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Testing immunity of active implantable medical devices to industrial magnetic field environments

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Abstract—The aim of this work is to develop a new method for testing the immunity of active implantable medical devices to low frequency industrial magnetic fields (between 50 Hz and 50 kHz) up to the high occupational exposure limits. It is based on an experimental approach using a specific test bench with the capability of reproducing real exposure situations and testing multiple orientations between the magnetic field and the device. The solution adopted was to combined 3 concentric Helmholtz coils on 3 perpendicular axes. The test bench was designed using a numerical simulation software. A good agreement between the numerical model and the test bench characterisation was observed. The determination of the interference threshold of a pacemaker as a function of the frequency (50 Hz to 50 kHz) is given as an example. The experimental results show between 50 Hz and 400 Hz an interference threshold between the public and the occupational exposure limits. Between 400 Hz and 50 kHz, no malfunction below the occupational high exposure limits was observed. The encountered malfunctions are completely reversible. It also appears that the occurrence of interferences strongly depends on the magnetic field orientation. This new test method will be applied to several pacemakers and could be used or adapted to other active medical implants such as cardioverter defibrillators or neurostimulators.

Keywords—Immunity test, AIMD, pacemaker, magnetic fields, Helmholtz coil, interference threshold.

I. Introduction

Cardiac implants have become a part of everyday life; more than 1 million pacemakers (PM) are implanted each year worldwide [1] and approximatively 67,000 in France alone [2] which represents around one implantation per 1,000 inhabitants. Taking into account the ageing of the population and the increase of pacing therapy indications, these numbers

are expected to grow [3]. Like every electronic system, the Active Implantable Medical Devices (AIMDs) are likely to be affected by electromagnetic interferences. These disturbances could lead to a device malfunction with potentially severe consequences. A large number of publications deals with the Electromagnetic Compatibility (EMC) of AIMDs but they mainly focus on medical applications [4], [5] or daily life equipment such as cell phones [6]–[8]. The patients are well informed about these common devices that may interfere with their cardiac implant and they are generally advised to keep them away from their chest. Because a part of the implanted people are in working age, the problematic of AIMDs EMC also occurs at workplace with industrial equipment. However, the available knowledge on this topic is limited. It is consequently difficult for the occupational physician to correctly estimate the associated risk. Furthermore, a worker is likely to be more exposed to electromagnetic fields during their work. Indeed in France and like other European countries, the occupational exposure limits [9] given by the European directive [10] are greater than the general public exposure limits [11].

According to a national survey about industrial sources of Electromagnetic Fields (EMF), they generally emit Low Frequency (LF) magnetic fields (under 50 kHz). For example, we can mention the resistance welding, arc welding, induction heating, magnetic particle inspection and so on.

AIMD manufacturers perform EMC tests on their cardiac implants in order to comply with European regulations [12]. These tests are provided by international standards [13], [14] and they essentially consist in injecting signals at the device input stages. Exposure to LF magnetic fields is only tested with the case alone (i.e. without leads) and for only three

spatial orientations. The signals used do not correspond to real exposure situations. According to some publications [15], [16], non-sinusoidal signals are more likely to cause a device malfunction. Moreover, at the considered LF magnetic field, the metal housing of the device does not shield the internal electronic circuit and thus the spatial orientation between the field and the electronic could be an important parameter. In addition, in work situation, the orientation between the implant and the industrial source presents a high degree of variability. For example, in [17], immunity test measurements of implantable medical devices with bipolar electrodes were performed thanks to a block-shaped model placed within a pair Helmholtz coils, but only one direction of the incident field was investigated for sinusoidal signals below 30 kHz.

Taking into account these considerations, there is a need to develop a new method to assess the immunity of AIMD considering real exposure situations and multiple orientations between the industrial source and the device. With this aim, a test bench was developed combining 3 concentric Helmholtz coils on 3 perpendicular axes. One of the objectives of this new test method is to determine the implant interference threshold, i.e. the amplitude above which a malfunction is likely to occur, as a function of frequency.

II. TEST BENCH

A. Specifications

1) Frequency

As explained above, many industrial sources of magnetic fields work between 50 Hz and 50 kHz. In order to cover the largest number of industrial processes, the test bench was designed to operate in this frequency range.

2) Amplitude

Considering the worker chest exposure, it normally should not exceed the occupational high exposure limit values. That is why, the test bench is required to be able to reach these limits on each axis. As the physiological effects depend on the field frequency, so do the restrictions. At 50 Hz this limit is 6 mT rms and decreases in $1/f$ over the range 50 Hz to 3 kHz. Between 3 kHz and 50 kHz, the limit is constant and equal to 100 μ T rms [10].

3) Reproducing an industrial magnetic field

One of the aims is to reproduce in laboratory a magnetic field emitted by an industrial source. The idea is to generate in a homogenous test volume the magnetic field measured in one point at workplace and corresponding to an occupational exposure situation.

4) Magnetic field orientation

The benefit of the test bench 3D structure is the ability to apply the same magnetic field in different space directions and thus to take into account multiple orientations between the source and the implant.

5) Magnetic field homogeneity and test medium

The aim of this method is to test the device in a position that approximates the clinical implantation. The geometric configuration of the implant and its leads must be contained

within a volume where the magnetic field tends to be homogenous.

The tested device is placed inside a container which is positioned in the centre of the test bench. The container is used to immerse the implant in a medium with electromagnetic properties close to human body and thus simulates the presence of the surrounding organs. As the container has to be large enough to hold the clinical implantation, its dimensions determine the size of the different coils and are therefore a key parameter for the test bench design. To characterise the implantation size, a study on anonymised radiographic images was carried out. From this, the selected length, width and height of the container are respectively 30x25x14 cm³.

B. Test bench design

1) Numerical simulation

The test bench was designed using the commercial numerical simulation software CST Studio Suite (see Fig. 1). Thanks to this software, different coil geometries were tested and the coil electrical parameters such as its resistance R or its inductance L were estimated. These quantities are essential for the test bench design, as they determine the currents and voltages required to reach the occupational high exposure limits. At the considered frequencies and test environment, the magnetoquasistatic approximation (MQS) could be made, i.e. the displacement current is neglected. In these conditions, the equations of the magnetostatic case like Biot-Savart law give a good estimation of the magnetic field distribution.

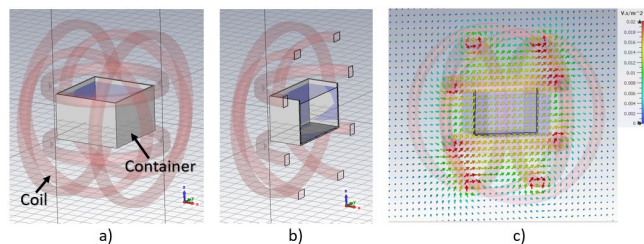


Fig. 1. Test bench design using CST Studio Suite: global overview (a), sectional view (b) and magnetic field distribution (c)

At low frequencies, the occupational exposure limits are higher and decrease in $1/f$. In these conditions, the reactive power required to reach these limits is proportional to L/f . At higher frequencies, the limit is lower and constant and thus the required reactive power is proportional to $L \cdot f$. It is difficult to obtain an inductance high enough to reach the exposure limits at low frequencies and low enough to not require at the highest frequencies extremely high reactive power that the amplifiers could not deliver. For this reason, two sets of coils with different inductances were made. The first one for frequencies from 50 Hz to 3 kHz and the second for the 3 kHz to 50 kHz range, hereafter referred respectively as LF and “High Frequency” (HF) test bench. The average coil diameters are identical, in order to have an equivalent magnetic field distribution between the two sets (see Table I).

TABLE 1. COIL GEOMETRICAL CHARACTERISTICS

| | Average diameter (cm) | N* for LF test bench | N* for HF test bench |
|---------|-----------------------|----------------------|----------------------|
| X coils | 62 | 148 | 1 |
| Y coils | 53 | 127 | 1 |
| Z coils | 44 | 105 | 1 |

* Number of turns

The simulated magnetic field distribution on the volume that encloses the pacemaker implantation ($22 \times 21 \times 3 \text{ cm}^3$) gives a field intensity homogeneity of $\pm 4\%$ and a field direction variation under 7° for the same set magnetic field on the three axes.

Five power amplifiers 7548 from AETechron were selected to supply the test bench: two times two in series for the x and the y axis and one for the z axis. They work in controlled-voltage mode and are driven by a National Instrument card: NI 9262. In order to avoid skin effect, Litz wires are used for the coil winding. The test bench functional block diagram is given in Fig. 2.

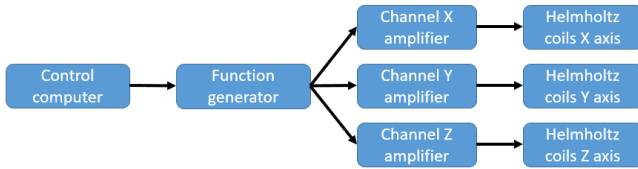


Fig. 2. Test bench functional block diagram

2) Study about the clinical implantation of pacemakers

The clinical implantations have been described in articles about PM EMC testing [18]–[21]. The most common and therefore relevant implantations are pectoral left and pectoral right. However, no implantation dimensions are given. For this reason, these dimensions were estimated on 69 anonymised radiographic images in DICOM format from patients with PM. The commercial DICOM viewer software RadiAnt was used to measure distances on the images. To characterise the implantation, i.e. the layout of the pacemaker and its leads, two dimensions were measured: the height and the width. These two dimensions are simply defined by the smallest rectangle which contains the complete device in the coronal plane with its height along the longitudinal axis and its width along the left-right axis. An example is given on Fig. 3.

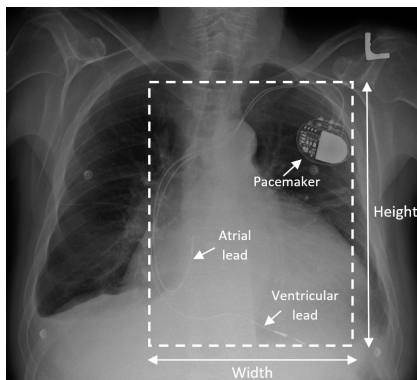


Fig. 3. Characterisation of a left pectoral implantation dimensions (original image under Creative Commons licence, author: James Heilman, M.D.)

On the considered 69 patients, there are 37 women and 32 men, 91 % have a pectoral left implantation ($N = 63$), 58 % are dual chamber ($N = 40$) and 42 % are single chamber ($N = 29$). The Table 2 gives information about the height and width observed for men and women for a pectoral left implantation.

TABLE 2. DIMENSIONS OF A PECTORAL LEFT IMPLANTATION FOR MEN AND WOMEN

| Men (N = 31) | Height (cm) | Width (cm) | Women (N = 32) | Height (cm) | Width (cm) |
|--------------|-------------|------------|----------------|-------------|------------|
| Mean (SD*) | 22 (2.7) | 20.7 (1.7) | Mean (SD*) | 20.1 (2.6) | 18.4 (2.5) |
| Max | 27.4 | 24.2 | Max | 24.2 | 23.7 |
| Min | 17.6 | 18.2 | Min | 15.4 | 12.7 |

* Standard Deviation

Because only 4 images are in sagittal plane, no relevant conclusion can be made concerning the implantation depth.

From these measured dimensions, a container, which can hold the implant and its leads, was designed in plexiglass.

C. Test bench realisation

1) Structure

The coil mechanical supports are made of PLA using 3D printing technology. These are printed separately and assembled like a puzzle to form the complete structure of the test bench (see Fig. 5). Then the winding was made manually.

2) Reproducing an industrial magnetic field

As the amplifiers work in controlled-voltage mode, it is necessary to take into account that the coil impedance is not constant and varies with the frequency for a multi-frequency signal. For this purpose, a digital filter was developed for each axis which determines the command voltage $u(t)$ to apply at the amplifier inputs from the required magnetic field $B(t)$ (see Fig. 4).

From the measured magnetic field, a low-pass filter is applied to denoise the signal and two spatial rotations are then applied to obtain $B(t)$ only in one space direction. For the considered applications in MQS, the direction of the magnetic field is constrained by the geometry of the source circuit (Biot and Savart). Thus $B(t)$ varies along a single space direction and depends on the amplitude and the frequency of the circuit current $I(t)$. Then the numerical filter is applied to obtain the control voltage $u(t)$.

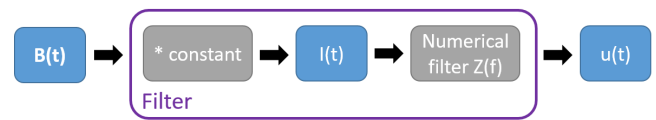


Fig. 4. Numerical filter block diagram

3) Magnetic field orientation

In order to test different spatial configurations between the implant and the source, it is necessary to select relevant orientations. One way to do this is to determine equispaced orientations along which the field is applied.

For each orientation, the three spatial components $B_x(t)$, $B_y(t)$ and $B_z(t)$ of the magnetic field $B(t)$ to be generated inside the test bench are determined. The three axis-specific digital filters are then applied to these components to obtain

the amplifier input voltage signals $u_x(t)$, $u_y(t)$ and $u_z(t)$ corresponding to the three amplification channels.

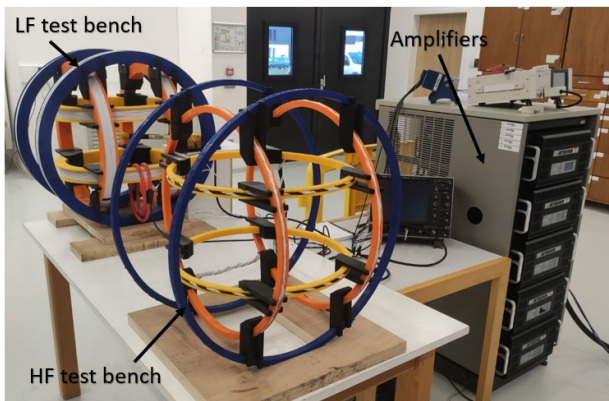


Fig. 5. Test bench overview

D. Test bench characterisation

1) Electrical properties characterisation

The coils were characterised using an impedance analyser (Keysight E4990A or Hioki IM3570). Because the coils have a parasitic capacitance, a resonant frequency was observed but beyond the operating frequencies. For the LF test bench, the difference between the simulated and the measured inductances are under 3 %. For the HF test bench, the wire and amplifier impedances, which were not simulated, are not negligible compared to the low inductance of the coils. All these electrical characteristics are input arguments of the control program which determines the coil supply voltages as a function of the amplitude and frequency of the required magnetic field.

2) Magnetic field measurement

a) Sinusoidal field

The magnetic field is measured at the center of the test bench using the WP-400-3 commercial probe from Wavecontrol. Less than 1 % difference between the required sinusoidal magnetic field and the measured one is observed.

b) Industrial field

For example, the field emitted by a resistive welding gun was measured at workplace, i.e. at 20 cm from the welding point, using a commercial probe Narda-ELT400 connected to an oscilloscope.

The filtered signal $u(t)$ is then applied to the amplifier inputs and the generated field is measured to compare with the initial industrial magnetic field. A good agreement between these two signals was observed (see Fig. 6).

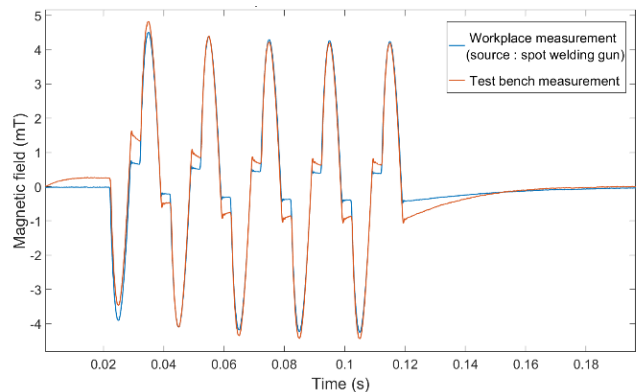


Fig. 6. Comparison between the measured field at workplace and the corresponding reproduced one inside the test bench

III. EMC TEST EXAMPLE

A. Test protocol

In this section, the determination of the interference threshold as a function of the frequency of a dual chamber PM in bipolar mode is given as an example. For this kind of test only sinusoidal fields are considered. A dual chamber PM allows testing the monitoring and the stimulating functions of the implant. The vast majority of pacemakers nowadays operate in bipolar mode [1], which provides better immunity to electromagnetic fields than unipolar mode [5], [8], [15], [16], [18].

To test the pacemaker functioning, a signal that simulates the atrial contraction is sent to the atrial lead. In reaction, the pacemaker generates a pulse on the ventricle lead after a delay (pacemaker in DDD mode). By measuring this delay and the pulse level, it is possible to monitor the functioning of the implant. If a variation of more or less 20 % on the delay or a decrease of 50 % of the pulse amplitude is observed [22], it is considered as a malfunction (see Fig. 7). The shape of the signal simulating the atrial contraction is given by manufacturer international standards like the ISO 14117 [14].

In order to send and measure signals on the pacemaker leads, some mini coaxial cables are connected to the inputs/outputs of the PM housing.

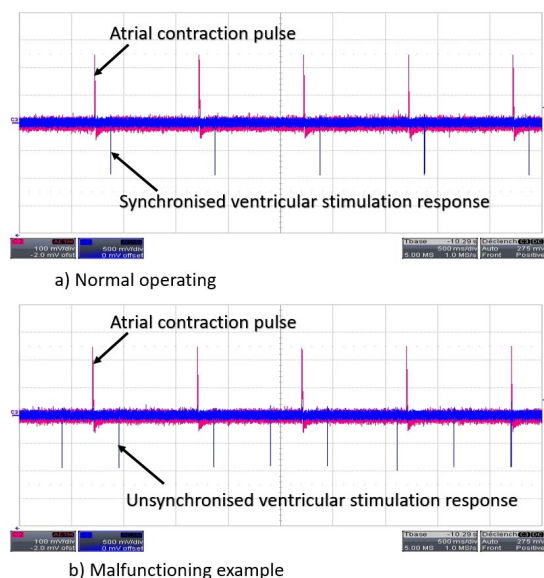


Fig. 7. Comparison between a normal pacemaker operating situation (a) and a repeatedly malfunctioning one (b)

The process is fully automated: the test operator selects the frequencies, the maximal and minimal magnetic field amplitudes, the amplitude increase step, the number of orientations to take into account and the test duration for each configuration. The number of malfunctions per configuration is then recorded in a results file.

To determine the interference threshold as a function of the frequency, two runs are made. The first one with a coarse step size to approach the threshold. The second one takes into account the previous results and applies a refined step size to improve the accuracy.

From the results file, the interference threshold is determined for each tested frequency among the different orientations. Because the orientation between the worker and the industrial source is difficult to predict, for each frequency, only the worst orientation is considered for the threshold evaluation. This threshold is defined as the magnitude of the magnetic field above which the device repeatedly malfunctions. A pacemaker is considered to be repeatedly malfunctioning when more than 10 % errors are observed during the test duration. For example, if more than 10 % errors are observed from 450 μT peak, the threshold will be 400 μT peak with a step size of 50 μT .

B. Test setup

The pacemaker was programmed to DDD mode and to the most sensitive setting for atrial pulse detection, i.e., 0.1 mV. The atrioventricular delay, i.e. the delay between the atrial pulse detection and the ventricular stimulation, is fixed. The pacemaker and its two leads—atrial (52 cm) and ventricular (58 cm)—are positioned as a left implantation inside the container (see Fig. 8). The whole system is immersed in a saline solution of 0.2 S/m electric conductivity, which corresponds to the average conductivity of human tissues [23].

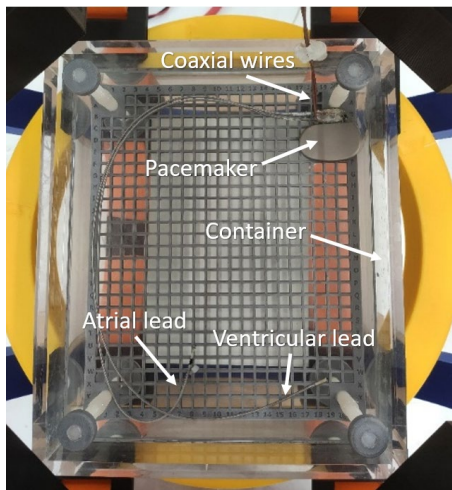


Fig. 8. Test setup

In our example, 8 orientations were considered for a test duration of 30 s per configuration. The atrial contraction pulse simulates a 60 ppm cardiac activity, i.e. during the test duration a total of 30 cardiac cycles are observed per configuration. The coarse step size is set to 200 μT and the refined one to 50 μT .

C. Results

Between 50 Hz and 400 Hz, the observed interference thresholds are between the general public exposure limits and the occupational ones (see Fig. 9). It complies with international standard requirements which specify that the AIMD should work properly for magnetic field up to the general public exposure limits. However, these limits could be exceeded at workplace.

Between 400 Hz and 50 kHz, the interference threshold exceeds the occupational high exposure limit values and couldn't be determined because the test bench amplitude limit was reached. However, these exposure levels are not expected in a normal working situation.

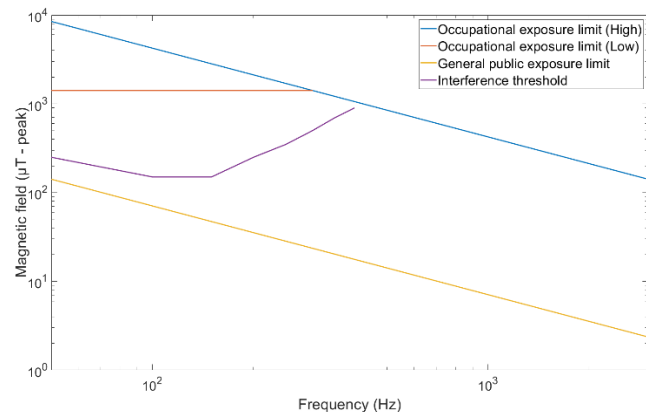


Fig. 9. Interference threshold compared to the occupational and public exposure limits (50 Hz – 3 kHz)

The interference threshold strongly depends on the magnetic field orientation, which justifies the development of a 3D test bench. Indeed, the orientation considered as the reference by many publications, i.e. the magnetic field being applied perpendicular to the plane formed by the device and its leads, does not correspond to the orientation most affected by the interferences.

The observed malfunctions are completely reversible, i.e. after the magnetic field exposure the device returns to normal operation. This intermittent malfunction may not be life threatening except for patient who are completely pacemaker-dependant. When a malfunction occurs, the ventricular contraction is no longer synchronised with the atrial contraction, the pacemaker holder may feel a discomfort. This situation is not suitable and should be avoided at workplace.

IV. CONCLUSION

A new AIMD EMC test method based on a test bench was developed and characterised. A first test was performed on a pacemaker; its interference threshold as a function of the signal frequency was determined. The magnetic field orientation appears to be a relevant parameter.

Thanks to this test method, a study on the EMC susceptibility of pacemakers will be carried out on several devices. In addition, the impact of various parameters such as the lead positions, the magnetic field orientation, the exposure signal, the medium conductivity etc will be investigated. This method could also be applied on Implantable Cardioverter Defibrillators (ICD) or adapted to other devices like neurostimulators.

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