ISO/IEC JTC 1 N 9507

2009-02-04

ISO/IEC JTC 1
Information Technology

Document Type:	**Proposed NP**
Document Title:	**SC 31 New Work Item Proposal - Information technology -- Automatic identification and data capture techniques -- Radio frequency identification for item management -- Experimental evaluation method for impact distance and mitigation method of Electromagnetic Interference (EMI) from RFID interrogators on active implantable medical devices**
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Reference:	
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Action ID:	**ACT**
Due Date:	**2009-05-04**
No. of Pages:	**54**

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ISO/IEC JTC 1/SC 31

Automatic Identification and Data Capture Techniques

Secretariat: ANSI (USA)

DOC TYPE:	**New Work Item Proposal**
TITLE:	**Information technology -- Automatic identification and data capture techniques -- Radio frequency identification for item management -- Experimental evaluation method for impact distance and mitigation method of Electromagnetic Interference (EMI) from RFID interrogators on active implantable medical devices**
SOURCE:	**National Body of Japan**
PROJECT:	
STATUS:	**The National Body of Japan proposes a new project as described in the attached "SC031-N-2730 - NWIP Form.doc", and this document is provided to supplement additional information on the proposal.** **P-members have an obligation to vote and are requested to cast votes on the SC 31 Web site (LiveLink) by the date indicated on this cover page. Per Resolution 5 of the Seoul Plenary Meeting, P-Members are requested to use the attached form (SC031 - Form 13B Comment Document.doc)**
ACTION ID:	**COM**
DUE DATE:	**2009-05-04**
DISTRIBUTION:	**ISO/IEC JTC 1/SC 31 members**
MEDIUM:	**ISO TC Portal (LiveLink)**
NO. OF PAGES:	**52 (including this cover)**

New Work Item Proposal

February 2009

PROPOSAL FOR A NEW WORK ITEM

Date of presentation of proposal: 2009-02-04	Proposer: JISC (National Body of Japan)
Secretariat: ANSI	**ISO/IEC JTC 1 N** xxxx ISO/IEC JTC 1/SC 31 N 2730

A proposal for a new work item shall be submitted to the secretariat of the ISO/IEC joint technical committee concerned with a copy to the ISO Central Secretariat.

Presentation of the proposal - to be completed by the proposer

Title (subject to be covered and type of standard, e.g. terminology, method of test, performance requirements, etc.)

Information technology -- Automatic identification and data capture techniques -- Radio frequency identification for item management -- Experimental evaluation method for impact distance and mitigation method of Electromagnetic Interference (EMI) from RFID interrogators on active implantable medical devices

Scope (and field of application)

This technical information can be applied to ISO18000 Series RFID interrogators.

(a) The purpose of this information is to present the method of configuring the standard test system and the test method, to evaluate the EMI from RFID interrogators on active implantable medical devices (cardiac pacemakers and cardioverter defibrillators).

(b) Propose a mitigation method using auxiliary radio wave (or a radio filler) to reduce EMI influence of RFID interrogators on active implantable medical devices.

Purpose and justification - attach a separate page as annex, if necessary

(a) Background

There are cases where electromagnetic waves emitted by RFID interrogators may cause EMI to active implantable medical devices, resulting in malfunctions.

It has already been confirmed that EMI characteristics depend on the radiation characteristics of the RFID interrogators' electromagnetic field and the immunity of active implantable medical devices.

The influence of radio waves from cellular phones is a similar EMI issue. A standard method to evaluate the influence experimentally (SAR measurement method, IEC TC106/84/FDIS) has been proposed (reference: AAMI), and Japanese guidelines have also been established, regarding 22 cm as an isolation distance where cellular phones can be used without causing any disturbance.

Regarding RFID, there is an EMI influence evaluation method that uses flat-plane phantom using a liquid that may only be handled by a qualified expert. Using this method, the isolation distance not influenced by RFID was measured, and the measured distance has been presented as a guideline. The Japanese guideline indicates that the required isolation distance is a radius of 1 m for UHF band high-power stationary RFID interrogators, and 22 cm for other RFID interrogators (same as that for cellular phones).

For RFID, however, no methods to prevent or mitigate EMI have been examined yet, in spite of the large isolation distance (radius of 1 m).

It is essential to establish a solution for this issue in order to expand usage of RFID systems and devices.

Therefore this document intends to investigate the following subjects in order to provide technical information that can be used for standardization:

(b) Details

(1) Basic method of configuring experimental evaluation system and test procedure,

(2) Suggestion of simple experimental system appropriate for standardization (use of phantom, a new material),

(3) Experimental evaluation results for typical devices,

(4) Basic configuration of technical countermeasures to reduce the distance of interference without affecting the RFID's communication performance

Programme of work

If the proposed new work item is approved, which of the following document(s) is (are) expected to be developed?

____ a single International Standard

____ more than one International Standard (expected number: .....)
____ a multi-part International Standard consisting of ..... parts
____ an amendment or amendments to the following International Standard(s) .....
_**X**__ a technical report , type3

And which standard development track is recommended for the approved new work item?

_**X**__ a. Default Timeframe

____b. Accelerated Timeframe

____c. Extended Timeframe

Relevant documents to be considered

ISO/IEC 18000-1, -2, -3, -4, -6, -7, 18046 - 1,- 2,- 3,18047 - 1,- 2,- 3,- 4,- 6,- 7

Cooperation and liaison

AIM Global

IEC TC106

Preparatory work offered with target date(s)

Working Draft will be prepared by the end of May from Prof. Nojima from Hokkaido University.

Signature: Ray Delnicki, ISO/IEC JTC 1/SC 31 Secretariat
Will the service of a maintenance agency or registration authority be required? **No** - If yes, have you identified a potential candidate? - If yes, indicate name Are there any known requirements for coding? **No** -If yes, please specify on a separate page Does the proposed standard concern known patented items? **No** - If yes, please provide full information in an annex

Comments and recommendations of the JTC 1 Secretariat - attach a separate page as an annex, if necessary

Comments with respect to the proposal in general, and recommendations thereon: It is proposed to assign this new item to JTC 1/SC 31/WG 4/SG 5

Voting on the proposal - Each P-member of the ISO/IEC joint technical committee has an obligation to vote within the time limits laid down (normally three months after the date of circulation).

Date of circulation:	**Closing date for voting:**	**Signature of JTC 1 Secretary:**
2009-02-04	2009-05-04	

NEW WORK ITEM PROPOSAL - PROJECT ACCEPTANCE CRITERIA		
Criterion	**Validity**	**Explanation**
A Business Requirement		
A.1 Market Requirement	Essential _**X**_ Desirable ___ Supportive _ _	For medical devices implanted patient, it is essential to reduce the effect from the electro magnetic influences from the RFID reader writers. Proposed mitigation method is to reduce EMI influence of RFID interrogators on active implantable medical devices. By this method the RFID devices can use in a safer manner for the implanted patient.
A.2 Regulatory Context	Essential ___ Desirable ___ Supportive __ Not Relevant _**X**_	
B. Related Work		

B.1 Completion/Maintenance of current standards	Yes __ No _**X**_	
B.2 Commitment to other organization	Yes ___ No _**X**_	
B.3 Other Source of standards	Yes __ No _**X**_	
C. Technical Status		
C.1 Mature Technology	Yes __ No _**X**_	
C.2 Prospective Technology	Yes _**X**_ No __	
C.3 Models/Tools	Yes _**X**____ No __	
D. Conformity Assessment and Interoperability		
D.1 Conformity Assessment	Yes __ No _**X**_	
D.2 Interoperability	Yes **__** No _**X**_	
E. Other Justification		

Notes to Proforma

A. Business Relevance. That which identifies market place relevance in terms of what problem is being solved and or need being addressed.

A.1. Market Requirement. When submitting a NP, the proposer shall identify the nature of the Market Requirement, assessing the extent to which it is essential, desirable or merely supportive of some other project.

A.2 Technical Regulation. If a Regulatory requirement is deemed to exist - e.g. for an area of public concern e.g. Information Security, Data protection, potentially leading to regulatory/public interest action based on the use of this voluntary international standard - the proposer shall identify this here.

B. Related Work. Aspects of the relationship of this NP to other areas of standardization work shall be identified in this section.

B.1 Competition/Maintenance. If this NP is concerned with completing or maintaining existing standards, those concerned shall be identified here.

B.2 External Commitment. Groups, bodies, or fora external to JTC 1 to which a commitment has been made by JTC for cooperation and or collaboration on this NP shall be identified here.

B.3 External Std/Specification. If other activities creating standards or specifications in this topic area are known to exist or be planned, and which might be available to JTC 1 as PAS, they shall be identified here.

C. Technical Status. The proposer shall indicate here an assessment of the extent to which the proposed standard is supported by current technology.

C.1 Mature Technology. Indicate here the extent to which the technology is reasonably stable and ripe for standardization.

C.2 Prospective Technology. If the NP is anticipatory in nature based on expected or forecasted need, this shall be indicated here.

C.3 Models/Tools. If the NP relates to the creation of supportive reference models or tools, this shall be indicated here.

D. Any other aspects of background information justifying this NP shall be indicated here.

D. Conformity Assessment and Interoperability

D.1 Indicate here if Conformity Assessment is relevant to your project. If so, indicate how it is addressed in your project plan.

D.2 Indicate here if Interoperability is relevant to your project. If so, indicate how it is addressed in your project plan

Annex

Discussion on New Work Item

Please see an attached Power point document too.

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

Wireless Technology & EMC Research Lab.
Graduate School of Information Science and Technology,
Hokkaido University, Japan.
Japan Automatic Identification Systems Association, Japan

Document No JAISA-RFID-TR080048

Contents

- 1. Introduction
- 2. Electromagnetic interference (EMI) measurement set-up
- 3. EMI investigations on active implantable medical devices
- 4. EMI mitigation method
- 5. Numerical EMI estimation method (informative)
- 6. Conclusions

1. Introduction

1.1 Electromagnetic Compatibility (EMC)

Wireless communication devices
Receivers

Electronics instruments

Medical equipments
(hospital, home)

Special electronics devices

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

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）

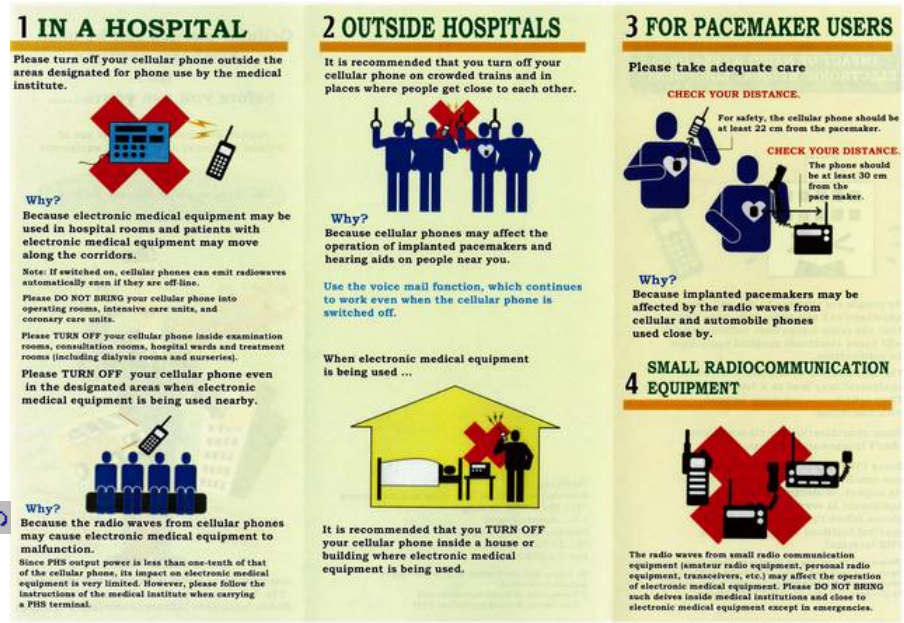
2. 植込み型医療機器の装着者は、体調に何らかの変化があると感じた場合は、担当医に相談すること。
3. 植込み型医療機器に対する据置きタイプRFID機器の影響を軽減するため、更なる安全性の検討を関係団体で行っていくこと。

100cm 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機種であることから、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員対して、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 even 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.

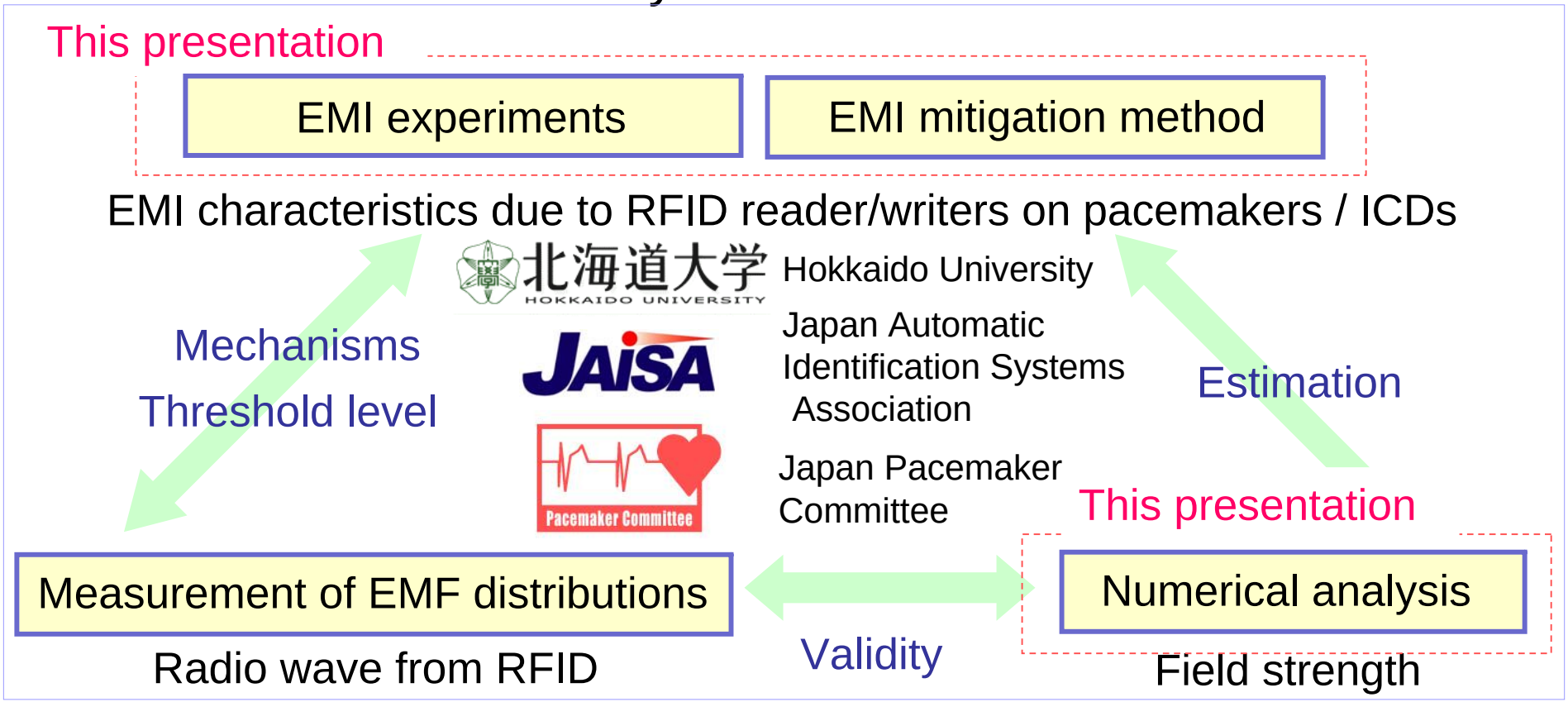
1.3 Active implantable medical devices

- 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.

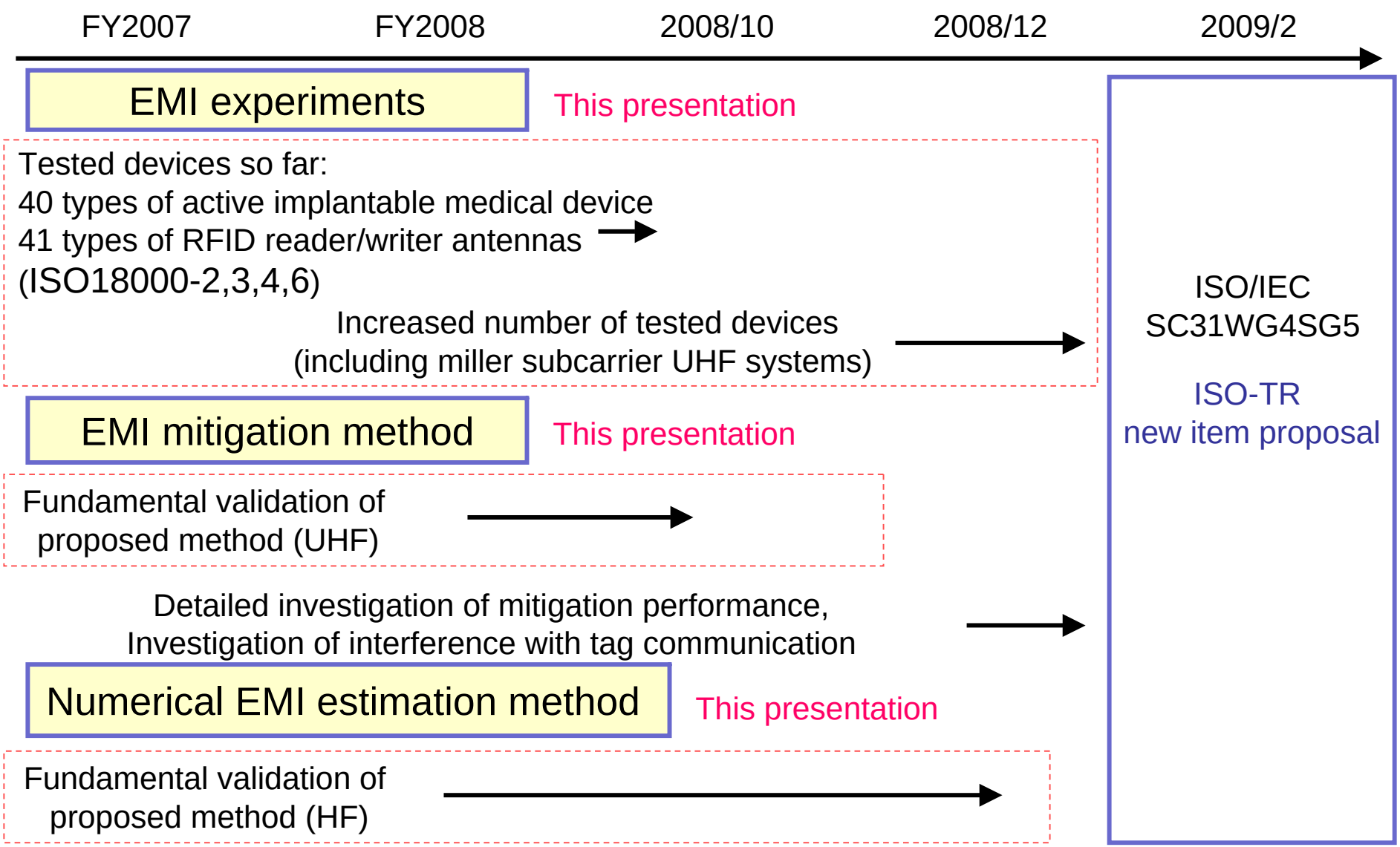
Because EMI characteristics of these two devices are almost same, it is not necessary to separate treatment.

1.4 Objectives

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

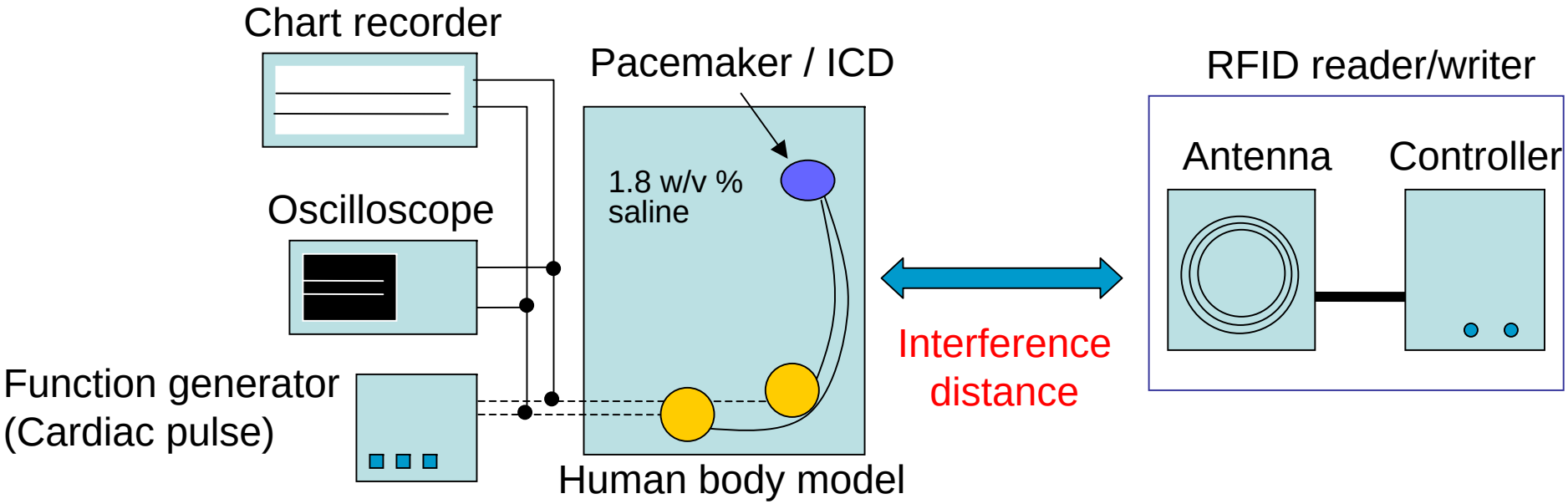


1.5 Schedule

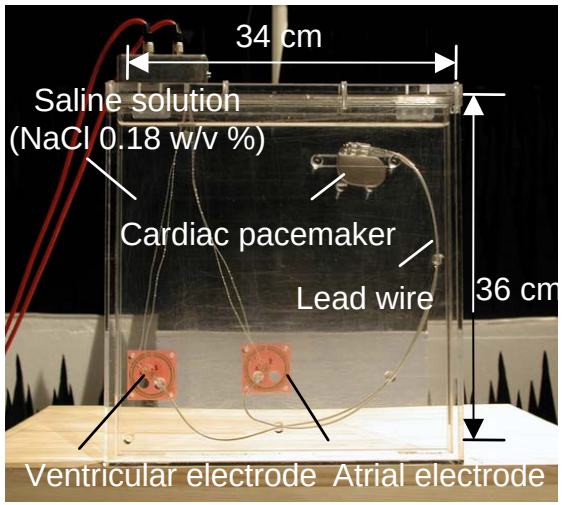

FY2007
FY2008
2008/10
2008/12
2009/2
EMI experiments
This presentation
Tested devices so far:
40 types of active implantable medical device
41 types of RFID reader/writer antennas
(ISO18000-2,3,4,6)
Increased number of tested devices
(including miller subcarrier UHF systems)
EMI mitigation method
This 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

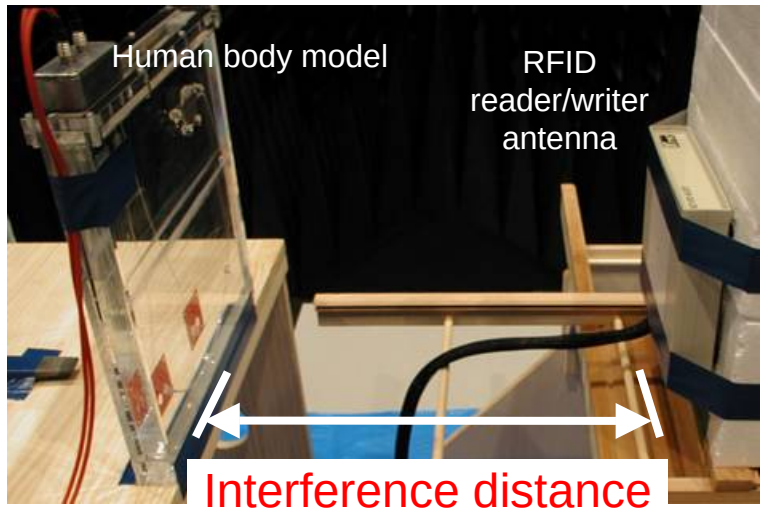
2. Electromagnetic interference (EMI) measurement set-up

2.1 Configuration of the measurement set-up

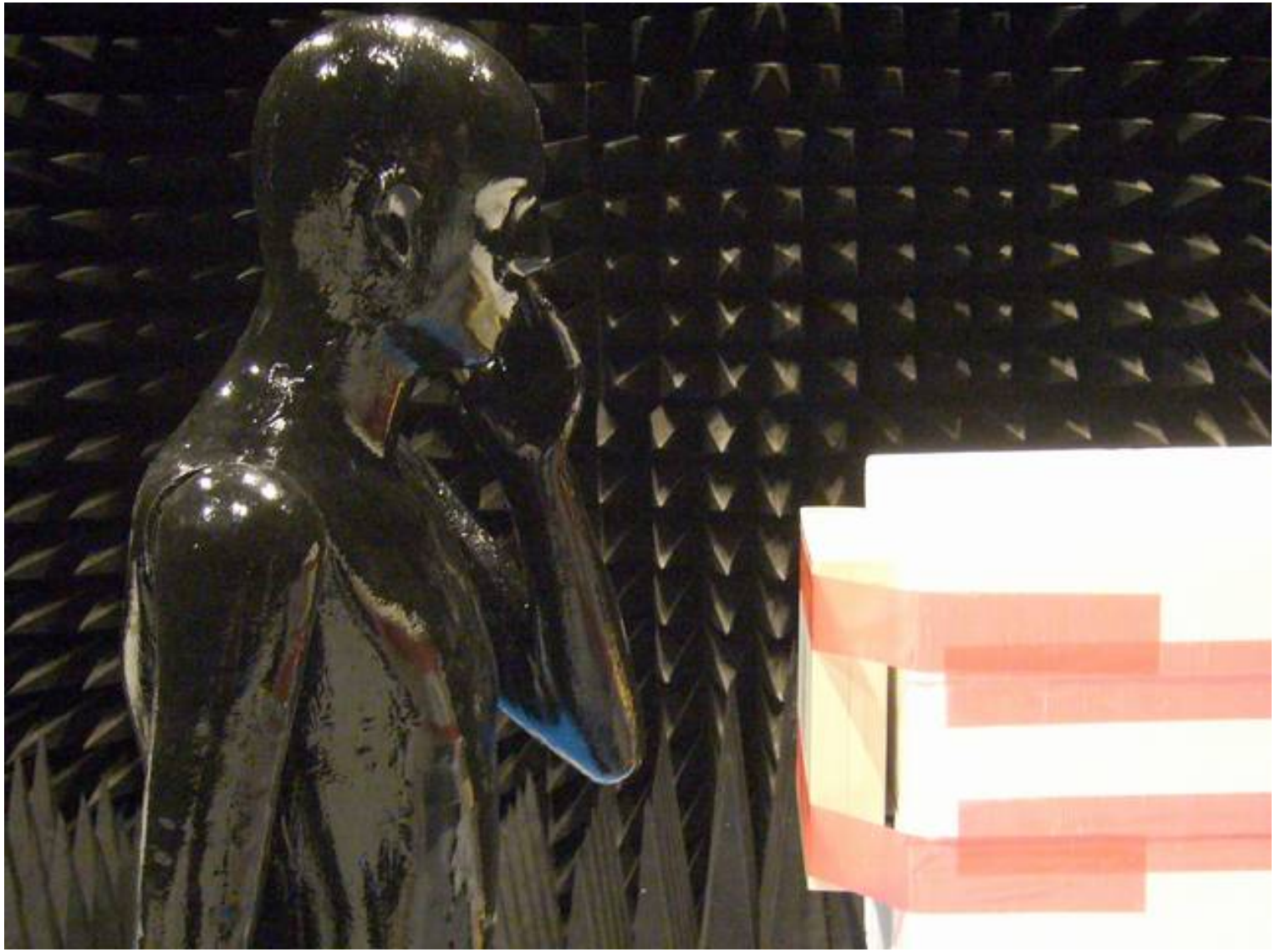


Function Generator
Oscilloscope
& Chart Recorder

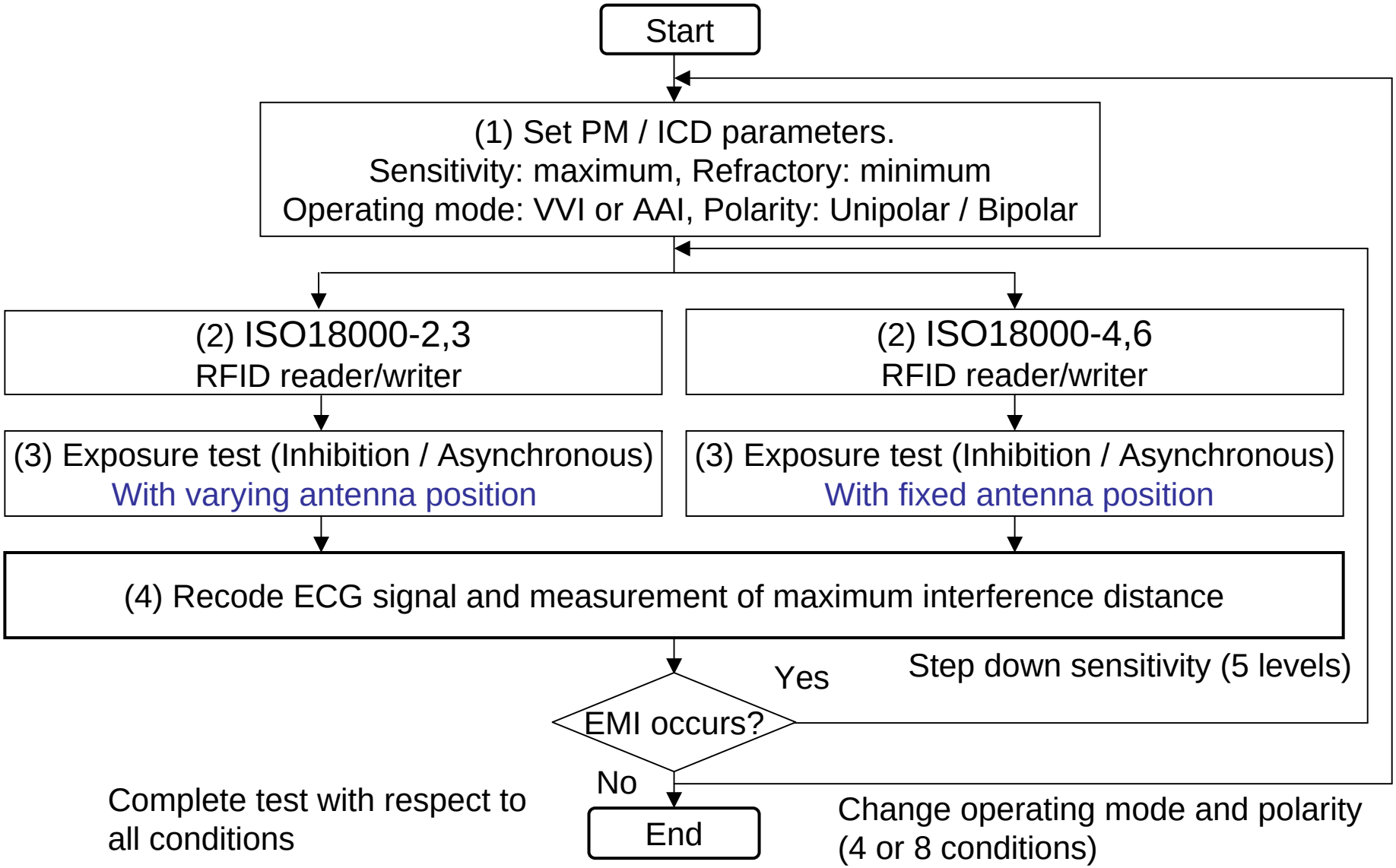




2.2 Overview of the measurement set-up

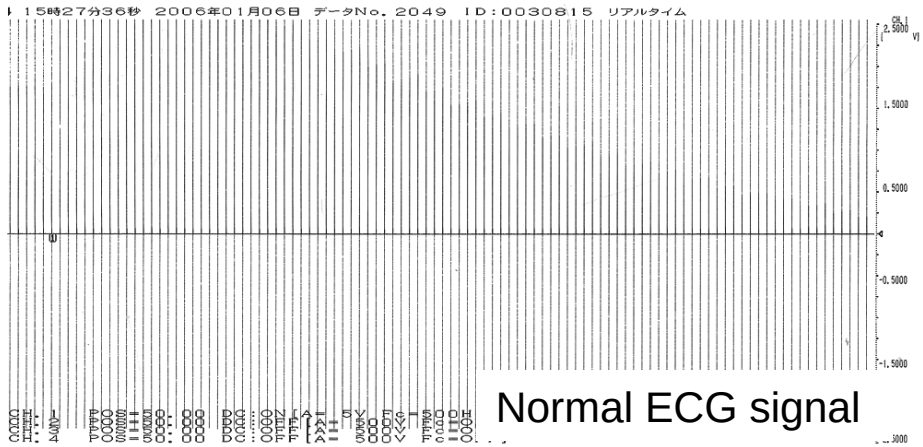


2.3 Procedure of the experiments



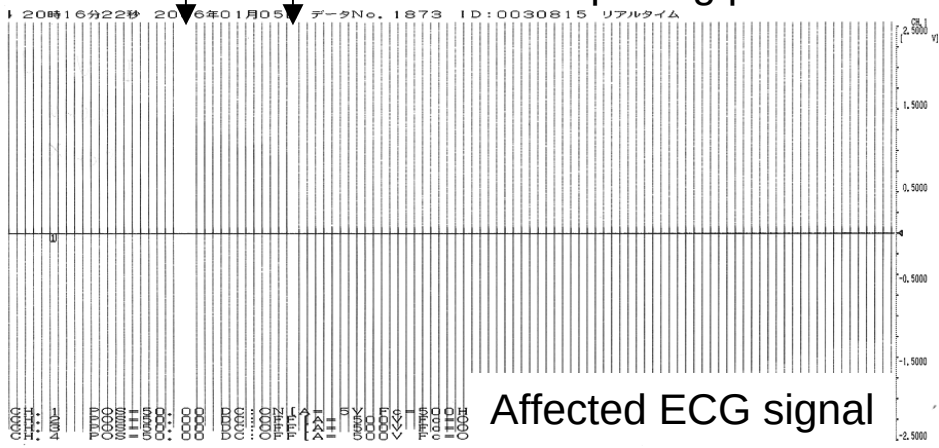
2.4 Examples of affected ECG signal

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



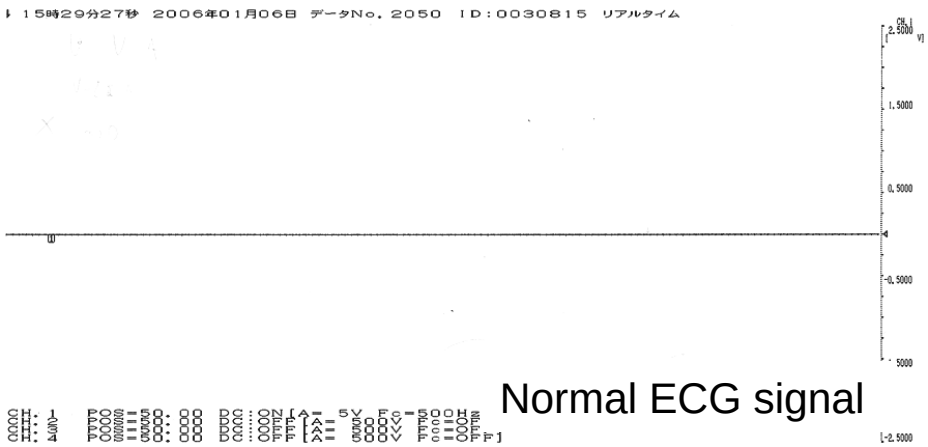
Normal ECG signal

Inhibition of pacing pulses



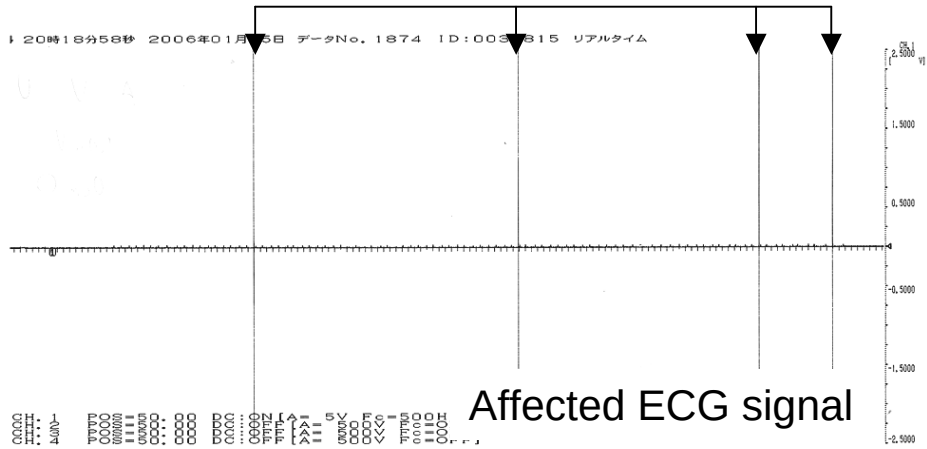
Affected ECG signal

- Asynchronous test: asynchronous pacing pulses are generated



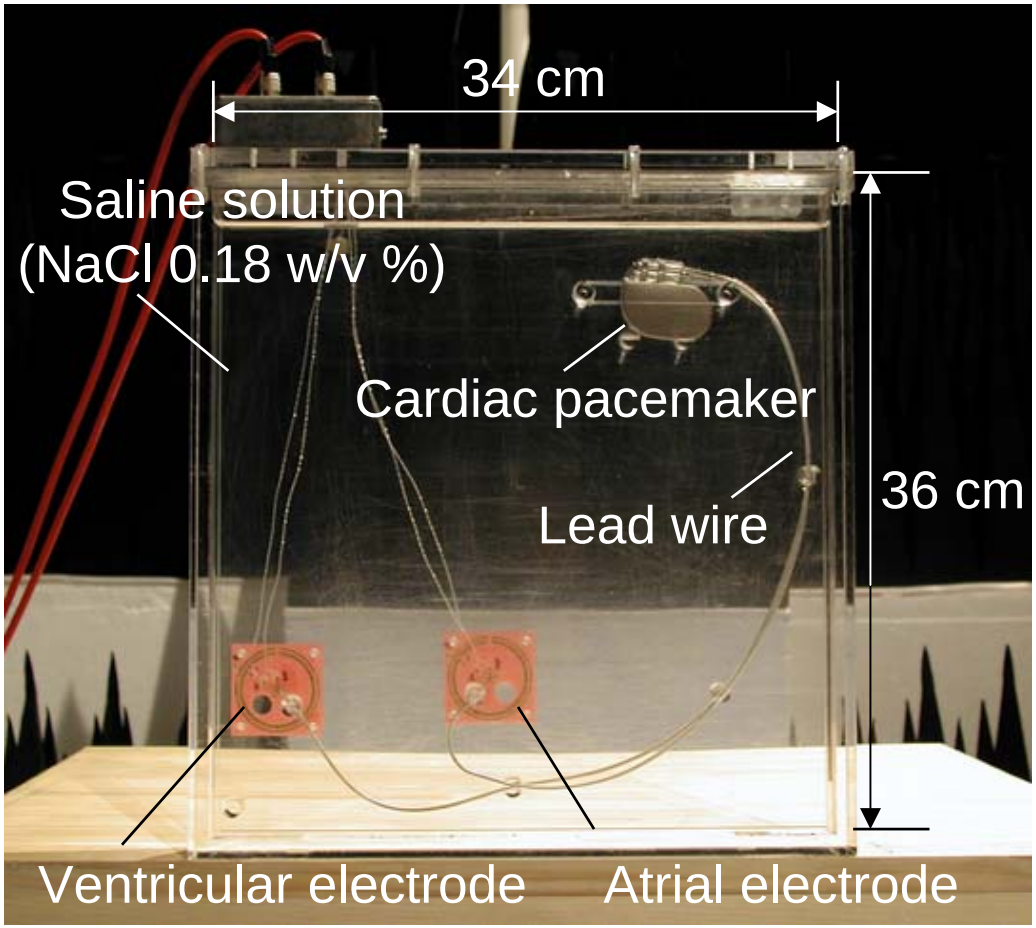
Normal ECG signal

Asynchronous pacing pulses



Affected ECG signal

2.5 The human torso phantom

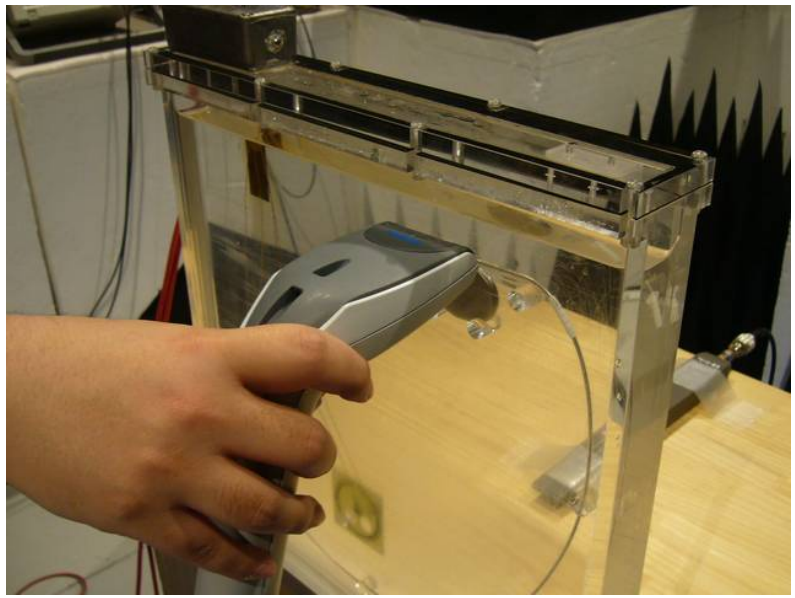


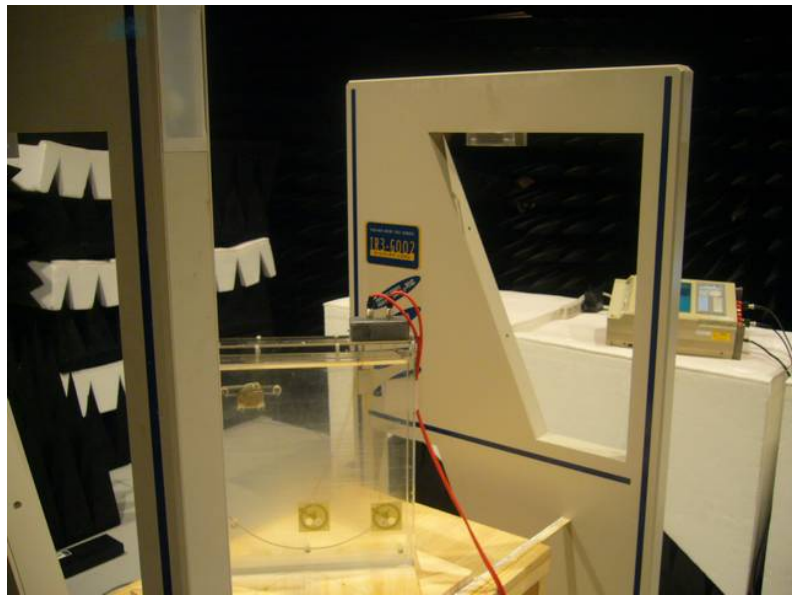
- The human torso phantom is based upon Irnich's flat torso phantom model.
- Both atrial and ventricular electrodes are modified and enable us to separate each chambers' signal by more than 20 dB.
- This phantom allows us to examine EMI with low interference by another chambers' signal.

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

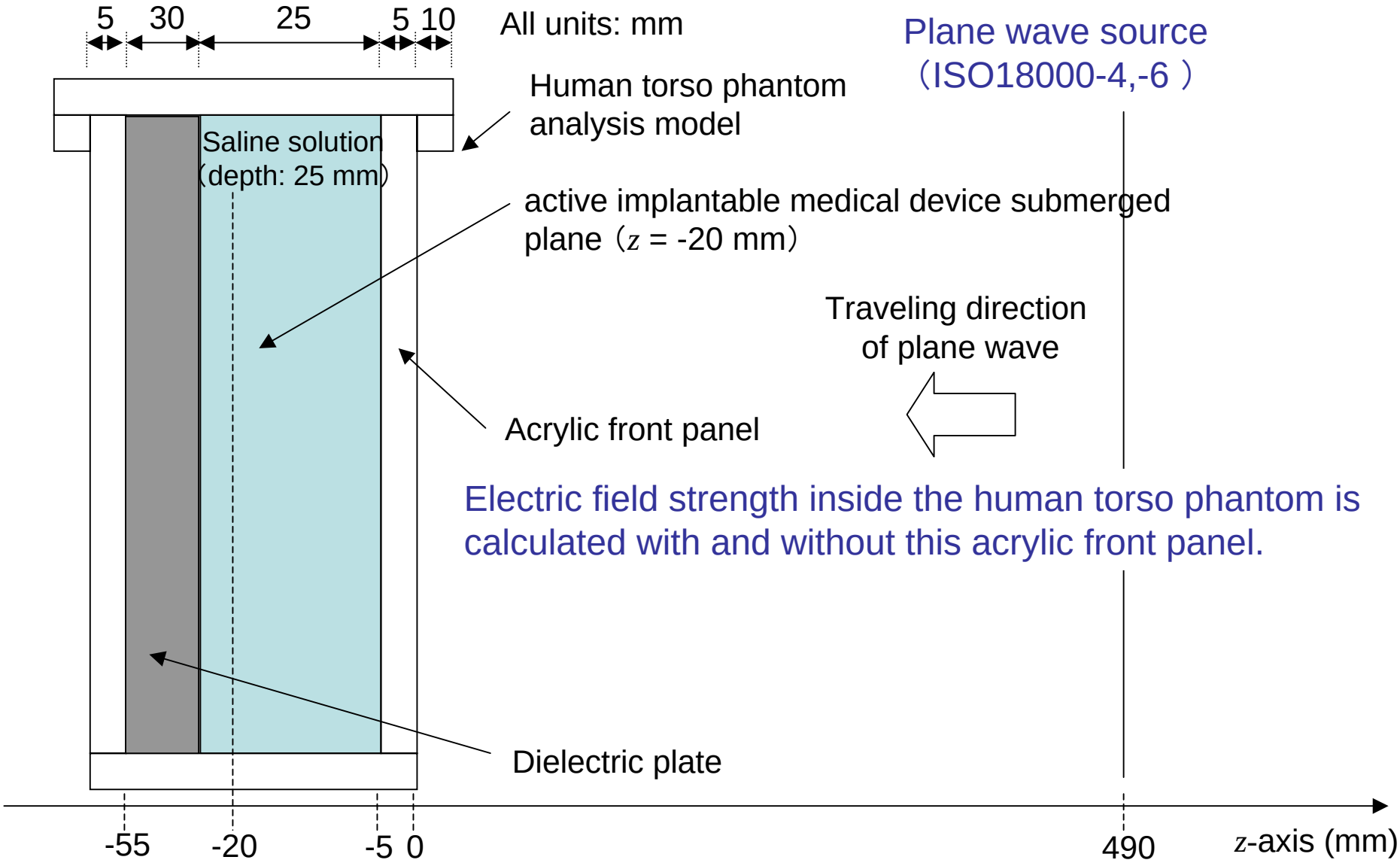
A. 1 Effect of Plexiglas (Acrylic front panel)

- 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.)

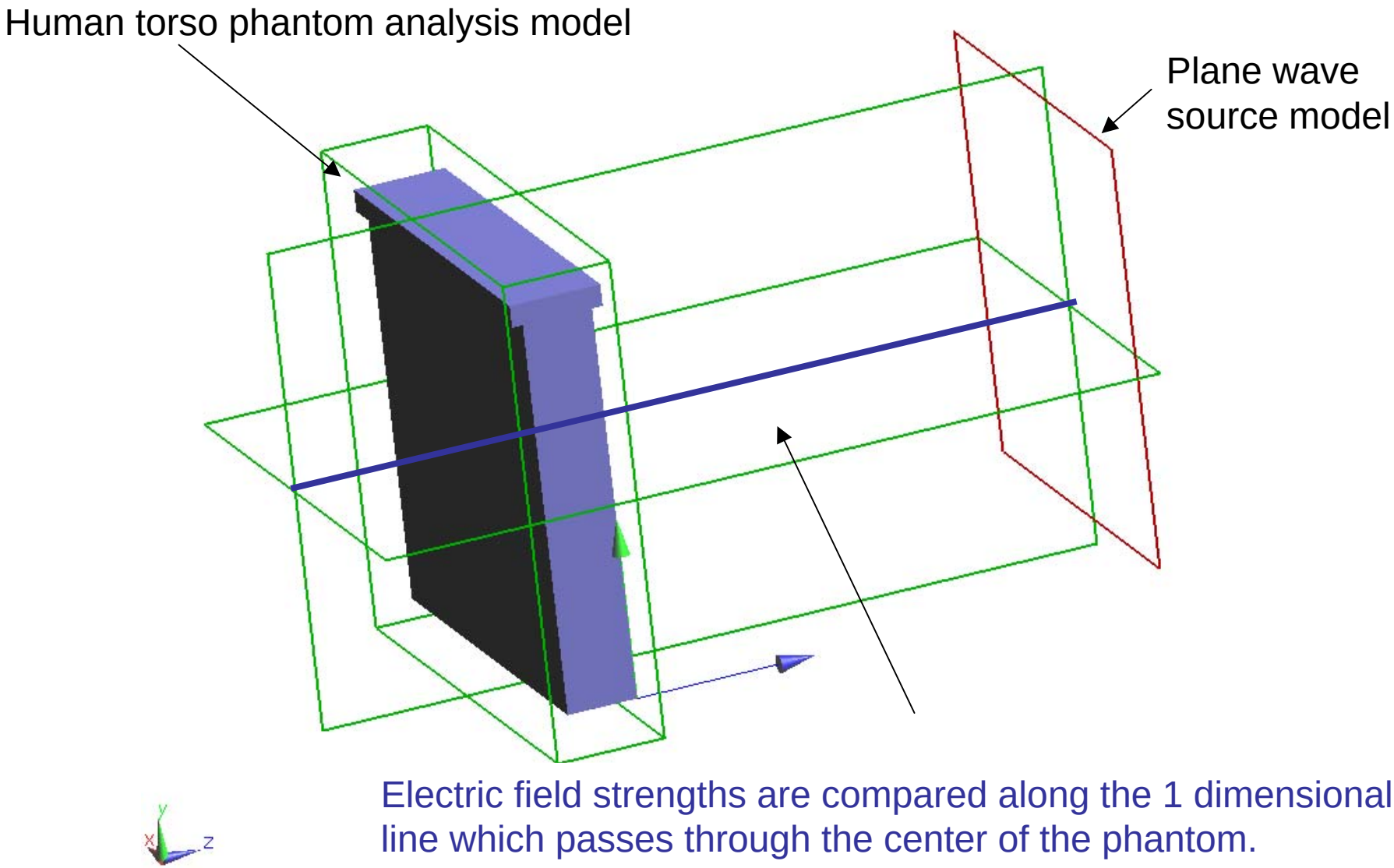
Material constants

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

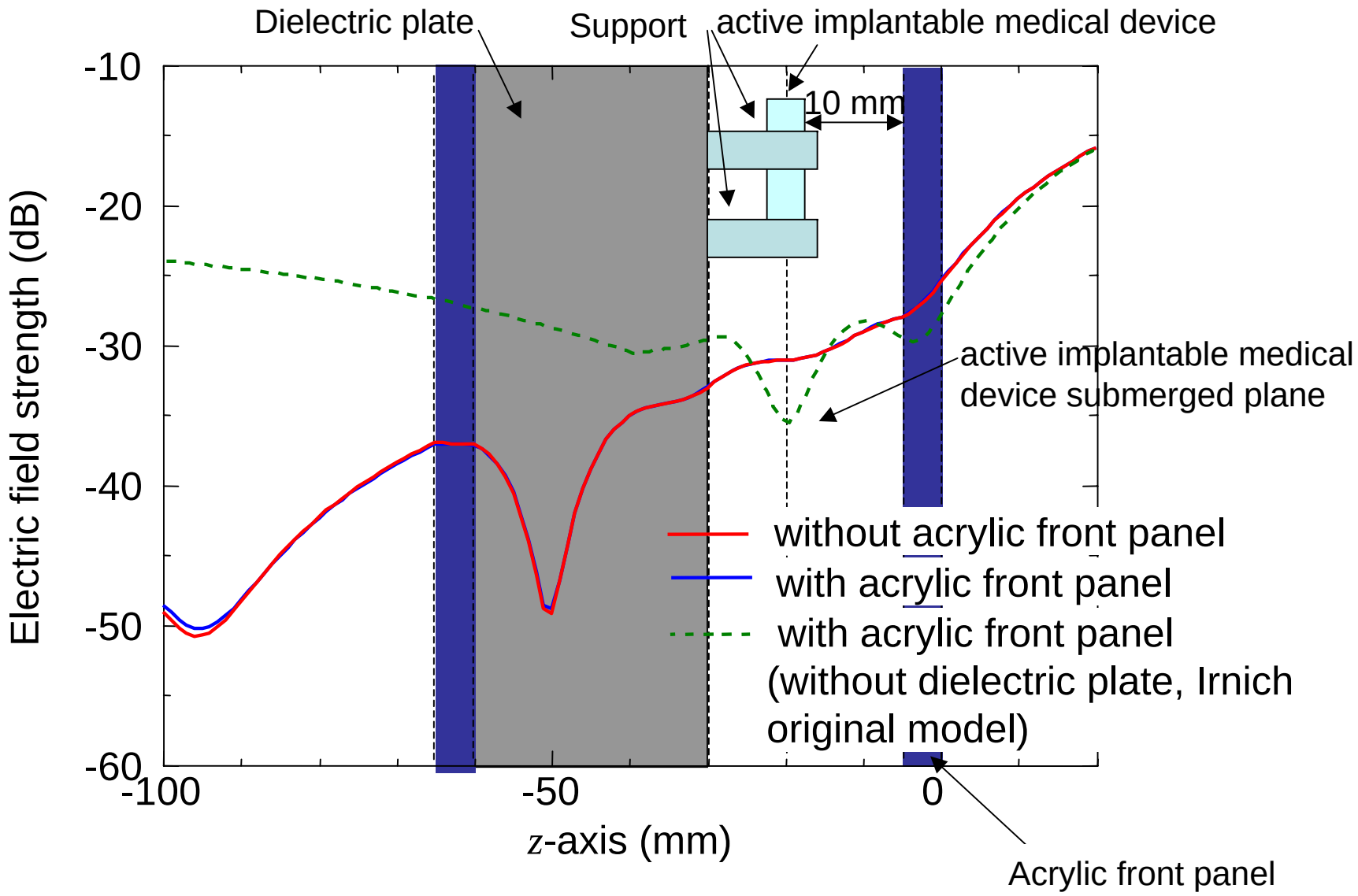
A. 2 Electromagnetic wave exposure condition



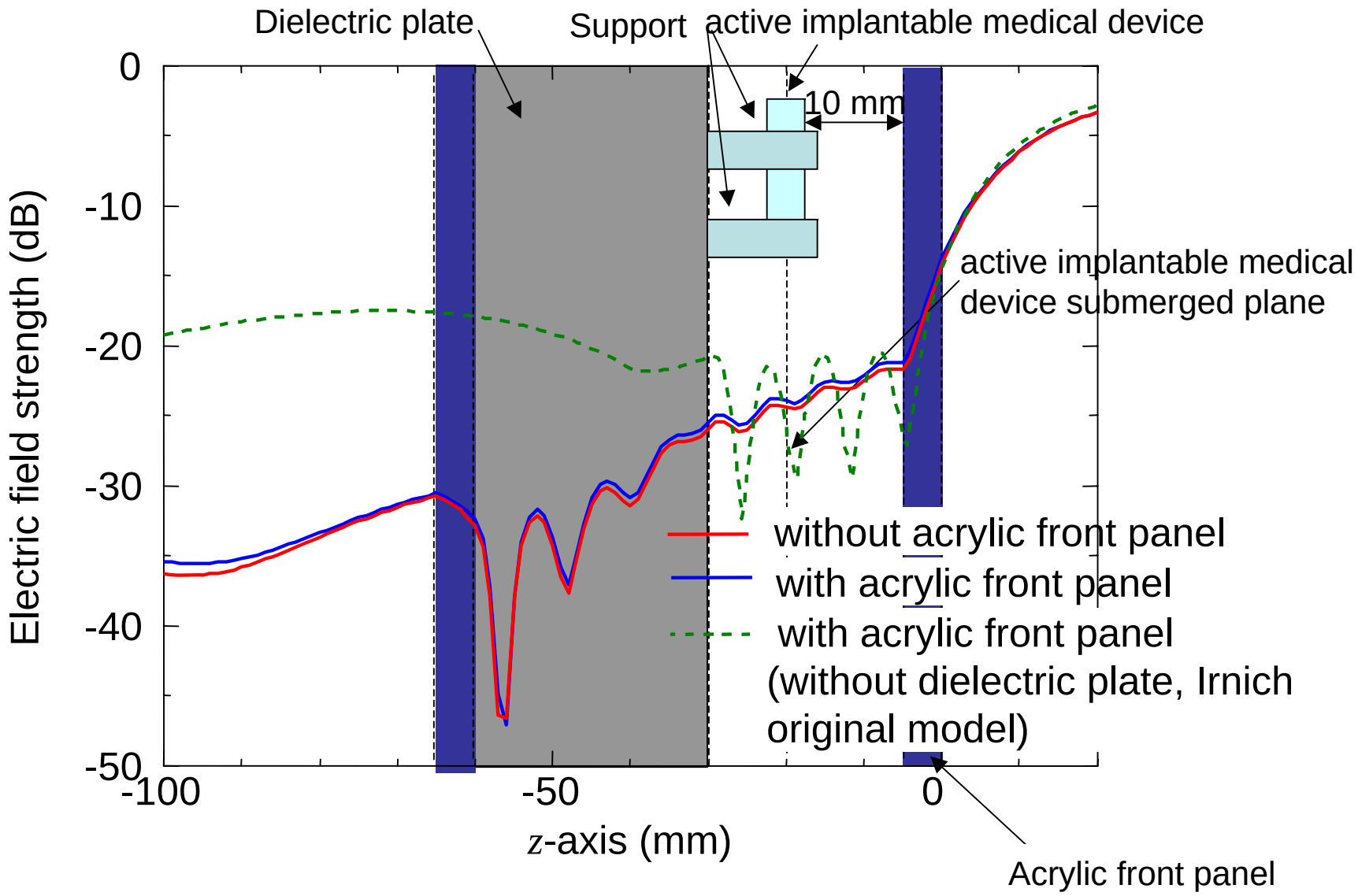
A. 3 3D human torso phantom analysis model



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

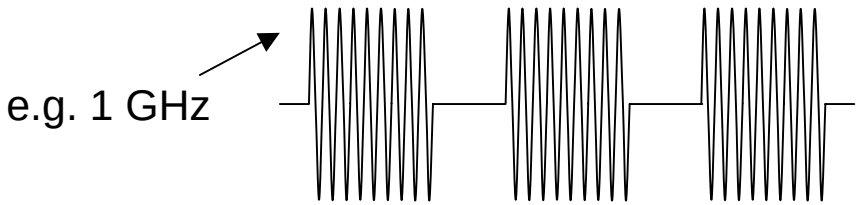
4.1 EMI mitigation method

- Mechanism of active implantable medical device EMI

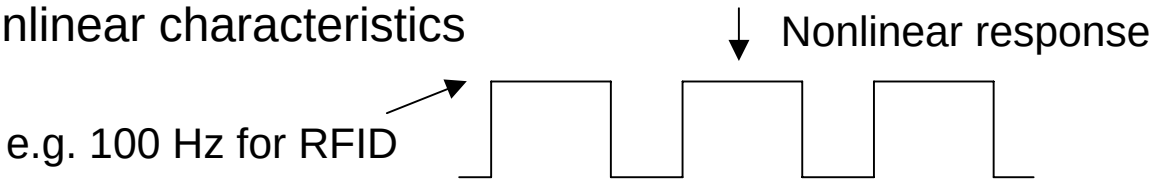
➢ Frequency bands of assigned to RFID reader/writer systems are among ISO18000-2,3,4,6. EMI frequencies are more than 2 to 6 orders higher than the operation frequency of active implantable medical devices (several kHz at most).

➢ 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

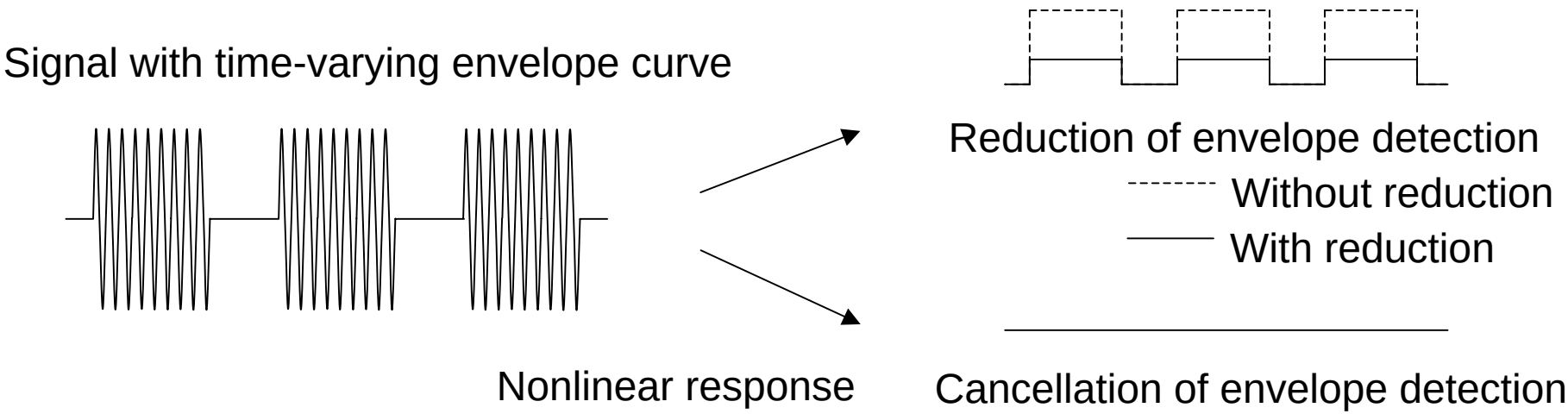


(b) Detected signal due to nonlinear characteristics



4.2 Principle of EMI mitigation

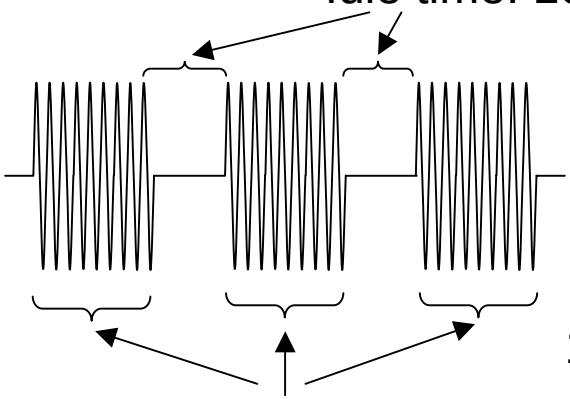
- Low frequency noises are generated with time-varying envelope curve signal exposure (i.e. amplitude modulation, pulse modulation, and intermittent signal).
- On the other hand, CW or CW-like signals (i. e. frequency modulation and phase modulation) do not generate low frequency noise. This is because 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.



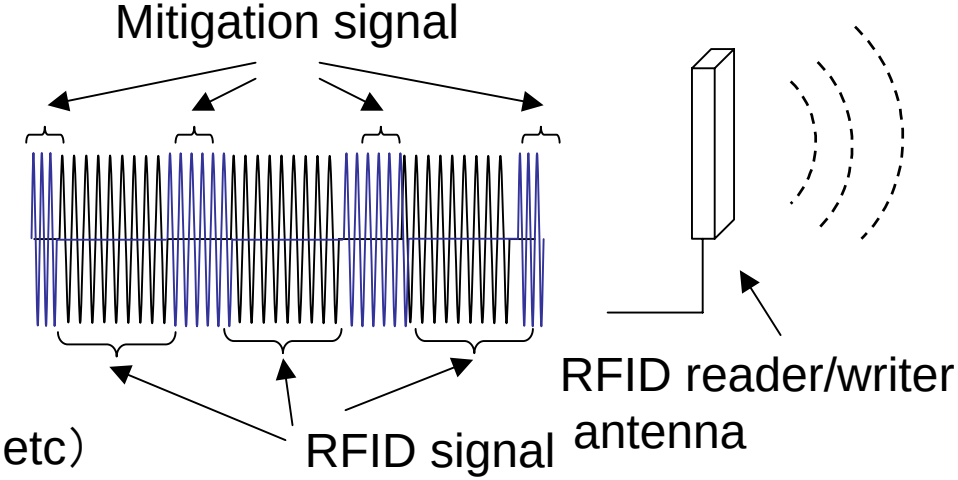
4.3 Fundamental construction

- 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.

(a) Signal from RFID reader/writer antenna

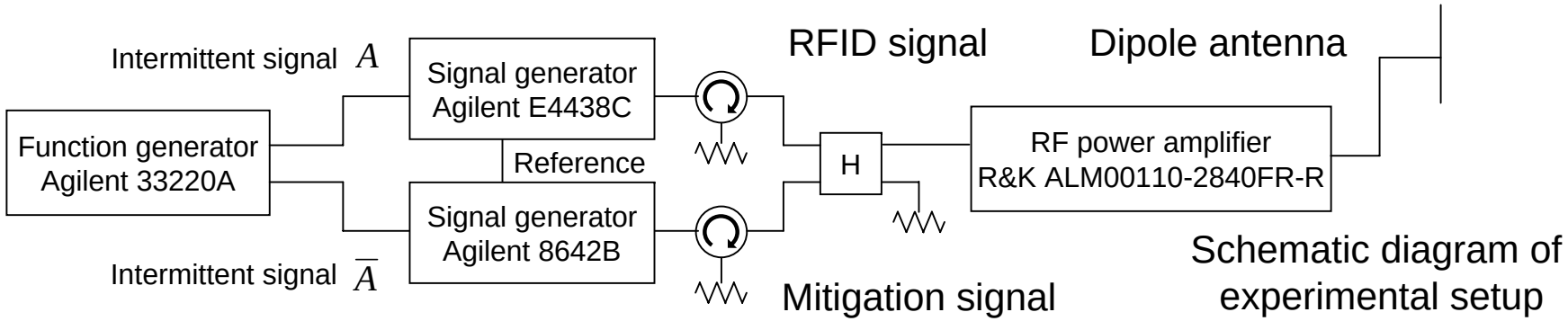


(b) RFID signal and mitigation signal

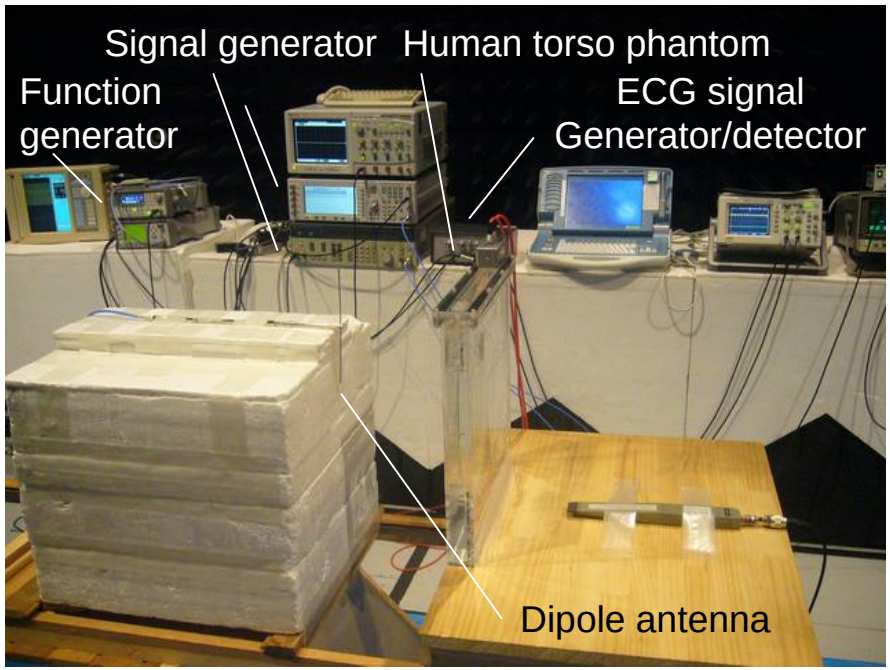


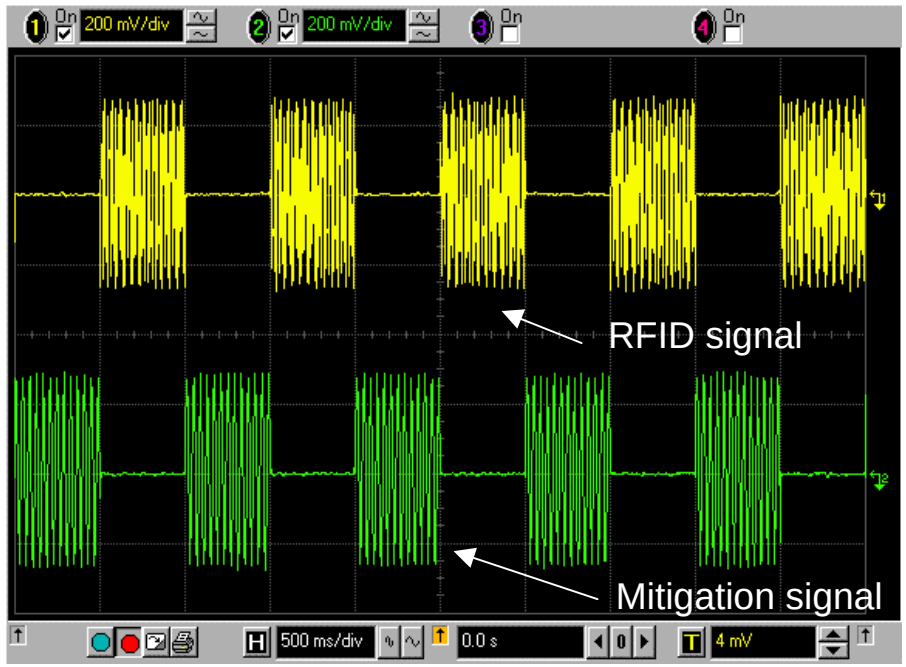
4.4 Experimental validation

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



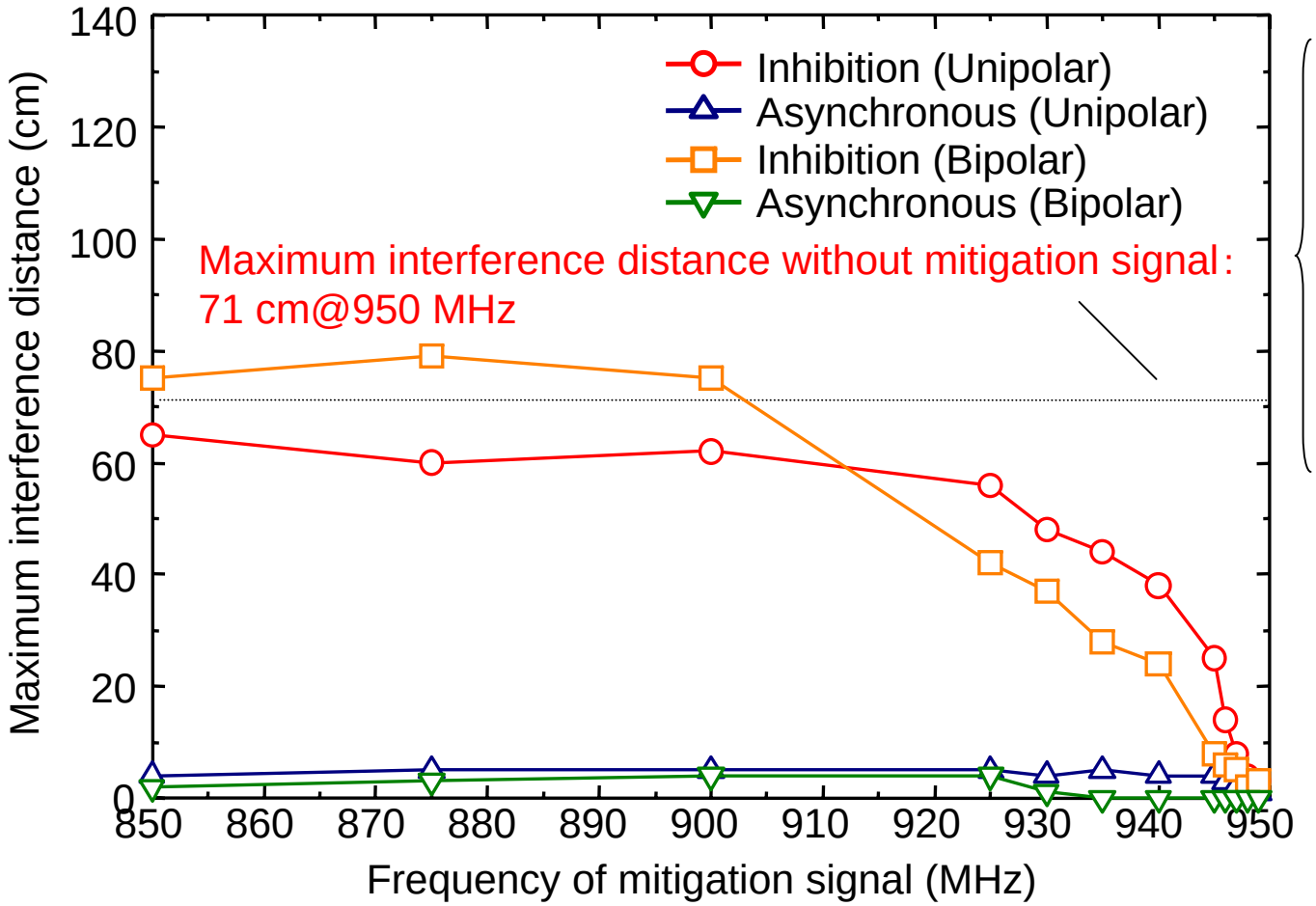
Schematic diagram of experimental setup





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

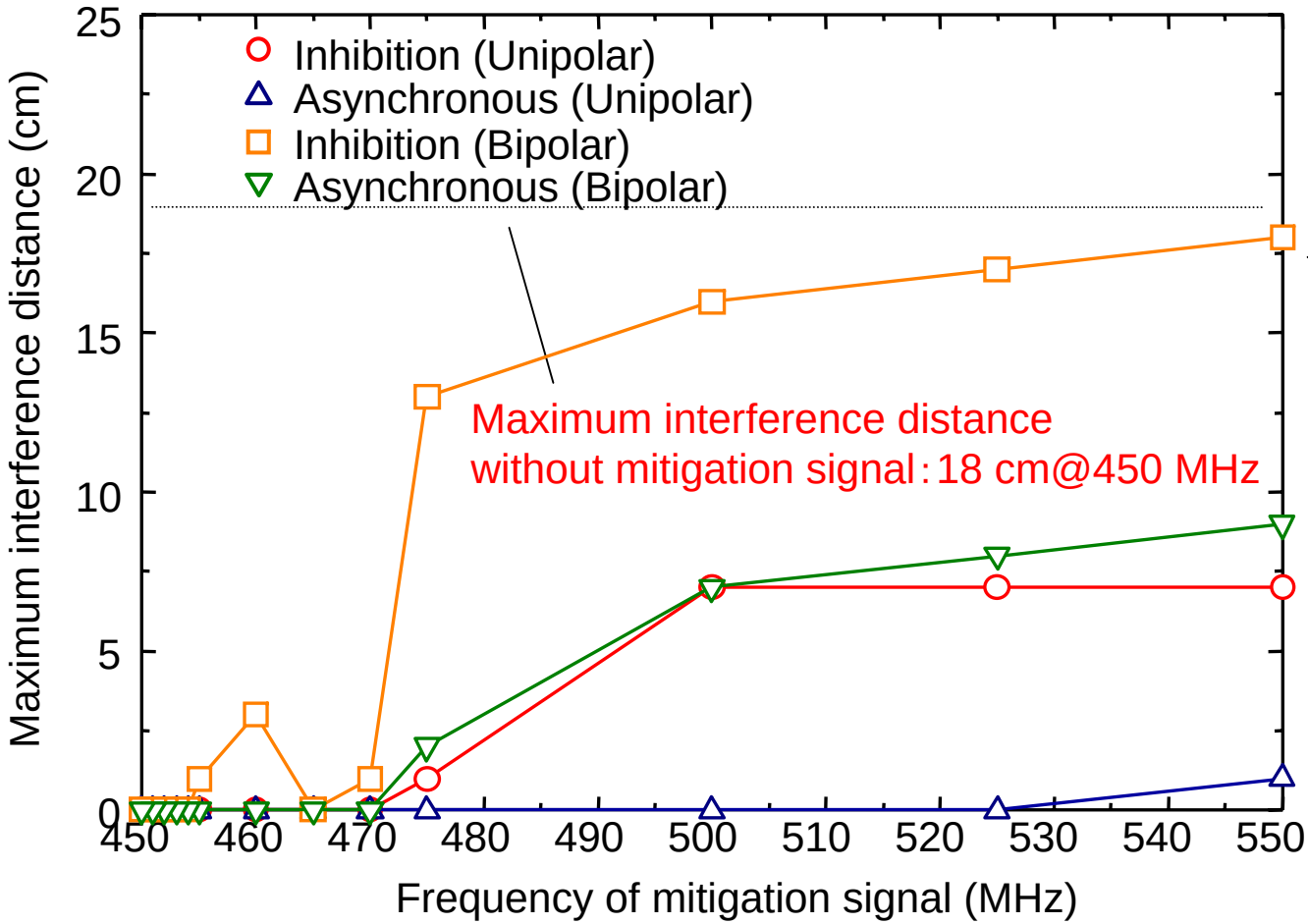
Frequency of mitigation signal: 850 – 950 MHz

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

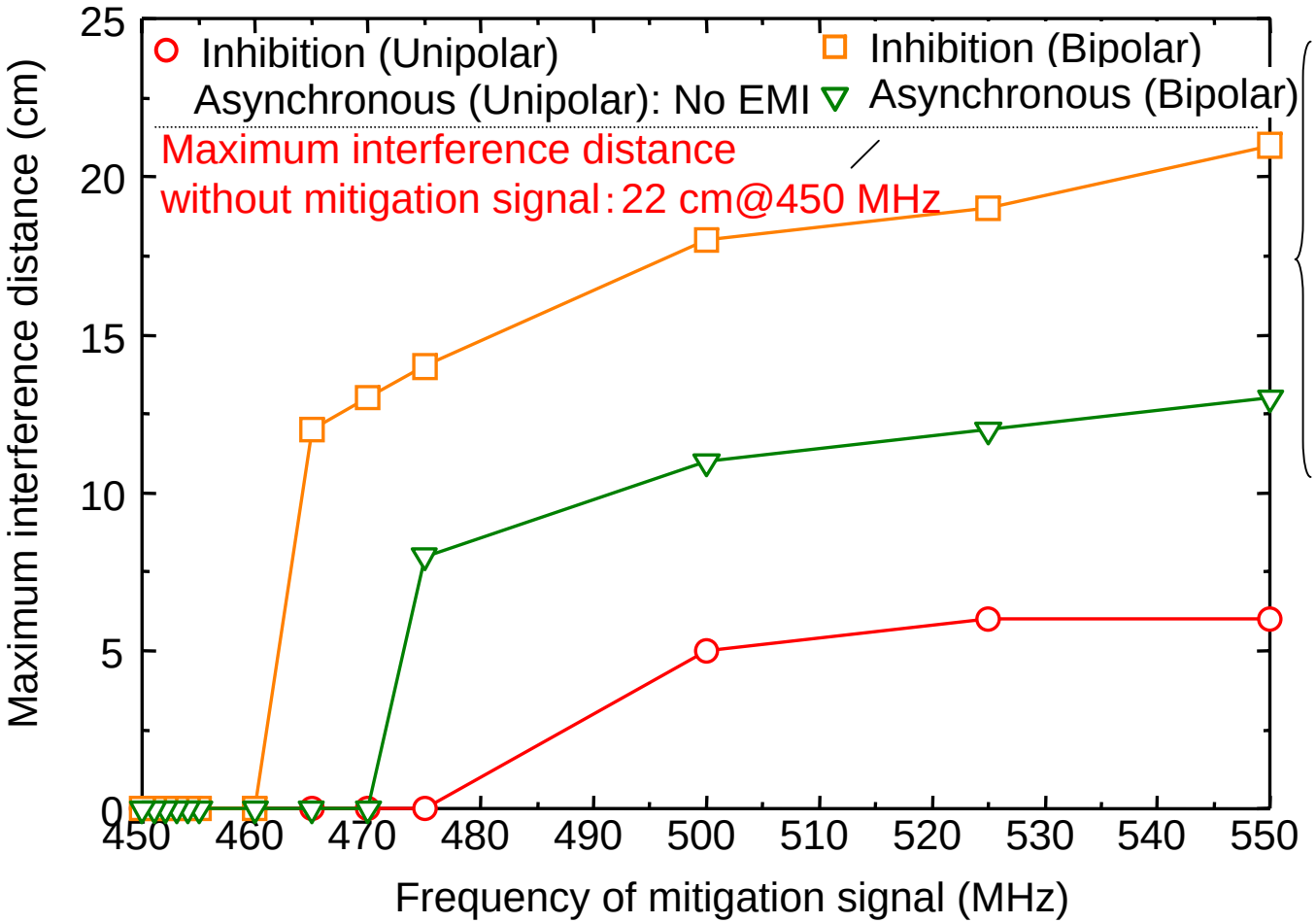
Frequency of mitigation signal: 450 – 550 MHz

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.

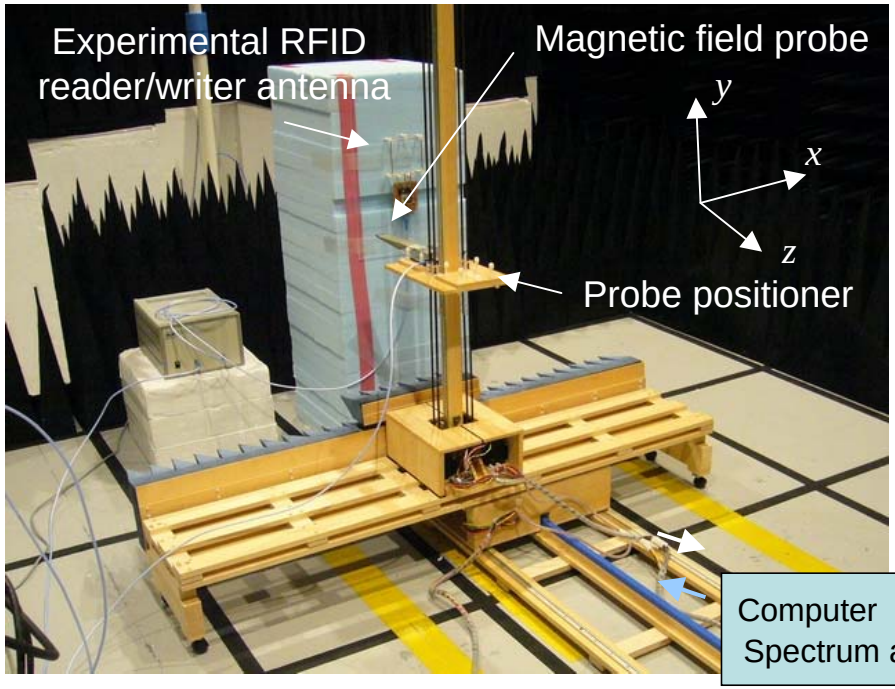
- More detailed investigation of mitigation performance such as EMI characteristics depending on the amplitude and the switching time of mitigation signal are now being carried out. In addition, interference with tag communication will be investigated.

5. Numerical EMI estimation method (informative)

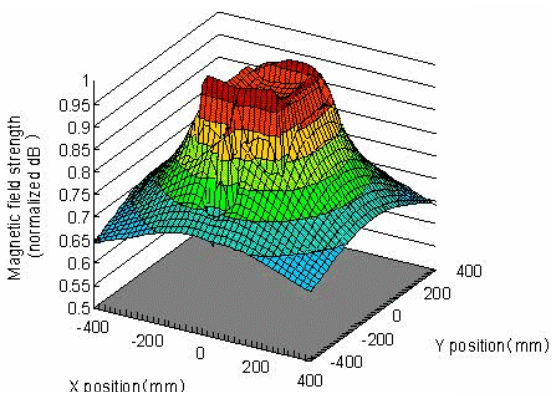
5.1 Numerical EMI estimation method

- 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.

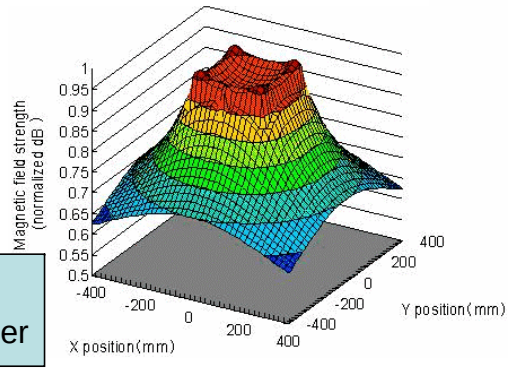
Magnetic field strength (antenna surface)
3 dimensional measurement system

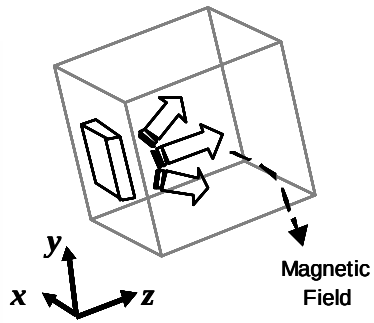


Measurement (xy-axis)



Calculation (xy-axis)

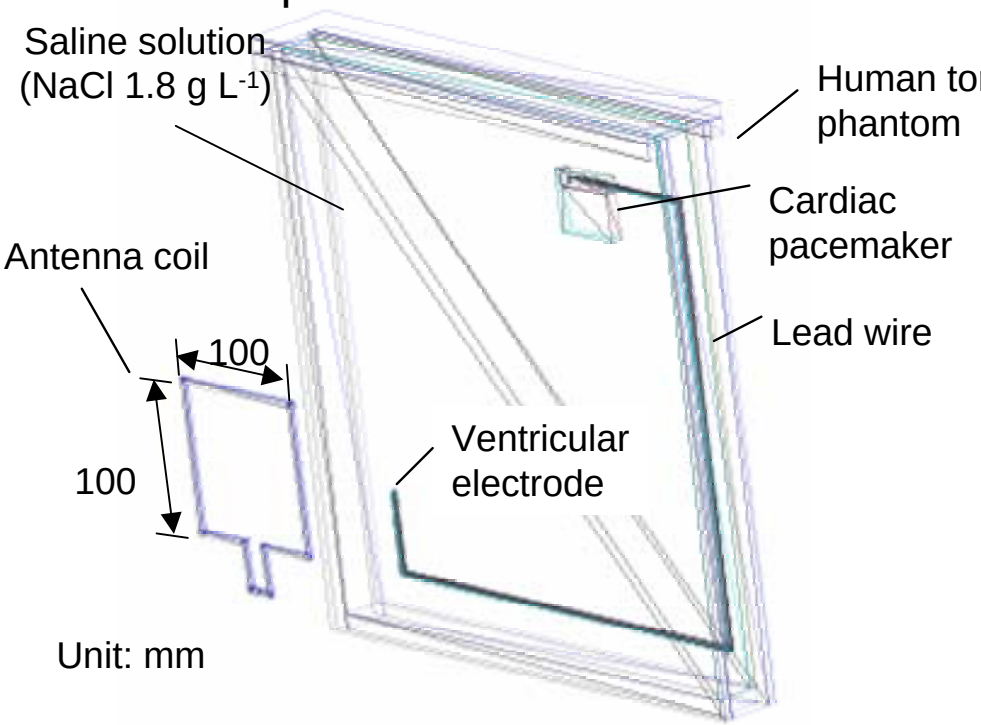




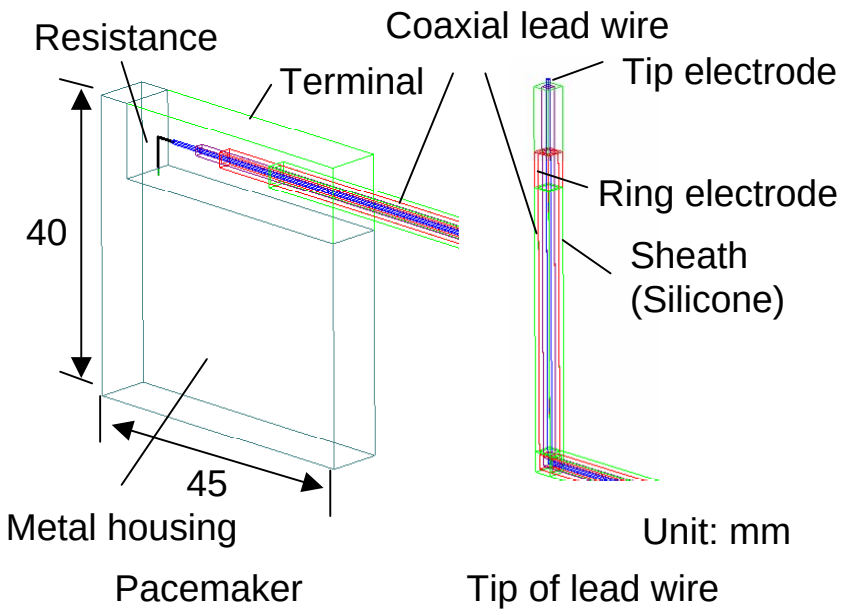
5.2 Torso phantom and pacemaker model

- 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

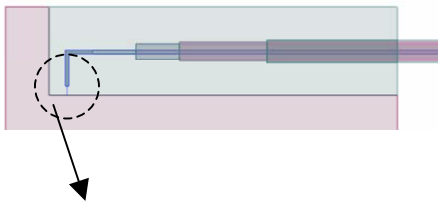


The numerical model of the pacemaker and the lead wire

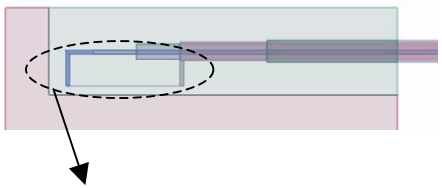


5.3 Analyzed interference voltage

- 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.

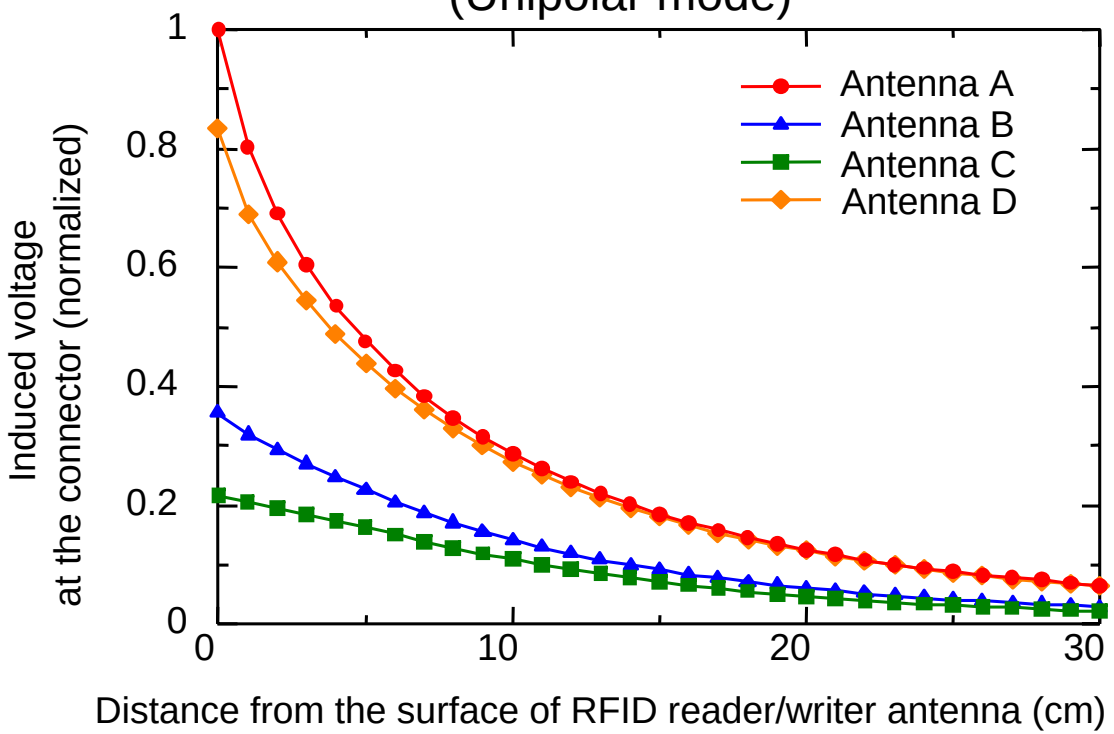


Unipolar mode: the metal housing of the pacemaker model and the inner conductor of coaxial lead wire model



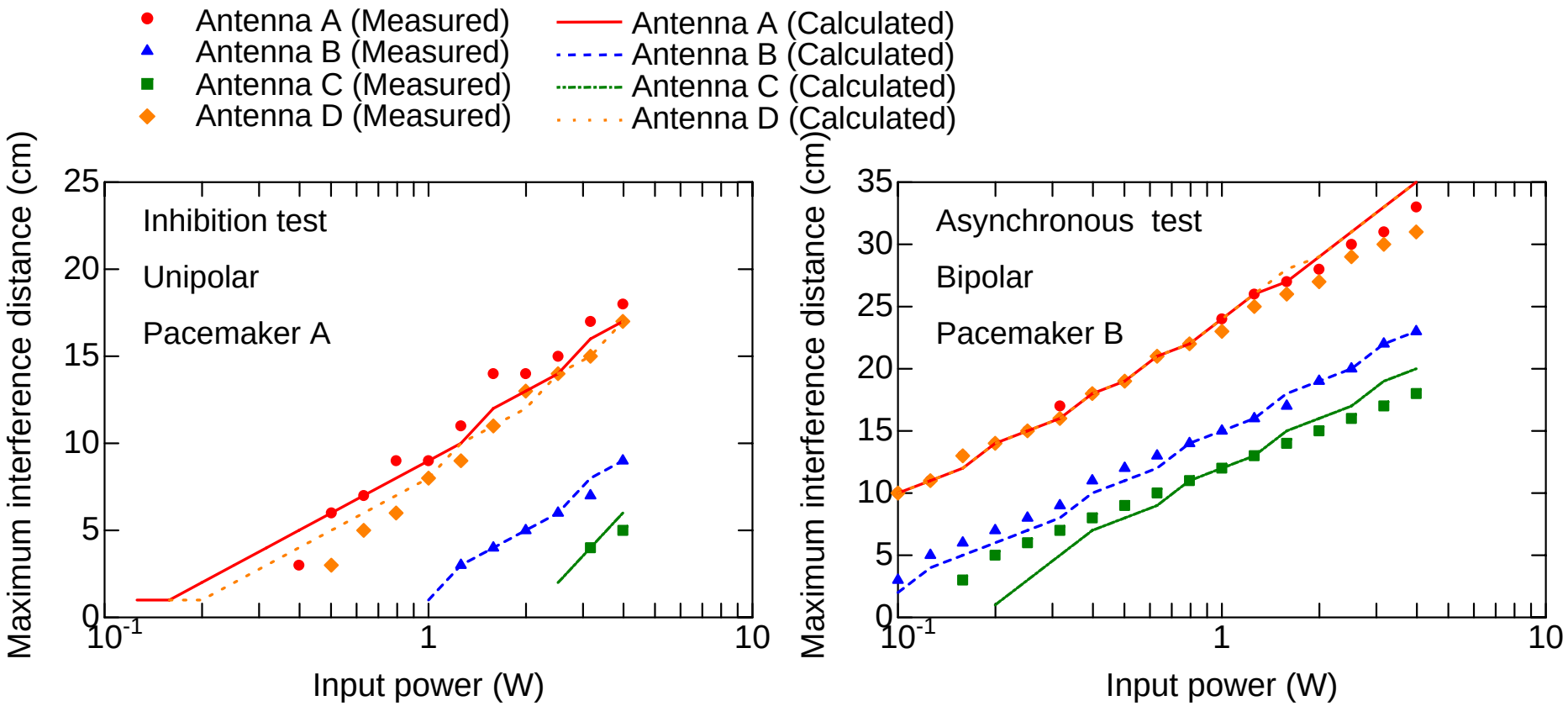
Bipolar mode: the outer conductor of coaxial lead wire model and the inner conductor of coaxial lead wire model

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.

Title: New Work Item Proposal from Japan

Dear Sirs,

The National Body of Japan proposes a new project as described in the attached "New Work Item Proposal", and this document is provided to supplement additional information on the proposal.

The purpose of this proposal is to establish an efficient method for measuring the intensity of impact on active implantable medical devices (cardiac pacemakers and cardioverter defibrillators) caused by electromagnetic interference (EMI) emitted from RFID interrogators and to develop a means to ease or reduce such impact on these active implantable medical devices. This new technology has already been implemented in an experimental project since 2005 under the auspices of the Ministry of Economy, Trade and Industry (METI) of Japan.

This project is currently being conducted as a joint project between Japan Automatic Identification Systems Association (JAISA) and Hokkaido University. Japan's New Work Item Proposal is created as a technical report based on the achievements of this project, the details of which were previously reported in the following four SC31 WG4 related meetings:

1. WG4/SG5 of March 16, 2006
2. WG4/SG5 of July 31, 2006
3. WG4/SG3 of August 18, 2006
4. WG4/SG5 of January 26, 2007

In addition to the above meetings, Japan's proposal was also publicly announced at the meetings of RFID expert groups of AIM Global.

The National Body of Japan regards this new technology as an essential instrument in evaluating the effects of EMI generated by RFID systems for the progress of RFID technology, especially in the consumer industries. We hope this document may be of some use in making your decision.

Yours faithfully,

SC31 Japan Chairman

Akira Shibata

Appendix

The following describes more information on the above four SC31 WG4 meetings:

1. WG4/SG5 of March 16, 2006

ISO/IEC JTC1/SC31/WG4 N0974

Three Contribution reports from Japan

Three presentations were made by Japan Automatic Identification Systems Association (JAISA) and RFID Consortium for consumer electronics products (Japan).

- The examination of effects from RFID devices on implant cardiac pacemakers
- The researches report on RF tag disposal.
- The scope of lifecycle management's model adopting RFID and Requirements for RFID applications.

2. WG4/SG5 of July 31, 2006

Meeting Minutes of ISO/IEC JTC1/SC31/WG4/SG5, at Pacific Palisades Hotel in Vancouver B.C, Canada. On July 31, pm 1:00- pm 5:00.

Presentations:

The contribution report: " The examination of effects from RFID devices on implanted cardiac pacemakers " was presented by Mr. Ben Koike JAISA (Japan Automatic Identification Systems).

3. WG4/SG3 of August 18, 2006

WG 4/SG 3 Draft Meeting Minutes August 17-18-2006

Venue: Paris, France

RFID effect on Implants

Mr. Watanabe from Japan gave a presentation on the JAISA preliminary findings on the RFID effect on implants. The preliminary finding are not conclusive, but indicate there is possible interference of RFID on the pacemakers.

It was agreed that Medtronic and JAISA will communicate directly on this. The document is SG3_200608_534_CDG_JAISA.pdf

4. WG4/SG5 of January 26, 2007

Resolutions of ISO/IEC JTC1/SC31/WG4/SG5 meeting: Sydney, Australia

Date: 2007-01-26

SC 31/WG 4/SG 5 expresses its appreciation to the Japanese contribution titled "Investigation of Implantable Medical Devices EMI to Radio Waves from RFID reader/writers" and presenter Mr. Shun-ichi Futatsumori for the excellent presentations and we look forward to their future contributions.

ISO commenting template/Report of voting

Date : 2009/02/04	**Document: SC031-N-XXXX**

MB[1]	**Clause / subclause (e. g. 3.1)**	**Para-graph/ Figure/ Table (e. g. Table 1)**	**Type of com-ment**[2] **(e. g. ed)**	**Comments: Justification for change**	**Proposed change**	***DRAFT – For Comment*** **Observations of the secretariat** on each comment submitted

[1] **MB = Member body (Enter two-letter country code, e. g. CN for China)**
[2] **Type of comment:** **ge** = general **te** = technical **ed** = editorial **NB Columns 1, 2, 4, 5 are compulsory**