

Three-Dimensional Automatic EMF Measurement System for the Assessment Methodology of Implantable Medical Devices EMI Due to RFID reader/writers

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1. Introduction

More than 50,000 implantable-cardiac pacemakers and -cardioverter-defibrillators (ICD) are implanted in Japan in the year 2005. One reason is that the population of 50's has been very large due to the so-called "baby-boom" generation. The implantable medical device EMI is one of the most important issues to investigate for the improvement of their patients' quality of life. It is required to ensure safe environments regarding the EMI from various kinds of radio devices and electronic devices, which emit electromagnetic fields. There is a lot of research being carried out to investigate the EMI [1]. We have carried out detailed in-vitro experiments to assess the EMI due to RFID reader/writers for implantable medical devices (RFID/IMD-EMI) [2]. In addition, a novel experimental assessment methodology for RFID/IMD-EMI that is based upon magnetic field distribution is proposed [3]. By using the results of the in-vitro experiments and magnetic field distribution measurement, applicability of the proposed methodology have been confirmed.

In this paper, a three-dimensional automatic EMF measurement system for the RFID/IMD-EMI assessment methodology is presented. Firstly, in-vitro experiments to assess RFID/IMD-EMI are discussed. Secondly, an RFID/IMD-EMI assessment methodology proposed so far is introduced. Next, a newly developed three-dimensional automatic EMF measurement system is explained. Finally, assessment results obtained by using the measurement system are compared to that obtained by a conventional styrene foam positioner. The result based upon the measurement system is more accurate than the conventional positioner. This is because the measurement system enables high positioning accuracy and repeatability.

2. In-vitro Experiments to Assess EMI Due to RFID reader/writers

To investigate characteristics of RFID/IMD-EMI, detailed in-vitro EMI test experiments have been carried out [2]. RFID/IMD-EMI occurs when the following two conditions are satisfied. First, the sensing circuit of pacemakers and ICDs receives a signal similar to an electrocardiogram (ECG) signal or receives obvious noise. Then, the disturbing signals' strength must be higher than the sensing threshold level. EMI due to low-band RFID reader/writers such as 125 kHz and HF (13.56 MHz) is assumed to be caused by alternating magnetic field from antennas. As shown in Table 1 and Table 2, EMI characteristics of 10 types of pacemakers and 3 types of ICDs from 6 types of commercially available low-band RFID reader/writer antennas are examined so far. The torso phantom employed for the experiments is a modification of Irnich's model as described in [2].

In the experiments, the maximum interference distance (distance where EMI disappears) is determined and recorded in centimetres.

3. EMI Assessment Methodology Based Upon Magnetic Field Distribution

Since the tissues of the human body are electric conductors, it is supposed that “one turn coil” is connected between different electrodes and indifferent electrodes of pacemakers and ICDs as shown in Fig. 1. The magnetic flux density through the coil varies when the alternating magnetic field is generated from RFID reader/writer antennas. Then, by following Faraday’s law of induction, an electromotive force arises between the electrodes. When this electromotive force exceeds the pacemakers’ sensing threshold level, they no longer detect ECG signals. To estimate this disturbing noise voltage, the methodology calculates the total magnetic flux integrated across the pacemaker and lead wire cross-section [3].

So far, magnetic field measurement is carried out using a conventional styrene foam positioner shown in Fig. 2. Magnetic field strength is determined for all RFID reader/writers antennas shown in Table 2. A total of 729 sample points including 70 cm × 70 cm × 70 cm (width × height × depth) with 10 cm separation are measured. In addition to this wide area measurement, we examined a finer separation for the depth direction (z -axis direction in Fig. 2) based on the maximum interference distance obtained from the EMI test experiments. A total of 1029 sample points including 70 cm × 70 cm × 20 cm (width × height × depth) at 1 cm separation for the depth direction are measured. The magnetic field probe Agilent 11941A is used for the measurement.

4. Three-Dimensional Automatic EMF Measurement System

A newly developed three-dimensional automatic measurement system is shown in Fig. 3. The constructed system enables fully automated measurements in high-throughput rate by controlling simultaneously the three-dimensional probe positioner and measurement instruments such as spectrum analyzer and probe amplifier. In addition, since the probe positioner is consists mostly of dry wood, absorption/reflection effects for EMF due to the probe positioner is very low.

RFID reader/writer antennas usually have different shapes and field distributions depending on their purpose, operating frequency bands and their manufacturers. To measure EMF distribution generated around these various RFID reader/writer antenna, the measurement area used is 100 cm × 100 cm × 100 cm (width × height × depth). In addition, minimum spatial resolutions of all axes are 2 mm. This is achieved by using stepping motors and reduction gears. A control diagram of the measurement system is shown in Fig. 4. All instruments are connected to one computer, which is controlled by National Instruments Labview. Figure 5 shows an example of three-dimensional magnetic field distribution obtained by the measurement system.

To compare with the conventional styrene foam positioner, EMF measurements are carried out with the same resolution as styrene foam positioner although the measurement using this system enables more high-resolution measurements. In addition, only magnetic field strength is employed for the assessment methodology, because the electric field from low-band RFID reader/writer antennas is much smaller than the magnetic field and negligible for EMI occurrence. The magnetic field probe is the same as the styrene foam positioner as described above.

5. Results

The estimated induced voltage calculated from the measurement results using the styrene foam positioner and the three-dimensional automatic measurement system is shown in Fig. 6. The induced voltage of each antenna is slightly different in the area 0 to 10 cm from the antenna surface. To evaluate these differences quantitatively, statistical processing is carried out. As shown in Fig. 7, maximum interference distances plotted on the lines of induced voltage are almost the same. Standard deviations of induced voltage for each pacemaker’s test mode are calculated. The evaluations are conducted for the 90 test modes, which are affected by more than two antennas. Test modes which are not affected, or affected by only one antenna are excluded from the evaluations.

Figure 8 shows the histogram of standard deviation calculated from two different types of probe positioners. By using the styrene foam positioner, frequency of standard deviation has a peak of 0.04 to 0.05 and the average value of standard deviation is 0.059, respectively. Then, by using the automatic measurement system, frequency of standard deviation has a peak of 0.07 to 0.09 and the average value of standard deviation is 0.069, respectively. This means that the estimation using developed three-dimensional automatic measurement system is twice as accurate than that using the conventional styrene foam probe positioner. This is because the measurement system enables high positioning accuracy and repeatability compared to the conventional positioner.

6. Conclusions

The newly developed three-dimensional automatic EMF measurement system for the assessment methodology of RFID/IMD-EMI was presented. The assessment methodology was based upon the total magnetic flux integrated across the pacemaker and lead cross-section, which was previously proposed. Then, assessment results obtained by using the measurement system were compared to those obtained by a conventional styrene foam positioner. The result obtained by using the measurement system was twice as accurate than that obtained by using the conventional positioner. Furthermore, measurement throughput was improved more than ten times.

Acknowledgments

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Table 1: Implantable medical devices

| Tested devices | Type of chambers | Number of devices |
|--|------------------|-------------------|
| Pacemaker | Single chamber | 5 |
| | Dual chamber | 5 |
| Implantable Cardioverter-Defibrillator | Single chamber | 1 |
| | Dual chamber | 2 |
| Total | | 13 |

Table 2: RFID reader/writer antennas

| Frequency bands | 125 kHz | HF |
|--------------------|---------|---------------|
| Specifications | - | ISO/IEC 15693 |
| Modulation method | ASK | ASK |
| Number of antennas | 4 | 2 |

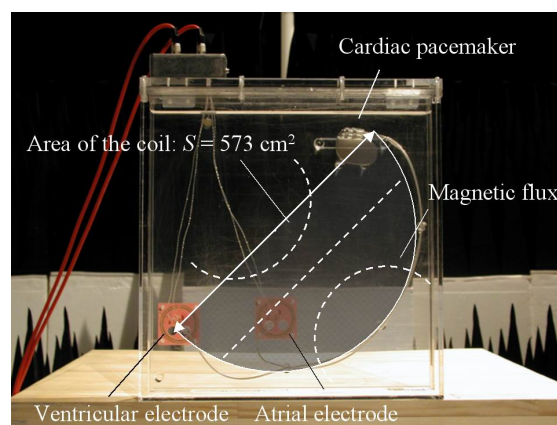


Figure 1: The torso phantom

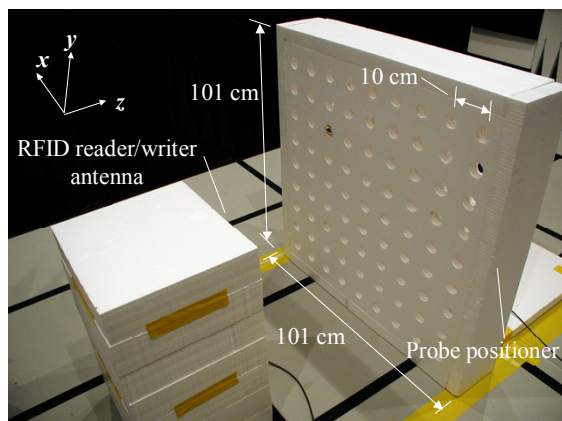


Figure 2: The styrene foam positioner

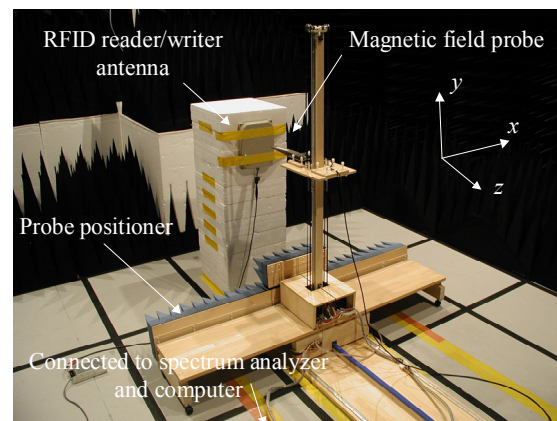


Figure 3: The three-dimensional automatic EMF measurement system

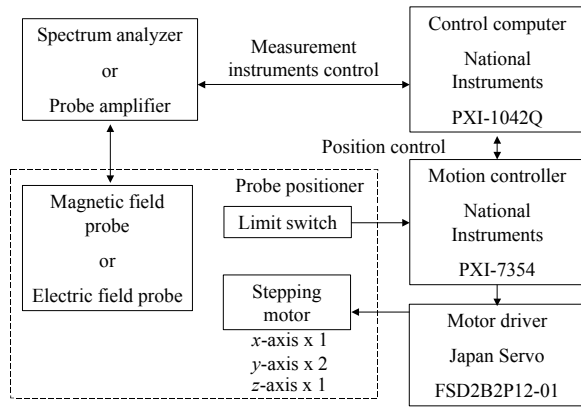


Figure 4: Control diagram

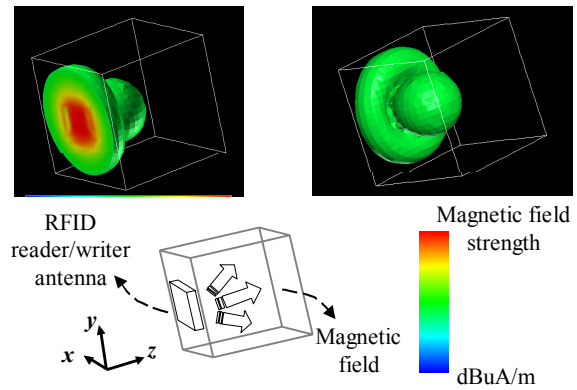


Figure 5: An example of three-dimensional magnetic field distribution obtained by the measurement system

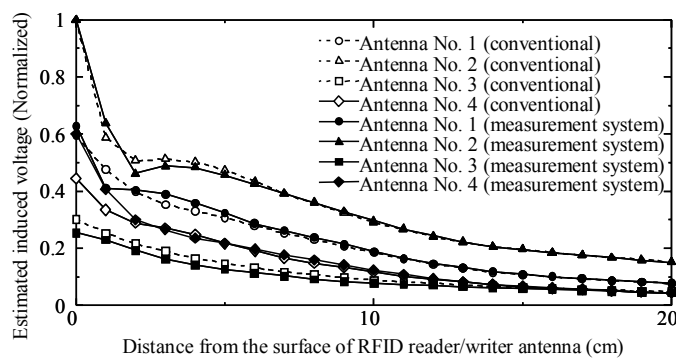


Figure 6: Estimated induced voltage calculated from the measurement results using the styrene foam positioner (conventional) and the three-dimensional automatic EMF measurement system

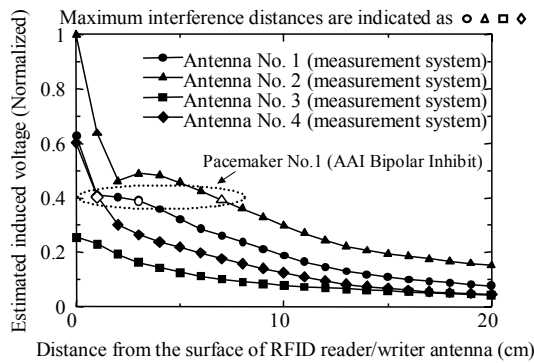


Figure 7: An example of a maximum interference distance plotted on the lines of induced voltage

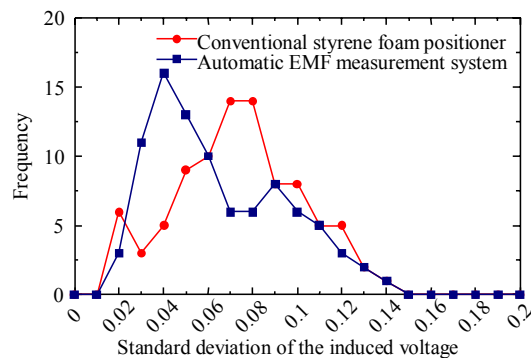


Figure 8: The histograms of standard deviation calculated from two type probe positioner

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