



FREQUENCY RESTRICTIONS FOR WIRELESS POWER TRANSFER OF IMPLANTABLE MEDICAL DEVICES

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ABSTRACT

Wireless power transfer (WPT) system is turning to be a reliable strategy to power implantable devices. However, WPT possess strong reactive near-field to induce electric fields in the body tissue of implant wearer. In addition, implantable devices with WPT may be exposed to the unwanted strong electromagnetic field and be disturbed functionally. These may pose potential direct health hazards or serious damage to the function of health via interference with medical implants. In this paper, the safety guidelines from different responsible organization are reviewed and discussed in the context of human safety. Based on the discussion and literature review, the effect and affect of state-of-the-art of the existing guidelines are discussed. As an outcome, several needs to be added as the extension of safety guidelines for coverage of persons with implants, more computationally efficient full wave solvers, more reliable human models has to be introduced.

Keywords: implantable devices, pacemaker, wireless power transfer, frequency restrictions.

INTRODUCTION

Miniaturized devices were first introduced by Richard Feynman in the lecture on miniaturization (Feynman, 1960). This lecture gave an extraordinary idea of nanoscale objects. This led scientists to some remarkable advancement for microscopic research including extreme miniaturization of objects, in other word, nanotechnology. Consequently, it guided to microscale geometry of electronic systems and devices (Roukes, 2001). As a result of consistent advancement and faster research, miniaturized devices have undergone a significant transformation over several decades and turning to be the essential tools for monitoring, measuring and soliciting responses in many different fields.

In recent years, rapid progresses have seen in the art of health care monitoring system. Instead of relying on the eyes or analog routine check, health care industry now depends on the medical technology. This technology offers devices that can monitor health status by using wired or wireless technologies can be worn or be implanted in the body. Among these, implanted devices have drawn significant attention in the health care industry due to the ease of application, since the first implantable heart pacemaker of 1958 (WEN, 2012). They are refereed as implanted medical devices (IMD). IMDs can measure a number of physiological parameters and can take necessary actions according to the control protocols. For instance, IMD can measure heart conditions and can

control in absence of proper rhythms, monitor hypertension, provide functional electrical stimulation of nerves, operate as glaucoma sensors, and monitor bladder and cranial pressure. In addition, they are cost effective, user friendly and more reliable. Hence, it is not far when the improvement of the IMDs will reach a level of intense development and miniaturization (Clark, 2009). In fact, it is expected that, within a short time IMDs will be able to monitor or control nearly every bodily function and movement with minimal cost and advanced technologies (Lau, 2014), (Mahn, 2013), (Mudawi, 2008).

Though the advancements of the IMDs have make them dependable devices for long term biological monitoring however, powering them has been a difficult challenge. Conventional powering allows IMDs to be powered through batteries, either external or internal. For both cases it requires a bulky battery and a painful long surgery to implant the device. Therefore, this solution is expensive, uncomfortable as well. In addition, they possess additional weight and inconvenient geometry. On top of everything, this process has to be repeated within 5 to 10 year over and over for further smooth activation of the device since the battery is charge limited. These factors may result a life risk and/or at least health degradation. A feasible solution of this addressed problem is the wireless power transfer (WPT) system for the IMDs. In case of WPT the operating frequencies can be ranged from several KHz to several GHz. These system may



induce high fields in human tissues with the strong reactive near field within a close distance. Therefore, operating frequency is the crucial factor for safety considerations in the WPT system.

The scope of this paper includes selection of the operating frequency for WPT system and study of the possible effects of them from human exposure according to the investigating organizations.

The rest of the paper is organized as follows; Section 2 presents wireless powering strategies for IMDs. Restrictions of frequencies to ensure human safety are discussed in Section 3 along with some previous incidents of investigation. Recommended frequency restrictions from responsible organizations for different criterias are described in Section 4 and 5. Section 6 sketches a discussion for the application of the limits. Finally, Section 7 concludes this paper with some remarks on future agenda.

POWERING IMPLANTABLE DEVICES

There are two ways to power an implantable device. Using a wired connection either powering from outside of body or using a central battery. For both cases it requires wire and communication way to carry the power. On the other hand, wireless power transfer (WPT) powers devices wirelessly. This system has shown its potential for different applications including portable devices, wireless charging, medical implants and so on (Waters, 2012), (Brecher, 2014), (Kesler, 2013). Consequently, WPT has achieved considerable technological development recently. Technically, inductive coupling WPT becomes more popular rather than direct coupling method through wires for short range power. In addition, some highly efficient WPT system uses adaptive and tightly coupled resonant coils (kurs, 2007), (Karalis, 2008), (Sample, 2011). Interestingly, WPT can penetrate low power for small devices as well as respectively high power for larger applications (Low, 2009), (Shin, 2013) with coil size of few centimetre to over a meter. Hence, WPT is highly potential to power up the IMDs.

Now, WPT has several strategies to function on the basis of operating frequency. WPT with resonant system operate with frequency of 1 to 50 MHz (kurs, 2007) and for some medical applications it is 402 to 405

MHz (IEEE, 2005), (ICNIRP, 2010). This WPT system with high reactive near field can cause large induced fields in human tissues. In worst case to consider, children absorb more radiation than adults (Morgan, 2014). Hence, the effect of this field need to be explained.

Though this is one of the on rising concerns however there is no regulatory standard currently for this issue. As a reason due to the inadequate appropriate standards, several difficulties have been identified by the U.S. Federal Communications Commission (FCC) in demonstrating compliance of a WPT (FCC, 2010). In addition, the protection of the medical implant wearer in the presence of EMF exposure is not decided yet (Kyriakou, 2012).

EXPOSURE RESTRICTIONS FOR HUMAN SAFETY

WPT provides convenience and safety to the public. However, WPT also possesses the potential danger of electromagnetic field (EMF) exposure for human safety. Extremely high frequency operated system may contain enough energy to break chemical bond (ionization) which can damage the genetic materials of cells. This event can lead to cancer or birth defects. Though there are no clear evidence of reverse biological impact of WPT system, however effect of long term usage yet to be defined. Therefore, the exposure of electromagnetic field by WPT needs to be controlled properly to ensure the human safety. Fortunately, there are several national and international organizations to investigate the adverse effect of EMF exposure. Among them the most prominent organizations are the International Commission on Non-Ionizing Radiation Protection (ICNIRP) and the Standards Coordinating Committee 28 (SCC28) of the IEEE. They continuously monitor latest findings to derive the EMF exposure limits and based on that they provide the up-to-date frequency and specific absorption rate (SAR) limits.

In 1974 it is determined from a study that above a certain frequency ranges absorbed radiation is increased up to nine times. Previously it was expected to be the minimum level (Gandhi, 1974). Consequently, one experiment was performed on rats which give evidence of abnormal mental functionality with SAR exposure as low as 1 W/kg (D'Andrea, 1975).

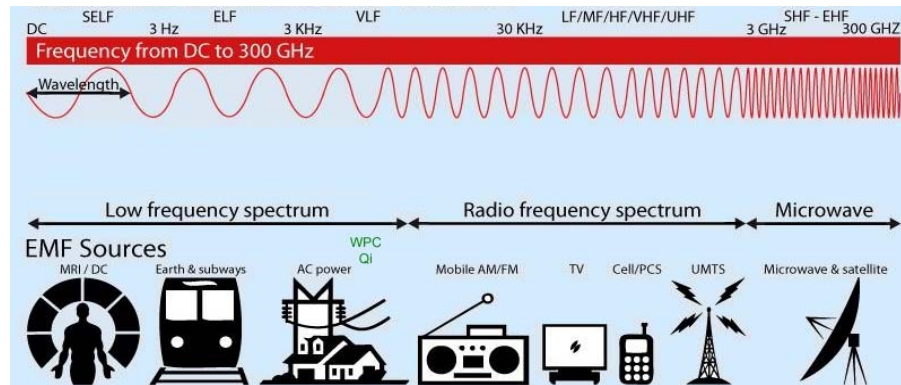


Figure-1. Electromagnetic spectrum [Source: (WPC)].

In 1982 the American National Standards Institute (ANSI) published a standard for exposure limits on the basis of behavioral effects. ANSI conclude the experiment with exposure range of 4 W/kg and 8 W/kg and claim the effect can take place as reversible. However, long term attachment may cause the effect irreversible (ANSI, 1982). Later, in 1991 IEEE reviewed ANSI standard and put up some minor corrections during 2005-2006 (IEEE, 1992). Nevertheless, FCC formed a two-tier system which includes Uncontrolled Environment and Controlled Environment. These environments can be defined as follows,

Uncontrolled Environment can be defined as the locations where exposed or potential to be exposed individuals are not aware about the exposure limit or the exposure of themselves to electromagnetic field or they do not have the control on the exposure limit. Living areas or workplaces can be potential as uncontrolled environment.

Controlled Environment is the location where the present individuals are aware about the exposure limit and their effects. In addition, it is expected that they have control on the exposure limit, if not they can avoid that area (indicated by notice or poster about the exposure).

In these environments, the whole body SAR should be up to 0.4W/kg and peak spatial SAR of 8 W/kg for any 1 gram of tissue averaged over 6 minutes. Later, it is revised as, 0.08 W/kg and the spatial peak SAR for any 1 gram of tissue to 1.6 W/kg averaged over 30 min for both exposure pattern (IEEE, 1991). This revised version was adopted by ANSI in 1992, referred to as, ANSI/IEEE C95.1-1992 and until 2005 this revision was unchanged (Gandhi, 2012).

FCC approve the ANSI/IEEE C95.1-1992 standard in 1996 and published the first U.S. regulations on maximum allowable cell phone radiation. In fact, FCC came up with a report called Bulletin 65 and described regulations for human exposure to electromagnetic fields based on 1991 IEEE standard (Cleveland, 1997). In the same year, FCC circulated an addition of the report called supplement C. Basically this one is the extension of the earlier published issues. However, several extended concerns were discussed in this version including portable devices, SAR evaluation and compliance. Certification for finite-difference time-domain (FDTD) were introduced in the same version to evaluate the far-field and near field applications.

Table-1. IEEE recommended frequency limits.

Organization	Frequency	E-field in V_{RMS}/m		H-field in A_{RMS}/m		Equiv. plane wave power density in W/m^2	
		Unc.	Con.	Unc.	Con.	Unc.	Con.
IEEE 2005	100KHz-1MHz	614	1842	$16.3/f_M$	$16.3/f_M$	1000	9000
	1MHz-134MHz	614	$1842/f_M$	$16.3/f_M$	$16.3/f_M$	1000	9000
	134MHz-3MHz	$832.8/f_M$	$1842/f_M$	$16.3/f_M$	$16.3/f_M$	$1800/f_M^2$	$9000/f_M^2$
	3MHz-30MHz	$832.8/f_M$	$1842/f_M$	$16.3/f_M$	$16.3/f_M$	$1800/f_M^2$	$9000/f_M^2$
	30MHz-3 GHz	-	-	-	-	10×10^{-7}	10×10^{-7}

Note: **Unc.** Represents uncontrolled environment and **Con.** Stands for Controlled environment.

**Table-2.** ICNIRP recommended frequency limits.

Organization	Frequency	Current Density in $\text{mA}_{\text{RMS}}/\text{m}^2$		E-field in $\text{V}_{\text{RMS}}/\text{m}$		H-field in $\text{A}_{\text{RMS}}/\text{m}$		Equiv. plane wave power density in W/m^2	
		Unc.	Con.	Unc.	Con.	Unc.	Con.	Unc.	Con.
ICNIRP 1998	100 KHz- 1 MHz	$f_H/500$	$f_H/100$	87	610	$0.73/f_M$	$1.6/f_M$	-	-
	1 MHz- 10 MHz	$f_H/500$	$f_H/100$	$87/\sqrt{f_M}$	$610/f_M$	$0.73/f_M$	$1.6/f_M$	-	-
	10 MHz- 400 MHz	-	-	28	61	0.073	0.16	2	10
ICNIRP 2010	3 KHz- 10 MHz	-	-	83	170	21	80	-	-

Note: **Unc.** Represents uncontrolled environment and **Con.** Stands for Controlled environment.

The International Commission on Non-Ionizing Radiation Protection (ICNIRP) was founded in 1992 by the International Radiation Protection Association (IRPA) as a non-government organization. The soul target of the organization was to provide protection guidance on non-ionizing radiation, i.e. radio, microwave, UV and infrared and their applications. Nevertheless, in 1998, ICNIRP provided a a regulation based on the two tier system. Interestingly they approve exposure time of average 6 min instead of 30 min, like the earlier proposal. In addition, a safety factor of 5 was introduced. Point to notice that, Switzerland was the first country to approve safety limits of 20 dB below the ICNIRP guidelines for permanent installations in sensitive areas (e.g., schools, living areas, hospitals). Switzerland approved it under the National regulations based on the ICNIRP Guidelines 1998 (Legislation Swiss, 1999). However, ICNIRP did not clarify neither the recommendation of the exposure standards IEEE lead nor the test requirements to evaluate the EMF measurement (Ahlbom, 1998). Nonetheless,

FCC provided revised supplement C in 2001 which was considered as standard and ideal for industry application with FDTD method. Later in practical European Union propose an instruction set in 2004 to protect workers from possible hazardous effects from electromagnetic field effect to apply in its member countries (Directive EU, 2004). Though the concerns of the exposure restrictions are below of the level of establishment however the uprising practices are promising.

FREQUENCY RESTRICTIONS

Frequency restrictions for human exposure are defined on the basis of current density and specific absorption rate (SAR). Thus, frequencies can be restricted accordingly. For convenience they are classified in to three groups (Sienkiewicz, 2010) as follows,

- Low frequencies
- Intermediate frequencies
- High frequencies

In this paper low frequencies are limited up to 300 Hz time-varying EMF; intermediate frequencies as EMF of 300 Hz to 100 kHz; and high frequencies are defined with the frequency range of 100 kHz and 300 GHz. Nevertheless, practicing frequency restrictions through direct measurement with human model is impractical. Hence, scientists rely on simplified anatomical models to evaluate the basic restrictions and define reference levels for the exposure incident for both near-field or far-field conditions. Exposure limits can be classified based on safety guidelines as,

- The basic restrictions
- The reference levels or the maximum permissible exposure

The Basic restrictions indicates a threshold value and crossing that value can have inverse effect on biological configuration within a safety factor. These effects includes tissue heating from radio frequency (RF) energy absorption above 100 kHz or nerve stimulation from contact currents or induced currents or fields in the body below 10 MHz. SAR limits the energy absorption for the whole body to prevent thermal stress. In addition, to prevent local thermal injuries it is recommended to avoid over any 10-g or 1-g tissue mass within the specific frequency range. Furthermore, to prevent unwanted and hazardous excitation of nerve tissue the induced fields are limited below 10 MHz. The limitations are usually defined in terms of current density or of electric fields averaged over a sufficiently large number of nerve cells. Table-3 illustrates the basic SAR limits.



IEEE recommended frequency limits

IEEE recommends safety standard in terms of exposures limits of incident external fields for controlled and uncontrolled environments which represents occupational and general public exposures, respectively. The IEEE frequency limits are given in Table 1 for controlled and uncontrolled environments. For both environments the suggested frequencies are ranged from 100 KHz to 3 GHz. The restrictions are necessarily decided in terms of electric field, magnetic field, equivalent plane wave power density. From table it is clear that, electric field can be permitted up to 27.76×10^{-3} for uncontrolled environment and 61.4×10^{-3} for controlled environment in V_{RMS}/m unit. For magnetic field and equivalent plane wave power density, maximum permitted limits are $5.4 \times 10^{-4} A_{RMS}/m$ and $10 \times 10^{-7} W/m^2$ for both environments. In addition, whole-body average and localized SAR are the key parameters to find the frequency range. Frequencies ranged from 0.1 to 6000 MHz, the whole-body average SAR limits of 0.4 W/kg and 0.08 W/kg for controlled and uncontrolled environments respectively as IEEE recommendation. Figure-1 illustrates the recommendation from IEEE.

ICNIRP recommended frequency limits

ICNIRP standardizes the frequency range from 100 KHz to 400 MHz, though can be peaked up to 6 GHz. Compared to IEEE, ICNIRP evaluate with additional parameter of current density of maximum $20 mA_{RMS}/m^2$ and $100 mA_{RMS}/m^2$ correspondingly for uncontrolled and controlled environment. Electric field is limited from $28 V_{RMS}/m$ to $61 V_{RMS}/m$, magnetic field is from $0.073 A_{RMS}/m$ to $0.16 A_{RMS}/m$, and equivalent plane wave power density is restricted between $2 W/m^2$ to $10 W/m^2$ for uncontrolled and controlled environment respectively. However, these values were updated in 2010 version where electric field revised to $83 V_{RMS}/m$ and $170 V_{RMS}/m$ with magnetic field $21 A_{RMS}/m$ and $80 A_{RMS}/m$. Table-2 describes the safety parameters from ICNIRP.

In addition with IEEE and ICNIRP, Sanitary Norms and Regulations (SanPiN) is monitoring the exposure limitations for safety as well. SanPiN is a Russian organization and part of Ministry of Health of the Russian Federation/ Russian Ministry of Health Protection (SanPiN, 2015). However, SanPiN limited its activity to define the regulations for incident field strengths only and no basic restrictions in terms of fields or currents induced in the body.

Table-3. Recommended exposure limits for uncontrolled environments.

Organization	SAR [W/kg] (Whole Body Avg)	SAR [W/kg] (Head/Trunk per 10g)	SAR [W/kg] (Limbs per 10g)
ICNIRP 1998	0.08	2	4
ICNIRP 2010	0.08	2	4
IEEE 2005	0.08	1.6 (per 1g)	4

RESTRICTIONS FOR IMPLANTABLE DEVICES

The safety standards from IEEE and ICNIRP do not consider the case where active and passive metallic implants are present in a potentially strong field and its enhancement. So far it is defined as an untested condition. However, an effect is expected from this event. Nevertheless, a study (Kyriakou, 2012) investigated the feasibility of effect of electromagnetic exposure to implant wearers. The study concluded that current guideline is not adequate to protect implant wearer against electromagnetic environment. In addition, it warns about upcoming stronger electromagnetic field, i.e. WPT. Presence of excessive electromagnetic fields can potentially effect the device functioning which can lead to temporary device malfunction or permanent damage. Again most of the implantable devices are installed deep into the tissues and cavities of the body. Therefore device maintenance is complicated and there are risks of health of the patient. Additionally, implant wearer can be exposed to resonance emitter which can be turned out as life threatening incident (Rezai, 2004). These can introduce several uncomfortable

event as heating, magnetic field interactions, induced currents, and interference with correct functioning of the implanted modules. Thus, it may result considerable damage in temporary or permanent context, in other explanation, transient dystonia, paralysis, coma, or death (Shinbane, 2011), (Gupte, 2011). Therefore, a proper and updated guideline needs to be presented for future references of implant wearer safety.

DISCUSSIONS

Several attempts were made to find out possible biological effects of EMF exposure for human safety. However, till now the existing evidences are considered as inadequate to reach a reliable decision (Sienkiewicz, 2010), (Maeda, et. al. 2008), (Zamanian, A., and Hardiman, C. 2005), (Havas, 2004). For low frequencies, effect of cancer, neurodegenerative diseases, cardiovascular diseases, reproductive effects were suspected. However, the evidences are either limited or inadequate to make a decision. Intermediate frequencies were restricted to long range radio, welding devices, CR



based monitors and MRI due to their induced fields in the past. However, due to the emergence of new technologies and limited data of possible health affects these restrictions are begun to be less effective. High frequencies were considered as less harmful in the frequency family due to their low power interaction. Nevertheless, some investigations are completed in need of recent emerging concerns. As outcome of the research, no harmful effects are available due to the exposure. Moreover, static or time-varying EMFs has insufficient verification of inverse effect on the blood pressure, heart rate, or EEG waveform during human exposure (Jauchem, 1997). For practical implementation whether in the case of IMDs or exposable conditions to EMF, mostly intermediate frequencies are preferable by the researchers which is below 10 kHz (Basar, et al., 2014), (Gherardini *et al.*, 2014). In fact, both IEEE and ICNIRP limit the frequency range up to 10 MHz. In the context of safety, high frequencies are considered as safe for their low power applications, not exceeding 10 MHz (Christ *et al.*, 2013). In effect, for the frequency range 1Hz to 300 GHz, E-field strength is limited to 137 Vm^{-1} for high frequency where low frequency can reach up to $20,000 \text{ Vm}^{-1}$. Again, H-field is limited in the frequency range from 0.36 Am^{-1} to 1.63×10^5 (Vecchia, 2007). However, the long term attachment might have unwanted effects.

Unfortunately, all these analysis were done considering short term effects, i.e. for upto 24 hours, whereas long term effect is being ignored or infeasible to investigate (WHO, 2007). Therefore, further research is necessary to make a concrete set of guidelines including short term and long term effects.

So far the suggested restriction limits from IEEE and ICNIRP are being followed by many countries. Namely, countries from EU, USA, New Zealand, Russia, India and so on are following the limits strictly, especially for portable and wireless applications. As the wireless applications are expected to be surged in future whereas it is already available for general purpose use, more countries will join the restrictions for practical implementations.

CONCLUSIONS

Powering implantable devices is a challenge due to the high cost, severe installation, sensitive maintenance and life threatening recharge process since the introduction of pacemaker. As a solution, WPT system has reached to the level of reliability and can power up an implanted device without engaging any wire. Besides WPT offers portability and cost effective operation. However, the demonstration of the effect of electromagnetic field in presence of an implantable device is yet to be defined. In this paper, the powering tactics for implantable devices are discussed with frequency restrictions and some trends of evolution of the restrictions. IEEE and ICNIRP recommended guidelines are discussed in details. In

addition the applicability and adaptability of these guidelines for implantable devices are described. From the existing literature it is evident that there is no proper set of instructions in the case of implantable devices. As the application of WPT is increasing with a fast pace it is mandatory to introduce a proper set of guideline for future references.

This paper focuses on the restriction limits for general purposes. Effects of practical implementation of the intermediate frequencies is our future agenda.

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