

EMC TEST REPORT

No. SH11071330-001

Applicant: TFE Hong Kong Limited
7/F., Gemmy Factory Building, 12 Hung To Road,
Kwun Tong, Kowloon, Hong Kong

Manufacturer: TFE Hong Kong Limited
7/F., Gemmy Factory Building, 12 Hung To Road,
Kwun Tong, Kowloon, Hong Kong

Equipment: Anti-Tamper Care Alarm

Type/Model: TS1011A, TS1011B, TS1012A, TS1012B, TS1013A,
TS1013B

TEST RESULT: PASS

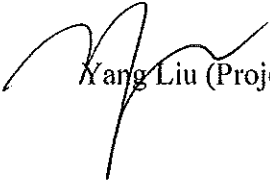
SUMMARY

The equipment complies with the requirements according to the following standard:

EN 60601-1-2: 2007: Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

Date of issue: October 21, 2011

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1. GENERAL INFORMATION

1.1 Description of Equipment Under Test (EUT)

EUT	:	Anti-Tamper Care Alarm
Description of EUT	:	The EUT has six models. All 6 types listed in this report are identical except small difference of optional accessories.
Model number	:	TS1011A, TS1011B, TS1012A, TS1012B, TS1013A, TS1013B
Rating	:	Main unit is internally powered by four 1.5Vdc alkaline batteries IR remote control is internally powered by one 3Vdc button Lithium battery
Mains lead	:	None
Data cable	:	None
Sample received date	:	July 15, 2011
Sample identification No	:	0110715-46-003
Date of test	:	July 15, 2011

1.2 Description of Client

Applicant:	TFE Hong Kong Limited 7/F., Gemmy Factory Building, 12 Hung To Road, Kwun Tong, Kowloon, Hong Kong
Manufacturer:	TFE Hong Kong Limited 7/F., Gemmy Factory Building, 12 Hung To Road, Kwun Tong, Kowloon, Hong Kong

1.3 Description of Test Facility

Name Intertek Testing Service Shanghai
Address Building 86, No. 1198 Qinzhou Road(North),
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Subcontractor:

Name Shanghai Institute of Measurement Technology
Address 716 Yishan Road, Shanghai 200233, P.R. China
Telephone 86 21 64700066

Name Jiangsu Electronic Products Supervision and
Inspection Institute
Address No. 10, Geixiang, Zhongqiao, Wuxi, P.R. China
Telephone 0510-85140037

2. TEST SPECIFICATIONS

2.1 Standards

EN 60601-1-2: 2007: Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

2.2 Mode of operation during the test / Test peripherals used

Within this test report, EUT was tested under all available operation modes and tested under its rating voltage and frequency. Other voltage and frequency is specified if used.

2.3 Instrument list

Selected	Instrument	EC no.	Model	Valid until date
<input type="checkbox"/>	Shielded room	EC 2838	GB88	2014-1-11
<input type="checkbox"/>	EMI test receiver	EC 2107	ESCS 30	2012-10-17
<input type="checkbox"/>	A.M.N.	EC 3119	ESH2-Z5	2012-1-9
<input type="checkbox"/>	A.M.N.	EC 3394	ENV 216	2012-8-11
<input type="checkbox"/>	Absorbing clamp	EC 2108	MDS 21	2012-1-11
<input type="checkbox"/>	Voltage probe	EC 3405	ESH2-Z3	2012-1-11
<input type="checkbox"/>	Tri-loop	EC 3384	HXYZ 9170	2012-6-18
<input type="checkbox"/>	Click meter	EC 2253	CL55C	2012-8-19
<input type="checkbox"/>	ISN	EC 3754	FCC-TLISN-T2-02	2012-1-9
<input type="checkbox"/>	ISN	EC 3755	FCC-TLISN-T4-02	2012-1-9
<input type="checkbox"/>	ISN	EC 3756	FCC-TLISN-T8-02	2012-1-9
<input type="checkbox"/>	Current probe	EC 3221	EZ-17	2012-1-11
<input type="checkbox"/>	Attenuator	EC 3043-9	68-6-44	2012-1-9
<input type="checkbox"/>	Harmonic/Flicker sys.	EC 2110	5001ix/PACS-1	2012-1-21
<input checked="" type="checkbox"/>	Shielded room	EC 2839	GB88	2014-1-11
<input checked="" type="checkbox"/>	ESD Gun	EC 2956	ditto	2012-4-20
<input type="checkbox"/>	Motorise Variac	EC 2957	MV 2616	Not required
<input type="checkbox"/>	Immunity system	EC 2958	UCS500M6	2012-1-22
<input type="checkbox"/>	Capacitive clamp	EC 2959	HFK	Not required
<input type="checkbox"/>	Immunity system	EC 2960	TSS500M	2012-4-27
<input type="checkbox"/>	Immunity system	EC 2961	TSS500M4	2012-1-11
<input type="checkbox"/>	Signal generator	EC 2338	SML 01	2012-4-7
<input type="checkbox"/>	Power amplifier	EC 3043-1	75A250	2012-8-16
<input type="checkbox"/>	Attenuator	EC 3043-3	ATT6/75	2012-1-9
<input type="checkbox"/>	CDN	EC 2113-1	M216	2012-8-04
<input type="checkbox"/>	CDN	EC 2113-2	M316	2012-8-04
<input type="checkbox"/>	CDN	EC 3043-2	T2	2012-1-9
<input type="checkbox"/>	CDN	EC 3043-4	T4	2012-1-9
<input type="checkbox"/>	EM clamp	EC 3043-6	EM 101	2012-10-10
<input checked="" type="checkbox"/>	Fully anechoic chamber	EC 3047	-	2012-5-20
<input checked="" type="checkbox"/>	Signal generator	EC 3044-1	SMR20	2012-8-16
<input checked="" type="checkbox"/>	Log-periodical antenna	EC 3044-7	AT1080	2013-5-21



<input checked="" type="checkbox"/>	Power amplifier	EC 3044-2	150W1000	2012-8-16
<input checked="" type="checkbox"/>	DDC	EC 3044-5	DC6180A	2012-8-05
<input checked="" type="checkbox"/>	Horn antenna	EC 3044-8	AT4002	2013-5-21
<input checked="" type="checkbox"/>	Power amplifier	EC 3044-4	25S1G4	2012-8-16
<input checked="" type="checkbox"/>	DDC	EC 3044-6	DC7144A	2012-1-9
<input checked="" type="checkbox"/>	Power sensor	EC 3043-7	PH 2000	2012-10-19
<input checked="" type="checkbox"/>	Power meter	EC 3043-8	PM 2002	2012-10-19
<input type="checkbox"/>	Field meter	EC 3044-9	FM5004	2012-4-9
<input type="checkbox"/>	Field sensor	EC 3044-3	FP6001	2012-4-9
<input checked="" type="checkbox"/>	Semi anechoic chamber	EC 3048	-	2012-5-20
<input checked="" type="checkbox"/>	EMI test receiver	EC 3045	ESIB26	2012-10-21
<input checked="" type="checkbox"/>	Broadband antenna	EC 4206	CBL 6112D	2013-5-15
<input type="checkbox"/>	Horn antenna	EC 3049	HF906	2013-5-12
<input type="checkbox"/>	Pre-amplifier	EC 3222	pre-amp 18	2012-9-17
<input type="checkbox"/>	DDC	EC 3043-5	DC2600	2012-1-9
<input type="checkbox"/>	Oscilloscope	EC 3515	DPO 4504	2012-1-17
<input type="checkbox"/>	TV generator	EC 3555	TG39	2012-4-5
<input type="checkbox"/>	Lum. Meter	EC 2451	TES 1332	2012-6-15



2.4. Test Summary

This report applies to tested sample only. This report shall not be reproduced in part without written approval of Intertek Testing Service Shanghai Limited.

TEST ITEM	RESULT	NOTE
Mains terminal continuous disturbance voltage	NA	-
Mains terminal discontinuous disturbance voltage	NA	-
Radiated emission	Pass	-
Harmonic Currents	NA	-
Flicks	NA	-
Electrostatic Discharge (ESD)	Pass	-
Electric Fast Transient /Burst (EFT/B)	NA	-
Surge	NA	-
Injected Current	NA	-
RF electromagnetic field susceptibility	Pass	-
Voltage dips and interruption	NA	-
Magnetic Fields	NA	-

Notes: 1: NA =Not Applicable

Emission Test

Classification for Equipment and Systems

Equipment and systems, except as specified in 1 through 3 below, shall be classified as group 1 or group 2 and class A or class B in accordance with CISPR11, based on their intended use, as specified by the manufacturer.

Equipment and systems shall comply with CISPR requirements, based upon their classification, with the exceptions and clarifications specified in 4 and 5 below.

1. *Simple electrical components*

Medical electrical equipment containing only simple electrical components like motors and switches and not utilizing any electronic circuitry that generates or uses frequencies above 9 kHz (e.g. some dental drills, some ventilators, some operating tables) may be classified in accordance with CISPR14-1. Classification to CISPR14-1, however, is limited to stand-alone equipment and is not applicable to systems or sub-systems.

2. *Lighting equipment*

Lighting equipment used in medical applications (e.g. equipment for illumination of x-ray films, lighting devices for operating theatres) may be classified in accordance with CISPR 15. Classification to CISPR 15, however, is limited to stand-alone equipment and is not applicable to systems or sub-systems.

3. *Information technology equipment (ITE)*

ITE connected to equipment and systems may be classified in accordance with CISPR 22 with the following restriction: CISPR 22 class B equipment may be used with CISPR 11 class a or class b systems, but CISPR 22 class A equipment may only be used with CISPR 11 class a systems.

4. *Equipment and systems specified for use only in a shielded location*

- For equipment and systems that are specified for use only in a shielded location, the electromagnetic radiation disturbance limits of CISPR 11 may be increased, when tests are performed on a test site, by an amount up to the applicable specified value of minimum RF shielding effectiveness, provided the minimum RF shielding effectiveness specification meets the requirements in EN60601-1-2.
- For equipment and systems that are specified for use only in a shielded location, the mains terminal disturbance voltage limits of CISPR 11 may be increased, when tests are performed on a test site, by an amount up to the applicable specified value of minimum RF filter attenuation for all cables that exit the shielded location, provided the minimum RF filter attenuation specification meets the requirements specified.

Moreover, the outside of equipment and systems shall be labeled with a warning that they should be used only in the specified type of shielded location.

5. *Equipment and systems that include radio equipment*

Equipment and systems that include radio equipment and have been tested and found to comply with applicable national radio regulations are exempt from testing to CISPR electromagnetic disturbance requirements, provided the emissions limits of the applicable national radio regulations are less than or equal to the corresponding applicable CISPR electromagnetic disturbance limits. Equipment and systems that include RF transmitters are exempt from the emissions requirements of this standard in the dedicated transmission band of the transmitter. Otherwise, and for equipment and systems intended only for countries with no national radio regulations, the emissions requirements of this standard shall apply.

Moreover, equipment and systems that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment shall be labeled with the following symbol for non-ionizing radiation.

Symbol for Non-Ionizing Radiation: 

Classification

Emission	Compliance	
RF emissions CISPR 11	Group 1	Group 2
RF emissions CISPR 11	Class A	Class B
RF emissions CISPR 22	Group 1	Group 2
RF emissions CISPR 22	Class A	Class B
RF emissions CISPR 14-1	Complies	
RF emissions CISPR 15	Complies	
Used only in a shielded location CISPR 11	Complies	
Including radio equipment	Complies	
Notes: The gray rows were the selected objects.		

Basic EMC standard for emission test

IEC 61000-3-2:2005/+A1:2008: Limits for harmonic current emissions (equipment input current $\leq 16\text{A}$ per phase)

IEC 61000-3-3:2008: Limitation of voltage fluctuations and flicker in low-voltage supply systems for equipment with rated current $\leq 16\text{A}$

CISPR 11:2003/+A1:2004/+A2:2006: Industrial, scientific and medical (ISM) radio-frequency equipment – Electromagnetic disturbance characteristics – Limits and methods of measurement

CISPR 14-1:2005: Electromagnetic compatibility-Requirements for household appliances, electric tools and similar apparatus Part 1: Emission

CISPR 15:2005/+A2:2008: Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment

CISPR 22:2005/+A1:2005/+A2:2006: Information technology equipment – Radio disturbance characteristics Limits and methods of measurement.

3. Mains Terminal Continuous Disturbance Voltage

Test result: NA

3.1 Terminal Voltage Limits for the frequency range 148.5 kHz to 30 MHz

3.1.1— Mains terminal disturbance voltage limits for class B equipment.

Class B equipment limits dB(μ V)		
Frequency band MHz	Groups 1 and 2	
	Quasi-peak	Average
0,15 – 0,50	66 Decreasing linearly with logarithm of frequency to 56	56 Decreasing linearly with logarithm of frequency to 46
0,50 – 5	56	46
5 – 30	60	50

NOTE Care should be taken to comply with leakage current requirements.

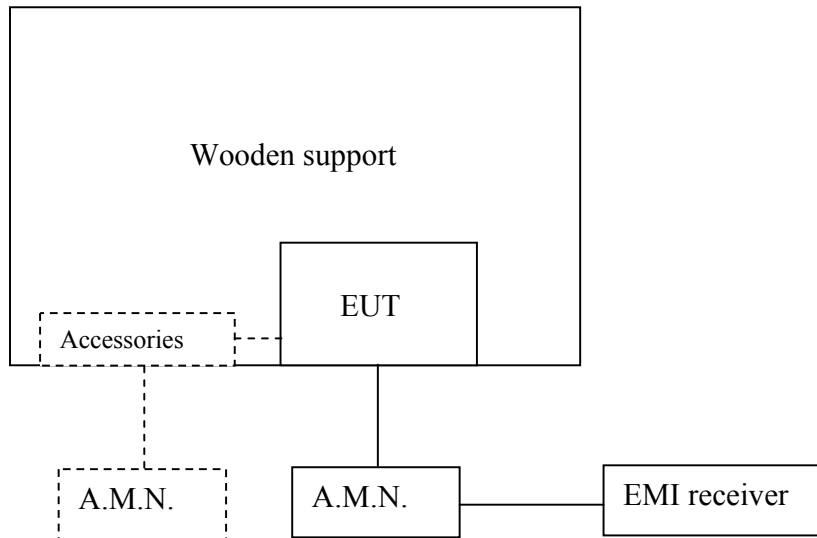
3.1.2— Mains terminal disturbance voltage limits for class A equipment.

Frequency band MHz	Class A equipment limits dB(μ V)					
	Group 1		Group 2		Group 2 ^a	
	Quasi-peak	Average	Quasi-peak	Average	Quasi-peak	Average
0,15 – 0,50	79	66	100	90	130	120
0,50 – 5	73	60	86	76	125	115
5 – 30	73	60	90 decreasing linearly with logarithm of frequency to 70	80 60	115	105

NOTE Care should be taken to comply with leakage current requirements.

3.2 Block Diagram of Test Setup

- At mains terminal



- For table top equipment, wooden support is 0.8m height table
- For floor standing equipment, wooden support is 0.1m height rack.

3.3 Test Setup and Test Procedure

Measurement was performed in shielded room.

According to RF emissions classification, the detailed test procedure and arrangement can be found in related Standard.

According to RF emissions classification, measurement methods and operation conditions of EUT can be found in related Standard.

Frequency range 150kHz – 30MHz was checked and EMI receiver measurement bandwidth was set to 9kHz.



3.4 Test Protocol

Temperature : °C
Relative Humidity : %

3.5 Measurement Uncertainty

The measurement uncertainty describes the overall uncertainty of the given measured value during the operation of the EUT.

Measurement uncertainty at mains terminal: $\pm 1.99\text{dB}$

Measurement uncertainty at load/control terminal: $\pm 1.99\text{dB}$

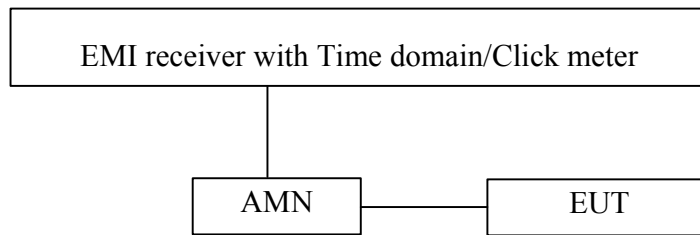
The measurement uncertainty is given with a confidence of 95%, $k=2$.

The measurement uncertainty is traceable to internal procedure TI-036.

4. Mains Terminal Discontinuous Disturbance Voltage

Test result: NA

4.1 Block Diagram of Test Setup



4.2 Test Set-up and Test Procedure

Measurement was performed in shielded room.

EMI receiver compliance to CISPR 16-1-1 with time domain function used during measurement.

EUT operation conditions were follow CISPR 16-2-1 clause 6.3.

The frequency 150 kHz, 500 kHz, 1.4 MHz and 30 MHz was checked.

The final judgment of test result was according to CISPR 16-2-1 clause 6.4.2.

4.3 In Particular

For diagnostic X-ray generators, operating in intermittent mode, the limit for clicks shall be the quasi-peak limit, as formulated in section 3.1.1 or 3.1.2 for continuous disturbance, increased by 20 dB.

4.4 Test Protocol

Temperature : °C Relative Humidity : %

Frequency (MHz)	0.15	0.5	1.4	30.0
Permitted limit for continuous interference (dB μ V)	-	-	-	-
Counted click number	-	-	-	-
Observed time (min)	-	-	-	-
Click duration (ms)	-	-	-	-
Click rate N	-	-	-	-
Factor	-	-	-	-
Permitted limits for clicks (dB μ v)	-	-	-	-
Counted clicks exceeding the limits	-	-	-	-
Test result	-	-	-	-
Any other descriptions: None				

4.5 Measurement Uncertainty

The measurement uncertainty describes the overall uncertainty of the given measured value during the operation of the EUT.

Measurement uncertainty of mains lead and auxiliary lead: ± 2.73 dB

The measurement uncertainty is given with a confidence of 95%, k=2

The measurement uncertainty is traceable to internal procedure TI-036.

5. Radiated emission

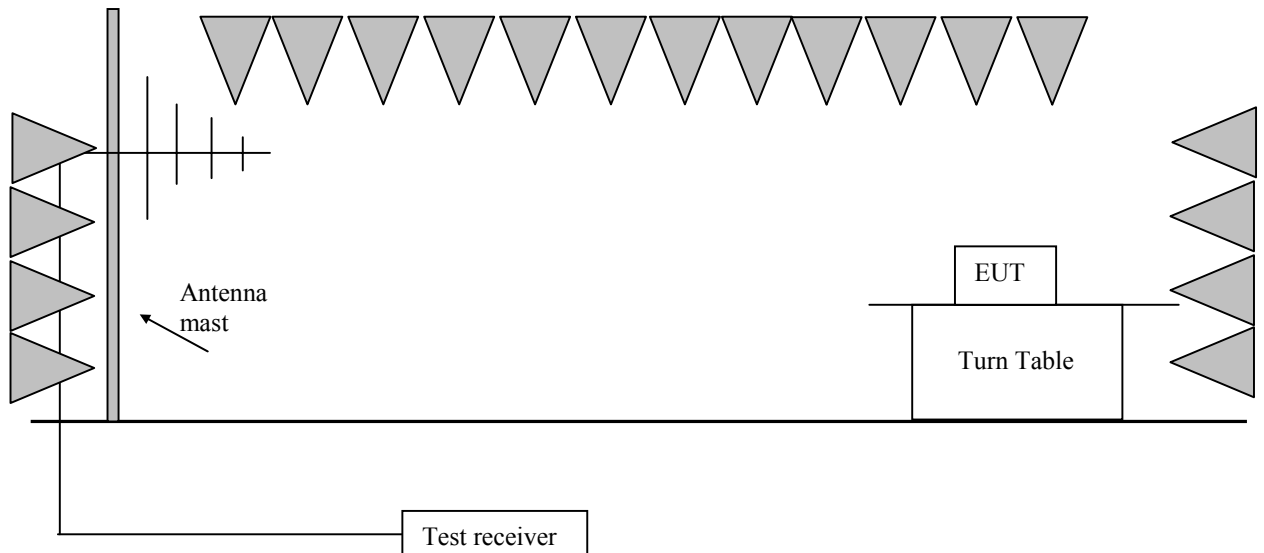
Test result: **PASS**

5.1 Radiated emission limit for group 1, class B equipment

Frequency (MHz)	Permitted limit in dB μ V/m (Quasi-peak) of Measurement Distance 3m	Permitted limit in dB μ V/m (Quasi-peak) of Measurement Distance 10m
30-230	40	30
230-1000	47	37

Note: for the measurement distance other than 3m and 10m, the limit is varied according to 20dB/10 decades.

5.2 Block diagram and test set up

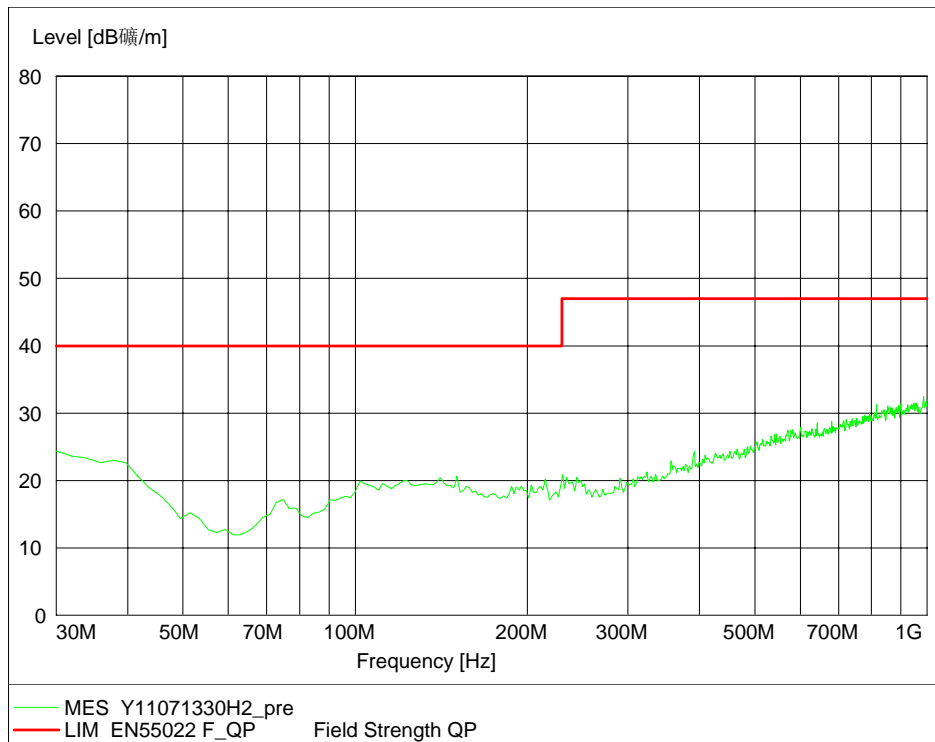


The measurement was applied in a semi-anechoic chamber.
Measurement and setting of EUT was applied according to classification for equipment and systems.
The bandwidth setting on R&S Test Receiver ESI26 was 120 kHz.
The frequency range from 30MHz to 1000MHz was checked

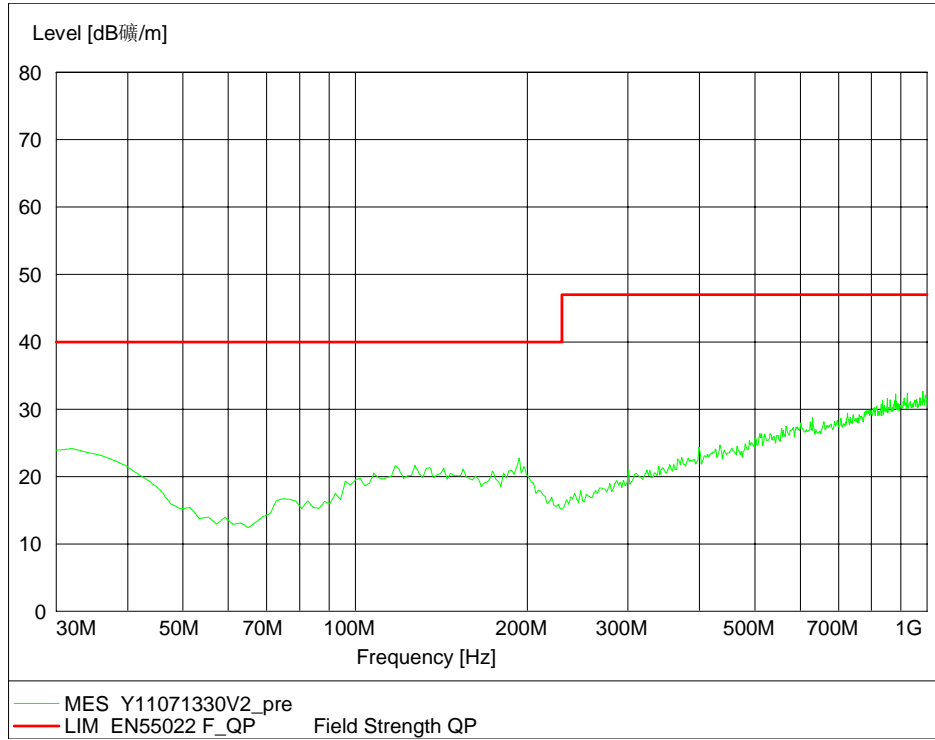
5.3 Test Protocol

Temperature : 22°C
Relative humidity : 50%

Horizontal



Vertical



Polarization	Frequency (MHz)	Emission level (dB μ V/m)	Limits (dB μ V/m)	Margin (dB μ V/m)
Horizontal	30.00	*	40.00	*
	60.00	*	40.00	*
	100.00	*	40.00	*
	500.00	*	47.00	*
	1000.00	*	47.00	*
Vertical	30.00	*	40.00	*
	60.00	*	40.00	*
	100.00	*	40.00	*
	500.00	*	47.00	*
	1000.00	*	47.00	*

Note: * means margin >10dB.



5.4 Measurement uncertainty

The measurement uncertainty describes the overall uncertainty of the given measured value during the operation of the EUT.

Measurement uncertainty of radiated emission is: $\pm 5.31\text{dB}$

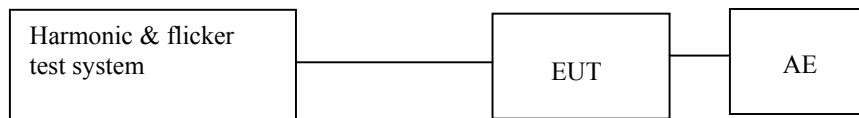
The measurement uncertainty is given with a confidence of 95%, $k=2$.

The measurement uncertainty is traceable to internal procedure TI-036.

6. Harmonics

Test result: NA

6.1 Block Diagram of Test Setup



6.2 Test Setup and Test Procedure

Harmonics of the fundamental current were measured up to 40 order harmonics using a digital power meter with an analogue output and frequency analyser which was integrated in the harmonic & flicker test system. The measurements were carried out under steady conditions.

- This product is not defined as lighting equipment, and has rated power less than 75W, therefore, no limit apply according to EN 61000-3-2
- Professional equipment with a total rated power greater than 1 kW, therefore, no limit apply according to EN 61000-3-2
- Symmetrically controlled heating elements with a rated power less than or equal to 200 W, therefore, no limit apply according to EN 61000-3-2
- Independent dimmers for incandescent lamps with a rated power less than or equal to 1kW, therefore, no limit apply according to EN 61000-3-2

6.3 Test Protocol

Temperature : °C
Relative Humidity : %

6.4 Measurement Uncertainty

The measurement uncertainty describes the overall uncertainty of the given measured value during the operation of the EUT.

Measurement uncertainty of harmonic test is: $\pm 5\%$

The measurement uncertainty is given with a confidence of 95%, $k=2$.

The measurement uncertainty is traceable to internal procedure TI-036.

6.5 Additions, Deviations and Exclusions from Standards

None

7. Voltage Fluctuations-Flicker

Test result **NA**

7.1 Block Diagram of Test Setup



7.2 Test Setup and Test Procedure

7.2.1 Definition

Flicker: impression of unsteadiness of visual sensation induced by a lighting stimulus whose luminance or spectral distribution fluctuates with time.

Pst: Short-term flicker indicator The flicker severity evaluated over a short period (in minutes); Pst=1 is the conventional threshold of irritability

Plt: long-term flicker indicator; the flicker severity evaluated over a long period (a few hours) Using successive Pst values.

dc: the relative steady-state voltage change

dmax: the maximum relative voltage change

d(t): the value during a voltage change

7.2.2 Test condition

The EUT was set to produce the most unfavorable sequence of voltage changes.

7.3 Test Protocol

The tested object operated under the operating condition specified in IEC61000-3-3.
The following limits apply

- “dc” shall not exceed 3.3%.
- “dmax” shall not exceed 4/6/7%
- “d(t)” shall not exceed 3.3% for more than 500ms.



The product no means to generate voltage fluctuation higher than the relevant limit, therefore, it is deemed to fulfill the requirements according to EN61000-3-3 without test.

Temperature : °C
Relative Humidity : %

7.4 Measurement Uncertainty

The measurement uncertainty describes the overall uncertainty of the given measured value during the operation of the EUT.

Measurement uncertainty of voltage fluctuation and flicker is: $\pm 12\%$

The measurement uncertainty is given with a confidence of 95%, $k=2$.

The measurement uncertainty is traceable to internal procedure TI-036.

7.5 Additions, deviations and exclusions from standards

None

Immunity Test

Performance criteria

The equipment or system shall be able to provide the essential performance and remain safe. The following degradations associated with essential performance and safety shall not be allowed:

- Component failures;
- Changes in programmable parameters;
- Reset to factory defaults (manufacturer's presets);
- Change of operating mode;
- False alarms;
- Cessation or interruption of any intended operation, even if accompanied by an alarm;
- Initiation of any unintended operation, including unintended or uncontrolled motion, even if accompanied by an alarm;
- Error of a displayed numerical value sufficiently large to affect diagnosis or treatment;
- Noise on a waveform in which the noise is indistinguishable from physiologically produced signals or the noise interferes with interpretation of physiologically-produced signals;
- Artefact or distortion in an image in which the artefact is indistinguishable from physiologically-produced signals or the distortion interferes with interpretation of physiologically-produced signals;
- Failure of automatic diagnosis or treatment equipment and systems to diagnose or treat, even if accompanied by an alarm.

For equipment and systems with multiple functions, the criteria apply to each function, parameter and channel.

The equipment or system may exhibit degradation of performance (e.g. deviation from manufacturer's specifications) that does not affect essential performance or safety.

Operating Mode and Configuration

During immunity testing, each function of the equipment or system that is associated with essential performance shall be tested in the mode that is most critical from a patient outcome perspective, based upon a risk analysis, using equipment options, cable layout and accessories in a typical configuration, consistent with normal use. This risk analysis is not required if all modes of the equipment or system are tested. If the equipment or system is not rated for continuous duty, the operating mode may instead be selected such that reliable operation is obtained for the applicable test duration.

Basic EMC standard for immunity test

IEC 61000-4-2: 1995/+A1:1998/+A2:2000: Electromagnetic Compatibility (EMC) – Part 4-2: testing and measurement techniques – Electrostatic discharge immunity test

IEC 61000-4-3: 2006/+A1:2007: Electromagnetic Compatibility (EMC) – Part 4-3: testing and measurement techniques – Radiated, radio frequency, electromagnetic field immunity test

IEC 61000-4-4: 2004: Electromagnetic Compatibility (EMC) – Part 4-4: testing and measurement techniques – Electric fast transient/burst immunity test

IEC 61000-4-5: 2005: Electromagnetic Compatibility (EMC) – Part 4-5: testing and measurement techniques – Surge immunity test

IEC 61000-4-6:2003/+A1:2004/+A2:2006: Electromagnetic Compatibility (EMC) – Part 4-6: testing and measurement techniques – Immunity to conducted disturbance, induced by radio frequency field.

IEC 61000-4-11: 2004: Electromagnetic Compatibility (EMC) – Part 4-11: testing and measurement techniques – Voltage dips, short interruption and voltage variations immunity test

IEC 61000-4-8: 1994/+A1: 2001: Electromagnetic Compatibility (EMC) – Part 4-8: Testing and measurement techniques — Power frequency magnetic field immunity test

8. Electrostatic Discharge (ESD)

Test result **PASS**

8.1 Severity Level

8.1.1 Test level

Contact discharge		Air discharge	
Level	Test voltage kV	Level	Test voltage kV
1	2	1	2
2	4	2	4
3	6	3	8

Notes: 1. The gray rows were the selected test level.
2. The requirements above shall apply to equipment and systems used in all environments. When the expected electromagnetic characteristics of the intended use environment justify higher immunity test levels, these higher immunity test levels shall take precedence.

8.1.2 Compliance Level

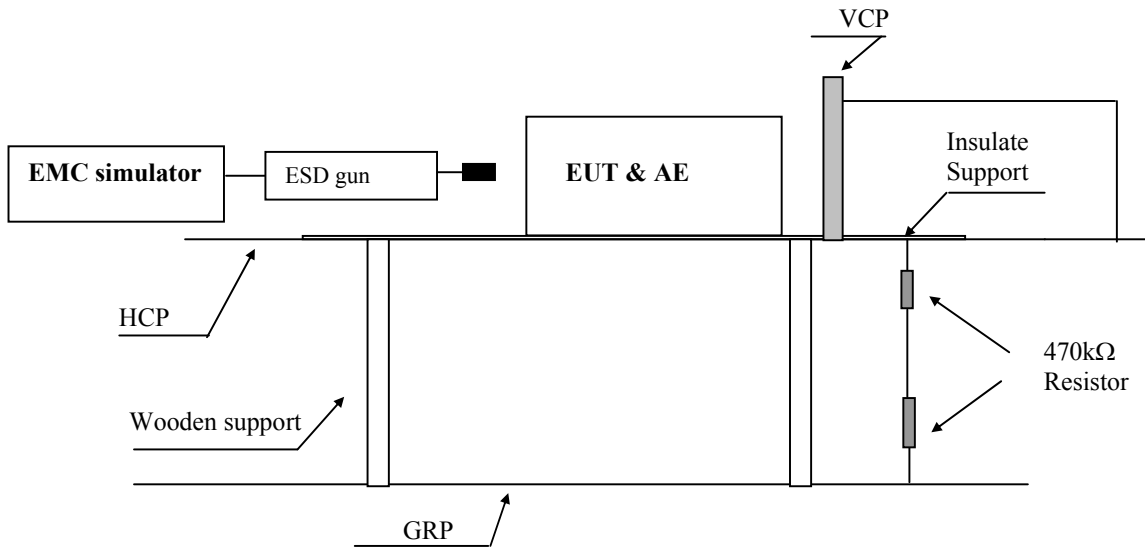
Lower immunity compliance levels are allowed, provided they are justified based on significant physical, technological or physiological limitations.

Discharge Class	Highest Compliance Level	Electromagnetic Environment
Contact discharge	6	All environments
	Others	Others
Air discharge	8	All environments
	Others	Others

Notes: The gray rows were the selected object.

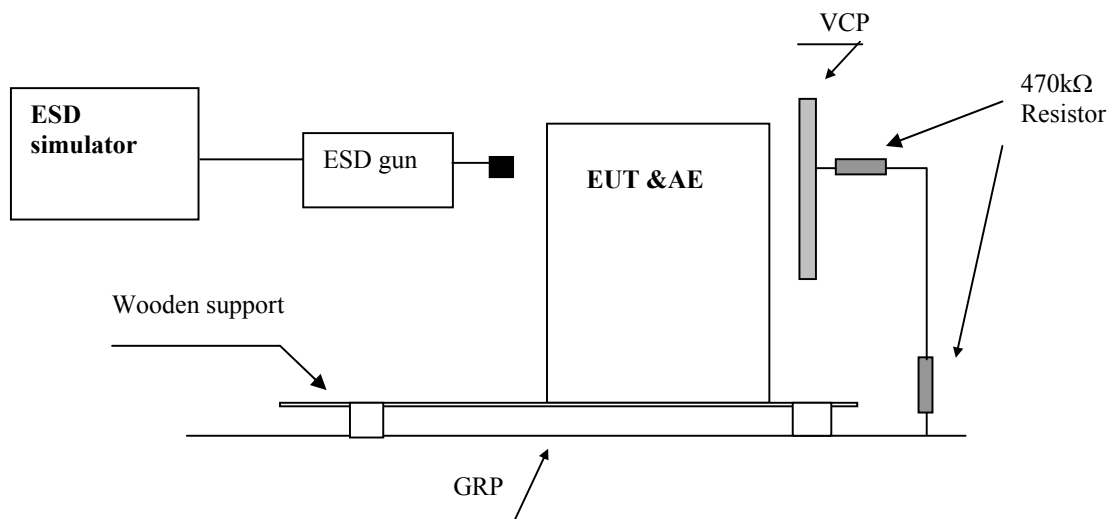
8.2 Block Diagram of Test Setup

For table-top equipment



Note: HCP means Horizontal Coupling Plane
VCP means Vertical Coupling Plane
GRP means Ground Reference Plane
Wooden support is a 0.8m height table

For floor standing equipment



Note: VCP means Vertical Coupling Plane
GRP means Ground Reference Plane
Wooden support is a 0.1m height rack

8.3 Test Setup and Test Procedure

Measurement was performed in shielded room.
Measurement and setting of EUT was applied according to IEC61000-4-2 clause 7.1.
The test method is specified by IEC61000-4-2 with the modifications by IEC60601-1-2 clause 36.202.2(b).

8.4 Test Protocol

Temperature: 22°C
Relative Humidity: 50%
Atmospheric Pressure: 101kPa

Direct discharge was applied at the following selected points:

Test point #	Test level [kV]	Air/Contact	Polarity (+/-)	Pass/Fail	Comment
A	2/4/6	Contact	+/-	Pass	all touchable screws of enclosure
B	2/4/6	Contact	+/-	Pass	Accessible metal parts of the EUT
C	2/4/8	Air	+/-	Pass	Air gap of the switch, button
D	2/4/8	Air	+/-	Pass	Slots around the EUT

Indirect contact discharges were applied to the VCP and the HCP at the following selected points:

For table top equipment

Point	Description	Point	Result
HCP f	0,1m from the front of the EUT	Edge of centre,corner on HCP	P
HCP b	0,1m from the back of the EUT	Edge of centre,corner on HCP	P
HCP r	0,1m from the right side of the EUT	Edge of centre,corner on HCP	P
HCP l	0,1m from the left side of the EUT	Edge of centre,corner on HCP	P
VCP f	0,1m from the front of the EUT	Edge of centre,corner on VCP	P
VCP b	0,1m from the back of the EUT	Edge of centre,corner on VCP	P
VCP r	0,1m from the right of the EUT	Edge of centre,corner on VCP	P
VCP l	0,1m from the left of the EUT	Edge of centre,corner on VCP	P

For floor standing equipment

Point	Description	Point	Result
VCP f	0,1m from the front of the EUT	Edge of centre,corner on VCP	-
VCP b	0,1m from the back of the EUT	Edge of centre,corner on VCP	-
VCP r	0,1m from the right of the EUT	Edge of centre,corner on VCP	-
VCP l	0,1m from the left of the EUT	Edge of centre,corner on VCP	-

Observation: All the functions were operated as normal during and after test.

Conclusion: providing the essential performance and remaining safe.

8.5 Measurement Uncertainty

The measurement uncertainty describes the overall uncertainty of the given measured value during the operation of the EUT.

Measurement uncertainty of ESD test is: $\pm 6.8 \%$

The measurement uncertainty is given with a confidence of 95%, $k=2$.

The measurement uncertainty is traceable to internal procedure TI-036.

8.6 Additions, deviations and exclusions from standards

None

9. Electromagnetic field susceptibility

Test result **Pass**

9.1 Severity Level

9.1.1 Test level

Level	Test field strength V/m	Equipment
1	3	Not life-supporting equipment
2	10	Life-supporting equipment

Notes: 1. The gray rows were the selected test level.
 2. The requirements above shall apply to equipment and systems used in all environments. When the expected electromagnetic characteristics of the intended use environment justify higher immunity test levels, these higher immunity test levels shall take precedence.
 3. “Life-supporting equipment” means the equipment or system that includes at least one function that is intended to actively keep alive or resuscitate patients and the failure is likely to lead to serious injury or death of a patient.

9.1.2 Class of equipment

Equipment	Used Location	Construction
Not life-supporting equipment	Not Only in Shield Location	Not Including Receivers of RF Electromagnetic Energy
Life-supporting equipment	Only in Shield Location	Including Receivers of RF Electromagnetic Energy

Notes: The gray rows were the selected object.

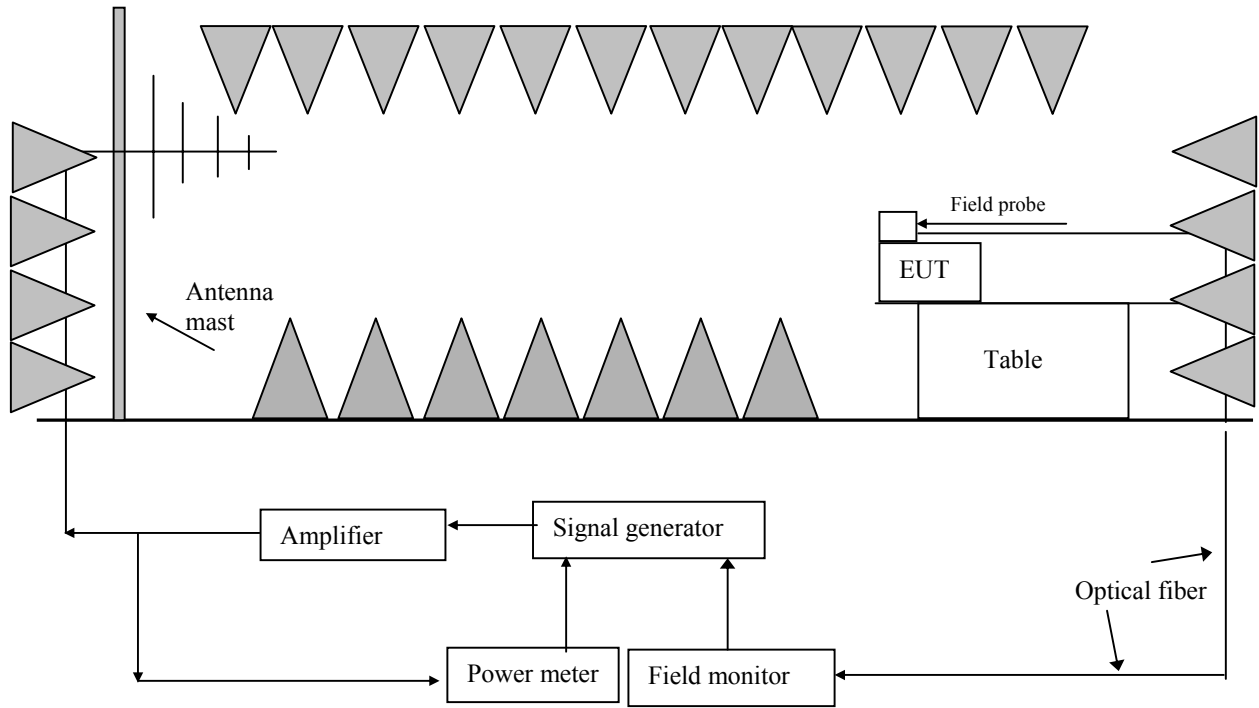


9.1.3 Compliance Level

Lower immunity compliance levels are allowed, provided they are justified based on significant physical, technological or physiological limitations.

Equipment	Highest Compliance Level	Electromagnetic Environment
Not life-supporting equipment	3	All environments
	Others	Others
Life-supporting equipment	10	All environments
	Others	Others
Notes: The gray rows were the selected object.		

9.2 Block diagram of test setup



9.3 Test Setup and Test Procedure

Measurement was performed in full-anechoic chamber.
Measurement and setting of EUT was applied according to IEC61000-4-3 clause 7.
The test method and equipment is specified by IEC61000-4-3 with additions and modifications by IEC60601-1-2 clause 36.202.3(b).



9.4 Test Protocol

Temperature: 22°C
Relative Humidity: 50%

Test no.:	Frequency (MHz)	Polarization	Test level V/m	Exposed location	Result
1	80-2500	H & V	3	All surfaces	Pass

Observation: All the functions were operated as normal during and after test.

Conclusion: providing the essential performance and remaining safe

9.5 Measurement Uncertainty

The measurement uncertainty describes the overall uncertainty of the given measured value during the operation of the EUT.

Measurement uncertainty of radiated susceptibility test is: $\pm 4.7\text{dB}$

The measurement uncertainty is given with a confidence of 95%, $k=2$.

The measurement uncertainty is traceable to internal procedure TI-036.

9.6 Additions, deviations and exclusions from standards

None



10. Electric Fast Transient/Burst Immunity Test

Test result **NA**

10.1 Severity Level

10.1.1 Test level

Open circuit output test voltage (+/-10%) and repetition rate of the impulses (+/- 20%)			
On A.C and D.C power cables ports		On signal and interconnecting cables ports	
Voltage peak kV	Repetition rate kHz	Voltage peak kV	Repetition rate kHz
2	5	1	5
<p>Notes: 1. The gray rows were the selected test level.</p> <p>2. The requirements above shall apply to equipment and systems used in all environments. When the expected electromagnetic characteristics of the intended use environment justify higher immunity test levels, these higher immunity test levels shall take precedence.</p> <p>3. Signal and interconnecting cables specified to be (i.e. restricted to) less than 3 m in length by the manufacturer of the equipment or system and all patient-coupled cables are not tested directly. However, the effects of any coupling between cables that are tested directly and cables that are not tested directly shall be taken into account.</p>			

10.1.2 Compliance Level

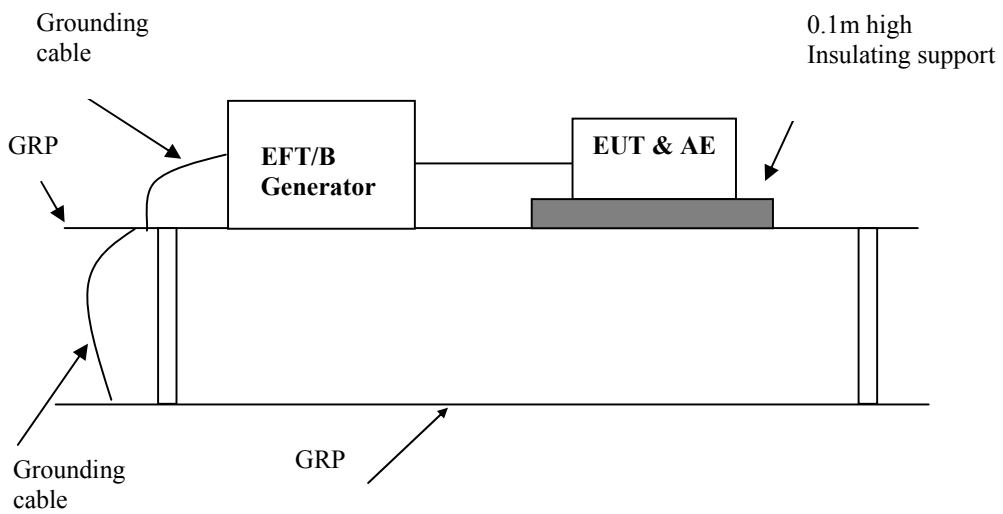
Lower immunity compliance levels are allowed, provided they are justified based on significant physical, technological or physiological limitations.

Cables Class	Highest Compliance Level	Electromagnetic Environment
A.C and D.C power cables ports	2	All environments
	Others	Others
Signal and interconnecting cables ports	1	All environments
	Others	Others
Notes: The gray rows were the selected object.		

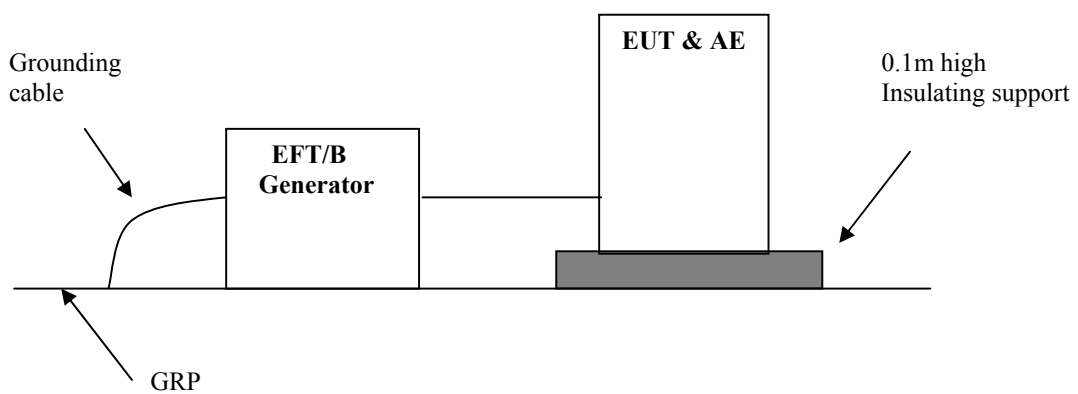
10.2 Block Diagram of Test Setup

10.2.1 Block Diagram for input a.c./d.c. power line

For table-top equipment

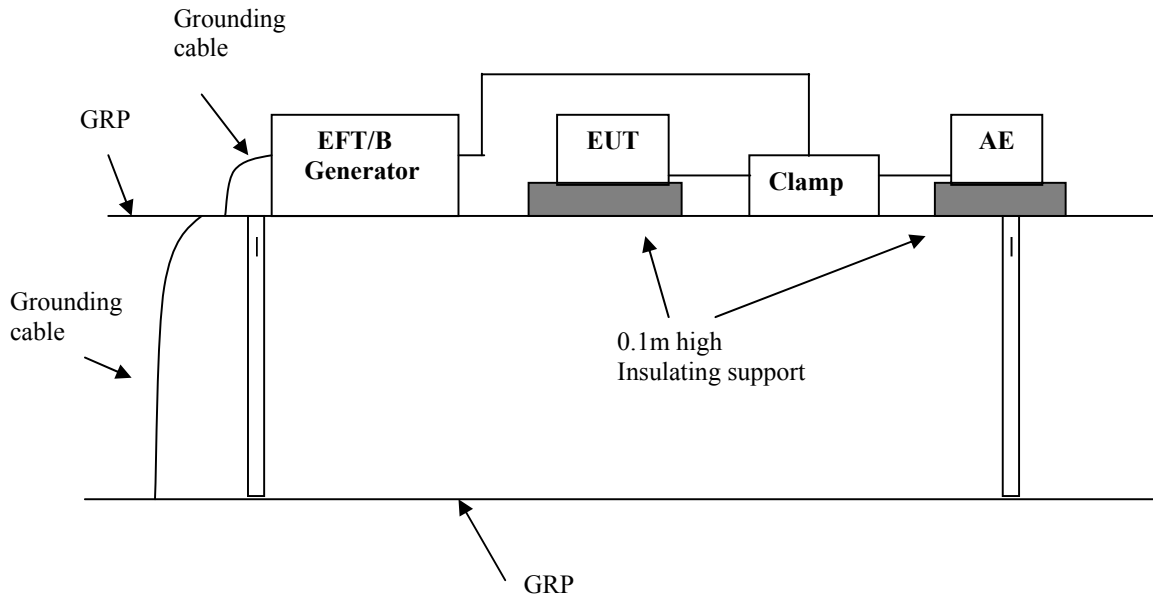


For floor standing equipment

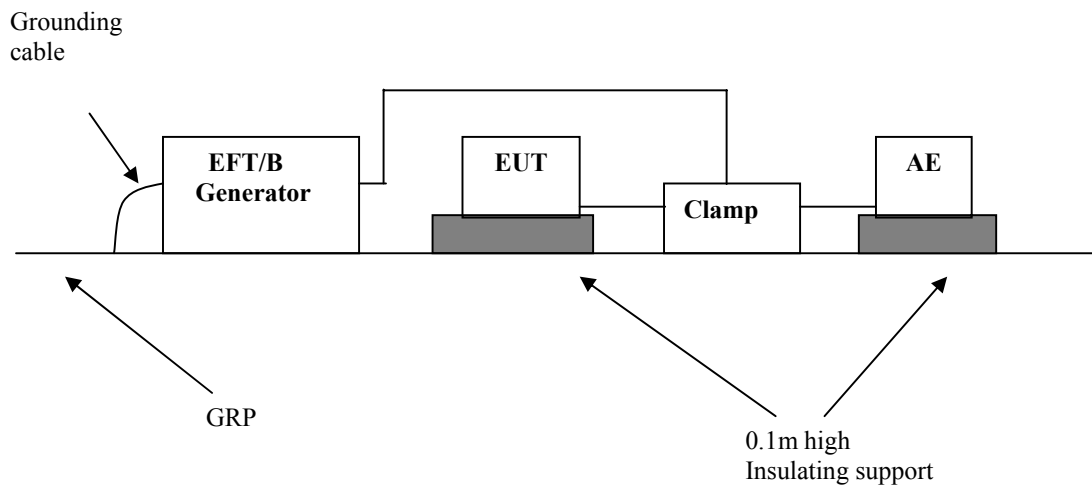


10.2.2 Block Diagram for output a.c./d.c. power line or signal/control lines

For table-top equipment



For floor standing equipment



10.3 Test Setup and Test Procedure

Measurement was performed in shielded room.
Measurement and setting of EUT was applied according to IEC61000-4-4 clause 7.2.
The test method and equipment is specified by IEC61000-4-4 with additions and modifications by IEC60601-1-2 clause 36.202.4(b).

10.4 Test Protocol

Temperature: °C
Relative Humidity: %

Test No. #	Level [kV]	Polarity +/-	Line for test	Pass/ Fail
1	2	+/-	L	
2	2	+/-	N	
3	2	+/-	PE	
4	2	+/-	L-N	
5	2	+/-	L-PE	
6	2	+/-	N-PE	
7	2	+/-	L,N,PE	
8	1	+/-	Signal cables	
9	1	+/-	interconnecting cables	

Note: NA means Not Applicable

Observation:
Conclusion:

10.5 Measurement Uncertainty

The measurement uncertainty describes the overall uncertainty of the given measured value during the operation of the EUT.

Measurement uncertainty of EFT test at main terminal is: $\pm 17.3\%$

Measurement uncertainty of EFT test at signal/telecom terminal is: $\pm 17.4\%$

The measurement uncertainty is given with a confidence of 95%, $k=2$.

The measurement uncertainty is traceable to internal procedure TI-036.

10.6 Additions, deviations and exclusions from standards

None



11. Surge Immunity Test

Test result **NA**

11.1 Severity Level

11.1.1 Test level

Level	Open-circuit test voltage +/-10% kV	
	A.C power line(s) to ground	A.C power line(s) to line(s)
1	0.5	0.5
2	1	1
3	2	Not applicable

Notes: 1. The gray rows were the selected test level.
 2. The requirements above shall apply to equipment and systems used in all environments. When the expected electromagnetic characteristics of the intended use environment justify higher immunity test levels, these higher immunity test levels shall take precedence.
 3. All other cables except AC power line are not tested directly. the determination of compliance with this requirement shall be based on the response of the equipment or system, considering each surge individually, taking into account the effects of any coupling between cables that are tested directly and cables that are not tested directly.

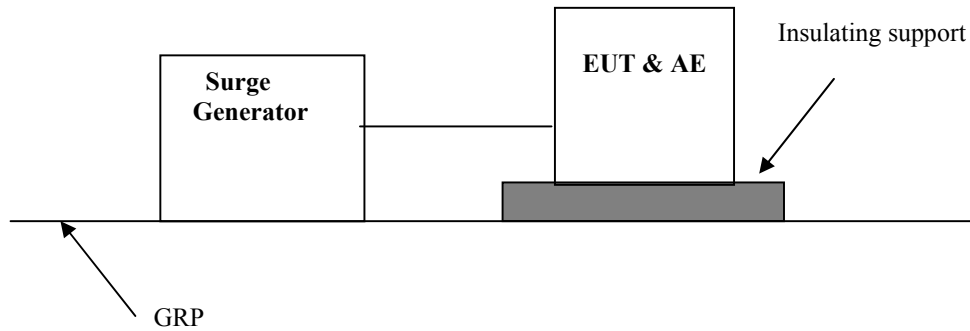
11.1.2 Compliance Level

Lower immunity compliance levels are allowed, provided they are justified based on significant physical, technological or physiological limitations.

Test Items	Highest Compliance Level	Electromagnetic Environment
A.C power line(s) to ground	2	All environments
	Others	Others
A.C power line(s) to line(s)	1	All environments
	Others	Others

Notes: The gray rows were the selected object.

11.2 Block Diagram of Test Setup



11.3 Test Setup and Test Procedure

Measurement was performed in shielded room.

Measurement and setting of EUT was applied according to IEC61000-4-5 clause 7.

The test method and equipment is specified by IEC61000-4-5 with modifications by IEC60601-1-2 clause 36.202.5(b).

11.4 Test Protocol

Temperature: °C
Relative Humidity: %

Test No.	Test level kV	Phase °	Polarity	Diff. / Com.	Result
1	0.5	0°,90°, 180°,270°	+/-, L-PE	Com.	
2	0.5	0°,90°, 180°,270°	+/-, N-PE	Com.	
3	1	0°,90°, 180°,270°	+/-, L-PE	Com.	
4	1	0°,90°, 180°,270°	+/-, N-PE	Com.	
5	2	0°,90°, 180°,270°	+/-, L-PE	Com.	
6	2	0°,90°, 180°,270°	+/-, N-PE	Com.	
7	0.5	0°,90°, 180°,270°	+/-, L-N	Diff.	
8	1	0°,90°, 180°,270°	+/-, L-N	Diff.	
Notes: "NA" means not applicable.					

Observation:

Conclusion:

11.5 Measurement Uncertainty

The measurement uncertainty describes the overall uncertainty of the given measured value during the operation of the EUT.

Measurement uncertainty of surge test at main terminal is: $\pm 18.8\%$

Measurement uncertainty of surge test at signal/telecom terminal is: $\pm 19.3\%$

The measurement uncertainty is given with a confidence of 95%, $k=2$.

The measurement uncertainty is traceable to internal procedure TI-036.

11.6 Additions, deviations and exclusions from standards

None

12. Immunity to Conducted Disturbances, Induced by Radio-frequency Fields

Test result **NA**

12.1 Severity Level

12.1.1 Test level

Level	Test field strength V/m	Equipment	Frequency range
1	3	Not life-supporting equipment	0.15MHz-80MHz
2	3	Life-supporting equipment	0.15MHz-80MHz
3	10	Life-supporting equipment	In the ISM frequency band

- Notes:
1. The gray rows were the selected test level.
 2. The requirements above shall apply to equipment and systems used in all environments. When the expected electromagnetic characteristics of the intended use environment justify higher immunity test levels, these higher immunity test levels shall take precedence.
 3. “Life-supporting equipment” means the equipment or system that includes at least one function that is intended to actively keep alive or resuscitate patients and the failure is likely to lead to serious injury or death of a patient.
 4. “ISM” means the industrial, scientific and medical.
 5. For internally powered equipment and systems that cannot be used during battery charging, do not have an option for AC power input and have no connection to ground, telecommunications systems, any other equipment or system or a patient, the start frequency shall be determined from figure B.1 of IEC 61000-4-6, using the maximum dimension of the equipment or system, including the maximum length of each cable connected.



12.1.2 Class of equipment

Equipment	Used Location	Construction
Not life-supporting equipment	Not Only in Shield Location	Not Including Receivers of RF Electromagnetic Energy
Life-supporting equipment	Only in Shield Location	Including Receivers of RF Electromagnetic Energy

Notes: The gray rows were the selected object.

12.1.3 Compliance Level

Lower immunity compliance levels are allowed, provided they are justified based on significant physical, technological or physiological limitations.

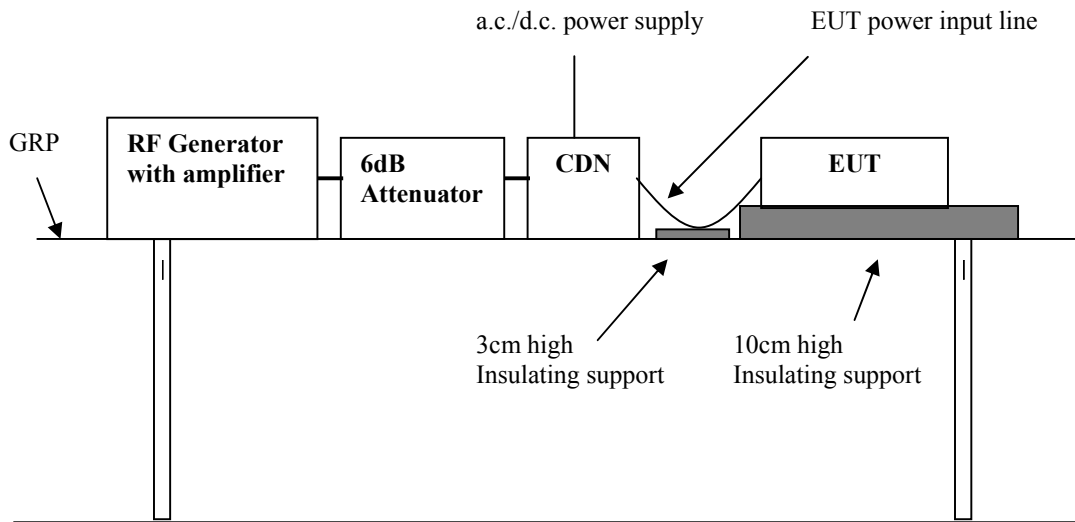
Frequency range	Equipment	Highest Compliance Level	Electromagnetic Environment
0.15MHz-80MHz	Not life-supporting equipment	3	All environments
		Others	Others
0.15MHz-80MHz	Life-supporting equipment	3	All environments
		Others	Others
In the ISM frequency band	Life-supporting equipment	10	All environments
		Others	Others

Notes: The gray rows were the selected object.

12.2 Diagram of Test Setup

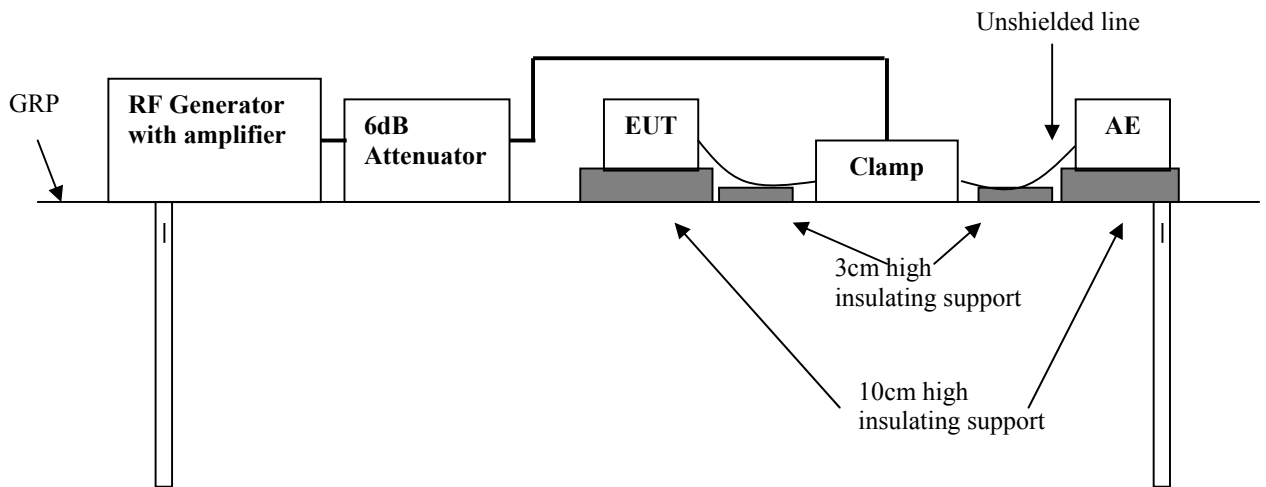
12.2.1 Block Diagram for a.c./d.c input power line

Block Diagram for a.c./d.c input power line

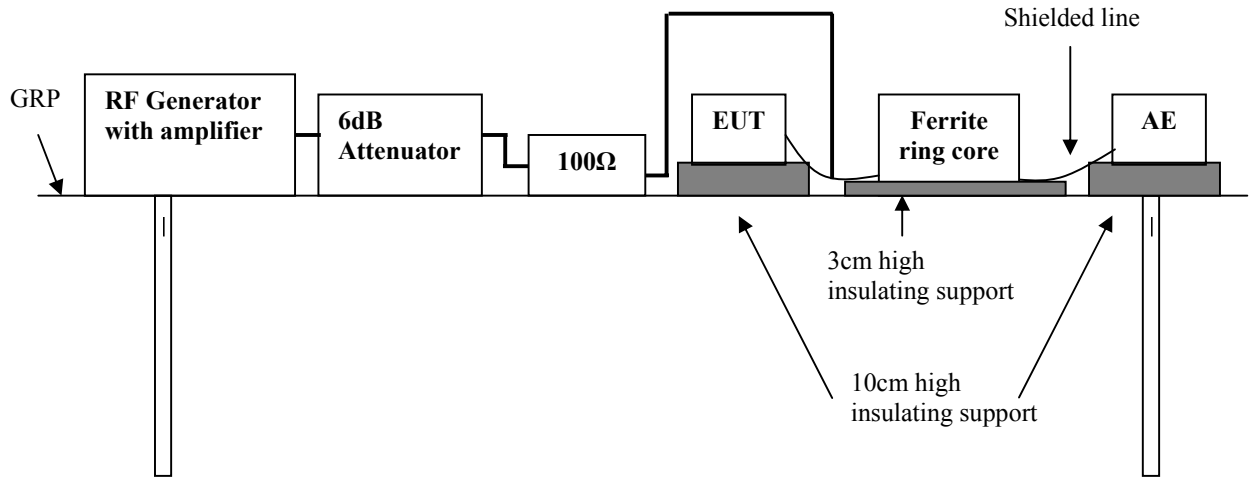


12.2.2 Block Diagram for output a.c./d.c. power line or signal/control lines

Unshielded line



Shielded line



12.3 Test Setup and Test Procedure

Measurement was performed in shielded room.

Measurement and setting of EUT was applied according to IEC61000-4-6 clause 7.

The test method and equipment is specified by IEC61000-4-6 with additions and modifications by IEC60601-1-2 clause 36.202.6(b).

12.4 Test Protocol

Temperature: °C
Relative Humidity: %

Test No.	Frequency (MHz)	Level V (e.m.f.)	Amplitude modulation	Injected point	Result
1	0.15~80	3	1kHz 80%	L-N	
2	0.15~80	3	2Hz 80%	L-N-PE	
3	ISM frequency band	10	1kHz 80%	L-N-PE	
2	ISM frequency band	10	2Hz 80%	L-N-PE	

Notes: "NA" means not applicable.

Observation:

Conclusion:

12.5 Measurement Uncertainty

The measurement uncertainty describes the overall uncertainty of the given measured value during the operation of the EUT.

Measurement uncertainty of injected current test at main terminal as well as unshielded signal terminal is: $\pm 2.9\text{dB}$

The measurement uncertainty is given with a confidence of 95%, $k=2$.

The measurement uncertainty is traceable to internal procedure TI-036.

12.6 Additions, deviations and exclusions from standards

None

13. Voltage Dips, Short Interruptions and Voltage Variations Immunity Test

Test result NA

13.1 Severity Level

13.1.1 Test level

Immunity Test Levels for Voltage Dips

Test level % UT	Voltage dip % UT	Duration (in period)
0	100	0.5
40	60	5
70	30	25

- Notes: 1. For 0.5 period, the test shall be made in positive and negative polarity, i.e. starting at 0° and 180° respectively.
 2. The gray rows are selected test level.
 3. Equipment and systems with a rated input power of 1kVA or less and all life supporting equipment and systems shall comply with the requirements.
 4. For equipment and systems that are not life-supporting and for which the rated input power is greater than 1kVA and the rated input current is less than or equal to 16A per phase, deviation from performance criteria is allowed, provided the equipment or system remains safe, experiences no component failures and is restorable to the pre-test state with operator intervention.
 5. Equipment and systems that are not life-supporting and for which the rated input current exceeds 16A per phase are exempt from the testing specification.

Immunity Test Level for Voltage Interruption

Test level % UT	Voltage Interruption % UT	Duration (s)
0	100	5

- Notes: 1. The gray rows are selected test level.
 2. Equipment and systems are allowed a deviation from the performance criteria at this immunity test level, provided the equipment or system remains safe, experiences no component failures and is restorable to the pre-test state with operator intervention. Life-supporting equipment and systems for which this allowance for a deviation from the performance criteria shall provide an alarm complying with applicable international standards to indicate cessation or interruption of an intended operation related to essential performance.



13.1.2 Compliance Level

Lower immunity compliance levels are allowed, provided they are justified based on significant physical, technological or physiological limitations.

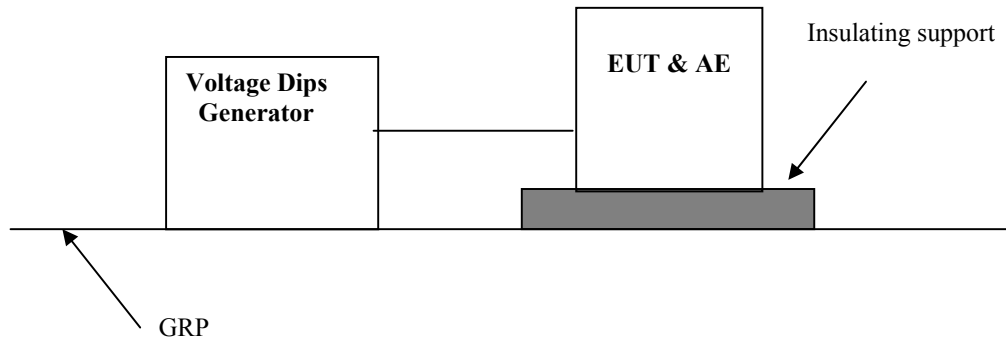
Compliance Level for Voltage Dips

Equipment	Highest Compliance Level (Duration in period))	Electromagnetic Environment
With rated input power $\leq 1\text{kVA}$ or life-supporting equipment	0.5, 5, 25	All environments
	Others	Others
Not life-supporting & rated input power higher than 1kVA & rated input current $\leq 16\text{A}$	0.5, 5, 25	All environments
	Others	Others
Not life-supporting & Rated input current $\geq 16\text{A}$	Exempt	
Notes: The gray rows were the selected object.		

Compliance Level for Voltage Interruption

Equipment	Highest Compliance Level (Duration in Seconds)	Electromagnetic Environment
All	5	All environments
	Others	Others
Notes: The gray rows were the selected object.		

13.2 Block diagram of test setup



13.3 Test Setup and Test Procedure

Measurement was performed in shielded room.
Measurement and setting of EUT was applied according to IEC61000-4-11 clause 7.
The test method and equipment is specified by IEC61000-4-11 with additions and modifications by IEC60601-1-2 clause 36.202.7(b).

13.4 Test Protocol

Temperature: °C
Relative Humidity: %

For Voltage Dips

Test no.	Voltage dip % UT	Test level % UT	Duration in periods of rated frequency	Pass/ Fail
1	30%	70%	25	
2	60%	40%	5	
3	100% pos half cycle	0	0,5	
4	100% neg half cycle	0	0,5	

Observation:

Conclusion:

For Voltage Interruption

Test no.	Voltage dip % UT	Test level % UT	Duration (Seconds)	Pass/ Fail
1	100%	0	5	

Observation:

Conclusion:

13.5 Measurement Uncertainty

The measurement uncertainty describes the overall uncertainty of the given measured value during the operation of the EUT.

Measurement uncertainty of voltage dips and interruption test is: $\pm 10.8\%$

The measurement uncertainty is given with a confidence of 95%, $k=2$.

The measurement uncertainty is traceable to internal procedure TI-036.

13.6 Additions, deviations and exclusions from standards

None



14. Magnetic Fields Immunity Test

Test result **NA**

14.1 Severity Level

14.1.1 Test level

Level	Magnetic field strength A/m
1	3

Note: The gray row is the selected test level.

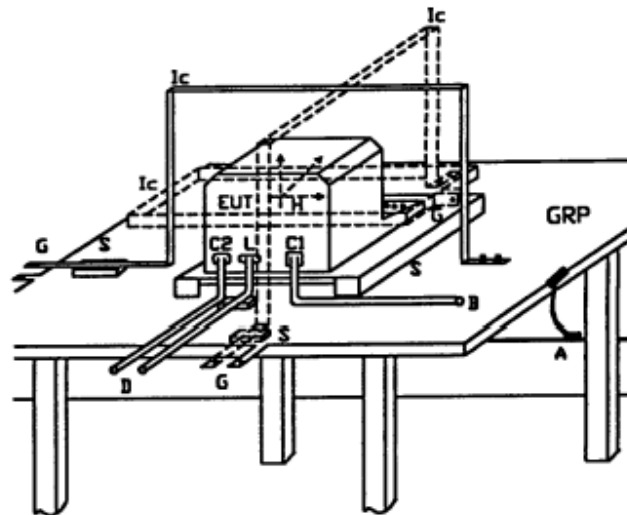
14.1.2 Compliance Level

Lower immunity compliance levels are allowed, provided they are justified based on significant physical, technological or physiological limitations.

Highest Compliance Level A/m	Electromagnetic Environment
3	All environments
Others	Others

Notes: The gray rows were the selected object.

14.2 Diagram of Test Setup



14.3 Test Setup and Test Procedure

Measurement was performed in shielded room.

Measurement and setting of EUT was applied according to IEC61000-4-8 clause 7.

The test method and equipment is specified by IEC61000-4-3 with modifications by IEC60601-1-2 clause 36.202.8(b).



14.4 Test Protocol

Temperature : °C
Relative Humidity: %

Test No.	Level A/m	Axis	Result	Comment
1	3	X		-
2	3	Y		-
3	3	Z		-

Observation:

Conclusion:

14.5 Measurement Uncertainty

The measurement uncertainty for magnetic fields test is under consideration.

14.6 Additions, deviations and exclusions from standards

None

Appendix I: Photograph of equipment under test



