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Deep brain stimulation and electromagnetic interference

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Abstract

Deep brain stimulation (DBS) has evolved into an approved and efficacious treatment for movement, obsessive-compulsive, and epilepsy disorders that are refractory to medical therapy, with current investigation into other disease conditions. However, there are unintentional and intentional sources of external electromagnetic interference (EMI) that can lead to either malfunctioning or damaged DBS devices, as well as injury to human tissue. Comprehensive studies and guidelines on such topics in the medical literature are scarce. Herein, we review the principles behind EMI, as well as the various potential sources of interference, both unintentional (e.g. stray EMI fields) and intentional (e.g. MRI scans, “brainjacking”). Additionally, we employ the Manufacturer and User Device Facility Experience (MAUDE) database to assess real-world instances of EMI (e.g., airport body scanners, magnetic resonance imaging (MRI), and electrosurgery) affecting DBS devices commonly implanted in the United States (US).

Keywords

Deep brain stimulation; Electromagnetic interference

1. Introduction

Deep brain stimulation (DBS) has become an increasingly popular therapy for the treatment of essential tremor (ET), Parkinson’s disease (PD), dystonia, obsessive-compulsive disorder, and epilepsy, with investigations underway for the management of depression, Tourette’s syndrome, Alzheimer’s disease and pain [1–8]. It is estimated that more than 160,000 patients worldwide with a variety of neurological and non-neurological conditions depend on these implanted devices [9]. As DBS devices have become more prevalent, so too have sources of unintentional (e.g. stray fields) and intentional (e.g. MRI scans, “brainjacking”) electromagnetic interference (EMI) in our environment. Therefore, interactions with therapeutic stimulators are a growing cause for serious concern. Indeed, interference may lead to device malfunction or damage, as well as irreversible injury to human tissue. For the patient with ET or PD benefiting from symptom relief or amelioration, EMI may result in recurrence of symptoms and increased disability, with potentially fatal outcomes [10].

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Declaration of Competing Interest

We have no conflicts of interest to disclose.

Currently, DBS devices used in the US are manufactured by Medtronic Neuromodulation (Minneapolis, MN), Abbott Neuromodulation (Plano, TX), and Boston Scientific (Valencia, CA). Each DBS device consists of three components: an implantable pulse generator (IPG), 4-channel (4CH) or 8-channel (8CH) leads implanted within the brain, and an extension cable connecting these two components. The 4CH leads have four cylindrical electrodes that can deliver stimulation in all directions around the lead. Besides two cylindrical electrodes, the 8CH has two central contacts consisting of three segments each, which can be activated independently to concentrate stimulation in one direction, thereby theoretically reducing current needed to produce meaningful therapeutic effects by up to 43 % [11].

During the normal operation of a DBS device, a pulse is generated in the IPG and passed through the extension cable to the neural contacts, stimulating the appropriate target. Medtronic has had four commercial generations of IPGs for DBS systems: 1) Itrel II/III dating back to 1997; 2) Soletra (single channel version) / Kinetra (dual channel version) dating back to 2002; 3) Activa, since 2009; and 4) Percept, beginning in 2020, as well as an additional research system (PC + S, RC + S) [12]. The recently approved Percept PC affords the ability to simultaneously record local field potential. More recently, Boston Scientific (Vercise, Vercise PC, Vercise Gevia) and Abbott (Libra, Libra XP, Brio, Infinity) models have also come into use [13–15]. The current generation of stimulating leads or electrodes consist of four cylindrical 80/20 platinum/iridium alloy leads at the distal end inter-connected to four non-interlacing fluropolymer-insulated platinum/iridium wires to a set of four nickel-alloy contacts. The Abbott Infinity 8CH DBS System and a similar Boston Scientific system have cylindrical and central electrodes (8CH) in a 1–3-3–1 configuration. The contacts are connected to the distal end of the extension cable which is made up of a non-magnetic nickel-cobalt alloy, embedded in ethylene tetrafluoroethylene and covered with polycarbonate polyurethane.

Such complex electromagnetic devices present several opportunities for unintentional or intentional EMI. By either inductive, conductive, or radiated energy transfer, the DBS system may be susceptible to unwanted currents which may lead to neurological risks to the patient or device malfunction. While some advances have been made with respect to shielding of DBS components as well as EM shielding of electronic appliances in proximity to patients, interference remains a practical concern for the ever-increasing population of patients living with these implanted devices. For example, case reports have described EMI causing DBS devices to inadvertently switch between ‘on’ and ‘off’ states, as well as permanent neurological damage [16]. In general, stray EMI interference should result in immediate shut-off of DBS systems to avoid both internal damage and inadvertent stimulation, however this does not always occur and can have devastating results.

There are specific features of DBS systems that may increase their susceptibility to EMI. A reed switch is an electrical switch that is controlled by an applied magnetic field. Reed switches were employed in early DBS system iterations to allow the patient or clinician to easily turn the device on or off using a handheld magnet [17]). Models that employ a reed switch include Medtronic’s Kinetra® Model 7428, Soletra® Model 7426, and Itrel II. Medtronic no longer produces models using a reed switch, however patients may still have

these models implanted and depend on them for their daily function. Devices from other manufacturers do not use reed switches.

Another feature that may predispose to EMI is unipolar configuration. Devices configured to provide unipolar stimulation may be more sensitive to interference than bipolar stimulation [18]. All devices mentioned above can be programmed to have unipolar, bipolar or multipolar configurations [15].

Examples of reported consequences of EMI include: (1) development of unexpected thalamic lesions, secondary to cardioversion [19]; (2) aphasia, dysarthria, and hemiparesis, resulting from a radiofrequency lesion produced by heating of a DBS electrode during MRI of the lumbar spine [20]; and even (3) persistent vegetative states due to lesions in the diencephalon and brainstem after pulse-modulated, radiofrequency diathermy [16]. In the aforementioned case, however, a common contraindication to diathermy (metal implants) appears to have been disregarded. Indeed, longer electrical pulses from an external source passed at higher frequencies have the ability to produce heat that is sufficient to burn tissue [21]. In this review, we describe other cases reported in the literature, sources of unintentional and intentional EMI, the physics of this phenomenon, as well as the implications for designing future DBS devices.

2. Electromagnetic interference

EMI can occur following radiation, induction, or conduction. Radiation related interference is caused by EM waves radiating from a device and interacting with electronic components of a secondary device resulting in unwanted currents. This phenomenon is commonly experienced with AM radio sound quality distortion near power lines, or vacuum cleaners near television sets. Interference can also occur via an inductive method when there is a magnetic or capacitive coupling between two devices. According to Faraday's law, induction within a wire (but particularly a coil of wires) is a product of a varying magnetic field, which induces unwanted currents. Human tissue itself contributes capacitance (e.g. between the feet and ground), meaning that it can hold electrostatic charge. At low frequencies, human tissue is a good conductor while at higher frequencies it becomes a poor conductor. These two properties are, therefore, inversely related and affect the capability of human tissue to shield a device from electromagnetic interference. Finally, conductive EMI requires direct contact between two devices. Transfer of energy across a physical connection is the mechanism of EMI in DBS from electrocautery or cardiac defibrillation.

Factors affecting EMI can be broadly classified into the properties of the device (frequency and power of emission), physical distance between the two sources of the electromagnetic waves, and the susceptibility of the device to interference (i.e., the device's electromagnetic shielding). The properties of the emitting device that factor into its potential for EMI are the wavelength/frequency and the power. The wavelength plays a key role in relation to the size of the electronic components in the susceptible device because these components act as antennae for receiving the unwanted signal. Large wavelength/low frequency emission transfers minimal energy while shorter wavelength/high frequency sources are often easily shielded. The power of the emitting source dictates the level of effect the source has on the

susceptible device. Newer devices are designed with attention to shielding and immunity from emitting sources. As an example, during MR imaging, RF magnetic fields induce large electric fields in the patient, giving rise to induced currents in SCS systems. The RF energy, especially higher RF frequency waves, will usually concentrate near long, conductive structures (e.g. DBS leads) due to antenna effects. Hence, we might expect smaller or shorter DBS leads in the future.

The physical distance between two devices is also important as the electromagnetic field strength decreases proportional to the square of the distance from the emitting source. Therefore, two important management considerations are distance from the emitting source and duration of exposure. Clinically relevant EMI with devices such as cell phones is uncommon with distances greater than 1 mm [22]. However, several devices may together create an aggregate signal or any one source can have enough power to result in dysfunction of the susceptible device.

Devices generating significant EMI are becoming increasingly ubiquitous in our environment, particularly with widespread use of MRI scanners and an increased understanding of intentional EMI hacking. Such devices may disrupt the proper functioning of secondary devices by way of electromagnetic conduction, radiation, or induction. The most tangible example of this phenomenon is radio signal interference; however, any two electronic circuits can have such a damaging interaction, resulting in disruption of functionality.

In the case of implantable medical devices such as DBS, disruption can result in harm to the patient, either inadvertent or intentional. Fortunately, many of the newer Medtronic IPGs and systems have been conditionally approved for some MRI scans since 2014, contingent upon intact system functioning and low impedances within the system, indicating electrode continuity. However, it is still important to acknowledge that a considerable number of devices predating those conditionally approved as MRI-compatible are still implanted and/or in use. Examples of devices that are MR-conditional include Medtronic’s Activa DBS and Abbott’s Infinity DBS systems.

Electromagnetic interference (EMI) is caused by external disturbances, man-made or natural, by way of electromagnetic energy transfer to an electromagnetic circuit. Such interference may degrade or entirely disrupt an electromagnetic signal. Radio frequency interference (RFI) is interference in a certain frequency range (several kHz to 30 MHz for conductive RFI and 30 MHz-10 GHz for radiated RFI). Table 1 illustrates some of the equipment commonly found in medical, work, and home environments that can cause EMI with DBS [23]. Such interference can cause: 1) death or serious injury from heating of the implanted system components; 2) system damage, resulting in change in symptomatic control or requiring surgical replacement; 3) changes in neurostimulator function causing it to turn off, or reset to factory settings requiring physician reprogramming; and 4) sudden unexpected changes in stimulation, resulting in momentary increases which are described as “jolting” or “shocking” by patients. The configuration of the extension wires can also be important, with “loops” of DBS wiring unintentionally creating a coil, which can enhance current induction [24].

2.1. Sources of EMI

As previously mentioned, the various device manuals accompanying Medtronic DBS systems provide a relatively comprehensive overview of potential sources of EMI (Table 1). Device manufacturers are required to report these possible sources of EMI to the Centers for Devices and Radiologic Health (CDRH), a division of the Food and Drug Administration (FDA), to regulate such issues. Health care professionals and consumers can also report adverse events through the Manufacturer and User Device Facility Experience (MAUDE) database on a voluntary basis (Table 3) [26]. Since reporting is voluntary, the adverse events reported in the MAUDE database likely underestimate the number of EMI cases experienced by patients. At the same time, there is a need for all manufacturers, new and old, to be more transparent in reporting such data for clinical assessments and better patient care.

Sources of EMI are stratified by the likelihood of an adverse event and categorized as safe, possible, or probable. Certain sources are less likely to be the cause of interference simply because patients are less likely to come into close proximity to such sources. Since the field strength of a device is inversely proportional to the square of the distance away from it, some devices have relatively weak field strengths that become significantly and problematically stronger at closer distances. One such example is stereo speakers, which can often contain strong magnets that pose no risk at a distance but become potentially harmful to DBS devices at close proximity. Additional sources cited by device manuals prepared by Abbott also include: (1) commercial electrical equipment (e.g., induction furnaces); (2) communications equipment (such as microwave transmitters and high-power amateur transmitters); (3) high-voltage power lines; (4) radiofrequency identification devices (RFID); and (5) medical procedures, particularly therapeutic radiation and electromagnetic lithotripsy [13,25]. Boston Scientific additionally provides other sources of EMI, including biaxial magnets and magnetic mattresses [27]. Other possible sources of EMI, not listed by Medtronic, Abbott, or Boston Scientific exist as well. These devices, while relatively new, are commonly encountered in everyday life. For example, wireless inductive charging mats that are used to charge cell phones and other devices may interact with DBS systems. Remote traffic microwave sensors used to detect and measure traffic at the intersections of roadways can also be a cause of EMI by radiation interference [28]. Lastly, tasers or conducted electrical weapons (CEW) can deliver 50,000 V of shock, which can travel through air or clothing and be a strong conductive means of interference. Table 2 is an example list of these emitting sources together with their associated frequencies and field strengths.

2.2. Common everyday electronic sources of EMI

Cellular phones have become a seemingly ever-present fixture in modern life. These devices are known to be potential sources of interference with pacemakers and defibrillators; however, very little is known regarding interference with DBS [29,30]. In a phantom study using the ITREL-III DBS model, cellular GSM phones with field strengths of 900 Hz and 1800 Hz were determined to cause neither inhibition nor shape changes to the stimulation pulse [31]. Newer generations of phones may pose different risks. More recently, Apple Inc. released the iPhone 12 which has a circular array of magnets around a central charging coil that makes the phone compatible with Mag-Safe accessories. This strong magnetic array has

proven to have a clinically significant EMI with cardiac defibrillators [32]. These findings led to a recommendation by Apple Inc. to “keep your iPhone and MagSafe accessories a safe distance away from your device (more than 6 in. / 15 cm apart or more than 12 in. / 30 cm apart if wirelessly charging).” Studies assessing DBS devices for similar susceptibility to EMI from newer generations of cellular phones are imperative. Other common household electronic items have also been known to cause clinically significant electromagnetic interference with implantable devices. In a 2009 study of 100 patients with either implantable pacemakers or cardiac defibrillators, 8 different models of portable headphones were tested by placing the headphones on the patient’s chest. Of those tested, 30 patients were shown to have clinically relevant interference [33]. In all but one of the cases, normal device function was restored with removal of the headphone. Such studies with deep brain stimulators specifically are lacking and warrant further investigation.

2.3. Work and industrial environment

The increasing prevalence of electric and hybrid cars prompted a study by the Mayo Clinic to assess potential electromagnetic interference with cardiac defibrillators [34]. The study concluded that a clinically relevant amount of interference was not generated by the vehicle (a 2012 Toyota Prius) either at various speeds or at different accelerations and decelerations. Regardless, case reports do exist of hybrid vehicle interference with DBS devices [35]. While anecdotal, DBS and electric vehicles as a source of EMI warrants further investigation. Other sources of electricity, such as high voltage power lines and transformers, have also been known to affect patients with other implantable devices, though not specifically DBS [36].

2.4. Airport security body scanners

Travelers are exposed to an increased amount of electromagnetic radiation both from airport security and the sun at high altitudes. Airport body scanners use either backscatter x-ray scanners or terahertz (millimeter amplitude wave) scanners. These technologies are designed to penetrate through clothing and reflect off the skin surface. Thus, scanners are able to define the contours of the travelers’ body; however, the radiation is not absorbed beyond the skin. More importantly, backscatter x-ray scanners emit 40–80 times less radiation than the flight itself, depending on the length of the trip [37]. As a result, such technologies pose minimal risk to patients carrying neurostimulators, although multiple instances of unintended deactivation of IPG at airport security gates have been previously reported [10].

2.5. Antitheft and metal detectors

In the past 15 years, the FDA has received approximately 11 reports of possible interference between antitheft devices and metal detectors commonly found at department stores, libraries and supermarkets, and patients with DBS. The number of reported cases likely underestimates the actual number of patients experiencing what is commonly described as an uncomfortable “jolting” sensation or the stimulation being unintentionally turned off from the interference.

2.6. Magnetic resonance imaging

As a demographic, many patients with DBS are older adults who may have or develop coexisting disease requiring diagnostics or treatments involving strong electromagnetic fields. One common example is interactions with strong magnetic fields generated by magnetic resonance imaging (MRI), leading to EMI from induced or coupled currents. Falowski et al. report approximately 57 % of DBS patients need an MRI within 5 years and 66–75 % within 10 years after implantation [38]. Of these MRIs, 92 % were of the head and 62 % were of the body. Currently available IPG models are MRI conditional. MRI examinations of the head only or the entire body can be performed depending on the DBS system components implanted and scanner conditions (see respective MRI guideline manuals). An MRI study requires three different types of magnetic fields, which can interact with a DBS device. The static magnetic field (typically 1.5–3.0 Tesla) is a steady-state field that is non-varying and typically always on even when a study is not underway. The gradient magnetic field is a low frequency pulsed field that is only activated during the time of study to temporarily reverse the static field, possibly inducing voltages that can trigger a stimulator to unintentionally turn on or off. The third type, radio-frequency field, is also a pulsed field present only during the study. Static field interactions with a DBS device typically involve displacement and torsional forces. Displacement forces are commonly associated with projectile movement of a ferromagnetic object in the presence of a magnetic field. The torsional force is the tendency of the device to rotate and align with the magnetic field. Testing of newer generation DBS systems with respect to these forces has shown that the magnitude of static field interactions has diminished to negligible levels [39]. Furthermore, once implanted, retentive forces arising from post-operative scar tissues and sutures can provide additional stability. The gradient magnetic field, which is responsible for the audible clicking of MRIs, can stimulate neural tissue. Moreover, the existence of a stimulator can exaggerate this response. In the presence of such a field, a current on the order of 5 V/meter can be induced, which, in a 60 cm DBS system, equates to 3 V [40]. However, the impedance of these systems limits an appreciable current induction. RF fields are similar to gradient fields in that they can induce native tissue effects without the presence of foreign devices. RF fields create precession of hydrogen-nuclei and can induce local currents capable of heating tissue. The presence of electrodes and other electronics can amplify such currents, leading to clinically significant tissue damage. Several phantom experiments have clearly demonstrated the potential for tissue damage from heating. Such heating depends on the conductive properties of the lead, adjacent tissue, lead placement with respect to the coil, as well as blood flow. In a prior study carried out by Shrivastava and colleagues in 2012, a cadaveric porcine model was designed to measure heat induction by MRI imaging [41]. By measuring temperatures via fluoroptic probes, the results demonstrated that heat transfer was significantly reduced (1.5–3.2 °C vs. 5.1–24.7 °C) when extra-cranial leads were placed parallel to the MRI head coil’s longitudinal axial direction, compared to other orientations.

2.7. Thermocautery and electrocautery

Thermocautery helps achieve hemostasis by providing direct thermal energy at the metal tip, but without delivering any current to the patient [42]. It appears to be a safe instrument for hemostasis in patients with implantable electronic devices (IED), though the risk of direct thermal damage to DBS hardware persists [43]. Electrocautery, on the other hand, does pose

a significant risk of EMI in patients with IEDs [44]. Here, a high-frequency alternating electrical current (AC) passes through either a single unheated electrode (monopolar) or through a two-electrode system (bipolar). In monopolar electrocautery, the pathway is from the electrode instrument to the site of surgery, through the patient's body to a grounding pad, then back to the electrosurgical unit to complete the circuit. Some low powered monopolar electrosurgical units are ideal for use in the outpatient setting and have optional grounding pads. However, the absence of a grounding pad may permit currents to disperse beyond the surgical site throughout the patient's body, leading to potential EMI [45]. Indeed, monopolar electrocautery might provoke electrical shocks when the IPG is not turned off; therefore, it is recommended that the IPG voltage be set to zero to avoid EMI when monopolar electrocautery is employed [46].

Other recommendations include (1) using a dispersive plate to avoid the electrical field disrupting the DBS system [10], (2) cauterizing for short periods of time (<5 s) and in infrequent bursts (>5 s in between) [42,47], and (3) maintaining the electrocautery current at 90° to a line drawn between the neurostimulator case and lead electrodes, in order to reduce conductive currents. Having fractures in the lead, incompetent insulation and not keeping the neurostimulator and lead system out of the conductive path can all further exacerbate the risk of potential EMI. These possibilities should, therefore, be actively identified and corrected or circumvented if monopolar electrosurgery is likely to be used in a surgery for changing IPGs or even when operating at other surgical sites in close proximity to the DBS system. A recent Medtronic device (PEAK PlasmaBlade™) uses lower temperatures and pulsed radiofrequency energy discharges, which theoretically may result in fewer incidences of tissue injury and device damage in DBS patients. Indeed, the cutting surface of the PlasmaBlade operates at 40 °C and 100 °C, which is significantly lower than the 250–350 °C found in conventional electrocautery electrodes [48]. At the same time, replacement of implanted pacemakers and defibrillator generators using PlasmaBlade has been associated with reduced risk of lead damage, shorter hospital stays, and greater cost effectiveness when compared to scissors and conventional electrocautery [49]. However, a recent study on transvenous cardiac defibrillators implanted in anesthetized pigs showed that the PlasmaBlade in the coagulation mode actually transferred more EMI to the implanted device than conventional monopolar and bipolar devices [50].

2.8. Other medical sources

Patients are also exposed to an ever-increasing number of sources of EMI in the hospital setting. Extensive literature exists on the interference of such devices, including TENS units, lithotripsy, electro-convulsive therapy (ECT), and radiotherapy with pacemakers [51–53]. Specifically, ECT in patients with DBS has been reported in both pallidal and STN electrodes. While the safety of ECT in DBS has not been well established, modelling of electric fields using finite element analysis suggests that electrical current is primarily shunted through bone and superficial soft tissue. As a result, insulated subcutaneous leads and skull defects from the burr are subject to the strongest electrical field. The aim is to maximize the distance between ECT electrode placement and the DBS electrodes and subcutaneous leads. There are no reported cases of ECT triggering or damaging DBS, whether left on or off. Ionizing radiation can also impair implantable devices by loading the

silicon dioxide insulator with excess electron-hole pairs, which may accumulate and create a net positive charge resulting in device malfunction [54]. Aside from therapeutic sources of interference, other electronic equipment in the clinical setting such as radiofrequency identification (RFID) card readers has also been reported to cause interference with the IPG [55].

3. Intentional EMI

The use of intentional EMI to effectively hack DBS systems has recently come under scrutiny with the discovery of a potential vulnerability in clinician programmers and the ability to access personal information about patients [56–59]. Beyond information theft, it is technically feasible for a third party to interfere with IPG to maliciously control brain implants; a process termed “brainjacking”. Unauthorized access could include interrupting stimulation, draining implant batteries and depending on the site of stimulation, impairing motor control, modulating reward pathways, impulse control emotions and affect, pain, off-target effects and potentially brain tissue damage. There are currently no reports of these incidences with respect to DBS however there are documented cases with other medical devices (insulin pumps, cardiac pacemakers, brain computer interfaces). In one instance, vulnerabilities were revealed to Medtronic’s CareLink programming devices used to access pacemakers, requiring the FDA to issue a safety notice [60]. While there are no documented cases of an attack, the bug uncovered could upload malicious software onto programmers and subsequently implanted pacemakers and cause malfunction.

Depending on the indication for DBS and the side effect profile, intentional third-party interference can theoretically undermine a patient’s autonomy [61]. This includes alterations in reward processing in nucleus accumbens stimulation or impulse control in subthalamic nucleus stimulation. Such attacks can be categorized as *passive* (“listening” for information during normal transmission) which may result in disruptions in authentication or loss of confidentiality, or *active* (send or modify messages to the IPG) which can alter therapy and side effect profile of stimulation [62]. With respect to closed loop systems, more information can be obtained because they combine the recording features of a brain-computer interface (BCI) along with conventional DBS. As an example, there are two types of closed loop systems for the Medtronic RC + S Summit systems. The first is an internal approach where the device measures a frequency band which then can alter the stimulation pattern through a lookup table. The second is an external approach where the device communicates to an external PC using a proprietary network to a “communicator” device. This external closed loop system is more susceptible to interference.

In a study by Marin et al. a neurostimulator device programmer was reverse engineered, demonstrating over the air transmissions were neither encrypted nor authenticated. Motivated by these findings, a security architecture is proposed that relies on using patient physiological signal for generating a symmetric key in the neurostimulator and transporting this key from the stimulator to the programmer through a secret out-of-band channel [63]. With the addition of the new Medtronic, Abbott and Boston Scientific DBS systems, devices can be controlled through applications on standard tablet computers. Compared to prior clinician programmers, newer programmer tablets allow for universal application updates

however this also creates a vulnerability at the software level. An additional example of cybersecurity vulnerability involves the radiofrequency-enabled Abbott implantable cardiac device and its corresponding transmitter [64]. Although no incidents causing harm to patients due to such a breach have been reported, a theoretical risk of an unauthorized user accessing a patient's cardiac device and causing it to administer inappropriate shocks or pacing has been brought up. These hypothetical situations do raise serious concerns and necessitate more resources directed towards developing better neurosecurity. Recent FDA guidelines may help reduce cybersecurity threats that are inherent to design features [65].

4. Conclusion

As DBS becomes an increasingly common treatment option for patients with various movement disorders and other neurological diseases, EMI and device malfunction, both intentional and unintentional become an important topic of discussion. Furthermore, given the ever-expanding number of indications/applications for DBS, such as in the developing field of treatment of psychiatric disorders, one can easily anticipate the potential for devastating consequences should therapeutic efficacy be compromised or lost due to EMI. High likelihood (but not very severe) outcomes include transient ON/OFF switching of stimulation when passing through theft detectors or screening devices at security check-points if EMI exposure is not anticipated and devices not switched off beforehand. Less likely (but potentially catastrophic) outcomes would include irreversible injury to brain or human tissue. Several factors, however, have been previously investigated to help mitigate and minimize interference, including the use of filtering systems used to filtering out the frequency bands of MRI, or the addition of fiber-optic components [66]. Further design alterations include modifying the coiling technique of wires (e.g., insuring air gaps between coil loops) and the addition of shielding materials to help filter out RF [67]. These device alterations can be introduced and incorporated via updated device designs by established manufacturers and the emergence of new device manufacturers. Ultimately, research on EMI effects on patients with DBS devices remains relatively sparse. Furthermore, with respect to cybersecurity medical devices remain far behind the computer industry in protecting devices from hackers. It is a great practical concern which warrants further timely investigation. More comprehensive and current characterization is essential to improving DBS device design and patient outcomes. By addressing the knowledge gap, this review represents one of the requisite first steps toward ultimately improving DBS system design, implementation, efficacy and safety with respect to EMI.

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Table 1

EMI Potential for DBS Interference. Data compiled from MAUDE database, case reports and manufacture product information.

Device / Procedure	Safe	Possible	Probable
Arc welding equipment			X
CAT scan		X	
Cautery			X
Cellular phone [a]	X		
Computer disk drive	X		
Defibrillation		X (implanted)	X (external)
Dental drill		X	
Ultrasound	X (diagnostic)		X (therapeutic)
Diathermy treatment			X
Electronic power generator			X
Electric substation			X
Electrocautery			X
Electroconvulsive therapy	X		
Fluoroscopy	X		
Freezer door	X		
Furnaces, industrial			X
Hair dryers		X	
Ham radio antennas			X
Hybrid vehicle, electric car		X	
Induction heater, industrial			X
Induction range		X	
Lithotripsy			X
Magnets, industrial			X
Magnetic Resonance Imaging			X
Mammography		X	
Microwave communication transmitter			X
Pacemaker		X	
Power lines			X
Power tool		X	
Radiation therapy			X
Radios, AM and FM	X		
Refrigerator door [a]	X		
Security gates		X	
Sewing machine	X		
Smooth top range	X		
Stereo speaker [a]	X		

Device / Procedure	Safe	Possible	Probable
Theft door		X	
Transmission towers for television and radio signals			X

[a] possible interference for Soletra DBS systems.

Table 2

EMI emitters and their relative field strengths [23].

Device	Frequency Range (Hz)	Magnetic field strength (nT)
DBS programmer	130–185	80,000
Background field in homes	50	100 – 200
Power lines *	50	1,000–10,000
Trains **	50	5000
Security Gate	100 – 3500	374,100
Electronic Article Surveillance	219	220,000
Magnetic Resonance Imaging	1000,000–300,000,000	$5 \times 10^8 – 3 \times 10^9$

* 100 m from the power line.

** Non-electrified.

Table 3

Incidence of adverse events reported in the Manufacturers and User Facility Device Experience (MAUDE) database. Search using 'Electromagnetic Interference' as the 'Product Problem' in the past 17 years (November 26, 2002 – November, 26, 2019) revealed only incidents involving Medtronic DBS systems, and none for St. Jude or Boston Scientific. Since the MAUDE database is voluntarily reported, it likely underestimates the actual incidence of these adverse events. [21].

Medtronic DBS systems (no events reported for St. Jude, Boston Scientific, or Medtronic Percept PC in the timeframe)		
Model	**# of events**	**Example event description**
Activa	130	IPG turned off and patient was unable to walk outside of a security booth at an airport (6,885,989) Feeling a "jolt", or dizziness after passing through security gate (2461796, 2,436,842) Tonic contractions following MRI scan (2,402,045) Pain spreading further than stimulation leads after passing through security points (6,968,427) Feeling tingling, lightheadedness, and dysarthria after passing a scanner (6,684,167) 'Burning' sensation in the right hemi-brain during an MRI with the neurostimulator turned off (6,594,120) Return of symptoms and loss of therapeutic effect after walking through a security gate (2,384,089) Turned off by a loudspeaker (1,643,896) Less efficacious following installment of computer router (2,337,283) Power on reset of neurostimulator occurred following cardiac pacemaker implantation procedure (2,189,621)
Kinetra	58	Loss of therapeutic effect while using a cordless drill (2,187,414) Brief right arm sensation during tissue dissection with RF ablation for lead revision (6,563,037) Buzzing sensation in brain when exposed to sound system, movie theaters, cars with stereo systems, even if car is driving by (2,074,609) Loss of therapeutic effect working near large generators (1,216,442) Persistent contralateral hand weakness after undergoing 1.5 T MRI scan (6,962,830)
Soletra	158	DBS turns off when going through grocery or other security devices (6,117,778) Loss of therapeutic effect following echocardiogram (1,195,895) Loss of therapeutic effect after programming a Bluetooth headset (1,084,035) Return of tremors when cell phone brought up to ear (1,038,708) Stimulation turned off near car with loud music (1,570,640) Return of stimulation after undergoing a CT scan (6,977,281) Shocking and jolting when in close proximity to welding equipment (5,637,376) Dyskinesia following CT scan (2,430,588)
Itrel	100	Stimulation turned on when getting in or out of minivan (1,484,722) Lead fractured following knee MRI (2,098,623) Stimulator turned on immediately after entering MRI machine. Following study, stimulator no longer functioned. During revision, lead was determined to be completely cut (2,052,533)