Impacts of Wireless Power on Medical Device Design Safety

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Wireless power holds great promise for solving many power distribution problems. Medical device designers will need to understand the impact of the electromagnetic coupling used for wireless power systems to design safe electromagnetic environments and safe medical devices. One question for designers will be whether or not current standards and requirements used for testing the electromagnetic compatibility (EMC) of medical devices and human exposure go far enough to insure safe environments and safe and reliable medical devices in the presence of wireless power. Electromagnetic energy can be transferred in three ways: through induction, radio frequency waves, or resonant evanescent coupling. Nonradiative inductive coupling uses the magnetic fields created when current is passed through one coil to create a current in a second coil that is located very near the first coil. These systems usually operate in the 50 KHz to 10 MHz range. Radio frequency energy can be transferred through radiating electromagnetic waves over great distances at frequencies from the upper KHz to many GHz. Most recently, work has been done on resonant evanescent coupling which transfers power between resonant objects over a distance of a couple of meters at frequencies from 1–10 MHz. Safety and reliability of medical devices is confirmed by testing EMC emissions and susceptibility to IEC60601-1-2 and supporting standards. For example, one of the supporting standards, CISPR 11 calls for measuring the electric field of radiated emissions over 30 MHz and the magnetic field below 30 MHz at distances of 3–10 meters. Many of the effects of wireless power systems are in the near field and are not covered in the current test standards. The AAMI PC69 series of standards have some near field requirements but these standards tend to be industry specific – such as drug pumps or pacemakers. EMC immunity standards used to test EMC susceptibility barely mention magnetic immunity. The only test for magnetic fields recommends testing fields at the power frequencies of 50 and 60 Hz. There are few standards detailing safe limits for human exposure to the near field effects of wireless power as well. Historically human exposure standards have been based on time average thermal effects on tissue and not medical devices. IEEE's C95.1b has requirements for specific absorption rate limits averaged over a 6 minute period. A pulsed wireless power system could meet these requirements and be safe for exposed tissue, but if a patient has an implanted device, or is wearing an external medical device, the pulsed EM energy could affect it during the pulse. The German BGV B11 standard lists human exposure limits for electric and magnetic fields based on a time average and limits exposure based on which portion of the body is exposed. However, it is meant as a workplace standard not a medical device standard. Currently the FDA does not require meeting either of these standards. It is necessary to determine the appropriate limits and tests to ensure that medical devices safely use wireless power and continue to operate safely in the presence of wireless power.

High-Density Transcranial Direct Current Stimulation (HD-tDCS): Hardware Interface

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Transcranial Direct Current Stimulation (tDCS) is a noninvasive procedure where a weak electrical current (260 μA to 2 mA) is applied across the scalp to modulate brain function. tDCS has been applied for therapeutic purposes (e.g., addiction, depression, mood and sleep disorders) as well as cognitive performance enhancement (e.g., memory consolidation, motor learning, language recall). Despite safety and cost advantages, the developments of tDCS therapies have been restricted by spatial targeting concerns using existing two-channel systems. We have developed novel technology for High-Density tDCS (HD-tDCS) that improves spatial focality. Our hardware interface integrates a multichannel stimulating guide with existing two channel tDCS stimulators, and can be configured to target specific brain regions using computational models of current flow and multichannel array accessories. The hardware interface provides real time stimulation quality and safety feedback, and is designed to be MRI and TMS compatible. An electrical "tickle" feature enables skin preconditioning to minimize sensation. The full system includes the hardware interface, cable assemblies, head gear, tDCS electrodes, tDCS gel, and electrode adaptors. The head gear allows fixing the electrode adaptors over cortical targets using conventional EEG electrode coordinates. The electrode adaptors "fin" design, tDCS gel composition, and electrode shape are optimized to reduce sensation during direct current stimulation with 2 mA for up to 22 minutes. A five electrode system (4×1-C1), for implementing optimally focal "4×1 ring configuration" protocols, and an 8 electrode system (4×4-S1), that can be configured for "4×4 cortical strip stimulation", are available. The entire system is robust, intuitive, and ultimately adaptable for home use. Our HD-tDCS system allows non-invasive, safe, and targeted modulation of selected cortical structures for electrotherapies that are individualized as well as optimized for a range of therapeutic applications.