Q-Sense fMRI in the MRI environment

An evaluation at the Erwin L. Hahn Institute for Magnetic Resonance Imaging, and at the Institute of Diagnostic and Interventional Radiology and Neuroradiology,

Essen University Clinic; Essen, Germany

Gilad Barzilay, Medoc Ltd. Advanced Medical Systems; Ramat Yishai, Israel July 2018

Introduction

In recent years, functional magnetic resonance imaging (fMRI) has become one of the most utilized tools for objectively quantifying pain intensity, evaluating and predicting effectiveness of analgesic medications and other pharmacological products --- while providing information as to changes (or lack thereof) in the brain's response to painful stimuli. Medoc Ltd. has offered Quantitative Sensory Testing (QST) devices for the last 25 years, systems which enable researchers and clinicians to obtain standardized testing of pain and sensory pathways, while fostering a deeper understanding of the perception of pain. Since 2008, The FDA-cleared Pathway and TSA devices have been widely used in fMRI research, providing a unique opportunity to apply painful stimulation in an fMRI environment.

Strict requirements must be met when a device is to be used in the MRI suite. A device must first be approved for MRI use as being either MR Safe or MR Conditional, with most medical electronic devices typically falling into the latter category. Imaging artifacts caused by electromagnetic noise interference can be the bane of many medical devices that are not carefully designed to be used in such an environment. While the MRI room is heavily shielded, there is still the possibility of electromagnetic noise penetrating via small ports and waveguides or to emanate from the device from within the room itself.

Medoc has recently developed the Q-Sense fMRI, based on the compact Q-Sense QST device. Q-Sense provides an easy-to-use and scientifically validated measure of warm, cool and heat pain thermal sensory thresholds. As a portable platform, the Q-Sense fMRI System can be used as a tabletop device with quick installation in an MRI scanner suite.

In order to validate the device as MR Conditional, the Q-Sense fMRI System has been subjected to testing at the Erwin L. Hahn Institute at Essen. The ELH Institute hosts a 7T MRI scanner. The institute also employs a 3T scanner at the Essen University Clinic. The scanners have particular test sequences to analyze noise interference (termed "rf noise" and "rf noise spectrum" by Siemens). These tests can provide valuable information noise levels in the room before and after introduction of external equipment. The tests scan the radiofrequency (RF) spectrum of interference (centered on the primary operational frequency of the scanner, namely 127 MHz and 295 MHz for 3T and 7T, respectively).

One additional measure which may be considered useful - arguably the most relevant check - is the fMRI test sequence, which is actually used in clinical research. The typical sequence used is echo planar imaging (EPI) with subsequent statistical analysis of the blood oxygenation level dependent (BOLD) effect. This happens to be one of the more intense sequences used in terms of the magnetic gradient field, which could be compromised by unwanted noise interference of visible stripes or dots appearing in the image.

Methods

A Q-Sense fMRI prototype device (Medoc Ltd, Ramat Yishai, Israel) was positioned on a desk in the control room outside the MRI scanner room, close to the penetration panel (see Fig 1). The penetration panel was equipped with waveguides and cutouts for filter connectors.



Figure 1 Q-Sense fMRI positioning in the control room

The Q-Sense fMRI System is available in both a single and dual thermode configuration, the latter for purposes of synchronized or sequential stimulation of multiple body sites in the scanner. The following test method involved use of both single and dual thermode configurations in the scanner.

Q-Sense fMRI thermodes are non-ferrous and have air tubes for heat removal and controlling system temperature. The thermodes and air tubes are introduced into the room via waveguides, with the signal cables splitting off the main cable harness, connecting via an EMI filter through the panel cutouts and re-entering the main cable. The EMI filter is used to block electronic noise on each of the harness wires from entering the scanner room. The thermodes were positioned at approximate arm's length from the isocenter. For 3T, this was at the entry to the bore, and for 7T, this was approximately 1m inside the bore.

The Q-Sense fMRI System is controlled via Medoc Main Station (MMS) software. The thermode stimulation temperature range is between 20°C and 50°C. A temperature profile was set up to cycle between these extremes of the temperature range over the full course of the test. This was done to simulate the maximal power use of the system which induces the maximal intensity of interference noise. The MRI test runs were performed by running rf_noise, rf_noise_spectrum and EPI protocols on a water phantom and a human volunteer. Noise was evaluated by observation of change in peaks in the RF spectrum compared to the baseline values (without any external equipment in the room). In addition, the frequency domain image was inspected for stripes or other interference above the background noise.

Lastly the final acquired EPI images were checked for stripes or other artifacts potentially caused by external electromagnetic interference. Setup of the Q-Sense fMRI System was completed by a Medoc technician. The MRI scanner was operated by research physicists at the institute. The institute's consent form was signed by the volunteer prior to testing.



 $Figure\ 2\ Volunteer\ in\ 7T\ scanner\ with\ 2\ thermodes\ applied\ to\ his\ forearm\ (left)\ and\ with\ one\ thermode\ applied\ to\ his\ forearm\ in\ the\ 3T\ scanner\ (right)$

Results

No noise was observed for the Q-Sense fMRI System in any of the rf_noise, rf_noise_spectrum or EPI protocols on either scanners. The tests were repeated twice for each combination of phantom/human, single/double thermode configuration.

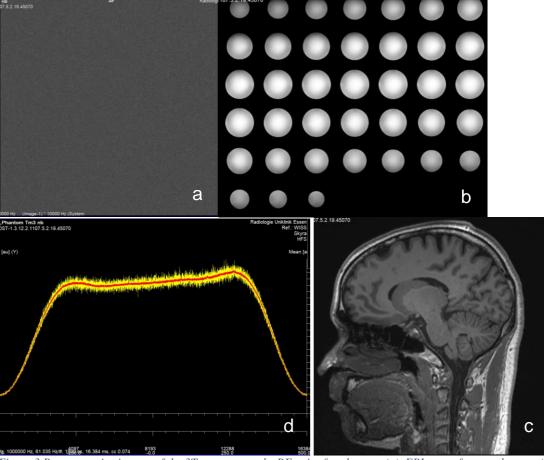
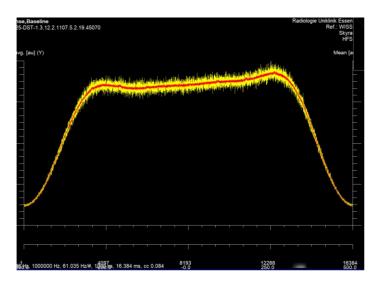


Figure 3 Representative images of the 3T scan protocols. RF noise for phantom (a), EPI scan of water phantom (b), EPI scan of head sagittal section (c), RF noise spectrum for phantom (d). Below: baseline rf_noise_spectrum test results [Data on file].



In order to evaluate grounding effects, a tin-plated copper braid was attached to the thermode cable in the control room and used to artificially create intermittent contact with the penetration panel during a scan of the water phantom. This resulted in a stripe that was observed during the rf_noise protocol, but not observed during the EPI imaging sequence. When the braid was connected in a stable fashion there was no noise observed. Nevertheless, it is recommended to have good grounding when using equipment in an MRI setting in general, and to avoid use of ancillary grounding aids such as copper braid or tape, which may be useable but could also cause more noise than they prevent.

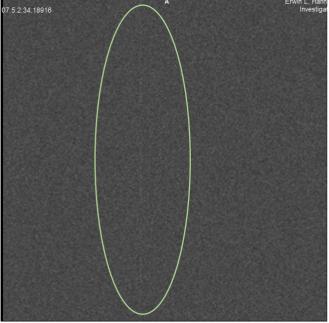


Figure 4 Faint stripes (marked in ellipse) in one of the rf_noise frequency slices. No imaging artifacts were seen in the corresponding EPI scan

Prior to the trial a numerical finite element analysis was conducted on the aluminium contact plate and heatsink of the thermode, to evaluate the thermal effect of ohmic heating expected due to magnetically-induced eddy currents. Worst-case parameters were used of 128 sequential passes of the gradient field used in typical image acquisition, each 500msec long were used over approximately 1/3 of a 15-minute long sequence. Field parameters of the 3T scanner were used rather than the 7T, as the 3T has a higher gradient field intensity per meter.

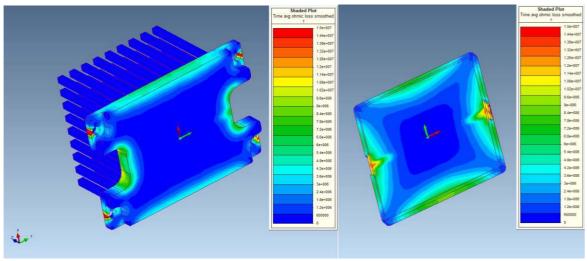


Figure 5 Ohmic heating in metallic parts of the Q-Sense fMRI thermode (on left: heatsink, right: contact plate)

It was found that the maximal theoretical increase in temperature rate would be $<0.25^{\circ}\text{C/sec}$, well within the control capabilities of the Q-Sense fMRI. No changes in temperature outside the $\pm0.3^{\circ}\text{C}$ temperature tolerance specification were observed during all MRI scan runs, verifying the feedback control was not affected by gradient fields.

In addition to ohmic heating, such rapidly changing magnetic fields are also expected to create an induced electromotive force (EMF) on current carrying conductors such as those present in the thermode, which may cause vibrations. In fact, the gradient coils themselves vibrating under the induced EMF are the source of the well-known acoustic noise generated during the MRI scan. Such vibrations were evaluated by holding the thermode close to the chest position (approximately 30cm from the isocenter in the 3T) compared to positioning the thermode at the entry to the bore. It was observed (subjectively by the volunteer) that the sensation of the MRI bore walls vibrating was comparable or more intense to that of the thermode when it was positioned at the entry to the bore, that the sensation was strongest in the area of the bore closest to the isocenter, and that overall the subjective sensation was of decreasing intensity in subsequent scan runs, possibly indicating that there may be some habituation effect involved.

There have been reportedly numerous physiological effects on the human body undergoing an MRI scan. Most notable are vertigo and nystagmus caused by the magnetic field inducing changes in ionic currents within the eye and inner ear, but also over the whole body, especially during high intensity activation of the gradient coils. When the thermode was moved towards the isocenter during the EPI protocol, the vibrations reportedly became felt in the thermode itself and increased as it was moved towards the isocenter. It is therefore recommended to keep the thermode at the bore entry in a 3T scanner. There was no such observable effect in the 7T scanner at any distance from the isocenter.

Conclusions

The Q-Sense fMRI System, in both its single and dual thermode configuration, passed the MRI scanner manufacturer QA testing and also the functional imaging test runs. No imaging artifacts or detectable electromagnetic interference noise were observed.

The system is suitable for use as an MR Conditional device in both 7T and 3T scanners.

It is recommended to keep the thermode positioned at the bore entry, especially when using high intensity gradient fields, such as those in the 3T scanner. In addition, it is recommended to have good grounding when using equipment in an MRI setting and to avoid use of ancillary grounding aids such as copper braid or tape, which may be useable but could also cause more noise than they prevent.