RF in Healthcare – Friend or Foe

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The application of radiation in healthcare of whatever frequency is predicated on the interaction of the radiation with tissue and the balance of risk and benefit to deliver patient benefit. For ionizing radiation this is well understood, however for non-ionizing radiation across the RF spectrum the balance of risk and benefit is less well understood. This is primarily due to the fact that the interaction with tissue is poorly characterized except in higher power applications. The continuing concern that mobile phone use has the potential to mediate brain tumours is an exemplar of the lack of clear evidence and understanding. The application of RF in healthcare environments is further complicated by the potential for adverse interactions between electrical and electronic systems. It is not often possible to test all potential interactions of devices in the healthcare context and thus regulation tends to restrict technology adoption especially where there is documented potential for patient harm.

Within this context, the application of RF in healthcare can be divided into a number of discrete classes. Firstly, communications and identification technologies where applications such as the management of medical devices and the asset base using RFID and radio communications are slowly being adopted. Healthcare will not be immune from the technology supporting 'the internet of things'. This application has the potential to greatly increase the efficiency and safety of use of medical devices. Secondly, the generation of heating within tissues to alleviate pain or provide cosmetic treatments. It can be used to kill tumour cells or modify abnormally functioning cells whilst preserving normal tissues – hyperthermia. At higher power it will lead to direct tissue ablation and destruction. The latter is used through a technique called diathermy to cauterize tissues during surgery and prevent excessive bleeding. One of the most important applications of RF in healthcare is in the development of MRI imaging. This has become one of the highest resolution, in-vivo imaging technologies with the growing potential to provide quantitative, functional discrimination of tissues, however the increase in magnetic field strength has led to safety concerns due to induced currents and heating within the body. The application of NMR in-vitro is an established technique. More recently there have been developments in the application of multi-spectral RF technologies to characterize tissues. This is being commercialized to provide a method to monitor cerebral blood volume and changes through intra-cerebral bleeds or stroke. This has the potential to significantly change clinical practice in the management of traumatic brain injury.

This paper provides a review of these key applications, the physical interactions that are exploited and often limit the application and the risks and benefits in the healthcare environment. The regulatory framework that needs to be applied will be highlighted.

INTRODUCTION

The use of radiation in the healthcare context is of great importance. The use of ionizing radiation for both diagnostic and therapeutic purposes is used worldwide as the basis for X-Ray imaging including CT imaging, gamma rays in Nuclear Medicine imaging and therapeutic applications and for Radiotherapy treatments using photon beams. The risks of the use of this radiation is well understood and exploited for treatment, or managed to permit screening and diagnostic procedures where the benefit to the patient outweighs the risk of the intervention. Whilst the risks are understood and control measures to mitigate risks are in place there remains considerable societal unease about the use of this radiation. There is much greater acceptance of the use of non-ionizing radiation where there is a perception of zero risk to the patient through the radiation itself. The use of radiofrequency radiation across a wide frequency spectrum has found important roles in a number of key areas of healthcare provision. As with ionizing radiation applications are found in diagnosis as well as therapies. Magnetic Resonance Imaging (MRI) applies RF to excite principally protons within the body and extract pseudo structural information. In other applications the ability to use RF power to generate tissue heating finds a wide range of applications. There is growing use of RF in the cosmetic industry as well as the established applications in surgery and the treatment of a range of conditions including cardiac arrhythmias and cancer. The use of multi-frequency RF is leading to new diagnostic and monitoring devices that have the potential to address unmet clinical needs. The application of RF is driven by the interaction of the radiation with tissue and in particular the Specific Absorption Rate (SAR) for the applied energy.

The use of RF as a communications tool is still under utilized in the healthcare environment for a number of reasons and there remain many opportunities to enhance the delivery of healthcare. Whilst radiofrequency identification is widely used in many industrial sectors its application in healthcare has been limited despite proven case studies of its cost and efficiency benefit. This, to a high degree has been tempered by concerns over the interaction of RF with medical devices. This remains a concern yet to be satisfactorily addressed. This issue is closely linked to the application and uptake of WiFi and other RF frequency communications and the development of the 'Internet of Things'. The security and safety of devices, especially medical devices, that communicate via WiFi remains of major concern. Concerns over the validation of data, the susceptibility to external radiation sources and to the malicious interference with the function of devices through hacking all lead to a reluctance to adopt technologies in safety critical environments.

LEGISLATIVE FRAMEWORK

The use and safety of workers from RF sources is governed by the European Physical Agents Directive. On June 29th, 2013, the European Commission published Directive 2013/35/EU on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (20th individual Directive within the meaning of Article 13(1) of Directive 89/391/EEC). Member States have been given 3 years, up to 1st July 2016, to transpose the Directive. This Directive is based upon the recommendations of the International Commission on non-Ionizing Radiation (ICNIRP) based upon the latest

scientific information available. Whilst the proposed European Directive seemed balanced and provided a sound basis for delivering a framework for occupational exposure safety it became clear that without modification there would be a significant negative impact on Magnetic Resonance Imaging (MRI) in healthcare especially with high magnetic field strengths. This is now widely understood and mechanisms now exist in the directive for member states to implement it in a manner that is not detrimental to the application of this technology in healthcare. Details of the relevant control mechanisms are awaited and EU guidance is expected in early 2016 with the Health and Safety Executive in the UK expected to publish its own guidance in a similar timeframe. More information can be found on the Health and Safety Executive web site (1).

Whilst the safety of workers who are occupationally exposed is important the safety of the patient or the volunteer in research studies is clearly of equal importance. The balance of risk and benefit in a clinical situation always drives the application of these techniques and technologies. This approach tends to push the envelope of safety beyond the limits which would be set for members of the public as the intention is to induce a change in the body to achieve the required therapeutic or diagnostic outcome. The recommendations of ICNIRP(2)are important in defining the exposure levels that are considered acceptable for members of the public and provide a benchmark against which enhanced risks can be assessed. The key parameter of interest if the Specific Absorption Rate (SAR) which is defined as the RF power absorbed per unit mass of the object in W/kg.

A further major concern is the effects of RF interference on Medical Devices and this is addressed in a number of European Directives including the Active Implantable Medical Device directive (90/385/EEC and amendments). This was transposed into UK law by the Medical Devices Regulations 2002. For 'general' medical devices by Directive 93/42/EEC applies. The government has published guidance (3) on the approach to be adopted to manage potential electromagnetic interference management in relation to medical devices. Needless to say this is a risk management approach and relies on an understanding of potential interactions and the clinical situation encountered.

In relation to RF based technologies there is one area where legislation is limited but the potential impacts are high. The growing use of WiFi and other RF technology to manage devices and transmit data presents the opportunity for both accidental and malicious interference with the performance of medical devices. The vulnerability of Medical Devices to 'hacking' has already been demonstrated and at present the challenge is to the manufacturers to limit the susceptibility of their products to such abuse.

ELECTROMAGNETIC INTERFERENCE

There are a number of key areas where electromagnetic interference might impinge on the performance of medical devices (4). This is particularly important for devices that have the potential to present a serious hazard to the patient including implantable devices such as pacemakers and cardioverter defibrillators. There are potentially issues with interference with non implantable devices such as ventilators, external defibrillators, ECG monitors and syringe and infusion pumps delivering drugs. Within the hospital environment there are a number of RF sources that raise concern including emergency vehicle and service radios, radiofrequency

identification devices (RFID), mobile phones, diathermy equipment, electromagnets and localization to lifts. All these in their own right are useful and essential technologies but to the patient can be the unseen enemy to health and wellbeing. Approaches to the management of these risks is outlined below.

- **Radiofrequency Identification (RFID)**

Radiofrequency Identification is used widely in modern systems and many of us will be carrying multiple RFID devices in daily living. Despite this widespread adoption the uptake and use of this technology in the healthcare sector has been slow despite there being clear evidence of the economic benefit of its use. The use of passive RFID tags is a relatively low cost and safe technology. The use of 'active' tags is more problematic and has raised significant concerns over electromagnetic interference. The technology was promoted as being able to locate, monitor and manage almost every thing to a spatial resolution of a bed space within the hospital. All staff would be locatable as well as patients, mobile equipment and instruments. Services and materials management could be coordinated with processes driven by 'just in time' delivery of all required resources. In such a complex environment the investment required in the infrastructure (typically WiFi) to deliver the location accuracy has proved prohibitive in most cases. The attachment or incorporation of RFID tags into medical devices for identification, location or telemetry purposes poses the greatest concerns. The technology covers a wide range of frequency bands from 125-134kHz to 433MHz, 915MHz and 2.4GHz. The identification and evaluation of an interference event is difficult as well as determining the potential impact on patient care. The effects are clearly distance and power related. Seidman SJ & Guag JW (5) amongst others point to measurable interference events in 15%-22% of the tests mainly at 915MHz although none were observed at 433MHz and 2.4GHz. Using the ANSI test standards (6), interactions were observed up to 136cm from the medical device although the majority occurred within 100cm. Medical devices are built to be compliant with the IEC 60601-1-2 standard. This specifies the frequencies to be tested and also the power and distance ranges. These are not all encompassing and do not cover all the frequency ranges used in current systems. To fully exploit this technology it is essential that further work is undertaken to manage and eliminate the risk of electro-magnetic interference. As an interim the Food and Drug Administration (FDA) in the USA have issued guidance for manufacturers of medical devices to provide transparency to users and certification bodies (7).

- **Mobile/Radio Phones**

Mobile and radio phones are treated in much the same way as RFID devices. They are known to interfere with medical devices although the approach to the management of this risk varies considerably. Initially healthcare institutions sought to ban the use of all mobile phones, however, this was an impossible position to adopt both from a public and staff perspective. Restrictions typically remain in intensive care and cardiac care areas where numerous critical life support systems exist. In all areas mobile phones are restricted from use within 100cm of medical equipment.

CONTROL SOFTWARE AND DATA SECURITY

The use of WiFi as a medium for data transmission and communications between systems and medical devices in a healthcare context is of particular concern. The security of wireless signals and the integrity of transmitted data must be actively managed. The methods required to achieve a secure data and control environment are many and include network management procedures as well as the design of the equipment, accessories and system. Interference between systems should be considered and risk assessed, especially where patients are discharged with medical devices into unknown environements. It is now a requirement that manufacturers and designers of computer networks consider the mechanisms in use to protect against unauthorised wireless access to device data and control software. It should be noted that many of the usual mechanisms such as anti-virus software are not compatible with the process of CE marking as Medical Devices since the interaction of this software with critical software applications cannot be predicted.

It is important to note that where computer systems and associated software control the action and performance of medical devices the entire system becomes a medical device and needs to be appropriately tested and risk assessed to mange these risks. There is thus a requirement to CE mark entire systems (or at least treat them) as Medical Devices and to demonstrate their safety and efficacy. The IEC 80001-1:2010 and following have been developed to manage the interconnection of Medical Devices to IT networks to effectively secure safe operating conditions.

Systems are being introduced which use proprietary low power RF transmissions to transfer data. These can use a range of frequency bands including 868MHz in the EU. The use of low power solutions is becoming important where ambulatory monitory is required over a period of days without the need for large battery power supplies or recharging circuits. Vital signs monitoring systems are now available using low power transmissions over 10-30m as a bridge to a standard WiFi gateway/network. The development of very low power systems will support the development of low cost monitoring systems and radically change healthcare delivery in both the hospital and community setting.

RF APPLICATIONS

- **Diathermy**

Diathermy is used principally in surgical procedures to cut or coagulate tissues. The technique uses high frequency current where the specific absorption rate of biological tissue is very high. The current is discharged from the tip of a fine live electrode which produces a high current density to desiccate or coagulate the tissue over a very small area. The arc generates temperatures in the region of 1000^0C using frequencies between 250-750kHz for coagulation and 500-2000kHz for cutting. Frequencies above 250kHz do not cause sensations of electric shock and have no effects on the heart. In modern systems the delivery of the current is switched at about 15kHz for coagulation purposes but operates in continuous mode for cutting. The process is dependent on creating a safe and effective current path through the patient or the area undergoing surgery. Systems operate in mono-polar or bi-polar modes. In mono-polar

mode a single large and flexible return electrode is placed on the opposite (back) side of the patient to provide a large return path for the current. This reduces the risk of burns and tissue heating by using as large a return path as possible. A large return path must be maintained within the patient. Where this is not permitted by the surgical procedures the system may be operated in a bi-polar configuration where the live and return electrode are placed close to each other whilst remaining insulated from each other to create a defined current path. This restricts the area subject to the electric current and avoids internal heating hot spots. This is the required technique where the patient undergoing surgery may have an implanted active device such as a pacemaker. Mono-polar systems cannot be used in these patients due to the potential for interference. Modern systems automatically control the power delivered by the system. Direct coupling producing stray currents as well as capacitive coupling where the procedure is performed internally are issues that should be avoided. Safe systems of work are essential where such equipment is used to avoid direct or indirect harm to patients and staff.

Diathermy is used to describe others techniques that deliver RF energy to create heating in tissue with a view to affecting a treatment. Radiofrequency Ablation (RFA) is a technique applied to the treatment of cardiac arrhythmias by the disruption of cardiac electrical conduction paths and to some cancers where a probe is inserted into the tumour and RF energy used to create localised interstitial heating to heat and kill cancer cells. Whilst not RF, this technique is being developed through the use of focussed high frequency ultrasound as another controllable method of creating targeted heating and destruction of tissues. There are a number of other treatments that use this technique to destroy and damage tissue particularly in the area of pain reduction. Systems exist to reshape the cornea and correct vision as an alternative to laser eye treatment. These techniques are also becoming widely used in cosmetic procedures. One application is in procedures for skin tightening and body contouring. In these procedures the heating levels in the tissue are much lower and it is thought create a micro-inflammatory process to stimulate the growth of new tissues. By modifying the delivery method and applying surface cooling the depth and extent of local heating can be controlled. This allows the heat to be focussed below the surface of the body. Commercial systems use frequencies between 1MHz and 45MHz, delivering 30-400W, depending on the application.

- **Magnetic Resonance Imaging (MRI)**

Magnetic resonance imaging is a non-invasive medical imaging technique that uses the interaction between radio frequency pulses, a strong magnetic field and body tissue to obtain images of slices/planes from inside the body. The magnets generate fields from approx. 2000 times up to 30000 times stronger than that of the Earth. Typical magnetic field strengths of 1-5T – 3T are used clinically with 7T and greater being introduced for research purposes. The use of nuclear magnetic resonance principles produces extremely detailed pictures of the body tissue without the need for x-ray exposure and gives diagnostic information for a range of various organs.

In the majority of imaging applications MRI relies on the excitation and relaxation of protons in the hydrogen atoms of the water molecules, the majority of elements in the body. Only a small number of them contribute to the measured signal, caused by their different alignment in the magnetic field. Protons are capable of absorbing energy if exposed to short radio wave pulses

(electromagnetic energy) at their resonant frequency. After the absorption of this energy, the nuclei release this energy so that they return to their initial state of equilibrium. These relaxation rates are typically called T1 & T2 leading to T1 and T2 imaging.

This transmission of energy by the nuclei as they return to their initial state is what is observed as the MRI signal. The subtle differing characteristic of that signal from different tissues combined is what enables MRI imaging to distinguish between various organs and tissues. Any imaging plane, or slice, can be projected and interpreted.

The measured signal intensity depends jointly on the spin density and the relaxation times (T1 time and T2 time), with their relative importance depending on the particular imaging technique and choice of pulse sequence. Any motion such as blood flow, respiration, etc. also affects the received signal.

Magnetic resonance imaging is particularly sensitive in assessing anatomical structures, organs and soft tissues for the detection and diagnosis of a broad range of pathological conditions. MRI pictures can provide contrast between benign and pathological tissues and may be used to stage cancers as well as to evaluate the response to treatment of malignancies. The need for biopsy or exploratory surgery can be eliminated in some cases, and can result in earlier diagnosis of many diseases.

MR systems operate in a very RF sensitive environment. The systems are built into Faraday cages to eliminate external RF interference. The systems use RF coils to stimulate the protons at the resonant frequency of the protons. The resonant frequency of the protons depends on the applied magnetic field and from the Larmour frequency for ^{1}H protons is 42.58MHz/Tesla. Radiofrequency magnetic fields thus operate between approx. 64MHz and 400MHz. The excitation coils can be used as detection coils or typically separate coils are used as detectors. The use of magnetic field gradient coils allows the selection of discrete imaging planes by the use of high resolution spectrometers for the detected signal

In MRI, the SAR governs the potential for heating of the patient's tissue due to the application of the RF energy necessary to produce the MR signal. Inhomogeneity of the RF field leads to a local exposure where most of the absorbed energy is applied to one body region rather than the entire person, leading to the concept of a local SAR. Hot spots may occur in the exposed tissue, to avoid or at least minimize effects of such theoretical complications, the frequency and the power of the radio frequency irradiation should be kept at the lowest possible level. Averaging over the whole body leads to the global SAR.

It increases with field strength, radio frequency power and duty cycle, transmitter-coil type and body size. The doubling of the field strength from 1.5 Tesla (1.5T) to 3 Tesla (3T) leads to a quadrupling of SAR. In high and ultrahigh fields, some of the multiple echo, multiple-slice pulse sequences may create a higher SAR than recommended by the regulators. SAR can be reduced by lower flip angle and longer repetition times, which could potentially affect image contrast.

Normally no threatening increase in temperature was shown. Even in high magnetic fields, the local skin temperature increases not more than 1°C.-2.1°C. Eddy currents may heat up implants and thus may cause local heating. Of more concern is the risk of heating from instrument leads and metallic objects which can potentially lead to tissue burns.

With the introduction of higher static magnetic fields to 7T side effects are more regularly seen as the body is moved through these fields where nerve stimulation and vertigo-like sensations are known to occur. The switched gradient fields can also result peripheral nerve stimulation under certain conditions. For the RF fields the key issue is tissue heating where limits have been set for the Specific Absorption Rate as below.

FDA SAR limits

- Whole body: 4W/kg/15-minute exposure averaged;
- Head: 3W/kg/10-minute exposure averaged;
- Head or torso: 8W/kg/5 minute exposure per gram of tissue;
- Extremities: 12W/kg/5 minute exposure per gram of tissue.

IEC (International Electro-Technical Commission) SAR limits for some European Countries:

- Level 0 (normal operating mode): Whole body 2W/kg; Head 3.2W/kg; Head or Torso (local) 10W/kg; Extremities (local) 20W/kg;
- Level I (first level controlled operating mode): Whole body 4W/kg; Head 3.2W/kg; Head or Torso (local) 10W/kg; Extremities (local) 20W/kg;
- Level II (second level controlled operating mode): All values are over Level I values.

(For more details: IEC 60601-2-33 (2002))

In most countries standard MRI systems are limited to a maximum SAR of 4. Specific UK guidance has been published by Public Health England (8)

- **Multi-Frequency RF**

The measurement of the impedance of biological tissues to multiple discrete applied RF electrical fields has been shown to be capable of tissue type discrimination using appropriately trained classifiers. A recent application is in the development of Volumetric Electromagnetic Phase Shift Spectroscopy (VEPS) of Brain Oedema and Haematoma by Gonzalez et al (9). This is being developed into a commercial product capable of providing a low cost, contactless monitoring device for patients with acquired brain injury (10). The device consists of two coupled coils in an inductor-sensor arrangement placed around the circumference of the head. An alternating current is injected into the inductor coil. The sensor coil measures the induced magnetic field modified by the intervening brain structures. The changes are measured by analysing the phase shift between the two coils as a function of injected current frequency. This produces the VEPS data used for subsequent classification. Measurements are taken across the frequency range from 1-200MHz at 1MHz intervals and normalized for the circumference of the head. Specific dielectric dispersion signals have been found at frequencies from 26-39MHz and 153-166MHz. By comparison with X-ray Computed Tomography scans in healthy volunteers and patients with brain damage the authors claim to be able to distinguish between oedema and haematoma. The system is capable of monitoring changes in these parameters with time and thus the non-invasive monitoring of patients at risk of developing a cerebral haematoma becomes a viable proposition. Preliminary, unpublished data, suggests that it is possible to measure absolute blood volumes within the brain to provide not only a monitoring device but

also a diagnostic device that could be used in a range of environments including remotely from an acute hospital environment to direct early intervention prior to hospitalization.

In general, measurement of the electromagnetic spectral characteristics of biological tissue provides information on the structure and changes in composition of the tissues, in particular the ratio of intracellular to extracellular fluids. The use of bioelectrical impedance measurements to detect water content and oedema in the body was suggested almost half a century ago. Bioelectric measurements have evolved into an imaging technology known as Electrical Impedance Tomography (EIT) (11) that uses arrays of contact electrodes to inject sub-sensory currents in the body and measure voltage to produce a map of electric impedance of tissue for use in various medical imaging applications, including detection of oedema. Bioelectrical measurements by electro-magnetic induction with non-contact electrical coils are considered a valuable alternative to contact electrode measurement. Inductive measurements do not require galvanic coupling between the electrode and the skin or the tissue under measurement. In the particular case of brain conductivity measurement for oedema detection, the skull does not represent a barrier for the magnetic field. Magnetic Induction Tomography (MIT) and its different variants (12) are examples of the use of radiofrequency signal application in the medical arena, however, the resolution of these systems remains poor and the mathematical solution to tomographic imaging is ill defined. Effective clinical applications are yet to be clearly identified.

CONCLUSION

Radiofrequency fields have a wide range of applications in healthcare. In almost all cases the balance Similarly for the operators of the technology who are exposed over a much greater timescale. Public concern still remains over the use of radio communication systems and their potential health impact. Within the health context much more concern exists over the integrity of communications and the potential for interference between systems impacting critical medical devices. The use of RF technology in surgery, cosmetic surgery, and cardiac and cancer therapy are well established and of proven benefit. The use of MRI as a high resolution imaging technique and much more will continue to grow as society moves away from the use of ionizing radiation in the form of X and gamma rays. Side effects are limited and appear transient. The development of other imaging techniques has been slow and with limited clinical application although the recent development of systems based on multi-spectral RF, non-contact monitoring for the detection of tissue changes may prove an invaluable tool in a range of applications.

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