Examination of Effects of Radio Waves from RFID Devices on Implanted Cardiac Pacemakers etc.

JAISA (Japan Automatic Identification Systems Association) RFID Technical Committee Medical Device Investigation WG
March 15, 2006
1. Organization of JAISA's RFID Activities

- RFID Technical Committee
  - Mr. Sakashita
- Medical Device Investigation WG
  - Mr. Sakashita
- Tag Disposal WG
  - Mr. Akatsuka
- UHF Band WG
  - Mr. Sakashita
- AIDC Basic Examination
  - Mr. Shibata
- BC Experts
- RFID Experts
- RFID Group
  - Mr. Teraura
- IEC TC106 WG
  - Mr. Sakashita
- Hokkaido University Project
  - Mr. Tateishi
- IR WG
  - Mr. Sasao
- Privacy WG
  - Matsutani/Mr. Honda
2. Activities of Medical Device Investigation WG

2.1 Effects on medical devices/equipment

Implanted medical devices, such as pacemakers

Interference with electrical signal (pacing pulse) that stimulates the heart's rhythm

Distorted screen image, etc.

Medical equipment used in medical institutions

Cellular phone
RFID
Wireless LAN etc.
2-2 Establishment of guidelines regarding effects on medical devices

(1) Guideline measures for preventing effects of RFID devices
-- FY2005 (announced in Aug. 2005) --

Guidelines for preventing effects of gate-type RFID devices on implanted medical devices

1. Any person with an implanted medical device should *quickly pass through the center of, not stopping at*, a passage where a gate-type RFID device is installed or an RFID sticker is attached.
2. Any person with an implanted medical device should not remain in the vicinity of a gate-type RFID device nor lean against this device.
3. Any person with an implanted medical device should consult their doctor if they feel any change in their physical condition.

Guidelines for preventing effects of other RFID devices on implanted medical devices

1. Any person with an implanted medical device should keep the antenna of a handheld RFID device *at least 22 cm away from* the area where the device is implanted.
2. Any person with an implanted medical device should keep the area where the device is implanted *at least 22 cm away from* the antenna of a stationary or module RFID device (including some types of printers).
(2) Guideline measures for preventing effects of RFID devices
-- FY2005 (announced in Aug. 2005) --

Reference  Guidelines for preventing effects of special RFID devices for controlled areas

These RFID devices (or units) are special pieces of equipment that are only to be used in a closed, controlled area, and may affect medical devices depending on how and where the RFID devices are used. When using these devices, you are required to observe the following:

Control the special RFID devices so that they are not delivered to and used in an uncontrolled area.

To reduce the effects of the gate-type RFID devices on implanted medical devices, the organizations concerned are required to examine an increase in safety.
(3) Purpose of joint investigation and research

The effects of RFID devices on medical devices have been investigated and researched.

- Research A: Until March 2006
  Information input in RFID device designs created by member companies in an effort to create RFID devices with less effect on medical devices

- Research B: Until March 2007
  Investigation of effects of prototypes in the design verification stage to contribute to achieving safer products

- Activity period: May 2005 to March 2007
3. Interim Report on Tests for Electromagnetic Interference with Implanted Cardiac Pacemakers etc. by Radio Waves from RFID Devices

3.1 Devices to be tested

1) Four types of RFID devices indicated in Fig. 1 Total 30 devices
2) Implanted cardiac pacemakers and implanted cardioverter-defibrillators (ICDs) indicated in Table 1 Total 35 devices

3.2 Configuration of test equipment

Test equipment consists of a phantom human body with an implanted cardiac pacemaker or ICD as shown in Fig 2, and a measurement system composed of an oscilloscope, pseudo potential generator, and direct-writing recorder as shown in Fig. 3. Tests are performed in an anechoic chamber where there are no metallic objects within 2 m of this test equipment.

3.3 Test conditions

Each implanted pacemaker and ICD is programmed so that it operates at the maximum sensitivity. Tests are performed with the implanted pacemaker or ICD operating.

Fig. 4 indicates the positional relationship between the gate-type RFID device and the implanted pacemaker or ICD during measurement.

Fig. 5 indicates the positional relationship between the handheld RFID device and the implanted pacemaker or ICD during measurement.

3.4 Test procedures

1) Setting sensitivity of implanted pacemaker or ICD
2) Testing gate-type RFID device

Before testing, place the phantom near the gate and scan the surface of the gate to determine the height of the phantom from the floor, at which the implanted pacemaker or ICD can be affected easily. Use this height of the phantom for subsequent tests.
3) Testing handheld RFID device

Before testing, place the antenna of the handheld RFID device so that it is on the same level as the implanted pacemaker or ICD in the phantom human body. Start testing while the antenna is in close contact with this phantom. Move the antenna along the electrode. When the antenna has reached the end of the electrode, set the antenna in the vertical direction to the floor and move the antenna again from the end of the electrode to the position of the pacemaker or ICD. When any effect on the pacemaker or ICD appears, stop moving the antenna and record the operation of the pacemaker or ICD for at least five seconds.

4) Determining occurrence/non-occurrence of interference

A. The following are criteria for determining whether interference has occurred.
   a. All tests: The programmer checks the internal state of the implanted cardiac pacemaker or ICD after each test. The pacemaker or ICD is determined to be affected when set value changes or other any unusual state is found.
   b. Inhibition tests, and VDD mode tests for special VDD models: The pacemaker or ICD is determined to be affected when any pulse inhibition or change in pulse interval is found for even one cycle during the observation period in each test, and this problem is reproduced when retested under the same conditions.
   c. Asynchronous tests: The pacemaker or ICD is determined to be affected when the occurrence of even one pulse is found during the observation period in each test and this occurrence is reproduced when retested under the same conditions.
   d. False positive tests for ICDs: The ICD is determined to be affected when charging of the capacitor begins or preparation for this charging begins to deliver an electric shock, during the inhibition or asynchronous test described above.
   e. False negative tests for ICDs: The ICD is determined to be affected when it loses the ability to detect fibrillation.

B. Classification of levels of effects due to electromagnetic field

Table 2 classifies the levels of general effects where the implanted cardiac pacemakers or ICDs are affected by an external electromagnetic field.

Tables 3 and 4 indicate effects found through our investigation, in reference to ideas presented during examination of the possible coexistence of medical devices and wireless systems in a hospital.

Table 3 indicates the levels of effects on implanted cardiac pacemakers.

Table 4 indicates the levels of effects on ICDs.
4. Analysis of Effects on Implanted Cardiac Pacemakers etc. Based on Test Results

4.1 Effects of gate-type RFID devices

(1) Effects on implanted cardiac pacemakers
   1) Recognized phenomena of levels 1 and 2 during inhibition test I indicated in Fig. 6.
   2) Recognized phenomena of levels 1 and 2 during asynchronous test I indicated in Fig. 7.
   3) Fig. 8 indicates the cumulative distribution of distances where the implanted cardiac pacemakers at the maximum sensitivity are affected.

(2) Effects on ICDs
   Recognized effects equal to level 4 that cause unnecessary defibrillation shock, in two out of seven ICD models in four test modes, during false positive tests where the antenna of the gate-type RFID device is in close contact with the acrylic surface of the phantom human body with an ICD.

4.2 Effects of handheld RFID devices

(1) Effects on implanted cardiac pacemakers
   1) Fig. 9 indicates the cumulative distribution of distances where implanted cardiac pacemakers at the maximum sensitivity are affected.

(2) Effects on ICDs
   1) Pacemaker function: Affected in 3% of 210 modes at a maximum separation of 3 cm
   2) Defibrillation function: Affected in 2% of 210 modes at a maximum separation of 2 cm
   3) Recognized effects equal to level 4 that cause an unnecessary defibrillation shock, in three out of seven ICD models in five test modes during false positive tests. These effects occurred at a maximum separation of 1 cm.
5. Prevention of Effects

Although our investigation this year is not sufficient to prepare guidelines for preventing the effects of the RFID devices on implanted cardiac pacemakers and the like, we have obtained some knowledge for the safe use of these devices through this investigation. We believe it is advisable to present several measures based on this knowledge.

5.1 Measures for persons with implanted cardiac pacemakers etc.

These persons are required not to intentionally allow their area of the body where the pacemaker etc. is implanted to become in close contact with the gate of a gate-type RFID device or the antenna of a handheld RFID device.

5.2 Measures by Japan Automatic Identification Systems Association (JAISA)

1) JAISA expects the manufacturers, distributors, and operators of RFID devices to understand, recognize, and consider the result of the investigation this year when developing, introducing, and operating an RFID device.

2) JAISA expects the manufacturers, distributors, and operators of RFID devices to consider clearly indicating the radio wave emitting sections (antennas) on RFID readers/writers (R/W) and clearly indicating this is a safety RFID device. These indications will be of benefit to persons with implanted cardiac pacemakers etc., and increases user safety.

5.3 Measures by Pacemaker Committee

Based on the results of the investigation this year, the Pacemaker Committee issued a "Notification regarding RFID effects on implanted cardioverter-defibrillators (ICDs)" to alert physicians and medical personnel.

5.4 Challenge for the coming year

Since there still are RFID devices to be tested that were not investigated this year, we should identify the models to be tested and continue investigating the levels of effects on implanted cardiac pacemakers etc.
### Types of RFID Devices

<table>
<thead>
<tr>
<th>Type</th>
<th>Frequency</th>
<th>Standards, etc.</th>
<th>Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gate type</td>
<td>135 kHz or lower</td>
<td>Guided-type communication equipment</td>
<td>Libraries, entrances &amp; exits, shops, amusement facilities</td>
</tr>
<tr>
<td></td>
<td>500 kHz</td>
<td>Guided-type communication equipment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>13.56 MHz</td>
<td>ARIB STD-T82</td>
<td></td>
</tr>
<tr>
<td>Handheld type</td>
<td>135 kHz or lower</td>
<td>Guided-type communication equipment</td>
<td>Sushi-go-round restaurants, events, goods control, distribution tracing, etc.</td>
</tr>
<tr>
<td></td>
<td>13.56 MHz</td>
<td>ARIB STD-T82</td>
<td></td>
</tr>
<tr>
<td></td>
<td>300 MHz</td>
<td>Faint radio waves</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.45 GHz</td>
<td>ARIB STD-T81</td>
<td></td>
</tr>
<tr>
<td>Stationary type</td>
<td>135 kHz or lower</td>
<td>Faint radio waves</td>
<td>Gas stations, amusement facilities, etc.</td>
</tr>
<tr>
<td></td>
<td>13.56 MHz</td>
<td>ARIB STD-T82</td>
<td></td>
</tr>
<tr>
<td></td>
<td>300 MHz</td>
<td>Faint radio waves</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.45 GHz</td>
<td>ARIB STD-T81 / STD-T1 / STD-29</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>135 kHz or lower</td>
<td>Guided-type communication equipment</td>
<td>Gas stations, amusement facilities, etc.</td>
</tr>
<tr>
<td></td>
<td>13.56 MHz</td>
<td>ARIB STD-T82 / Faint radio waves</td>
<td></td>
</tr>
<tr>
<td></td>
<td>300 MHz</td>
<td>Faint radio waves</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.45 GHz</td>
<td>ARIB STD-T81</td>
<td></td>
</tr>
</tbody>
</table>
Table 1: Models, Marketed periods, and Quantities of Implanted Cardiac Pacemakers and ICDs

<table>
<thead>
<tr>
<th>Period marketed in Japan</th>
<th>Model (quantity)</th>
<th>Implantable cardiac pacemakers</th>
<th>ICDs</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SSI</td>
<td>DDD</td>
<td>VDD</td>
<td>ICD-S</td>
</tr>
<tr>
<td>Old (1995 and before)</td>
<td>4</td>
<td>2</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Medium (1996 to 1998)</td>
<td>2</td>
<td>4</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Recent (1999 and after)</td>
<td>1</td>
<td>10</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>7</td>
<td>16</td>
<td>5</td>
<td>4</td>
</tr>
</tbody>
</table>

SSI: Single-chamber implanted cardiac pacemaker
DDD: Dual-chamber implanted cardiac pacemaker
VDD: Single-path VDD implanted cardiac pacemaker
ICD-S: Single-chamber implanted cardioverter-defibrillators (ICDs)
ICD-D: Dual-chamber implanted cardioverter-defibrillators (ICDs)
Fig. 2  Configuration of Phantom Human Body

Phantom human body filled with saline containing 0.18% salt by weight (acrylic tank)

Implanted cardiac pacemaker

Atrium electrode

Ventricle electrode

Electrode used for detecting pacing pulse and applying pseudo cardiac potential

Unit: mm
Fig. 3  Configuration of Measurement System for Phantom Human Body
Fig. 4  Positional Relationship Between Gate-type RFID Device and Phantom Human Body
Fig. 5 Positional Relationship Between Handheld RFID Device and Phantom Human Body

- Phantom human body
- Antenna
- Main body of RFID device
- Stand for height adjustment
- L
- H
### Table 2  Classification of Levels of Effects

<table>
<thead>
<tr>
<th>Level</th>
<th>Effect criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No effects</td>
</tr>
<tr>
<td>1</td>
<td>May cause momentary palpitations, dizziness, etc.</td>
</tr>
<tr>
<td>2</td>
<td>May cause continuous palpitations, dizziness, etc., but the patient can recover to normal on their own by leaving the area, for example.</td>
</tr>
<tr>
<td>3</td>
<td>May aggravate the patient's condition when no treatment is provided for the patient.</td>
</tr>
<tr>
<td>4</td>
<td>May aggravate the patient's condition immediately.</td>
</tr>
<tr>
<td>5</td>
<td>May directly endanger the life of the patient.</td>
</tr>
</tbody>
</table>

### Table 3  Levels of Effects on Implanted Cardiac Pacemakers

<table>
<thead>
<tr>
<th>Physical phenomenon</th>
<th>Damage status</th>
<th>Normal condition</th>
<th>Reversible effects</th>
<th>Irreversible effects</th>
<th>Direct damage to living body</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implanted cardiac pacemakers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maintenance of normal function</td>
<td>Level 0</td>
<td></td>
<td></td>
<td>Setting can be changed from outside body</td>
<td>Surgical replacement required</td>
</tr>
<tr>
<td>Abnormal pacing/sensing within 1 cycle (recovery within 2 s)</td>
<td>Level 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abnormal pacing/sensing over 1 cycle (2 s) or more</td>
<td>Level 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pacemaker resetting</td>
<td></td>
<td></td>
<td></td>
<td>Setting can be changed from outside body</td>
<td>Surgical replacement required</td>
</tr>
<tr>
<td>Permanent change in program settings</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continuous breakdown</td>
<td>Level 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Permanent breakdown</td>
<td>Level 5</td>
<td></td>
<td></td>
<td>Setting can be changed from outside body</td>
<td>Surgical replacement required</td>
</tr>
<tr>
<td>Electromotive force applied to lead generates heat.</td>
<td>Level 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 4  Levels of Effects on ICDs

<table>
<thead>
<tr>
<th>Physical phenomenon</th>
<th>Damage status</th>
<th>Normal condition</th>
<th>Reversible effects</th>
<th>Irreversible effects</th>
<th>Direct damage to living body</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implanted cardiac pacemakers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Surgical replacement required</td>
</tr>
<tr>
<td>Maintenance of normal function</td>
<td>Level 0</td>
<td></td>
<td></td>
<td>Setting can be changed from outside body</td>
<td></td>
</tr>
<tr>
<td>Abnormal pacing/sensing within 1 cycle (recovery within 2 s)</td>
<td>Level 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abnormal pacing/sensing over 1 cycle (2 s) or more</td>
<td>Level 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temporary loss of ability to detect defibrillation</td>
<td>Level 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unnecessary defibrillation shock</td>
<td>Level 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in program settings</td>
<td>Level 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continuous breakdown</td>
<td>Level 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Permanent breakdown</td>
<td>Level 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electromotive force applied to lead generates heat.</td>
<td>Level 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Fig. 6 Inhibition Test

The implanted cardiac pacemaker generates pulses at a set rate without any signals input.

(a) Normal pacing waveform

1 pacing pulse is inhibited.

(b) Observed waveform where 1 pacing pulse was inhibited (level 1)

2 or more pacing pulses are inhibited.

(c) Observed waveform where 2 or more pacing pulses were inhibited (level 2)
Fig. 7 Asynchronous Test

The implanted cardiac pacemaker senses pseudo cardiac potential signals at a rate 10 to 20% higher than the set rate, and pulse output is inhibited.

(a) Waveform of pseudo cardiac potential signals

(b) Observed waveform where a single pacing pulse was output (level 1)

(c) Observed waveform where three pacing pulses were output (level 2)
Fig. 8 Interference with Implanted Cardiac Pacemakers by Gate-type RFID Devices

Cumulative distances from gate when implanted cardiac pacemakers are affected (test processes 2 and 3)
Fig. 9 Interference with Implanted Cardiac Pacemakers by Handheld RFID Devices

Cumulative distances from handheld device when implanted cardiac pacemakers are affected

Distance (cm)