Emissions Test Report

EUT Name: NeuroPace® RNS® Neurostimulator

Model No.: RNS-300M

CFR 47 Part 15.205, 15.207, 15.209: 2010

Prepared for:

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Report/Issue Date: 15 October 2010
Report Number: 31051315.001

Statement of Compliance

Manufacturer:	NeuroPace Inc. 1375 Shorebird Way Mountain View, CA 94043 (650) 237-2700
Requester / Applicant:	Barbara Gibb
Name of Equipment:	NeuroPace® RNS® Neurostimulator
Model No.	RNS-300M
Type of Equipment:	Intentional Radiator
Application of Regulations:	CFR 47 Part 15.205, 15.207, 15.209: 2010
Test Dates:	4 October 2010 to 12 October 2010

Guidance Documents:

Emissions: ANSI C63.10: 2009

Test Methods:

Emissions: ANSI C63.10: 2009

The electromagnetic compatibility test and documented data described in this report has been performed and recorded by TUV Rheinland, in accordance with the standards and procedures listed herein. As the responsible authorized agent of the EMC laboratory, I hereby declare that the equipment described above has been shown to be compliant with the EMC requirements of the stated regulations and standards based on these results. If any special accessories and/or modifications were required for compliance, they are listed in the Executive Summary of this report.

This report must not be used to claim product endorsement by NVLAP or any agency of the U.S. Government. This report contains data that are not covered by NVLAP accreditation. This report shall not be reproduced except in full, without the written authorization of TUV Rheinland of North America.

Jeremy Luong	18 October 2010	Conan Boyle	28 October 2010
Test Engineer	Date	NVLAP Signatory	Date

NVLAP	FC	Industries Canada
100411-0	**US5251**	**2932D-1**

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1 Executive Summary

1.1 Scope

This report is intended to document the status of conformance with the requirements of the CFR 47 Part 15.205, 15.207, 15.209: 2010 based on the results of testing performed on 4 October 2010 through 12 October 2010 on the NeuroPace® RNS® Neurostimulator Model RNS-300M manufactured by NeuroPace Inc.. This report only applies to the specific samples tested under the stated test conditions. It is the responsibility of the manufacturer to assure that additional production units of this model are manufactured with identical or EMI equivalent electrical and mechanical components. This report is further intended to document changes and modifications to the EUT throughout its life cycle. All documentation will be included as a supplement.

1.2 Purpose

Testing was performed to evaluate the EMC performance of the EUT in accordance with the applicable requirements, procedures, and criteria defined in the application of regulations and application of standards listed in this report.

1.3 Summary of Test Results

Table 1: Summary of Test Results

Test	Test Method ANSI C63.10 2009	Test Parameters (from Standard)	Result
Restricted Bands of Operation	CFR47 15.205	Class B	**Complied**
AC Conducted Emission	CFR47 15.207	Class B	**Not Applicable**
Spurious Emission in Transmitted Mode	CFR47 15.209	Class B	**Complied**

Note: AC conducted emission is not applicable for the Neurostimulator: it is battery powered.

1.4 Special Accessories

No special accessories were necessary in order to achieve compliance.

1.5 Equipment Modifications

None

2 Laboratory Information

2.1 Accreditations & Endorsements

2.1.1 US Federal Communications Commission

TUV Rheinland of North America at 1279 Quarry Lane, Ste. A, Pleasanton, CA 94566 is accredited by the commission for performing testing services for the general public on a fee basis. These laboratory test facilities have been fully described in reports submitted to and accepted by the FCC (US5254). The laboratory scope of accreditation includes: Title 47 CFR Parts 15, 18, 74, 90, 95, and 97. The accreditation is updated every 3 years.

2.1.2 NIST / NVLAP

TUV Rheinland of North America is accredited by the National Voluntary Laboratory Accreditation Program, which is administered under the auspices of the National Institute of Standards and Technology. The laboratory has been assessed and accredited in accordance with ISO Guide 17025:2005 and ISO 9002 (Lab Code 100411-0). The scope of laboratory accreditation includes emission and immunity testing. The accreditation is updated annually.

2.1.3 Canada – Industry Canada

TUV Rheinland of North America at the 1279 Quarry Lane, Ste. A, Pleasanton, CA 94566 address is accredited by Industry Canada for performing testing services for the general public on a fee basis. This laboratory test facilities have been fully described in reports submitted to and accepted by Industry Canada (File Number 2932D-1). This reference number is the indication to the Industry Canada Certification Officers that the site meets the requirements of RSS 212, Issue 1 (Provisional). The accreditation is updated every 3 years.

2.1.4 Japan – VCCI

The Voluntary Control Council for Interference by Information Technology Equipment (VCCI) is a group that consists of Information Technology Equipment (ITE) manufacturers and EMC test laboratories. The purpose of the Council is to take voluntary control measures against electromagnetic interference from Information Technology Equipment, and thereby contribute to the development of a socially beneficial and responsible state of affairs in the realm of Information Technology Equipment in Japan. TUV Rheinland of North America at 1279 Quarry Ln, Pleasanton, CA 94566 has been assessed and approved in accordance with the Regulations for Voluntary Control Measures. (Registration Nos. R-2366, C-2585, C-2586, T-1635).

2.1.5 Acceptance by Mutual Recognition Arrangement

The United States has an established agreement with specific countries under the Asia Pacific Laboratory Accreditation Corporation (APLAC) Mutual Recognition Arrangement. Under this agreement, all TUV Rheinland at 1279 Quarry Lane, Ste. A, Pleasanton, CA 94566 test results and test reports within the scope of the laboratory NIST / NVLAP accreditation will be accepted by each member country.

2.2 Test Facilities

Test facilities are located at 1279 Quarry Lane, Pleasanton, California 94566, U.S.A. and 2305 Mission College, Santa Clara, 95054, U.S.A. (Santa Clara is the Pleasanton Annex).

2.2.1 Emission Test Facility

The Semi-Anechoic chamber and AC Line Conducted measurement facility used to collect the radiated and conducted data has been constructed in accordance with ANSI C63.7:1992. The site has been measured in accordance with and verified to comply with the theoretical normalized site attenuation requirements of ANSI C63.4:2003, at test distances of 3 and 10 meters. The site is listed with the FCC and accredited by NVLAP (Lab Code 100411-0). The 3/10-meter semi-anechoic chamber used to collect the radiated data has been verified to comply with the theoretical normalized site attenuation requirements of ANSI C63.4:2003, at test distances of 3 and 10 meters. A report detailing this site can be obtained from TUV Rheinland of North America.

2.2.2 Immunity Test Facility

ESD, EFT, Surge, PQF: These tests are performed in an environmentally controlled room with a 3.7 m x 4.8 m x 3.175 mm thick aluminum floor connected to PE ground.

For ESD testing, tabletop equipment is placed on an insulated mat with a surface resistivity of 10^9 Ohms/square on a 1.6 m x 0.8 m x 0.8 m high non-conductive table with a 3.175 mm aluminum top (Horizontal Coupling Plane). The HCP is connected to the main ground plane via a low impedance ground strap through two 470-kΩ resistors. The Vertical Coupling Plane consists of an aluminum plate 50 cm x 50 cm x 3.175 mm thick. The VCP is connected to the main ground plane via a low impedance ground strap through two 470-kΩ resistors.

For EFT, Surge, PQF, the HCP and VCP are removed.

RF Field Immunity testing is performed in a 7.3m x 4.3m x 4.1m anechoic chamber.

RF Conducted and Magnetic Field Immunity testing is performed on a 4.8m x 3.7m x 3.175mm thick aluminum ground plane.

All test areas allow a minimum distance of 1 meter from the EUT to walls or conducting objects.

2.3 Measurement Uncertainty

Two types of measurement uncertainty are expressed in this report, per *ISO Guide To The Expression Of Uncertainty In Measurement*, 1st Edition, 1995.

The Combined Standard Uncertainty is the standard uncertainty of the result of a measurement when that result is obtained from the values of a number of other quantities; it is equal to the positive square root of the sum of the variances or co-variances of these other quantities, weighted according to how the measurement result varies with changes in these quantities. The term *standard uncertainty* is the result of a measurement expressed as a standard deviation.

The Expanded Uncertainty defines an interval about the result of a measurement that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the measurand. The fraction may be viewed as the coverage probability or level of confidence of the interval.

Table 2: Summary of Uncertainties

	U_{lab}	U_{cispr}
Radiated Disturbance @ 10m		
30 MHz – 1,000 MHz	3.2 dB	5.2 dB
Conducted Disturbance @ Mains Terminals		
150 kHz – 30 MHz	2.4 dB	3.6 dB
Disturbance Power		
30 MHz – 300 MHz	3.92 dB	4.5 dB
Measurement Uncertainty Immunity		
The estimated combined standard uncertainty for ESD immunity measurements is ± 4.1%.		
The estimated combined standard uncertainty for radiated immunity measurements is ± 2.05 dB.		
The estimated combined standard uncertainty for conducted immunity measurements is ± 1.83 dB.		
The estimated combined standard uncertainty for damped oscillatory wave immunity measurements is ± 8.8%.		
The estimated combined standard uncertainty for harmonic current and flicker measurements is ± 2.50%.		
Keytek CE Master		
The estimated combined standard uncertainty for EFT fast transient immunity measurements is ± 2.92%.		
The estimated combined standard uncertainty for surge immunity measurements is ± 2.92%.		
The estimated combined standard uncertainty for power frequency magnetic field immunity measurements is ± 5.8%.		
The estimated combined standard uncertainty for pulse magnetic field immunity measurements is ± 5.8%.		
The estimated combined standard uncertainty for voltage variation and interruption measurements is ± 1.74%.		

The expanded uncertainty at a level of 95% confidence is obtained by multiplying the combined standard uncertainty by a coverage factor of 2. Compliance criteria are not based on measurement uncertainty.

2.4 Calibration Traceability

All measurement instrumentation is traceable to the National Institute of Standards and Technology (NIST). The measurement method complies with ANSI/NCSL Z540-1-1994 and ISO Standard 17025:2005.

3 Product Information

3.1 Product Description

The NeuroPace® RNS® Neurostimulator model RNS-300M and patient Leads are medical products that are implanted by trained surgeons in order to treat a patient with a neurological disorder. The Neurostimulator contains sensing, therapy and data storage functions. The Neurostimulator senses brain waves called Electrocorticograms (ECoGs) across the patient electrodes located on the implanted Leads and performs A/D conversion of the ECoG signals. The Neurostimulator delivers electrical pulses through one or more implanted Lead(s) to the selected brain area in order to provide therapeutic stimulation. ECoG signals and other diagnostic data are stored in SRAM for review by a physician.

The inductive telemetry Wand must be placed within several centimeters of the implanted Neurostimulator to perform efficient telemetry. The Neurostimulator communication is via induction, a coil-to-coil interface.

The RF circuitry and inductive telemetry coil for the Neurostimulator are enclosed in a hermetically sealed titanium enclosure.

The user control of telemetry is by running NeuroPace® Application Software on the Programmer or Remote Monitor with connected Wand, and selecting telemetry functions including programming and interrogating. The communication protocol used between the Neurostimulator and Wand is used to send to the Neurostimulator operating parameters that control EEG sensing, therapy and data storage functions (programming), and to receive from the Neurostimulator diagnostics that include sensed brain waves, or Electrocorticograms (ECoGs), and operating diagnostics (interrogating).

The Neurostimulator, Wand and Programmer and Remote Monitor Application Software have no user operational adjustments which can be used to modify telemetry, including frequency and transmit power.

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3.2 Equipment Configuration

A description of the equipment configuration is given in Section 7. The EUT was tested as called for in the test standard and was configured and operated in a manner consistent with its intended use. The EUT was powered by the internal battery and allowed to reach intended operating conditions. The placement of the EUT system components was guided by the test standard and selected to represent typical installation conditions.

In the case of an EUT that can operate in more than one configuration, preliminary testing was performed to determine the configuration that produced maximum radiation.

The final configuration was selected to produce the worst case radiation for emissions testing.

3.3 Operating Mode

A description of the operation mode is given in Section 7. In the case of an EUT that can operate in more than one state, preliminary testing was performed to determine the operating mode that produced maximum radiation.

The final operating mode was selected to produce the worst case radiation for emissions testing.

3.4 Unique Antenna Connector

An intentional radiator shall be designed to ensure that no antenna other than that furnished by the responsible party shall be used with the device. The use of a permanently attached antenna or of an antenna that uses a unique coupling to the intentional radiator shall be considered sufficient to comply with the provisions of this Section. The manufacturer may design the unit so that a broken antenna can be replaced by the user, but the use of a standard antenna jack or electrical connector is prohibited. This requirement does not apply to carrier current devices or to devices operated under the provisions of CFR47 Parts 15.211, 15.213, 15.217, 15.219, or 15.221.

3.4.1 Results

The NeuroPace® RNS® Neurostimulator is used an integrated coil antenna for inductive telemetry communication.

4 Emissions

Testing was performed in accordance with CFR 47 Part 15.205, 15.207 and 15.209. These test methods are listed under the laboratory's NVLAP Scope of Accreditation. This test measures the levels emanating from the EUT, thus evaluating the potential for the EUT to cause radio frequency interference to other electronic devices. Procedures described in Section 8 of the standard were used.

4.1 Transmitter Spurious Emissions

Transmitter spurious emissions are emissions outside the frequency range of the equipment when the equipment is in transmit mode; per requirement of CFR47 15.205, and 15.209: 2010

4.1.1 Test Methodology

4.1.1.1 Preliminary Test

A test program that controls instrumentation and data logging was used to automate the preliminary RF emission test procedure. The frequency range of interest was divided into sub-ranges to yield a frequency resolution of approximately 120 kHz and provide a reading at each frequency for no more than 12° of turntable rotation. For each frequency sub-range the turntable was rotated 360° while peak emission data was recorded and plotted over the frequency range of interest in horizontal and vertical antenna polarization's.

Preliminary emission profile testing was performed inside the anechoic chamber. The EUT was placed on a 1.0m x 1.5m non-conductive table 80cm above the floor. The EUT was positioned as shown in the setup photographs. The receiving antenna was placed at a distance of 3m at a fixed height of 1m. Measurement equipment was located outside of the chamber. A video camera was placed inside the chamber to view the EUT.

To determine the worst axis, the pre-scans performed on X-Axis, Y-Axis, and Z-Axis.

4.1.1.2 Final Test

For each frequency measured, the peak emission was maximized by manipulating the receiving antenna from 1 to 4 meters above the ground plane and placing it at the position that produced the maximum signal strength reading. The turntable was then rotated through 360° while observing the peak signal and placing the EUT at the position that produced maximum radiation. The six highest emissions relative to the limit were measured unless such emissions were more than 20 dB below the limit. If less than six emissions are within 20 dB of the limit, than the noise level of the receiver is measured at frequencies where emissions are expected. Multiples of all oscillator and microprocessor frequencies were also checked.

Final testing was performed on an NSA compliant test site. The EUT was placed on a 1.0m x 1.5m non-conductive table 80cm above the ground plane. The placement of EUT and cables were the same as for preliminary testing and is shown in the setup photographs.

The final scans performed on the Z-Axis for 9 kHz to 30 MHz, and X-Axis for 30 MHz to 1 GHz.

See Test Plan Section for the setup mode and configuration

4.1.1.3 Deviations

None.

4.1.2 Transmitter Spurious Emission Limit

The spurious emissions of the transmitter shall not exceed the values in CFR47 Part 15.205, 15.209

Frequency (MHz)	Field strength (microvolts/meter)	Measurement distance (meters)
0.009-0.490......................	2400/F(kHz)	300
0.490-1.705......................	24000/F(kHz)	30
1.705-30.0.......................	30	30
30-88............................	100 **	3
88-216...........................	150 **	3
216-960..........................	200 **	3
Above 960........................	500	3

4.1.3 Test Results

The final measurement data was taken under the worst case operating modes, configurations, and/or cable positions. It also reflects the results including any modifications and/or special accessories listed in Sections 1.4 and 1.5.

As originally tested, the EUT was found to be compliant to the requirements of the test standard(s).

SOP 1 Radiated Emissions

Tracking # 31051315.001 Page 1 of 5

EUT Name	NeuroPace® RNS® Neurostimulator	**Date**	October 8, 2010
EUT Model	RNS-300M	**Temp / Hum in**	23°C / 49% rh
EUT Serial	105092	**Temp / Hum out**	N/A
EUT Config.	Integral Antenna	**Line AC / Freq**	120 Vac, 60 Hz
Standard	CFR47 Part 15.205 and 15.209	**RBW / VBW**	9 kHz / 30 kHz
Dist/Ant Used	3m / EMCO 6505	**Performed by**	Jeremy Luong

Emission Freq (MHz)	ANT Polar	ANT Pos (cm)	Table Pos (deg)	FIM (Pk) Pk (dBuV/m)	FIM QP/Ave (dBuV/m)	Total CF dBuV	E-Field QP/Ave (dBuV/m)	Spec Limit (dBuV/m)	Spec Margin (dB)	Type
Test ID # 8, 17: 9 kHz to 30 MHz at 3m, Mode 1 (TX)										
0.061*	Facing	100	155	68.57	67.17	11.88	79.05	111.39	-32.35	Spurious
0.448*	Facing	100	160	63.34	30.32	11.62	41.94	94.56	-52.62	Spurious
0.577	Facing	100	160	58.86	54.24	11.66	65.90	72.38	-6.48	Spurious
0.800	Facing	100	161	54.17	49.65	11.78	61.43	69.54	-8.11	Spurious
0.823	Facing	100	160	53.82	49.25	11.79	61.04	69.29	-8.25	Spurious

Spec Margin = E-Field QP/Ave - Limit, E-Field QP/Ave = FIM QP/Ave + Total CF ± Uncertainty
Total CF= Amp Gain + Cable Loss + ANT Factor

Combined Standard Uncertainty $u_c(y)$ = ± 3.2 dB Expanded Uncertainty $U = ku_c(y)$ k = 2 for 95% confidence

Notes: (*) Average measurement.
Final scan performed on Z-Axis; worst orientation.
RBW / VBW Setting:
200 Hz / 1kHz for 9 kHz to 150 kHz
9 kHz / 30 kHz for 150 kHz to 30 MHz

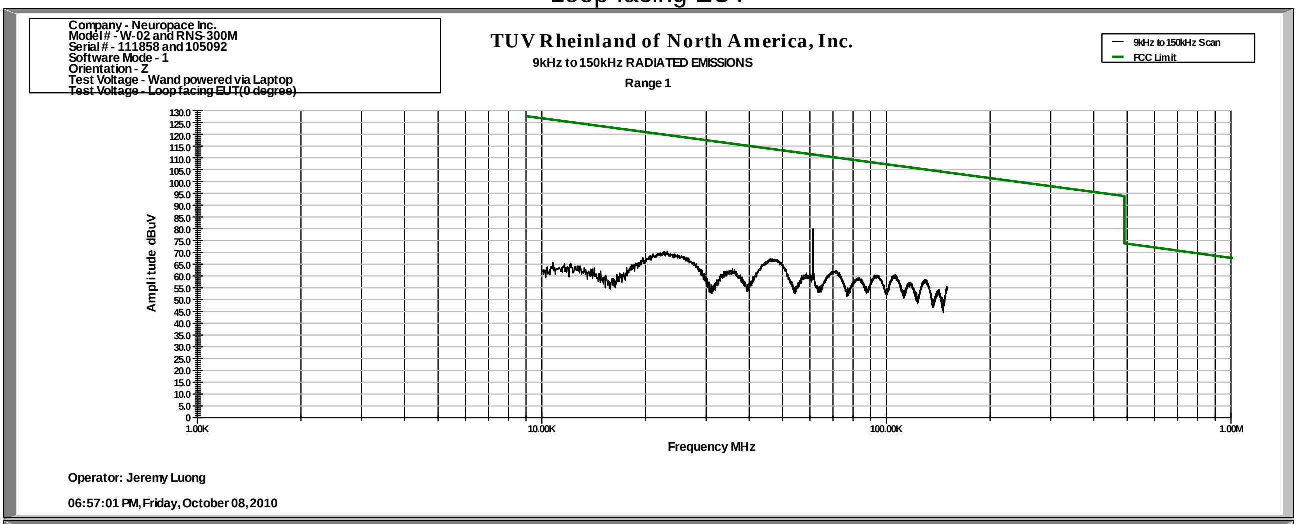
SOP 1 Radiated Emissions — Tracking # 31051315.001 Page 2 of 5

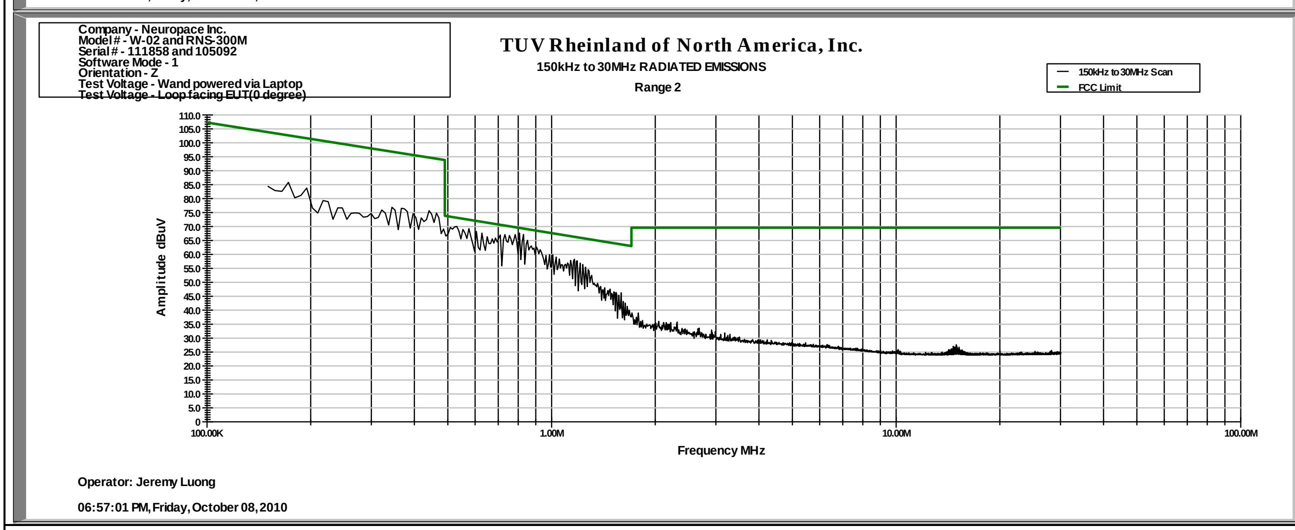
EUT Name	NeuroPace® RNS® Neurostimulator	**Date**	October 8, 2010
EUT Model	RNS-300M	**Temp / Hum in**	22°C / 37% rh
EUT Serial	105092	**Temp / Hum out**	N/A
EUT Config.	Integral Antenna	**Line AC / Freq**	120 Vac, 60 Hz
Standard	CFR47 Part 15.205 and 15.209	**RBW / VBW**	See below
Dist/Ant Used	3m / EMCO6505	**Performed by**	Jeremy Luong

Emission Freq (MHz)	ANT Pos	ANT Pos (cm)	Table Pos (deg)	FIM (Pk) Pk (dBuV/m)	FIM Ave (dBuV/m)	Total CF dBuV	E-Field Ave (dBuV/m)	Spec Limit (dBuV/m)	Spec Margin (dB)	Type

Test ID # 8, 17: 9 kHz to 30 MHz at 3m, Mode 1 (TX)

Loop facing EUT





Spec Margin = E-Field QP/Ave - Limit, E-Field QP/Ave = FIM QP/Ave + Total CF ± Uncertainty
Total CF= Amp Gain + Cable Loss + ANT Factor

Combined Standard Uncertainty $u_c(y) = \pm 3.2$ dB Expanded Uncertainty $U = ku_c(y)$ $k = 2$ for 95% confidence

Notes: None.

SOP 1 Radiated Emissions — Tracking # 31051315.001 Page 3 of 5

EUT Name	NeuroPace® RNS® Neurostimulator	**Date**	October 8, 2010
EUT Model	RNS-300M	**Temp / Hum in**	23°C / 49% rh
EUT Serial	105092	**Temp / Hum out**	N/A
EUT Config.	Integral Antenna	**Line AC / Freq**	120 Vac, 60 Hz
Standard	CFR47 Part 15.205 and 15.209	**RBW / VBW**	See Note Below
Dist/Ant Used	3m / EMCO 6505	**Performed by**	Jeremy Luong

Emission Freq (MHz)	ANT Polar	ANT Pos (cm)	Table Pos (deg)	FIM (Pk) Pk (dBuV/m)	FIM QP/Ave (dBuV/m)	Total CF dBuV	E-Field QP/Ave (dBuV/m)	Spec Limit (dBuV/m)	Spec Margin (dB)	Type
Test ID # 8, 17: 9 kHz to 30 MHz at 3m, Mode 1 (TX)										
0.061*	Away	100	80	64.49	63.17	11.88	75.05	111.40	-36.35	Spurious
0.576	Away	100	75	54.93	49.46	11.66	61.12	72.39	-11.27	Spurious
0.623	Away	100	75	52.31	47.72	11.69	59.41	71.71	-12.30	Spurious
0.800	Away	100	75	49.38	44.90	11.78	56.68	69.54	-12.86	Spurious

Spec Margin = E-Field QP/Ave - Limit, E-Field QP/Ave = FIM QP/Ave + Total CF ± Uncertainty
Total CF= Amp Gain + Cable Loss + ANT Factor

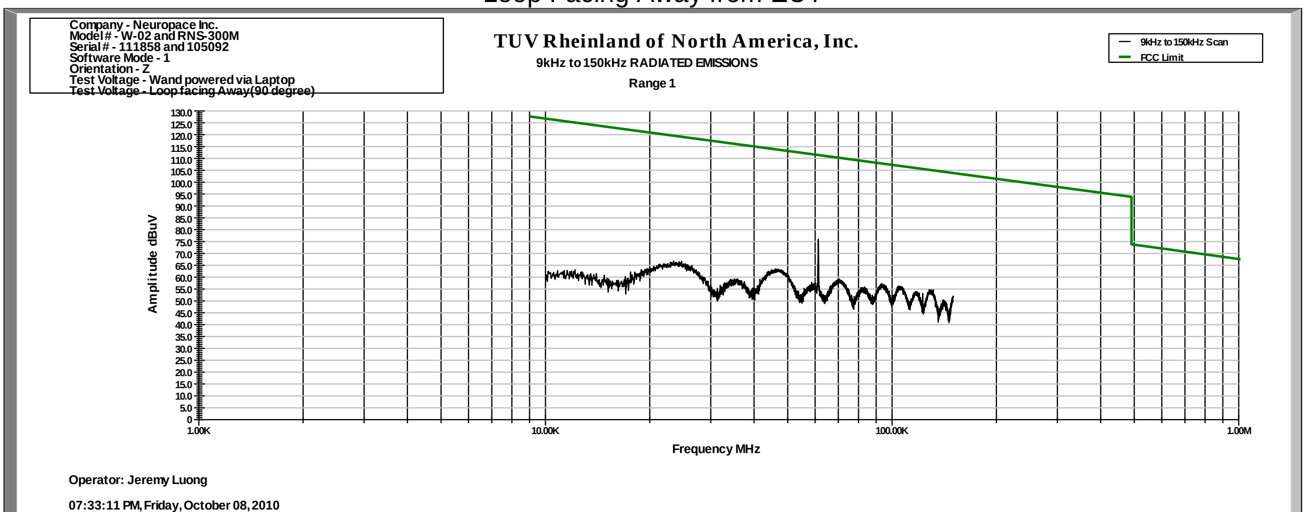
Combined Standard Uncertainty $u_c(y)$ = ± 3.2 dB Expanded Uncertainty $U = ku_c(y)$ k = 2 for 95% confidence

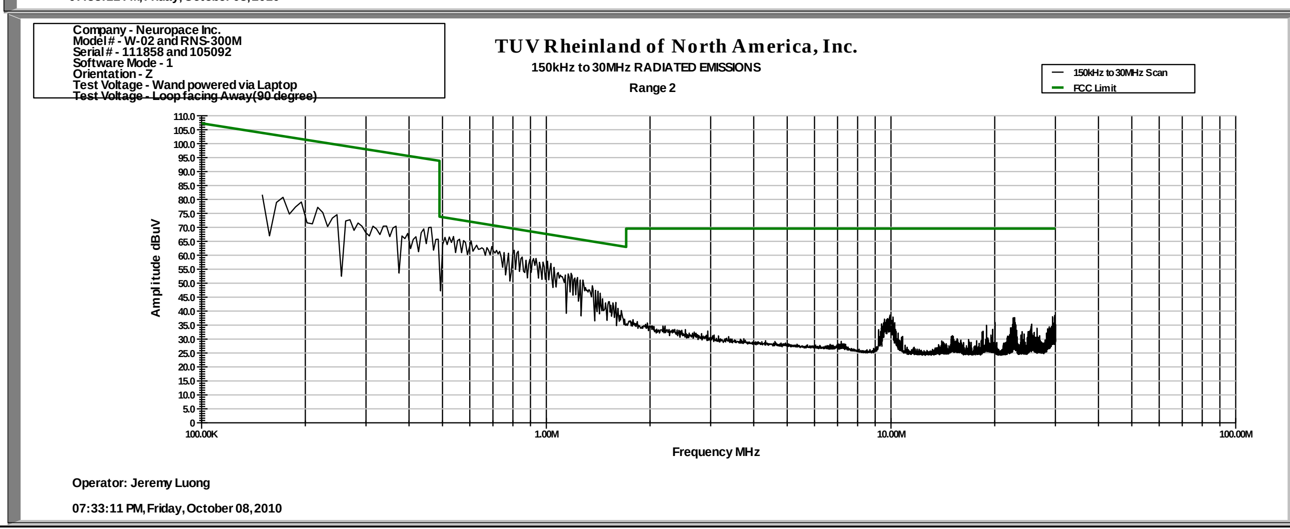
Notes: (*) Average measurement.
Final scan performed on Z-Axis; worst orientation.
RBW / VBW Setting:
200 Hz / 1kHz for 9 kHz to 150 kHz
9 kHz / 30 kHz for 150 kHz to 30 MHz

SOP 1 Radiated Emissions — Tracking # 31051315.001 Page 4 of 5

EUT Name	NeuroPace® RNS® Neurostimulator	**Date**	October 8, 2010
EUT Model	RNS-300M	**Temp / Hum in**	22°C / 37% rh
EUT Serial	105092	**Temp / Hum out**	N/A
EUT Config.	Integral Antenna	**Line AC / Freq**	120 Vac, 60 Hz
Standard	CFR47 Part 15.205 and 15.209	**RBW / VBW**	See below
Dist/Ant Used	3m / EMCO6505	**Performed by**	Jeremy Luong

Emission Freq (MHz)	ANT Pos	ANT Pos (cm)	Table Pos (deg)	FIM (Pk) Pk (dBuV/m)	FIM Ave (dBuV/m)	Total CF dBuV	E-Field Ave (dBuV/m)	Spec Limit (dBuV/m)	Spec Margin (dB)	Type
Test ID # 8, 17: 9 kHz to 30 MHz at 3m, Mode 1 (TX)										
Loop Facing Away from EUT										





Spec Margin = E-Field QP/Ave - Limit, E-Field QP/Ave = FIM QP/Ave + Total CF ± Uncertainty
Total CF= Amp Gain + Cable Loss + ANT Factor

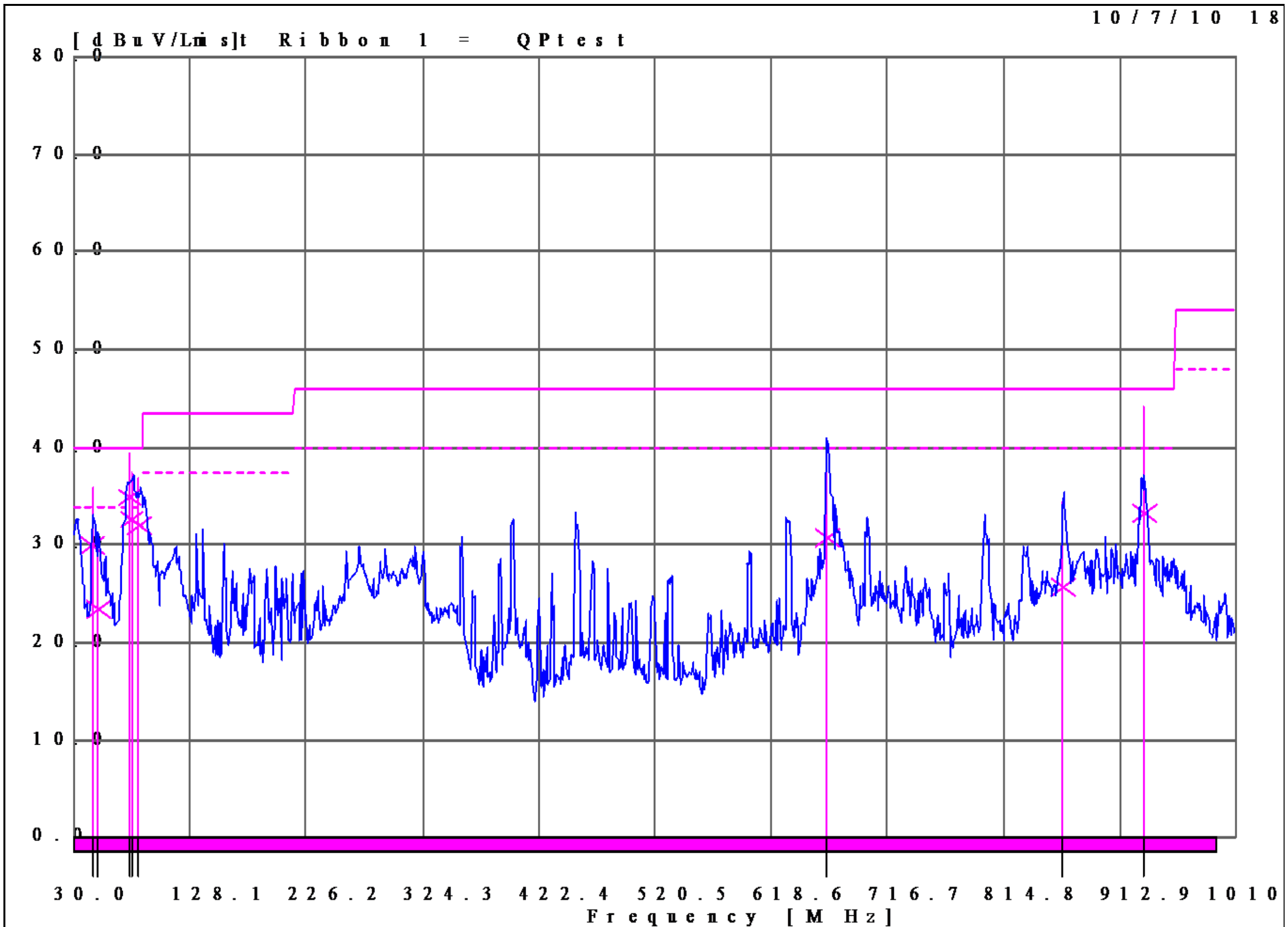
Combined Standard Uncertainty $u_c(y)$ = ± 3.2 dB Expanded Uncertainty $U = ku_c(y)$ k = 2 for 95% confidence

Notes: None.

SOP 1 Radiated Emissions — Tracking # 31051315.001 Page 5 of 5

EUT Name	NeuroPace® RNS® Neurostimulator	**Date**	October 4, 2010
EUT Model	RNS-300M	**Temp / Hum in**	23°C / 51% rh
EUT Serial	105092	**Temp / Hum out**	N/A
EUT Config.	Integral Antenna	**Line AC / Freq**	120 Vac, 60 Hz
Standard	CFR47 Part 15.205 and 15.209	**RBW / VBW**	120 kHz / 300 kHz
Dist/Ant Used	3m / EMCO3142	**Performed by**	Jeremy Luong

Emission Freq (MHz)	ANT Polar (H/V)	ANT Pos (cm)	Table Pos (deg)	FIM (Pk) Pk (dBuV/m)	FIM QP (dBuV/m)	Total CF dBuV	E-Field QP (dBuV/m)	Spec Limit (dBuV/m)	Spec Margin (dB)	Type
Test ID – 01: 30 MHz to 1000GHz at 3 meter. Mode 1 (TX)										
45.446	Vert	101	58	56.93	51.08	-21.09	29.99	40.00	-10.01	Spurious
50.467	Vert	103	182	53.52	46.00	-22.57	23.43	40.00	-16.57	Spurious
77.430	Vert	101	238	64.14	59.74	-24.81	34.93	40.00	-5.07	Spurious
78.657	Vert	102	239	62.02	57.30	-24.73	32.57	40.00	-7.43	Spurious
85.001	Vert	148	107	61.38	56.48	-24.44	32.04	40.00	-7.96	Spurious
665.862	Vert	102	321	48.06	38.93	-8.16	30.77	46.00	-15.23	Spurious
865.375	Vert	101	270	40.01	31.20	-5.52	25.68	46.00	-20.32	Spurious
933.328	Vert	120	32	48.38	37.27	-4.04	33.23	46.00	-12.77	Spurious



Spec Margin = E-Field QP - Limit, E-Field QP = FIM QP+ Total CF ± Uncertainty Total CF= Amp Gain + Cable Loss + ANT Factor
Combined Standard Uncertainty $u_c(y)$ = ± 3.2 dB Expanded Uncertainty $U = ku_c(y)$ k = 2 for 95% confidence
Notes: X-Axis was the worst orientation.

4.1.4 Sample Calculation

The field strength is calculated by subtracting the Amplifier Gain and adding the Cable Loss and Antenna Correction Factor to the measured reading. The basic equation is as follows:

Field Strength (dBμV/m) = FIM - AMP + CBL + ACF

Where: FIM = Field Intensity Meter (dBμV)
AMP = Amplifier Gain (dB)
CBL = Cable Loss (dB)
ACF = Antenna Correction Factor (dB/m)

$$\mu V/m = 10^{\frac{dB\mu V/m}{20}}$$

4.2 Receiver Spurious Emissions

Receiver spurious emissions are emissions at any frequency when the equipment is in receive mode.

The spurious emissions of the receiver shall not exceed the values in CFR47 Part 15.209: 2010

4.2.1 Test Methodology

4.2.1.1 Preliminary Test

A test program that controls instrumentation and data logging was used to automate the preliminary RF emission test procedure. The frequency range of interest was divided into sub-ranges to yield a frequency resolution of approximately 120 kHz and provide a reading at each frequency for no more than 12° of turntable rotation. For each frequency sub-range the turntable was rotated 360° while peak emission data was recorded and plotted over the frequency range of interest in horizontal and vertical antenna polarization's.

Preliminary emission profile testing was performed inside the anechoic chamber. The EUT was placed on a 1.0m x 1.5m non-conductive table 80cm above the floor. The EUT was positioned as shown in the setup photographs. The receiving antenna was placed at a distance of 3m at a fixed height of 1m. Measurement equipment was located outside of the chamber. A video camera was placed inside the chamber to view the EUT.

To determine the worst axis, the pre-scans performed on X-Axis, Y-Axis, and Z-Axis.

4.2.1.2 Final Test

For each frequency measured, the peak emission was maximized by manipulating the receiving antenna from 1 to 4 meters above the ground plane and placing it at the position that produced the maximum signal strength reading. The turntable was then rotated through 360° while observing the peak signal and placing the EUT at the position that produced maximum radiation. The six highest emissions relative to the limit were measured unless such emissions were more than 20 dB below the limit. If less than six emissions are within 20 dB of the limit, than the noise level of the receiver is measured at frequencies where emissions are expected. Multiples of all oscillator and microprocessor frequencies were also checked.

Final testing was performed on an NSA compliant test site. The EUT was placed on a 1.0m x 1.5m non-conductive table 80cm above the ground plane. The placement of EUT and cables were the same as for preliminary testing and is shown in the setup photographs.

The final scans performed on the Z-Axis for 9 kHz to 30 MHz, and X-Axis for 30 MHz to 1 GHz.

4.2.1.3 Deviations

None.

4.2.2 Receiver Spurious Emission Limit

The spurious emissions of the receiver shall not exceed the values in CFR47 Part 15.209: 2010

Frequency (MHz)	Field strength (microvolts/meter)	Measurement distance (meters)
0.009-0.490......................	2400/F(kHz)	300
0.490-1.705......................	24000/F(kHz)	30
1.705-30.0.......................	30	30
30-88............................	100 **	3
88-216...........................	150 **	3
216-960..........................	200 **	3
Above 960........................	500	3

4.2.3 Test Results

The final measurement data indicates the worst case operating modes, configurations, and/or cable positions. It also reflects the results including any modifications and/or special accessories listed in Sections 1.4 and 1.5.

As originally tested, the EUT was found to be compliant to the requirements of the test standard(s).

4.2.3.1 Final Data

The data recorded in this section contains the final results under the worst-case conditions and without any modifications or special accessories implemented as the manufacturer intends.

SOP 1 Radiated Emissions — Tracking # 31051315.001 Page 1 of 5

EUT Name	NeuroPace® RNS® Neurostimulator	**Date**	October 8, 2010
EUT Model	RNS-300M	**Temp / Hum in**	23°C / 48% rh
EUT Serial	105092	**Temp / Hum out**	N/A
EUT Config.	Integral Antenna	**Line AC / Freq**	120 Vac, 60 Hz
Standard	CFR47 Part 15.209	**RBW / VBW**	See below
Dist/Ant Used	3m / EMCO 6505	**Performed by**	Jeremy Luong

Emission Freq (MHz)	ANT Polar	ANT Pos (cm)	Table Pos (deg)	FIM (Pk) Pk (dBuV/m)	FIM QP/Ave (dBuV/m)	Total CF dBuV	E-Field QP/Ave (dBuV/m)	Spec Limit (dBuV/m)	Spec Margin (dB)	Type
Test ID # 7,18 : 9 kHz to 30 MHz at 3 meter Distance Mode 2 (Loop facing EUT)										
0.022*	Facing	100	181	78.54	67.94	14.76	82.70	119.97	-37.27	Spurious
0.044*	Facing	100	180	77.21	66.45	12.46	78.91	114.11	-35.20	Spurious
0.057*	Facing	100	183	73.70	63.05	12.00	75.05	112.03	-36.99	Spurious
0.101*	Facing	100	183	70.67	59.99	11.56	71.55	107.14	-35.59	Spurious
0.523	Facing	100	195	60.57	57.28	11.63	68.91	73.23	-4.32	Spurious
0.600	Facing	100	195	58.83	56.49	11.67	68.16	72.04	-3.88	Spurious
0.699	Facing	100	195	57.06	54.12	11.75	65.87	70.71	-4.84	Spurious

Spec Margin = E-Field QP/Ave - Limit, E-Field QP/Ave = FIM QP/Ave + Total CF ± Uncertainty
Total CF= Amp Gain + Cable Loss + ANT Factor

Combined Standard Uncertainty $u_c(y)$ = ± 3.2 dB Expanded Uncertainty $U = ku_c(y)$ k = 2 for 95% confidence

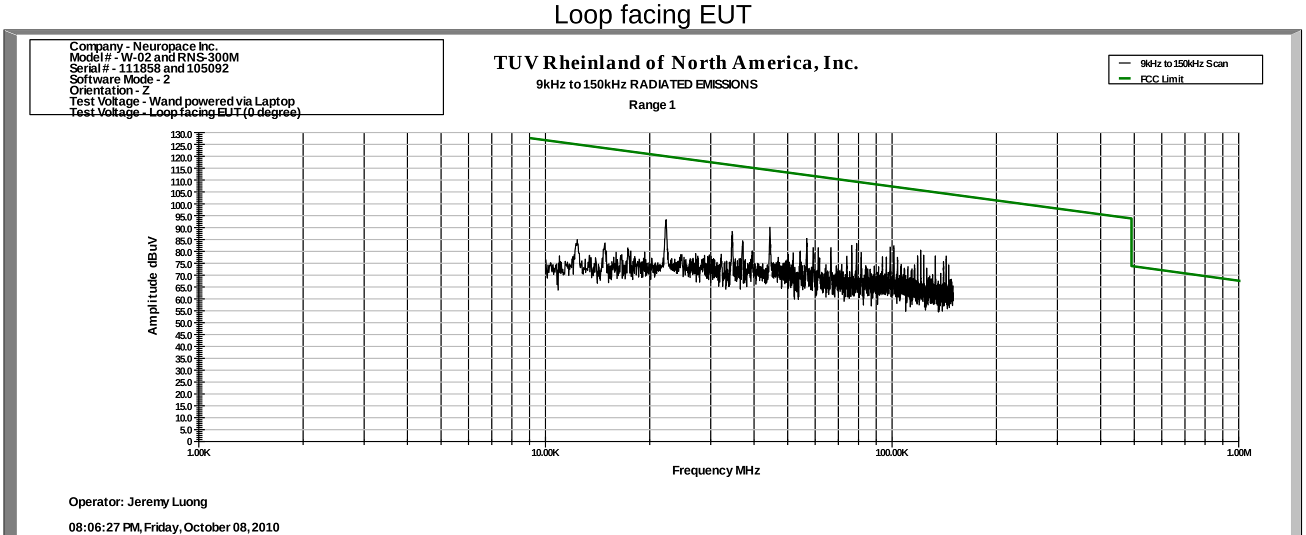
Notes: (*) Average measurement.
Final scan performed on Z-Axis; worst orientation.
RBW / VBW Setting:
200 Hz / 1kHz for 9 kHz to 150 kHz
9 kHz / 30 kHz for 150 kHz to 30 MHz

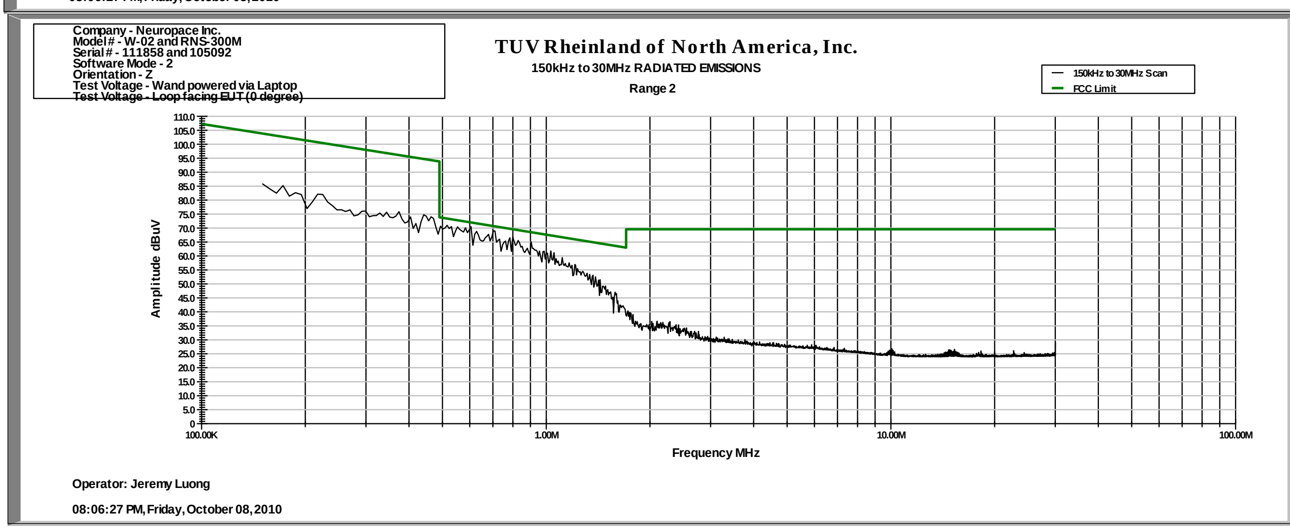
SOP 1 Radiated Emissions — Tracking # 31051315.001 Page 2 of 5

EUT Name	NeuroPace® RNS® Neurostimulator	**Date**	October 8, 2010
EUT Model	RNS-300M	**Temp / Hum in**	23°C / 48% rh
EUT Serial	105092	**Temp / Hum out**	N/A
EUT Config.	Integral Antenna	**Line AC / Freq**	120 Vac, 60 Hz
Standard	CFR47 Part 15.209	**RBW / VBW**	See below
Dist/Ant Used	3m / EMCO 6505	**Performed by**	Jeremy Luong

Emission Freq (MHz)	ANT Polar	ANT Pos (cm)	Table Pos (deg)	FIM (Pk) Pk (dBuV/m)	FIM Ave (dBuV/m)	Total CF dBuV	E-Field Ave (dBuV/m)	Spec Limit (dBuV/m)	Spec Margin (dB)	Type
Test ID # 7,18 : 9 kHz to 30 MHz at 3 meter Distance Mode 2 (Loop facing EUT)										

Loop facing EUT





Spec Margin = E-Field QP/Ave - Limit, E-Field QP/Ave = FIM QP/Ave + Total CF ± Uncertainty
Total CF= Amp Gain + Cable Loss + ANT Factor

Combined Standard Uncertainty $u_c(y)$ = ± 3.2 dB Expanded Uncertainty $U = ku_c(y)$ k = 2 for 95% confidence

Notes: Final scan performed on Z-Axis; worst orientation.

SOP 1 Radiated Emissions

Tracking # 31051315.001 Page 3 of 5

EUT Name	NeuroPace® RNS® Neurostimulator	**Date**	October 8, 2010
EUT Model	RNS-300M	**Temp / Hum in**	23°C / 48% rh
EUT Serial	105092	**Temp / Hum out**	N/A
EUT Config.	Integral Antenna	**Line AC / Freq**	120 Vac, 60 Hz
Standard	CFR47 Part 15.209	**RBW / VBW**	See below
Dist/Ant Used	3m / EMCO6505	**Performed by**	Jeremy Luong

Emission Freq (MHz)	ANT Pos	ANT Pos (cm)	Table Pos (deg)	FIM (Pk) Pk (dBuV/m)	FIM QP/Ave (dBuV/m)	Total CF dBuV	E-Field QP/Ave (dBuV/m)	Spec Limit (dBuV/m)	Spec Margin (dB)	Type
Test ID # 7,18 : 9 kHz to 30 MHz at 3 meter Distance Mode 2 (Loop facing away)										
0.022*	Away	100	82	74.14	63.04	14.76	77.80	119.97	-42.17	Spurious
0.044*	Away	100	76	72.54	61.21	12.46	73.67	114.11	-40.43	Spurious
0.099*	Away	100	97	66.45	55.68	11.56	67.24	107.35	-40.11	Spurious
0.576	Away	100	262	55.57	53.09	11.66	64.75	72.39	-7.64	Spurious
0.700	Away	100	262	52.94	50.11	11.75	61.86	70.71	-8.85	Spurious

Spec Margin = E-Field QP/Ave - Limit, E-Field QP/Ave = FIM QP/Ave + Total CF ± Uncertainty
Total CF= Amp Gain + Cable Loss + ANT Factor

Combined Standard Uncertainty $u_c(y)$ = ± 3.2 dB Expanded Uncertainty $U = ku_c(y)$ k = 2 for 95% confidence

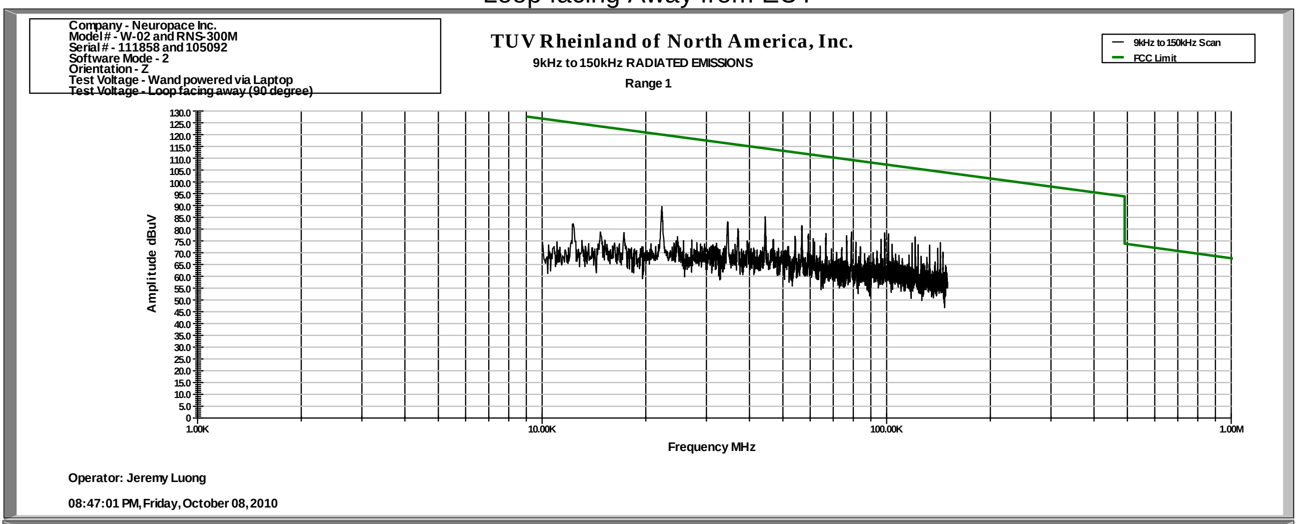
Notes: (*) Average measurement.
Final scan performed on Z-Axis; worst orientation.
RBW / VBW Setting:
200 Hz / 1kHz for 9 kHz to 150 kHz
9 kHz / 30 kHz for 150 kHz to 30 MHz

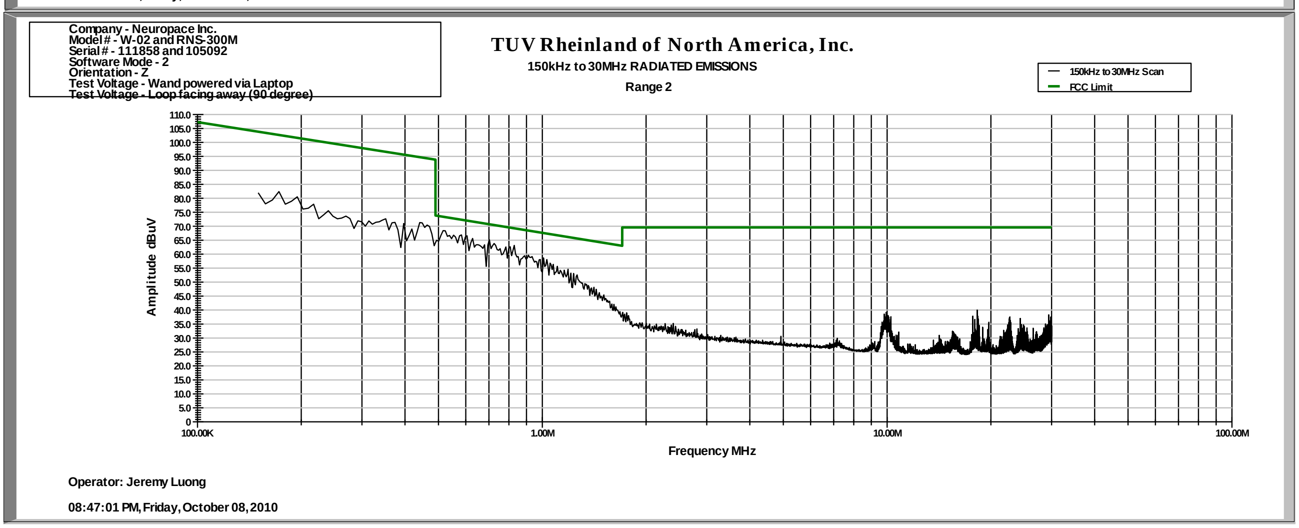
SOP 1 Radiated Emissions   Tracking # 31051315.001 Page 4 of 5

EUT Name	NeuroPace® RNS® Neurostimulator	**Date**	October 8, 2010
EUT Model	RNS-300M	**Temp / Hum in**	23°C / 48% rh
EUT Serial	105092	**Temp / Hum out**	N/A
EUT Config.	Integral Antenna	**Line AC / Freq**	120 Vac, 60 Hz
Standard	CFR47 Part 15.209	**RBW / VBW**	See Below
Dist/Ant Used	3m / EMCO6505	**Performed by**	Jeremy Luong

Emission Freq (MHz)	ANT Pos	ANT Pos (cm)	Table Pos (deg)	FIM (Pk) Pk (dBuV/m)	FIM Ave (dBuV/m)	Total CF dBuV	E-Field Ave (dBuV/m)	Spec Limit (dBuV/m)	Spec Margin (dB)	Type
Test ID # 7,18 : 9 kHz to 30 MHz at 3 meter Distance Mode 2 (Loop facing away)										

Loop facing Away from EUT





Spec Margin = E-Field QP/Ave - Limit, E-Field QP/Ave = FIM QP/Ave + Total CF ± Uncertainty
Total CF= Amp Gain + Cable Loss + ANT Factor

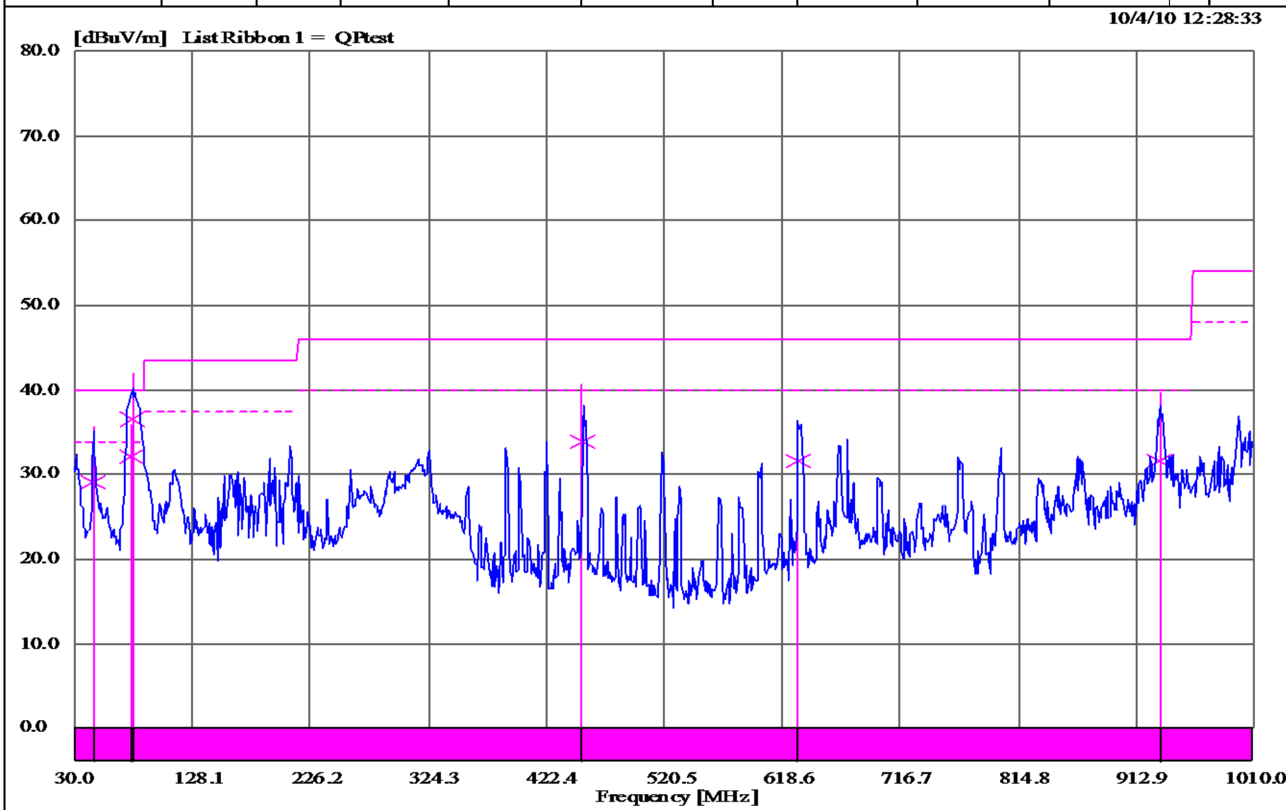
Combined Standard Uncertainty $u_c(y) = \pm 3.2$ dB   Expanded Uncertainty $U = ku_c(y)$ $k = 2$ for 95% confidence

Notes: Final scan performed on Z-Axis; worst orientation.

SOP 1 Radiated Emissions — Tracking # 31051315.001 Page 5 of 5

EUT Name	NeuroPace® RNS® Neurostimulator	**Date**	October 4, 2010
EUT Model	RNS-300M	**Temp / Hum in**	23°C / 48% rh
EUT Serial	105092	**Temp / Hum out**	N/A
EUT Config.	Integral Antenna	**Line AC / Freq**	120 Vac, 60 Hz
Standard	CFR47 Part 15.209	**RBW / VBW**	120 kHz / 300 kHz
Dist/Ant Used	3m / EMCO3142	**Performed by**	Jeremy Luong

Emission Freq (MHz)	ANT Polar (H/V)	ANT Pos (cm)	Table Pos (deg)	FIM (Pk) Pk (dBuV/m)	FIM QP (dBuV/m)	Total CF dBuV	E-Field QP (dBuV/m)	Spec Limit (dBuV/m)	Spec Margin (dB)	Type
Test ID 02: 30 MHz to 1000GHz at 3 meter. Mode 2 (RX)										
45.550	Vert	102	127	56.78	50.27	-21.13	29.14	40.00	-10.86	Spurious
77.155	Vert	103	220	60.70	56.99	-24.81	32.18	40.00	-7.82	Spurious
77.600	Vert	101	224	66.30	61.23	-24.81	36.42	40.00	-3.58	Spurious
452.815	Vert	104	192	52.89	46.02	-12.14	33.88	46.00	-12.12	Spurious
631.401	Vert	102	86	44.30	39.95	-8.40	31.55	46.00	-14.45	Spurious
932.562	Horz	99	56	43.82	35.67	-4.09	31.58	46.00	-14.42	Spurious



Spec Margin = E-Field QP - Limit, E-Field QP = FIM QP+ Total CF ± Uncertainty
Total CF= Amp Gain + Cable Loss + ANT Factor

Combined Standard Uncertainty $u_c(y)$ = ± 3.2 dB Expanded Uncertainty $U = ku_c(y)$ k = 2 for 95% confidence

Notes: Final scan performed on X-Axis; worst orientation.

4.2.4 Sample Calculation

The field strength is calculated by subtracting the Amplifier Gain and adding the Cable Loss and Antenna Correction Factor to the measured reading. The basic equation is as follows:

Field Strength (dBμV/m) = FIM - AMP + CBL + ACF

Where: FIM = Field Intensity Meter (dBμV)
AMP = Amplifier Gain (dB)
CBL = Cable Loss (dB)
ACF = Antenna Correction Factor (dB/m)

$$\mu V/m = 10^{\frac{dB\mu V/m}{20}}$$

4.3 AC Conducted Emissions

Testing was performed in accordance with ANSI C63.10:2009, RSS-210. These test methods are listed under the laboratory's NVLAP Scope of Accreditation.

This test measures the levels emanating from the EUT' AC input port, thus evaluating the potential for the EUT to cause radio frequency interference to other electronic devices.

The AC conducted emissions of equipment under test shall not exceed the values in CFR47 Part 15.207

4.3.1 Test Methodology

A test program that controls instrumentation and data logging was used to automate the AC Power Line Conducted emission test procedure. The frequency range of interest was divided into sub-ranges such as to yield a frequency resolution of 9 kHz. Each phase and neutral of the AC power line were measured with respect to ground. Measurements were performed using a set of 50 μH / 50 Ω LISNs.

Testing is performed in Lab 2. The setup photographs clearly identify which site was used. The vertical ground plane used in the semi-anechoic chamber is a 2m x 2m solid aluminum frame and panel, and it is bonded to the horizontal ground plane.

In the case of tabletop equipment, the EUT is placed on a 1.0m x 1.5m non-conductive table 80cm above the ground plane and 40cm from a vertical ground reference plane. The rear of the EUT was positioned flush with the backside of the table and directly over the LISNs. The power and I/O cables were routed over the edge of the table and bundled approximately 40cm from the ground plane. Support equipment was powered from a separate LISN.

4.3.1.1 Deviations

There were no deviations from this test methodology.

4.3.2 Test Results

AC conducted emission is not applicable for neurostimulator since the NeuroPace® RNS® Neurostimulator was powered by 3.2V QMR (SVO / CFx) battery.

5 Test Equipment Use List

5.1 Equipment List

Equipment	Manufacturer	Model #	Serial/Inst #	Last Cal dd/mm/yy	Next Cal dd/mm/yy	Test
EMI Receiver (Receiver Section)	HP	85462A	3807A00445	01/20/2010	01/20/2011	RE
EMI Receiver (RF Filter Section)	HP	85460A	3704A00407	01/20/2010	01/20/2011	RE
EMI Receiver (Receiver Section)	HP	85462A	3942A00514	02/23/2010	02/23/2011	CE
EMI Receiver (RF Filter Section)	HP	85460A	3330A00174	02/23/2010	02/23/2011	CE
9 kHz – 1 GHz Preamplifier	Sonoma	310	185516	01/20/2010	01/20/2011	RE
Bilog Antenna Emissions	EMCO	3142	9701-1117	07/14/2010	07/14/2011	RE
Loop Antenna	EMCO	6502	9110-2683	08/13/2010	08/13/2012	RE
LISN	Solar	9348-50-R-24-BNC	961012	01/21/2010	01/21/2011	CE
Spectrum Analyzer	Rhode & Schwarz	ESIB	832427	01/22/2010	01/22/2011	RE

Note: CE = Conducted Emissions, CI= Conducted Immunity, DP=Disturbance Power, EFT=Electrical Fast Transients, ESD = Electrostatic Discharge, FLI=Flicker, HAR=Harmonics, MF=Magnetic Field Immunity, RE=Radiated Emissions, RI=Radiated Immunity, SI=Surge Immunity, VDSI=Voltage Dips and Short Interruptions

6 Photo

6.1 Test Setup Photo

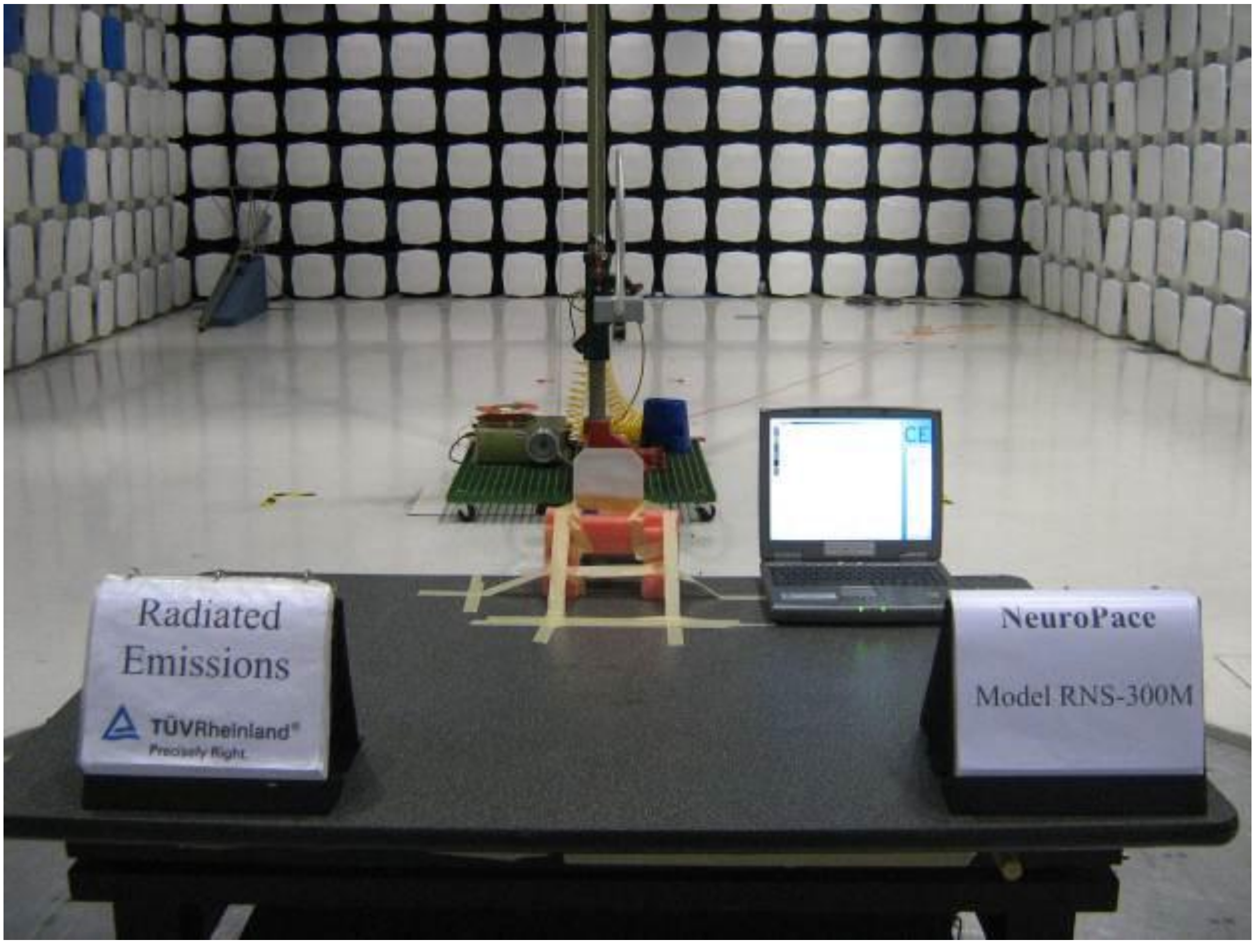


Figure 1: Test Setup for 9 kHz to 30 MHz Radiated Emission (Front View) – Loop Facing Away

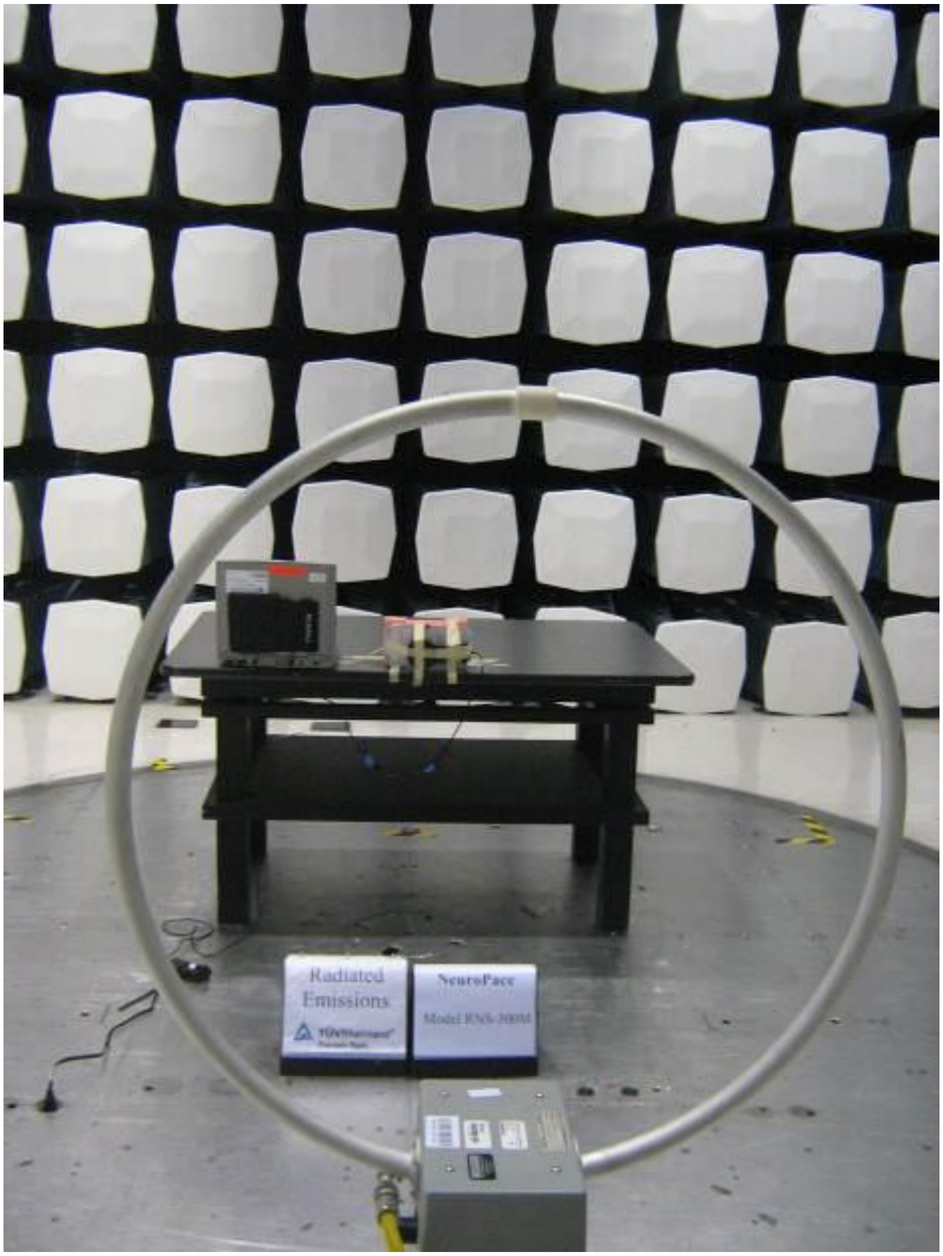


Figure 2: Test Setup for 9 kHz to 30 MHz Radiated Emission (Rear View) – Loop Facing EUT

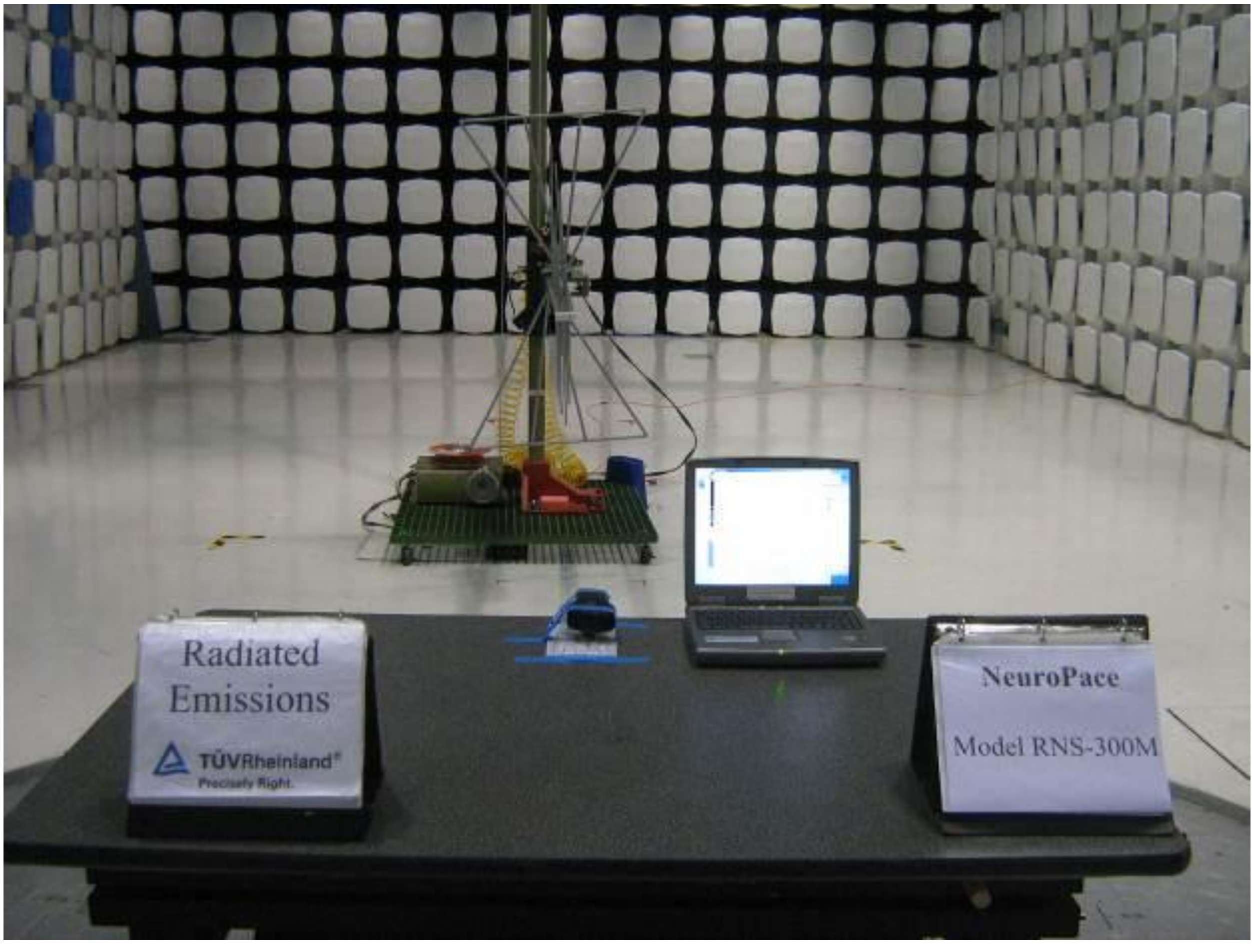


Figure 3: Test Setup for 30 MHz to 1000 MHz Radiated Emission (Front View)

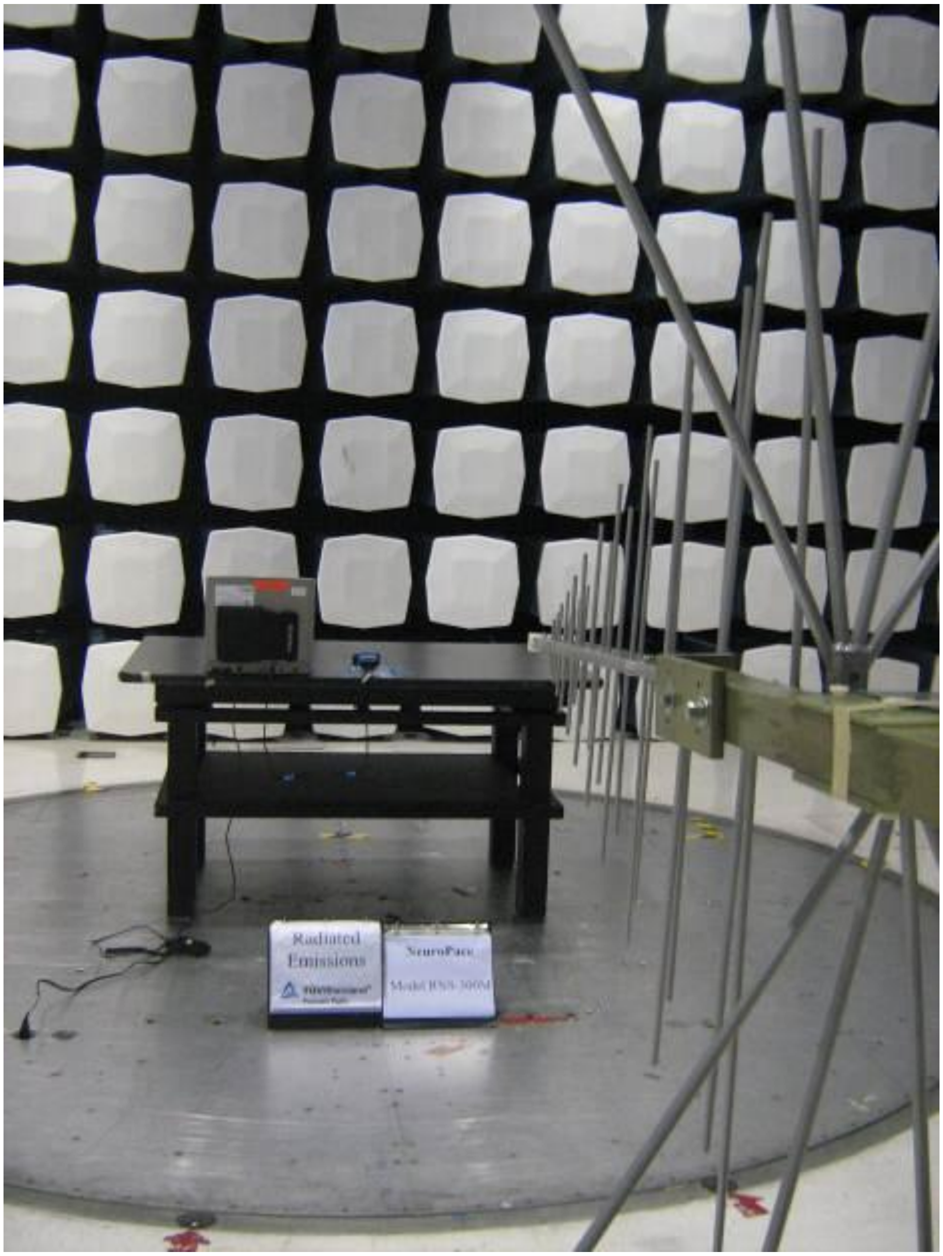


Figure 4: Test Setup for 30 MHz to 1000 MHz Radiated Emission (Rear View)

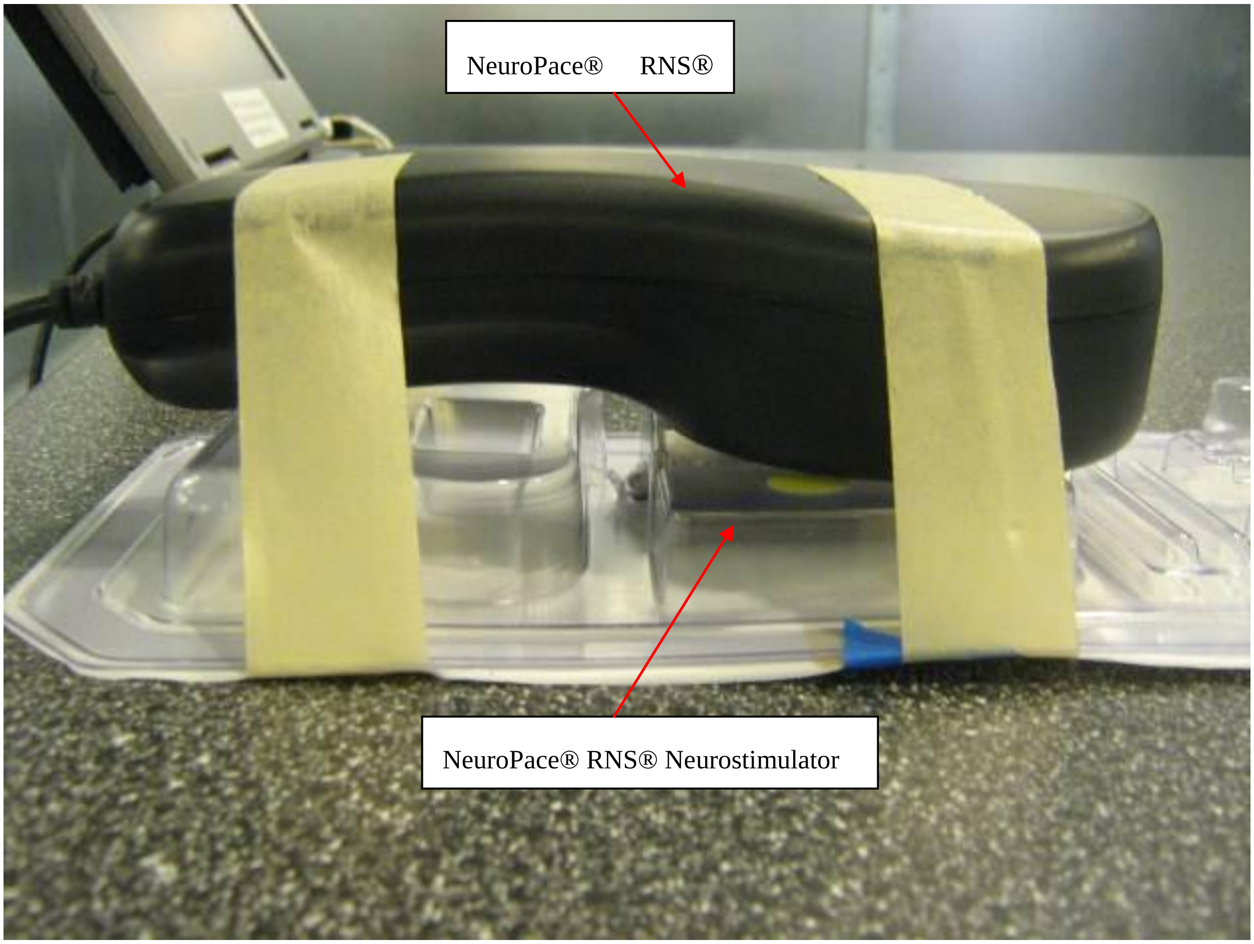


Figure 5: Setup Photo of NeuroPace® RNS® Neurostimulator and NeuroPace® RNS® Neurostimulator (Side View)

6.2 Product Under Test Photo

Figure 6: External Photo of RNS-300M (Top View)

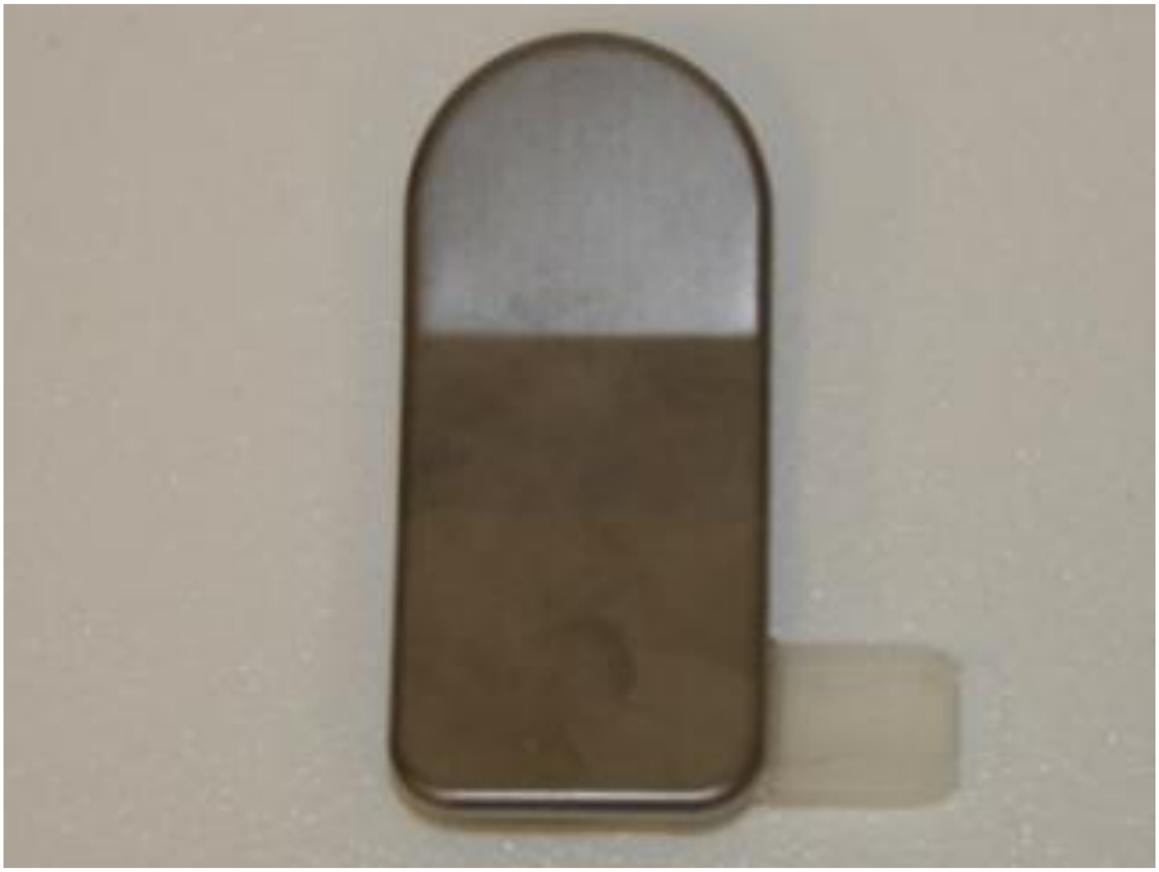


Figure 7: External Photo of RNS-300M (Bottom View)

Figure 8: External Photo of RNS-300M (Side View)

7 EMC Test Plan

7.1 Introduction

This section provides a description of the Equipment Under Test (EUT), configurations, operating conditions, and performance acceptance criteria. It is an overview of information provided by the manufacturer so that the test laboratory may perform the requested testing.

7.2 Customer

Table 3: Customer Information

Company Name	NeuroPace Inc.
Address	1375 Shorebird Way
City, State, Zip	Mountain View, CA 94043
Country	USA
Phone	(650) 237-2700
Fax	(650) 237-2701

Table 4: Technical Contact Information

Name	Barbara Gibb
E-mail	bgibb@neuropace.com
Phone	(650) 237-2700
Fax	(650) 237-2701

7.3 Equipment Under Test (EUT)

Table 5: EUT Specifications

Dimensions	Width: 28 mm Length: 60 mm Thickness: 7.7 mm
Mass	16 grams
Supply	$V_{nominal}$: 3.2 Vdc
Environment	Implant
Operating Temperature Range:	14 to 42° C
Feeds:	☒ Yes and how many 1
Operating Band	Inductive Telemetry
Transmitter Frequency Band	50 kHz
Receiver Frequency Band	20-25 kHz
Rated Power Output	< 3.5 pW (not measurable above the noise floor)
# Operating Channel	1
Antenna Type	Integrated Rectangular shape Coil Antenna
Antenna Gain	Not Specific (Unknown)
Modulation Type	☐ AM ☐ FM ☐ Phase ☒ Other describe: Half Duplex.
Type of Equipment	☒ Table Top ☐ Wall-mount ☐ Floor standing cabinet ☒ Other *Describe: Implant Device*
Clocks/Oscillating Frequency	10 kHz, 50 kHz, 100 kHz.

Table 6: Interface Specifications

Interface Type	Cabled with what type of cable?	Is the cable shielded?	Maximum potential length of the cable?	Metallic (M), Coax (C), Fiber (F), or Not Applicable?
Induction	None	☒ None	☒ None	☒ NA

Table 7: Supported Equipment

Equipment	Manufacturer	Model	Serial
Laptop	Dell, Inc.	PP08L	CN-0F3553-12961-4A8-8212
Laptop Power Supply	Dell, Inc.	PA-1650-05D2	CN-0F7970-71515-91J-2E43
Wand	NeuroPace, Inc.	W-02	111858

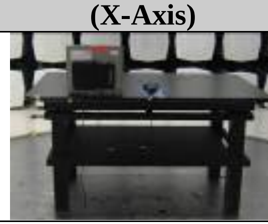
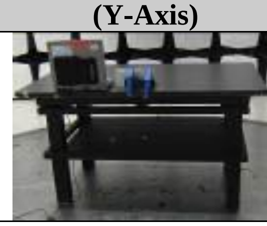
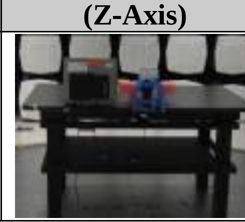
Table 8: Samples used for Testing

Device	Serial #	Requirements	Scan Type
NeuroPace® RNS® Neurostimulator	105092	CFR47 Part 15.207	N/A: EUT is battery powered.
NeuroPace® RNS® Neurostimulator	105092	CFR47 Part 15.205, 15.209,	Pre-scan, radiated measurement for 3 orientations.
NeuroPace® RNS® Neurostimulator	105092	CFR47 Part 15.205, 15.209	Final, radiated measurement on the worst orientation.

7.4 Test Setup

7.4.1 Test Configuration

Table 9: Description of Test Configuration used for Radiated Measurement.

Device	Antenna	Mode	Setup Photo (X-Axis)	Setup Photo (Y-Axis)	Setup Photo (Z-Axis)
NeuroPace® RNS® Neurostimulator	Attached	Transmit/ Receive			
Remark: Pre-scans were performed on all three orientations, and the worst orientation was selected for final testing.					

7.4.2 Test Software

Engineering Programmer II Test software, P/N 1005682 was installed on test laptop. EM Test Software, P/N 1006922 was installed on test laptop and installed on Neurostimulator. They were used to configure the software mode.

7.4.3 Test Mode

Software Mode	Wand Mode	Neurostimulator Mode	Notes
1	Transmit	Receive	The Neurostimulator is continuously streaming Real-Time ECoGs to the Wand
2	Receive	Transmit	The Wand is continuously downloading code into the Neurostimulator

7.4.4 Radiated Emission Test Matrix

Table 10: Test Matrix for Radiated Emission

Test #	Freq Range	Software Mode	Orientation	Antenna Distance	Notes
1	30 MHz – 1 GHz	1	X	3m	None
2	30 MHz – 1 GHz	2	X	3m	None
3	30 MHz – 1 GHz	2	Y	3m	None
4	30 MHz – 1 GHz	1	Y	3m	None
5	30 MHz – 1 GHz	1	Z	3m	None
6	30 MHz – 1 GHz	2	Z	3m	None
7	150 kHz – 30 MHz	2	Z	3m	None
8	150 kHz – 30 MHz	1	Z	3m	None
9	150 kHz – 30 MHz	1	Y	3m	None
10	150 kHz – 30 MHz	2	Y	3m	None
11	150 kHz – 30 MHz	2	X	3m	None
12	150 kHz – 30 MHz	1	X	3m	None
13	9 kHz – 150 kHz	1	X	3m	None
14	9 kHz – 150 kHz	2	X	3m	None
15	9 kHz – 150 kHz	2	Y	3m	None
16	9 kHz – 150 kHz	1	Y	3m	None
17	9 kHz – 150 kHz	1	Z	3m	None
18	9 kHz – 150 kHz	2	Z	3m	None

7.5 Test Specifications

Testing requirements

Table 11: Test Requirements

Emissions	
Standard	Requirement
CFR 47 Part 15.205, 15.207, 15.209	All, intended for NeuroPace® RNS® Neurostimulator Model RNS-300M.

8 Revision History

Revision No.	Date	Reason for Change	Author
0	October 15, 2010	Original Document	N/A
1	August 12, 2011	Change Table 5 (pg 41) Rated Power Output from "300 uW" to "< 3.5 pW (not measureable above the noise floor)"	Conan Boyle
2	January 31, 2012	Update plot on Page 20	Jeremy Luong
3	February 6, 2012	Remove EUT detailed information in Table 5	Conan Boyle

Note: Latest revision report will replace all previous reports.

END OF REPORT