Experimental Estimation and Mitigation Methods to be Used for Electromagnetic Interference From RFID reader/writers on Active Implantable Medical Devices

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2. Electromagnetic interference (EMI) measurement set-up

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1. Introduction
1.1 Electromagnetic Compatibility (EMC)

A strong electromagnetic field such as antennas’ near field may cause electromagnetic interference (EMI).

- Wireless communication devices
- Receivers
- Electronics instruments
- Medical equipments (hospital, home)
- Special electronics devices
- active implantable medical device
1.2 MIC guidelines for preventing EMI

The Ministry of Internal Affairs and Communication (MIC) of Japan carried out investigations independently.

The MIC reported that ISO18000-6 high-power RFID reader/writer may affect pacemakers at a distance of 75 cm.
1.3 Active implantable medical devices

- **Active Implantable Cardiac Pacemaker (Pacemaker)**
  - An active implantable medical device which uses electrical impulses, delivered by electrodes contacting the heart muscles, to regulate the beating of the heart.

- **Active Implantable Cardioverter-Defibrillator (ICD)**
  - A small battery-powered electrical impulse generator which is implanted in patients who are at risk of sudden cardiac death due to ventricular fibrillation.
  - In addition to the function described above, ICDs commonly have the same functions as active implantable cardiac pacemakers.

Because EMI characteristics of these two devices are almost same, it is not necessary to separate treatment.
1.4 Objectives

- Precise EMI assessment on active implantable medical devices
- Develop EMI estimation method: computer simulation
- Contribute to the study of countermeasures

EMI characteristics due to RFID reader/writers on pacemakers / ICDs

- Measurement of EMF distributions
- Radio wave from RFID
- EMI experiments
- EMI mitigation method
- Estimation
- Numerical analysis
- Validity
- Field strength
- Hokkaido University
- Japan Automatic Identification Systems Association
- Japan Pacemaker Committee
- This presentation
1.5 Schedule

**EMI experiments**
- Tested devices so far:
  - 40 types of active implantable medical device
  - 41 types of RFID reader/writer antennas (ISO18000-2,3,4,6)
- Increased number of tested devices (including miller subcarrier UHF systems)

**EMI mitigation method**
- Fundamental validation of proposed method (UHF)
- Detailed investigation of mitigation performance,
  Investigation of interference with tag communication

**Numerical EMI estimation method**
- Fundamental validation of proposed method (HF)

This presentation

ISO/IEC SC31WG4SG5
ISO-TR
new item proposal
2. Electromagnetic interference (EMI) measurement set-up
2.1 Configuration of the measurement set-up

- **Oscilloscope** & **Chart Recorder**
- **Function generator** (Cardiac pulse)
- **Pacemaker / ICD**
- **Human body model**
- **RFID reader/writer**
  - **Antenna**
  - **Controller**

**Interference distance**

- **1.8 w/v % saline**
- **34 cm** Lead wire
- **36 cm**

- **Ventricular electrode**
- **Atrial electrode**
- **Function Generator**
- **Oscilloscope**
- **Chart Recorder**
- **Cardiac pacemaker**
- **Saline solution** (NaCl 0.18 w/v %)

**RFID reader/writer antenna**

**Interference distance**
2.2 Overview of the measurement set-up

- Human torso phantom
- Two-axis measurement platform
- Chart recorder
- ECG signal generator/detector
- Oscilloscope
- RFID reader/writer antenna (Stationary-type)
2.3 Procedure of the experiments

Start

(1) Set PM / ICD parameters.
   Sensitivity: maximum, Refractory: minimum
   Operating mode: VVI or AAI, Polarity: Unipolar / Bipolar

(2) ISO18000-2,3
   RFID reader/writer

(3) Exposure test (Inhibition / Asynchronous)
   With varying antenna position

(4) Recode ECG signal and measurement of maximum interference distance

EMI occurs?
Yes  Step down sensitivity (5 levels)
No   Change operating mode and polarity (4 or 8 conditions)

Complete test with respect to all conditions

End
2.4 Examples of affected ECG signal

- **Inhibition test:** pacing pulses are inhibited or pulse interval are changed

- **Asynchronous test:** asynchronous pacing pulses are generated
2.5 The human torso phantom

- The human torso phantom is based upon Irnich’s flat torso phantom model.
- Both atrial and ventricular electrodes are modified and enable us to separate each chambers’ signal by more than 20 dB.
- This phantom allows us to examine EMI with low interference by another chambers’ signal.

This construction of a human torso phantom is confirmed to give more conservative results for EMI estimations.
2.6 Conclusions on the measurement set-up

- The measurement set-up is constructed based upon AAMI Standard PC69 and EMI experiments reported by the MIC of Japan.
- The most important feature of this measurement set-up is that the modified Irnich phantom is employed for the experiments.
- Since this phantom is a vertical type, this is suitable for investigating the various types of actual RFID reader/writers, which include the stationary-type, the handheld-type and the gate-type.
3. EMI investigations on active implantable medical devices
3.1 EMI experiments (FY2005 - FY2007)

Breakdown of EMI experiments

- EMI of different operating mode and functions – pacing/sensing polarity, single/dual chamber mode, and antitachycardia functions are examined.

- RFID reader/writers operated in the frequency bands ISO18000-2, 3, 4, 6 are tested.

<table>
<thead>
<tr>
<th>Tested devices</th>
<th>Type of chambers</th>
<th>Number of devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pacemakers</td>
<td>Single chamber</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>Dual chamber</td>
<td>14</td>
</tr>
<tr>
<td>ICDs</td>
<td>Single chamber</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Dual chamber</td>
<td>6</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>40</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Frequency bands</th>
<th>Number of antennas</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO18000-2</td>
<td>8</td>
</tr>
<tr>
<td>ISO18000-3</td>
<td>27</td>
</tr>
<tr>
<td>ISO18000-6</td>
<td>4</td>
</tr>
<tr>
<td>ISO18000-4</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>41</td>
</tr>
</tbody>
</table>
3.2 EMI experiments (FY2008 - )

EMI experiments scheduled for FY2008

- Number of RFID reader/writers (ISO18000-6) and active implantable medical devices will be increased.

- **UHF RFID reader/writer systems which using miller subcarrier modulation** will be tested.

<table>
<thead>
<tr>
<th>active implantable medical devices</th>
<th>RFID reader/writer antennas</th>
</tr>
</thead>
<tbody>
<tr>
<td>** Tested devices</td>
<td>Frequency bands</td>
</tr>
<tr>
<td>Pacemakers</td>
<td>Number of antennas</td>
</tr>
<tr>
<td>Single chamber</td>
<td>ISO18000-6</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Dual/triple chamber</td>
<td>Miller subcarrier</td>
</tr>
<tr>
<td>22</td>
<td></td>
</tr>
<tr>
<td>ICDs</td>
<td>ISO18000-6</td>
</tr>
<tr>
<td>Single chamber</td>
<td>0</td>
</tr>
<tr>
<td>12</td>
<td>1</td>
</tr>
<tr>
<td>Dual/triple chamber</td>
<td>Baseband</td>
</tr>
<tr>
<td>Total 37</td>
<td>Total 5</td>
</tr>
<tr>
<td>Total</td>
<td></td>
</tr>
</tbody>
</table>
3.3 Test results for bradycardia functions
- Inhibition and asynchronous -

- Both for pacemakers and ICDs.

- The active implantable medical devices are programmed to have the maximum sensitivity (most conservative EMI condition).

### Results of EMI experiments (Maximum sensitivity)

<table>
<thead>
<tr>
<th>Frequency (Type)</th>
<th>Tested Modes (A)</th>
<th>Affected modes (B)</th>
<th>Maximum interference distance</th>
<th>Affected rate (B/A)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO18000-2 (Stationary)</td>
<td>638</td>
<td>194</td>
<td>17 cm</td>
<td>30.4 %</td>
</tr>
<tr>
<td>ISO18000-3 (Stationary)</td>
<td>814</td>
<td>19</td>
<td>15 cm</td>
<td>2.3 %</td>
</tr>
<tr>
<td>ISO18000-3 (Handheld)</td>
<td>1,021</td>
<td>8</td>
<td>4 cm</td>
<td>0.8 %</td>
</tr>
<tr>
<td>ISO18000-3 (Gate)</td>
<td>438</td>
<td>14</td>
<td>22.5 cm</td>
<td>3.2 %</td>
</tr>
<tr>
<td>ISO18000-6 (Stationary)</td>
<td>1,134</td>
<td>53</td>
<td>75 cm</td>
<td>4.7 %</td>
</tr>
<tr>
<td>ISO18000-4 (Stationary)</td>
<td>256</td>
<td>0</td>
<td>No EMI</td>
<td>0 %</td>
</tr>
</tbody>
</table>
3.4 Test results for tachycardia functions

- These are the inappropriate defibrillation treatments (caused by inappropriate tachycardia detections) (only for ICDs).
- The active implantable medical devices are programmed to have the maximum sensitivity are shown.

<table>
<thead>
<tr>
<th>Frequency (Type)</th>
<th>Tested Modes (A)</th>
<th>Affected modes (B)</th>
<th>Maximum interference distance</th>
<th>Affected rate (B/A)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18000-2 (Stationary)</td>
<td>90</td>
<td>6</td>
<td>1 cm</td>
<td>6.7 %</td>
</tr>
<tr>
<td>18000-3 (Stationary)</td>
<td>118</td>
<td>0</td>
<td>No EMI</td>
<td>0 %</td>
</tr>
<tr>
<td>18000-3 (Handheld)</td>
<td>146</td>
<td>0</td>
<td>No EMI</td>
<td>0 %</td>
</tr>
<tr>
<td>18000-3 (Gate)</td>
<td>25</td>
<td>1</td>
<td>3 cm</td>
<td>4.0 %</td>
</tr>
<tr>
<td>18000-6 (Stationary)</td>
<td>198</td>
<td>0</td>
<td>No EMI</td>
<td>0 %</td>
</tr>
<tr>
<td>18000-4 (Stationary)</td>
<td>44</td>
<td>0</td>
<td>No EMI</td>
<td>0 %</td>
</tr>
</tbody>
</table>
3.5 Conclusions on the EMI experiments

- As ISO18000-2 RFID reader/writer antennas generate relatively strong magnetic fields and time-varying envelope signals, the probability of EMI is higher than other frequency bands.

- Regarding the bradycardia functions, the largest effects are both complete missing of pacing pulses and continuous generation of asynchronous pulse.

- The defibrillation shock is generated by few ICDs, but only when they are located very close (<3 cm) to the antenna, and are set at maximum sensitivity.

- For ISO18000-6 RFID reader/writer antennas, only a few pacemakers are affected over the maximum interference distance of 22 cm. These are observed when the pacemakers are set at maximum sensitivity. The maximum interference distance is drastically shortened when their sensitivities are reduced.
Appendix: The human torso phantom based on Irnich model
A. 1 Effect of Plexiglas (Acrylic front panel)

- To confirm that the acrylic front panel of a human torso phantom does not affect the EMI test results of ISO18000-6, -4 RFID reader/writers, electric field strengths inside the phantom are analyzed using a 3 dimensional phantom model.

- The electric field strength inside the phantom with/without the acrylic front panel is calculated based on 3 dimensional FDTD (Finite-difference time-domain method) analysis.

- The human torso phantom used in the EMI test is modeled. (An active implantable medical device model is not included.)

<table>
<thead>
<tr>
<th>Materials</th>
<th>Relative dielectric constant</th>
<th>Electric conductivity (S/m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acrylic panel</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Saline solution</td>
<td>75</td>
<td>1</td>
</tr>
<tr>
<td>Dielectric plate</td>
<td>50</td>
<td>2</td>
</tr>
</tbody>
</table>
A. 2 Electromagnetic wave exposure condition

Electric field strength inside the human torso phantom is calculated with and without this acrylic front panel.
A. 3D human torso phantom analysis model

Electric field strengths are compared along the 1 dimensional line which passes through the center of the phantom.
A. 4 Analysis results of electric field (ISO18000-6)

Electric field strength (dB)

-100 -50 0 -60 -30 -20 -10

z-axis (mm)

Dielectric plate
Support
active implantable medical device submerged plane

Dielectric plate
Support
active implantable medical device

-10 mm

without acrylic front panel
with acrylic front panel
(without dielectric plate, Irnich original model)

Acrylic front panel
A. 5 Analysis results of electric field (ISO18000-4)

- Electric field strength (dB)
- z-axis (mm)

- Dielectric plate
- Support
- Active implantable medical device submerged plane
- 10 mm
- Acrylic front panel
- Active implantable medical device
- Without acrylic front panel
- With acrylic front panel
- With acrylic front panel (without dielectric plate, Irnich original model)
- Acrylic front panel
A. 6 Conclusions on the human torso phantom

- The electric field strength value is slightly higher when the phantom has the acrylic front panel. The difference in the analyzed electric field strength is very small (within 0.03 dB for ISO18000-6 and 0.45 dB for ISO18000-4 in the active implantable medical device’s submerged plane.

- For the frequency regions around ISO18000-4,-6, the relative dielectric constant and the electric conductivity of acrylic panel are approximately 3 and 0, respectively. On the other hand, the relative dielectric constant and the electric conductivity of the saline solution (1.8 g/L) are 75 and 1, respectively.

- Since the relative dielectric constant and the electric conductivity of free space are 1 and 0, the mismatching of free space impedance is dominant between the saline solution and the free space. The absorption or reflection due to the acrylic panel is negligible compared to that caused by the saline solution inside the phantom.
4. EMI mitigation method
4.1 EMI mitigation method

Mechanism of active implantable medical device EMI

- Frequency bands of assigned to RFID reader/writer systems are among ISO18000-2,3,4,6. EMI frequencies are more than 2 to 6 orders higher than the operation frequency of active implantable medical devices (several kHz at most).

- However, signals from RFID reader/writer antennas are detected by nonlinear characteristics of an internal circuit of active implantable medical devices (envelope detection). When the detected signal is similar to a human heart beat signal, and then malfunctions could occur.

(a) RFID signal with time-varying envelope curve

<table>
<thead>
<tr>
<th>e.g. 1 GHz</th>
</tr>
</thead>
</table>

(b) Detected signal due to nonlinear characteristics

<table>
<thead>
<tr>
<th>e.g. 100 Hz for RFID</th>
</tr>
</thead>
</table>
4.2 Principle of EMI mitigation

- Low frequency noises are generated with time-varying envelope curve signal exposure (i.e. amplitude modulation, pulse modulation, and intermittent signal).

- On the other hand, **CW or CW-like signals (i.e. frequency modulation and phase modulation) do not generate low frequency noise.** This is because the envelopes of these signals do not contain the 0.5 – 100 Hz.

- If the detected low frequency signal is reduced or cancelled, the EMI could be mitigated or eliminated.

![Signal with time-varying envelope curve](image)

- Reduction of envelope detection
  - Without reduction
  - With reduction

- Nonlinear response
- Cancellation of envelope detection
4.3 Fundamental construction

- The newly proposed method is based on a “mitigation signal” which fulfills a time gap in an RFID transmission signal.

- Some RFID systems transmit signals intermittently in a certain idle time. The idle times are typically 10 to 500 ms depending on the system. The difference in field strength at the transmitting time and the idle time causes a low frequency signal in active implantable medical devices.

- To reduce a time-varying envelope curve, the proposed method transmits a “mitigation signal” from the RFID or different antenna.

(a) Signal from RFID reader/writer antenna
Idle time: 10 - 500 ms

(b) RFID signal and mitigation signal
Mitigation signal

RFID burst signal (Modulation: ASK, FSK, etc)
4.4 Experimental validation

➢ To confirm the proposed method, fundamental experiments are carried out.

![Schematic diagram of experimental setup](image)

- **Intermittent signal**: Agilent 33220A
- **RFID signal**: Agilent 8642B
- **Mitigation signal**: Agilent E4438C
- **RF power amplifier**: R&K ALM00110-2840FR-R
- **Dipole antenna**
- **Signal generator**: Agilent 8642B
- **Human torso phantom**
- **ECG signal generator/detector**
- **Function generator**

![Experimental setup image](image)
4.5 Example of mitigation (pacemaker A)

- Maximum interference distance at different mitigation signal frequency

- Maximum interference distance without mitigation signal: 71 cm@950 MHz

- Frequency of RFID signal: 950 MHz
- Intermittent period of RFID signal: 1 Hz with 0.5 duty factor
- Frequency of mitigation signal: 850 – 950 MHz
- Antenna input power: 1 W

- Maximum interference distance 71 cm is improved to 3 cm. (Frequency offset: 1 MHz)
4.6 Example of mitigation (pacemaker B)

- Maximum interference distance at different mitigation signal frequency

- Frequency of RFID signal: 450 MHz
- Intermittent period of RFID signal: 14 Hz with 0.17 duty factor
- Frequency of mitigation signal: 450 – 550 MHz
- Antenna input power: 1 W

EMI is completely cancelled at the frequency offset between 0 MHz and 4 MHz.
4.7 Example of mitigation (pacemaker C)

- Maximum interference distance at different mitigation signal frequency

![Graph showing maximum interference distance at different mitigation signal frequencies.]

- Frequency of mitigation signal: 450 – 550 MHz
- Frequency of RFID signal: 450 MHz
- Intermittent period of RFID signal: 14 Hz with 0.17 duty factor
- Antenna input power: 1 W
- EMI is completely cancelled at the frequency offset between 0 MHz and 10 MHz.
4.8 Conclusions on the EMI mitigation method

➢ To confirm the validity of the proposed EMI mitigation method, experimental results of the 3 different pacemakers are presented.

➢ The proposed method enables to the maximum interference distance to be shortened to less than one-tenth at frequency offset within 3 MHz.

➢ Since the EMI characteristics of pacemakers and ICDs depend on the frequency, a small frequency offset of mitigation signal is effective to mitigate the EMI.

➢ More detailed investigation of mitigation performance such as EMI characteristics depending on the amplitude and the switching time of mitigation signal are now being carried out. In addition, interference with tag communication will be investigated.
5. Numerical EMI estimation method (informative)
5.1 Numerical EMI estimation method

- **FDTD analysis of active implantable medical device EMI**
  - The fundamental validation for the EMI due to HF (ISO18000-3) reader/writers is confirmed based on measured and analysis results.

Magnetic field strength (antenna surface)

**3 dimensional measurement system**

- **Experimental RFID reader/writer antenna**
- **Magnetic field probe**
- **Probe positioner**
- **Spectrum analyzer**
- **Computer**

**Measurement (xy-axis)**

**Calculation (xy-axis)**
5.2 Torso phantom and pacemaker model

- The maximum interference distance obtained by the experiments and the numerical analyses are compared. The interference voltage generated by the 4 types of antennas is obtained by using the FDTD method.
- The torso phantom model and RFID reader/writer antennas are modeled and analyzed.

An example of the numerical model

The numerical model of the pacemaker and the lead wire
5.3 Analyzed interference voltage

- Dielectric constant and electric conductivity values at ISO18000-3 are used in the calculations. In addition, the torso phantom model is set to be parallel to the antenna model, which is the same condition used in the experiments.

- The interference voltage is evaluated at both ends of the resistance.

Unipolar mode: the metal housing of the pacemaker model and the inner conductor of coaxial lead wire model

Bipolar mode: the outer conductor of coaxial lead wire model and the inner conductor of coaxial lead wire model

The interference voltage obtained by the analysis (Unipolar mode)
5.4 Comparison of maximum interference distances

Examples of the measured and calculated maximum interference distance

- Antenna A (Measured)
- Antenna A (Calculated)
- Antenna B (Measured)
- Antenna B (Calculated)
- Antenna C (Measured)
- Antenna C (Calculated)
- Antenna D (Measured)
- Antenna D (Calculated)

These results clarify the interference voltages due to the magnetic field generated around the HF RFID reader/writer and they can be estimated by using precise and detailed analysis.
6. Conclusions

Detailed experiments to assess the EMI due to RFID reader/writers on active implantable medical devices were conducted.

- Maximum interference distance of EMI
  - 18000-2: 17 cm
  - 18000-3: 22.5 cm (gate-type)
  - 18000-6: 75 cm
  - 18000-4: no EMI

The validity of the proposed EMI mitigation method was confirmed by the experimental results of 3 types of pacemakers.

- Maximum interference distances were improved to 3 cm or less.
- More detailed investigations are now being carried out.

The numerical assessment methodology of the EMI was confirmed based on the result of the experiments and the numerical analyses.

- There was good agreement between the maximum interference distances obtained by the experiments and the FDTD analysis.