EMC - TEST REPORT

Test Report No.:	CPSC0134580 rev.03	May 26, 2014 Date of issue

Model Name : i-CHROMA™ Reader

Modified Model List : None

Type : IMMUNOFLUOROMETER EQUIPMENT

Applicant : BodiTech Med Inc.

Address : 43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do,
200-863, Republic of Korea

Manufacturer : The same as applicant

Test Standards : EN 60601-1-2:2007
EN 61326-2-6:2006

Test Result : Complied

This test report consists of 44 pages. The test report only responds to the tested sample only.
It's not allowed to copy this report partly without the allowance of the test laboratory.

Contents

Test Standards

- EN 61326-2-6:2006
  Electrical equipment for measurement, control and laboratory use – EMC requirements - Part 2-6:
  Particular requirements – In vitro diagnostic (IVD) medical equipment
- 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

Referenced document

- CISPR 11:2009+A1:2010
  Industrial, scientific and medical (ISM) radio-frequency equipment – Radio disturbance characteristics - Limits and methods of measurement
- IEC 61000-3-2:2005+A1:2008+A2:2009
  Electromagnetic compatibility (EMC) – Part 3-2: Limits - Limits for harmonic current emissions (equipment input current up to and including 16 A per phase)
- IEC 61000-3-3:2008
  Electromagnetic compatibility (EMC) – Part 3-3: Limits - Limitation of voltage fluctuations and flicker in low-voltage supply systems for equipment with rated current <= 16 A
- IEC 61000-4-2:2008
  Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test.
- IEC 61000-4-3:2006
  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 - Electrical fast transient/burst immunity test.
- IEC 61000-4-5:2005
  Electromagnetic compatibility (EMC) – Part 4-5: Testing and measurement techniques - Surge immunity test.
- IEC 61000-4-6:2008
  Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields.
- IEC 61000-4-8:2009
  Electromagnetic compatibility (EMC) – Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test
- IEC 61000-4-11: 2004
  Electromagnetic compatibility (EMC) – Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests.

Additions, deviations and exclusions from standards

No additions, deviations or exclusions have been made from standards.

Test Environment

Address of the Test Laboratory

- **Korea EMC Laboratory Co., Ltd.**

#28, Mosan-gil, Jeongnam-myeon,
Hwaseong-si, Gyeonggi-do,
445-963, Republic of Korea

Environmental condition

During the immunity testing, the environmental conditions were within the listed ranges:

	1st tests in 2010	2nd tests in 2013
Temperature:	(23.1 – 29.5) °C	(23.3 – 27.3) °C
Relative Humidity:	(32.6 – 36.8) %	(63.2 – 67.2) %

Statement of measurement uncertainty

The data and results referenced in this document are true and accurate. The reader is cautioned that there may be errors within the calibration limits of the equipment and facilities that can account for a nominal measurement error of ± 3.2 dB for conducted emission and ± 4.4 dB for radiated emission. Furthermore, component and process variability of devices similar to that tested may result in additional deviation. The manufacturer has the sole responsibility of continued compliance of the device.

Test Operation Mode of the Equipment Under Test (EUT) :

During the testing, the equipment under test was operated under the following conditions:

☐ Stand-by

☐ Test Program (H-Pattern)

☐ Test Program (Customer Specified)

■ Normal Operating Mode: Test mode & data transfer mode using RS232 port which are test method offered by manufacturer

☐ _____

_____

_____

The following peripheral devices and interface cables were connected during the testing:

■	Reader	Type :	i-CHROMA™ reader / Boditech Med Inc.
■	Adapter	Type :	BPM060S12FXX / BridgePower Corp
■	Thermal Printer	Type :	STP-103 / BIXOLON Co., Ltd.
■	Adapter	Type :	SAD03624-UV / Yantai Sam Hwa Polymers Co.,Ltd.
■	ID Chip	Type :	BTSCC0705 / -
■	System Control Cartridge	Type :	-

■ Unshielded Cable (POWER cable): 1.5 m

■ Shielded Cable (Adapter cable): 1.8 m

■ Shielded Cable (RS-232 cable to the Thermal Printer): 1.5 m

■ Shielded Cable (Thermal Printer Adapter cable): 1.8 m (Ferrite Core was applied)

GENERAL REMARKS:

■ Electric rating of EUT:

- Input of adapter: (100-240) V a.c., (50-60) Hz, 1.5 A
- Output of adapter: 12 V d.c., 5.0 A

SUMMARY:

All tests according to the standards cited on page 3 were

■ Performed

☐ **Not** Performed

The Equipment Under Test

■ **Fulfills** the general approval requirements cited on page 3.

☐ **Does not** fulfill the general approval requirements cited on page 3.

SUMMARY

General Remarks

The results in this report apply only to sample tested.
No additions, deviations or exclusions have been made from standard.
All tests are performed with the contents of the accreditation.

Final Assessment

We confirm that the product tested without reasonable doubt will fulfil the requirements concerning electromagnetic compatibility according to the above mentioned standard harmonised with the In-Vitro Diagnostic Medical Devices Directive 98/79/EC and Medical Devices Directive 93/42/EEC.

Date of receipt of test sample : July 07, 2010

1st test for basic model : July 07 - 13, 2010

2nd test for modified model : August 06 - 07, 2013

Reviewed by: Tested by (1st test): (2nd Test)

Su-Gil, Moon / Technical Manager of KEMC

Sung-Jae Lee / EMC Engineer of KEMC

Deok-Chang Choi / EMC Engineer of KEMC

Witnessed by:

TÜV SÜD Korea Ltd.

Test Results

Order No.: CPSC0134580

Manufacture	BodiTech Med Inc.	Type	IMMUNOFLUORO-METER EQUIPMENT	■ Approval Test (EMI/EMS)
Applicant	BodiTech Med Inc.	Incoming date	Feb. 05, 2010 Aug. 06, 2013	☐ Retest / Pre-test
Model	i-CHROMA™ Reader	Outgoing date	Feb. 08, 2010 Aug. 07, 2013	☐ Mass Production test
M/L models	None			☐ Technical Documentation

Test are made according to the EN 61326-2-6 and EN 60601-1-2.

Kind of Test		Serial No.: None			
Emission		Max. Limit exceeding	O.K		Not O.K
			1st test	2nd test	
2.1	Mains terminal disturbance voltage (0.15 – 30 MHz)		■	N/A	☐
2.2	Radiated disturbance (30 – 1000 MHz)		■	■	☐
2.3	Harmonic current / Voltage fluctuation & flicker		■	N/A	☐
Immunity					
2.4	ESD (EN 61000-4-2)		■	■	☐
2.5	Radiated immunity test (EN 61000-4-3)		■	N/A	☐
2.6	EFT/Burst (EN 61000-4-4)		■	N/A	☐
2.7	Surge (EN 61000-4-5)		■	N/A	☐
2.8	Immunity to conducted disturbance (EN 61000-4-6)		■	N/A	☐
2.9	Rated power frequency magnetic field (EN 61000-4-8)		■	N/A	☐
2.10	Voltage dips and variations (EN 61000-4-11)		■	N/A	☐

Remarks: The 2nd test is performed caused by change of enclosure's shape.

2.1	Conducted Emissions (a.c. power ports)		
Type	*IMMUNOFLUOROMETER EQUIPMENT*		
Model No.	**i-CHROMA™ READER**	*Applicant*	**BodiTech Med Inc.**
Serial No.	**NONE**	*Test Engineer*	**Sung-Jae Lee**

TEST CONDITIONS AND RESULTS

The **measurement of the Conducted Emission** was performed in a shielded room.

☐ **- Test not applicable**

- Conducted Emission Data

Freq. (MHz)	EUT State	Polarity (H/N)	Level		LIMIT		Margin	
			Q.P(dBμV)	A.V(dBμV)	Q.P(dBμV)	A.V(dBμV)	Q.P(dB)	A.V(dB)
0.155	Normal operating mode	L1	39.3	-	79.0	66.0	39.7	-
0.177		L2	41.4	-	79.0	66.0	37.6	-
0.223		L1	37.0	-	79.0	66.0	42.0	-
0.355		L1	31.9	-	79.0	66.0	47.1	-
0.513		L1	39.4	-	73.0	60.0	33.6	-
1.804		L2	28.3	-	73.0	60.0	44.7	-
2.247		L1	28.9	-	73.0	60.0	44.1	-
2.625		L2	28.4	-	73.0	60.0	44.6	-

Notes: For the detailed data, see the Appendix C.

Remarks:

Test instrumentation

Equipment	Manufacturer	Type	Serial No.	Due calibration
Test receiver	R&S	ESCS30	100054	2010.10.08
LISN	Kyoritsu	KNW-407	8-883-14	2010.10.29
Two line V-Network	R&S	ESH3-Z5	860685/005	2010.10.29

2.2	Radiated disturbance (30 MHz – 1000 MHz)		
Type	*IMMUNOFLUOROMETER EQUIPMENT*		
Model / Type No.	**i-CHROMA™ READER**	*Applicant*	**BodiTech Med Inc.**
Serial No.	**NONE**	*Test Engineer*	**Sung-Jae Lee / Deok-Chang Choi**

TEST CONDITIONS AND RESULTS

The **measurement of the Radiated disturbance** was performed in 10 m open area test site.

☐ **- Test not applicable**

*** 1st test**

Freq.	Hor./Ver.	Total Results	Correction Factor	Result	Limit	Margin
(MHz)		(dBuV)	(dB/m)	(dBuV/m)	(dBuV/m)	(dB)
33.7	V	36.4	-2.6	33.8	40.0	6.2
47.4	V	34.0	-3.6	30.4	40.0	9.6
113.4	V	30.8	-4.5	26.3	40.0	13.7
169.7	V	23.3	-0.4	22.9	40.0	17.1
260.9	H	24.2	-0.8	23.4	47.0	23.6
359.8	H	22.5	4.3	26.7	47.0	20.3
472.3	V	19.3	5.8	25.1	47.0	21.9

- Radiated Disturbance Data

Note) Correction Factor (dB/m) = Antenna Factor (dB/m) + Cable loss (dB) + attenuator (dB) - Amp gain (dB)

Remarks:

Test instrumentation

Equipment	Manufacturer	Type	Serial No.	Due calibration
Test Receiver	R&S	ESCS30	100054	2010.10.09
Bi-Log Antenna	Schwarzbeck	VULB9160	3121	2011.12.16
Amplifier	HP	8447E	2434A02093	2011.01.16
Attenuator	Agilent Technology	8491A	30907	2011.10.08

* 2nd test

- Radiated Disturbance Data

Freq.	Hor./Ver.	Total Results	Correction Factor	Result	Limit	Margin
(MHz)		(dBuV)	(dB/m)	(dBuV/m)	(dBuV/m)	(dB)
35.6	V	43.9	-20.2	23.7	40.0	16.3
50.0	V	42.7	-18.9	23.8	40.0	16.2
85.3	V	45.1	-21.7	23.4	40.0	16.6
197.5	V	46.7	-19.7	27.0	40.0	13.0
450.0	H	38.1	-10.9	27.2	47.0	19.8
800.1	H	33.9	-4.1	29.8	47.0	17.2

Note) Correction Factor (dB/m) = Antenna Factor (dB/m) + Cable loss (dB) + attenuator (dB) - Amp gain (dB)

Remarks:

Test instrumentation

Equipment	Manufacturer	Type	Serial No.	Due calibration
Test Receiver	R&S	ESCI	100561	2013.10.03
Bi-Log Antenna	Schwarzbeck	VULB9160	3049	2013.10.05
Amplifier	SONOMA	310N	185938	2014.01.14

2.3	Harmonic current / Voltage fluctuations & flicker		
Type	*IMMUNOFLUOROMETER EQUIPMENT*		
Model / Type No.	**i-CHROMA™ READER**	*Applicant*	**BodiTech Med Inc.**
Serial No.	**NONE**	*Test Engineer*	**Sung-Jae Lee**

Harmonic current emissions

The requirement is kept.

Voltage fluctuations flicker

The requirement is kept.

Note: For the detailed data, see the following 2 pages of graphic data.

Test instrumentation

Equipment	Manufacturer	Type	Serial No.	Due calibration
Universal Power Analyzer	Voltech	PM6000	200006700344	2010.07.23
Reference Impedance Network	Voltech	IEC Standard 555	1307/9036	2012.01.14
AC Power Source	Pacific	125AMX-UPC12	0211	2012.01.14

Graphic data (1/2):

korea EMC

Product:	I-CHROMA	12 Jul 2010 2:52pm
Serial no:		Page 1 of 1
Description:		
Result Name:	I-CHROMA	
Voltech IEC61000-3 Windows Software 1.14.06RC1		Test Date: 12 Jul 2010 1:41pm
Type of Test:	Fluctuating Harmonics Test - Worst Case Table (2006)	
Power Analyzer:	Voltech PM6000 SN: 200006700344 Firmware version: v1.20.06RC4	
	Channel(s):	
	1. SN: 090015501058, 28 Adjusted Date: 21 JUL 2009. 2. SN:None Adjusted Date:None	
	3. SN:None Adjusted Date:None 4. SN:None Adjusted Date:None	
	5. SN:None Adjusted Date:None 6. SN:None Adjusted Date:None	
	Shunt(s):	
	1. SN: 091024301051, 4 Adjusted Date: 22 JUL 2009. 2. SN:None Adjusted Date:None	
	3. SN:None Adjusted Date:None 4. SN:None Adjusted Date:None	
	5. SN:None Adjusted Date:None 6. SN:None Adjusted Date:None	
AC Source:	Mains / Manual Source	
Overall Result: **N/A**		

Class	Class A
Class Multiplier	1

Harm	Limit 1	Limit 2	Average Reading	<L1	<L2	Max Reading	<L2	Pass FAIL	Harm	Limit 1	Limit 2	Average Reading	<L1	<L2	Max Reading	<L2	Pass FAIL
2	1.0800A	1.6200A	1.043mA	Y	Y	1.275mA	Y	N/A	3	2.3000A	3.4500A	13.07mA	Y	Y	14.80mA	Y	N/A
4	430.0mA	645.0mA	1.010mA	Y	Y	1.232mA	Y	N/A	5	1.1400A	1.7100A	12.77mA	Y	Y	14.43mA	Y	N/A
6	300.0mA	450.0mA	0.993mA	Y	Y	1.186mA	Y	N/A	7	770.0mA	1.1550A	12.37mA	Y	Y	13.94mA	Y	N/A
8	230.0mA	345.0mA	0.910mA	Y	Y	1.103mA	Y	N/A	9	400.0mA	600.0mA	11.83mA	Y	Y	13.29mA	Y	N/A
10	184.0mA	276.0mA	0.859mA	Y	Y	1.037mA	Y	N/A	11	330.0mA	495.0mA	11.21mA	Y	Y	12.54mA	Y	N/A
12	153.3mA	230.0mA	0.849mA	Y	Y	0.986mA	Y	N/A	13	210.0mA	315.0mA	10.47mA	Y	Y	11.65mA	Y	N/A
14	131.4mA	197.1mA	0.709mA	Y	Y	0.829mA	Y	N/A	15	150.0mA	225.0mA	9.672mA	Y	Y	10.69mA	Y	N/A
16	115.0mA	172.5mA	0.626mA	Y	Y	0.720mA	Y	N/A	17	132.3mA	198.5mA	8.797mA	Y	Y	9.641mA	Y	N/A
18	102.2mA	153.3mA	0.549mA	Y	Y	0.616mA	Y	N/A	19	118.4mA	177.6mA	7.904mA	Y	Y	8.593mA	Y	N/A
20	92.00mA	138.0mA	0.463mA	Y	Y	0.508mA	Y	N/A	21	107.1mA	160.7mA	6.975mA	Y	Y	7.526mA	Y	N/A
22	83.63mA	125.4mA	0.380mA	Y	Y	0.414mA	Y	N/A	23	97.82mA	146.7mA	6.057mA	Y	Y	6.482mA	Y	N/A
24	76.66mA	115.0mA	0.366mA	Y	Y	0.398mA	Y	N/A	25	90.00mA	135.0mA	5.149mA	Y	Y	5.453mA	Y	N/A
26	70.76mA	106.1mA	0.242mA	Y	Y	0.278mA	Y	N/A	27	83.33mA	125.0mA	4.295mA	Y	Y	4.501mA	Y	N/A
28	65.71mA	98.57mA	0.199mA	Y	Y	0.237mA	Y	N/A	29	77.58mA	116.3mA	3.465mA	Y	Y	3.567mA	Y	N/A
30	61.33mA	92.00mA	0.176mA	Y	Y	0.204mA	Y	N/A	31	72.58mA	108.8mA	2.735mA	Y	Y	2.813mA	Y	N/A
32	57.50mA	86.25mA	0.167mA	Y	Y	0.200mA	Y	N/A	33	68.18mA	102.2mA	2.089mA	Y	Y	2.169mA	Y	N/A
34	54.11mA	81.17mA	0.169mA	Y	Y	0.207mA	Y	N/A	35	64.28mA	96.42mA	1.557mA	Y	Y	1.627mA	Y	N/A
36	51.11mA	76.66mA	0.174mA	Y	Y	0.219mA	Y	N/A	37	60.81mA	91.21mA	1.184mA	Y	Y	1.287mA	Y	N/A
38	48.42mA	72.63mA	0.174mA	Y	Y	0.215mA	Y	N/A	39	57.69mA	86.53mA	0.990mA	Y	Y	1.114mA	Y	N/A
40	46.00mA	69.00mA	0.177mA	Y	Y	0.212mA	Y	N/A									

Graphic data (2/2):

korea EMC

Product:	I-CHROMA	12 Jul 2010 2:49pm
Serial no:		Page 1 of 1
Description:		
Result Name:	I-CHROMA	
Voltech IEC61000-3 Windows Software 1.14.06RC1		Test Date: 12 Jul 2010 2:08pm
Type of Test:	Flickermeter Test - Table	
Power Analyzer:	Voltech PM6000 SN: 200006700344 Firmware Version: v1.20.06RC4 Channel(s): 1. SN: 090015501058, 28 Adjusted Date: 21 JUL 2009. 2. SN:None Adjusted Date:None 3. SN:None Adjusted Date:None 4. SN:None Adjusted Date:None 5. SN:None Adjusted Date:None 6. SN:None Adjusted Date:None Shunt(s): 1. SN: 091024301051, 4 Adjusted Date: 22 JUL 2009. 2. SN:None Adjusted Date:None 3. SN:None Adjusted Date:None 4. SN:None Adjusted Date:None 5. SN:None Adjusted Date:None 6. SN:None Adjusted Date:None	
AC Source:	Mains / Manual Source	
Overall Result: **PASS**	Notes: Plt test duration only 30 minutes Measurement method - Voltage	

	Plt
Limit	0.650
Reading	0.060

	Pst	dc (%)	dmax (%)	d(t) > 3.3%(ms)
Limit	1.000	3.300	4.000	500
Reading 1	0.095	0.085	0.351	0
Reading 2	0.096	0.085	0.359	0
Reading 3	0.096	0.085	0.362	0

2.4	Electrostatic Discharge (ESD)		
Type	*IMMUNOFLUOROMETER EQUIPMENT*		
Model / Type No.	**i-CHROMA™ READER**	*Applicant*	**BodiTech Med Inc.**
Serial No.	**NONE**	*Test engineer*	**Sung-Jae Lee / Deok-Chang Choi**

TEST CONDITIONS AND RESULTS

The **measurement of the immunity against electrostatic discharge** was performed in a shielded room.

☐ **- Test not applicable**

Test location:

■ Shielded room

☐ Anechoic chamber

☐ Full compact chamber

Test specifications:

Discharge voltage Conducted:	☐ 1 kV	■ 2 kV	☐ 3 kV
	■ 4 kV	■ 6 kV	☐ __ kV
Discharge voltage Air:	■ 2 kV	■ 4 kV	☐ 6 kV
	■ 8 kV	☐ 15 kV	☐ __ kV
Discharge impedance:	■ 330 Ω / 150 pF	☐ 150 Ω / 150 pF	
Discharge factor:	■ 1 s		
Number of discharges:	■ ≥ 50 times at all locations		
Kind of discharges:	Direct discharge	■ Air discharge	
		☐ Contact discharge	
	Indirect discharge	■ Contact discharge	
Polarity:	■ Positive	■ Negative	

Location of discharge:

■ - See drawing in Appendix D

■ - Each location on the surface touchable by hand

■ Horizontal Coupling Plane (HCP)

■ Vertical Coupling Plane (VCP)

□ _____

* 1st test

Result:

■ No degradation of function	- Met Criterion A
□ Distortion of function	- Met Criterion B
□ Error of function	- Met Criterion C
□ Loss of function	- Unrecoverable Failure
□ Safe failure	
□ Unsafe failure	

Remarks:

Method	No.	Application point	Discharge	Criterion	Result	Ramark
Indirect	HCP		Contact Discharge	B	A	-
	VCP			B	A	-
Direct	1	Front	Air Discharge	B	A	-
	2	Rear Side	Air Discharge	B	A	-
	3	Left Side (Switch, Port)	Air Discharge	B	A	-
	4	Right Side	Air Discharge	B	A	-

Test instrumentation

Equipment	Manufacturer	Model	Serial No.	Due Calibration
ESD Simulator System	Haefely	PESD 1600	H006303	2010.10.08

**** 2nd test***

Result:

- ■ No degradation of function - Met Criterion A
- ☐ Distortion of function - Met Criterion B
- ☐ Error of function - Met Criterion C
- ☐ Loss of function - Unrecoverable Failure
- ☐ Safe failure
- ☐ Unsafe failure

Remarks: The software is automatically reset when the air discharge is generated to "Print port".

Method	No.	Application point	Discharge	Criterion	Result	Ramark
Indirect	HCP		Contact Discharge	B	A	-
	VCP			B	A	-
Direct	1	Front	Air Discharge	B	A	-
	2	Rear Side	Air Discharge	B	A	-
	3	Left Side (Switch, Port)	Air Discharge	B	B	-
	4	Right Side	Air Discharge	B	A	-

Test instrumentation

Equipment	Manufacturer	Model	Serial No.	Due Calibration
ESD Generator	EM Test	ESD30N	V1045107926	2014.02.23

2.5	Immunity to radiated electromagnetic fields		
Type	*IMMUNOFLUOROMETER EQUIPMENT*		
Model / Type No.	i-CHROMA^{TM} READER	*Applicant*	BodiTech Med Inc.
Serial No.	NONE	*Test engineer*	Sung-Jae Lee

TEST CONDITIONS AND RESULTS

The measurement of the immunity against radiated electromagnetic fields was performed in a chamber.

☐ **- Test not applicable**

Test location:

☐ Anechoic chamber

■ Full compact chamber

Test specifications:

Frequency - range:
☐ 27 MHz - 500 MHz ☐ 26 MHz - 1000 MHz
■ 80 MHz - 1000 MHz ■ 1400 MHz - 2700 MHz
☐ (900±5) MHz for PM

Field strength:
■ 1 V/m (2000 MHz – 2700 MHz)
■ 3 V/m (80 MHz – 1000 MHz, 1400 MHz – 2000 MHz)
☐ 10 V/m ☐ 20 V/m

Distance of antenna - EUT:
☐ 1 m ■ 3 m ☐ __ m

Modulation:
■ AM 80 % with 1 kHz sinewave
☐ FM : kHz
☐ PM 50 % with 200 Hz
☐ un-modulated

Frequency step / duration:
☐ 0.0015 decades/s
■ 1 % / 3 s ☐ 1 % / 1 s

Polarization of antenna:
■ Horizontal ■ Vertical ☐ circular

Position of EUT:
■ Front ■ Rear ■ Right ■ Left

Result:

■	No degradation of function	- Met Criterion A
☐	Distortion of function	- Met Criterion B
☐	Error of function	- Met Criterion C
☐	Loss of function	- Unrecoverable Failure
☐	Safe failure	
☐	Unsafe failure	

Remarks:

Test instrumentation

Equipment	Manufacturer	Model	Serial No.	Due calibration
Signal Generator	Marconi instrument	2024	112225-092	2011.01.15
Power Meter	R&S	NRVD	101176	2011.02.05
Power Sensor	R&S	NRV-Z51	100921	2011.02.05
Power Sensor	R&S	NRV-Z51	100922	2011.02.05
Power Amplifier	AR	500W1000M5	21402	-
Power Amplifier	AR	100S1G4M1	309165	-
Bi-Log Antenna	EMCO	3142	9704-1175	-
Horn Antenna	AR	AT4002A	310148	-
Isotropic Field Probe	ETS-Lindgren	HI-4455	44512	2010.09.10
Isotropic Field Probe	ETS-Lindgren	HI-4422	79830	2011.02.03
Directional Coupler	AR	DC6180	21034	2011.01.11
Directional Coupler	AR	DC7144A	310783	2011.01.11
Multifunction Synthesizer	NF Corporation	WF1943B	440901	2010.12.11

2.6	Electrical Fast Transients (BURST)		
Type	*IMMUNOFLUOROMETER EQUIPMENT*		
Model / Type No.	**i-CHROMA™ READER**	*Applicant*	**BodiTech Med Inc.**
Serial No.	**NONE**	*Test engineer*	**Sung-Jae Lee**

TEST CONDITIONS AND RESULTS

The measurement of the immunity against electrical fast transients was performed in a shielded room.

☐ **Test not applicable**

Test location:

■ Shielded room

☐ Anechoic chamber

☐ Full compact chamber

Test specifications:

Pulse Amplitude-	■ 0.5 kV	■ 1.0 kV	☐ Coupling Clamp
AC Power Port	■ 2.0 kV	☐ 4.0 kV	■ C/D Network
Pulse Amplitude-	☐ 0.5 kV	☐ 1.0 kV	☐ Coupling Clamp
DC Power Port	☐ 2.0 kV	☐ 4.0 kV	☐ C/D Network
Pulse Amplitude- Signal/Data	☐ 0.5 kV	☐ 1.0 kV	☐ Coupling Clamp
Non Control Port	☐ 2.0 kV	☐ ___ kV	
Pulse Amplitude- Process	☐ 0.5 kV	☐ 1.0 kV	☐ Coupling Clamp
Audio/Video Signal Port	☐ 2.0 kV	☐ ___ kV	
Burst frequency:	☐ 2.5 kHz	■ 5.0 kHz	☐ ___
Coupling time:	☐ ≥ 120 s	■ 60 s	
Polarity:	■ Positive	■ Negative	

Test points of coupling:

Name of lines:	Power line	
type of lines:	☐ shielded (with core)	■ unshielded
status of lines:	☐ passive	■ active
kind of transmission:	■ analogue	☐ digital
length of lines:	■ 1.5 m	

Result:

■ No degradation of function	- Met Criterion A
☐ Distortion of function	- Met Criterion B
☐ Error of function	- Met Criterion C
☐ Loss of function	- Unrecoverable Failure
☐ Safe failure	
☐ Unsafe failure	

Remarks:

Test instrumentation

Equipment	Manufacturer	Model	Serial No.	Due calibration
EFT-Burst Generator	Haefely	PEFT JUNIOR	083658-20	2010.10.09

2.7	Surge		
Type	*IMMUNOFLUOROMETER EQUIPMENT*		
Model / Type No.	**i-CHROMA™ READER**	*Applicant*	**BodiTech Med Inc.**
Serial No.	**NONE**	*Test engineer*	**Sung-Jae Lee**

TEST CONDITIONS AND RESULTS

The measurement of the immunity against surge was performed in a shielded room.

☐ **Test not applicable**

Test location:

■ Shielded room

☐ Anechoic chamber

☐ Full compact chamber

Test specifications:

Test Voltage -	■ 0.5 kV	■ 1.0 kV	☐ Coupling Clamp
AC Power Port (Differential)	☐ 2.0 kV	☐ 4.0 kV	■ C/D Network
Test Voltage -	■ 0.5 kV	■ 1.0 kV	☐ Coupling Clamp
AC Power Port (Common mode)	■ 2.0 kV	☐ 4.0 kV	■ C/D Network
Source Impedance	■ 18 μF	■ 10 Ω + 9 μF	
	☐ 42 Ω + 0.1 μF	☐ 42 Ω + 0.5 μF	
Phase	■ 0, 90, 180, 270 degrees		☐ other _____ degree
Number of surges:	■ 5 times / angle	☐ ___ times	
Polarity:	■ positive	■ negative	
Repetition Rate	■ 60 s	☐ ____ s	

Test points of coupling:

name of lines:	Power line	
type of lines:	☐ shielded	■ unshielded
status of lines:	☐ passive	■ active
kind of transmission:	■ analogue	☐ digital
length of lines:	■ - 1.5 m	

Result:

■ No degradation of function	- Met Criterion A
☐ Distortion of function	- Met Criterion B
☐ Error of function	- Met Criterion C
☐ Loss of function	- Unrecoverable Failure
☐ Safe failure	
☐ Unsafe failure	

Remarks:

Test instrumentation

Equipment	Manufacturer	Model	Serial No.	Due calibration
EMC Immunity test system	Thermo Electron Corporation	EMCPRO PLUS	0612197	2011.01.14

2.8	Immunity to conducted disturbance		
Type	*IMMUNOFLUOROMETER EQUIPMENT*		
Model / Type No.	**i-CHROMA™ READER**	*Applicant*	**BodiTech Med Inc.**
Serial No.	**NONE**	*Test engineer*	**Sung-Jae Lee**

TEST CONDITIONS AND RESULTS

The measurement of the immunity against conducted disturbance was performed in a shielded room.

☐ **Test not applicable**

Test location:

■ Shielded room

☐ Anechoic chamber

☐ Full compact chamber

Test specifications:

Frequency - range:
☐ 27 MHz - 80 MHz ☐ 26 MHz - 230 MHz
■ 150 kHz - 80 MHz ☐ other _____

Field strength:
☐ 1 V ■ - 3 Vrms
☐ 10 V ☐ - __V/m

Modulation:
■ AM 80% with 1 kHz sinewave
☐ FM : kHz
☐ sine wave 1000 Hz
☐ un-modulated
☐ PM 1 Hz (0.5 s ON: 0.5 s OFF)

Frequency step / Dwell time:
☐ 0.0015 decades/s
■ 1% / 3 s ☐ 1% / 1 s.

Test points of coupling:

Name of lines:	Power line	
Type of lines:	☐ shielded	■ unshielded
Status of lines:	☐ passive	■ active
Kind of transmission:	■ analogue	☐ digital
Length of lines:	■ 1.5 m	

Result:

■ No degradation of function	- Met Criterion A
☐ Distortion of function	- Met Criterion B
☐ Error of function	- Met Criterion C
☐ Loss of function	- Unrecoverable Failure
☐ Safe failure	
☐ Unsafe failure	

Remarks:

Test instrumentation

Equipment	Manufacturer	Model	Serial No.	Due calibration
Conducted Immunity Test System	Frankonia EMV-Mess Systeme	CIT-10/75	102C3121	2011.01.14
CDN	FCC	FCC-801-M3-16	9755	2011.01.07

2.9	Rated power frequency magnetic field		
Type	*IMMUNOFLUOROMETER EQUIPMENT*		
Model / Type No.	**i-CHROMA^{TM} READER**	*Applicant*	**BodiTech Med Inc.**
Serial No.	**NONE**	*Test engineer*	**Sung-Jae Lee**

TEST CONDITIONS AND RESULTS

The measurement of the immunity against Rated power frequency magnetic field was performed in a shielded room.

☐ **Test not applicable**

Test location:

- ■ Shielded room
- ☐ Anechoic chamber no.1
- ☐ Anechoic chamber no.2
- ☐ Full compact chamber

Test specifications:

Test level	■ 3 A/m	☐ 10 A/m	☐ other ____ A/m
Frequency tested	■ 50 Hz	■ 60 Hz	☐ Hz

Result:

- ■ No degradation of function - Met Criterion A
- ☐ Distortion of function - Met Criterion B
- ☐ Error of function (for voltage interruption) - Met Criterion C
- ☐ Loss of function - Unrecoverable Failure
- ☐ Safe failure
- ☐ Unsafe failure

Remarks:

Test instrumentation

Equipment	Manufacturer	Model	Serial No.	Due calibration
M-Filed Tester	Haefely	MAG100.1	862 839-07	2010.10.12
Voltage dip/ interruption/ variation test	Haefely	PLINE	083 732-21	2010.10.09

2.10	Interruptions & variations		
Type	*IMMUNOFLUOROMETER EQUIPMENT*		
Model / Type No.	i-CHROMA™ READER	*Applicant*	BodiTech Med Inc.
Serial No.	NONE	*Test engineer*	Sung-Jae Lee

TEST CONDITIONS AND RESULTS

The measurement of the immunity against interruptions & variations was performed in a shielded room.

☐ **Test not applicable**

Test location:

■ Shielded room

☐ Anechoic chamber

☐ Full compact chamber

Test specifications:

Voltage reduction	■ 30 %	■ 60 %	■ > 95 %	■ 95 %
Duration of reduction @ 50 Hz	■ 25 @ 30 %	■ 5 @ 60 %	☐ 1 @ > 95 %	
(number of cycles)	■ 250 @ 100 %			
Duration of reduction @ 60 Hz	■ 30 @ 30 %	■ 6 @ 60 %	☐ 1 @ > 95 %	
(number of cycles)	■ 300 @ 95 %			
Duration of Interruption	☐ 250 cycles @ > 95 %		■ 1 cycle @ 100 %	
Number of reduction	■ 3 times	☐ other _____ times		
Interval between reduction	■ 10 s	☐ other ____ s		
Voltage fluctuation	☐ 0.6 Un ~ 1.4 Un at 0.1 s			
Nominal voltage (V_{nom})	■ 100 Va.c.	■ 240 Va.c.		
Nominal frequency	■ 50 Hz.	■ 60 Hz		

Result:

■	No degradation of function	- Met Criterion A
☐	Distortion of function	- Met Criterion B
☐	Error of function	- Met Criterion C
☐	Loss of function	- Unrecoverable Failure
☐	Safe failure	
☐	Unsafe failure	

Remarks:

Test instrumentation

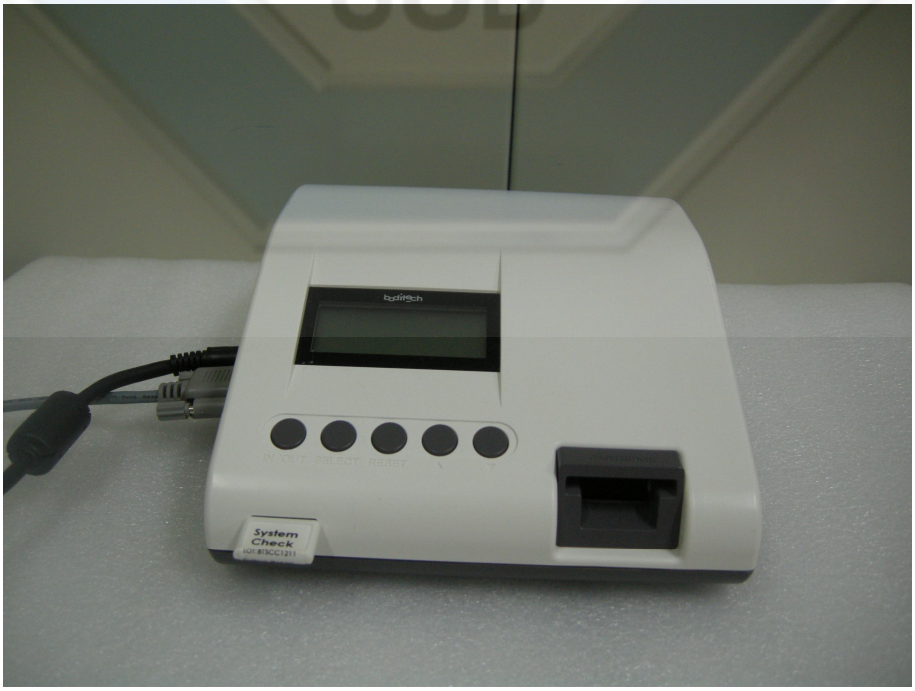
Equipment	Manufacturer	Model	Serial No.	Due calibration
Voltage dip / interruption / variation Test	Haefely	PLINE 1610	083 732-21	2010.10.09

APPENDIX A. Photographs of EUT

Front View of Product

- **Basic model**

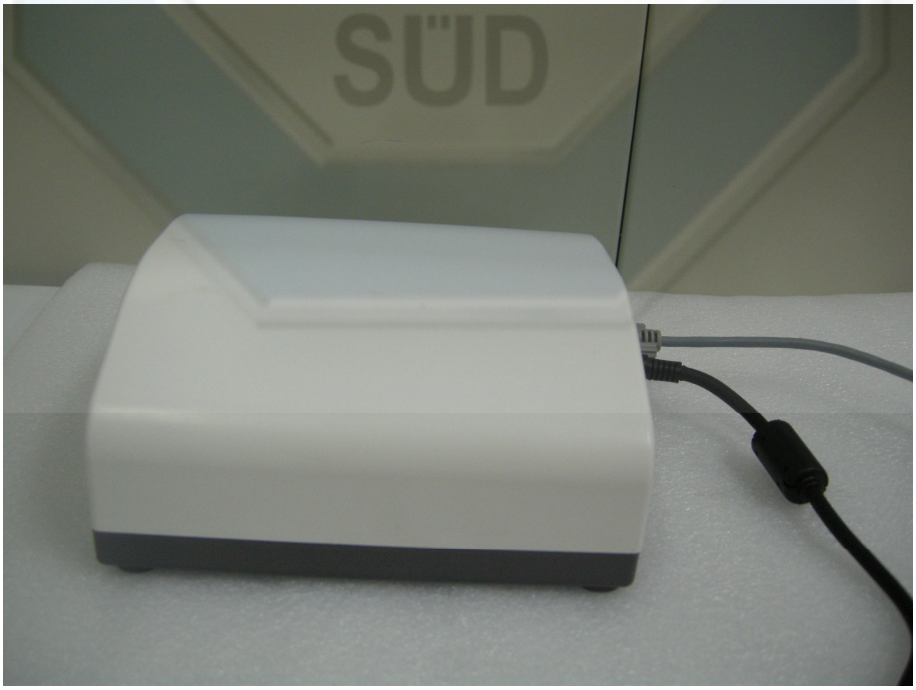
- **Modified model**



Side View of Product

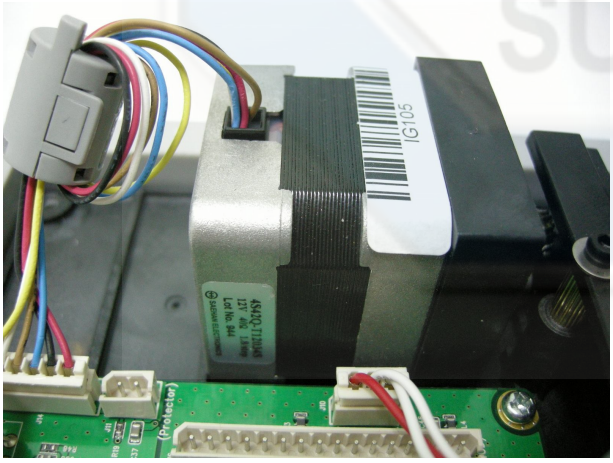
- **Basic model**

- **Modified model**



Power adapter

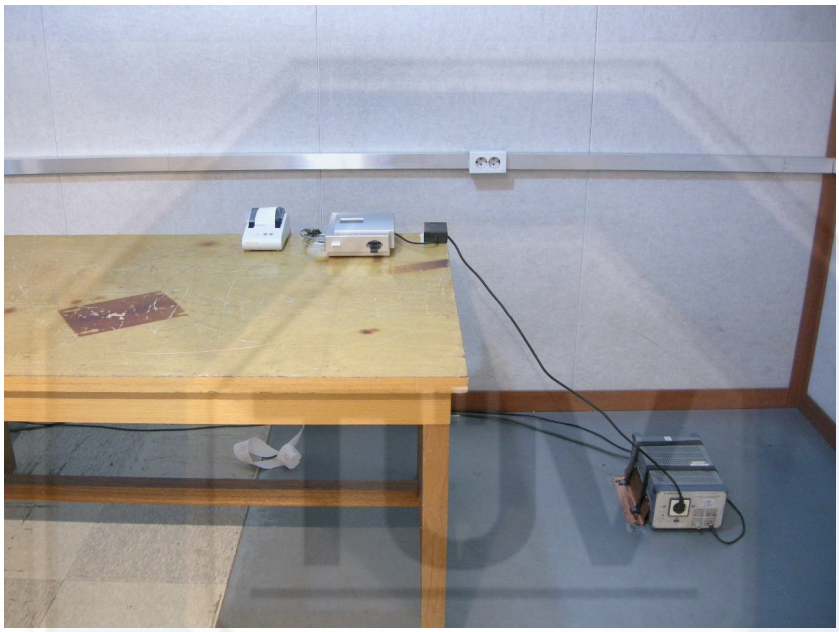
EUT improvement



APPENDIX B. Photographs of Test Set-up

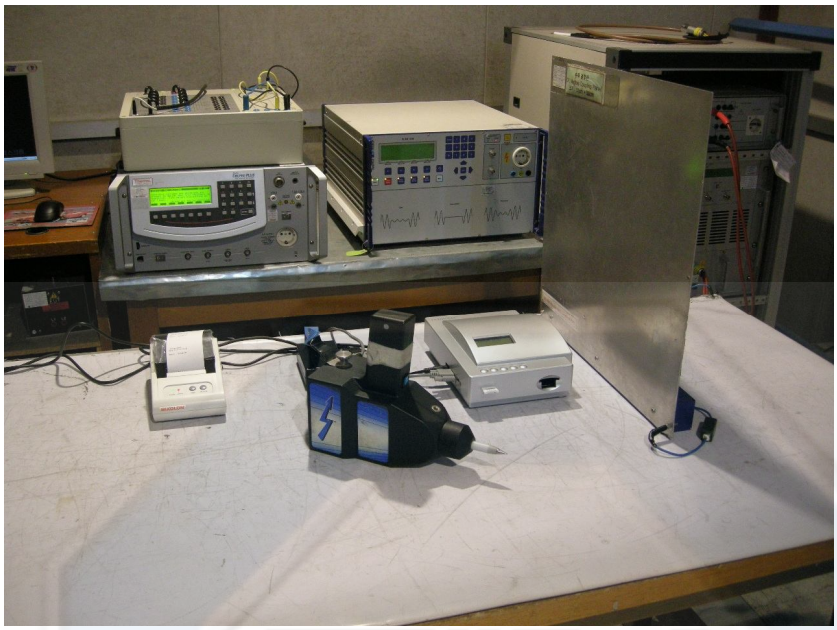
*** 1st tests for Basic model**

B1. Mains terminal conducted disturbance (0.15 MHz ~ 30 MHz)

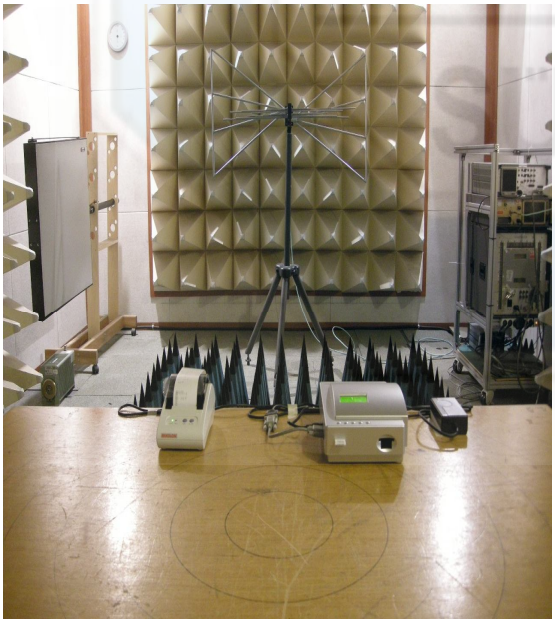


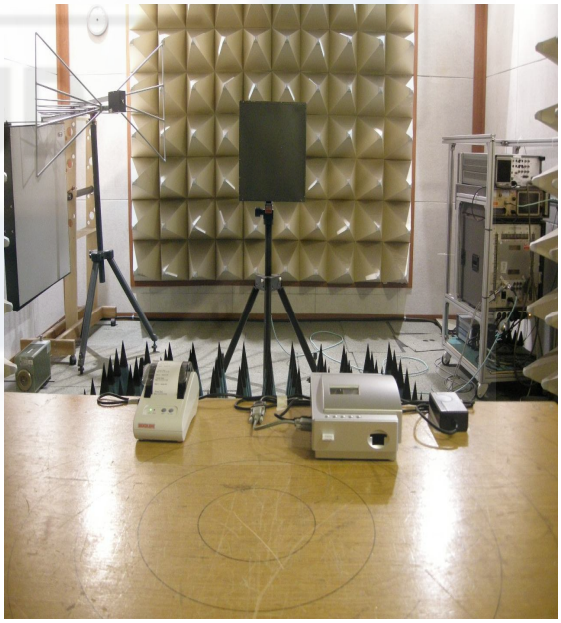
B2. Radiated disturbance (30 MHz ~ 1000 MHz)

B3. ESD



B4. Radiated immunity test (80 MHz – 2700 MHz)

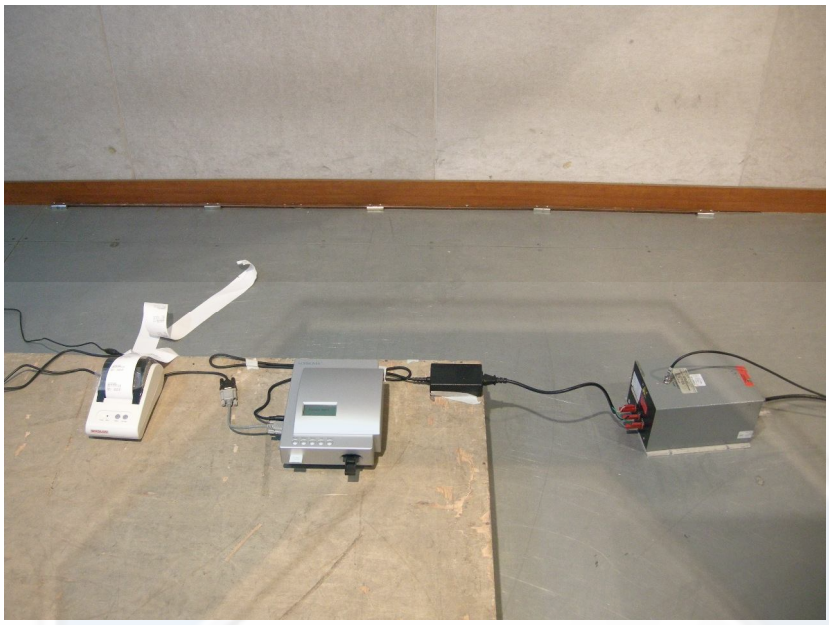




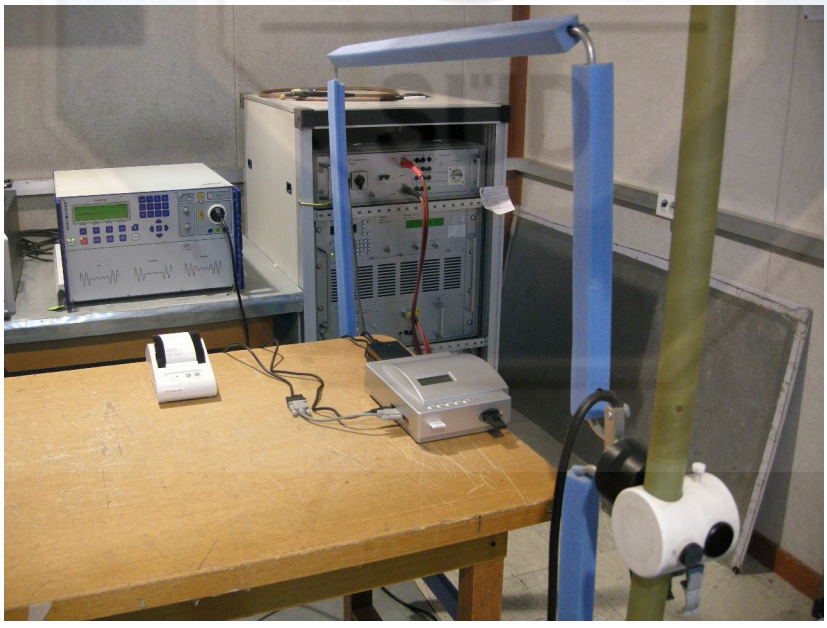
B5. Fast transient (Burst)

B6. Surge transient

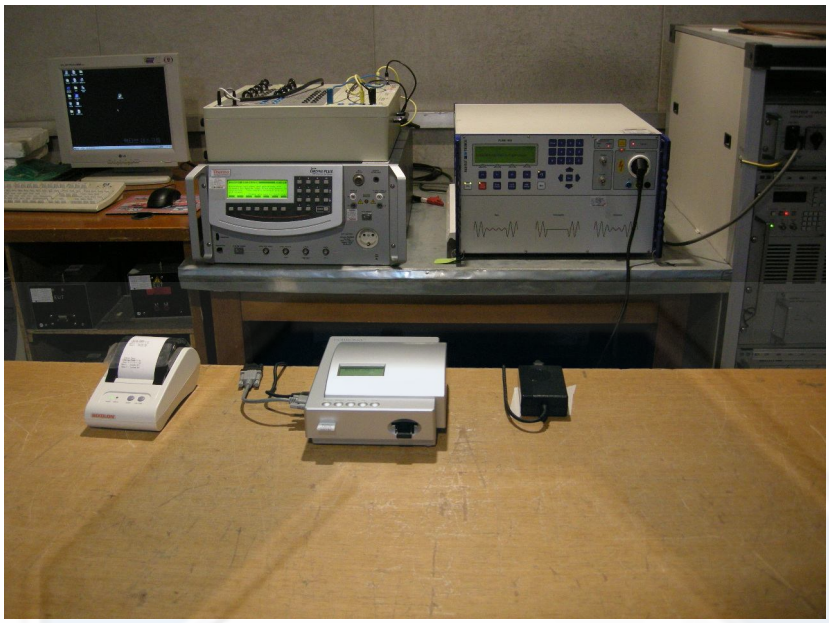
B7. Conducted disturbance



B8. Magnetic field immunity



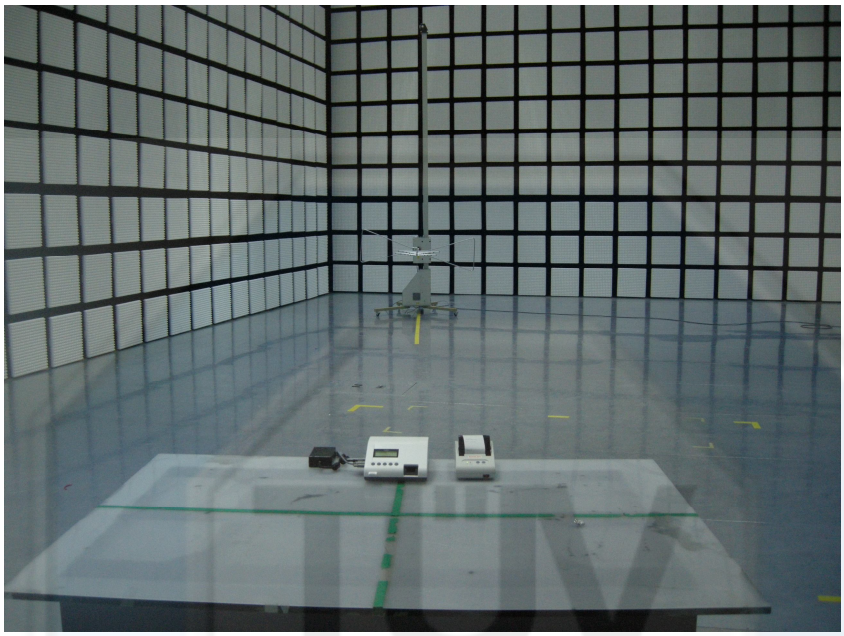
B9. Interruption & variation



B10. Harmonics/Flicker

*** 2nd tests for Modified model**

B11. Radiated disturbance (30 MHz ~ 1000 MHz)

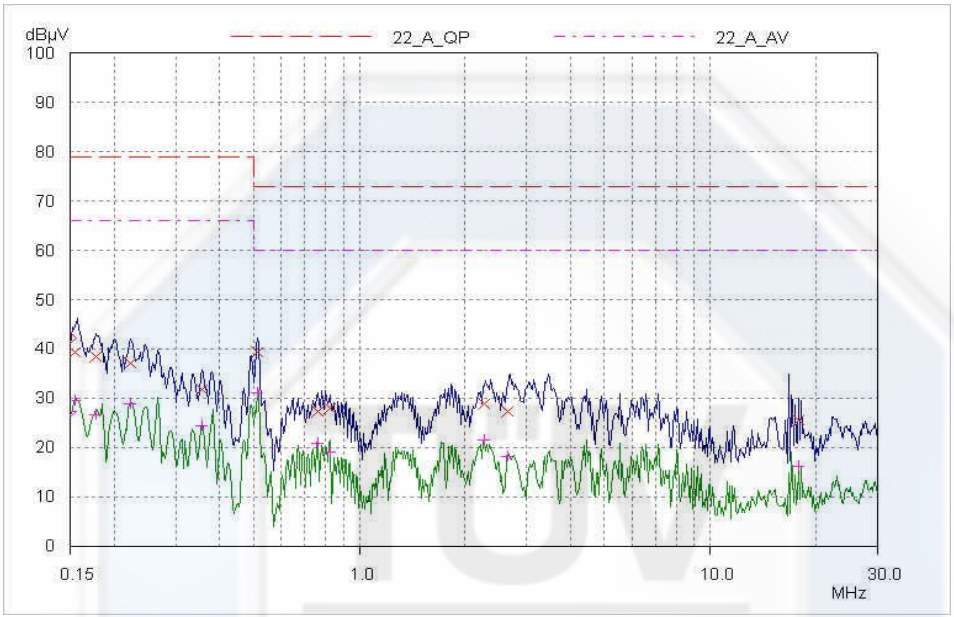


B12. ESD

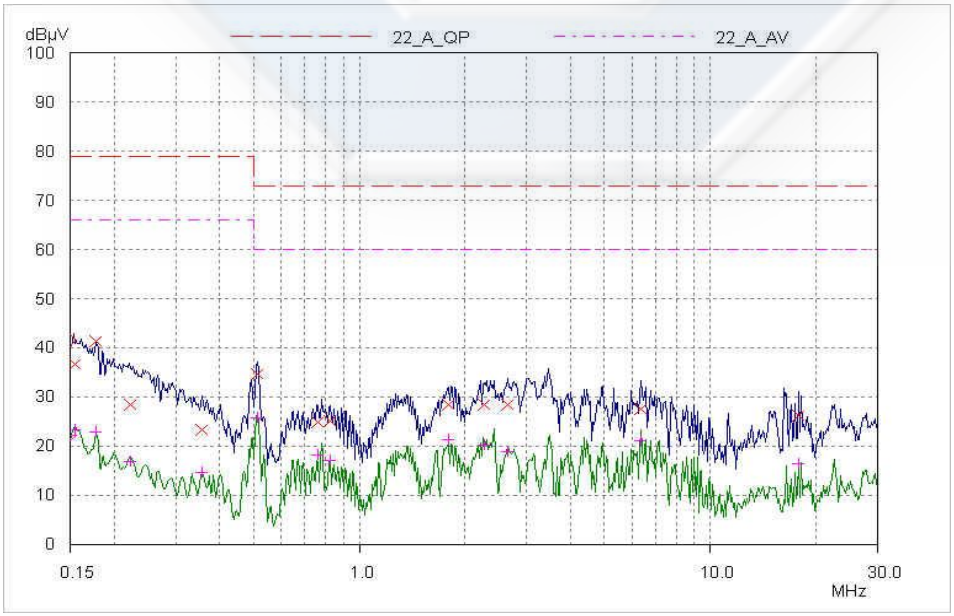
APPENDIX C. Test graph / data

*** 1st tests for Basic model**

C1. Line 1



C2. Line 2



* 2nd tests for Modified model

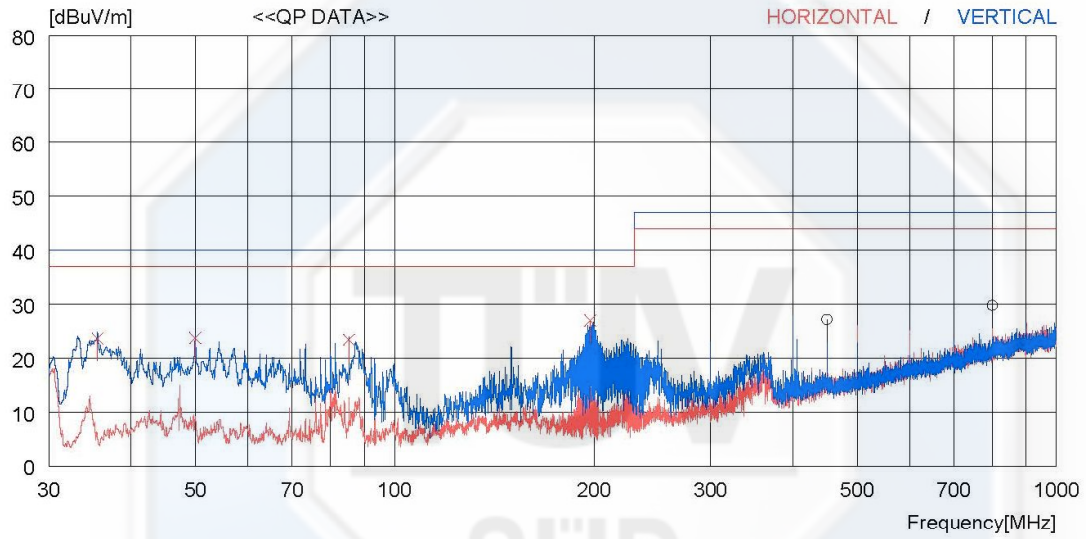
Results of Radiated Emissions(KEL)

EMC Test Room

Company Name	:		Reference No.	:	
Type	:		Power Supply	:	
Model Name	:	i-CHROMA Reader White	Temp/Humi	:	25.3 / 65.2
Test Condition	:		Operator	:	Choi Doc Chang

Memo :

LIMIT : CISPR Pub.22 Class A (10m)
MARGIN: 3 dB



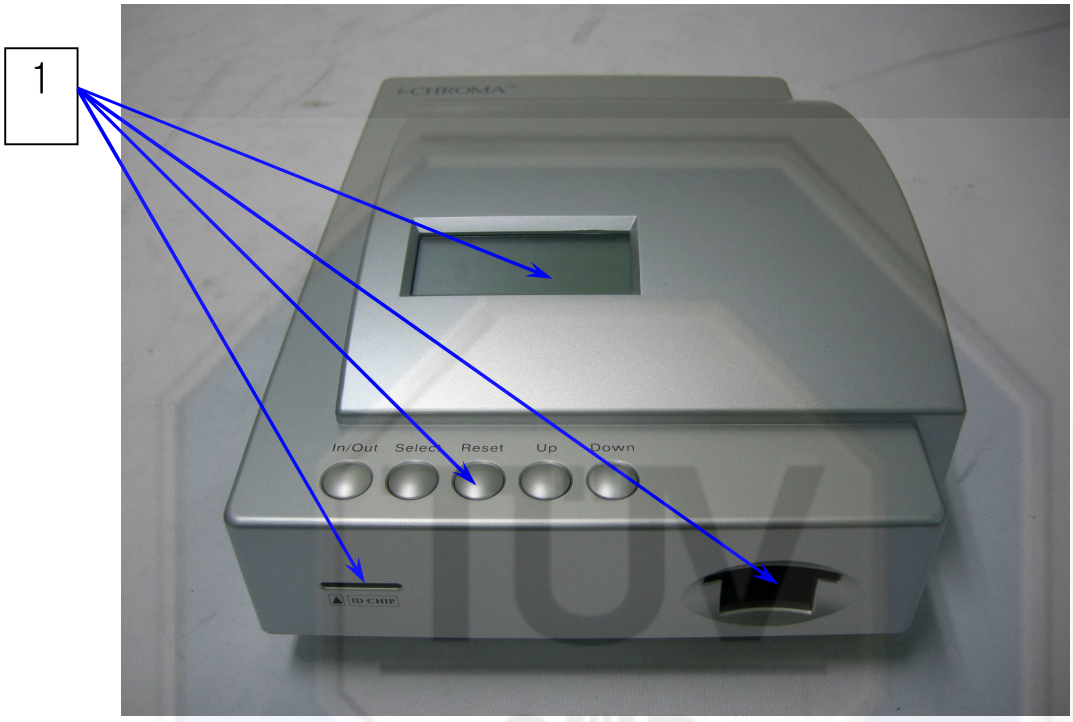
No.	FREQ [MHz]	READING QP [dBuV]	ANT FACTOR [dB]	LOSS [dB]	GAIN [dB]	RESULT QP [dBuV/m]	LIMIT [dBuV/m]	MARGIN [dB]	ANTENNA [cm]	TABLE [deg]
----- Horizontal ------										
1	449.977	38.1	16.8	3.9	31.6	27.2	47.0	19.8	150	320
2	800.134	33.9	22.5	5.1	31.7	29.8	47.0	17.2	110	240
----- Vertical ------										
3	35.578	43.9	10.6	1.0	31.8	23.7	40.0	16.3	100	340
4	50.006	42.7	11.7	1.2	31.8	23.8	40.0	16.2	100	230
5	85.290	45.1	8.6	1.5	31.8	23.4	40.0	16.6	100	240
6	197.532	46.7	9.7	2.3	31.7	27.0	40.0	13.0	100	30

APPENDIX D. Injection point of ESD

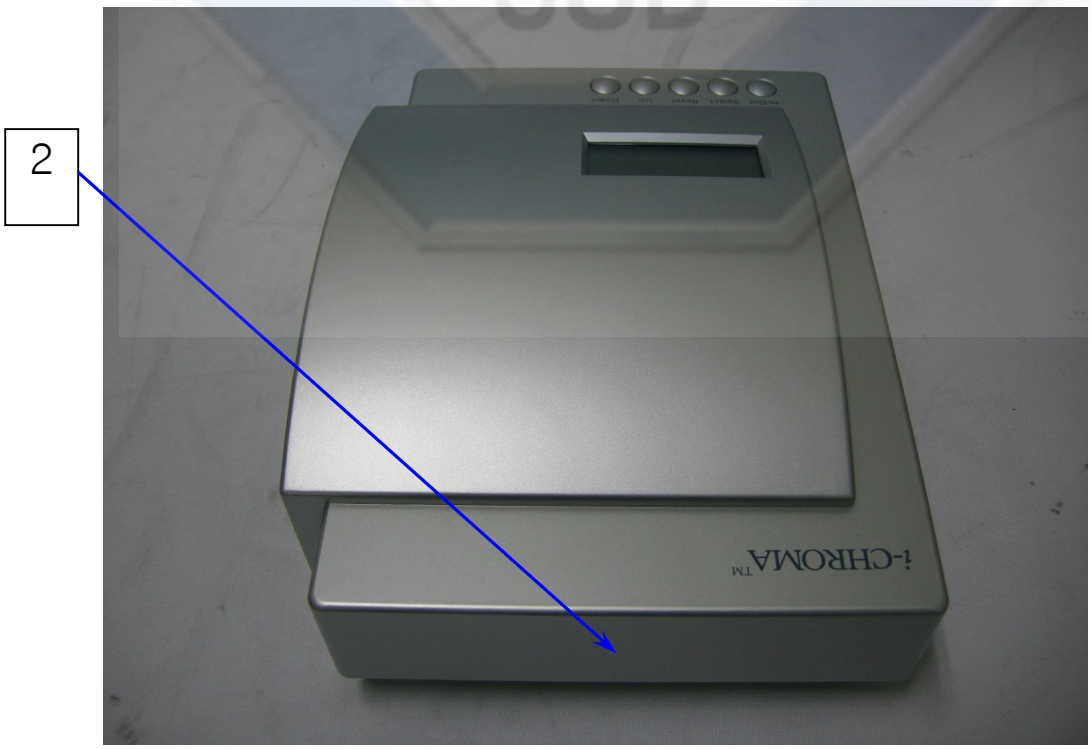
*** The application points of *ESD* (*BLUE LINE*: Air Discharge, *RED LINE*: Contact Discharge) :**

*** 1st tests for Basic model**

[Front of EUT]

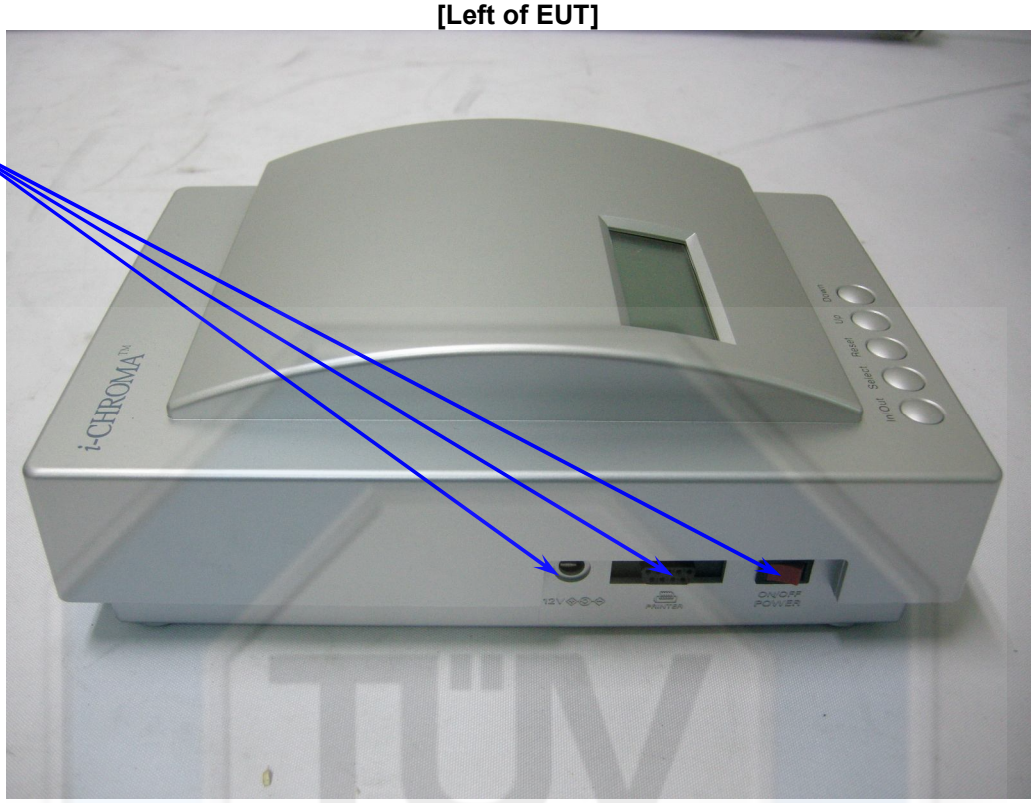


[Rear of EUT]



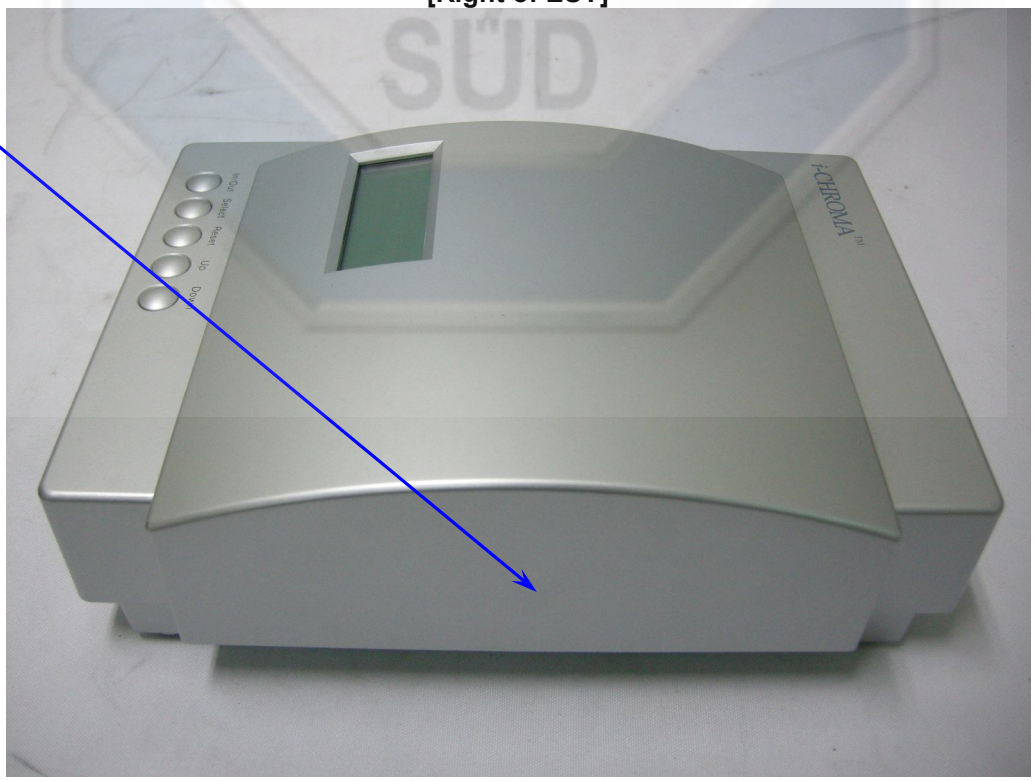
[Left of EUT]

3



[Right of EUT]

4



*** 2nd tests for Modified model**