Electromagnetic Susceptibility of Implantable Medical Devices: An Experimental Assessment

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***Abstract*—Electromagnetic waves can cause electronic devices to malfunction unintentionally. Implantable medical devices must be specially designed to be immune to radio frequency interference. Measuring the electric field around an IMD is one approach to determine whether it might malfunction. This paper presents an experimental set-up that emulates the conditions of a medical device implanted inside a human body. Using an electric field probe for liquids, the field around the IMDs is measured. As result, the heat maps around the IMDs are shown, which allows us to infer that at frequencies of 850 MHz there is no reason to consider that the device may have malfunctioned.**

***Index Terms*—Implantable Medical Devices (IMDs), Electromagnetic Compatibility, Peacemakers.**

I. Introduction

With the continued growth of the number and variety of Implantable Medical Devices (IMDs) used worldwide, along with the advancement of technologies that use the radio spectrum in human-accessible environments, there is growing concerned about the potential generation of risk situations for IMD carriers. To ensure the harmonious development and use of these technologies, it is necessary to quantitatively analyze the interaction of electromagnetic fields with IMDs in realistic scenarios, as well as to determine the impact of this interaction on the devices and their carriers, while taking into account reference information such as relevant international standards, technical and medical specifications on device operation, and manufacturer's documentation. The results of the analysis will allow recommendations to be generated for the interested parties.

There has been a growing interest in determining the susceptibility of IMDs to electromagnetic fields since the 1970s. For example, the authors in [1] tested pacemakers implanted in large canines at eleven different frequencies ranging from 10 MHz to 3050 MHz, whereas the authors in [2] investigated the effect of FM and television signals in response to various reports of documented device malfunctions. Recently, due to reports of pacemaker failures when users pass metal detecting systems, a metal detector emulator system was developed in [3] to evaluate the electromagnetic susceptibility of pacemakers. Similar to [4], an implantable cardiac defibrillator's immunity to electromagnetic noise was assessed in an anechoic RF chamber.

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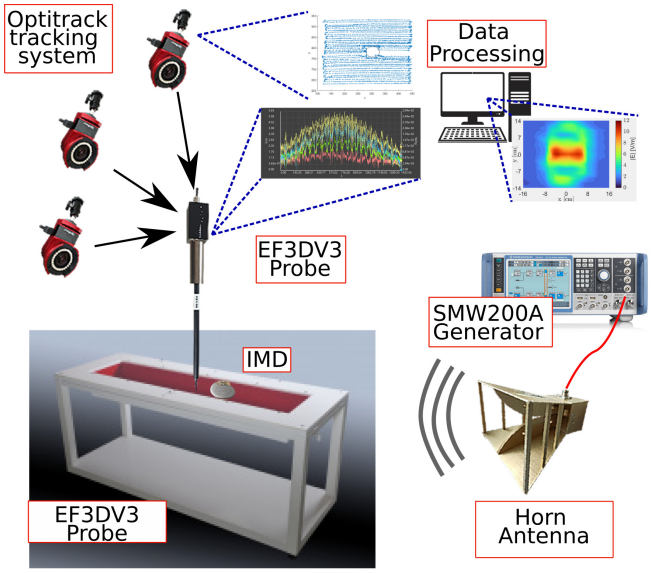

Fig. 1. Experimental setup for the measurement workflow

There are currently several standards that seek to guarantee the safety of people exposed to electromagnetic fields, and refer directly or indirectly to the possibility of the presence of implantable medical devices [5], [6]. The standard IEC60601-1-2 [7] is particularly related with the requirements and tests for electromagnetic compatibility of medical electrical equipment and systems. This standard gives the immunity levels for a given electromagnetic disturbance incident on life and non-life supporting medical devices, equipments or systems.

This paper presents an experimental assessment for electromagnetic susceptibility tests of IMDs.The measurement of electric field heat maps around an IMD is performed using the experimental work assembly depicted in Fig. 1. The remainder of the article is organized as follows. Section II describes the different types of IMDs examined in this document. Section III describes the experimental setup, as well as the equipment and conditions used to emulate a IMD interaction and the interference of a radiocommunication technology. Section IV presents and discusses the results obtained. Finally, the conclusions and future work are presented.

II. IMDs UNDER TEST

There are life-support medical devices on which a failure caused by electromagnetic interference would be fatal. Two IMDs are worked on in this article, the first a real pacemaker and the second a cochlear implant dummy.

A. Pacemarkers

Pacemakers are class III biomedical devices, they are categorized as very high-risk devices since they are life-supporting and therefore are subject to additional controls [8]. The IMD risk is related to the health of the patient and is high because it is directly related to the cardiac system in an invasive way since it is implanted through surgical procedures. Various health problems can be treated with pacemakers [9]:

- Asystole: The heart's spontaneous electrical signals entirely stop, and the heart also halts pumping blood.
- Heart blocks: Although the sinus heart rate may be normal, sinus rhythm may not be maintained or heart impulses may not go all the way through the heart.
- Bradycardia: A slow or irregular heartbeat, typically less than 60 beats per minute.
- Arrhythmias: Heart rate disorders where the typical number of beats per minute rises, such as tachycardia.

When the patient's heart presents a malfunction, the peacemaker transmits electrical pulses to the heart to stimulate the contractions required for healthy blood circulation [10].

Since the invention of implantable pacemakers in the 1960s, conventional pacing systems consist of an electronic device powered by batteries, usually implanted in a subcutaneous pocket in the chest. In general, pacemakers are manufactured in semi-oval structures with a sealed titanium alloy casing and the connector head coating is made of materials such as epoxy, thermoplastic, polyurethane and polysulfone [11] as shown in Fig. 2. In addition, pacemakers are implanted with leads, which are in charge of transporting the electrical stimulus to the heart through the veins. The leads are made up of an iridium platinum electrode, and the conductor has the helical form of MP35N (Co—Ni—Cr—Mo alloy), with silicone rubber insulation of polyurethane to avoid damages such as erosion, material fatigue, fracture, and material oxidation [12].

B. Cochlear implant

Cochlear implants are categorized as class IIB, and therefore they are only high risk since they are non-life supporting, which means that devices must comply with particular design and manufacturing requirements to prove their effectiveness and safety. These devices carry a high risk of harm to the patient because the auditory system is directly affected. Additionally, because these devices must be implanted during surgery, there is a danger of infection, harm, and discomfort in the surgical area [8].

There are three main types of technology in hearing implants (Cochlear implant, implant for bone conduction, and implants from the middle ear) that vary depending on their placement in the anatomical region and the patient's pathology [13].

These biomedical devices were developed to help people (children or adults) with severe hearing loss and increase their ability to perceive sound [14]. The cochlear implant consists of an internal component (implant and electrode array) and an external component (sound processor and receiving antenna). The electrode array stimulates the auditory nerve directly by sending signals to the auditory nerve, which then transmits those signals to the brain where they are translated into sounds [15].

III. EXPERIMENTAL SETUP

An implantable medical device is invasively inside a human body and exposed to different radiofrequency waves that can cause malfunctions. According to the standard [7], an implantable life supporting device must be compliant to radiated electric fields up to 10 V/m in the frequency range of 80 MHz to 2.5 GHz. This section describes the experimental setup used to make measurements around the implantable medical devices.

A. Measurements workflow

To emulate the volume of a human body, a non-anthropomorphic flat phantom model is used. The dimensions of the Phantom are 154 cm × 34 cm with a depth of 18 cm. The phantom is filled with a tissue-equivalent liquid HBBL600-10000V6. This liquid emulates the average electromagnetic properties of the human tissues in accordance with the standard (i.e., IEC 62209 [16], IEEE 1528 [17]). The measurements of the dielectric properties of the liquid were reported in [18] (In frequency 850 MHz, ϵ' 45.36 and σ 0.9 S/m). The Implantable Medical Device (IMD) is located within the phantom in order to have similar propagation conditions found within the human body. To generate the radio frequency signals that represent the wireless communication produced by a certain technology, a SMW200A [19] and a horn antenna SAS-571 are used [20]. The electric field is measured with a linear and isotropic e-field

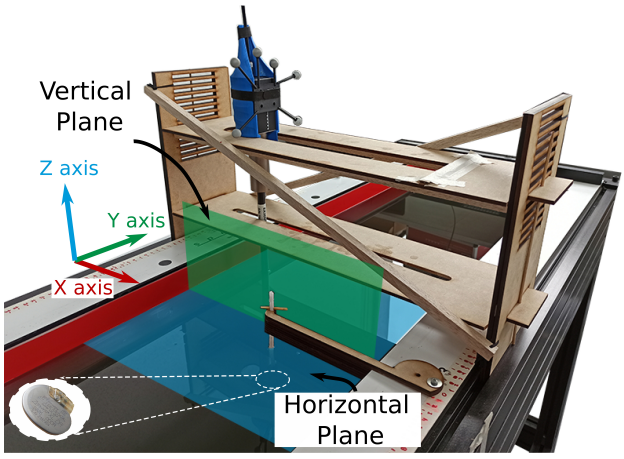

Fig. 2. E-field probe and IMDs supports for measurements in horizontal (blue) and vertical (green) planes.

probe EF3DV3 [21], which is specially designed for Specific Absorption Rate (SAR) characterization in liquids. This probe allows the electric field to be measured in areas very close to the IMD. The position of the probe is tracked with a high resolution optical system as shown in [22].

The experimental setup for the measurement workflow is shown in Fig. 1. First, the IMD is introduced in the tissue-equivalent liquid through support. Second, a continuous wave signal is generated from the vector signal generator SMW200A and then radiated by using a double ridge horn antenna. The antenna is pointed from the bottom directly toward the phantom model. Third, a 2D probe scan is made with the supporting structure shown in Fig. 2. Finally, after E-field data and tracked positions are registered, post-processing is done to obtain 2D hot maps of the field intensity. This procedure is adjustable for different depths so vertical and horizontal hot maps can be obtained for electromagnetic compatibility assessment of the IMD.

B. Implanted device model

At this work, we worked with pacemakers and cochlear implants. We aimed to work with real implanted devices, although it was not always easy to get real or functional ones.

In order to understand the operation of a cochlear implant and how it is affected by the surrounding electric field strength level, it is necessary to make one test based on a real model, which was consulted in the literature and corresponds to one of the industrial manufacturers. This implant, like many of its kind, has two coils (One outside the skull and the other inside the skull), two magnets (One for each coil), a signal processing circuit, and a plastic coating that must be capable of withstanding the liquids found inside the skull.

The coil that is outside the skull, through the process of electromagnetic induction, sends the audio signal to the coil that is inside the skull, which will be processed and later sent to the cochlea. The magnets are used to fix the device in its position, in such a way that it is possible to avoid as much as possible the losses that can originate as a result of the resistance that the human skull has and, in turn, help the greatest amount of induced signal to be absorbed focused on the coil inside the skull.

Taking into account the device operation, an inductive coupling of a cochlear device was constructed (Fig. 3) and tested. The dimensions of the coils were taken from commercial devices (i.e. diameter of 30 mm) and they were made of 12 turns with 18-gauge insulated copper wire. The used magnets are of neodymium, with a diameter of 10 mm and a thickness of approximately 4 mm.

C. IMD inside the phantom

Those prototypes helped us to make preliminary testing and allowed us to know which features of the experimental setup should be modified or added. For example, we identified the need for a support that would maintain the devices in a given position. One of the first ideas we explored was to hang the device from a string and leave it submerged into the liquid.

Fig. 3. Inductive coils of the dummy implantable cochlear device.

However, this alternative was discarded due to the movement the probe could generate, and the given that we needed the device to stay in an exact point. We created a support that was built using medium-density fibreboard (MDF) a laser cut and anchored to the phantom (Fig. 4). We needed to make it as small as possible, so we designed a shape just one-centimeter wide, and long enough to reach the center of the phantom. The tip has a small hole that receives a little structure holding in this case the pacemaker thanks to a slim nylon net. It is also designed to have an adjustable range of height and stays locked thanks to a pin. On the other hand, when the electric field probe is submerged, its end cannot be seen, so it may collide with the submerged IMD and break. To keep the e-field probe from colliding with the pacemaker, we installed a circular guide on the upper part of the support that allows it to skirt the silhouette of the submerged IMD.

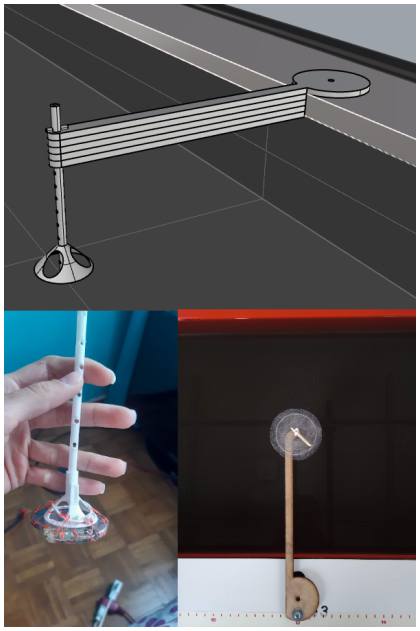

Fig. 4. Support for IMDs on the phantom model

IV. Results

With the conditions that emulate critical cases of interaction between a radiofrequency technology and a medical device implanted inside the human body, the electric field intensities around it are measured.

A. Peacemaker test

The horn antenna is located at the bottom of the phantom and pointing up. A 850 MHz wave is generated (i.e., one band used by mobile phones in Colombia) with a power of 30 dBm. This exposure scenario involves a user who is in close proximity to a 2G or 3G mobile terminal, both of which are still widely used. An real pacemaker without wires is placed at a depth of 16 cm, approximately 2 cm from the horn antenna, and subsequently, the electric field is measured in different planes. Two representative examples of the measured electric field are shown in Fig. 5. Figure 5a and 5b correspond to the horizontal heat map of the electric field without and with pacemakers, respectively. Similarly, Fig. 5c and 5d show the heat map of the electric field in the vertical plane. In the case of presence the position of the pacemaker is represented in white in the figures.

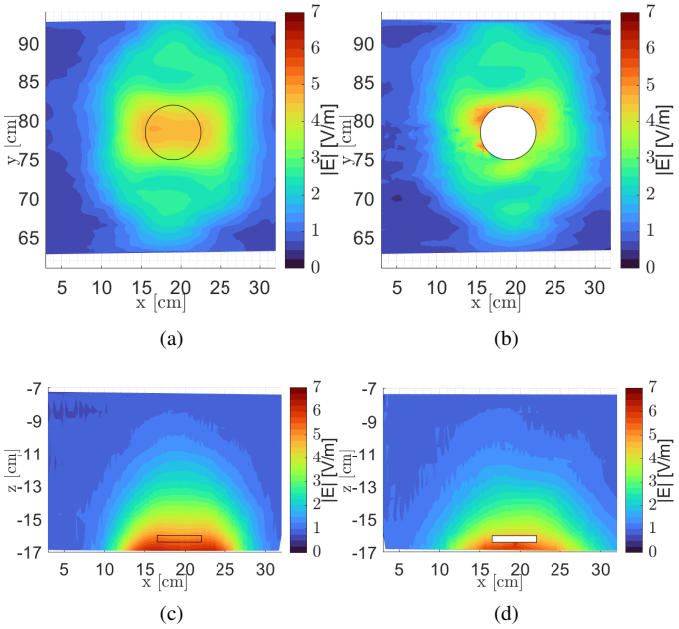

Fig. 5. Experimentally measured electric field on the Phantom model. **a)** Horizontal plane without a pacemaker. **b)** Horizontal plane with pacemaker.**c)** Vertical plane without a pacemaker. **d)** Vertical plane with pacemaker.

When the heat maps from the pacemaker are compared, there are some differences in the distribution of the field, but no significant change in intensity. On one hand, it can be seen in the horizontal plane that the pacemaker generates a point of high intensity in the upper left area, this is probably due to the acute shape of the carcass in that position. On the other hand, the vertical plane shows how the pacemaker shadows the electric field radiation reducing the field intensity as expected. It is worth to notice that despite the fact that the antenna is very close to the pacemaker, it is not possible to exceed the compliance E-field levels of 10 V/m given by the standard. From the foregoing, it can be inferred that there is insufficient evidence to consider that the pacemaker may be affected in that frequency band.

B. Cochlear implant test

The constructed dummy implant was introduced in the bottom of the flat phantom and radiated with the same configuration as the case of the pacemaker. E-field measurement results are shown in Fig. 6. In this case we only report the results obtained in the horizontal plane. From the results, we can conclude that there is a compliance in the maximum exposure limits of the device obtaining a maximum electric field intensity of 8 V/m. The maximum field intensity is obtained around the device as it is shown in Fig. 6b. In addition, regarding the case without the implantable device in Fig. 6a, the field intensity decays with the presence of the inductive coil, this is due probably because the coil acts as a electromagnetic filter obstructing the propagation of the radiofrequency signal.

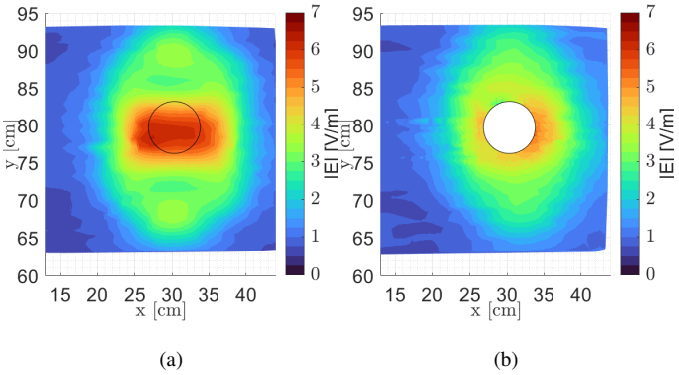

Fig. 6. Experimental measurement of the electric field with a simple cochlear implant model at a depth of 17 cm. **a** E-fields results without cochlear implant. **b** E-fields results with cochlear implant

V. Conclusions and Future Work

Measuring the electric field around an IMD can help establish if it is susceptible to electromagnetic interference caused by radio frequency signals. In this work, the conditions of a pacemaker and cochlear implant found inside the human body were experimentally emulated. To emulate the volume of a body, a Phantom model was used to emulate the dielectric properties of a special liquid and the electric field produced by an 850 MHz wave around the IMD submerged in the liquid was measured. The experimental results show that the electric field does not exceed the regulations established in IEC60601, so it can be inferred that the IMDs are not affected by the wave at this frequency. As future work, it should be analyzed whether other frequencies, other radiation powers and different antenna positions can generate an electric field that puts the operation of IMDs at risk.

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