Compatibility of Medical Devices with Electromagnetic and Wireless Signals

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Magnetic induction has long been present in modern society, typically without the knowledge of the general public. The walk-through metal detectors at the airport and the anti-theft gates at the exits of retail stores are among the largest and most commonly-encountered sources of magnetic induction. Other smaller devices, such as hand-held metal detectors (think of the person at the beach searching for jewelry) and induction cooktops that heat cooking pans without heating the surface of the cooktop itself, also make use of magnetic induction. A somewhat different form of magnetic induction is involved in the radiofrequency identification (RFID) used to pay highway tolls without the need for stopping and the RFID used in shipping containers. Magnetic induction is even used inside the highly-specialized coils of a magnetic resonance imaging machine. The magnetic induction from each of these devices is described by Faraday’s law, a basic law of electromagnetics, which states that if a time-varying magnetic field passes through the surface of any conducting loop, a voltage will be induced in that loop. The voltage induced in this loop is proportional to the time-varying change in magnetic flux (i.e., the amount of magnetic field that enters the loop perpendicular to its surface), as shown in Figure 1.

Figure 1. A magnetic field passing through the surface of a loop induces a voltage in the terminals of a loop

More recently, the mobile revolution and the explosion of wirelessly-connected devices as part of the “Internet of Things” (IoT) has created a desire to be able to conveniently charge devices without the need to plug them into a wall outlet. Wireless charging is among the fastest-growing segments of technology, particularly related to portable devices.
Devices such as mobile phones, tablets, and laptop computers are being outfitted with the built-in capability to charge their batteries wirelessly. In addition, larger items such as electric vehicles will soon be available with wireless charging capabilities.

Along with this proliferation of wireless connectivity and charging capabilities comes a potential cost, known in the industry as electromagnetic compatibility (EMC). Each of these devices (and countless others) needs to be able to operate successfully in the presence of potential interference from other devices (i.e., electromagnetic susceptibility or immunity) and each one needs to consider the possible effects of their own emissions on other devices (i.e., electromagnetic interference).

Arguably medical devices are the most important group of devices in need of high electromagnetic immunity, particularly those with life-saving capabilities such as pacemakers and implanted cardioverter defibrillators (ICD). The need for pacemakers and ICDs to operate correctly in the presence of external magnetic-field sources is of keen interest to medical device manufacturers; it is equally important to manufacturers, distributors, and users of inductively-coupled devices that these devices operate without a disruption to their proper function.

The following brief discussion focuses on pacemakers, but other implantable and wearable medical devices, such as ICDs, cochlear implants, neurostimulators, wearable continuous glucose monitors, and wearable insulin pumps, are also of concern when considering EMC.

Pacemakers are electronic devices that are surgically implanted in patients to monitor and control irregularities in a patient’s natural heart activity. The two main functions of a pacemaker are sensing and controlling (i.e., pacing) heart rhythm. These functions involve using a pulse generator and lead wires that are configured as either unipolar (shown in Figure 2b) or bipolar (not shown). Typically, while in “sensing mode” the pacemaker monitors the patient’s heart activity through these lead wires. If only natural heart activity is present, the pacemaker will not enter the pacing mode, but if the patient’s heart rhythm is too slow or is interrupted, the pacemaker sends an electrical impulse to the heart to regulate the patient’s heartbeat.
Electromagnetic interference with the function of a pacemaker from magnetic induction occurs when the magnetic field from an outside source passes through the loop formed by the pacemaker’s lead and the pacemaker’s housing. The potential for interference can be calculated by using Faraday’s law of induction (described above). Pacemakers are particularly susceptible to electromagnetic interference from magnetic induction because the leads of the pacemaker sense the very small levels of electrical activity within the heart and therefore small induced voltages can interfere with the proper functioning of a pacemaker. As shown in Figure 3, even a small amount of external interference induced onto the leads of a pacemaker can mask the cardiac rhythm being sensed, potentially interfering with the proper function of the pacemaker.
In general, the influence of electromagnetic interference on a pacemaker can be controlled to some extent by the patient. For example, if a patient is aware that a particular source has the potential to influence the pacemaker (information garnered through either their physician or the medical device manufacturer) then he or she can try to stay as far away as possible from the source, or can pass by the source quickly. The patient, however, has little or no control over the intrinsic properties of an electromagnetic source, such as the frequency of its operation, the modulation of the output signal, and power output.

Since there are factors that the patient cannot control, medical device manufacturers build safeguards into the design of pacemakers. These safeguards assure that the device continues to provide clinically acceptable therapy in the presence of typically-encountered levels of electromagnetic interference. In addition, pacemakers are designed to revert to a conservative mode of operation even if the pacemaker no longer senses how the heart muscle is functioning. In this state the pacemaker will provide pacing activity at a pre-determined fixed rate. Though a pacemaker may “fly blind” without its sensing function while in the presence of a source of electromagnetic interference, it is still under software control. This operation, where the pacemaker reverts to a limited but functional state during an interference event, is known as Noise Reversion or Safety Mode.

Since devices emitting magnetic fields are now so common in everyday life, they are often implicated in cases where a patient either had a medical incident or where a medical device malfunctioned; yet other factors need to be considered in a failure analysis, such as the influence of a patient’s overall health, the typical lifetime of a medical device, or known failure incidents of the medical device. Government resources (such as the Food and Drug Administration’s Manufacture and User Facility Device Experience [MAUDE] database) provide a way to locate information on the performance of a given device. If hundreds of thousands of devices have been implanted in patients throughout the United States over several years and no failure incidents related to electromagnetic interference have been reported, then it is important to consider other root causes for a failure. Medical devices are typically designed to operate safely in diverse electromagnetic environments, and manufacturers of devices that emit electromagnetic fields typically keep the intensity of emission as low as possible.

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