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Health Impacts of RF Radiation

13-84

1. IMPLANTED MEDICAL DEVICES — SCIENTIFIC EVIDENCE OF ELECTROMAGNETIC INTERFERENCE

1.1. Electromagnetic interference and cardiac implantable electronic devices

Electromagnetic interference (EMI) can affect the operation of implanted pacemakers and implantable cardioverter-defibrillators (ICDs). A peer-reviewed review published in 2022 states:

"EMI from other sources can potentially inhibit pacing and trigger shocks in permanent pacemakers (PPM) and implantable cardioverter defibrillators (ICD), respectively."

Barmore W, Patel H, Voong C, Tarallo C, Calkins JB. Effects of medically generated electromagnetic interference from medical devices on cardiac implantable electronic devices: A review. World Journal of Cardiology. 2022;14(8):446–455. doi: 10.4330/wjc.v14.i8.446.

The authors describe the mechanisms by which interference may disrupt device operation:

"EMI can be interpreted by PPM as an intrinsic cardiac signal and result in inhibition of pacing, leading to bradycardia, and potentially cardiac arrest."

Barmore W, Patel H, Voong C, Tarallo C, Calkins JB. World Journal of Cardiology. 2022;14(8):446–455. doi: 10.4330/wjc.v14.i8.446.

1.2. Radiofrequency identification systems and implanted devices

An experimental study published in Heart Rhythm investigated interference from radiofrequency identification (RFID) readers operating at 134 kHz, 13.56 MHz, and 915 MHz. The investigators tested 15 pacemakers and 15 ICDs.

The authors reported:

"While being exposed to LF RFID, a reaction was observed for 67% of all pacemaker tests (maximum distance 60 cm) and 47% of all ICD tests (maximum distance 40 cm)."

Seidman SJ, Brockman R, Lewis BM, et al. In vitro tests reveal sample radiofrequency identification readers inducing clinically significant electromagnetic interference to implantable pacemakers and implantable cardioverter-defibrillators. Heart Rhythm. 2010;7(1):99–107. doi: 10.1016/j.hrthm.2009.09.047.

The study reported reactions that included pacing inhibition, inappropriate pacing, changes in pacing rate, inappropriate antitachycardia pacing, inappropriate high-voltage shocks, and a device programming change. The investigators found that low-frequency RFID readers produced the most reactions in their experimental setup; high-frequency readers produced fewer, and no reactions were observed with the tested ultra-high-frequency readers. These findings apply to the specific devices and exposure conditions tested.

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1.3. Personal medical devices and walk-through metal detectors

A separate experimental investigation tested implanted cardiac pacemakers, ICDs, neurostimulators, and insulin pumps using simulated walk-through metal-detector waveforms.

The investigators reported:

“Testing the sample PMEDs using the WTMD simulator revealed EMI effects on two implantable pacemakers and one implantable neurostimulator for exposure field strength comparable to actual WTMD field strength.” Mattei E, Triventi M, Calcagnini G, et al. Personal medical electronic devices and walk-through metal detector security systems: assessing electromagnetic interference effects. BioMedical Engineering OnLine. 2017;16:36. doi: 10.1186/s12938-017-0322-0.

The observed interference was transient, and the affected devices returned to their pre-exposure operation within seconds after removal from the simulated fields. The study did not establish clinical consequences, and the authors called for additional research across a broader range of security systems.

1.4. Implanted devices and external electromagnetic fields

A peer-reviewed review of external electrical and magnetic fields and cardiac implants explains:

“Nevertheless, EMI sporadically results in harmful consequences.”

Misiri J, Kusumoto FM, Goldschlager N. Electromagnetic interference and implanted cardiac devices: the nonmedical environment (part I). Clinical Cardiology. 2012;35(5):276–280. doi: 10.1002/clc.21997.

The literature identifies device design, lead configuration, exposure characteristics, and the strength and frequency of external fields as factors affecting susceptibility. Consequently, the existence and severity of interference must be evaluated for the particular implanted device and exposure conditions rather than assumed to be identical across all implants.

1.5. References specified in the original FCC submission

The document Effects on Implanted Medical Devices identifies the following seven references. The submission itself is a one-page bibliography and incorporates the linked works by reference.

1. Seidman SJ, Guag JW. Adhoc Electromagnetic Compatibility Testing of Non-Implantable Medical Devices and Radio Frequency Identification. BioMedical Engineering OnLine. 2013;12:71. Article.

2. Lakshmanadoss U, Chinnachamy P, Daubert JP. Electromagnetic Interference of the Pacemakers. In: Modern Pacemakers—Present and Future. IntechOpen; 2011. Chapter.

3. Censi F, Calcagnini G, Triventi M, Mattei E, Bartolini P. Interference Between Mobile Phones and Pacemakers: A Look Inside. Annali dell’Istituto Superiore di Sanità. 2007;43(3):254–259. Publication record.

4. Erdogan O. Electromagnetic Interference on Pacemakers. Indian Pacing and Electrophysiology Journal. 2002;2(3):74–78. Full text.

5. de Sousa M, Klein G, Korte T, Niehaus M. Electromagnetic Interference in Patients with Implanted Cardioverter-Defibrillators and Implantable Loop Recorders. Indian Pacing and Electrophysiology Journal. 2002;2(3):79–84. Full text.

6. IEEE Committee on Man and Radiation. Radiofrequency Interference with Medical Devices: A Technical Information Statement. IEEE Engineering in Medicine and Biology Magazine. 1998;17(3):111–114.

7. Ellenbogen KA, Wood MA. Cellular Telephones and Pacemakers: Urgent Call or Wrong Number? Journal of the American College of Cardiology. 1996;27(6):1478–1479.