Experimental and numeric investigation about electromagnetic interference between implantable cardiac pacemaker and magnetic fields at power line frequency

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Summary. The present contribute describes the investigation about the implantable pacemaker (PM) immunity against high level magnetic interfering fields at 50 Hz that a pacemaker wearer could find in his working environment. To this purpose, a test bench has been set up based on a Helmholtz coil for producing extremely low frequency (ELF) magnetic fields and a heart simulator rightly fed by electric signals that simulate atrium and ventricle signals. A widely diffused PM has been tested, under different operation modes and configurations, for both continuous interfering waves (CW) and variously pulsed interfering waves (PW). Pertaining the obtained results, high levels of CW field, only in unipolar mode, produce a behaviour called "asynchronous mode" (not dangerous). For PW fields, under particular and rare conditions, the complete inhibition occurred (the most dangerous effect for PM wearer). In order to validate experimental results, a numerical 3-D model has been developed to simulate the whole bench system formed by Helmholtz coil, human trunk, pacemaker case and its electric leads. In this model the electromagnetic problem is solved by reconstructing the inhomogeneous bench system associating the relative values of conductivity to each cubic cell in which the whole system is discretized. Application of Maxwell's equations in their integral form has allowed to obtain a 3-D electrical network, whose solution gives the current density distribution inside the heart simulator.

Key words: artificial pacemaker, electromagnetic fields, immunity, electric power supplies.

Riassunto (*Studio sperimentale e numerico sull'interferenza elettromagnetica tra pacemaker cardiaci impiantabili e campi magnetici alla frequenza delle linee di alimentazione*). Il presente contributo descrive una ricerca sulla immunità di pacemaker impiantabili (PM) ai campi magnetici di alta intensità, a 50 Hz, che un portatore di pacemaker potrebbe incontrare nel proprio ambiente di lavoro. Per questo scopo è stato messo a punto un test di prova basato su una bobina di Helmholtz per la creazione di campi elettromagnetici a bassissima frequenza (ELF), e su di un simulatore di camere cardiache in grado di simulare i segnali elettrici tipici di atri e ventricoli. Un modello di pacemaker largamente diffuso sul mercato è stato provato, in diversi modi di funzionamento e configurazioni, sia in presenza di campi interferenti ad onda continua (CW), sia di tipo pulsato (PW). Per quanto riguarda i risultati ottenuti, alti campi magnetici CW, solo nel caso di configurazione unipolare, hanno indotto sul PM un comportamento di tipo "asincrono" (non pericoloso). Per campi pulsati, in condizioni molto particolari e rare, è stata osservata una inibizione totale (la condizione più pericolosa per un portatore di PM). Per confermare i risultati sperimentali, è stato sviluppato un modello numerico 3-D per simulare l'intero sistema di test formato dalla bobina di Helmholtz, il tronco umano, l'involucro del PM e i suoi cateteri. In questo modello il problema elettromagnetico è risolto associando ad ogni cella cubica del sistema discretizzato i valori relativi di conduttività. L'applicazione delle equazioni di Maxwell nella formulazione integrale ha consentito di ottenere una rete elettrica 3-D, la cui soluzione fornisce la distribuzione della densità di corrente all'interno del simulatore di cuore.

Parole chiave: pacemaker artificiale, campi elettromagnetici, immunità, fonti di energia elettrica.

INTRODUCTION

The immunity of implantable cardiac pacemaker (PM) against magnetic fields has been widely investigated in radio frequency (RF) range and there are lots of papers in literature dealing with electromagnetic interaction between PM and RF fields (above all cellular phones and electric security systems) [1-6]. On the contrary, the effects of extremely low frequency (ELF) fields have not been sufficiently considered because the PM wearer, until few years ago,

was typically an old no-worker person, living in a domestic environment, where strong ELF fields are a rare occurrence [7, 8]. Nowadays, in order to allow to more people to live a normal life, the average age of the PM wearer is considerably lowered, and therefore PM wearer could be a worker operating in a factory near high power machines. This paper deals with the electromagnetic compatibility (EMC) between an implanted cardiac PM and high level magnetic fields at ELF (typically 50 Hz) that can be found above all in industrial environments. Such investigation started with a PM programmed with only one chamber (right atrium or right ventricle), and successively was extended to dual chambers PM (right atrium and right ventricle). In this paper only the results of dual chambers PM are reported, because of the similar behaviors with those obtained for a single chamber one [9].

The principal coupling mechanism between the PM and the external magnetic field, at ELF, is due to the loop formed by the stimulating and sensing electrode system through the human tissues. Such loop area depends on the unipolar and bipolar pacing and sensing (in the following named "polarity system"): for every lead it can be unipolar or bipolar (*Figure 1*).

In the unipolar system, PM has one electrode that lies within the heart as cathode, whereas the anode is the metallic case of PM itself.

The distance between both can extend up to 25 cm. The loop formed by current path starts from the PM output connection, follows the lead till its tip inside the heart, and returns back to the PM metallic case through the human tissue. In a large human this area can reach a maximum value of 250 cm^2. It is important to observe that through this loop the exogenous field induces a not desired voltage (easily calculated according to Faraday's induction law) that is added to spontaneous heart signal. Obviously such voltage
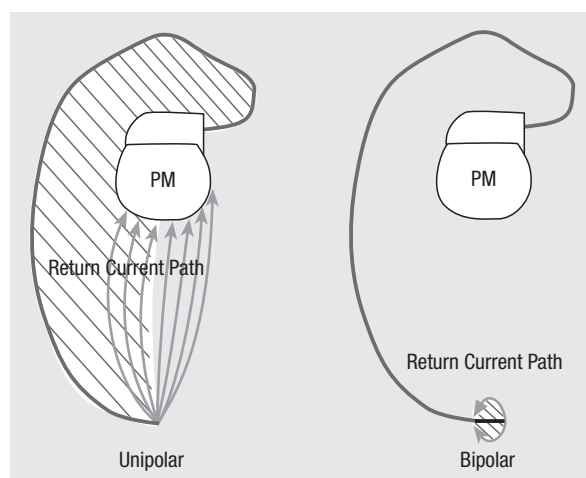
reaches its maximum value if the magnetic flux density is orthogonal to loop area. Moreover loop area depends on the position of PM in human torax.

The bipolar system has been realized for reducing PM susceptibility to exogenous signals. In fact, the lead, that exhibits a coaxial structure, has two electrodes very close within the heart (about 3 cm distant), therefore the loop formed is very small (about 15-20 times less than the unipolar system) and electromagnetic interference (EMI) effect is much less than unipolar system. Utilization of this system is not always allowed because its bigger dimensions need a sufficiently large caves vena. Moreover, the clinical experience highlights that bipolar leads require a more frequent substitution. Generally dual chambers PM system has bipolar atrium chamber and unipolar ventricle chamber.

Furthermore, modern PM are provided with hardware filters (generally low-pass filters) and software filters. So if interfering signal rate is included between about 10 Hz and 300 Hz, the signal goes across input circuits and is computed by the internal PM algorithm that should recognize heart signal from exogenous signal. If such acknowledge happens, PM starts to pace at a programmed fixed rate (asynchronous mode), and remains in this condition for all interfering signal time.

The main EMI effects upon PM are:
- standard asynchronous (SA): EMI is recognized and PM switches into a state of periodic pacing at a programmable fixed rate (*e.g.*, 60 beats/min);
- irregular asynchronous (IA): hybrid state in which PM does not recognize always EMI signals and therefore sometimes misses one pulse or delays it;
- complete inhibition (CI): EMI is always confused as heart signal and PM does not produce any stimulation pulse;
- atrium tracking (AT): false atrial sensing inhibits atrial pacing and drives ventricle pacing;
- random inhibition (RI): PM is inhibited only under particular conditions depending on interfering signal start point and on some programmable PM parameters;
- no effect (NE): the PM behaviour is absolutely as expected.

Finally, a numerical 3-D model was used to further confirm the results obtained using the experimental set-up. This model, previously developed and validated [9], is based on a model designed in order to study the stimulation of the brain cortex [10, 11]. Such model provides a discretized description of the volume including the PM metallic body, its insulated leads and the human trunk simulator. The voltages induced at the PM inputs have been calculated and compared to those observed during the experimental tests.

MATERIAL AND METHODS

The PM tested is one of the most diffused on trade and can operate as a single, double or triple chamber device. *Figure 2* shows the used test set-
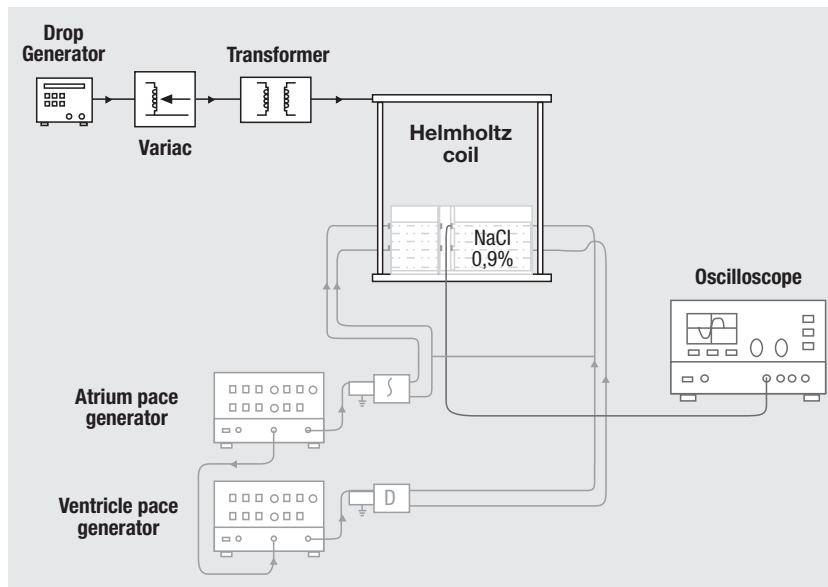

Fig. 1 | *Graphical sketch of current path for the unipolar and bipolar configuration.*

Fig. 2 | *Test set-up bench.*
Drop generator: Shaffner Model NSG 603 A.
Variac: Belotti Model V-20-NC.
Oscilloscope: Tektronics TDS-3054.
Generators: HP8011A.

up. The Helmholtz coil is supplied by a variac and a transformer and generates a magnetic field at 50 Hz vertically oriented (the cross-polarized components are at least 26 dB below the main one) allowing to set a whatever value from 0 up to 2 mT (CW mode). The addition of a programmable drop generator allows to produce pulsed fields (PW mode). A plastic box, divided in three chambers (one for the atrium, one for the ventricle and one for the PM lodging), is allocated inside the Helmholtz coil in order to simulate the human heart. For the atrium and the ventricle chambers two rightly synchronized pulse generators simulate electric heart signals. They are applied to two electrode plates on opposite sides. Lastly, the electric signals inside the boxes are detected by two electrodes usually used for electrocardiogram (ECG) analysis and are coupled to an oscilloscope.

A first chamber simulates the right atrium (30 cm × 20 cm), the second chamber simulates the right ventricle (30 cm × 30 cm), and the third is the lateral lodging for PM (15 cm × 15 cm). Further details and a photo of the 3 chamber cardiac simulator can be found in [9]. This box simulator was similar to that previously adopted by Angeloni *et al.* [12]. The boxes dimensions are not critical and are due to detect more easily every electrical signal inside the boxes. The three plastic boxes are filled by a saline solution (NaCl 0.9%) in order to offer an impedance similar to the human one (between 200 and 600 Ohm). Obviously all chambers are electrically connected through proper openings. For positioning the PM and the relative leads every chamber contain a plastic reference grid (adjustable in height) for leads displacements in order to guarantee the right reproducibility of every test. Every chamber is provided with both sensing and stimulating electrodes, and reproduces the electrical activity of one single heart chamber. Simulated heart activity signals were in-

jected in the box by avoiding any ohmic connections between PM leads and instruments wires.

Description of the pacemaker under test

The PM utilized in every test is one of the most diffused on trade. The PM was programmed as follows: atrial and vertical pulse amplitude 3.8 V; pulse duration 400 µs; pacing rate 60 min -1; minimum and maximum atrial sensitivity: 0.5/1.0 mV; minimum and maximum ventricular sensitivity: 1.0/2.0 mV; PM polarity settings: pacing always unipolar and sensing both unipolar and bipolar. The pacemaker was tested in the following operating modes (ICHD code): VVI, AAI and DDD. Details on these operating mode can be found in [9].

Leads configurations

In the tests two different configurations of the leads have been considered to investigate the voltage induced under different orientations with respect to the external field (and consequently the different PM behaviour for the same field value): in configuration 1 the exceeding ventricle part of the lead forms a vertical loop, parallel to the magnetic field, which does not couple to the external; in configuration 2 the same loop is orthogonal to the magnetic field and therefore it is completely coupled with the external field. In both configurations the atrium lead is allocated in the same position because its length (about 380 mm) and flexibility do not allow substantial modifications. On the contrary, the ventricular lead, being usually longer than the necessary length (about 580 mm), can be oriented in various ways.

RESULTS
Results with CW fields

The tests have been carried out using the two previous configurations and increasing external field from

Table 1 | *CW Field: atrium (sensing and pacing unipolar) and ventricle unipolar (only pacing)*

Configuration	1	2	1	2
Atrium sensitivity (mV)	0.5		1.0	
Ventricle sensitivity (mV)	1.0		2.0	
Minimum field for EMI (μT)	58	42	119	91
PM behaviour	SA	SA	SA	SA

SA = standard asynchronous

Table 2 | *CW Field: atrium (sensing bipolar and pacing unipolar) and ventricle unipolar (only pacing)*

Configuration	1	2	1	2
Atrium sensitivity (mV)	0.5		1.0	
Ventricle sensitivity (mV)	1.0		2.0	
Minimum field for EMI (μT)	2000	950	2000	1300
PM behaviour	NE	IA	NE	IA

IA = irregular asynchronous; NE = no effect.

0 μT up to a maximum value of 2000 μT. During the scanning, some PM EMI effects have been recorded. The results are summarized in *Table 1* and *Table 2*. In every table the minimum field value that produces the EMI effect is reported.

Two typical sensitivity values have been chosen for each polarity system. The *Tables* indicate the minimum field value that generates the EMI effect. In *Table 1*, in which both atrium and ventricle are in unipolar mode, the only observed effect was the SA, whereas in *Table 2* the only observed effect was the IA. The field value at which the effect occurs is lower for the configuration 2 in which the field coupling is higher, as we expected. Moreover, the critical field value is proportional to the programmed PM sensitivities. The system polarity with ventricle bipolar provides the same results for atrium both unipolar and bipolar. Furthermore it must be remarked that PM inhibition (that is the most dangerous for wearer's life) was never obtained.

Results with PW fields

Successively, in order to simulate the effects due to intermittent operating machines , the pulsed excitation was considered: in particular three signals with different ratios between period T and time T_{on} were considered, whereas the sinusoidal frequency was always 50 Hz:
- signal 1, whose period T is less than T_{PM};
- signal 2, whose period T is similar to T_{PM};
- signal 3, whose period T is much larger than T_{PM}.

The tests with pulsed fields have been carried out with the same interfering signal already used for CW fields, but interfaced by a drop generator. The obtained results are summarized in *Table 3* and *Table 4*. Only one sensitivity value has been set (the worst).

Generally, it can be remarked that, if the external field pulse (T_{on}) starts before the well defined sensing time, it will be recognized as an EMI signal, otherwise the PM confuses the first sinusoidal wave of interfering signal as a cardiac spontaneous pulse, and consequently PM misses the relative pulse.

In particular in *Table 3* polarity system was unipolar both for the atrium and for the ventricle. With signal 1, there are two effects for two different field values. The first EMI effect is AT. Atrial tracking behavior means that a false atrium sensing drives ventricle pacing, so if the atrium has misinterpreted the interfering signal as a heart signal, the PM paces the ventricle with a period equal to the interfering signal (*e.g.*, 700 ms, that is 85 beats per minute – not dangerous). The second effect was CI. Complete inhibition, has to be considered a potentially lethal effect for the patient.

Table 3 | *Pulsed Field: atrium unipolar and ventricle unipolar*

Configuration	1		2	
Field and EMI effect	B (μT)	PM behavior	B (μT)	PM behavior
Signal 1 T_{on} = 500 ms T = 700 ms < T_{PM}	14	AT	13	AT
	52	CI	38	CI
Signal 2 T_{on} = 100 ms T = 1000 ms = T_{PM}	15	RI	12	RI
Signal 3 T_{on} = 5000 ms T = 10000 ms > T_{PM}	14	RI	11	RI

AT = atrium tracking; CI = complete inhibition; RI = random inhibition.

Table 4 | *Pulsed Field: atrium bipolar and ventricle unipolar*

Configuration	1		2	
Field and EMI effect	B (μT)	PM behavior	B (μT)	PM behavior
Signal 1 T_{on} = 500 ms T = 700 ms < T_{PM}	50	CI	35	CI
Signal 2 T_{on} = 100 ms T = 1000 ms = T_{PM}	50	RI	35	RI
Signal 3 T_{on} = 5000 ms T = 10000 ms > T_{PM}	50	SA	35	SA

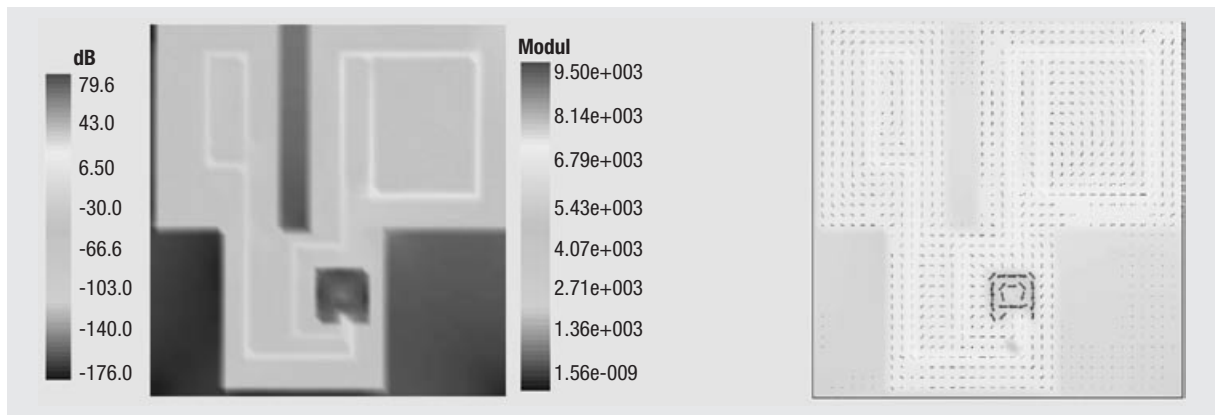*CI = complete inhibition; RI = random inhibition; SA = standard asynchronous.*

Fig. 3 | *Left panel: amplitude of current density (dBA/m2) in a horizontal section at 10 mm depth for configuration 1. Right panel: corresponding vectorial plot.*

Moreover, if the total period is nearly equal to PM programmed period (*e.g.*, for signal 2), the EMI effect depends on interference starting point and PM inhibition becomes random. Different is the case of a longer Ton (signal 3), where the PM omits the first pacing pulse, but immediately switches into the asynchronous mode for all the remaining T_{on}, as in the CW mode. Obviously, during the T_{off} the PM works as expected. In other words, we can observe that the EMI effects, for short T_{on} signal, strongly depend on interference starting point.

In *Table 4* the polarity system was bipolar for the atrium and unipolar for the ventricle and almost the same EMI effects have been observed for signal 1 and signal 2, whereas for signal 3 SA effect was always obtained.

For the polarity systems with atrium unipolar and ventricle bipolar, we have obtained the same effects recorded with atrium bipolar and ventricle unipolar, but with field values lower than the ones shown before. Lastly, no EMI effect has been observed if both atrium and ventricle are bipolar.

NUMERICAL SIMULATION WITH 3-D MODEL

This tool simulates the whole bench system formed by Helmholtz coil, heart simulator (plastic boxes), pacemaker case and its electrical leads. The aim is to develop a general purpose numerical tool able to analyze different magnetic or electric fields sources, different implanted devices (*e.g.*, defibrillators), different heart simulator (plastic boxes) and different configurations of the leads.

Model theory and development

The electromagnetic problem is to calculate electric fields and current density distribution induced in the biological tissues by a time-varying fields. Human trunk, discretized into cubic cells, is represented with a resistive 3D net characterized by the typical tissue

conductivity. The method used to solve this problem consists of the application of one Maxwell's equation and continuity equation, both in their integral form. Since all electric quantities are slowly time-varying in the ELF domain, the quasistatic approach is applied. In particular volume charge density wasn't considered depending on time and, since the minimum wavelength of magnetic field is much greater than cell edge, all electromagnetic quantities can be considered constant inside every cell. The analytical details of the method are described in [9].

3D numerical model

From the knowledge of conductivity of human tissues, the procedure assigns its conductivity to every cell depending on the material, frequency and temperature. In the case of human tissue the Cole-Cole formula is applied [13], in the case of a saline solution the interpolating formula are applied [14, 15]. Successively every object of test bench can be inserted, substituting the proper conductivity in the involved cells. So the three boxes filled with saline solution (conductivity = 1.55 S/m) and with the same experimental dimensions have been inserted within the 3D model. The presence of a a metallic box (pacemaker case) was simulated at 10 mm depth, with two load resistances of 10 k for the electric leads (between the case and every pacemaker in-

Table 5 | *Induced current densities in the lead and voltage levels at PM input, as obtained by the numerical model*

Configuration	1	2
J_{atrial}	2.8 mA/m^2	2.5 mA/m^2
$J_{ventricular}$	2.48 mA/m^2	1.2 mA/m^2
V_{atrial}	2.8 mV	2.5 mV
$V_{Ventricular}$	2.48 mV	1.2 mV

put) in order to simulate the unipolar mode. Lastly, the two insulated wires, representing the leads following the two configurations previously described, are placed in the model.

A proper mathematic software solves the linear system previously obtained and a graphic software shows the results [9]. *Figure 3* left panel shows the J magnitude results for configuration 1 in a horizontal section including the PM at 50 Hz.

An external field with an amplitude of 76.5 µT has been considered. The current span is very large and the currents are concentrated on the metal structure. *Figure 3* right panel shows the same results in a vectorial plot highlighting the current paths. The currents flow through the openings for electrical connection, whose path starts from the outer edge of the greater box and terminates upon titanium case. In general, current path follows the configuration of the leads.

Now, the voltage values have been computed at the PM input impedances for the two analyzed configurations because they represent the final effect of the external field and therefore are responsible for the PM behavior. *Table 5* compares current density values and voltage induced values in the two configurations of the leads. The computed voltage values have the same order of magnitude of the sensitivity values of the PM (between 0.5 mV and 2 mV) and so such voltages are really able to modify PM behaviour, as shown in the experimental tests.

CONCLUSIONS

The bipolar system for EMI effects is always better than the unipolar one, in particular for CW waves which generated only the "standard asynchronous" EMI effect (not dangerous). In the unipolar system, leads orientation in the boxes is very important for EMI effect thresholds.

Pulsed fields are more dangerous than continuous fields, specially if their period is shorter than PM period therefore sensitivity value should be set as high as possible. Some EMI effects occur for field values below the limits suggested by international organizations (*i.e.*, ICNIRP limits are: 100 µT for general public, 500 µT for occupational) [16].

Every EMI effect disappeared when interfering signal has been stopped.

The developed 3D numerical model has demonstrated its capability to reproduce the real experimental situation for both the current distribution inside the human trunk and for the disturbance induced at the PM inputs. Numerical results showed a good agreement with the experimental results.

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