Estimated Measurement Uncertainty (EMU) in Calorimetrically-Determined Whole Body SAR Values for Medical Device Evaluation Using Benchtop Radiofrequency Exposure Systems

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INTRODUCTION

A standardized test method for *in vitro* assessment of true RF whole-body specific absorption rate (WB-SAR) utilizes direct measurement of RF-induced heating in a phantom [1].

For the characterization of MR-conditional medical devices, the WB-SAR value is used to determine the effective exposure level and to normalize the heating results of devices under test.

Because the WB-SAR value associated with a device heating measurement factors directly into the final labeling conditions, it is of paramount importance to continually characterize and understand the uncertainty in the WB-SAR measurement. F2182-11a does not address uncertainty assessment of the heating experiment.

In this study, we present our measured values for short-term measurement repeatability (repeated measurements within a single session) and long-term measurement reproducibility (across multiple sessions).

PURPOSE

The aim of this study was three fold:

1. To estimate the Estimated Measurement Uncertainty (EMU) of WB-SAR from short-term (within-a-day) measured repeatability (repeated measurements within a single session) and long-term (day-to-day) measurement reproducibility (across multiple sessions).
2. To support inter-laboratory and intra-laboratory comparisons.
3. Demonstrate procedures for estimating uncertainty of measurements required by ISO/IEC 17025.

METHODS

Exposure System

All calorimetry measurements performed on two different transmit-only body RF birdcage Medical Implant Test Systems (MITS, Figure 1) 1.5 and 3.0 [2], corresponding to frequencies of 64 and 128 MHz, respectively [2].

Figure 1: MITS 1.5/64 MHz (right) and 3.0/128 MHz (left) bench top exposure systems [2].

Table 1: MITS sequence parameters (Software v1.12.10 [2]).

Parameters	MITS 1.5	MITS 3.0
RF on [s]:	900, 1200, or 1800	
Pulse type:	sinc2π	sinc2π
Duty cycle [%]:	40	40
Pulse rep. rate [kHz]:	1.0	1.0
Polarization [°]:	270	90
Frequency [MHz]:	63.8	127.7
Power [dBm]:	59.0	60.2
$B_{1,rms}$ [μT]:	4.1	2.9

Phantom

Two different ASTM phantoms (42 × 65 × 16.5 cm and 42 × 60 × 16.5 cm) filled with saline (2.5 g/L NaCl in distilled water (Figure 2), yielding electrical conductivity of 0.47 S/m ± 10 %), to a fluid height of 9.0 cm, corresponding to a total volume of ~24.5 L.

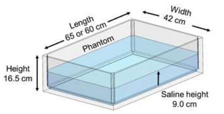

Figure 2: 3-D illustration of phantom container filled with saline.

METHODS

The phantoms were thermally insulated with 1" thick polystyrene foam. The geometric center of the phantom fluid (height of 4.5 cm) was aligned with the geometric center of the MITS (Figure 3).

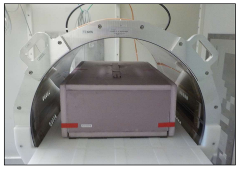

Figure 3: MITS bench top exposure system loaded with insulated ASTM phantom [2].

Temperature Monitoring

Normal temperature procedures were followed with acceptable temporal rates [1].

Omniflex signal conditioner [3] with eleven submerged T1C optical fiber temperature probes [3] near the isocenter of the fluid monitored temperature rise. Three (n=3) repeated measurements of 15-, 20- and/or 30-minute RF exposure at both 64 and 128 MHz.

Figure 4: Omniflex temperature system (left) and T1C fiber optic temperature probes (right) [4].

Data collected by a custom built Labview program.

A precision calibrated RTD TL1-R thermometer [4] was used to verify the average of the 11 fiber-optic probe temperature measurements.

Analysis

Measurement repeatability was evaluated within a single session (i.e. same day) by repeating measurement without any changes to the physical setup.

Measurement reproducibility was performed on different sessions, separated by approximately 12 months, by replicating the experiment setup (i.e. phantom position, probe placement).

The measured temperature change after exposure was converted to a WB-SAR value by using: SAR = c(ΔT/Δt), where c is 4150 J/kg°C (the heat capacity of the phantom material), ΔT is temperature change in °C, and Δt is RF exposure duration in seconds.

RESULTS

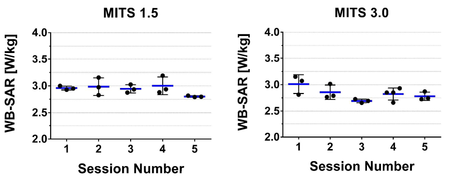

Figure 5: Calorimetrically determined WB-SAR on 65-cm long ASTM phantom. Mean WB-SAR (i.e. long-term reproducibility) for all five sessions is 2.94 ± 0.12 W/kg and 2.83 ± 0.15 W/kg for MITS 1.5 and MITS 3.0, respectively.

RESULTS

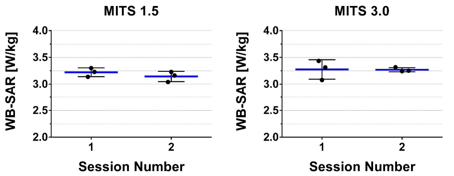

Figure 6: Calorimetrically determined WB-SAR on 60-cm long ASTM phantom. Mean WB-SAR (i.e. long-term reproducibility) for all sessions is 3.18 ± 0.09 W/kg and 3.27 ± 0.12 W/kg for MITS 1.5 and MITS 3.0, respectively.

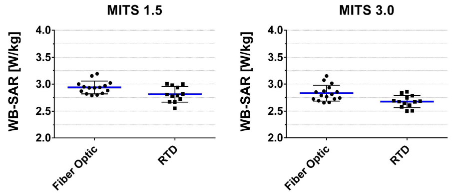

Figure 7: Calorimetrically determined WB-SAR on 65-cm long ASTM phantom using fiber optic (circle marker) and RTD thermometer (square marker). For MITS 1.5, WB-SAR is 2.94 ± 0.12 W/kg (fiber, n=15) and 2.81 ± 0.14 W/kg (RTD, n=12). For MITS 3.0, WB-SAR is 2.83 ± 0.15 W/kg (fiber, n=16) and 2.68 ± 0.11 W/kg (RTD, n=13).

DISCUSSION AND CONCLUSION

The percent error of all measurements was under 11%, the highest being for the 65-cm long phantom in MITS 3.0.

There was not substantial difference between the within-session and the between-session measurement uncertainties. As shown in Figure 7, the difference between multi-probe averaged fiber optic temperature-resolved and RTD thermometer-resolved WB-SAR was 4.5% and 5.5%, for MITS 1.5 and MITS 3.0, respectively.

These results provide our laboratory EMU and a method for assessing intra- vs. inter-session variability.

Long term monitoring of calorimetry data using these methods provides a method for tracking changes in the system performance.

We also compared group fiber vs. RTD measurements, demonstrating similar results.

These measurements support the conclusion that RF-induced WB-SAR measurements made with bench-top RF exposure systems can be made with a total EMU of approximately 11% (k=1). Additional data will enable the EMU to be estimated with more confidence.

ACKNOWLEDGEMENTS

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REFERENCES

[1] ASTM F2182-11a. [2] (ZMT, Zurich, Switzerland). [3] (Neoptix, Québec, Canada). [4] (ThermoProbe Inc., Pearl, MS USA).