Oversensing and Undersensing of Implantable Cardiac Medical Devices Exposed to EMI

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Abstract— Oversensing and undersensing issues of Implantable Cardiac Medical Devices (ICMDs) are addressed in this paper. Particularly, an extensive experimental study has been performed in order to highlight that EMI affects ICMD sensing performances in correspondence of specific heartbeat status in terms of both frequency and amplitude. Experiments have been carried out on both a Pacemaker and an Implantable Cardioverter Defibrillator within an anechoic chamber. This guarantees a proper EMI injection, whose frequency has been chosen in accordance with ANSI/AAMI ISO 14117: standard 2012. In addition, such an environment also guarantees and appropriate shielding against external EMI sources, thus ensuring the reliability of the tests.

1. INTRODUCTION

Electromagnetic Compatibility (EMC) is extremely important in medical applications, where a number of electrical and electronic devices may suffer from Electromagnetic Interference (EMI). This is due to their exposition to several EMI sources, such as portable and RFID devices, telemetry systems, computers and Wi-Fi networks [1]. Particularly, EMI immunity of Implantable Cardiac Medical Devices (ICMDs) must be assured because their failure can lead to losing consciousness or, even, to death [2].

In this context, EMI immunity of ICMDs is a growing issue, particularly electromagnetic interactions between ICMDs and intentional and unintentional EMI sources may impair ICMD sensing performances [3, 4]. Consequently, the device may interpret spurious signals as threatening arrhythmias, starting unsuitable pacing activities or providing an improper defibrillation shock. Despite the use of appropriate filtering systems and/or recognition algorithms, misunderstandings can still occur, leading to undersensing or oversensing. Particularly, undersensing prevents ICMD to detect the heartbeat, whereas oversensing makes ICMD sensitive to spurious signals. Although international standards provide some procedures in order to determine EMC sensitivity of ICMDs, a more accurate testing on sensing performances should be required [5–7].

In this paper, oversensing and undersensing induced by EMI are considered and analysed in detail referring to two different types of ICMD, i.e., a pacemaker (PMK) and an Implantable Cardioverter Defibrillator (ICD). Particularly, an extensive experimental study has been performed in order to highlight that EMI affects ICMD sensing performance in correspondence of specific heartbeat status in terms of both frequency and amplitude. Experiments have been carried out within an anechoic chamber, which guarantees a proper EMI injection, the frequency of which has been chosen in accordance with ANSI/AAMI ISO 14117. In addition, such an environment also guarantees and appropriate shielding against external EMI sources, thus ensuring the reliability of the tests.

2. IMPLANTABLE CARDIAC MEDICAL DEVICES

Implantable Cardiac Medical Devices (ICMDs) are nowadays commonly employed from even a very young age, allowing more people to live a normal life. Therefore, it is no longer unusual for people wearing an ICMD to work in environments characterized by not negligible EMI levels. The most widespread ICMDs are Pacemakers (PMKs) and Implantable Cardioverter Defibrillator (ICDs), which are coupled to the heart through appropriate leads, as shown in Fig. 1. PMK operation consists of continuously monitoring the spontaneous heartbeat (sensing) and eventually stimulate the heart as needed (pacing) with the aim of preventing the bradycardia, i.e., a rapid decrease of the heartbeat frequency. Whereas ICDs are also able to deliver a certain amount of energy to the heart (up to 40 J) in order to cut off dangerous fast arrhythmias, such as ventricular tachycardia, flutter and fibrillation.

Both PMK and ICD are constituted mainly by a pacing circuit supplied by a battery and controlled through a sensing circuit, all these being enclosed into a titanium case, as shown in Fig. 2. Both these devices may be exposed to EMI, especially through their leads, which can act as antenna for several external signals. Particularly, if the sensing circuit is not able to detect an

Figure 1: Examples of ICMD: PMKs (A), ICDs (B) and leads (C).

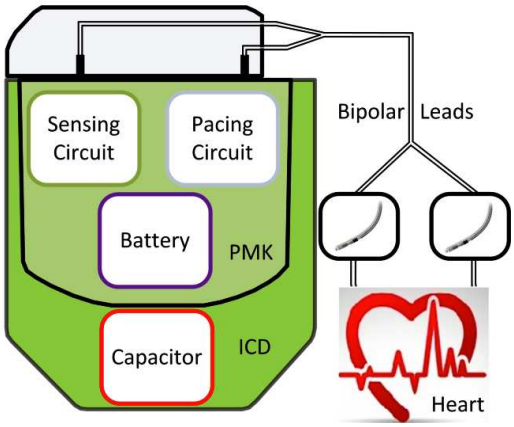

Figure 2: Schematic representation of an ICMD.

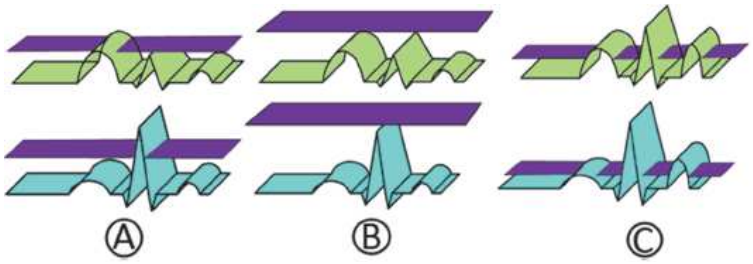

Figure 3: Atrial (top) and ventricular (bottom) sensing: (A) proper sensing, (B) undersensing, (C) oversensing.

abnormal heartbeat, no therapy is provided to the heart when needed; this is called undersensing. Alternatively, oversensing may occur when inappropriate pacing is provided due to the detection of spurious signals, which are misinterpreted as anomalous heartbeat. It is worth noting that atrial and ventricular sensing must be considered separately because they consist of detecting the P and R wave respectively, as shown in Fig. 3. From a medical point of view, atrial undersensing can cause stimulation in the vulnerable period, as well as prevent atrium contraction, leading to atrial or ventricular fibrillation respectively. Whereas ventricular undersensing may leads to dangerous and sometimes fatal arrhythmias. Similarly, atrial oversensing causes fast and irregular heartbeat, and even atrial fibrillation, whereas ventricular oversensing leads to device inhibition. All these side effects reveal the need of ensuring a high level of immunity for both PMK and ICD against EMI.

3. EMC TEST

With the aim of investigating undersensing and/or oversensing issues due to EMI, several experimental tests have been carried out inside the anechoic chamber shown in Fig. 4. Hence, referring to Fig. 5, the ICMD under test is placed inside an appropriate supporting structure, i.e., a Human Body Model or Torso Simulator, which has been accurately designed and manufactured in order to reproduce the realistic ICMD operating conditions [8]. Subsequently, the ICMD is linked to a Multifunction DAQ board (NI 6211) driven by a notebook. Particularly, the NI 6211 is used to acquire pacing signals provided by the ICMD and to emulate the human heartbeat simultaneously. Whereas EMI signals are generated in accordance with ANSI/AAMI ISO 14117 by means of a Log Periodic Antenna (Schaffner CBL6143), which is suppliedby the EMI signal generator (Rohde & Schwarz SML03) througha directional coupler and an amplifier (Schaffner CBA9433). The directional coupler also allows the connection between the Log Periodic Antenna and a power meter (Rohde & Schwarz NRVD) in order to monitor the power level of EMI signals.

Experiments firstly refer to PMK that operates over AAI and VVI, which means that the pacing is provided only to atrium or ventricle respectively. The corresponding results are depicted in Fig. 6 and Fig. 7, which show the numbers of pacing events per second detected by monitoring PMK pacing activity during 50 one-minute tests. It can be seen that the number of pacing events significantly decreases in presence of EMI at 875 MHz, whereas it increases in case of EMI

Figure 4: The anechoic chamber.

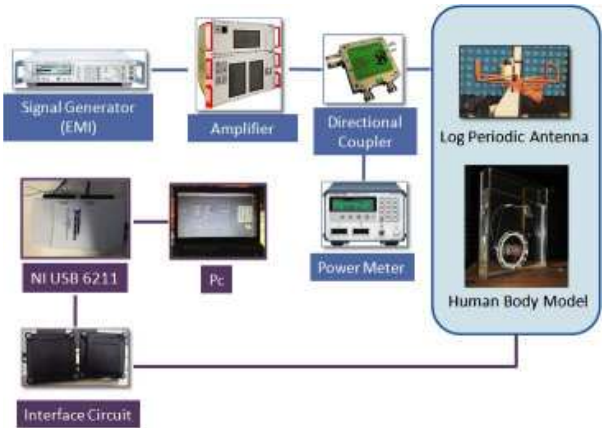

Figure 5: Experimental setup.

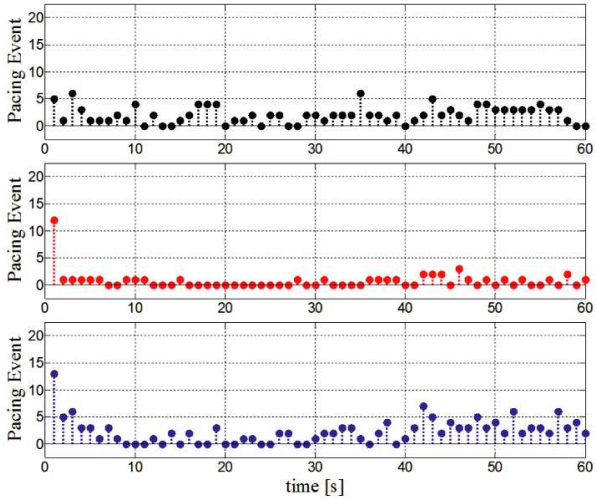

Figure 6: Experimental results (PMK, AAI): no EMI (black), 875 MHz (red) and 930 MHz (blue).

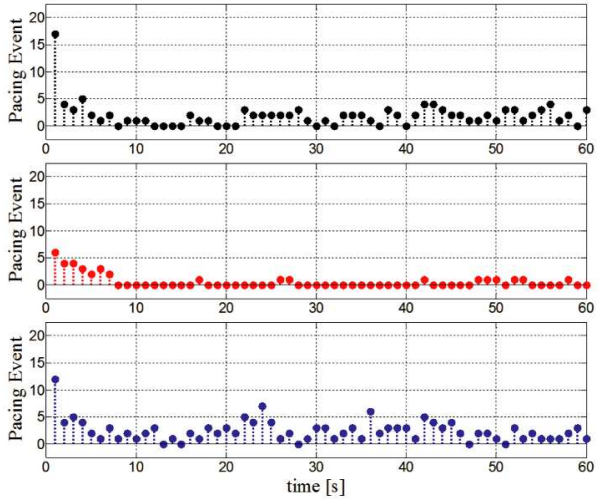

Figure 7: Experimental results (PMK, VVI): no EMI (black), 875 MHz (red) and 930 MHz (blue).

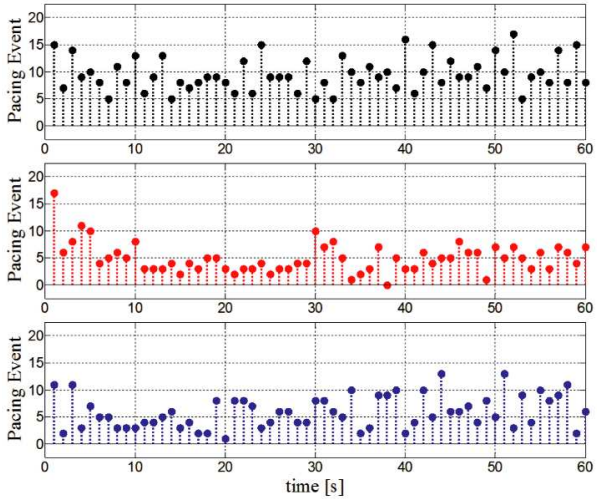

Figure 8: Experimental results (ICD, AAI): no EMI (black), 875 MHz (red) and 930 MHz (blue).

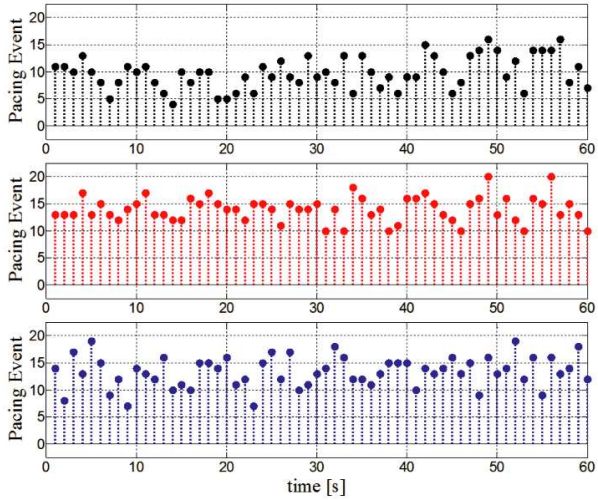

Figure 9: Experimental results (ICD, VVI): no EMI (black), 875 MHz (red) and 930 MHz (blue).

at 930 MHz. Consequently, undersensing and potential oversensing occur at 875 and 930 MHz respectively, thus revealing PMK susceptibility against EMI. It is worth noting that such results have been achieved by imposing a constant heartbeat frequency of 63 beat-per-minute. Whereas the heartbeat amplitude is set quite close to the sensitivity threshold [3], which represents the

Table 1: Overall experimental results.

		no EMI		**875 MHz**		**930 MHz**	
		N	**Δ**	**N**	**Δ**	**N**	**Δ**
PMK	**AAI**	124	- - -	44	−64.5%	140	+12.9%
	VVI	115	- - -	34	−70.4%	147	+27.8%
ICD	**AAI**	573	- - -	293	−48.9%	357	−37.7%
	VVI	586	- - -	840	+43.3%	802	+36.9%

worst operating condition in terms of potential undersensing and oversensing issues. This is also highlighted by the few number of pacing events occurring in absence EMI, which denote a sporadic pacing activity.

Different considerations can be made regarding an ICD, whose experimental results are depicted in Fig. 8 and Fig. 9. It can be seen that pacing events significantly decrease over AAI at both 875 and 930 MHz, the opposite occurring over VVI. It is worth noting that, also in this case, the heartbeat frequency has been set constant to 63 beat-per-minute, whereas the heartbeat amplitude has been chosen quite close to the ICD sensitivity threshold, as previously. It is also worthy of note that ICD pacing activity is more frequent than PMK, as highlighted by an increased number of pacing events in absence of EMI.

In conclusion, the overall experimental results are resumed in Table 1, which refers to the overall number of pacing events detected over 50 minutes (50 one-minute tests). These corroborates that both PMK and ICD are affected by EMI, although this occurs in correspondence of critical operating conditions, i.e., very close to the sensitivity threshold.

4. CONCLUSION

Oversensing and undersensing issues of Implantable Cardiac Medical Devices have been investigated in this paper. Particularly, several experiments have been performed in order to verify the effects of Electromagnetic Interference (EMI) on both a Pacemaker (PMK) and an Implantable Cardioverter Defibrillator (ICD). Experimental results have highlighted that oversensing and undersensing issues may arise due to EMI exposition in correspondence of critical PMK and ICD operating conditions. This reveals the need of accurate characterization of ICMD sensing performances, which should be suggested and even incorporated by international standards.

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