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Electromagnetic compatibility of active cardiovascular implants to occupational magnetic field environments: impact of the field direction

Etude de la compatibilité électromagnétique des dispositifs cardiaques actifs aux champs magnétiques industriels basses fréquences : impact de l'orientation du champ

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Abstract. Active Implantable Medical Devices (AIMD) are nowadays a part of everyday life, with for example more than one million pacemakers (PMs) implanted each year worldwide. Like every electronic devices they are sensitive to electromagnetic interferences but the consequences are potentially severe. A large number of publications deals with electromagnetic compatibility (EMC) with common equipment but only a few concern industrial sources. Furthermore, the field encountered at workplace is potentially higher. Taking these into account, a new test method to assess the EMC of AIMDs against occupational magnetic field sources was developed. It is based on an experimental approach using a specific test bench able to generate a controlled magnetic field in all space directions up to the high occupational exposure limits between 50 Hz and 3 kHz. To do this, three Helmholtz coil systems are combined on three orthogonal space directions. This specificity makes it possible to take into account the high variability of the operator's position compared to the industrial source.

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In this paper, the study focused on the impact of the magnetic field direction on the PM's functioning with bipolar leads, as is the case for the vast majority of devices implanted nowadays. It appears that the magnetic field direction has an impact on the PM's functioning and is consequently a relevant parameter for evaluating their EMC. These observations led us to the hypothesis that the lead in bipolar mode is more sensitive to electric field than magnetic field. This assumption remains to be confirmed by further studies.

Résumé. Les dispositifs médicaux implantables actifs (DMIA) font aujourd'hui partie de la vie courante, en effet plus d'un million de pacemakers sont implantés chaque année dans le monde. Comme tous les appareils électroniques, ceux-ci sont susceptibles d'être perturbés par les champs électromagnétiques environnants. De telles interférences peuvent avoir des conséquences dramatiques sur la santé du porteur. Un grand nombre de publications traitent de la compatibilité électromagnétique (CEM) des DMIA avec des équipements de la vie courante. Cependant, peu d'études concernent les sources de champ industrielles. De plus, les limites d'exposition professionnelle étant supérieures à celles pour la population générale, l'exposition est potentiellement plus intense au poste de travail. Compte tenu de ces éléments, une nouvelle méthode d'essai pour évaluer la CEM des DMIA en milieu industriel a été mise au point. Elle repose sur l'utilisation d'un banc d'essai spécifique capable de générer un champ magnétique entre 50 Hz et 3 kHz dans toutes les directions de l'espace et jusqu'aux limites hautes concernant l'exposition professionnelle. Pour ce faire, trois systèmes de Helmholtz ont été combinés selon trois directions de l'espace orthogonales. Cette spécificité permet de considérer la grande variabilité du positionnement de l'opérateur vis-à-vis d'une source industrielle.

L'étude présentée dans cet article s'est portée sur l'impact de l'orientation du champ magnétique sur le fonctionnement des pacemakers munis de sondes bipolaires, comme c'est le cas de la quasi-totalité des dispositifs implantés de nos jours. Il apparaît que la direction du champ magnétique a un impact sur le fonctionnement des pacemakers et constitue ainsi un paramètre pertinent pour l'évaluation de la CEM. Ces observations nous ont conduit à formuler l'hypothèse selon laquelle la sonde en mode bipolaire serait plus sensible aux champs électriques qu'aux champs magnétiques. Cette hypothèse demande à être confirmée par d'autres études.

Keywords. AIMD, Pacemaker, EMC, Occupational exposure, Magnetic fields, Helmholtz coil.

Mots-clés. DMIA, Pacemaker, Exposition professionnelle, Champ magnétique, Bobines d'Helmholz, CEM.

Note. This article follows the URSI-France workshop held on 21 and 22 March 2023 at Paris-Saclay.

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1. Introduction

Cardiac implants are now part of everyday life, with more than one million pacemakers (PMs) implanted each year worldwide [1] and around 67,000 in France [2]. PMs have two main functions: sensing cardiac activity and stimulating the heart muscle if an irregularity is detected. Like every electronic device, they are sensitive to interactions with electromagnetic fields. The principal mechanism of interaction is a perturbation of the measured signals, leading to a lack or inadequate stimulation. Such interference can lead to potentially severe consequences. These Electromagnetic Compatibility (EMC) issues of PMs are the topic of a large number of publications, especially concerning everyday life equipment [3–5]. The patients are generally well informed about the potential risk and they are advised to stand away from some common sources. For example, the device manufacturers specify a minimal distance between the pacemaker and a cell phone, which is usually around 20 cm. Except some studies about power distribution [6], only a few deal with EMC at workplace [7–10]. It is therefore difficult for an occupational physician to correctly assess the risks in the case of an employee equipped with a PM. Furthermore, a worker is likely to be more exposed to electromagnetic fields at work. Indeed, in Europe, occupational exposure limits [11] are generally higher than the general public ones [12]. No major pacemaker malfunction in industrial environment was published, but several articles [7,10] or standards [13] highlight the potential adverse effects using *in vitro* tests. The absence of documented accident at workplace could be explained by various suggestions: malfunctions are generally reversible and do not directly threaten patient safety, this type of malfunction is not reported by the cardiologist and high-risk workers are generally properly protected from electromagnetic sources.

Cardiac implants are more sensitive to low-frequency (LF) magnetic fields. Indeed, these devices are designed to pick up cardiac signals which are LF with a frequency range up to 500 Hz [14]. The higher frequencies are generally filtered out at the device input stage. According to an internal study, the industrial sources, such as a spot welding gun, an induction oven or an arc welding station, generally emit LF magnetic field.

In order to comply with European directives, implant manufacturers perform EMC tests according to international standards [14, 15]. These standards combine different approaches: injection tests for which the signals are directly injected at the pacemaker input stage through a "tissue-equivalent interface circuit" and a radiative test using a simple coil for magnetic field exposure. Some magnetic field thresholds between 0 Hz and 3 GHz are defined to guarantee the implant functioning during daily life situation, that's why they follow or generally exceed the public exposure limits. For information, these limits reach 100 μT (RMS) at 50 Hz, then decrease in inverse proportion to frequency up to 800 Hz and remain constant at 6.25 μT (RMS) up to 150 kHz. To determine the voltage amplitude required for injection tests from the magnetic field thresholds, the standards consider the induced voltage through the inductive loop formed by the pacemaker and its leads. A "worst case" loop dimension, taking into account the length of the leads and the clinical implantation, is considered for the calculation, which tends to maximise the test voltages. This inductive loop consideration is only valid for unipolar (single electrode) mode leads, however almost all PMs implanted in Europe nowadays operate in bipolar (two electrodes) mode [1], which is only partially considered by the literature or international standards [14, 15]. Historically the lead polarity was only unipolar, in this mode the sensing and the pacing are made between an electrode at the lead extremity and the pacemaker case itself which is metallic. Electrical continuity is ensured by the conductivity of the intermediate tissues. In bipolar mode, the electrocardiogram (ECG) monitoring and the pacing are made between two electrodes at the lead extremity. In this case, there is no inductive loop formed by the leads. The differences between these two lead configurations are illustrated in Figure 1. Bipolar probes are thus reputed to be less sensitive to electromagnetic interference, that is why standards EMC tests consider an injected voltage for this mode ten times lower than for unipolar mode [14, 15]. Considering that, the tests proposed by the international standards are limited in some aspects: the considered mechanism of interaction only concerns the case of unipolar leads, the magnetic field exposure test does not consider the PM's leads and the magnetic field is only applied along three mutually perpendicular directions, no signal corresponding to real exposure situations is tested, etc.

According to the previous considerations, there is a need to develop a new test method for estimating the EMC of PMs to occupational LF magnetic fields. The method proposed here is based on an experimental approach using a test bench. It makes it possible to determine the impact of different parameters on the implant behaviour. In our case, the study focused on the impact of the magnetic field direction on the PM with bipolar leads.

2. Material and method

A test bench was designed using the numerical simulation software CST studio suite. A frequency domain solver for LF applications based on the finite element method (FEM) was used. As the system dimensions are significantly smaller than the wavelength at the considered frequencies, the magneto-quasistatic approximation was made, i.e. the displacement current is neglected compared to the conduction current in Maxwell–Ampere equation. Like the human body, the saline solution used to test the PMs has a relatively low electrical conductivity, which implies—considering the system's dimensions—an induced current too low to generate a significant magnetic field. In these conditions and with a test setup made of non-magnetic material ($\mu_r \approx 1$),

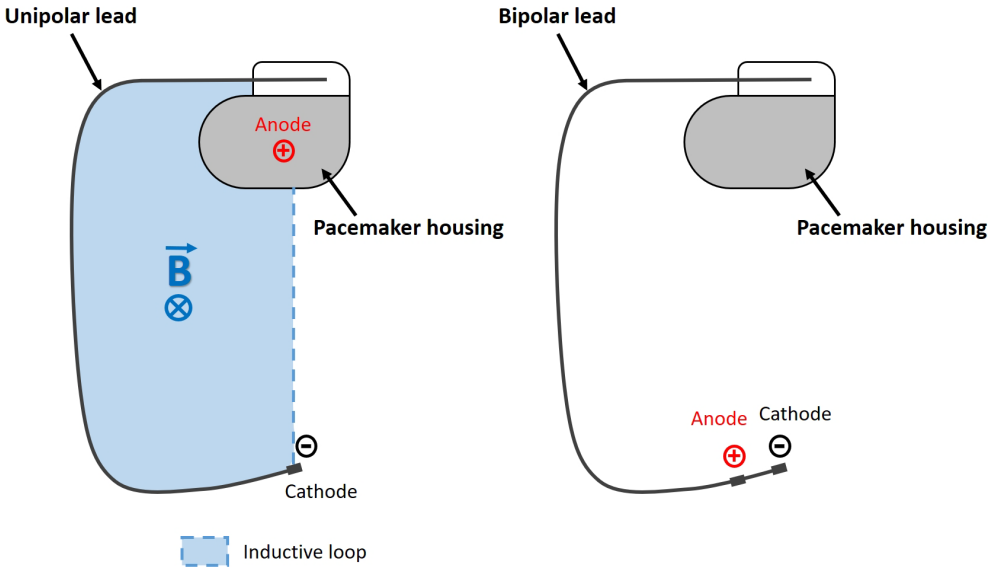


Figure 1. Differences between unipolar and bipolar lead configurations. The unipolar lead has a single electrode (cathode) at its extremity, detection and stimulation are made between it and the pacemaker housing (anode). The bipolar lead has two electrodes at its extremity, detection and stimulation are made between them.

the magnetic field distribution is not impacted by its presence. Also, considering the range of frequencies and the type of biological tissues around the pacemaker, using an equivalent homogeneous solution is a standard experimental approach widely used in the literature [6, 7, 10, 16]. The aim of the test bench is to generate a homogeneous and controlled LF magnetic field over a volume that can encompass an implant with its leads in a configuration approaching a clinical implantation. In order to take into account the high variability of the implant's position relatively to the source, the field can be generated in every space direction. In order to cover a wide range of industrial sources, the test bench was designed to operate between 50 Hz and 3 kHz. In terms of magnitude, the magnetic field is able to reach the high occupational exposure limits over the frequency range, which is theoretically the maximum level that an implant can be exposed. For information, these limits reach 6 mT (RMS) at 50 Hz and decrease in inverse proportion to frequency up to 3 kHz. Concerning the field homogeneity, a maximal variation of ±5% over a volume that encompasses the pacemaker and its leads is researched. The test bench is also able to reproduce a non-sinusoidal magnetic field representative of a real exposure at workplace.

The solution adopted to ensure the technical specifications mentioned above was to combine 3 Helmholtz coil systems in three orthogonal spatial directions (see Figure 2). Numerical simulation was particularly useful to characterise the field homogeneity inside the test bench and to determine the coil inductances, which is essential for selecting the power supply solution. The coils are thus supplied by 5 power amplifiers (model 7548 from AETechron). The geometrical characteristics of the coils are given in Table 1. The high-voltage supply generates unwanted electric fields that can interfere with implants. To avoid these parasitic fields and obtain a source of magnetic field only, the coils are shielded with a conductive layer (see Figure 3). Aluminium was used due to its relative magnetic permeability close to unity, which does not significantly affect the magnetic field distribution.

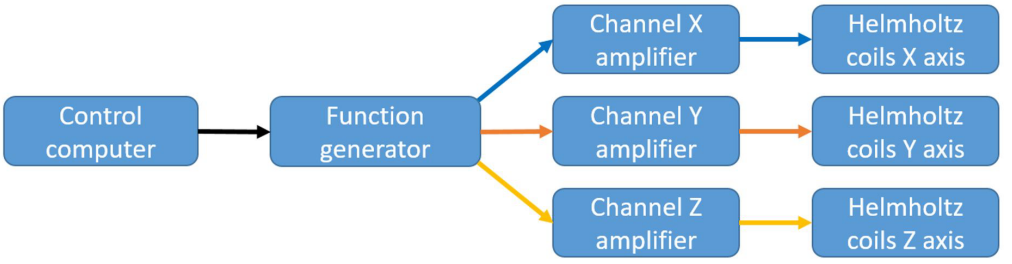


Figure 2. Test bench functional block diagram.

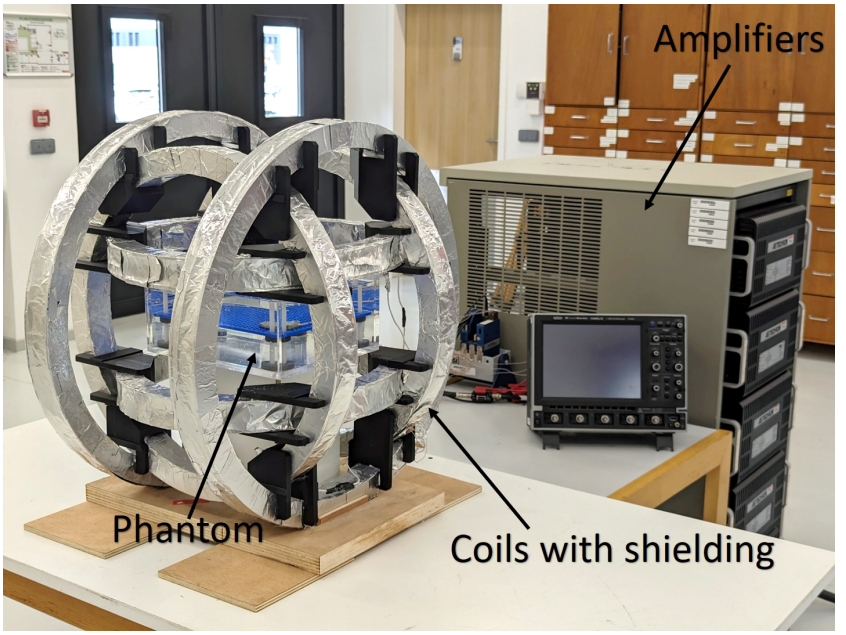


Figure 3. Test bench composed of the set of coils with shielding, the phantom and 5 power amplifiers: 2 in series for the x and y axes and only one for the z-axis, which requires less power.

Table 1. Coil geometrical characteristics

	Average diameter (cm)	N* for LF test bench
X coils	62	148
Y coils	53	127
Z coils	44	105

* Number of turns.

The test bench was characterised and complies with the specifications detailed above. The simulated magnetic field distribution presents, in the centre of the test bench when the 3 axes generate a same field intensity, a maximum variation in intensity of ±5% and a variation of field direction below 8° over a volume of $24 \times 22 \times 3$ cm^3 that can encompass the pacemaker

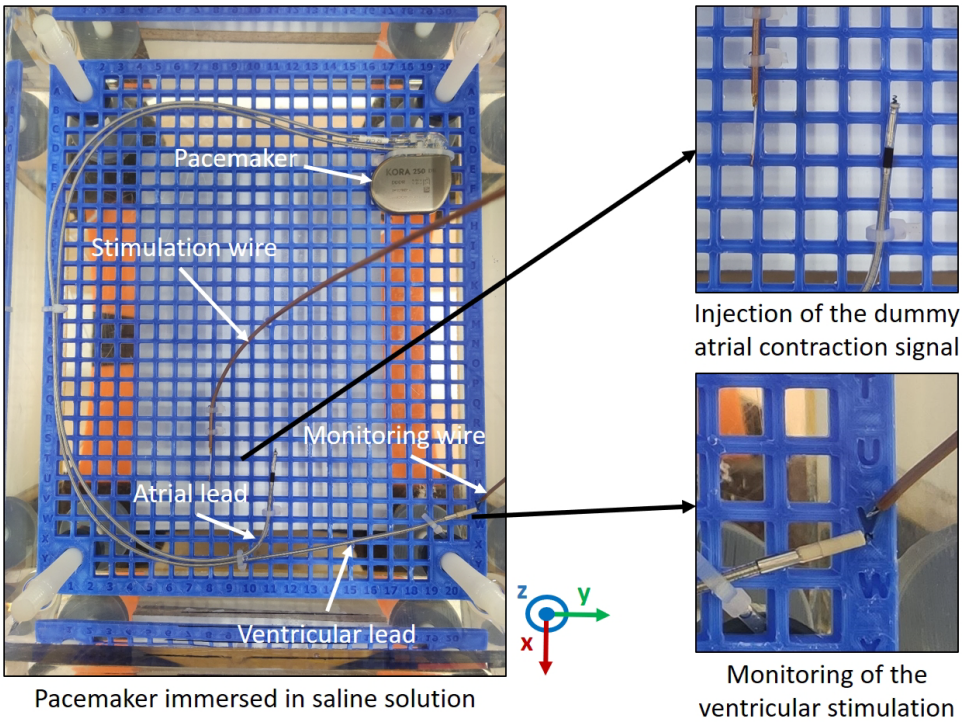


Figure 4. Test setup: monitoring and positioning of the pacemaker inside the phantom.

implantation. A good agreement of the generated magnetic field for a given voltage excitation was observed between the numerical simulation and the experimental measurements, with less than 1% difference.

For more information about the test bench, a related conference paper details its functioning, design and characterisation [17].

To test the implant's behaviour to magnetic field, it is immersed in a saline solution that simulates the electromagnetic properties of the human body. The solution conductivity is around 0.54 S/m, which corresponds to the average conductivity of human blood [18]. The whole system—composed of a plexiglass container with the saline solution, the PM under test and a plastic grid to support it—is placed at the middle of the Helmholtz coils as illustrated in Figure 4. The implant's functioning is monitored during the magnetic field exposure.

Concerning the pacemaker's settings, the tested device is configured in bipolar mode and operates in DDD mode corresponding to the standard setting for a dual-chamber pacemaker, which is the most implanted device configuration in Europe [1]. According to the international nomenclature, these three letters indicate that sensing and stimulation can be carried out on the atrium and on the ventricle, and that the device can either compensate cardiac stimulation irregularities or be inhibited if spontaneous cardiac activity is detected. This configuration permits to test the PM's sensing function as well as its stimulation function. The detection sensitivity is set to the most sensitive case, i.e. the lowest value: 0.1 mV. It corresponds to a worst-case situation. Indeed, the more the detection is sensitive, the more the PM is subject to electromagnetic interference. The PM with its leads is placed inside the container in a position approaching a typical left-sided pectoral implantation, which is the most common implantation (see Figure 3).

Table 2. Unit vectors associated with the 8 considered field directions

Orientation	Coordinates		
	x	y	z
1	0	0	1
2	−0.74	0.59	0.32
3	−0.60	−0.05	−0.80
4	0.88	0.34	0.32
5	−0.70	−0.70	0.16
6	0.45	−0.88	0.16
7	0.14	0.92	−0.35
8	0.55	−0.22	−0.80

In our case, the study focused on the effect of the magnetic field direction, the other parameters are fixed. Eight different directions equi-distributed in space are considered (see Figure 7(a)). The frequency is set to 50 Hz which corresponds to many industrial applications in Europe. The different magnetic field amplitudes applied are between 0 μT and 400 μT with a step size of 10 μT.

The implant monitoring is made with two coaxial wires immersed in the saline solution; the stimulation wire is used to send an ECG signal which simulates the atrial contraction and the monitoring wire is used to detect the ventricular stimulation response generated by the PM (see Figure 4).

In "normal" operating mode, the PM detects the dummy atrial contraction signal and the absence of ventricular contraction, and thus generates a stimulation pulse on the ventricular lead after a pre-programmed delay. During the magnetic field exposure, if a decrease of 50% of the pulse amplitude or a variation of more than 20% on the delay between the atrial contraction and the ventricular stimulation is observed, it is considered as a malfunction [16]. A comparison between a normal operating mode and a malfunctioning situation is presented in Figure 5. The limits considered for proper operation are defined from a reference measurement made without magnetic field (see Figure 6). For each considered magnetic field amplitude, a sequence of 100 cardiac cycles is played at a rate of 60 bpm and the number of malfunctions is recorded. It is then possible to plot the percentage of malfunctions versus the applied magnetic field for each considered direction.

3. Results

The spatial orientations of the eight considered field directions relative to the PM (numbered from 1 to 8) are illustrated in Figure 7(a), the coordinates of the associated unit vectors are given in Table 2. The percentage of malfunction versus the magnetic field amplitude is given for these eight directions in Figure 7(b). In order to better visualise and compare the results in Figure 7(b), the measurements for each direction are fitted by a power function which matches well to the observed trend.

The direction of the magnetic field has a significant impact on the operation of the pacemaker in bipolar mode.

No malfunctioning was observed between 0 and 400 μT for the 6th direction. However it occurs for higher magnetic field amplitudes.

After exposure to the magnetic field, the PM resumes a normal activity. No long-term effect of the magnetic field on the PM is observed. These intermittent malfunctions imply a desynchronisation of the atrial and ventricular contractions which may lead to discomfort. This situation

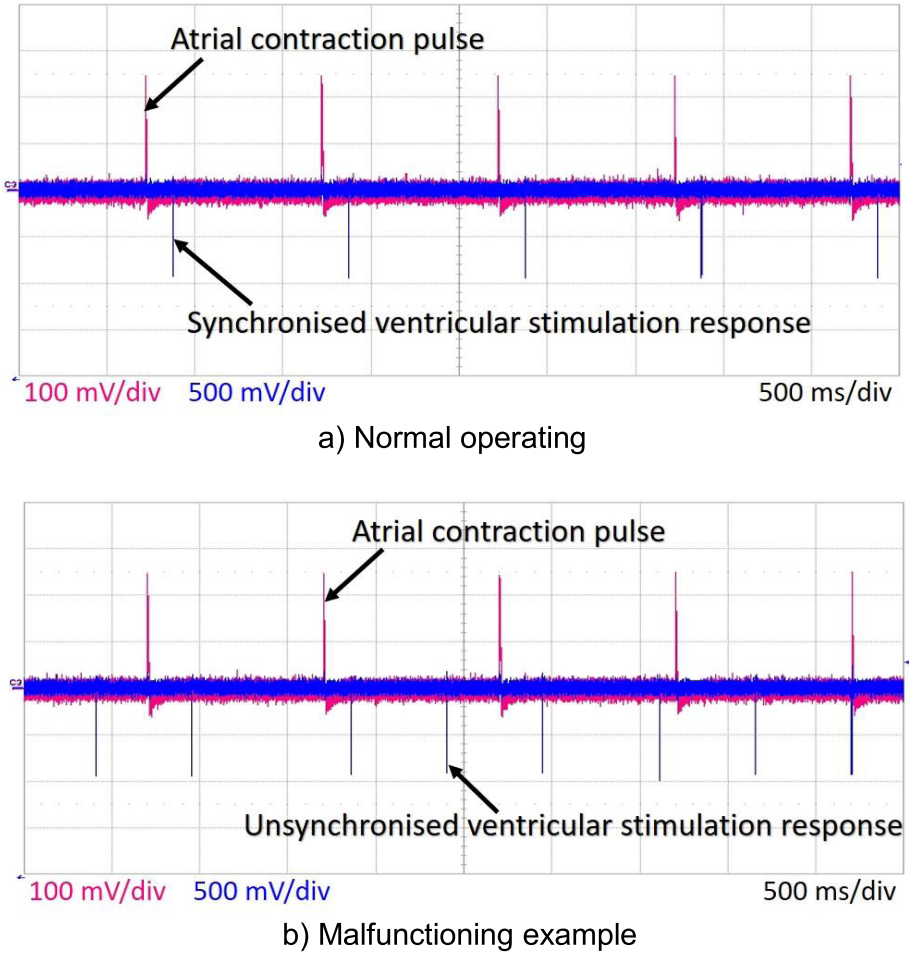


Figure 5. Comparison between a normal operating mode and a malfunctioning situation.

is not suitable especially at workplace—where exposure is repeated and prolonged—and should be avoided. However, this is not life-threatening for the PM holder, except for patients who are entirely PM-dependant.

4. Discussion

The magnetic field direction has an impact on the PM's functioning in bipolar mode. The direction with the highest malfunction rate doesn't correspond to the direction considered as the reference for EMC testing by international standards [14, 15] and the literature [16, 19]. This reference direction corresponds to orientation 1, i.e. the magnetic field perpendicular to the plane formed by the PM and its leads, a situation where a unipolar PM senses the maximum of magnetic flux.

The rational given by international standards and literature, based on an inductive area formed by the electrodes, seems inadequate for a bipolar PM. Indeed for this latter one, the highest malfunction rate doesn't correspond to the highest magnetic flux through an inductive area. Our hypothesis, based on this observation and others, is that the lead in bipolar mode

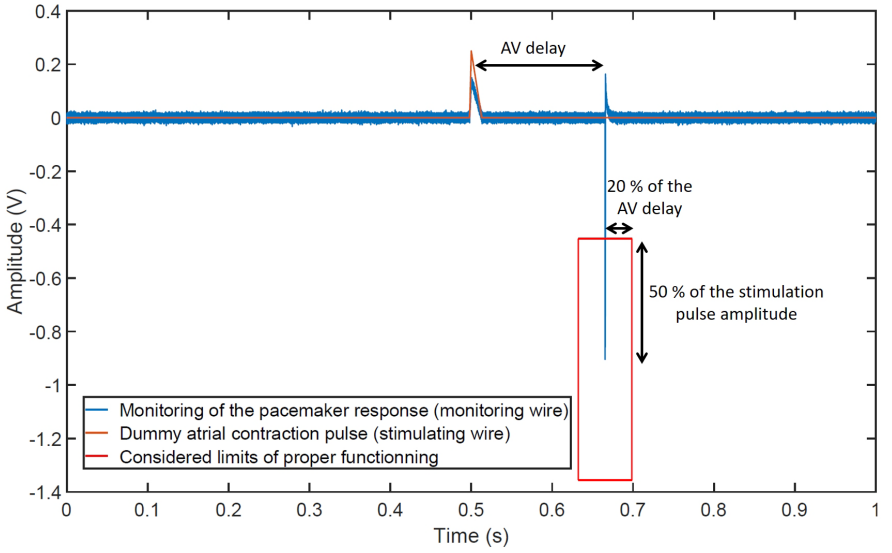


Figure 6. Determination of the proper functioning limits.

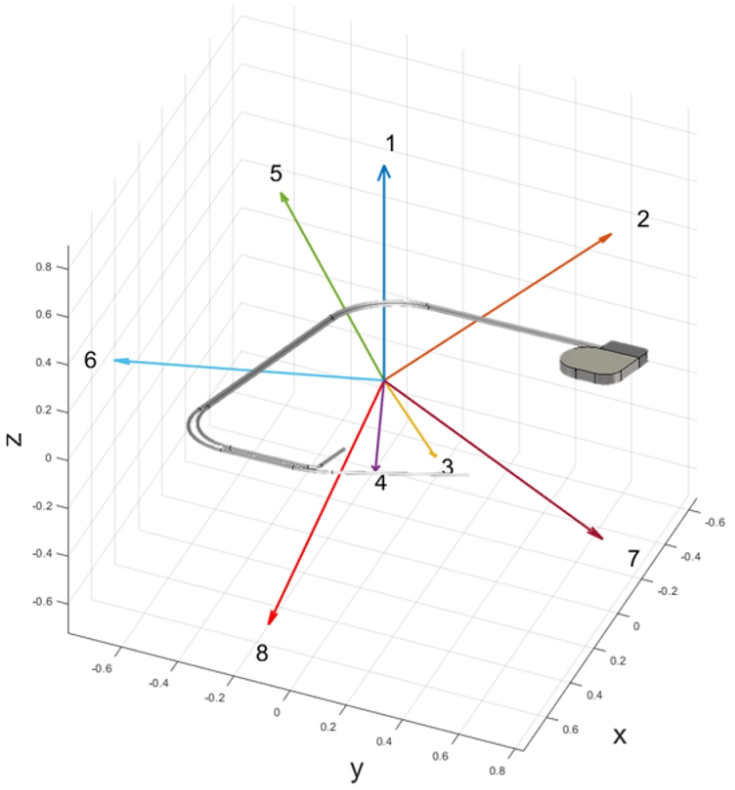
is more sensitive to electric field than magnetic field. Indeed, in bipolar mode the induced voltage cannot be derived easily from the evaluation of a magnetic flux through a given surface, but it can be expressed directly as a line integral of the electric field along a path between the two electrodes. In bipolar polarity mode, the lead seems to interact more like a short monopole antenna. In our case, the interfering electric field inside the phantom derives from the time-varying magnetic field (Maxwell–Faraday). Unlike the magnetic field, the electric field distribution over the phantom, obtained by numerical simulation, is inhomogeneous. Indeed, its distribution principally depends on the phantom geometry, the magnetic field direction and the material inside the container, such as the grid or the PM itself. It's therefore relatively complex to accurately predict the electric field distribution over the phantom. However, the fact that the electric field distribution varies according to the magnetic field direction could explain its impact on the PM's functioning.

No long-term effect on the PM is observed, which is in accordance with the requirements of the international standards. However, a relatively high malfunction rate is observed for magnetic field, even below the general public exposure limits. This could be explain by a detection sensitivity of 0.1 mV, which is outside the scope of international standards. It is indeed a key parameter regarding to electromagnetic interference.

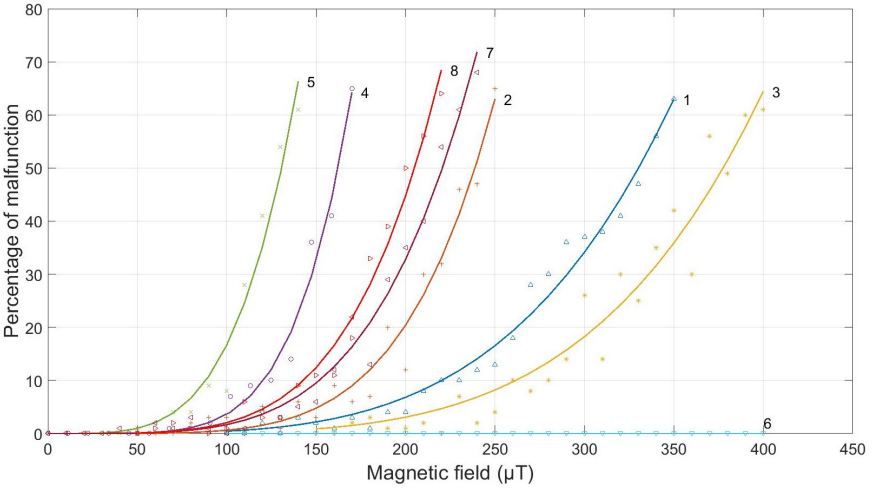
5. Conclusion

A new method for assessing the EMC of AIMDs was developed and characterised, then applied to PMs. The first tests showed that the direction of the magnetic field is a relevant parameter for the EMC study of PMs in bipolar mode. Furthermore, the induced voltage cannot be derived easily from the evaluation of a flux through an inductive surface. These observations led us to the hypothesis that the leads in bipolar mode are more sensitive to electric field than magnetic field. This assumption remains to be confirmed by further studies.

The impact of other parameters on the PM's functioning such as the saline solution conductivity, the field frequency or the device positioning is tested using the test bench. A comparative study between different PMs from different manufacturers is also carried out.



(a)



(b)

Figure 7. (a) Visualisation of the unit vectors associated with the 8 considered field directions (the pacemaker and its leads are in the xy-plane). (b) Percentage of malfunction in function of the magnetic field amplitude for the 8 considered field directions when exposed to a 50 Hz sinusoidal magnetic field.

This test method could be applied or adapted to other AIMDs such as implantable cardioverter defibrillators or neurostimulators.

Declaration of interests

The authors do not work for, advise, own shares in, or receive funds from any organization that could benefit from this article, and have declared no affiliations other than their research organizations.

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