Interference thresholds for active implantable cardiovascular devices in occupational low-frequency electric and magnetic fields: a numerical and in vitro study

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Title

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Abstract

In light of concerns regarding the occupational safety and health of workers wearing active implantable medical devices (AIMDs), this study aims to investigate the potential risks of electromagnetic interference (EMI) between AIMDs and low-frequency 50/60 Hz electromagnetic fields (EMFs) in the workplace.

A total of 58 AIMDs, consisting of pacemakers (PMs) and implantable cardiac defibrillators (ICDs) of different brands, models, and configurations were tested to determine the immunity thresholds for high-voltage electric fields (EFs) and magnetic fields (MFs) at 50/60 Hz. The EFs and MFs at the levels in workplaces are reproduced by setups using Helmholtz coils and aluminum plates, respectively, to ensure that the EM/MF exposures are controllable and reproducible. The EMI thresholds were recorded by observing the occurrences of PM or ICD dysfunctions. In addition, numerical studies on anatomical models were carried out using CST® software.

The results indicate that the recorded thresholds all exceed the EF and MF public exposure limits given in the ICNIRP 2010 guidelines. No dysfunction was observed among four ICDs tested under MF exposure up to 2750 μT at 50 Hz and 2480 μT at 60 Hz. However, among the 43 PMs and 11 ICDs tested under EF exposures, potential hazards may occur below the occupational exposure level proposed in the ICNIRP guidelines.

Keywords: Electromagnetic Interference (EMI), Active Implantable Medical Device (AIMD), Occupational exposure, Immunity thresholds, 50/60 Hz

Introduction

Active implantable medical devices (AIMDs) are extensively used in the treatment and diagnosis of various diseases. Cardiovascular disease is the leading cause of death in the United States, responsible for approximately 659,000 deaths per year, accounting for 25% of all deaths[1]. In Europe, it causes 3.8 million deaths each year, accounting for 45% of all deaths[2]. Approximately 500,000 pacemaker (PM) implantations were performed in 2016, and 100,000 cardioverter defibrillators (ICDs)[3] were implanted in Europe. On the other hand, with the continuous upgrading of global electrification and wireless technologies, humans are confronting unprecedented and inevitable EMFs in their surroundings. From medical radiography using X-ray to every power socket associated with low-frequency EMFs, EMF sources play an important role in human daily life. Thus, the fact of AIMD carriers submitted to electromagnetic fields (EMFs) is a subject of great concern. This is especially the case for patients bearing cardiac implants.

The risks to AIMDs in the presence of strong EMFs must be assessed. They cannot be neglected, considering that cardiac implants are vital and life-saving devices. Numerous studies have been carried out aiming to test AIMDs in electric fields (EFs) or magnetic fields (MFs) in different frequency ranges and by different approaches. *In vitro* tests for the risk assessment were conducted in Italy for workers with AIMDs exposed to different EMF sources: an electrosurgical unit, transcranial magnetic stimulation, and an arc welder[4]. PMs and ICDs were studied in Finland using a human-shaped phantom exposed to EMFs under a 400kV power line and at 220kV/400kV substations[5][6][7]. Other *in vivo* studies investigated the occurrence of electromagnetic interference with PMs caused by common environmental sources of EMFs: mobile phone base stations, electrically powered commuter trains, overhead high-voltage transmission lines, and magnetic resonance imaging[8][9][10].

Exposures to high-power EMFs (50/60 Hz) are commonly found in the electrical supply industry, where workers may be exposed to MFs, which can exceed 1000 µT, and to MFs, which can exceed 10 kV/m. For such occupational environments, the risk of malfunction and that of other safety threats to cardiac implant wearers need to be investigated. Thus, a system of validation needs to be set up which allows employers to verify whether workers can return to their posts after having cardiac AIMDs implanted. The EMF limit values are defined as a basic restriction in ICNIRP 2010 guidelines[11], to prevent the possibility of adverse health effects caused by external EFs and MFs. According to ICNIRP guidelines, reference levels for general public exposure are defined as 5 kV/m for EFs and 200 µT for MFs at 50 Hz; 4.17 kV/m for EFs and 200 µT for MFs at 60 Hz. For occupational exposure, the reference levels are defined as 10 kV/m for EFs and 1000 µT for MFs at 50 Hz; 8.33 kV/m for EFs and 1000 µT for MFs at 60 Hz. Risk assessment of active implantable devices in professional low-frequency EMF environments is proposed in the European standard series EN 50527[12]. They provide the procedures for evaluating the risks of EMF exposures to a worker bearing a cardiac implant (PM or ICD) in the occupational environment.

Since 2005, our team has developed different studies to evaluate the immunity of PMs and ICDs under low frequency (mainly 50/60 Hz) EMF exposure. These studies were conducted both theoretically as well as experimentally, *in vitro*. Our main goal was to establish a risk assessment for cardiac implant wearers under occupational exposures. In previous investigations, we performed numerical studies and *in vitro* studies which allowed more controllable experimental conditions, such as frequency ranges, system configurations, sensitivity levels of implanted devices, and more. We conducted *in vitro* studies on the immunity of cardiac implants exposed to MFs[13] and EFs[14], respectively. The studies involved PMs and ICDs. An *in vitro* cost-effective test bench was proposed in order to reproduce induced phenomena on a cardiac implant inside a human body exposed to EFs[15]. A phantom respecting the induction occurring inside the human body was used in the *in vitro* experiments, referring to the induction level simulated on an anatomical human body model. Interference with PMs for various lead

configurations and implantation positions were also computed on the anatomical model exposed to a 50Hz EF, using CST EM® 3D software[16].

In this paper, we have summarized the methods applied and the results obtained by our group for MF and EF exposure. They are discussed in the frame of the risk assessments proposed by the standard EN 50527.

Methods

According to Faraday's law of induction, a time-varying MF induces an electric current in the conductor. For a human body exposed to an MF, internal currents may be induced in the body's tissues. EN 62226-2-1 proposed different methods for calculating this induced EF in simple 2D models under MF exposures[17]. For a single frequency, assuming the body, or the part of the body exposed, is a circular section of radius r, with conductivity σ, the induced current density can be calculated by reference to the external magnetic flux density, as follows:

$$J_{in} = \sigma \pi r f B_{ex} \quad [1],$$

where J_{in} is the current density induced at the circle of radius r, f is the frequency, and B_{ex} is the external magnetic flux density. The value of induced currents is minimum at the center and maximum at the edge.

Alternating EFs cause displacement of electric charges in conductive media, resulting in an "induced" alternating current inside it. For a human body exposed to an EF, the induced current may occur in the body. EN 62226-3-1[18] proposed methods for calculating the internal induced current under low-frequency EF exposures. The relation between the external field and the internal induced current density can be determined using a shape factor, as follows:

$$J_{in} = k \times f \times E_{ex} \quad [2],$$

where J_{in} is the current density induced within the conductive material, f is the frequency, E_{ex} is the vertical external EF, and k is the shape factor, which depends on the geometry. In other words, for a human body exposed to an EF at a certain frequency, the induced current depends on its geometry, the ratio of length to the radius (L/R) of the body, and the location within the body where J_{in} is calculated.

From the value of the induced current density J_{in}, the internal electric field E_i can be easily derived according to Ohm's law:

$$J_{in} = \sigma \times E_i \quad [3],$$

where J_{in} is the current density induced, σ is the conductivity, and E_i is the internal electric field. In other words, the internal electric fields are induced in the body tissues when exposed to an EF or an MF. For an AIMD wearer exposed to an EF or an MF, the internal EF will be induced as well as on the device input, which may be disturbed by the EM interference. The investigation of the susceptibility of AIMDs was based on the estimation of the induced voltage on the device input.

A cardiac implant (PM or ICD) consists of an impulse generator embedded in a closed metallic box and a lead with two possible configurations: unipolar or bipolar. In unipolar sensing mode, the cardiac signal is sensed between the metallic container and an electrode at the end of the lead; in bipolar sensing mode, the cardiac implant senses the signal between two electrodes (tip and ring) at the respective extremities of the lead. The evaluation of the induced voltage on the cardiac implant can be obtained by integration according to the following classical equation[22]:

$$U = \int_{Tip}^{Generator\ /\ Ring} \vec{E} \cdot dl \quad [4].$$

In this study, theoretical modeling of the behavior of PMs and ICDs exposed to EMFs was carried out in parallel with experimental studies. CST EM® software, based on the finite integration technique, was used for the simulations with the electro/magneto-quasi-static equations. We limited the frequency band of the occupational exposures to the low frequency EM fields (50/60 Hz); thus the studies of exposures to the EFs and MFs were carried out separately.

1. Numerical approach

- Cardiac Implant Model

The model of a cardiac implant is composed of a metallic box representing the impulse generator (Dimensions: 3 cm×4 cm for PM, 4 cm×6 cm for ICD) and a bipolar lead with electrodes at the tip (Figure 1). In the numerical modeling, the container of the impulse generator is made of titanium (σ: 2.38×10^6 S/m) and the lead electrodes are made of platinum (σ: 9.52×10^6 S/m). The insulator of the lead has a conductivity of 10^{-12} S/m and a permittivity of 6. This model of cardiac implant remains the same for EF exposure and MF exposure.

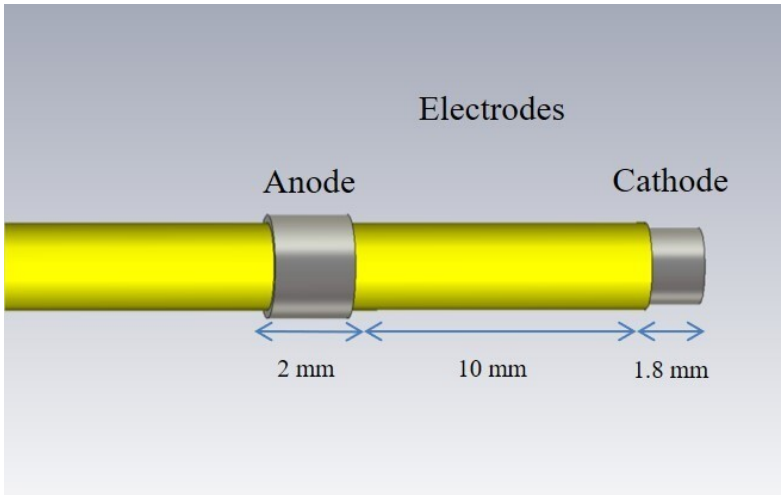

Figure 1. Structure and Dimensions of a Bipolar Probe of the Cardiac Implant (the Lead Electrodes in Gray and the Insulator in Yellow)

- Anatomical Model

M Numerical

An anatomical human body model, derived from high resolution magnetic resonance images of healthy volunteers[19], was used in the numerical simulation of MFs. The model represents a 34-year-old male of 1.77 m and 76 kg, based on a realistic external shape composed of 5 mm cubic voxels. Each voxel is characterized by the conductivity corresponding to the associated tissue from calculations based on the algorithms provided in Camelia Gabriel's (1996) report. The anatomical model implanted with a cardiac device was placed in a homogeneous MF. A systematic study on the induced voltage calculation between the distal and proximal electrodes was carried out in terms of the source position and frequency.

E Numerical

In the study of EF exposures, a 2 mm resolution surface-based model (Ansoft, Ansys®) was used, presenting an anatomical male of 183.6 cm tall in standing position, with arms closed on the side and

grounded feet. The model, constructed with 272 organs and 32 tissues with the dielectric properties of the IT'IS database[20], was simulated under 1 kV/m 50 Hz EF exposure. Compared to the voxel model using hexahedral mesh, the tetrahedral mesh of Ansoft model respects the rounded geometries of organs and avoids the step effect. The induced EFs on the organs are given in Table 1.

Table 1. Ansoft body model (2 mm resolution) exposed to a 50 Hz uniform EF, maximum induced EF on the organs (mV/m) per 1 kV/m

Organ Name	Isotropic σ[20]	E_{avg}	E_{max}
Unit	**S/m**	**mV·m^{-1}**	**mV·m^{-1}**
Brain	0.08	0.9	1.7
Heart muscle	0.08	1.14	4
Heart lumen	0.70	0.545	2.44
Muscle	0.35	1.25	29.4
Skin	0.10	1.43	77.3

The cardiac implant model was implanted in the 2 mm resolution Ansoft anatomical model under 1 kV/m 50 Hz exposure for numerical computations. The induced voltage on the cardiac implant can be affected by several factors. We performed studies on the influence of the sensing mode, the lead dimensions, the tip position, the chamber impact, and the sensitivity settings of the cardiac implant[16].

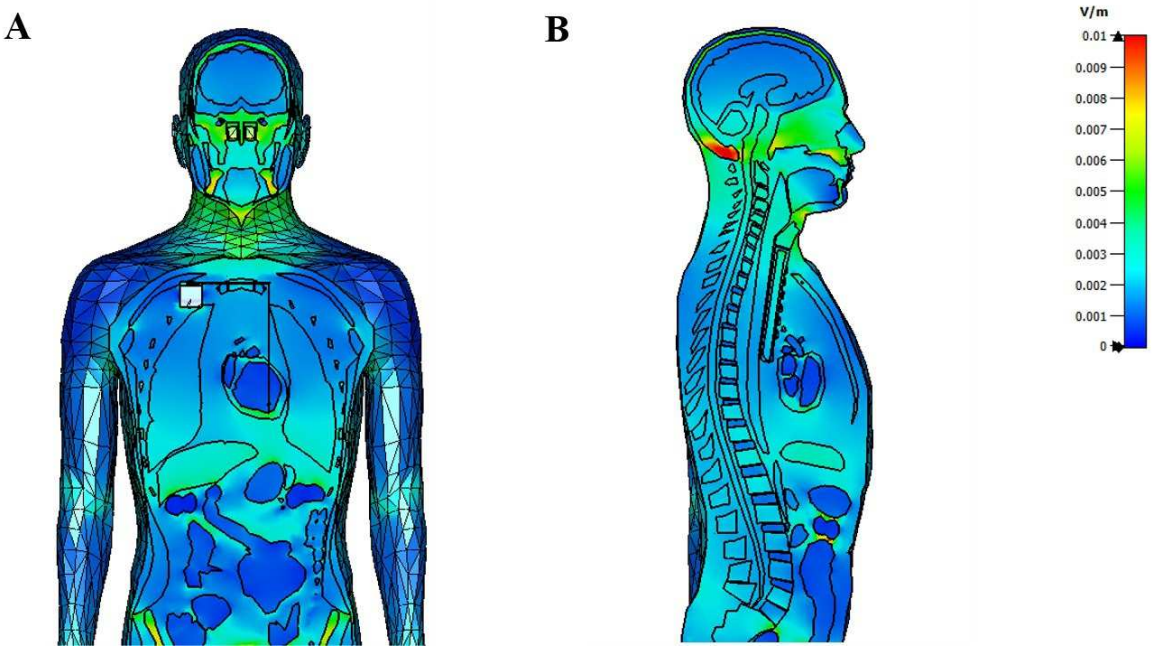

Figure 2. Induced EFs on the 2 mm resolution Ansoft anatomical model with a cardiac implant under 1 kV/m 50 Hz exposure (A) Front view; (B) Side view.

- Exposure system

M Numerical

Numerical studies of the experimental exposure systems were conducted as well. The Helmholtz coil is most commonly used for low frequency MF sources, due to the homogeneity it provides. To ensure that the experimental model was entirely exposed in the homogeneous MF, we used two coils with radii of

520 mm, 520 mm apart. This is the MF exposure source we chose for both the modeling and the experimental approaches. A phantom tank (Height: 15 cm; Width: 30 cm) filled with gelatin, to simulate the electrical properties of biological tissues based on the study of Marchal et al.[21], was used in the experiments. The phantom tank was modeled as a homogeneous brick filled with a 0.1 S/m solution in the numerical simulation, close to the conductivity of heart muscle in the voxel model 0.087 S/m[19]. A bipolar ICD model was inserted into the brick. The distance between the two bipolar electrodes (tip to ring) was set to the typical distance of 10 mm. The tip-to-ring pair was placed in perpendicular to an imaginary line from the impulse generator and the tip-to-ring pair, in order to reach to the maximum induction area.

E Numerical

In the study of EF exposure, a homogeneous EF was generated between two parallel square plate conductors (aluminum σ: 3.56×10^{7} S/m), each with a side length of 2 m, separated by a distance of 0.75 m. A potential V was applied on one plate; the other plate was grounded. The porcelain insulators (ε: 6; σ: 10^{-15} S/m) as supports between the plates were also investigated. We barely detected any influence of the insulators on the EF, except in a zone close to them (r: 5 cm). The dimensions and construction of the exposure system are preserved in the experimental approach.

Rectangular phantoms and human-shape phantoms are commonly used in *in vitro* experiments simulating body tissues. Due to the complexity of the human body, these phantoms cannot present the shape influence of the human body or the induction diversity of different tissues for EF exposure. According to the numerical analysis of the Ansoft anatomical model, under 1 kV/m 50 Hz electric field exposure, the maximum induced EF in the heart is 4 mV/m, and the mean induced EF over the thorax is 0.8 mV/m. In the study of EF exposures, we used a phantom that reproduces the environment where the PM or ICD is implanted. The phantom was reduced to 1/5 height (L4: 0.352 m) of the human reference. To maintain the shape factor k, which depends on the ratio L/R, the circumference was deduced accordingly. The phantom is made of 3.3 mm glass filled with a 0.2 S/m solution, composed of a cylinder part and a cone part. Under 1 kV/m 50 Hz electric field exposure, constant EF induction (4 mV/m) occurs in the cylinder part (D2: 0.046 m, L2: 0.135 m), representing the maximum induction over the heart where the probe is placed in the human body. The probe was always placed parallel to the external EF, in order to reach the maximum induction. The cone part (D4: 0.3 m) represents the mean level of induction over the thorax (0.8 mV/m), which contains the generator (Figure 3). A metallic pedestal (D1: 0.046 m, D0: 0.12 m) is plugged into the bottom of the container to keep the phantom in the vertical position and grounded. L3 and D3 represent the height and the diameter, respectively, of the filled solution. In this case, the phantom is fulfilled (L3: 0.352 m, D3: 0.3 m).

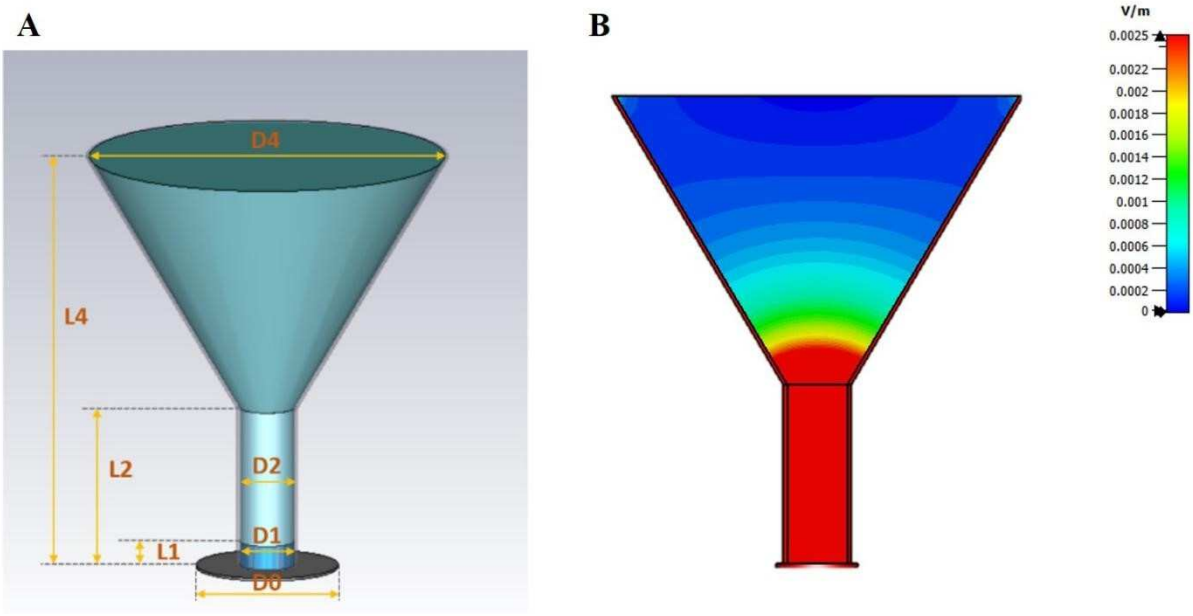

Figure 3. Experimental phantom. (A) Dimensions of phantom; (B) Induced EF in the experimental phantom.

2. Experimental set up

M Experimental

As introduced above, the magnetic source is Helmholtz coil. It consists of two loops of 520 mm diameter; each loop consists of 12 contiguous turns made by 16 mm^2 thick wire (Figure 4). To avoid external electromagnetic disturbances, the Helmholtz coils were placed in a Faraday cage (Lindgren), where the MF exposures for cardiac implants were carried out. The low-frequency exposure system produces homogeneous MFs up to 4000 µT at 50 Hz and 3900 µT at 60 Hz, 20 times higher than the limits given in the ICNIRP guidelines. A triaxial MF meter (ESM-100, Maschek Elektronik) was used for monitoring the field strength during tests. Experimental results showed agreement with the analytical solution within ±2% error[13].

The Helmholtz coils were supplied by a signal generator (HP33120) via a power amplifier (25 VAC, 20 A, 500 VA, 40 Hz-400 kHz). Thanks to a matching system (two transformers), 450 VA was allowed to transmit to the coils. The power unit and the measurement system are all located outside of the Faraday cage, as are a field meter, a digital oscilloscope (TDS3032, Tektronix, Inc.), and a personal computer for data recording. The induction coils and the implanted phantom, as the DUT, are placed on a wooden support in the Faraday cage to avoid distortion of the MF. The cardiac implant is fixed in the experimental phantom tank with a plexiglass support, which ensures reproducible positioning of the ICD and its probe. The distance between the impulse generator of the cardiac implant and the tip electrode is a minimum of 22 cm, based on a 3D scan of an ICD implanted in a human body. The tip-to-ring pair was placed perpendicular to an imaginary line from the impulse generator to the tip-to-ring pair. Based on the numerical study, the field direction was set perpendicular to the induction area, in order to perform the tests in the worst case scenario (frontal exposure). MFs of different strengths and frequencies monitored by the oscilloscope were applied to the cardiac implants for immunity investigation. A coaxial cable was used to inject the simulated heart signal into the cardiac implants. Three types of ECG signal were used: the normal cardiac signal (sinus rhythm (SR), frequency base of 1 Hz), two pathological signals, i.e., ventricular tachycardia (VT, fixed frequency of 2.77 Hz), and ventricular fibrillation (VF, fixed frequency of 3.5 Hz). An amplitude of 5 mV was used for the ECG

signals, given that under-sensing is less likely when the SR has a higher amplitude, compared to the sensing device's sensitivity, which in turn defines the minimum myocardial voltage required to be detected as a heart signal.

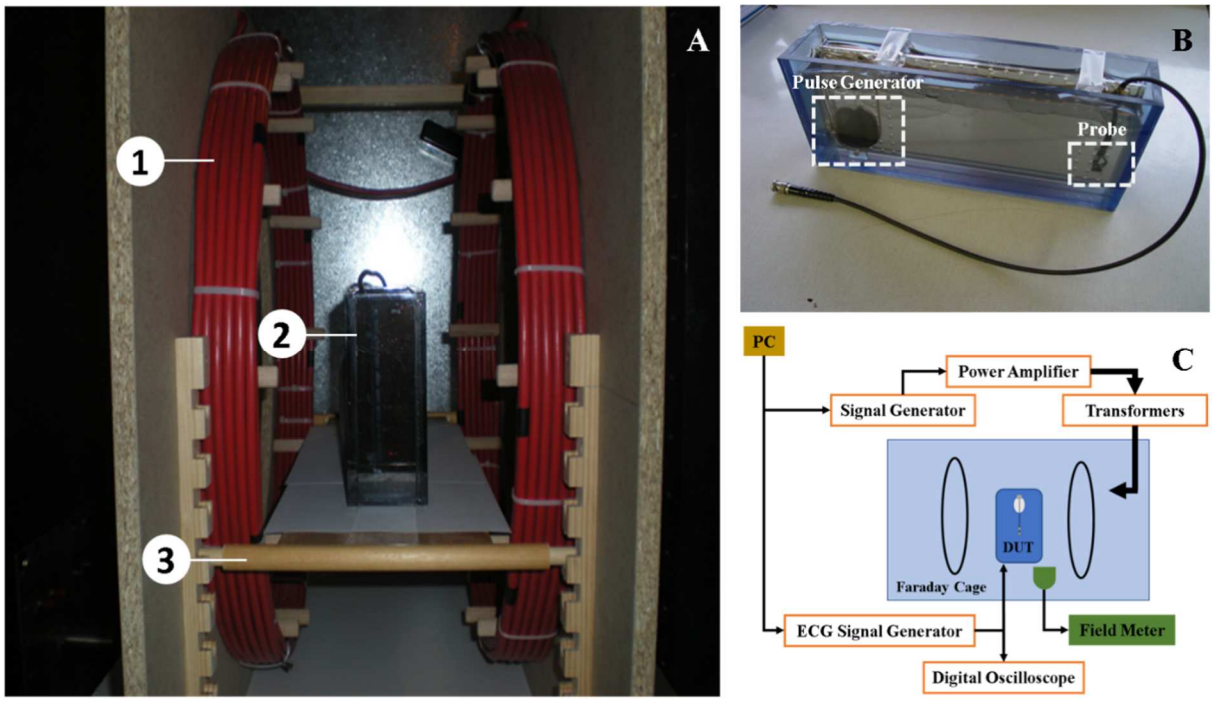

Figure 4. MF exposure experimental setting. (A) Inside view of Faraday cage: 1) Helmholtz coils; 2) DUT; 3) Wooden support. (B) ICD implanted phantom tank (DUT). (C) Schematic diagram of the implementation

Two test protocols were applied in the experimental study. The first followed a provocative study intending to observe the "false detections," namely a "dysfunction." In other words, the goal was to ascertain whether the cardiac implants interpret the perturbations as arrhythmia. Initially, the magnetic flux density was set to a minimum value, the frequency of disturbance was fixed (50 or 60 Hz), and an SR ECG signal was applied to the cardiac implant. A step consisting of 15s pause and 45s exposure was repeated, with each step increasing by a fixed amount (25 μT) from 0 μT to the maximum value. The second protocol aimed to verify whether the perturbations inhibit the detection of arrhythmia. The initial factors were the same but the perturbation was continuously applied for the second protocol without pauses. In addition, instead of a contentiously SR ECG signal, the cardiac implant received the following signals: VT (15s); SR (45s); VT (15s); SR (45s); VF (15s); SR (45s); VF (15s); SR (45s). A test system was designed to execute the measurement session automatically, using virtual instrument software HP VEE under IEEE 488 protocol communication.

E Experimental

The experimental EF exposure system was designed to deliver an EF up to 100 kV/m for 50 Hz and 83 kV/m for 60 Hz. The homogeneous EF fields were generated by two aluminum plates (2 m × 2 m) of 10 mm thickness placed in parallel, 750 mm apart with 4 PVC supports in between. The upper plate was supplied with a high voltage; the lower plate was grounded. The experimental setup consisted of a signal generator delivering sinusoidal signals, a power supply, and two transformers that allowed a high voltage of up to 80 kV to be sent to the conductive plates. A 3D H/E field meter (Maschek ESM-100) was used to measure the generated field. The room humidity was recorded and maintained at 30–55% during the experiments, as was temperature, at 19–28 °C . The experimental phantom was placed in the center on

the lower plate and filled with a solution possessing conductivity of 0.19-0.21 S/m. The conductivity of the solution was checked by a conductivity meter, HI 99300. The dimensions of the experimental phantom were the same as those of the numerical study. Plexiglass support allowed the implant housing to be positioned reproducibly in the container. The end of the probe was guided towards the lower part (cylindrical part) of the phantom, parallel to the direction of the EF, in order to produce the worst-case scenario. The phantom was grounded via a connection between its metal bottom and the lower grounded plate. The setup is shown in Figure 5.

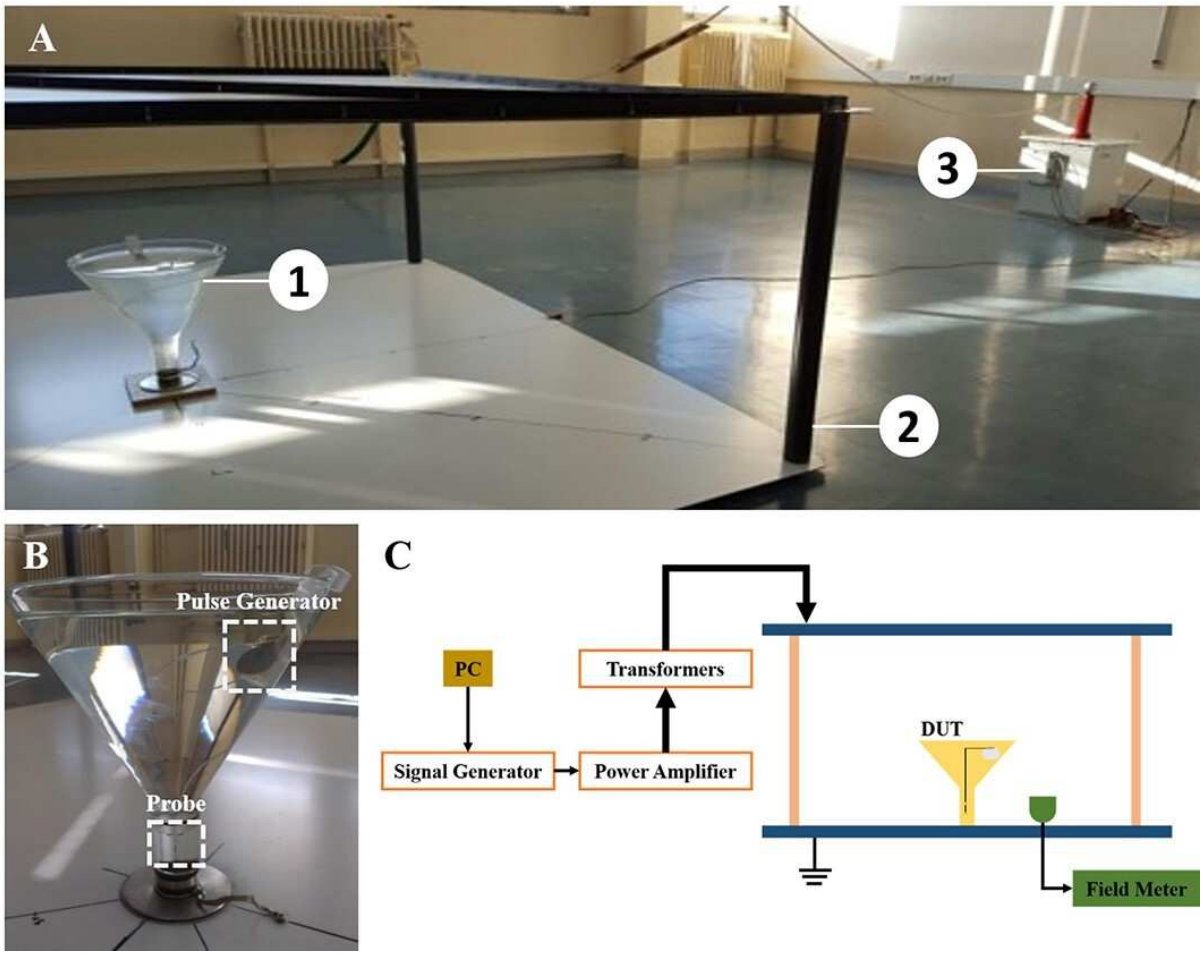

Figure 5. EF exposure experimental setting. (A) General view: 1) DUT; 2) Aluminum plates and PVC supports; 3) High voltage transformer. (B) AIMD implanted phantom (DUT). (C) Schematic diagram of the implementation

The cardiac implants were always checked and reset before the tests. Their therapy functions were turned off. An EF at 1 kV/m was applied to the system at the beginning and increased to 10 kV/m, 3.3 kV/m, and 1 kV/m, for each trial, until a malfunction occurred. Malfunctions were recorded by the cardiac implant and retrieved via remote cardiac telemetry after exposure. The malfunctions were tested again to check their reproducibility. Once identified as reproducible, the EF was decreased to pinpoint the threshold of the malfunction. We did not apply any cardiac signal to the implant, due to the experimental difficulty of delivering a cardiac signal without disturbing the induced EF.

3. Results

M Numerical

In the numerical study of a bipolar ICD under MF exposures in the vertical position, the induced voltage on the probe was 0.099 µV/µT for the anatomical model and 0.039 µV/µT for the homogeneous brick model. The worst-case was found in the frontal position; the induced voltage on the ICD probe was 0.152 µV/µT in the homogeneous brick model.

M Experimental

In the experimental study of MF exposures, four ICDs (three from St. Jude Medical; one from Guidant) were investigated in a gelatin experimental phantom for nominal sensitivity configurations according to the established experimental protocol. At the frequency of 50 Hz, no dysfunction was recorded for exposures up to 2750 µT. At the frequency of 60 Hz, none of the four ICDs showed any malfunction for exposures up to 2480 µT.

E Numerical

In the study of the anatomical model under EF exposures, the induced voltage between the probe and the generator in unipolar sensing mode was found to be 223.7 µV; the induced voltage between the two electrodes of the probe in bipolar sensing mode was found to be 29.4 µV. We found that the induced voltage in unipolar sensing mode is 10 times greater in bipolar sensing mode in the case of the right atrium or right ventricle implantation. The tip-to-ring distance of the lead may have had an influence of up to 46% on the induced EF. In the bipolar sensing mode, the induced voltage of the right ventricle implantation was 41% higher than that of the right atrium implantation. The numerical investigation results yielded an estimated dysfunction threshold of 7.24 kV/m for bipolar sensing mode under the maximum sensitivity setting. In the simulation of the experimental phantom under 1 kV/m 50 Hz exposure generated by the exposure system introduced in the previous part, the induced voltage on the probe of the cardiac implant is 73 µV in the bipolar sensing mode and is 550 µV in the unipolar sensing mode. An equivalent factor can be defined between the anatomical model and the experimental phantom: 2.45 for the unipolar sensing mode; 2.48 for the bipolar sensing mode.

E Experimental

Experimental tests were carried out at 50 and 60 Hz to obtain the threshold of dysfunction in the worst-case scenario. The equivalent factors are applied to the level of EF exposure. 43 PMs and 11 ICDs, from manufacturers Medtronic, St. Jude Medical, and Vitatron, were tested (see Table 2).

Table 2. Manufacturer, quantity, models of tested cardiac implants

Type	Manufacturer	Quantity	Model
Implanted Cardiac Defibrillator	Medtronic	10	6
	St. Jude Medical	1	1
Total		11	7
Pacemaker	Medtronic	22	9
	St. Jude Medical	10	8
	Vitatron	11	6
Total		43	28

No dysfunction was detected on the PMs in ventricular-inhibited (VVI) unipolar sensing mode under EF exposures up to 245 kV/m at 50 Hz and 198 kV/m at 60 Hz, as well as on the PMs in VVI bipolar sensing mode up to 248 kV/m at 50 Hz and 200 kV/m at 60 Hz. (Among the 43 PMs, one model worked only in unipolar sensing mode.) The dysfunction thresholds of the PMs in atrial-inhibited mode (AAI) with unipolar and bipolar sensing configurations are given in Figure 6.

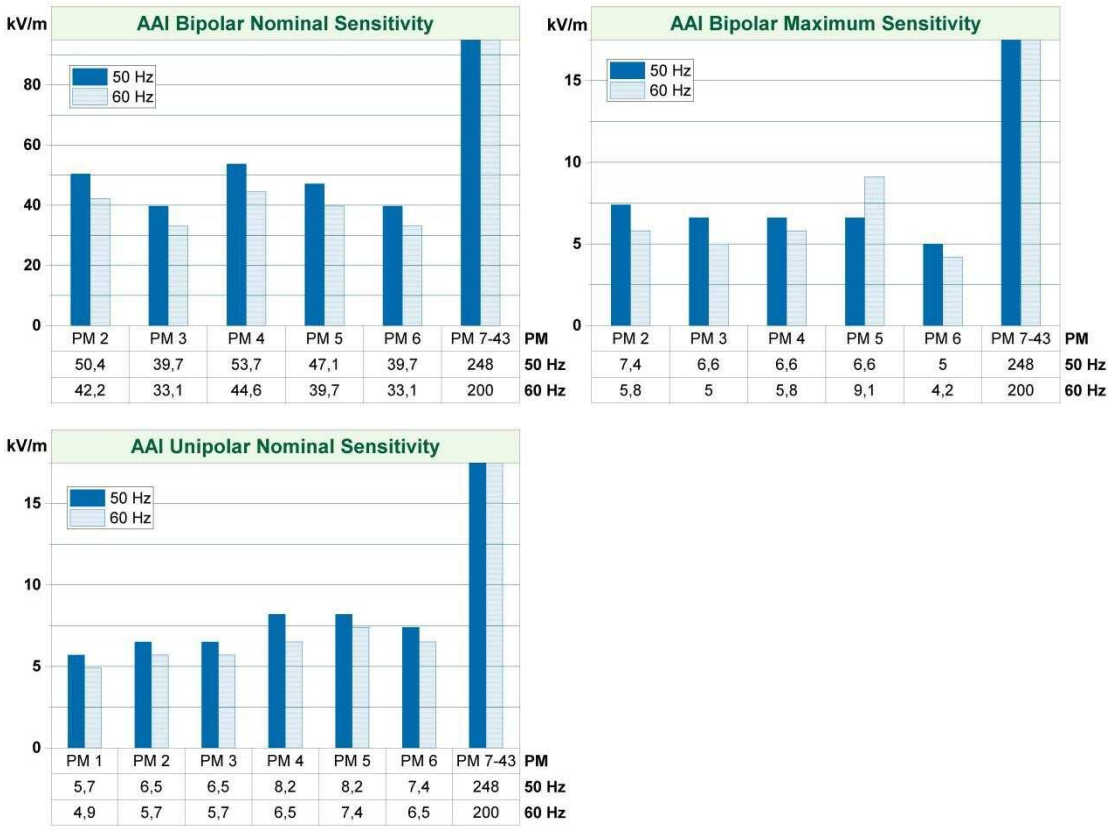

Figure 6. PM malfunction thresholds under 50 Hz and 60 Hz EF exposure at nominal sensitivity (2 mV) and maximum sensitivity (0.2mV)

The dysfunction thresholds of ICDs under 50 Hz and 60 Hz EF exposures were investigated for nominal sensitivity (0.6 mV) and maximum sensitivity (0.15 mV for Medtronic ICDs, 0.2 mV for St. Jude ICDs). All 11 ICDs reacted to the EF during the test. The results are given in Figure 7.

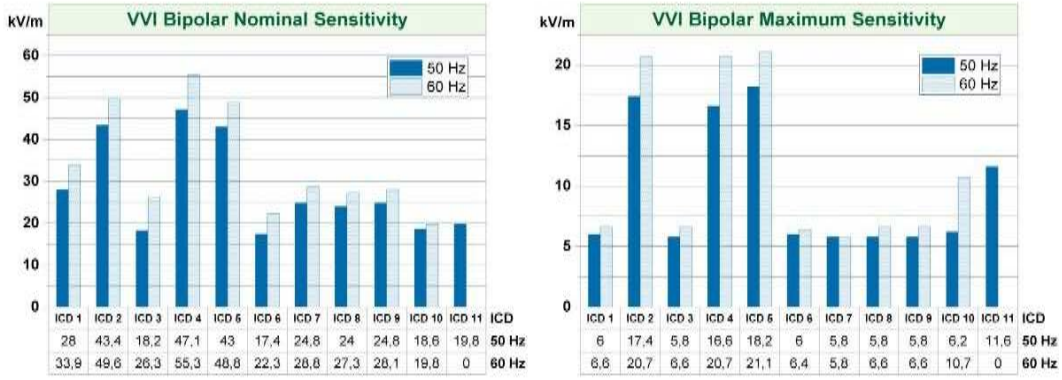

Figure 7. ICD malfunction thresholds under 50Hz and 60 Hz EF exposure at nominal sensitivity (0.6mV) and maximum sensitivity (0.15 / 0.2mV)

Discussion

In the study of MF exposure, the induced voltage on the probe of a bipolar ICD under exposure was found to be 0.152 μV/μT for the worst case, which provided a reference value for future experimental studies. In the *in vitro* study, none of the four ICDs were susceptible to EMI in very high MFs (2.75 mT at 50 Hz, 2.48 mT at 60 Hz). This supports the premise that ICDs are safe in terms of MF dysfunction. Among the reasons for the good ICD performance in our tests is the fact that the bipolar sensing mode of the electrodes is significantly improved compared to unipolar sensing (Trigano, 2005). Moreover, the input/output filters of the tested ICDs provide excellent immunity to low-frequency MFs. ICDs did not misinterpret noise from EMI as VT or VF, nor did they deliver inappropriate defibrillation. MF intensities applied in this study are rare or even altogether absent in the industrial workplace. These settings and protocols provide useful tools for researchers and clinicians, allowing for the testing of ICDs in a realistic way and also ensuring repeatability of results. They could also be useful in the design of risk assessments for ICD wearers returning to their jobs in EM professional environments after having devices implanted. Our team also carried out a study on PMs under MF exposures in the 2000s. However, with the rapid development of AIMD technology, the latest models of PMs should be taken into consideration. Thus, future investigations of PMs under occupational exposures could be conducted with the new setup proposed in this study.

In the EF exposure component of this work, equivalent factors between the models were found in the numerical study. Between the anatomical model and the experimental phantom, an equivalent factor of 2.45 was found for the unipolar sensing mode; 2.48 was found for the bipolar sensing mode. The equivalent factor enables the conversion of study from the anatomical model to the experimental model. The results of induced voltage provide reference values for future experimental measurements. Our *in vitro* experimental study tested 54 cardiac implants, including 7 different types over 11 ICDs and 28 different types of 43 PMs, in the presence of EFs up to 248 kV/m at 50 Hz and 200 kV/m at 60 Hz. The results pinpoint the field levels that lead to potential risks of EMI-caused dysfunctions, which may cause clinically significant events. Results were obtained for the very disadvantaged scenarios, the worst case of the given conditions or very close to it. We observed rare cases where EMI caused PMs and ICDs to switch into noise mode, which means that they continued to deliver the standard heartbeat. No risk of false treatment under public exposure was observed. When PMs and ICDs are configured with maximum bipolar sensitivity or nominal unipolar sensitivity, occupational exposure may present some risks. According to our results, there is no risk for implants configured in bipolar mode with nominal sensitivity in working environments (conforms to EU directives).

CONCLUSION

In this work, theoretical and experimental studies of cardiac implant wearers exposed to extremely low frequency (50/60 Hz) EF and MF were carried out. We presented a protocol and a setup dedicated to investigating the operational integrity of cardiac implants under low frequency homogeneous electromagnetic exposures. An analysis of the EFs induced in the human body during exposure aimed at determining the induction in each organ of a virtual anatomical model. Likewise, the numerical calculation of the voltage induced at the tip of the probe was performed in the virtual human model containing a cardiac implant. The calculations are based on a finite integral method element model using CST® software.

Experimentally, *in vitro* tests were carried out in very high MF/EF levels (up to 4 mT for MF; up to 248 kV/m for EF). We note from our results that a significant risk of dysfunction occurred on carriers of PMs in the unipolar mode under EF exposure. Our results suggest that, in almost all cases, workplaces exposing employees to a 50 Hz MF or EF are not likely to cause electromagnetic interference, given a setting with nominal sensitivity; in contrast, a maximum sensitivity configuration may lead to a risk of interference. A case-by-case risk assessment study is required. Conducting a thorough and detailed study

of each situation, accounting for patients' shape features as well as the implant configuration, must be considered.

Studying the treatment performance of AIMD under EMF exposures provides the complementary characterization of AIMD behaviors. Real-time measurements of the induced voltage on the cardiac implant probe under exposure allowed us to conduct further observations of the behaviors of cardiac implants and to draw comparisons with the theoretical results.

ABBREVIATIONS

AIMD: Active implantable medical devices; EMF: Electromagnetic field; EF: Electric field; MF: Magnetic field; PM: Pacemaker; ICD: Implantable cardioverter defibrillator; Hz: Hertz; A/m: Amperes per meter; kV/m: Kilovolt/meter; μ(m)T: Micro (Milli) Tesla; S/m: Siemens per meter; DUT: Device under test; SR: Sinus rhythm; VT: Ventricular tachycardia; VF: Ventricular fibrillation; VVI: Ventricular-inhibited mode. AAI: Atrial-inhibited mode.

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Declaration of interest

The authors declare no competing interests.

Ethical Approval

Not required.

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