A New Improved Electrode for the Human Body Model: Application for EMI Assessment of Active Implant Medical Devices

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The newly developed electrode for human body model, which is used for evaluation of EMI to a cardiac Active Implant Medical Device (AIMD), is reported. The electrode consists of applying and monitoring of signal portion and reduces crosstalk and signal leakage in application of cardiac pacing and sensing. It is practical and sufficient means of simulating EMI effects to an AIMD.

Keywords—EMI; Pacemaker; Human body model; AIMD; Electrode; Leakage; Signal crosstalk

I. INTRODUCTION

Recent widely spread cellphone use caused concerns on EMI to the implanted cardiac device such as pacemaker and Implantable Cardioverter-Defibrillator (ICD.) An international guideline specifies 15 cm as the safe distance between a cellphone and an AIMD [1]. However Japan guideline specified it was 22cm till 2012 and it was revised in 2013 to 15cm. The difference between two guidelines was due to difference on emitting and modulation characteristics in Japan. The Japan guideline was put forward by Ministry of Internal Affairs and Communications (MIC) and was investigating on the effects of radio wave emitting devices to the AIMD consecutively for more than 10 years. Another aspect in Japan, the newer technologies such as Electric Vehicle and Quick Charger system, RFID (radio frequency identification) system, and Induction Heating system demand for further investigation on the effect of those to AIMD in Japan. Thus the need to test the effects of those new technologies to AIMDs is high. It is necessary to use human body model to assess the effect of EMI to the AIMD because the device is situated in biological environment. Currently used human body model is based on the idea of W. Irnich [2][3]. We modified the model to be able to apply simulated cardiac signal and measure the output of the AIMD in two locations in single saline tank and developed new electrode and drive circuitry to eliminate the crosstalk from the other location's cardiac signal. Two locations are regarded as right ventricle and right atrium of human heart and the model is suitable to simulate dual chamber pacemaker application.

II. DESIGN

A. Requirements

The model needs to meet the following requirements:
1.Inhibit Test: The AIMD is monitoring patient's heart beat and is programed to inhibit pacing when detecting patient's intrinsic heartbeat. When the external noise is induced and if it is similar to intrinsic heart beat i.e. frequency and amplitude, then AIMD is not able to distinguish the noise and intrinsic heart beat thus inhibit the pacing. This is called "Inhibit Test" and shown in Fig.1. The model needs to be able to perform the test.

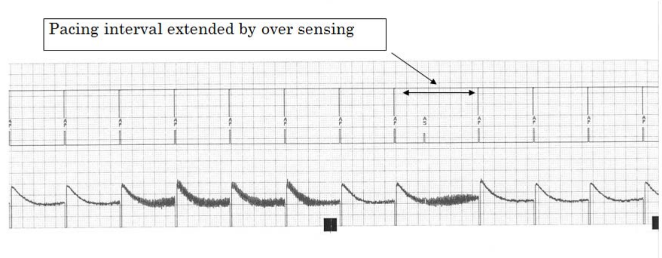

Fig.1 Example of inhibition test

2. Asynchronous Test: When external continuous noise injected above the AIMD's detection level i.e. amplitude, AIMD is programed to prolong the refractory period until detection stops. During the refractory period, AIMD will be pacing in programed rate. Generally, this algorithm is called reversion pacing or EMI protection mode. This is called "Asynchronous Test" and shown in Fig.2. The model needs to be able to perform the test.

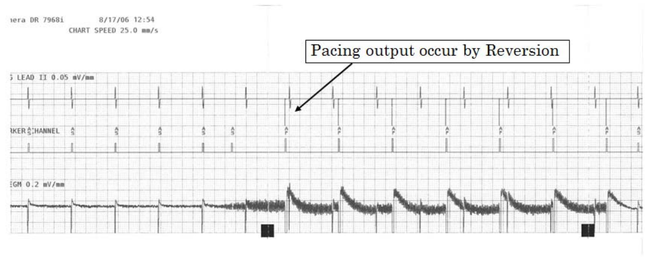

Fig.2 Example of asynchronous test

3. False Positive/ False Negative Test: For an ICD, two more tests are required. False Positive test is to see if the ICD is to deliver shock therapy when detecting induced noise. And False Positive test is to observe loss of detection capability of tachy arrhythmia due to induced noise. The model needs to be able to perform the test.

Thus for all of the evaluation testing described above, it is important for the model to monitor AIMD's output in both channels accurately without any crosstalk or leakage from the other channel.

B. Current Model

Current Irnich's human body model (Fig.3) is simply adding electrode pairs to monitor output of AIMD, or apply simulated cardiac signal to it. Each electrode is placed close to an AIMD's lead avoiding direct contact between them [4]. In this settings, there is a cross leakage between atrial and ventricular electrode (Fig.4).

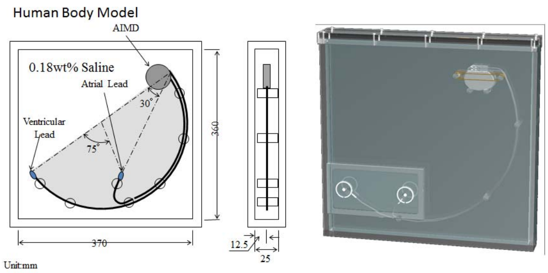

Fig.3 Irnich's human body model

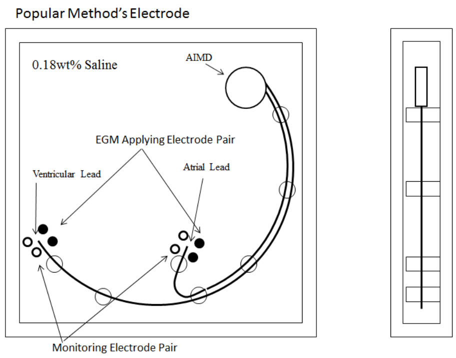

Fig.4 Popular method's electrode

C. New Imploved electrode to eliminate Signal Leakage

An improved electrode is shown in Fig.5 and it is made on a print circuit board. The electrode is structured by glass epoxy substrate and gold-plated copper of 30 micron thickness. This structure will build up an equipotential wall in the saline water and the wall surrounds the electrodes. This technic is widely used in shield engineering. One pair of the electrode is connected to differential amplifier with high input impedance to monitor AIMD's output, and the other pair of electrode is connected to balanced output driver to apply simulated cardiac signal to the electrode (Fig.6). Fig.7 shows a block diagram of atrial and ventricular channel of monitoring and applying simulated cardiac signal circuitry. Fig.8 shows balanced driver circuit and differential amplifier with high voltage protection circuit.

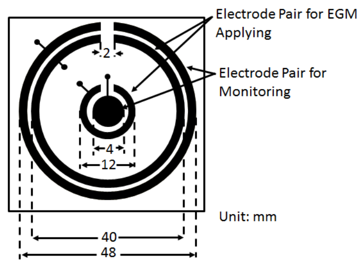

Fig.5 Improved new electrode

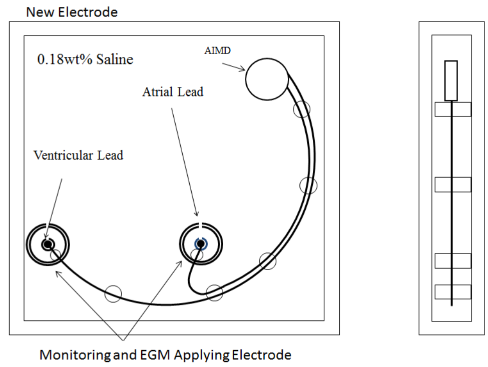

Fig.6 New electrode set in Irnich's model

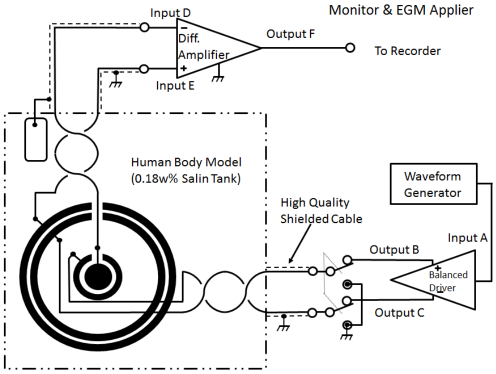

Fig.7 Block wiring diagram of atrial or ventricular chamber

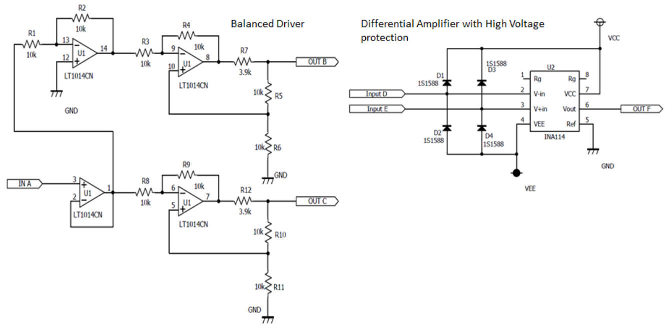

Fig.8 Circuit diagram of balance driver and differential amplifier for atrial or ventricular chamber

III. Method of Verification

A. Pacing Output leakage.

AIMD was set to pacing mode and let ventricular channel to pace. Pacing pulse amplitudes were changed from 1.0V to 7.5V which is the maximum voltage of an AIMD. Leakage voltage in atrial electrode was measured by an oscilloscope. There are two pacing configurations i.e. unipolar and bipolar settings of AIMD and both were tested. The same test was performed switching channels of pacing and monitoring. Results were compared between by current model and by the new model.

B. Simulated cardiac signal leakage.

AIMD was set to sensing mode and simulated cardiac signal was applied to ventricular electrode. The applied simulated cardiac signal voltage was adjusted according to the sensitivity of the AIMD. Atrial chamber sensitivity was set to from the least sensitive (11.2mV) to the most sensitive (0.18mV) and the sensing threshold was found. Both unipolar and bipolar settings were tested. The same test was performed switching channels of applying signal and sensing. Results were compared between by current model and by the new model.

IV. Results

A. Pacing output leakage compare with current method’s electrode and new electrode.

The leakage of pacing output to the opposite side of monitoring electrode was 2.1% at maximum in new electrode compared to the current method’s electrode of 45.7%. This is -6.8dB to -33.6dB reduction. Ventricular and atrial pace setting are shown in Fig.9 and Fig.10 respectively.

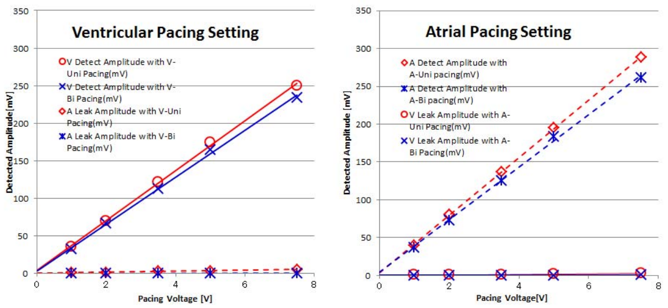

Fig.9 Pacing output leakage of new electrode

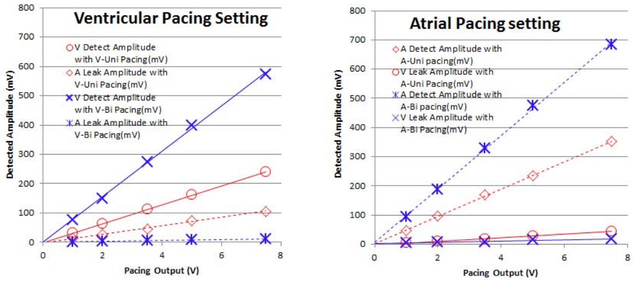

Fig.10 Pacing output leakage of current models

B. Simulated cardiac signal leakage compare with current method’s electrode and new electrode.

The leakage of simulated cardiac signal to opposite side electrode was unmeasurable as lower than 0.18mV in new electrode (Table 1). In current method’s electrode, the worst case showed 71% of leakage where 11.2mV was applied to ventricular electrode with unipolar while atrial leakage showed 8mV (Table 2). This is only -3dB reduction.

Table 1 New Electrode

Applied Electrode	Sensitivity [mV]	Leakage to [mV]			
		Atrial Uni	Atrial Bi	Ventricular Uni	Ventricular Bi
V Uni	11.2	<0.18	<0.18	-	-
	8	<0.18	<0.18	-	-
	5.6	<0.18	<0.18	-	-
	2.8	<0.18	<0.18	-	-
V Bi	11.2	<0.18	<0.18	-	-
	8	<0.18	<0.18	-	-
	5.6	<0.18	<0.18	-	-
	2.8	<0.18	<0.18	-	-
A Uni	11.2	-	-	<0.18	<0.18
	8	-	-	<0.18	<0.18
	5.6	-	-	<0.18	<0.18
	2.8	-	-	<0.18	<0.18
A Bi	11.2	-	-	<0.18	<0.18
	8	-	-	<0.18	<0.18
	5.6	-	-	<0.18	<0.18
	2.8	-	-	<0.18	<0.18

Table 2 Popular Methods

Applied Electrode	Sensitivity [mV]	Leakage to [mV]			
		Atrial Uni	Atrial Bi	Ventricular Uni	Ventricular Bi
V Uni	11.2	1	0.5	-	-
	8	0.7	0.35	-	-
	5.6	0.5	0.25	-	-
	2.8	<0.5	<0.18	-	-
V Bi	11.2	<0.5	0.18	-	-
	8		<0.18	-	-
	5.6			-	-
	2.8			-	-
A Uni	11.2	-	-	8	1
	8	-	-	5.6	0.7
	5.6	-	-	4	0.7
	2.8	-	-	2.8	0.35
A Bi	11.2	-	-	2.8	0.35
	8		-	2	0.25
	5.6	-	-	1.4	0.18
	2.8	-	-	0.7	<0.18

V. DISCUSSION

As mentioned above in simulated cardiac signal leakage testing for new electrode, leakage was not measurable. Even if this is enough to monitor output of AIMD, a test was conducted applying higher voltage to measure the leakage. We assume that the linearity of generator's voltage to the applied voltage to the electrode as shown in Fig.11. From this curves, the simulated cardiac signal applied to the electrode is about 214mV at generator's maximum output of 20V. Even with this voltage sensing did not happen with the most sensitive setting of 0.18mV at the opposite side of electrode with both unipolar and bipolar configurations. This value is less than -60dB of the leakage.

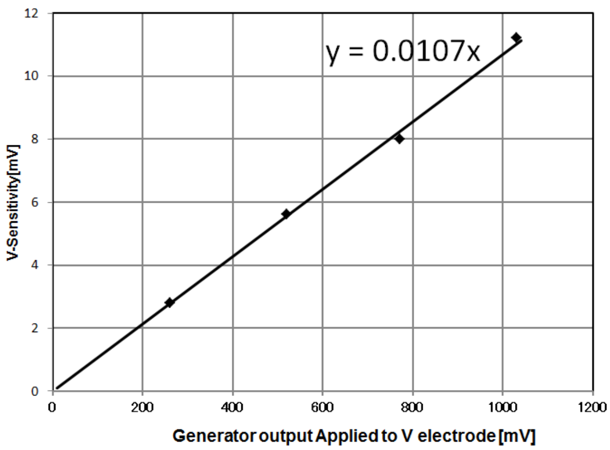

Fig.11 Linearity of sensitivity VS generator output

VI. COCLUSION

The new electrodes showed electrical isolation between two channels which represents ventricular and atrial in single saline tank. The maximum leakage of pacing output is reduced from 45.7% (-6.8dB) to 2.1% (-33.6dB) compare with current methods. Simulated cardiac signal leakage was reduced from 71% (-3dB) to less than limitation of our measuring equipment. Estimating actual simulated cardiac signal leakage is less than -60dB. This new electrode and driver circuit showed good characteristics for minimizing crosstalk and signal leakage and is practical and sufficient to use in evaluation of EMI to AIMD.

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