Development of Methods for the Compliance Testing with Safety Limits for RF Exposure of Implantable Medical Devices with Wireless Links

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An increasing number of active implantable medical devices (AIMDs) is equipped with wireless communication links allowing for enhanced monitoring and control. For the demonstration of their compliance with RF safety limits and the induced thermal load, standardized testing procedures have not been developed yet. Purely numerical approaches suffer from poor control of the uncertainty of the results, and the experimental methods, which have been developed for wireless transmitters outside the body, cannot be applied for measurements in the immediate vicinity of the device. To determine worst-case exposure, different configurations must be considered, including the evaluation of the mounting location, the tissue composition and the position of attachments, e.g., pacemaker leads. The evaluation of the patient exposure with known uncertainty is only possible using a combined numerical and experimental approach.

The goals of this study are to propose a sound procedure for demonstrating compliance of AIMDs with safety limits, to assess its overall uncertainty and to evaluate the variability of the results with respect to the worst case configuration.

An accurate numerical model of the device under test must first be developed based on CAD data. This model is validated by measurements of the feed-point impedance, the radiation efficiency, the distribution of the E- and H-fields close to the device. Numerical parameters, such as the grid resolution, the dielectric properties of the RF relevant parts or the thermal parameters of the anatomical model must be considered. The numerical method must be capable of rendering the fine complex details of the model, e.g. using non-uniform meshes. Because of the high gradient fields in the close vicinity of the transmitting element, the near field and temperature probes must provide excellent spatial resolution ($<<1$mm) and spherical isotropy (<0.3 dB, E- and H- probes). After experimental validation, the numerical model evaluates worst case operation conditions in generic tissue structures, the peak spatial average SAR and the thermal load. Other effects, including impedance changes, e.g., due to leads are wrapped around the pacemaker, will still need experimental confirmation. The results of the worst-case configurations are then validated using high resolution anatomical phantoms in which the device is implanted. For the overall uncertainty assessment, both the experimental and the numerical uncertainty are considered. The procedure is demonstrated with the aid of a pacemaker with an RF telemetry link.

The suggested method for the compliance testing of AIMDs represents a rigorous and conservative approach for evaluating patient exposure. The tests will also confirm that the devices operate within their intended specifications.