Temperature Sensor Implant for Analysis of RF Safety of Active Implantable Medical Devices under MRI

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Target audience: This study can be of interest researchers who work in the field of implant MRI safety

Purpose: The aim of this study is to present a prototype of the implantable temperature sensor which will be used in animal studies to emulate the situation of a patient with an Active Implantable Medical Device (AIMD) inside the MRI and investigate possible tissue damage due to the RF induced tissue heating.

Introduction: It is well known that coupling of metallic implants to the RF transmit coils causes localization of E-field around the implant, usually proximity of the electrode, and cause tissue heating. Although, this problem is well investigated and excessive tissue heating is shown with many phantom experiments, however phantoms do not have perfusion. There are very few in vivo studies investigating this problem due to the complexity of temperature measurement setups. Replacement of temperature probes requires surgery which alters the perfusion properties of the tissue. A way to overcome this problem is waiting for recovery after implantation of the temperature probes, however still it is required connection of probes to data recording units and cables coming out of the subject[1]. In this abstract, we will present an implantable temperature sensor, which can communicate through a low power Bluetooth protocol, and has capability of recording data to on site memory. This temperature sensor implant will enable us to imitate the situation of a patient with an active implant under MRI.

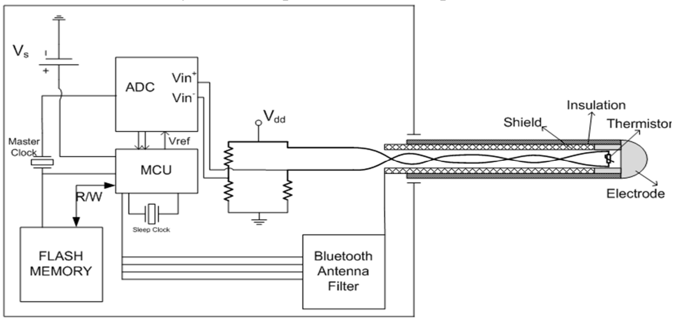

Figure 1: Diagram of the temperature sensor implant circuit

Methods: Proposed temperature sensor implant is designed similar to an active implant with one electrode, the lead and the case. The case is a 4.5cm x 3.8cm x 2cm copper box and inside of it there is anembedded MCU unit with a Bluetooth 4.0 module is placed. The electrode is a half copper sphere with 3.1mm diameter and has a NTC thermistor inside of it as temperature sensor. The NTC thermistor has 10kΩ resistance at 25°C, β equals to 3695K and glass cylindrical body with 1.5mm diameter and 3.5mm height. As shown in Fig.1 the lead has a twisted pair with 0.34mm thickness, a shield with 1.5mm diameter, insulation with 0.5mm thickness and the total diameter of the lead is 2.5mm and length is 24cm. The shield of the lead is both used for connection of the electrode and the Bluetooth monopole antenna. It is connected to the Bluetooth module through a high pass filter, with S21 equals to -0.8dB at the Bluetooth operating frequency (2.4GHz) and -59dB at MRI RF frequency (123MHz). With this configuration lead is directly connected to the case at MRI RF frequency, which is a possible situation for implants during MRI scan.For data collection ADC of the MCU programmed to a differential input mode with 12 bit resolution and 512 decimation rate. ADC is used with 1 sec sampling rate, however for 12 bit resolution ADC can be reprogrammed up to 150Hz sampling frequency. As shown in Fig.1, the input of the ADC is connected to midpoints of the Wheatstone bridge which is built using three 13.3kΩ resistors and the thermistor inside the electrode. Voltage across the midpoints of the Wheatstone bridge is recorded and used for calculation of the thermistors' resistance, and then using the thermistors' resistance temperature of the electrode is calculated. The Bluetooth 4.0 module is BLE112 provided by Bluegiga Technologies Inc. The integrated chip supports Bluetooth Low Energy mode which enable us to operate at low power energies. The current consumption of the chip is 6.7mA for active mode and 200µA at power down mode. The system can operate between 2 to 3.6V. We used a 3V CR2032 lithium battery for powering the whole system. An Android™ v4.3 phone application has been written for data exchange via Bluetooth.

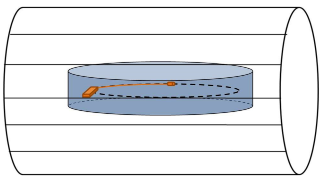

Figure 2: Position of lead inside the phantom and phantom replacements inside the birdcage coil

To test the temperature sensor implant, itwas placed inside a circular phantom with 40cm diameter on a circular path as shown in Fig.2. Phantom was filled with 14g/liter Hydroxyethyl cellulose and 0.5g/liter NaCL. Also a fiber optic temperature sensor was placed 2mm away from the electrode. Before the MRI scan, while patient table was at home position and phantom was placed on the patient table, temperature sensor implant was remotely activated for data recording via the Bluetooth connection. Then the phantom was positioned in the center of the body coil as shown in Fig.2 and GRE sequence with TR of 1.8ms and FA of 36 degrees was applied using a Siemens 3T TimTrio scanner. For the validation temperature data was also recorded using the fiber optic sensors during the experiment. During the MRI scanning, thetemperature data was recorded to the flash memory of the module. Later, therecorded datawas transferred from the implant via Bluetooth while the implant was still inside the phantom on the patient table at its home position. Data transfer could be done successfully up to a distance of 3.5m by using a mobile phone with the Android operating system.

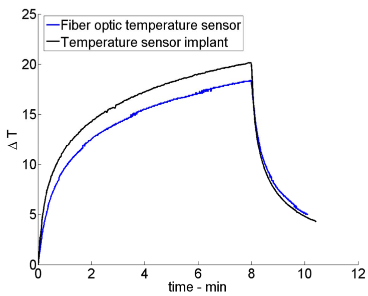

Figure 3: Temperature change at the tip of the electrode. Black line is the measurement with the temperature sensor implant, and blue line is the measurement with the fiber optic sensor

Results: In Fig.3 temperature measurements with the temperature sensor implant and fiber optic sensor at the electrode tip is shown. The difference between the two measurements was less than 11%.

Discussion and Conclusion: In this study, an implantable temperature sensor in the form of an active implantable medical device with capability of recording temperature data and sending it while inside the body is presented. With the low power consumption of the system this implant can be used approximately for 3 months with two 3V coin batteries. With the current configuration the implant is capable of recording data for 1 hour; however with integration of additional memory units, data recording duration can be increased. Also, sampling frequency of the ADC can be increase up to 150Hz for 12 bit resolution.

This implant will also enable us to do MRI safety studies with animals unaffected by bleeding of new scar tissues or extra cables coming out of the subject. Although here only the temperature recording is presented, we plan to modify the Bluetooth module hardware and software can for monitoring long term effects of MRI scan of patients with implants by ECG recording and lead impedance measurements. Also, implanting this device to animals for MRI safety of AIMDs is future work of this study.

References: [1] Luechinger, Roger, et al. "In vivo heating of pacemaker leads during magnetic resonance imaging." European Heart Journal 26.4 (2005): 376-383.