STUDY REPORT ON THE EFFECT OF RADIO WAVES ON MEDICAL DEVICES

March, 2007

Ministry of Internal Affairs and Communications (MIC)
Introduction

We are moving toward the creation of a ubiquitous network society that makes it possible to connect “anytime, from anywhere, with any device, by anyone” and allows us free access to information (FY 2006 Information and Communications White Paper, MIC). As a result, the use of radio waves has increased dramatically and is becoming an essential part of daily life. At the same time, the effects of radio waves on pacemakers and other medical equipment has become a broad public concern. Thus, it is important to provide the public with information based on the latest studies and relieve their concern in this regard.

The question of the effects of radio waves on medical equipment was first raised in March 1997, in a paper entitled Guidelines on the Use of Radiocommunication Equipment such as Mobile Phones and Safeguards for Electronic Medical Equipment, written by the Electromagnetic Compatibility Conference (currently the Electromagnetic Compatibility Conference Japan). Later, the MIC conducted a study of the effects of radio waves on implantable cardiac pacemakers.

A series of studies were conducted in the ensuing years: Effects of Mobile Telephones (2001), Wireless Card Systems and Electronic Article Surveillance (EAS) Devices (2002); Effects of Gate and Handheld RFID Devices, EAS Devices, and Wireless LAN Equipment (2003); and Effects of RFID Devices and Mobile Telephones. Then, in August 2005 the results of these studies were announced and became the basis of policy advices. A new study was conducted in 2005 on the effects of radio wave emissions from mobile telephones on implantable cardiac pacemakers, based on a study of the effects of mobile terminals as well as the results of other studies, using both domestic and international standards.

RFID devices that use the UHF band were introduced into the market in fiscal 2005. The penetration of the mobile telephone has also been dramatic, and there have been many new models and types introduced into the market since the last study in fiscal 2005. In the world of implantable cardiac pacemakers as well, there have been many new devices approved for use. There is also a need for a new investigation into whether an electromagnetic environment is being maintained for the safe use of these RFID devices and mobile telephone terminals.

As a result, the Ministry of Internal Affairs and Communications (MIC) contracted the Association of Radio Industries and Businesses (ARIB) to conduct a study on the effects of emissions from RFID devices and mobile telephones on implantable cardiac pacemakers and implantable cardioverter defibrillators.

The Association of Radio Industries and Businesses established the Study Group on the Effects of Radio Waves on Medical and Other Equipment to conduct a study of the radio waves emitted from mobile telephones and their effects on implantable cardiac pacemakers with the purpose of applying the results to amending existing policy. This study group received the typical devices being used in Japan today from the Pacemaker Committee, the Japan Automatic Identification Systems Association, and telecommunications carriers, and conducted a study on the effects of radio waves on medical and other equipment. They also conducted electro-magnetic interference tests to examine the effects of radio waves emitted from RFID devices and mobile telephones on implantable cardiac pacemakers, and performed an analysis of the effects of the radio waves from RFID devices on implantable cardiac pacemakers.

Included in this report are the results of these studies and research.
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A study on the radio waves emitted from RFID devices and their effect on medical equipment was conducted in fiscal 2003 using gate and handheld RFID devices. Then, in fiscal 2004, another study was conducted using stationary and other types of RFID devices. Both studies sought to determine the EMI of these devices on medical equipment.

The use of the UHF band in RFID devices was subsequently approved in fiscal 2005, and devices using the UHF band started to appear on the market. At that point, another study was conducted on radio waves emitted from RFID devices operating in the UHF band and their effect on implantable cardiac pacemakers and implantable cardioverter defibrillators. In this study, the selected devices were thoroughly irradiated.

The following report presents the results of this study.
Chapter 1

Electromagnetic Interference Test of UHF Radio Waves from RFID Devices on Implantable Cardiac Pacemakers

For consistency, the methodology used in this study was basically the same as that described in the fiscal 2004 and fiscal 2005 reports from the MIC. [1],[2] The human phantom used to replicate the conditions of an implantable cardiac pacemaker in a human being was the same type as that used in the previous studies.

The RFID devices operating in the UHF band that were studied conformed with ARIB STD-T89[3] and ARIB STD-T90[4] as put forth by the Association of Radio Industries and Businesses.

1.1 Devices tested

1.1.1 Implantable cardiac pacemakers

The average life of implantable cardiac pacemakers is 5 to 7 years. New models enter the market every two years or so. Usually, a group of devices are released at one time, with different specifications such as single chamber models, double chamber models, with or without a rate response function. However, these devices are all a subset of the same device, and the electrical properties are identical for each. Thus, the consistency of the implantable cardiac pacemakers and implantable cardioverter defibrillators can be assured if the most common model of each device is selected from each generation of devices. Thus, studies performed after fiscal 2000 use the most common devices, which could be interpreted as being consistent in their electrical properties with all devices on the market, including those from Period I (1995 and before), Period II (1996 – 1998), Period III (1999 – 2002), Period IV (2003 and beyond), and new models approved for import thereafter were the subject of additional studies.

The implantable cardiac pacemakers and other equipment tested were received from the Pacemaker Committee of the Japan Association of Medical Equipment Industries. Table I–1–1 shows the implantable cardiac pacemakers tested and the categories on sale at that time.

<table>
<thead>
<tr>
<th>Period sold in Japan</th>
<th>Types (number of)</th>
<th></th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SSI</td>
<td>DDD</td>
<td>VDD</td>
</tr>
<tr>
<td>Period I (1995 and before)</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Period II (1996 – 1998)</td>
<td>3</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Period III (1999 – 2002)</td>
<td>1</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>Period IV (2003 and beyond)</td>
<td>0</td>
<td>12</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>6</td>
<td>20</td>
<td>3</td>
</tr>
</tbody>
</table>

The following is an explanation of the abbreviations used in this table.

SSI : Single-chamber implantable cardiac pacemaker
DDD : Dual-chamber implantable cardiac pacemaker
VDD : Single-path VDD implantable cardiac pacemaker
CRT-P(TDD) : Triple-chamber implantable cardiac pacemaker for treating cardiac failure
ICD-S : Single-chamber implantable cardioverter defibrillator
ICD-D : Dual-chamber implantable cardioverter defibrillator
CRT-D : Triple-chamber implantable cardioverter defibrillator

Many of the implantable cardiac pacemakers can be set to one of several pacing modes. In this study, each pacing mode was tested for all implantable cardiac pacemaker models. The implantable cardiac pacemaker models are explained below.

AAI : Uses an atrial electrode. If no autogenic atrial rhythm is detected, an electrical stimulation is generated to contract the atrium. When an autogenic atrial rhythm is detected, the stimulation is restrained.

VVI : Uses a ventricular electrode. If no autogenic ventricular rhythm is detected during the preset time period, an electrical stimulation is generated to contract the ventricle. When an autogenic ventricular rhythm is detected, the stimulation is restrained.

SSI : The basic unit of the AAI, and VVI implantable cardiac pacemakers are the same, and they are both known by those in the industry by this term.

DDD : Uses electrodes in the atrium and ventricle. This type has functions of both AAI and VVI, and it operates when the atrium and ventricle are out of synch, which is called an AV delay. The operational conditions are complex, but it provides physiological pacing.

VDD : A single electrode with a sensing electrode inside the atrium reaches to the ventricle, and pacing is provided to the ventricle when the atrium and ventricle are out of synch, which is called an AV delay. The atrial electrode floats in the heart chamber, which achieves a higher sensitivity than other methods.

CRT-P (TDD): Used to treat heart failure due to the left and right ventricles being out of synch, and it re-synchronizes both ventricles by stimulating them to contract. This is essentially the same as a dual-chamber pacemaker.

ICD-S : Automatically detects ventricular fibrillation (VF) and ventricular tachycardia (VT) and treats it with an electrical stimulation. (includes an SSI pacing function)

ICD-D : Automatically detects ventricular fibrillation (VF) and ventricular tachycardia (VT) and treats it with an electrical stimulation. (includes a DDD pacing function)

CRT-D : Automatically detects ventricular fibrillation (VF) and ventricular tachycardia (VT) and treats it with an electrical stimulation. (includes a CRT-P pacing function)

1.1.2 RFID devices

RFID use has dramatically increased in recent years with the miniaturization of the RF tag, and it is now used in many fields, from manufacturing and logistics, to warehousing, product checkout, product history, position detection, theft prevention, accident prevention, and many more. RF tags are considered a vital component in creating the ubiquitous network, a network that can be connected to by anyone, any time, and any where. RFID systems comprise a reader-writer and an RF tag. Communication between the two devices
is effected through radio waves. The effect on implantable cardiac pacemaker and other equipment is generally relative to the strength of the radio waves. This study irradiated implantable cardiac pacemakers with the radio waves emitted from the RFID reader-writer.
(2) RFID device types

RFID is used in many environments, but in this study, we tested four types of RFID devices that can be easily recognized by the average person: gate, handheld, stationary, and module types. Figure I–1–1 shows a common example of each, and table I–1–2 shows their application.

Gate: the reader-writer is set up like a gate
Hand-held: the writer-reader is held in the hand and is portable
Stationary: the reader-writer is fixed in one place
Modular: the reader-writer is installed inside another device, such as a printer

High-output 950 MHz passive tag system

Figure I–1–1 RFID Device Types
Table I–1–2  Applications for Each Type of RFID

<table>
<thead>
<tr>
<th>Type</th>
<th>Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gate</td>
<td>Libraries, door monitoring, stores, game centers, etc.</td>
</tr>
<tr>
<td>Hand-held</td>
<td>Fast food restaurants, events, inventory management, logistics, product tracing, etc.</td>
</tr>
<tr>
<td>Stationary</td>
<td>Gas stations, game centers, etc.</td>
</tr>
<tr>
<td>Modular</td>
<td>Printers, bookshelves, and other places where they can be embedded</td>
</tr>
</tbody>
</table>

(3) RFID devices tested

The RFID devices used in this most recent study were either high-output 950 MHz passive tag system (complies with ARIB STD-T899[3]) or the low-output 950 MHz passive tag system (complies with ARIB STD-T90[4]). The devices included in this study were either available on the market or were soon to be released. Table I – 1 – 3 shows the RFID devices by type selected for this study. Gates formed by using a stationary device (with the antenna pointing horizontally) were included in the stationary type category. The same device is included more than once in the types table if the device was used more than once with different transmission parameters.

Table I–1–3  RFID Devices Included in this Study

<table>
<thead>
<tr>
<th>Type</th>
<th>Qty</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hand-held device</td>
<td>3</td>
<td>Complies with the ARIB STD-T90 standard</td>
</tr>
<tr>
<td>Stationary device</td>
<td>12</td>
<td>Complies with the ARIB STD-T89 standard</td>
</tr>
<tr>
<td>Modular device</td>
<td>2</td>
<td>Complies with the ARID STD-T90 standard</td>
</tr>
<tr>
<td>Total</td>
<td>17</td>
<td>–</td>
</tr>
</tbody>
</table>

The RFID devices used in this study were provided by member companies of the Japan Automatic Identification Systems Association.

ARIB STD (standard) is a standard for systems that use radio frequencies and is based on the National Technology Standard, an obligatory standard whose purpose is to promote the effective use of frequencies and prevent interference, and the Public Technology Standard, a voluntary standard whose purpose is promote the compatibility of wireless equipment, maintain transmission quality, and increase convenience for wireless device makers and users.

1.2 Structure of the tested devices

1.2.1 Configuration of the human phantom and implantable cardiac pacemaker

To simulate the dampening effects of human tissue and the induction of electrical current in the body due to electromagnetic interference, the implantable cardiac pacemaker was placed inside a human phantom shown in Figure I – 1 – 2, which was then filled with 0.18% saline solution (by weight), a condition for immunity testing for implantable cardiac pacemakers using the 450 MHz to 3 GHz range, as prescribed for the evaluation of implantable medical advices in EN45502, which quotes ANSI/AAMI PC69:2000[5].
The implantable cardiac pacemaker electrode was connected as usual (including the lead wires), and the unit was installed. The study used the electrodes provided with the equipment, but when no electrodes were provided, the study used electrodes from Medtronic.

For single-chamber implantable cardiac pacemakers and dual-chamber implantable cardiac pacemakers, one electrode each was placed in the atrium and ventricle. For triple-chamber implantable cardiac pacemakers, an electrode was placed in the atrium, and one electrode in each ventricle.

![Diagram of human phantom structure](image)

**Figure I–1–2  Structure of the human phantom**

### 1.2.2 Configuration of measuring equipment

Figure I–1–3 shows a simplified wiring diagram for the measurement equipment used in this study. The human phantom’s pacing pulse detection and pseudo cardiac potential electrode sends a pseudo-cardiac potential signal to the implantable cardiac pacemaker to monitor and record its operation, and to control the operation of the pacemaker when changing operating modes. To perform these functions, the electrode detects the signal from both the atrium and ventricle through a differential amplifier, and after conversion to an unbalanced output, it was connected to a chart recorder and oscilloscope. To deliver the pseudo cardiac potential signal to the implantable cardiac pacemaker, the output of the balanced output amplifier passes through a 2k ohm resistor (embedded in the pseudo cardiac potential generator), and connects to the atrial and ventricular pacing pulse detection and pseudo-cardio potential electrode. The waveform of the pseudo cardiac potential signal is shown in Figure I–1–4. The amplitude is set at approximately 2 times the smallest amplitude when the implantable cardiac pacemaker starts to respond.
1.2.3 Test location
Tests were conducted in an anechoic chamber with a metal floor and no metallic objects within two meters of the test equipment.

1.3 Test conditions
1.3.1 Implantable cardiac pacemaker program configuration
In the following description, the (R) in the instructions for the implantable cardiac pacemaker pacing mode indicates that the device has a rate response feature. This feature mechanically compensates and assists when the pulse rises due to exercise or other activity. In this case, the implantable cardiac pacemaker has a sensor, and when the pulse needs to increase to perform some action, the pacemaker automatically increases the pulse and maintains the pulse output volume. During testing, this function was disabled.
1. Single-chamber implantable cardiac pacemaker
   Operating mode .......... Either AAI (R) or VVI (R), whichever mode had the higher sensitivity.
   Electrode used............. Human phantom ventricular electrode
   Electrode polarity .......... When the polarity could be selected, the test was conducted first in
                               unipolar mode, and then in dipolar mode.
   Rate.......................... 60 ppm
   Refractory period.......... Shortest setting
   Sensitivity .................. Following the measurement procedure. However, when the sensitivity
                               could not be selected in a particular mode, the mode was changed in the
                               middle of the test.
   Other items ................. The other settings were the default settings for this equipment

2. Dual-chamber implantable cardiac pacemaker
   Operating mode .......... Both AAI (R) and VVI (R)
   Electrode used............. Human phantom atrial electrode and ventricle electrode using the normal
                               DDD connection
   Electrode polarity .......... When the polarity could be selected, the test was conducted first in
                               unipolar mode, and then in bipolar mode in both atrium and ventricle.
   Rate.......................... 60 ppm
   Refractory period.......... Shortest setting for both atrium and ventricle
   Sensitivity .................. Following the measurement procedure.
   Other items ................. The other settings were the default settings for this equipment

3. Single-chamber VDD implantable cardiac pacemaker
   Operating mode .......... Both VVI (R) and VDD (R) modes. Tests in VDD mode are performed
                           with a synchronous signal with a rate of 60 ppm and pseudo cardiac
                           potential signal amplitude set at two times the smallest response amplitude
                           for the device, which is sent to the ventricle.
   Electrode used............. Maker-provided electrode
   Electrode polarity .......... When the polarity could be selected, the test was conducted first in
                               unipolar mode, and then in bipolar mode. When using VDD (R) mode, a
                               bipolar electrode is used in the ventricle.
   Rate.......................... VVI (R) mode, 60 ppm; VDD (R) mode, 50 ppm
   Refractory period.......... Shortest setting for both atrium and ventricle
   Sensitivity .................. In VVI (R) mode the ventricle is measured. In VDD (R) mode the atrium
                               is measured. When using VDD (R) mode, the default settings are used for
                               the ventricle.
   Other item................... The other settings were the default settings for this equipment

4. Triple-chamber implantable cardiac pacemaker
   Operating mode .......... Both AAI (R) and VVI (R)
   Electrode used............. Human phantom atrial electrode and ventricle electrode using the normal
                               DDD connection
   Electrode polarity .......... When the polarity could be selected, the test was conducted first in
                               unipolar mode, and then in bipolar mode in both atrium and ventricle.
Rate: 60 ppm
Refractory period............. Shortest setting for both atrium and ventricle
Sensitivity .................. Following the measurement procedure.
Other items .................. The other settings were the default settings for this equipment

5. Single-chamber implantable cardioverter defibrillator
Operating mode ............. Tests are conducted using VVI (R)
Electrode used.............. Human phantom ventricular electrode
Electrode polarity .......... When the polarity could be selected, the test was conducted first in
unipolar mode, and then in bipolar mode.
Rate.......................... 60 ppm
Refractory period........... Shortest setting
Sensitivity .................. Following the measurement procedure. For modes that cannot be set to
the sensitivity indicated in the testing procedure, the device is set to the
sensitivity closest to the required sensitivity.
Other items .................. The tachycardia and fibrillation detection function are set to ON for
implantable cardioverter defibrillators. During this time, any actual
treatment functions that can be set to OFF are set to OFF. The device’s
standard settings are used as the criteria for detection of tachycardia and
fibrillation.

6. Dual-chamber implantable cardioverter defibrillator
Operating mode ............ Both AAI (R) and VVI (R). However, when testing in AAI (R) mode, the
standard sensitivity is used on the ventricle.
Electrode used............... Human phantom atrial electrode and ventricle electrode using the normal
DDD connection
Electrode polarity .......... When the polarity could be selected, the test was conducted first in
unipolar mode, and then in bipolar mode in both atrium and ventricle.
Rate.......................... 60 ppm
Refractory period........... Shortest setting
Sensitivity .................. Following the measurement procedure. For models that cannot be set to
the sensitivity indicated in the testing procedure, the device is set to the
sensitivity closest to the required sensitivity.
Other items .................. The tachycardia and fibrillation detection function are set to ON for
implantable cardioverter defibrillators. During this time, any actual
treatment functions that can be set to OFF are set to OFF. The device’s
standard settings are used as the criteria for detection of tachycardia and
fibrillation.

7. Triple-chamber implantable cardioverter defibrillator
Operating mode ............ Both AAI (R) and VVI (R). However, when testing in AAI (R) mode, the
standard sensitivity is used on the ventricle.
Electrode used............... Human phantom atrial electrode and ventricle electrode using the normal
DDD connection
Electrode polarity .......... When the polarity could be selected, the test was conducted first in
unipolar mode, and then in bipolar mode in both atrium and ventricle.

Rate.................................60 ppm
Refractory period...........Shortest setting
Sensitivity .......................Following the measurement procedure. For models that cannot be set to the sensitivity indicated in the testing procedure, the device is set to the sensitivity closest to the required sensitivity.

Other items .....................The tachycardia and fibrillation detection function are set to ON for implantable cardioverter defibrillators. During this time, any actual treatment functions that can be set to OFF are set to OFF. The device’s standard settings are used as the criteria for detection of tachycardia and fibrillation. The left and right ventricles are stimulated simultaneously.

1.3.2 Implantable cardiac pacemaker operating conditions

1. Inhibit Test: The implantable cardiac pacemaker receives no input signal, and the test is conducted with the unit emitting a pulse at the set rate. This test is applied for single-path VDD implantable cardiac pacemakers in VVI mode as well, but it is not applied in VDD mode.

2. Asynchronous Test: A pseudo cardiac potential of 10 to 20% higher (75 ppm) than the set rate of the implantable cardiac pacemaker is detected, and the output pulse is inhibited. At this time, the pseudo cardiac potential amplitude is set at two times the smallest amplitude of the implantable cardiac pacemaker response. This test is applied for single-path VDD implantable cardiac pacemakers in VVI mode as well, but it is not applied in VDD mode.

3. Tests in VDD mode are performed with a synchronous signal with a rate of 60 ppm and pseudo cardiac potential signal amplitude set at two times the smallest response amplitude for the device, which is sent to the ventricle.

4. False Positive Test: This test is conducted to determine if a fibrillation has been falsely detected (False Positive) when some effect is detected during an Inhibit or Asynchronous test on an implantable cardioverter defibrillator.

5. False Negative Test: For implantable cardioverter defibrillators there are the Inhibit and Asynchronous Tests, in addition to which there is the False Negative test, which tests for the detection of a fibrillation at a pseudo cardiac potential rate that should be detected by the device (240 ppm). However, for implantable cardioverter defibrillators that detect a fibrillation where there is none, as described in (4) above, the false negative test is not done.

1.3.3 Placement of the implantable cardiac pacemakers and the RFID devices

1. The distance between the RFID device and the human phantom is measured from the antenna.

2. The human phantom is positioned 110 cm as measured from the floor to the center of the human phantom (Figure I – 1 – 5; H)

3. The distance between the RFID device and the human phantom (Figure I – 1 – 5; L) is measured from the surface of the antenna of the RFID device and the surface of the human phantom.
1.4 Test protocol

1.4.1 Implantable cardiac pacemaker sensitivity settings

Implantable cardiac pacemaker sensitivity is set to the highest sensitivity setting and then tested. However, when an effect on the implantable cardiac pacemaker occurs at a distance of more than 15 cm, or an unnecessary defibrillation shock occurs, in the case of an implantable cardioverter defibrillator, then the test is conducted with a sensitivity of 1.0, 2.4, or 5.6 mV, or the lowest sensitivity possible for that implantable cardiac pacemaker or other device.

1.4.2 Test procedure

(1) Test 1

At the beginning of the test, the RFID antenna is placed on the surface of the implantable cardiac pacemaker in the human phantom, and then a check is made to see if there is any effect at this close distance (Figure I – 1 – 5; L). If some effect is detected, the antenna is moved away from that location to a distance at which no effect is detected. From that distance, the antenna is turned and otherwise moved to change the polarization and strength of the radio waves, and the distance between the antenna and human phantom (Figure I – 1 – 5; L) is shortened and the distance at which an effect appears is recorded.

Then, at that time, the antenna is moved from above the implantable cardiac pacemaker in the human phantom, along the electrode, and the antenna is positioned at a right angle to the floor and moved from the electrode to above the implantable cardiac pacemaker, and otherwise moved to produce the largest effect possible. When an effect occurs, the chart recorder of the implantable cardiac pacemaker is allowed to run for 5 seconds in that condition.

(2) Test 2

If, during test 1, an effect is detected in the implantable cardiac pacemaker at a distance of more than 15 cm, or the implantable cardioverter defibrillator gives an unnecessary defibrillation shock, the following test is done.

The implantable cardiac pacemaker is set to the next to the highest sensitivity setting and Test 1 is performed again. If the effect appears again, the sensitivity of the implantable cardiac pacemaker is lowered again and Test 1 and Test 2 are repeated. This is done repeatedly.

If the implantable cardiac pacemaker sensitivity setting reaches the lowest setting, the testing is concluded after the last chart is recorded.
1.4.3 Determining the existence of interference

(1) Interference decision

1. After all tests are done, software is used to do an internal check on the implantable cardiac pacemaker, and if a change in the settings or other abnormal change in the unit is detected, interference is determined to have occurred.

2. In Inhibit Tests or in tests of units that are single-path VDD-only implantable cardiac pacemakers in VDD mode, if a pulse is inhibited or there is a change in the pulse interval of even 1 cycle during the observation period of each test, the test is repeated with the same conditions, and if the same effect is observed, interference is determined to have occurred.

3. If during an Asynchronous Test if even one pulse occurs, the test is repeated with the same conditions, and if the same effect is observed, interference is determined to have occurred.

4. During a False Positive Test on implantable cardioverter defibrillators, if the condenser starts to charge for a shock discharge during the Inhibit or Asynchronous Test above, or if arrhythmia is detected, interference is determined to have occurred.

5. During a False Negative test on an implantable cardioverter defibrillator, if the ability to detect a fibrillation is lost, interference is determined to have occurred.

(2) Categorizing the level of effect of the electromagnetic environment

For the sake of consistency, this study uses the same categories of levels of effect of radio waves as that reported in the fiscal 2005 MIC report. The categories of the level of effect are shown in Table I–1–4. The interference observed during this study is categorized using this table. Specific changes observed in
implantable cardiac pacemakers is shown in Table I–1–5, and that for implantable cardioverter defibrillators is shown in Table I–1–6.

**Table I–1–4  Classification of Levels of Effect**

<table>
<thead>
<tr>
<th>Level</th>
<th>Effect criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No effect</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 on their own, such as by leaving the area</td>
</tr>
<tr>
<td>3</td>
<td>May aggravate the patient’s condition if 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 I–1–5  Levels of effects on implantable cardiac pacemaker**

<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>Maintenance of normal function</td>
<td>Level 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abnormal pacing/sensing within 1 cycle (recovery within 2 s)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abnormal pacing/sensing over 1 cycle (2 s)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Pacemaker resetting</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></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></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Permanent breakdown</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Level 5</td>
</tr>
<tr>
<td>Electromotive force applied to lead generates heat</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Level 5</td>
</tr>
</tbody>
</table>

**Table I–1–6  Levels of effects on implantable cardioverter defibrillator**

<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>Maintenance of normal function</td>
<td>Level 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abnormal pacing/sensing within 1 cycle (recovery within 2 s)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Level 1</td>
</tr>
<tr>
<td>Abnormal pacing/sensing over 1 cycle (2 s)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Level 2</td>
</tr>
<tr>
<td>Temporary loss of ability to detect fibrillation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Level 3</td>
</tr>
<tr>
<td>Unnecessary defibrillation shock</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Level 4</td>
</tr>
<tr>
<td>Change in program settings</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Level 4</td>
</tr>
<tr>
<td>Continuous breakdown</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Level 5</td>
</tr>
<tr>
<td>Permanent breakdown</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Level 5</td>
</tr>
<tr>
<td>Electromotive force applied to lead generates heat</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Level 5</td>
</tr>
</tbody>
</table>
1.4.4 Test procedure flow chart

This chart shows the order of tests for testing the effects of RFID devices on implantable cardiac pacemakers.

In this chart, an implantable cardiac pacemaker is referred to as “pacemaker,” and implantable cardioverter defibrillator is referred to as an ICD. The flow chart is shown below.

(1) Single-chamber pacemaker/ICD flow chart

This flow chart applies to both Inhibit and Asynchronous tests.

- The record of the operation at the distance at which an effect occurs should be at least 5 seconds long.
- The distance recorded should be that distance at which no effect occurs.
- In the case of an ICD, check should be made for detection of tachycardia and fibrillation.
This flow chart applies to both Inhibit and Asynchronous tests.

- The record of the operation at the distance at which an effect occurs should be at least 5 seconds long.
- The distance recorded should be that distance at which no effect occurs.
- In the case of an ICD, check should be made for detection of tachycardia and fibrillation.
This flow chart applies to both Inhibit and Asynchronous tests. However, in VDD mode, the test was made only in synchronous operation.

- The record of the operation at the distance at which an effect occurs should be at least 5 seconds long.
- The distance recorded should be that distance at which no effect occurs.
Chapter 2

Analysis of the effect on implantable cardiac pacemakers using the test results

Below are the results of the tests on the effects of the radio waves emitted from UHF RFID devices on implantable cardiac pacemakers. Many implantable cardiac pacemakers have multiple pacing modes, so tests were conducted on the implantable cardiac pacemakers in each of the modes available. In this section, the term “test mode” refers to the mode of the device used when the test was conducted. In addition, the results shown here represent those obtained when the implantable cardiac pacemaker was set to maximum sensitivity, which is the mode in which it is most sensitive to electromagnetic influences in the environment.

2.1 Effects on Handheld UHF RFID devices

We conducted a test on the effects on implantable cardiac pacemakers of the radio waves emitted from handheld UHF RFID devices with a low-output, 950 MHz passive system, called “handheld UHF RFID device (low output)” below. The test used two handheld UHF RFID devices (low output). The same RFID device but with a different antenna was considered a separate type of device, and so the total number of devices tested were 3.

2.1.1 Effect on implantable cardiac pacemakers

Three handheld UHF RFID devices (low output) were tested with 31 implantable cardiac pacemakers. The implantable cardiac pacemakers were each tested in each pacing mode available, resulting in a total of 645 test modes.

Test results showed zero (0) test modes were affected, and so there was no effect of handheld UHF RFID devices (low output) on implantable cardiac pacemakers.

2.1.2 Effect on implantable cardioverter defibrillators

Three handheld UHF RFID devices (low output) were tested with 14 implantable cardioverter defibrillators. Implantable cardioverter defibrillators have several pacing modes that can be selected, as well as selectable pacemaker functions and defibrillation functions. The test results for each function are given below.

(1) Effect on pacemaker function

Test results showed zero (0) test modes were affected out of 144 tested, and so there was no effect of handheld UHF RFID devices (low output) on the pacemaker function of implantable cardioverter defibrillators.

(2) Effect on defibrillator function

Test results showed zero (0) test modes were affected out of 144 tested, and so there was no effect of handheld UHF RFID devices (low output) on the defibrillator function of implantable cardioverter defibrillators.

2.2 Effects of Stationary UHF RFID devices

We conducted a test on the effects on implantable cardiac pacemakers of the radio waves emitted from
handheld UHF RFID devices with a high-output, 950 MHz passive system, called “stationary UHF RFID device (high output)” below. The test used nine stationary UHF RFID devices (low output). Even when the same RFID device was used, it was considered a different model if the number of antennas was changed, or the time that it emits radio waves differed. Thus, the total number of models tested was 12.

2.2.1 Effect on implantable cardiac pacemakers

Twelve stationary UHF RFID devices (high output) were tested with 31 implantable cardiac pacemakers. The implantable cardiac pacemakers were each tested in each pacing mode available, resulting in a total of 2,580 test modes.

(1) Frequency of occurrence of an effect

The number of test modes in which an effect was detected, with each implantable cardiac pacemaker set to the highest sensitivity, was 163, or 6.32% of the test modes. All of the effects were reversible, with a level 1 effect in one test mode and a level 2 effect in 162 test modes. The effect level and test mode relationship are shown in I – 2 – 1. The effect levels are explained in Chapter 1.

<table>
<thead>
<tr>
<th>Effect detected</th>
<th>Number of test modes</th>
<th>Ratio (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>2,580</td>
<td>100</td>
</tr>
<tr>
<td>No effect</td>
<td>2,417</td>
<td>93.68</td>
</tr>
<tr>
<td>Level 1</td>
<td>1</td>
<td>0.04</td>
</tr>
<tr>
<td>Level 2</td>
<td>162</td>
<td>6.28</td>
</tr>
<tr>
<td>Level 3 or above</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Total</td>
<td>163</td>
<td>6.32</td>
</tr>
</tbody>
</table>

(2) Distance at which effect occurs

The greatest distance at which an effect was created was 75 cm, with the implantable cardiac pacemaker set at the highest sensitivity. The effect level at that distance was level 2. The only implantable cardiac pacemaker for which the effect disappeared at a distance of greater than 20 cm was 1 model approved for sale in Japan in 1996, which falls into Period II.

The cumulative distribution of distances at which effects disappeared is shown in table I – 2 – 1.
2.2.2 Effect on implantable cardioverter defibrillators

In this test, 12 stationary UHF RFID devices (high output) were tested with 14 implantable cardioverter defibrillators. Implantable cardioverter defibrillators have several pacing modes that can be selected, as well as selectable pacemaker functions and defibrillation functions. The test results for each function are given below.

(1) Effect on pacemaker function

In this test of the effects of stationary UHF RFID devices (high output) and implantable cardioverter defibrillators with pacemaker functions, there were 552 test modes.

The number of test modes in which the implantable cardioverter defibrillator’s pacemaker function was affected was 17, or 3.08% of the total. The effect level and test mode relationship are shown in Table I–2–2.

<table>
<thead>
<tr>
<th>Effect detected</th>
<th>Total</th>
<th>No effect</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3 or above</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of test modes</td>
<td>552</td>
<td>535</td>
<td>4</td>
<td>13</td>
<td>0</td>
<td>17</td>
</tr>
<tr>
<td>Ratio (%)</td>
<td>100</td>
<td>96.92</td>
<td>0.72</td>
<td>2.36</td>
<td>0.00</td>
<td>3.08</td>
</tr>
</tbody>
</table>

The greatest distance at which an effect was created was 10 cm, with the implantable cardiac pacemaker set at the highest sensitivity. All of the effects were reversible, with a level 1 or level 2 effect. The implantable cardioverter defibrillator affected was one model that was sold in Japan in 2000, during Period III.

The cumulative distribution of distances at which effects disappeared is shown in Table I–2–2.

Figure I–2–2 Relationship between the effect level on implantable cardioverter defibrillators with pacemaker functions of stationary UHF RFID devices (high output) and the distance at which the effect disappears

(2) Effect on defibrillator function

In this test of the effects of stationary UHF RFID devices (high output) and implantable cardioverter defibrillators with defibrillator function, there were 552 test modes.

The number of test modes in which the implantable cardioverter defibrillator’s defibrillator function was...
affected was 17, or 3.08% of the total. This effect was during a False Positive test, in which an unnecessary shock occurred (level 4). The effect level and test mode relationship are shown in I – 2 – 3.

Table I–2–3  The effects of stationary UHF RFID devices (high output) on the defibrillator function of implantable cardioverter defibrillators

<table>
<thead>
<tr>
<th>Total</th>
<th>No effect</th>
<th>Effect detected</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Level 3 or lower</td>
</tr>
<tr>
<td>Number of test modes</td>
<td>552</td>
<td>535</td>
</tr>
<tr>
<td>Ratio (%)</td>
<td>100</td>
<td>96.92</td>
</tr>
</tbody>
</table>

The greatest distance of the device at which the effect (unnecessary shock: Level 4, during False Positive test) occurred was 10 cm. The implantable cardioverter defibrillator affected was one model that was sold in Japan in 2000, during Period III.

The cumulative distribution of distances at which effects disappeared is shown in table I – 2 – 3.

2.3 Effects of modular UHF RFID devices

We conducted a test on the effects on implantable cardiac pacemakers of the radio waves emitted from modular UHF RFID devices with a low-output, 950 MHz passive system, called “modular UHF RFID device (low output)” below. The test used two modular UHF RFID devices (low output). The same RFID device but with a different radio wave emission time was considered a separate device type, and the total number of devices tested were 2.

2.3.1 Effect on implantable cardiac pacemakers

Two modular UHF RFID devices (low output) were tested with 31 implantable cardiac pacemakers. The implantable cardiac pacemakers were each tested in each pacing mode available, resulting in a total of 430 test modes.

Test results showed zero (0) test modes were affected, and so there was no effect of modular UHF RFID devices (low output) on implantable cardiac pacemakers.
2.3.2 Effect on implantable cardioverter defibrillators

Two modular UHF RFID devices (low output) were tested with 14 implantable cardioverter defibrillators. Implantable cardioverter defibrillators have several pacing modes that can be selected, as well as selectable pacemaker functions and defibrillation functions. The test results for each function are given below.

(1) Effect on pacemaker function

Test results showed zero (0) test modes were affected out of 96 tested, and so there was no effect of modular UHF RFID devices (low output) on the pacemaker function of implantable cardioverter defibrillators.

(2) Effect on defibrillator function

Test results showed zero (0) test modes were affected out of 96 tested, and so there was no effect of modular UHF RFID devices (low output) on the defibrillator function of implantable cardioverter defibrillators.
Chapter 3
Measures to prevent interference

3.1 Test Results
RFID devices are expected to find an ever growing range of applications, such as in inventory management, product checkout, prevention of theft, library administration, and even as digital money at game centers and other facilities. This study examines the effects of the radio waves from UHF RFID devices on implantable cardiac pacemakers and implantable cardioverter defibrillators.

3.1.1 Devices tested
This study used the UHF RFID devices and implantable cardiac pacemakers and implantable cardioverter defibrillators listed below.

1 There were 17 UHF RFID devices used in this study: 3 handheld, 12 stationary, and 2 modular devices that represent a comprehensive selection of devices that are available on the market or soon will be.
2 To get a representative sample of the implantable cardiac pacemakers now available, we selected devices on sale in Japan produced in each of the following periods: Period I (1995 or earlier), Period II (1996 to 1998), Period III (1999 to 2002), and Period IV (2003 and later). A total of 31 devices implantable cardiac pacemakers were selected.
3 A comprehensive array of implantable cardioverter defibrillators were also selected in the same manner as implantable cardiac pacemakers. A total of 14 devices were used in this study.

3.1.2 Test results
(1) Handheld UHF RFID devices
1 Of all the implantable cardiac pacemakers tested at the highest sensitivity (total test modes was 645), there were zero (0) that were affected during testing. Thus, the handheld UHF RFID devices (low output) did not affect implantable cardiac pacemakers.
2 Of all the implantable cardioverter defibrillators tested at the highest sensitivity (total test modes was 144), there were zero (0) that were affected during testing. Thus, the handheld UHF RFID devices (low output) did not affect implantable cardioverter defibrillators.

(2) Stationary UHF RFID devices
1 Of all the implantable cardiac pacemakers tested at the highest sensitivity (total test modes was 2,580), there were 163 were affected during testing. The greatest distance at which an effect was created was 75 cm, with the implantable cardiac pacemaker set at the highest sensitivity, and the next greatest distance at which the device was affected was 13 cm. All of the effects were reversible, with a level 1 effect in one test mode and a level 2 effect in 162 test modes. There were no occurrences of level 3 effects or higher, such as the program of the implantable cardiac pacemaker resetting. The only implantable cardiac pacemaker for which an effect was created at a distance of greater than 15 cm was one model approved for sale in Japan in 1996, which falls into Period II.
2 Of all the implantable cardiac pacemakers tested at the highest sensitivity (total test modes was 552,
including pacemaker functions and defibrillator functions), there were 17 test modes that were affected, and the greatest distance at which an effect was created was 10 cm. All of the effects were reversible, with a level 1 or level 2 effect. There were 17 defibrillator functions that were effected, and the greatest distance as which an effect was created was 10 cm. The effect created was an unnecessary defibrillator shock, which is classified as a level 4 effect. The implantable cardioverter defibrillator affected was one model that was approved for sale in Japan in 2000, during Period III.

(3) Modular UHF RFID devices

1 Of all the implantable cardiac pacemakers tested at the highest sensitivity (total test modes was 430), there were zero (0) that were affected during testing. Thus, the modular UHF RFID devices (low output) did not affect implantable cardiac pacemakers.  
2 Of all the implantable cardioverter defibrillators tested at the highest sensitivity (total test modes was 96), there were zero (0) that were affected during testing. Thus, the modular UHF RFID devices (low output) did not affect implantable cardioverter defibrillators.

3.2 Policy for preventing radio wave effects on implantable cardiac pacemakers

RFID devices are expected to be used widely in a broad range of fields, and it is necessary to secure a radio wave environment in which UHF RFID devices and people with implantable cardiac pacemakers can safely coexist. Thus, it is important to develop measures to prevent the ill effects of UHF RFID device radio waves on implantable cardiac pacemakers.

Based on the results of this study, the following policies are indicated for the use of handheld, stationary, and modular UHF RFID devices.

3.2.1 Measures for handheld UHF RFID devices

Handheld UHF RFID devices (low output) did not have an effect on implantable cardiac pacemakers and implantable cardioverter defibrillators. However, handheld UHF RFID devices (low output) are difficult to differentiate from other handheld RFID devices that use another frequency band, and so the measures for people with implantable cardiac pacemakers is based on those measures for handheld devices described in the 2005 study [2].

• The antenna on handheld UHF RFID devices (low output) should not be brought within 22 cm of a person with an implantable cardiac pacemaker.

3.2.2 Measures for stationary UHF RFID devices

Stationary UHF RFID devices (high output) are capable of creating Level 2 effects, which are reversible, on implantable cardiac pacemakers at a distance of up to 75 cm. In addition, Level 4 effects, the occurrence of unnecessary defibrillation shocks, have occurred at a distance of up to 10 cm, and thus the measures for stationary UHF RFID devices (high output) are as follows.

• Because there was an effect on one type of implantable cardiac pacemaker at a distance greater than 22 cm—the value indicated in previous advices on stationary RFID devices—the Pacemaker Committee should advise all member companies that handle implantable cardiac pacemakers, all patient groups, and all medical institutions of this information and make them aware of this fact. In addition, to enable people
with implantable cardiac pacemakers to coexist safely with UHF RFID devices (high output), patients groups and medical institutions should be consulted when forming a policy regarding this situation.

- Japan Automatic Identification Systems Association (JAISA) should establish an information distribution system for guidelines on the use of UHF RFID devices to enable people with implantable cardiac pacemakers to access this information.
- Other than for the one type of implantable cardiac pacemaker that experienced an effect at a distance greater than 22 cm—the value indicated in previous advices on stationary RFID devices—people with implantable cardiac pacemakers should follow the operational regulations for handheld RFID devices described in the RFID Device Guidelines, which is based on the 2005 study [2].
- When using walkthrough UHF RFID devices (high output), follow the operational regulations for walk-through UHF RFID devices described in the RFID Device Guidelines, which is based on the 2005 study [2].

Note:
1. When passing through a passage where a walk-through RFID device is installed or an RFID sticker is visible, people with implanted medical devices should should not stop but should quickly pass through the center of the device.
2. People with implanted medical devices should not remain in the vicinity of a walk-through RFID device nor lean again the device.
3. People with implanted medical devices should consult their doctor if they feel any change in their physical condition.

- People with the model of implantable cardiac pacemaker that experienced an effect at a distance of more than 22 cm, which is the index value for handheld RFID devices, should stay at least one (1) meter away from stationary UHF RFID devices (high output) (annex 3).

### 3.2.3 Measures for modular UHF RFID devices

Modular UHF RFID devices (low output) did not have an effect on implantable cardiac pacemakers and implantable cardioverter defibrillators. Thus, the following measures for modular RFID devices, which are based on the 2005 study [2], is recommended for people with implantable cardiac pacemakers.

- The antenna on modular UHF RFID devices (low output) should not be brought within 22 cm of a person with an implantable cardiac pacemaker.

This study recommends the following measures to reduce the effect of RFID devices on people with implantable cardiac pacemakers.

- RFID devices should carry the sticker recommended in the RFID Device Guideline.
- Related organizations should continue to examine ways to improve the safety of these devices.

### 3.3 Industry measures

Based on the index described in section 3.2, the Japan Automatic Identification Systems Association and the Pacemaker Committee of the Japan Association of Medical Equipment Industries (JAMEI) should take the
following actions to ensure safety.

3.3.1 Measures to be taken by the Japan Automatic Identification Systems Association

1 Guide member companies to improve compliance with placing stickers on UHF RFID devices as well, based on the currently active RFID Device Guidelines. In addition, they should distribute a copy of the RFID Device Guideline to related divisions.
2 Make the RFID Device Guidelines known even to non-member companies through Web sites, magazine advertisements, seminars, and other activities.
3 To reduce the effect of RFID devices on newly developed implantable cardiac pacemakers, the Japan Automatic Identification Systems Association should arrange information exchanges and joint studies between the Pacemaker Committee and universities and other research organizations.
4 Questions posed by people with pacemakers should be answered based on the RFID Device Guideline.

3.3.2 Measures to be taken by the Pacemaker Committee

1 Measures for people with implantable cardiac pacemaker, physicians, and medical institutions regarding UHF RFID devices should be made broadly known by posting them on the committee’s website and through other channels.
2 Because there was an effect on one type of implantable cardiac pacemaker at a distance greater than 22 cm—the value indicated in previous advices on stationary RFID devices—member companies handling this model or devices based on this model should advise all patients, doctors, and medical institutions about these test results and give them a warning.
3 Because handheld UHF RFID devices (high output) had an effect on an implantable cardiac pacemaker at a distance of greater than 22 cm, and because a Level 4 effect—unnecessary defibrillation shock—occurred within 22 cm of an implantable cardioverter defibrillator, the Japan Automatic Identification Systems Association and university research institutions should conduct a joint study to understand the mechanism of this effect, and work to improve safety.

3.4 Issues for the next fiscal year

To reveal the mechanism behind the effects created on implantable cardiac pacemakers by radio waves, a detailed factor analysis test should also be conducted, and an effort made to reduce the effects of radio waves on medical devices.

References
[3] Local base station 950 MHz band mobile device identification wireless equipment
[4] Special low-power base station 950 MHz band mobile device identification wireless equipment

AAMI: Association for the Advancement of Medical Instrumentation.
Researching the effects of radio waves emitted from mobile telephone terminals on electrical medical devices, the Unnecessary Electromagnetic Waves Problem Resolution Conference (currently the Electromagnetic Compatibility Conference) conducted a detailed study on the use of mobile telephone terminals and the standard dipolar antenna. The results of this study were used to create the Policy on the Use of Mobile Telephone Terminals for the Prevention of Effects of Radio Waves on Electric Medical Devices. This policy prescribes that “mobile telephone terminals be used or carried at least 22 cm or more from the location of an implantable cardiac pacemaker.” Then again in fiscal 2000 and 2001 a study was conducted on the effects of radio waves on new implantable cardiac pacemakers and implantable cardioverter defibrillators released after the previous study was conducted. This study used standard dipolar antennas and mobile telephone terminals used by all the telephone service providers at that time. The results of this study validated the policy mentioned earlier [2]. In addition, another study was conducted in fiscal 2004 to confirm that the policy of maintaining a distance of 22 cm was valid for the mobile telephones and implantable cardiac pacemakers released since fiscal 2001 and to maintain an electromagnetic environment in which mobile telephone terminals could be used safely. This study used the mobile telephone terminals, including the card transmitters for laptop computers, and standard dipolar antennas to irradiate a representative selection of implantable cardiac pacemakers and implantable cardioverter defibrillators released in fiscal 2004. The effects were observed, and the 22 cm policy was validated [3]. The same study was conducted in fiscal 2005—again using the mobile telephone terminals and standard dipolar antennas and implantable cardiac pacemakers and implantable cardioverter defibrillators released that year—and again the 22 cm policy was validated. This contributed to the maintainence of an electromagnetic environment in which mobile telephone terminals could be safely used by the public.

However, mobile telephone services that use new frequencies have since been released. Thus, a similar study was conducted in fiscal 2006 to validate the 22 cm policy and to maintain an electromagnetic environment in which mobile telephone terminals can be safely used under this policy. This study used the mobile telephone terminals and the standard dipolar antennas used in the mobile telephone services released in 2006 to irradiate a representative sample of implantable cardiac pacemakers and implantable cardioverter defibrillators also introduced in that year, and the effects of the radio waves were studied. The following report presents the results of this study.
Chapter 1
Electromagnetic Interference Test of 1.7 GHz Radio Waves from W-CDMA Mobile Telephones on Implantable Cardiac Pacemakers

For the sake of consistency with the data of the April 1997 report of the Unnecessary Electromagnetic Waves Problem Resolution Conference [1], the 2002 MIC Report [2], the 2005 MIC Report [3], and the 2006 MIC Report [4], the methodology used in this study to evaluate the effects of the radio waves from mobile telephone terminals on implantable cardiac pacemakers and implantable cardioverter defibrillators was essentially the same as that used in these earlier studies. The human phantom used to replicate the conditions of an implantable cardiac pacemaker in a human being was the same type as that used in the previous studies. In addition to tests using actual mobile telephone terminals, tests were also conducted using the standard dipolar antenna to create the worst possible conditions in this study.

1.1 Devices tested

1.1.1 Implantable cardiac pacemakers

The average life of implantable cardiac pacemakers is 5 to 7 years. New models enter the market every two years or so. Usually, a group of devices are released at one time, with different specifications such as single chamber models, double chamber models, with or without a rate response function. However, these devices are all a subset of the same device, and the electrical properties are identical for each. Thus, the consistency of the implantable cardiac pacemakers and implantable cardioverter defibrillators can be assured if the most common model of each device is selected from each generation of devices. Thus, studies performed after fiscal 2000 use the most common devices, which could be interpreted as being consistent in their electrical properties with all devices on the market, including those from Period I (1995 and before), Period II (1996 – 1998), Period III (1999 – 2002), Period IV (2003 and beyond), and new models approved for import thereafter were the subject of additional studies.

The implantable cardiac pacemakers and other equipment tested were received from the Pacemaker Committee of the Japan Association of Medical Equipment Industries. Table II–1–1 shows the implantable cardiac pacemakers tested and the categories on sale at that time.

<table>
<thead>
<tr>
<th>Period sold in Japan</th>
<th>Types (number of)</th>
<th>Types (number of)</th>
<th>Types (number of)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Implantable cardiac pacemakers</td>
<td>Implantable cardioverter defibrillators</td>
<td>Total</td>
<td></td>
</tr>
<tr>
<td></td>
<td>SSI</td>
<td>DDD</td>
<td>VDD</td>
<td>CRT-P (TDD)</td>
</tr>
<tr>
<td>Period I (1995 and before)</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Period II (1996 – 1998)</td>
<td>3</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Period III (1999 – 2002)</td>
<td>1</td>
<td>8</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Period IV (2003 and beyond)</td>
<td>0</td>
<td>10</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>6</td>
<td>20</td>
<td>3</td>
<td>2</td>
</tr>
</tbody>
</table>
The following is an explanation of the abbreviations used in this table.

SSI : Single-chamber implantable cardiac pacemaker
DDD : Dual-chamber implantable cardiac pacemaker
VDD : Single-path VDD implantable cardiac pacemaker
CRT-P(TDD): Triple-chamber implantable cardiac pacemaker for treating cardiac failure
ICD-S : Single-chamber implantable cardioverter defibrillator
ICD-D : Dual-chamber implantable cardioverter defibrillator
CRT-D : Triple-chamber implantable cardioverter defibrillator

Many of the implantable cardiac pacemakers can be set to one of several pacing modes. In this study, each pacing mode was tested for all implantable cardiac pacemaker models. The implantable cardiac pacemaker models are explained below.

AAI : Uses an atrial electrode. If no autogenic atrial rythym is detected, an electrical stimulation is generated to contract the atrium. When an autogenic atrial rythym is detected, the stimulation is restrained.

VVI : Uses a ventricular electrode. If no autogenic ventricular rhythm is detected during the preset time period, an electrical stimulation is generated to contract the ventricle. When an autogenic ventricular rhythm is detected, the stimulation is restrained.

SSI : The basic unit of the AAI, and VVI implantable cardiac pacemakers are the same, and they are both known by those in the industry by this term.

DDD : Uses electrodes in the atrium and ventricle. This type has functions of both AAI and VVI, and it operates when the atrium and ventricle are out of synch, which is called an AV delay. The operational conditions are complex, but it provides physiological pacing.

VDD : A single electrode with a sensing electrode inside the atrium reaches to the ventricle, and pacing is provided to the ventricle when the atrium and ventricle are out of synch, which is called an AV delay. The atrial electrode floats in the heart chamber, which achieves a higher sensitivity than other methods.

CRT-P (TDD): Used to treat heart failure due to the left and right ventricles being out of synch, and it re-synchronizes both ventricles by stimulating them to contract. This is essentially the same as a dual chamber pacemaker.

ICD-S : Automatically detects ventricular fibrillation (VF) and ventricular tachycardia (VT) and treats it with an electrical stimulation. (includes an SSI pacing function)

ICD-D : Automatically detects ventricular fibrillation (VF) and ventricular tachycardia (VT) and treats it with an electrical stimulation. (includes A DDD pacing function)

CRT-D : Automatically detects ventricular fibrillation (VF) and ventricular tachycardia (VT) and treats it with an electrical stimulation. (includes a CRT-P pacing function)

1.1.2 Mobile telephone terminals

The study this fiscal year uses the mobile telephone terminals from the systems noted in Table II – 1 – 2,
which began service in fiscal 2005. All of the mobile telephone terminals used in this service conform with ARIB standards, and as with previous studies, the mobile telephone terminals used as sources of radio waves were selected from those devices that are available at the time of this study.

The antennas of the mobile telephone terminals used had a gain of -2dBd (the equivalent gain of a complete half-wave antenna). A test was also conducted on the standard dipole antenna using the same amount of power called for in the specifications of the mobile telephone terminal.

The settings of the mobile telephone terminal—transmission power, radio wave output form (continuous output, intermittent output), frequency, and other specifications—were set using an artificial base station.

The radio wave source used in testing the standard dipole antenna was a device composed of a standard dipole antenna and an artificial mobile telephone signal generator. The dimensions of the standard dipole antenna are shown in Table II – 1 – 3.

This study used two types of radio signal generators as shown in Table II – 1 – 4. Mobile telephones—handheld type with dipole antennas—are abbreviated DP in this report.

### Table II–1–2  Wireless attributes of the mobile telephone terminals used in this study

<table>
<thead>
<tr>
<th>ARIB standard name (Standard number)</th>
<th>IMT-2000 DS-CDMA System (STD-T63)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Format name</td>
<td>W-CDMA</td>
</tr>
<tr>
<td>Service name or common name</td>
<td>FOMA</td>
</tr>
<tr>
<td>Transmission frequency band</td>
<td>1700 MHz band</td>
</tr>
<tr>
<td>Access method</td>
<td>CDMA</td>
</tr>
<tr>
<td>Duplexing</td>
<td>FDD</td>
</tr>
<tr>
<td>Number of channels per carrier</td>
<td>Variable</td>
</tr>
<tr>
<td>Bandwidth occupied by carrier</td>
<td>5MHz (variable in increments of 200 kHz)</td>
</tr>
<tr>
<td>Modulation method</td>
<td>First modulation: PSK</td>
</tr>
<tr>
<td></td>
<td>Second modulation: direct diffusion</td>
</tr>
<tr>
<td>Carrier modulation speed</td>
<td>3.84 Mcps (chip rate)</td>
</tr>
<tr>
<td>Maximum output</td>
<td>250mW</td>
</tr>
<tr>
<td>Transmission power control</td>
<td>-1, -2, -3 dB step above 65 dB</td>
</tr>
</tbody>
</table>

### Table II–1–3  Basic specifications of dipole antenna used in this study

<table>
<thead>
<tr>
<th>Name</th>
<th>Maker model name</th>
<th>Frequency range</th>
<th>Gain (Nominal)</th>
<th>VSWR</th>
<th>Connector and nominal input Impedance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1700 MHz dipole antenna</td>
<td>Anritsu</td>
<td>1700-1950MHz</td>
<td>2dBi</td>
<td>Less than 2.0</td>
<td>SMA-J 50Ω</td>
</tr>
</tbody>
</table>

### Table II–1–4  Radio signal generators used in this study as mobile telephone terminals

<table>
<thead>
<tr>
<th>Name</th>
<th>Format name</th>
<th>Service name or common name</th>
<th>Transmission frequency band</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>W-CDMA</td>
<td>FOMA</td>
<td>1700 MHz band</td>
<td>Mobile telephone terminals</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>DP</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Handheld type</td>
</tr>
</tbody>
</table>
1.2 Structure of the tested devices

1.2.1 Configuration of the human phantom and implantable cardiac pacemaker

To simulate the dampening effects of human tissue and the induction of electrical current in the body due to electromagnetic interference, the implantable cardiac pacemaker was placed inside a human phantom shown in Figure II–1–1, which was then filled with 0.18% saline solution (by weight), a condition for immunity testing for implantable cardiac pacemakers using the 450 MHz to 3 GHz range, as prescribed for the evaluation of implantable medical advices in EN45502, which quotes ANSI/AAMI PC69:2000[6]. The implantable cardiac pacemaker electrode was connected as usual (including the lead wires), and the unit was installed on the pacemaker base immersed in 18 mm of water. The study used the electrodes provided with the equipment, but when no electrodes were provided, the study used electrodes from Medtronic. For single-chamber implantable cardiac pacemakers and dual-chamber implantable cardiac pacemakers, one electrode each was placed in the atrium and ventricle. For triple chamber implantable cardiac pacemakers, in addition to the atrial electrode and ventricle electrode, a third electrode was placed in along side the ventricular electrode.

![Image of human phantom and implantable cardiac pacemaker setup](image-url)

**Figure II–1–1** Structure of human phantom used in the testing of mobile telephone terminals

1.2.2 Configuration of measuring equipment

Figure II–1–2 shows a simplified wiring diagram for the measurement equipment used in this study. The human phantom’s pacing pulse detection and pseudo cardiac potential electrode sends a pseudo-cardiac potential signal to the implantable cardiac pacemaker to monitor and record its operation, and to control the...
operation of the pacemaker when changing operating modes. To perform these functions, the electrode detects the signal from both the atrium and ventricle through a differential amplifier, and after conversion to an unbalanced output, it was connected to a chart recorder and oscilloscope. To deliver the pseudo cardiac potential signal to the implantable cardiac pacemaker, the output of the balanced output amplifier passes through a 2k ohm resistor (embedded in the pseudo cardiac potential generator), and connects to the atrial and ventricular pacing pulse detection and pseudo-cardio potential electrode. The waveform of the pseudo cardiac potential signal is shown in Figure II – 1 – 3. The amplitude is set at approximately 2 times the smallest amplitude when the implantable cardiac pacemaker starts to respond.

Figure II–1–2  Configuration of measuring equipment

Figure II–1–3  Wave form of the pseudo cardiac potential

1.2.3  Test location
Tests were conducted in an anechoic chamber with a metal floor and no metallic objects within two meters of the test equipment.

1.3  Test conditions
1.3.1 Implantable cardiac pacemaker program configuration

In the following description, the (R) in the instructions for the implantable cardiac pacemaker pacing mode indicates that the device has a rate response feature. This feature mechanically compensates and assists when the pulse rises due to exercise or other activity. In this case, the implantable cardiac pacemaker has a sensor, and when the pulse needs to increase to perform some action, the pacemaker automatically increases the pulse and maintains the pulse output volume. During testing, this function was disabled.

1. Single-chamber implantable cardiac pacemaker
   Operating mode .............. Either AAI (R) or VVI (R), whichever mode had the higher sensitivity.
   Electrode used............... Human phantom ventricular electrode
   Electrode polarity .......... When the polarity could be selected, the test was conducted first in unipolar mode, and then in bipolar mode.
   Rate .......................... 60 ppm
   Refractory period.......... Shortest setting
   Sensitivity .................. Following the measurement procedure. However, when the sensitivity could not be selected in a particular mode, the mode was changed in the middle of the test.
   Other items .................. The other settings were the default settings for this equipment

2. Dual-chamber implantable cardiac pacemaker
   Operating mode .............. Both AAI (R) and VVI (R)
   Electrode used.............. Human phantom atrial electrode and ventricle electrode using the normal DDD connection
   Electrode polarity .......... When the polarity could be selected, the test was conducted first in unipolar mode, and then in bipolar mode in both atrium and ventricle.
   Rate .......................... 60 ppm
   Refractory period.......... Shortest setting for both atrium and ventricle
   Sensitivity .................. Following the measurement procedure.
   Other items .................. The other settings were the default settings for this equipment

3. Single-chamber VDD implantable cardiac pacemaker
   Operating mode .............. Both VVI (R) and VDD (R) modes. Tests in VDD mode are performed with a synchronous signal with a rate of 60 ppm and pseudo cardiac potential signal amplitude set at two times the smallest response amplitude for the device, which is sent to the ventricle.
   Electrode used............... Maker-provided electrode
   Electrode polarity .......... When the polarity could be selected, the test was conducted first in unipolar mode, and then in bipolar mode.
   When using VDD (R) mode, a bipolar electrode is used in the ventricle.
   Rate .......................... VVI (R) mode, 60 ppm; VDD (R) mode, 50 ppm
   Refractory period.......... Shortest setting for both atrium and ventricle
   Sensitivity .................. In VVI (R) mode the ventricle is measured. In VDD (R) mode the atrium is measured. When using VDD (R) mode, the default settings are used for the ventricle.
   Other items .................. The other settings were the default settings for this equipment
4. Triple-chamber implantable cardiac pacemaker for heart failure treatment
Operating mode ................ Both AAI (R) and VVI (R)
Electrode used .................. Human phantom atrial electrode and ventricle electrode using the normal
                            DDD connection
Electrode polarity ............. When the polarity could be selected, the test was conducted first in
                            unipolar mode, and then in bipolar mode in both atrium and ventricle.
Rate ............................. 60 ppm
Refractory period ............. Shortest setting for both atrium and ventricle
Sensitivity ....................... Following the measurement procedure.
Other items ...................... The other settings were the default settings for this equipment

5. Single-chamber implantable cardioverter defibrillator
Operating mode ............... Tests are conducted using VVI (R)
Electrode used ................. Human phantom ventricular electrode
Electrode polarity ............. When the polarity could be selected, the test was conducted first in
                            unipolar mode, and then in bipolar mode.
Rate ............................. 60 ppm
Refractory period ............. Shortest setting
Sensitivity ....................... Following the measurement procedure. For models that cannot be set to
                            the sensitivity indicated in the testing procedure, the device is set to the
                            sensitivity closest to the required sensitivity.
Other items ...................... The tachycardia and fibrillation detection function are set to ON for
                            implantable cardioverter defibrillators. During this time, any actual
                            treatment functions that can be set to OFF are set to OFF. The device’s
                            standard settings are used as the criteria for detection of tachycardia and
                            fibrillation.

6. Dual-chamber implantable cardioverter defibrillator
Operating mode ............... Both AAI (R) and VVI (R). However, when testing in AAI (R) mode, the
                            standard sensitivity is used on the ventricle.
Electrode used ................. Human phantom atrial electrode and ventricle electrode using the normal
                            DDD connection
Electrode polarity ............. When the polarity could be selected, the test was conducted first in
                            unipolar mode, and then in bipolar mode in both atrium and ventricle.
Rate ............................. 60 ppm
Refractory period ............. Shortest setting
Sensitivity ....................... Following the measurement procedure. For models that cannot be set to
                            the sensitivity indicated in the testing procedure, the device is set to the
                            sensitivity closest to the required sensitivity.
Other items ...................... The tachycardia and fibrillation detection function are set to ON for
                            implantable cardioverter defibrillators. During this time, any actual
                            treatment functions that can be set to OFF are set to OFF. The device’s
                            standard settings are used as the criteria for detection of tachycardia and
                            fibrillation.
7. Triple-chamber implantable cardioverter defibrillator for use in treating heart failure
Operating mode .............. Both AAI (R) and VVI (R). However, when testing in AAI (R) mode, the standard sensitivity is used on the ventricle.

Electrode used..................... Human phantom atrial electrode and ventricle electrode using the normal DDD connection

Electrode polarity .............. When the polarity could be selected, the test was conducted first in unipolar mode, and then in bipolar mode in both atrium and ventricle.

Rate ......................... 60 ppm

Refractory period ............ Shortest setting

Sensitivity ....................... Following the measurement procedure. For models that cannot be set to the sensitivity indicated in the testing procedure, the device is set to the sensitivity closest to the required sensitivity.

Other items ..................... The tachycardia and fibrillation detection function are set to ON for implantable cardioverter defibrillators. During this time, any actual treatment functions that can be set to OFF are set to OFF. The device’s standard settings are used as the criteria for detection of tachycardia and fibrillation. The left and right ventricles are stimulated simultaneously.

1.3.2 Implantable cardiac pacemaker operating conditions

1. Inhibit Test: The implantable cardiac pacemaker receives no input signal, and the test is conducted with the unit emitting a pulse at the set rate. This test is applied for single-path VDD implantable cardiac pacemakers in VVI mode as well, but it is not applied in VDD mode.

2. Asynchronous Test: A pseudo cardiac potential of 10 to 20% higher (75 ppm) than the rate setting of the implantable cardiac pacemaker is detected, and the output pulse is inhibited. At this time, the pseudo cardiac potential amplitude is set at two times the smallest amplitude of the implantable cardiac pacemaker response. This test is applied for single-path VDD implantable cardiac pacemakers in VVI mode as well, but it is not applied in VDD mode.

3. Tests in VDD mode are performed with a synchronous signal with a rate of 60 ppm and pseudo cardiac potential signal amplitude set at two times the smallest response amplitude for the device, which is sent to the ventricle.

4. False Positive Test: This test is conducted to determine if a fibrillation has been falsely detected (False Positive) when some effect is detected during an Inhibit or Asynchronous test on an implantable cardioverter defibrillator.

5. False Negative Test: For implantable cardioverter defibrillators there are the Inhibit and Asynchronous Tests, in addition to which there is the False Negative test, which tests for the detection of a fibrillation at a pseudo cardiac potential rate that should be detected by the device (240 ppm). However, for implantable cardioverter defibrillators that detect a fibrillation where there is none, as described in (4) above, the false negative test is not done.

1.3.3 Radio wave emissions and modulation format

During transmission from a mobile telephone terminal, the base station emits instructions to reduce power usage to the minimum required to effect transmission. Thus, during normal transmission, the device is not
always transmitting at maximum power, and the power is never constant. This study, however, uses the most severe test conditions (err on the side of safety)—and from the point of reproducibility of test data as well—uses a radio transmission mode that is never seen under normal conditions by using the base station to instruct the mobile telephone terminals to constantly emit the maximum output power. In order to create the worst possible conditions for testing the effects of radio waves, this study used the standard dipole antenna, which has a higher gain than an actual mobile telephone, and used a high frequency generator to emit the high frequency modulation format used by mobile telephones, and increased power using a high frequency power amp to boost the power to the specified level.

Tests with mobile telephone terminals were conducted on implantable cardiac pacemakers that received interference during testing with standard dipole antennas.

Previous studies reported that interference at the connector of the pacemaker was determined by the strength of the radio signal, transmission conditions (continuous or intermittent), direction of polarization, carrier frequency, and modulation format.[1] Thus, this study used the same test conditions, which were as follows.

1. The radio waves were emitted from the standard dipole antenna or the actual mobile telephone terminals. When a human body is nearby, it has an absorbing effect, and the antenna gain in the direction of the transmission is several tens of percent lower than when transmitting in open space. Thus, normal transmission without a human body nearby will produce extreme values. In addition, the rectangular human phantom will give an exaggerated evaluation.

2. We confirmed that when the cycle of intermittent radio waves is close to that of the operating period of the pacemaker (the pulse period), electromagnetic interference is greater. Thus, we tested using two conditions as shown in Figure II – 1 – 4(a) and (b): continuous transmission and intermittent transmission in which the interval is 1 second, which is not a normal condition for these telephones. In addition, the implantable cardiac pacemaker’s rate was set at 50 ppm when tested with intermittent radio wave emissions because when set to 60 ppm, the same as the radio wave intermittent cycle, it might enter a cycle that makes it difficult for the effect to cause interference.

3. The antenna feeder current orientation of the standard dipole antenna and actual mobile telephone terminals were set parallel to the surface of the human phantom (x-y), parallel to the x axis (the direction of the access of the pacemaker electrodes), parallel to the y axis (in the direction of the pacemaker lead axis), and in the direction between the two.

4. Because there was almost no difference in the interference effect between different band widths, the carrier frequency of the radio waves was set to one band for these tests. The standard dipole antenna was set at maximum gain in the middle frequencies for these tests.

5. Modulation signal format complied with the standards put forth by the Association of Radio Industries and Businesses.
1.3.4 Placement of the implantable cardiac pacemakers and the radio wave emission source

When the standard dipole antenna is emitting radio waves, a standing wave is created, and the magnetic field is strongest at the feed point (the center), while the electrical field is strongest at the ends. In previous studies, the magnetic field produced the predominant effect, so this study also focused on the connection at the center of the antenna.

1. The reference point used in these tests was the feeder point on the standard dipole antenna and the actual mobile telephone terminal (the center of the standard dipole antenna and the point on the mobile telephone terminal where the antenna connects to the device on the housing surface). During the tests, the antenna was rotated from 0 degrees (parallel with the pacing electrode) to 90 degrees (perpendicular to the electrode) with respect to the implantable cardiac pacemaker.

2. The reference point on the pacemaker was the connection between the electrode lead pin and the connector, on single-electrode connectors, and between the two connectors in a dual-electrode connector.

3. The distance between the implantable cardiac pacemakers and standard dipole antenna or mobile telephone terminal is measured from a source point that is on the surface of the water directly above the implantable cardiac pacemaker’s reference point.

4. The distance at which interference is created on the implantable cardiac pacemakers by the standard dipole antenna or mobile telephone terminal is the distance from the implantable cardiac pacemaker to the standard dipole antenna or mobile telephone terminal.

1.4 Test protocol

1.4.1 Implantable cardiac pacemaker sensitivity settings

Before the test was begun, the implantable cardiac pacemaker sensitivity was set to the highest level.
Thereafter, each time an effect occurred, the test was run again with the sensitivity at 1.0, 2.4, and 5.6 mV or the lowest sensitivity possible on that particular implantable cardiac pacemaker (on devices that could not be set to the sensitivity specified, the closest possible value was selected).

1.4.2 Test procedure

Compared to the antenna on an actual mobile telephone terminal, the standard dipole antenna is much more efficient at emitting radio waves, and thus the effect on implantable cardiac pacemakers is greater. Thus, as in previous studies, the standard dipole antenna is used in screening [2][3][4]. Specifically, first test 1 and test 2 described below were conducted using the standard dipole antenna, and the implantable cardiac pacemaker’s operating mode and electrode polarity were changed during this tests. For those implantable cardiac pacemakers on which an effect was noted during even one operating mode or electrode polarity, test 1 and test 2 were run again using an actual mobile telephone terminal, including all the operating modes and electrode polarities. Figure II – 1 – 5 shows the test procedures

![Test procedure diagram]

**Figure II–1–5 Test procedure**

(1) Test 1

The sensitivity of the implantable cardiac pacemaker is set to the highest level, and the test is begun with the radio wave generator at the source point (the surface of the water directly above the reference point of the implantable cardiac pacemaker).

When an effect occurs, the chart recorder of the implantable cardiac pacemaker is allowed to run for 5 seconds.

Next, the radio wave generator is moved away, and the distance at which the effect no longer occurs is recorded.

(2) Test 2

The following test is conducted on implantable cardiac pacemakers on which an effect occurs.

The affected implantable cardiac pacemaker is set to the next highest sensitivity setting as described in section 1.4.1 and the procedure in test 1 is run again.
If the effect appears again, the sensitivity of the implantable cardiac pacemaker is lowered again in accordance with section 1.4.1, and test 1 and test 2 are repeated.

If the implantable cardiac pacemaker sensitivity setting reaches the lowest setting, the testing is concluded after the last chart is recorded.

### 1.4.3 Determining the existence of interference

#### (1) Interference decision

1. After all tests are done, software is used to do an internal check on the implantable cardiac pacemaker, and if a change in the settings or other abnormal change in the unit is detected, interference is determined to have occurred.

2. In Inhibit Tests or in tests of units that are single-path VDD-only implantable cardiac pacemakers in VDD mode, if a pulse is inhibited or there is a change in the pulse interval of even 1 cycle during the observation period of each test, the test is repeated with the same conditions, and if the same effect is observed, interference is determined to have occurred.

3. If during an Asynchronous Test if even one pulse occurs, the test is repeated with the same conditions, and if the same effect is observed, interference is determined to have occurred.

4. During a False Positive Test on implantable cardioverter defibrillators, if the condenser starts to charge for a shock discharge during the Inhibit or Asynchronous Test above, or if arrhythmia is detected, interference is determined to have occurred.

5. During a False Negative test on an implantable cardioverter defibrillator, if the ability to detect a fibrillation is lost, interference is determined to have occurred.

#### (2) Categorizing the level of effect of the electromagnetic environment

For the sake of consistency, this study uses the same categories of the level of effect of radio waves as that reported in the fiscal 2005 MIC report [3] and the fiscal 2006 MIC report [4]. The categories of the level of effect are shown in Table II – 1 – 5. The effect observed during this study is categorized using this table.

Specific changes observed in implantable cardiac pacemakers is shown in Table II – 1 – 6, and that for implantable cardioverter defibrillators is shown in Table II – 1 – 7.

<table>
<thead>
<tr>
<th>Level</th>
<th>Effect criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No effect</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 on their own, such as by leaving the area</td>
</tr>
<tr>
<td>3</td>
<td>May aggravate the patient’s condition if 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 II–1–6 Levels of effects on implantable cardiac pacemaker

<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>Maintenance of normal function</td>
<td>Level 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abnormal pacing/sensing within 1 cycle (recovery within 2 s)</td>
<td></td>
<td></td>
<td>Level 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abnormal pacing/sensing over 1 cycle (2 s)</td>
<td></td>
<td></td>
<td></td>
<td>Level 2</td>
<td></td>
</tr>
<tr>
<td>- Pacemaker resetting</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Permanent change in program settings</td>
<td></td>
<td></td>
<td></td>
<td>Level 3</td>
<td></td>
</tr>
<tr>
<td>Continuous breakdown</td>
<td></td>
<td></td>
<td></td>
<td>Level 5</td>
<td></td>
</tr>
<tr>
<td>Permanent breakdown</td>
<td></td>
<td></td>
<td></td>
<td>Level 5</td>
<td></td>
</tr>
<tr>
<td>Electromotive force applied to lead generates heat</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Level 5</td>
</tr>
</tbody>
</table>

### Table II–1–7 Levels of effects on implantable cardioverter defibrillator

<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>Maintenance of normal function</td>
<td>Level 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abnormal pacing/sensing within 1 cycle (recovery within 2 s)</td>
<td></td>
<td></td>
<td>Level 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abnormal pacing/sensing over 1 cycle (2 s)</td>
<td></td>
<td></td>
<td></td>
<td>Level 2</td>
<td></td>
</tr>
<tr>
<td>Temporary loss of ability to detect fibrillation</td>
<td></td>
<td></td>
<td></td>
<td>Level 3</td>
<td></td>
</tr>
<tr>
<td>Unnecessary defibrillation shock</td>
<td></td>
<td></td>
<td></td>
<td>Level 4</td>
<td></td>
</tr>
<tr>
<td>Change in program settings</td>
<td></td>
<td></td>
<td></td>
<td>Level 5</td>
<td></td>
</tr>
<tr>
<td>Continuous breakdown</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Level 5</td>
</tr>
<tr>
<td>Permanent breakdown</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electromotive force applied to lead generates heat</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Level 5</td>
</tr>
</tbody>
</table>
1.4.4 Test procedure flow chart

This diagram shows the order of tests for testing the effects of standard dipole antennas or actual mobile telephone terminals on implantable cardiac pacemakers.

In this chart, an implantable cardiac pacemaker is referred to as “pacemaker,” and implantable cardioverter defibrillator is referred to as an ICD. The flow chart is shown below.

(1) Single-chamber pacemaker/ICD flow chart

This flow chart applies to both Inhibit and Asynchronous tests.

- The record of the operation at the distance at which an effect occurs should be at least 5 seconds long.
- The distance recorded should be that distance at which no effect occurs.
- In the case of an ICD, check should be made for detection of tachycardia and fibrillation.
Dual and triple chamber pacemaker/ICD flow chart

This flow chart applies to both Inhibit and Asynchronous tests.

- The record of the operation at the distance at which an effect occurs should be at least 5 seconds long.
- The distance recorded should be that distance at which no effect occurs.
- In the case of an ICD, check should be made for detection of tachycardia and fibrillation.
This flow chart applies to both Inhibit and Asynchronous tests.

- The record of the operation at the distance at which an effect occurs should be at least 5 seconds long.
- The distance recorded should be the distance at which no effect occurs.
Chapter 2
Analysis of the effect on implantable cardiac pacemakers using the test results

Below are the results of the tests on the effects of the radio waves emitted from 1.7 GHz W-CDMA devices on implantable cardiac pacemakers. The tests in this study, as mentioned in Chapter 1, are conducted under the strictest conditions—the continuous or intermittent maximum power output of radio waves, which does not occur with mobile telephone terminals under normal use—and so the results obtained are not applicable to comparing the safety of each mobile telephone format under normal transmission conditions.

2.1 Effect on implantable cardiac pacemakers
The tests of the effects of radio waves emitted by mobile telephone terminals on implantable cardiac pacemakers consisted of a combination of actual mobile telephone terminals and standard dipole antennas, and 31 implantable cardiac pacemakers. Many of the implantable cardiac pacemakers can be set to different pacing modes, and in these tests, each mode of a single device was counted as a different type of device. Thus, though there were 31 implantable cardiac pacemakers, with their different pacing mode settings counted separately, there were 56 implantable cardiac pacemakers tested.

In this test, the sensitivity settings of the implantable cardiac pacemakers were set to the highest possible sensitivity for each device.

2.1.1 Test results
Table II – 2 – 1 shows the total number of implantable cardiac pacemakers, the number of devices on which an effect did not occur, the number of devices on which an effect occurred, and the greatest distance at which that effect occurred.

<table>
<thead>
<tr>
<th>Format name</th>
<th>W-CDMA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transmission frequency band</td>
<td>1.7 GHz</td>
</tr>
<tr>
<td>Maximum output</td>
<td>250 mW</td>
</tr>
<tr>
<td>Radio wave generator</td>
<td>DP</td>
</tr>
<tr>
<td>Implantable cardiac pacemakers tested</td>
<td>56</td>
</tr>
<tr>
<td>Number of devices unaffected</td>
<td>52</td>
</tr>
<tr>
<td>Number of devices affected</td>
<td>4</td>
</tr>
<tr>
<td>The greatest distance at which an effect occurred</td>
<td>3</td>
</tr>
</tbody>
</table>

1. The percentage of devices on which an effect occurred was 7.1% for standard dipole antennas and 1.8% for handheld mobile telephone terminals. All effects were reversible, and the effect level was level 2.
2. The greatest distance at which an effect occurred was 3 cm (level 2) for DP, and less than 1 cm (level 2) for the handheld device.
3. The implantable cardiac pacemakers that were affected were approved for sale in 1997, which falls into the Period II category of this study.
2.1.2 Distribution of effects

Figure II–2–1 shows the accumulative distribution of distances at which the effect ceased to occur between the implantable cardiac pacemakers set to the highest sensitivity and the mobile telephone terminals or standard dipole antenna.

![Figure II–2–1](image)

**Figure II–2–1** The ratio of implantable cardiac pacemakers affected by the W-CDMA (1.7 GHz, 250 mW) and the distance at which the effect stops

As mentioned also in Chapter 1, section 1.4.2, the standard dipole antenna is much more efficient at emitting radio waves than the actual mobile telephone terminal, and so its effect on the implantable cardiac pacemakers is much greater, thus, implantable cardiac pacemakers that were not affected in any of the operational modes or polarities of the electrodes were exempted from testing with an actual mobile telephone terminal.

2.2 Effect on implantable cardioverter defibrillators

The tests of the effects of radio waves emitted by mobile telephone terminals on implantable cardioverter defibrillators consisted of a combination of actual mobile telephone terminals and standard dipole antennas, and 14 implantable cardioverter defibrillators. Implantable cardioverter defibrillators have defibrillation functions and pacemaking functions, as well as several pacing mode settings. In this test, each pacing mode was counted as a separate device even though the physical device is the same. Thus, though there were 14 implantable cardioverter defibrillators, with their different pacing mode settings counted separately, there were 24 implantable cardioverter defibrillators tested. In this test, the sensitivity settings of the implantable cardioverter defibrillators were set to the highest possible sensitivity for each device.
2.2.1 Effect on pacemaker function

As shown in Table II–2–2, there was no effect on the pacemaker function from mobile telephone terminals or standard dipole antennas.

<table>
<thead>
<tr>
<th>Format name</th>
<th>W-CDMA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transmission frequency band</td>
<td>1.7GHz</td>
</tr>
<tr>
<td>Maximum output</td>
<td>250mW</td>
</tr>
<tr>
<td>Radio wave generator</td>
<td>DP Handheld type</td>
</tr>
<tr>
<td>Implantable cardiac pacemakers tested</td>
<td>24 24</td>
</tr>
<tr>
<td>Number of devices unaffected</td>
<td>24 24</td>
</tr>
<tr>
<td>Number of devices affected</td>
<td>0 0</td>
</tr>
<tr>
<td>The greatest distance at which an effect occurred</td>
<td>– –</td>
</tr>
</tbody>
</table>

2.2.2 Effect on defibrillator function

As shown in Table II–2–3, there was no effect on the defibrillator function from mobile telephone terminals or standard dipole antennas.

<table>
<thead>
<tr>
<th>Format name</th>
<th>W-CDMA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transmission frequency band</td>
<td>1.7GHz</td>
</tr>
<tr>
<td>Maximum output</td>
<td>250mW</td>
</tr>
<tr>
<td>Radio wave generator</td>
<td>DP Handheld type</td>
</tr>
<tr>
<td>Implantable cardiac pacemakers tested</td>
<td>24 24</td>
</tr>
<tr>
<td>Number of devices unaffected</td>
<td>24 24</td>
</tr>
<tr>
<td>Number of devices affected</td>
<td>0 0</td>
</tr>
<tr>
<td>The greatest distance at which an effect occurred</td>
<td>– –</td>
</tr>
</tbody>
</table>
3.1 Existing policy

In March 1997, the Unnecessary Electromagnetic Waves Problem Resolution Conference (currently the Electromagnetic Compatibility Conference) released the Policy on the Use of Mobile Telephone Terminals for the Prevention of Effects of Radio Waves on Electric Medical Devices [1] to help prevent the effects of radio waves on implantable cardiac pacemakers, and in that policy it says, “mobile telephone terminals should be used or carried at least 22 cm or more from the location of an implantable cardiac pacemaker.” Then in fiscal 2000 and 2001, and again in fiscal 2004 and 2005, they conducted a study and confirmed that this policy was still applicable [2] [3] [4].

3.2 Test results

As in Chapter 2 of this section, tests were conducted to determine the effect of radio waves emitted from mobile telephone terminals on a selection of implantable cardiac pacemakers and implantable cardioverter defibrillators that could be considered a representative sample of all the devices available in Japan. The results of those tests follow.

The farthest distance at which an effect occurred on an implantable cardiac pacemaker from a W-CDMA (1.7 GHz) mobile telephone terminal was less than 1 cm. There were no effects on implantable cardioverter defibrillators.

Thus the maximum interference distance of the effect of a W-CDMA (1.7 GHz) mobile telephone terminal on implantable cardiac pacemakers is very short at under one 1 cm.

3.3 The validity of existing policy

Based on the results of this study, we can say that the maximum distance at which an effect is created on an implantable cardiac pacemaker by a W-CDMA (1.7 GHz) mobile telephone terminal is short at 1 cm. However, even though this study used the same type of implantable cardiac pacemakers and mobile telephone terminals as those used in the 1997 study, an effect did occur, and the existing policy of “mobile telephone terminals should be used or carried at least 22 cm or more from the location of an implantable cardiac pacemaker” is still valid.

References
test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators”
AAMI: Association for the Advancement of Medical Instrumentation.
Chapter 1

Factor analysis of the effect of radio waves from mobile telephones on implantable cardiac pacemakers and electromagnetic interference test

In a factor analysis on the effects of radio waves emitted from mobile telephone terminals on implantable cardiac pacemakers and implantable cardioverter defibrillators, factors such as frequency, continuous waveform/intermittent waveform, antenna power, rise and fall times, and continuous transmission time were tested and the factors revealed.

1.1 Settings of implantable cardiac pacemakers and implantable cardioverter defibrillator

1.1.1 Implantable cardiac pacemakers tested

The implantable cardiac pacemakers that were tested are shown in Table III–1–1.

<table>
<thead>
<tr>
<th>Type</th>
<th>Implantable cardiac pacemaker</th>
<th>Implantable cardioverter defibrillator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qty</td>
<td>SSI</td>
<td>VDD</td>
</tr>
<tr>
<td>ID number</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

The following is an explanation of the abbreviations used in this table.

SSI : Single-chamber implantable cardiac pacemaker
DDD : Dual-chamber implantable cardiac pacemaker
VDD : Single-path VDD implantable cardiac pacemaker
CRT-P(TDD) : Triple-chamber implantable cardiac pacemaker for treating cardiac failure
ICD-S : Single-chamber implantable cardioverter defibrillator
ICD-D : Dual-chamber implantable cardioverter defibrillator
CRT-D : Triple-chamber implantable cardioverter defibrillator

Many of the implantable cardiac pacemakers can be set to one of several pacing modes.

In this study, each pacing mode was tested for all implantable cardiac pacemaker models.

The implantable cardiac pacemaker models are explained below.

AAI : Uses an atrial electrode. If no autogenic atrial rhythm is detected, an electrical stimulation is generated to contract the atrium. When an autogenic atrial rhythm is detected, the
stimulation is restrained.

**VVI**

Uses a ventricular electrode. If no autogenic ventricular rhythm is detected during the preset time period, an electrical stimulation is generated to contract the ventricle. When an autogenic ventricular rhythm is detected, the stimulation is restrained.

**SSI**

The basic unit of the AAI, and VVI implantable cardiac pacemakers are the same, and they are both known by those in the industry by this term.

**DDD**

Uses electrodes in the atrium and ventricle. This type has functions of both AAI and VVI, and it operates when the atrium and ventricle are out of synch, which is called an AV delay. The operational conditions are complex, but it provides physiological pacing.

**VDD**

A single electrode with a sensing electrode inside the atrium reaches to the ventricle, and pacing is provided to the ventricle when the atrium and ventricle are out of synch, which is called an AV delay. The atrial electrode floats in the heart chamber, which achieves a higher sensitivity than other methods.

**CRT-P (TDD)**

Used to treat heart failure due to the left and right ventricles being out of synch, and it re-synchronizes both ventricles by stimulating them to contract. This is essentially the same as a dual chamber pacemaker.

**ICD-S**

Automatically detects ventricular fibrillation (VF) and ventricular tachycardia (VT) and treats it with an electrical stimulation. (includes an SSI pacing function)

**ICD-D**

Automatically detects ventricular fibrillation (VF) and ventricular tachycardia (VT) and treats it with an electrical stimulation. (includes a DDD pacing function)

**CRT-D**

Automatically detects ventricular fibrillation (VF) and ventricular tachycardia (VT) and treats it with an electrical stimulation. (includes a CRT-P pacing function)

### 1.1.2 Structure of the tested devices

#### 1.1.2.1 Configuration of the human phantom and implantable cardiac pacemaker

To simulate the dampening effects of human tissue and the induction of electrical current in the body due to electromagnetic interference, the implantable cardiac pacemaker was placed inside a human phantom shown in Figure III – 1 – 1, which was then filled with 0.18% saline solution (by weight), a condition for immunity testing for implantable cardiac pacemakers using the 450 MHz to 3 GHz range, as prescribed for the evaluation of implantable medical devices in EN45502, which quotes ANSI/AAMI PC69:2000[2]. The implantable cardiac pacemaker electrode was connected as usual (including the lead wires), and the unit was installed on the pacemaker base immersed in 18 mm of water. The study used the electrodes provided with the equipment, but when no electrodes were provided, the study used electrodes from Medtronic.

For single-chamber implantable cardiac pacemakers and dual-chamber implantable cardiac pacemakers, one electrode each was placed in the atrium and ventricle. For triple chamber implantable cardiac pacemakers, in addition to the atrial electrode and ventricle electrode, a third electrode was placed along side the ventricular electrode.
1.1.2.2 Configuration of measuring equipment

Figure III–1–2 shows a simplified wiring diagram for the measurement equipment used in this study. The human phantom’s pacing pulse detection and pseudo cardiac potential electrode sends a pseudo-cardiac potential signal to the implantable cardiac pacemaker to monitor and record its operation, and to control the operation of the pacemaker when changing operating modes. To perform these functions, the electrode detects the signal from both the atrium and ventricle through a differential amplifier, and after conversion to an unbalanced output, it was connected to a chart recorder and oscilloscope. To deliver the pseudo cardiac potential signal to the implantable cardiac pacemaker, the output of the balanced output amplifier passes through a 2k ohm resistor (embedded in the pseudo cardiac potential generator), and connects to the atrial and ventricular pacing pulse detection and pseudo-cardio potential electrode. The waveform of the pseudo cardiac potential signal is shown in Figure III – 1 – 3. The amplitude is set at approximately 2 times the smallest amplitude when the implantable cardiac pacemaker starts to respond.

Figure III–1–1 Structure of the human phantom used in factor analysis EMI testing
1.1.3 Test conditions

1.1.3.1 Implantable cardiac pacemaker program configuration

In the following description, the (R) in the instructions for the implantable cardiac pacemaker pacing mode indicates that the device has a rate response feature. This feature mechanically compensates and assists when the pulse rises due to exercise or other activity. In this case, the implantable cardiac pacemaker has a sensor, and when the pulse needs to increase to perform some action, the pacemaker automatically increases the pulse and maintains the pulse output volume. During testing, this function was disabled.

1. Single-chamber implantable cardiac pacemaker
   Operating mode .............. Either AAI (R) or VVI (R), whichever mode had the higher sensitivity.
   Electrode used............... Human phantom ventricular electrode
   Electrode polarity .......... When the polarity could be selected, the test was conducted first in unipolar mode, and then in bipolar mode.
   Rate.......................... 60 ppm
Refractory period .......... Shortest setting
Sensitivity .................... Set to the highest sensitivity
Other items .................... The other settings were the default settings for this equipment

2. Dual-chamber implantable cardiac pacemaker
Operating mode .......... Both AAI (R) and VVI (R)
Electrode used ............... Human phantom atrial electrode and ventricle electrode using the normal
                           DDD connection
Electrode polarity .......... When the polarity could be selected, the test was conducted first in
                           unipolar mode, and then in bipolar mode in both atrium and ventricle.
Rate ............................ 60 ppm
Refractory period .......... Shortest setting for both atrium and ventricle
Sensitivity .................... Set to the highest sensitivity
Other items .................... The other settings were the default settings for this equipment

3. Single-chamber VDD implantable cardiac pacemaker
Operating mode .......... Both VVI (R) and VDD (R) modes. Tests in VDD mode are performed
                           with a synchronous signal with a rate of 60 ppm and pseudo cardiac
                           potential signal amplitude set at two times the smallest response amplitude
                           for the device, which is sent to the ventricle.
Electrode used ............... Maker-provided electrode
Electrode polarity .......... When the polarity could be selected, the test was conducted first in
                           unipolar mode, and then in bipolar mode. When using VDD (R) mode, a
                           bipolar electrode is used in the ventricle.
Rate ............................ VVI (R) mode, 60 ppm; VDD (R) mode, 50 ppm
Refractory period .......... Shortest setting for both atrium and ventricle
Sensitivity .................... Set to the highest sensitivity
Other items .................... The other settings were the default settings for this equipment

4. Triple-chamber implantable cardiac pacemaker
Operating mode .......... Both AAI (R) and VVI (R)
Electrode used ............... Human phantom atrial electrode and ventricle electrode using the normal
                           DDD connection
Electrode polarity .......... When the polarity could be selected, the test was conducted first in
                           unipolar mode, and then in bipolar mode in both atrium and ventricle.
Rate ............................ 60 ppm
Refractory period .......... Shortest setting for both atrium and ventricle
Sensitivity .................... Set to the highest sensitivity
Other items .................... The other settings were the default settings for this equipment

5. Single-chamber implantable cardioverter defibrillator
Operating mode .......... Tests are conducted using VVI (R)
Electrode used ............... Human phantom ventricular electrode
Electrode polarity .......... When the polarity could be selected, the test was conducted first in
                           unipolar mode, and then in bipolar mode.
Rate ............................ 60 ppm
Refractory period..........Shortest setting
Sensitivity .................Set to the highest sensitivity
Other items .................The tachycardia and fibrillation detection function are set to ON for implantable cardioverter defibrillators. During this time, any actual treatment functions that can be set to OFF are set to OFF. The device’s standard settings are used as the criteria for detection of tachycardia and fibrillation.

6.  Dual-chamber implantable cardioverter defibrillator
Operating mode ..........Both AAI (R) and VVI (R). However, when testing in AAI (R) mode, the standard sensitivity is used on the ventricle.
Electrode used.............Human phantom atrial electrode and ventricle electrode using the normal DDD connection
Electrode polarity ..........When the polarity could be selected, the test was conducted first in unipolar mode, and then in bipolar mode in both atrium and ventricle.
Rate ..........................60 ppm
Refractory period..........Shortest setting
Sensitivity .................Set to the highest sensitivity
Other items .................The tachycardia and fibrillation detection function are set to ON for implantable cardioverter defibrillators. During this time, any actual treatment functions that can be set to OFF are set to OFF. The device’s standard settings are used as the criteria for detection of tachycardia and fibrillation.

7.  Triple-chamber implantable cardioverter defibrillator
Operating mode ..........Both AAI (R) and VVI (R). However, when testing in AAI (R) mode, the standard sensitivity is used on the ventricle.
Electrode used.............Human phantom atrial electrode and ventricle electrode using the normal DDD connection
Electrode polarity ..........When the polarity could be selected, the test was conducted first in unipolar mode, and then in bipolar mode in both atrium and ventricle.
Rate ..........................60 ppm
Refractory period..........Shortest setting
Sensitivity .................Set to the highest sensitivity
Other items .................The tachycardia and fibrillation detection function are set to ON for implantable cardioverter defibrillators. During this time, any actual treatment functions that can be set to OFF are set to OFF. The device’s standard settings are used as the criteria for detection of tachycardia and fibrillation. The left and right ventricles are stimulated simultaneously.

1.1.3.2 Implantable cardiac pacemaker operating conditions

1.  Inhibit Test: The implantable cardiac pacemaker receives no input signal, and the test is conducted with the unit emitting a pulse at the set rate. This test is applied for single-path VDD implantable cardiac pacemakers in VVI mode as well, but it is not applied in VDD mode.
2. Asynchronous Test: A pseudo cardiac potential of 10 to 20% higher (75 ppm) than the rate setting of the implantable cardiac pacemaker is detected, and the output pulse is inhibited. At this time, the pseudo cardiac potential amplitude is set at two times the smallest amplitude of the implantable cardiac pacemaker response. This test is applied for single-path VDD implantable cardiac pacemakers in VVI mode as well, but it is not applied in VDD mode.

3. Tests in VDD mode are performed with a synchronous signal with a rate of 60 ppm and pseudo cardiac potential signal amplitude set at two times the smallest response amplitude for the device, which is sent to the ventricle.

4. False Positive Test: This test is conducted to determine if a fibrillation has been falsely detected (False Positive) when some effect is detected during an Inhibit or Asynchronous test on an implantable cardioverter defibrillator.

5. False Negative Test: For implantable cardioverter defibrillators there are the Inhibit and Asynchronous Tests, in addition to which there is the False Negative test, which tests for the detection of a fibrillation at a pseudo cardiac potential rate that should be detected by the device (240 ppm). However, for implantable cardioverter defibrillators that detect a fibrillation where there is none, as described in (4) above, the false negative test is not done.

1.1.3.3 Placement of the implantable cardiac pacemakers and the radio wave emission source

When the standard dipole antenna is emitting radio waves, a standing wave is created, and the magnetic field is strongest at the feed point (the center), while the electrical field is strongest at the ends. In previous studies, the magnetic field produced the predominant effect, so this study also focused on the connection at the center of the antenna.

In this test, the standard dipole antenna’s feed point (central part) was used as the reference point. During the tests, the antenna was rotated from 0 degrees (parallel with the pacing electrode) to 90 degrees (perpendicular to the electrode) with respect to the implantable cardiac pacemaker.

1. The reference point on the pacemaker was the connection between the electrode lead pin and the connector, on single-electrode connectors, and between the two connectors in a dual-electrode connector.

2. The distance between the implantable cardiac pacemakers and standard dipole antenna is measured from a source point that is on the surface of the water directly above the implantable cardiac pacemaker’s reference point.

3. The distance at which interference occurs between the implantable cardiac pacemakers and standard dipole antenna is the distance between the implantable cardiac pacemaker and the standard dipole antenna.

1.1.3.4 Implantable cardiac pacemaker sensitivity settings

Implantable cardiac pacemaker’s were set to the highest sensitivity.

1.1.3.5 Determining the existence of interference

(1) Interference decision

1. After all tests are done, software is used to do an internal check on the implantable cardiac pacemaker setting.
pacemaker, and if a change in the settings or other abnormal change in the unit is detected, interference is determined to have occurred.

2. In Inhibit Tests or in tests of units that are single-path VDD-only implantable cardiac pacemakers in VDD mode, if a pulse is inhibited or there is a change in the pulse interval of even 1 cycle during the observation period of each test, the test is repeated with the same conditions, and if the same effect is observed, interference is determined to have occurred.

3. If during an Asynchronous Test if even one pulse occurs, the test is repeated with the same conditions, and if the same effect is observed, interference is determined to have occurred.

4. During a False Positive Test on implantable cardioverter defibrillators, if the condenser starts to charge for a shock discharge during the Inhibit or Asynchronous Test above, or if arrhythmia is detected, interference is determined to have occurred.

5. During a False Negative test on an implantable cardioverter defibrillator, if the ability to detect a fibrillation is lost, interference is determined to have occurred.

(2) Categorizing the level of effect of the electromagnetic environment

For the sake of consistency, this study uses the same categories of the level of effect of a radio waves as that reported in the fiscal 2005 MIC report. The categories of the level of effect are shown in Table III–1–2. The effect observed during this study is categorized using this table. Specific changes observed in implantable cardiac pacemakers is shown in Table III–1–3, and that for implantable cardioverter defibrillators is shown in Table III–1–4.

<table>
<thead>
<tr>
<th>Level</th>
<th>Effect criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No effect</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 on their own, such as by leaving the area</td>
</tr>
<tr>
<td>3</td>
<td>May aggravate the patient’s condition if 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 III–1–3  Levels of effects on implantable cardiac pacemaker

<table>
<thead>
<tr>
<th>Physical phenomenon</th>
<th>Damage status</th>
<th>Reversible effects</th>
<th>Irreversible effects</th>
<th>Direct damage to living body</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance of normal function</td>
<td>Level 0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abnormal pacing/sensing within 1 cycle (recovery within 2 s)</td>
<td></td>
<td>Level 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abnormal pacing/sensing over 1 cycle (2 s)</td>
<td></td>
<td>Level 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Pacemaker resetting</td>
<td></td>
<td></td>
<td>Level 3</td>
<td></td>
</tr>
<tr>
<td>• Permanent change in program settings</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continuous breakdown</td>
<td></td>
<td></td>
<td>Level 5</td>
<td></td>
</tr>
<tr>
<td>Permanent breakdown</td>
<td></td>
<td></td>
<td>Level 5</td>
<td></td>
</tr>
<tr>
<td>Electromotive force applied to lead generates heat</td>
<td></td>
<td></td>
<td></td>
<td>Level 5</td>
</tr>
</tbody>
</table>

### Table III–1–4  Levels of effects on implantable cardioverter defibrillator

<table>
<thead>
<tr>
<th>Physical phenomenon</th>
<th>Damage status</th>
<th>Reversible effects</th>
<th>Irreversible effects</th>
<th>Direct damage to living body</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance of normal function</td>
<td>Level 0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abnormal pacing/sensing within 1 cycle (recovery within 2 s)</td>
<td></td>
<td>Level 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abnormal pacing/sensing over 1 cycle (2 s)</td>
<td></td>
<td>Level 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temporary loss of ability to detect fibrillation</td>
<td></td>
<td>Level 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unnecessary defibrillation shock</td>
<td></td>
<td>Level 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in program settings</td>
<td></td>
<td></td>
<td>Level 4</td>
<td></td>
</tr>
<tr>
<td>Continuous breakdown</td>
<td></td>
<td></td>
<td>Level 5</td>
<td></td>
</tr>
<tr>
<td>Permanent breakdown</td>
<td></td>
<td></td>
<td>Level 5</td>
<td></td>
</tr>
<tr>
<td>Electromotive force applied to lead generates heat</td>
<td></td>
<td></td>
<td></td>
<td>Level 5</td>
</tr>
</tbody>
</table>

### 1.2 Basic test for electromagnetic interference testing

As part of the factor analysis and EMI test on the effects of radio waves on implantable cardiac pacemaker, a basic test was run on the modulation method and the intermittent transmission of radio waves.

Three modulation types were compared: TDMA, CDMA, and no modulation.

As a result of the comparison, the modulation method for radio waves used in the tests for factor analysis was un-modulated (CW) (see annex 1).
1.3 Frequency test

1.3.1 Test protocol

The implantable cardiac pacemakers used in the tests were SSI (1), VDD (2), DDD (3), CRT-P (4), and the implantable cardioverter defibrillators were ICD-S (5), ICD-D (6), and CRT-D (7).

The test evaluated the effects of the characteristics of different frequencies by fixing the test distance at that distance at which an effect occurred between the surface of the water of the human phantom and the standard dipole antenna, and finding the antenna input power (at the antenna’s coaxial junction) at which an effect is created on the implantable cardiac pacemaker at each frequency.

1.3.2 Basic specifications of measuring equipment used

Figure III – 1 - 5 shows the specifications of the measuring equipment.

<table>
<thead>
<tr>
<th>Device name</th>
<th>Maker (Model name)</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard signal generator</td>
<td>Agilent technology</td>
<td>Freq. range: 250 kHz to 3 GHz&lt;br&gt;Resolution: 0.01 Hz&lt;br&gt;Output: -136 dBm to + 10 dBm</td>
</tr>
<tr>
<td>RF power amp</td>
<td>R&amp;K A0825-4343-R</td>
<td>Freq. range: 800 kHz to 2.5 GHz&lt;br&gt;Gain: 40 dB&lt;br&gt;Output: 20 W</td>
</tr>
<tr>
<td>Spectrum analyzer</td>
<td>Agilent technology</td>
<td>Freq. range: 9 kHz to 3 GHz&lt;br&gt;Dynamic range: max 97 dB&lt;br&gt;Resolution bandwidth: 10 Hz to 5 Mhz: -151 dBm to + 30 dBm</td>
</tr>
<tr>
<td>Dipole antenna</td>
<td>Anritsu (MA5612A2)</td>
<td>Freq. range: 880 kHz to 960 MHz&lt;br&gt;Input impedance: 50 ohms</td>
</tr>
<tr>
<td>Dipole antenna</td>
<td>Anritsu (MA5612A3)</td>
<td>Freq. range: 1.4 GHz to 1.55 GHz&lt;br&gt;Input impedance: 50 ohms</td>
</tr>
<tr>
<td>Dipole antenna</td>
<td>Anritsu (MA5612B2)</td>
<td>Freq. range: 1.7 GHz to 1.95 GHz&lt;br&gt;Input impedance: 50 ohms</td>
</tr>
<tr>
<td>Dipole antenna</td>
<td>Anritsu (MA5612B3)</td>
<td>Freq. range: 1.95 GHz to 2.25 GHz&lt;br&gt;Input impedance: 50 ohms</td>
</tr>
<tr>
<td>Digital oscilloscope</td>
<td>Agilent technology</td>
<td>Channels: 4&lt;br&gt;Max sample: 10GS/s&lt;br&gt;Frequency band: 2 GHz</td>
</tr>
<tr>
<td>Pseudo cardiac potential</td>
<td>Japan Medtronic</td>
<td>Voltage periodic rate to simulate a pulse: 60ppm, 75ppm, 180ppm, 220ppm</td>
</tr>
<tr>
<td>generator</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chart recorder</td>
<td>NEC Sanei (RA2300)</td>
<td>Channels: max 16&lt;br&gt;Sampling: 1 μs to 1 s</td>
</tr>
</tbody>
</table>

Figure III – 1- 4 shows the configuration of the measuring equipment.
1.3.3 Settings and fixed parameters

The fixed frequencies were 920 MHz, 1475 MHz, 1825 MHz, and 2100 MHz.

Table III–1–6 shows the fixed parameters.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modulation method</td>
<td>No modulation (CW)</td>
</tr>
<tr>
<td>Antenna input power</td>
<td>Maximum 5 W</td>
</tr>
<tr>
<td>Waveform</td>
<td></td>
</tr>
<tr>
<td>Period</td>
<td>990ms</td>
</tr>
<tr>
<td>Duty ratio</td>
<td>50%</td>
</tr>
<tr>
<td>Rise time/fall time</td>
<td>30ns/30ns</td>
</tr>
</tbody>
</table>

1.3.4 Test results

The following results were obtained when testing implantable cardiac pacemakers and implantable cardioverter defibrillators for the power at which an effect is created due to different impressed voltage frequencies.

Implantable cardiac pacemakers 2 and 4 and implantable cardioverter defibrillator 7 did not experience any effect even when the maximum power input was used.

The test results are expressed using the relative power value, which is the standardized power value that creates the smallest frequency at which an effect had occurred.

Figure III–1–5 and Figure III–1–6 show the impressed voltage frequency and the power level at which an effect was created on the implantable cardiac pacemaker and implantable cardioverter defibrillator’s pacemaker function, respectively. The effect created on the implantable cardioverter defibrillator’s defibrillation function was not an unnecessary defibrillation shock (False Positive).

Based on these results, the power level at which an effect occurs on an implantable cardiac pacemaker is dependent upon the impressed frequency, and at 920 MHz and 1825 MHz, there was about a 15 dB difference.
Figure III – 1 – 5 Impressed frequencies and power levels at which effects occurred on an implantable cardiac pacemaker with single electrode setting

Figure III – 1 – 6 Impressed frequencies and power levels at which effects occurred on an implantable cardiac pacemaker in bipolar mode
Figure III–1–7  Impressed frequencies and power levels at which effects occurred on an implantable cardioverter defibrillator in bipolar mode

1.4  Antenna input power test

1.4.1  Test protocol

The implantable cardiac pacemakers and implantable cardioverter defibrillators that exhibited an effect during the frequency test were tested: SSI (1), DDD (3), ICD-S (5), ICD-D (6).

In this test, the input power was fixed (at the antennas coaxial input), and the distance between the standard dipole antenna and the water surface of the human phantom was changed. The distance at which the device was affected was then recorded, and the power input and effect distance were evaluated.
### 1.4.2 Basic specifications of measuring equipment used

Figure III – 1 – 7 shows the specifications of the measuring equipment.

#### Table III–1–7 Specifications of the measuring equipment

<table>
<thead>
<tr>
<th>Device name</th>
<th>Maker (Model name)</th>
<th>Specifications</th>
</tr>
</thead>
</table>
| Standard signal generator       | Agilent technology (E4421B) | Freq. range: 250 kHz to 3 GHz  
Resolution: 0.01 Hz  
Output: -136 dBm to + 10 dBm |
| RF power amp                    | R&K A0825-4343-R    | Freq. range: 800 kHz to 2.5 GHz  
Gain: 40 dB  
Output: 20 W |
| Spectrum analyzer               | Agilent technology (E4402B) | Freq. range: 9 kHz to 3 GHz  
Dynamic range: max 97 dB  
Resolution bandwidth: 10 Hz to 5 Mhz: -151 dBm to + 30 dBm |
| Dipole antenna                  | Anritsu (MA5612A2)  | Freq. range: 880 kHz to 960 MHz  
Input impedance: 50 ohms |
| Digital oscilloscope            | Agilent technology (54852A) | Channels: 4  
Max sample: 10GS/s  
Frequency band: 2 GHz |
| Pseudo cardiac potential generator | Japan Medtronic | Voltage periodic rate to simulate a pulse: 60ppm, 75ppm, 180ppm, 220ppm |
| Chart recorder                  | NEC Sanei (RA2300)  | Channels: max 16  
Sampling: 1 μs to 1 s |

The configuration of the measurement equipment is the same as that described in the frequency test is section 1.3. (Figure III – 1 – 4)

### 1.4.3 Settings and fixed parameters

The power settings for the antenna were 10 mW, 30 mW, 300 mW, 1 W, and 3 W.

Table III – 1 – 8 shows the fixed parameters.

#### Table III–1–8 Fixed parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>920 MHz</td>
</tr>
<tr>
<td>Modulation method</td>
<td>No modulation (CW)</td>
</tr>
<tr>
<td>Waveform</td>
<td></td>
</tr>
<tr>
<td>Period</td>
<td>990ms</td>
</tr>
<tr>
<td>Duty ratio</td>
<td>50%</td>
</tr>
<tr>
<td>Rise time/fall time</td>
<td>30ns/30ns</td>
</tr>
</tbody>
</table>

### 1.4.4 Test results

The distance at which an effect occurs on an implantable cardiac pacemaker or implantable cardioverter defibrillator are shown in Figure III – 1 – 8 and Figure III – 1 – 9.

These results show that, on implantable cardiac pacemakers and implantable cardioverter defibrillators, the greater the impressed power, the larger the effect distance.
1.5 Intermittent waveform test

1.5.1 Test protocol

The implantable cardiac pacemakers and implantable cardioverter defibrillators that exhibited an effect during the frequency test were tested: SSI (1), DDD (3), ICD-S (5), ICD-D (6).

The test evaluated the effects of the characteristics of intermittent frequencies by fixing the test distance...
at that distance at which an effect occurred between the surface of the water of the human phantom and the standard dipole antenna, and finding the antenna input power (at the antenna’s coaxial junction) at which an effect is created on the implantable cardiac pacemaker at each intermittent frequency.

1.5.2 Basic specifications of measuring equipment used

The specifications of the measurement equipment are the same as those described in the antenna power input test in section 1.4. (Table III – 1 – 7)

The configuration of the measurement equipment is the same as that described in the frequency test is section 1.3. (Figure III – 1 – 4)

1.5.3 Settings and fixed parameters

The period of the intermittent wave form was 0.6 Hz, 1.01 Hz, 2 Hz, 4 Hz, 10 Hz, 100 Hz, and 500 Hz. Table III – 1 – 9 shows the fixed parameters.

Table III–1–9  Fixed parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>920 MHz</td>
</tr>
<tr>
<td>Modulation method</td>
<td>No modulation (CW)</td>
</tr>
<tr>
<td>Antenna input power</td>
<td>Variable</td>
</tr>
</tbody>
</table>
| Waveform                    | Duty ratio
|                             | 5% (In test and Fp test)        |
|                             | 95% (As test)                   |
| Rise time/fall time         | 30ns/30ns                       |

1.5.4 Test results

The following results were obtained when testing implantable cardiac pacemakers and implantable cardioverter defibrillators for the effect created due to intermittent frequencies of the radio waves.

The test results are expressed using the relative power value, which is the standardized power value that creates the smallest frequency at which an effect had occurred.

The relationship between power level at which an effect is created and the radio wave intermittent frequency are shown in Figure III – 1 – 10 and Figure III – 1 – 11 Implantable cardiac pacemakers, and Figure III – 1 – 12 and Figure III – 1 – 13 Implantable cardioverter defibrillators.

The results show that there is no difference in the effect on the implantable cardiac pacemakers or the pacemaker function of the implantable cardioverter defibrillators for intermittent frequencies below the 4 Hz level, and above that level, there is a maximum 10 dB difference. In addition, the implantable cardioverter defibrillator’s defibrillation function showed a tendency to give an unnecessary defibrillation shock (False Positive) at lower power levels when the radio wave intermittent frequency was at the 4 Hz and 10 Hz level, as shown in Figure III – 1 – 13
Figure III–1–10  Intermittent frequencies and power levels at which effects occurred on an implantable cardiac pacemaker in unipolar mode.

Figure III–1–11  Intermittent frequencies and power levels at which effects occurred on an implantable cardiac pacemaker in bipolar mode.
Relative power that causes an effect [dB] 
Lowest power level that caused an effect during the inhibit test 
Lowest power level that caused an effect during the asynchronous test  
(The effect created was the reset of the defibrillator) 

Intermittent frequency [Hz] 

Figure III–1–12  Intermittent frequencies of the radio waves and power levels at which effects occurred on an implantable cardioverter defibrillator (pacemaker function)  

Figure III–1–13  Intermittent frequencies of the radio waves and power levels at which effects occurred on an implantable cardioverter defibrillator (defibrillator function)
1.6 Continuous time test

1.6.1 Test protocol

The implantable cardiac pacemakers and implantable cardioverter defibrillators that exhibited an effect during the frequency test were tested: SSI (1), DDD (3), ICD-S (5), ICD-D (6).

The test evaluated the effects of the duty ratio by fixing the test distance at that distance at which an effect occurred between the surface of the water of the human phantom and the standard dipole antenna, and finding the antenna input power (at the antenna’s coaxial junction) at which an effect is created on the implantable cardiac pacemaker at each duty ratio.

1.6.2 Basic specifications of measuring equipment used

The specifications of the measurement equipment are the same as those described in the antenna power input test in section 1.4. (Table III – 1 – 7)

The configuration of the measurement equipment is the same as that described in the frequency test is section 1.3. (Figure III – 1 – 4)

1.6.3 Settings and fixed parameters

The duty ratios used were 1%, 2%, 5%, 10%, 30%, 50%, 70%, 90%, 95%, 98%, 99%.

Table III – 1 – 10 shows the fixed parameters.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>920 MHz</td>
</tr>
<tr>
<td>Modulation method</td>
<td>No modulation (CW)</td>
</tr>
<tr>
<td>Antenna input power</td>
<td>Variable</td>
</tr>
<tr>
<td>Waveform</td>
<td></td>
</tr>
<tr>
<td>Period</td>
<td>990 ms</td>
</tr>
<tr>
<td>Rise time/fall time</td>
<td>30ns/30ns</td>
</tr>
</tbody>
</table>

1.6.4 Test results

The following results were obtained when testing implantable cardiac pacemakers and implantable cardioverter defibrillators for the power at which an effect is created due to different duty ratios.

The test results are expressed using the relative power value, which is the standardized power value that creates the smallest frequency at which an effect had occurred.

The relationship between power level at which an effect is created and the duty ratio are shown in Figure III – 1 – 14 and Figure III – 1 – 15 for implantable cardiac pacemakers and Figure III – 1 – 16 and Figure III – 1 – 17 for implantable cardioverter defibrillators.

As shown in Figure III – 1 – 14, the implantable cardiac pacemaker in unipolar mode is more likely to be affected during the Inhibit test when the duty ratio is 5% or 10%, and when the duty ratio is 1% to 2% or above 30%, the power difference become up to 5 dB greater.

In the Asynchronous test, an effect is created when the duty ratio is above 30%, but above 50%, the power level was 10 dB higher than at the 30% level, and an effect occurred, though it was small.
Figure III – 1 – 15 shows the test results for implantable cardiac pacemakers in bipolar mode. During the Inhibit test, there was no difference in the power level at which an effect was created due to different duty ratios, but when the duty ratio was smaller, there was a slight increase in the power level.

In the Asynchronous test, there was an effect when the duty rate was 50% or higher, but as the duty rate increased, the power decreased.

Figure III – 1 – 16 shows the duty rate and the effect on the implantable cardioverter defibrillator’s pacemaker function. The power that created an effect in the Asynchronous test decreased by about 5 dB when the duty rate was between 2% and 50%, but it leveled out when the duty rate was 70% or greater. Figure III – 1 – 17 shows the duty rate of the impressed radio waves and the effect on the implantable cardioverter defibrillator’s defibrillation function. The unnecessary defibrillation shock (False Positive) occurred only at a duty rate of 70% or above.

Figure III–1–14 Duty ratio and power levels at which effects occurred on an implantable cardiac pacemaker in unipolar mode
Figure III–1–15  Duty ratio and power levels at which effects occurred on an implantable cardiac pacemaker in bipolar mode.

(The effect created was the reset of the defibrillator)

Figure III–1–16  Duty ratio and power levels at which effects occurred on an implantable cardioverter defibrillator (pacemaker function)
Figure III–1–17  Duty ratio and power levels at which effects occurred on an implantable cardioverter defibrillator (defibrillator function)

1.7  Rise time/fall time test

1.7.1  Test protocol

The implantable cardiac pacemakers and implantable cardioverter defibrillators that exhibited an effect during the frequency test were tested: SSI (1), DDD (3), ICD-S (5), ICD-D (6).

The test evaluated the effects of the differing rise time/fall times by fixing the test distance at that distance at which an effect occurred between the surface of the water of the human phantom and the standard dipole antenna, and finding the antenna input power (at the antenna’s coaxial junction) at which an effect is created on the implantable cardiac pacemaker to evaluate the relationship with the rise and fall time.
1.7.2 Basic specifications of measuring equipment used

Figure III -11 shows the specifications of the measuring equipment.

<table>
<thead>
<tr>
<th>Device name</th>
<th>Maker</th>
<th>Specifications</th>
</tr>
</thead>
</table>
| Pulse generator              | Agilent technology (81110A) | Freq. range: 1 mHz to 330 MHz  
Timing resolution: 3.5 digits, 5 ps  
Amplitude: 11 mVpp to 3.8 Vpp (50 ohm load)  
Transition time range 0.8 ns or 1.6 ns (selectable) |
| RF power amp                | R&K A0825-4343-R           | Freq. range: 800 kHz to 2.5 GHz  
Gain: 40 dB  
Output: 20 W |
| Spectrum analyzer           | Agilent technology (E4402B) | Freq. range: 9 kHz to 3 GHz  
Dynamic range: max 97 dB  
Resolution bandwidth: 10 Hz to 5 Mhz: -151 dBm to + 30 dBm |
| Dipole antenna              | Anritsu (MA5612A2)         | Freq. range: 880 kHz to 960 MHz  
Input impedance: 50 ohms |
| Digital oscilloscope        | Agilent technology (54852A) | Channels: 4  
Max sample: 10GS/s  
Frequency band: 2 GHz |
| Pseudo cardiac potential generator | Japan Medtronic           | Voltage periodic rate to simulate a pulse: 60ppm, 75ppm, 180ppm, 220ppm |
| Chart recorder              | NEC Sanei (RA2300)         | Channels: max 16  
Sampling: 1 μs to 1 s |

Figure III – 1 – 18 shows the configuration of the measuring equipment.
1.7.3 Settings and fixed parameters

The rise time/fall times were 50µs, 100µs, 500µs, 1ms, 5ms, 10ms, 50ms, 100ms.

Table III– 1 – 12 shows the fixed parameters.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>920 MHz</td>
</tr>
<tr>
<td>Modulation method</td>
<td>No modulation (CW)</td>
</tr>
<tr>
<td>Antenna input power</td>
<td>Variable</td>
</tr>
<tr>
<td>Waveform</td>
<td></td>
</tr>
<tr>
<td>Period</td>
<td>990ms</td>
</tr>
<tr>
<td>Duty ratio</td>
<td>50%</td>
</tr>
</tbody>
</table>

1.7.4 Test results

The following results were obtained when testing implantable cardiac pacemakers and implantable cardioverter defibrillators for the effect created due to rise times and fall times of the radio waves.

The test results are expressed using the relative power value, which is the standardized power value that creates the smallest frequency at which an effect had occurred.

The rise times and fall times of the radio waves and the power level at which an effect was created are show in Figure III – 1 – 19 and Figure III – 1 – 20 for the implantable cardiac pacemaker and Figure III – 1 – 21 for the implantable cardioverter defibrillator’s pacemaker function. The effect created on the implantable cardioverter defibrillator’s defibrillation function was not an unnecessary defibrillation shock (False Positive).

From these results, we can see that the implantable cardiac pacemaker and implantable cardioverter defibrillator both experienced no change for rise and fall times of between 0.05 msec and 5 msec, but at 10 msec or higher, the power increased by a maximum of 12 dB during the Inhibit test, showing a tendency towards a dependence on the rise and fall times.
Unipolar

Relative power that causes an effect [dB]

Lowest power level that caused an effect during the inhibit test

Lowest power level that caused an effect during the asynchronous test

Rise time/fall time [msec]

Figure III–1–19  Rise and fall times and power levels at which effects occurred on an implantable cardiac pacemaker in unipolar mode

Bipolar

Relative power that causes an effect [dB]

Lowest power level that caused an effect during the inhibit test

Lowest power level that caused an effect during the asynchronous test

Rise time/fall time [msec]

Figure III–1–20  Rise and fall times and power levels at which effects occurred on an implantable cardiac pacemaker in bipolar mode
Relative power that causes an effect [dB]

Lowest power level that caused an effect during the inhibit test
Lowest power level that caused an effect during the asynchronous test
(The effect created was the reset of the defibrillator)

Rise time/fall time [msec]

Figure III–1–21  Rise and fall times and power levels at which effects occurred on an implantable cardioverter defibrillator (pacemaker function)
Chapter 2
Factor analysis of the effect of radio waves from RFID devices on implantable cardiac pacemakers

2.1 RFID device types

RFID devices can be categorized by their appearance: (1) gate type, (2) handheld type, (3) stationary type, and (4) modular type.

Table III – 2 – 1 shows the RFID devices by type.

<table>
<thead>
<tr>
<th>Type</th>
<th>Frequency</th>
<th>Specifications</th>
<th>Output power</th>
<th>Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gate type</td>
<td>Less than 135 kHz*</td>
<td>Induction communication equipment</td>
<td>Annex 2, Figure 1</td>
<td>Libraries, door monitoring, stores, game centers, etc.</td>
</tr>
<tr>
<td></td>
<td>500kHz</td>
<td>Induction communication equipment</td>
<td>Annex 2, Figure 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>13.56MHz</td>
<td>ARIB STD-T82</td>
<td>Annex 2, Table 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>950MHz</td>
<td>ARIB STD-T89</td>
<td>Less than 1 W</td>
<td></td>
</tr>
<tr>
<td>Hand-held type</td>
<td>Less than 135 kHz*</td>
<td>Induction communication equipment</td>
<td>Annex 2, Figure 1</td>
<td>Fast food restaurants, events, inventory management, logistics, product tracing, etc.</td>
</tr>
<tr>
<td></td>
<td>13.56MHz</td>
<td>ARIB STD-T82</td>
<td>Annex 2, Table 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>300MHz</td>
<td>Weak base station</td>
<td>Annex 2, Figure 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>950MHz</td>
<td>ARIB STD-T90</td>
<td>Less than 10 mW</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.45GHz</td>
<td>ARIB STD-T81</td>
<td>Annex 2, Table 2</td>
<td></td>
</tr>
<tr>
<td>Stationary type</td>
<td>Less than 135 kHz*</td>
<td>Induction communication equipment</td>
<td>Annex 2, Figure 1</td>
<td>Gas stations, game centers, etc.</td>
</tr>
<tr>
<td></td>
<td>13.56MHz</td>
<td>ARIB STD-T82</td>
<td>Annex 2, Table 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>300MHz</td>
<td>Weak base station</td>
<td>Annex 2, Figure 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>950MHz</td>
<td>ARIB STD-T89</td>
<td>Less than 1 W</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.45GHz</td>
<td>ARIB STD-T81/ RCR STD-1/ RCR STD-29</td>
<td>Annex 2, Table 2</td>
<td>Less than 300 W</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Less than 10 mW</td>
</tr>
<tr>
<td>Modular type</td>
<td>Less than 135 kHz*</td>
<td>Induction communication equipment</td>
<td>Annex 2, Figure 1</td>
<td>Printers, bookshelves, and other places where they can be embedded</td>
</tr>
<tr>
<td></td>
<td>13.56MHz</td>
<td>ARIB STD-T82/weak base station</td>
<td>Annex 2, Table 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>300MHz</td>
<td>Weak base station</td>
<td>Annex 2, Figure 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>950MHz</td>
<td>ARIB STD-T90</td>
<td>Less than 10 mW</td>
<td></td>
</tr>
</tbody>
</table>

* 125kHz, 134.2kHz, 135kHz
2.2 Test parameter selection

Because the applications of stationary short-distance electromagnetic coupling RFID devices are so specialized, there is little concern that people with implantable cardiac pacemakers will get close to them, so we examined the possibility of not doing a factor analysis test. The basic concept behind electromagnetic induction and radio waves is different, so we selected test parameters that matched the operating principles of the equipment.

Through prior tests, we confirmed the special effects of EMI from frequency, signal waveform, and antenna input power, so we evaluated the effect of the following test parameters.

Summary of each test type

**Frequency test (changes due to frequency EMI characteristics)**

- Electromagnetic induction RFID (125 kHz, 13.56 MHz)
- Radio wave RFID (953 MHz, 2.45 GHz)

  - Test mode: CW or intermittent waveform
  - Pulse modulation format: period 1 s, duty ratio 50%
  - For each test mode, we compared the effect when the antenna was stationary and in motion
  - Antenna power input: 1 W

**Intermittent waveform test (changes due to frequency EMI characteristics)**

- Electromagnetic induction RFID (125 kHz, 13.56 MHz)
- Radio wave RFID (953 MHz, 2.45 GHz)

  - Test mode: Intermittent waveform
  - Pulse modulation format: period 2 ms to 2 s, duty ratio 50%
  - Antenna power input: 1 W

  * 125 kHz R/W can be set to any of the following periods: 2ms, 5ms, 10ms, 20ms, 50ms, 100ms, 200ms, 500ms, 1s, 2s, 5s
Antenna input power test (changes due to antenna power input)

Electromagnetic induction RFID (125 kHz, 13.56 MHz)
- Test mode: CW or intermittent waveform
- Pulse modulation format: period 1 s, duty ratio 50%
- Antenna input power: Within the tolerance of the antenna on the actual equipment
- Magnetic field strength: Measured for each different antenna input power
- Rise and fall time: Not set
  * Due to the performance of electromagnetic induction antennas, there are limitations in the rise and fall times

Radio wave RFID (953 MHz, 2.45 GHz)
- Test mode: CW or intermittent waveform
- Pulse modulation format: period 1 s, duty ratio 50%
- Antenna power input: 10 mW to 10 W
- Rise and fall time: Not set
  * For example, in Agilent's SG + standard dipole antenna test, the rise and fall times are controlled, so Signal Studio was needed

Rise and fall time test (Changes based on waveform)

Electromagnetic induction RFID (125 kHz, 13.56 MHz)
- Test mode: Intermittent waveform
- Pulse modulation format: period 1 s, duty ratio 50%
- Antenna power input: 1 W
- Rise and fall time: 500 $\mu$s to 100 ms
  * Due to the performance of electromagnetic induction antennas, there are limitations in the rise and fall times

Radio wave RFID (953 MHz, 2.45 GHz)
- Test mode: Intermittent waveform
- Pulse modulation format: period 1 s, duty ratio 50%
- Antenna power input: 1 W
- Rise and fall time: 500 $\mu$s to 100 ms
  * For example, in Agilent's SG + standard dipole antenna test, the rise and fall times are controlled, so Signal Studio was needed

2.2.1 Frequency test

(1) Electromagnetic induction method R/W

Frequency was set to 125 kHz and 13.56 MHz.
  Table III – 2 – 2 shows the fixed parameters.
Table III–2–2  Fixed Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous wave (CW)</td>
<td>Antenna power input: 1 W</td>
<td>Used for testing the antenna while static and while moving (back and forth about once per second)</td>
</tr>
<tr>
<td>Intermittent waveform</td>
<td>Antenna power input: 1 W</td>
<td>Antenna stationary</td>
</tr>
<tr>
<td></td>
<td>Period: 1 sec</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Duty ratio 50%</td>
<td></td>
</tr>
</tbody>
</table>

(2) Radio wave method R/W

Frequency was set to 953 kHz and 2.45 Ghz.
Table III–2–3 shows the fixed parameters.

Table III–2–3  Fixed Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous wave (CW)</td>
<td>Antenna power input: 1 W</td>
<td>Used for testing the antenna while static and while moving (back and forth about once per second)</td>
</tr>
<tr>
<td>Intermittent waveform</td>
<td>Antenna power input: 1 W</td>
<td>Antenna stationary</td>
</tr>
<tr>
<td></td>
<td>Period: 1 sec</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Duty ratio 50%</td>
<td></td>
</tr>
</tbody>
</table>

2.2.2 Antenna input power test

Antenna input power was altered, and the effect was observed for changes.

(1) Electromagnetic induction method R/W

Frequency was set to 125 kHz and 13.56 MHz.
The antenna power input used was restricted to that input capacity of the loop antenna of the actual mobile telephone terminal. (The step width is to be discussed.)
The magnetic field strength within the communications band was measured for each different level of antenna power input. (The measurement methods are to be discussed.)
Table III – 2 – 4 shows the fixed parameters.
### Table III–2–4  Fixed Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous wave (CW)</td>
<td>Not set</td>
<td></td>
</tr>
<tr>
<td>Intermittent waveform</td>
<td>Rise and fall time Not set</td>
<td>Antenna stationary</td>
</tr>
<tr>
<td></td>
<td>Period: 1 sec</td>
<td>* Due to the performance of electromagnetic induction antennas, there are limitations in the rise and fall times</td>
</tr>
<tr>
<td></td>
<td>Duty ratio 50%</td>
<td></td>
</tr>
</tbody>
</table>

### Radio wave method R/W

Frequency was set to 953 kHz and 2.45 GHz.

The antenna power input was set to between 10 mW and 10 W. (The step width is to be discussed.) Table III – 2 – 5 shows the fixed parameters.

### Table III–2–5  Fixed Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous wave (CW)</td>
<td>Not set</td>
<td></td>
</tr>
<tr>
<td>Intermittent waveform</td>
<td>Rise and fall time Not set</td>
<td>Antenna stationary</td>
</tr>
<tr>
<td></td>
<td>Period: 1 sec</td>
<td>* For example, in Agilent's SG + standard dipole antenna test, the rise and fall times are controlled, so Signal Studio was needed</td>
</tr>
<tr>
<td></td>
<td>Duty ratio 50%</td>
<td></td>
</tr>
</tbody>
</table>

#### 2.2.3 Intermittent waveform test

The period of the intermittent waveform was between 2 ms and 2 sec.

### Electromagnetic induction method R/W

Frequency was set to 125 kHz and 13.56 Mhz.

Table III – 2– 6 shows the fixed parameters.

### Table III–2–6  Fixed Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intermittent waveform</td>
<td>Antenna power input: 1 W</td>
<td>Antenna stationary</td>
</tr>
<tr>
<td></td>
<td>Period: 2 msec to 2 sec</td>
<td>* 125 kHz R/W has can be set to any of the following periods: 2ms, 5ms, 10ms, 20ms, 50ms, 100ms, 200ms, 500ms, 1s, 2s, 5s</td>
</tr>
<tr>
<td></td>
<td>Duty ratio 50%</td>
<td></td>
</tr>
</tbody>
</table>

### Radio wave method R/W

Frequency was set to 953 kHz and 2.45 Ghz.

Table III – 2– 7 shows the fixed parameters.
### Table III–2–7  Fixed Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intermittent waveform</strong></td>
<td>Antenna power input: 1 W</td>
<td>Antenna stationary</td>
</tr>
<tr>
<td></td>
<td>Period: 2 msec to 2 sec</td>
<td>* UHF band anti-collisions function LBT can be max transmission time 4s, min cessation time of 50 ms (high output type), or max transmission time 1 s, min cessation time of 100 ms (low output time)</td>
</tr>
<tr>
<td></td>
<td>Duty ratio 50%</td>
<td></td>
</tr>
</tbody>
</table>

### 2.2.4 Rise time/fall time test

Observe the changes in effect with differing intermittent waveform rise and fall times.

1. **Electromagnetic induction method R/W**

Frequency was set to 125 kHz and 13.56 MHz.

The rise and fall time was set to between 500 μs to 100 ms. (The step width is to be discussed.)

Table III – 2 – 8 shows the fixed parameters.

#### Table III–2–8  Fixed Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intermittent waveform</strong></td>
<td>Antenna power input: 1 W</td>
<td>Antenna stationary</td>
</tr>
<tr>
<td></td>
<td>Period: 1 sec</td>
<td>* Due to the performance of electromagnetic induction antennas, there are limitations in the rise and fall times</td>
</tr>
<tr>
<td></td>
<td>Duty ratio 50%</td>
<td></td>
</tr>
</tbody>
</table>

2. **Radio wave method R/W**

Frequency was set to 953 kHz and 2.45 Ghz.

The rise and fall time was set to between 0.1 μs to 100 ms. (The step width is to be discussed.)

Table III – 2 – 9 shows the fixed parameters.

#### Table III–2–9  Fixed Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intermittent waveform</strong></td>
<td>Antenna power input: 1 W</td>
<td>Antenna stationary</td>
</tr>
<tr>
<td></td>
<td>Period: 1 sec</td>
<td>* For example, in Agilent's SG + standard dipole antenna test, the rise and fall times are controlled, so Signal Studio was needed</td>
</tr>
<tr>
<td></td>
<td>Duty ratio 50%</td>
<td></td>
</tr>
</tbody>
</table>
2.3 Test protocol

2.3.1 Structure of the human phantom

A vertical human phantom was used in this test. Figure III – 2 – 1 shows the configuration of the measuring equipment.

![Configuration of measuring equipment]

Figure III–2–1  Configuration of measuring equipment

2.3.2 RFID device simulation system

(1) Electromagnetic induction method (LF: 125 kHz, HF: 13.56 MHz) . . . using a loop antenna from a mobile telephone terminal

The simulation was conducted using a modified existing reader/writer. Figure III – 2 – 2 shows the electromagnetic induction simulation system.

![Electromagnetic induction simulation system]

Figure III–2–2  Electromagnetic induction simulation system
(2) Radio wave (UHF: 953 Mhz, Microwave: 2.45 Ghz) . . . Dipole antenna

Designed with reference to the mobile telephone test.

Figure III – 2 – 3 shows the radio wave simulation system.

References


AAMI: Association for the Advancement of Medical Instrumentation.

SECTION IV EFFECT OF RADIO WAVES FROM MOBILE TELEPHONES IN AUTOMOBILES ON IMPLANTABLE CARDIAC PACEMAKERS

1 Background

This study group conducted experiments on the electromagnetic fields emitted by mobile telephones and their effect on implantable cardiac pacemakers by direct irradiation. The effect of the electromagnetic field is strongest in the proximity of the antenna. In some cases, this is based on the fact that this was a component of the magnetic conjunction at the antenna.

Hondo Tsuyoshi, assistant at Tohoku University's Faculty of Science stated in a letter [1] to the Journal of the Physical Society of Japan that a 22 cm safe distance may not always be achieved because radio waves from mobile telephones may form a high electromagnetic field domain farther away from the antenna when they are accumulated inside of a commuter train, elevator, or other environment that is surrounded by metal. Then in the July 25, 2006 Yomiuri Shimbun, it was reported that a strong electromagnetic field domain (hotspot) was created. The details of these test results were reported by Hondo in the Journal of the Physical Society of Japan. [2]

2 Study done by the Association of Radio Industries and Businesses, Electromagnetic Environment Committee

The Association of Radio Industries and Businesses, Electromagnetic Environment Committee, and the National Institute for Information and Communications Technology (NICT) worked together and conducted a study to evaluate quantitatively the exact electromagnetic environment present in the train cars and elevators that people use. They first reported their findings on the electromagnetic environment inside a commuter train car, and they confirmed through a simulation that the distance prescribed in the policy of the Unnecessary Electromagnetic Waves Problem Resolution Conference (currently the Electromagnetic Compatibility Conference) was maintained inside a train car.

This study used a typical commuter train car for their measurements, and they conducted tests to determine the appropriate method of calculation and analysis, and then they conducted a Finite Difference Time Domain using parameters that faithfully reproduced the actual characteristics of the environment. [3] [4]

The results showed that the person carrying the mobile telephone and the other passengers absorb the radio waves, and thus the formation of a localized strong electromagnetic field domain (hotspot) was not observed, and the 22 cm policy for emissions of radio waves from mobile phones is generally maintained, and that outside of that area, there is no risk of electromagnetic interference [EMI].

3 Opinion of the study group

Based on the results of the tests conducted by the Association of Radio Industries and Businesses, Electromagnetic Environment Committee, the radio waves from mobile telephones within a passenger train will leak out the windows and also be absorbed by the person carrying the phone and the other passengers, and so no electromagnetic field domain (hotspot) is formed that will affect implantable cardiac pacemakers.
References


Basic tests used in conducting factor analysis

1. Object of the tests

When performing a factor analysis test on the effects of radio waves emitted from mobile telephone terminals on implantable cardiac pacemakers, basic tests were performed to try and understand the dependency of the level of effect and the radio wave modulation method.

2. Test protocol

These tests were based on the test methods for determining the effect on implantable cardiac pacemakers of radio waves emitted from mobile telephone terminals (see Section II, Chapter 1 of this report), and to clarify the differences in this effect, the antenna’s input power was made much higher than that normally used in communications. For the same reason, the implantable cardiac pacemakers used in this basic test were those that were affected the most in past studies.

The specific test conditions for radio wave emissions are listed below.

(1) Radio wave generator: Uses a single generator (SG), amp and dipole antenna
(2) Antenna power input: 1 W (TDMA method used 333 mW, which becomes 1 W during a burst)
(3) Modulation method: TDMA, CDMA, and no modulation (CW)
(4) Radio wave intermittency: Continuous or intermittent (based on past test conditions, the period was 1 sec and duty ratio 1/2)

Here, the intermittent conditions were created by applying a pulse to the external modulation input terminal on the SG, but the TDMA modulation method does not respond to this pulse input, and so the SG’s RF output switch was used to switch on and off. These two methods had greatly different rise times, 30 nsec and 8 msec respectively, and to check the difference between these two methods as well, the RF output switch on/off method was also applied to the CDMA modulation method. As a result, there were four tests run.

Test I : TDMA modulation method, intermittency supplied by turning the RF output switch on and off
Test II : CDMA modulation method, intermittency supplied by turning the RF output switch on and off
Test III : CDMA modulation method, external modulation of intermittent pulse
Test IV : No modulation, intermittent external modulation of intermittent pulse

3. Test results

Test results are shown in Table 1.

(1) Dependency of level of effect on modulation method

Comparing Test I and Test II, when including the intermittent condition, the maximum distance at which an effect occurred was 12 cm for all devices with both TDMA modulation method and the CDMA method. At the same time, Test III and Test IV showed that the CDMA modulation method and the no
modulation method (CW) had a maximum effect distance of 24 cm and 25 cm, respectively.

Thus, though the effect distance of CDMA modulation on an SSI implantable cardiac pacemaker is smaller when the antenna input power (during a burst) and the rise and fall times during intermittent transmissions are the same, the dependency of the effect level on the modulation method is slight.

In fact, the difference between the CDMA modulation method and CW is insignificant regardless of implantable cardiac pacemaker type or mode. Thus, it seemed possible to conduct tests with CW, which makes it easy to change the characteristics of the radio waves, rather than fixing the radio wave modulation method in the factor analysis test.

(2) Dependency on rise and fall times on the level of effect in the intermittent tests
A comparison of Test II and Test III showed that for SSI type implantable cardiac pacemakers being tested, the maximum effect distance varied wildly when the rise and fall times were short. Based on these findings, it seems that the rise and fall times of the radio waves emitted is one factor of interest in this study.
<table>
<thead>
<tr>
<th>Type</th>
<th>Device number used in this test</th>
<th>Mode</th>
<th>Year approved and sales period in Japan</th>
<th>Antenna polarity</th>
<th>Lead polarity</th>
<th>Antenna: Standard dipole</th>
<th>SG: Agilent E4438C</th>
<th>Intermittence: Switch on/off</th>
<th>Period: 990 msec</th>
<th>Duty ratio: 1/2</th>
<th>Rise time: 8 msec</th>
<th>Fall time: 500 μsec</th>
<th>Rise time through TDMA modulation signal: 50 μsec</th>
<th>TDMA modulation</th>
<th>CDMA modulation</th>
<th>CDMA modulation</th>
<th>No modulation (CW)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SSI</td>
<td>1 Vvi</td>
<td>1995</td>
<td>Continuous, Intermittent</td>
<td>Unipolar</td>
<td>12</td>
<td>11</td>
<td>12</td>
<td>11</td>
<td>3</td>
<td>24</td>
<td>25</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No effect</td>
</tr>
<tr>
<td>DDD</td>
<td>2 VVI</td>
<td>2003</td>
<td>Continuous, Intermittent</td>
<td>Unipolar</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No effect</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Continuous, Intermittent</td>
<td>Bipolar</td>
<td>7</td>
<td>6</td>
<td>7</td>
<td>6</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No effect</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Continuous, Intermittent</td>
<td>Bipolar</td>
<td>9</td>
<td>7</td>
<td>10</td>
<td>7</td>
<td>6</td>
<td>5</td>
<td>12</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No effect</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Continuous, Intermittent</td>
<td>Bipolar</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No effect</td>
</tr>
</tbody>
</table>

**Table 1 Basic test results for factor analysis test**

- **SSI**: Standard dipole
- **SG**: Agilent E4438C
- **Intermittence**: Switch on/off
- **Period**: 990 msec
- **Duty ratio**: 1/2
- **Rise time**: 8 msec
- **Fall time**: 500 μsec
- **Rise time through TDMA modulation signal**: 50 μsec
- **TDMA modulation**: 920 MHz / 333mW (Burst, 1 W)
- **CDMA modulation**: 920 MHz / 1 W
- **Continuous, Intermittent**: Continuous
- **In**: Inhibit test
- **As**: Asynchronous test

**Figure**
- Distance at which Level 2 effect occurred (cm)
- Antenna input power: Set to 1 W, which is more power than an actual mobile telephone, in order to clearly see the different effects
- **In**: Inhibit test
- **As**: Asynchronous test
Annex 2

Field intensity tolerance of low-power wireless base stations and induction method communications equipment, ARIB standards, and antenna power

Figure 1  Field intensity tolerance of low-power wireless base stations and induction method communications equipment

Table 1 ARIB standards and antenna power

<table>
<thead>
<tr>
<th>Standard</th>
<th>Frequency</th>
<th>Antenna power</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>RCR STD-1</td>
<td>2.4GHz</td>
<td>Less than 300 mW</td>
<td>License required</td>
</tr>
<tr>
<td>RCR STD-29</td>
<td>2.4GHz</td>
<td>Less than 10 mW</td>
<td>No license required</td>
</tr>
<tr>
<td>RCR STD-T81</td>
<td>2.4GHz</td>
<td></td>
<td>No license required</td>
</tr>
<tr>
<td>RCR STD-T82</td>
<td>13.56MHz</td>
<td></td>
<td>No license required</td>
</tr>
<tr>
<td>RCR STD-T89</td>
<td>950MHz</td>
<td>Less than 1 W</td>
<td>License required</td>
</tr>
<tr>
<td>RCR STD-T90</td>
<td>950MHz</td>
<td>Less than 10 mW</td>
<td>No license required</td>
</tr>
</tbody>
</table>

RCR STD-1 : On-premise wireless station 2.4 GHz, wireless equipment for detecting mobile terminals
RCR STD-29 : Specified low-power wireless station 2.4 GHz, wireless equipment for detecting mobile terminals
ARIB STD-T81 : Specified low-power wireless station using frequency hoping, 2.4 GHz wireless equipment for detecting mobile terminals
ARIB STD-T82 : Induction method R/W communications equipment (wireless card systems etc.)
ARIB STD-T89 : On-premise wireless station 950 MHz wireless equipment for detecting mobile terminals
ARIB STD-T89 : Specified low-power wireless station 950 MHz wireless equipment for detecting mobile terminals
### Table 2  ARIB STD-T81 Antenna Power

A. Uses 2,400 Mhz or more and less than 2,427 MHz, or above 2,470.75 MHz and up to 2,483.5 MHz. The average power output in the 1 MHz range was under 10 mW. However, the total power was under 260 mW.

![Antenna Power Diagram](image)

B. 2,400 MHz or more and less than 2,483.5 MHz. However, we used 2,427 MHz or above and 2,470.75 MHz or less. The average power output in the 1 MHz range was under 3 mW.

![Antenna Power Diagram](image)

### Table 3  ARIB STD-T82 field intensity leak

The field intensity leak within 10 meters is given below.

1. For frequencies between 13.553 MHz or more and 13.567 MHz or less: 47.544 millivolts per meter.
2. For frequencies between 13.41 MHz or more and less than 13.553 MHz, or more than 13.567 MHz and 13.71 MHz or less: 1.061 millivolts per meter.
3. For frequencies between 13.11 MHz or more and less than 13.41 MHz, or more than 13.71 MHz and 14.01 MHz or less: 316 millivolts per meter.
4. For frequencies outside of those listed in (1) to (3) (excluding high frequencies and low frequencies), it was 150 microvolts per meter.
Implantable cardiac pacemaker sensitivity alteration test

For implantable cardiac pacemakers that exhibited an effect at 75 cm from the radio waves emitted from a stationary UHF RFID device (high power), tests were conducted with different sensitivity settings, and the distance at which an effect occurred are shown in figure 1. Because devices showed a larger effect distance in the Inhibit test than the Asynchronous test, the Inhibit test was run.

Based on the results of this test, we can say that an implantable cardiac pacemaker will not be affected at distance of at least 1 meter from a stationary UHF RFID device (high output).

Sensitivity setting: 0.4 mV (maximum output), 1.0 mV, 2.4 mV, 5.6 mV

![Figure 1. Setting and effect distances](image)

Note: Inhibit Test: The implantable cardiac pacemaker receives no input signal, and the test is conducted with the unit emitting a pulse at the set rate.

Asynchronous Test: A pseudo cardiac potential of 10 to 20% higher (75 ppm) than the rate setting of the implantable cardiac pacemaker is detected, and the output pulse is inhibited.
CONCLUSION

The Study Group on the Effects of Radio Waves on Medical and Other Equipment conducted a detailed investigation, including many experiments, on radio waves emitted from RFID devices and mobile telephone terminals and their effect on implantable cardiac pacemakers. As a result, the concerns of people with implantable cardiac pacemakers were reduced, and a radio wave environment in which RFID devices and mobile telephone terminals can be used safely was obtained.

In this study, we found that the 22 cm rule currently used for handheld, stationary, and modular RFID devices applies equally to new UHF RFID devices, which makes it possible to maintain a safe electromagnetic environment. We also confirmed that the 22 cm rule currently applied to mobile telephone terminals is equally valid with the new 1.7 GHz W-CDMA mobile telephone terminals and enables the maintenance of a safe electromagnetic environment. Through electromagnetic interference tests, the factors involved in the effect of radio waves from mobile telephones on implantable cardiac pacemakers was clarified. In addition, an analysis was conducted on the effects of radio waves from RFID devices on implantable cardiac pacemakers, which clarified the issues and items that were to become the subject of a more focused and in-depth study. We hope that this report will help reduce the concerns of the public and contribute to the establishment of an electromagnetic environment in which RFID devices and mobile telephone terminals can be used safely.

In closing, we would like to thank the all the members and the chairman of the Study Group on the Effects of Radio Waves on Medical and Other Equipment, Dean Takakura from the Tokyo Women’s Medical University, as well as the organizations whose cooperation was indispensable: Pacemaker Committee, Japan Automatic Identification Systems Association, and the telecommunications carriers.
ANNEXES

(1) Establishment of the Study Group on the Effects of Radio Waves on Medical and Other Equipment ................................................................. Annex 1

(2) Outline of the Study Group on the Effects of Radio Waves on Medical and Other Equipment, Pacemaker Subcommittee Establishment ........................................... Annex 4

(3) Discussion of the Study Group on the Effects of Radio Waves on Medical and Other Equipment........................................................................................................ Annex 10
1. Name
The name of this group is the Study Group on the Effects of Radio Waves on Medical and Other Equipment (abbreviated as “Study Group”).

2. Purpose
The Study Group conducts tests on the radio waves emitted from wireless systems and their effect on medical devices, and then contributed the test results to the creation of new policies so as to secure a radio wave environment in which wireless systems can be used safely.

3. Study themes
Studies are conducted on the following items and the results of these studies documented.
(1) Studies on the characteristics of radio waves emitted from wireless systems and the ability to exclude interrupting radio waves.
(2) Experiments to duplicate electromagnetic interference between wireless systems and medical devices
(3) Categorization and analysis of the malfunction of medical devices based on the results of experiments in (2)
(4) Examination of policies to prevent the creation of radio waves that are harmful to medical devices

4. Structure
(1) The Study Group is composed of a chairman, deputy chairman, members, and observers. These people are listed on an separate annex.
(2) The Study Group can establish sub-committees whose members are decided by the Study Group.

5. Operation
(1) The Study Group is convened by the chairman, who presides over the meeting.
(2) Other operational matters of the Study Group are decided by the Study Group.

6. Term of Establishment
(1) The Study Group is established at the Association of Radio Industries and Businesses.
(2) The Study Group is established from the initial establishment date until a date decided by the Study Group (but in any case not later than March 30, 2007).

7. Office
The secretariat of the Study Group is managed by the Association of Radio Industries and Businesses.

8. Other
(1) The permission of the Association of Radio Industries and Businesses or the Ministry of Internal Affairs and Communications is generally required before making public the results of studies conducted by the Study Group.
(2) The copyrights to all reports from the Study Group inhere to the Ministry of Internal Affairs and Communications
Members of the Study Group on the Effects of Radio Waves on Medical and Other Equipment (Fiscal 2006)

(As of April 1, 2007)

(Company/Affiliated Institution Listed in Alphabetical Order, Titles Omitted)

<table>
<thead>
<tr>
<th>Name</th>
<th>Affiliated Organization/Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chairman</td>
<td>TAKAKURA Kintomo, Dean, Tokyo Women's Medical University</td>
</tr>
<tr>
<td>Deputy Chairman</td>
<td>FURUHATA Hiroshi, Professor, Medical Engineering Laboratory, General Medical Research Center, Jikei University</td>
</tr>
<tr>
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<td>TANIKAWA Kouji, ISO/TC210 Japan Committee (Deputy Director, Quality Assurance, Olympus Medical Systems Inc.)</td>
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<td>HATTORI Mitsuo, ITU-T SG5 WP2 Chairman (EMC Center Director, Access Network Division, NTT Advanced Technology Corporation)</td>
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<td>Member</td>
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<td>Member</td>
<td>SUZUKI Kazunori, Assistant Manager, Medical and Welfare Devices Industry Office, Services Industry Section, Commerce and Information Policy Bureau, Ministry of Economy Trade and Industry</td>
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<tr>
<td>Member</td>
<td>ENO Hideo, Assistant Manager, Safety Policy Section, Medicine and Food Bureau, Ministry of Health, Labour and Welfare</td>
</tr>
<tr>
<td>Member</td>
<td>KANO Takashi, Professor, School of Biomedical Engineering, Faculty of Health and Medical Care, Saitama Medical University</td>
</tr>
<tr>
<td>Member</td>
<td>KUGIMIYA Toyoki, Professor, Department of Anesthesiology/Pain Clinic, Juntendo University School of Medicine</td>
</tr>
<tr>
<td>Member</td>
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</tr>
<tr>
<td>Member</td>
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</tr>
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<td>Member</td>
<td>TAKABE Masao, Deputy Manager, Electromagnetic Environment Research Department, Telecom Engineering Center</td>
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<tr>
<td>Member</td>
<td>HAYASHI Kunihiro, Telecommunications Carriers Association (Radio Wave Division Manager, Network Headquarters, NTT DoCoMo, Inc.)</td>
</tr>
<tr>
<td>Member</td>
<td>KIKUCHI Shinichi, Telecommunications Carriers Association (Radio Wave Manager, Technology Public Relations Office, KDDI, Director)</td>
</tr>
<tr>
<td>Member</td>
<td>KASANUKI Hiroshi, Senior Professor, Cardiology Internal Medicine Course, Tokyo Women's Medical University</td>
</tr>
<tr>
<td>Member</td>
<td>SHIBATA Masaru, Chief Researcher, EMC Subcommittee, Japan Federation of Medical Devices (Leader, Quality Assurance First Section, Quality Assurance Department, Tokyo Office, Aloka Co., Ltd.)</td>
</tr>
<tr>
<td>Member</td>
<td>KOIKE Ben, Director General, Secretariat, Japan Automatic Identification Systems Association</td>
</tr>
<tr>
<td>Member</td>
<td>KATO Tetsuo, Deputy Councillor, Safe Electromagnetic Center, Japan Quality Assurance Organization</td>
</tr>
<tr>
<td>Member</td>
<td>TOYOSHIMA Takeshi, Chairman, Electromagnetic Interference/Trouble Investigation Committee, Japanese Heart Rhythm Society, (Technical Fellow, Cardiac Rhythm Disease Management, Japan Medtronic)</td>
</tr>
<tr>
<td>Member</td>
<td>UCHIYAMA Akihiko, Managing Director, Public Health Research Center</td>
</tr>
<tr>
<td>Role</td>
<td>Name</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>Member</td>
<td>ISHIKAWA Yasuhiko</td>
</tr>
<tr>
<td>Member</td>
<td>NOJIMA Toshio</td>
</tr>
<tr>
<td>Observer</td>
<td>NAKAMA Hiroshi</td>
</tr>
<tr>
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<td>NAGASAWA Teruaki</td>
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<tr>
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<tr>
<td>Secretariat</td>
<td>IGARASHI Kiyoshi</td>
</tr>
<tr>
<td>Secretariat</td>
<td>SHINOZAKI Kaoru</td>
</tr>
</tbody>
</table>

– Annex 3 –
1. **Establishment**
   Based on the regulations of Establishment of the Study Group on the Effects of Radio Waves on Medical and Other Equipment 4 (2), the Pacemaker Subcommittee (abbreviated as “Subcommittee”) was established.

2. **Topics of deliberation**
   The Subcommittee will study the radio waves emitted by RFID devices and mobile telephone terminal antennas, and their effect on implantable cardiac pacemakers; they will conduct electromagnetic interference tests as part of a factor analysis of the effects of radio waves from mobile telephone terminals on implantable cardiac pacemakers; and they will conduct factor analyses on RFID devices, as well as create the draft reports.

3. **Structure**
   (1) The Subcommittee is composed of a chief investigator, deputy investigator, members, and observers. These people are listed on a separate annex.
   (2) The Subcommittee can establish work groups whose members are decided by the Subcommittee.

4. **Operation**
   (1) The Subcommittee is convened by the chief investigator, who presides over the meeting.
   (2) Other operational matters of the Subcommittee are decided by the Subcommittee.

5. **Term of establishment**
   The Subcommittee is established from the initial establishment date until a date decided by the Study Group (but in any case not later than March 30, 2007).

6. **Secretariat**
   The Subcommittee secretariat is located at the Association of Radio Industry Businesses.
# Membership of the Study Group on the Effects of Radio Waves on Medical and Other Equipment, Pacemaker Subcommittee

(As of January 4, 2007)

(Company/Affiliated Institution Listed in Alphabetical Order, Titles Omitted)

<table>
<thead>
<tr>
<th>Name</th>
<th>Affiliated Organization/Position</th>
</tr>
</thead>
</table>
| Chief investigator | KASANUKI Hiroshi  
Senior Professor, Cardiology Internal Medicine Course, Tokyo Women's Medical University                                                                         |
| Deputy Chief Investigator | TOYOSHIMA Takeshi  
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| Member            | HATTORI Mitsuo  
ITU-T SG5 WP2 Chairman (EMC Center Director, Access Network Division, NTT Advanced Technology Corporation)                                                         |
| Member            | TARUSAWA Yoshiaki  
Lead Researcher, NTT DoCoMo Research Laboratories                                                                                                                     |
| Member            | SUZUKI Kazunori  
Assistant Manager, Medical and Welfare Devices Industry Office, Services Industry Section, Commerce and Information Policy Bureau, Ministry of Economy Trade and Industry |
| Member            | SHIMADA Masashi  
Section Leader, Planning and Systems Group, Radio Wave Division, Technology Public Relations Office, KDDI                                                                 |
| Member            | ENO Hideo  
Assistant Manager, Safety Policy Section, Medicine and Food Bureau, Ministry of Health, Labour and Welfare                                                                 |
| Member            | KANO Takashi  
Professor, School of Biomedical Engineering, Faculty of Health and Medical Care, Saitama Medical University                                                                 |
| Member            | WATANABE Soichi  
Research Manager, EMC Group, Electromagnetic Interference Measurement Research Center, Third Research Division, National Institute for Information and Communications Technology |
| Member            | NAKAMA Hiroshi  
Assistant Manager, Electromagnetic Environment Division, Radio Department, Telecommunications Bureau, Ministry of Internal Affairs and Communications |
| Member            | TAKABE Masao  
Deputy Manager, Electromagnetic Environment Research Department, Telecom Engineering Center                                                                 |
| Member            | FURUHATA Hiroshi  
Professor, Medical Engineering Laboratory, General Medical Research Center, Jikei University                                                                              |
| Member            | SAKASHITA Hitoshi  
Chairman, RFID Committee, Japan Automatic Identification Systems Association (General Manager, Info-communications Materials Department, Advanced Materials Division, Lintec Corporation) |
| Member            | KATO Tetsuo  
Deputy Councillor, Safe Electromagnetic Center, Japan Quality Assurance Organization                                                                                   |
| Member            | UCHIYAMA Akihiko  
Managing Director, Public Health Research Center                                                                                                                        |
| Member            | IWAI Hiroshi  
Chairman, EMC Subcommittee, Pacemaker Committee (Pharmaceutical Filing Manager, CRM, Pharmaceutical Affairs and Clinical Division, Japan Guidant Corporation;) |
| Observer          | NAGASAWA Teruaki  
Section Chief of Bioelectromagnetic Environment Section, Electromagnetic Environment Division, Radio Department, Telecommunications Bureau, Ministry of Internal Affairs and Communications |
| Observer          | NAMIKI Tsuyoshi  
Bioelectromagnetic Environment Section, Electromagnetic Environment Division, Radio Department, Telecommunications Bureau, Ministry of Internal Affairs and Communications |
<table>
<thead>
<tr>
<th>Secretariat</th>
<th>NOMI Tadashi</th>
<th>Deputy Director, Research and Development Headquarters, Association of Radio Industries and Businesses (until December 2006)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secretariat</td>
<td>IGARASHI Kiyoshi</td>
<td>Development Center Manager, Research and Development Headquarters, Association of Radio Industries and Businesses (starting January 2007)</td>
</tr>
<tr>
<td>Secretariat</td>
<td>SHINOZAKI Kaoru</td>
<td>Lead Researcher, Development Center, Research and Development Headquarters, Association of Radio Industries and Businesses</td>
</tr>
</tbody>
</table>
## Membership of the RFID Device Work Group, Study Group on the Effects of Radio Waves on Medical and Other Equipment

(As of January 4, 2007)
(Company/Affiliated Institution Listed in Alphabetical Order, Titles Omitted)

<table>
<thead>
<tr>
<th>Name</th>
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<tbody>
<tr>
<td><strong>Chief investigator</strong></td>
<td><strong>TOYOSHIMA Takeshi</strong> Chairman, Electromagnetic Interference/Trouble Investigation Committee, Japanese Heart Rhythm Society, (Technical Fellow, Cardiac Rhythm Disease Management, Japan Medtronic)</td>
</tr>
<tr>
<td><strong>Deputy Chief Investigator</strong></td>
<td><strong>MORI Toshinori</strong> Deputy Director, EMC Center, Access Network Division, NTT Advanced Technology Corporation</td>
</tr>
<tr>
<td><strong>Member</strong></td>
<td><strong>ONO Toshiaki</strong> Manager, EMC Center, Access Network Division, NTT Advanced Technology Corporation</td>
</tr>
<tr>
<td><strong>Member</strong></td>
<td><strong>TATEISHI Shunzo</strong> Chairman, RFID Medical Work Group, Japan Automatic Identification Systems Association (Expert, RFID Business Development Division, Business Development Headquarters, Omron Corporation)</td>
</tr>
<tr>
<td><strong>Member</strong></td>
<td><strong>TAKAHASHI Tsuyoshi</strong> Lead Researcher, Research and Development Center, Japan Automatic Identification Systems Association</td>
</tr>
<tr>
<td><strong>Member</strong></td>
<td><strong>FUJIMOTO Hiro</strong> Leader, Technology Specialists, Education Department, CRDM Division, Japan Medtronic</td>
</tr>
<tr>
<td><strong>Member</strong></td>
<td><strong>ISHIKAWA Norio</strong> EMC Subcommittee, Pacemaker Committee (Product Group 1, Circulation Equipment BG, Product Business Headquarters, Nihon Koden Corporation)</td>
</tr>
<tr>
<td><strong>Member</strong></td>
<td><strong>ISHII Yoshihiro</strong> EMC Subcommittee, Pacemaker Committee Cardiac Lab Business Division, Fukuda Denshi Company Limited</td>
</tr>
<tr>
<td><strong>Observer</strong></td>
<td><strong>NAGASAWA Teruaki</strong> Section Chief of Bioelectromagnetic Environment Section, Electromagnetic Environment Division, Radio Department, Telecommunications Bureau, Ministry of Internal Affairs and Communications</td>
</tr>
<tr>
<td><strong>Observer</strong></td>
<td><strong>NAMIKI Tsuyoshi</strong> Bioelectromagnetic Environment Section, Electromagnetic Environment Division, Radio Department, Telecommunications Bureau, Ministry of Internal Affairs and Communications</td>
</tr>
<tr>
<td><strong>Secretariat</strong></td>
<td><strong>NOMI Tadashi</strong> Deputy Director, Research and Development Headquarters, Association of Radio Industries and Businesses (until December 2006)</td>
</tr>
<tr>
<td><strong>Secretariat</strong></td>
<td><strong>IGARASHI Kiyoshi</strong> Development Center Manager, Research and Development Headquarters, Association of Radio Industries and Businesses (starting January 2007)</td>
</tr>
<tr>
<td><strong>Secretariat</strong></td>
<td><strong>SHINOZAKI Kaoru</strong> Lead Researcher, Development Center, Research and Development Headquarters, Association of Radio Industries and Businesses</td>
</tr>
</tbody>
</table>

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Annex 7
Members of the Mobile Telephone Terminals Work Group,  
Study Group on the Effects of Radio Waves on Medical and  
Other Equipment  
(As of January 4, 2007)  
(Company/Affiliated Institution Listed in Alphabetical Order, Titles Omitted)

<table>
<thead>
<tr>
<th>Name</th>
<th>Affiliated Organization/Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chief investigator</td>
<td>TOYOSHIMA Takeshi  Chairman, Electromagnetic Interference/Trouble Investigation Committee, Japanese Heart Rhythm Society, (Technical Fellow, Cardiac Rhythm Disease Management, Japan Medtronic)</td>
</tr>
<tr>
<td>Deputy Chief Investigator</td>
<td>MORI Toshinori  Deputy Director, EMC Center, Access Network Division, NTT Advanced Technology Corporation</td>
</tr>
<tr>
<td>Member</td>
<td>ONO Toshiaki  Manager, EMC Center, Access Network Division, NTT Advanced Technology Corporation</td>
</tr>
<tr>
<td>Member</td>
<td>TARUSAWA Yoshiaki  Lead Researcher, NTT DoCoMo Research Laboratories</td>
</tr>
<tr>
<td>Member</td>
<td>IKENO Junichi  Wireless Technology Development Group, Mobile Device Development Division, Product Planning Headquarters, au Business Headquarters, Consumer Business Management Headquarters, KDDI</td>
</tr>
<tr>
<td>Member</td>
<td>FUJIMOTO Hiro  Leader, Technology Specialists, Education Department, CRDM Division, Japan Medtronic</td>
</tr>
<tr>
<td>Member</td>
<td>ISHIKAWA Norio  EMC Subcommittee, Pacemaker Committee (Product Group 1, Circulation Equipment BG, Product Business Headquarters, Nihon Koden Corporation)</td>
</tr>
<tr>
<td>Member</td>
<td>ISHII Yoshihiro  EMC Subcommittee, Pacemaker Committee Cardiac Lab Business Division, Fukuda Denshi Company Limited</td>
</tr>
<tr>
<td>Observer</td>
<td>NAGASAWA Teruaki  Section Chief of Bioelectromagnetic Environment Section, Electromagnetic Environment Division, Radio Department, Telecommunications Bureau, Ministry of Internal Affairs and Communications</td>
</tr>
<tr>
<td>Observer</td>
<td>NAMIKI Tsuyoshi  Bioelectromagnetic Environment Section, Electromagnetic Environment Division, Radio Department, Telecommunications Bureau, Ministry of Internal Affairs and Communications</td>
</tr>
<tr>
<td>Secretariat</td>
<td>NOMI Tadashi  Deputy Director, Research and Development Headquarters, Association of Radio Industries and Businesses (until December 2006)</td>
</tr>
<tr>
<td>Secretariat</td>
<td>IGARASHI Kiyoshi  Development Center Manager, Research and Development Headquarters, Association of Radio Industries and Businesses (starting January 2007)</td>
</tr>
<tr>
<td>Secretariat</td>
<td>SHINOZAKI Kaoru  Lead Researcher, Development Center, Research and Development Headquarters, Association of Radio Industries and Businesses</td>
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− Annex 8 −
### Members of the Factor Analysis Work Group, Study Group on the Effects of Radio Waves on Medical and Other Equipment

(As of January 4, 2007)
*(Company/Affiliated Institution Listed in Alphabetical Order, Titles Omitted)*

<table>
<thead>
<tr>
<th>Name</th>
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</table>
| Chief investigator    | NOJIMA Toshio  
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| Deputy Chief Investigator | TARUSAWA Yoshiaki  
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| Member                | TANIKAWA Kouji  
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| Member                | TOYOSHIMA Takeshi  
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| Member                | ONO Toshiaki  
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| Member                | ISHII Yoshihiro  
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| Observer              | NAMIKI Tsuyoshi  
  Bioelectromagnetic Environment Section, Electromagnetic Environment Division, Radio Department, Telecommunications Bureau, Ministry of Internal Affairs and Communications |
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| Secretariat           | SHINOZAKI Kaoru  
  Lead Researcher, Development Center, Research and Development Headquarters, Association of Radio Industries and Businesses |
The following tables list the discussions that took place at each of the meetings of the Study Group on the Effects of Radio Waves on Medical and Other Equipment, Pacemaker Subcommittee and each Work Group.

<table>
<thead>
<tr>
<th>Open date</th>
<th>Meeting</th>
<th>Discussion points</th>
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<tbody>
<tr>
<td>September 29, 2006</td>
<td>First Study Group</td>
<td>(1) Plan for fiscal 2006 &lt;br&gt; (2) Establishment of Pacemaker Subcommittee &lt;br&gt; (3) Study plan &lt;br&gt; (4) Section I, Test methods for UHF RFID devices &lt;br&gt; (5) Section II, Test methods for 1.7 GHz mobile telephone terminals &lt;br&gt; (6) Section III, Methods for factor analysis and tests on effects</td>
</tr>
<tr>
<td>December 7, 2006</td>
<td>Second Study Group</td>
<td>(1) Review meeting minutes for First Study Group &lt;br&gt; (2) Methods for testing UHF RFID devices &lt;br&gt; (3) Results of UHF RFID device tests &lt;br&gt; (4) Results of basic tests for factor analysis tests &lt;br&gt; (5) Test parameters for RFID devices</td>
</tr>
<tr>
<td>March 1, 2006</td>
<td>Third Study Group</td>
<td>(1) Review meeting minutes (draft) for Second Study Group &lt;br&gt; (2) Study Group Report (draft)</td>
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## Deliberations of the Pacemaker Subcommittee of the Study Group on the Effects of Radio Waves on Medical and Other Equipment

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| October 2, 2006 | First Pacemaker Committee| (1) Subcommittee plan \(\)  
(2) Methods for testing UHF RFID devices \(\)  
(3) Methods for testing 1.7 GHz mobile telephone terminals \(\)  
(4) Section III, Methods for factor analysis and tests on effects |
| November 30, 2006 | Second Pacemaker Committee | (1) Review meeting minutes (draft) for meeting \(\)  
(2) Methods for testing RFID devices \(\)  
(3) Results from tests on RFID devices \(\)  
(4) Basic results of factor analysis electromagnetic interference testing \(\)  
(5) Test parameters for RFID devices |
| February 8, 2007 | Third Pacemaker Committee | (1) Review meeting minutes (draft) for Second Study Group \(\)  
(2) Methods for testing UHF RFID devices \(\)  
(3) Results from tests on RFID devices \(\)  
(4) Section Section Study Report \(\)  
(5) Factor analysis test results \(\)  
(6) Test parameters for RFID devices \(\)  
(7) Articles regarding the use of mobile telephones on commuter trains \(\)  
(8) Annexes |
| February 22, 2006 | Fourth Pacemaker Committee | (1) Review meeting minutes (draft) for meeting \(\)  
(2) Study Group Report (draft) |
### Deliberations of the RFID Device Work Group,
Study Group on the Effects of Radio Waves on Medical and Other Equipment

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### Deliberations of the Mobile Telephone Terminals Work Group,
Study Group on the Effects of Radio Waves on Medical and Other Equipment

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<td>(3) Testing methods for mobile telephone terminals</td>
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### Deliberations of the Factor Analysis Work Group,
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<td>February 2, 2007</td>
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