

Effects of Longer Leadwire Length on Radiofrequency Heating in Multi-Leadwire Arrays in Nonstandard Configurations

Abstract

Objective: This report documents the activities and results from testing various MR Conditional EEG Electrodes in a 3T (128Mhz) birdcage coil for the purpose of determining the relationship between leadwire length and radiofrequency heating observed at the electrode. The data collected during testing may be used to further research and development activities to produce improved product designs for use in a magnetic resonance environment.

Keywords: EEG, cEEG (Continuous EEG), FDA (Food and Drug Administration), MRI (Magnetic Resonance Imaging), American Society for Testing and Materials (ASTM), MR Conditional

Introduction: The ability to keep external medical devices on patients during imaging procedures such as MRI scans can be a major advantage to medical staff and patients. In particular, the ability to keep neurodiagnostic electrodes used for electroencephalography (EEG) on a patient during scanning saves a significant amount of time and money by not requiring an EEG technician to remove and reapply electrodes for each scan. However, external leadwires can pose a risk of thermal injury to patients if left on during an MRI procedure and therefore must be designed to minimize radiofrequency (RF) induced heating and undergo specific testing to ensure safe and effective design and use.

Alternating RF electric fields can cause conductive devices to deposit power into nearby tissue due to the antenna effect, potentially resulting in thermal burns such as those shown in Image 1 below.

Image 1: Examples of RF-induced burns from Non-MR Conditional electrodes.



Examples of RF-induced thermal burns. Burns due to an electrical monitoring device (left) and an EKG pad with lead attached (right) which had been left in place during MRI scanning [4][7]

While there are many factors that can contribute to unwanted heating at an electrode-to-patient interface, leadwire length carries the greatest impact on RF-induced heating for MR Conditional EEG Electrodes and must be considered in the device design to ensure patient safety. The objective of this study was to correlate leadwire length to RF induced heating in multi-lead arrays.

Harmonized Standards:

ASTM F2182-19E2 - Standard Test Method for Measurement of Radio Frequency Induced Heating on or Near Passive Implants During Magnetic Resonance Imaging

Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment, FDA Guidance 2023

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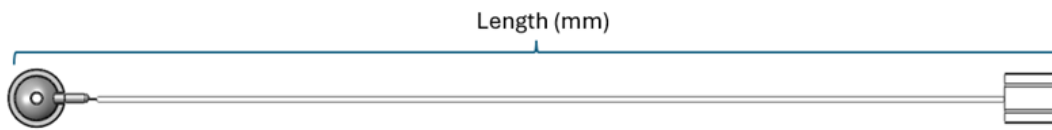
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Method: Five test groups of different length multi-lead electrode arrays were tested. The 195mm sample length is representative of the currently cleared RhythmLink MR Conditional/CT Quick Connect Electrodes. The other samples had increasing lengths up to 295mm at 25mm increments, for a total of 5 groups, each testing in triplicate total of 15 data points. Figure 2 shows how total device length is measured.

All samples were constructed out of identical or equivalent materials, including insulated carbon fiber leadwires, glass filled ABS electrodes coated in AgAgCl, and the same touchproof multi-pin connector. The samples were tested for RF-induced heating at the electrode-to-skin interface in a bench top phantom and RF-coil representative of a 3T MRI system, setup according to ASTM F2182-19E2. Samples were exposed to 15 min pulse sequences with temperature changes recorded continuously at 1 second intervals. The maximum temperature increase reached at the end of 15 minutes was recorded.

Figure 2: Leadwire Length

The leadwire length is measured as the total device length, inclusive of electrode and connector.



Results

Figures 3 & 4 and Table 1, below, summarize the results.

Figure 3: Multi-lead RF-induced Heating due to leadwire length in nonstandard configurations

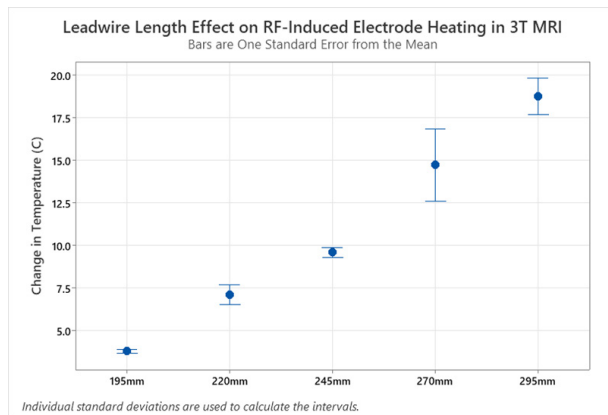
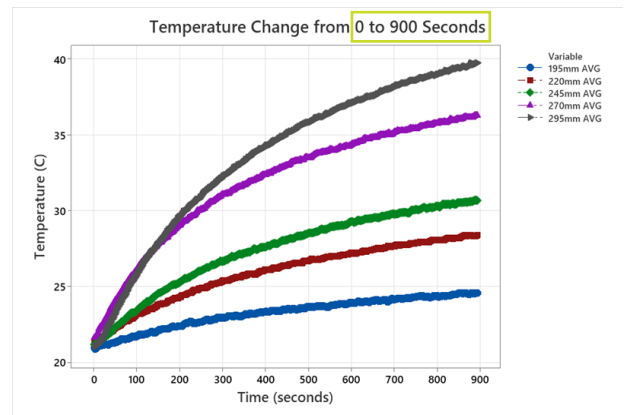


Figure 4: Measured temperature rises at the electrode interface during 15 minute pulse sequences.



In nonstandard configurations the longer samples heated more rapidly than the shorter sample, with the 270mm and greater samples breaking the 4°C increase threshold (per FDA guidance) in less than 1.5 minutes in nonstandard configurations. Note: The 195mm sample never reached a 4°C increase.

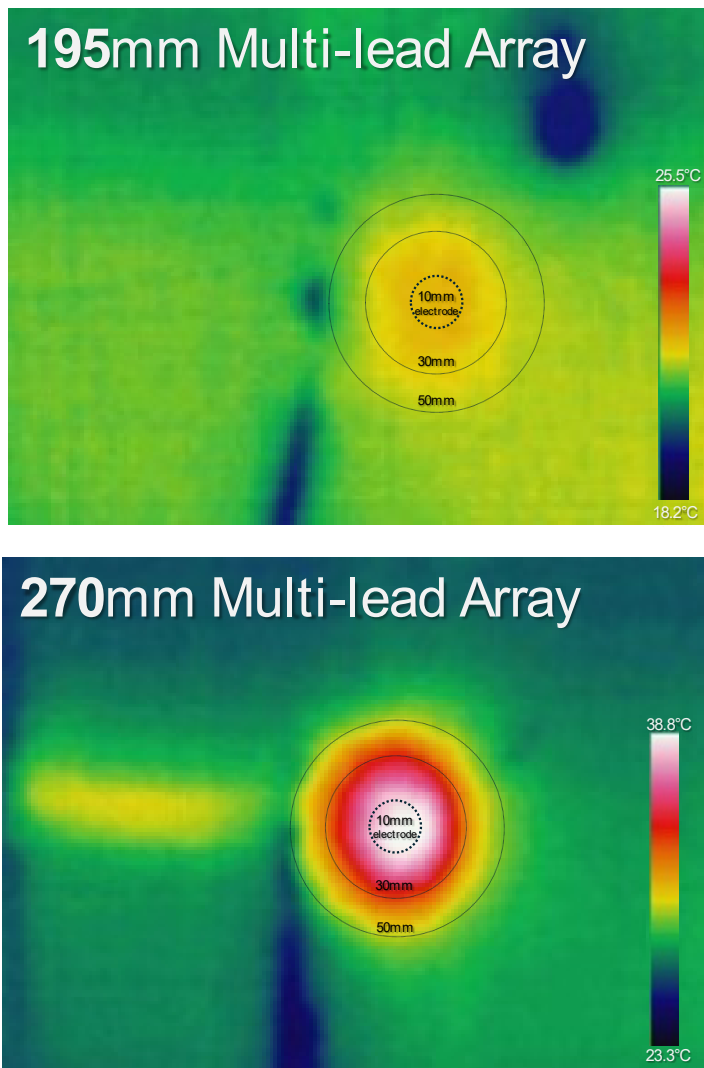
Table 1: Time to reach 4°C temperature rise.

Array Length	Time to Reach FDA Threshold of $\Delta 4^{\circ}\text{C}$ Increase(sec)
195mm	N/A*
220mm	300
245mm	194
270mm	87

* The 195mm sample only increased 2.5C after 15 minutes. Per FDA guidance, this sample would confidently remain under 4C for up to or greater than 1 hour (>3,600 sec)

Figure 5 and 6: Thermal images of RF-Induce heating for 195mm (top) and 270mm (bottom) long Multi-lead EEG Arrays.

Thermal images were captured immediately following 15 minutes of the same RF pulse sequence to visualize the effects of RF-Induce heating in proximity to the electrode. The location and extent of heating around the electrode is visible for both samples, with a significantly higher temperature rise observed in the 270mm length multi-lead array sample in nonstandard configurations.



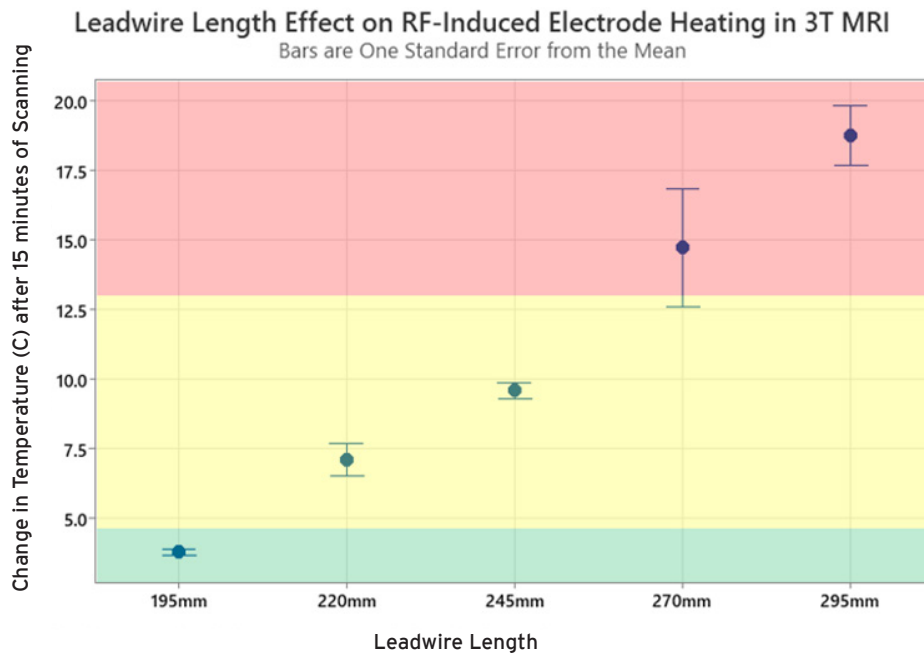
Discussion & Conclusions

Based on the experimental data, it can be concluded that leadwire length significantly affects the amount of energy absorbed at the electrode interface (eg, patient tissue) due to the antenna effect, particularly in nonstandard configurations. An increase in leadwire length can result in increased RF-induced heating at an electrode placed on a patient's head during an MRI scan. This is clinically significant as when used in nonstandard configurations, it directly impacts the safety of patients undergoing MR imaging procedures with external, multi-leadwire array devices applied.

Based on the current FDA Guidance for Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment, devices which exhibit higher than 4°C heating after 15 minutes of continuous scanning must have a cooling period provided by the manufacturer. [2] Additionally, according to common measures of thermal damage such as the principle of CEM43°C, a rise of 13°C for 18 minutes has the potential to cause epidermal necrosis. [3][5][8][9][10] Given that a typical brain MRI scan can last for 30 minutes to 1 hour, the need to keep unwanted RF heating to a minimum is evident.[6]

Taking these thresholds of 4°C and 13°C into account, Figure 14 charts the average temperature change after a 15-min pulse sequence with three zones displayed indicating “Below $\Delta 4^{\circ}\text{C}$ ”

Figure 7: Multi-Lead Array Leadwire Length Effect on RF-induced Tissue Heating in 3T MRI



Leadwire length significantly affects RF induced heating in external leadwires connected to patients undergoing MR imaging and must be considered when assessing patient safety. Increasing leadwire length in a multi-leadwire array can increase the magnitude of power absorbed and deposited at the electrode-to-skin interface due to the antenna effect, resulting in greater potential for thermal burns to occur during MR imaging. External, multi-leadwire array devices commonly used in EEG procedures greater than 195mm in length have the potential to produce heating results above the suggested limits provided by the FDA without additional considerations for patient safety being addressed.

Many factors must be considered when determining the risk of potential burns when using external leadwires in an MR environment. Leadwire length certainly is one of the most critical factors as seen by the data presented above, however other factors that can contribute to increased heating and the potential for thermal damage include electrode and leadwire dressings, pressure between electrode and skin, variation in skin thickness and patient thermotolerance, skin and electrode application moisture content, blood circulation, length of MRI scan, external leadwire routing, and machine scan parameters to name a few.

Assessing heating risks quickly becomes complex due to the number of factors involved, therefore mitigating the amount of RF induced heating starting from the design of the device, i.e. leadwire length, is an optimal approach to ensure the temperature at the electrode-to-skin interface remains within a safe limit for the entire length of the scan.

Conflict of Interest Disclaimer: Authors include employees of RhythmLink International, LLC. RhythmLink is a medical device manufacturer and distributor of Mr Conditional EEG electrodes.

Additional References

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