Safety testing of performing MRI scans with implanted Soletra pulse generator at 3 tesla

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Performing MRI with implanted neurostimulators imposes safety issue, which needs to be properly addressed. Recently safety of running functional MRI with active, fully implanted, deep brain stimulation (DBS) systems at 1.5 T and 3 T using Medtronic Kinetra IPG has been studied. We have performed safety testing by performing MRI scans of a gel phantom (1) with a Soletra 7426 implantable pulse generator (IPG) placed within the phantom. A pair of 3387-40 DBS leads was placed within the phantom with one lead connected to the IPG, while the other lead was left in the gel. The IPG was placed on the left side of the phantom. Fluoroptic temperature sensors (model m3300, Luxtron, Santa Clara, CA, USA) were used for temperature measurement. The points of contact of the probes were contacts 0 and 3 of the right and left DBS leads (0 is the distal contact), the IPG case and a reference point midway between the contact region of the right and left leads. MR scans were performed using a 3 tesla whole body Siemens Total Imaging Matrix Trio system with a circularly polarized transmit/receive head coil. Since the stimulator is expected to change its ON/OFF state in presence of a magnetic field, we had to ensure that the IPG is ON in the scanner by measuring voltage constantly during scan. For this purpose a 100 ohm resistor was inserted in series (Fig. 1) to the wire leading to contact 3, and voltage across the resistor was measured using an oscilloscope (Tektronix TDS 3054B, Tektronix Inc., Beaverton, OR, USA).

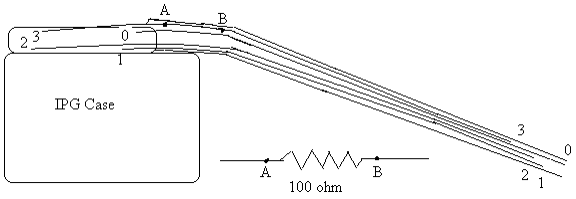

Fig. 1. Voltage is measured across points A and B

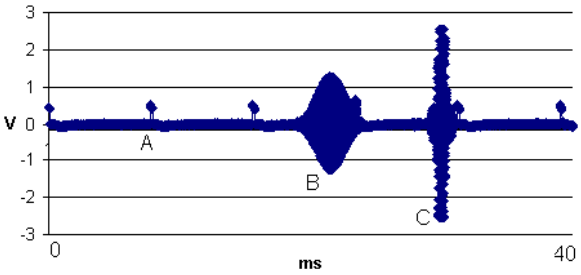

Fig. 2. Voltage measurement during fMRI (Scan 4). A, B and C denote voltages measured during the pulse generated by IPG, fat saturation pulse and excitation pulse repectively.

The IPG was programmed to generate 6 V pulses with a width of 130 μs at a frequency of 130 Hz. The following MR scans were performed: *Scan 1:* Whole brain **3D MPRAGE** scan with the following scan parameters: 256 mm × 256 mm FOV, 256 × 256 matrix, 120 axial slices to cover the whole brain, TI 900 ms, TE 1.71 ms, TR 1900 ms, flip angle 8^0, receiver bandwidth (BW) 490 Hz/pixel., *Scan 2*: **Turbo spin echo** scan with the following parameters: 300 mm × 300 mm FOV, 251 × 256 matrix, 5 mm thick axial slice, TR 2000 ms, TE 82 ms, flip angle 180^0, turbo factor 7, 130 Hz/pixel BW, *Scan 3*: ***fMRI*** scan with the following parameters: 90^0 flip angle, TE 29 ms, TR 2800 ms, number of axial slices 32, slice thickness 4 mm, gap 0 mm, **64 × 64 matrix**, 256 mm × 256 mm FOV, 1954 Hz/pixel BW, 160 repetitions., *Scan 4*: **fMRI** scan with the following parameters: 90^0 flip angle, TE 29 ms, TR 2800 ms, number of axial slices 32, slice thickness 4 mm, gap 0 mm, **128 × 128 matrix**, 256 mm × 256 mm FOV, 1954 Hz/pixel BW, 160 repetitions.

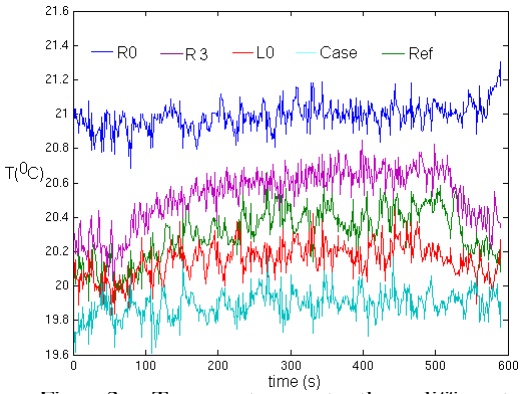

Fig. 3. Temperature at the different measurement points during scan 4. R and L denote right and left leads respectively, 0 and 3 are the electrode contacts, Ref is the reference point.

Each set of temperature measurement was taken for 10 minutes such that the MR scan was started 1 minute after the start of the temperature measurement, and the temperature measurement was continued after the end of MR scan for the remaining time. The maximum rise in temperature during scan was 0.7812^0C for scan 3 at contact no. 3 of the right lead. The maximum rise in mean temperature during the scan compared to that prior to scan was 0.4225^0C for scan 3 at contact no. 3 of the right lead. The maximum drop in mean temperature after the scan compared to that during scan was $0.1680\ ^0$C for scan 1 at contact no. 3 of the right lead. **No appreciable heating was observed during MRI scans with fully implanted stimulator in our 3T scanner with the gel phantom**. It should also be noted that voltage reading from the oscilloscope indicated that the IPG was always ON while in the magnetic field.

1. Baker KB, Tkach JA, Phillips MD, Rezai AR. Variability in RF-induced heating of a deep brain stimulation implant across MR systems. J Magn Reson Imaging 2006;24(6):1236-1242.