

In vitro Assessment of EMI from RFID Interrogator on Implantable Cardiac Pacemakers and Implantable Cardioverter Defibrillators

Takashi Hikage^{#1}, Masami Shirafune^{#2}, Toshio Nojima^{#3}, Hiroshi Fujimoto^{*4}, Takeshi Toyoshima^{*5}

[#]Graduate School of Information Science and Technology, Hokkaido University

Kita-14, Nishi-9, Kita-ku, Sapporo, Hokkaido, Japan

¹⁻³ {hikage,shirafune,nojima}@wtemc.ist.hokudai.ac.jp

^{*}Medtronic japan Co., Ltd. , Tokyo, Japan

⁴⁻⁵ { hiro.fujimoto, takeshi.toyoshima }@ medtronic.com

Abstract—Electromagnetic interference (EMI) characteristics of implantable cardiac pacemakers and cardioverter defibrillators (ICDs) based on assessments of RFID interrogators are described in this paper. Examples of interrogators operating in various RF bands are tested to estimate EMI experienced by pacemakers and ICDs. The EMI test set-up and some experimental evaluation results for practical devices are shown. Observed characteristics of the EMI occurrence are discussed based upon the transmission radio wave specifications.

I. INTRODUCTION

Wireless devices, such as mobile phones, radio frequency Identification (RFID), Electric Article Surveillance and wireless power transmission, are essential components for realizing the ubiquitous society. However, the electromagnetic fields from these wireless devices raises concern that they may cause other electronic devices to malfunction. Accordingly, investigations of electromagnetic interference (EMI) have become more important issues. Especially, EMI on implantable medical devices, such as implantable-cardiac pacemakers and implantable-cardioverter-defibrillators (ICD) should be precisely investigated. The EMI caused by mobile phone systems is being investigated on a massive scale [1]-[6]. Some guidelines to suppress the EMI have been published in Japan [7], [8].

Recently, RFID technologies are expected to achieve various applications and are expanding practical applications to various living spaces. And there are some reports on human safety and/or EMI issues for RFID interrogators [9]-[11]. This paper describes EMI characteristics of implantable-cardiac pacemakers and ICDs based upon assessments of RFID interrogators operating in various RF bands. Typical examples of interrogators specified by ISO/IEC 18000-2 (~135 kHz), -3 (13.56 MHz), -4 (2.45 GHz), and -6 (UHF) are tested to assess the EMI characteristics experienced by various types of implantable-cardiac pacemakers and ICDs. In-vitro EMI measurement system and test protocol are explained. The measurement system can be applied to various types of electromagnetic emitters and pacemakers/ICDs in practical use and is capable of estimating the EMI and the maximum interference distance (MID: distance at which EMI disappears)

characteristics. Some experimental EMI evaluation results for typical AMIDs are presented.

II. IN VITRO EMI MEASUREMENT SYSTEM CONFIGURATION

The basic configuration of the in vitro EMI measurement system and pictures of the actual set-up are shown in Figs. 1 and 2, respectively [8]. This basic configuration mirrors those used for RF device tests such as cellular phones [1]-[5]. The torso phantom employed for the in-vitro measurement system is a modification of Irnich's model as described in [2]. This phantom is composed of an acrylic tank. It is filled with saline solution (1.8 g/litre). In the Fig. 1, the simulated ECG signal generator/AIMD monitor supplies the simulated ECG signal to the pacemakers and ICDs through the atrial/ventricular electrodes and lead wire(s). Both pacemakers and ICDs need to sense the ECG signal in order to operate properly in the human body. The output signal data of the pacemaker or ICD is recorded using oscilloscope and chart recorder. And the data allows the occurrence of EMI to be assessed. The distance between the interrogator and the human torso equivalent phantom front surface can be varied during the test; the MID is measured.

The operating modes of pacemakers and ICDs are VVI mode (Ventricle-chamber is paced, the Ventricle-chamber is sensed, and the response to sensing is Inhibited) and AAI mode (Atrium-chamber is paced, the Atrium-chamber is sensed, and the response to sensing is Inhibited). For each of the operating modes, two types of test modes are conducted - one with an injected ECG signal (typical inhibition), and one with no injected ECG signal (typical asynchronous pacing).

The Procedure of the EMI test procedure is shown in follows.

1) Program both sensitivity and refractory period of pacemakers and ICDs to maximum sensitivity and minimum time, respectively. This setting gives the most conservative results.

2) Set configurations of interrogators to actual operating mode.

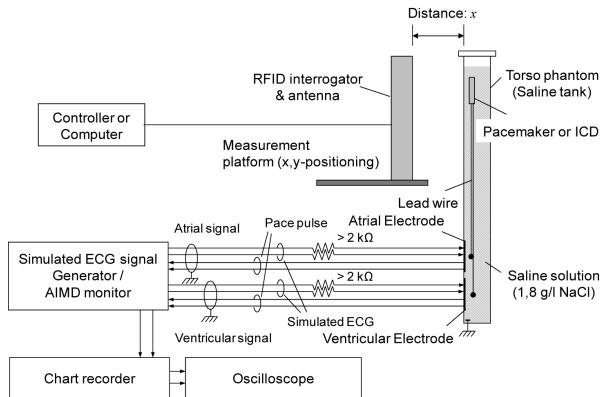
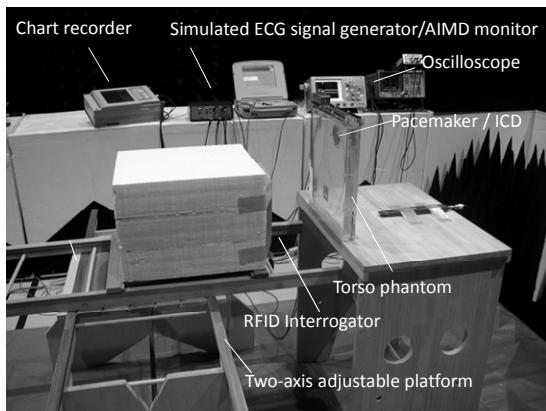


Fig. 1. Basic configuration of Implantable Cardiac Pacemakers /ICDs EMI measurement system



(a) Overview of measurement system

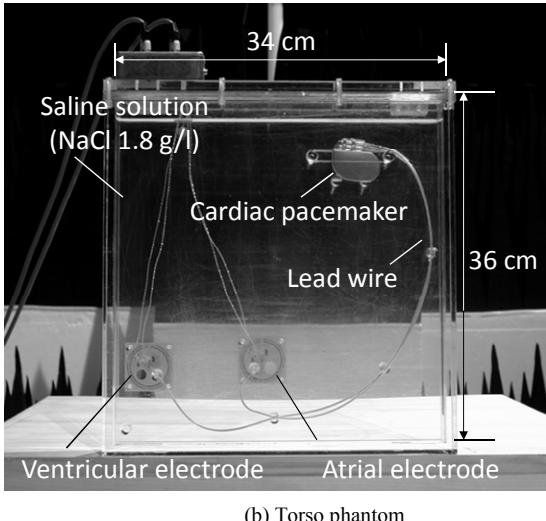


Fig. 2. Pacemakers /ICDs EMI measurement system

3) Record ECG signal for each mode on the paper for 100 seconds. The distance between antennas and the torso phantom is increased when interference occurs. In this case, the MID is determined and recorded in centimeters. Then, step

down sensitivity of pacemakers and ICDs and record the MID, as long as interference exists.

4) Carry out experiments for combinations of all interrogators and implantable devices. The operating modes of pacemakers and ICDs include unipolar/bipolar mode and VVI/AII mode.

III. MEASUREMENT RESULTS OF INTERROGATOR EXAMPLES

Tested interrogators and pacemakers/ICDs are summarized in Table I and Table II, respectively. Herein, a total of 27 pacemakers/ICDs were estimated in the presence of LF-, HF- and 2.45GHz-band interrogators; a total of 37 pacemakers/ICDs were examined under UHF-band exposure.

TABLE I
RFID INTERROGATORS TESTED (ISO/IEC 18000 -2, -3, -4 AND -6)

	Frequency			
	LF: Less than 135 kHz	HF: 13.56 MHz	UHF: 952-954 MHz	μ W: 2.45 GHz
Transmission	Magnetic coupling	Magnetic coupling	Radio wave	Radio wave
Max. commun. distance guaranteed	~50 cm	~60 cm	~5 m	~1.5 m / ~30 cm
Modulation	ASK (100%)	ASK (100% and 10%)	ASK (80% to 100%)	ASK (100%)
Air interface protocol	ISO 18000-2 Type A	ISO 18000-3 Mode 1	ISO 18000-6 Type C	ISO 18000-4 Mode 1
Bit rate	Average 5.2 kbit/s	26.48 kbit/s, 1,65 kbit/s	26.7 kbit/s to 128 kbit/s	20 kbit/s to 40 kbit/s
Number of Tested devices	4	27	10	4

TABLE II
NUMBER OF IMPLANTABLE CARDIAC PACEMAKERS / ICDs USED FOR TESTS

	Pacemaker		ICD	
	Single chamber	Dual chamber	Single chamber	Dual chamber
LF / HF	11	9	2	5
UHF	3	22	0	12
μ W	10	9	3	5

For these interrogators, measurement results gathered from the inhibition and the asynchronous tests with the pacemakers set at maximum sensitivity are shown in Fig. 3, as an example. In addition, the test results with ICD set at maximum sensitivity are shown in Fig. 4. These results are graded based on clinically significance as defined in [4], [11].

In these figures, the vertical axis plots the reaction rate which is defined as

$$P = \frac{M_{\text{affected}}}{M_{\text{total}}} \times 100 [\%]. \quad (1)$$

Where, M_{affected} is obtained as the number of affected modes in each frequency band, and M_{total} is the total test mode number of the pacemakers/ICDs for each frequency band.

As shown in Fig. 3, with exposure to LF-band interrogators, reaction was observed in pacemaker tests as Class I : 18.6 % and Class III : 10.6 %. For HF interrogator exposure, a reaction was observed as Class I : 1.82 % and Class III : 0.46 %. There were no reactions observed for pacemakers exposed to μ W (2.45 GHz) interrogators. With exposed to UHF interrogators, a reaction was observed as Class I : 2.7 % and Class III : 1.2 %.

With regards to ICDs test results, a reaction was observed in tests with exposure to LF-band interrogators as Class I : 7.3 %. For HF interrogator exposure, a reaction was observed as Class I : 4 %. There were no reactions observed for ICDs exposed to either UHF or μ W (2.45 GHz) interrogators.

With LF interrogator exposure, a reaction was observed at the maximum distance of 16 cm for pacemakers and at the maximum distance of 4 cm for ICDs. With HF interrogator exposure, a reaction was observed at the maximum distance of 23 cm for pacemakers and at the maximum distance of 3 cm for ICDs. With UHF interrogator exposure, a reaction was observed at the maximum distance of 75 cm with one pacemaker but other pacemakers all exhibited distances of less than 20 cm.

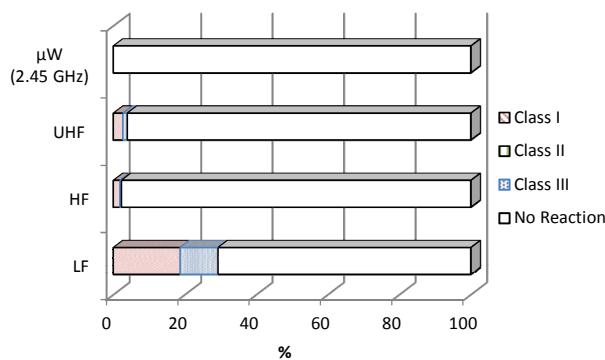


Fig. 3. Percentage of pacemaker reactions graded according to clinical significance

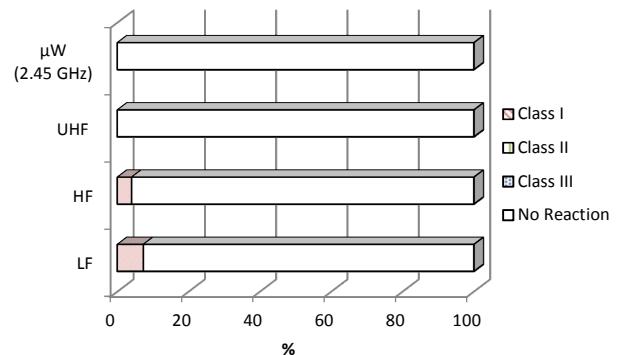


Fig. 4. Percentage of ICD reactions graded according to clinical significance

IV. CONCLUSION

In this paper, in-vitro EMI measurement system and test protocol for implantable-cardiac pacemaker/ICD were described. And some experimental test results for typical devices of ISO/IEC 18000 series radio frequency identification interrogators were presented. EMI events on pacemakers/ICDs depends upon the combination of devices, operation mode, performance of EMI-filter and various parameters such as lead length etc. of pacemakers/ICDs, and the power-, frequency-, pulse repetition rate-, modulation depth- of emitted signal, and the distance between the interrogator and the torso phantom. Even if different manufacturer's interrogators are constructed to comply with the same standard and/or frequency band, the corresponding EMI characteristics are not necessarily the same. This is because the EMF distribution around the interrogator's antenna is a key factor in EMI effect occurrence.

In the future, the present EMI estimation method and measurement system could be used to assess other devices, such as wireless power transmission systems and electric vehicle charger.

ACKNOWLEDGMENT

The authors would like to thank the members of Japan Arrhythmia Device Industry Association and Japan Automatic Identification Association for their cooperation and support. And this work has been partly supported by JSPS KAKENHI Grant Number 2456039.

REFERENCES

- [1] V. Barbaro, P. Bartolini, A. Donato and C. Militello, "Electromagnetic interference of analog cellular telephone with pacemakers," *J. Pacing and Clinical Electrophysiology*, vol. 19, no. 10, pp. 1410-1418, Oct. 1996.
- [2] W. Irnich, L. Batz, R. Muller and R. Tobisch, "Electromagnetic interference of pacemakers by mobile phones," *J. Pacing and Clinical Electrophysiology*, vol. 19, no. 10, pp. 1431-1446, Oct. 1996.
- [3] T. Toyoshima, M. Tsumura, T. Nojima and Y. Tarusawa, "Electromagnetic interference of implantable cardiac pacemakers by portable telephones," *Japanese J. Cardiac Pacing and Electrophysiology*, vol. 12, no.5, pp. 488-497, 1996.

- [4] D. L. Hayes, P. J. Wang, D. W. Reynolds, M. Estes III, J. L. Griffith, R. A. Steffens, G. L. Carlo, G. K. Findlay and C. M. Johnson, "Interference with cardiac pacemakers by cellular telephones," *New Engl. J. Med.*, vol. 336, no. 21, pp. 1473-1479, May 1997.
- [5] Active Implantable Medical Device - Electromagnetic Compatibility - EMC Test Protocols for Implantable Cardiac Pacemakers and Implantable Defibrillators, AAMI Standard PC69, 1999.
- [6] C. K. Tang, K. H. Chan, L. C. Fung, and S. W. Leung, "Electromagnetic Interference Immunity Testing of Medical Equipment to Second-and Third-Generation Mobile Phones," *IEEE Transaction on Electromagnetic Compatibility*, Vol. 51, No. 3, pp. 659-664 (2009)
- [7] "Guidelines on the use of radio communication equipment such as cellular telephones - Safeguards for electric medical equipment," presented at the EMC Conf. Japan, Electromagnetic Medical Equipment Study Group, 1997.
- [8] "Guidelines on the use of radio communications equipment for implanted medical devices," Ministry of Internal Affairs and Communication of Japan, Aug. 2005.
- [9] S. Futatsumori, T. Kono, T. Hikage, T. Nojima, and B. Koike, "Experimental test system to assess the EMI from RFID reader/writer on implantable cardiac pacemaker", *Proc. Progress in Electromagnetics Research Symposium*, 2P3-5, p. 210, Aug. 2006.
- [10] L. C. Fung, K. H. Chan, W. K. Lam, S. W. Leung, Y. F. Wong, Paul W. K. Wu, and C. K. Tang, "Electromagnetic assessment on human safety of RFID system at Hong KongInternational Airport," *Microwave and Optical Technology Letters*, Vol. 49, No. 4, pp. 924-928 (2007)
- [11] Seidman S., Brockman R., Lewis B., Guag J., Shein M., Clement W., Kippola J., Digby D., Barber C., and Huntwork D.: In vitro tests reveal sample radiofrequency identification readers inducting clinically significant electromagnetic interference to implantable pacemakers and implantable cardioverter-defibrillators, *Heart Rhythm*, vol. 7, no. 1, pp. 99-107, 2010