EMC - TEST REPORT

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

Test Report File No.	:	**SC1010487B-01-02** Date of Issue: **17 January 2011**
Model / Serial No.	:	**MODEL: X10 / S/N: 101000003**
Product Type	:	**B-ALERT SYSTEM**
Configuration Test Mode	:	**CHARGE 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	:	**SC1010487B**
Total pages - Test Report	:	**72**

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

DIRECTORY
Test Report

Technical Documentation

Appendices

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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**

■ - SR-3, Shielded Room, 12' x 20' x 8', Metal Chamber

Test Equipment Used:

Model No.:	Prop. No.:	Description:	Manufacturer:	Serial No./Version No.:
ESHS 20	2534	EMI Test Receiver	Rohde & Schwarz	837055/003
CAT-20	8634	20 dB Attenuator	Mini-Circuits	--
FCC-LISN-50-25-2	6837	LISN	Fisher Custom Comm.	5025
ESHS 20	--	Test Software	Rohde & Schwarz	3.21

Limit margin:	110 VAC / 60 Hz	-10.2 dB	at	1.025	MHz
Limit margin:	230 VAC / 50 Hz	-5.6 dB	at	0.15	MHz

Result:
■ - Pass ☐ - Fail

OPERATING MODE DESCRIPTION: Charge Mode with Laptop USB Port

Remarks: One year calibration cycle for all test equipment.

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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:	Charge Mode with Laptop USB Port
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:	Charge Mode through Laptop. Testing Not Applicable.

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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:	Charge Mode through Laptop. 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	6783	ESD Simulator System	Schaffner	387
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: Charge Mode with Laptop USB Port

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: Charge Mode with Laptop USB Port

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

■ - TR-1, Test Room, 20.5' x 17' x 9'

Test Equipment Used:

Model No.:	Prop. No.:	Description:	Manufacturer:	Serial No./Version No.:
EMC-PRO	6531	Advanced EMC Test System	Keytek	9912299
CEWare32	--	Test Software	Thermo Electron Corporation	4.0

Test Specification:

Pulse Amplitude - AC Power Port:	■ - 1.0 kV ☐ - 4.0 kV	☐ - 2.0 kV ■ - 0.5 kV	
Pulse Amplitude - DC Power Port:	☐ - 1.0 kV ☐ - 4.0 kV	☐ - 2.0 kV ☐ - ___ kV	
Pulse Amplitude - Signal/Data Non control Port:	☐ - 0.5 kV ☐ - 2.0 kV	☐ - 1.0 kV ☐ - ___ kV	
Pulse Amplitude - Process Measurement & Control Port:	☐ - 0.5 kV ☐ - 2.0 kV	☐ - 1.0 kV ☐ - ___ kV	
Burst Frequency:	☐ - 2.5 kHz	■ - 5.0 kHz	☐ - ___ kHz
Time of Coupling:	■ - 60 seconds	☐ - ___ seconds	
Coupling Method:	■ - Coupling/decoupling network		☐ - Coupling clamp
Polarity:	■ - Positive	■ - Negative	

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Test Conditions: FAST TRANSIENTS (BURST), continued

Location of Coupling:

Name of lines:	AC MAINS	
Type of lines:	☐ - shielded	■ - unshielded
Status of lines:	☐ - passive	■ - active
Kind of transmission:	■ - analog	☐ - digital
Length of lines:	1 meter	

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: Charge Mode with AC adapter

Remarks:

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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:	Charge Mode through Laptop. Testing Not Applicable.

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Test Conditions: CONDUCTED DISTURBANCE

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

☐ - Test not applicable

■ - TR-, Test Room, 16' x 7.5' x 9'

Test Equipment Used:

Model No.:	Prop. No.:	Description:	Manufacturer:	Serial No./Version No.:
FCC-801-M3-25	6514	Coupling/Decoupling Network	Fischer Custom Comm.	49
F2031-32MM	6830	EM Clamp	Fischer Custom Comm.	475
C5086	6591	Directional Coupler	Werlatone Inc.	2422
8648C	7544	Signal Generator	Hewlett Packard	3426A00529
500A100	6607	Power Amplifier	Amplifier Research	14938
436A	6436	Power Meter	Hewlett Packard	1918A05312
8482A	6826	Power Sensor	Hewlett Packard	3318A23844
50FHA0-006-250	7526	Attenuator	JFW	--
C3	--	Test Software	TESEQ	4.01.0 Build 0

Test Specification:

Frequency Range:	■ - 0.15 MHz - 80 MHz		☐ - 0.15 MHz - 230 MHz	
Voltage Level (EMF):	☐ - 1 V	■ - 3 V	☐ - 10 V	☐ - ___ V
Modulation:	■ - AM: ☐ - Un-Modulated ■ - Sine Wave:	☐ - FM: ☐ - Pulse	■ - 80 % ON/OFF	■ - 1 kHz Duty Cycle: ___ %
Step:	☐ - 1 second dwell	■ - 3 seconds dwell	■ - 1%	

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Test Conditions: CONDUCTED DISTURBANCE, continued

Location of Coupling:

Name of lines:	USB Cable	
Type of lines:	■ - shielded	☐ - unshielded
Status of lines:	☐ - passive	■ - active
Kind of transmission:	☐ - analog	■ - digital
Length of lines:	1 meter	

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: Charge Mode with Laptop USB Port

Remarks:

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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: Charge Mode with Laptop USB Port

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:	Charge Mode through Laptop. Testing Not Applicable.

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Equipment Under Test (EUT) Test Operation Mode:

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

Charge Mode:

- Charge Mode with Laptop USB port
- Charge Mode with AC adapter (EFT Only)

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:

Charge Mode:

- Charge Mode with Laptop USB port
- Charge Mode with AC adapter (EFT Only)

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: 14 January 2011

- TÜV SÜD AMERICA, INC. -

Reviewing Engineer:

David Gray,
(Senior EMC Engineer)

Test Engineer:

Lan Sayasane,
(EMC Technician)

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Technical Documentation

Test Data Sheets

and

Test Setup Drawing(s)

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TUV America
Conducted Emissions

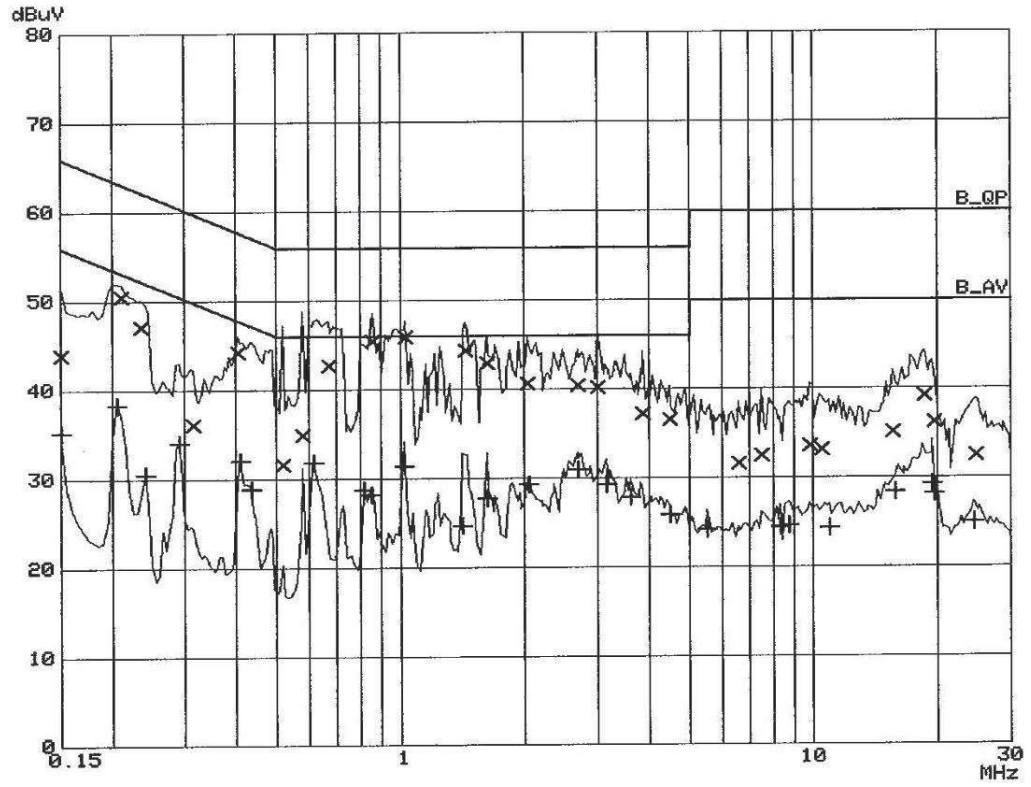
EUT: B-Alert X10
Manuf: Advanced Brain Monitoring Systems
Op Cond: Charge mode with Laptop USB port
Operator: Lan Sayasane
Test Spec: EN55011 Class B
Comment: 110Vac 60Hz Line 1
SC1010487
Date: 30. Nov 10 10:32

Scan Settings (2 Ranges)

Frequencies			Receiver Settings				
Start	Stop	Step	IF BW	Detector	M-Time	Atten	Preamp	OpRge
150k	1M	5k	10k	PK+AV	100ms	AUTO	LN OFF	60dB
1M	30M	5k	10k	PK+AV	2ms	AUTO	LN OFF	60dB

Transducer No.	Start	Stop	Name
1	9k	30M	20dBLISN

Final Measurement: x QP / + AV
Meas Time: 1 s
Subranges: 25
Acc Margin: 25dB



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TUV America
Conducted Emissions

EUT: B-Alert X10
Manuf: Advanced Brain Monitoring Systems
Op Cond: Charge mode with Laptop USB port
Operator: Lan Sayasane
Test Spec: EN55011 Class B
Comment: 110Vac 60Hz Line 1
SC1010487
Date: 30. Nov 10 10:32

Final Measurement Results:

Frequency MHz	QP Level dBuV	QP Limit dBuV
0.15000	44.0	66.0
0.21000	50.5	63.2
0.23500	47.1	62.3
0.31500	36.1	59.8
0.40500	44.2	57.8
0.52000	31.6	56.0
0.58000	34.9	56.0
0.67000	42.7	56.0
0.85500	45.4	56.0
1.02500	45.8	56.0
1.44000	44.3	56.0
1.62000	42.9	56.0
2.03500	40.6	56.0
2.68500	40.4	56.0
3.00000	40.2	56.0
3.86500	37.2	56.0
4.49000	36.6	56.0
6.58500	31.6	60.0
7.50500	32.5	60.0
9.77500	33.6	60.0
10.47500	33.2	60.0
15.61000	35.1	60.0
18.64500	39.2	60.0
19.66500	36.2	60.0
24.68500	32.5	60.0

Frequency MHz	AV Level dBuV	AV Limit dBuV
0.15000	35.2	56.0
0.20500	38.3	53.4
0.24000	30.5	52.1
0.29000	34.0	50.6
0.41000	32.1	47.7
0.43500	28.9	47.2
0.61500	31.9	46.0
0.81500	28.8	46.0
0.85000	28.2	46.0
1.02000	31.4	46.0
1.41000	24.6	46.0
1.62000	27.7	46.0
2.04500	29.2	46.0

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TUV America
Conducted Emissions

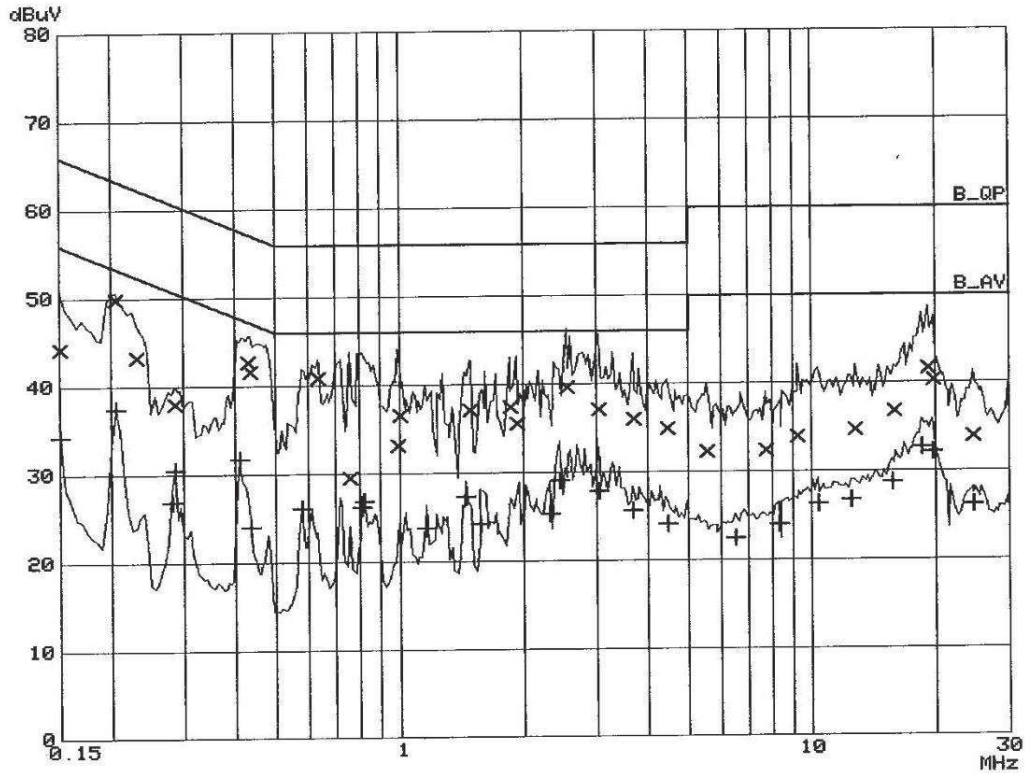
EUT:	B-Alert X10
Manuf:	Advanced Brain Monitoring Systems
Op Cond:	Charge mode with Laptop USB port
Operator:	Lan Sayasane
Test Spec:	EN55011 Class B
Comment:	110Vac 60Hz Line 2
	SC1010487
Date:	30. Nov 10 10:43

Scan Settings (2 Ranges)

Frequencies			Receiver Settings				
Start	Stop	Step	IF BW	Detector	M-Time	Atten	Preamp	OpRge
150k	1M	5k	10k	PK+AV	100ms	AUTO	LN OFF	60dB
1M	30M	5k	10k	PK+AV	2ms	AUTO	LN OFF	60dB

Transducer No.	Start	Stop	Name
1	9k	30M	20dBLISN

Final Measurement: x QP / + AV
Meas Time: 1 s
Subranges: 25
Acc Margin: 25dB



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

TUV America
Conducted Emissions

EUT: B-Alert X10
Manuf: Advanced Brain Monitoring Systems
Op Cond: Charge mode with Laptop USB port
Operator: Lan Sayasane
Test Spec: EN55011 Class B
Comment: 110Vac 60Hz Line 2
SC1010487
Date: 30. Nov 10 10:43

Final Measurement Results:

Frequency MHz	QP Level dBuV	QP Limit dBuV
0.15000	44.2	66.0
0.20500	49.8	63.4
0.23000	43.3	62.4
0.28500	38.0	60.7
0.43000	42.8	57.3
0.43500	41.6	57.2
0.63500	40.8	56.0
0.75500	29.5	56.0
0.99000	33.1	56.0
1.00000	36.6	56.0
1.48000	37.1	56.0
1.85500	37.4	56.0
1.92000	35.6	56.0
2.54500	39.6	56.0
3.04000	37.1	56.0
3.69500	36.0	56.0
4.45500	34.9	56.0
5.54500	32.2	60.0
7.73500	32.4	60.0
9.24500	33.9	60.0
12.74500	34.6	60.0
15.86000	36.7	60.0
19.12000	41.6	60.0
19.70500	40.3	60.0
24.56000	33.9	60.0

Frequency MHz	AV Level dBuV	AV Limit dBuV
0.15000	34.2	56.0
0.20500	37.4	53.4
0.28000	26.8	50.8
0.28500	30.5	50.7
0.41000	31.7	47.7
0.43500	23.9	47.2
0.58000	26.1	46.0
0.81000	26.2	46.0
0.82000	26.9	46.0
1.16000	23.8	46.0
1.44500	27.3	46.0
1.56500	24.2	46.0
2.31500	25.3	46.0

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