Experimental Set Up to Test the Exposition of Implantable Medical Devices to Electromagnetic Fields

E. Pineda*, R. Urbina†, Z. Cucaita*, M. Barajas*, A. Gallego*, M. Pérez †, J.L. Araque*
* Dept. of Electr. Eng. Universidad Nacional de Colombia, Bogotá 111321, Colombia
† Dept. of Electronics Engineering, Pontificia Universidad Javeriana, Bogotá 110231, Colombia
Corresponding author: efpinedava@unal.edu.co

***Abstract*—Two real implantable medical devices were analyzed when they are subjected to electromagnetic radiation from radio communication systems to assess conformance to the IE 60601-1-2 Ed.2 2014, ISO ISO14708-2:2019 and ISO14708-7:2019 standards in exposition scenarios commonly found in Colombia.**

***Index Terms*—Cardiac Peacemakers, cochlear implant, Electromagnetic Compatibility, IEC 60601-1-2 Ed.2 2014, Implantable Medical Devices (IMDs), ISO ISO14708-2:2019, ISO14708-7:2019.**

I. Introduction

The electromagnetic environment can cause electronic devices to fail in their normal mode of operation due to interference produced by electromagnetic fields. In order to assess these effects, electromagnetic immunity tests are normally carried out, which enable determination of the impact of electromagnetic fields on the devices, and to some extent the relevant failure mechanisms. Specifically, we evaluate the exposition of two Implantable Medical Devices (IMD's) to electromagnetic fields due to radio communication systems. The devices considered are a cardiac pacemaker and a cochlear implant. The resulting field values were analyzed referring to the applicable standars: IEC Std 60601-1-2 Ed.2 2014, ISO ISO14708-2:2019 and ISO14708-7:2019 depending on the technology and frequency band considered [1]–[3].

The cardiac pacemaker used was the Syncra CRT-P C2TR01 from the Medtronic company, which is enclosed in a metal cover that provides among others, protection against electromagnetic interactions. This cardiac pacemaker can be seen in the Fig. 1a.

The cochlear implant used for the experiments is the Nucleus CI24RE with the Contour Advance electrode from Cochlear, as shown in the Fig. 1b. According to the manufacturer, this device is safe for MRI (Magnetic Resonance Imaging) of up to 3 Teslas, thanks to its removable magnet.

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(a) (b)

Fig. 1. Implantable medical devices **a)** Cardiac pacemaker. **b)** Cochlear implant. [4] [5]

II. Experimental setup

The experimental setup shown in Fig. 2 is used to emulate interference conditions between a radio-frequency technology and an IMD. The IMD sits inside a Phantom, which emulates the volume of an average human body (dimensions 154 cm x 34 cm x 18 cm). The Phantom is filled with a liquid that emulates the average dielectric properties of the human body. The electromagnetic wave is generated and radiated to the IMD using an SMW200A vector signal generator and a horn antenna. With a power of 30 dBm @ 850 MHz and the antenna opening in contact with the Phantom's bottom. These conditions are representative of a scenario in which a patient bearing an IMD approaches a mobile phone terminal, which is one of the most critical according to our extensive validation of various scenarios.

An Isotropic E-Field Probe (i.e, EF3DV3 manufactured by SPEAG) is used to measure the electric field inside the liquid, in the close vicinity of the IMD. In order to provide a spatial reference to the measurements, infrared markers were attached to the probe such that its location was recorded by an array of infrared cameras. This allows the generation of spatial heat maps throughout the measurement zone.

Pacemakers belong to category III IMDs, and any malfunction entails a very high risk. The pacemaker is placed 2 cm above the Phantom's bottom, which is representative of the

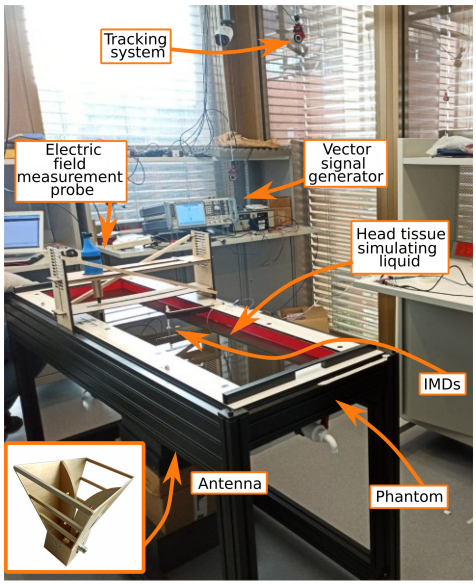
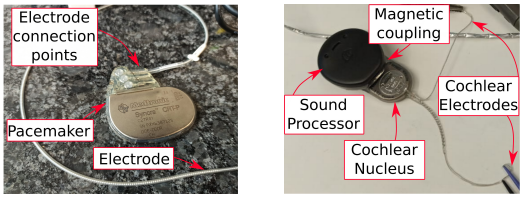


Fig. 2. Experimental setup to emulate the exposition of IMDs to the electromagnetic field of radio communication systems.



(a) (b)

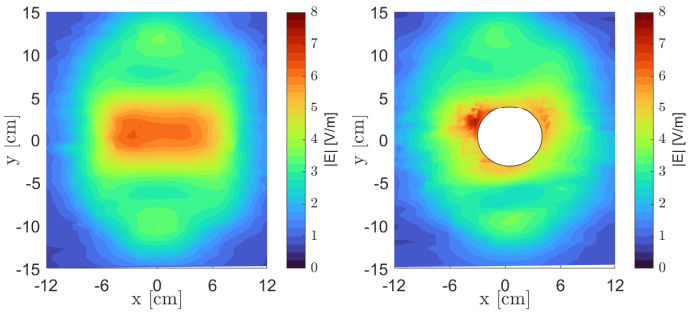
Fig. 3. Implantable medical devices: a) Pacemaker, b) Cochlear implant.

situation within a real patient. The cochlear implant belongs to the IIB category IMDs because it is not life-sustaining; however, given that it relies on wireless technology and its malfunction would deprive the patient of the hearing sense, it remains of interest for our study. The cochlear implant is placed in the Phantom's bottom, with the processor outside and the nucleus inside the liquid, held together by a magnet, just like in a real patient.

III. Results

The electric field was measured at a sampling rate of 2.5 Hz, and the probe's position was tracked at a rate of 30 Hz. The data are time-synchronized, and electric field heat maps are generated, allowing comparison of field distribution with and without IMDs. Fig. 4 depicts one of the measured planes, which corresponds to a transversal plane with a depth of 17 cm inside the Phantom and was performed with the pacemaker as IMDs. Similarly, more heat map measurements were taken on transversal and sagittal planes at various distances. These heat maps were also taken with the cochlear implant inside the phantom.

The results show that despite the extreme radiation conditions, the electric field levels in the vicinity of the IMDs do not exceed 10 V/m, a safety margin given by the IEC60601 standard [1]. Differences in distribution can be seen when comparing heat maps obtained with and without the presence of the IMD. When introducing the pacemaker, the electric field is concentrated in some areas, as shown in Fig. 4; this could be explained by the sharper geometry in certain parts of the device.



(a) (b)

Fig. 4. Heat maps of the electric field at a depth of 17 cm around the IMD a) Without a cardiac pacemaker and b) with a cardiac pacemaker in place.

IV. Conclusions

The proposed experimental setup allows for the emulation of radiation conditions experienced by a medical device implanted in the human body. The measurements of heat maps of the electric field around the IMD allow for a comparison of the intensity distribution based on the geometry and material of manufacture of the medical device. Under the conditions tested, the electric field intensity of 8 V/m was not exceeded, which allows us to infer that the IMD is not affected when it complies with the relevant standards.

Acknowledgment

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