IMPLANTABLE CARDIAC PACEMAKER INTERFERENCE BY MAGNETIC FIELDS AT POWER LINE FREQUENCY: EXPERIMENTAL AND NUMERICAL INVESTIGATION

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1. INTRODUCTION

The immunity of Implantable Cardiac Pacemaker (PMK) 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 PMK and RF systems (e.g. cellular phones, security systems and so on ..) [1]. On the contrary, the effects of Extremely Low Frequency (ELF) fields have not been sufficiently considered because the PMK 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. Nowadays, in order to allow to more people to live a normal life, the average age of the PMK wearer is considerably lowered, and therefore PMK wearer could be a worker operating in a factory near high power machines. The aim of the present work is to investigate PMK immunity against high level magnetic fields at ELF (typically 50 Hz.) that can be found in industrial environments. Such investigation started with a PMK programmed with only one chamber (right atrium or right ventricle), and was already described in previous Congress [2]. The present work concerns the same PMK previously tested, but programmed with dual chambers (right atrium and right ventricle). Moreover the investigation has been carried out both with experimental tests and with numerical 3-D model. The 3-D numeric model, obtained modifying a previous model designed in order to study the stimulation of the brain cortex [3], provides a discretized description of the volume including the PMK metallic body, its insulated leads and the human trunk simulator. The voltages induced at the PMK inputs have been calculated in order to justify the PMK behaviors observed during the experimental tests. Numerical results have showed a good agreement with the experimental results.
The PMK tested has the same features already described [2], but operates with dual chambers in DDD mode. In this code the first D indicates that both atrium and ventricle chamber can be paced, the second D indicates that both atrium and ventricle chamber can be sensed, the third D indicates that a sensed atrium event will inhibit the atrium pace and will start a so called A-V delay. If no ventricle sensing occurs within that delay, a ventricle pace should be emitted.
The principal coupling mechanism between the PMK and the external field is due to the loop formed by the stimulating and sensing electrode system through the human tissues. Such loop area depends on system polarity that, for every lead, can be unipolar or bipolar. Therefore, in the unipolar system, the loop formed by current path can reach a maximum value of 550 cm^2. On the contrary, in the bipolar system, the loop area is very small (about 15-20 times less than the unipolar system) [2] and the EMI effect is less than the unipolar system. But the utilization of this system is not always allowed because it needs a sufficiently large cave vena and suffers a worse durability. Generally a dual chambers PMK system has a bipolar atrium chamber and a unipolar ventricle chamber. Furthermore, modern PMKs are provided with hardware filters (generally low-pass filters) in order to stop upper frequency signals, and with a software procedure that often recognizes heart signal from a not heart signal. So if an exogenous signal rate is less of filter cut rate and is recognized as an interfering signal, the PMK starts to pace at a programmed fixed rate (pacing rate of asynchronous mode), and remains in this condition for all interfering signal duration.

2. TESTING PROCEDURE

Fig. 1 shows the used test set-up. The Helmholtz coil is fed 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). The addition of a programmable drop generator allows to produce pulsed fields. A plastic box, divided in three chambers (one for the atrium, one for the ventricle and one for the PMK 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.
The Fig. 2 shows a photo of the cardiac simulator, where first chamber simulates the right atrium (30cm x 20 cm), the second the right ventricle (30 cm x 30 cm), and the third is a lateral lodging for PMK (15 cm x 15 cm). 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 PMK and the relative leads every chamber contain a plastic reference grid (adjustable in height) for leads displacements 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.

2. 1 Expected Electromagnetic Interference (EMI) Effects

These are the main EMI effects upon PMK :

Standard Asynchronous (SA): EMI is recognized and PMK switches into a state of periodic pacing at a programmable fixed rate.(e.g. 60 beats/min).

Irregular Asynchronous (IA): hybrid state in which PMK does not recognize always EMI signals and therefore sometimes misses one pulse or delays it. (only for CW waves)

Complete Inhibition (CI): EMI is confused as heart signal and PMK does not produce any stimulation pulse.

Atrial Tracking (AT) : Atrium sensing drives ventricle pace (only for PW waves)

Random Inhibition (RI) : PMK is inhibited only under particular conditions depending on interfering signal start point and on some programmable PMK parameters (only for PW waves)

No Effect (NE)

2. 2 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 PMK behaviour for the same field value).These configurations are reported in fig. 3 and represent two of some possible real situations in actual implantation systems. In both configurations it can be observed that the atrium lead is allocated in the same position because its length (about 38 cm.) and flexibility do not allow substantial modifications. On the contrary, the ventricular lead being usually longer than the necessary length (about 58 cm.), can be oriented in various ways and the following two configurations have been chosen:

1. the exceeding ventricle part of the lead forms a vertical loop which does not couple with the external field;
2. the same loop is orthogonal to the magnetic field and therefore it is completely coupled with the external field.

3. RESULTS

3.1 Results With CW Fields

The tests have been carried out using the two previous configurations and rightly synchronizing heart signals for atrium and ventricle. Increasing external field from 0 µT up to a maximum value of 2000 µT, some PMK EMI effects have been recorded. The results are summarized in Table I and Table II. 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 I, in which

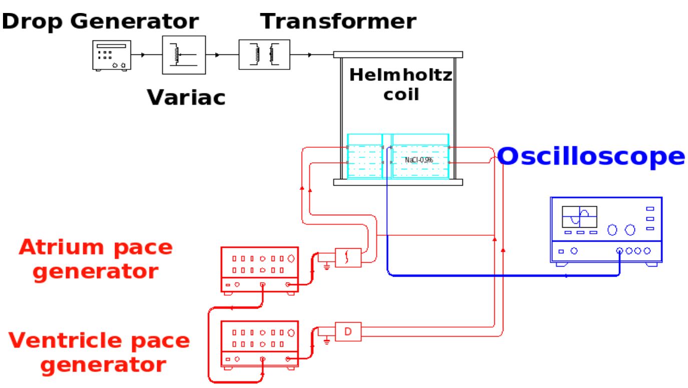

Fig. 1 – Test set-up

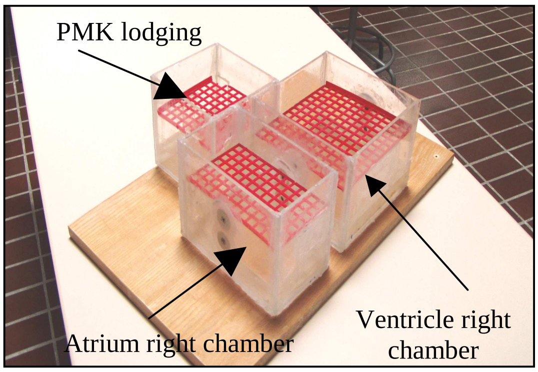

Fig. 2 – Cardiac simulator photo

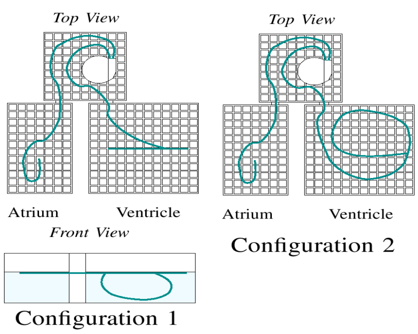

Fig. 3 – configuration 1 (standard) and configuration 2 (worst)

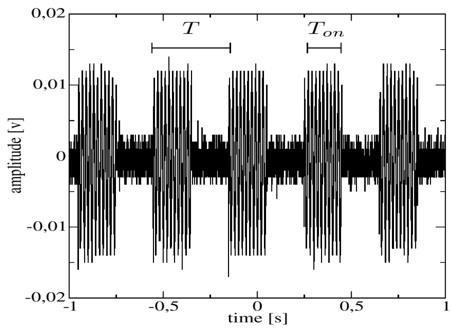

Fig. 4 – Pulsed waves

both atrium and ventricle are in unipolar mode, the only observed effect was the SA whereas in table II 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 PMK sensitivities. The system polarity with ventricle bipolar provides the same results for atrium both unipolar and bipolar. Furthermore it is to be remarked that PMK inhibition (that is the most dangerous for wearer's life) was never obtained.

3.2 Results With PW Fields

Successively, 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 (Fig. 4) :

- Signal 1, whose period T is less than T_{PMK}
- Signal 2, whose period T is equal to T_{PMK}
- Signal 3, whose period T is larger than T_{PMK}

The aim was to simulate the effects due to intermittent operating machines. 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 III e Table IV. Only one sensitivity value has been set (the worst) .

In table III 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. AT behavior means that atrium sensing drives ventricle pacing, so if the atrium has misinterpreted the interfering signal as a heart signal, the PMK 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 : it is very dangerous and can lead the patient to death. With the other signals we have always the RI EMI effect. In Table IV the polarity system was bipolar for the atrium and unipolar for the ventricle and almost the same EMI effects have been observed. Generally, it can be remarked that, if the external field pulse starts before the sensing time, it will be recognized as an EMI, otherwise the PMK confuses the first sinusoidal wave of interfering signal as a cardiac spontaneous pulse, and consequently PMK misses one pulse. For signal 1 this situation always occurs so that PMK is completely inhibited. For signal 2 this situation is random and for signal 3 this situation occurs only for the first wave,
because successively interfering signal is recognized as an exogenous interference and PMK switches to AS mode. In other words, we can observe that the EMI effects strongly depend on interference starting point. 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.

4. 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 (eg: defibrillators), different heart simulator (plastic boxes) and different configurations of the leads.

Table I : atrium unipolar and ventricle unipolar

Chamber	Atrium	Ventricle	Atrium	Ventricle
Sensitivity (mV)	0.5	1	1	2
Field and EMI effect	B (μT)	PMK behavior	B (μT)	PMK behavior
Configuration 1	58	SA	119	SA
Configuration 2	42	SA	91	SA

Table II : atrium unipolar/bipolar and ventricle unipolar

Chamber	Atrium	Ventricle	Atrium	Ventricle
Sensitivity (mV)	0.5	1	1	2
Field and EMI effect	B (μT)	PMK behavior	B (μT)	PMK behavior
Configuration 1	2000	NE	2000	NE
Configuration 2	950	IA	1300	IA

Table III : atrium unipolar and ventricle unipolar

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

Table IV : atrium bipolar and ventricle unipolar

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

4. 1 Model Theory and Development

The 3-D model has been obtained by a previous model designed for reproducing magnetic stimulation of the brain cortex [3]. The electromagnetic problem is to calculate electric fields and current density distribution induced in the biological tissues by a time-varying fields. 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.

From the knowledge of conductivity of human tissues, the procedure assigns its conductivity to every cell depending on the material, frequency and temperature[4]. Successively every object of test bench can be inserted, substituting the proper conductivity in the involved cells.(metallic box simulates PMK case at 10 mm. depth with two input resistances of 10 kΩ connected to the termination of the electric leads, between the case and every PMK input., 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 described and a graphic software shows the results. Fig. 5 shows the J magnitude results for configuration 1 in a horizontal section including the PMK: at 50 Hz. the external field has been considered with an amplitude of 76.5 μT. The current span is very large and the currents are concentrated on the metal structure. Fig. 6 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 PMK input impedances for the two analyzed configurations because they represent the final effect of the external field and therefore are responsible for the PMK behavior. Table V 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 PMK (between 0.5 mV and 2 mV) and so such voltages are able to modify PMK behavior as shown in the experimental tests.

5. CONCLUSIONS

The bipolar system for EMI effects is always better than the unipolar one.
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 PMK period.
Some EMI effects occur for field values below the limits suggested by international organizations.
Every EMI effect disappeared when interfering signal has been stopped.
The developed 3_D 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 PMK inputs.

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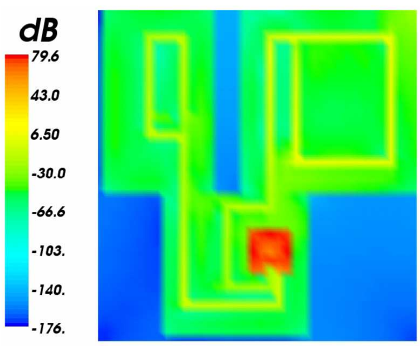

Fig. 5 – Amplitude of current density in a horizontal section at 10 mm depth for configuration 1

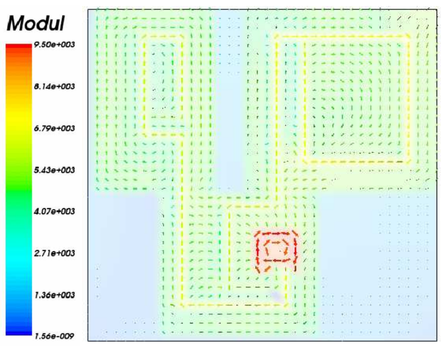

Fig. 6 - Relative vectorial plot

Table V : Current and voltage comparisons

	Configuration 1	Configuration 2
J_{atrial}	2.8 mA/m^2	2.5 mA/m^2
$J_{ventricular}$	2.4 mA/m^2	1.2 mA/m^2
V_{atrial}	2.8 mV	2.5 mV
$V_{ventricular}$	2.4 mV	1.2 mV