



Wireless Charging Devices and Their Effects on Medical Devices

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The Manufacturer and User Facility Device Experience (MAUDE) database of the U.S. Food and Drug Administration (FDA) identified 2,843 cases of malfunctions of medical devices induced by electromagnetic interference (EMI) between January 2010 and March 2017.¹ Whereas discussions of EMI often center on smart phones and consumer electronics, a multitude of items have the potential to create EMI in the form of oscillating magnetic fields—from induction stoves, to anti-theft detection systems in retail stores, to wireless chargers. The global wireless charging market alone is expected to reach \$24 billion globally by 2023.² Wireless chargers provide welcome cost-efficiencies by eliminating the use of physical connectors and maintaining a continuous transfer of power through the process of magnetic induction. Unfortunately, the magnetic fields emanating from these devices can potentially interfere with cochlear implants, heart monitors, continuous glucose monitors, and other implantable medical devices. A multitude of manufacturers have faced litigation from individuals claiming to have lost hearing or experienced other health complications due to EMI affecting their implantable medical devices. Manufacturers of wireless chargers, wireless communication systems, and implantable medical devices can mitigate safety and legal risks by proactively assessing their products for creating EMI or, alternatively, by minimizing the effects of externally created EMI on their products.

Exponent has partnered with manufacturers of magnetic inductive devices, such as wireless chargers and security devices, as well as with manufacturers of implantable medical devices, to build safeguards that limit EMI and its effects. For example, manufacturers of wireless power transfer devices for electric vehicles have configured their charger coils and protection guards so that the magnetic fields are contained under a vehicle and user access to high field strengths is prevented during operation. Safeguards such as these help ensure that the vehicle wireless charger is not emitting unsafe EMI levels within range of an individual that has fallen down or is otherwise incapacitated on a garage floor. Similarly, heart monitor manufacturers have configured wire lead sensors to be less susceptible to potential interference (e.g., by using bipolar leads instead of unipolar leads) and programmed safe modes into the device which cause it to operate in a predetermined manner that reduces potential harm when specific interference

thresholds are encountered, allowing patients to walk through the strong oscillating magnetic field of a retail store's anti-theft detection system without experiencing untoward responses from their medical devices. While there is currently no way to manufacture a device that is completely immune to EMI, manufacturers can take steps to help ensure safe operation in multiple environments, and patients are advised to "not linger or lean" near EMI emitting machines.

It is important for manufacturers of implantable medical devices to consider guidelines from expert consensus standards organizations, such as the International Electrotechnical Commission (IEC) and International Standards Organization (ISO), for safe user operation. Exponent has conducted numerous gap analyses to help medical device manufacturers understand which required examinations they may lack. Examples include, but are not limited to, IEC 60601, a series of

¹ Electromagnetic interference in cardiac electronic implants caused by novel electrical appliances emitting electromagnetic fields in the intermediate frequency range: a systematic review. Driessen, et al. European Society of Cardiology. June 2018.

² <https://www.marketwatch.com/press-release/wireless-charging-market-2018-global-size-research-analysis-growth-factors-emerging-trends-development-status-opportunity-assessment-competitive-landscape-and-regional-forecast-to-2023-2018-10-17>

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technical standards for the safety and effectiveness of medical electrical equipment, and ISO 14117, a set of electromagnetic compatibility (EMC) test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization devices.^{3,4} Similar standards can help manufacturers of wireless power transfer devices optimize user safety. In particular, the Society of Automotive Engineers (SAE) Recommended Practice J2954 defines acceptable criteria for interoperability, EMC and emission limits, and methodologies for testing conformance, which have been discussed with the American Association of Medical Instrumentation (AAMI) and FDA, for wireless charging of electric vehicles.⁵ Although these standards are complex, compliance can help manufacturers optimize both product performance and user safety.

EMI safety testing should occur in the early design stages of both implantable medical devices and wireless charger products. Manufacturers who delay testing until products are near completion may face costly redesigns if safety standards are not met. Manufacturers should also choose a testing partner who provides more than a pass or fail product evaluation. An understanding of the specifics behind a failing mark can help manufacturers complete product redesigns more cost-effectively and bring their products to market more quickly.

Exponent's multidisciplinary team has the in-depth knowledge required to help manufacturers assess EMI; develop critical product safeguards; and ensure compliance to important safety standards.

³ <https://webstore.iec.ch/publication/2603>

⁴ <https://www.iso.org/standard/73915.html>

⁵ https://www.sae.org/standards/content/j2954_201711/



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