

Statement of Program of Study

The program of study is designed to investigate the viability of a RF telemetry link for an implantable medical device using the frequencies outlined in this application. Once satisfactory results indicate the RF telemetry link is viable, to proceed in implementing as a new feature in a marketable product.

Description of Experimentation

1. Experimentation to show viability will involve demonstrating that RF energy is capable of penetrating various human tissue models with acceptable levels of signal attenuation.
2. The experimentation will include tests characterize the RF telemetry link performance in the absence of interference and in the presence of known interfering source at various distances.
3. Experimentation will be performed to evaluate transceiver functional parameters.
4. Tests to functionally operate the transceiver to verify the design meets critical design specifications and device interaction specifications.
5. Experiments conducted to demonstrate the communications protocol and verify functional operation in various end cases.

Objectives:

1. Verify ability penetrate tissue.
2. Characterize telemetry link reliability
3. Characterize transceiver performance
4. Verify integration of transceiver into implantable device
5. Verify communication protocol

The program of experimentation is design to show that a RF telemetry link is a viable feature to add to implantable medical devices. Market research has shown that such a telemetry link would add clinical value to these implantable devices and has potential to improve the level of patient care.