RF EXPOSURE TEST REPORT

Report Number: 103494026MPK-011
Project Number: G103494026

Report Issue Date: September 11, 2018
Rev1 Issue date: January 15, 2019
Equipment Tested: Pulsante SPG Microstimulator System
Model Tested: RC-300

Standards: CFR 47 Part 2, Sub part J, 2.1093
Radiofrequency radiation exposure evaluation: portable devices.

Tested by:
Intertek Testing Services NA, Inc.
1365 Adams Court
Menlo Park, CA 92630
USA

Client:
Autonomic Technologies, Inc.
355 Ravendale Drive
MOUNTAIN VIEW, CA 94043
USA

Report prepared and Reviewed by

Suresh Kondapalli
Senior Staff Engineer

Table of Contents

1 Introduction and Conclusion

The tests indicated in section 2.0 were performed on the product constructed as described in section 4.0. The remaining test sections are the verbatim text from the actual data sheets used during the investigation. These test sections include the test name, the specified test Method, a list of the actual Test Equipment Used, documentation Photos, Results and raw Data. No additions, deviations, or exclusions have been made from the standard(s) unless specifically noted.

Based on the results of our investigation, we have concluded the product tested **complies** with the requirements of the standard(s) indicated. The results obtained in this test report pertain only to the item(s) tested. Intertek does not make any claims of compliance for samples or variants which were not tested.

2 Test Summary

Section	Test full name	Result
3	Client Information	-
4	Description of Equipment Under Test and Variant Models	-
5	System Setup and Method	-
6	Electric Field IEEE C95.1-2005	Compliant
7	Magnetic Field IEEE C95.1-2005	Compliant
8	Revision History	-

3 Client Information

This EUT was tested at the request of:

Client: Autonomic Technologies, Inc.
355 Ravendale Dr
MOUNTAIN VIEW, CA 94043
USA

Contact: Scott Herring
Telephone: 650-395-4290
Fax:
Email: Scott Herring <sherring@ati-spg.com>

4 Description of Equipment Under Test and Variant Models

Manufacturer: Autonomic Technologies, Inc.
355 Ravendale Dr
MOUNTAIN VIEW, CA 94043
USA

Equipment Under Test			
Description	Manufacturer	Model Number	Serial Number
Remote Controller of Pulsante SPG Microstimulator System	Autonomic Technologies, Inc.	RC-300	EMC-001
Nero Simulator	Autonomic Technologies, Inc.	NS-100	

Receive Date:	5/09/2018	Test Started:	5/23/2018
Received Condition:	Good	Test Completed:	8/24/2018
Type:	Production		

Description of Equipment Under Test (provided by client)

The equipment under test (EUT) is Pulsante SPG Microstimulator System.

Neurostimulator: Implantable device used to treat cluster headache attacks by generating biphasic rectangle stimulation pulses. This is device does not have battery and powered externally through resonant inductive coupling technology. Graphical image of neurostimulator is shown in figure 1.

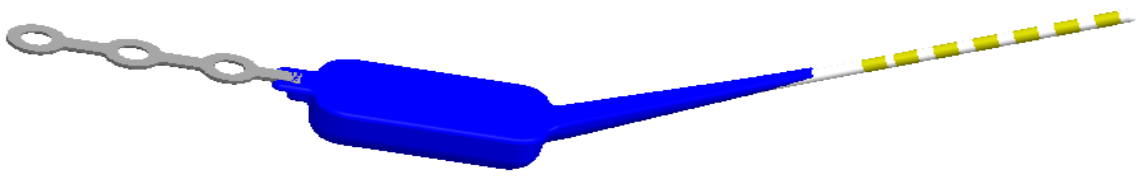


Figure1

Remote Controller: Battery operated handheld external device shown in figure 2 used to power and communicate wirelessly with the neurostimulator to generate stimulation pulses. Operating Frequency 126±3KHz Type of Modulation: BFSK

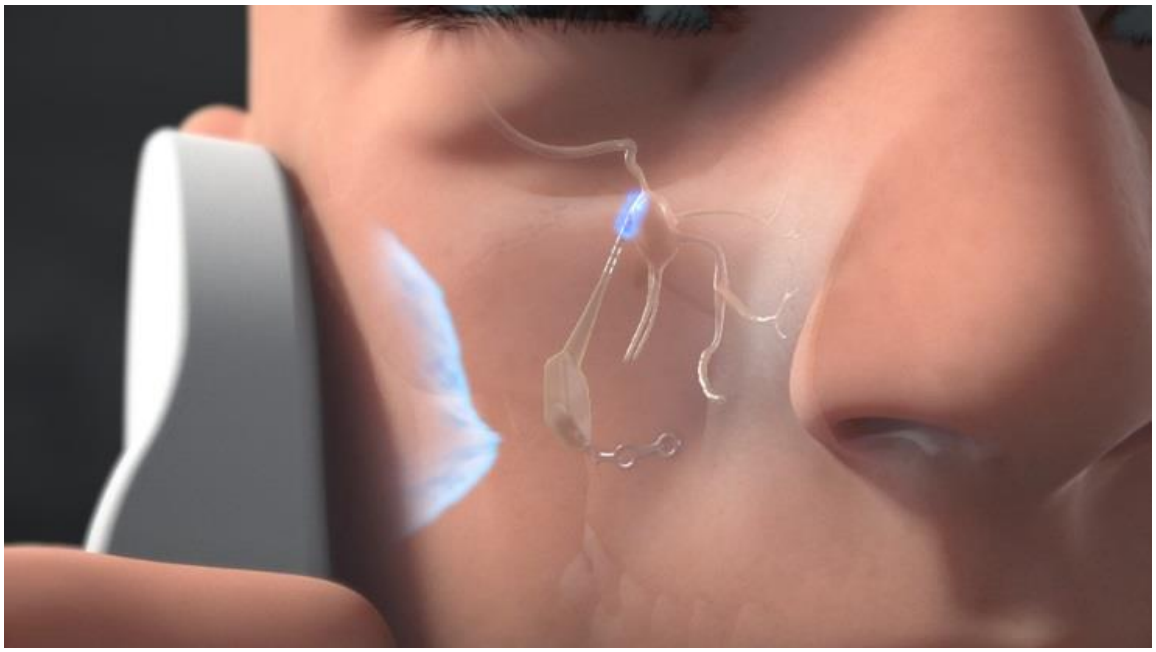


Figure 2

Clinician Programmer: A off the shelf medical grade tablet shown in figure 3 (non-Medical Equipment) used as a support device to program the neurostimulator through the remote controller via USB link.

Reference	Part Number	Description	Omnify Revision	ME Equipment	Model Number	Device Name	Implantable
1	4085002	Remote Controller	1.0	Yes	RC-300	Casper	No
4	2525	Remote Controller Charger (Part of 4085002)	A	Yes	RA-200	RC Charger	No
2	2603	Neurostimulator	D	Yes	NS-100	Niffler	Yes

Operating modes of the EUT:

No.	Description of EUT Exercising
1	Remote Controller locating/ charging the Neuro-Stimulator

Variant Models:

None

5 System Setup and Block Diagram:

5.1 System Setup:

Configuration as required by CFR 47 Part 2, Sub part J, 2.1093

Measurements were performed on all sides of the device and the worst-case results are recorded.

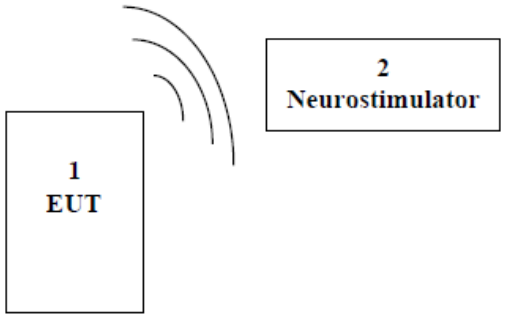
Measurement Uncertainty:

Measurement uncertainty is estimated 2.0 dB for the coverage factor of 2.

5.2 EUT Block Diagram:

The diagram shown below details the interconnection of the EUT and support equipment. For specific layout, refer to the test configuration photograph in the relevant section of this report.

Battery Mode:



6 Electric Field

6.1 Performance Requirement(s)

IEEE std C95.1 -2005

Table 9—Action level (MPE for the general public when an RF safety program is unavailable) (see Figure 4 for graphical representation)

Frequency range (MHz)	RMS electric field strength (E)[a] (V/m)	RMS magnetic field strength (H)[a] (A/m)	RMS power density (S) E-field, H-field (W/m^2)	Averaging time[b] $\|E\|^2$, $\|H\|^2$ or S (min)	
0.1–1.34	614	$16.3/f_M$	$(1000, 100\,000/f_M^2)$[c]	6	6
1.34–3	$823.8/f_M$	$16.3/f_M$	$(1800/f_M^2, 100\,000/f_M^2)$	$f_M^2/0.3$	6
3–30	$823.8/f_M$	$16.3/f_M$	$(1800/f_M^2, 100\,000/f_M^2)$	30	6
30–100	27.5	$158.3/f_M^{1.668}$	$(2, 9\,400\,000/f_M^{3.336})$	30	$0.0636 f_M^{1.337}$
100–400	27.5	0.0729	2	30	30
400–2000	–	–	$f_M/200$	30	
2000–5000	–	–	10	30	
5000–30 000	–	–	10	$150/f_G$	
30 000–100 000	–	–	10	$25.24/f_G^{0.476}$	
100 000–300 000	–	–	$(90f_G–7000)/200$	$5048/[(9f_G–700)f_G^{0.476}]$	

NOTE—f_M is the frequency in MHz, f_G is the frequency in GHz.

[a]For exposures that are uniform over the dimensions of the body, such as certain far-field plane-wave exposures, the exposure field strengths and power densities are compared with the MPEs in the Table. For non-uniform exposures, the mean values of the exposure fields, as obtained by spatially averaging the squares of the field strengths or averaging the power densities over an area equivalent to the vertical cross section of the human body (projected area) or a smaller area depending on the frequency (see NOTES to Table 8 and Table 9 below), are compared with the MPEs in the Table.

[b]The left column is the averaging time for $|E|^2$, the right column is the averaging time for $|H|^2$. For frequencies greater than 400 MHz, the averaging time is for power density S

[c]These plane-wave equivalent power density values are commonly used as a convenient comparison with MPEs at higher frequencies and are displayed on some instruments in use.

6.2 Method

Tests are performed in accordance with IEEE C95.1-2005.

The EMC-20 three-axis electric field probe with X, Y, Z field sensors was used.

Direct measurement was used. Measurements were performed on all sides of the device and the worst result is recorded. Fully charged battery was used for testing.

Test Site:

The test facility is located at 1365 Adams Court, Menlo Park CA 94025 USA. This test laboratory has been accredited by A2LA and registered with ISED, company number: 2042L.

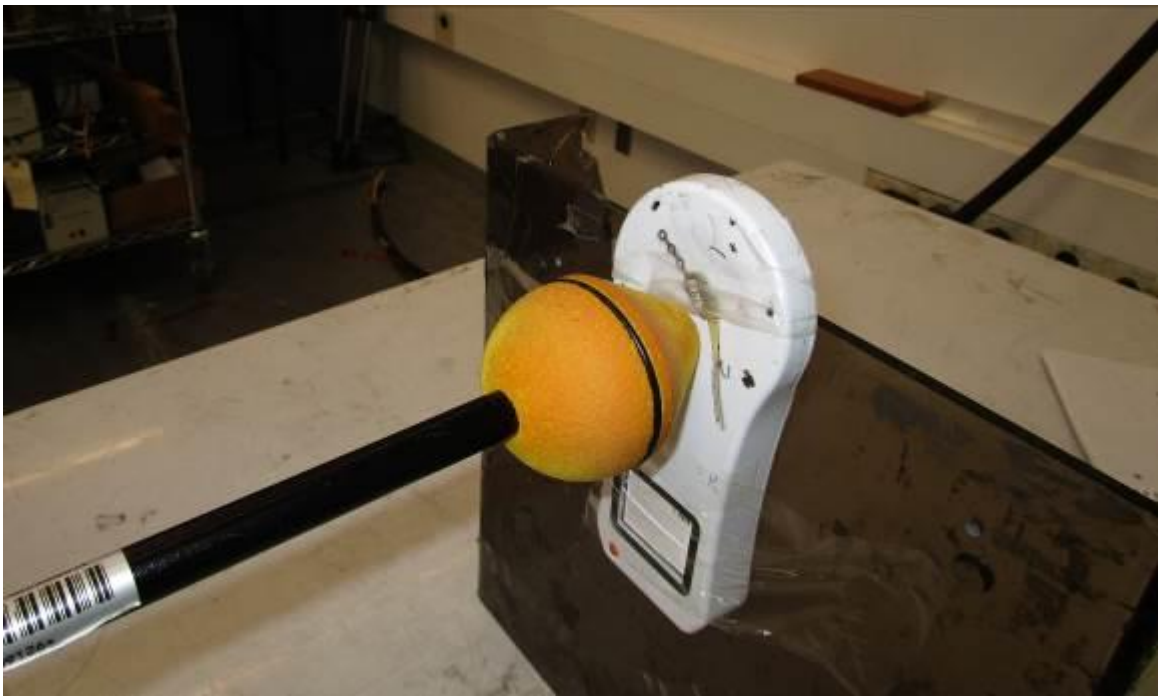
6.3 Test Equipment Used:

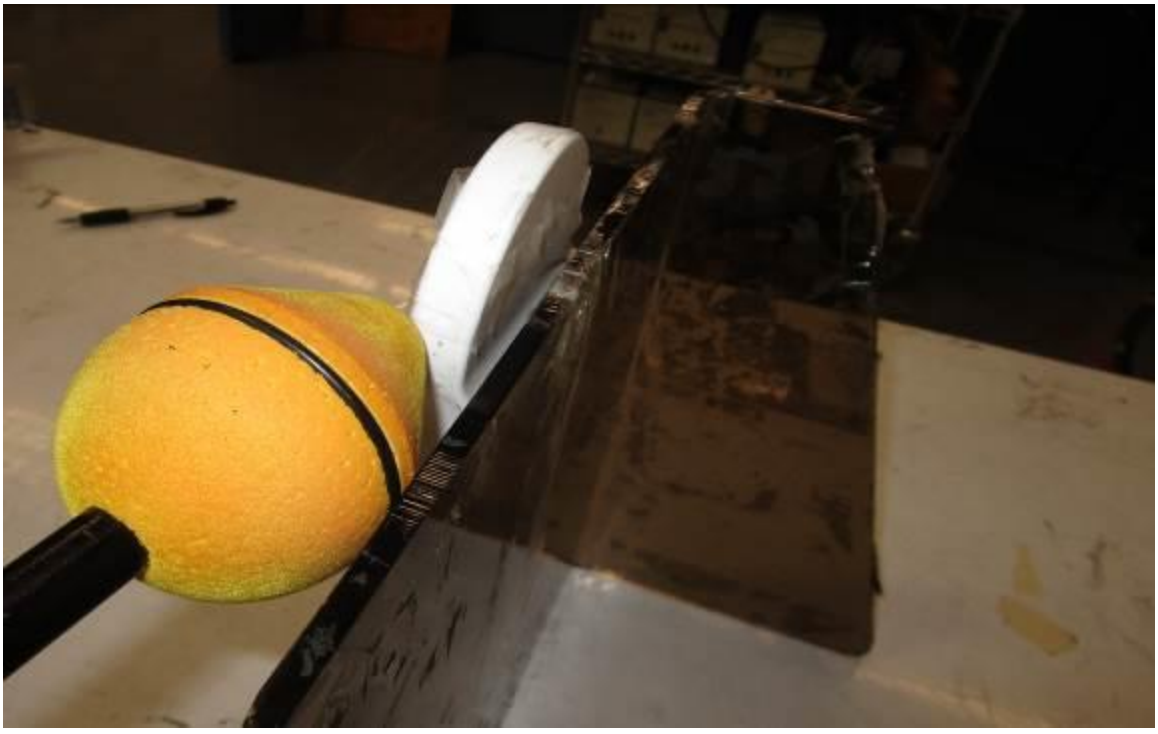
Description	Manufacturer	Model	Serial	Cal Date	Cal Due
Probe Interface	Wandel & Golterman	Type 8.2	None	02/23/218	02/13/2019
Electric Field Probe	Wandel & Goltermann	EMC-20	BN2244/29	02/23/218	02/13/2019

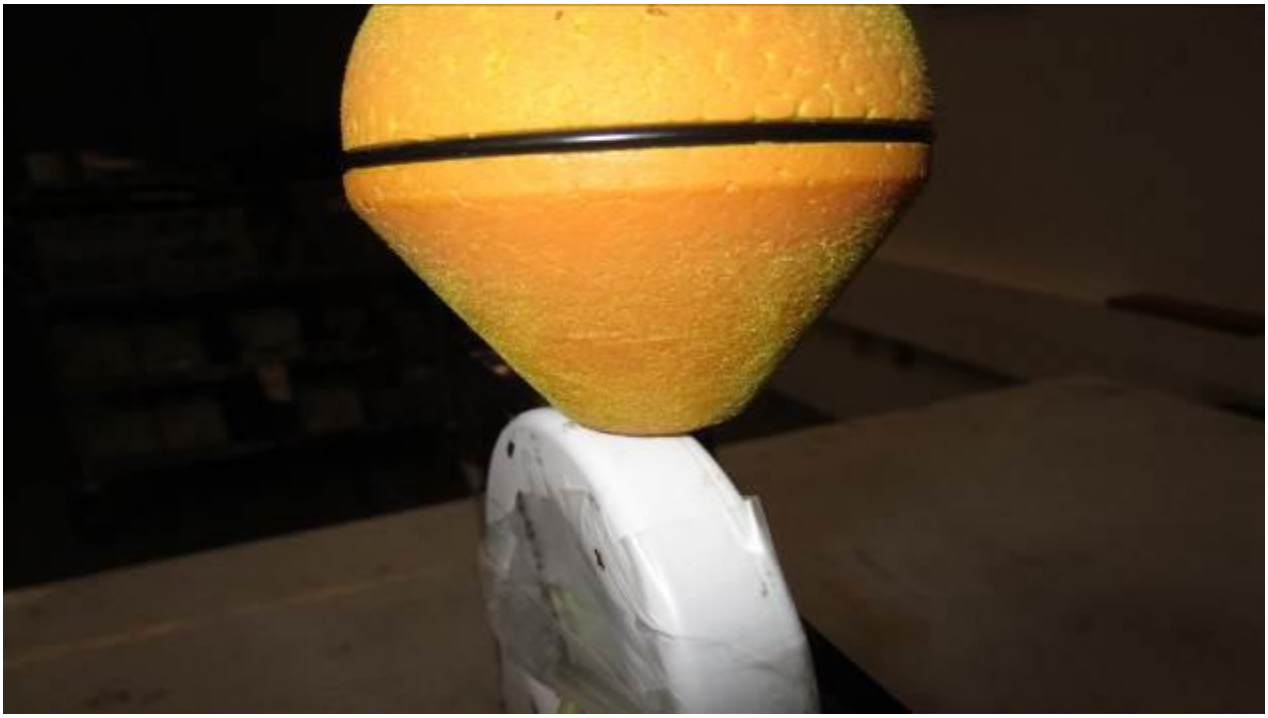
6.4 Results:

The sample tested was found to Comply at 0 mm from the probe.

6.5 Setup Photographs:







6.6 Data:

EUT Location (worst-case)	Measured Value (V/m rms)	Duty Cycle applied dB	Final value (V/m rms)	Limit (V/m rms)
Top	45.48	0	45.48	164
Left Side	29.42	0	29.42	164
Right Side	44.50	0	44.50	164
Front Side	59.61	0	59.61	164
Bottom	46.30	0	46.30	164
Back side	92.30	0	92.30	164

1) Test was performed with probe touching the EUT i.e. 0mm from EUT. The values indicated above are highest instantaneous values observed on the meter used for measurement.

2) No duty cycle was applied.

3) Compliance is required for H-field only as per KDB 680106 D01 RF Exposure Wireless Charging App v03. E-field measurements performed earlier are retained in the report for information.

Test Result: The **EUT PASSED** at 0mm

Test Personnel:	Suresh Kondapalli	Test Date:	08/24/2018
Product Standard:	IEEE C95.1-2005	Limit Applied:	IEEE C95.1-2005
Input Voltage:	Fully Charged Battery	Ambient Temperature:	24.9 ºC
Pretest Verification w/ Ambient Signals or BB Source:	Yes	Relative Humidity:	53.6 %
		Atmospheric Pressure:	989 mBar

Deviations, Additions, or Exclusions: None

7 Magnetic Field

7.1 Performance Requirement(s)

IEEE std C95.1 -2005

Table 9—Action level (MPE for the general public when an RF safety program is unavailable) (see Figure 4 for graphical representation)

Frequency range (MHz)	RMS electric field strength (E)[a] (V/m)	RMS magnetic field strength (H)[a] (A/m)	RMS power density (S) E-field, H-field (W/m^2)	Averaging time[b] $\|E\|^2$, $\|H\|^2$ or S (min)	
0.1–1.34	614	$16.3/f_M$	$(1000, 100\,000/f_M^2)$[c]	6	6
1.34–3	$823.8/f_M$	$16.3/f_M$	$(1800/f_M^2, 100\,000/f_M^2)$	$f_M^2/0.3$	6
3–30	$823.8/f_M$	$16.3/f_M$	$(1800/f_M^2, 100\,000/f_M^2)$	30	6
30–100	27.5	$158.3/f_M^{1.668}$	$(2, 9\,400\,000/f_M^{3.336})$	30	$0.0636 f_M^{1.337}$
100–400	27.5	0.0729	2	30	30
400–2000	–	–	$f_M/200$	30	
2000–5000	–	–	10	30	
5000–30 000	–	–	10	$150/f_G$	
30 000–100 000	–	–	10	$25.24/f_G^{0.476}$	
100 000–300 000	–	–	$(90f_G–7000)/200$	$5048/[(9f_G–700)f_G^{0.476}]$	

NOTE—f_M is the frequency in MHz, f_G is the frequency in GHz.

[a]For exposures that are uniform over the dimensions of the body, such as certain far-field plane-wave exposures, the exposure field strengths and power densities are compared with the MPEs in the Table. For non-uniform exposures, the mean values of the exposure fields, as obtained by spatially averaging the squares of the field strengths or averaging the power densities over an area equivalent to the vertical cross section of the human body (projected area) or a smaller area depending on the frequency (see NOTES to Table 8 and Table 9 below), are compared with the MPEs in the Table.

[b]The left column is the averaging time for $|E|^2$, the right column is the averaging time for $|H|^2$. For frequencies greater than 400 MHz, the averaging time is for power density S

[c]These plane-wave equivalent power density values are commonly used as a convenient comparison with MPEs at higher frequencies and are displayed on some instruments in use.

7.2 Method

The narda ELT-400 Exposure Level Tester measures magnetic field in the frequency range 1 Hz to 400 kHz. Its display takes all frequency components into account automatically. It uses a standard-compliant three-axis 100 cm² probe.

Direct measurement was used. Measurements were performed at 0mm (Touching) EUT represents worst case. Measurements were performed on all sides of the device and the worst result is recorded.

Test Site:

The test facility is located at 1365 Adams Court, Menlo Park USA. This test laboratory has been accredited by A2LA and registered with ISED, company number: 2042L.

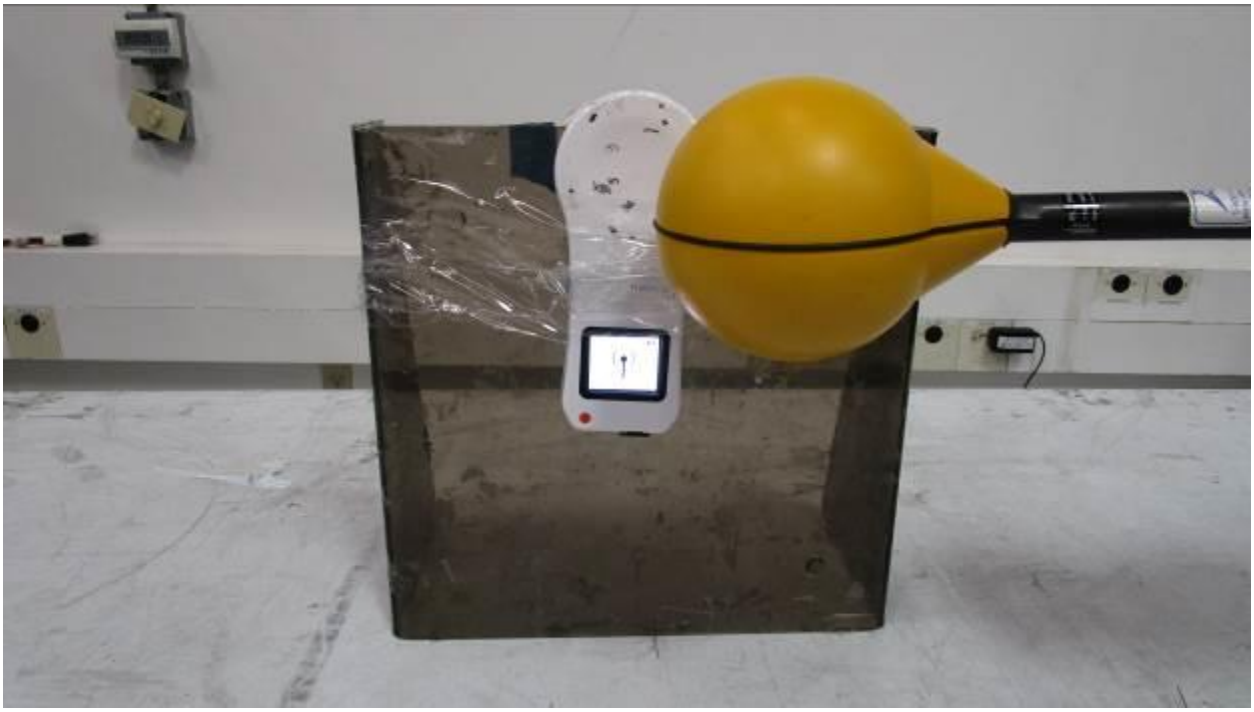
7.3 Test Equipment Used:

Description	Manufacturer	Model	Serial	Cal Date	Cal Due
Exposure Level Tester	Narda	ELT-400	N-0044	09/15/2017	09/15/2018
B-Field Probe	Narda	2300/90.10	M-0487	09/15/2017	09/15/2018
Exposure Level Tester	Narda	ELT-400	N-0044	09/19/2018	09/19/2019
B-Field Probe	Narda	2300/90.10	M-0487	09/19/2018	09/19/2019
Spectrum Analyzer	Rhode & Schwarz	FSU	1100.100020	01/24/2018	01/24/2019

7.4 Results:

Test Result: The **EUT PASSED at 0mm**

7.5 Setup Photographs:



7.6 Data:

Test Mode A: Wand (RC-300) seeking implant device (NS-100)

In this mode Wand was seeking implant device, wand will be placed close to skin or touching skin.

EUT Location (worst-case)	Measured Value (uT)	Measured Value (A/m rms)	Duty Cycle applied dB	Final value (A/m rms)	Limit (A/m rms) 16.4/F(MHz)	50% of the Limit
Top	16.80	13.33	0	13.33	130	65
Left Side	12.38	9.82	0	9.82	130	65
Right Side	19.80	15.71	0	15.71	130	65
Front Side	44.00	34.90	0	34.90	130	65
Bottom	3.80	3.01	0	3.01	130	65
Back side	40.10	31.80	0	31.80	130	65

Calculated Value (A/m) = Measured Value (uT) /1.26

1) Test was performed with probe touching the EUT i.e. 0mm from EUT. The values indicated above are highest instantaneous rms values observed on the meter used for measurement. In this mode Wand was seeking implant device, wand will be placed close to skin or touching skin.

2) In the mode device has duty cycle of 63.7%. On time of 2.18Sec in total period of 3.42Sec. See duty cycle plots at page 20. No duty correction was applied as transmit pulse time exceeds 100ms. The above values show the device complies without applying duty cycle correction.

3) Tests were performed without Implant device. Only highest readings are reported here.

Test Mode B: Power transfer mode (Wand RC-300 connected to implant device NS-100)

In this mode RC-300 is connected to NS-100 in wireless mode in active power transfer mode

EUT Location (worst-case)	Measured Value (uT)	Measured Value (A/m rms)	Duty Cycle applied dB	Final value (A/m rms)	Limit (A/m rms) 16.4/F(MHz)	50% of the Limit
Top	19.18	15.22	0	15.22	130	65
Left Side	22.08	17.52	0	17.52	130	65
Right Side	22.20	17.62	0	17.62	130	65
Front Side	32.50	25.79	0	25.79	130	65
Bottom	3.40	2.69	0	2.69	130	65
Back side	48.27	38.30	0	38.30	130	65

Calculated Value (A/m) = Measured Value (uT) /1.26

1) Test was performed with probe touching the EUT i.e. 0mm from EUT. The values indicated above are highest instantaneous rms values observed on the meter used for measurement. In this mode wand is connected to implant device and transferring power to implant device. In this mode device can be touching or 0mm from skin.

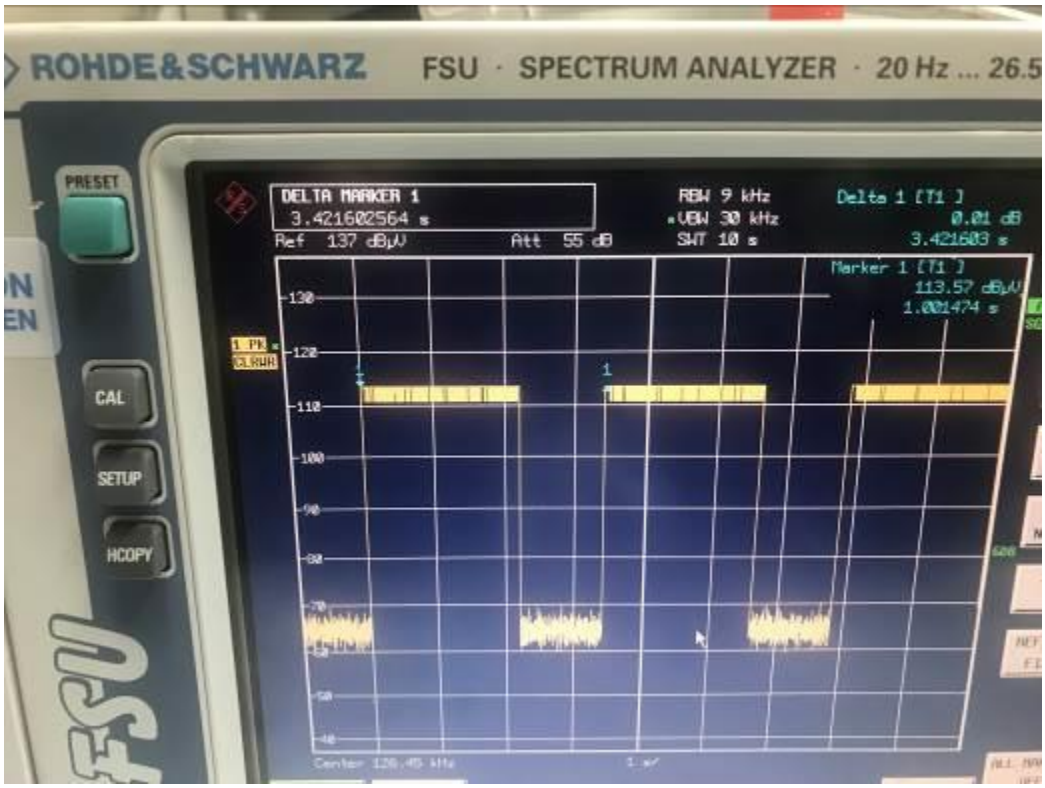
2) EUT transmits 100% of the time. No duty cycle can be applied.
3) Tests were performed with Implant device in the vicinity (0 to 3cm) of Wand.

Test Result: The **EUT PASSED** with probe **0mm** from the EUT.

Test Personnel:	Suresh Kondapalli	Test Date:	08/24/2018 & 01/10/2019
Product Standard:	IEEE C95.1-2005	Limit Applied:	IEEE C95.1-2005
Input Voltage:	Fully Charged battery	Ambient Temperature:	24.9 ºC & 22.0 ºC
Pretest Verification w/ Ambient Signals or		Relative Humidity:	53.6 % & 53%
BB Source:	Yes	Atmospheric Pressure:	989 mBar

Deviations, Additions, or Exclusions: None

Duty cycle plots in wand seeking implant device



Plot 1 Cycle time (3.42Secs)

Plot 2 ON time (2.18Secs)

Duty Cycle= 2.18/3.42 = 0.6374 or 63.74%

8 Revision History

Revision Level	Date	Report Number	Prepared By	Notes
0	September 11, 2018	1034940MPK-011	SK	Initial Release
1	January 15, 2019	1034940MPK-011	SK	Revised to add test data for wand seeking implant device mode, duty cycle plots for seeking mode