NORTHWEST EMC

Boston Scientific Neuromodulation

Implantable Pulse Generator Model SC-1140

FCC 15.209:2016

Inductive Radio Module

Report # BOSN0057

NVLAP Lab Code: 200676-0

CERTIFICATE OF TEST

NORTHWEST EMC
2014-12-10

Last Date of Test: June 21, 2016
Boston Scientific Neuromodulation
Model: SC-1140

Radio Equipment Testing

Standards

Specification	Method
FCC 15.209:2016	ANSI C63.10:2013

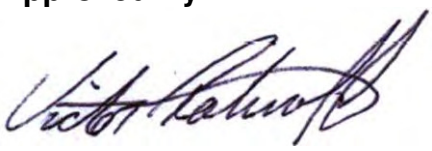
Results

Method Clause	Test Description	Applied	Results	Comments
6.2	Powerline Conducted Emissions	No	N/A	Not required for a battery powered EUT.
6.4	Field Strength of Fundamental	Yes	Pass	
6.4, 6.5	Spurious Radiated Emissions	Yes	Pass	

Deviations From Test Standards

None

Approved By:



Victor Ratinoff, Operations Manager

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. 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. This report reflects only those tests from the referenced standards shown in the certificate of test. It does not include inspection or verification of labels, identification, marking or user information.

REVISION HISTORY

NORTHWEST EMC
REV 2014.10.14

Revision Number	Description	Date	Page Number
00	None		

ACCREDITATIONS AND AUTHORIZATIONS

NORTHWEST EMC
REV 2016.3.22

United States

FCC - Designated by the FCC as a Telecommunications Certification Body (TCB). Certification chambers, Open Area Test Sites, and conducted measurement facilities are listed with the FCC.

A2LA - Accredited by A2LA to ISO / IEC 17065 as a product certifier. This allows Northwest EMC to certify transmitters to FCC and IC specifications.

NVLAP - Each laboratory is accredited by NVLAP to ISO 17025

Canada

IC - Recognized by Industry Canada as a Certification Body (CB). Certification chambers and Open Area Test Sites are filed with IC.

European Union

European Commission – Validated by the European Commission as a Notified Body under the R&TTE Directive.

Australia/New Zealand

ACMA - Recognized by ACMA as a CAB for the acceptance of test data.

Korea

MSIP / RRA - Recognized by KCC's RRA as a CAB for the acceptance of test data.

Japan

VCCI - Associate Member of the VCCI. Conducted and radiated measurement facilities are registered.

Taiwan

BSMI – Recognized by BSMI as a CAB for the acceptance of test data.

NCC - Recognized by NCC as a CAB for the acceptance of test data.

Singapore

IDA – Recognized by IDA as a CAB for the acceptance of test data.

Israel

MOC – Recognized by MOC as a CAB for the acceptance of test data.

Hong Kong

OFCA – Recognized by OFCA as a CAB for the acceptance of test data.

Vietnam

MIC – Recognized by MIC as a CAB for the acceptance of test data.

SCOPE

For details on the Scopes of our Accreditations, please visit:
http://www.nwemc.com/accreditations/
http://gsi.nist.gov/global/docs/cabs/designations.html

MEASUREMENT UNCERTAINTY

TMU.2015.07.10

Measurement Uncertainty

When a measurement is made, the result will be different from the true or theoretically correct value. The difference is the result of tolerances in the measurement system that cannot be completely eliminated. To the extent that technology allows us, it has been our aim to minimize this error. Measurement uncertainty is a statistical expression of measurement error qualified by a probability distribution.

A measurement uncertainty estimation has been performed for each test per our internal quality document QM205.4.6. The estimation is used to compare the measured result with its "true" or theoretically correct value. The expanded measurement uncertainty (K=2) can be found included as part of the applicable test description page. Our measurement data meets or exceeds the measurement uncertainty requirements of the applicable specification; therefore, the test data can be compared directly to the specification limit to determine compliance. The calculations for estimating measurement uncertainty are based upon ETSI TR 100 028 (or CISPR 16-4-2 as applicable), and are available upon request.

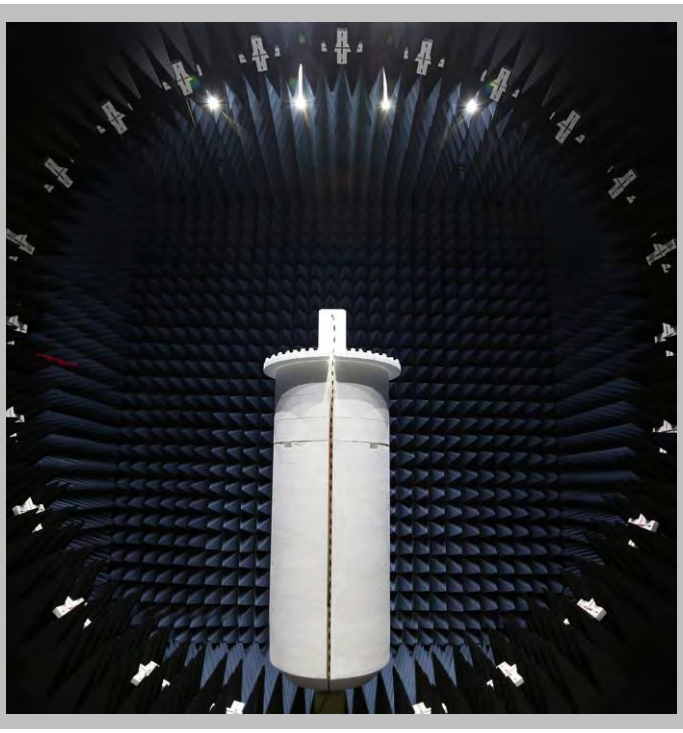
The following table represents the Measurement Uncertainty (MU) budgets for each of the tests that may be contained in this report.

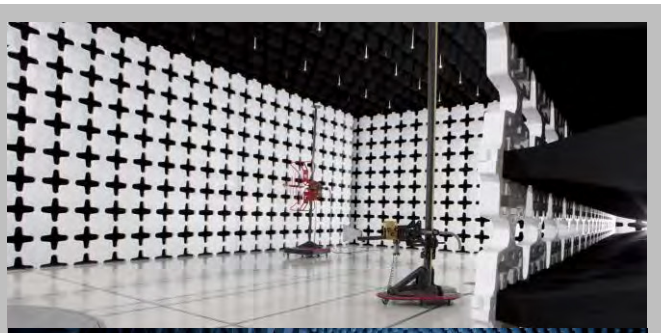
Test	+ MU	- MU
Frequency Accuracy (Hz)	0.0007%	-0.0007%
Amplitude Accuracy (dB)	1.2 dB	-1.2 dB
Conducted Power (dB)	0.3 dB	-0.3 dB
Radiated Power via Substitution (dB)	0.7 dB	-0.7 dB
Temperature (degrees C)	0.7°C	-0.7°C
Humidity (% RH)	2.5% RH	-2.5% RH
Voltage (AC)	1.0%	-1.0%
Voltage (DC)	0.7%	-0.7%
Field Strength (dB)	5.2 dB	-5.2 dB
AC Powerline Conducted Emissions (dB)	2.4 dB	-2.4 dB

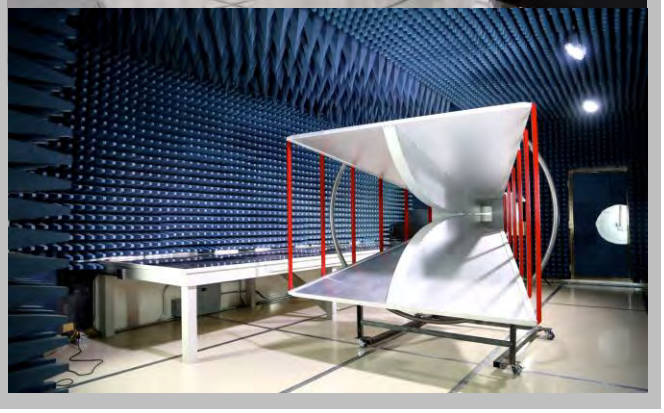
FACILITIES

NORTHWEST EMC
REV 2015.2.19

California	Minnesota	New York	Oregon	Texas	Washington
Labs OC01-13 41 Tesla Irvine, CA 92618 (949) 861-8918	Labs MN01-08, MN10 9349 W Broadway Ave. Brooklyn Park, MN 55445 (612)-638-5136	Labs NY01-04 4939 Jordan Rd. Elbridge, NY 13060 (315) 554-8214	Labs EV01-12 22975 NW Evergreen Pkwy Hillsboro, OR 97124 (503) 844-4066	Labs TX01-09 3801 E Plano Pkwy Plano, TX 75074 (469) 304-5255	Labs NC01-05 19201 120th Ave NE Bothell, WA 98011 (425)984-6600
NVLAP					
NVLAP Lab Code: 200676-0	NVLAP Lab Code: 200881-0	NVLAP Lab Code: 200761-0	NVLAP Lab Code: 200630-0	NVLAP Lab Code:201049-0	NVLAP Lab Code: 200629-0
Industry Canada					
2834B-1, 2834B-3	2834E-1	N/A	2834D-1, 2834D-*2*	2834G-1	2834F-1
BSMI					
SL2-IN-E-1154R	SL2-IN-E-1152R	N/A	SL2-IN-E-1017	SL2-IN-E-1158R	SL2-IN-E-1153R
VCCI					
A-0029	A-0109	N/A	A-0108	A-0201	A-0110
Recognized Phase I CAB for ACMA, BSMI, IDA, KCC/RRA, MIC, MOC, NCC, OFCA					
US0158	US0175	N/A	US0017	US0191	US0157







PRODUCT DESCRIPTION

NORTHWEST EMC
2014-12-10

Client and Equipment Under Test (EUT) Information

Company Name:	Boston Scientific Neuromodulation
Address:	25155 Rye Canyon Loop
City, State, Zip:	Santa Clarita, CA 91355
Test Requested By:	Habet Ter-Petrosyan
Model:	SC-1140
First Date of Test:	June 21, 2016
Last Date of Test:	June 21, 2016
Receipt Date of Samples:	June 21, 2016
Equipment Design Stage:	Production
Equipment Condition:	No Damage

Information Provided by the Party Requesting the Test

Functional Description of the EUT:
Implantable Pulse Generator

Testing Objective:
To demonstrate compliance of the inductive portion of the device to FCC Part 15.209 specifications.

CONFIGURATIONS

NORTHWEST EMC 2014-12-10

Configuration BOSN0057- 1

Software/Firmware Running during test	
Description	**Version**
App FW Version	9028384-102-00#18

EUT			
Description	**Manufacturer**	**Model/Part Number**	**Serial Number**
Primary Cell Implantable Pulse Generator	Boston Scientific Neuromodulation	SC-1140	100112

Peripherals in test setup boundary			
Description	**Manufacturer**	**Model/Part Number**	**Serial Number**
Lead 1	Boston Scientific Neuromodulation	SC-2218-50	None
Lead 2	Boston Scientific Neuromodulation	SC-2218-50	None
Human Torso Simulator	Northwest EMC	None	None

Cables					
Cable Type	**Shield**	**Length (m)**	**Ferrite**	**Connection 1**	**Connection 2**
Lead 1	No	0.5m	No	IPG Model SC-1140	Saline
Lead 2	No	0.5m	No	IPG Model SC-1140	Saline

MODIFICATIONS

NORTHWEST EMC
2014-12-10

Equipment Modifications

Item	Date	Test	Modification	Note	Disposition of EUT
1	6/21/2016	Field Strength of Fundamental	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	6/21/2016	Spurious Radiated Emissions	Tested as delivered to Test Station.	No EMI suppression devices were added or modified during this test.	Scheduled testing was completed.

FIELD STRENGTH OF FUNDAMENTAL

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. The test data represents the configuration / operating mode/ model that produced the highest emission levels as compared to the specification limit.

MODES OF OPERATION

Transmitting at 125kHz

POWER SETTINGS INVESTIGATED

Battery

CONFIGURATIONS INVESTIGATED

BOSN0057 - 1

FREQUENCY RANGE INVESTIGATED

Start Frequency	9 kHz	Stop Frequency	490 kHz

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
Cable	Northwest EMC	10kHz-1GHz RE Cables	OCH	3/3/2016	12 mo
Antenna	EMCO	6502	AZB	8/14/2015	24 mo
Analyzer - Spectrum Analyzer	Agilent	N9010A	AFJ	2/9/2016	12 mo

MEASUREMENT BANDWIDTHS

Frequency Range (MHz)	Peak Data (kHz)	Quasi-Peak Data (kHz)	Average Data (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

TEST DESCRIPTION

The antennas to be used with the EUT were tested. The EUT was continuously transmitting while set to the channel specified.

Per ANSI C63.10 sections 6.4.4.1 and 6.4.4.2, the emissions from the EUT were maximized by rotating the EUT on the turntable. Also, the EUT and/or associated antenna was positioned in 3 orthogonal planes. A calibrated active loop antenna was used for this test in order to provide sufficient measurement sensitivity per section 4.5.1. The center of the loop antenna was maintained at 1m above the ground plane during the testing.

As outlined in 15.209(e) and 15.31(f)(2), measurements may be performed at a distance closer than what is specified with the limit. The limit at the specified distance is shown on the data sheet. Measurements are made at a closer distance and the data is adjusted using a distance correction factor of 40dB/decade for comparison to the limit.

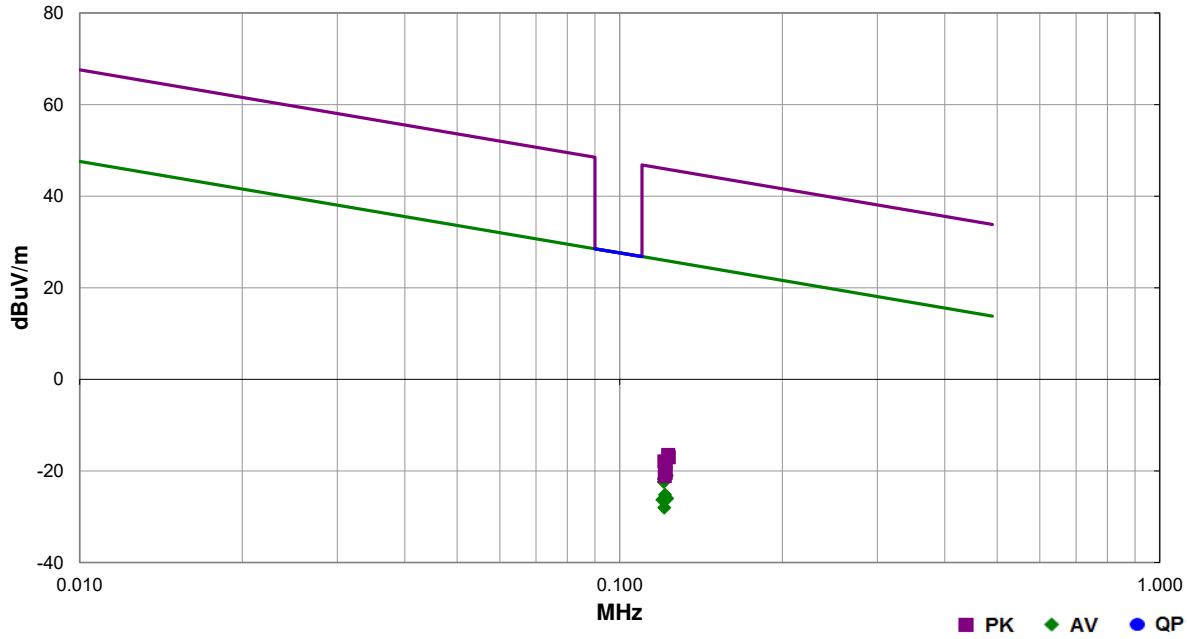
If there are no detectable emissions above the noise floor, the data included will show noise floor measurements for reference only.

FIELD STRENGTH OF FUNDAMENTAL

Work Order:	BOSN0057	**Date:**	06/21/16		
Project:	None	**Temperature:**	22.2 °C		
Job Site:	OC10	**Humidity:**	49.8% RH		
Serial Number:	100112	**Barometric Pres.:**	1017 mbar	**Tested by:**	Mark Baytan
EUT:	IPG Model SC-1140				
Configuration:	1				
Customer:	Boston Scientific Neuromodulation				
Attendees:	Habet Ter-Petrosyan				
EUT Power:	Battery				
Operating Mode:	Transmitting at 125kHz				
Deviations:	None				
Comments:	EUT was placed in a torso simulation filled with saline solution.				

Test Specifications	**Test Method**
FCC 15.209:2016	ANSI C63.10:2013

Run #	3	**Test Distance (m)**	3	**Antenna Height(s)**	1 to 4(m)	**Results**	Pass



Freq (MHz)	Amplitude (dBuV)	Factor (dB)	Antenna Height (meters)	Azimuth (degrees)	Test Distance (meters)	External Attenuation (dB)	Polarity/ Transducer Type	Detector	Distance Adjustment (dB)	Adjusted (dBuV/m)	Spec. Limit (dBuV/m)	Compared to Spec. (dB)	Comments
0.122	48.7	10.3	1.1	193.0	3.0	0.0	Parallel to EUT	AV	-80.0	-21.0	25.9	-46.9	EUT Vertical
0.121	48.7	10.3	1.0	44.0	3.0	0.0	Perp to EUT	AV	-80.0	-21.0	25.9	-47.0	EUT on Side
0.121	48.0	10.3	1.0	65.0	3.0	0.0	Parallel to EUT	AV	-80.0	-21.7	26.0	-47.7	EUT on Side
0.121	47.9	10.3	1.1	146.0	3.0	0.0	Perp to EUT	AV	-80.0	-21.8	26.0	-47.8	EUT Vertical
0.121	47.3	10.3	1.0	347.0	3.0	0.0	Parallel to EUT	AV	-80.0	-22.4	26.0	-48.4	EUT Horizontal
0.121	44.5	10.3	1.0	144.0	3.0	0.0	Parallel to GND	AV	-80.0	-25.2	25.9	-51.2	EUT Horizontal
0.122	43.7	10.3	1.5	241.0	3.0	0.0	Perp to EUT	AV	-80.0	-26.0	25.9	-51.9	EUT Horizontal
0.120	43.4	10.3	1.0	206.0	3.0	0.0	Parallel to GND	AV	-80.0	-26.3	26.2	-52.5	EUT on Side
0.121	41.7	10.3	1.0	206.0	3.0	0.0	Parallel to GND	AV	-80.0	-28.0	26.0	-54.0	EUT Vertical
0.123	53.2	10.3	1.1	146.0	3.0	0.0	Perp to EUT	PK	-80.0	-16.5	45.7	-62.3	EUT Vertical
0.123	52.7	10.3	1.1	193.0	3.0	0.0	Parallel to EUT	PK	-80.0	-17.0	45.8	-62.8	EUT Vertical
0.121	51.8	10.3	1.0	347.0	3.0	0.0	Parallel to EUT	PK	-80.0	-17.9	46.0	-63.9	EUT Horizontal
0.122	51.7	10.3	1.0	65.0	3.0	0.0	Parallel to EUT	PK	-80.0	-18.0	45.9	-64.0	EUT on Side
0.122	51.7	10.3	1.0	44.0	3.0	0.0	Perp to EUT	PK	-80.0	-18.0	45.9	-64.0	EUT on Side
0.121	49.7	10.3	1.0	144.0	3.0	0.0	Parallel to GND	PK	-80.0	-20.0	45.9	-66.0	EUT Horizontal
0.122	49.3	10.3	1.5	241.0	3.0	0.0	Perp to EUT	PK	-80.0	-20.4	45.9	-66.3	EUT Horizontal
0.121	49.2	10.3	1.0	206.0	3.0	0.0	Parallel to GND	PK	-80.0	-20.5	45.9	-66.5	EUT on Side
0.121	48.6	10.3	1.0	206.0	3.0	0.0	Parallel to GND	PK	-80.0	-21.1	46.0	-67.1	EUT Vertical

SPURIOUS RADIATED EMISSIONS

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. The test data represents the configuration / operating mode/ model that produced the highest emission levels as compared to the specification limit.

MODES OF OPERATION

Transmitting at 125kHz

POWER SETTINGS INVESTIGATED

Battery

CONFIGURATIONS INVESTIGATED

BOSN0057 - 1

FREQUENCY RANGE INVESTIGATED

Start Frequency	9 kHz	Stop Frequency	30 MHz

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
Cable	Northwest EMC	10kHz-1GHz RE Cables	OCH	3/3/2016	12 mo
Antenna	EMCO	6502	AZB	8/14/2015	24 mo
Analyzer - Spectrum Analyzer	Agilent	N9010A	AFJ	2/9/2016	12 mo

MEASUREMENT BANDWIDTHS

Frequency Range (MHz)	Peak Data (kHz)	Quasi-Peak Data (kHz)	Average Data (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

TEST DESCRIPTION

The antennas to be used with the EUT were tested. The EUT was continuously transmitting while set to the channel specified.

Per ANSI C63.10 sections 6.4.4.1 and 6.4.4.2, the emissions from the EUT were maximized by rotating the EUT on the turntable. Also, the EUT and/or associated antenna was positioned in 3 orthogonal planes. A calibrated active loop antenna was used for this test in order to provide sufficient measurement sensitivity per section 4.5.1. The center of the loop antenna was maintained at 1m above the ground plane during the testing.

For measurements below 30 MHz, as outlined in 15.209(e) and 15.31(f)(2), measurements may be performed at a distance closer than what is specified with the limit. The limit at the specified distance is shown on the data sheet. Measurements are made at a closer distance and the data is adjusted using a distance correction factor of 40dB/decade for comparison to the limit. Per FCC 15.33(a)(4), measurements were taken up to the highest frequency range of either the 10th harmonic of the fundamental or the applicable digital frequency test range.

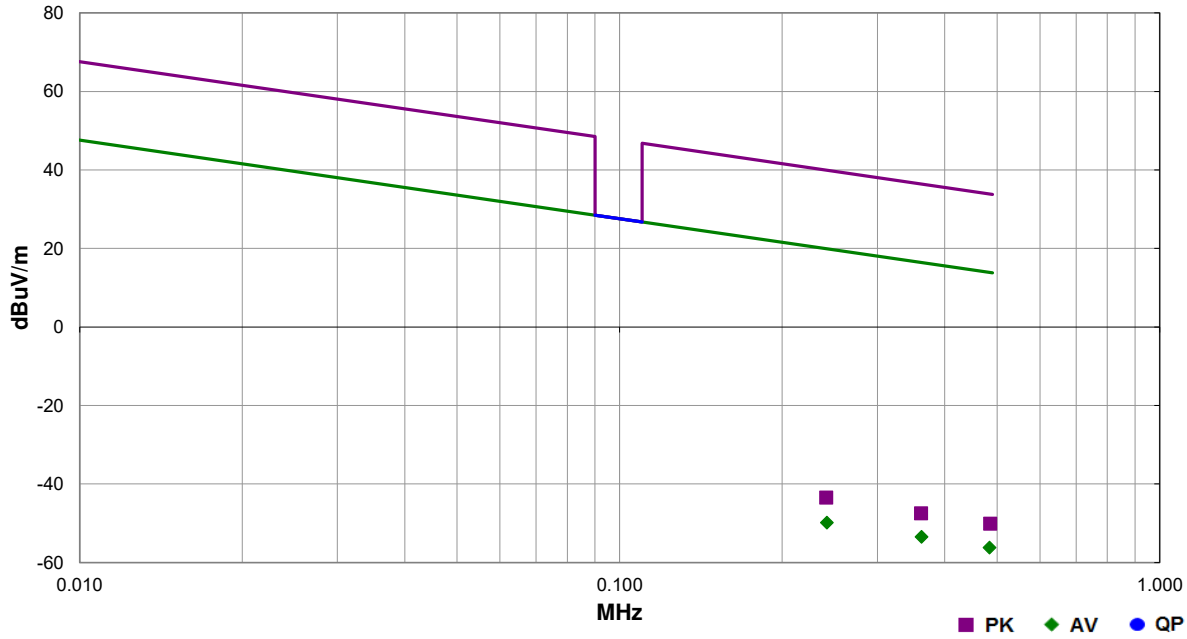
If there are no detectable emissions above the noise floor, the data included will show noise floor measurements for reference only.

SPURIOUS RADIATED EMISSIONS

Work Order:	BOSN0057	**Date:**	06/21/16		
Project:	None	**Temperature:**	23.4 °C		
Job Site:	OC10	**Humidity:**	49% RH		
Serial Number:	100112	**Barometric Pres.:**	1017 mbar	**Tested by:**	Mark Baytan
EUT:	IPG Model SC-1140				
Configuration:	1				
Customer:	Boston Scientific Neuromodulation				
Attendees:	Habet Ter-Petrosyan				
EUT Power:	Battery				
Operating Mode:	Transmitting at 125kHz				
Deviations:	None				
Comments:	EUT was placed in a torso simulation filled with saline solution.				

Test Specifications	**Test Method**
FCC 15.209:2016	ANSI C63.10:2013

Run #	10	**Test Distance (m)**	1	**Antenna Height(s)**	1 to 4(m)	**Results**	Pass



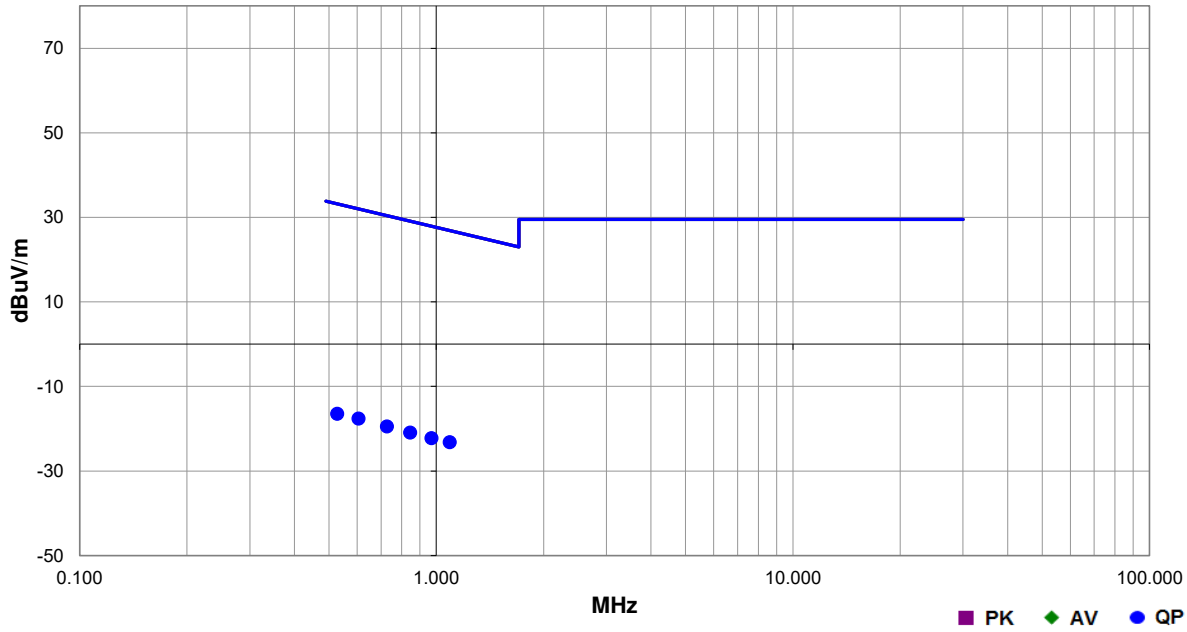
Freq (MHz)	Amplitude (dBuV)	Factor (dB)	Antenna Height (meters)	Azimuth (degrees)	Test Distance (meters)	External Attenuation (dB)	Polarity/ Transducer Type	Detector	Distance Adjustment (dB)	Adjusted (dBuV/m)	Spec. Limit (dBuV/m)	Compared to Spec. (dB)	Comments
0.242	39.1	10.1	2.2	239.0	1.0	0.0	Horz	AV	-99.1	-49.9	19.9	-69.8	
0.362	35.5	10.1	1.0	200.0	1.0	0.0	Horz	AV	-99.1	-53.5	16.4	-69.9	
0.484	32.6	10.3	1.0	266.0	1.0	0.0	Horz	AV	-99.1	-56.2	13.9	-70.1	
0.241	45.5	10.1	2.2	239.0	1.0	0.0	Horz	PK	-99.1	-43.5	40.0	-83.4	
0.362	41.5	10.1	1.0	200.0	1.0	0.0	Horz	PK	-99.1	-47.5	36.4	-83.9	
0.485	38.7	10.3	1.0	266.0	1.0	0.0	Horz	PK	-99.1	-50.1	33.9	-84.0	

SPURIOUS RADIATED EMISSIONS

Work Order:	BOSN0057	**Date:**	06/21/16		
Project:	None	**Temperature:**	23.4 °C		
Job Site:	OC10	**Humidity:**	49% RH		
Serial Number:	100112	**Barometric Pres.:**	1017 mbar	**Tested by:**	Mark Baytan
EUT:	IPG Model SC-1140				
Configuration:	1				
Customer:	Boston Scientific Neuromodulation				
Attendees:	Habet Ter-Petrosyan				
EUT Power:	Battery				
Operating Mode:	Transmitting at 125kHz				
Deviations:	None				
Comments:	EUT was placed in a torso simulation filled with saline solution.				

Test Specifications	**Test Method**
FCC 15.209:2016	ANSI C63.10:2013

Run #	13	**Test Distance (m)**	1	**Antenna Height(s)**	1 to 4(m)	**Results**	Pass



Freq (MHz)	Amplitude (dBuV)	Factor (dB)	Antenna Height (meters)	Azimuth (degrees)	Test Distance (meters)	External Attenuation (dB)	Polarity/ Transducer Type	Detector	Distance Adjustment (dB)	Adjusted (dBuV/m)	Spec. Limit (dBuV/m)	Compared to Spec. (dB)	Comments
0.605	31.1	10.4	1.0	1.0	1.0	0.0	Horz	QP	-59.1	-17.6	32.0	-49.6	
0.528	32.3	10.3	1.0	54.0	1.0	0.0	Horz	QP	-59.1	-16.4	33.2	-49.6	
0.727	29.2	10.4	1.0	300.0	1.0	0.0	Horz	QP	-59.1	-19.5	30.4	-49.9	
0.845	27.7	10.4	1.0	297.0	1.0	0.0	Horz	QP	-59.1	-20.9	29.1	-50.0	
1.091	25.1	10.8	2.4	238.0	1.0	0.0	Horz	QP	-59.1	-23.2	26.9	-50.1	
0.969	26.2	10.6	1.0	96.0	1.0	0.0	Horz	QP	-59.1	-22.2	27.9	-50.1	