Electromagnetic Compatibility between Implantable Cardiac Pacemakers and RFID Systems: Experimental Set-up, Test Protocol and Preliminary Results

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Abstract— An experimental set-up for the evaluation of the electromagnetic interference (EMI) between implantable cardiac pacemakers (PMs) and radiofrequency identification (RFID) readers operating in the low-frequency (LF — 125 kHz) and high frequency (HF — 13.56 MHz) range is described. Two development kits were used to generate the RFID signal at 125 kHz and 13.56 MHz, and the EMI tests were performed with and without the presence of the RFID tag (passive). Eight PMs from 5 manufactures were tested inside a human torso simulator filled with a saline solution appropriate for each frequency. No significant degradations of the basic performances of the device were observed. Noteworthy, the field strength generated by the RFID readers used in this study is lower than the maximum values allowed by the RFID international standards: the magnetic field generated by the two RFID emitters during the EMI tests reached a peak value at 1 cm from the RFID antenna of 35.3 A/m at 125 kHz and 0.024 A/m at 13.56 MHz. The adopted experimental set-up and test protocol is suitable for further investigations, using other types of RFID readers and higher values of field.

1. INTRODUCTION

Radiofrequency identification (RFID) emissions have the potential to affect electronic devices. Particular care has to be paid for the electromagnetic interference (EMI) to implantable pacemakers (PMs) and implantable cardioverter-defibrillators (ICDs). A recent study conducted by the Food and Drug Administration in collaboration with major implantable PM and ICD manufacturers [1], demonstrates the effects of emissions from RFID readers on common implantable cardiac devices. Significant effects were observed especially for low frequency RFID readers, and the authors concludes that "are concerned that the continued proliferation of RFID without taking electromagnetic interference into consideration could cause clinically significant events for patients", even if they "do not believe the current situation reveals an urgent public health risk". Other comprehensive studies on the electromagnetic compatibility between implantable devices and RFID systems are scarce. The effects of the RFID signal have been wider investigated for not-implanted medical devices. In 2008, Van der Togt et al. [2] published a study on the interference between RFID readers and critical care medical equipment: in 123 tests, RFID induced 34 EMI incidents, among which 22 were classified as hazardous, 2 as significant, and 10 as light. The median distance between the RFID reader and the medical device in all incidents was 30 cm (range, 0.1–600 cm). In the same year, another group [3] performed EMI tests using an experimental set-up similar to the one adopted by Van der Togt et al., but, over more than 1500 tests, no significant effects on the performances of the medical devices were observed. A recent study [4] has also shown that the effect of the RFID signal depends on the presence or not of the RFID tag. This implies that the EMI tests must be also performed with a close-loop transmission between the RFID reader and tag. It seems thus clear how, given the rapid expansion of RFID technology in many settings of our every-day life and the lack of exhaustive data on the potential effects on electronic medical devices, further studies in this field are needed.

In this paper, an experimental in-vitro set-up for the evaluation of the electromagnetic interference (EMI) between implantable cardiac PMs and RFID readers, operating in the low-frequency (LF — 125 kHz) and high frequency (HF — 13.56 MHz) range, is proposed. The results of EMI tests on 8 PMs from 5 manufactures (Sorin, Medico, Biotronik, Medtronic, S. Jude) are also presented.

2. METHODS AND MATERIALS

The set-up and the test protocol adopted for the evaluation of the electromagnetic interferences between RFID systems and PMs are derived from the standard ANSI/AAMI PC69:2007 [5]. However, since this standard specifically addresses electromagnetic compatibility issues at high frequencies

(> 400 MHz), proper changes were needed, to better take into account the coupling mechanisms with electromagnetic fields at lower frequencies.

A human torso simulator (PVC rectangular box $-60 \times 40 \times 15\,\mathrm{cm}^3 \sim 28.61$ inner volume) was used to host the PM and its leads. The torso simulator was filled with a saline solution whose concentration was properly chosen in order to account for the dielectric properties of the human tissues at the frequencies of interest. In particular, a conductivity of 0.2 S/m and 0.35 S/m was chosen for the tests in the LF and HF ranges, respectively.

The PM and the lead were fixed over a PVC grid ($20 \times 38\,\mathrm{cm}^2$) and the lead path was arranged to form a loop with an area similar to the one of a realistic worst-case PM implant (about $225\,\mathrm{cm}^2$ for a unipolar stimulation). The torso simulator was equipped with two couples of stainless steel plates mounted at the center of each of the 4 inner walls of the rectangular box. The first couple was used to monitor the PM activity; the second couple was used to simulate the electrical activity of the heart, in such a way that the PM recognizes it as an inhibition signal (Figure 1). For each PM, two tests were performed: in the first one, the inhibition signal was OFF and EMI was considered to occur if, after the activation of the RFID signal, the deviation in pace-to-pace interval exceeded 10% of the programmed rate; in the second test, the simulated heart signal was ON and no EMI was registered if the PM did not exhibit any pace pulse during application of the inhibition signal and RF signals. The monitoring of the PM activity as well as the generation of the inhibition signal was obtained by an acquisition/generation card (NI DAQ Card PCI 6052E — National Instruments, US) connected to a PC. A software interface developed in Labview (National Instruments, US) allowed to monitor in real-time the activity of the PM, to generate the simulated heart signal and to verify the correct behavior of the devices during the EMI tests. The programmed parameters of the PMs were kept as set by the manufactures. Six PMs were tested in the unipolar pacing/sensing modality, whereas 2 in the bipolar modality. As RFID sources, two development kits operating at the frequency of 125 kHz (Melexis, DVK90109) and 13.56 MHz (Texas Instruments, TRF7960) were used. Both the systems can communicate with passive tags; a PC-based interface was used to set the desired transmission protocol and to establish a close-loop communication between the reader and the tag.

The flow chart of the test protocol is reported in Figure 2. The initial distance between the reader and the PM was 10 cm. If no EMI phenomena occurred, the distance was reduced by a step of 2.5 cm, till a minimum distance of 2.5 cm from the device. The EMI tests were first performed with just the reader transmitting (open-loop signal); then with a tag placed near the PM and sending its ID to the reader (close-loop signal). In order to correlate possible EMI effects to the field strength generated by the RFID emitters, the magnetic fields generated by the two RFID emitters were measured at 1 cm and 2 cm from the RFID antenna, with and without the presence of the tag. Measurements at 13.56 MHz were performed by a near field H-probe (Rohde & Schwarz, HZ-14) connected to a spectrum analyzer (Advantest U3641). At 125 kHz, the magnetic field was evaluated by measuring the voltage induced on a custom-made loop (single turn — diameter = 1.8 cm) connected to a high-impedance oscilloscope (LeCroy WavePro 7000A). The magnetic

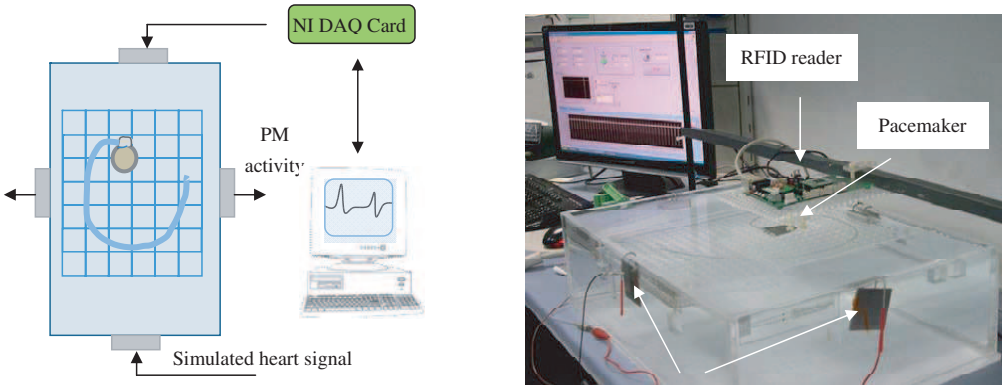

Figure 1: Experimental set up for the EMI test: (a) schematic representation and (b) picture of the actual set-up.

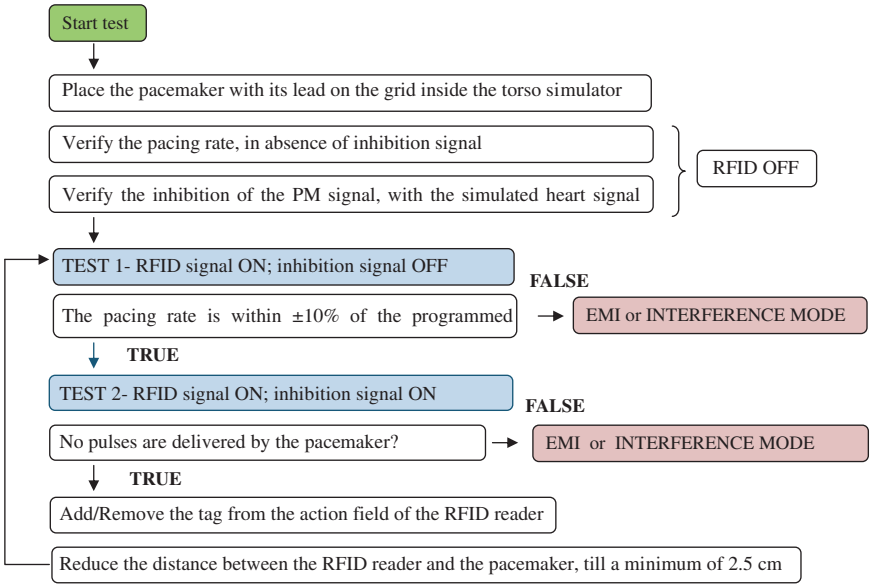

Figure 2: Flow chart of the test protocol.

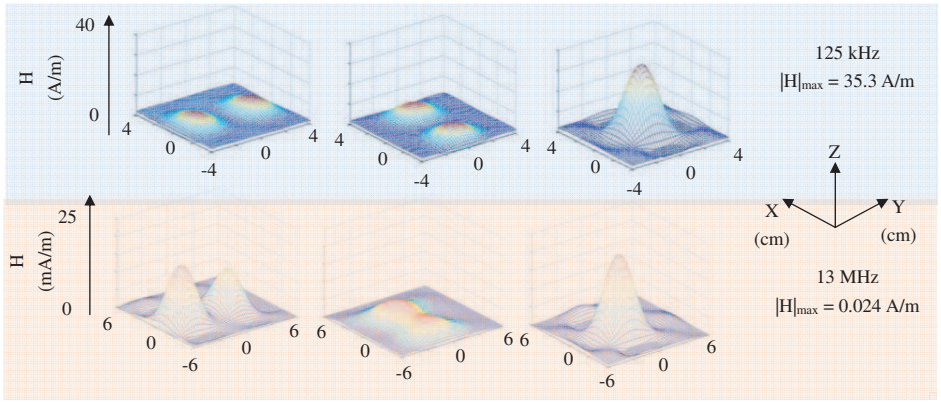

Figure 3: Spatial components of the magnetic field distribution at 1 cm from the RFID antennas: 125 kHz (upper panel); 13.56 MHz (lower panel).

field was obtained according to the relation:

$$H_{rms} = \frac{B_{rms}}{\mu_0} = \frac{V_{rms}}{2\pi f S} \tag{1}$$

where H_{rms} is the RMS value of the magnetic field strength, B_{rms} the magnetic field, μ_0 the magnetic permeability of free space ($4\pi \cdot 10^{-7}$ N/A^2), V_{rms} the RMS voltage induced in the loop, f the frequency of the time-varying signal (i.e., 125 kHz) and S the area of the loop.

3. RESULTS

The magnetic field distribution at 1 cm from the RFID antenna is reported in Figure 3: a peak value of 35.3 A/m at 125 kHz and 0.024 A/m at 13 MHz was observed. The presence of the tag does not substantially modify the magnetic field strength around the antenna. The magnetic field peak values with the tag placed next to the RFID reader become 34.9 A/m at 125 kHz and 0.023 A/m at 13.56 MHz. These differences are lower than the uncertainty of the measurement itself (±0.3 A/m for the LF; ±2 dB for the HF). In all the EMI tests, no significant degradations of the basic performances of the PMs were observed, even when the RFID transmitter was placed in close proximity of the device. During the tests without the simulated heart signal, the pulse rate of the PM was not affected by the activation of the RFID signal, both for the LF and the HF reader. When the inhibition signal was applied to the torso simulator, the PM correctly recognized it and stopped delivering the pulses, even with the RFID readers ON. The presence of the tag was not

related to any particular effects caused by the RFID transmitters on the devices.

4. DISCUSSION

The definition of a proper experimental set-up and test protocol for the evaluation of the possible EMI phenomena induced by RFID systems on implantable PMs is a crucial aspect for the assessment of immunity levels/safety distances to be adopted to ensure the safety of the patient. Our proposal is based on the standard ANSI/AAMI PC69:2007, which provides indications on how to perform EMI tests in order to verify the electromagnetic compatibility of implantable PMs and ICDs in the frequency range between 450 MHz and 3 GHz. The LF and HF RFID systems transmit over lower frequency ranges and the coupling mechanism they used to communicate with the tag is much more an inductive coupling than an electromagnetic wave propagation. Appropriate modification of the standard are thus needed. First, the electrical conductivity of the saline solution has to be modified to account for the frequency dependences of the different dielectric of the human tissues. Another important aspect is the implant configuration during the test: since the RFID transmission at LF and HF generally provides the data transfer through a time-varying magnetic field, the PM lead path must be chosen to maximize the area covered by the implant. In addition, since the antennas of LF and HF RFID reader is generally a coil that generates the time-varying magnetic field, the EMI test has to be performed with the axes of the antenna coil perpendicular to the plane where the implant is reproduced. There is no need to perform additional tests with different orientations of the antenna. In the preliminary EMI tests that were performed no significant degradations of the basic performances of the PMs were observed. For the 8 PMs tested, the pulse rate as well as the sensing activity was not affected by the activation of the RFID signal. However, the field strength generated by the RFID readers used in these tests is not the maximum output level allowed. This may explain the differences respect to the results found by other groups [1].

5. CONLCUSION

The experimental set-up and test protocol described in this paper is suitable for the evaluation of the electromagnetic compatibility between PM and RFID system operating in the LF and HF range. In the preliminary tests that were performed, no EMI phenomena were observed. Noteworthy, the field strength generated by the RFID readers used in this study is lower than the maximum values allowed by the RFID international standards. The same experimental set up and test method can be adopted for further investigations, using other types of RFID readers and higher values of field.

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