Continuous Monitoring of RF-safety for Implantable MR-conditional Devices

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Introduction The presence of an implantable active device (e.g. pacemaker or deep brain stimulator) usually represents a contraindication for an MR examination. Currently, effort is spent on the development of MR-conditional implantables. An important safety risk factor of all active implantable devices is potential RF coupling to conducting parts which may lead to RF heating. RF coupling is a complex phenomenon and depends on the state of the device, implant geometry, scanning position, effectiveness of safety measures and the patient. Therefore, continuous safety monitoring of potential RF-coupling during MR scanning of such devices is highly desirable. Recently, a method for the real-time MR-system based detection of RF-coupling to active catheter devices used during an intervention, using the so-called pick-up coil (PUC) monitoring, was proposed [1,2]. Based on this method, a new non-invasive detection method of RF coupling with conductive parts of stationary devices, i.e. e.g. implanted devices, is proposed. The presence of such devices was detected reliably by the MR-system in real-time for a group of volunteers some holding a device near their body during scanning. The system even allowed detection of MR-conditional devices in the non-resonant, safe case, indicating an extremely high sensitivity.

Methods RF coil properties can be influenced by the patient as well as medical devices. Influences due to loading of an RF coil or due to RF coupling with an active device leads to a detectable amplitude/phase change, which can be exploited for detection of dangerous, resonant RF coupling during MRI scans.

For the experiments, a whole body 3T MRI system (based on Achieva, Philips Healthcare, Netherlands), equipped with eight parallel RF transmit channels [3], was used. It was equipped with an 8-channel real-time RF transmission monitoring system [4] to measure the complex currents of each of the eight RF transmit elements of the multi-channel body coil (MBC) [5]. The PUCs are used for detecting potentially unsafe system operation [6] as well as for system calibration purposes [7]. The PUCs were calibrated prior to the scan to show identical signal strength/intensity (see Fig. 1a). The system was furthermore equipped with a modified patient table, allowing for continuous, reproducible table movement during data acquisition [8].

A low SAR scan (FFE, TR = 160ms, TE = 3.5ms, $\alpha = 30°$, whole body SAR < 0.1W/kg) was applied with the device/volunteer moving into the final imaging position under automatic control of the patient support advancing with a constant velocity of 50 mm/s (adjustable).

In a first phantom experiment, several pacemaker devices, with connected or disconnected leads (mimicking a broken lead) of different types and length were used. They were located in a tubular, water-filled phantom and moved into the scanner while being monitored with the PUCs. The signals of the RF pulses were displayed on a real-time GUI (see Fig. 1b) for visual inspection. The experiment was repeated for different locations of the device in the scanner as well as a high SAR sequence with the device at a fixed position. The PUC signal was acquired simultaneously with temperature measurements using a fiber-optic temperature measurement setup (Luxtron790, LumaSense Technologies, Santa Clara, CA, USA) at the tip of the pacemaker lead. For the temperature mapping, a scan was performed using the PRF method [9] with first order temporal drift correction was used. The experiment was controlled via a real-time interactive GUI with color image overlay over the magnitude images [10].

In a second in-vivo experiment, eight healthy male volunteers were scanned. The experiment was repeated with a resonant combination of a pacemaker and lead placed next to the arms and legs similar to the phantom experiment.

Results and Discussion For the first measurement, most devices resulted in well detectable alterations of the PUC signals (see Fig. 2). In this case, a drop of the PUC signal of about 80% was observed for the coil being nearest to the device. Using a high SAR sequence, a 0.1°C increase in temperature was measured for positions 0-100 cm as indicated in Fig. 2 which corresponds to a position of little PUC signal alteration from nominal. However, at the location marked with a circle, corresponding to strong PUC signal alteration from nominal, a temperature increase of 2°C was obtained in 2.8s indicating strong RF coupling and device-induced heating. The results are in line with previous studies that showed a good correlation between PUC signal alteration and RF heating for catheter-like devices [1,2]. The same experiment, as was carried out for the unsafe devices, was repeated for a safe catheter. Even here, a PUC signal drop of 10% could be detected. In [11], it was shown that only a negligible heating was observed for this device. As a consequence, a safety margin of 10% is defined, as indicated in Figure 2.

In the second experiment, it turned out that the PUC signal for the volunteers with similar weight and height (N=6, mean weight = 80kg, mean height = 1,83cm) agreed well in terms of the RMSE (root mean square error). The RMSE between the averaged PUC signals and the PUC signals of the individual volunteers were in the range of 0.28-0.59. Exemplarily, the signal of one volunteer with an RMSE of 0.36 is shown in Fig. 3. However, when the volunteers were holding one of the tested implantable devices close to their abdominal body region, a statistically significant difference was detected. Consequently, the RMSE between the mean curves of the volunteer PUC signals and the signal for an individual volunteer holding a device was determined as 1.42-1.78.

The signals of the RF pulses were also displayed on a real-time GUI (see Fig. 1b) for visual inspection during the scan.

Conclusion RF-coupling to medical devices, as e.g. implants, may lead to potentially unsafe situations for the patient. Therefore, a continuous monitoring of potential RF coupling to conductive parts of MR-conditional devices before and during MR examinations is important. The new approach allows for the detection of even very weak RF coupling to implantable active or passive conducting devices by continuous monitoring of the state of the RF-chain of the MR scanner. Volunteers holding such a device close to their body could be clearly distinguished from a volunteer ensemble without devices. This indicates that the system and method has sufficient sensitivity and selectivity for the detection of potential RF-coupling to implantable devices. The method can be combined with PRF-based temperature mapping providing spatially resolved temperature maps which may yield an interesting alternative for the assessment of the RF-safety during approval of devices. The real-time GUI for displaying the RF pulses offers a fast possibility of finding unsafe situations by continuously varying the setup/moving the device under investigation.

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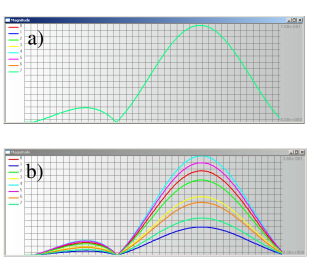

Fig. 1: Real-time display of the RF pulses for each RF Tx channel. (a) top PUC signals calibrated, (b) PUC signal deviation due to device RF coupling with device.
x-axis: time, y-axis: amplitude.

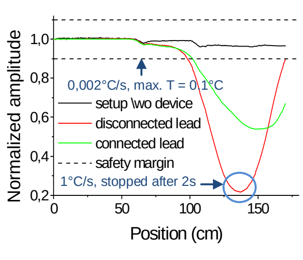

Fig. 2: Detection of the unsafe pacemaker while moving inside the bore. No temperature increase was observed until a z-position of 100cm, however, at the location of the blue circle a temperature increase of 2°C in 2.8s occurred.

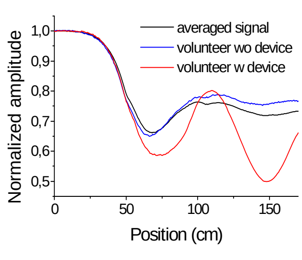

Fig. 3: RMSE between averaged PUC signal for 6 out of 8 volunteers (black) and signal of one volunteer (blue) is 0.36.
RMSE of same volunteer with resonant device results in 1.53 (red).

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