Measurement Repeatability and Reproducibility in Radiofrequency Implant Heating in Benchtop Exposure Systems

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PURPOSE: The purpose of this study was to experimentally quantify the short- and long-term measurement repeatability and reproducibility of RF-induced implant heating measurements in benchtop RF exposure systems (64 and 128 MHz).

INTRODUCTION: The standardized test method for RF-related implant heating is described in the technical specifications standard of ASTM International F2182-11a, and utilizes a direct measurement of RF-induced heating of the implant within a standardized phantom. Measurement reproducibility reflects experimental errors (e.g. from positioning of the phantom or device), instrument uncertainty (e.g. calibration, coil geometries), and material variations (e.g. electrical conductivity). The aim of this study was to quantify measurement reproducibility (day-to-day) and repeatability (repeated measurements within a single session) directly from RF-induced temperature heating and temperature resolved local specific absorption rate (LSAR) in a representative orthopedic implant.

METHODS: Measurements were performed using two different RF bench top exposure systems, commercially available as Medical Implant Testing Systems, or MITS 1.5 and 3.0, corresponding to nominal frequencies of 64 and 128 MHz. The parameters for MITS 1.5 and 3.0 were: pulse type = sinc2π, duty cycle = 40 %, pulse repetition rate = 1 kHz, polarization = circular 270 ° & 90 °, frequency = 63.3 & 127.6 MHz, input power = 59.0 & 60.2 dBm, whole-body SAR = 2.97 ± 0.04 & 3.01 ± 0.18 W/kg, and $B_{1,rms}$ = 2.86 & 4.40 µT in air at the coils' geometric isocenter. **Figure 1** shows a 3-D representation of the measurement setup. An ASTM specific human torso acrylic phantom (42×65×16.5 cm) was filled to a height of 9.0 cm of gelled saline made of Hydroxyethyl cellulose (HEC), formulated to match the electrical conductivity (0.47 S/m ± 10 %) of human tissue and limit thermal convection from affecting the temperature distribution. The geometric center of the gel (i.e. 4.5 cm) was aligned with the geometric center of the MITS. Short-term measurement reproducibility and repeatability of temperature change was compared using representative test plates with screws. Three (n = 3) repeated measurements of 15-minute RF exposure were performed at both 64 and 128 MHz. Measurement repeatability was performed by repeating measurement without any changes to the physical setup. Measurement reproducibility was performed by replicating the experiment setup (i.e. phantom position, probe placement) by another experimenter between measurements. **Figure** shows a photograph of device as tested at 128 MHz with indicated temperature probe placements. A 0.60 mm diameter T1C fiber optic temperature sensor [3] (resolution = 0.1 °C, accuracy = 0.2 °C) was placed on each end of the plate and on the tip of a screw to monitor temperature with a calibrated Omniflex signal conditioner [3]. Temperature data were taken at points submerged in the gel parallel to the long-sided wall 33 mm from the x-axis wall and 52 mm from the phantom floor (y-axis). Long-term measurement repeatability was studied by comparing LSAR values resolved from a standardized 10.0 cm long Ti reference rod completed at two different locations (52 and 62 mm from the phantom floor) in both systems, over a period of 14 months. The 10.0 cm long rod was machined from 1/8-inch diameter Grade 5 Ti, with two 1.0 mm diameter holes drilled through for temperature sensors and placed 1.0 mm from each end of the rod. The measured temperature change from the 10.0 cm rod was normalized by a LSAR scalar factors of 1.30 and 1.45 °C/W/kg for 64 and 128 MHz, respectively [1]. Percent error was taken from corresponding standard deviation (SD) of the mean temperature change.

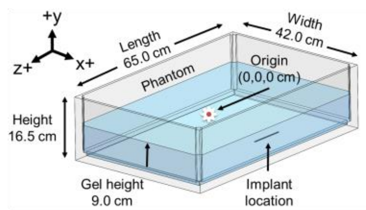


Figure 1: 3-D illustration of phantom container with a reference implant at the implant location for a device test measurement at 128 MHz.

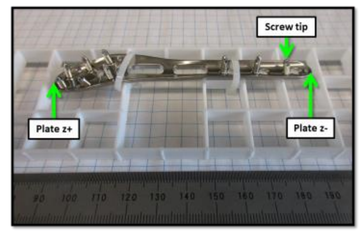
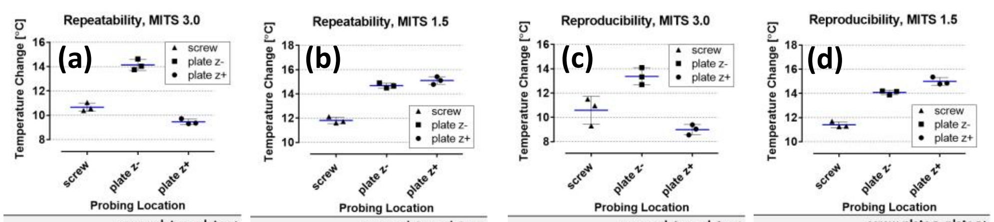


Figure 2: Photograph of a stainless steel (grade 316L) distal fibula test plate with screws for testing at 128 MHz. Green arrows indicate temperature sensor locations.

RESULTS AND DISCUSSION: The measurement repeatability and reproducibility results are presented in **Figure 1** as scatter plots with mean & SD (top) and corresponding summary tables (bottom) with mean, SD, percent error, and standard error of the mean. The highest temperature percent error was 3.18 % and 2.22 % for measurement repeatability and 10.82 % and 2.08 % for measurement reproducibility, in MITS 3.0 and 1.5, respectively. Although most of the measurements results fall within 5.24 % error, occasionally 10% or more error can be seen between measurement reproducibility. **Table 1** summarizes the results for long-term repeatability measurements of resolved LSAR *in vitro* obtained from RF-heating of an ASTM 10 cm Ti rod. The highest percent errors at 64 and 128 MHz were < 3.36 % (n = 37) and < 4.39 % (n = 25), respectively. These results indicate that the systematic errors are as large or larger than statistical. Future work will involve optimizing experimental techniques to reduce this error.



(a)

	screw	plate z-	plate z+
Mean [°C]	10.66	14.14	9.46
SD [°C]	0.34	0.45	0.22
Pct. Error [%]	3.18	3.18	2.36
Std Err. of Mean [°C]	0.20	0.26	0.13

(b)

	screw	plate z-	plate z+
Mean [°C]	11.81	14.68	15.11
SD [°C]	0.26	0.21	0.32
Pct. Error [%]	2.22	1.41	2.09
Std Err. of Mean [°C]	0.15	0.12	0.18

(c)

	screw	plate z-	plate z+
Mean [°C]	10.58	13.38	8.99
SD [°C]	1.14	0.70	0.42
Pct. Error [%]	10.82	5.24	4.69
Std Err. of Mean [°C]	0.66	0.40	0.24

(d)

	screw	plate z-	plate z+
Mean [°C]	11.41	14.08	15.00
SD [°C]	0.24	0.18	0.32
Pct. Error [%]	2.08	1.28	2.11
Std Err. of Mean [°C]	0.14	0.10	0.18

Figure 1: Measurement scatter plot results with mean and SD (top) and summary tables (bottom) for repeatability in (a) MITS 3.0 & (b) MITS 1.5, and reproducibility in (c) MITS 3.0 & (d) MITS 1.5.

Table 1: Long-term repeatability of resolved LSAR *in vitro* from RF-field induced heating of an ASTM 10.0 cm long Ti rod.

MITS	Δy [cm]	n	Local SAR [W/kg]	SD [W/kg]	Percent Error [%]	95% Confidence Interval
1.5	0.7	32	7.61	0.20	2.62	7.54 - 7.68
1.5	1.7	37	8.38	0.28	3.36	8.37 - 8.55
3.0	0.7	25	10.22	0.45	4.39	10.04 - 10.39
3.0	1.7	8	13.36	0.50	3.71	13.02 - 13.71

CONCLUSION: This study presents quantitative determination of RF-induced implant measurement repeatability and reproducibility values corresponding to test cases involving conductive medical implants in an RF benchtop exposure system.

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REFERENCES: [1] ASTM F2182: Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging. Pennsylvania, USA: ASTM International, 2013. [2] (ZMT, Zurich, Switzerland). [3] (Neoptix, Québec, Canada). [4] (Speag, Zurich, Switzerland).