Determination of in-vivo temperature rise and gradient induced voltage during MRI of cut sacral neuromodulation leads

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Target Audience: (a) Researchers in MRI safety of active implant leads; (b) clinicians working with patients with remnants of implanted sacral neuromodulation leads.

Purpose: Perform heating tests in phantoms and calculations in a female human model ("Susie" from IT'IS Foundation) to determine in-vivo temperature rise and the gradient induced voltage during MRI of cut Neuromodulation leads (Medtronic lead models 3889 and 3093) which were retained in-vivo after being used for treatment of urinary incontinence in women.

Methods: The overall method follows the procedure described in ISO-IEC 10974.[1] (a) Temperature rises were measured in phantoms at 64 MHz and 128 MHz according to ASTM F2182-11a on 5- and 7-cm long distal segments (electrode ends) of the neuromodulation leads. (b) The electric field transfer function[2] for the electrodes was measured for an intact 28-cm lead using a fixture with a toroidal coil for exciting current waves on the lead. (c) From the measured transfer function, the wavelength and damping parameter for transmission of RF-induced currents was determined. (d) The transfer function was validated by a “cut-down” test in which temperature rise in a phantom at the electrode was measured for different lengths of cut leads. (e) Paths for the cut retained lead remnants were defined in the female human model. (f) The tangential electric field along each lead path in the patient in the bore of 1.5 and 3T MRI systems was calculated with FDTD. (g) From the non-clinical measurements and calculations, the temperature rises at the electrodes and the cut ends of the retained leads were determined. (h) The gradient induced voltage along the lengths of the leads in gradient dB/dt was calculated using an impedance method.

Results. Figure 1 shows measured and fit transfer functions for a 28-cm cut lead at 64 MHz. The measured transfer function is fit well by a wave model with wavelength $\lambda = 99$ cm and damping $\alpha = 0.63$. Figure 2 shows calculated and measured temperature rise scaled to local background SAR at the distal electrode for different lengths of a cut lead. Temperature rises in phantom tests were greater at the cut end than at the electrode. Model calculations made with method of moments yielded that the temperature rise at the cut ends will be relatively independent of the exposed length of metal beyond the insulation in the typical range of 1-2 mm. Table 1 summarizes the in-vivo temperature rises in the female human model for 30 minute RF exposure at whole body (WB) SAR of 2 W/kg. The rises are maximum values from numerous calculations for different lead paths, MRI landmarks, and rotation sense. Maximum gradient induced voltage under conservative assumptions of dB/dt = 100 T/s simultaneously for the X-,Y- and Z- gradient coils yielded maximum induced voltages in the human model of approximately 100-mV for a 5-cm cut lead and 200 –mV for a 7 cm lead.

Discussion and Conclusions: The in-vitro tests demonstrate the efficacy of the transfer function for predicting temperature rise at the electrode based on the tangential electric field along the length of the leads. The maximum temperature rises in Table 1 result in absolute temperatures less than the maximum safe temperature described for neurological tissues of 43 °C, for 30 minutes[3]. The maximum gradient-induced voltage is unlikely to induced stimulation given that higher voltages are required for stimulation with a generator and furthermore because the large impedance at the cut end will limit the current flow through the electrode.

References: 1) ISO/TS 10974:2012, Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device, 2012.

2) Park SM, Kamondetdacha R, Nyenhuis JA. Calculation of MRI-Induced Heating of an Implanted Medical Lead Wire with an Electric Field Transfer Function, J. Mag. Reson. Imag. 2007; 26:1278-1285.

3) Coffey RJ, Kalin R, Olsen JM, Magnetic Resonance Imaging Conditionally Safe Neurostimulation Leads: Investigation of the Maximum Safe Lead Tip Temperature. Neurosurgery, 2013.

Length (cm)	B_0	ΔT_{max} at cut	ΔT_{max} at electrode
7 cm	1.5 T	2.4 °C	0.33 °°C
7 cm	3 T	3.7 °C	0.49 °C
5 cm	1.5 T	1.5 °C	0.16 °C
5 cm	3 T	1.7 °C	0.19 °C

Table 1. Maximum in-vivo temperature rises at WB SAR = 2 W/kg.

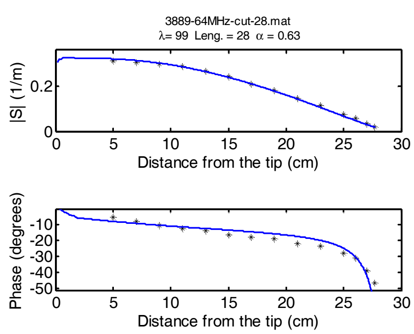

Fig 1. Measured and fit transfer function S for a 28-cm lead with cap at generator.

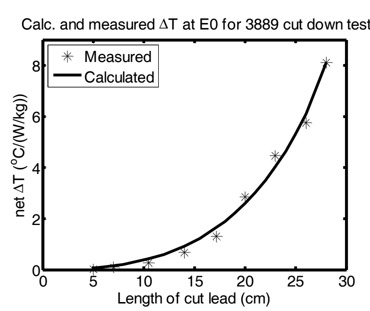

Fig. 2. Calculated and fit temperature rises vs. length of cut-down lead.