EMC - TEST REPORT

EUROPEAN STANDARD EN 60601-1-2: 2007 and IEC 60601-1-2: 2007

Test Report File No.	:	**SC1010487A-01-02** Date of Issue: **13 January 2011**
Model / Serial No.	:	**MODEL: X10 / S/N: 101000003**
Product Type	:	**B-ALERT SYSTEM**
Configuration Test Mode	:	**PATIENT MODE**
Applicant	:	**ADVANCED BRAIN MONITORING SYSTEMS**
Manufacturer	:	**ADVANCED BRAIN MONITORING SYSTEMS**
License holder	:	**ADVANCED BRAIN MONITORING SYSTEMS**
Address	:	**2850 Pio Pico Drive, Suite A**
	:	**Carlsbad, CA 92008 – USA**
Test Result	:	■ **Positive** ☐ **Negative**
Test Project Number	:	**SC1010487A**
Total pages - Test Report	:	**48**

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TEST REGULATIONS:

The tests were performed according to the following regulations:

■ - IEC 60601-1-2: 2007 ■ - EN 60601-1-2: 2007

■ - CISPR 11: 2009	☐ - Class A	■ - Class B
■ - EN 55011: 2007; Amendment A2: 2007	☐ - Class A	■ - Class B

☐ - EN 61000-3-2: 2006
☐ - IEC 61000-3-2: 2005; Amendment 1, 2008

☐ - EN 61000-3-3: 1995, Amendment 2: 2006
☐ - IEC 61000-3-3: 2008

■ - IEC 61000-4-2: 2008	EN 61000-4-2: 1995; Amendment 2, 2001
■ - IEC 61000-4-3: 2008	EN 61000-4-3: 2006, Amendment 1, 2008
☐ - IEC 61000-4-4: 2007	EN 61000-4-4: 2004
☐ - IEC 61000-4-5: 2005	EN 61000-4-5: 2006
☐ - IEC 61000-4-6: 2008	EN 61000-4-6: 2007
■ - IEC 61000-4-8: 2001	EN 61000-4-8: 1993; Amendment 1, 2001
☐ - IEC 61000-4-11: 2004	EN 61000-4-11: 2004

Note: Un-dark squares are not applicable

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Environmental Conditions In The Laboratory:

	Actual
Temperature	: 18 – 25 °C
Relative Humidity	: 42 – 55 %
Atmospheric Pressure	: 98.9 – 100.8 kPa

Power Supply Utilized:

Power supply system	: 3.7 VDC

Symbol Definitions:

■ - Applicable
☐ - Not Applicable

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Test Conditions: CONDUCTED EMISSIONS (Interference Voltage)

The *CONDUCTED EMISSIONS (Interference Voltage)* measurements were performed in the following location at the San Diego Testing Facility:

■ - Test not applicable

OPERATING MODE DESCRIPTION:	
Remarks:	DC Powered. Testing Not Applicable.

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Test Conditions: RADIATED EMISSIONS (Electric Field)

The *RADIATED EMISSIONS (Electric Field)* measurements were performed in the following location at the San Diego Testing Facility:

☐ **- Test not applicable**

■ - SR6 (3 and 10 meter Semi-Anechoic Chamber), San Diego, CA
(Date of listing June 21, 2010. Site Verification NSA)

Testing was performed at a test distance of:

■ - 10 meters

Test Equipment Used:

Model No.:	Prop. No.:	Description:	Manufacturer:	Serial No./Version No.:
3142C	SA1033	Antenna, Bilog	EMCO	44556
ESMI	SA1043,44	EMI Test Receiver	Rhode & Schwarz	848926/003
PAM-0202	SA1016	Pre-Amplifier	PAM	187
ES-K1	--	Test Software	Rohde & Schwarz	1.60 Service Pack 2

Result:
■ - Pass ☐ - Fail

OPERATING MODE DESCRIPTION:	Patient Mode
Remarks:	One year calibration cycle for all test equipment.

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Test Conditions: CURRENT HARMONICS TEST

The *CURRENT HARMONICS TEST* measurements were performed in the following location at the San Diego Testing Facility:

■ - Test not applicable

OPERATING MODE DESCRIPTION:	
Remarks:	DC Powered. Testing Not Applicable.

Test Conditions: VOLTAGE FLUCTUATION AND FLICKER TEST

The *VOLTAGE FLUCTUATION AND FLICKER TEST* measurements were performed in the following location at the San Diego Testing Facility:

■ - Test not applicable

OPERATING MODE DESCRIPTION:	
Remarks:	DC Powered. Testing Not Applicable.

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Test Conditions: ELECTROSTATIC DISCHARGE (ESD)

The immunity against *ELECTROSTATIC DISCHARGE (ESD)* was performed in the following location at the San Diego Testing Facility:

☐ **- Test not applicable**

■ - TR-1, Test Room, 20.5' x 17' x 9'

Test Equipment Used:

Model No.:	Prop. No.:	Description:	Manufacturer:	Serial No./Version No.:
NSG435	6541	ESD Simulator System	Schaffner	751
HCP	--	Horizontal Coupling Plane	TÜV SÜD America	--
VCP	--	Vertical Coupling Plane	TÜV SÜD America	--
NSG435	--	Test Software	Schaffner	--

Test Specification:

Discharge Voltage (Air):	■ - ± 2 kV	☐ - ± 6 kV	☐ - ± 15 kV
	■ - ± 4 kV	■ - ± 8 kV	☐ - ± ___ kV
Discharge Voltage (Contact):	■ - ± 2 kV	■ - ± 4 kV	☐ - ± 8 kV
	☐ - ± 3 kV	■ - ± 6 kV	☐ - ± ___ kV
Discharge Impedance:	■ - 330 Ω / 150 pF		
Discharge Repetition Rate:	■ - ≥ 1 sec.		
Number of Discharges:	■ - 10 Positive	■ - 10 Negative	
Kind of Discharges:	Direct Discharge	Indirect Discharge	
	■ - Air	■ - HCP	
	■ - Contact	■ - VCP	
Polarity:	■ - Positive	■ - Negative	
Location of Discharge:	■ - See Data Record(s)	☐ - Each location on the surface touchable by hand	

Result:

■ - Pass ☐ - Fail

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

OPERATING MODE DESCRIPTION: Patient Mode

Remarks:

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Test Conditions: RADIATED ELECTROMAGNETIC FIELDS

The immunity against *RADIATED ELECTROMAGNETIC FIELDS* was performed in the following location at the San Diego Testing Facility:

☐ **- Test not applicable**

■ - SR-1, Shielded Room, 12' x 24' x 10', Metal, Compact Anechoic Chamber

Test Equipment Used:

Model No.:	Prop No.:	Description:	Manufacturer:	Serial No./Version No.:
STLP9149	7535	Antenna, Log Periodic	Schwarzbeck	9149-022
AT5080M1	7508	Antenna, Log Periodic	Amplifier Research	0323556
FM 2000	6507	Isotropic Field Monitor	Amplifier Research	14677
FP 2000	6689	Isotropic Field Probe	Amplifier Research	14803
7005	7510	RF Power Amplifier	Ophir, 0.8 – 6GHz	1001
436A	6584	Power Meter	Hewlett Packard	1911A04722
8481A	6534	Power Sensor	Hewlett Packard	1926A27807
N5181A	7504	Signal Generator	Agilent	MY46240083
C3	--	Test Software	TÜV SÜD America	4.01.0 BUILD 0

Test Specification:

Frequency Range:	☐ - 80 - 1000 MHz	■ - 80 - 2500 MHz	☐ - 80 - 2700 MHz	
Field Strength:	☐ - 1 V/m	■ - 3 V/m	☐ - 10 V/m	☐ - ___ V/m
Distance Antenna - EUT:	☐ - 1 m	■ - 3 m		
Modulation:	■ - AM:	☐ - FM:	■ - 80 %	■ - 10 Hz
	☐ - Un-Modulated			
	■ - Sine Wave:	☐ - Pulse	ON/OFF	Duty Cycle: ___ %
Step:	☐ - 1 second dwell	■ - 3 seconds dwell	■ - 1%	
Polarization of Antenna:	■ - Horizontal	■ - Vertical		

Result:

■ - Pass ☐ - Fail

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

OPERATING MODE DESCRIPTION: Patient Mode

Remarks:

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Test Conditions: FAST TRANSIENTS (BURST)

The immunity against *FAST TRANSIENTS (BURST)* was performed in the following location at the San Diego Testing Facility:

■ - Test not applicable

OPERATING MODE DESCRIPTION:	
Remarks:	DC Powered. Testing Not Applicable.

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Test Conditions: SURGE TRANSIENTS

The immunity against *SURGE TRANSIENTS* was performed in the following location at the San Diego Testing Facility:

■ - Test not applicable

OPERATING MODE DESCRIPTION:	
Remarks:	DC Powered. Testing Not Applicable.

Test Conditions: CONDUCTED DISTURBANCE

The immunity against *CONDUCTED DISTURBANCE* was performed in the following location at the San Diego Testing Facility:

■ - Test not applicable

OPERATING MODE DESCRIPTION:	
Remarks:	DC Powered. Testing Not Applicable.

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Test Conditions: POWER FREQUENCY MAGNETIC FIELD

The immunity against *POWER FREQUENCY MAGNETIC FIELD* was performed in the following location at the San Diego Testing Facility:

☐ **- Test not applicable**

■ - TR-2, Test Room, 16' x 10' x 9'

Test Equipment Used:

Model No.:	Prop. No.:	Description:	Manufacturer:	Serial No./Version No.:
1C-1m	6543	Loop Injection Coil	TÜV SÜD America	N/A
1000-8	6525	Magnetic Field Generator	TÜV SÜD America	N/A

■ - Test requires no software.

Test Specification:

Frequency Range:	■ - 50 Hz	■ - 60 Hz	☐ - 400 Hz
Field level (EMF):	☐ - 1 A/m	■ - 3 A/m	☐ - 10 A/m
	☐ - 30 A/m	☐ - 100 A/m	☐ - ___ A/m
Short Field (1-3 sec):	☐ - 300 A/m	☐ - 1000 A/m	☐ - ___ A/m
Duration:	■ - 60 seconds	☐ - ___ seconds	
Axis of Orientation:	■ - X-axis	■ - Y-axis	■ - Z-axis

Result:

■ - Pass ☐ - Fail

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

OPERATING MODE DESCRIPTION: Patient Mode

Remarks:

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Test Conditions: VOLTAGE DIPS, INTERRUPTIONS & VARIATIONS

The immunity against *VOLTAGE DIPS, INTERRUPTIONS & VARIATIONS* was performed in the following location at the San Diego Testing Facility:

■ **- Test not applicable**

OPERATING MODE DESCRIPTION:	
Remarks:	DC Powered. Testing Not Applicable.

Equipment Under Test (EUT) Test Operation Mode:

The equipment under test was operated under the following conditions during testing:

Patient Mode

Configuration of the equipment under test:

☐ - See Constructional Data Form in Appendix B

■ - See Product Information Form(s) in Appendix B

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

☐ - _____ Type: _____

☐ - _____ Type: _____

☐ - _____ Type: _____

☐ - _____ Type: _____

☐ - _____ Type: _____

☐ - _____ Type: _____

☐ - Unshielded power cable

☐ - Unshielded cables

☐ - Shielded cables MPS. No.: _____

☐ - Customer specific cables

☐ - _____

☐ - _____

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GENERAL REMARKS:

Patient Mode using Calibration Generator for each test function.

SUMMARY:

The tests marked with darkened squares were performed according to the regulations cited on page 3

■ - **Performed**

The Equipment Under Test

■ - **Fulfills** all of the general approval requirements cited on page 3

Statement of Measurement Uncertainty

The data and results referenced in this document are true and accurate. The test system for conducted emissions is defined as the LISN, tuned receiver or spectrum analyzer, and coaxial cable. This test system has a measurement uncertainty of ±1.8 dB. The test system for radiated emissions is defined as the antenna, the pre-amplifier, the spectrum analyzer and the coaxial cable. This test system has a measurement uncertainty of ±4.8 dB. The measurement uncertainty values for conducted and radiated emissions meet the requirements as expressed in CISPR 16-4-2. The equipment comprising the test systems is calibrated on an annual basis. The reader is cautioned that there is some measurement variability due to the tolerances of the test equipment that can contribute to a nominal product measurement uncertainty. Furthermore, component differences and manufacturing process variability of production units similar to that tested may result in additional product uncertainty. If necessary, refer to the test lab for the actual measurement uncertainty for specific tests.

Equipment Received Date: 30 November 2010

Testing Start Date: 30 November 2010

Testing End Date: 12 January 2011

- TÜV SÜD AMERICA, INC. -

Reviewing Engineer: Test Engineer:

David Gray,
(Senior EMC Engineer)

Lan Sayasane,
(EMC Technician)

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Technical Documentation

Test Data Sheets

and

Test Setup Drawing(s)

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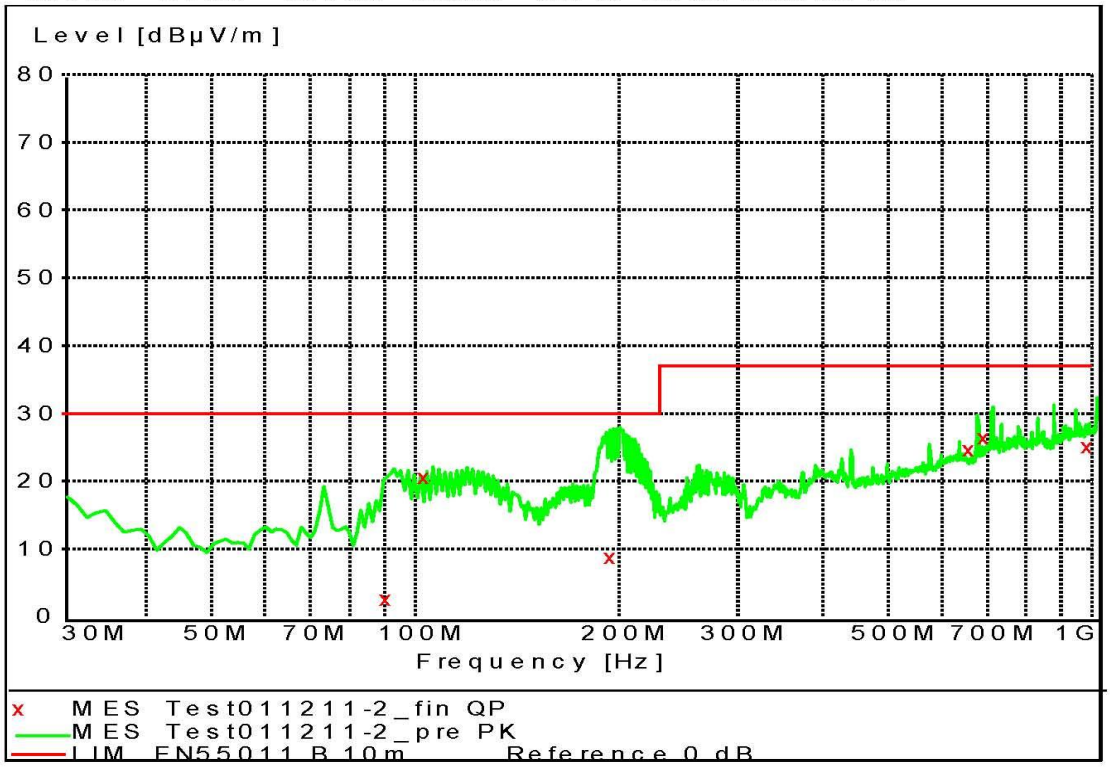
TUV SC1010487

EUT:	B-Alert X10
Manufacturer:	Advance Brain Monitoring Systems
Operating Condition:	Patient mode with calibration generator
Test Site:	SR6
Operator:	Kathy MacKenzie
Test Specification:	EN55011 class B
Comment:	Internal Battery powered
Start of Test:	1/12/2011 / 11:24:01AM

SCAN TABLE: "EN55011 10M(BCL)"

Short Description: EN 55011 Field Strength

Start Frequency	Stop Frequency	Step Width	Detector	Meas. Time	IF Bandw.	Transducer
30.0 MHz	1.0 GHz	80.0 kHz	MaxPeak	10.0 ms	120 kHz	3142C 556 10m



MEASUREMENT RESULT: "Test011211-2_fin QP"

1/12/2011 12:47PM

Frequency MHz	Level dBµV/m	Transd dB	Limit dBµV/m	Margin dB	Height cm	Azimuth deg	Polarisation
91.200000	2.60	-21.5	30.0	27.4	356.0	191.00	HORIZONTAL
103.840000	20.60	-21.1	30.0	9.4	342.0	354.00	HORIZONTAL

1/12/2011 1:02PM Test011211-2

MEASUREMENT RESULT: "Test011211-2_fin QP"

(continued)

Frequency MHz	Level dBµV/m	Transd dB	Limit dBµV/m	Margin dB	Height cm	Azimuth deg	Polarisation
196.080000	8.80	-18.2	30.0	21.2	346.0	294.00	HORIZONTAL
663.680000	24.70	-5.0	37.0	12.3	102.0	24.00	VERTICAL
699.680000	26.40	-3.5	37.0	10.6	181.0	32.00	VERTICAL
995.280000	25.10	-0.5	37.0	11.9	177.0	318.00	VERTICAL

1/12/2011 1:02PM Test011211-2

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ESD IMMUNITY

Test Report #:	SC1010487	Test Area:	TR-1		
EUT Model #:	X10	Date:	December 21, 2010		
EUT Serial #:	101000003	EUT Power:	Battery 3.7 VDC	Temperature:	21.3 °C
Test Method:	EN61000-4-2			Air Pressure:	100.0 kPa
Customer:	Advanced Brain Monitoring Systems			Relative Humidity:	58.7 %
EUT Description:	B-Alert System			Page:	1 of 4
Notes:	Patient mode with calibration generator				
	ND = No Discharge				

Test Point Location	Discharge Type: Direct/ Indirect	Discharge Type: Air/ Contact	2 kV Reps +	2 kV Reps -	4 kV Reps +	4 kV Reps -	6 kV Reps +	6 kV Reps -	8 kV Reps +	8 kV Reps -	kV Reps +	kV Reps -	Complies: Yes	Complies: No	Criteria Met	Remarks
Front	Indirect	Contact	10	10	10	10	10	10					✓		A	HCP
Left	↓	↓	10	10	10	10	10	10					✓		A	↓
Right	↓	↓	10	10	10	10	10	10					✓		A	↓
Rear	↓	↓	10	10	10	10	10	10					✓		A	↓
Front	↓	↓	10	10	10	10	10	10					✓		A	VCP
Left	↓	↓	10	10	10	10	10	10					✓		A	↓
Right	↓	↓	10	10	10	10	10	10					✓		A	↓
Rear	↓	↓	10	10	10	10	10	10					✓		A	↓
A1	Direct	Air	ND	ND	ND	ND			ND	ND			✓		A	
A2	↓	↓	ND	ND	ND	ND			ND	ND			✓		A	
A3	↓	↓	ND	ND	ND	ND			ND	ND			✓		A	
A4	↓	↓	ND	ND	ND	ND			ND	ND			✓		A	
A5	↓	↓	ND	ND	ND	ND			10	10			✓		B	
A6	↓	↓	ND	ND	ND	ND			ND	ND			✓		A	
A7	↓	↓	ND	ND	ND	ND			ND	ND			✓		A	
A8	↓	↓	ND	ND	ND	ND			ND	ND			✓		A	
A9	↓	↓	ND	ND	ND	ND			ND	ND			✓		A	
A10	↓	↓	ND	ND	ND	ND			ND	ND			✓		A	

Tested by: Lan Sayasane (Printed) — (Signature)

Reviewed by: Stephen Rackleff (Printed) — (Signature)

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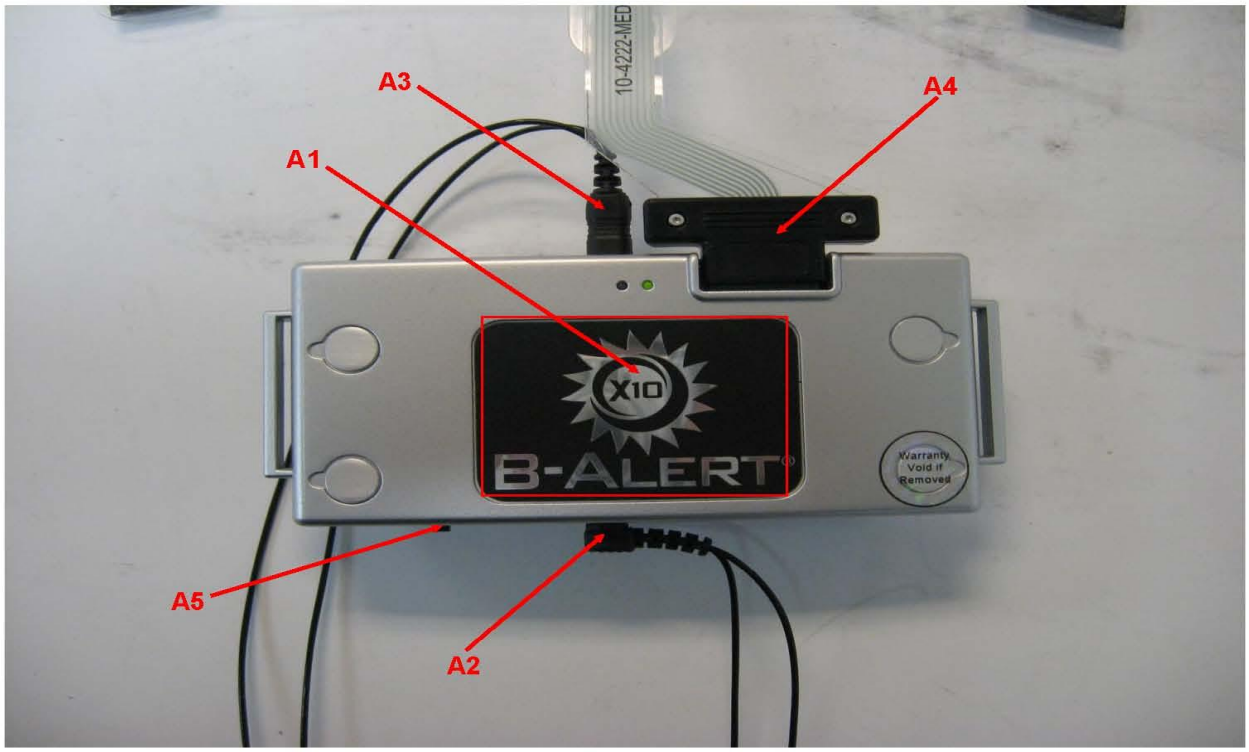
ESD IMMUNITY

Test Report #:	SC1010487	Test Area:	TR-1		
EUT Model #:	X10	Date:	December 21, 2010		
EUT Serial #:	101000003	EUT Power:	Battery 3.7 VDC	Temperature:	21.3 °C
Test Method:	EN61000-4-2			Air Pressure:	100.0 kPa
Customer:	Advanced Brain Monitoring Systems			Relative Humidity:	58.7 %
EUT Description:	B-Alert System			Page:	2 of 4
Notes:	Patient mode with calibration generator				
	ND = No Discharge				



Tested by: Lan Sayasane
Printed

Signature

Reviewed by: Stephen Rackleff
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Signature

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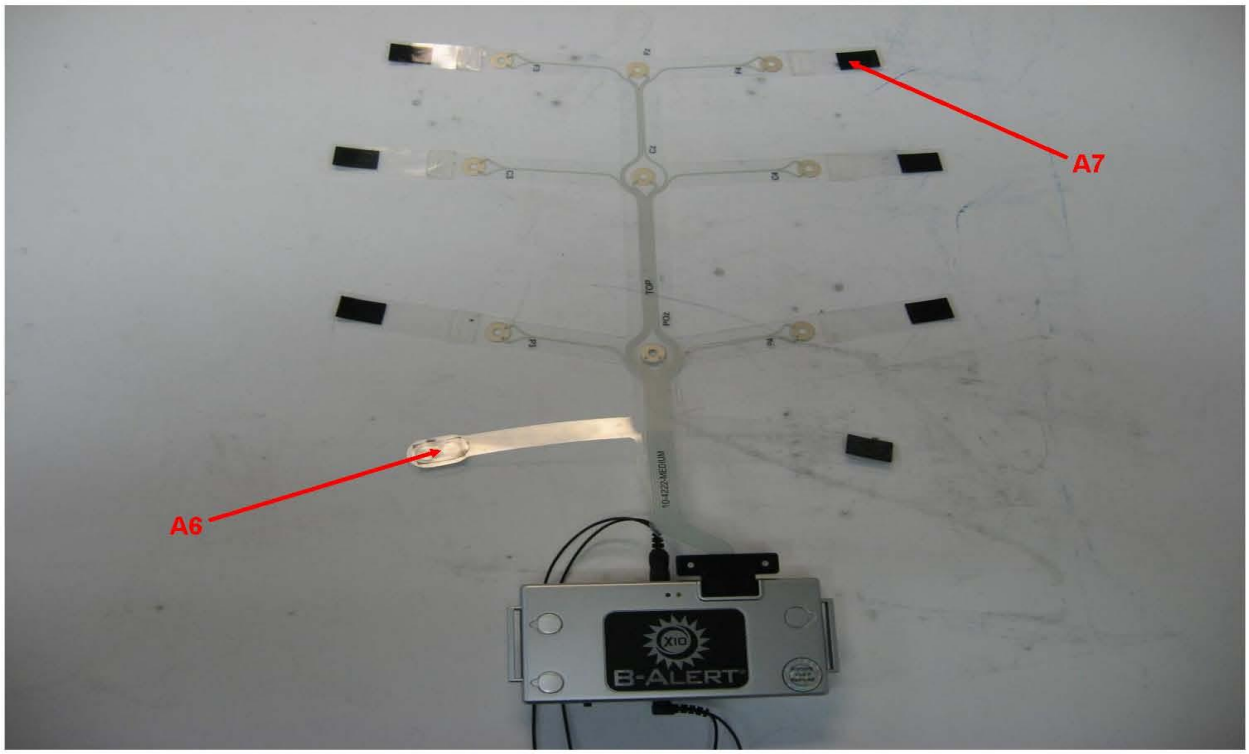
ESD IMMUNITY

Test Report #:	SC1010487	Test Area:	TR-1		
EUT Model #:	X10	Date:	December 21, 2010		
EUT Serial #:	101000003	EUT Power:	Battery 3.7 VDC	Temperature:	21.3 °C
Test Method:	EN61000-4-2			Air Pressure:	100.0 kPa
Customer:	Advanced Brain Monitoring Systems			Relative Humidity:	58.7 %
EUT Description:	B-Alert System			Page:	3 of 4
Notes:	Patient mode with calibration generator				
	ND = No Discharge				



Tested by: Lan Sayasane (Printed) _____ (Signature)

Reviewed by: Stephen Rackleff (Printed) _____ (Signature)

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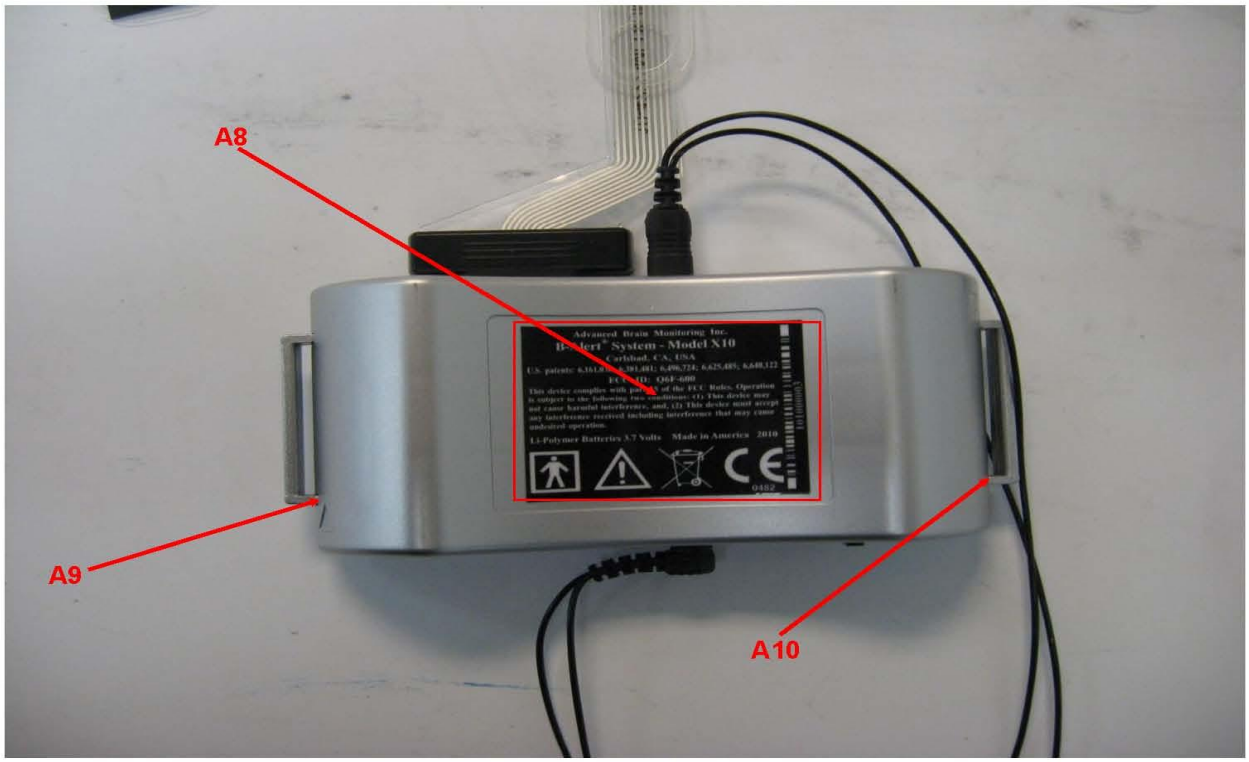
ESD IMMUNITY

Test Report #:	SC1010487	Test Area:	TR-1		
EUT Model #:	X10	Date:	December 21, 2010		
EUT Serial #:	101000003	EUT Power:	Battery 3.7 VDC	Temperature:	21.3 °C
Test Method:	EN61000-4-2			Air Pressure:	100.0 kPa
Customer:	Advanced Brain Monitoring Systems			Relative Humidity:	58.7 %
EUT Description:	B-Alert System			Page:	4 of 4
Notes:	Patient mode with calibration generator				
	ND = No Discharge				



Tested by: Lan Sayasane (Printed) _____ (Signature)

Reviewed by: Stephen Rackleff (Printed) _____ (Signature)

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RADIATED IMMUNITY

Test Report #: SC1010487 Test Area: SR-1

EUT Model #: X10 Date: Dec. 1 & 20, 2010

EUT Serial #: 101000003 EUT Power: Battery 3.7 VDC

Test Method: EN61000-4-3

Customer: Advanced Brain Monitoring Systems

EUT Description: B-Alert System

Notes: Patient mode with calibration generator

FACE DEFINITION (TOP VIEW)

T = Top
U = Under Side

B
L R
F (Front)

Temperature: 21.5 °C

Air Pressure: 100.6 kPa

Relative Humidity: 24.3 %

Page: 1 of 1

Test Frequency (MHz)	Test Level (V/m)	Modulation Type (See Key)	Field Polar. (H/V)	Antenna Dist. (Meters)	Step Size (%)	Dwell Time (sec.)	EUT Face	Complies Yes	Complies No	Criteria Met	Remarks
80-1000	3	4	V	3	1	3	F	✓		A	
80-1000	3	4	H	3	1	3	F	✓		A	
80-1000	3	4	H	3	1	3	L	✓		A	
80-1000	3	4	V	3	1	3	L	✓		A	
80-1000	3	4	V	3	1	3	R	✓		A	
80-1000	3	4	H	3	1	3	R	✓		A	
80-1000	3	4	H	3	1	3	B	✓		A	
80-1000	3	4	V	3	1	3	B	✓		A	
80-1000	3	4	V	3	1	3	T	✓		A	
80-1000	3	4	H	3	1	3	T	✓		A	
80-1000	3	4	H	3	1	3	U	✓		A	
80-1000	3	4	V	3	1	3	U	✓		A	
1000-2500	3	4	V	3	1	3	F	✓		A	
1000-2500	3	4	H	3	1	3	F	✓		A	
1000-2500	3	4	H	3	1	3	L	✓		A	
1000-2500	3	4	V	3	1	3	L	✓		A	
1000-2500	3	4	V	3	1	3	R	✓		A	
1000-2500	3	4	H	3	1	3	R	✓		A	
1000-2500	3	4	H	3	1	3	B	✓		A	
1000-2500	3	4	V	3	1	3	B	✓		A	
1000-2500	3	4	V	3	1	3	T	✓		A	
1000-2500	3	4	H	3	1	3	T	✓		A	
1000-2500	3	4	H	3	1	3	U	✓		A	
1000-2500	3	4	V	3	1	3	U	✓		A	

Tested by: Lan Sayasane
Printed

Signature

Reviewed by: Stephen Rackleff
Printed

Signature

Modulation Key

#	Type	Freq.	Shape	Duty	Depth
1	AM	1 kHz	Sine	N/A	80%
2	PM	200 Hz	Square	50%	100%
3	AM	2 Hz	Sine	N/A	80%
4	AM	10 Hz	Sine	N/A	80%
5					

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MAGNETIC FIELD IMMUNITY

Test Report #: SC1010487 Test Area: TR-2

EUT Model #: X10 Date: November 30, 2010

EUT Serial #: 101000003 EUT Power: Battery Temperature: 23.1 °C

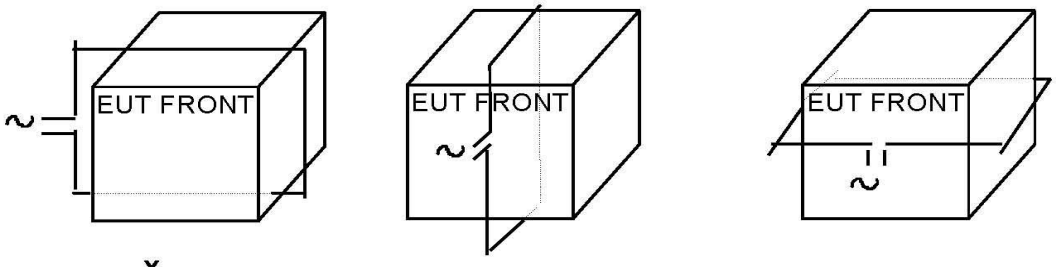
Test Method: EN61000-4-8 Air Pressure: 101.3 kPa

Customer: Advanced Brain Monitoring Systems Relative Humidity: 24.1 %

EUT Description: B-Alert System Page: 1 of 1

Notes: Patient mode with calibration generator

AXIS (X,Y,Z)	FIELD STRENGTH (A/m)	TIME FIELD APPLIED (SECONDS)	FREQUENCY OF MAG FIELD (Hz)	COMPLIES YES	COMPLIES NO	CRITERIA MET	REMARKS
X	3	60	50	✓		A	
Y	3	60	50	✓		A	
Z	3	60	50	✓		A	
X	3	60	60	✓		A	
Y	3	60	60	✓		A	
Z	3	60	60	✓		A	



X Y Z

Tested by: Lan Sayasane
Printed

Signature

Reviewed by: Stephen Rackleff
Printed

Signature

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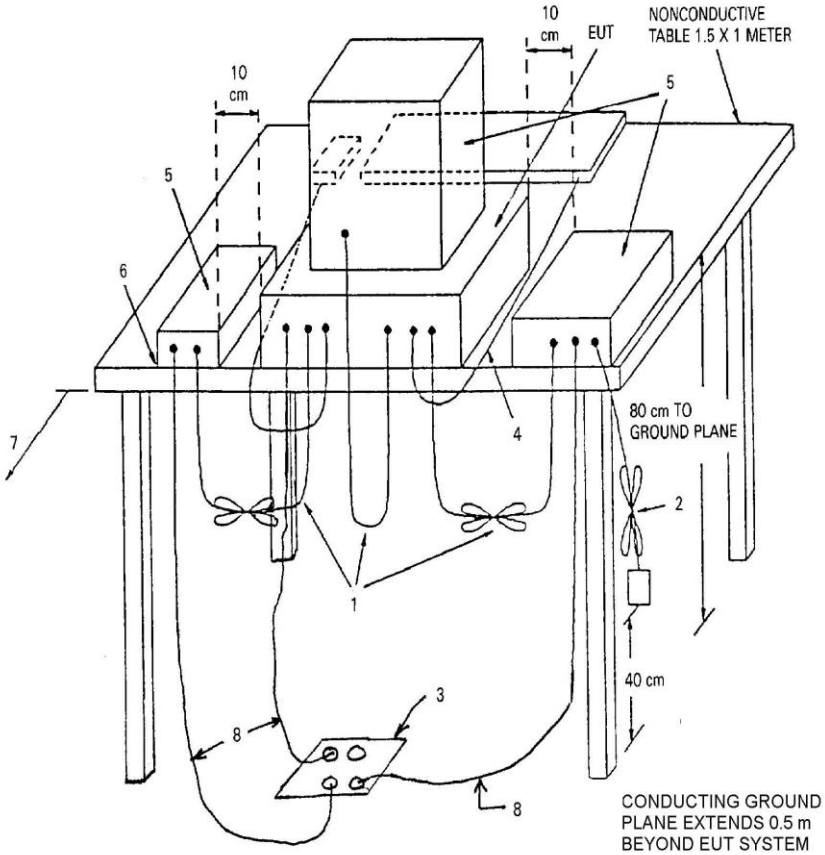
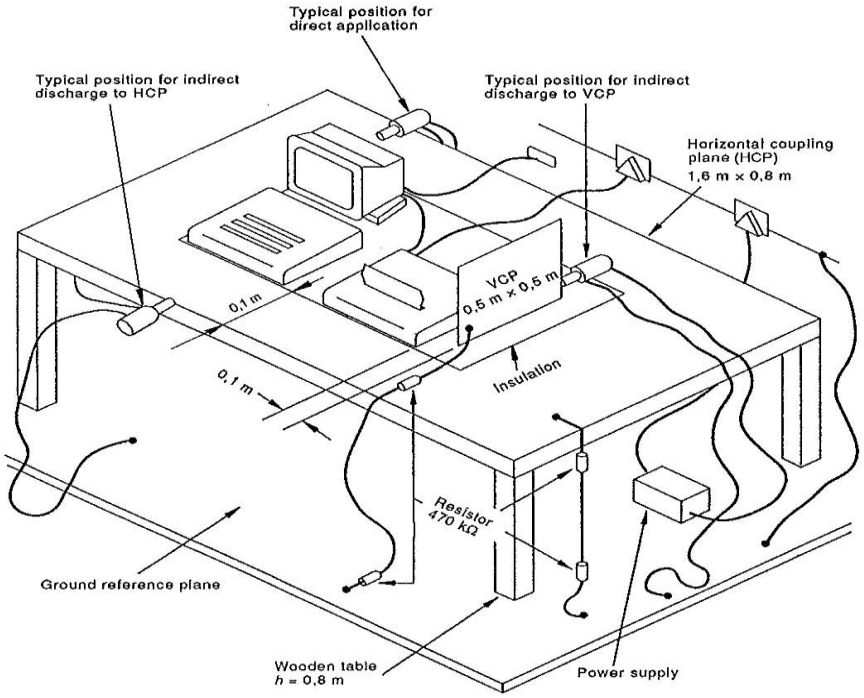
Radiated Emissions Test Setup, 30 to 1000 MHz

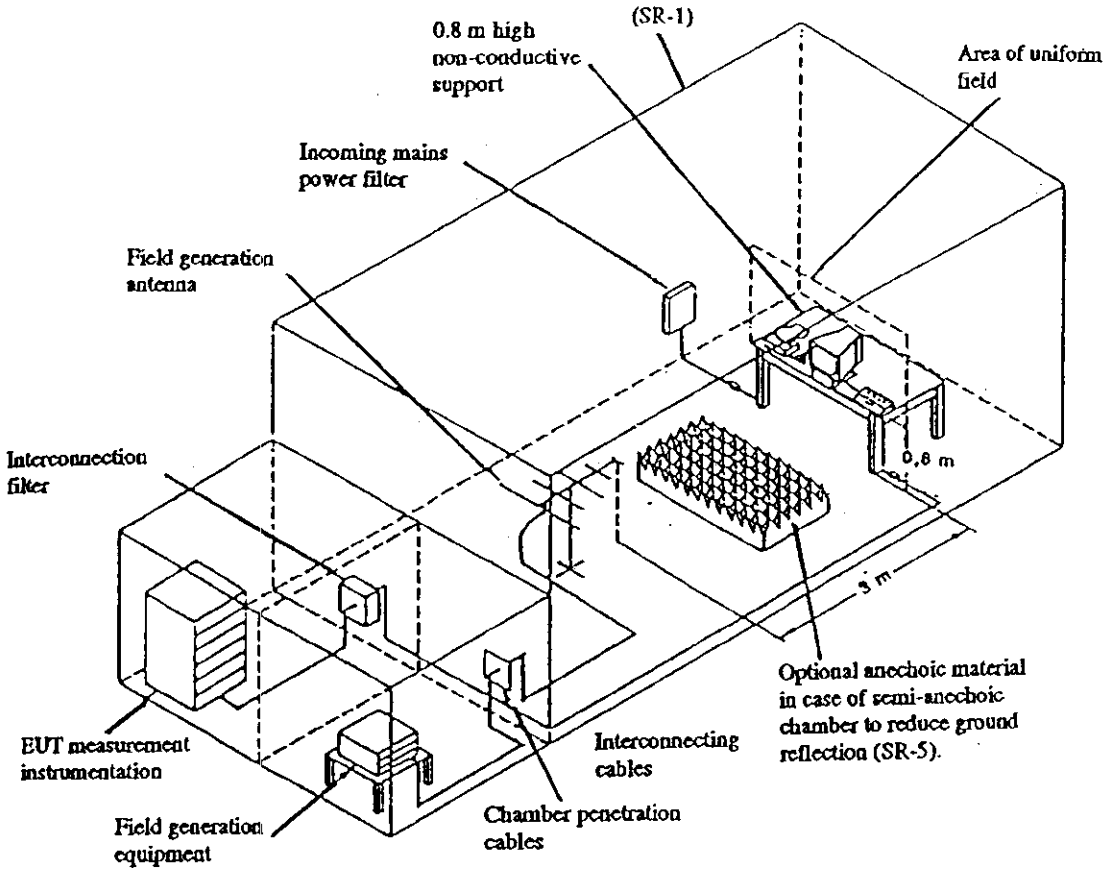


Test Configuration for ESD, Tabletop Unit



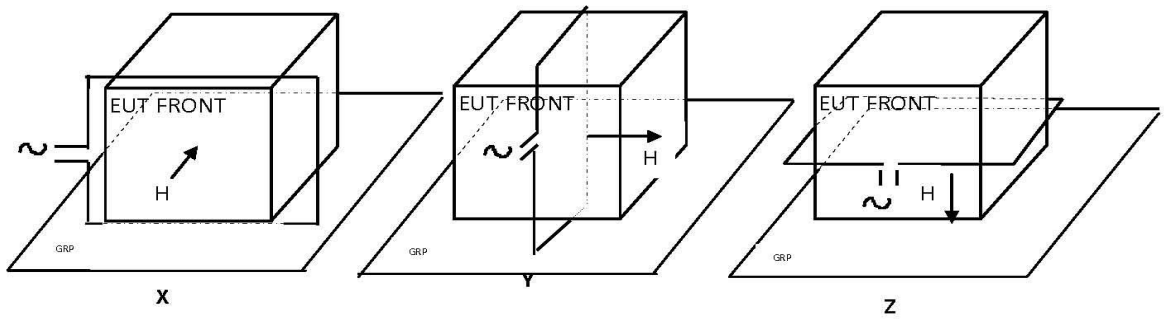
Dimensions in metres

Test Configuration for Radiated E Fields Immunity



NOTE - Anechoic lining material on walls and ceiling has been omitted for clarity.

Test Setup for Power Frequency Magnetic Field



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Appendix A

Test Setups
(Photographs)

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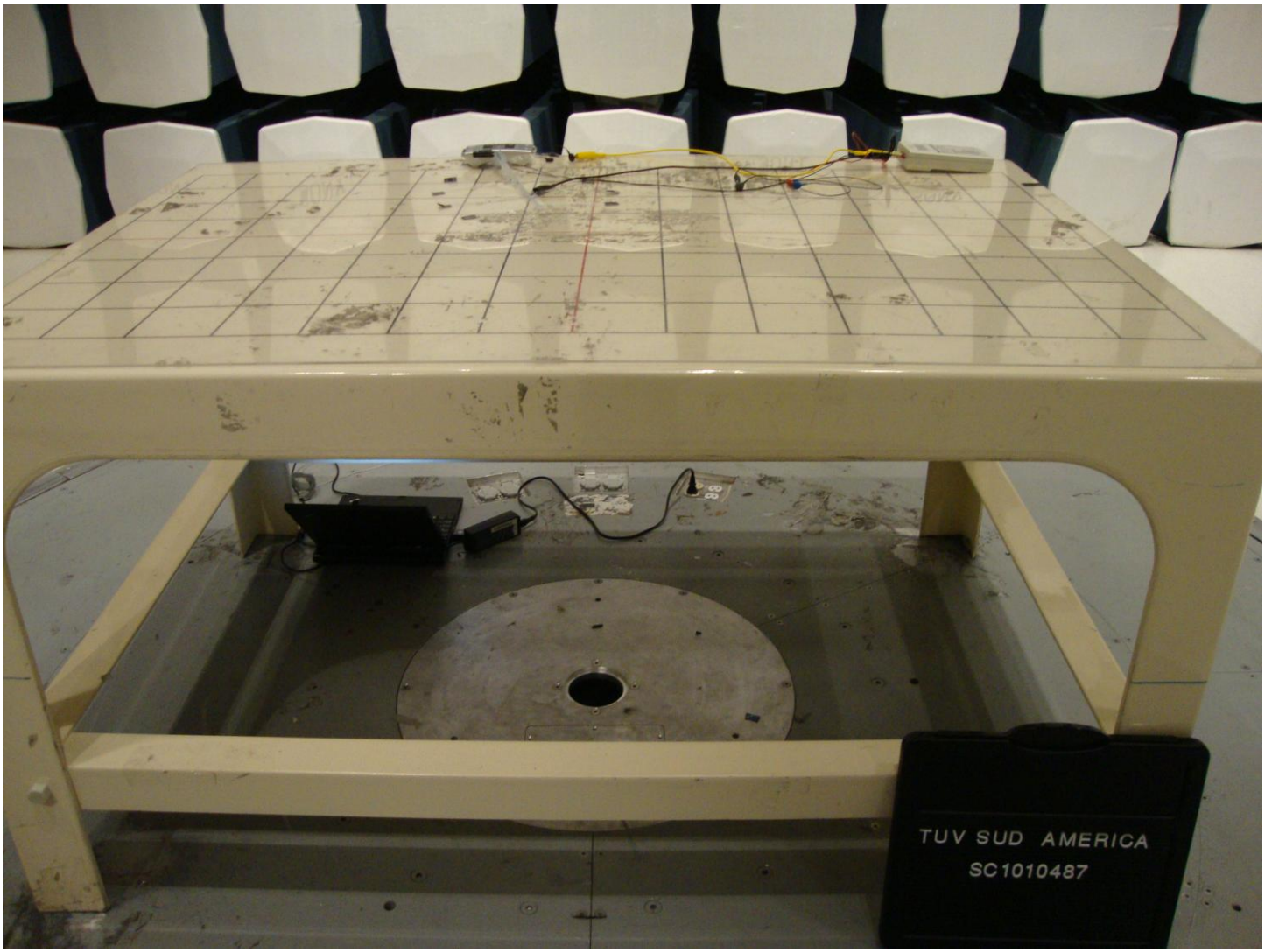
Photograph of Test Setup:
Radiated Emissions:



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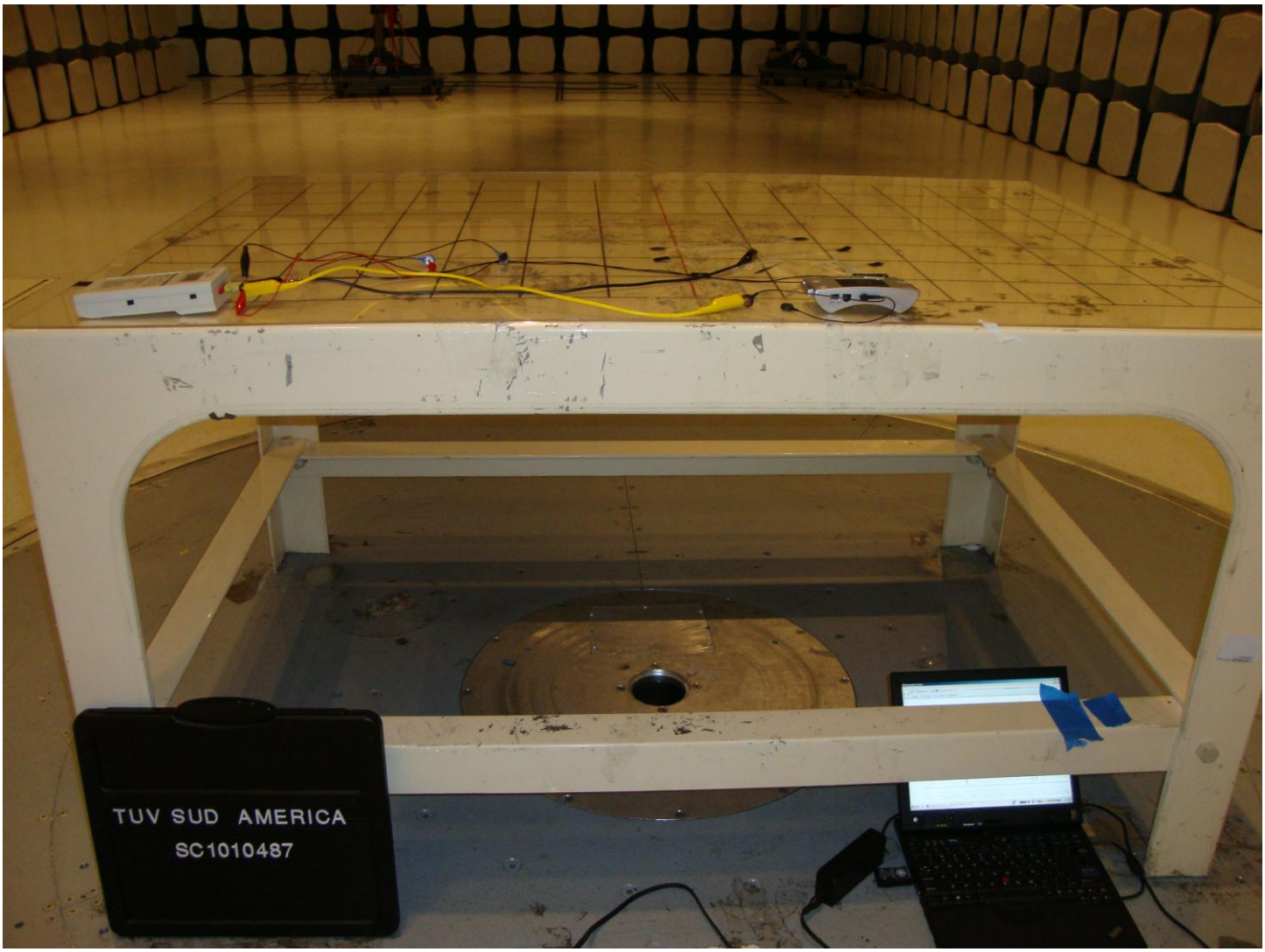
Photograph of Test Setup:
Radiated Emissions:



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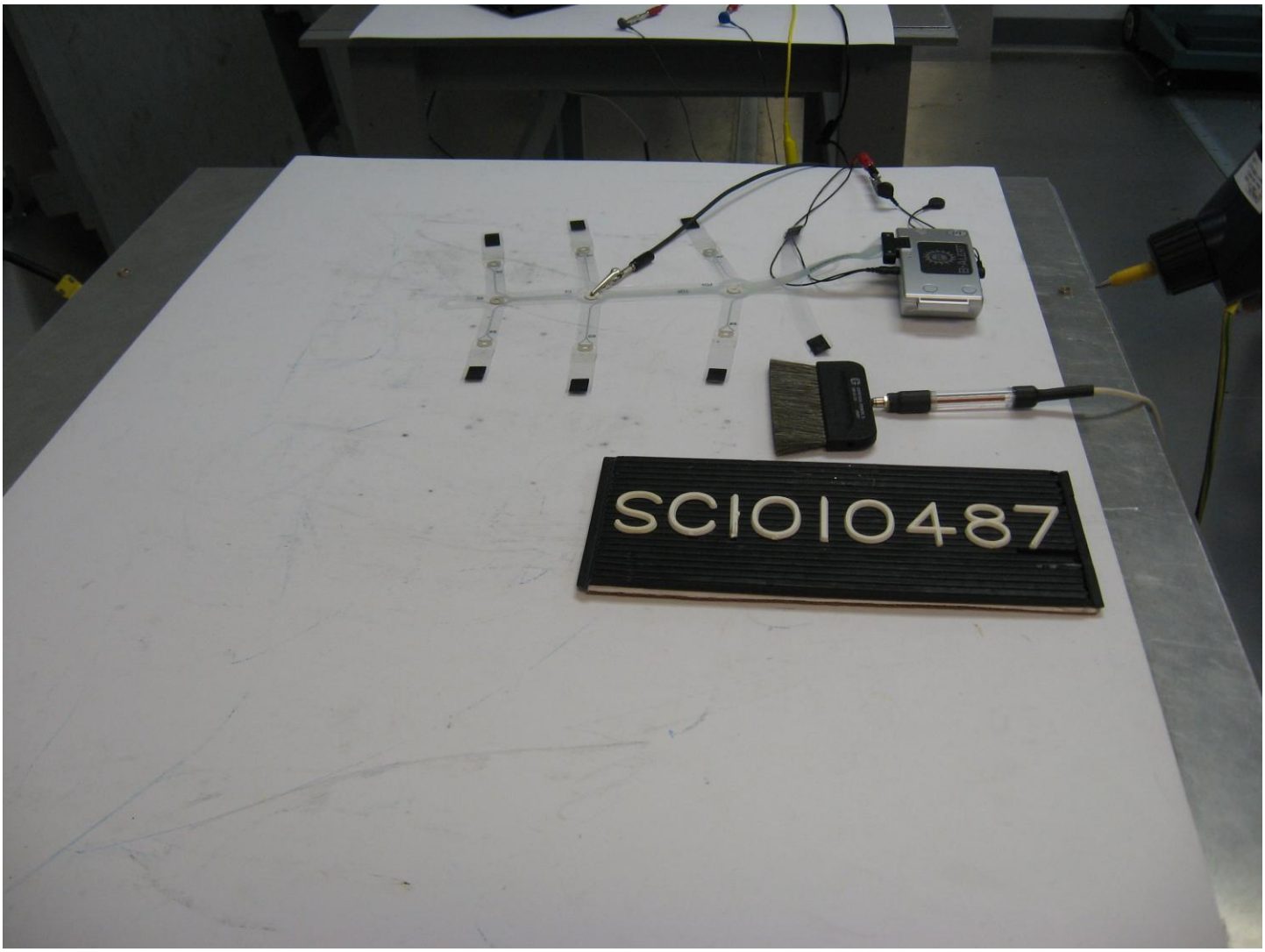
Photograph of Test Setup:
Electrostatic Discharge (ESD):



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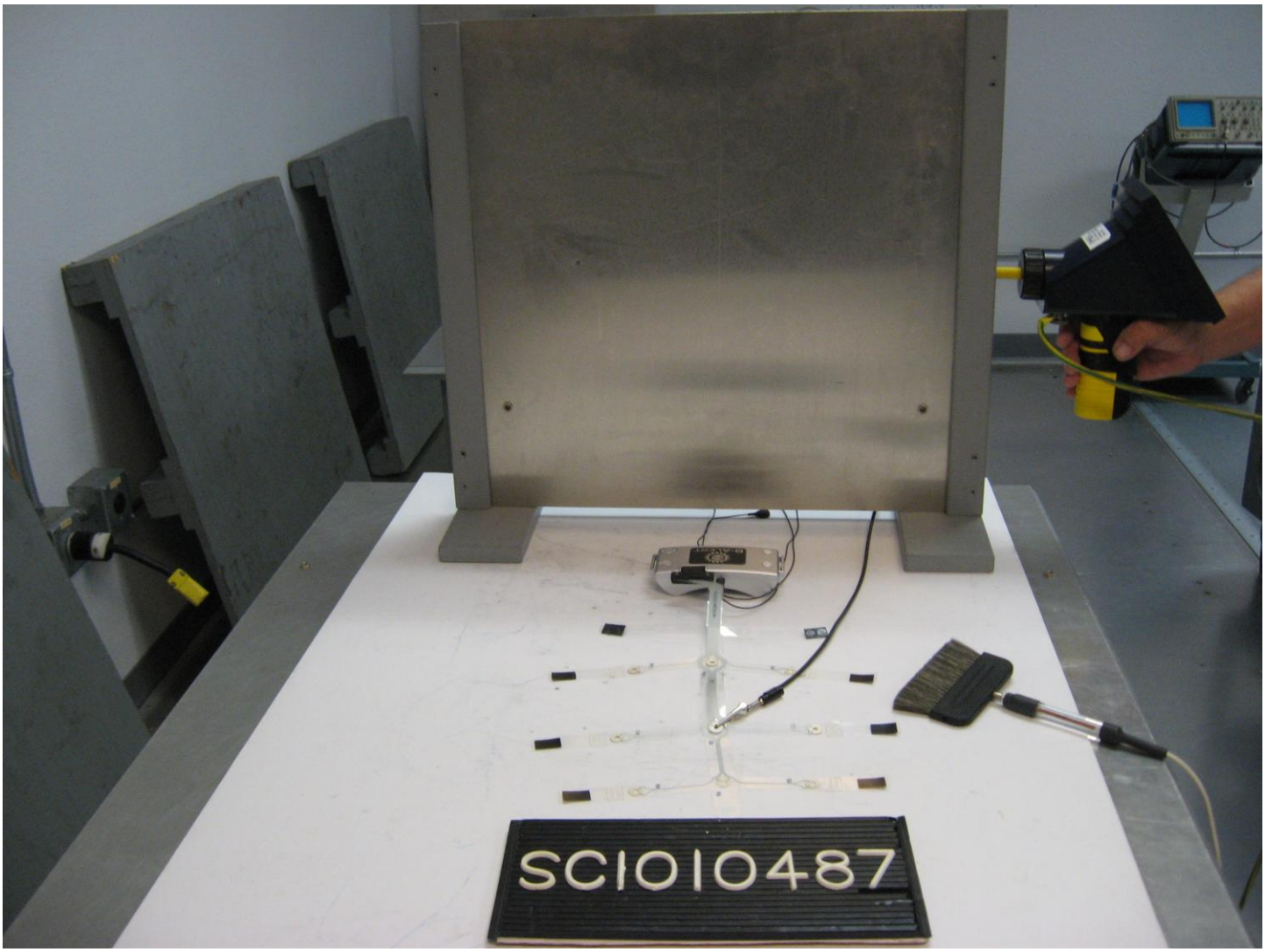
Photograph of Test Setup:
Electrostatic Discharge (ESD):



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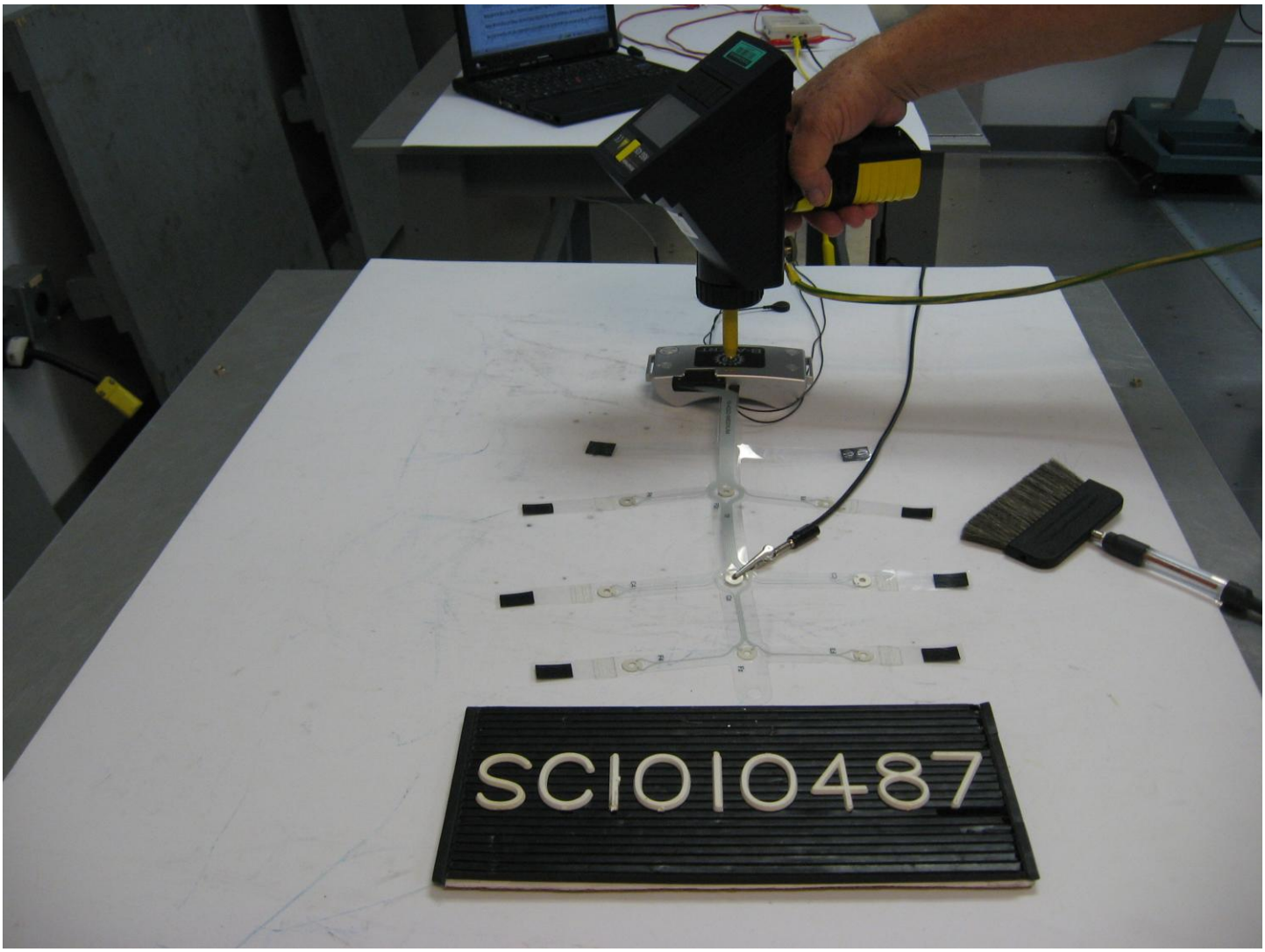
Photograph of Test Setup:
Electrostatic Discharge (ESD):



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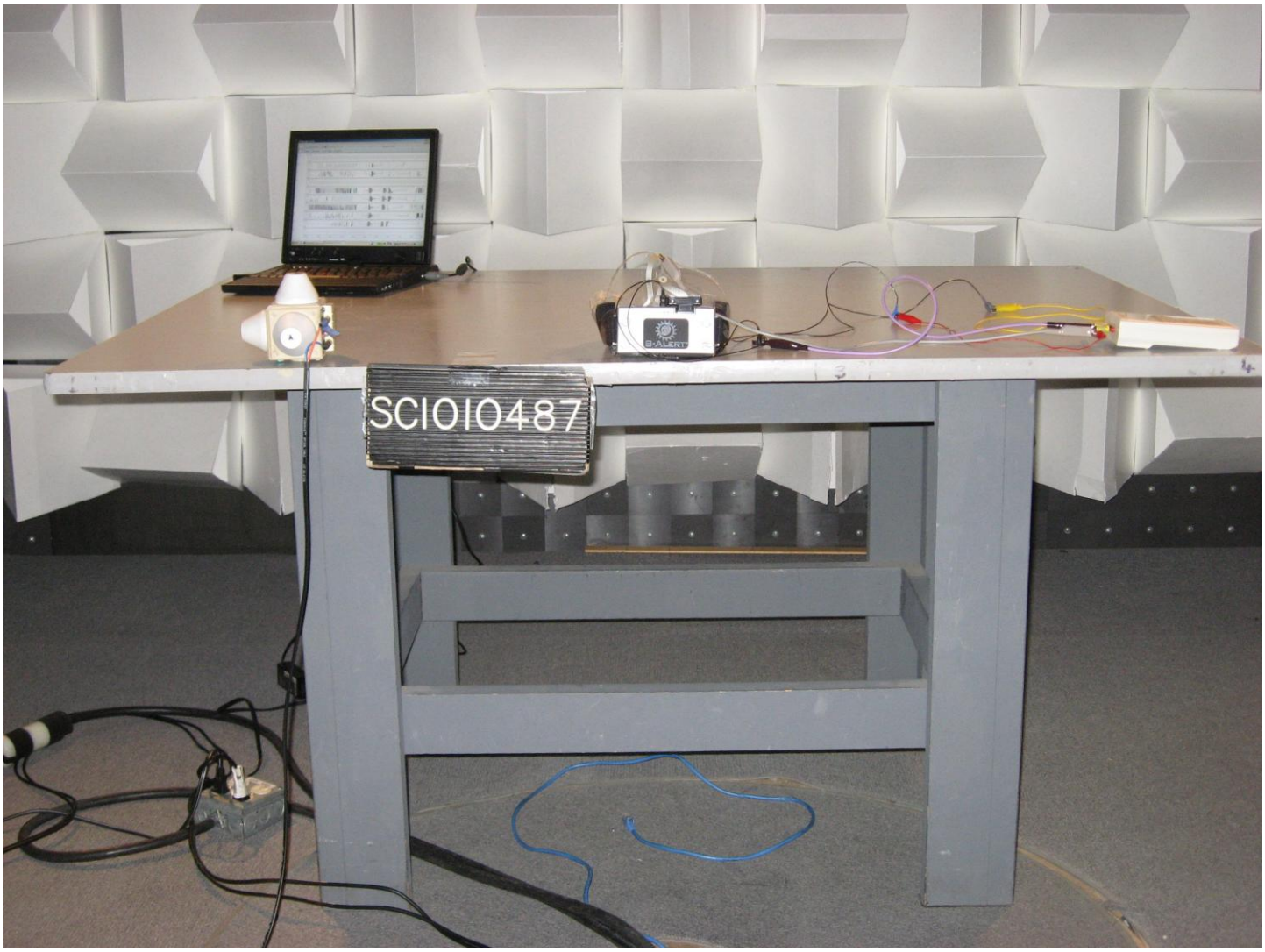
Photograph of Test Setup:
Radiated Electromagnetic Fields:



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Photograph of Test Setup:
Radiated Electromagnetic Fields:

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Photograph of Test Setup:
Power Frequency Magnetic Field:

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Appendix B

Product Information Form(s)

TÜV SÜD AMERICA INC 10040 Mesa Rim Road San Diego, CA 92121-2912 Phone: 858 678 1400 FAX: 858 546 0364

Form

EMC Test Plan and Constructional Data Form

PLEASE COMPLETE THIS DOCUMENT IN FULL, ENTERING N/A IF THE FIELD IS NOT APPLICABLE. IF TESTING RESULTS IN MODIFICATIONS TO THE EQUIPMENT, PLEASE SUBMIT A REVISED TP/CDF INDICATING THOSE MODIFICATIONS.
NOTE: This information will be input into your test report as shown below. Press the F1 key at any time to get HELP for the current field selected.

Company:	Advanced Brain Monitoring, Inc.		
Address:	2237 Faraday Avenue, Suite 100		
	Carlsbad, CA 92008		
Contact:	Gene Davis	Position:	Technical Sales and Services Director
Phone:	760-720-0099 x 6007	Fax:	760-476-3620
E-mail Address:	Gene@b-alert.com		

General Equipment Description -- ***NOTE: This information will be input into your test report as shown below.***

EUT Description	10 Channel System with 9 channels of EEG and 1 channel of ECG		
EUT Name	B-Alert X10		
Model No.:	X10	Serial No.:	101000003
Product Options:			
Configurations to be tested:			

Equipment Modification (***If applicable, indicate modifications since EUT was last tested. If modifications are made during this testing, submit revised TP/CDF after testing is complete.)***

Modifications since last test: _____

Modifications made during test: _____

Test Objective(s): ***Please indicate the tests to be performed, entering the applicable standard(s) where noted.***

- ☐ EMC Directive 2004/108/EC (EMC) Std: _____
- ☐ Machinery Directive 89/392/EEC (EMC) Std: _____
- ☒ Medical Device Directive 93/42/EEC (EMC) Std: _____
- ☐ Vehicle Directive: ☐ 2001/3/EC (EMC) ☐ 2004/104/EC (EMC) ☐ Other Vehicle Std: _____
- ☐ FDA Reviewers Guidance for Premarket Notification Submissions (EMC)

- ☐ FCC: Class ☐ A ☐ B Part _____
- ☐ VCCI: Class ☐ A ☐ B
- ☐ BSMI: Class ☐ A ☐ B (Separate Report)
- ☐ Canada: Class ☐ A ☐ B
- ☐ Australia: Class ☐ A ☐ B
- ☐ Other: _____

Third Party Certification, if applicable (*Signature on Page 6 Required)

- ☐ Attestation of Conformity (AoC)*
- ☐ Statement of Compliance (previously CoC)*
- Protection Class (N/A for vehicles) ☐ Class I ☐ Class II ☐ Class III
  (Press **F1** when field is selected to show additional information on Protection Class.)
- ☐ FCC / TCB Certification
- ☐ E-Mark Certification
- ☐ EMC Certification (used with Octagon Mark)*
- ☐ Compliance Document*
- ☐ Industry Canada / FCB Certification
- ☐ Taiwan Certification

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Form

EMC Test Plan and Constructional Data Form

Attendance

Test will be: ☐ Attended by the customer ☐ Unattended by the customer

Failure - *Complete this section if testing will not be attended by the customer.*

If a failure occurs, TÜV SÜD America should:

☒ Call contact listed above, if not available then stop testing. (After hrs phone): 760-716-8757

☐ Continue testing to complete test series.

☐ Continue testing to define corrective action.

☐ Stop testing.

EUT Specifications and Requirements

Length: 5" Width: 2 and 1/8" Height: 1 and 1/8" Weight: 4 ounces

Power Requirements

Regulations require testing to be performed at typical power ratings in the countries of intended use. (i.e., European power is typically 230 VAC 50 Hz or 400 VAC 50 Hz, single and three phase, respectively)

Voltage: Powered by 2 3.7V Lithium Ion Batteries (If battery powered, make sure battery life is sufficient to complete testing.)

# of Phases: 1

Current (Amps/phase(max)): 50mA Current (Amps/phase(nominal)): 40mA

Other

Other Special Requirements

Typical Installation and/or Operating Environment

(ie. Hospital, Small Business, Industrial/Factory, etc.)
Prepared, charged and applied at Health Care Facility by Trained Technician. Worn by patient at Health Care Facility.

EUT Power Cable

☐ Permanent OR ☐ Removable Length (in meters):

☐ Shielded OR ☐ Unshielded

☒ Not Applicable

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Form

EMC Test Plan and Constructional Data Form

EUT Interface Ports and Cables			During Test		Qty	Shielding								
Type	Analog	Digital	Active	Passive		Yes	No	Type	Termination	Connector Type	Port Termination	Length tested (in meters)	Removable	Permanent
EXAMPLE: *RS232*	☐	☒	☒	☐	*2*	☒	☐	*Foil over braid*	*Coaxial*	*Metallized 9-pin D-Sub*	*Characteristic Impedance*	*6*	☒	☐
B-Alert Dongle	☐	☒	☒	☐		☐	☒			USB A			☐	☐
USB A To Micro-B For Charging	☐	☒	☒	☐		☒	☐	Foil over braid		USB A and USB Micro-B		1	☐	☐
	☐	☐	☐	☐		☐	☐						☐	☐
	☐	☐	☐	☐		☐	☐						☐	☐
	☐	☐	☐	☐		☐	☐						☐	☐
	☐	☐	☐	☐		☐	☐						☐	☐
	☐	☐	☐	☐		☐	☐						☐	☐
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	☐	☐	☐	☐		☐	☐						☐	☐
	☐	☐	☐	☐		☐	☐						☐	☐
	☐	☐	☐	☐		☐	☐						☐	☐

FILE: EMCU_F09.02E, REVISION 10, Effective: 20 Feb 2008 Page 3 of 6

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Form

EMC Test Plan and Constructional Data Form

EUT Software.

Revision Level: ROME 2.0.2, ATHENA 2.0.2

Description: Software is used for connecting to and acquiring data from the wireless EEG Headset

Equipment Under Test (EUT) Operating Modes to be Tested -- list the operating modes to be used during test. It is recommended the equipment be tested while operating in a typical operation mode. FCC testing of personal computers and/or peripherals requires that a simple program generate a complete line of upper case H's. Provide a general description of all software, firmware, and PLD algorithms used in the equipment. List all code modules as described above, with the revision level used during testing. Consult with your TÜV Product Service Representative if additional assistance is required.

1. Acquisition
2. Battery Charging
3.

Equipment Under Test (EUT) System Components -- List and describe all components which are part of the EUT. For FCC & Taiwan testing a minimum configuration is required. (ie. Mouse, Printer, Monitor, External Disk Drive, Motherboard, etc)

Description	Model #	Serial #	FCC ID #
B-Alert X10	X10	101000003	????

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Form

EMC Test Plan and Constructional Data Form

Support Equipment -- List and describe all support equipment which is not part of the EUT. (i.e. peripherals, simulators, etc) This information is required for FCC & Taiwan testing.

Description	*Model #*	*Serial #*	*FCC ID #*
Charging Kit for Headset	EK-5200	NA	

Oscillator Frequencies

Manufacturer	*Frequency*	*Derived Frequency*	*Component # / Location*	*Description of Use*
Citizen	5.0688MHz	5.0688MHz	Q1	Main processor oscillator clock

Power Supply

Manufacturer	*Model #*	*Serial #*	*Type*
NA - battery Powered			☐ Switched-mode: (Frequency) _____ ☐ Linear ☐ Other: _____
			☐ Switched-mode: (Frequency) _____ ☐ Linear ☐ Other: _____

Power Line Filters

Manufacturer	*Model #*	*Location in EUT*
NA - battery powered		

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Form

EMC Test Plan and Constructional Data Form

Critical EMI Components (Capacitors, ferrites, etc.)

Description	*Manufacturer*	*Part # or Value*	*Qty*	*Component # / Location*
Ferrite	Murata	BLM18BN252SN1D	2	L1,L2

EMC Critical Detail -- Describe other EMC Design details used to reduce high frequency noise.

All ferrite parts are used to reduce EMI.

PLEASE ENTER NAMES BELOW (INSERT ELECTRONIC SIGNATURE IF POSSIBLE)

Authorization (Signature Required if a Third Party Certification is checked on pg 1)

Gene Davis	November 29, 2010
Customer authorization to perform tests according to this test plan.	Date
Gene Davis	November 29, 2010
Test Plan/CDF Prepared By (please print)	Date

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Appendix C

Change History

Not Applicable

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Appendix D

Supplemental Information

Not Applicable

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