

Emissions Test Report

EUT Name: NeuroPace® RNS® Neurostimulator

Model No.: RNS-320

CFR 47 Part 15.205, 15.207, 15.209: 2016

Prepared for:

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Report/Issue Date: December 08, 2016
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Statement of Compliance

Manufacturer: NeuroPace, Inc.
455 Bernardo Ave.
Mountain View, CA 94043
(650) 237-2700

Requester / Applicant: Erica Lundmark

Name of Equipment: NeuroPace® RNS® Neurostimulator

Model No. RNS-320

Type of Equipment: Intentional Radiator

Application of Regulations: CFR 47 Part 15.205, 15.207, 15.209: 2016

Test Dates: 6-7 December 2016

Guidance Documents:

Emissions: ANSI C63.10: 2013

Test Methods:

Emissions: ANSI C63.10: 2013

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.

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Kerwinn Corpuz 08 December 2016

Test Engineer

Date

David Spencer

A2LA Signatory

08 December 2016

Date



Testing Cert #3331.02



US5254



Industry
Canada Industrie
Canada

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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: 2016 based on the results of testing performed on 6-7 December 2016 on the NeuroPace® RNS® Neurostimulator Model RNS-320 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 2013	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, Battery powered
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

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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 / A2LA



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 Testing Cert #3331.02). 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 2932M-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.

VCCI Registration No. for Pleasanton: A-0031

VCCI Registration No. for Santa Clara: A-0032

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 / A2LA 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 C63.7:2015. The site has been measured in accordance with and verified to comply with the theoretical normalized site attenuation requirements of ANSI C63.4:2014, at test distances of 3 and 5 meters. The site is listed with the FCC and accredited by A2LA (Lab Code Testing Cert #3331.02). The 3/5-meter semi-anechoic chamber used to collect the radiated data has been verified to comply with the theoretical normalized site attenuation requirements of ANSI C63.4:2014, at test distances of 3 and 5 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-k Ω 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-k Ω 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

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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.

2.3.1 Sample Calculation – radiated & conducted emissions

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:

$$\text{Field Strength (dB}\mu\text{V/m)} = \text{RAW} - \text{AMP} + \text{CBL} + \text{ACF}$$

Where: RAW = Measured level before correction (dBμV)

AMP = Amplifier Gain (dB)

CBL = Cable Loss (dB)

ACF = Antenna Correction Factor (dB/m)

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

Sample radiated emissions calculation @ 30 MHz

Measurement +Antenna Factor–Amplifier Gain+Cable loss=Radiated Emissions (dBuV/m)

$$25 \text{ dBuV/m} + 17.5 \text{ dB} - 20 \text{ dB} + 1.0 \text{ dB} = 23.5 \text{ dBuV/m}$$

Table 2: Summary of Uncertainties

	U _{lab}	U _{cispr}
Radiated Disturbance @ 10m		
30 MHz – 1,000 MHz	2.25 dB	4.51 dB
Radiated Disturbance @ 3 meters		
30 – 1,000 MHz	2.26 dB	4.52 dB
1 – 6 GHz	2.12 dB	4.25 dB
6 – 18 GHz	2.47 dB	4.93 dB
Conducted Disturbance @ Mains Terminals		
150 kHz – 30 MHz	1.09 dB	2.18 dB
Disturbance Power		
30 MHz – 300 MHz	3.92 dB	4.3 dB
Measurement Uncertainty Immunity		
The estimated combined standard uncertainty for ESD immunity measurements is ± 8.2%.		Per IEC 61000-4-2
The estimated combined standard uncertainty for radiated immunity measurements is ± 4.10 dB.		Per IEC 61000-4-3

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The estimated combined standard uncertainty for conducted immunity measurements with CDN is ± 3.66 dB	Per IEC 61000-4-6
The estimated combined standard uncertainty for power frequency magnetic field immunity is $\pm 2.9\%$.	Per IEC 61000-4-8
Thermo Keytek EMC Pro	
The estimated combined standard uncertainty for EFT fast transient immunity measurements is $\pm 2.6\%$.	
The estimated combined standard uncertainty for surge immunity measurements is $\pm 2.6\%$.	
The estimated combined standard uncertainty for voltage variation and interruption measurements is $\pm 1.74\%$.	

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.

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3 Product Information

3.1 Product Description

The NeuroPace® RNS® Neurostimulator model RNS-320 and patient Leads are medical products that are implanted by trained surgeons in order to treat a patient with a neurological disorder. The RNS-320 allows sensing of physiological signals on up to 2 patient leads, each containing 4 electrodes. The Neurostimulator contains sensing, therapy and data storage functions. The RNS-320 contains support for short range inductive telemetry at 20-50 kHz. Telemetry is sustained only when RNS-320 is in very near proximity to the Programmer or Remote Monitor with connected NeuroPace Wand.

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.

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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 uses an integrated coil that is internal to the welded-closed device case and is not accessible to the user. This coil is used for inductive telemetry communication.

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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 A2LA 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: 2016

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, then 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 all 3 axis for 9 kHz 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).

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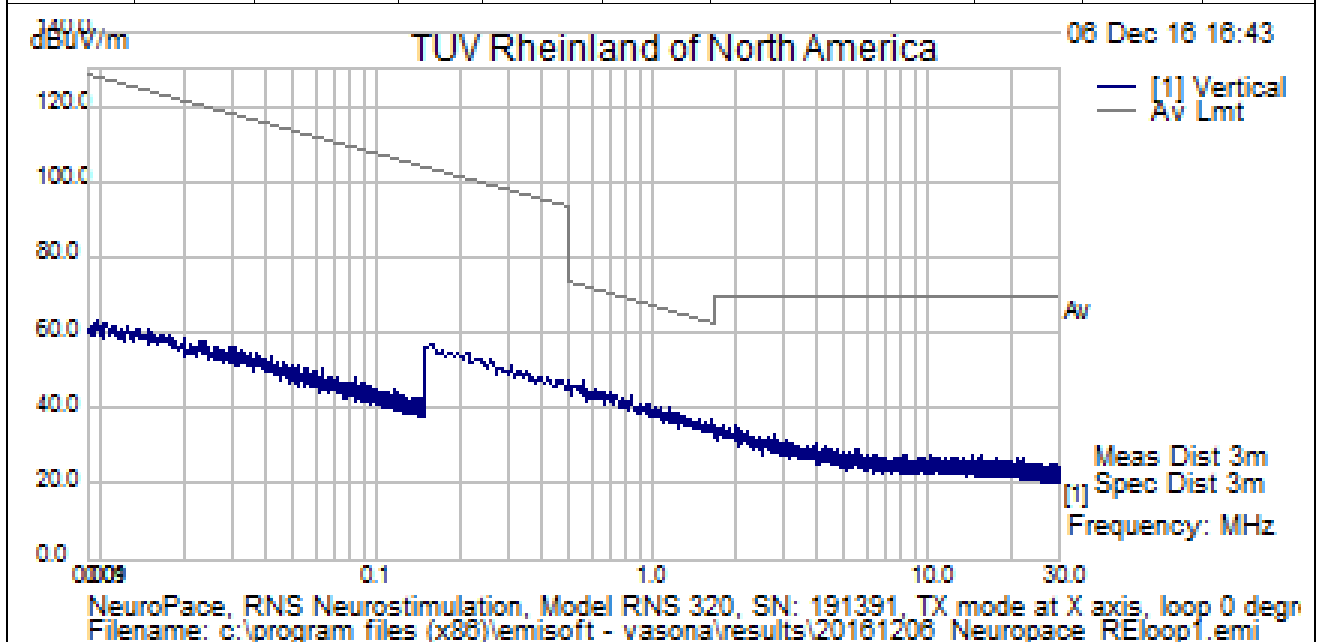
SOP 1 Radiated Emissions

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EUT Name	NeuroPace® RNS® Neurostimulator	Date	December 6, 2016
EUT Model	RNS-320	Temp / Hum in	22°C / 41% rh
EUT Serial	191391	Temp / Hum out	N/A
EUT Config.	Integral Antenna / TX mode / X axis	Line AC / Freq	N/A – EUT DC powered
Standard	CFR47 Part 15.205 and 15.209	RBW / VBW	See Note
Dist/Ant Used	3m / EMCO 6505	Performed by	Kerwinn Corpuz

Loop facing EUT (9 kHz – 30 MHz)

Frequency (MHz)	Raw (dBuV/m)	Cable Loss (dB)	AF (dB)	Level (dBuV/m)	Detector	Polarity	Height (cm)	Azimuth (deg)	Limit (dBuV/m)	Margin (dB)
0.62	32.34	2.06	10.30	44.70	Peak	Facing	100	57	71.71	-27.01
0.97	28.63	2.08	10.54	41.25	Peak	Facing	100	196	67.88	-26.64
1.26	25.96	2.09	10.60	38.65	Peak	Facing	100	99	65.61	-26.96
2.03	22.78	2.11	10.60	35.49	Peak	Facing	100	106	69.50	-34.01
2.82	20.21	2.14	10.52	32.87	Peak	Facing	100	196	69.50	-36.64
3.93	17.97	2.16	10.69	30.82	Peak	Facing	100	164	69.50	-38.68



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

Note: RBW / VBW Setting: 200 Hz / 1kHz for 9 kHz – 150 kHz; 9 kHz / 30 kHz for 150 kHz – 30 MHz.

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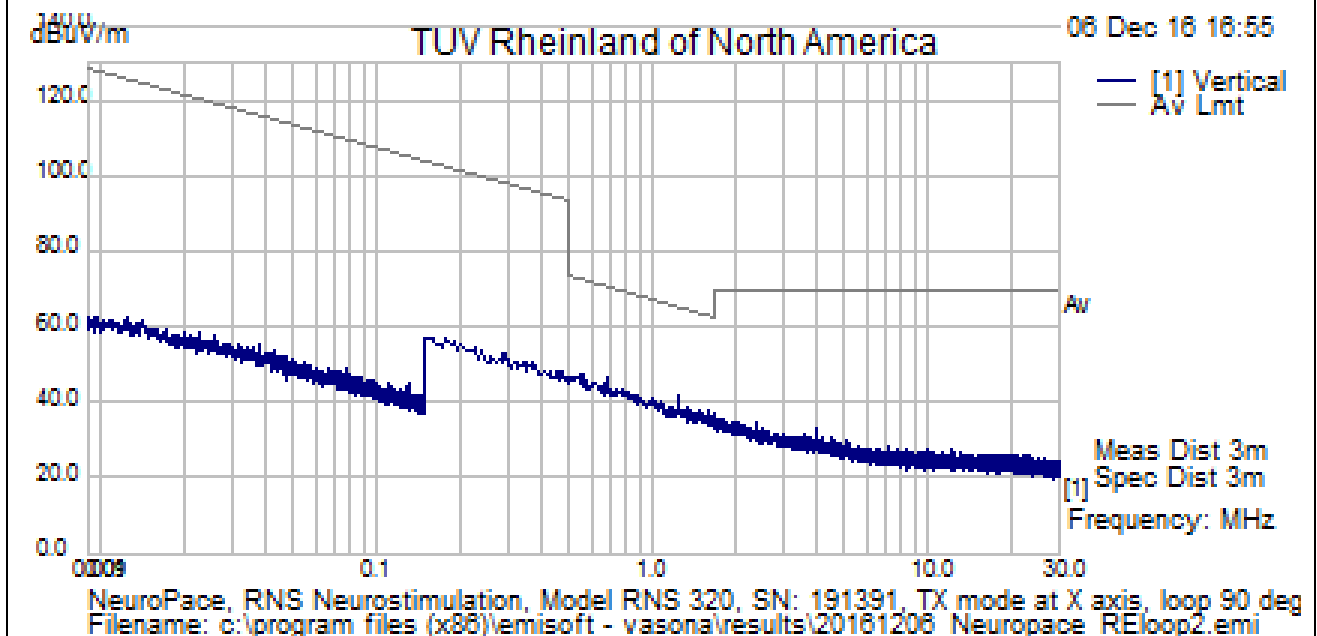
SOP 1 Radiated Emissions

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EUT Name	NeuroPace® RNS® Neurostimulator	Date	December 6, 2016
EUT Model	RNS-320	Temp / Hum in	22°C / 41% rh
EUT Serial	191391	Temp / Hum out	N/A
EUT Config.	Integral Antenna / TX mode / X axis	Line AC / Freq	N/A – EUT DC powered
Standard	CFR47 Part 15.205 and 15.209	RBW / VBW	See Note
Dist/Ant Used	3m / EMCO 6505	Performed by	Kerwinn Corpuz

Loop facing 90° angle from EUT (9 kHz – 30 MHz)

Frequency (MHz)	Raw (dBuV/m)	Cable Loss (dB)	AF (dB)	Level (dBuV/m)	Detector	Polarity	Height (cm)	Azimuth (deg)	Limit (dBuV/m)	Margin (dB)
0.68	33.99	2.06	10.30	46.35	Peak	Facing 90°	100	236	70.97	-24.62
1.25	29.20	2.09	10.60	41.89	Peak	Facing 90°	100	191	65.64	-23.75
1.35	26.07	2.09	10.60	38.76	Peak	Facing 90°	100	300	65.00	-26.24
1.79	23.20	2.11	10.60	35.91	Peak	Facing 90°	100	144	69.50	-33.59
2.38	21.93	2.12	10.56	34.61	Peak	Facing 90°	100	294	69.50	-34.89
3.94	20.41	2.16	10.69	33.26	Peak	Facing 90°	100	187	69.50	-36.24
4.50	17.72	2.17	10.70	30.59	Peak	Facing 90°	100	267	69.50	-38.91



NeuroPace, RNS Neurostimulation, Model RNS 320, SN: 191391, TX mode at X axis, loop 90 deg
Filename: c:\program files (x86)\emisoft - vasona\results\20161206_Neuropace_REloop2.emi

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

Note: RBW / VBW Setting: 200 Hz / 1kHz for 9 kHz – 150 kHz; 9 kHz / 30 kHz for 150 kHz – 30 MHz.

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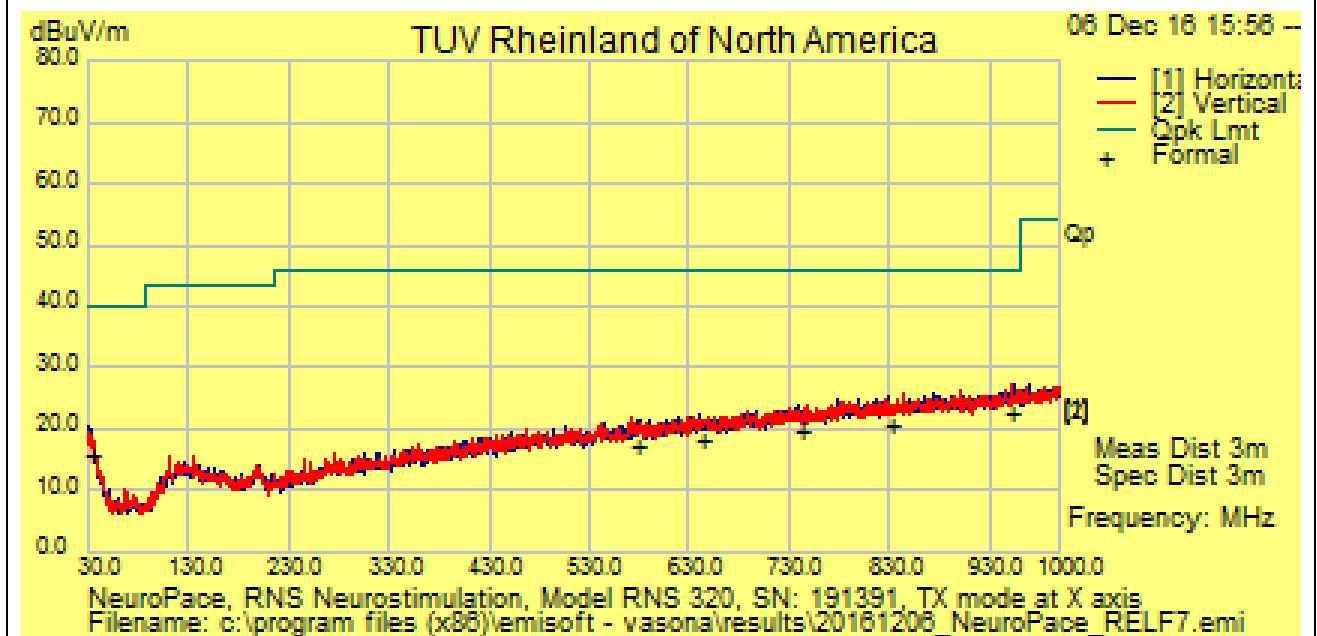
SOP 1 Radiated Emissions

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EUT Name	NeuroPace® RNS® Neurostimulator	Date	December 6, 2016
EUT Model	RNS-320	Temp / Hum in	22°C / 41% rh
EUT Serial	191391	Temp / Hum out	N/A
EUT Config.	Integral Antenna / TX mode / X axis	Line AC / Freq	N/A – EUT DC powered
Standard	CFR47 Part 15.205 and 15.209	RBW / VBW	120 kHz / 300 kHz
Dist/Ant Used	3m / EMCO3142	Performed by	Kerwinn Corpuz

(30 MHz – 1000 MHz)

Frequency (MHz)	Raw (dBuV/m)	Cable Loss (dB)	AF (dB)	Level (dBuV/m)	Detector	Polarity (H/V)	Height (cm)	Azimuth (deg)	Limit (dBuV/m)	Margin (dB)
31.21	22.14	1.57	-8.08	15.63	QP	H	175	244	40.00	-24.37
643.68	22.61	3.51	-7.73	18.40	QP	H	330	218	46.00	-27.60
742.03	22.16	3.72	-6.40	19.48	QP	H	110	76	46.00	-26.52
832.13	22.06	3.90	-5.22	20.74	QP	H	192	178	46.00	-25.26
950.96	21.50	4.11	-3.17	22.44	QP	H	341	78	46.00	-23.56
575.61	22.12	3.37	-8.53	16.96	QP	V	224	2	46.00	-29.04



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

Note: None

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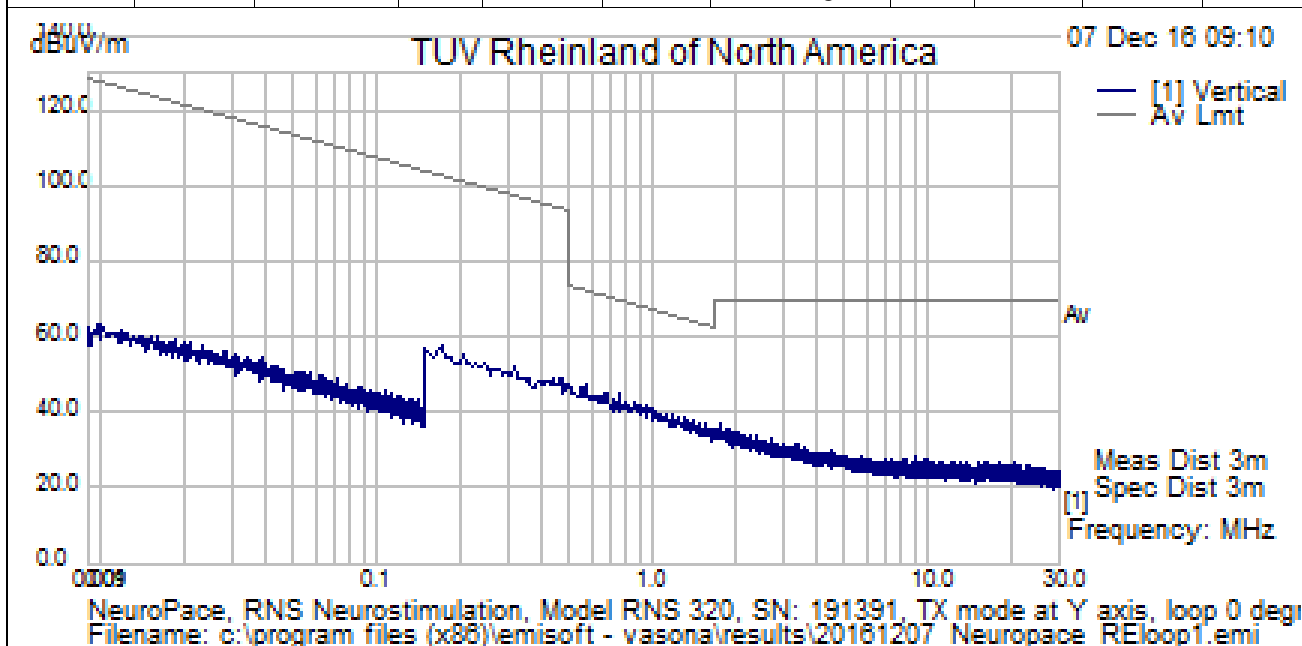
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EUT Name	NeuroPace® RNS® Neurostimulator	Date	December 7, 2016
EUT Model	RNS-320	Temp / Hum in	23°C / 37% rh
EUT Serial	191391	Temp / Hum out	N/A
EUT Config.	Integral Antenna / TX mode / Y axis	Line AC / Freq	N/A – EUT DC powered
Standard	CFR47 Part 15.205 and 15.209	RBW / VBW	See Note
Dist/Ant Used	3m / EMCO 6505	Performed by	Kerwinn Corpuz

Loop facing EUT (9 kHz – 30 MHz)

Frequency (MHz)	Raw (dBuV/m)	Cable Loss (dB)	AF (dB)	Level (dBuV/m)	Detector	Polarity	Height (cm)	Azimuth (deg)	Limit (dBuV/m)	Margin (dB)
0.68	33.08	2.06	10.30	45.44	Peak	Facing	100	78	70.97	-25.54
0.90	29.70	2.08	10.41	42.19	Peak	Facing	100	316	68.48	-26.29
1.32	25.79	2.09	10.60	38.48	Peak	Facing	100	279	65.21	-26.73
1.92	23.04	2.11	10.60	35.75	Peak	Facing	100	181	69.50	-33.75
2.74	20.24	2.13	10.52	32.90	Peak	Facing	100	178	69.50	-36.60
3.58	18.13	2.15	10.62	30.90	Peak	Facing	100	136	69.50	-38.60



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

Note: RBW / VBW Setting: 200 Hz / 1kHz for 9 kHz – 150 kHz; 9 kHz / 30 kHz for 150 kHz – 30 MHz.

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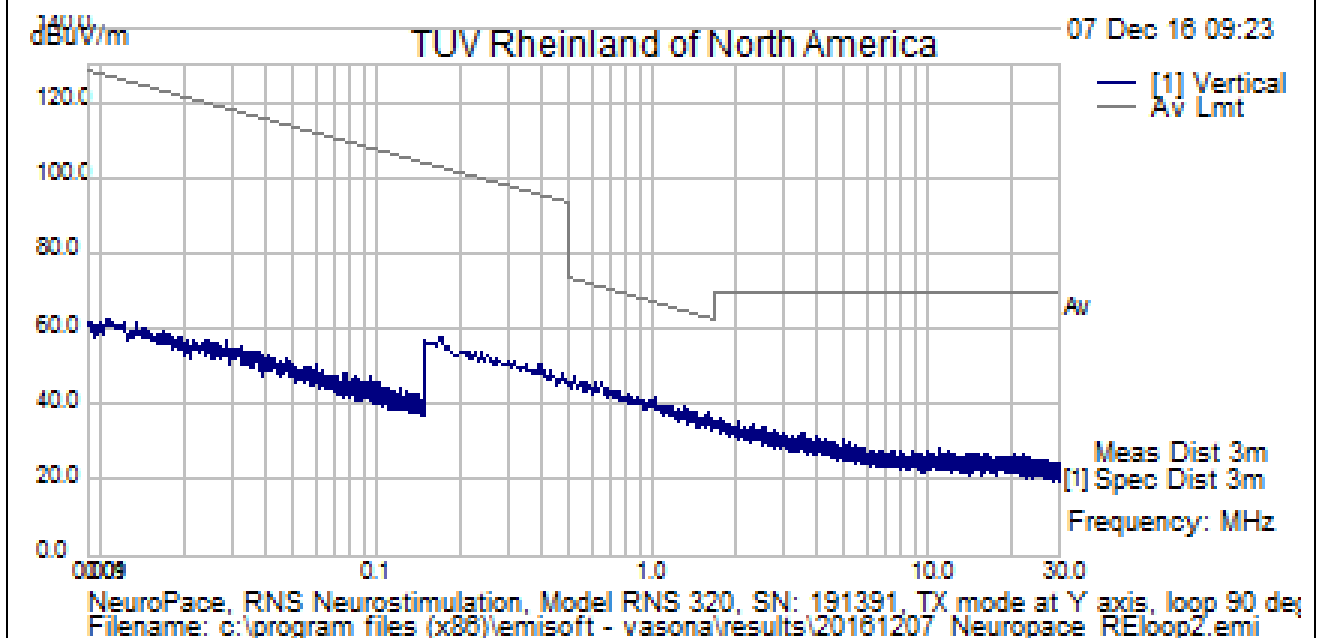
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Tracking # 31663720.001 Page 5 of 9

EUT Name	NeuroPace® RNS® Neurostimulator	Date	December 7, 2016
EUT Model	RNS-320	Temp / Hum in	23°C / 37% rh
EUT Serial	191391	Temp / Hum out	N/A
EUT Config.	Integral Antenna / TX mode / Y axis	Line AC / Freq	N/A – EUT DC powered
Standard	CFR47 Part 15.205 and 15.209	RBW / VBW	See Note
Dist/Ant Used	3m / EMCO 6505	Performed by	Kerwinn Corpuz

Loop facing 90° angle from EUT (9 kHz – 30 MHz)

Frequency (MHz)	Raw (dBuV/m)	Cable Loss (dB)	AF (dB)	Level (dBuV/m)	Detector	Polarity	Height (cm)	Azimuth (deg)	Limit (dBuV/m)	Margin (dB)
0.69	31.74	2.06	10.30	44.10	Peak	Facing 90°	100	249	70.85	-26.75
1.32	27.11	2.09	10.60	39.80	Peak	Facing 90°	100	301	65.18	-25.38
1.79	23.89	2.11	10.60	36.60	Peak	Facing 90°	100	47	69.50	-32.90
2.32	21.81	2.12	10.56	34.49	Peak	Facing 90°	100	40	69.50	-35.01
2.79	20.28	2.13	10.52	32.93	Peak	Facing 90°	100	86	69.50	-36.57
3.91	18.47	2.16	10.68	31.31	Peak	Facing 90°	100	232	69.50	-38.19
4.90	17.66	2.18	10.70	30.54	Peak	Facing 90°	100	214	69.50	-38.96



NeuroPace, RNS Neurostimulation, Model RNS 320, SN: 191391, TX mode at Y axis, loop 90 deg
Filename: c:\program files (x86)\emisoft - vasona\results\20161207_Neuropace_REloop2.emi

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

Note: RBW / VBW Setting: 200 Hz / 1kHz for 9 kHz – 150 kHz; 9 kHz / 30 kHz for 150 kHz – 30 MHz.

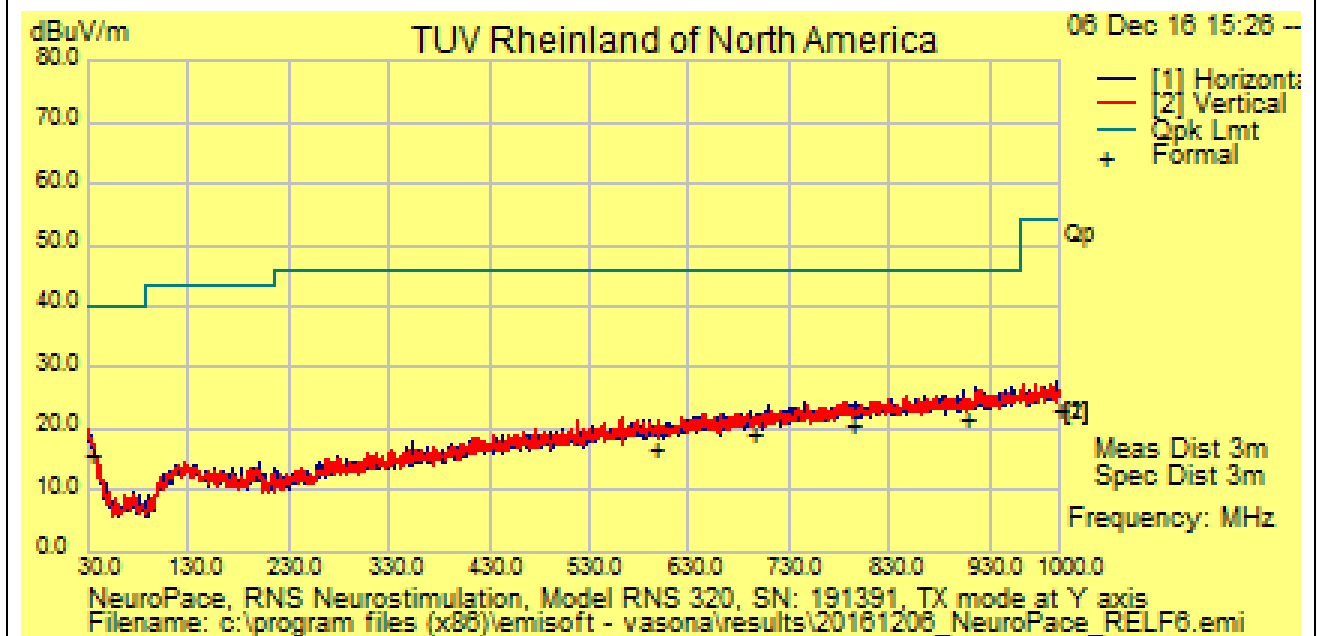
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EUT Name	NeuroPace® RNS® Neurostimulator	Date	December 6, 2016
EUT Model	RNS-320	Temp / Hum in	22°C / 41% rh
EUT Serial	191391	Temp / Hum out	N/A
EUT Config.	Integral Antenna / TX mode / Y axis	Line AC / Freq	N/A – EUT DC powered
Standard	CFR47 Part 15.205 and 15.209	RBW / VBW	120 kHz / 300 kHz
Dist/Ant Used	3m / EMCO3142	Performed by	Kerwinn Corpuz

(30 MHz – 1000 MHz)

Frequency (MHz)	Raw (dBuV/m)	Cable Loss (dB)	AF (dB)	Level (dBuV/m)	Detector	Polarity (H/V)	Height (cm)	Azimuth (deg)	Limit (dBuV/m)	Margin (dB)
594.56	22.29	3.44	-8.85	16.88	QP	H	117	342	46.00	-29.12
694.62	22.57	3.61	-7.20	18.98	QP	H	336	338	46.00	-27.02
906.46	21.95	4.02	-4.42	21.55	QP	H	256	180	46.00	-24.45
997.80	21.34	4.20	-2.55	22.99	QP	H	227	270	54.00	-31.01
31.97	22.49	1.58	-8.58	15.49	QP	V	130	292	40.00	-24.52
791.10	22.48	3.83	-5.88	20.44	QP	V	233	318	46.00	-25.56



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

Note: None

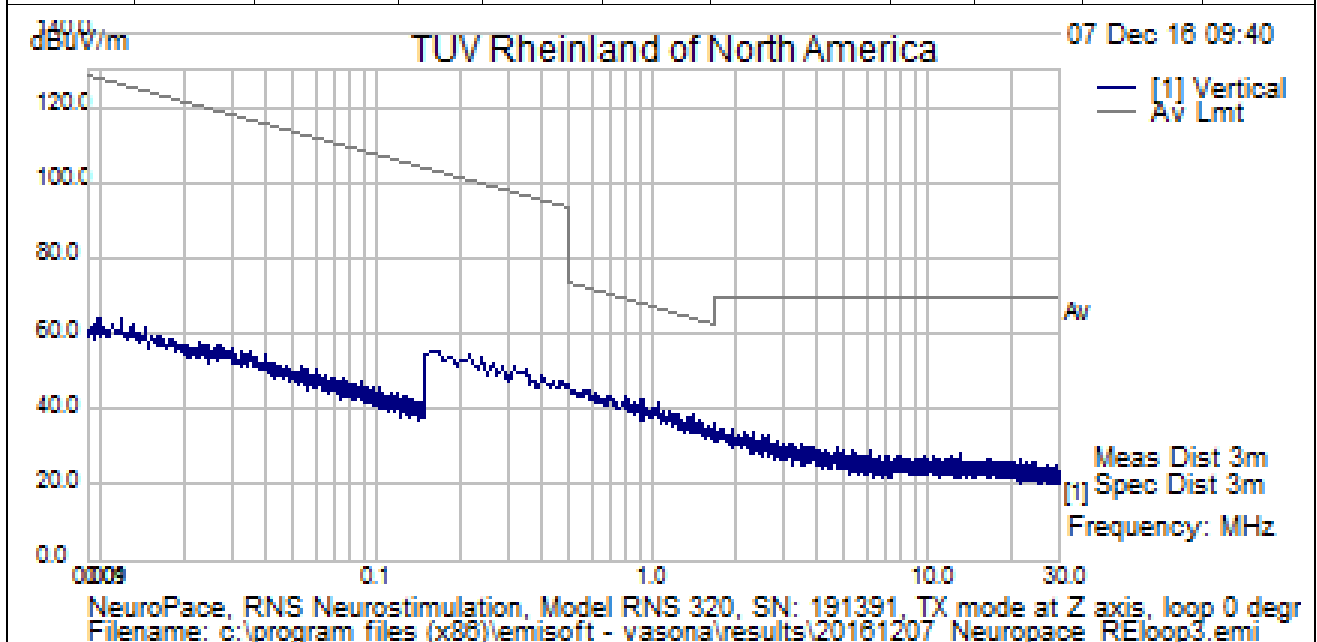
SOP 1 Radiated Emissions

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EUT Name	NeuroPace® RNS® Neurostimulator	Date	December 7, 2016
EUT Model	RNS-320	Temp / Hum in	23°C / 37% rh
EUT Serial	191391	Temp / Hum out	N/A
EUT Config.	Integral Antenna / TX mode / Z axis	Line AC / Freq	N/A – EUT DC powered
Standard	CFR47 Part 15.205 and 15.209	RBW / VBW	See Note
Dist/Ant Used	3m / EMCO 6505	Performed by	Kerwinn Corpuz

Loop facing EUT (9 kHz – 30 MHz)

Frequency (MHz)	Raw (dBuV/m)	Cable Loss (dB)	AF (dB)	Level (dBuV/m)	Detector	Polarity	Height (cm)	Azimuth (deg)	Limit (dBuV/m)	Margin (dB)
0.62	31.61	2.06	10.30	43.97	Peak	Facing	100	6	71.71	-27.73
0.92	30.25	2.08	10.44	42.77	Peak	Facing	100	306	68.35	-25.58
1.15	26.89	2.09	10.60	39.58	Peak	Facing	100	3	66.37	-26.79
1.40	25.84	2.09	10.60	38.54	Peak	Facing	100	48	64.68	-26.14
1.68	23.42	2.10	10.60	36.12	Peak	Facing	100	300	63.12	-27.00
2.19	21.58	2.12	10.58	34.28	Peak	Facing	100	19	69.50	-35.22
2.65	20.69	2.13	10.53	33.35	Peak	Facing	100	359	69.50	-36.15
2.82	19.12	2.14	10.52	31.77	Peak	Facing	100	6	69.50	-37.73
3.45	17.71	2.15	10.60	30.46	Peak	Facing	100	6	69.50	-39.04
4.71	16.75	2.17	10.70	29.62	Peak	Facing	100	19	69.50	-39.88



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 $U = k u_c(y)$ $k = 2$ for 95% confidence
Note: RBW / VBW Setting: 200 Hz / 1kHz for 9 kHz – 150 kHz; 9 kHz / 30 kHz for 150 kHz – 30 MHz.

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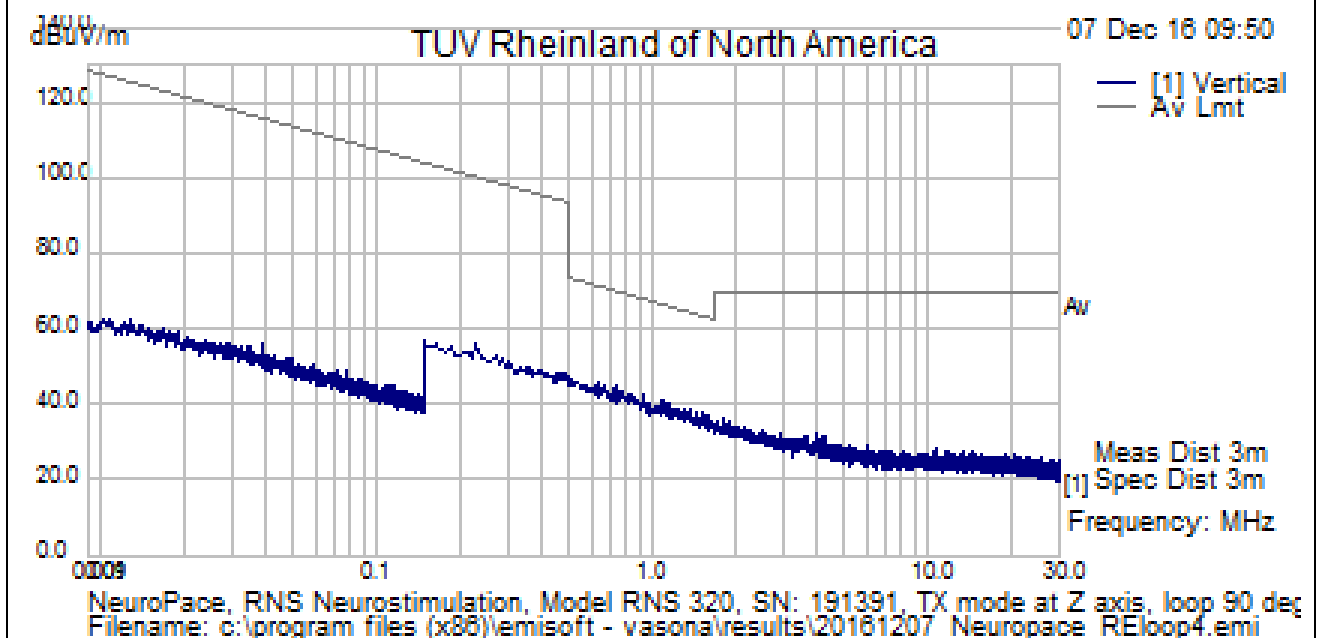
SOP 1 Radiated Emissions

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EUT Name	NeuroPace® RNS® Neurostimulator	Date	December 7, 2016
EUT Model	RNS-320	Temp / Hum in	23°C / 37% rh
EUT Serial	191391	Temp / Hum out	N/A
EUT Config.	Integral Antenna / TX mode / Z axis	Line AC / Freq	N/A – EUT DC powered
Standard	CFR47 Part 15.205 and 15.209	RBW / VBW	See Note
Dist/Ant Used	3m / EMCO 6505	Performed by	Kerwinn Corpuz

Loop facing 90° angle from EUT (9 kHz – 30 MHz)

Frequency (MHz)	Raw (dBuV/m)	Cable Loss (dB)	AF (dB)	Level (dBuV/m)	Detector	Polarity	Height (cm)	Azimuth (deg)	Limit (dBuV/m)	Margin (dB)
0.51	34.22	2.06	10.39	46.66	Peak	Facing 90°	100	356	73.40	-26.74
0.74	32.35	2.07	10.30	44.72	Peak	Facing 90°	100	295	70.18	-25.47
0.92	29.81	2.08	10.45	42.34	Peak	Facing 90°	100	249	68.31	-25.97
1.37	26.20	2.09	10.60	38.89	Peak	Facing 90°	100	273	64.85	-25.96
1.81	23.26	2.11	10.60	35.96	Peak	Facing 90°	100	320	69.50	-33.54
2.50	20.62	2.13	10.55	33.29	Peak	Facing 90°	100	30	69.50	-36.21
3.94	19.12	2.16	10.69	31.97	Peak	Facing 90°	100	347	69.50	-37.53



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

Note: RBW / VBW Setting: 200 Hz / 1kHz for 9 kHz – 150 kHz; 9 kHz / 30 kHz for 150 kHz – 30 MHz.

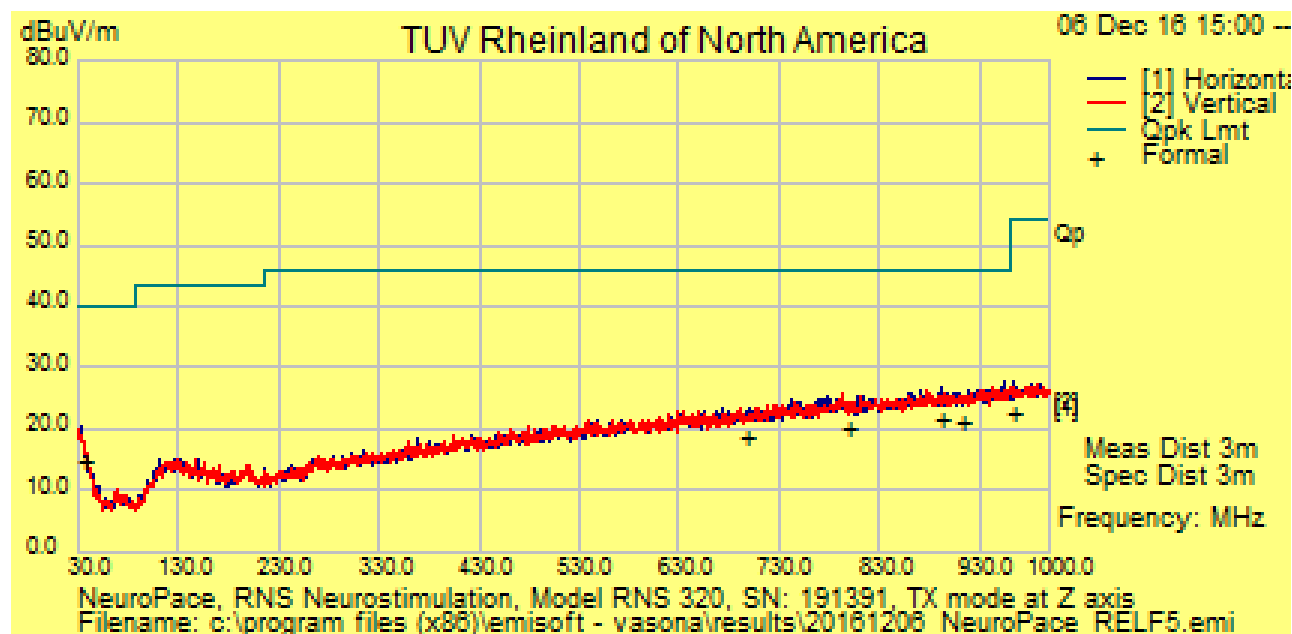
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EUT Name	NeuroPace® RNS® Neurostimulator	Date	December 6, 2016
EUT Model	RNS-320	Temp / Hum in	22°C / 41% rh
EUT Serial	191391	Temp / Hum out	N/A
EUT Config.	Integral Antenna / TX mode / Z axis	Line AC / Freq	N/A – EUT DC powered
Standard	CFR47 Part 15.205 and 15.209	RBW / VBW	120 kHz / 300 kHz
Dist/Ant Used	3m / EMCO3142	Performed by	Kerwinn Corpuz

(30 MHz – 1000 MHz)

Frequency (MHz)	Raw (dBuV/m)	Cable Loss (dB)	AF (dB)	Level (dBuV/m)	Detector	Polarity (H/V)	Height (cm)	Azimuth (deg)	Limit (dBuV/m)	Margin (dB)
34.36	23.27	1.59	-10.07	14.79	QP	H	198	361	40.00	-25.21
891.01	22.06	4.01	-4.51	21.57	QP	H	136	238	46.00	-24.43
964.07	21.47	4.13	-3.16	22.44	QP	H	351	336	54.00	-31.56
696.73	22.51	3.62	-7.26	18.87	QP	V	202	132	46.00	-27.13
797.51	22.32	3.83	-5.84	20.30	QP	V	156	154	46.00	-25.70
911.72	21.65	4.03	-4.37	21.32	QP	V	237	222	46.00	-24.68



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

Note: None

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:

$$\text{Field Strength (dB}\mu\text{V/m)} = \text{FIM} - \text{AMP} + \text{CBL} + \text{ACF}$$

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

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

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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: 2016

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, then 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 all axis for 9 kHz 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: 2016

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.

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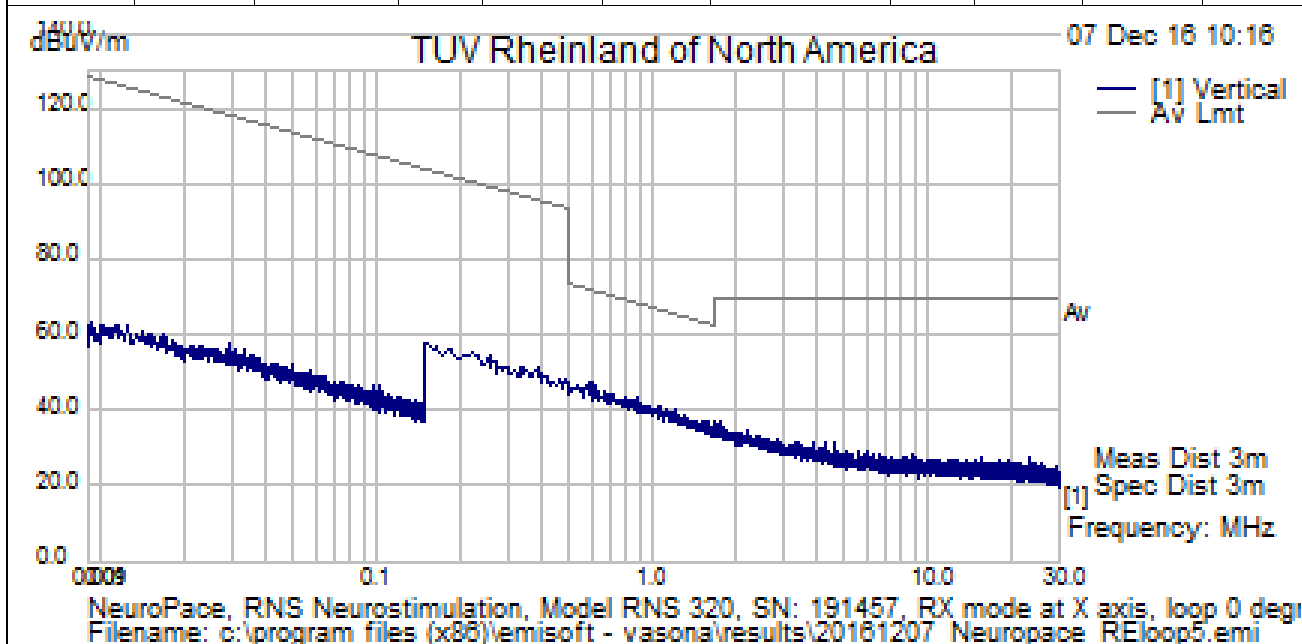
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EUT Name	NeuroPace® RNS® Neurostimulator	Date	December 7, 2016
EUT Model	RNS-320	Temp / Hum in	23°C / 37% rh
EUT Serial	191457	Temp / Hum out	N/A
EUT Config.	Integral Antenna / RX mode / X axis	Line AC / Freq	N/A – EUT DC powered
Standard	CFR47 Part 15.205 and 15.209	RBW / VBW	See Note
Dist/Ant Used	3m / EMCO 6505	Performed by	Kerwinn Corpuz

Loop facing EUT (9 kHz – 30 MHz)

Frequency (MHz)	Raw (dBuV/m)	Cable Loss (dB)	AF (dB)	Level (dBuV/m)	Detector	Polarity	Height (cm)	Azimuth (deg)	Limit (dBuV/m)	Margin (dB)
0.89	31.16	2.08	10.39	43.62	Peak	Facing	100	124	68.66	-25.04
1.21	27.31	2.09	10.60	40.00	Peak	Facing	100	356	65.93	-25.93
1.75	24.44	2.10	10.60	37.14	Peak	Facing	100	191	69.50	-32.36
2.22	22.42	2.12	10.57	35.11	Peak	Facing	100	61	69.50	-34.39
2.85	19.64	2.14	10.51	32.29	Peak	Facing	100	23	69.50	-37.21
4.55	18.34	2.17	10.70	31.22	Peak	Facing	100	358	69.50	-38.29



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

Note: RBW / VBW Setting: 200 Hz / 1kHz for 9 kHz – 150 kHz; 9 kHz / 30 kHz for 150 kHz – 30 MHz.

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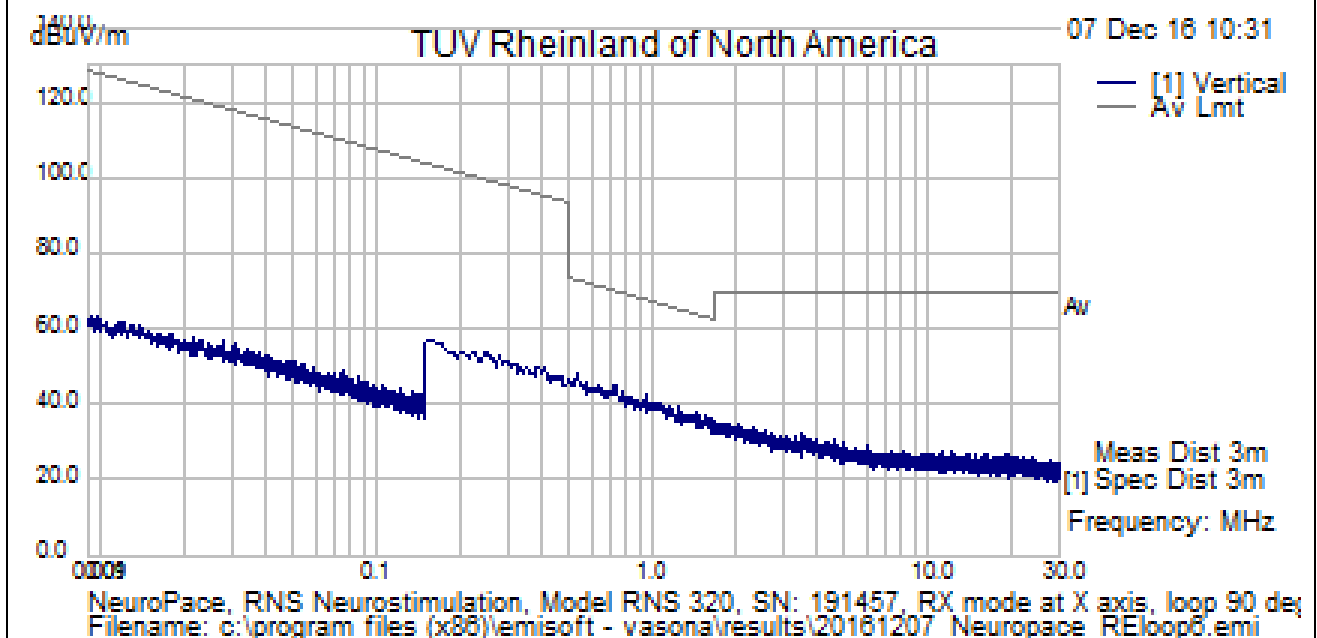
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EUT Name	NeuroPace® RNS® Neurostimulator	Date	December 7, 2016
EUT Model	RNS-320	Temp / Hum in	23°C / 37% rh
EUT Serial	191457	Temp / Hum out	N/A
EUT Config.	Integral Antenna / RX mode / X axis	Line AC / Freq	N/A – EUT DC powered
Standard	CFR47 Part 15.205 and 15.209	RBW / VBW	See Note
Dist/Ant Used	3m / EMCO 6505	Performed by	Kerwinn Corpuz

Loop facing 90° angle from EUT (9 kHz – 150 kHz)

Frequency (MHz)	Raw (dBuV/m)	Cable Loss (dB)	AF (dB)	Level (dBuV/m)	Detector	Polarity	Height (cm)	Azimuth (deg)	Limit (dBuV/m)	Margin (dB)
0.54	35.48	2.06	10.36	47.90	Peak	Facing 90°	100	298	73.02	-25.12
0.78	31.07	2.08	10.30	43.45	Peak	Facing 90°	100	231	69.71	-26.26
1.15	26.55	2.09	10.60	39.23	Peak	Facing 90°	100	133	66.41	-27.17
1.65	23.87	2.10	10.60	36.57	Peak	Facing 90°	100	126	63.26	-26.69
2.34	21.34	2.12	10.56	34.02	Peak	Facing 90°	100	291	69.50	-35.48
3.52	19.90	2.15	10.61	32.66	Peak	Facing 90°	100	294	69.50	-36.84
3.91	17.86	2.16	10.68	30.70	Peak	Facing 90°	100	224	69.50	-38.80



NeuroPace, RNS Neurostimulation, Model RNS 320, SN: 191457, RX mode at X axis, loop 90 deg
Filename: c:\program files (x86)\emisoft - vasona\results\20161207_Neuropace_REloop8.emi

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

Note: RBW / VBW Setting: 200 Hz / 1kHz for 9 kHz – 150 kHz; 9 kHz / 30 kHz for 150 kHz – 30 MHz.

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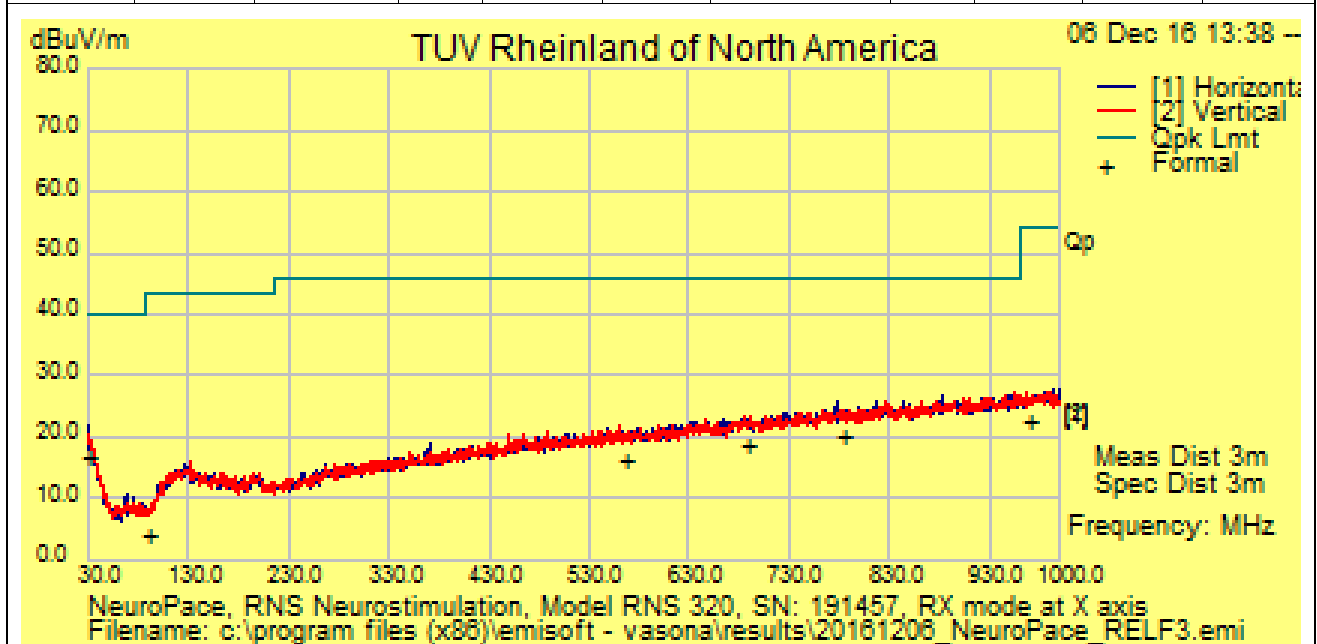
SOP 1 Radiated Emissions

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EUT Name	NeuroPace® RNS® Neurostimulator	Date	December 6, 2016
EUT Model	RNS-320	Temp / Hum in	22°C / 41% rh
EUT Serial	191457	Temp / Hum out	N/A
EUT Config.	Integral Antenna / RX mode / X axis	Line AC / Freq	N/A – EUT DC powered
Standard	CFR47 Part 15.205 and 15.209	RBW / VBW	120 kHz / 300 kHz
Dist/Ant Used	3m / EMCO3142	Performed by	Kerwinn Corpuz

(30 MHz – 1000 MHz)

Frequency (MHz)	Raw (dBuV/m)	Cable Loss (dB)	AF (dB)	Level (dBuV/m)	Detector	Polarity (H/V)	Height (cm)	Azimuth (deg)	Limit (dBuV/m)	Margin (dB)
30.00	22.63	1.56	-7.26	16.93	QP	H	117	336	40.00	-23.07
88.27	22.64	1.92	-20.60	3.97	QP	H	381	284	43.50	-39.53
563.58	21.97	3.34	-9.08	16.23	QP	H	332	264	46.00	-29.77
687.49	22.38	3.60	-7.31	18.68	QP	H	373	2	46.00	-27.32
783.01	22.16	3.81	-5.88	20.09	QP	H	183	292	46.00	-25.91
969.24	21.55	4.16	-3.02	22.70	QP	V	328	348	54.00	-31.31



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

Note: None

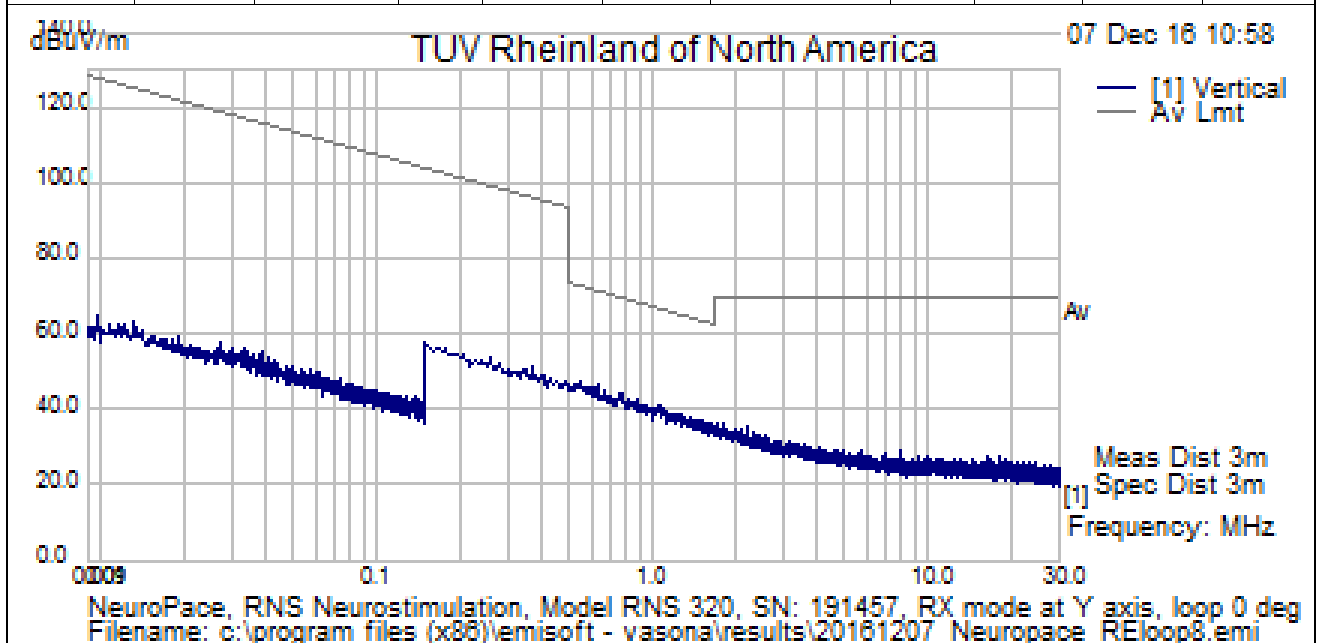
SOP 1 Radiated Emissions

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EUT Name	NeuroPace® RNS® Neurostimulator	Date	December 7, 2016
EUT Model	RNS-320	Temp / Hum in	23°C / 37% rh
EUT Serial	191457	Temp / Hum out	N/A
EUT Config.	Integral Antenna / RX mode / Y axis	Line AC / Freq	N/A – EUT DC powered
Standard	CFR47 Part 15.205 and 15.209	RBW / VBW	See Note
Dist/Ant Used	3m / EMCO 6505	Performed by	Kerwinn Corpuz

Loop facing EUT (9 kHz – 30 MHz)

Frequency (MHz)	Raw (dBuV/m)	Cable Loss (dB)	AF (dB)	Level (dBuV/m)	Detector	Polarity	Height (cm)	Azimuth (deg)	Limit (dBuV/m)	Margin (dB)
0.66	32.77	2.06	10.30	45.13	Peak	Facing	100	264	71.15	-26.02
1.04	28.16	2.08	10.60	40.84	Peak	Facing	100	0	67.29	-26.44
1.48	24.35	2.10	10.60	37.05	Peak	Facing	100	75	64.21	-27.16
2.21	22.54	2.12	10.58	35.23	Peak	Facing	100	257	69.50	-34.27
2.84	18.75	2.14	10.51	31.40	Peak	Facing	100	141	69.50	-38.10



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

Note: RBW / VBW Setting: 200 Hz / 1kHz for 9 kHz – 150 kHz; 9 kHz / 30 kHz for 150 kHz – 30 MHz.

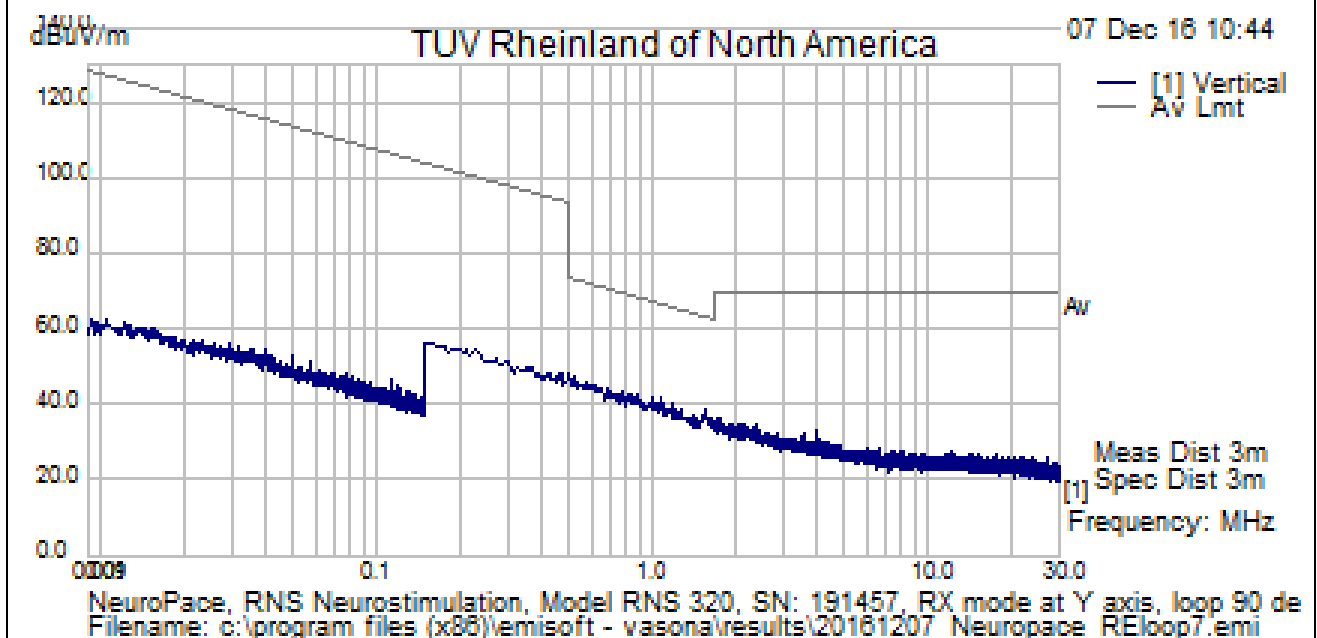
SOP 1 Radiated Emissions

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EUT Name	NeuroPace® RNS® Neurostimulator	Date	December 7, 2016
EUT Model	RNS-320	Temp / Hum in	23°C / 37% rh
EUT Serial	191457	Temp / Hum out	N/A
EUT Config.	Integral Antenna / RX mode / Y axis	Line AC / Freq	N/A – EUT DC powered
Standard	CFR47 Part 15.205 and 15.209	RBW / VBW	See Note
Dist/Ant Used	3m / EMCO 6505	Performed by	Kerwinn Corpuz

Loop facing 90° angle from EUT (9 kHz – 30 MHz)

Frequency (MHz)	Raw (dBuV/m)	Cable Loss (dB)	AF (dB)	Level (dBuV/m)	Detector	Polarity	Height (cm)	Azimuth (deg)	Limit (dBuV/m)	Margin (dB)
0.58	33.17	2.06	10.32	45.55	Peak	Facing 90°	100	159	72.37	-26.82
1.00	29.38	2.08	10.60	42.06	Peak	Facing 90°	100	194	67.60	-25.54
1.57	26.30	2.10	10.60	39.00	Peak	Facing 90°	100	40	63.68	-24.68
1.79	23.83	2.11	10.60	36.54	Peak	Facing 90°	100	232	69.50	-32.96
2.42	21.71	2.12	10.55	34.39	Peak	Facing 90°	100	162	69.50	-35.11
3.94	19.90	2.16	10.69	32.75	Peak	Facing 90°	100	270	69.50	-36.75
4.21	17.47	2.16	10.70	30.33	Peak	Facing 90°	100	47	69.50	-39.17



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

Note: RBW / VBW Setting: 200 Hz / 1kHz for 9 kHz – 150 kHz; 9 kHz / 30 kHz for 150 kHz – 30 MHz.

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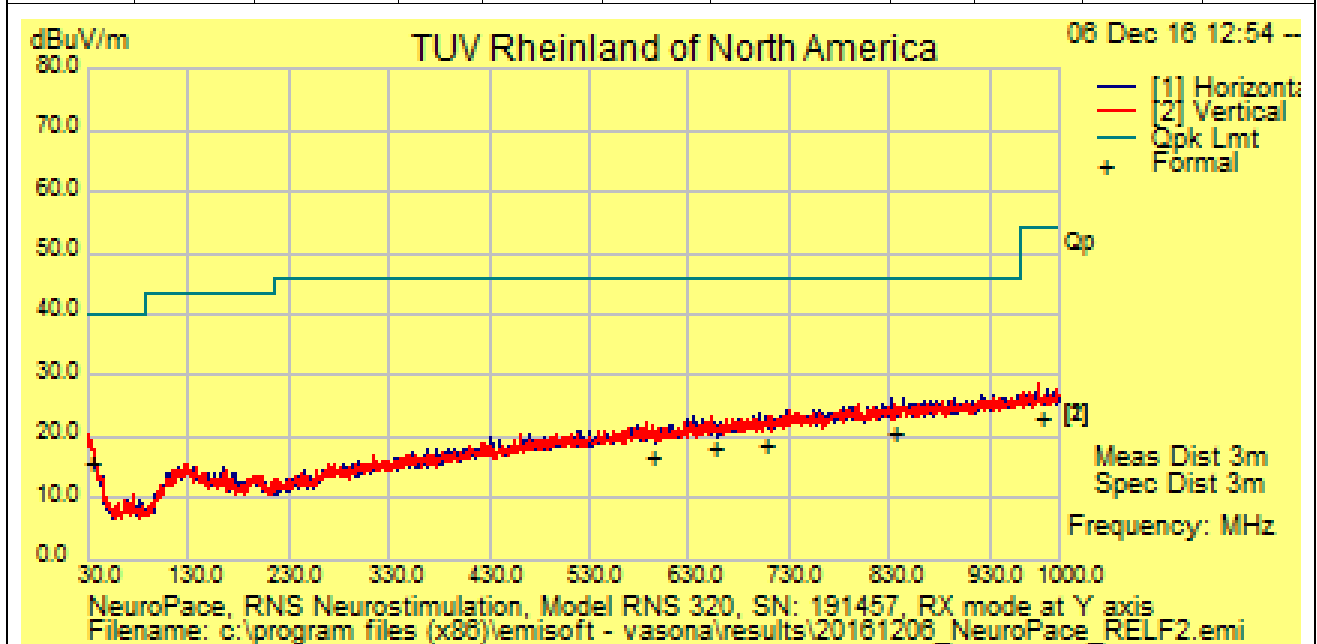
SOP 1 Radiated Emissions

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EUT Name	NeuroPace® RNS® Neurostimulator	Date	December 6, 2016
EUT Model	RNS-320	Temp / Hum in	22°C / 41% rh
EUT Serial	191457	Temp / Hum out	N/A
EUT Config.	Integral Antenna / RX mode / Y axis	Line AC / Freq	N/A – EUT DC powered
Standard	CFR47 Part 15.205 and 15.209	RBW / VBW	120 kHz / 300 kHz
Dist/Ant Used	3m / EMCO3142	Performed by	Kerwinn Corpuz

(30 MHz – 1000 MHz)

Frequency (MHz)	Raw (dBuV/m)	Cable Loss (dB)	AF (dB)	Level (dBuV/m)	Detector	Polarity (H/V)	Height (cm)	Azimuth (deg)	Limit (dBuV/m)	Margin (dB)
705.42	22.25	3.64	-7.35	18.54	QP	H	378	38	46.00	-27.46
833.16	21.98	3.90	-5.24	20.64	QP	H	226	194	46.00	-25.36
31.10	22.09	1.57	-8.01	15.65	QP	V	242	262	40.00	-24.35
591.05	22.04	3.42	-8.78	16.68	QP	V	237	138	46.00	-29.32
654.62	22.27	3.56	-7.80	18.03	QP	V	331	88	46.00	-27.97
981.75	21.42	4.15	-2.60	22.98	QP	V	236	21	54.00	-31.02



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

Note: None

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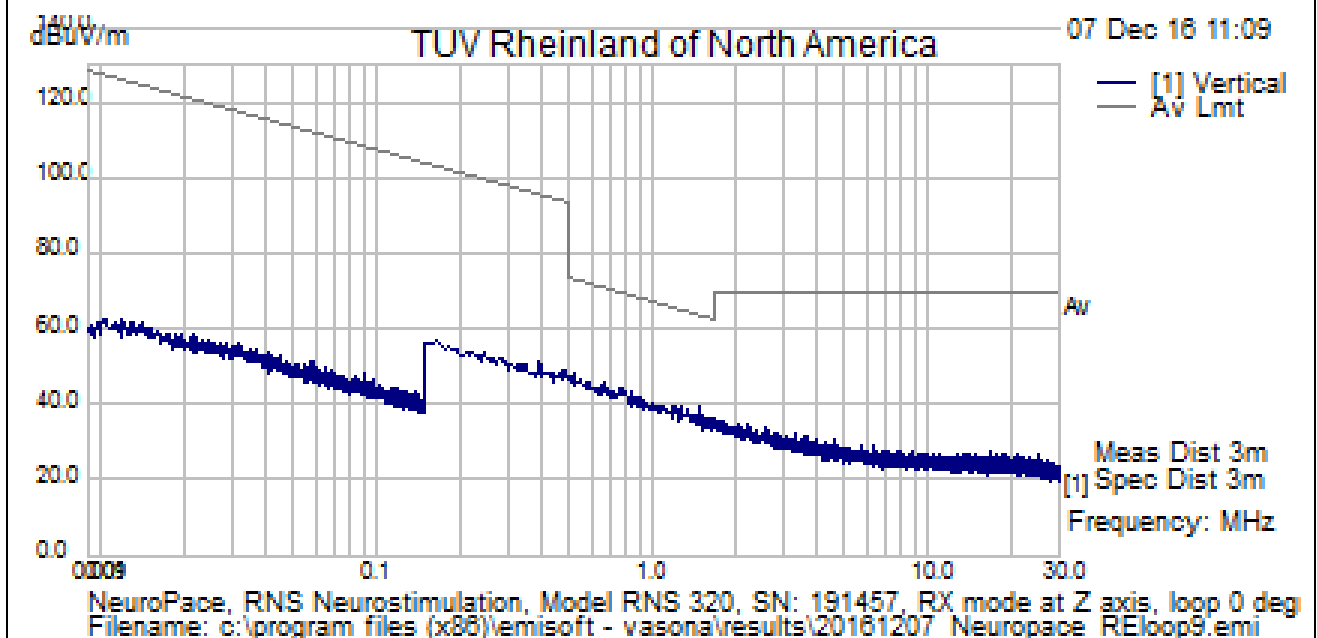
SOP 1 Radiated Emissions

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EUT Name	NeuroPace® RNS® Neurostimulator	Date	December 7, 2016
EUT Model	RNS-320	Temp / Hum in	23°C / 37% rh
EUT Serial	191457	Temp / Hum out	N/A
EUT Config.	Integral Antenna / RX mode / Z axis	Line AC / Freq	N/A – EUT DC powered
Standard	CFR47 Part 15.205 and 15.209	RBW / VBW	See Note
Dist/Ant Used	3m / EMCO 6505	Performed by	Kerwinn Corpuz

Loop facing EUT (9 kHz – 30 MHz)

Frequency (MHz)	Raw (dBuV/m)	Cable Loss (dB)	AF (dB)	Level (dBuV/m)	Detector	Polarity	Height (cm)	Azimuth (deg)	Limit (dBuV/m)	Margin (dB)
0.60	33.45	2.06	10.30	45.81	Peak	Facing	100	196	72.10	-26.29
0.84	30.84	2.08	10.35	43.27	Peak	Facing	100	358	69.08	-25.81
1.27	27.04	2.09	10.60	39.73	Peak	Facing	100	361	65.55	-25.82
1.54	24.07	2.10	10.60	36.77	Peak	Facing	100	59	63.84	-27.07
2.30	20.97	2.12	10.57	33.66	Peak	Facing	100	41	69.50	-35.84
3.35	19.63	2.15	10.58	32.36	Peak	Facing	100	220	69.50	-37.14
4.60	17.60	2.17	10.70	30.47	Peak	Facing	100	324	69.50	-39.03



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
Note: RBW / VBW Setting: 200 Hz / 1kHz for 9 kHz – 150 kHz; 9 kHz / 30 kHz for 150 kHz – 30 MHz.

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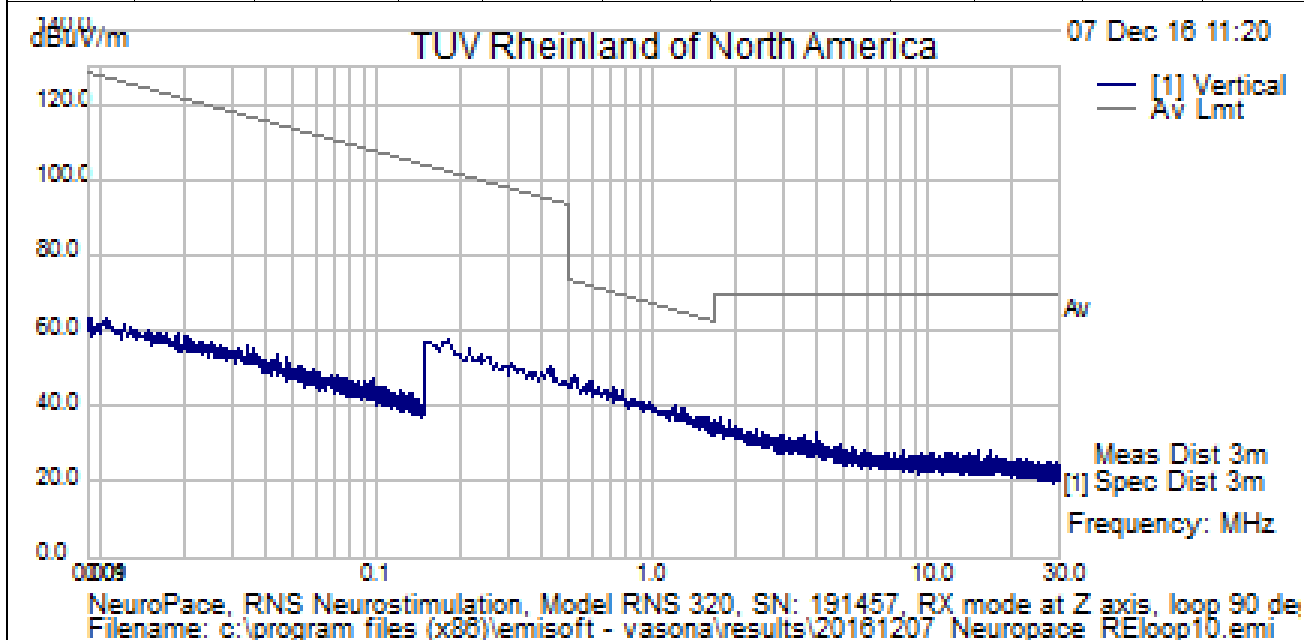
SOP 1 Radiated Emissions

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EUT Name	NeuroPace® RNS® Neurostimulator	Date	December 7, 2016
EUT Model	RNS-320	Temp / Hum in	23°C / 37% rh
EUT Serial	191457	Temp / Hum out	N/A
EUT Config.	Integral Antenna / RX mode / Z axis	Line AC / Freq	N/A – EUT DC powered
Standard	CFR47 Part 15.205 and 15.209	RBW / VBW	See Note
Dist/Ant Used	3m / EMCO 6505	Performed by	Kerwinn Corpuz

Loop facing 90° angle from EUT (9 kHz – 30 MHz)

Frequency (MHz)	Raw (dBuV/m)	Cable Loss (dB)	AF (dB)	Level (dBuV/m)	Detector	Polarity	Height (cm)	Azimuth (deg)	Limit (dBuV/m)	Margin (dB)
0.52	35.66	2.06	10.38	48.09	Peak	Facing 90°	100	167	73.24	-25.15
0.73	32.84	2.07	10.30	45.21	Peak	Facing 90°	100	178	70.35	-25.14
0.83	29.52	2.08	10.33	41.93	Peak	Facing 90°	100	278	69.22	-27.29
1.36	24.98	2.09	10.60	37.67	Peak	Facing 90°	100	310	64.91	-27.24
2.01	21.96	2.11	10.60	34.67	Peak	Facing 90°	100	0	69.50	-34.83
3.93	20.15	2.16	10.69	33.00	Peak	Facing 90°	100	223	69.50	-36.50
4.85	17.23	2.18	10.70	30.11	Peak	Facing 90°	100	236	69.50	-39.39



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

Note: RBW / VBW Setting: 200 Hz / 1kHz for 9 kHz – 150 kHz; 9 kHz / 30 kHz for 150 kHz – 30 MHz.

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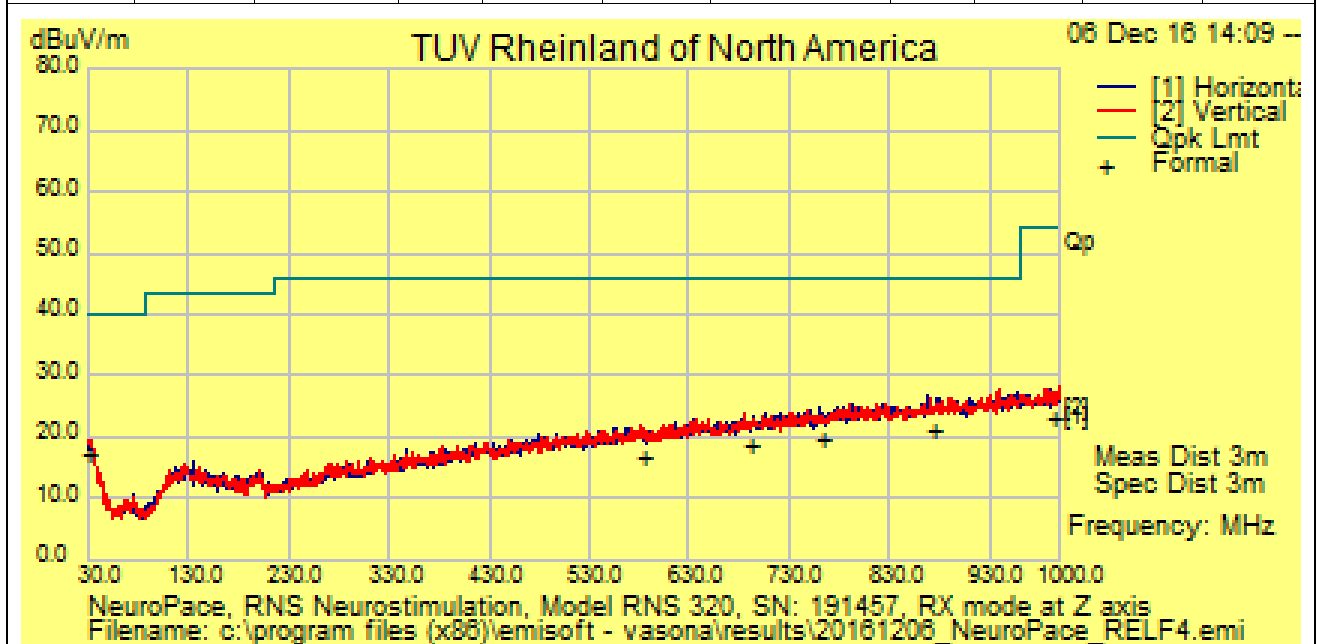
SOP 1 Radiated Emissions

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EUT Name	NeuroPace® RNS® Neurostimulator	Date	December 6, 2016
EUT Model	RNS-320	Temp / Hum in	22°C / 41% rh
EUT Serial	191457	Temp / Hum out	N/A
EUT Config.	Integral Antenna / RX mode / Z axis	Line AC / Freq	N/A – EUT DC powered
Standard	CFR47 Part 15.205 and 15.209	RBW / VBW	120 kHz / 300 kHz
Dist/Ant Used	3m / EMCO3142	Performed by	Kerwinn Corpuz

(30 MHz – 1000 MHz)

Frequency (MHz)	Raw (dBuV/m)	Cable Loss (dB)	AF (dB)	Level (dBuV/m)	Detector	Polarity (H/V)	Height (cm)	Azimuth (deg)	Limit (dBuV/m)	Margin (dB)
762.12	22.16	3.76	-6.49	19.43	QP	H	251	146	46.00	-26.57
872.04	22.07	3.96	-4.85	21.19	QP	H	155	358	46.00	-24.81
30.00	22.67	1.56	-7.26	16.97	QP	V	232	118	40.00	-23.03
582.17	22.07	3.38	-8.59	16.87	QP	V	282	264	46.00	-29.13
689.91	22.42	3.61	-7.30	18.73	QP	V	185	36	46.00	-27.27
991.69	21.32	4.18	-2.61	22.90	QP	V	301	42	54.00	-31.10



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

Note: None

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:

$$\text{Field Strength (dB}\mu\text{V/m)} = \text{FIM} - \text{AMP} + \text{CBL} + \text{ACF}$$

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

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

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4.3 AC Conducted Emissions

Testing was performed in accordance with ANSI C63.10:2013. These test methods are listed under the laboratory's A2LA Scope of Accreditation.

This test measures the levels emanating from the EUT's 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 μ H / 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 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
Bilog Antenna	Sunol Sciences	JB3	A102606	06/15/2016	06/15/2018	RE
9 kHz – 1 GHz Preamplifier	Sonoma Instruments	310	185516	01/18/2016	01/18/2017	RE
Loop Antenna	EMCO	6502	9110-2683	06/13/2016	06/13/2017	RE
EMI Receiver	Agilent	N9038A	MY51210195	01/26/2016	01/26/2017	RE
Spectrum Analyzer	Rhode & Schwarz	ESIB40	839283/005	01/19/2016	01/19/2017	CE
Transient Limiter	HP	11947A	3107A03612	01/19/2016	01/19/2017	CE
LISN	Com-Power	LI-215	12111	01/20/2016	01/20/2017	CE

Note: CE = Conducted Emissions and RE=Radiated Emissions

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6 EMC Test Plan

6.1 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.

6.2 Customer

Table 3: Customer Information

Company Name	NeuroPace, Inc.
Address	455 Bernardo Ave.
City, State, Zip	Mountain View, CA 94043
Country	USA
Phone	(650) 237-2700
Fax	(650) 237-2701

Table 4: Technical Contact Information

Name	Erica Lundmark
E-mail	elundmark@neuropace.com
Phone	(650) 237-2700
Fax	(650) 237-2701

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6.3 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:	<input type="checkbox"/> Yes and how many 0
Operating Band	Inductive Telemetry
Transmitter Frequency Band	50 kHz
Receiver Frequency Band	20-25 kHz
Measured Power Output	< 37.25 nW – Peak (not measurable – emission below the noise floor)
# Operating Channel	1
Antenna Type	Integrated Rectangular shape Coil Antenna
Antenna Gain	Not Specific (Unknown)
Modulation Type	<input type="checkbox"/> AM <input type="checkbox"/> FM <input type="checkbox"/> Phase <input checked="" type="checkbox"/> Other describe: Half Duplex.
Type of Equipment	<input type="checkbox"/> Table Top <input type="checkbox"/> Wall-mount <input type="checkbox"/> Floor standing cabinet <input checked="" type="checkbox"/> Other <i>Describe: Implant Device</i>
Clocks/Oscillating Frequency	10 kHz, 50 kHz, 100 kHz, 2.5 MHz (1.5 MHz – 3 MHz variable), and 100 kHz – 400 kHz (variable).

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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	<input checked="" type="checkbox"/> None	<input checked="" type="checkbox"/> None	<input checked="" type="checkbox"/> NA

Table 7: Supported Equipment

Equipment	Manufacturer	Model	Serial
N/A			

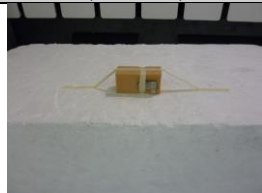


Table 8: Samples used for Testing

Device	Serial #	Requirements	Scan Type
NeuroPace® RNS® Neurostimulator	191391 & 191457	CFR47 Part 15.207	N/A: EUT is battery powered.
NeuroPace® RNS® Neurostimulator	191391 & 191457	CFR47 Part 15.205, 15.209,	Pre-scan, radiated measurement for 3 orientations.
NeuroPace® RNS® Neurostimulator	191391 & 191457	CFR47 Part 15.205, 15.209	Final, radiated measurement for 3 orientations.

6.4 Test Setup

6.4.1 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 and final testing were performed on all three orientations.

6.4.2 Test Software

Test software was installed on the neurostimulator using a test laptop computer and an inductive telemetry Wand. The test software was used to configure the implant into its two modes (Receive and Transmit) used for this emissions testing. This software will be documented with the NeuroPace verification protocol results for this testing.

6.4.3 Test Mode

Software Mode	Neurostimulator Mode	Notes
1	Receive	Worst case high speed clock operation plus receiver enabled.
2	Transmit	Worst case high speed clock operation plus worst case transmit operation.

6.4.4 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	9 kHz – 30 MHz	2	Z	3m	None
8	9 kHz – 30 MHz	1	Z	3m	None
9	9 kHz – 30 MHz	1	Y	3m	None
10	9 kHz – 30 MHz	2	Y	3m	None
11	9 kHz – 30 MHz	2	X	3m	None
12	9 kHz – 30 MHz	1	X	3m	None

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6.5 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-320.

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7 Revision History

Revision No.	Date	Reason for Change	Author
0	December 08, 2016	Original Document	N/A

Note: Latest revision report will replace all previous reports.

END OF REPORT

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