

Boston Scientific Neuromodulation

Implantable Pulse Generator Model SC-1132

Report No. BOSN0010.3

Report Prepared By



www.nwemc.com
1-888-EMI-CERT

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EMC Test Report



22975 NW Evergreen Parkway
Suite 400
Hillsboro, Oregon 97124

Certificate of Test
Last Date of Test: May 24, 2011
Boston Scientific Neuromodulation
Model: SC-1132

Emissions			
Test Description	Specification	Test Method	Pass/Fail
Field Strength of Fundamental	FCC 15.209:2011	ANSI C63.10:2009	Pass
Field Strength of Spurious Emissions	FCC 15.209:2011	ANSI C63.10:2009	Pass

Modifications made to the product

See the Modifications section of this report

Test Facility

The measurement facility used to collect the data is located at:

Northwest EMC, Inc.
41 Tesla Ave.
Irvine, CA 92618

Phone: (503) 844-4066 Fax: 844-3826

This site has been fully described in a report filed with and accepted by the FCC (Federal Communications Commission) and Industry Canada (Site filing #2834B-1).

Approved By:

Tim O'Shea, Operations Manager



NVLAP Lab Code: 200676-0

This report must not be used to claim product certification, approval, or endorsement by NVLAP, NIST, or any agency of the federal government of the United States of America.

Product compliance is the responsibility of the client, therefore the tests and equipment modes of operation represented in this report were agreed upon by the client, prior to testing. This Report may only be duplicated in its entirety. The results of this test pertain only to the sample(s) tested. The specific description is noted in each of the individual sections of the test report supporting this certificate of test.

Revision Number	Description	Date	Page Number
00	None		

Barometric Pressure

The recorded barometric pressure has been normalized to sea level.



Accreditations and Authorizations

FCC

Accredited by NVLAP for performance of FCC radio, digital, and ISM device testing. Our Open Area Test Sites, certification chambers, and conducted measurement facilities have been fully described in reports filed with the FCC and accepted by the FCC in letters maintained in our files. Northwest EMC has been accredited by ANSI to ISO / IEC Guide 65 as a product certifier. We have been designated by the FCC as a Telecommunications Certification Body (TCB). This allows Northwest EMC to certify transmitters to FCC specifications in accordance with 47 CFR 2.960 and 2.962.

NVLAP

Northwest EMC, Inc. is accredited under the National Voluntary Laboratory Accreditation Program (NVLAP) for satisfactory compliance with the requirements of ISO/IEC 17025 for Testing Laboratories. NVLAP is administered by the National Institute of Standards and Technology (NIST), an agency of the U.S. Commerce Department. The NVLAP accreditation encompasses Electromagnetic Compatibility Testing in accordance with the European Union EMC Directive 2004/108/EC, and ANSI C63.4. Additionally, Northwest EMC is accredited by NVLAP to perform radio testing in accordance with the European Union R&TTE Directive 1999/5/EEC, the requirements of FCC, and the RSS radio standards for Industry Canada.

Industry Canada

Accredited by NVLAP for performance of Industry Canada RSS and ICES testing. Our Open Area Test Sites and certification chambers comply with RSS-Gen, Issue 2 and have been filed with Industry Canada and accepted. Northwest EMC has been accredited by ANSI to ISO / IEC Guide 65 as a product certifier. We have been designated by NIST and recognized by Industry Canada as a Certification Body (CB) per the APEC Mutual Recognition Arrangement (MRA). This allows Northwest EMC to certify transmitters to Industry Canada technical requirements. (*Site Filing Numbers - Hillsboro: 2834D-1, 2834D-2, Sultan: 2834C-1, Irvine: 2834B-1, 2834B-2, Brooklyn Park: 2834E-1*)

CAB

Designated by NIST and validated by the European Commission as a Conformity Assessment Body (CAB) to conduct tests and approve products to the EMC directive and transmitters to the R&TTE directive, as described in the U.S. - EU Mutual Recognition Agreement.

Australia/New Zealand

The National Association of Testing Authorities (NATA), Australia has been appointed by the ACA as an accreditation body to accredit test laboratories and competent bodies for EMC standards. Accredited test reports or assessments by competent bodies must carry the NATA logo. Test reports made by an overseas laboratory that has been accredited for the relevant standards by an overseas accreditation body that has a Mutual Recognition Agreement (MRA) with NATA are also accepted as technical grounds for product conformity. The report should be endorsed with the respective logo of the accreditation body (NVLAP).



Accreditations and Authorizations

VCCI

Accepted as an Associate Member to the VCCI, Acceptance No. 564. Conducted and radiated measurement facilities have been registered in accordance with Regulations for Voluntary Control Measures, Article 8. *(Registration Numbers. - Hillsboro: C-1071, R-1025, G-84, C-2687, T-1658, and R-2318, Irvine: R-1943, G-85, C-2766, and T-1659, Sultan: R-871, G-83, C-1784, and T-1511, Brooklyn Park: R-3125, G-86, G-141, C-3464, and T-1634).*

BSMI

Northwest EMC has been designated by NIST and validated by C-Taipei (BSMI) as a CAB to conduct tests as described in the APEC Mutual Recognition Agreement (US0017).

GOST

Northwest EMC, Inc. has been assessed and accredited by the Russian Certification bodies Certinform VNIINMASH, CERTINFO, SAMTES, and Federal CHEC, to perform EMC and Hygienic testing for Information Technology Products. As a result of their laboratory assessment, they will accept test results from Northwest EMC, Inc. for product certification

KCC

Northwest EMC, Inc is a CAB designated by MRA partners and recognized by Korea. *(Assigned Lab Numbers: Hillsboro: US0017, Irvine: US0158, Sultan: US0157, Brooklyn Park: US0175)*

VIETNAM

Vietnam MIC has approved Northwest EMC as an accredited test lab. Per Decision No. 194/QD-QLCL (dated December 15, 2009), Northwest EMC test reports can be used for Vietnam approval submissions.

SCOPE

For details on the Scopes of our Accreditations, please visit:

<http://www.nwemc.com/accreditations/>



Northwest EMC Locations



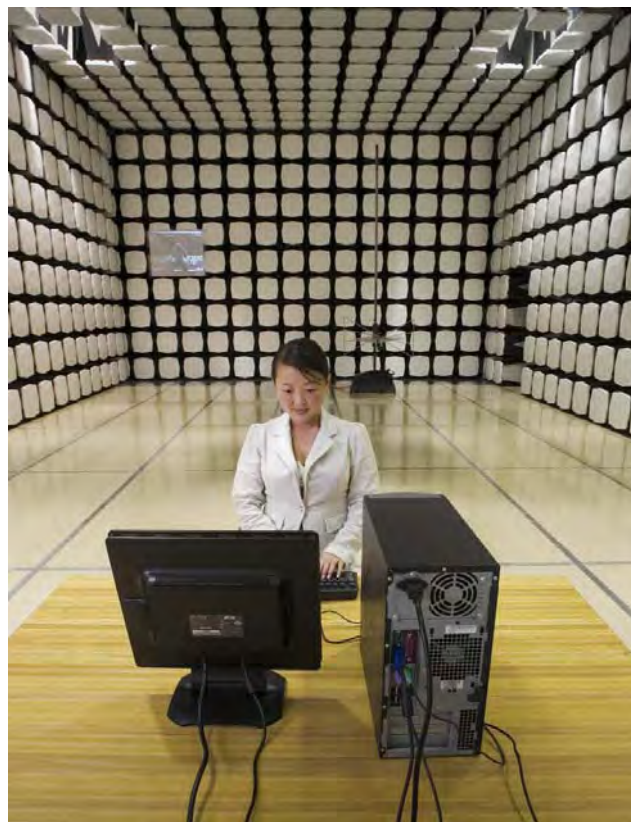
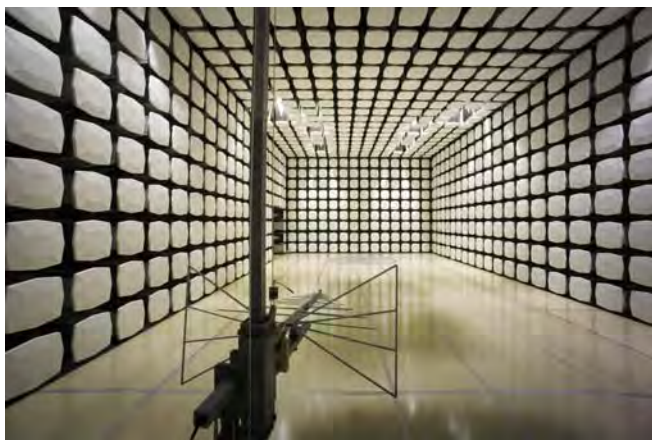
Oregon
Labs EV01-EV12
22975 NW Evergreen Pkwy
Suite 400
Hillsboro, OR 97124
(503) 844-4066

California
Labs OC01-OC13
41 Tesla
Irvine, CA 92618
(949) 861-8918

Minnesota
Labs MN01-MN08
9349 W Broadway Ave.
Brooklyn Park,
MN 55445
(763) 425-2281

Washington
Labs SU01-SU07
14128 339th Ave. SE
Sultan, WA 98294
(360) 793-8675

New York
Labs WA01-WA04
4939 Jordan Rd.
Elbridge, NY 13060
(315) 685-0796



Party Requesting the Test

Company Name:	Boston Scientific Neuromodulation
Address:	25155 Rye Canyon Loop
City, State, Zip:	Santa Clarita, CA 91355
Test Requested By:	Mizan Rahman
Model:	Implantable Pulse Generator Model SC-1132
First Date of Test:	5/23/2011
Last Date of Test:	5/24/2011
Receipt Date of Samples:	5/23/2011
Equipment Design Stage:	Production
Equipment Condition:	No Damage

Information Provided by the Party Requesting the Test**Functional Description of the EUT (Equipment Under Test):**

Generates electrical pulses used to stimulate different nerve fibers depending upon the application, e.g., mitigation of chronic pain.

Testing Objective:

To demonstrate compliance to FCC requirements.

CONFIGURATION 1 BOSN0010

EUT			
Description	Manufacturer	Model/Part Number	Serial Number
Remote Control	Boston Scientific	SC-5232/ M365SC52320/ 7095990-001	100046
IPG	Boston Scientific	SC-1132/ M365SC11320/ 7096018-001	100096

Cables					
Cable Type	Shield	Length (m)	Ferrite	Connection 1	Connection 2
Leads (1)	No	.5m	No	IPG	8x365 Ohm
Leads (2)	No	.5m	No	IPG	8x365 Ohm
PA = Cable is permanently attached to the device. Shielding and/or presence of ferrite may be unknown.					

Equipment modifications					
Item	Date	Test	Modification	Note	Disposition of EUT
1	5/23/2011	Field Strength of Spurious Emissions	Tested as delivered to Test Station.	No EMI suppression devices were added or modified during this test.	EUT remained at Northwest EMC following the test.
2	5/24/2011	Field Strength of Fundamental	Tested as delivered to Test Station.	No EMI suppression devices were added or modified during this test.	Scheduled testing was completed.

Testing was performed using the mode(s) of operation and configuration(s) noted within the report. The individuals and/or the organization requesting the test provided the modes, configurations and settings used to complete the evaluation. The actual test parameters are specified in the test data, this includes items such as investigated frequency range (scanned) and test levels. The testing methods and performance specifications, as well as the test site used for the evaluation are indicated in the test data.

MODES OF OPERATION

Transmitting at 125 kHz

POWER SETTINGS INVESTIGATED

Battery Powered

AXIS INVESTIGATED

X-Axis

Y-Axis

Z-Axis

FREQUENCY RANGE INVESTIGATED

Start Frequency	9 kHz	Stop Frequency	30 MHz
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SAMPLE CALCULATIONS

Radiated Emissions: Field Strength = Measured Level + Antenna Factor + Cable Factor - Amplifier Gain + Distance Adjustment Factor + External Attenuation

TEST EQUIPMENT

Description	Manufacturer	Model	ID	Last Cal.	Interval
Antenna, Loop	EMCO	6502	AZB	12/6/2010	24
OC10 Cables	N/A	10kHz-1GHz RE Cables	OCH	4/1/2010	15
Spectrum Analyzer	Agilent	E4446A	AAY	1/11/2011	12

MEASUREMENT BANDWIDTHS

	Frequency Range	Peak Data	Quasi-Peak Data	Average Data
	(MHz)	(kHz)	(kHz)	(kHz)
	0.01 - 0.15	1.0	0.2	0.2
	0.15 - 30.0	10.0	9.0	9.0
	30.0 - 1000	100.0	120.0	120.0
	Above 1000	1000.0	N/A	1000.0

Measurements were made using the bandwidths and detectors specified. No video filter was used.

MEASUREMENT UNCERTAINTY

A measurement uncertainty estimation has been performed for each test per our internal quality document WP 342. The estimation is used to compare the measured result with its "true" or theoretically correct value. Our measurement data meets or exceeds the measurement uncertainty requirements of CISPR 16-4. The measurement uncertainty estimation is available upon request.

TEST DESCRIPTION

The antennas to be used with the EUT were tested. The EUT was transmitting and receiving while set at the transmitting channel available. While scanning, emissions from the EUT were maximized by rotating the EUT, adjusting the measurement antenna height and polarization, and manipulating the EUT antenna in 3 orthogonal planes (per ANSI C63.10:2009).

EUT: Implantable Pulse Generator, Model SC-1132					Work Order: BOSN0010	
Serial Number: 100096					Date: 05/24/11	
Customer: Boston Scientific Neuromodulation					Temperature: 20.3	
Attendees: Mizan Rahman					Humidity: 52%	
Project: None					Barometric Pres.: 1014.4	
Tested by: Jaemi Suh			Power: Battery Powered		Job Site: OC10	

TEST SPECIFICATIONS

FCC 15.209:2011

TEST METHOD

ANSI C63.10:2009

TEST PARAMETERS

Antenna Height(s) (m)	1 - 2.75	Test Distance (m)	3
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COMMENTS

RC and IPG. X-Axis

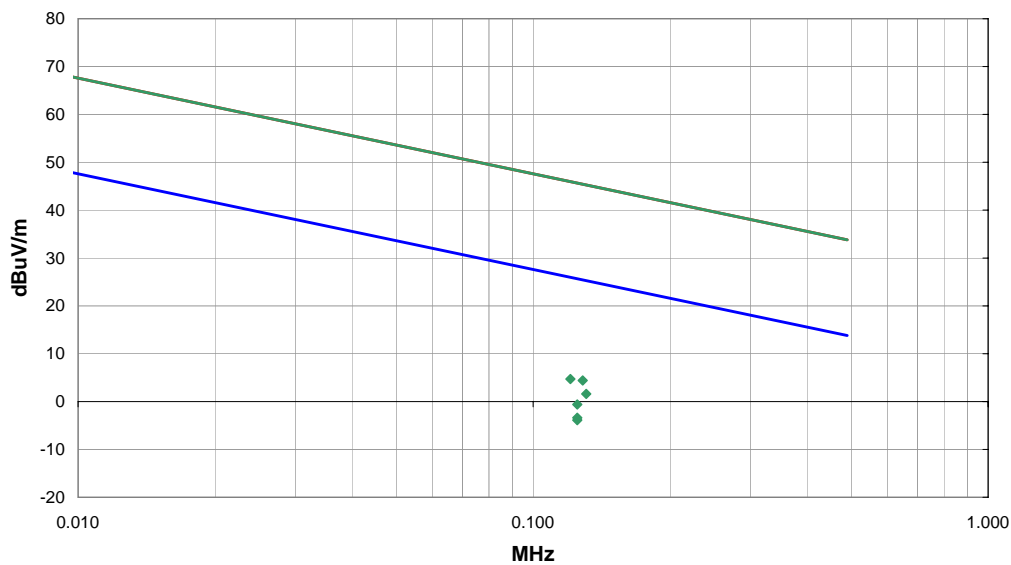
EUT OPERATING MODES

Transmitting at 125 kHz

DEVIATIONS FROM TEST STANDARD

No deviations.

Run #	4	Signature 
Configuration #	1	
Results	Pass	



Freq (MHz)	Amplitude (dBuV)	Factor (dB)	Azimuth (degrees)	Height (meters)	Distance (meters)	External Attenuation (dB)	Polarity	Detector	Distance Adjustment (dB)	Adjusted dBuV/m	Spec. Limit dBuV/m	Compared to Spec. (dB)	Comments
0.125	68.9	10.5	296.0	1.0	3.0	0.0	Loop	AV	-80.0	-0.6	25.7	-26.3	Antenna parallel to grnd, parallel to eut.
0.125	66.1	10.5	283.0	1.0	3.0	0.0	Loop	AV	-80.0	-3.4	25.7	-29.1	Antenna parallel to grnd, perp to eut.
0.125	65.6	10.5	292.0	1.0	3.0	0.0	Loop	AV	-80.0	-3.9	25.7	-29.6	Antenna perp to ground, perp to eut.
0.129	73.9	10.5	296.0	1.0	3.0	0.0	Loop	PK	-80.0	4.4	45.4	-41.0	Antenna parallel to grnd, parallel to eut.
0.121	74.2	10.5	283.0	1.0	3.0	0.0	Loop	PK	-80.0	4.7	46.0	-41.3	Antenna parallel to grnd, perp to eut.
0.131	71.1	10.5	291.0	1.0	3.0	0.0	Loop	PK	-80.0	1.6	45.3	-43.7	Antenna perp to ground, perp to eut

Testing was performed using the mode(s) of operation and configuration(s) noted within the report. The individuals and/or the organization requesting the test provided the modes, configurations and settings used to complete the evaluation. The actual test parameters are specified in the test data, this includes items such as investigated frequency range (scanned) and test levels. The testing methods and performance specifications, as well as the test site used for the evaluation are indicated in the test data.

MODES OF OPERATION

Transmitting at 125 kHz

POWER SETTINGS INVESTIGATED

120VAC/60Hz

AXIS INVESTIGATED

X-Axis

Y-Axis

Z-Axis

FREQUENCY RANGE INVESTIGATED

Start Frequency	9 kHz	Stop Frequency	30 MHz
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SAMPLE CALCULATIONS

Radiated Emissions: Field Strength = Measured Level + Antenna Factor + Cable Factor - Amplifier Gain + Distance Adjustment Factor + External Attenuation

TEST EQUIPMENT

Description	Manufacturer	Model	ID	Last Cal.	Interval
Antenna, Loop	EMCO	6502	AZB	12/6/2010	24
OC10 Cables	N/A	10kHz-1GHz RE Cables	OCH	4/1/2010	15
Spectrum Analyzer	Agilent	E4446A	AAY	1/11/2011	12

MEASUREMENT BANDWIDTHS

	Frequency Range	Peak Data	Quasi-Peak Data	Average Data
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	0.01 - 0.15	1.0	0.2	0.2
	0.15 - 30.0	10.0	9.0	9.0
	30.0 - 1000	100.0	120.0	120.0
	Above 1000	1000.0	N/A	1000.0

Measurements were made using the bandwidths and detectors specified. No video filter was used.

MEASUREMENT UNCERTAINTY

A measurement uncertainty estimation has been performed for each test per our internal quality document WP 342. The estimation is used to compare the measured result with its "true" or theoretically correct value. Our measurement data meets or exceeds the measurement uncertainty requirements of CISPR 16-4. The measurement uncertainty estimation is available upon request.

TEST DESCRIPTION

The antennas to be used with the EUT were tested. The EUT was transmitting and receiving while set at the transmitting channel available. While scanning, emissions from the EUT were maximized by rotating the EUT, adjusting the measurement antenna height and polarization, and manipulating the EUT antenna in 3 orthogonal planes (per ANSI C63.10:2009).

FIELD STRENGTH OF SPURIOUS EMISSIONS

EUT:	Implantable Pulse Generator, Model SC-1132	Work Order:	BOSN0010
Serial Number:	100096	Date:	05/23/11
Customer:	Boston Scientific Neuromodulation	Temperature:	20.3
Attendees:	Mizan Rahman	Humidity:	52%
Project:	None	Barometric Pres.:	1014.4
Tested by:	Jaemi Suh	Power:	120VAC/60Hz
		Job Site:	OC10

TEST SPECIFICATIONS

FCC 15.209:2011

TEST METHOD

ANSI C63.10:2009

TEST PARAMETERS

Antenna Height(s) (m) 1 - 2.75 Test Distance (m) 3

COMMENTS

RC and IPG. X-Axis

EUT OPERATING MODES

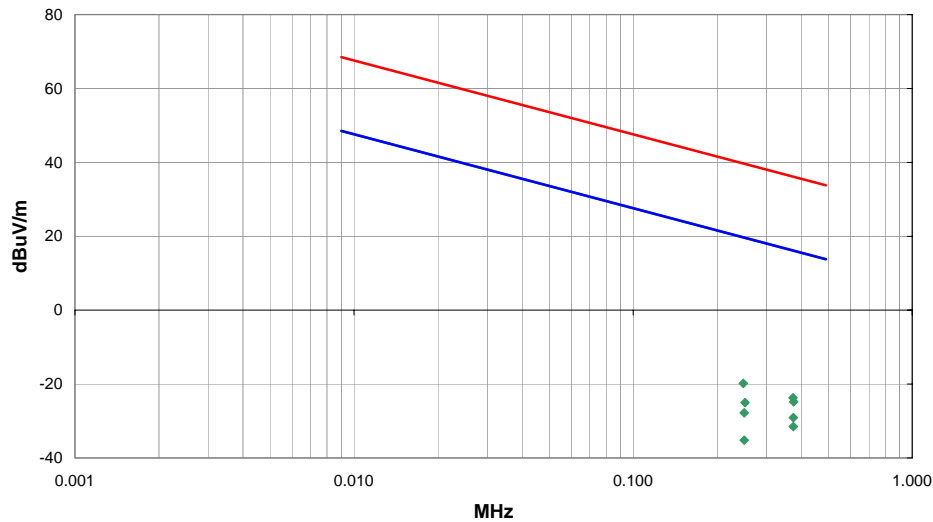
Transmitting at 125 kHz

DEVIATIONS FROM TEST STANDARD

No deviations.

Run #	3
Configuration #	1
Results	Pass

Signature



Freq (MHz)	Amplitude (dBuV)	Factor (dB)	Azimuth (degrees)	Height (meters)	Distance (meters)	External Attenuation (dB)	Polarity	Detector	Distance Adjustment (dB)	Adjusted dBuV/m	Spec. Limit dBuV/m	Compared to Spec. (dB)	Comments
0.375	40.6	10.3	358.0	1.0	3.0	0.0	Loop	AV	-80.0	-29.1	16.1	-45.2	Antenna perp to grnd, EUT parallel to grnd
0.250	41.8	10.4	339.0	1.0	3.0	0.0	Loop	AV	-80.0	-27.8	19.6	-47.4	Antenna parallel to grnd, EUT parallel to grnd
0.375	38.2	10.3	322.0	1.0	3.0	0.0	Loop	AV	-80.0	-31.5	16.1	-47.6	Antenna parallel to grnd, EUT parallel to grnd
0.250	34.4	10.4	357.0	1.0	3.0	0.0	Loop	AV	-80.0	-35.2	19.6	-54.8	Antenna perp to grnd, EUT parallel to grnd
0.248	49.8	10.4	339.0	1.0	3.0	0.0	Loop	PK	-80.0	-19.8	39.7	-59.5	Antenna parallel to grnd, EUT parallel to grnd
0.374	46.0	10.3	358.0	1.0	3.0	0.0	Loop	PK	-80.0	-23.7	36.1	-59.8	Antenna perp to grnd, EUT parallel to grnd
0.376	44.9	10.3	322.0	1.0	3.0	0.0	Loop	PK	-80.0	-24.8	36.1	-60.9	Antenna parallel to grnd, EUT parallel to grnd
0.252	44.6	10.4	357.0	1.0	3.0	0.0	Loop	PK	-80.0	-25.0	39.6	-64.6	Antenna perp to grnd, EUT parallel to grnd

NORTHWEST

EMC

FIELD STRENGTH OF SPURIOUS EMISSIONS

PSA 2011.05.11
EMI 2010.9.21

EUT: Implantable Pulse Generator, Model SC-1132				Work Order: BOSN0010			
Serial Number: 100096				Date: 05/23/11			
Customer: Boston Scientific Neuromodulation				Temperature: 20.3			
Attendees: Mizan Rahman				Humidity: 52%			
Project: None				Barometric Pres.: 1014.4			
Tested by: Jaemi Suh		Power: 120VAC/60Hz		Job Site: OC10			

TEST SPECIFICATIONS

FCC 15.209:2011

TEST METHOD

ANSI C63.10:2009

TEST PARAMETERS

Antenna Height(s) (m)1 - 2.75Test Distance (m)3

COMMENTS


RC and IPG. X-Axis

EUT OPERATING MODES

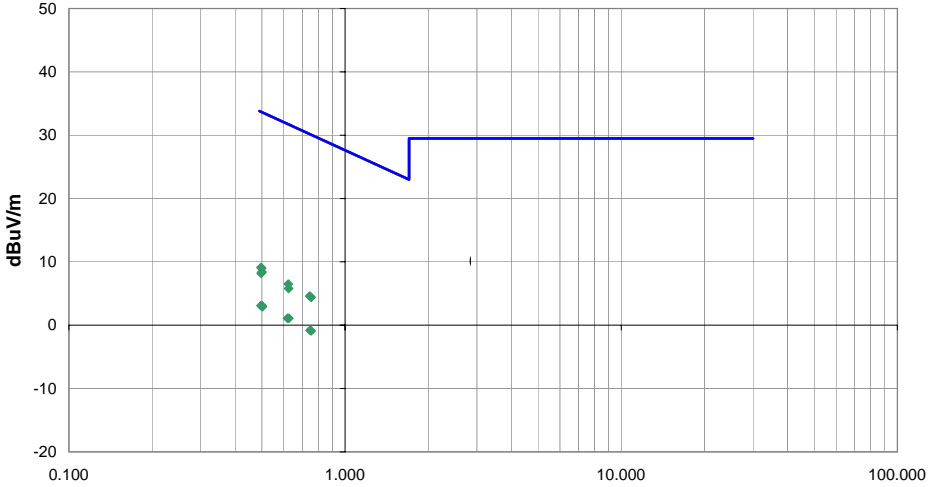
Transmitting at 125 kHz

DEVIATIONS FROM TEST STANDARD

No deviations.

Run #	3	Signature 
Configuration #	1	
Results	Pass	

dBuV/m



MHz

Freq (MHz)	Amplitude (dBuV)	Factor (dB)	Azimuth (degrees)	Height (meters)	Distance (meters)	External Attenuation (dB)	Polarity	Detector	Distance Adjustment (dB)	Adjusted dBuV/m	Spec. Limit dBuV/m	Compared to Spec. (dB)	Comments
0.496	38.8	10.3	194.0	1.0	3.0	0.0	Loop	PK	-40.0	9.1	33.7	-24.6	Antenna parallel to grnd, EUT parallel to grnd
0.499	38.7	10.3	359.0	2.1	3.0	0.0	Loop	PK	-40.0	9.0	33.6	-24.6	Antenna perp to grnd, EUT parallel to grnd
0.501	38.1	10.3	25.0	2.1	3.0	0.0	Loop	PK	-40.0	8.4	33.6	-25.2	Antenna parallel to grnd, EUT parallel to grnd
0.623	36.2	10.3	154.0	1.0	3.0	0.0	Loop	PK	-40.0	6.5	31.7	-25.2	Antenna parallel to grnd, EUT parallel to grnd
0.496	37.9	10.3	357.0	1.0	3.0	0.0	Loop	PK	-40.0	8.2	33.7	-25.5	Antenna perp to grnd, EUT perp to grnd
0.745	34.3	10.3	329.0	1.0	3.0	0.0	Loop	PK	-40.0	4.6	30.2	-25.6	Antenna parallel to grnd, EUT parallel to grnd
0.754	34.1	10.3	356.0	3.6	3.0	0.0	Loop	PK	-40.0	4.4	30.1	-25.7	Antenna perp to grnd, EUT parallel to grnd
0.624	35.5	10.3	356.0	1.0	3.0	0.0	Loop	PK	-40.0	5.8	31.7	-25.9	Antenna perp to grnd, EUT parallel to grnd
0.499	32.8	10.3	357.0	1.0	3.0	0.0	Loop	QP	-40.0	3.1	33.6	-30.5	Antenna parallel to grnd, EUT parallel to grnd
0.626	30.8	10.3	154.0	1.0	3.0	0.0	Loop	QP	-40.0	1.1	31.7	-30.6	Antenna parallel to grnd, EUT parallel to grnd
0.502	32.7	10.3	25.0	2.1	3.0	0.0	Loop	QP	-40.0	3.0	33.6	-30.6	Antenna parallel to grnd, EUT parallel to grnd
0.496	32.8	10.3	194.0	1.0	3.0	0.0	Loop	QP	-40.0	3.1	33.7	-30.6	Antenna parallel to grnd, EUT parallel to grnd
0.619	30.8	10.3	356.0	1.0	3.0	0.0	Loop	QP	-40.0	1.1	31.8	-30.7	Antenna perp to grnd, EUT parallel to grnd
0.502	32.6	10.3	359.0	2.1	3.0	0.0	Loop	QP	-40.0	2.9	33.6	-30.7	Antenna perp to grnd, EUT parallel to grnd
0.747	28.9	10.3	329.0	1.0	3.0	0.0	Loop	QP	-40.0	-0.8	30.1	-30.9	Antenna parallel to grnd, EUT parallel to grnd
0.754	28.8	10.3	356.0	3.6	3.0	0.0	Loop	QP	-40.0	-0.9	30.1	-31.0	Antenna perp to grnd, EUT parallel to grnd