenario.

Figure 2: *1) Sitting with device on the leg; 2) Sitting with device on the torso; 3) Sitting with device placed away from the body; 4) Straight*

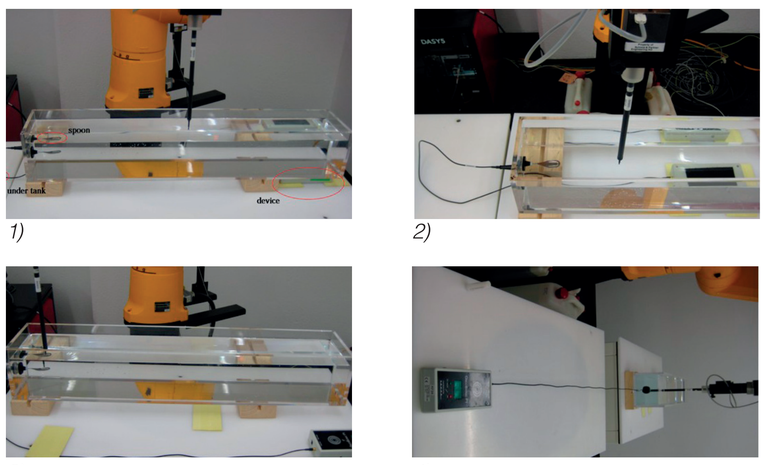

Figure 3: *1) Device is under buttom at the furest point, 2) device is at the middle under the tank, 3) device is beside the tank, 4) device is away from the tank*

Device characteristics:
· carrier frequency of 27.12 MHz
· amplitude-modulated (RF AM EMF) 85% modulation depth.

Both homogeneous and inhomogeneous Duke model was simulated for different positions to determine SAR distributions and to analyze the organ specific SAR (shown in Figure 2).

	1	2	3	4
mean SAR (mW/kg)	13.4	13.4	13.2	10.1
std deviation (mW/kg)	44.6	57.4	50.2	61.6
Power dissipation in the body (W)	0.978	0.977	0.967	0.723
radiated power (W)	0.003	0.003	0.012	0.262
Total power (W)	0.98	0.98	0.98	0.99

Table1: *Simulation power budget for human model, nominal input power 1W*

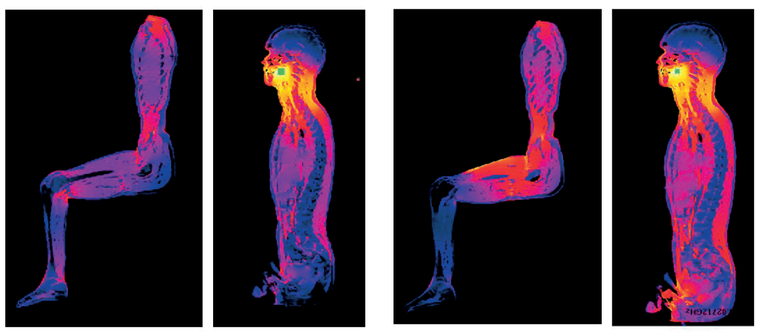

Figure 4: *Measurement setup for different positions. Two left pictures: Device on the leg. Two right pictures: Device away*

The validation measurements were realized using a simple tank phantom with tissue simulating liquid had εr = 78.9 and σ = 0.435 s/m. The measurement configurations are shown in Figure 3.

RESULTS

The power delivered by the device is shown in the Table 1. The key point is that there is more radiated power when the device is far away from the body. Radiated power is not absorbed by the body or taken part in the desired treatment. The distance between the device and human body influences the pattern of absorption in the body.

The standard deviation gives an insight to how uniform the distribution of the SAR is in the body. Organ specific SAR was simulated for most commonly used device positions 1) and 3). SAR distribution for different positions is shown in the Figure 4. The organ specific SAR normalized to the 1W input power is shown in the Table 2. The measurements verification of the tank for position 1) and 3) are shown in the Figure 5.

Organ specific SAR	position 1 device on the leg			position 3 device away		
(mW/kg) for 1W input power	Mean SAR	SP(10g)	SP(1g)	Mean SAR	SP(10g)	SP(1g)
whole body	13.5	2583.1	6900.3	13.4	3398.7	9110.0
Brain_grey_matter	2.2	10.1	15.7	2.5	14.2	22.1
Brain_white_matter	1.0	3.0	4.6	1.0	3.5	6.3
Midbrain	3.7	3.9	5.4	3.9	4.2	5.9
Heart_lumen	8.9	11.2	14.9	5.8	7.6	10.8
Heart_muscle	7.7	13.7	15.8	4.9	8.1	9.3
Liver	8.4	16.0	29.2	4.2	7.5	14.7
Lung	13.9	59.7	92.1	11.2	63.7	99.6

Table2: *Specific organs spatial peak SAR comparison*

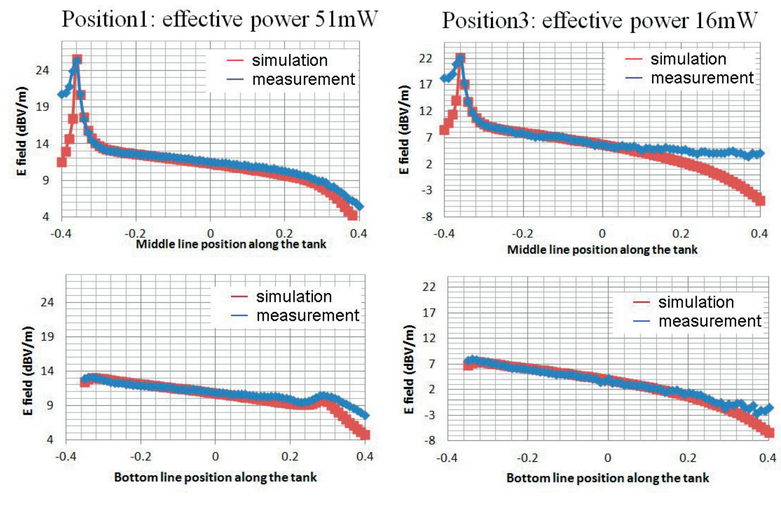

Figure5: *Measurement and simulation comparison for position1 and 3*

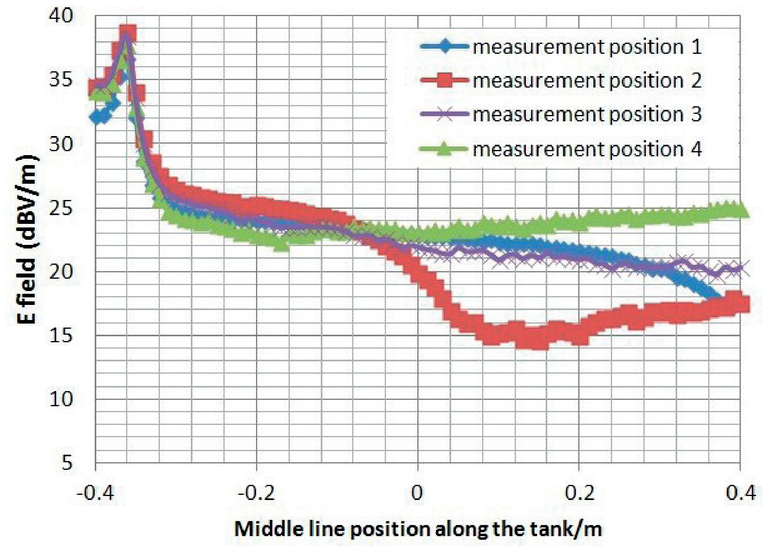

Figure 6: *Measurement result normalized to the 1W input power for the middle line in the phantom*

When matched, the output power of the Therabonic device is 111mW. Removing the effect of the mismatch, the middle and bottom line E field from different positions are shown in the Figure 6.

SUMMARY AND CONCLUSIONS

The SAR distribution changes dependant on the device position. The current device exhibits poor matching in many cases has a whole body mean SAR in the range from 0.2 to 1 mW/kg, with peak spatial SAR over 1g in the range from 150 to 350mW/kg.

The device complies with limits in the ICNIRP standard [4]. To improve the efficiency of the treatment, it is recommended that further dosimetry is performed and measurements made to determine the range of impedances for the population and the matching network(s) designed accordingly.

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