MRI-induced Vibrations in Active Implantable Medical Devices: Effect on the Device

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Introduction: Gradient-induced vibrations can represent a failure hazard to MRI-conditional active-implantable medical devices (AIMD). MRI gradient fields generate eddy currents in the electrically conductive components within the AIMD, which upon interaction with the strong static magnetic field of the MRI can generate vibrations in these components. Depending on the frequency and the magnitude of the induced vibrations, the components of the AIMD may fatigue and breakdown especially if the vibrations are close to their resonant frequencies. This may lead to partial or total failure of the device. The objective of this study was to develop a method for evaluating the effects of gradient-induced vibrations on AIMDs, more specifically on pacemaker devices. The study is composed of two phases with the first phase aimed to characterize the gradient induced vibrations in the AIMD while the second phase is aimed to determine if the AIMD can survive the vibrations.

Methods: *Phase-1 Characterize the Vibrations*: A non-contact optical vibrometer (MTI-2100, MTI Instruments Inc., Albany, NY) was used to measure the vibrations from the different components within a pacemaker with a half-opened case. A special fixture was designed to aim the light-beam emitted from the vibrometer's probe to the different components of the pacemaker. The testing was performed in 3 clinical 1.5T MRI scanners namely the Siemens Avanto, Philips Intera, and the Siemens Symphony. The fixture was positioned within the bore of each MRI at the location of the highest gradient rate of change (dB/dt) while running the sequence known to generate the highest dB/dt as reported by Butala et al. [1]. The latter report concluded that the Siemens Avanto scanner generates the highest dB/dt of 56.5 T/s at an intermediate position between the bore's entrance and isocenter while running a TRUFI sequence (FISP). The analog output of the vibrometer was digitized using a data acquisition system (USB-6259 BNC, National Instruments, Austin, TX) and the data was analyzed offline using Matlab (Mathworks, Natick, MA) to determine the magnitude of the displacement, the acceleration, the peak frequency and the power spectrum density (PSD) of the measured vibrations. *Phase-2 Determine if the Vibrations would damage the AIMD*: A programmable shaker-table was used to vibrate the pacemaker at the entire acceleration and frequency range determined in Phase I above. After exposure to the shaker-table vibrations, the pacemaker is then checked for damage by running a comprehensive automated functional test.

Results: *Phase-1 Characterize the Vibrations*: Figure 1 shows a typical waveform of the gradient-induced vibrations acquired from the telemetry coil of the pacemaker while being tested in the Siemens Avanto MRI scanner. The pacemaker components generating the highest vibrations are shown in Table 1 along with the corresponding vibrations magnitude and frequency range. The corresponding PSD are shown in Figure 2. *Phase-2 Determine if the Vibrations would damage the AIMD*: The pacemaker passed the comprehensive automated functional test and survived the vibrations test.

Table 1 Pacemaker components generating the highest vibrations

MRI Scanner	Component	Max Displacement	Freq. Range
Siemens Avanto	Battery	25.1 [um]	0 – 2 kHz
Philips Intera	Telemetry Coil	16.7 [um]	0 – 2 kHz
Siemens Symphony	Battery	3.8 [um]	0 - 2 kHz

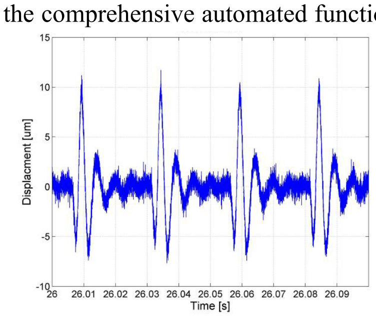

Figure 1 Typical gradient-induced vibrations measured during the test.

Conclusions: The frequency range of gradient-induced vibrations measured in three different clinical MRI scanners of various manufactures was found to be between 0 - 2 kHz. The highest vibration of about 25um peak-to-peak displacement was measured on the battery when tested in the Siemens Avanto MRI scanner. Vibration measurements were performed in air by directing the light beam to the device component of interest. Therefore this measurement method captures the worst-case vibrations because the latter are not dampened by the presence of tissue in-vivo or by the weight of accelerometers commonly used for measuring vibrations.

References: [1] Butala NB, Shehada RE, Costandi PN, Dianaty A, and Jurkowski K, (2011), Maximum dB/dt and Switching Noise in 1.5T MRI Scanners for Safety Evaluation of Active Implantable Medical Device, *Proceedings of ISMRM*, 19: 1788.

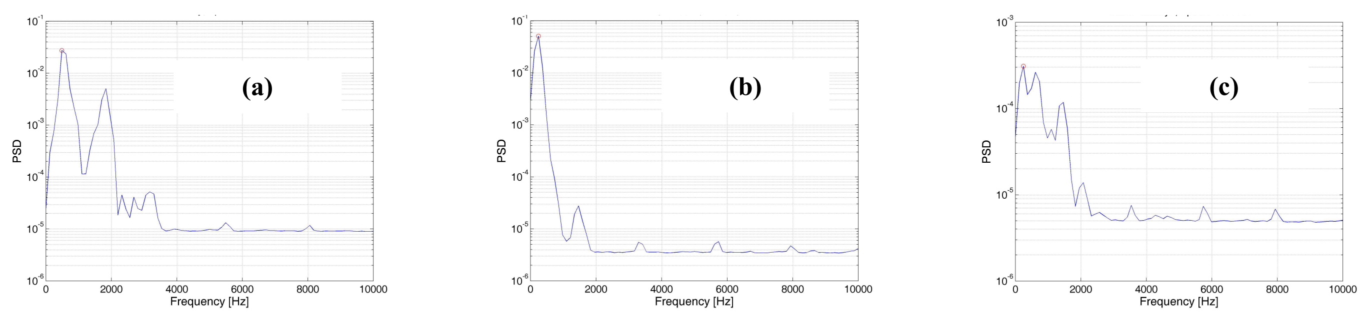

Figure 2 PSD of the highest vibrations measured from: (a) the battery in the Siemens Avanto, (b) the telemetry coil in the Philips Intera, and (c) the battery in the Siemens Symphony, MRI scanners.