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

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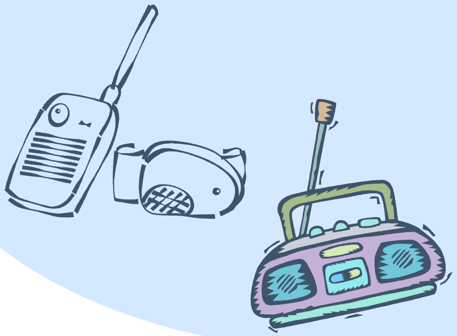
1. Introduction

1.1 Electromagnetic Compatibility (EMC)

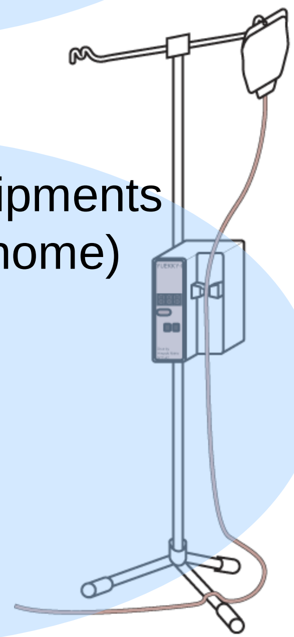
Wireless communication devices
Receivers



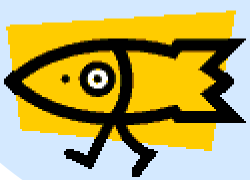
Electronics instruments

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

Medical equipments
(hospital, home)



Special electronics devices



active implantable medical device

1.2 MIC guidelines for preventing EMI

RFID(電子タグ)機器

RFID機器：電子回路を内蔵したタグとリーダライタとの間で非接触で通信を行い、タグのデータを読み書きすることが可能な機器であり、物流、在庫管理、商品の清算など、さまざまな分野で利用されています。

ここでは、RFID機器をリーダライタの形状から次のように分類している。
- ゲートタイプ：リーダライタがゲート状に設置されるもの
- ハンディタイプ：リーダライタを手に持つなど携帯して使用するもの
- 据置きタイプ：リーダライタを据え置いて使用するもの
- モジュールタイプ：プリンタ等に内蔵して使用するもの

■ゲートタイプRFID機器

1. 植込み型医療機器の装着者は、ゲートタイプRFID機器が設置されている場所及びRFIDステッカ(下図)が貼付されている場所では、立ち止まらずに通路の中央をまっすぐに通過すること。

RFID ゲートタイプRFID機器用

2. 植込み型医療機器の装着者は、ゲートタイプRFID機器の周囲に留まらず、また、寄りかかったりしないこと。
3. 植込み型医療機器の装着者は、体調に何らかの変化があると感じられる場合は、担当医師に相談すること。
4. 植込み型医療機器に対するゲートタイプRFID機器の影響を軽減するため、更なる安全性の検討を関係団体で行っていくこと。

■ハンディタイプ、据置きタイプ及びモジュールタイプのRFID機器

1. ハンディタイプRFID機器の操作者は、ハンディタイプRFID機器のアンテナ部を植込み型医療機器の装着部位より22cm程度以内に近づけないこと。（ハンディタイプ）
2. 植込み型医療機器の装着者は、装着部位を据置きタイプ及びモジュールタイプのRFID機器のアンテナ部より22cm程度以内に近づけないこと。（据置きタイプ）
3. 植込み型医療機器に対するハンディタイプ、据置きタイプ及びモジュールタイプのRFID機器の影響を軽減するため、更なる安全性の検討を関係団体で行っていくこと。

RFID JAISA その他のタイプのRFID機器用

[注意]ここでは、公共施設や商業区域などの一般環境下で使用されるRFID機器を対象としており、工場内など一般人が入ることができない管理区域でのみ使用されるRFID機器(管理区域専用RFID機器)については対象外としている。なお、管理区域専用RFID機器については、(社)日本自動認識システム協会において、一般環境への流出を防止するため、取扱説明書等に注意書きを記載するとともに、管理区域専用RFID機器用ステッカ(下図)を貼付することとされている。

RFID JAISA 管理区域専用RFID機器用

※RFIDステッカは、(社)日本自動認識システム協会の許諾を得て使用しています。

■据置きタイプ(高出力型950MHz帯パッシブタグシステム)のRFID機器

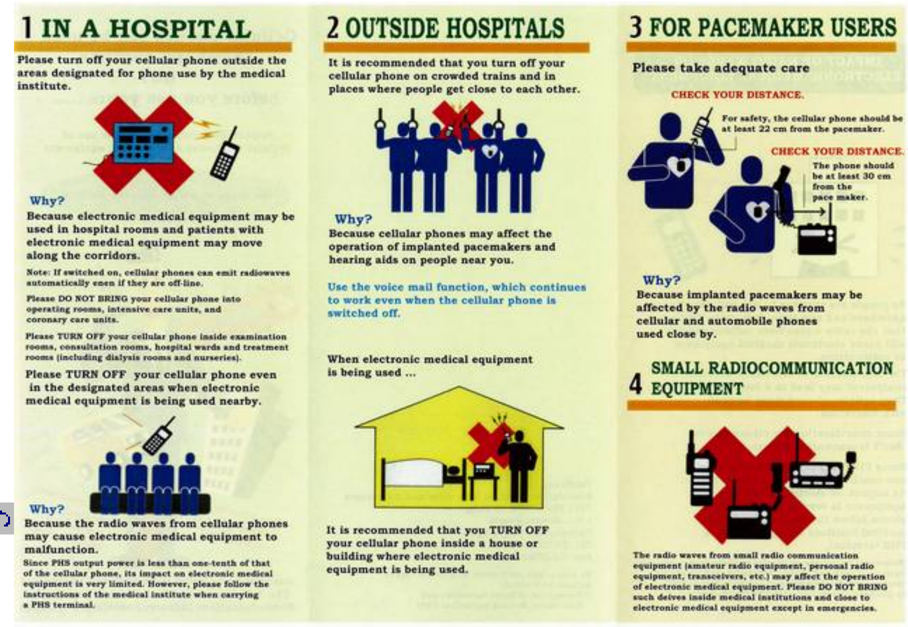
1. 植込み型医療機器の装着者は、据置きタイプRFID機器が設置されている場所及びRFIDステッカ(その他のタイプのRFID機器用と高出力型950MHz帯パッシブタグシステム用を組み合わせたもの)が貼付されている場所の半径1m以内には近づかないこと。（据置きタイプ(高出力型950MHz帯パッシブタグシステム)）
2. 植込み型医療機器の装着者は、体調に何らかの変化があると感じた場合は、担当医に相談すること。
3. 植込み型医療機器に対する据置きタイプRFID機器の影響を軽減するため、更なる安全性の検討を関係団体で行っていくこと。

100 cm 据置きタイプRFID機器(高出力型950MHz帯パッシブタグシステム)用

※据置きタイプRFID機器（高出力型950MHz帯パッシブタグシステム）ステッカは、ペースメーカ協議会の許諾を得て使用しています。

無線LAN機器

無線LAN機器によって影響を受けた植込み型医療機器は、1機種であ…ことから、厚生労働省の協力を得て、医療機関を通じ同機種の利用者全…対して、試験結果に基づく注意喚起が行われている。
よって、現時点で特段の注意をされていない植込み型医療機器の装着者は、無線LAN機器に対しては特別の注意は必要としない。



1 IN A HOSPITAL

Please turn off your cellular phone outside the areas designated for phone use by the medical institute.

Why?
Because electronic medical equipment may be used in hospital rooms and patients with electronic medical equipment may move along the corridors.

Note: If switched on, cellular phones can emit radiowaves automatically enen if they are off-line.

Please DO NOT BRING your cellular phone into operating rooms, intensive care units, and coronary care units.

Please TURN OFF your cellular phone inside examination rooms, consultation rooms, hospital wards and treatment rooms (including dialysis rooms and nurseries).

Please TURN OFF your cellular phone even in the designated areas when electronic medical equipment is being used nearby.

Why?
Because the radio waves from cellular phones may cause electronic medical equipment to malfunction.

Since PHS output power is less than one-tenth of that of the cellular phone, its impact on electronic medical equipment is very limited. However, please follow the instructions of the medical institute when carrying a PHS terminal.

2 OUTSIDE HOSPITALS

It is recommended that you turn off your cellular phone on crowded trains and in places where people get close to each other.

Why?
Because cellular phones may affect the operation of implanted pacemakers and hearing aids on people near you.

Use the voice mail function, which continues to work even when the cellular phone is switched off.

When electronic medical equipment is being used ...

It is recommended that you TURN OFF your cellular phone inside a house or building where electronic medical equipment is being used.

3 FOR PACEMAKER USERS

Please take adequate care

CHECK YOUR DISTANCE.
For safety, the cellular phone should be at least 22 cm from the pacemaker.

CHECK YOUR DISTANCE.
The phone should be at least 30 cm from the pace maker.

Why?
Because implanted pacemakers may be affected by the radio waves from cellular and automobile phones used close by.

4 SMALL RADIOCOMMUNICATION EQUIPMENT

The radio waves from small radio communication equipment (amateur radio equipment, personal radio equipment, transceivers, etc.) may affect the operation of electronic medical equipment. Please DO NOT BRING such deives inside medical institutions and close to electronic medical equipment except in emergencies.

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

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

1.3 Active implantable medical devices

- Active Implantable Cardiac Pacemaker (Pacemaker)
  - An active implantable medical device which uses electrical impulses, delivered by electrodes contacting the heart muscles, to regulate the beating of the heart.
- Active Implantable Cardioverter-Defibrillator (ICD)
  - A small battery-powered electrical impulse generator which is implanted in patients who are at risk of sudden cardiac death due to ventricular fibrillation.
  - In addition to the function described above, ICDs commonly have the same functions as active implantable cardiac pacemakers.

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

1.4 Objectives

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

This presentation

EMI experiments

EMI mitigation method

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

北海道大学 HOKKAIDO UNIVERSITY — Hokkaido University

JAISA — Japan Automatic Identification Systems Association

Pacemaker Committee — Japan Pacemaker Committee

Mechanisms

Threshold level

Estimation

This presentation

Measurement of EMF distributions

Radio wave from RFID

Validity

Numerical analysis

Field strength

1.5 Schedule

FY2007 → FY2008 → 2008/10 → 2008/12 → 2009/2

EMI experiments — This presentation

Tested devices so far:
40 types of active implantable medical device
41 types of RFID reader/writer antennas →
(ISO18000-2,3,4,6)

Increased number of tested devices
(including miller subcarrier UHF systems) →

EMI mitigation method — This presentation

Fundamental validation of proposed method (UHF) →

Detailed investigation of mitigation performance,
Investigation of interference with tag communication →

Numerical EMI estimation method — This presentation

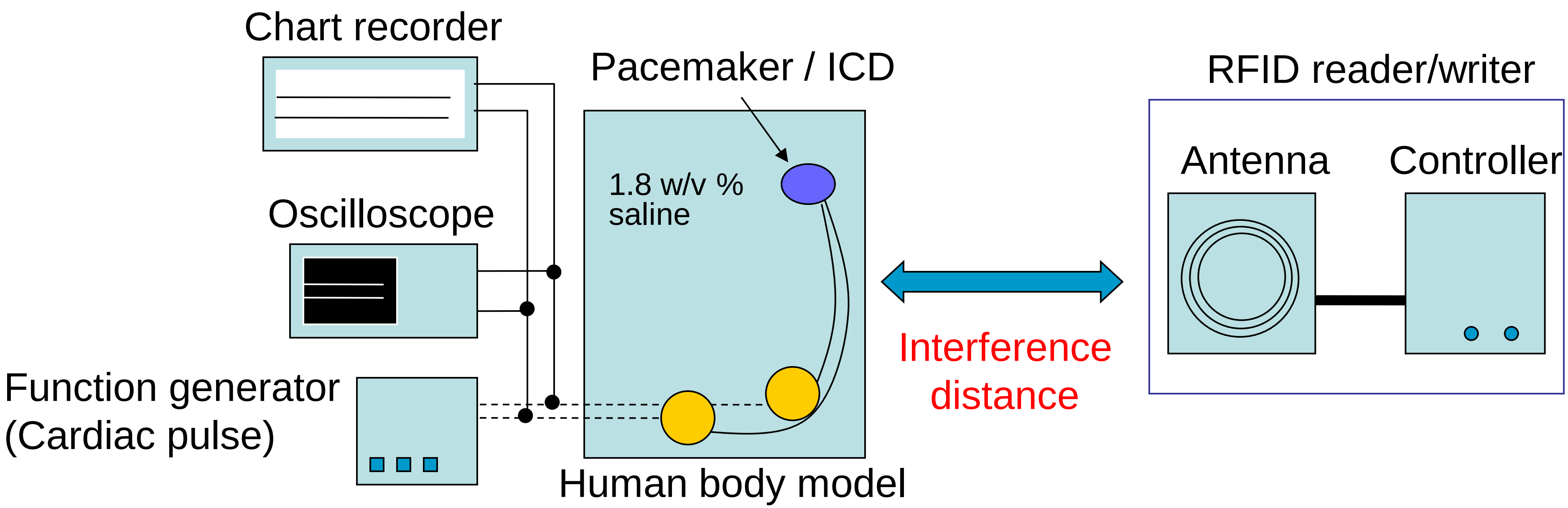
Fundamental validation of proposed method (HF) →

ISO/IEC SC31WG4SG5

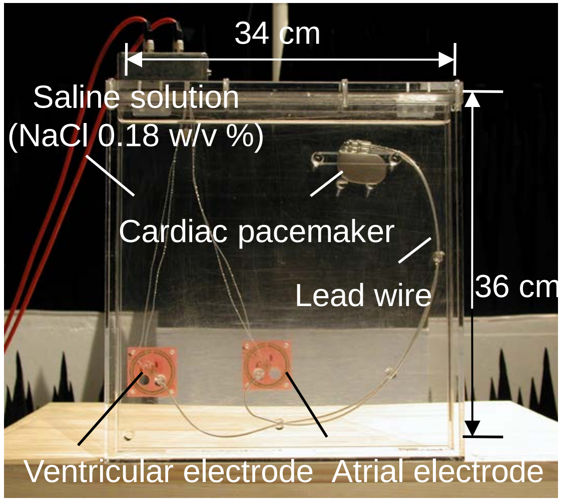
ISO-TR new item proposal

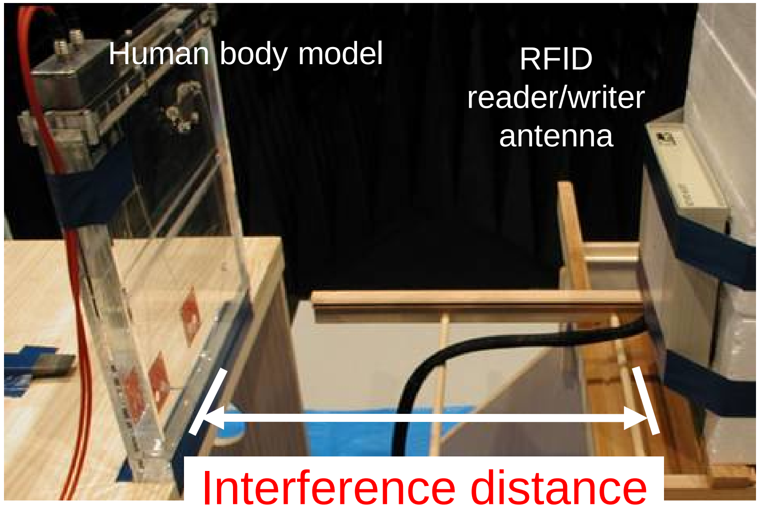
2. Electromagnetic interference (EMI) measurement set-up

2.1 Configuration of the measurement set-up

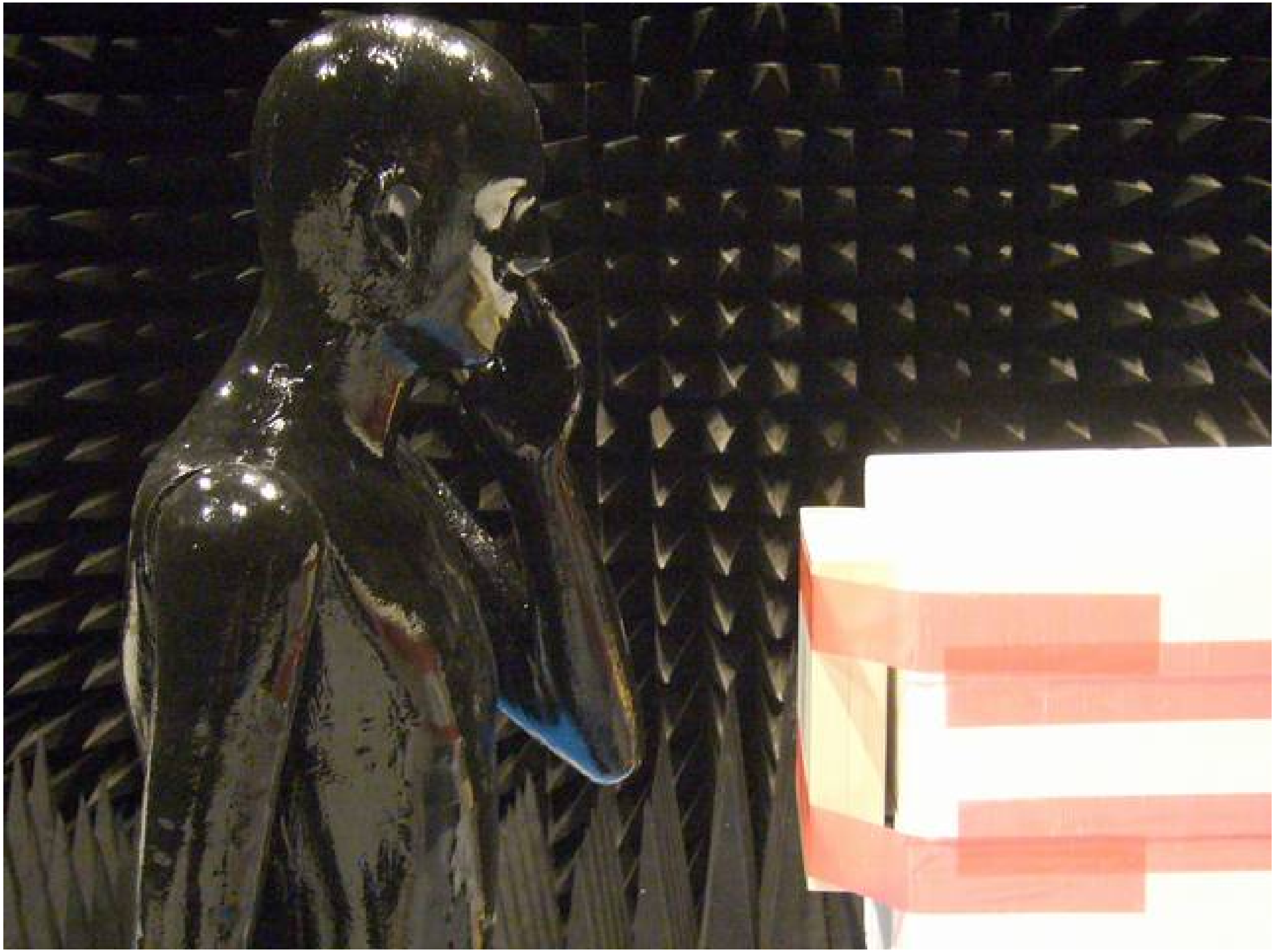


Function Generator
Oscilloscope
& Chart Recorder

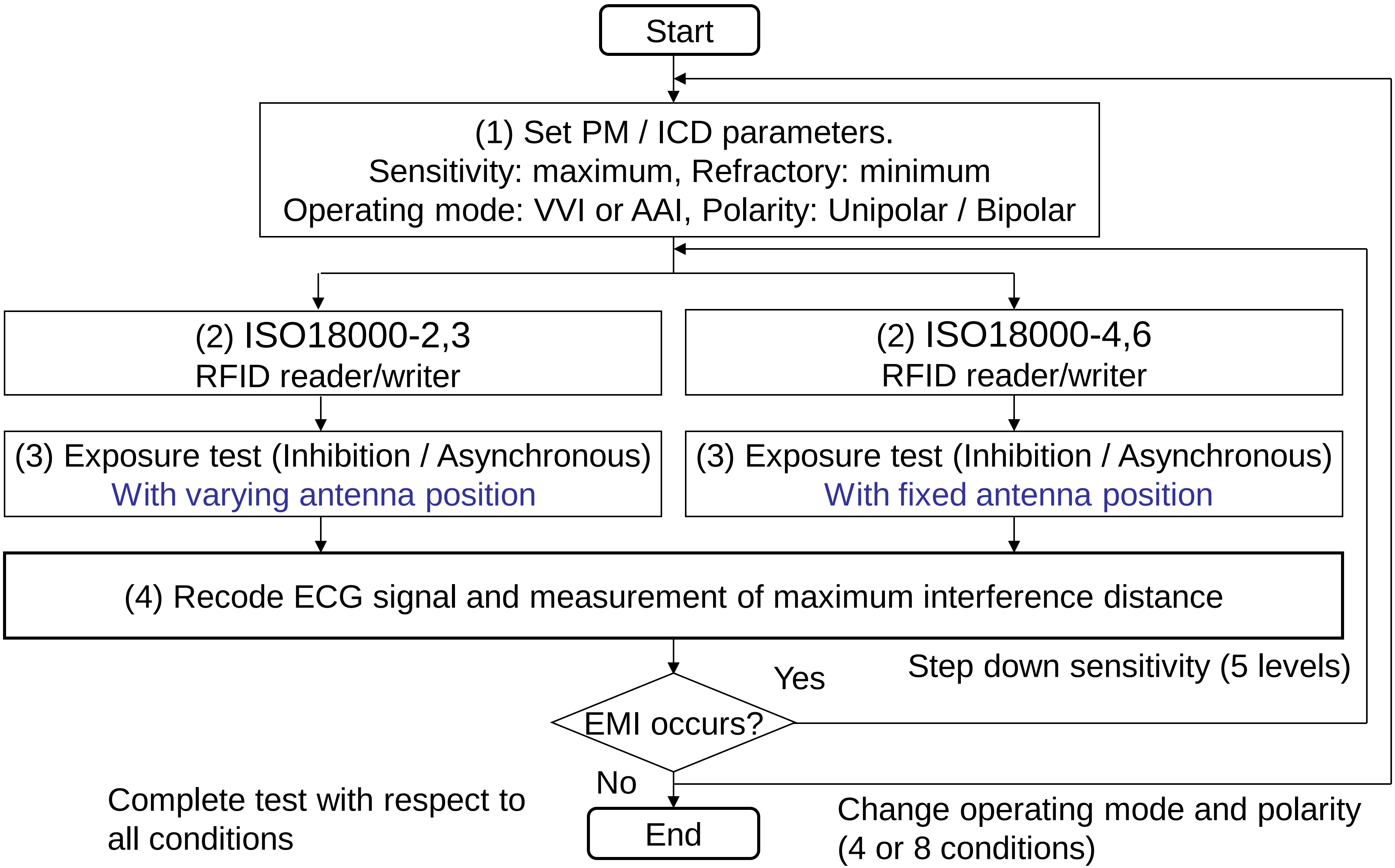




2.2 Overview of the measurement set-up

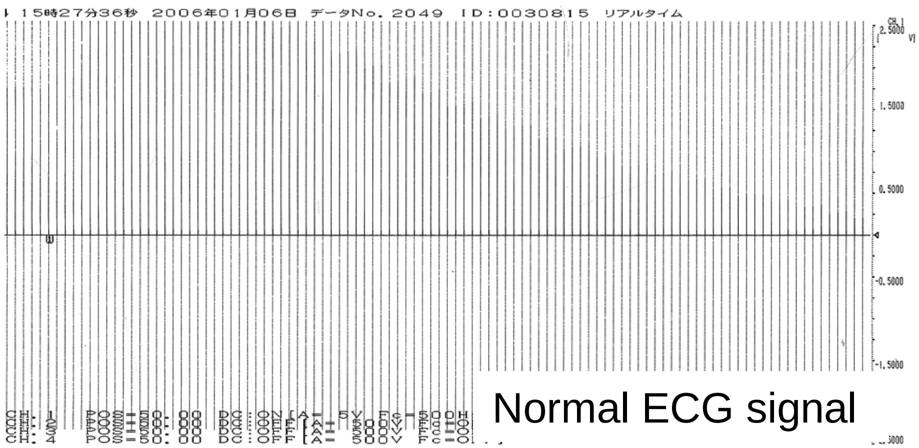


2.3 Procedure of the experiments

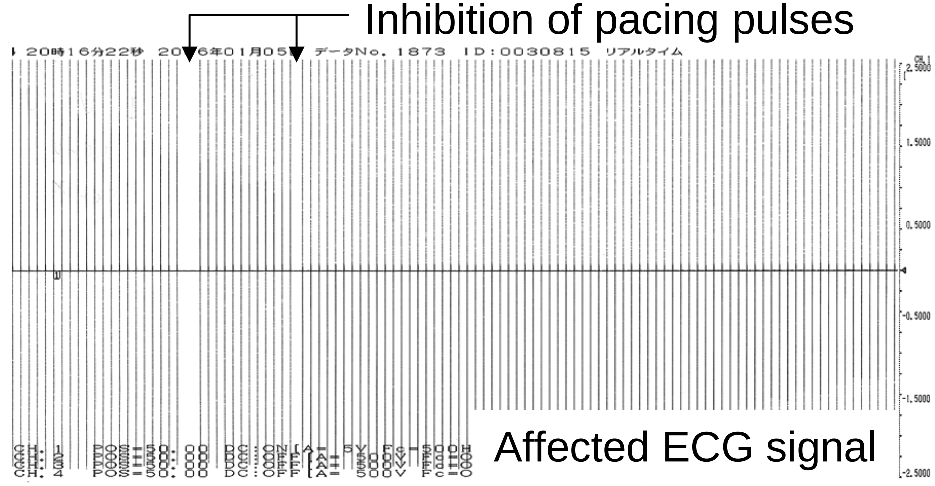


2.4 Examples of affected ECG signal

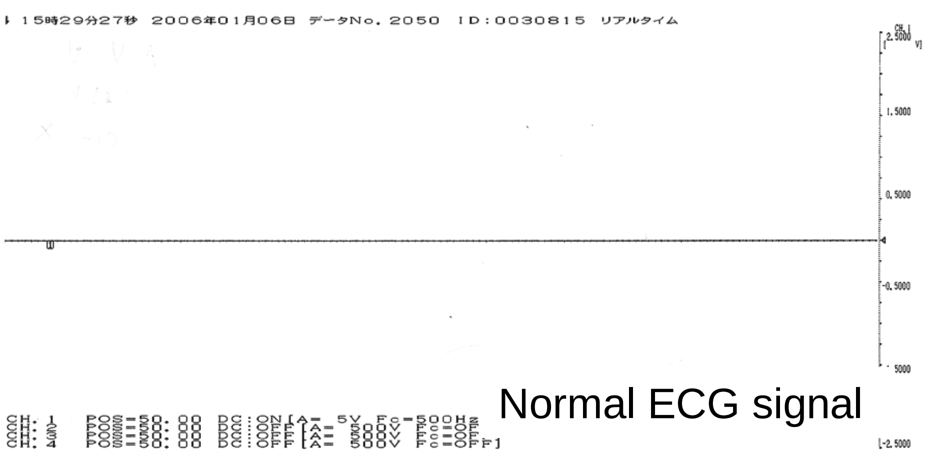
- **Inhibition test:** pacing pulses are inhibited or pulse interval are changed


Normal ECG signal

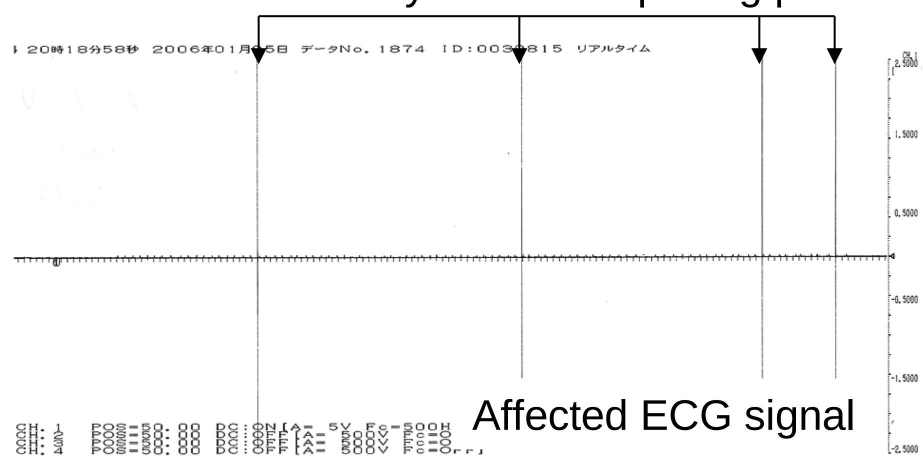
Inhibition of pacing pulses


Affected ECG signal

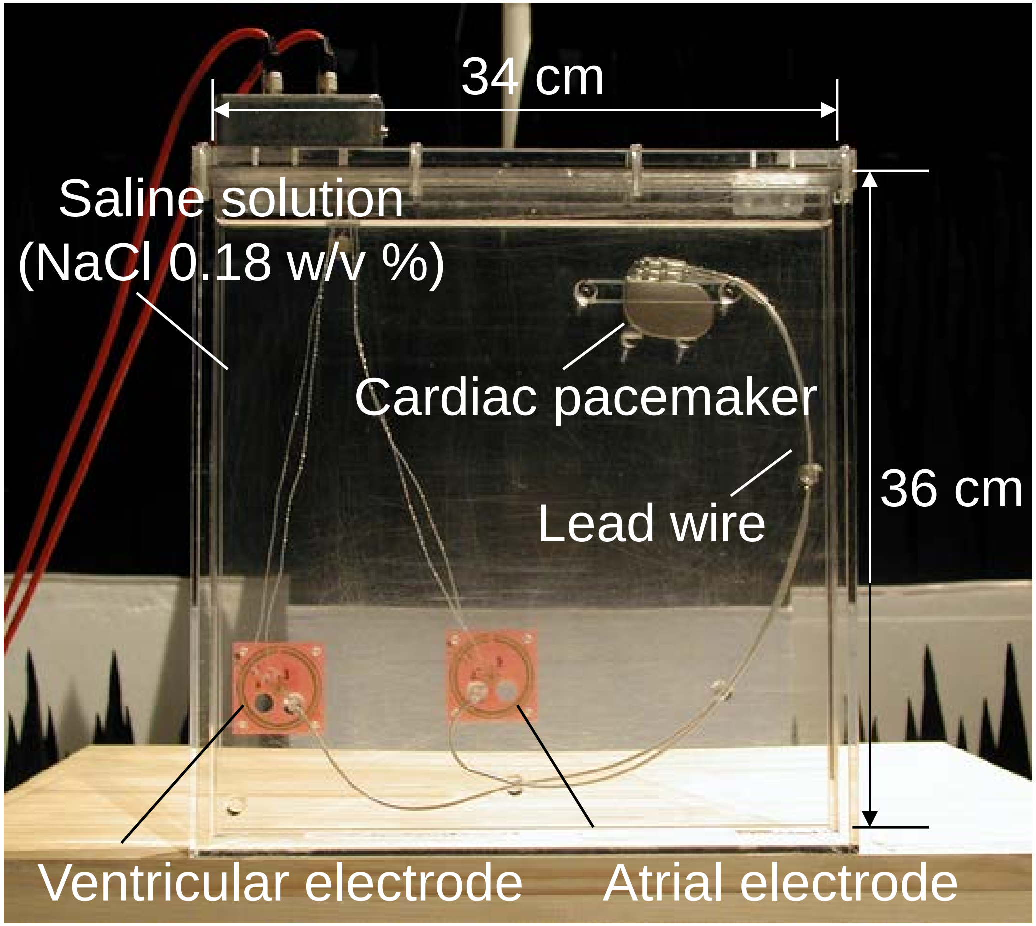
- **Asynchronous test:** asynchronous pacing pulses are generated


Normal ECG signal

Asynchronous pacing pulses


Affected ECG signal

2.5 The human torso phantom

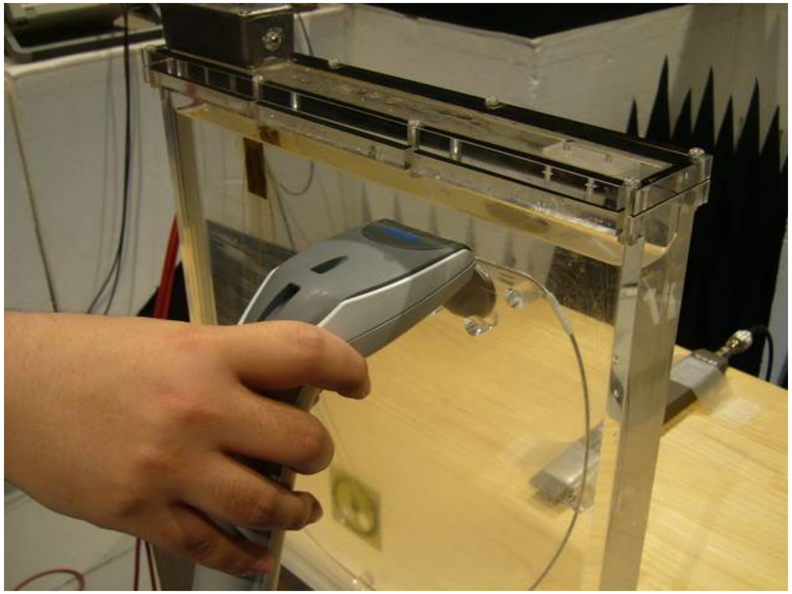


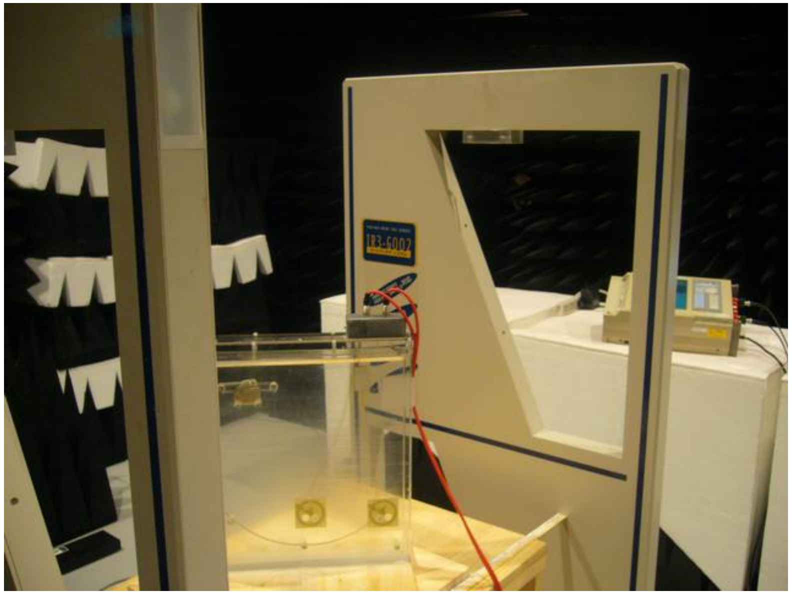
- The human torso phantom is based upon Irnich's flat torso phantom model.
- Both atrial and ventricular electrodes are modified and enable us to separate each chambers' signal by more than 20 dB.
- This phantom allows us to examine EMI with low interference by another chambers' signal.

This construction of a human torso phantom is confirmed to give more conservative results for EMI estimations.

2.6 Conclusions on the measurement set-up

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





3. EMI investigations on active implantable medical devices

3.1 EMI experiments (FY2005 - FY2007)

- Breakdown of EMI experiments
  - EMI of different operating mode and functions – pacing/sensing polarity, single/dual chamber mode, and antitachycardia functions are examined.
  - RFID reader/writers operated in the frequency bands ISO18000-2,3,4,6 are tested.

active implantable medical devices
(9 manufactures)

Tested devices	Type of chambers	Number of devices
Pacemakers	Single chamber	16
	Dual chamber	14
ICDs	Single chamber	4
	Dual chamber	6
Total		40

RFID reader/writer antennas
(10 manufactures)

Frequency bands	Number of antennas
ISO18000-2	8
ISO18000-3	27
ISO18000-6	4
ISO18000-4	4
Total	41

3.2 EMI experiments (FY2008 -)

- EMI experiments scheduled for FY2008
  - Number of RFID reader/writers (ISO18000-6) and active implantable medical devices will be increased.
  - UHF RFID reader/writer systems which using miller subcarrier modulation will be tested.

active implantable medical devices

Tested devices	Type of chambers	Number of devices
Pacemakers	Single chamber	3
	Dual/triple chamber	22
ICDs	Single chamber	0
	Dual/triple chamber	12
Total		37

RFID reader/writer antennas

Frequency bands	Number of antennas
ISO18000-6 Miller subcarrier	4
ISO18000-6 Baseband	1
Total	5

3.3 Test results for bradycardia functions - Inhibition and asynchronous -

- Both for pacemakers and ICDs.

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

Results of EMI experiments (Maximum sensitivity)

Frequency (Type)	Tested Modes (A)	Affected modes (B)	Maximum interference distance	Affected rate (B/A)
ISO18000-2(Stationary)	638	194	17 cm	30.4 %
ISO18000-3 (Stationary)	814	19	15 cm	2.3 %
ISO18000-3 (Handheld)	1,021	8	4 cm	0.8 %
ISO18000-3(Gate)	438	14	22.5 cm	3.2 %
ISO18000-6 (Stationary)	1,134	53	75 cm	4.7 %
ISO18000-4(Stationary)	256	0	No EMI	0 %

3.4 Test results for tachycardia functions

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

Results of EMI experiments (Maximum sensitivity)

Frequency (Type)	Tested Modes (A)	Affected modes (B)	Maximum interference distance	Affected rate (B/A)
18000-2 (Stationary)	90	6	1 cm	6.7 %
18000-3 (Stationary)	118	0	No EMI	0 %
18000-3 (Handheld)	146	0	No EMI	0 %
18000-3 (Gate)	25	1	3 cm	4.0 %
18000-6(Stationary)	198	0	No EMI	0 %
18000-4 (Stationary)	44	0	No EMI	0 %

3.5 Conclusions on the EMI experiments

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

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

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

➢ For ISO18000-6 RFID reader/writer antennas, only a few pacemakers are affected over the maximum interference distance of 22 cm. These are observed when the pacemakers are set at maximum sensitivity. The maximum interference distance is drastically shortened when their sensitivities are reduced.

Appendix: The human torso phantom based on Irnich model

A. 1 Effect of Plexiglas (Acrylic front panel)

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

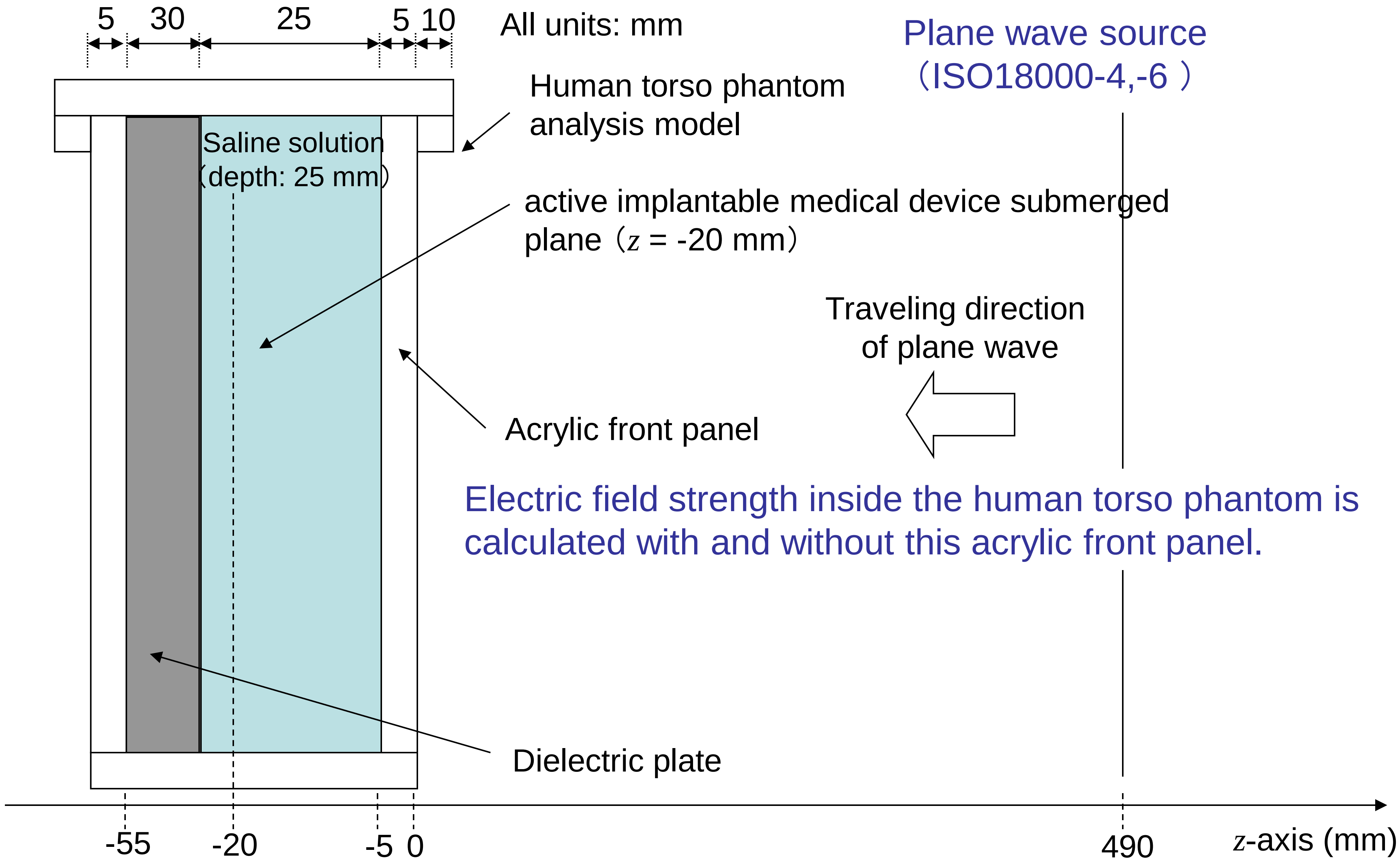
- The electric field strength inside the phantom with/without the acrylic front panel is calculated based on 3 dimensional FDTD (Finite-difference time-domain method) analysis.

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

Material constants

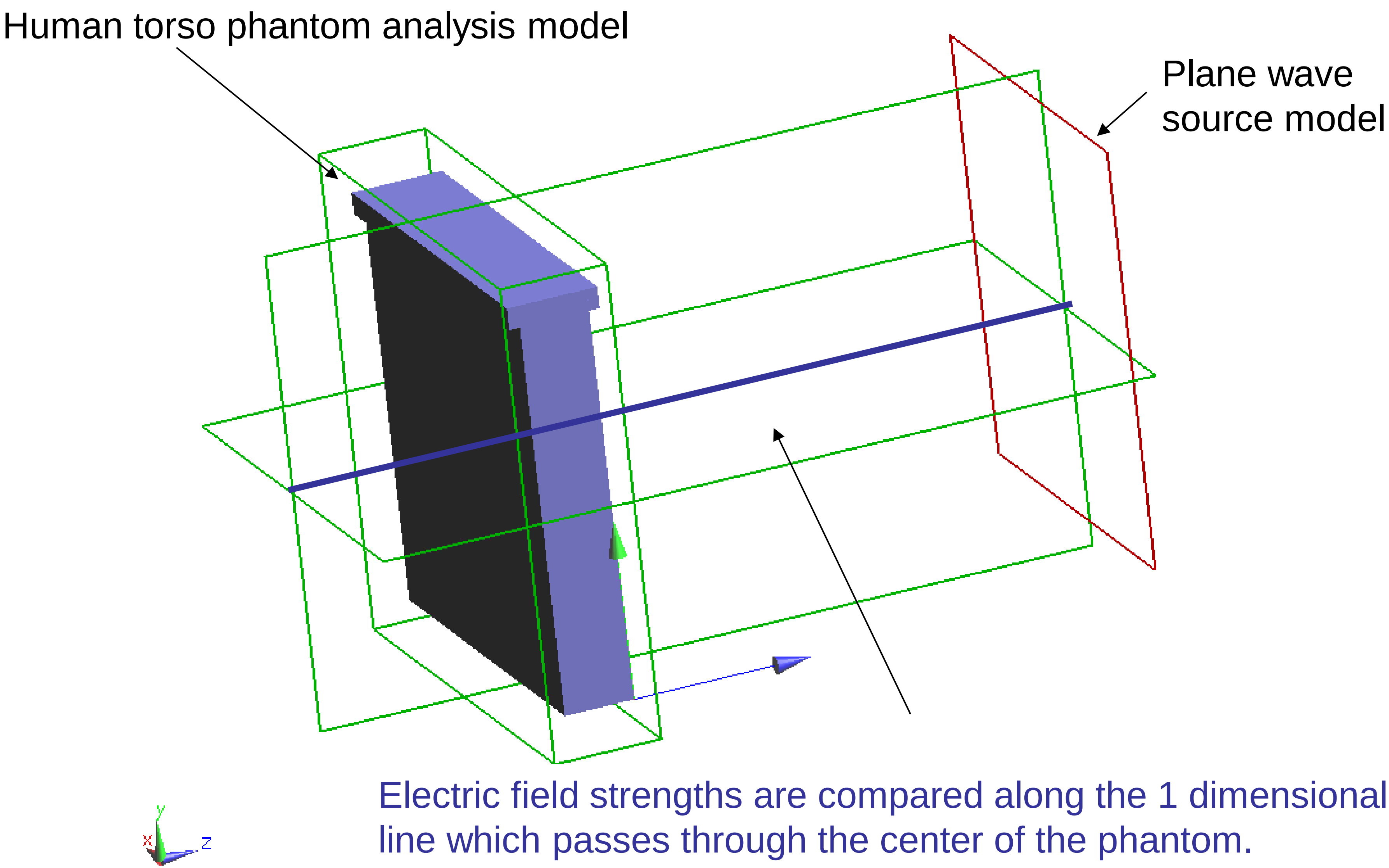
Materials	Relative dielectric constant	Electric conductivity（S/m）
Acrylic panel	3	0
Saline solution	75	1
Dielectric plate	50	2

A. 2 Electromagnetic wave exposure condition



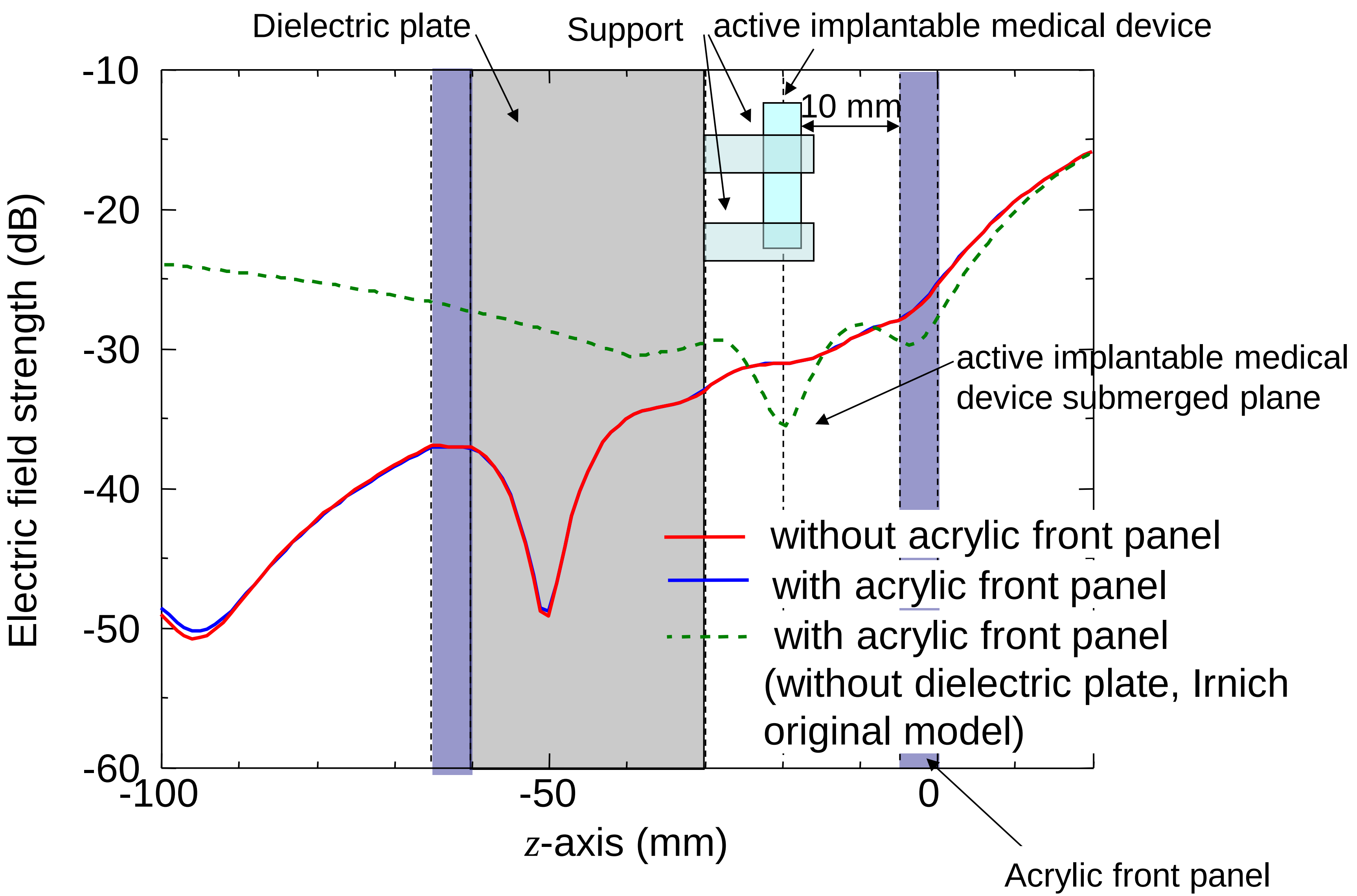
Electric field strength inside the human torso phantom is calculated with and without this acrylic front panel.

A. 3 3D human torso phantom analysis model

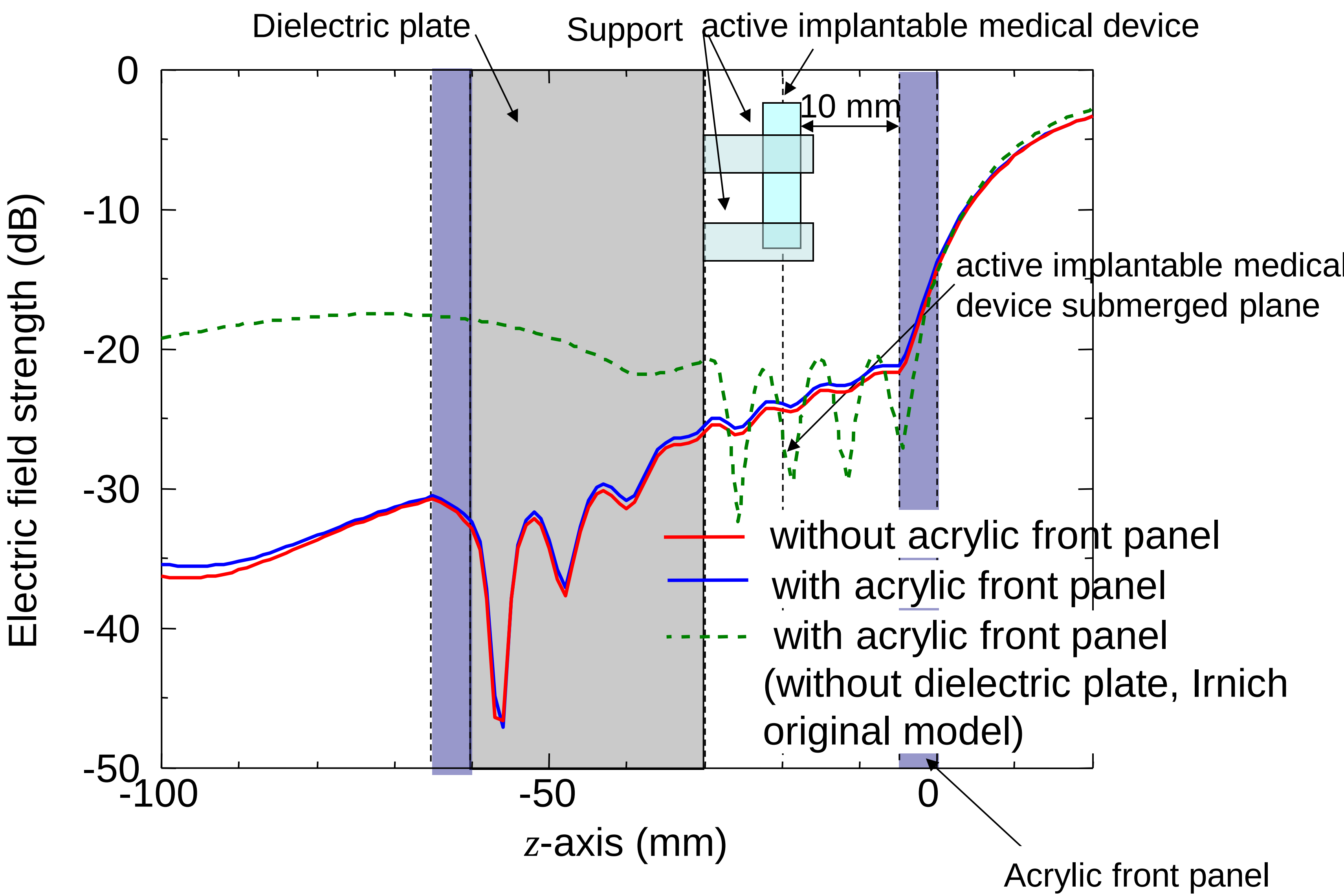


Electric field strengths are compared along the 1 dimensional line which passes through the center of the phantom.

A. 4 Analysis results of electric field (ISO18000-6)



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



A. 6 Conclusions on the human torso phantom

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

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

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

4. EMI mitigation method

4.1 EMI mitigation method

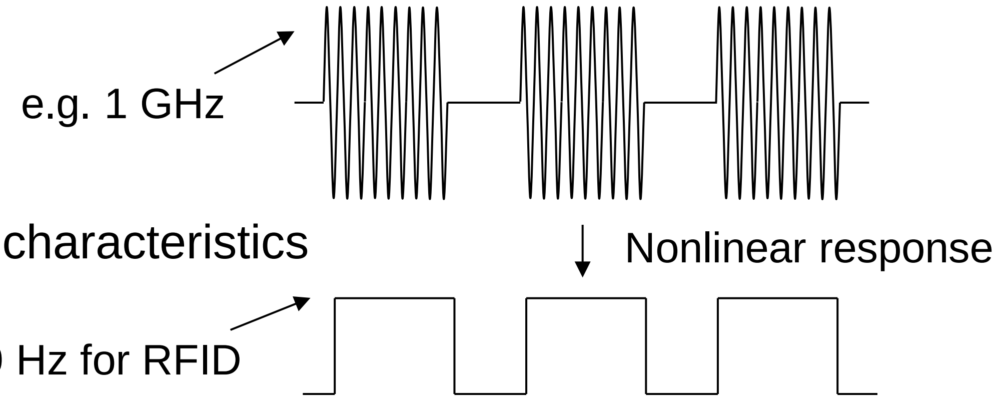
- Mechanism of active implantable medical device EMI

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

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

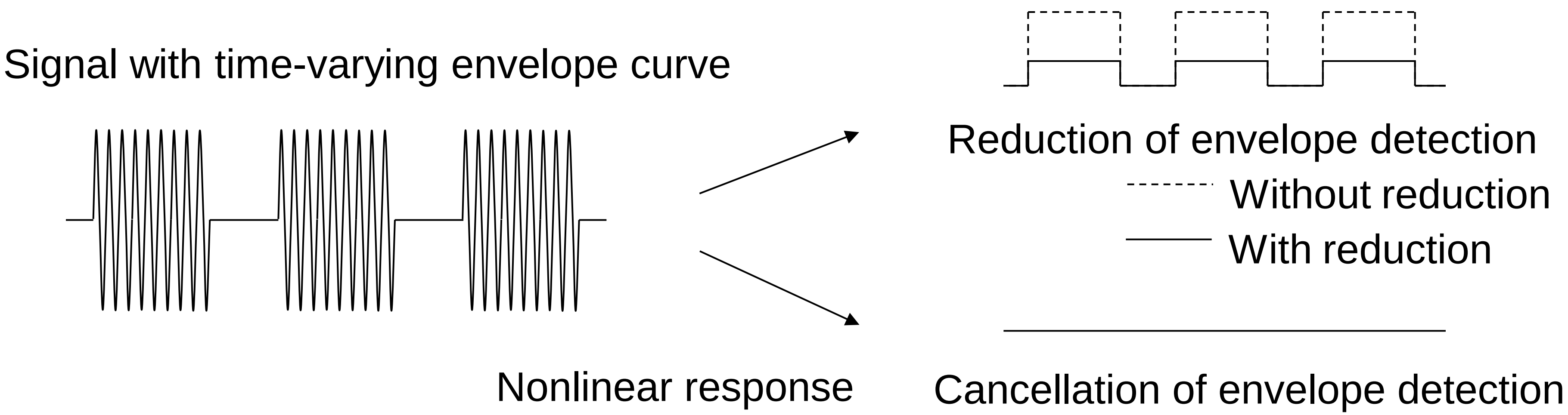
(a) RFID signal with time-varying envelope curve

(b) Detected signal due to nonlinear characteristics



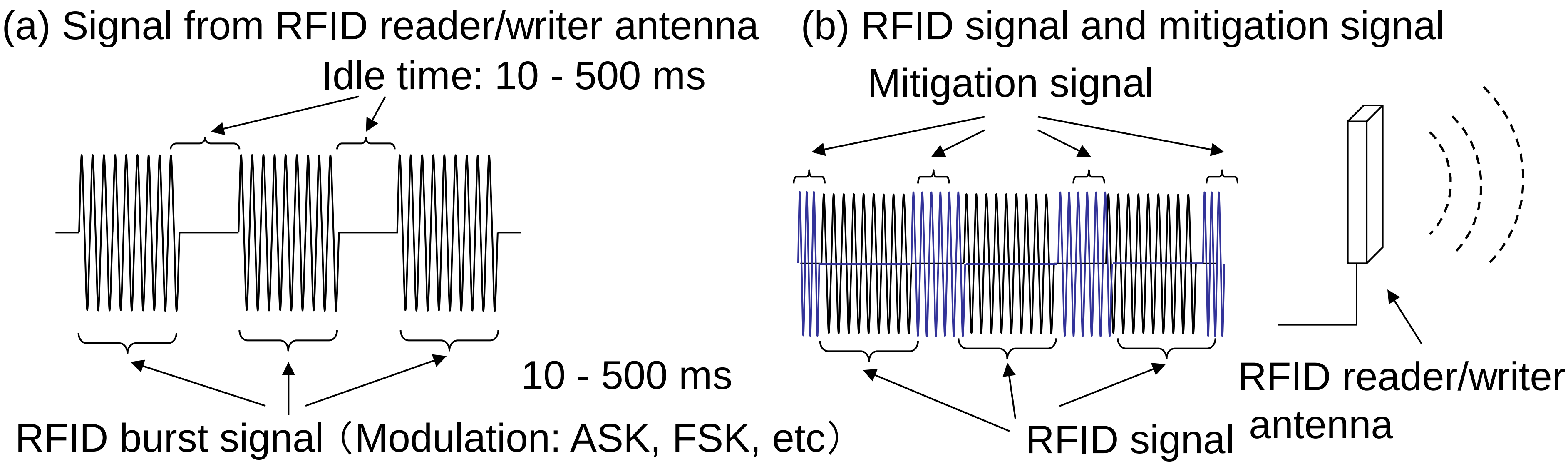
4.2 Principle of EMI mitigation

- Low frequency noises are generated with time-varying envelope curve signal exposure (i.e. amplitude modulation, pulse modulation, and intermittent signal).
- On the other hand, CW or CW-like signals (i. e. frequency modulation and phase modulation) do not generate low frequency noise. This is because the envelopes of these signals do not contain the 0.5 – 100 Hz.
- If the detected low frequency signal is reduced or cancelled, the EMI could be mitigated or eliminated.



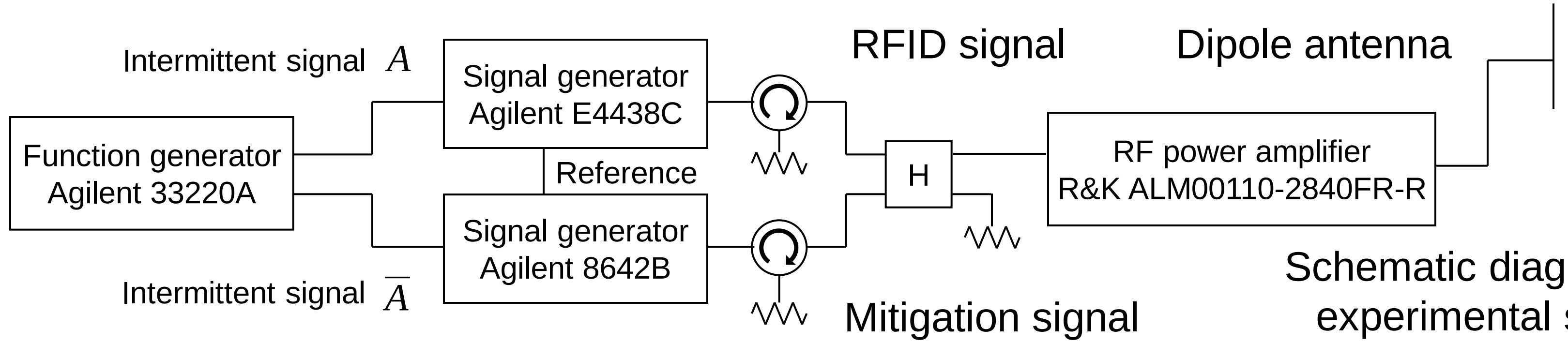
4.3 Fundamental construction

- The newly proposed method is based on a “mitigation signal” which fulfils a time gap in an RFID transmission signal.
- Some RFID systems transmit signals intermittently in a certain idle time. The idle times are typically 10 to 500 ms depending on the system. The difference in field strength at the transmitting time and the idle time causes a low frequency signal in active implantable medical devices.
- To reduce a time-varying envelope curve, the proposed method transmits a “mitigation signal” from the RFID or different antenna.

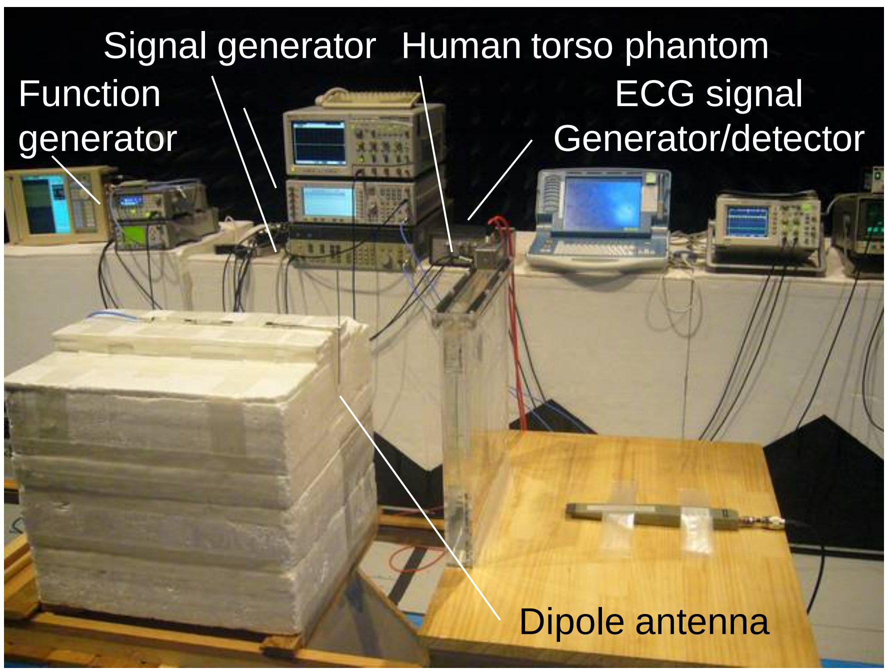


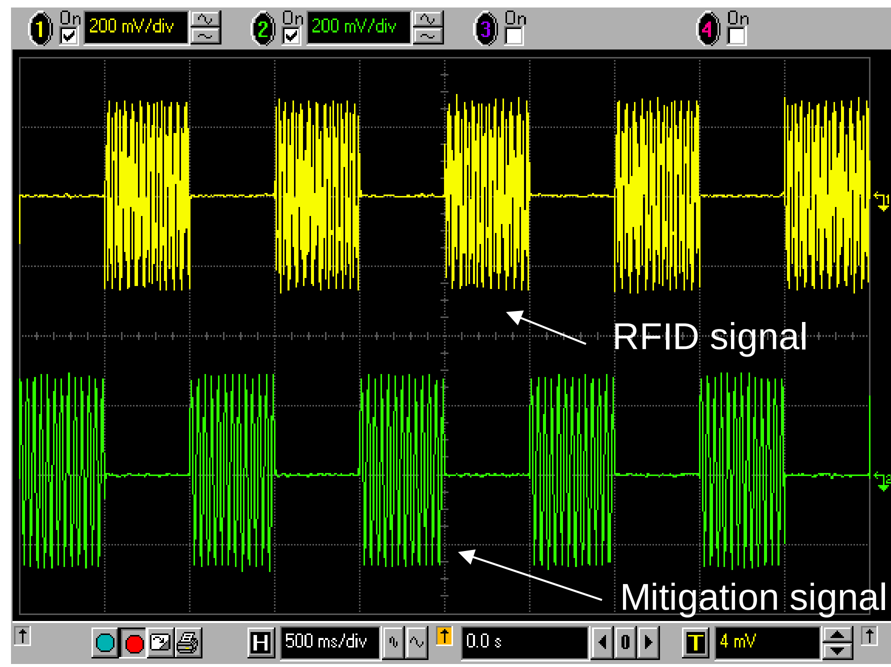
4.4 Experimental validation

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



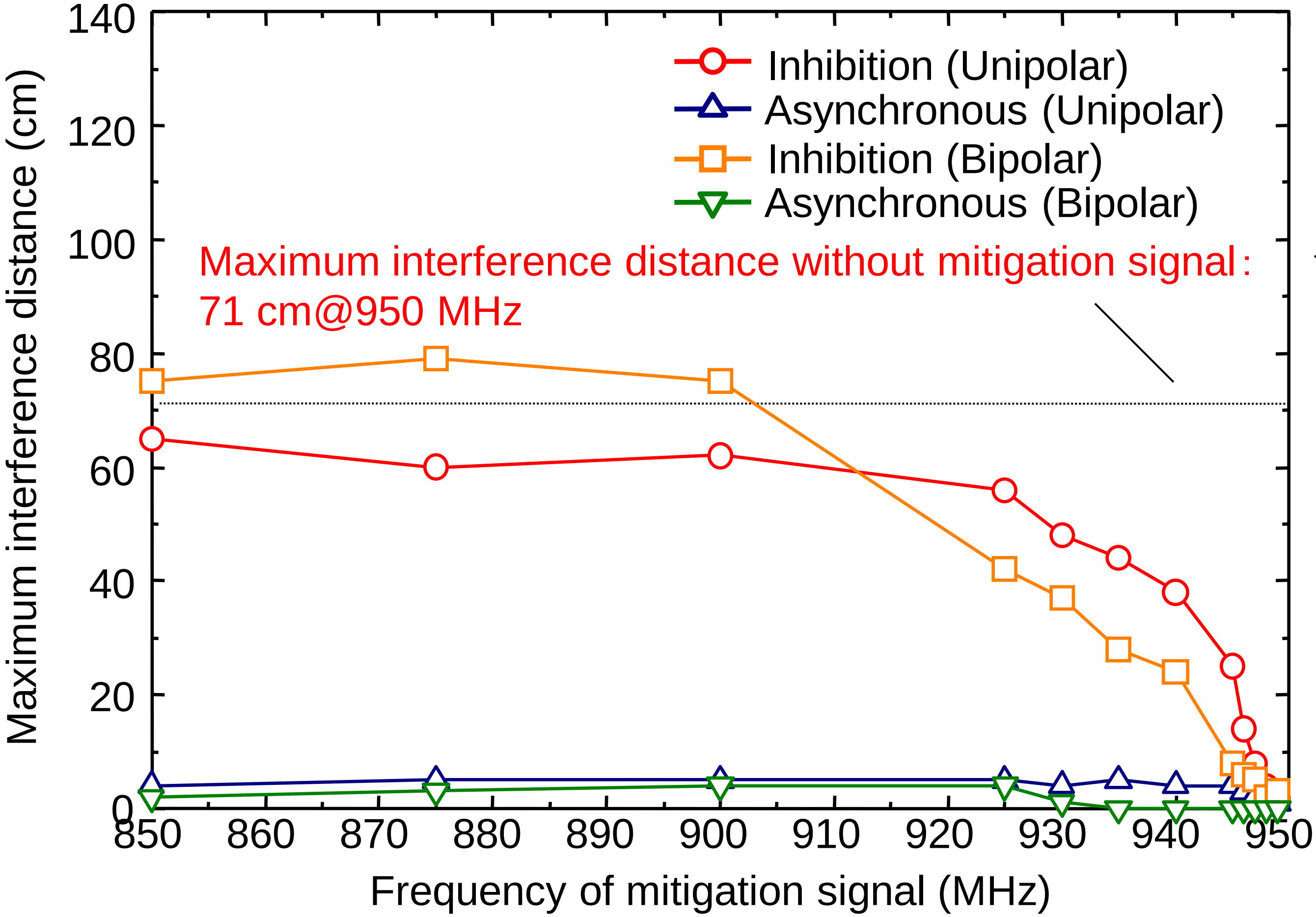
Schematic diagram of experimental setup





4.5 Example of mitigation (pacemaker A)

- Maximum interference distance at different mitigation signal frequency



Frequency of RFID signal: 950 MHz

Intermittent period of RFID signal: 1 Hz with 0.5 duty factor

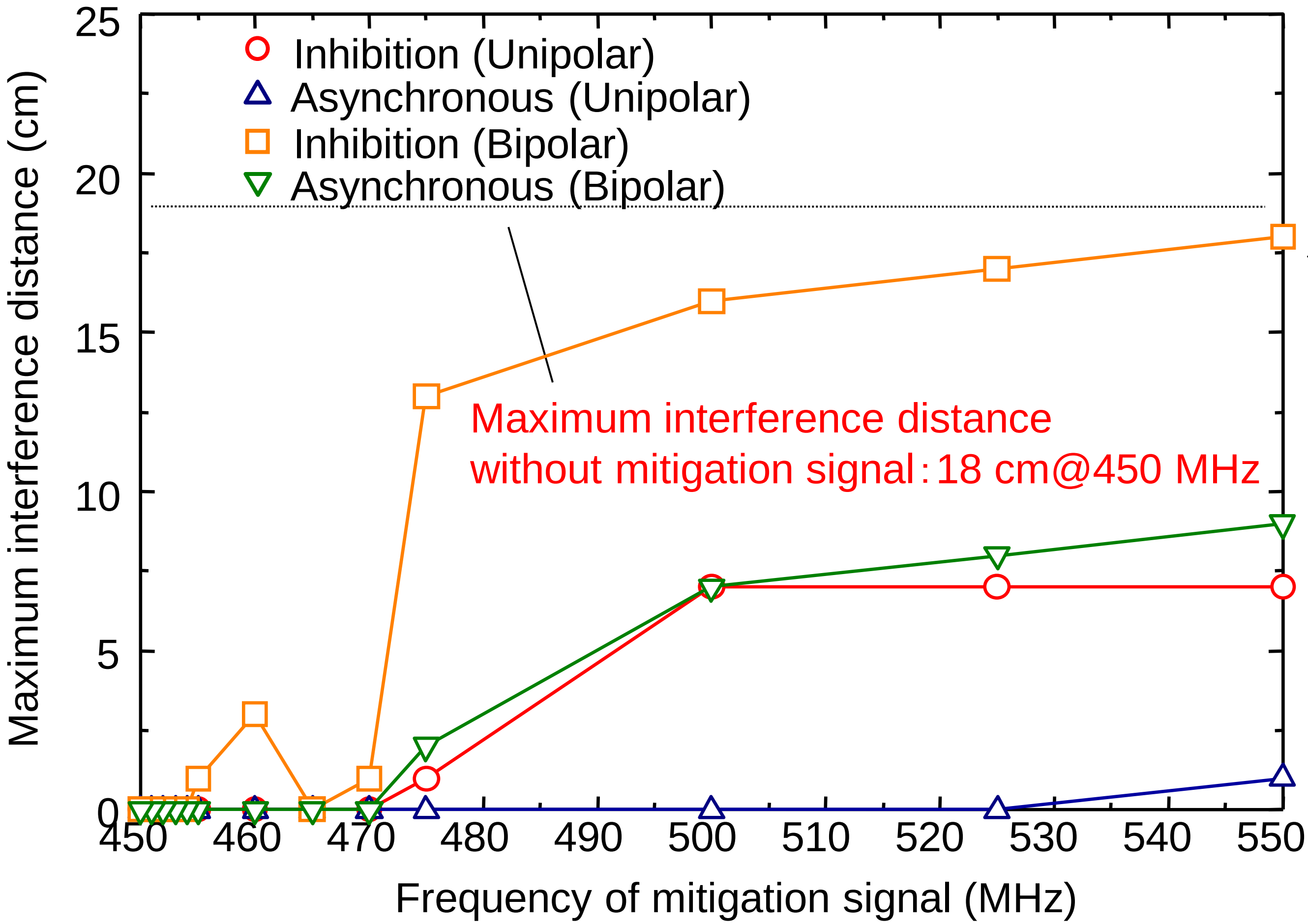
Frequency of mitigation signal: 850 – 950 MHz

Antenna input power: 1 W

Maximum interference distance 71 cm is improved to 3 cm. (Frequency offset: 1 MHz)

4.6 Example of mitigation (pacemaker B)

- Maximum interference distance at different mitigation signal frequency



Frequency of RFID signal: 450 MHz

Intermittent period of RFID signal: 14 Hz with 0.17 duty factor

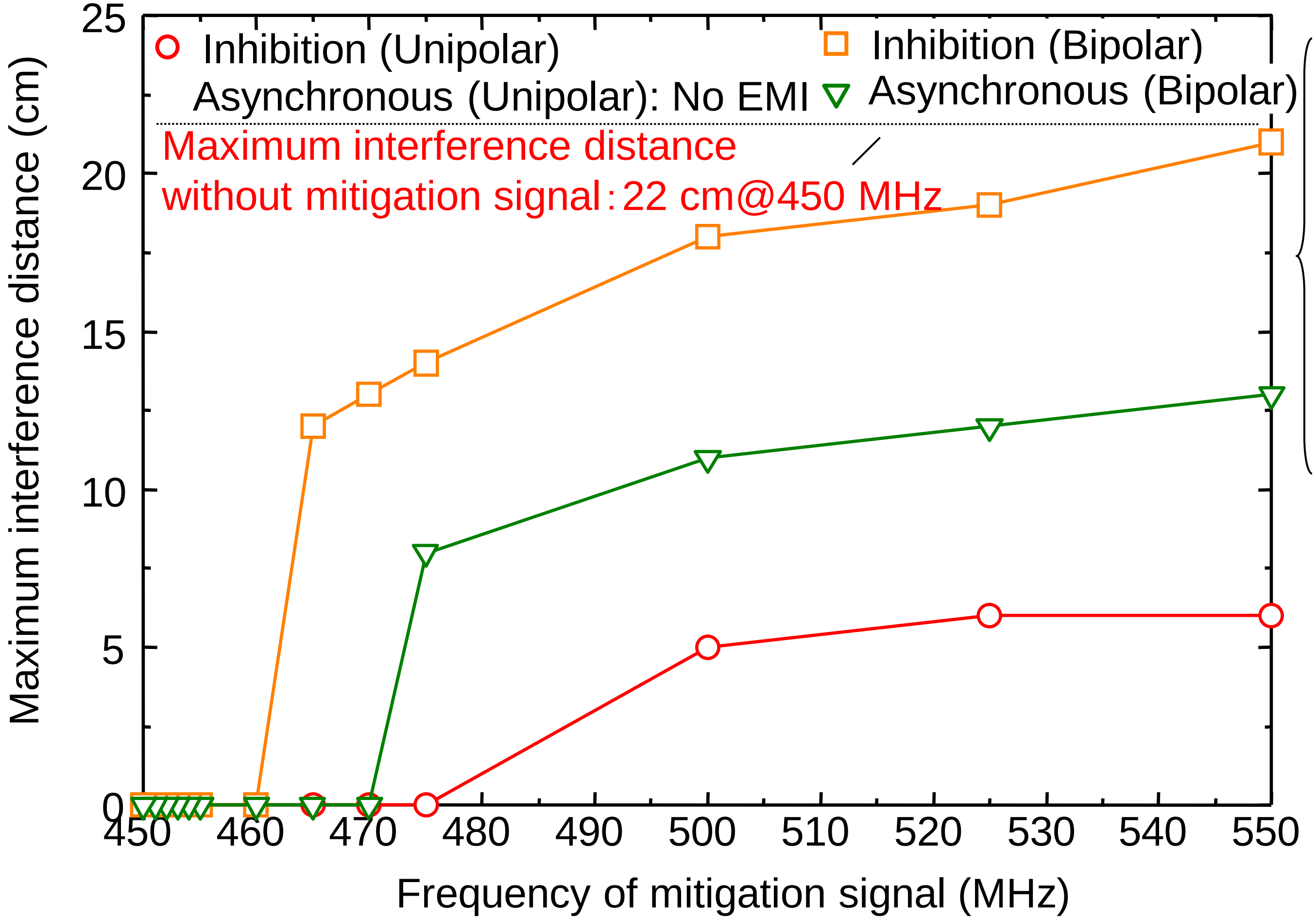
Frequency of mitigation signal: 450 – 550 MHz

Antenna input power: 1 W

EMI is completely cancelled at the frequency offset between 0 MHz and 4 MHz.

4.7 Example of mitigation (pacemaker C)

- Maximum interference distance at different mitigation signal frequency



Frequency of RFID signal: 450 MHz

Intermittent period of RFID signal: 14 Hz with 0.17 duty factor

Frequency of mitigation signal: 450 – 550 MHz

Antenna input power: 1 W

EMI is completely cancelled at the frequency offset between 0 MHz and 10 MHz.

4.8 Conclusions on the EMI mitigation method

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

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

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

- More detailed investigation of mitigation performance such as EMI characteristics depending on the amplitude and the switching time of mitigation signal are now being carried out. In addition, interference with tag communication will be investigated.

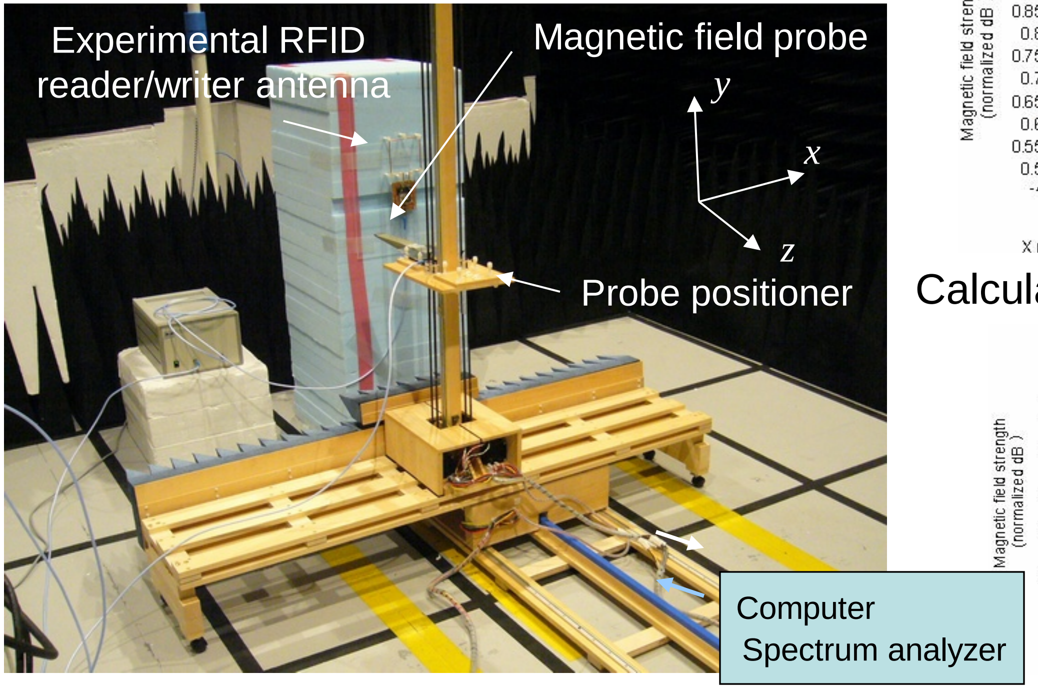
5. Numerical EMI estimation method (informative)

5.1 Numerical EMI estimation method

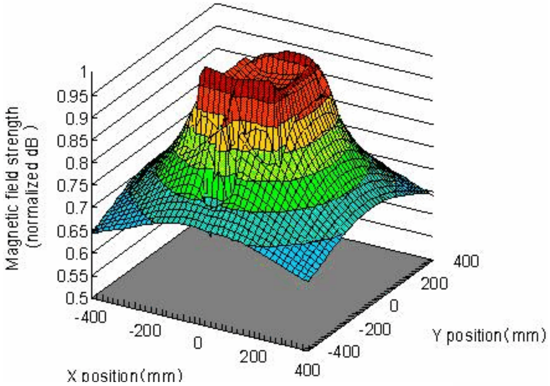
- FDTD analysis of active implantable medical device EMI
  - The fundamental validation for the EMI due to HF (ISO18000-3) reader/writers is confirmed based on measured and analysis results.

Magnetic field strength (antenna surface)

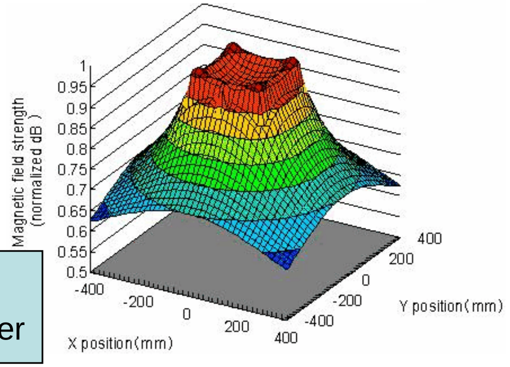
3 dimensional measurement system

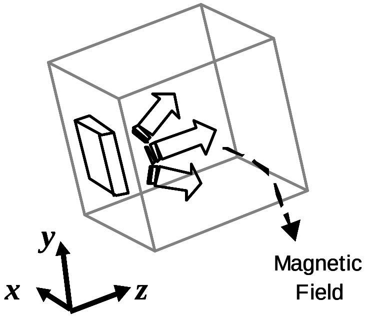


Measurement (*xy*-axis)



Calculation (*xy*-axis)

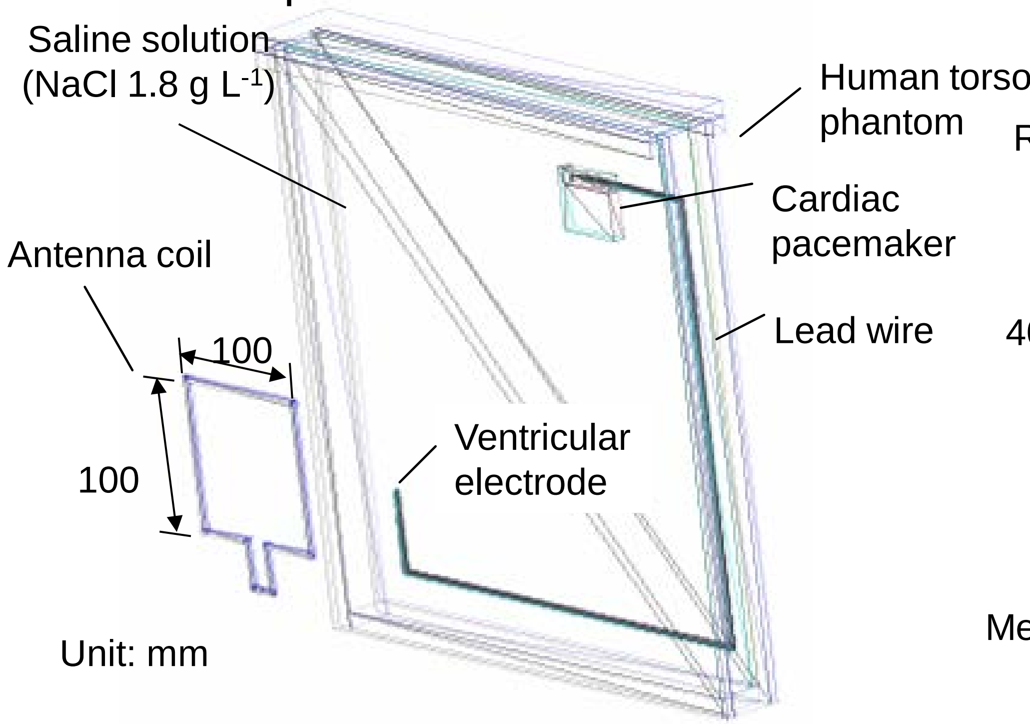




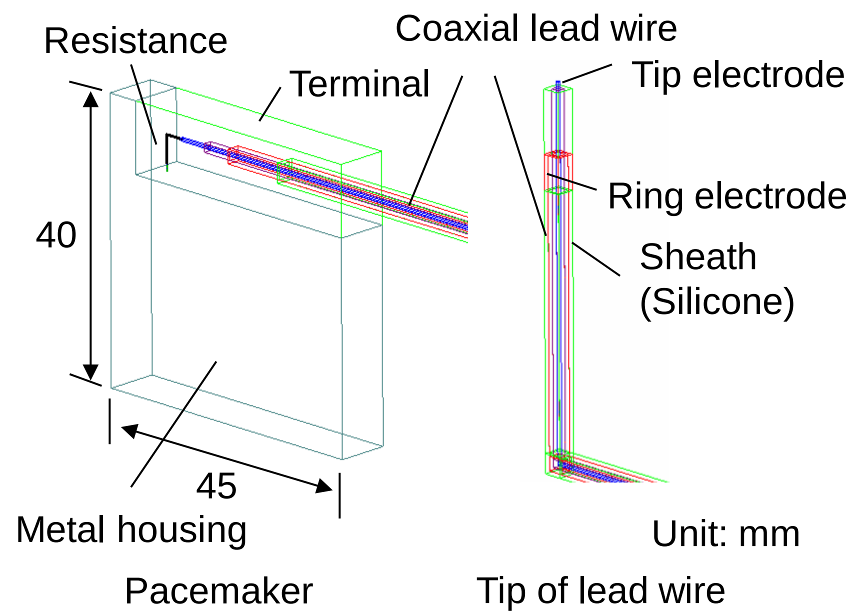
5.2 Torso phantom and pacemaker model

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

An example of the numerical model

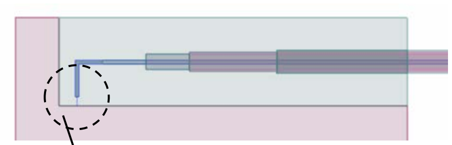


The numerical model of the pacemaker and the lead wire

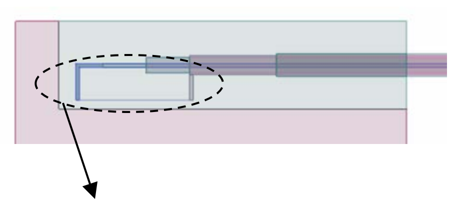


5.3 Analyzed interference voltage

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

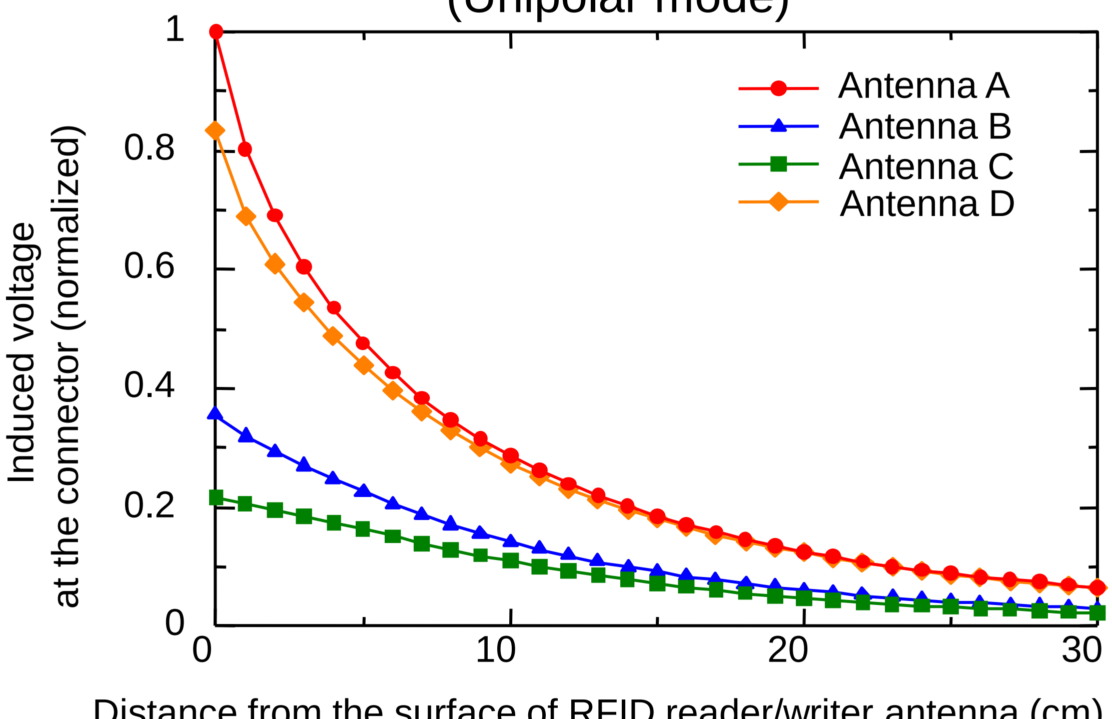


Unipolar mode: the metal housing of the pacemaker model and the inner conductor of coaxial lead wire model



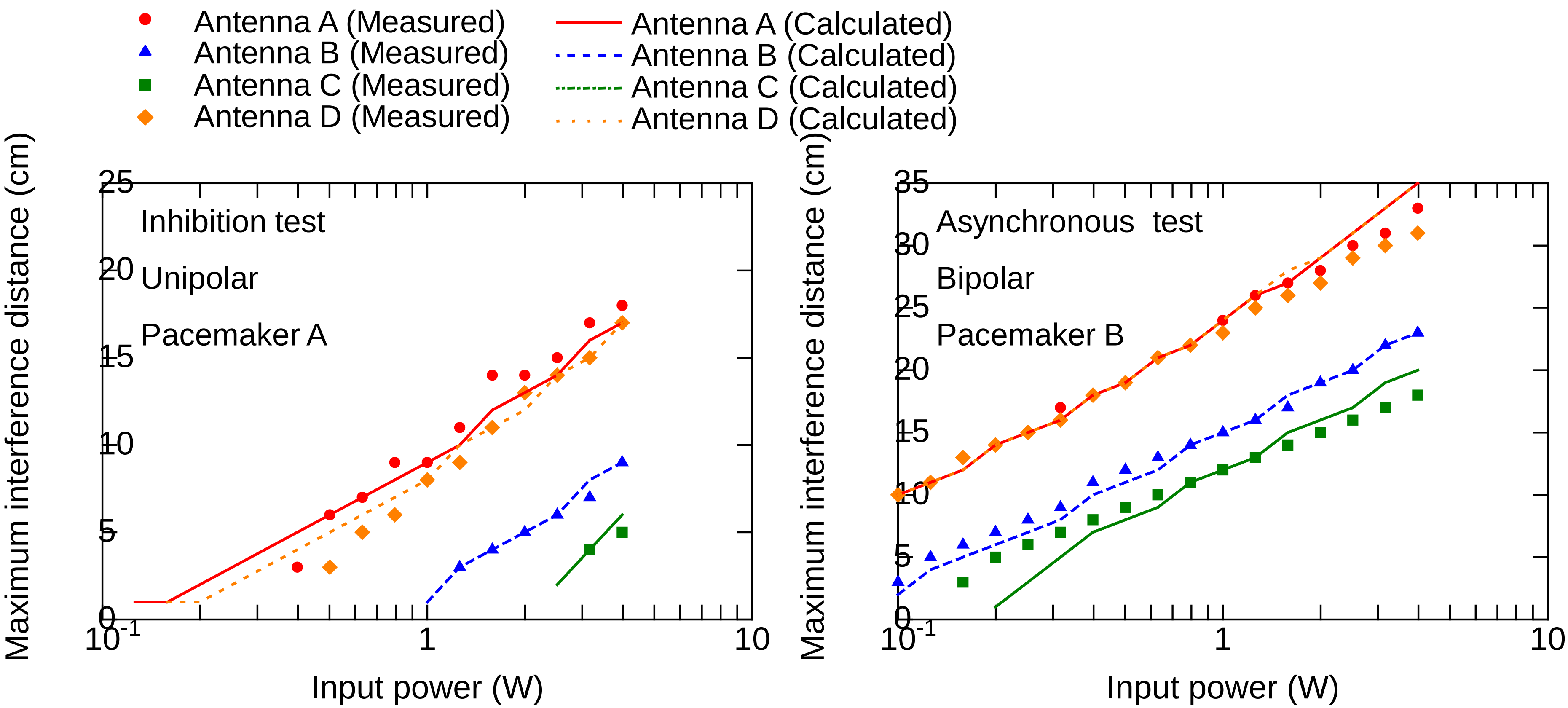
Bipolar mode: the outer conductor of coaxial lead wire model and the inner conductor of coaxial lead wire model

The interference voltage obtained by the analysis (Unipolar mode)



5.4 Comparison of maximum interference distances

Examples of the measured and calculated maximum interference distance



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

6. Conclusions

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

- Maximum interference distance of EMI

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

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

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

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

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