Effects of Electromagnetic Fields on Implantable Medical Devices

Muhammad Ali Assad
Ian Buzanoski
Jared Lindros
William Tolli

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Advisors:
Richard Vaz
Demetrios Papageorgiou

Effects of EM Fields on Medical Implants

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Muhammad Ali Assad

Ian Buzanoski

Jared Lindros

William Tolli

Date: December 22, 2003

Approved:

Professor Richard F. Vaz, Major Advisor

Professor Demetrios Papageorgiou, Co-Advisor

Abstract

The purpose of this project was to determine the effects of electromagnetic fields on implantable medical devices. This was accomplished through correspondence with manufacturers of these devices, physicians, medical experts, and engineers. It was found that electromagnetic fields can cause dislodgment, heating, and malfunction in certain implantable medical devices. To avoid these effects, certain active and passive implantable medical devices should not be exposed to more than 1.0 Gauss[45] and 1.0 Tesla[31] fields respectively.

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Authorship

This project report was a collective effort of Muhammad Ali Assad, Ian Buzanoski, Jared Lindros and William Tolli. The major research sections were divided among the group members as follows:

Research on implantable medical devices and manufacturers
Ian Buzanoski and William Tolli

Research on measurement methods for magnetic fields
Jared Lindros

Research on standards and regulations from government organizations and industry regulators
Muhammad Ali Assad

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Executive Summary

Electromagnetic fields of some magnitude are emitted from all powered electrical devices. These fields propagate outwards in all directions and attenuate at a rate proportional to square of the distance from the source. Electromagnetic (EM) fields can be harmful to human health. Studies have shown that prolonged exposure to high levels of these fields may contribute to the development of cancers[18], such as Leukemia and brain tumors[23].

Medical implants are used to perform different functions in the body. Most of these implants consist of ferromagnetic materials and electronics that can be affected by EM fields. The actual effects of these fields on these devices and safe exposure levels for these implants are unknown. This project was conducted to gather this critical information about the effects of EM fields on implantable medical devices (IMDs).

The interaction between electromagnetic fields and IMDs can have varying consequences, such as heating, displacement, or even complete failure of the implants. Active implants have several failure modes, such as being forced into reprogram mode when exposed to electromagnetic fields. These implants can also obtain false readings from their leads due to electromagnetic interference. The safe exposure levels for active implants with programmable memory, such as pacemakers, ranges from 1.0 Gauss[45] in a standard 60Hz field to a maximum of 5.0 Gauss[1] in a static magnetic field. Safe levels for passive implants such as aneurysm clips and stents are generally higher, because the primary concern is movement as opposed to electronic failure. These implants should not be exposed to more than 1.0 Tesla field[31].

There are few standards and regulations from government organizations and regulatory agencies pertaining to the safety of IMDs. EN 50061[2] and ANSI/AAMI PC69[3] are the two primary safety standards used by the manufacturers of IMDs, particularly Medtronic and Guidant[4]; however, these standards only cover the safety of cardiac pacemakers and cardiac defibrillators. Standards for other IMDs are currently under development by CENELEC. These standards will focus on safety requirements for cochlear implants, cardiac defibrillators, nerve stimulators and dental implants[2].

The measurement of EM fields to determine the degree of exposure of a patient with an IMD is a complicated process. Methods have been developed to differentiate and measure the exposure from different sources of magnetic fields, to estimate the average magnetic flux measurement in an area, and to calculate actual exposure levels by personal monitoring. The method of personal monitoring requires the patient to carry a measurement device as he/she goes about their daily work. This is an effective method to map out the possible dangerous exposure levels to which the patient was exposed.

The failure of medical implants in the presence of EM fields is a matter of great concern. More standards and regulations need to be developed that focus on the electromagnetic compatibility (EMC) of medical implants. Accidents from failures of these devices should be reported so that they can be prevented in the future. Manufacturers of medical implants need to perform critical testing of their products in different levels of magnetic fields before marketing their products. In turn, this information should be disclosed to the medical community and made available to other concerned parties.

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Acronyms

AAMI	Association for the Advancement of Medical Instrumentation
AC	Alternating Current
ACGIH	American Conference of Governmental Industrial Hygienists
AICD	Automatic Implantable Cardioverter Defibrillator
ANSI	American National Standards Institute
ASTM	American Society for Testing and Materials
ASTM	American Society of Testing and Materials
BIPM	International Bureau of Weights and Measurements
CDRH	Center for Devices and Radiological Health
CENELEC	European Committee for Electrotechnical Standardization
CIPM	International Conference of Weights and Measurements
DC	Direct Current
ECG	Electrocardiogram
EE	Electrical Engineering
ELF	Extra Low Frequency
EM	Electromagnetic
EMC	Electromagnetic Compatibility
EMF	Electromagnetic Field
EMI	Electromagnetic Interference
EU	European Union
Euromet	A European Collaboration in Measurement Standards
FCC	Federal Communication Commission
FDA	Food and Drug Administration
ICD	Implantable Cardioverter Defibrillators
ICNIRP	International Commission on Non-Ionizing Radiation Protection
ICNIRP	International Commission on Non-Ionizing Radiation Protection
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineering
IMD	Implantable Medical Device
ISO	International Organization for Standardization
ISO	International Organization for Standardization
MRI	Magnetic Resonance Imaging
NIOSH	National Institute for Occupational Safety and Health
OSHA	Occupational Safety and Hazards Administration
PMA	Pre-market Approval
RMS	Root Mean Square
SAR	Specific Absorption Rate
UNEP	United Nations Environment Program
WHO	World Health Organization

1 Introduction

Every electrical current or voltage potential radiates some magnitude of either an electric, magnetic or electromagnetic field (EMF) in its vicinity. Electric motors and generators, electric power distribution systems and all common electrical appliances can produce these fields. Even though electric and magnetic fields attenuate quickly with distance from such sources, the interaction of these fields with electronic and metallic devices may cause an anomaly in their normal operational behavior. Among the devices that may be affected are implantable medical devices (IMDs) such as pacemakers, neurostimulators, aneurysm clips, stunts and replaceable joints.

The effect of EM fields on medical implants may either be acute or chronic. Whether the effect is significant or not, any deviation from the normal behavior of these devices may result in a serious threat to the health of the patient. Historically, some accidents caused by the failure of medical implants have been attributed to magnetic interference[46,47]. Despite these accidents, very little research has been done to determine the safe levels of electromagnetic exposure for IMDs.

Research has been conducted to outline the effects of EM fields on the health of an individual. However, most of this research was directed towards the biological risks caused by EM fields. In the early 1960's, the introduction of IMDs revolutionized the medical industry, but it also introduced new concerns about the susceptibility of an individual to magnetic fields due to the failure of the IMD. Since then, little in-depth research has been conducted to recognize the danger to medical devices from magnetic fields. Some government agencies such as the European Committee for Electrotechnical Standardization (CENELEC) and the Center for Devices and Radiological Health (CDRH) have developed a few safety standards[2], although more work still needs to be done.

The goal of this project was to identify safe exposure levels of EM fields for persons with IMDs, as well as the possible failure modes of IMDs when exposed to EM fields. One of the objectives of this project was to identify and categorize IMDs according to their purpose, manufacturer, safe levels of EM field exposure, and the effects EM radiation has on them. In addition, the methods for measuring and testing the size and strength of EM fields were identified. Furthermore, a list of current government standards and industry regulations regarding IMDs and EM fields was compiled. Then, a history of past IMD/EMF problems as well as previous case studies, especially those related to power generation and power transmission, were assembled to help assess the necessity of this project along with a collection of unsolved problems and suggested solutions. In the end, recommendations were made for future work to pave the way for advanced research and testing in this field.

To achieve these objectives, background information was collected on EM fields and implantable medical devices. This information, primarily gathered from textbooks and web resources, helped to differentiate the relevant information and to maintain focus on the project goals. The background research has been summarized in Chapter 2.

2 Background Research

Determining safe exposure levels for medical implants and identifying major sources of electromagnetic (EM) fields required some basic understanding of EM fields. The focus of this chapter was to better understand EM fields and their effects. Some questions that we sought to answer include:

- What are electromagnetic fields?
- How are they related to magnetic and electric fields?
- How do they affect humans and medical implants?
- How do you measure these fields?
- Are there any health related hazards from these fields?

To answer these questions, we conducted background research on EM fields and implantable medical devices (IMDs). The results of this research have been compiled below.

2.1 Sources and measurements of electromagnetic fields

Electromagnetic fields are created whenever electricity is generated or used. These fields are produced by all operating electrical equipment such as power lines, electric wiring, electric equipment and everyday appliances. The frequency or rate of fluctuation of these fields is measured in hertz (Hz, or cycles per second) and is directly dependent on the supply frequency[5]. There are both man-made and natural sources of electromagnetic fields. Magnetic Resonance Imaging (MRI) machines are a common example of a man-made source as opposed to the sun which is a natural source of electromagnetic fields.

2.1.1 Understanding electromagnetic fields

An electric field results from an electrical potential between two points, such as the plates in a capacitor. This field can either be constant or time varying[6]. These fields are generally characterized by a region of space that imparts a force on an electrically charged particle. Field lines are used to describe the potential forces that radiate in all directions from a source of electric field. The spacing of the lines indicates the field magnitude in that area similar to relief lines on a map, as shown in Figure 1. The size, shape and strength of these fields depend on the source's size, design and amount of shielding[7]. Conductive, magnetic, and dielectric materials also influence electric fields. Signal carrying wires, such as those going from a pacemaker to the ventricles of the heart, can be shielded from electric fields with a thin layer of metal foil around the insulator containing the signal carrying wire[6]. To reduce the electric fields emitted by a wire, a shield connected to the ground can be placed around it. This will absorb most of the electrical emissions.

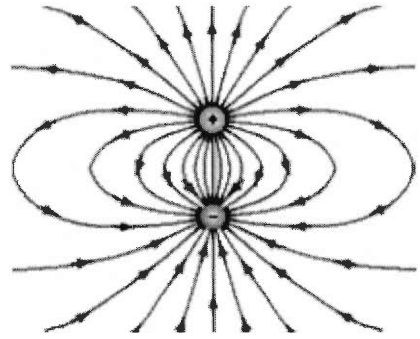

Figure 1: Electric field lines between charged particles[8]

Magnetic fields can be produced by moving electric charge or a permanent magnet. The magnetic field patterns around a current carrying conductor are shown in Figure 2 below. Both sources, either a current carrying wire or a permanent magnet, can create static or dynamic fields. A static magnetic field is only capable of exerting a force on a ferromagnetic object such as a steel implant. On the other hand, a dynamic magnetic field can induce an electric current in a coil or a metal object[6] in the presence of magnetic flux.

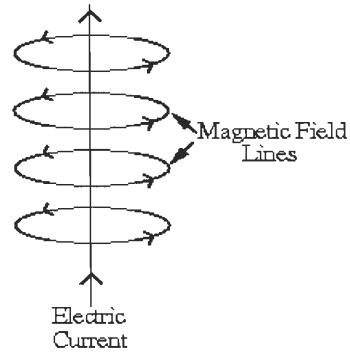

Figure 2: Magnetic field pattern around current carrying conductor[9]

Magnetic fields also attenuate at a fast rate, but are not shielded as easily as electric fields. Only certain materials can interact with magnetic fields. Materials are categorized in three different groups. Diamagnetic materials exhibit no magnetic properties, paramagnetic materials experience a weak magnetic attractive force and ferromagnetic materials exhibit strong magnetic attractions[6].

In Figure 3 below, the relationship between current, magnetic flux and magnetic field is shown. Since an electric field is perpendicular to its respective magnetic field, the magnetic flux through a conducting material will induce a circular current around its surface. Metallic materials that can form complete loops will develop currents to dissipate energy. The lower the resistivity of the material, the higher is the induced current. These loops, known as eddy currents, can be so small that thousands of them can be present at the same time in a metal surface[6]. The fields encountered in an industrial setting will not be strong enough to cause significant heating through induction, though there are specific machines designed for this task, such as an induction welder.

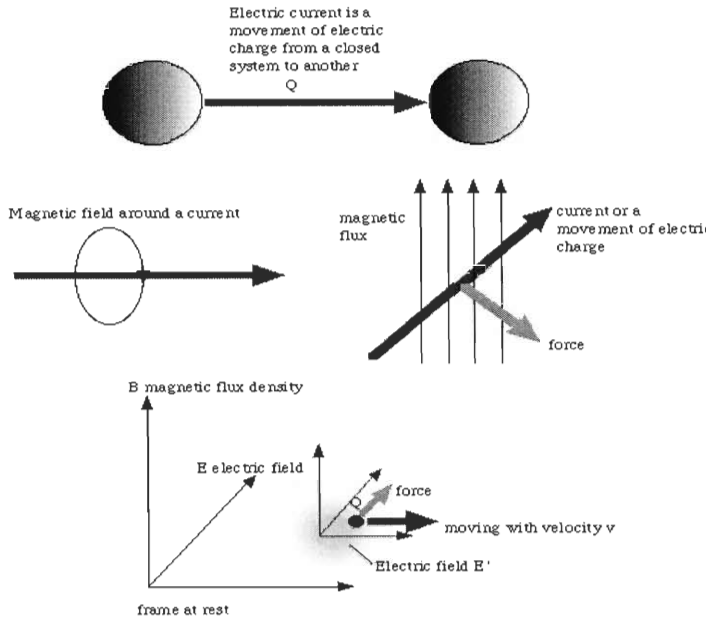

Figure 3: Current, Magnetic Flux and Magnetic Field[10]

All electrically charged particles are surrounded by electric fields. When these charged particles are set in motion, they produce magnetic fields. A change in velocity of these charged particles will produce an electromagnetic field. Hence, an electromagnetic field is produced by an accelerating charged particle, such as an electron[11]. Electromagnetic fields can be defined as intentionally coupled waves consisting of varying magnetic fields that are perpendicular to varying electric fields traveling in the same direction. This is shown in Figure 4 below. The oscillation of the two waves together reinforces the wave by switching the energy from one wave to the other, making it possible to travel long distances. This is the principle of radio operation. Radio emitters can produce large electromagnetic fields that can disrupt sensitive electronics. This effect is accomplished by using an antenna that transmits electromagnetic waves which can travel great distances through free space[6]. Light is the most common real world example of an electromagnetic wave.

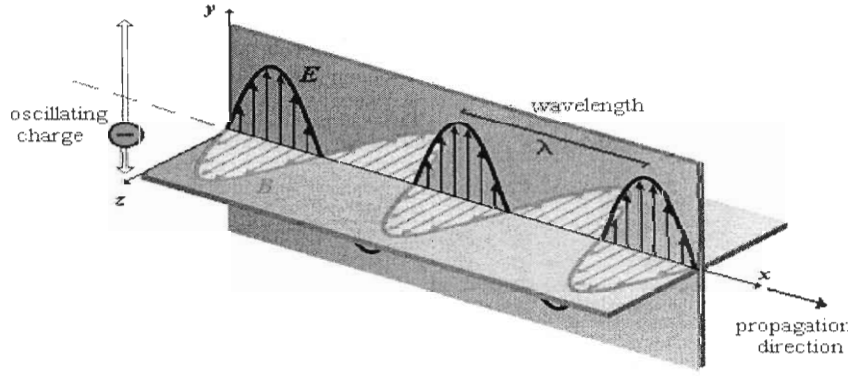

Figure 4: Transverse electromagnetic wave[12]

2.1.2 Measurements of electromagnetic fields

Now that the difference between electric and magnetic fields has been established, a basis is needed for measuring the fields to determine what field levels are potentially dangerous. Also, the standard measurement devices for measuring these fields need to be identified.

When measurements are taken, the units are usually measured in Standard International units (SI units), although many American companies still use English units. These standards were set by International Conference of Weights and Measurements (CIPM), International Bureau of Weights and Measurements (BIPM), and Euromet. As this is the case in most international instances, we will use SI units but will try to include English units whenever possible to accommodate the engineers who still use them. Most simple fundamental standards of magnetic flux density are based on the accurately known dimensions of a long, uniformly wound solenoid carrying a known current[13]. The flux is then calculated by measuring the opposing induced current. Magnetic flux is measured in units of Gauss (G), Tesla (T) (10,000G = 1T)[14] or Lines per square inch (lines/in^2) (1G = 6.4516 lines/in^2)[15].

There are three main instruments for measuring electric and magnetic fields, the fluxmeter, the ballistic galvanometer, and the Hall-Effect instrument. The flux meter uses a permanent magnet with a moving coil of low inertia and negligible control torque. The fluxmeter makes use of the current induced in the coil rather than the charge[13].

The ballistic galvanometer, on the other hand, makes use of the charge resulting from a time integral of voltage impressed on a known resistance rather than currents[13]. Like the fluxmeter it also has a coil which rotates between magnets, but unlike the fluxmeter the coil has a large moment of inertia. Beryl Clotfelter[16] describes how it works, "Its large moment of inertia permits the passage of a quantity of charge before the coil moves significantly. The passage of the charge produces an impulse, a momentary torque, which then causes the coil to swing slowly to some maximum position. Such a galvanometer was often used to standardize capacitors".

The Hall-Effect instrument is another instrument used for measuring electromagnetic fields, primarily large magnetic fields. A thin-film Hall probe is placed in the magnetic field and the transverse voltage (on the order of microvolts) is measured[17].

The three types of instruments are primarily used for different field strengths. Each uses either induced current in the meter, induced charge from the magnetic field or the effect the magnetic field has on the electrons inside the device. These are used as a basis for methods of measuring magnetic waves. To measure the magnetic waves and actually acquire useful information with these measurements, one or more of the complete methods must be followed. Four methods relating to implantable medical devices are devised in the results and analysis chapter of this report.

2.2 EM fields and interaction with biological systems

When electromagnetic fields interact with biological systems, such as the human body, they may cause certain effects such as cancer[18]. The exact reasons for these effects are still debated in the scientific and medical fields. Some scientists are still skeptical

whether weak EM fields, less than 300V/m (7.62V/in) for electric fields or 500mG (3.22lines/in^2) for magnetic fields, can cause any biological effects because the human body has much electrical activity that would overshadow these weak fields[19]. However, prolonged exposure to EM fields can cause changes in the human body, so several theories have been put forward to explain the phenomena.

One theory is that electrical currents are induced in the body tissues by the movement of magnetic fields. These currents could then be responsible for possible biological effects. A biological effect is any change that may occur in an organism, rather than a mechanical device. These currents are extremely small compared to other bodily currents, so this theory is more of a starting point than a final explanation. A continuation of this theory addresses transient currents that are proportional to the change in the surrounding magnetic field. This explains that sudden changes in the magnetic field will induce much larger currents for short lengths of time, which could be harmful to the body[19]. A third theory is that certain frequencies of EMF cause a resonance condition on the surface of the cell. This resonance causes certain ions to move more quickly through cell membranes, which could accelerate or inhibit certain processes in the body[19]. The last theory is related to static magnetic fields. Cells in human tissue may be able to sense static magnetic fields and respond to them, causing biological functions to be altered[19].

There are other cellular effects that have been studied. Research shows that 60 Hz EM fields, the most common power-frequency in North America and many other areas, may cause the production of stress response proteins in cells[20]. These proteins assist in the transport and rebuilding of other proteins in the cells. This reaction seems to be a product of EMF that accelerates the electron transfer rate of electrons moving in cellular DNA[20].

Research has shown that exposing cells to an extra low frequency (ELF) electric field may cause the formation of both an internal ELF potential that is dependant on cellular size and an external ELF field that is constant for an applied electric field[21]. These forces may cause serious problems in the body, such as inhibiting cellular functions or causing shape or size changes. During a test on Pisum sativum, the garden pea, root growth was significantly slowed with an applied electric field over 290V/m (7.37V/in.), and continued to decrease with increased field strength until growth was essentially stopped at 490V/m (12.44V/in.)[21]. By varying the ratio of current density to field density, it was determined that the growth rate was related to the electric field and not the currents. Similar effects may be found in animals, but no such testing has been conducted[21].

Another notable biological effect of electric fields is in bone growth. It has been found that electrical currents in broken bones can accelerate healing and re-growth. However, the field strengths necessary for this are much higher than what one would encounter in everyday life[19].

2.3 Safe exposure levels for human health

Many government agencies and international organizations have developed safe exposure levels of electric and magnetic fields. In 1984, the World Health organization regarded an electrical field intensity of 10kV/m (0.25kV/in.) safe for all populations. It said that exposure should be limited to levels as low as reasonably possible, but there is no need to limit access to regions with fields of less than 10kV/m (0.25kV/in)[21]. In 1980, Poland set

standards of 1kV/m (0.03kV/in.) for continuous residency and between 1kV/m and 10kV/m (0.03kV/in to 0.25kV/in) for recreational use for less than a full day. Any area with fields stronger than 10kV/m (0.25kV/in) was prohibited for occupancy by the general public[21].

In 1979, the Alpen Committee set several standards for DC magnetic field exposure levels. These standards applied to research personnel and workers in high magnetic fields. The safe level for an 8 hour work day was set at 0.01T (0.6k lines/in.^{2}), with a 0.1T (6k lines/in.^{2}) field safe for less than 1 hour and 0.5T (.03M lines/ in.^{2}) safe for less than 10 minutes[21]. However, these are not recognized globally, and there are questions concerning these levels.

While there are currently no federal standards in the United States for EMF exposure, several states have set limits, as have several organizations. In 1998, the International Commission on Non-Ionizing Radiation Protection (ICNIRP) published a set of guidelines for both occupational and general exposure. They have set guidelines for occupational electric and magnetic fields of 8.3kV/m (0.21kV/in.) and 4.2G (0.027k lines/in.^{2}) respectively, and 4.2kV/m (0.11kV/in.) and 0.833G (5.37lines/in.^{2}) for the general public[22]. However, there is no federal standard; hence some people do not follow these guidelines. This discrepancy will continue until specific safe levels have been proven and adopted globally. Table 1 provides a summary of the safe exposure guidelines for magnetic and electric fields.

Table 1: Summary of the exposure guidelines for people

Date	Organization	Guidelines	Comments
1979	Alpen Committee	0.01 T (0.06k lines/in^2)	8 hour work day
		0.1 T (0.6k lines/in^2)	less than 1 hour
		0.5 T (0.03M lines/in^2)	less than 10 minutes
1980	Poland	1 kV/m (0.03kV/in)	Continuous residence permitted
		<10 kV/m (0.3kV/in)	Permissible for recreational use, less than full day
		>10 kV/m	Prohibited for occupancy by general public
1984	World Health Organization	10 kV/m (0.3kV/in)	Limit exposure when possible, but anything below the guideline need not be restricted access
1998	International Commission on Non-Ionizing Radiation Protection	8.3 kV/m (0.21kV/in)	occupational
		4.2 kV/m (0.11kV/in)	general public
		4.2 G (27 lines/in^2)	occupational
		0.833 G (5.37 lines/in^2)	general public

2.4 Health hazards from electromagnetic phenomena

Since the mid-1900s, there has been a rising concern about human health being affected by electric and magnetic fields. During the 1960s, studies were conducted on employees of electrical substations (higher voltages transformed to a lower voltage) in the Soviet Union. The studies showed that the workers experienced certain minor health symptoms, such as headaches and sleeplessness, at higher than expected rates[20]. Subsequent studies in other countries have had mixed results. Some studies have proven inconclusive, while others have provided solid evidence of health risks caused by electric and magnetic fields. While it is generally accepted that electric and magnetic fields have adverse biological effects on humans, there has been a rising concern about the effects on implantable medical devices.

2.4.1 Hazards to human health from electromagnetic fields

The results of the many studies performed have produced answers that indicate a connection between electromagnetic fields and health symptoms in humans. These studies have primarily been about the biological effects of the fields, such as changes in the body or growth. Few studies have been performed on humans with implantable medical devices.

Perhaps the most well-known health risk associated with electromagnetic fields is cancer. Nearly one hundred occupational studies have been performed on the hazards of electromagnetic fields[23]. Though the studies have varied greatly in methods and subjects, there is a reliable increase in leukemia and brain tumors in workers with high levels of exposure to EM fields, especially in electrical workers[23]. This indicates that power frequency EM fields may have adverse affects on the human body and could lead to cancer over time.

There has been recent investigation into the interaction between the pineal gland and electromagnetic fields. The pineal gland secretes melatonin, mostly at night, and is involved in reproduction and maintenance of biological rhythms[19]. In laboratory animals, some studies have noticed a suppression of melatonin during EMF exposure, though no conclusive results have been produced. A study on humans has shown that not all humans react to the exposure, though some do show a decrease in melatonin levels[19].

While many studies have been performed, and the scientific field generally accepts the concept of biological health risks associated with electric and magnetic fields, there are still many questions to be answered. Because the studies have used a wide range of frequencies, intensities and exposure times, it is difficult to draw conclusions about the effects of EMFs on biological health. Also, some studies, such as those on extra low frequency (ELF) fields, combined electric and magnetic field exposure, so the effects cannot be separated[21].

2.4.2 Hazards to medical implants from electromagnetic fields

While the effects of EM fields on the human body are not completely understood, even less is known about the effects of EM fields on implantable medical devices. While it is mostly understood why there might be a failure due to fields, the exact nature of the

failure and field necessary to cause the failure are not fully understood. There has not been much research into this interaction, and most manufacturers have not done extensive testing to set specific guidelines for EM exposure for their products. This lack of specific restrictions has led to confusion for patients with medical implants and manufacturers of equipment that produce large EM fields.

One of the biggest concerns with EM fields and IMDs is that the fields will cause failure of the electronic components. For instance, many pacemakers are designed to be reprogrammable, and they may enter the reprogram mode when exposed to a 5G field[24]. If a person with a pacemaker were exposed to a magnetic field of this magnitude, the pacemaker might stop functioning properly. If exposed to a strong enough fluctuating field, the electronics could even be damaged by induced heating or currents which can harm many of the electrical components. The device could also interpret the field, especially an electric one, as an irregular heartbeat and try to correct it when there is actually nothing wrong[24].

Another potential problem with IMDs is heating. Fluctuating magnetic fields could induce eddy currents in metallic parts and cause the parts to heat up, possibly causing internal burns[24]. Along with current induced heating, the magnetic fields could cause movement of the devices. A strong magnetic field could shift or dislodge ferromagnetic devices or devices containing ferromagnetic parts. The devices also will try to orient themselves along the field lines, so rotation could occur[24]. These movements could be of great concern to a person with a clip or staple that might be more likely to move than a joint replacement. An example of an incident was recorded during a MRI exam, where the machine caused a shift of the clip, resulting in the death of the patient[25].

There is much evidence to support the theory of electric and magnetic fields causing biological health risks, and having adverse effects on implantable medical devices. However, there are still no studies that can prove the precise effects on biological systems and medical implants.

3 Methodology

A plan was developed in order to fulfill the project objectives stated in the introduction. This plan not only includes the desired objectives but also states the methods used to fulfill them. This plan was created before beginning the background research. The research consisted of gathering and identifying relevant information, followed by an analysis of the relevant data. From this analysis a guide was developed which is designed to be used as a reference..

3.1 Information from implanted device manufacturers and other web resources

It is known that EM fields can have adverse effects on all humans. This makes it necessary to identify the biological effects of these fields. There are many studies on the effects of electromagnetic radiation on human, so this could easily be done by searching for previous studies on the internet. Although there are many published studies on this subject, there are very few which deal with the effects EM fields may have on implanted devices.

3.1.1 Implanted devices

To facilitate research, a list of implantable medical devices and manufacturers was compiled. This was mainly achieved by performing an internet search for available medical devices and searching through books on implantable medical devices both active and inactive. After a list of medical devices was compiled, the major manufacturers for the devices found were researched. This was also carried out on the internet. This resulted in a list of medical devices and manufacturers. An attempt was made to contact each medical device manufacturer. The email sent to these companies inquired about any standards or precautions practiced, any known problems with EMI, and especially any experiments with EMI that they may have done in the past. Since most of these companies did not respond to the email inquiries, phone calls and letters were sent as a follow-up to these companies.

3.1.2 Standards and regulations

Since it was established that EM fields can have negative effects on humans, especially with implanted devices, standards and regulations governing electromagnetic field emission were sought. Information on relevant standards and regulations were gathered from the various standards organizations. Some of these standards were also found in the reference section of the Gordon Library at Worcester Polytechnic Institute. There are many independent organizations that have developed guidelines governing EMF exposure or emission. However, there is no main organization setting the standards for all companies throughout the world. Therefore, several standard setting organizations had to be explored.

3.1.3 Methods for measuring fields

We had to determine how dangerous an EM field can be in order to establish a basis for safe levels. Methods used for measuring the magnetic fields were outlined. This information was collected primarily from the internet, with information also obtained from the physics departments of a few college websites, international organizations' sites such as NIOSH (National Institute for Occupational Safety and Health) and bits of information from electrical engineering (EE) reference books.

3.1.4 Physician recommendations

Physicians and MRI technicians may be able to provide useful information regarding regulations and precautions followed when giving a patient an implantable device. They were contacted through emails and phone calls in the same manner as the device manufacturers. As for the design aspect and shielding from EMF in a device, the physicians contacted were only be able to give examples of accidents when EMI has caused a disturbance with an implanted device and standards that they follow.

3.2 Grouping and analysis of information

Once all the necessary information was obtained, it was analyzed. Analysis involved categorizing the data so that related issues can be readily identified. The devices were grouped by their susceptibility levels and effects on the devices.

3.2.1 Grouping the information

One of the major categories was the susceptibility ranges of the devices, such as strength of the EM field, different frequencies, time the device is exposed to the field, and distance from the EM field source. This also provided the field values in each category which are most dangerous. Since the safe exposure levels were different for each device, the lowest safe exposure value was used to formulate a general safety level for medical devices. The other major category was the effects of EMF on each device, including malfunction or failure, a device going into reprogram mode, dislodging or dislocation of the device, and heating of a device due to induced currents. This helped to determine which fields are more dangerous than others

3.2.2 Analysis

Once the data was grouped, it was analyzed. The major concern was the susceptibility levels of the devices. This told us what field values are dangerous to a person with an implanted device. The dangerous field levels helped us create a guide that can give restrictions on the fields emitted by electrical devices. By limiting the field values so that they never reach the dangerous levels (levels which begin to affect the medical devices), or restricting a person with an IMD so that they never enter a field of a dangerous level, future incidents involving implanted devices and EMI can be prevented.

4 Results and Analysis

This chapter presents the results that were obtained using the methods listed in Chapter 3, and provides an analysis of the results. The research areas discussed in this chapter correspond to our project objectives. These areas include the susceptibility and possible failure modes of implantable medical devices when exposed to electromagnetic fields, standards and regulations governing the medical devices, methods of measuring magnetic fields and accidents and case studies conducted on implantable medical devices. An annotated bibliography of the useful references is provided in Appendix E.

4.1 Implantable medical devices

In the background research section, we established the evidence of biological health risks from EM fields. The risk from EM fields can be greater for a person with an IMD since IMDs can contain metallic materials and electronic parts. This section will discuss the types of implantable medical devices, their susceptibility to electromagnetic fields and the possible failure modes in case of exposure to these fields.

4.1.1 Types of implantable medical devices

Implantable medical devices are usually categorized as either active implants or non-active implants. Active implants require some source of energy. Common energy sources may be electrical, mechanical, or pneumatic. The electrical sources can be a battery or an implanted coil that is powered by an external coil to transfer energy to the device. Active implants generally contain numerous metallic parts that are susceptible to damage by EMF and RF interference. Many of these implants also have leads to monitor the patient implanted with the device. The electrodes in the sensor may receive false readings, in the presence of interference, that could adversely affect its operation[24]. Some of the active implantable devices are discussed below:

- *Cardiac pacemakers and cardioverter defibrillators* help to regulate heart rhythm in patients whose ability to do so has been hindered. They are considered to be at major risk for damage due to stray magnetic fields[24]. An example of a pacemaker is shown in Figure 5. The leads are clearly visible coming from the device. This configuration is very similar to cardioverter defibrillators and neurostimulators.

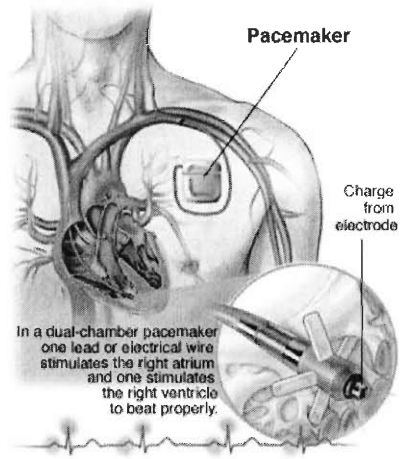

Figure 5: Implanted Pacemaker[26]

- *Neurostimulators* are implants that control pain, stimulate muscles and nerves for movement, deep brain stimulation in the treatment of involuntary movement such as Parkinson's Disease, bladder/bowel control, or control of epileptic seizures. An example of implanted neurostimulator to control pain is shown in Figure 6. Also among nerve stimulation implants are cochlear implants for artificial hearing apparatus. Neurostimulator modules may be placed anywhere in the body with electrodes running subcutaneously to the target site[24].

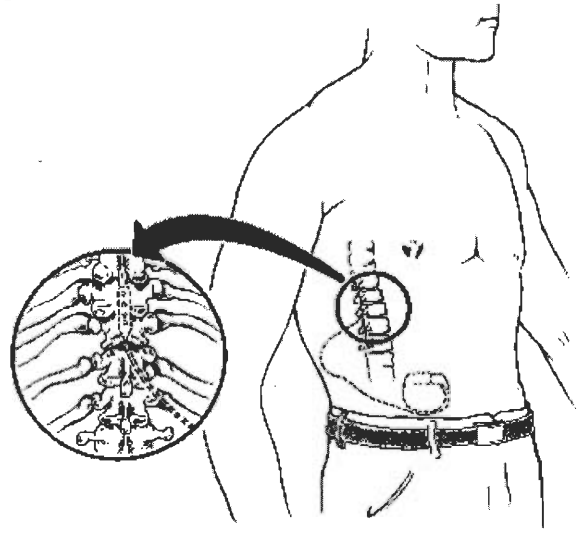

Figure 6: Typical Implantation of neurostimulator to control chronic pain[27]

- *Drug infusion pumps* are active devices that are intended to provide long term, continuous or intermittent drug infusion. They generally contain ferromagnetic components that put the patient at risk in the presence of EMF. These pumps are usually constant flow devices and have no risk of reprogramming in an intense field. They can be powered by a battery, mechanical mechanism similar to a wind up clock, or by gas pressure through an internal pneumatic pressure reservoir system[24].

- *Programmable hydrocephalus shunts* are active devices that drain cerebrospinal fluid in patients whose body produces an excess of this fluid. These devices are also considered at risk to magnetic fields[24].

Non-active implants, such as joint replacements, heart valves, aneurysm clips, coronary stents and tissue implants such as breast augmentation prosthetics require no power to function. These types of implants may or may not contain metallic parts that could be damaged or cause damage to the patient in the presence of a magnetic field[24]. Some of the non-active implantable devices are mentioned below:

- *Joint replacement parts and bone restructuring plates* are used to support broken or fractured bone, stimulate re-growth and replace entire structures such as a hip joint. They may contain large metallic parts. These parts are almost exclusively non-ferromagnetic and since they are always fixed to the skeletal structure. So there is little concern for displacement or heating in the industrial environment[24].
- *Clips, staples, intravascular stents, filters, coils, needles, sutures, and dental implants* are some of the other non-active implants. Examples of an intravascular stent and dental implant are shown in Figure 7. The susceptibility of these types of implants is dependant on fibrosis and the material used in the implant. Fibrosis occurs when an implant is enveloped with tissue securing it in the body. Since these devices are generally applied to vessels within the body, tissues will usually envelope the device within six weeks of insertion[24].

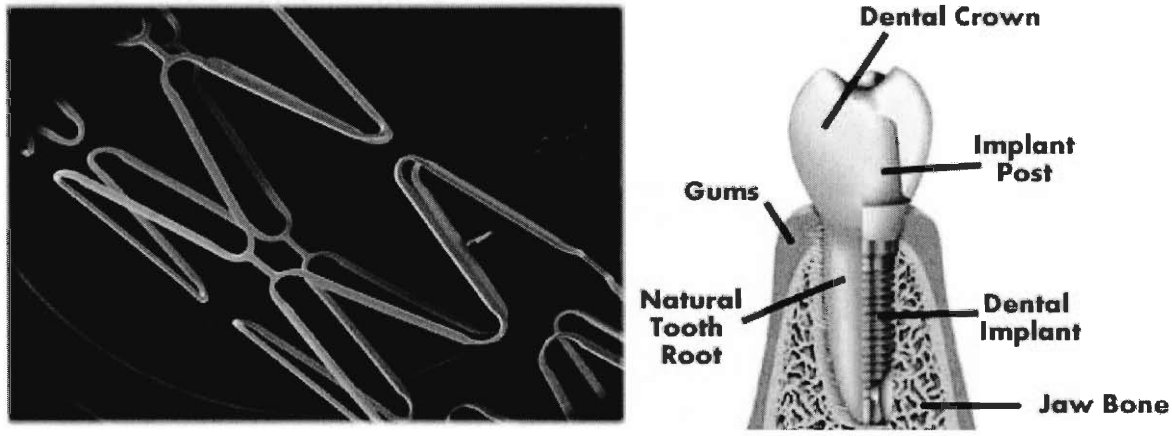

Figure 7: Intravascular stent[28](left) and Dental implant[29](right)

- *Artificial heart valves* are devices that replace a failed valve restoring proper blood flow. They are implanted in an artery near the heart and are of little concern from effects by magnetic fields because the force exerted on them by the heart pumping is many times greater than that of a magnetic field of several Tesla[24].
- New *ocular implants* have a permanent polymer implant to support the eye socket and surrounding tissues. A flexible fake eye sheet is then placed in the eye socket and is able to move like the patients original eye. However, older ocular implants used a permanently implanted magnet to align the false eye. Also there

are small metal tacks that are used in a regular eye to reattach a retina in a person whose retina has become detached from the back of the eye. These older devices can experience displacement forces in magnetic fields; however, a patient would most likely feel a sensation of pain, thus signaling them to leave the area [24].

- *Tissue expanders* used for cosmetic augmentation can contain metallic injection sites that would be susceptible to displacement or localized heating. These devices can also be used in patients who have a physical deformity and a patient may be reluctant to reveal the presence of such a device. The metallic injection points may be susceptible to displacement forces and heating, however in an industrial environment these effects would not be a concern[24].
- Miscellaneous non-medical objects may also be present in a patient. Objects such as *bullets, pellets, shrapnel, body piercing rings and other magnetic objects*, particularly ferromagnetic objects, are at risk of localized heating or displacement when exposed to EM fields. If the object is near soft tissues significant damage may be possible. It should be noted that patients may not always be aware of these objects in their bodies[24].

4.1.2 Major manufacturers of implantable medical devices

There are several companies that make the different kinds of medical implants mentioned above. The companies that were contacted are listed below. Note that in 1994, Saint Jude Medical acquired the cardiac sector of Siemans AG. It has also been estimated that nearly 100% of the pacemakers are produced by the first three companies[30].

- Guidant – Producer of Implantable Cardioverter Defibrillators (ICD), Cardiac Resynchronization Therapy Devices, and Pacemakers. Provides large quantity of EMI information on their webpage
- Saint Jude Medical – Producer of Implantable Cardioverter Defibrillators (ICD), Pacemakers, artificial heart valves and other non-active implants.
- Medtronic – Producer of Implantable Cardioverter Defibrillators (ICD), Pacemakers, artificial heart valves, neurostimulators, drug infusion pumps, spinal structuring non-active implants and other non-active implants
- Cochlear Corporation– Producer of cochlear implants
- Biomet – Producer of Orthopedic Implants
    - Cobalt Chrome
    - Ti 6 4 Vanadium
    - Ultra High Molecular Weight Polyethylene
- Bio-eye – Producer of Ocular Implants
- 3Implant – Producer of Dental Implants

4.1.3 Summary of susceptibility and possible failure modes

In this section we present the various medical devices in a summarized and tabulated form. The "Susceptibility" is scaled such that "High" indicates the maximum level of concern. This level does not necessarily mean that the person's life is in danger or that the operation of their implant is in danger. An elevated "Susceptibility" rating means that additional precautions may be required. The different "Susceptibility" ratings were assigned for different ranges of safe magnetic field exposures.

- "High" for safe exposure between 1 – 5 Gauss,
- "Medium" for safe exposure around 15 Gauss,
- "Low" for safe exposure less than 1 Tesla, and
- "None" for safe exposure over 1 Tesla.

All of these devices are designed to operate in day to day interference levels. The problem exists where biorhythms, or the electrical pulses created by bodily operations are within the window of 10Hz to 100Hz. As a result, active implants with filters could still receive a false trigger when near 60Hz systems. However, these problems occur at levels that are several times that of normal daily exposure. Implants with strong fixed magnets may experience an attractive force to static magnetic fields. This force may be noticeable but is very unlikely to be of any risk of injury to the patient.

Small passive implants, ferromagnetic and diamagnetic, have such a small interaction factor that they are of minimal concern in almost any field environment. Large passive implants are made exclusively from non-ferromagnetic materials such as Cobalt Chrome, Ti 6 4 Vanadium and Ultra High Molecular Weight Polyethylene and are of little concern. (Appendix C: Phone Contacts, Biomet) The following table lists different types of devices and explains their function and possible failure modes. It is important to know that each of these categories has hundreds of different variations depending on device programming and device manufacturers. If there is a specific concern in an environment these variations need to be considered.

In this report we have attempted to isolate the lowest common denominator among different devices. Most of the information in this table came from the 'Reference Manual for MR Safety' written by Frank Shellock[31]. Although the focus of this book is primarily on MRI, there is valuable information about implant composition and the areas of concern on specific types of implants.

Table 2: Summary of susceptibility and failure modes of implantable medical devices

Implantable Medical Device	Description	Susceptibility	Possible Failure Modes
Heart Valves and Annuloplasty Rings	A retaining ring holds metal or plastic flaps in place to open or close them when the heart beats. These devices replace normal heart valves or support the surrounding tissue, restoring natural valve operation.	None	Due to the volume of blood flowing past these implants heating is of no concern. The force of the beating heart exerts approximately 7.2N on the device[31]. This is significantly greater than any attractive forces to a field source. The safe exposure level for the heart valves is limited to a 3 Tesla field. (*Guidant Attachment #2*)
Clips	These devices are used to hold different tissues in place during and after surgery. May be made of almost anything. These types of devices are also used to clamp off the supply blood vessel to an aneurysm.	Low	Some of these are highly ferromagnetic, but since they are all very small relative to their surface area, low level fields would have a minimal effect on them. Clips used for aneurysms are of greater concern because of the delicate tissues involved. Slight displacement forces could rupture an artery. However, these kinds of forces occur when the surrounding field is on the order of 1.0 Tesla (6.5 k lines/in^2).
Needles	Used to place stitches, identify an area on a radiograph or provide an entry point for a catheter.	Low	These are generally removed after surgery so it is unlikely that they would cause any great concern in the industrial setting.
Staples	Used as a fast and easy replacement for sutures.	Low	These are generally temporary until an incision has healed. Although attractive forces may exist, they are of no concern except in extremely large fields.

Table 2(continued): Summary of susceptibility and failure modes of implantable medical devices

Implantable Medical Device	Description	Susceptibility	Possible Failure Modes
Intravascular Stents	These are devices designed to support the walls of an artery after placement. Generally they can be inserted using a special surgical catheter.	Low	Similar to a heart valve, any attractive force would be smaller than the force exerted by the beating of the heart. Also these devices become securely integrated into the vessel wall 6 to 8 weeks after implantation, by means of fibrosis.
Coils	Similar to stents and may be used to treat a variety of internal support problems. Generally more flexible than stents.	Low	
Intravascular Filters	These devices are implanted in the same way as stents and are used to catch blood clots suspended in the blood stream. These devices can be metallic.	Low	
Sutures	These are generally temporary implants, however some internal suturing is meant to be permanent. Most sutures are made of some kind of non-metallic thread, however some are metallic.	None	There is little concern for sutures that have had their needles detached inside of patients. Even metallic thread is of little concern simply because it has relatively low mass compared to its surface area. Since sutures form a coil, its magnet interactions would be amplified, but high frequency EMI could cause resonance, similar to broken catheters.
Dental Implants	These implants can be fillings, bridgework, braces, dentures, retainers, etc. Some of these implants can contain a small magnet to provide fixation.	Low	The small magnet may be of concern in extremely powerful fields (order of Tesla), but because dental work is very well attached there is little risk of displacement. Heating is also of little concern due to the small size of these implants.

Table 2(continued): Summary of susceptibility and failure modes of implantable medical devices

Implantable Medical Device	Description	Susceptibility	Possible Failure Modes
Pacemakers	Provides a small low current regular pulse to regulate heart beating in patients who have erratic heart rates.	High	These devices contain reed switches that are used as part of the programming process. Magnetic fields can trip this switch causing the device to enter a different mode while waiting to be programmed. Generally this is not life threatening unless the patient is dependant on the device to survive. These devices can also enter a different mode in response to EMI. This mode may not reflect the patient's current state and could be damaging. Manufacturers suggest that this condition would be temporary unless the interference is sufficient to damage the internal circuitry. Manufacturer recommendations vary from 1 to 15 Gauss (6.5 to 97 lines/in^2) as safe levels. Static fields are considered safe when less than 5 to 10 Gauss (32 to 65 lines/in^2). Time varying fields up to 3KHz are considered safe when below 2.0 Gauss (13 lines/in^2) RMS. Electric Fields are Considered safe if under 6.0kV/m (150 V/in) RMS and 140kV/m (3.56 kV/in) at high frequencies. Broken leads for these devices can cause resonance at high frequencies that can be of particular danger to patients since high temperatures and voltages will occur at the ends of the leads. Fortunately, this occurs in less than .02% of implantees that have leaded devices implanted[31]. Modules may be placed anywhere in the body with electrodes running subcutaneously to the target site.
Cardioverter Defibrillators	These devices are similar to pacemakers with the difference that they have the capability to shock the heart with a high current pulse, when ventricular fibrillation or heart failure is detected. These devices don't need to be active all the time like pacemakers and in fact can be intentionally disabled by the presence of a magnetic field. This can be problematic if the patient does not know their ICD has been disabled in a field that is strong enough to trip a reed switch.	High	
Neurostimulators	Neurostimulators are used for a wide variety of treatments involving nerve stimulation. These devices are used for pain control in patients with nerve damage or chronic pain. Parkinson's Disease patients also benefit from this technology. Other uses include muscle control and bodily function control. Malfunction of these devices is generally not considered life threatening. These devices are generally activated by a static magnetic field passed over the implant site, and are charged using a fluctuating magnetic field over the implant site.	High	

Table 2(continued): Summary of susceptibility and failure modes of implantable medical devices

Implantable Medical Device	Description	Susceptibility	Possible Failure Modes
Miscellaneous Objects	Small things such as bullets, shrapnel, body piercings, metal splinters and beads from welding fall into this category. A common place for these implants is in the abdomen, legs, hands, and eyes. Patients are not always aware of the presence of this kind of implant.	Medium	These items may be of concern in high strength fields but are generally too small to be of concern in low strength fields. The largest concern in this category comes from ferromagnetic objects implanted in the eye. In moderate to strong fields these objects can be displaced causing pain, injury and possibly blindness. Generally a patient would feel discomfort or pain before any damage occurs. This would enable the patient to leave the area before incurring further damage.
Orthopedic Implants	Implants such as joint replacements, bone restructuring hardware, internal fixation devices, and cartilage replacements.	None	These implants are generally made of materials that are non-ferromagnetic and fixed to the skeletal structure such that displacement forces are of no concern. Due to the size of these implants any resultant heating would require an extremely dense field to effect any significant temperature change.
Cochlear Implants	This is the next generation of hearing aids. People who have lost their hearing and still have intact cochlear nerves can have a nerve stimulator implanted that will translate sounds into electrical pulses read by the brain as sounds. This device generally consists of an implanted module that is inductively coupled to an external device that contains a power source and audio pickup. The external device is generally held on by a permanent magnet that is part of the sub-dermal portion of the implant.	Medium	Magnetic coupling with the pick-up under the skin can theoretically cause a humming or other interference to be heard by the patient in a sufficiently strong field. Also the device may experience a slight displacement force due to the fixed magnet. This would not be harmful to the patient. For example, in an MRI environment the fixation magnet was demagnetized during safety evaluations and would have had to be replaced if it was in a patient[31].

Table 2(continued): Summary of susceptibility and failure modes of implantable medical devices

Implantable Medical Device	Description	Susceptibility	Possible Failure Modes
Drug Infusion Pumps	These implanted pumps are used to deliver drugs to a patient without the need for the presence of an intra-venous line. The injection site to refill the reservoir generally has a small support ring or a magnetic ring to guide the needle into the reservoir. They can be powered by a battery, mechanism similar to a wind up clock, or by gas pressure through an internal pneumatic pressure reservoir system.	Medium	Slight displacement forces are possible with these devices due to the presence of some ferromagnetic material, but would most likely not be noticeable. The catheter that carries the drugs to the injection site may contain a wire for stiffness. If broken away from the implant this could resonate in a high frequency field causing discomfort or injury to a patient. Otherwise, failure of these devices is generally not considered to be life threatening.
Tissue Expanders	These implants are generally made entirely of polymers but they can contain injection sites similar to implantable drug infusion pumps. These sites enable the doctor to inject fluid into the implant or remove fluid from the implant.	Medium	
Programmable Hydrocephalus Shunts	These are relatively simple pressure release valves for patients that produce too much spinal fluid. The release pressure can be varied by application of an external magnet.	Medium	A sufficiently large field could possibly cause a pressure change that could lead to deterioration in patient health until functionality is restored. Generally not life threatening unless left inoperative or malfunctioning.
Bone Growth Stimulator	These are electrical implants that simply provide a small constant current supply to a site to stimulate bone growth. These are generally used to treat spinal injuries to speed the healing process.	Low	Failure of this device is not life threatening. Similar to the pacemakers if a lead becomes detached, high frequency electric or magnetic fields could cause resonance which could be harmful to a patient. This implant is simple in design and operation and has no microprocessor that might become disabled in the presence of interference.

Table 2(continued): Summary of susceptibility and failure modes of implantable medical devices

Implantable Medical Device	Description	Susceptibility	Possible Failure Modes
Troutman Ocular Implant	This ocular implant used a strong magnet to maintain the alignment of the false eye. One magnet would be placed in the orbit's muscle tissue so similar movement could be observed between the false eye and the real eye.	Medium	The fixation magnet in this implant can be of concern in strong magnetic fields, but risk of injury to the patient, in fields that are several orders of magnitude lower than 1.00 Tesla (65 k lines/in^2), is minimal
New Ocular Implants	New ocular implants use polymers to restructure the orbit and replace the iris and pupil.	None	There are no ferromagnetic or conductive parts in the false eye implant, so interaction with any kind of field is negligible.
Other Ocular Implants	There are small metal tacks that are used in a regular eye to reattach a retina in a person whose retina has become detached from the back of the eye. There are also wires that are used to reconstruct the orbit or support an eyelid.	Low	Retinal tacks are a concern in large fields but are generally safe in fields that are orders of magnitude lower than 1.00 Tesla (65 k lines/in^2).
Contraceptive Diaphragm	These devices are used as a female contraceptive and contain a metal ring to support the implant.	None	These implants use non-ferromagnetic metals for the support ring and therefore displacement is of little concern. Heating is of no concern in static fields, and because of the orientation of the device in the patient there would be minimal current induced in the ring.

4.2 Standards and industry regulations for medical devices

Implantable medical devices, as discussed in the previous sections, have become a common solution to a range of health problems. These devices are frequently used to treat cardiovascular diseases, neurological disorders and to replace joints and bones in the body. This has made it necessary to establish standards and regulations for monitoring the safe and hygienic use of these devices. Standards and regulations have been established by different government organizations and industry regulators. This section provides a brief summary of these government institutions. In addition, a summary of the available standards is also provided.

4.2.1 Government organizations and industry regulators

It is very important that standards and regulations are developed to monitor the safety of implantable medical devices to minimize failures due to design, environmental effects and harmful emissions. Some of the government organizations and industry regulators involved in the development of standards and regulations for the medical devices are discussed below:

International Organization for Standardization (ISO):

ISO is a non-governmental organization, meaning its members are not delegates of national governments. It is a network of national standards institutes of 147 countries with a central secretariat in Geneva that coordinates the system. International standards provide the technological and scientific bases underpinning health, safety and environmental legislation. The conformity of products and services to International Standards provides assurance about their quality, safety and reliability[32]. With respect to medical devices, ISO has developed some standards related to surgical implants and has also provided methods to test the liability of medical devices with in areas of high magnetic fields (Magnetic Resonance Imaging machines).

American Society of Testing and Materials (ASTM):

ASTM International was created in 1898 as a voluntary standards developing organization. ASTM is a not-for-profit organization that provides a forum for the development of standards for materials, products, systems and services. Some of the subject areas covered by ASTM standards are steel, petroleum, medical devices, property management, consumer products, and many more[33].

Institute of Electrical and Electronics Engineers (IEEE):

IEEE is an electrical engineering based society which develops standards and publishes reviews from experts in different fields of electrical engineering. It also hosts conferences and seminars between engineers from different countries to promote the flow of knowledge into developing countries. The IEEE Electromagnetic Compatibility (EMC) Society is the sub-organization which was contacted for information about standards related to the medical devices. The IEEE EMC Society strives for the enhancement of electromagnetic compatibility through the generation of engineering

standards, measurement techniques and test procedures, measuring instruments, equipment and systems characteristics, improved techniques and components, education in EMC and studies of the origins of interference[34].

World Health Organization (WHO) and United Nations Environment Programme (UNEP):

WHO and UNEP are the sub-organizations of the United Nations Organization. They collaborate to ensure the safety of medical devices. WHO is also hosting an International EMF project to gather information about different effects of EMF on human health due to electromagnetic interference. These organizations have hosted conferences and meetings to discuss the safety of implantable medical devices.

International Commission on Non-Ionizing Radiation Protection (ICNIRP):

ICNIRP's principal aim is to disseminate information and advice on the potential health hazards of exposure to non-ionizing radiation to everyone with an interest in the subject. ICNIRP's information and advice covers all of the non-ionizing radiations including, optical radiations (ultraviolet, visible and infrared - and lasers), static and time-varying electric and magnetic fields and radiofrequency (including microwave) radiation, and ultrasound[35].

American Conference of Governmental Industrial Hygienists (ACGIH):

The American Conference of Governmental Industrial Hygienists (ACGIH®) is a member-based organization and community of professionals that advances worker health and safety through education and the development and dissemination of scientific and technical knowledge[36]. This organization has been working with ICNIRP to formulate safe exposure levels for the workers with medical devices, pacemaker in particular.

International Electrotechnical Commission (IEC):

IEC is a global organization that prepares and publishes international standards for all electrical, electronic and related technologies. These standards serve as a basis for national standardization and as references when drafting international tenders and contracts. IEC embraces all electro-technologies, including electronics, magnetics and electromagnetics, electroacoustics, multimedia, telecommunication, as well as associated general disciplines such as electromagnetic compatibility, measurement and performance, safety and the environment[37].

European Union (EU):

EU is a group of democratic European countries working together for peace and prosperity in the region. European Commission is the working body of the Union which carries out its policies. One of the objectives of this commission is to verify the electromagnetic compatibility of medical devices and to ensure the availability of safe medical products to the public. This organization is the only major standards organization in Europe which deals with the safety of medical instruments and devices.

Center for Devices and Radiological Health (CDRH):

CDRH is the sub-organization of the Food and Drug Administration (FDA) which is responsible for ensuring the safety and effectiveness of medical devices and eliminating unnecessary human exposure to man-made radiation from medical, occupational and consumer products. Radiation-emitting products regulated by FDA include microwave ovens, video display terminals, and medical ultrasound and x-ray machines[38]. CDRH has also issued a Safe Medical Device Act which has been commissioned by FDA for the regulation of manufactured medical devices.

European Committee for Electrotechnical Standardization (CENELEC):

CENELEC was created in 1973 as a result of the merger of two previous European organizations: CENELCOM and CENEL. Nowadays, CENELEC is a non-profit technical organization set up under Belgian law and composed of the National Electrotechnical Committees of 23 European countries. CENELEC members have been working together in the interests of European harmonization since the 1950s, creating both standards requested by the market and harmonized standards in support of European legislation and which have helped to shape the European Internal Market. Its work directly increases market potential, encourages technological development and guarantees the safety and health of consumers and workers[39].

Association for the Advancement of Medical Instrumentation (AAMI):

The Association for the Advancement of Medical Instrumentation (AAMI), founded in 1967, is an alliance of over 6,000 members united by the common goal of increasing the understanding and beneficial use of medical instrumentation. AAMI is the primary source of consensus and timely information on medical instrumentation and technology[40]. It has compiled few standards in regards to medical devices and instruments and is also concerned with the EMC of medical devices.

Occupational Safety and Health Administration (OSHA):

OSHA was created in 1971 to ensure safe and healthful workplaces in America. Since then, workplace fatalities have been cut into half[41]. OSHA has many standards related to the protection of workers from ionizing and non-ionizing radiations found in the work places. These standards also address the effects of Extra Low Frequency (ELF) fields which are the 60Hz magnetic fields emitted from power generation equipment. However, all these standards address the effects of ELF fields on biological health of the workers and none of these standards deal with the effects on medical devices.

These organizations and regulators have developed guidelines and regulations for both the manufacturers and the consumers. There are also some standards for effective measurement of the intensity of magnetic fields and the corresponding levels over which these methods are valid. There are standards and regulations for the electromagnetic compatibility of medical devices, IMD design and manufacture and electromagnetic emissions. These standards and regulations are discussed below.

4.2.2 Standards and regulations on EMC of medical devices

This section lists all the available standards and regulations for the electromagnetic compatibility of medical devices. The standards are grouped with respect to the organization which either developed them or included them in their database. Each standard listed includes the standard's numerical identification, title and a short explanation. This short explanation has been taken from the scope of the standard mentioned by the developer. The explanation is based exclusively on the information provided by the developer, since obtaining any further information would require purchasing the standards.

CENELEC:

EN 60601-1-2: Medical electrical equipment -- Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests

This standard specifies requirements and tests for electromagnetic compatibility of medical electrical equipment and medical electrical systems and serves as the basis of electromagnetic compatibility requirements and tests in particular standards. The existence of electromagnetic emission requirements is essential for the protection of: - safety services; - other medical electrical equipment and medical electrical systems; - non-medical electrical equipment (e.g. computers); - telecommunications (e.g. radio/TV, telephone and radio-navigation). The existence of electromagnetic immunity requirements is essential to assure safety of equipment and systems. The immunity test levels specified in this standard (EN 60601 test levels) represent the range found in the general medical use environment.

EN 60601-1-4 and EN 60601-1-4/A1: Medical electrical equipment -- Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems

This standard specifies requirements for the process by which a programmable electrical medical system is designed. It serves as the basis of requirements of particular standards, including serving as a guide to safety requirements for the purpose of reducing and managing risk. This standard covers requirement specification, architecture, detailed design and implementation software development, modification, verification and validation, marking and accompanying documents.

EN 60601-2-4: Medical electrical equipment -- Part 2-4: Particular requirements for the safety of cardiac defibrillators

This standard specifies the requirements for the safety of cardiac defibrillators. This standard covers requirement specification, architecture, detailed design and implementation software development, modification, verification and validation, marking and accompanying documents.

EN 60601-2-10 and EN 60601-2-10/A1: Medical electrical equipment -- Part 2-10: Particular requirements for the safety of nerve and muscle stimulators

This standard specifies particular requirements for the safety of electrical stimulators of muscles and nerves in the specialized practice of physical medicine. It excludes

stimulators used with implanted electrodes, brain stimulation, neurological research, cardiac pacemakers, defibrillators and other surgical procedures.

EN 60601-2-31 and EN 60601-2-31/A1: Particular requirements for the safety of external cardiac pacemakers with internal power source

This standard specifies the particular safety requirements for external pacemakers powered by an internal electrical power source. It also applies to patient cables but does not apply to equipment which can be directly or indirectly connected to supply mains.

EN 61326: Electrical equipment for measurement, control and laboratory use - EMC requirements

This standard specifies minimum requirements for immunity and emissions regarding electromagnetic compatibility (EMC) for electrical equipment, operating from a supply of less than 1000 V A.C or 1500 V D.C intended for professional, industrial process and educational use, including equipment and computing devices for: measurement and test; control; laboratory use; accessories intended for use with the above (such as sample handling equipment), intended to be used in industrial and non-industrial locations. Computing devices and assemblies and similar equipment within the scope of information technology equipment (ITE) and complying with applicable ITE EMC standards can be used without additional testing. Where a relevant dedicated EMC standard exists, it shall take precedence over all aspects of this product-family standard. The following equipment is covered in this standard: a) electrical measurement and test equipment - - this is equipment which by electrical means This equipment which controls one or more output quantities to specific values, with each value determined by manual settings, by local or remote programming, or by one or more input variables. This includes industrial process measurement and control (IPMC) equipment, which consists of devices such as: process controllers and regulators; programmable controllers (PC); b) power supply units of equipment and systems (centralized or dedicated); analogue/digital indicators and recorders; process instrumentation; transducers, positioners, intelligent actuators, etc. c) Electrical laboratory equipment - This equipment which measures, indicates, monitors or analyzes substances, or is used to prepare materials. This equipment may also be used in areas other than laboratories.

EN 50061: Safety of implantable cardiac pacemakers

This standard is currently in use by many manufacturers of implantable medical devices. Medtronic is one of the manufacturers who use this standard. This standard specifies safety and other requirements exclusively for all types of wholly implantable cardiac Pacemakers. This standard also establishes basic terminology and definitions and includes requirements for the marking of pacemakers and their packaging. In addition, minimum requirements are specified for the ability of pacemakers to withstand environmental stress conditions. Appropriate test methods are given. This standard specifies the requirements for the reliable operation of pacemakers only insofar as they affect safety. It does not cover the antitachyarrythmia and defibrillation functions of pacemakers, nor pacemakers operated by isotopic cells.

EN 50061/A1: Amendment to subclause 6.3 and addition of annex E

This is the amendment in one of the clauses of the above mentioned pacemaker standard.

AAMI/ANSI:

ANSI/AAMI PC69:2000: Active implantable medical devices - Electromagnetic compatibility - EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators

This standard specifies test methods appropriate to the interference frequencies at issue. The standard may specify performance limits or require disclosure of performance in the presence of electromagnetic emitters where appropriate. It provides manufacturers of electromagnetic emitters with information about the level of immunity to be expected from active implantable cardiovascular devices. This standard is currently used by Medtronic.

4.2.3 Standards and regulations on IMD design and manufacture

This section lists all the standards which discuss the safety requirements of the different medical devices. These standards also list the requirements for the manufacturers of the medical devices with regards to both design and safety measures. In addition to these, the guidelines and directives from the government organizations have also been included. The short explanation included with the standards has been taken from the scope of the standard mentioned by the developer. The standards in this section are also grouped according to the organization which developed them.

CENELEC:

EN 45502-1: Active implantable medical devices -- Part 1: General requirements for safety, marking and information to be provided by the manufacturer

This part 1 of EN 45502 specifies requirements that are generally applicable to active implantable medical devices. For particular types of active implantable medical devices, these essential requirements are supplemented or modified by the requirements of particular standards which form additional parts of this European standard. The tests that are specified in EN 45502 are type tests and are to be carried out on samples of a device to show compliance. This part of EN 45502 is applicable not only to active implantable medical devices that are electrically powered but also to those powered by other energy sources (for example by gas pressure or by springs). This part of EN 45502 is also applicable to some non-implantable parts and accessories of the devices. The device that is commonly referred to as an active implantable medical device may in fact be a single device, a combination of devices, or a combination of a device or devices and one or more accessories. Not all of these parts are required to be either partially or totally implantable, but there is a need to specify some requirements of non-implantable parts and accessories if they could affect the safety or performance of the implantable device. The terminology used in this European Standard is intended to be consistent with the terminology of Directive 90/385/EEC.

prEN 45502-2-1: Active Implantable Medical Devices Part 2-1: Particular Requirements for Active Implantable Medical Devices Intended to Treat Bradyarrhythmia (Cardiac Pacemakers)

The information about this guideline is evident from the title of the standard. It is currently in use by Medtronic as one of the reference standards.

prEN 45502-2-2: Active Implantable Medical Devices Part 2-2: Particular Requirements for Active Implantable Medical Devices Intended to Treat Tachyarrhythmia (Includes Implantable Defibrillators)

The information about this guideline is evident from the title of the standard.

prEN 45502-2-X: Active implantable medical devices -- Part 2-X: Cochlear implants

This guideline under development addresses the safety of cochlear implants.

EN 1642: Medical devices for dentistry – Dental implants

The document specifies general requirements for dental implants. Surgically implantable dental materials defined as restorative materials are specifically excluded.

ISO:

ISO 14708-1: Implants for surgery -- Active implantable medical devices -- Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

This standard provides the general requirements for safety, marking and for information to be provided by the manufacturer.

ASTM

ASTM F561-97: Practice for Retrieval and Analysis of Implanted Medical Devices, and Associated Tissues

1.1 This practice covers recommendations for the retrieval, handling, and analysis of implantable medical devices and associated specimens which are removed from patients, during revision surgery, at postmortem, or as part of animal studies. The aim is to provide guidance in preventing damage to the associated specimens which could obscure the investigational results, and in gathering data at the proper time and circumstance to validate the study.

1.2 This practice offers guidelines for the analysis of retrieved implants to limit damage to them, and to allow comparisons between investigational results from different studies. The protocols are divided into three stages, where Stage I is the minimum non-destructive analysis, Stage II is more complete non destructive analysis, and Stage III is destructive analysis. Standard protocols for the examination and collection of data are provided for specific types of materials in relation to their typical applications. For particular investigational programs, additional, more specific, protocols may be required. If special analytical techniques are employed, the appropriate handling procedures must be specified.

1.3 This practice recommendation should be applied in accordance with national regulations or legal requirements regarding the handling and analysis of retrieved implants and excised tissues, especially with regard to handling devices which may become involved in litigation, as per Practice E 860.

1.4 A significant portion of the information associated with a retrieved implant device is often at the device-tissue interface or in the tissues associated with the implant and

related organ systems. Attention should be given to the handling of adjacent tissues, so as not to interfere with study of the particles in the adjacent tissue, a chemical analysis for the byproducts of degradation of the implant, or a study of the cellular response to the implant.

1.5 This standard may involve hazardous materials, operations, and equipment. As a precautionary measure, removed implants should be sterilized or minimally disinfected by an appropriate means that does not adversely affect the implant or the associated tissue that may be subject to subsequent analysis. This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

FDA (CDRH):

Safe Medical Devices Act (SMDA)

This is a list of regulatory documents that have been the basis of approval for any medical device built in United States. The Safe Medical Devices Act consists of three major documents that need to be filled by the manufacturer for getting safety approval on a particular medical device. These documents are:

- 515(i) Reclassification letter to manufacturers
- SMDA changes – Pre-market Approval (PMA)
- SMDA changes – Pre-market notification; regulatory requirements for medical devices

Each of these documents has a series of related documents which needs to be submitted for approval. All these documents can be requested from CDRH.
The standards for the safe exposure levels and electromagnetic compatibility of medical devices are usually incorporated from IEC. There are no particular standards for the immunity of the implantable medical devices from electromagnetic fields. In 1979, FDA developed one pacemaker standard MDS-201-0004 which is now considered a voluntarily standard. However, this standard is old, so FDA recommends the new standard EN 60601-1-2 included by CENELEC for testing the devices for EMC.

EU (European Commission)

The European Commission has three directives that regulate the medical devices. These directives define the essential requirements that devices must meet before being placed on the market. They establish conformity assessment procedures and create mechanisms available to national competent authorities to manage implementation or to intervene on the market when reasons of public health so require; they are based on the New Approach and, thus, contain provisions on conformity assessment procedures involving Notifies Bodies and Harmonized Standard elaborated by CEN, CENELEC or ETSI, providing a presumption of conformity with the Directives' essential requirements. These directives are listed below:

- Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD)
- Council Directive 93/42/EEC on Medical Devices (MDD)

- Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDMD)

These directives are available online on the European Commission's website. A link to these documents has been included in Table 3.

4.2.4 Standards and regulations on emissions

This section discusses the standards and regulations on the different classifications of EMI emissions. These standards also include the electromagnetic compatibility requirement for different emissions in different environments. These standards are grouped according to the organizations which developed them. The short explanation that has been included with these standards and regulations has been taken from the information provided by the developer.

CENELEC

EN50081-1: Generic emissions standard for domestic, commercial and light industrial environments

This standard for emission requirements applies to electrical and electronic apparatus intended for use in the residential, commercial and light-industrial environment for which no dedicated product or product-family emission standard exists. Apparatus designed to radiate electromagnetic energy for radio communications purposes is excluded from this standard. Where a relevant dedicated product or product-family EMC emission standard exists, this shall take precedence over all aspects of this generic standard. Apparatus installed in the locations covered by this standard are considered to be directly connected to low-voltage public mains supplies or to a dedicated DC source which is intended to interface between the apparatus and the low-voltage public mains supply. Apparatus intended to be connected to an industrial power network or to special power supply sources are covered by EN50081-2 generic standard discussed below.

EN50081-2: Generic emissions standard for industrial environment, used when no product specific standards exist.

This standard for emission requirements applies to electrical and electronic apparatus intended for use in the industrial environment for which no dedicated product or product-family emission standard exists. Apparatus designed to radiate electromagnetic energy for radio communications purposes is excluded from this standard. Where a relevant dedicated product or product-family emission standard exists, it shall take precedence over all aspects of this generic standard. The environments encompassed by this standard are industrial, both indoor and outdoor. Apparatus covered by this standard is not intended for connection to a public mains network but is intended to be connected to a power network supplied from a high or medium-voltage transformer dedicated for the supply of an installation feeding manufacturing or similar plant. This standard applies to apparatus intended to operate in industrial locations or in proximity to industrial power installations.

FCC

FCC Part 18: Regulation for industrial, scientific and medical (ISM) equipment

The rules in this part, in accordance with the applicable treaties and agreements to which the United States is a party, are promulgated pursuant to section 302 of the Communications Act of 1934, as amended, vesting the Federal Communications Commission with authority to regulate industrial, scientific, and medical equipment (ISM) that emits electromagnetic energy on frequencies within the radio frequency spectrum in order to prevent harmful obstructs or repeatedly interrupts a radio communication service. This part also includes information on equipment or appliances designed to generate and use local RF energy for industrial, scientific, medical, domestic or similar purposes, excluding applications in the field of telecommunication.

4.2.5 List of relevant standards and regulations

This section compiles all the relevant standards and regulations concerning implantable medical devices in a tabular form as shown below in Table 3. The information about the location of these standards is also included. These standards are grouped according to the standards organizations that developed them.

Table 3: List of relevant standards

Standards Organizations	Standards	Location
CENELEC	EN 60601-1-2 EN 60601-1-4 EN 60601-1-4/A1 EN 60601-2-4 EN 60601-2-10 EN 60601-2-10/A1 EN 60601-2-31 EN 60601-2-31/A1 EN 61326 EN 50061 EN 50061/A1 ANSI/AAMI PC69 EN 45502-1 prEN 45502-2-1 prEN 45502-2-2 prEN 45502-2-X EN 1642 EN50081-1 EN50081-2	http://www.cenelec.org/Cenelec/Code/Frameset.aspx
AAMI/ANSI	ANSI/AAMI PC69	http://www.nssn.com/search.html
ISO	ISO 14708-1	http://www.nssn.com/search.html
ASTM	ASTM F561-97	http://www.nssn.com/search.html

Standards Organizations	Standards	Location
FDA (CDRH)	Safe Medical Devices Act	http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/topicindex/topindx.cfm?alpha=s
EU (European Commission)	Directive 90/385/EEC Directive 93/42/EEC Directive 98/79/EC	SEE MDD 90/385/EEC SEE MDD 93/42/EEC SEE MDD 98/79/EC

4.3 Methods of magnetic field measurement

There are many methods to measure a magnetic field in a certain area. Each of these methods is useful for different situations. Although they can make use of the same meter for the actual measuring, the real difference lies in how the field is measured, where it is measured, time intervals, and the metrics of the measurement. In the case of magnetic fields, the metric is chosen to describe how much a person is exposed to the field. There are many methods, but 4 major ones were found to be relevant to IMDs. These four methods are developed by NIOSH[42] and IEEE[44] and are discussed below.

4.3.1 Methods for measuring magnetic field strength

Method 1 involves an initial walk-through survey of the exposure area. It helps to find any possible sources of EMF. This method is best done before any other methods to assess where the sources to be concerned with are located. Method 2 helps to find the magnetic flux through a given room or area; this is useful in finding the average exposure of a person over time. Method 3 allows one to find the EMF emanating from AC transmission lines, which can have very large fields and carry current constantly. This is useful as a general guideline for people with IMDs. Method 4 describes a personal monitoring of a person with an IMD to see how much EMI the person is exposed to in an average day. This is the most straightforward and can probably give the most accurate description of one's exposure level. Accompanying these four measurement methods is the deflection angle test. This is used primarily to find out if aneurysm clips are ferromagnetic or not, but can pertain to any small metallic object to test its ferromagnetism. This test comes from *Magnetic Resonance Procedures: Health Effects and Safety* by Frank G. Shellock[43]. These methods can be used solely or together. It is best to find out which method or methods are most advantageous before any actual measurements are taken. The methods are listed below by section number according to the number of the method.

4.3.1.1 Initial walk-through survey

When assessing the exposure in an area with many potential magnetic field sources, an initial walk-through survey is useful. If any of the other three methods described below are to be used, it may be very useful to complete this method first. Begin by drawing or acquiring a floor plan and include all electrical devices. It may be useful to find out any

outside sources that may also propagate magnetic waves into the building. These outside sources include but are not limited to generators, power lines, transformers, air conditioning units, etc. This should all be done keeping in mind that a magnetic field propagates though walls with little to no attenuation.

When the floor plan is finished, the actual measuring can begin. This measurement method is accomplished by taking many spot measurements around the potential magnetic field emitting devices. Keep track of distances and strengths and write them right on the floor plan. If a strong field is found coming from an area with no marked device, it is important that the source be found so it can be shielded or avoided if necessary. The affected persons with IMDs should also be added to the drawing at the location(s) where they would typically be in a normal day. This can be done by placing a 'X' in their location(s). When every source has been checked, look over the map to find any overlaps of the attenuating magnetic field and a person with an IMD. If the field in the overlapping region is of a significant value (anything over 1.0 Gauss[45] (6.5 lines/in^2) is potentially dangerous to persons with an IMD) the person with IMD should be moved and should not be present in the field for any reason. The exposure metric in this case would be the exposure of a person with an IMD to each of the magnetic field sources found by this method. This method is used as a primary walk-through assessment of the area.

4.3.1.2 Average flux measurement

This method is used to determine the average flux of a magnetic field through a certain room. This is done by setting up five stands, about one meter (40 in) high each, in a two-dimensional horizontal array. Keep track of the distances between the measurement points.

Next, calculate resultants from the three orthogonal components and average over five points. This will give the spatial average of the static magnetic field magnitude. For static magnetic fields from high-intensity magnets or DC currents, a Hall-effect Gaussmeter is required. Since the measurements are taken at a single elevation, they will not characterize any variations in the static magnetic field magnitudes with elevation. The procedure, as described by NIOSH, is as follows:

1. Take static field measurements with an axial flux-gate magnetometer probe inserted into three orthogonal holes drilled into a plexiglass block mounted on a stand 1 meter above the ground. Orient the stand so the horizontal axes form a left-handed coordinate system aligned with respect to building:
x-axis = perpendicular to the front of the building
y = parallel
z = vertical
On the data sheet, record each component of the static magnetic field. If the absolute direction of the field vector may be required, record the sign of the magnetometer reading as well.

2. At each site, take four additional measurements at an equal distance away from the central site equal to 3.0 m (120 in) or a lesser distance (if necessary). The five measurement sites form a cross along the x- and y-axes. On the data sheet, record

the distance between sites as well as the static field components so that the spatial variability can be calculated as a gradient.

3. One set of measurements will be taken out-of-doors away from any building or metallic objects. At this site, use the same axes with respect to the building orientation.

Calculations

1. For each point in the five-point grid, calculate the static field magnitude by taking the resultant of the x, y, and z components. Average the field over the five points.
2. Calculate the partial derivatives in the x- and y-directions.

The partial derivatives, when drawn out on the map as vectors, will map out the magnetic field with the vectors pointing in the direction of highest magnetic potential. The exposure metric for this method is the average magnetic flux a person is exposed to for a given time period in a certain area.

4.3.1.3 Field measurements from power-frequency AC transmission lines

The third method presented here is used primarily to measure a power-frequency EMF from an AC transmission line. This report does not generally cover AC transmission lines, but the fields propagating from them are still important in a world full of stray EMFs. If there are high power transmission lines near the desired location, this may be a useful method to try.

This method is best done a few different days, to get the time-weighted average and maximum values since stronger EMF may be emitted from them on different days. The measurements are done parallel to the wires, about one meter off the ground. Start directly under the wires and work out towards the location of the people who may be affected. The measurements should be done in a few different locations along the wires. Keep the distances perpendicular to the wire consistent as you continue along the wires, moving the measurement points outward. Each measurement along the wires should be essentially the same value as the parallel measurement point, the same distance from the wires. Do this on a few different days and calculate the average value. This will yield the average amount of EMFs per day to which an affected person is exposed.

Even if the area containing the person or persons with IMDs receive only a small amount of EMI from the lines, since the lines are being used everyday, this adds up over time. The magnetic flux density should be measured. IEEE[44] recommends using a meter containing three-axis induction coils for this task, calibrating it with power-frequency magnetic fields to around 50-60 Hz. The exposure metric used in this case is the measured EMF vs. distance from the transmission lines. The measurements should be done away from towers, which could interfere with the readings.

When all the data has been collected, a map should be drawn showing lines parallel to the transmission lines, where the measurements were taken. This is best done after Method 1 has been applied. The map of the field lines from the transmission lines can be drawn on the same map used in Method 1. The average values should be written in at each parallel

point to show how the field decays. If the overlapping value is higher than 1.0 Gauss[45] (6.5 lines/in2) the person or persons with the IMD should be relocated to a safer area.

4.3.1.4 Personal monitoring

This method involves monitoring of an individual with an IMD. The person wears a Gaussmeter; once again, a device containing three-axis induction coils (ferrite-core) is recommended, as it measures his/her exposure to EMF throughout the day. The person should wear the meter for at least four hours. The device should be set up at a sampling rate of about one measurement every 1 to 5 seconds. In this case, the exposure metric would be the magnitude of the magnetic field exposure over time.

This method has proven to be the most reliable among many other methods to measure direct exposure. This method is typically used for epidemiological studies. In our case, the person with the IMD will be monitored to see how much their IMD is exposed to the EMI. Method 1 is recommended before this to find if there are any fields exceeding 1.0 Gauss[45] (6.5 lines/in^2). The person with the meter in this method should avoid those areas, even when carrying out this method. Many meters can upload the data to a computer. If this is possible, it is recommended since the computer can map out the day's exposure for the person. If not, the data should be collected and graphed so that the total amount and the maximum value of exposure can be assessed.

4.3.2 Testing ferromagnetism of materials using deflection angle test

This test is used primarily to determine if an aneurysm clip is ferromagnetic. It is the official method of FDA and ASTM for electromagnetic compatibility of aneurysm clips with MRI machines. Since this test will not work in a time-varying field, this test can only pertain to static magnetic fields. A ferromagnetic clip has the potential to be dangerous in a strong static magnetic field where a non-ferromagnetic clip is safe in a field even as strong as a MRI machine (1.5 Tesla or 97 k lines/in^2)).

The clip to be examined is suspended at the end of a string and held stationary in the vertical direction and is placed in position at the climax of the magnetic field; that is the point where the highest spatial gradient field exists. This can be determined using the measurement methods provided. Once the clip is released, the deflection of the clip on the string is then observed. This is also a good way to determine the direction of the magnetic field lines. If the deflection of the string forms an angle less than 45° to the vertical axes, the gravitational force is stronger than the magnetic force. ASTM recommends a string length of 30.0 cm (11.8 in) and 4.0 silk or a similar low weight material be used for the testing for an MRI machine. The same recommendation can be used for this test.

The angle formed by the string relative to the vertical axes determines whether or not the clip is safe (non-ferromagnetic). ASTM states that the safety line can be drawn at 45°, meaning anything below this is safe, anything 45° or greater is not safe (ferromagnetic).

When a doctor implants a clip, he/she should present the patient with the necessary information about the clip. This information includes the manufacturer and the clip's model number. With this information, the manufacturer should be contacted and another clip of the exact same model can be sought. The test can be done using a similar clip of

the same make and model. It is extremely important that the test is done with same model clip since different models can have very different magnetic properties.

4.4 Accidents and case studies

Magnetic fields from many devices can be dangerous to IMDs. Many injuries to people with IMDs have been attributed to the interference with magnetic fields. Most of these injuries occur from an EMF in the range of 5.0mG (0.032 lines/in^2) or greater and have also occurred from an MRI machine (1.5 T or 97 k lines/in^2). Since the MRI produces such a strong magnetic field, the magnetic force or even currents induced in an IMD from the MRI can be very harmful to the person. There have been at least 15 documented magnetic resonance imaging (MRI) related incidents[46] and 23 documented case studies and non-MRI related incidents[47] involving medical implants where electromagnetic interference was found to be the cause of the problem.

MRI related incidents

Below is a list, acquired from the FDA[46], of ten accidents due to EMI from an MRI machine and the dates on which they occurred. The list contains both implanted devices and even some incidents involving non-implanted devices.

- A patient with an implanted cardiac pacemaker died during an MR exam. (12/2/92)

- A patient with an implanted cardiac pacemaker died during or shortly after an MR exam. The coroner determined that the death was due to the interruption of the pacemaker by the MR system. (9/18/89)

- A patient with an implanted intracranial aneurysm clip died as a result of an attempt to scan her. The clip reportedly shifted when exposed to the magnetic field. The staff apparently had obtained information indicating that the material in this clip could be scanned safely. (11/11/92)

- Dislodgement of an iron filing in a patient's eye during MR imaging resulted in vision loss in that eye. (1/8/85)

- A patient complained of double vision after an MR exam. The MR exam as well as an x-ray revealed the presence of metal near the patient's eye. The patient was sedated at the time of the exam and was not able to inform anyone of this condition. (12/15/93)

- An IV pole was attracted to the magnet and struck a patient, cutting his arm. The patient required stapling of the cut. (8/30/94)

- A pair of scissors was pulled out of a nurse's hand as she entered the magnet room. The scissors hit a patient causing a cut on the patient's head. (8/2/93)

- An oxygen bottle struck a patient while the patient was being placed in the magnet bore. The patient received injuries requiring sutures. (6/2/91)

- Two steel tines (parts of a fork lift) weighing 80 pounds each were accelerated by the magnet striking a technician and knocking him over 15 feet resulting in serious injury. (6/5/86)

Current induced heating on IMDs

When a magnetic field varies with time, as in pulsed gradient magnetic and pulsed radio frequency fields, a current can be induced in an IMD, especially when a loop can be created in the metal or even leads of the implant. The induced current can increase greatly to the point where it produces enough heat to burn the tissue. Below are 6 more accidents, acquired from the FDA[46], in which heating occurred in a medical device, not necessarily implanted, due to inducted currents.

- An electrically conductive lead was looped and placed against bare skin causing a burn on the patient's upper arm. (5/19/95)

- A child received a burn to the right hand from an ECG cable while the patient was anesthetized. A skin graft was required to treat the affected area. (1/26/95)

- A patient received a 1.5" x 4" blistered burn to the left side of the back near the pelvis from an ECG gating cable. (9/23/91)

- A patient received blistered burns on the finger where a pulse oximeter was attached during MR scanning. A skin graft was required to treat the affected area. (2/27/95)

- A patient received small blistered burns to the left thumb and left thigh. Reportedly, the operator input an inaccurate patient weight resulting in an incorrect SAR value. (2/10/93)

- A patient with an implanted insulin infusion pump was placed in an MR scanner resulting in movement of the device. The pump was removed from the patient and subsequently found to be non-functional (1/13/88).

Injuries and case studies accomplished from non-MRI interference

The above cases relate to incidents from an MRI machine. There are many other devices that can emit a magnetic current strong enough to cause an injury to a person with an IMD. Medical Device Accidents by Leslie A. Geddes[47] compiled many incidents and case studies involving EMI with IMDs caused by a source other than MRI machines. These outside interferences came from many different electrical devices such as TV's, cell phones, walkie-talkies, etc. In a few cases, a case study was done following the

injury in order to replicate the problem. These case studies are marked in italics following the injury. Most of the examples acquired by Geddes were from another source. The 16 injuries are listed below with the original source cited.

- A 14 year old was referred to the Mayo Clinic EEG lab for evaluation of generalized tonic-colic seizure. During the procedure both parents were present in the same recording room as the patient and the technologist. After approximately three minutes of recording, an unusual artifact appeared which then recurred approximately every 40-120 seconds. Both parents had the cellular phones which were turned on but had not rung or otherwise used. Upon removing of the cell phones from the recording room to approximately 20 feet away, no further artifacts occurred. This occurred because the cell phone sends out an EMI pulse about every 40 seconds[48].

- In 1992, a doctor installed an apparently unnecessary pacemaker in a patient's chest after an electrocardiogram telemetry system made by SpaceLabs Inc. displayed "long periods of flat line." That evening the same phenomenon recurred. Nurses discovered that the patient was next to a TV set when the flat lines occurred[49].

- A ventilator experienced keyboard lockup, due to interference from a guard's walkie-talkie. Two ventilators that were within 20 feet of each other alarmed simultaneously. That day the ventilators alarmed frequently; it was discovered that the power company was using walkie-talkies in the area. The hospital staff was able to duplicate the problem using walkie-talkies in the hospital[50].

- The operations and readouts of ventilators were affected by keying of two-way hand-held FM radios, both in the same room and in the next room. The low minute volume alarm would sound, the analog display would indicate an exhaled minute volume of zero, and the digital display would indicate negative values of exhaled minute volume[50].

- A microprocessor-based intensive care ventilator ceased operating and alarmed, and microprocessor-based infusion pumps stopped working when a portable X-ray machine was turned off in the vicinity[50].

- While in use during a flight, a portable ventilator operating on battery power stopped cycling and alarmed several times. Factory evaluation revealed that radio frequency interference cause false signals. The unit was updated and the cable was shielded[50].

- An infusion pump changed rate when a cellular phone was placed on the instrument stand[50].

- The reading of all invasive blood pressure monitors in an ICU/CCU jumped from 3 to 10 mm Hg when a 150-W paging transmitter on the hospital roof was activated. Displays of telemetry patient monitor would "flat-line" when a paging company transmitted digital control information to its remote sites[50].

- In Denmark a single-patient haemodialysis monitor stopped working when a mobile telephone was used on the floor under the dialysis department. In another case a dialysis monitor malfunctioned in Sweden when a patient used his own mobile phone during dialysis in a hospital. The patient noticed the alarm from the monitor and stopped using his phone. The incidence of malfunction then ceased[51].

- A patient with an automatic implantable cardioverter defibrillator (AICD) received two inadvertent shocks when a magnet was placed over the pacer during a routine permanent pacer check. As a follow up to this incident, five patients were found of whom the AICD was in the inactive state because of prior exposure to magnetic fields of various origins. Four of them clearly appeared to be from accidental contact with magnets in the everyday environment; two from magnetic bingo wands, one from a magnet placed in a jacket pocket, and one from a magnet inside a large stereo speaker which was carried by the patient. Once reactivated, the devices functioned normally without evidence of battery depletion[52].

- Another deactivated AICD case, caused by a loudspeaker, was reported by Karson (1989). The patient had moved his speaker by hugging it a picking it up, which lasted for about 30 seconds. The magnetic field at the speaker gap was discovered to be 1160 gauss. Cardiac Pacemaker, the manufacturer of the cardioverter-defibrillator, indicated that it required a 10 gauss field at the surface of the device to deactivate it[53].

- A few more cases of deactivated AICDs were reported by Schmitt (1991). The patient had worked with a loudspeaker of his radio that came into close proximity of the device. This loudspeaker was found to have a magnetic field of 295 gauss at the surface. The device was found to be deactivated and in stand-by mode[54].

- One patient was in close contact with magnetized screws needed for construction of bookshelves. These screws were in close proximity to the device for about 30 seconds, which was enough to deactivate the device. The strongest field found from the screws was 30 gauss[54].

- A patient's AICD was deactivated by the magnetic activator of an antitachycardiac pacemaker. The interference occurred as far away as 40 cm. The patient carried the activator in his pocket. An automatic pacemaker was then installed[54].

- An arc welder operator received an AICD and the welder was tested for EMI before he could return to work. A field of 1 to 3 gauss was measured 10 cm away from the welder (the closest distance the AICD would typically be). It was stated that a magnetic field in excess of 90 gauss will definitely close the reed switch, and a constant DC magnetic field of 20 gauss or more may result in closure. Thus, the welder was found to be safe enough for the patient to use[55].

- One year after implantation, a patient reported an episode of defibrillator discharger while operating a hand held remote control to a radiofrequency modulate toy car. The patient did not experience any symptoms prior to the defibrillator discharge[56].

- Two epicardial pacemaker screw-in leads were placed on the inferior surface of a patient's right ventricle during a surgical procedure to replace pacemaker with a broken lead. Ventricular fibrillation occurred because of the direct conduction of current from the tip of an electrosurgery applicator to the surrounding tissue, and then via the exposed ends of the inner portion of severed pacing wires to the myocardium[57].

Other case studies and authors' conclusions

Three other case studies, listed below, also describe the possibility of an accident due to EMI on IMDs. The authors cite their conclusions for each case study. The first two case studies involve pace makers and the third is a cardioverter defibrillator interaction with a pacemaker.

- Many case studies have been performed by Butros (1983). They concluded their findings by saying, "The differences in behavior between different pacemaker models must be due to differences in the design of their sensing and filtration circuitry. It is encouraging that some models appear to be completely immune to interference by electric fields as high as 20 kV/m. Despite abnormal behavior seen with some pacemaker models, it should be stressed that power transmission lines, even those operating at the highest voltages (400 kV in the U.K.), should not be considered potentially hazardous to members of the general public who are fitted with pacemakers[58]."

- A study involving a Siemens pacemaker and arc-welding machines was performed. Machines up to 225 A did no affect these pacemakers. Arc-welding machines using 1000 A or more inhibited the in-vitro test system within 1 or 2 meters of the weld or power generator. Electric welding machines with high-frequency voltage superimposed on the welding current affected the pacemaker within 2 meters of the power unit and within 1 meter of the weld itself. Also found that very large industrial degaussing coils affected pacemakers within 2 meters. AC welding machines using a square wave will probably result in a much higher EMI than one using a sine wave since a square wave has more components (infinite for an ideal model). All these welding units were tested using a sinusoidal waveform[59].

- Hauser (1994) found that the main concern during cardioversion and defibrillation in a patient with a pacemaker is the potential for circuitry damage. Energy may also be coupled to the leads causing myocardial damage. Another possible occurrence is inadvertent resetting of the pacemaker's programmed parameters. To minimize these occurrences, anterior-posterior paddles should be used rather

than two anterior paddles, and should be placed at least five inches from the pacemaker[60].

5 Conclusions and Recommendations for Future Work

The primary goal of this project was to identify the safe exposure levels for Implantable medical devices (IMDs), as well as the different failure modes of IMDs when exposed to electromagnetic (EM) fields. The effects of EM fields on IMDs have been compiled in this report. The safe exposure levels for active implants with programmable memory, such as pacemakers, ranges from 1.0 Gauss[45] in a standard 60Hz field to a maximum of 5.0 Gauss[61] in static magnetic field. Safe levels for passive implants such as aneurysm clips and stents are higher, because the primary concern is movement as opposed to electronic failure. These implants should not be exposed to more than 1.0 Tesla field[31].

Active implants have several modes of operation. The mode of operation is determined by the feed back from the leads of these implants placed in the body. Pacemakers and cardiac defibrillators are two such active implants that utilize several different operating modes. Electromagnetic interference can result in false feedback from the leads of these implants and can force an implant into a different operating mode. Guidant is the only company that has provided us with a list of operating modes of their devices. These modes are summarized in Guidant Attachment #2. Safe exposure levels for the implants manufactured by Guidant are included in Guidant Attachment #3.

Research has led us to conclude that there is a lack of standards and guidelines for safe exposure levels for patients with medical implants. This demonstrates the need for extensive research in this field and the development of additional standards and regulations. Most of the manufacturers that were contacted provided very little information about the susceptibility of their devices, possibly due to proprietary issues.

In United States, the Center for Devices and Radiological Health (CDRH), a sub-organization of the FDA, is responsible for ensuring the safety of medical devices in the market. The documentation required from the manufacturers of these medical devices does not include electromagnetic exposure levels over which their devices will operate properly. The information provided by the manufacturers in these applications usually states that their product is unsafe for MR machines, but no specific safe exposure levels are provided. To ensure the safety of any implantable medical devices, especially those classified as life threatening by FDA (Class III devices), more research and experiments need to be conducted to identify a safe range over which these devices can work properly.

The available standards for safe exposure levels from EMFs are primarily developed by ICNIRP. These standards, however, relate to the general public and not necessarily to people with medical implants. ACGIH is another organization which develops safe exposure levels for workers. According to ACIGH, a worker with a pacemaker should not be exposed to more than 1.0 Gauss[45] of magnetic field. The available standards for the safety of IMDs have been developed by IEC, CENELEC and AAMI/ANSI. However, these standards only address cardiac pacemakers and defibrillators. CENELEC is developing standards for other medical devices, and the information about these standards has been included in section 4.3 of this report. All the standards included in section 4.3 provide relevant information about the safety of medical implants. These standards should be reviewed before any safety measures are developed.

We recommend that additional research be performed on medical implants for each individual patient separately, keeping in mind that IMD manufacturers recommend a maximum EM field value of 1.0 Gauss[45] for active implants and 1.0 Tesla[31] for passive implants. Patients with passive implants will be at little risk in the industrial environment. However, if an attractive force or a sensation of heating is noted by a patient in the vicinity of the implant, he/she should leave that area immediately. This may not be intuitive for some patients so it would be prudent to make them aware of this. Patients with active implants are at greater risk of injury, especially those patients who are dependent on their implant for life support. These patients should be restricted to areas where the magnetic fields do not exceed 1.0 Gauss.

Any patient receiving an implant should be made aware of its safety in magnetic fields. However, one cannot depend on that knowledge. If a patient needs to enter an area where 1.0 Gauss is exceeded, additional research should be performed on the specific implant before allowing entry into that area.

To truly determine if a specific IMD is safe, testing of the specific device model should be performed. This can be done by acquiring a replica of the exact model and following Measurement Method 4 described in section 4.3.1.4 Personal monitoring, but replacing the meter with the medical device. By noting the field strengths (measurement methods) and locations where the device malfunctions, an accurate safety plan can be established. For some medical implants, such as pacemakers, there are test kits that can be purchased for this exact task. This process is necessary because there is a lack of precisely defined exposure levels.

Recently, new designs have been developed for pacemakers to make them MRI safe. Biophan Technologies Inc. is one of the leading companies in this field. This company engineers new designs for medical devices to make them MRI safe, but do not manufacture these devices. These newer implants are being designed to be unaffected by magnetic and electric fields that would be present in MRI systems, so there should be limited concern in an industrial setting for such devices. Even after these newer pacemakers enter the market, the degree of concern should remain the same as there may still be patients with older pacemakers or other high risk implants.

WHO International EMF Project is an ongoing project to determine the possible health effects of exposure to EMF. The objectives of this project are listed below. These objectives are taken from 'International EMF Project' website[62]:

1. Provide a coordinated international response to concerns about possible health effects of exposure to EMF,
2. Assess the scientific literature and make a status report on health effects,
3. Identify gaps in knowledge needing further research to make better health risk assessments,
4. Encourage a focused research program in conjunction with funding agencies,
5. Incorporate the research results into WHO's Environmental Health Criteria monographs where formal health risk assessments will be made on exposure to EMF,
6. Facilitate the development of internationally acceptable standards for EMF exposure,
7. Provide information on the management of EMF protection programs for national and other authorities, including monographs on EMF risk perception, communication and management, and
8. Provide advice to national authorities, other institutions, the general public and workers, about any hazards resulting from EMF exposure and any needed mitigation measures.

This project will develop standards and regulations related to risks from EMF exposure. This will be a good resource for future work; however, the results will not be available until 2007. Nevertheless, we recommend that the results and evaluations of the WHO project are taken into account when they become available. Some of the more important meetings and workshops in regards to this project are mentioned below. These meetings will discuss some key issues regarding the exposure levels for medical devices and will be a very good reference for exposure guidelines.

World Health Organization & US Air Force Asia Pacific EMF Conference
26 January 2004 - 30 January 2004
The following topics will be discussed in this conference. The fourth topic is related to medical devices.

- To review and update the biological effects from exposure to electromagnetic fields (EMFs)
- To review the latest developments in EMF exposure dosimetry
- To identify and discuss possible health consequences of EMF exposure
- To identify issues relating to electromagnetic interference with medical devices
- To discuss EMF exposure policy and risk communication
- To summarize a framework for the harmonization of international EMF exposure standards
- To present and discuss a model for EMF exposure regulation and compliance

International Commission on Non-Ionizing Radiation Protection (ICNIRP)
5th Non-Ionizing Radiation Workshop
Seville – Spain, 20 May 2004 - 22 May 2004

In this workshop, internationally recognized experts in all non-ionizing radiation (NIR) specialties will present lectures on characteristics, dosimetry, interaction mechanisms, biology and health effects, standards and protective measures covering all NIR, from static fields to ultraviolet radiation. Highlights will include mobile telephones, ICNIRP's Philosophy on NIR protection, NIR Programs of WHO, EMFs and the Precautionary Principle, and Medical Aspects of NIR. The information that will be presented in this workshop will be relevant to the determination of safe exposure levels. We recommend that the conclusions of this meeting should be reviewed for more information on present and future standards and regulations.

Appendix A: Emails Sent to Companies

Email to medical implant manufacturers

Subject: Electromagnetic Interference and Implanted Devices

This email is sent on behalf of Muhammad Ali Assad, William Tolli, Ian Buzanoski and Jared Lindros. We are a group of Worcester Polytechnic Institute Electrical Engineering students who are reporting on the near-term and long-term effects of Electromagnetic Interference (EMI – Emitted by household appliances), Radio Frequency Interference (RFI – Emitted by items such as cell phones), and Electrostatic Fields (Emitted by permanent magnets and some large industrial equipment) on implanted medical devices. We are interested in understanding resultant heating, dislocation, damage and possible failure or malfunction of an implant due to said interference. We would greatly appreciate any pertinent information you may be able to provide, including recommendations, safety standards and specifications, regarding (company's devices). Any other Active implants or Non-active implants containing ferromagnetic or paramagnetic material are also of interest. Results will be used to assess the possible effects of EMI and RFI emitted from products on persons with implanted medical devices. We are willing to share findings and conclusions if your company is interested. Thank you for your time.

Email to ocular implants companies

This email is sent on behalf of Muhammad Ali Assad, William Tolli, Ian Buzanoski and Jared Lindros. We are a group of Worcester Polytechnic Institute Electrical Engineering students who are reporting on the near-term and long-term effects of Electromagnetic Interference (EMI – Emitted by household appliances), Radio Frequency Interference (RFI – Emitted by items such as cell phones), and Electrostatic Fields (Emitted by permanent magnets and some large industrial equipment) on implanted medical devices. We are interested in understanding resultant heating, dislocation, damage and possible failure or malfunction of an implant due to said interference. We would greatly appreciate any pertinent information you may be able to provide, including recommendations, safety standards and specifications, regarding your ocular implants. Specifically, we have read that newer technology for these types of implants does not use ferromagnetic or paramagnetic material. However, older technology is still in use and might be more pertinent to our study. Any additional information along those lines would be appreciated. Results will be used to assess the possible effects of EMI and RFI emitted from products on persons with implanted medical devices. We are willing to share findings and conclusions if your company is interested.
Thank you for your time.

Appendix B: Email Responses from Companies

Guidant produces Implantable Cardioverter Defibrillators (ICD), Cardiac Resynchronization Therapy Devices, and Pacemakers. They provided a large quantity of EMI information on their webpage: http://www.guidant.com/patient/living/ The email reply that they sent were three attachments. All of these attachments have useful information about implantable medical devices and are included in Appendix D.

Hello Muhammad Ali Assad, William Tolli, Ian Buzanoski, and Jared Lindros:
Thank you for your recent inquiry regarding the effects of EMI, radiowave frequency interference and electrostatic fields on Guidant implanted cardiac rhythm management devices.

Please find three GUIDANT Fact Sheets which we distribute to customers who have similar inquiries. I hope this assists you in your research. Please contact me if I can be of further assistance, and thank you for your interest.

Sincerely,
Christi Catron

Saint Jude Medical produces Implantable Cardioverter Defibrillators (ICD), Pacemakers, artificial heart valves and other non-active implants. Jerry Hadock replied twice, first contained a document file, second contained list of terminology. The Document that was included in the first reply is included in Appendix D.

First reply:
(EMI) is a frequent topic directed to Technical Services. Attached is a good technical piece that we frequently send out that might be helpful for your group.

Second Reply:

Thank you for your subsequent query. Here are some definitions, that I hope help.

TENS: (Transcutaneous nerve stimulation) A device frequently uses for pain management that induces electrical current into the patient for nerve or muscle stimulation.
Diathermy: The passage of localized heat through body tissues by use of a high-frequency electric current.
Bipolar pacing or sensing: Pacing lead that has two electrodes. The first pole is the tip electrode that contacts the heart tissue. The second pole is a ring electrode, 10-15 mm up the lead, for return path of the circuit. The sensing antenna length in this case is 10-15 mm long, completely in the heart and less susceptible to EMI forces.
Unipolar pacing or sensing: Pacing lead that has one electrode. The only pole is the tip electrode of the lead. The current return is to the anode window on the pacemaker case. The length of the antenna is then from the tip of the lead back to the pacemaker can, usually 15-20 cm depending on the size of the patient. Unipolar sensing is more susceptible to EMI forces as the antenna is partially outside the heart and much longer.

If you are interested in more information about cardiac pacing, I suggest the following text. A Practical Guide to Cardiac Pacing by H. Weston Moses is a great starting point in learning about pacemakers and leads.

This reply was sent to us after we submitted a query about the details of bipolar and unipolar pacing. This information was useful in helping our understanding of active implants and helped us formulate factually accurate statements in the report.

Third Reply:

Thank you for your contact. I suggest you start with the book I suggested. Today's pacemakers are very sophisticated and contain multiple programmable mode options. Our Identity ADx DR 5380 pacemaker is a dual chamber pacemaker that contains 25 different pacing modes alone. I do not have data on specific failure modes that I can provide to you. I suggest you find the most recent copy of the Stimarec report and review that. Also you might wish to review the NASPE web site for additional information about pacing and electrophysiology, http://www.naspe.org

Regards,
Jerry Hadduck

The reports at the NASPE website suggested in the previous email response yielded no useful information pertaining to our topic. This resource contained information on cardiac health, diseases, and techniques for controlling cardiac pacing. This is a good resource for patients concerned about their cardiac health, but has little information on the effects of electromagnetic fields on the body or any related implants.

Medtronic is a producer of Implantable Cardioverter Defibrillators (ICD), Pacemakers, artificial heart valves, neurostimulators, drug infusion pumps, spinal structuring non-active implants and other non-active implants. No return to any of our emails was sent so we sent a letter. After still receiving no useful information we called a contact at Medtronic. Joel Peltier responded with places where some active implant standards can be purchased. He seemed very interested in the topic, but was unable to provide us with all the info we requested due to legal reasons.

First Reply:

All implantable Medtronic Heart Valve products are safe with MRI scanners up to 3.0 Tesla.

Our devices either have no metal components or are constructed of metals that do not contain iron (non-ferromagnetic). No adverse effects have been experienced with MRI imaging (even when imaging close to the devices) using up to 3.0T MRI.

In continued effort to provide updated safety information, in March 2001, Emanuel Kanal, MD, performed MRI studies on all Medtronic Heart Valves and annuloplasty products. All products were tested for magnetic field interactions and artifact using a shielded 3.0 Tesla MRI system and determined safe for MRI at 3.0T.

We appreciate your concerns and thank you for your interest in Medtronic Heart Valve products. If you have additional questions, or if we can be of assistance to you in any way, do not hesitate to contact us at your convenience.

Medtronic Heart Valves, Technical Service

Second Reply:

Because Medtronic is made up of a large conglomerate of businesses, we can only answer for the business we represent, which is Medtronic Heart Valves. We apologize for the tardiness of our colleagues, however as they are larger businesses, it generally takes longer to get to the right person.

Regards,
Medtronic Heart Valves.

There were no subsequent replies, from Medtronic, to the response following the previous email. After making phone contact we received the following response from Joel Peltier:

Third Reply:

Here's some information that I hope you will find useful:

The most prevalent pacemaker EMI standards are EN 50061 + Amendment A1 (1995), prEN 45502-2-1 (2002) & ANSI/AAMI PC69 (2000). In general, the larger pacemaker manufacturers follow these standards. Since the standards are copyrighted, I cannot send you copies but I can point you to a couple of websites where you may be able to purchase the standards. For the EN (European) standards, use: www.ili.com or www.cenelec.org; For the ANSI/AAMI standard use www.aami.org or www.nssn.org (Through NSSN you can also find the EN documents).

As for device response to EMI, it is difficult to provide a definitive answer as the response varies depending on device features, device programmed parameters and the device manufacturer. Generally speaking, devices are not damaged when exposed to electromagnetic fields. Allowable device responses are provided in the above-mentioned standards and these responses are designed to keep patients safe.

I hope that this information is helpful and I wish you the best in your project.

Sincerely

Joel Peltier
EMI Specialist
Medtronic Inc

MRI Safety is an online company that specializes in safety information distribution pertaining to MRI. One of the categories was for medical implants. Frank Shellock replied to our email. Although most of this information did not apply to our project, we did purchase the Reference Manual by Shellock and found that moderately helpful.

Thanks for your interest. You can start with the following, keeping in mind that much of what has been done in the field of MRI may or may not apply to your project.

Sincerely,

Frank Shellock, PhD
Here is list of magnetic resonance imaging safety resources (textbooks, video/DVD programs, and web sites):

TEXTBOOKS:

Reference Manual for Magnetic Resonance Safety: 2003 Edition
-The latest information from the peer-reviewed literature and other sources.
-Includes THE LIST, with comprehensive information for over 1,100 implants and devices, 150 tested at 3-Tesla

Order at:
http://www.us.elsevierhealth.com/product.jsp?isbn=1931884048
or call (800) 545-2525, mention order number (1-931884-04-8)

Magnetic Resonance Procedures: Health Effects and Safety (copyright 2001)
-an authoritative text on MRI safety with chapters of interest to virtually all MRI healthcare workers
-written by 15 contributing MRI safety experts
-the definitive MRI safety best seller

Order at http://www.crcpress.com, www.Amazon.com or www.BarnesandNoble.com, search "Shellock" or call CRC Press at (800) 272-7737

VIDEOTAPE/DVD PROGRAMS:

*MAGNETIC RESONANCE PROCEDURES: HEALTH EFFECTS, SAFETY, AND PATIENT MANAGEMENT**

Faculty
Frank G. Shellock, Ph.D.
Adjunct Clinical Professor of Radiology
University of Southern California
and
Founder, Institute for Magnetic Resonance
Safety, Education, and Research

An accredited video/DVD program with manual designed for those professionals who work directly in the magnetic resonance environment and interact with patients in a professional capacity. This video/DVD program was produced by Educational Symposia in accordance with the Accreditation Council for Continuing Medical Education (ACCME) Essential Elements and Standards.

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Frank G. Shellock, Ph.D.
Adjunct Clinical Professor of Radiology
University of Southern California
and
Founder, Institute for Magnetic Resonance Safety, Education, and Research

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CME application	*$35*		
MAGNETIC RESONANCE IMAGING SAFETY..... FOR NON-MRI TRAINED PERSONNEL	*$75*	*$90*	

WEBSITES:
http://www.MRIsafety.com
- The definitive MRI safety resource with useful information on all aspects of MRI bioeffects, safety, and patient management, a searchable database of The List• , containing over 1,100 implants and objects tested for safety in the MRI environment, and •downloadable• screening forms for patients and other individuals. Over 27,000 registered users utilize www.MRIsafety.com

http://www.IMRSER.org
-The web site for the Institute for Magnetic Resonance Safety, Education, and Research. Information includes guidelines developed by the Medical, Scientific, and Technology Advisory Board and the Corporate Advisory Board.
-Recently published, peer-reviewed MRI safety articles are available to be downloaded as PDF files.

www.MagneticResonanceSafetyTesting.com
-The web site for Magnetic Resonance Safety Testing Services, a company with unsurpassed expertise in all aspects of MR safety and MR compatibility testing of implants, devices, instruments and accessories.

Appendix C: Phone Contacts

Cochlear Corporation was well regarded as a large producer of cochlear (hearing) implants, but did not have much information to share. We could not get a hold of an engineer.

BioMet is a producer of Orthopedic Implants. Ken Beres responded with some information and seemed interested in our work. He stated that the material used in their products is weakly ferromagnetic and will not be a concern when exposed to magnetic fields:

- Cobalt Chrome
- Ti 6 4 Vanadium
- Ultra High Molecular Weight Polyethylene

Bio-Eye produces ocular implants. We were not able to solicit a response.

3Implant is a producer of dental implants. They did not respond to email and when we made phone contact they indicated that their implants are of little concern in a MRI machine so there should be absolutely no trouble in a commercial field.

Chris Sotak on the WPI campus was contacted via interview, because of his experience with MRI machines. He was able to provide a large packet of information, mostly related to MRI procedures and safety, although we did find some useful material from this. He mentioned a group responsible for keeping track of IMD failures; the ECRI.

Appendix D: Email Reply Attachments

Guidant Attachment #1

GUIDANT ICD/Pacing Systems and Cellular Phones

In certain cases, a cellular phone could affect the operation of an implanted cardioverter defibrillator (ICD) or pacing system if the phone is closer than six inches (15 cm) to the pulse generator. This interaction is temporary, and moving the phone away from the implanted device's location should return the medical device to proper function. To reduce the chance of interaction, follow these precautions. These precautions apply to GSM, digital, and analog cellular phones:

• Maintain a distance of at least six inches (15 cm) between the cellular phone and the implanted device. If the phone transmits more than 3 Watts, increase the distance to 12 inches (30 cm).

• Hold the cellular phone to the ear opposite the side of the implanted device.

• Do not carry a cellular phone in a breast pocket or on a belt if that places the phone within six inches (15 cm) of the implanted device.

Note: Digital, analog, and GSM phones meet EMI standards AAMI PC69 in the US and clause 27.5 of EN45502-2-1 in Europe. Guidant uses these EMI standards to test ICDs and pacing systems.

Guidant Attachment #2

GUIDANT ICD/Pacing Systems and Electromagnetic Interference (EMI)

Guidant adheres to the Association for the Advancement of Medical Instrumentation (AAMI) standards for testing of Implantable Cardioverter Defibrillators (ICDs) and implantable pacemakers in the presence of electromagnetic interference (EMI). These standards are also used during the design of new products. All Guidant devices are tested to ensure proper operation in the presence of such electromagnetic radiation. This includes testing at 27 and 72 MHz at field strengths up to 200 V/m at 1 m, using pulse modulations most readily detectable by the device. Testing also includes a close proximity exposure at 450 MHz to 3 GHz with a radiated power of 40 mW at a distance of 2 cm.

However, ICD systems and pacemakers are still sensitive to strong electrical or magnetic fields. Because of the diversity of the environment in which we live, an all-inclusive listing of equipment that may cause electromagnetic interference (EMI) cannot be made. Most of the things patients may handle or work around on a daily basis do not affect the ICD or pacing system. For instance, ICD and pacemaker patients can continue to safely operate around most appliances, tools, office and light industrial equipment that is well-grounded and in good repair.

ICD SYSTEMS

Temporary Interference

Certain types of electrical equipment may generate electric signals that may temporarily interfere with ICD sensing. If an electric signal of sufficient amplitude passes through the body, it may

mimic the electrical activity of the heart or be interpreted by the device as electrical noise. This interference may be manifested as 1) temporary device inhibition with inability to deliver needed therapy, 2) delivery of unnecessary shocks, 3) tracking of the interference as if it were a heart signal, or 4) asynchronous pacing at the lower rate limit.

Inhibition / Suppression of Therapy

• EMI that mimics heart signals may inhibit the device from providing appropriate therapy. Brady pacing may not be provided when needed and tachycardia shocks may not be delivered if required.

• When the patient moves away from the EMI source, the device should resume normal operation.

Unnecessary Shocks

• If the EMI mimics a heart rate in the tachy zone, the ICD system may sense this interference as a rapid heart rate and deliver unnecessary shocks to the patient.

• Electrocautery, diathermy, arc welding equipment, robotic jacks and magnetic resonance imaging (MRI) are some examples of potential sources of EMI that may result in unnecessary shock delivery or asynchronous pacing.

• When the patient moves away from the EMI source, the device should resume normal operation.

Noise Mode Pacing (Asynchronous Pacing)

• EMI that has a very high pulse rate or is continuous in nature may cause the device to pace asynchronously at the lower rate limit (LRL) or may inhibit pacing output, depending on how the noise mode parameter is programmed.

Tracking of the Noise Source

• If the EMI is detected by one chamber of the device but not the other chamber, it is possible for the paced rate to track the rate of the EMI. This may result in a lack of pacing in one chamber and an increased rate of pacing in the other chamber.

Potential Device Deactivation Interference

EMI that produces large magnetic fields — greater than 10 gauss (with a DC frequency up to 10 Hz) at the surface of the ICD — may also interfere with the device.

• Examples of equipment that can produce these large magnetic fields include arc welders, large electrical generators, transformers, electric smelting furnaces and other devices which may contain large magnets.

• Depending upon device programming, the device may emit beeping or continuous tones. Any magnetic field strong enough to cause the device to beep may also result in the deactivation of the ICD if the patient remains in the magnetic field for 30 seconds or longer.

• If beeping is heard from the ICD, the patient should immediately move away from the EMI source *and the physician should be contacted.*

PACING SYSTEMS

Temporary Interference

Certain types of electrical equipment may temporarily interfere with pacemaker sensing. If an electrical signal of sufficient amplitude passes through the body, it may mimic the electrical activity of the heart or be interpreted by the device as electrical noise. This interference may be manifested as 1) temporary device inhibition with inability to deliver needed therapy, 2) tracking of the interference as if it were a heart signal, or 3) asynchronous pacing at the lower rate limit.

Inhibition / Suppression of Pacing

• EMI that mimics heart signals may inhibit the device and prevent appropriate pacing therapy.

• When the patient moves away from the EMI source, the device should resume normal operation.

Noise Mode Pacing (Asynchronous Pacing)

• EMI that has a very high pulse rate or is continuous in nature may cause the device to pace asynchronously at the lower rate limit (LRL) or inhibit pacing output, depending on how the noise mode parameter is programmed.

• When the patient moves away from the EMI source, the device should resume normal operation.

Tracking of the Noise Source

• If the EMI is detected by one chamber of the device but not the other chamber, it is possible for the paced rate to track the EMI. This may result in a lack of pacing in one chamber and an increased rate in the other chamber.

• When the patient moves away from the EMI source, the device should resume normal operation.

Potential Device Interference from Large, Low Frequency Magnetic Fields

Electric equipment that produces large magnetic field — greater than 10 gauss (with a DC frequency up to 10 Hz) at the surface of the ICD — may also interfere with the device.

• Examples of this type of equipment include arc welders, large electrical generators, transformers, electric smelting furnaces, and other devices that may contain large magnets.

• If the pacemaker is exposed to a magnetic field of greater than 10 gauss at the surface of the pacemaker, with a DC frequency up to 10 Hz, it will temporarily revert to an asynchronous mode pacing at the magnet rate.

• Any effect the equipment may have on the pulse generator will only be temporary. Moving away from the equipment or turning it off, if possible, should return the pulse generator to its normal mode of operation with no long-term effects.

Guidant Attachment #3

GUIDANT ICD/Pacing Systems and Electromagnetic Interference (EMI) in Work Environments

Guidant Implantable Cardioverter Defibrillator (ICD), Cardiac Resynchronization with Defibrillation (CRT-D), and pacing systems have been manufactured to provide protection against electromagnetic interference levels common in most public, home and occupational environments. Most work environments do not pose electromagnetic interference (EMI) risks to patients with Guidant ICD, CRT-D or pacing systems.

Certain types of electrical equipment, however, may produce levels of EMI that can temporarily interfere with ICD, CRT-D or pacemaker performance. For ICDs, CRT-Ds and pacemakers, this interference may cause device inhibition with failure to deliver needed therapy. In the case of ICD and CRT-D devices, the interference may result in delivery of unnecessary shocks or in device disablement. In workplace environments that contain equipment capable of producing potentially large levels of electromagnetic interference, an assessment may be necessary to determine the levels of EMI that a patient may encounter while performing job duties.

Guidant CRM Technical Services is happy to provide technical information to professional testing consultants regarding operation and specifications of Guidant ICD, CRT-D and pacing systems. Guidant CRM Technical Services can also provide information regarding EMI parameters for which testing has been conducted and proper device operation ensured. Table 1, below, lists those parameters. Table 2 provides an example of the instrumentation required for accurate measurement of EMI parameters.

Guidant does not perform environmental EMI testing. We recommend that only trained individuals employed by bonded and certified professional testing agencies perform environmental assessments. However, Table 3 is a list of companies that perform on-site workplace environmental testing. This list is provided as a service, and is not an all-inclusive list. The companies listed on this table have been contacted and have agreed to be included on this list. It is in no way an endorsement of these agencies. Other consultants are available throughout the United States.

The results of a workplace EMI assessment and evaluation may provide information that will help in determining whether or not potential workplace EMI levels are likely to affect an employee's implanted device. The decision as to whether a patient may or may not return to work is a medical decision, and must be made cooperatively by the physician, the employer and the employee.

Table 1: Limits & types of emissions for which testing has been conducted and proper device operation ensured for Guidant implantable devices.

Code	Target Field Intensity	Field Type	Unit of Measurement
1	2 Gauss RMS	Low frequency H-fields (0.1 Hz to 3 kHz)	Gauss (G)
2	10 Gauss	DC Magnetic fields	Gauss (G)
3	6.0 kV/m RMS	Low frequency E-fields (under 1 kHz)	kiloVolts / meter (kV/m)
4	140 V/m RMS	High frequency E-fields (500 kHz to 6 GHz)	Volts / meter (V/m)

Table 2: Examples of instrumentation required for accurate EMI measurement

Manufacturer	Description	Model No.	Frequency Range	Cal Period	Cal Date
NoRad	ELF E-Field Meter	EFM	0.3 – 3000 Hz		
Walker Sci.	Gauss Meter	MG-4D	DC-20kHz		
Walker Sci.	Gauss Meter	ELF-50D	50-60 Hz		
Amp. Res.	E-Field Sensor	FP4000	0.01-1000MHz		

Table 3. Environmental Testing Consultant List

Company	City	State	Phone	Website
American Industrial Hygiene Association (AIHA) *Have locations across the country	Fairfax	VA	(703) 849-8888	www.aiha.org
CKC Laboratories	Mariposa	CA	(209) 966-5240	www.ckc.com
TUV Rheinland of America	Newtown	CT	(203) 426-0888	www.us.tuv.com
Global Certification Labs	Haddam	CT	(860) 873-1451	no website available
E.F. Electronics Co.	Aurora	IL	(630) 897-1950	no website available
Lindgren R.F. Enclosures, Inc.	Glendale Hts.	IL	(630) 307-7200	www.lindgrenrf.com
Radiometrics Midwest Corp.	Romeoville	IL	(815) 293-0772	www.radiomet.com
Windermere Information Technology Systems	Annapolis	MD	(410) 266-1737	no website available
MET Laboratories, Inc.	Baltimore	MD	(410) 354-3300	www.metlab.com
F-Squared Engineering	Damascus	MD	(301) 253-4500	www.f2labs.com
Mantech Environmental	Rockville	MD	(301) 315-0080	www.mantech.com
Washington Labs, Ltd.	Gaithersburg	MD	(800) 839-1649	www.wll.com
Advanced Testing Services, Inc.	Albuquerque	NM	(505) 292-2032	no website available
American Environments Co.	Medford	NY	(631) 736-5883	www.aeco.com
Shielding Resources Grp., Inc.	Tulsa	OK	(918) 663-1985	www.shieldingresources.com
Radiation Sciences, Inc.	Harleysville	PA	(215) 256-4133	email: rasciences@aol.com
Amuneal Manufacturing Corp.	Philadelphia	PA	(215) 535-3000	www.amuneal.com
IIT Research Institute R&B Operation	West Conshohocken	PA	(610) 825-1960	www.iitri.org
Advanced Testing Services, Inc.	Chantilly	VA	(703) 263-9200	no website available
DNB Engineering	Fullerton	CA	(714) 870-7781	www.dnbenginc.com
DNB Engineering	Chalk Creek	UT	(714) 870-7781	www.dnbenginc.com
DNB Engineering	Riverside	CA	(714) 870-7781	www.dnbenginc.com
IAQ Services	Fishers	IN	(317) 598-0148	www.indoorairsite.com

NOTE: *This list is provided as a service and is not an endorsement of the listed consultants. Other consultants are available throughout the U.S.*

SJM Attachment

ELECTROMAGNETIC INTERFERENCE
AND THE PACEMAKER PATIENT

While clinically significant problems with electromagnetic interference (EMI) are rare, a pacemaker's response to EMI becomes more diverse as technology advances. Pacemaker manufacturers continue to develop interference protection circuitry to keep up with these vast sources of EMI.

The pacemaker's response to EMI is dependent on the characteristics of the EMI, proximity to the interference, available shielding, and the sensing characteristics and polarity of the pacemaker. The pacemaker circuitry is designed to attenuate any interference outside the normal intracardiac range (10 Hz - 100 Hz). This is achieved by using bandpass filters.

EMI sources can be broadly classified as galvanic, electromagnetic or magnetic.

- Galvanic interference requires direct contact with electrical current. This is most often seen in defibrillation/cardioversion, cautery, TENS units and diathermy.
- Electromagnetic or electrically coupled interference does not require direct body contact. This interference is most often seen with arc welders, ham radios, electrical appliances, metal detectors, therapeutic ultrasound and high voltage power lines.
- Magnetic interference occurs when a patient comes in close proximity with an intense magnetic field. This is often seen in nuclear magnetic resonance imaging (NMR/MRI) and steel mill induction furnaces.

EMI with signal modulation can mimic normal intracardiac signals. When detected, the response to EMI may present itself as a single beat inhibition, total inhibition, noise reversion/asynchronous pacing, rate increase, erratic pacing, or no output. These responses are usually temporary, but can be permanent if the pulse generator circuitry is damaged.

A pacemaker's response to EMI is highly dependent on the specific EMI source, the pacemaker's mode, and sensing polarity. Included is a list that details the interaction of commonly encountered pacemaker EMI

sources. Accompanying this list is a summary table of these sources and reported associated pacemaker responses.

EMI Sources

Ablation (RF): Loss of capture - exit block is frequently seen during RF ablations. Arrhythmia induction, undersensing, inhibition, rate increase and noise reversion pacing are also possible. Circuit damage is less likely than DC ablation.

Acupuncture: Low frequency electroacupuncture may cause inhibition and noise reversion at high frequencies.

Airport detector/Metal detectors: Single beat inhibition is rare and seen only on unipolar devices.

Anti-theft devices/Electronic Article Surveillance (EAS): Possible inhibition or rate increase reported primarily on unipolar devices especially if patient leans or lingers near EAS. An increased incidence of cross-talk is seen on unipolar DDD pacers.

Arc welders: Single beat inhibition is commonly seen on unipolar devices each time the arc is struck. High magnetic fields from the cables may cause reed switch closure resulting in asynchronous pacing.

Bone Stimulator: Possible inhibition on unipolar devices.

Cardioversion: Cardioversion, performed at high energies similar to that of defibrillation or performed directly over the pulse generator, may damage circuitry resulting in no output, erratic pacing, or rate increases. Energy conducted through the lead may cause arrhythmias and myocardial burning.

Cautery: Cautery used near the pacing system may result in inhibition, asynchronous pacing and/or circuit damage. Energy conducted through the lead may cause arrhythmias and myocardial burning. Impedance-based rate responsive pulse generators may exhibit erratic pacing or rate increases.

CB radio: Single beat inhibition may be seen with microphone keying on unipolar devices.

Cellular Phone: Total inhibition or asynchronous pacing is possible with some digital cell phones if placed within 6 inches of the pacemaker. Current SJM pacemakers (Identity, Integrity, Affinity, Trilogy, Synchrony, Paragon, Solus) are cellular tested.

CT Scan: No documented reports of interference to date from CT scanners or full body scans.

Defibrillation: Defibrillation performed at high energies, or defibrillation directly over the pulse generator, may damage circuitry resulting in no output, erratic pacing, or rate increases. Energy conducted through the lead may cause arrhythmias and myocardial burning.

Dental scaler: Older ferromagnetic ultrasonic scalers may cause single beat inhibition on unipolar pacemakers. Piezo-electric scalers have no effect. Activity rate responsive devices may exhibit increased pacing rates.

Diathermy: Used in the near vicinity of the pacing system, diathermy may result in inhibition, asynchronous pacing, and/or circuit damage. Energy conducted through the lead may cause arrhythmias and myocardial burning.

Electric blanket/ Heating pad: Single beat inhibition is rare and seen only on unipolar devices.

Electric shaver: Single beat inhibition is rare and seen only on unipolar devices.

Electric switch: Single beat inhibition may be seen on unipolar devices.

Electric tools: Single beat inhibition is rare and may be seen on unipolar devices during use of power tools like drills and saws.

Electric toothbrush: No effect from standard or ultrasonic models.

Electro-convulsive shock therapy (ECT/EST): Inhibition and/or noise reversion is possible, especially with unipolar pulse generators. Activity sensor rate responsive pulse generators may track the seizure activity.

Electrotome (dental device): Single beat inhibition is rare and seen primarily on unipolar devices.

Ham radio: Single beat inhibition may be seen on unipolar devices during microphone keying.

Lithotripsy - ESWL: No effect on VVI and VOO pulse generators. DDD pulse generators may track to maximum rate or totally inhibit ventricular output due to ESWL triggering off the atrial output. Activity sensor rate responsive pulse generators may also track to maximum rate or be permanently damaged (piezo crystal shatters near focal point).

Magnet therapy: Asynchronous pacing possible if magnetic pads/objects are used within 18 inches of pacemaker. Prolonged asynchronous pacing from magnetic mattress pads is not recommended. Magnetic pads used below the waist will not interfere with pacemaker operation.

Microwave ovens: In 1976 the FDA stated there is no longer substantial risk of pulse generator interference from microwave ovens which are now built with leakage protection. Pulse generators are now manufactured to prevent interference from microwaves.

MRI (Magnetic Resonance Imaging): Frequent effect from MRI is asynchronous pacing. Reed switch magnetization, rate increases in DDD, single beat inhibitions, component damage, lead dislodgment, Rapid pacing (300 PPM), and generator movement within the pocket are also possible but not common.

PET Scan: Possible CMOS damage. See Radiation.

Power lines, high voltage: 400 kvolt high voltage power lines may cause asynchronous pacing, especially if patient is near a large metal object (e.g. car).

Pulp tester: Single beat inhibition is rare but may be seen on unipolar devices.

Radar: Single beat inhibition is rare but may be seen on unipolar devices.

Radiation, Diagnostic: No effect, even with cumulative doses.

Radiation, Therapeutic: Damage to the CMOS circuitry can occur as low as 2000 rads in some pacemakers. Devices now manufactured by SJM are tested to 3000 rads. Effect is cumulative in dose and affects both bipolar and unipolar pulse generators. Failure modes include circuit damage, run-away pacer, erratic pacing, sensing anomalies, and no output.

Radio transmitter, AM: If signal modulation occurs, inhibition may be seen on unipolar pulse generators, relative to power, frequency, modulation, and proximity. Noise reversion pacing is possible.

Radio transmitter, FM: If signal modulation occurs, inhibition may be seen on unipolar pacemakers relative to power, frequency modulation, and proximity. Noise reversion pacing is possible.

Respiratory/ECG monitors: Impedance based ECG/respiratory monitors may cause upper rate pacing in impedance based pacemakers especially with monitors emitting a current signal parallel to the pacer system.

Shaw scalpel: This non-electric cautery is thermally coupled and will not cause any interference.

TENS (Transcutaneous Electrical Nerve Stimulator): Normally used high frequencies (>30 Hz) may cause noise reversion on unipolar pulse generators. Low frequencies (<10 Hz) may cause inhibition on unipolar pulse generators. Burst mode on newer TENS units is contraindicated due to probable device inhibition.

TV transmitter: Although rare, inhibition and noise reversion of unipolar devices has been documented.

Ultrasound, Diagnostic: No effect.

Ultrasound, Therapeutic: Single beat inhibition is rare and may be seen on unipolar devices. Therapy should not be given directly over the pulse generator. Activity sensor rate responsive pulse generators may exhibit piezo crystal shatter.

OF COMMONLY ENCOUNTERED SOURCES AND RESPONSES

Source	Pacer Damage	Total Inhibition	1 Beat Inhibition	Asynch /Noise	Rate Increase	Unipolar Bipolar
Ablation (RF)	Y*	Y	Y	Y	Y*	U & B
Acupuncture	N	Y	Y	Y	N	U & B
Airport detector	N	N	Y	N	N	U
Anti-theft device(EAS)	N	Y	Y	Y	Y*	U&B
Arc welder	N	Y	Y	Y	N	U & B
Bone stimulator	N	Y	Y	Y	N	U
Cardiokymography	N	Y	Y	N	Y	U & B
Cardioversion	Y	N	N	N	N	U & B
Cautery/coagulation	Y	Y	Y	Y	Y[1]	U & B
CB radio	N	N	Y	N	N	U
Cellular phone	N	Y[4]	Y[4]	Y[4]	N	U & B
CT Scan	N	N	N	N	N	-
Defibrillation	Y	N	N	N	N	U & B
Dental scaler	N	N	Y*	Y*	Y[3]	U
Diathermy	Y	Y	Y	Y	Y	U & B
ECT/EST	N	N	Y	Y	Y[3]	U
Electric blanket/heating pad	N	N	Y*	N	N	U
Electric shaver	N	N	Y*	N	N	U
Electric switch	N	N	Y	N	N	U
Electric tools	N	N	Y*	N	N	U
Electric toothbrush	N	N	N	N	N	-
Electrolysis	N	N	Y	Y	N	U
Electrotome	N	N	Y*	N	N	U
Ham radio	N	N	Y	N	N	U
Lithotripsy	N	N	N	Y	N	U & B
Magnet therapy	N	N	N	Y	Y	U & B
Microwave	N	N	N	N	N	-
MRI	Y	N	Y	Y	Y[2]	U & B
PET scanner	Y	N	N	N	N	U & B
Powerline, high voltage	N	N	N	Y	N	U & B
Pulp tester	N	Y*	Y*	Y	N	U
Radar	N	N	Y*	N	N	U
Radiation - Diagnostic	N	N	N	N	N	-
Radiation - Therapeutic	Y	N	N	N	Y	U & B

Radio transmitter AM	N	N	Y*	N	N	U
Radio transmitter FM	N	N	Y*	Y*	N	U
Respiratory Monitor (Impedance based)	N	N	N	N	Y[1]	U & B
Shaw scalpel	N	N	N	N	N	-
TENS	N	Y	N	Y	Y[2]	U
TV transmitter	N	Y*	Y*	Y*	N	U
Ultrasound - Diagnostic	N	N	N	N	N	-
Ultrasound - Therapeutic	Y[3]	N	Y*	N	N	U

1 = Impedance-based pulse generators
2 = DDD mode only
3 = Piezo crystal-based pulse generators
4 = SJM devices (Identity,Integrity,Affinity,Trilogy,Synchrony,Paragon,Solus) are cellular tested
* = Remote potential for interference

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Appendix E: Annotated bibliography of useful references

WHO's International EMF project worldwide EMF guidelines
http://www.who.int/docstore/peh-emf/EMFStandards/who-0102/Worldmap.htm
This website is an outcome of one of the objectives of the International EMF project sponsored by WHO. This website compiles all the EMF related standards practiced in different countries all around the world. These standards, however, are general exposure guidelines for general public and are not related to the implantable medical devices. So the results from this website are not included in the report. This website can still be useful when relating the general EMF exposure requirements in different countries.

EMF Research database of WHO's International EMF Project
http://www.who.int/peh-emf/research/database/en/
This database consists of case studies on various topics including some on implantable medical devices. This database is being updated until 2007, which is the completion date for the project. At present, there are 30 case studies in the WHO database and 14 case studies in the IEEE database on the following website, which are relevant to our project. The documents for these case studies have to be requested from WHO, these are not available in the databases.

National Institute for Occupational Safety and Health (NIOSH), 'Manual for Measuring Occupational Electric and Magnetic Field Exposures', NIOSH manual # 98-154, October 1998
This is the manual which provides many different methods for measuring one's exposure level to EMFs. These are the standard methods used by NIOSH. The four measurement methods listed in the measurement methods section were mostly assembled from this document.

Shellock, Frank G., Magnetic Resonance Procedures: Health effects and Safety. CRC Press, 2001.
This book presents the issues related to MR imaging. It contains comprehensive safety information for over 700 implants, devices, and materials; a list of medical devices and products for interventional MR procedures; and a summary of MR safety studies conducted by radiologists, scientists and physicists with expertise in this field.

Sagan, Leonard. "Electric and Magnetic Fields: Invisible Risks?" Netherlands: Gordon and Breach Science Publishers, 1996.
This book discusses some of the different biological effects of electromagnetic fields and some of the concerns related to this topic. It also details past studies about health issues that may be related to magnetic and electric fields.

National resource for global standards
www.nssn.com
This website allows a comprehensive search for standards information from several different sources at one time.

Shellock, Frank. 'Reference Manual for Magnetic Resonance Safety', Salt Lake City, Utah: AMIRSYS Inc., 2003

This reference manual is the premier source of information on metallic objects that have been tested for safety in the Magnetic Resonance environment. The text consists of safety recommendations plus the "The List", containing tabulated information for over 1100 objects tested for MR safety, with new data for over 150 objects tested at 3.0 Tesla. These objects include the full range of metallic implants, devices, and objects that may be encountered in patients.

National Institute for Occupational Safety and Health (NIOSH), 'Manual for Measuring Occupational Electric and Magnetic Field Exposures', NIOSH manual # 98-154, October 1998

This manual provides a number of useful measuring techniques and methods for magnetic fields. Some are more specific to certain situations than others, but they cover a broad range of methods.

National Institute of Environmental Health and Sciences, 'Questions and Answers – EMFs in the Workplace'

http://www.niehs.nih.gov/emfrapid/html/Q&A-Workplace.html#Human

This website provides a detailed analysis of the different effects of electromagnetic fields found in the Workplace. It lists different biological effects such as Lukemia and Brain cancer. This website can be helpful if the detailed information about the biological hazards of EM fields is required.

OSHA, 'Non-Ionizing Radiation: Extremely low frequency fields'

http://www.osha.gov/SLTC/elfradiation/index.html

This website lists many different issues related to electromagnetic fields. This list includes the different organizations related to electromagnetic fields. The website will be very helpful as it provides many links related to the safety issues concerning low frequency electromagnetic fields.

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