RESULTS OF ASSESSMENT ON ELECTROMAGNETIC INTERFERENCE DUE TO WIRELESS POWER TRANSFER SYSTEMS

TECHNICAL REPORT

BWF TR-02 Edition 1.0

Published on March 14, 2016

Broadband Wireless Forum

Preface

The Broadband Wireless Forum (hereinafter referred to as the “BWF”) was established on July 3, 2009 to contribute to the quality development of new systems and services utilizing radio waves. The forum has been performing various activities on wireless communications technologies, such as the research, development, and investigation of new wireless technology, the collection of information, liaison and coordination with related organizations, and dissemination and awareness-raising activities for the early realization and international expansion of systems and services using new wireless communications technology. Technical information parts of the results of these activities have been compiled and released as "technical reports."

In the area of wireless power transmission/transfer technology, a technical report titled *Guidelines for the Use of Wireless Power Transmission/Transfer Technologies* was published in April 2011. In states where we can expect the early, practical application of new wireless power transmission/transfer technology due to steady progress, this report will serve as a set of guidelines that specify basic matters with which product manufacturers and service providers applying such technology should comply in order to improve convenience for users and to guarantee the safety of such users.

This technical report was compiled based on the results of assessment that were conducted under a three-party framework composed of Hokkaido University, Japan Arrhythmia Device Industry Association (hereinafter referred to as the “JADIA”), and the BWF from fiscal year 2011 to 2014 in order to clarify the influence of wireless power transfer systems on active implantable medical devices.

We hope that these technical reports will be actively utilized by machine manufacturers, service providers, and users.

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RESULTS OF ASSESSMENT ON ELECTROMAGNETIC INTERFERENCE DUE TO WIRELESS POWER TRANSFER SYSTEMS

1. Scope

This technical report was compiled based on the results of assessment that were conducted by Hokkaido University, the JADIA, and the BWF from fiscal year 2011 to 2014 in order to clarify the influence of wireless power transfer systems (WPTs) on active implantable medical devices (AIMDs). We conducted the assessment using implantable cardiac pacemakers and implantable cardiac defibrillators (ICDs) as the AIMDs.

2. Definitions

The definitions of the main terms used in this technical report are shown below.

2.1 Implantable cardiac pacemaker: An implantable medical device used to maintain an adequate heart rate by electrically stimulating the heart; the main body (pulse generator) has an electric circuit and a battery both embedded in its small metal case, and a thin conducting wire called a “lead” is connected in order to convey electric stimuli sent from the main body to the heart. The pacemaker monitors the motion of the heart continuously. When the pacemaker finds that the heart rate becomes pathologically slow, it sends weak electric stimuli to the heart via the lead for correcting the heart rate by forcing the heart to contract in synchronization with such electric stimuli.

2.2 Implantable cardiac defibrillator (ICD): A medical device to treat a heart rate that exceeds the normal rate (tachycardia); like a pacemaker, an ICD is configured of a main body that has an electric circuit and a battery both embedded in a small metal case and a conducting wire called a “lead” that conveys electric stimuli sent out from the ICD main body to the heart. Electroshock pulses with large energy are used for tachycardia treatment.

3. assessment method for electromagnetic interference

The configuration of equipment as well as the settings and modes of the devices (AIMDs) were determined in the manner described in *Investigation report on the influence of radio waves to medical devices* [1] published by the Ministry of Internal Affairs and Communications (Annex A). To put it concretely, as shown in Fig. 1, an AIMD was placed in a torso phantom that was designed to simulate a human body, and the AIMD was checked regarding whether or not it malfunctioned when a WPT was brought close to the torso phantom. For the criteria to evaluate the influence levels of malfunctions, refer to Annex B. While simulated ECG signals generated by a simulated ECG signal generator were input into the AIMD, the pacing signals generated by the

AIMD were monitored with an AIMD monitor and an oscilloscope, and the results were recorded with a chart recorder. Note that a torso phantom is an acrylic vessel in which a 0.18 g/l saline solution is filled to simulate the electrical characteristics of a human body. Figure 2 shows an example where an AIMD is placed in a torso phantom. Concrete information regarding the installation of WPT units and the assessment procedure are described in Annex C.

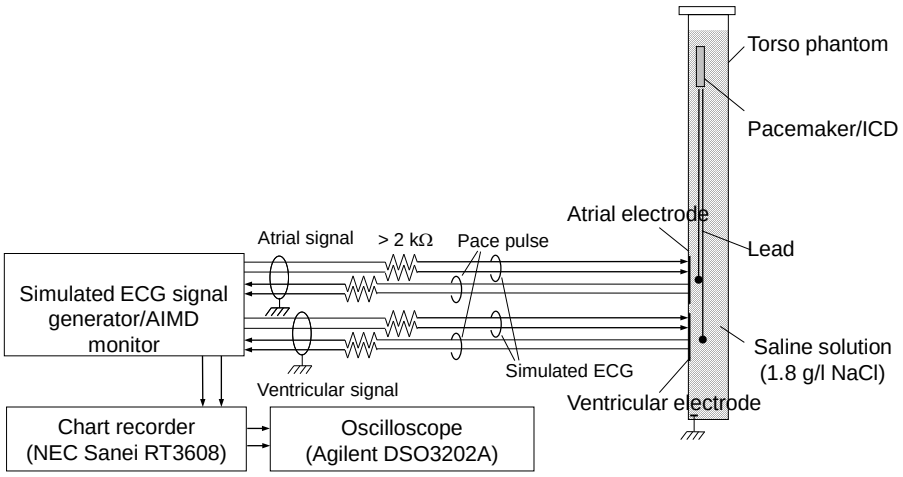

Fig. 1: Evaluation system for electromagnetic interference on an AIMD (courtesy of Hokkaido University)

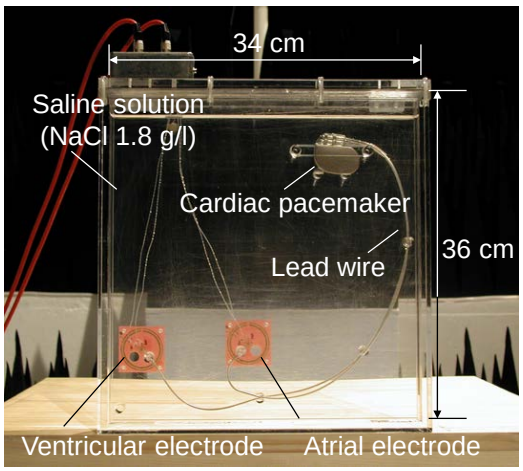

Fig. 2: AIMD installed in a torso phantom (courtesy of Hokkaido University)

4. WPT units used for assessment

The WPT units used for the assessment are summarized below. The assessment were conducted by using 15 WPT units in total, which were comprised of products that were available in the market at the time of testing and prototypes that were to be launched in the future. For details, refer to Annexes D and E.

1.1 Magnetic field couplings (resonant type)

1.1.1 Electric vehicles (EVs)

Frequency	85 kHz
Transmitted power	Up to 3 kW
Number of units	3

1.1.2 Mobile devices

Frequency	135, 400 kHz, 6.78 MHz
Transmitted power	Up to 18.2 W
Number of units	3

1.2 Magnetic field couplings

1.2.1 Mobile devices

Frequency	70, 110 to 210 kHz
Transmitted power	Up to 15 W
Number of units	7

1.3 Electric field couplings

1.3.1 Mobile devices

Frequency	200, 460 kHz
Transmitted power	Up to 40 W
Number of units	2

5. Results

The assessment results are shown in Table 1. For details, refer to Annexes D and E. Influences were found with some units, even though the occurrence rates were very small. It was confirmed that, however, the influences were reversible and disappeared when the unit moved away from the torso phantom.

Table 1: Summary of assessment results

System	Application	Transmitted power	Frequency		
			Up to 100 kHz	100 to 500 kHz	6.78 MHz
Magnetic field coupling	EVs	Up to 3 kW	0 / 3		
			-		
	Mobile devices	Up to 5 W	0 / 1	4 / 6	
			-	L2 / 2 cm	
		5 to 20 W		0 / 2	0 / 1
				-	-
Electric field coupling	Mobile devices	Up to 40 W		1 / 2	
				L2 / 1 cm	

Upper rows: Number of models having influence / Number of assessment models

Lower rows: Influence level / Maximum distance at which interference disappeared

L2 (Level 2): Abnormal pacing/sensing for one cycle or longer

6. Conclusion

This technical report was compiled based on the results of assessment that were conducted under a three-party framework composed of Hokkaido University, the JADIA, and the BWF from fiscal year 2011 to 2014 in order to clarify the influence of wireless power transfer systems on active implantable medical devices. Although influences were found with some models, all the distances at which the interference disappeared were 2 cm or shorter even when the sensitivity of the AIMD was set to the maximum level, which indicates that no influence will occur unless the WPT is brought very closely into intimate contact with the AIMD. We will continue assessment to accumulate data as much as possible and will aim to contribute to the safe and secure use of wireless power transfer systems.

Finally, we are deeply grateful to Emeritus Professor, Toshio Nojima and Assistant Professor, Takashi Hikage at Hokkaido University, who gave us a great deal of assistance and advice through actual assessment for investigating the influence of wireless power transfer systems on active implantable medical devices.

We would also like to express our gratitude to various people from the Japan Arrhythmia Device Industry Association, who, with good grace, provided us with the active implantable medical devices to be used for the investigation.

References

[1] Ministry of Internal Affairs and Communications, *Investigation report on the influence of radio waves to medical devices*, March, 2007

http://www.tele.soumu.go.jp/resource/j/ele/medical/img/h18_report.pdf

Related presentations

[1] Hikage, et al., "In vitro Assessments of Active Implantable Medical Devices EMI from Radio Wave Emitted by Wireless Power Transfer Devices," IEICE General Conference, BI-4-4, 2014. (in Japanese)

[2] Hikage, et al., “In vitro assessment of electromagnetic interference due to electric vehicle wireless power transfer system on active implantable medical devices,” ISMICT2015, March, 2015.

[3] Hikage, et al., "Assessments of Electromagnetic Interference Due to Electric Vehicle Wireless Power Transfer System on Active Implantable Medical Devices," IEICE Technical Report WPT2015-29, 2015. (in Japanese)

[4] Hikage, et al., "Example assessment on electromagnetic interference due to wireless power transfer systems on implantable cardiac pacemakers/ICDs," NICT EMC-net, July, 2015. (in Japanese)

[5] Onishi, "International trend in human body protection from wireless power transfer and EMI on implantable medical devices," CEATEC Japan 2015, IEICE serial program, October, 2015. (in Japanese)

[6] Onishi, "Front line related to human body protection from radio waves emitted from wireless charging and mobile devices," EMC Forum 2015, October, 2015. (in Japanese)

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Annex A Types and settings of AIMDs

In this assessment, the following types of AIMDs were used.

- Implantable cardiac pacemaker (pacemaker) – dual-chamber

  An implantable medical device used to maintain an adequate heart rate by electrically stimulating the heart

- Cardiac re-synchronization therapy pacemaker (CRT-P) – triple-chamber

  CRT: Cardiac re-synchronization therapy

- Implantable cardiac defibrillator (ICD) – single- or dual-chamber

  A medical device to treat a heart rate that exceeds the normal rate (tachycardia); electroshock pulses with large energy are used for treatment.

- Cardiac re-synchronization therapy defibrillator (CRT-D) – triple-chamber

  Categorized as the ICD

Table 1 shows the list of modes used for EMI assessement. In the assessement, the sensitivity of the AIMD was set to the maximum level initially, and was then lowered step-by-step when influence was found. As a result, the AIMD was assessed at up to five sensitivity steps (the maximum sensitivity, 1.0 mV, 2.4 mV, 5.6 mV, and the minimum sensitivity).

Table 1: Electromagnetic interference assessement modes

	VVI In.		VVI As.		AAI In.		AAI As.		FP.	FN.	Total number of modes
	UNI	BI	UNI	BI	UNI	BI	UNI	BI	BI	BI	
Pacemaker (per model)	1	1	1	1	1	1	1	1	-	-	8
ICD (per model)	-	1	-	1	-	1	-	1	2	2	8

The details of the modes are as follows.

Operation modes

- VVI: Using the ventricle electrode, the AIMD generates electric stimuli when no ventricle native rhythm can be detected within a predetermined period of time.
- AAI: Using the atrium electrode, the AIMD generates electric stimuli when no atrium native rhythm can be detected within a predetermined period of time.

Pacemaker/ICD common test modes (test modes for the pacing function)

- Inhibit test (In): A test mode where no signal is input from the simulated ECG signal generator; the AIMD senses the absence of generated normal signals (ECG) and generates pacing pulses to stimulate the heart. When the influence of electromagnetic interference occurs, the pulses that should be generated by the AIMD will not be generated.
- Asynchronous test (As): A test mode where a signal is always input from the simulated ECG signal generator; the AIMD senses generated normal signals (ECG) and suppresses pacing pulses from the AIMD. When the influence of electromagnetic interference occurs, the pulses that should be suppressed by the AIMD will be generated.

ICD test modes (test modes for the defibrillation function)

- False-positive test (FP): This test checks whether or not the ICD makes a false detection of ventricular fibrillation or ventricular tachycardia during inhibit and asynchronous tests above. When the influence of electromagnetic interference occurs, the ICD will wrongly generate defibrillation pulses.
- False-negative test (FN): This test checks whether or not the ICD can normally detect a signal simulating ventricular fibrillation that is input from the simulated ECG signal generator. When the influence of electromagnetic interference occurs, the defibrillation pulses that should be generated by the ICD will not be generated.

Configuration of leads

- Unipolar (UNI): Sensing and paging are carried out by using the AIMD main body (made of metal) and the inner conductor of a lead.
- Bipolar (BI): Sensing and paging are carried out between the inner and outer conductor of a lead.

Annex B Criteria for evaluating reaction levels

The criteria that the Ministry of Internal Affairs and Communications has been using for pacemakers and ICDs were used as the criteria for the reaction evaluation [1]. The degrees of influence for ICDs are the same as those for pacemakers.

Table 1: Reaction level vs. clinical significance on patients (pacemakers)

	Normal state	Reversible reaction	Irreversible reaction		Direct reaction on living bodies
			Externally removable	Replacement surgery required	
Normal operations maintained	Level 0				
Abnormal pacing/sensing within one cycle (recovered within 2 seconds)		Level 1			
Abnormal pacing/sensing for one cycle (2 seconds) or longer		Level 2			
Pacemaker reset Permanent change in program settings			Level 3		
Persistent failure			Level 5		
Permanent failure				Level 5	
Induction of electromotive force/heat in the lead					Level 5

Level	Degree of reaction (conventional classification)
0	No reaction
1	Reactions that could cause instantaneous palpitations or dizziness
2	Reactions that could cause persistent palpitations or dizziness, from which the patient can recover with their own action, such as by removing themselves from that location
3	Reactions that can deteriorate the patient's condition if left as-is
4	Reactions that can deteriorate the patient's condition immediately
5	Reactions that can bring the patient's life to a critical condition

Table 2:Reaction level vs. clinical significance on patients (ICDs)

	Normal state	Reversible reaction	Irreversible reaction		Direct reaction on living bodies
			Externally removable	Replacement surgery required	
Normal operations maintained	Level 0				
Abnormal pacing/sensing within one cycle (recovered within 2 seconds)		Level 1			
Abnormal pacing/sensing for one cycle (2 seconds) or longer		Level 2			
Temporary loss of defibrillation detection ability		Level 3			
Occurrence of unnecessary defibrillation shocks		Level 4			
Permanent change in program settings			Level 4		
Persistent failure			Level 5		
Permanent failure				Level 5	
Induction of electromotive force/heat in the lead					Level 5

Annex C Installation of WPT units and assessment procedure

This annex explains how to install WPT units and their assessment procedure.

Figure 1 shows how a WPT unit other than an EV should be installed. For EVs, refer to Annex E. The following describes the scanning procedure of WPT units.

1 Place the WPT unit around the center of the phantom. At that time, make sure that the distance between the WPT unit and the phantom is 0 cm (i.e., that they are in intimate contact).
2 Move the unit in such a way as to scan the surface of the phantom, and check whether or not influence occurs. When influence occurs, record the position.
3 At the position where the influence occurs, locate the unit away from the phantom by 1 cm at a time and record the maximum distance at which the influence occurs.

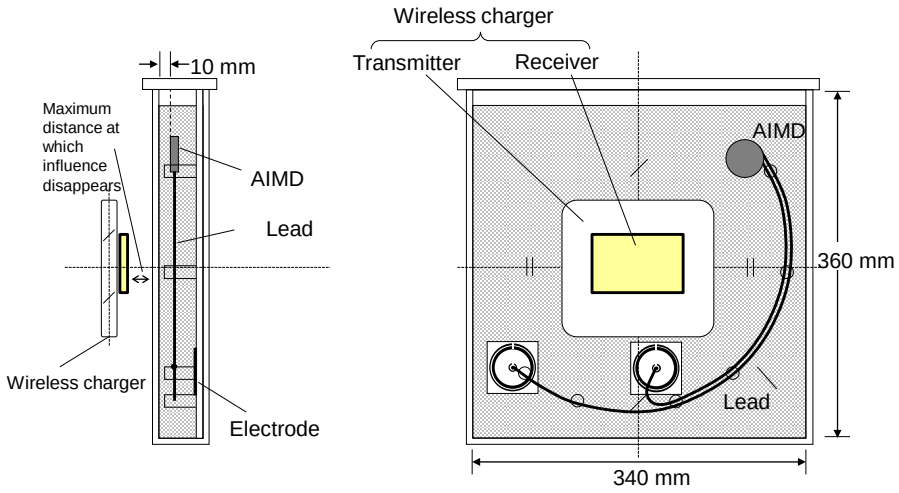

Fig. 1: Torso phantom and WPT unit (courtesy of Hokkaido University)

In the next place, Fig. 2 shows the test procedure. The summary is as follows.

1 Set the parameters of the WPT unit and the AIMD. There are two modes for the WPT unit: stand-by mode (where no power-receiving unit exists) and charging mode (where a power-receiving unit is being charged). The initial setting of the AIMD sensitivity should be the maximum.

2 Move the unit in such a way as to scan the surface, and check whether or not influence occurs.

2.1 When no influence is found, proceed to the next condition.

2.2 When influence is found, determine the distance at which the influence disappears.

3 When influence is found, reduce the sensitivity and repeat.

3.1 When no influence is found, proceed to the next condition.

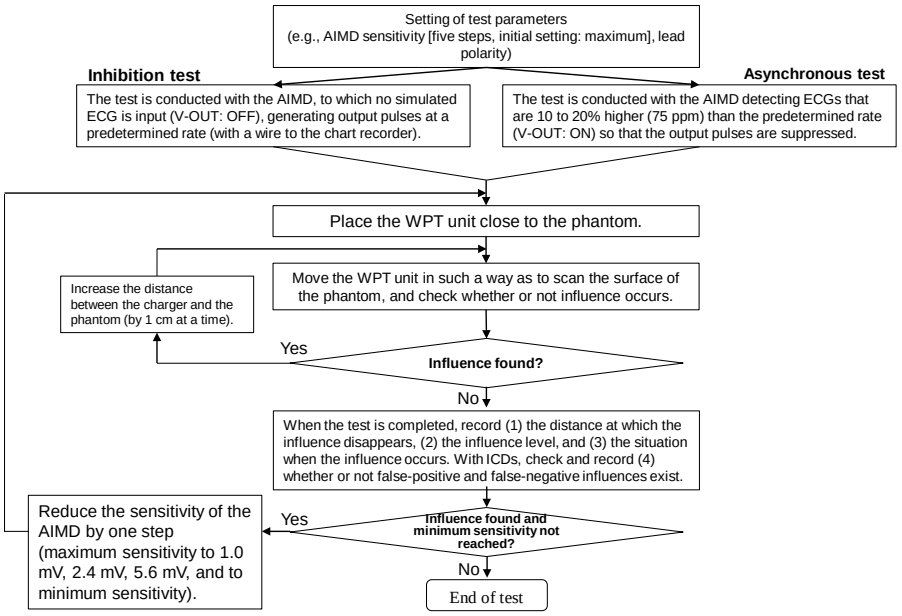

Fig. 2: assessment procedure

Annex D Specifications of WPT units (mobile devices) and detailed results

1 WPT units used for assessment

The WPT units were selected from products that were already available in the Japanese market and from prototypes that were to be launched in the future. The major parameters that should be taken into account are the charging system, frequency, and output. Table 1 shows a summary of the WPT units for mobile devices, excluding EVs.

Table 1: Specifications of the WPT units

Unit under test	Charging system	Frequency	Transmitted power
A	Magnetic field coupling	70 kHz	0.2 W
B	Electric field coupling	200 kHz	13 W
C	Magnetic field coupling	110 to 183 kHz*	Up to 15 W
D	Magnetic field coupling	110 to 210 kHz*	Up to 15 W
E	Magnetic field coupling	110 kHz	5 W
F	Magnetic field coupling	110 kHz	5 W
G	Magnetic field coupling	110 kHz	5 W x2
H	Magnetic field coupling	110 kHz	5 W
I	Electric field coupling	460 kHz	Up to 40 W
J	Magnetic field coupling	400 kHz	Approx. 0.4 W
K	Magnetic field coupling	6.78 MHz	18.2 W
L	Magnetic field coupling	134.5 kHz	Approx. 1.4 W

* Differs depending on the operation mode

2 AIMDs used for assessment

JADIA provided models that were available in the period of time of assessment as the AIMDs. Table 2 shows the number of models for each unit under the assessment.

Table 2: Number of AIMD models

Unit	Pacemaker	CRT-P	ICD	CRT-D
A to D	11	2	5	7
E to H	11	5	8	8
I	10	2	6	7

J, K	11	3	7	9
L	11	3	8	8

3 Results

Table 3: Summary of results

Model	Results: Level, distance at which reaction disappears (number of influence modes/number of modes)	
	Pacemaker	ICD
A	No influence (0/208)	No influence (0/192)
B	L2 / 1 cm / (2/208)	No influence (0/192)
C	No influence (0/208)	No influence (0/192)
D	No influence (0/208)	No influence (0/192)
E	L1 / 1 cm / (3/620)	No influence (0/600)
F	No influence (0/620)	L1 / 1 cm / (1/600) *
G	L1 / 1 cm / (3/620)	No influence (0/600)
H	L1 / 1 cm / (1/620) L2 / 1 cm / (1/620)	No influence (0/600)
I	No influence (0/96)	No influence (0/104)
J	No influence (0/336)	No influence (0/384)
K	No influence (0/224)	No influence (0/256)
L	L2 / 2 cm / (1/448)	No influence (0/512)

* Only in pacemaker mode

Annex E Details of WPT units (EVs) and detailed results

1 WPT units used for assessment

Table 1: Specifications of the WPT units

Unit	Charging system	Frequency	Transmitted power	Conditions
M	Magnetic field coupling	85 kHz	2 to 3 kW	Simulator wheeled platform/real vehicle
N	Magnetic field coupling	85 kHz	3 kW	Real vehicle

2 AIMDs used for assessment

Table 2: Number of AIMDs

Unit	Pacemaker	CRT-P	ICD	CRT-D
M, N	5	2	5	5

3 WPT layout

Figures 1 and 2 show the WPT layout for assessment with a simulator wheeled platform and a real vehicle, respectively.

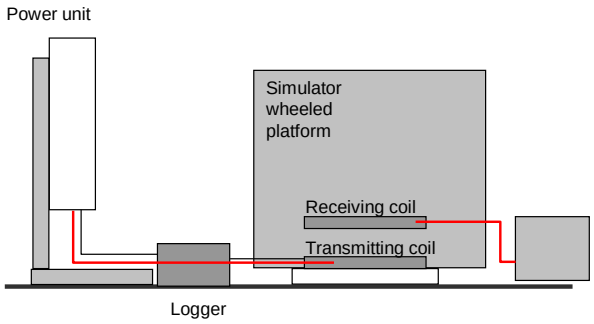

Fig. 1: WPT layout with a simulator wheeled platform (courtesy of Hokkaido University)

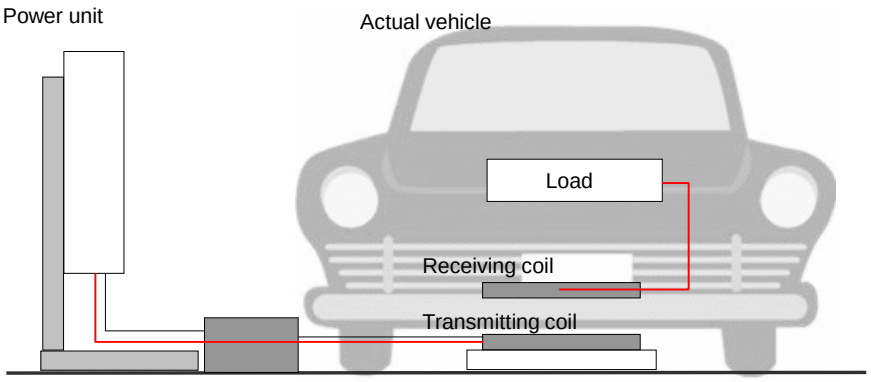

Fig. 2: WPT layout with a real vehicle (courtesy of Hokkaido University)

4 Assessment procedure

4.1 While changing the height and the orientation of the phantom, check the operation of the AIMD. With reference to the midpoint of the distance between the transmitting coil and the receiving coil, the layout consists of three points at the center (A), 25 cm (B), and 50 cm (C) (Fig. 3).

4.2 Starting the test at a position 1 m away, move the phantom to the point that is the closest to the coil unit. Figure 4 shows pictures of a scene in which a simulator wheeled platform was used.

4.3 Record the distance of the point at which influence was first found as the influence distance.

4.4 In tests where a real vehicle is used, assuming that a passenger is in the cabin during charging, conduct the test not only at the back of the vehicle (scenario A) and at the side of a rear wheel (scenario B), but also at the center of the rear seat of the vehicle (scenario C), which is closest to the coil position (Fig. 5).

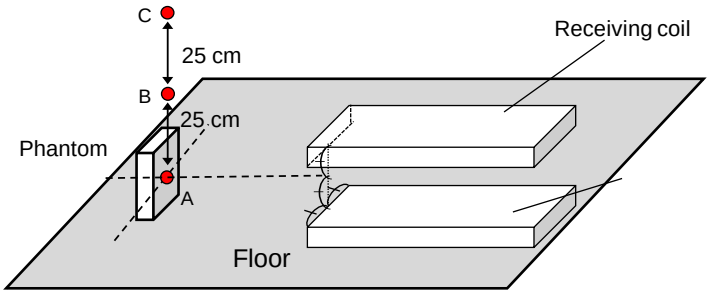

Fig. 3: Positional relationship between the WPT and the phantom

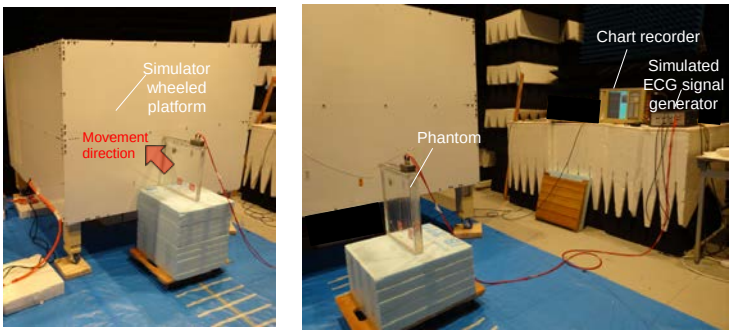

Fig. 4: Scene in which a simulator wheeled platform was used (courtesy of Hokkaido University)

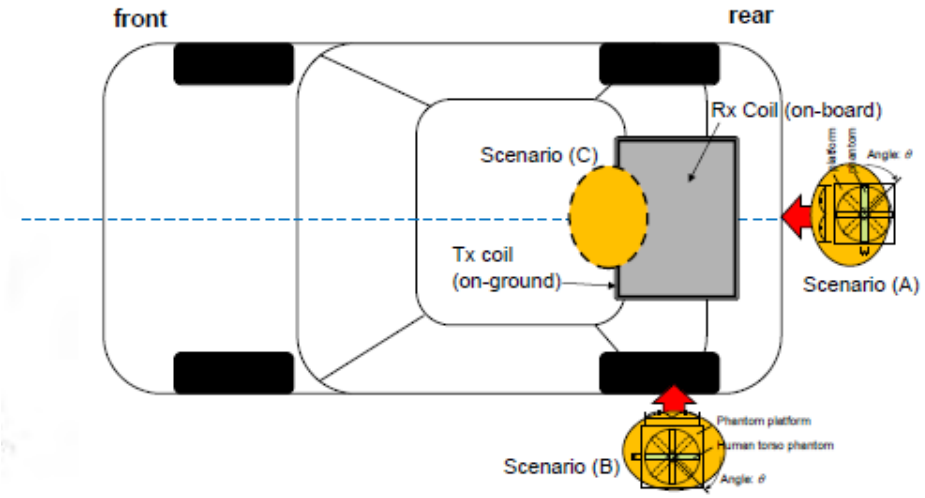

Fig. 5: Scene in which a real vehicle was used (courtesy of Hokkaido University)

5 Results

Table 3: Summary of results

Model	Results: Level, distance at which reaction disappears (number of influence modes/number of modes)	
	Pacemaker	ICD
M (simulator wheeled platform)	No influence (0/56)	No influence (0/80)
M (real vehicle)	No influence (0/56)	No influence (0/80)
N (real vehicle)	No influence (0/56)	No influence (0/80)

Annex F (Informative) Framework of electromagnetic interference assessment

The BWF and the JADIA provided Hokkaido University with WPTs and AIMDs, respectively, asking for the conducting of electromagnetic interference (EMI) assessment.

Table 1: Framework of assessment

	In charge
Interference sources (WPTs) provider	BWF
Units (AIMDs) provider	JADIA
EMI assessment	Hokkaido University