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CERTIFICATION TEST REPORT

In Accordance With:	FCC Part 95 Subpart I
Applicant:	Spinal Modulation Inc. 1135 O'Brien Dr. Menlo Park, CA 94025
Equipment Under Test (EUT):	Implantable Neurostimulator Model: MN0200
FCC ID:	Y8L-MN0200
Tested By:	Nemko USA Inc. 11696 Sorrento Valley Road, Suite F San Diego, CA 92121
PREPARED ON	January 17, 2011
REPORT NUMBER:	2011 01160678 FCC
PROJECT NUMBER:	53259
NEx Number:	160678
Total Number of Pages:	19

Section1: Summary of Test Results

1.1 General

All measurements are traceable to national standards

These tests were conducted on a sample of the equipment for the purpose of demonstrating compliance with FCC Part 95 Subpart I. Radiated tests were conducted is accordance with ANSI C63.4-2003. Radiated emissions are made on an open area test site. A description of the test facility is on file with the FCC.

The assessment summary is as follows:

Apparatus Assessed:	Implantable Neurostimulator
Model:	MN0200
Serial:	DB0931
Specifications:	FCC Part 95 Subpart I
Date Received in Laboratory:	January 4, 2011
Compliance Status:	Complies
Exclusions:	None
Non-compliances:	None

1.2 Document History

REVISION	DATE	COMMENTS	
-	January 17, 2011	Prepared By:	Alan Laudani
-	January 17, 2011	Initial Release:	Alan Laudani

Note that the results contained in this report relate only to the items tested and were obtained in the period between the date of initial receipt of samples and the date of issue of the report.

This test report has been completed in accordance with the requirements of ISO/IEC 17025.

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TESTED BY:  Date: January 17, 2011
Alan Laudani, RF/EMC Engineer

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Section 2: Equipment Under Test

1.3 Product Identification

The Equipment Under Test was identified as follows:

Description	Serial No.
Implantable Neurostimulator Model: MN0200	DB0931

1.4 Technical Specifications of the EUT

Manufacturer:	Spinal Modulation Inc.
Transmit Frequency:	402.150 MHz to 404.850 MHz
Rated Power:	2.18 µW
Modulation:	2FSK
Emission Designator:	245KF1D
Antenna:	helix type antenna
Antenna Connector:	Integral to circuitry
Power Source:	BATTERY

Section 3: Test Conditions

3.1 Test Environment

All tests were performed under the following environmental conditions:

Temperature range	:	21-31 ºC
Humidity range	:	18-70 %
Pressure range	:	101.2 kPa
Power supply range	:	102-132 Vac 60 Hz

3.2 Test Equipment

Nemko ID	Device	Manufacturer	Model	Serial Number	Cal Date	Cal Due Date
111	Antenna, LPA	EMCO	3146	1382	11/29/2010	11/29/2012
128	Antenna, Bicon	EMCO	3104	2882	2/9/2009	2/9/2011
317	Preamplifier	HP	8449A	2749A00167	5/7/2010	5/7/2011
752	Antenna, DRWG	EMCO	3115	4943	12/2/2010	12/2/2012
835	Spectrum Analyzer	Rohde & Schwarz	RHDFSEK	829058/005	7/12/2010	7/12/2011
836	Signal Generator	Agilent	E8254A	US41140229	2/5/2010	2/5/2011
815	Multimeter	Fluke	111	78130066	8/4/2010	8/4/2011
877	Antenna, DRG Horn, .7-18GHz	AH Systems	SAS-571	688	8/16/2010	8/16/2011
919	Preamplifier	Spacek Labs MM-Wave Technology	100MHz to 40GHz	3M12 (SLK-35-3) and 3M13 (SLKa-35-4)	12/14/2010	12/14/2011
N149	Environmental Chamber	Cincinnati Sub-Zero	ZPHS-32-2-2-H/AC	ZP0552665	6/22/2010	6/22/2011
926	UWave Freq Counter	Anritsu	MF2512B	6200229301	2-Mar-10	2-Mar-11
E1013	DRG Horn (Small)	EMCO	3116	00119488	12/23/2009	12/23/2011
E1018	9kHz to 7GHz Spectrum Analyzer	Rohde & Schwarz	FSP7	835363/0003	1/22/2010	1/22/2011
911	Spectrum Analyzer	Agilent	E4440A	US41421266	10/26/2010	10/26/2011
client	DC Power Supply	Gwinstek	GPS-30300	NA	NCR	NCR
NA	20 dB Attenuator	Winschel	24-20-234	NA	Verified	Verified

NVLAP LAB CODE: 200116-0.
Registration of the OATS are on file with the Federal Communications Commission, under the VCCI under registration number R-3027, and are also registered with Industry Canada under Site Numbers 2040B-1 and 2040B-2.

Section 4: Observations

4.1 Modifications Performed During Assessment

None

4.2 Record Of Technical Judgments

No technical judgments were made during the assessment.

4.3 EUT Parameters Affecting Compliance

The user of the apparatus could not alter parameters that would affect compliance.

4.4 Test Deleted

No Tests were deleted from this assessment.

4.5 Additional Observations

There were no additional observations made during this assessment.

Section 5: Results Summary

5.1. Test Result summary table

FCC Part 95 Subpart I:

The column headed “Required” indicates whether the associated clauses were invoked for the apparatus under test. The following abbreviations are used:

N No: not applicable / not relevant
Y Yes: Mandatory i.e. the apparatus shall conform to this test.
N/T Not Tested, mandatory but not assessed. (See section 4.4 Test deleted)

The results contained in this section are representative of the operation of the apparatus as originally submitted.

FCC	Test/Requirement Description	Required	Result
95.628 (a)	Frequency Monitoring	N	*NR
95.628 (e)(2)	Frequency vs Temperature	Y	Complies
95.628 (a) (6) (i); 95.633 (e) (3)	Emission Bandwidth	Y	Complies
95.635 (d)	Unwanted Radiation	Y	Complies
95.639 (f)	Maximum Transmitter Power	Y	Complies
95.631 (h)	Emission Types	Y	Complies
95.603 (f); 95.605	Certification Required	Y	Complies

*Not required

Appendix A: Test Results

A1. Frequency Monitoring – Not required

95.628 (a) (a) *Frequency monitoring.* Except as provided in (b) of this section, all MedRadio programmer/control transmitters operating in the 401–406 MHz band must operate under the control of a monitoring system that incorporates a mechanism for monitoring the channel or channels that the MedRadio system devices intend to occupy. The monitoring system antenna shall be the antenna normally used by the programmer/control transmitter for a communications session. Before the monitoring system of a MedRadio programmer/control transmitter initiates a MedRadio communications session, the following access criteria must be met:
(1) The monitoring system bandwidth measured at its 20 dB down points must be equal to or greater than the emission bandwidth of the intended transmission.
(2) Within 5 seconds prior to initiating a communications session, circuitry associated with a MedRadio programmer/control transmitter must monitor the channel or channels the system devices intend to occupy for a minimum of 10 milliseconds per channel.
(3) Based on use of an isotropic monitoring system antenna, the monitoring threshold power level must not be more than 10logB(Hz) −150 (dBm/Hz) + G(dBi), where B is the emission bandwidth of the MedRadio communications session transmitter having the widest emission and G is the MedRadio programmer/control transmitter monitoring system antenna gain relative to an isotropic antenna. For purposes of showing compliance with the above provision, the above calculated threshold power level must be increased or decreased by an amount equal to the monitoring system antenna gain above or below the gain of an isotropic antenna, respectively.
(4) If no signal in a MedRadio channel above the monitoring threshold power level is detected, the MedRadio programmer/control transmitter may initiate a MedRadio-communications session involving transmissions to and from a medical implant or medical body-worn device on that channel. The MedRadio communications session may continue as long as any silent period between consecutive data transmission bursts does not exceed 5 seconds. If a channel meeting the criteria in paragraph (a)(3) of this section is unavailable, MedRadio transmitters that are capable of operating on multiple channels may transmit on the alternate channel accessible by the device with the lowest monitored ambient power level. Except as provided in paragraph (b) of this section, MedRadio transmitters that operate on a single channel and thus do not have the capability of operating on alternate channels may not transmit unless no signal on the single channel of operation exceeds the monitoring threshold power level.
(5) When a channel is selected prior to a MedRadio communications session, it is permissible to select an alternate channel for use if communications are interrupted, provided that the alternate channel selected is the next best choice using the above criteria. The alternate channel may be accessed in the event a communications session is interrupted by interference. The following criteria must be met:
(i) Before transmitting on the alternate channel, the channel must be monitored for a period of at least 10 milliseconds.
(ii) The detected power level during this 10 millisecond or greater monitoring period must be no higher than 6dB above the power level detected when the channel was chosen as the alternate channel.
(iii) In the event that this alternate channel provision is not used by the MedRadio system or if the criteria in paragraphs (a)(5)(i) and (ii) are not met, a channel must be selected using the access criteria specified in paragraphs (a)(1) through (a)(4) of this section.
(6) As used in this section, the following definitions apply:
(i) *Emission bandwidth* — Measured as the width of the signal between the points on either side of carrier center frequency that are 20 dB down relative to the maximum level of the modulated carrier. Compliance will be determined using instrumentation employing a peak detector function and a resolution bandwidth approximately equal to 1% of the emission bandwidth of the device under test.
(ii) *MedRadio channel* —Any continuous segment of spectrum in the MedRadio band that is equal to the emission bandwidth of the device with the largest bandwidth that is to participate in a MedRadio communications session. Note to paragraph (a)(6)(ii): The rules do not specify a channeling scheme for use by MedRadio systems.
(iii) *MedRadio communications session* —A collection of transmissions, that may or may not be continuous, between MedRadio system devices.

A2. Frequency vs Temperature

95.628 (e) (2)
(e) Frequency stability. Each transmitter in the MedRadio service must maintain a frequency stability of ±100 ppm of the operating frequency over the range:
(2) 0 °C to 55 °C in the case of MedRadio programmer/control transmitters and MedRadio body-worn transmitters.

Conditions:

Model:	MN0200	Temperature:	19ºC
Date:	1-11-2011	Humidity:	33%
Modification State:	None	Tester:	Alan Laudani
		Laboratory:	Nemko

Observations:
Method of Measurement:
Modulation: CW.

Spectrum Analyzer settings: 3 kHz RBW, 10 kHz VBW and/or use of frequency counter.

Direct connection to the spectrum analyzer (or frequency counter) was used for measurements using the test boards.

The Neurostimulator Circuit Board, model AD1518 Rev 1, SN 200849 was used as a representative sample of the Neurostimulator: Implant MNO200, Trial MN0100.

Test Conditions: Ambient Temperature: 19°C
Relative Humidity: 33%

Measurement Data: Table below.

Limits: The frequency shall remain within 100 ppm of the channel frequency.
±100ppm x 405 MHz = ±40,500 Hz

EUT complies

Voltage Input Test Condition	Frequency (MHz)	Frequency Delta (Hz)
2.72 VDC	402.14236	-7640
2.52 VDC	402.14235	-7650
2.31 VDC	402.14235	-7650
2.13 VDC	402.14237	-7630
2.03 VDC	402.14235	-7650
1.92 VDC	402.14236	-7640
1.81 VDC	402.14235	-7650
1.70 VDC	402.14236	-7640
1.61 VDC	402.14235	-7650
1.51 VDC	402.14237	-7630
1.41 VDC	402.14237	-7630
1.30 VDC	402.14237	-7630
1.20 VDC	402.14235	-7650
1.15 VDC	402.14235	-7650
1.11 VDC	402.14236	-7640
1.10 VDC	OFF	

Temperature Test Condition	Frequency (MHz)	Frequency Delta (Hz)
20°C	402.141600	-8400
30°C	402.138800	-11200
40°C	402.135543	-14457
50°C	402.131670	-18330
55°C	402.129690	-20310
-10°C	402.148370	-1630
0°C	402.147670	-2330
10°C	402.145190	-4810
20°C	402.142580	-7420

A3. Emission Bandwidth

95.628 (a) (6) (i) *Emission bandwidth* — Measured as the width of the signal between the points on either side of carrier center frequency that are 20 dB down relative to the maximum level of the modulated carrier. Compliance will be determined using instrumentation employing a peak detector function and a resolution bandwidth approximately equal to 1% of the emission bandwidth of the device under test.

95.633 (e) (3) Emission bandwidth will be determined by measuring the width of the signal between points, one below the carrier center frequency and one above the carrier center frequency, that are 20 dB down relative to the maximum level of the modulated carrier. Compliance with the emission bandwidth limit is based on the use of measurement instrumentation employing a peak detector function with an instrument resolution bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.

Conditions:

Model:	MN0200	Temperature:	19ºC
Date:	1-11-2011	Humidity:	33%
Modification State:	None	Tester:	Alan Laudani
		Laboratory:	Nemko

Observations:

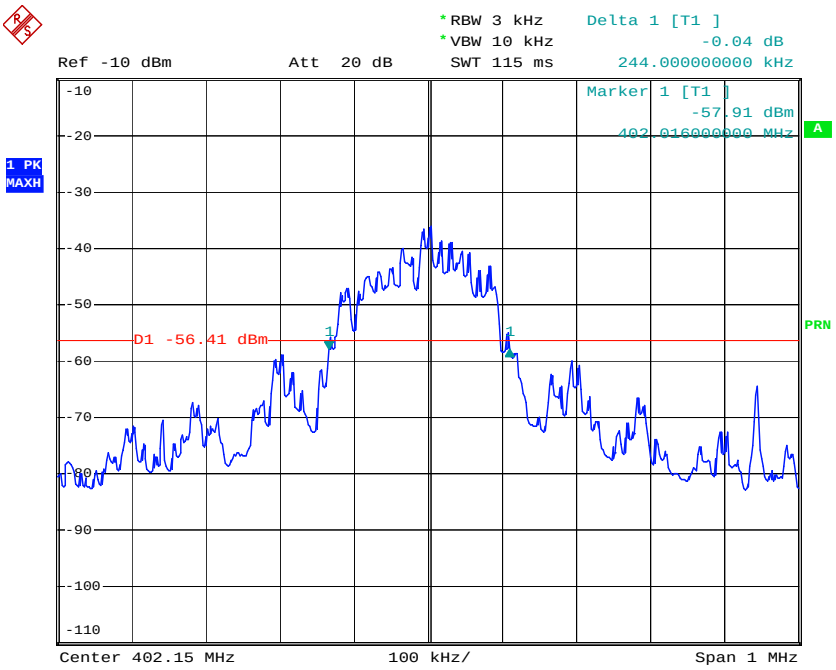
Peak, max hold emission, continuous test mode.

The Neurostimulator Circuit Board, model AD1518 Rev 1, SN 200849 was used as a representative sample of the Neurostimulator: Implant MNO200, Trial MN0100.

Test Results: Complies

Test Data: See attached plots.

INS



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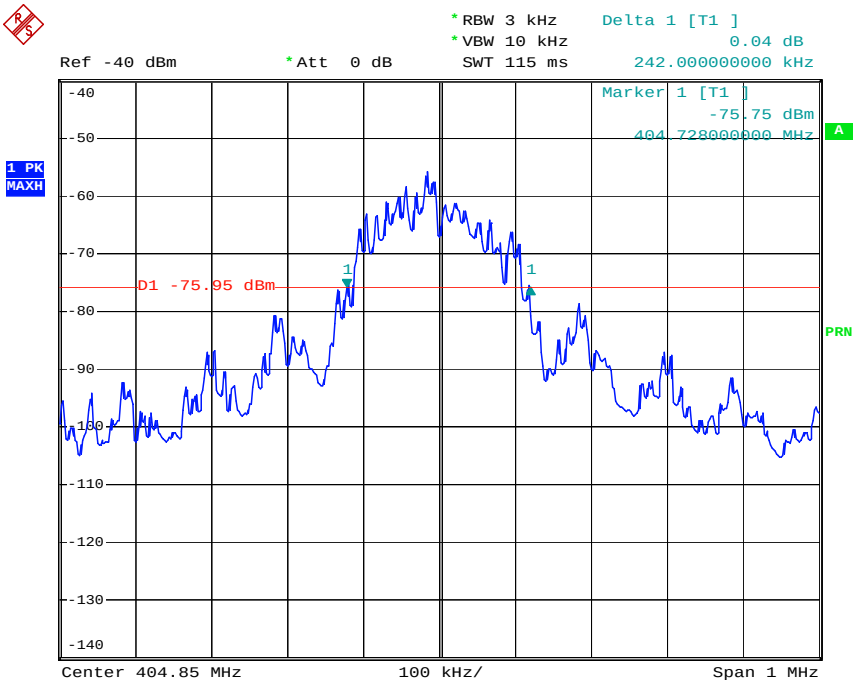

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A4. Unwanted Radiation

Para. No.: 95.635 (d)

(d) For transmitters designed to operate in the MedRadio service, emissions shall be attenuated in accordance with the following: (paragraphs (d)(1) through (d)(5) pertain to MedRadio transmitters operating in the 402–405 MHz band; paragraphs (d)(6) through (d)(10) pertain to MedRadio transmitters operating in the 401–402 MHz or 405–406 MHz bands).
(1) Emissions from a MedRadio transmitter more than 250 kHz outside of the 402–405 MHz band shall be attenuated to a level no greater than the following field strength limits:

Frequency (MHz)	Field strength (μV/m)	Measurement distance (m)
30–88	100	3
88–216	150	3
216–960	200	3
960 and above	500	3

Note—At band edges, the tighter limit applies.
(2) The emission limits shown in the table of paragraph (d)(1) are based on measurements employing a CISPR quasi-peak detector except that above 1 GHz, the limit is based on measurements employing an average detector. Measurements above 1 GHz shall be performed using a minimum resolution bandwidth of 1 MHz. *See also* §95.605.
(3) The emissions from a MedRadio transmitter must be measured to at least the tenth harmonic of the highest fundamental frequency designed to be emitted by the transmitter.

6.
Conditions:

Model:	MN0200	Temperature:	13ºC
Date:	1-12-2011	Humidity:	36%
Modification State:	Nomal	Tester:	Alan Laudani
		Laboratory:	Nemko

Observations: Peak hold detection worst case over quasi-peak detector.

Test Results: Complies

Test Data:

NOTE: The spectrum was searched to 5 GHz. All emissions within 20 dB of the specification limit are reported.

Implant NeuroStimulator transmitter

Radiated Emissions Data

Job # :	43259-1	Date :	1-12-2011	Page 1 of 1	
NEX #:	160678	Time :	1440		
		Staff :	aal		
Client Name :	Spinal Modulation, Inc.			NOATS	
EUT Name :	Inplant NeuroStimulator			SOATS	X
EUT Model # :				Distance < 1000 MHz:	3 m
EUT Serial # :	DB0931			Distance > 1000 MHz:	3 m
EUT Config. :	Continuous Transmit				
Loop Ant. #:	NA				
Bicon Ant.#:	114_3m	Temp. (°C) :	16		
Log Ant.#:	111_3m	Humidity (%) :	36		
DRG Ant. #	NA	Spec Analyzer #:	E1017		
Cable LF#:	soats	Analyzer Display #:	E1017		
Cable HF#:	877	Quasi-Peak Detector #:	E1017		
Preamp LF#:	902	Preselector #:	E1017		
Preamp HF#	NA				

Quasi-Peak	RBW: 120 kHz
	Video Bandwidth 300 kHz
Peak	RBW: 300 kHz
	Video Bandwidth 1 MHz
Average = Peak + DCF	
DCF = -10.5	

Measurements below 1 GHz are Quasi-Peak values, unless otherwise stated.
Measurements above 1 GHz are Average values, unless otherwise stated.

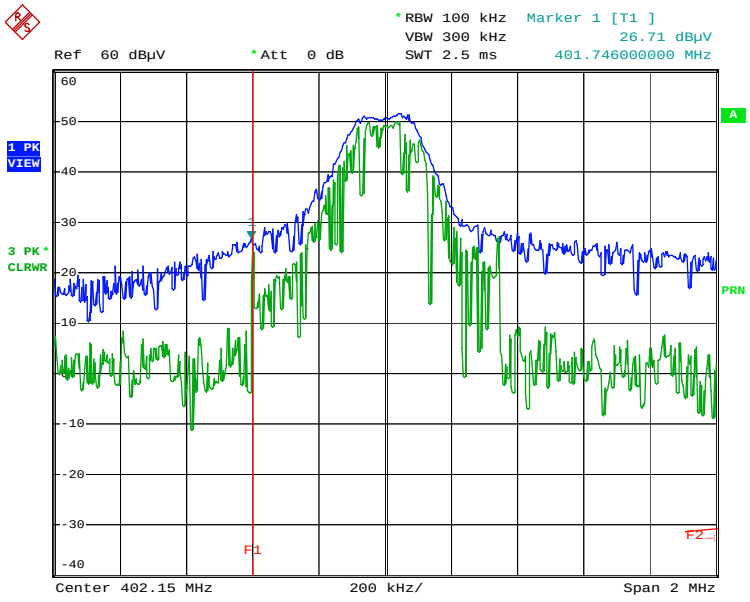
Meas. Freq. (MHz)	Meter Reading **Vertical**	Meter Reading **Horizontal**	Det.	EUT Side F/L/R/B	Ant. Height m	Max. Reading (dBµV)	Corrected Reading (dBµV/m)	Spec. limit (dBµV/m)	CR/SL Diff. (dB)	Pass Fail	Comment
402.15	51.5	51.3	P		2.5	51.5	70.6	79.2	-8.6	Pass	channel 0
402.15	41.0	40.8	A		1.0	41.0	60.1	79.2	-19.1	Pass	
401.75	26.6	25.6	Q		1.2	26.6	45.7	46.0	-0.3	Pass	lower band edge
405.25	25.2	25.6	Q		1.2	25.6	44.7	46.0	-1.3	Pass	upper band edge
404.85	49.7	51.1	P		2.4	51.1	70.2	79.2	-9.0	Pass	channel 9
404.85	39.2	40.6	A		1.0	40.6	59.7	79.2	-19.5	Pass	

Substitution Method For Radiated Emissions

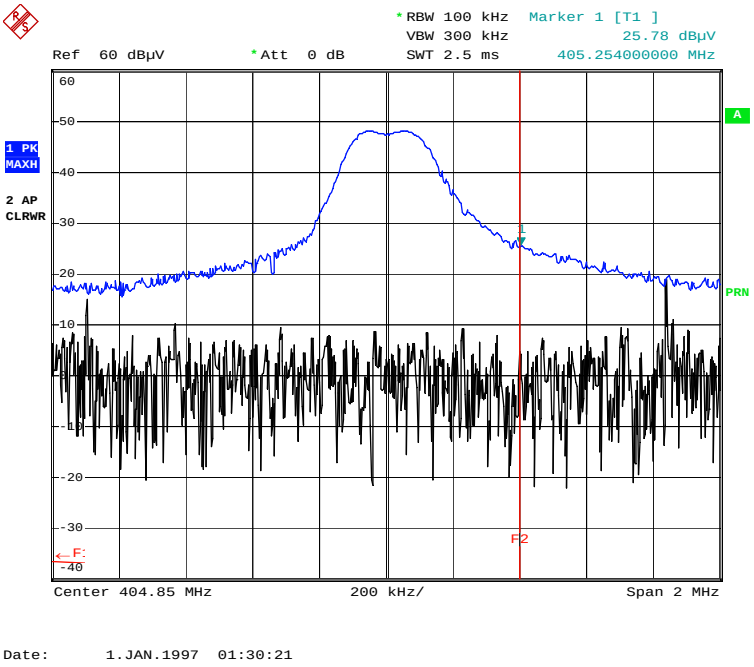
Target		Dipole	Cable	Signal	Total	Total	Spec	Margin
Frequency	Level	ant.	loss	Generator	(EIRP)	(EIRP)		
MHz	dBuV/m	gain	dB	dBm	dBm	µW	µW	dB
402.15	51.5	1.68	5.0	-23.7	-27.0	1.99	25	-11.0
404.85	51.1	1.68	5.0	-23.3	-26.6	2.18	25	-10.6

Radiated Band Edge

Implant NeuroStimulator
Channel 0, 250 kHz below 402 MHz



Implant NeuroStimulator
Channel 9, 250 kHz Above 405 MHz



A5. Maximum Transmitter Power

Para. No.: 95.639 (f)

(f) In the MedRadio Service for transmitters that are not excepted under §95.628(b) from the frequency monitoring requirements of §95.628(a), the maximum radiated power in any 300 kHz bandwidth by MedRadio transmitters operating at 402–405 MHz, or in any 100 kHz bandwidth by MedRadio transmitters operating at 401–402 MHz or 405–406 MHz shall not exceed 25 microwatts EIRP. For transmitters that are excepted under §95.628(b) from the frequency monitoring requirements of §95.628(a), the power radiated by any station operating in 402–405 MHz shall not exceed 100 nanowatts EIRP confined to a maximum total emission bandwidth of 300 kHz centered at 403.65 MHz. For transmitters that are excepted under §95.628(b) from the frequency monitoring requirements of §95.628(a), the power radiated by any station operating in 401–401.85 MHz or 405–406 MHz shall not exceed 250 nanowatts EIRP in any 100 kHz bandwidth and in 401.85–402 MHz shall not exceed 25 microwatts in the 150 kHz bandwidth. *See* §§95.633(e). The antenna associated with any MedRadio transmitter must be supplied with the transmitter and shall be considered part of the transmitter subject to equipment authorization. Compliance with these EIRP limits may be determined as set forth in §95.628(g).

Conditions:

Model:	MN0200	Temperature:	13ºC
Date:	1/12/2011	Humidity:	36%
Modification State:	Normal	Tester:	Alan Laudani
		Laboratory:	Nemko

Observations:
Field strength was substituted for to result in output power EIRP.

Test Results: Passed
The maximum field strength is 2.18 µW.

Test Data: See attached tables

Radiated Emissions Data

Job # :	43259-1	Date :	1-12-2011	Page	1 of 1
NEX #:	160678	Time :	1440		
		Staff :	aal		
Client Name :	Spinal Modulation, Inc.			NOATS	
EUT Name :	Inplant NeuroStimulator			SOATS	X
EUT Model # :				Distance < 1000 MHz:	3 m
EUT Serial # :	DB0931			Distance > 1000 MHz:	3 m
EUT Config. :	Continuous Transmit				
Loop Ant. #:	NA				
Bicon Ant.#:	114_3m	Temp. (°C) :	16		
Log Ant.#:	111_3m	Humidity (%) :	36		
DRG Ant. #	NA	Spec Analyzer #:	E1017		
Cable LF#:	soats	Analyzer Display #:	E1017		
Cable HF#:	877	Quasi-Peak Detector #:	E1017		
Preamp LF#:	902	Preselector #:	E1017		
Preamp HF#	NA				

Quasi-Peak	RBW: 120 kHz
	Video Bandwidth 300 kHz
Peak	RBW: 300 kHz
	Video Bandwidth 1 MHz
Average = Peak + DCF	
DCF = -10.5	

Measurements below 1 GHz are Quasi-Peak values, unless otherwise stated.
Measurements above 1 GHz are Average values, unless otherwise stated.

Meas. Freq. (MHz)	Meter Reading **Vertical**	Meter Reading **Horizontal**	Det.	EUT Side F/L/R/B	Ant. Height m	Max. Reading (dBµV)	Corrected Reading (dBµV/m)	Spec. limit (dBµV/m)	CR/SL Diff. (dB)	Pass Fail	Comment
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402.15	41.0	40.8	A		1.0	41.0	60.1	79.2	-19.1	Pass	
401.75	26.6	25.6	Q		1.2	26.6	45.7	46.0	-0.3	Pass	lower band edge
405.25	25.2	25.6	Q		1.2	25.6	44.7	46.0	-1.3	Pass	upper band edge
404.85	49.7	51.1	P		2.4	51.1	70.2	79.2	-9.0	Pass	channel 9
404.85	39.2	40.6	A		1.0	40.6	59.7	79.2	-19.5	Pass	

Substitution Method For Radiated Emissions

Target		Dipole	Cable	Signal	Total	Total	Spec	Margin
Frequency	Level	ant.	loss	Generator	(EIRP)	(EIRP)		
MHz	dBuV/m	gain	dB	dBm	dBm	µW	µW	dB
402.15	51.5	1.68	5.0	-23.7	-27.0	1.99	25	-11.0
404.85	51.1	1.68	5.0	-23.3	-26.6	2.18	25	-10.6

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Phone (858) 755-5525 Fax (858) 452-1810

A6. Emission Types

Para. No.: 95.631 (h)

(h) A MedRadio station may transmit any emission type appropriate for communications in this service. Voice communications, however, are prohibited.

Conditions:

Model:	MN0200	Temperature:	13ºC
Date:	10/11/2010	Humidity:	35%
Modification State:	Normal	Tester:	Alan Laudani
		Laboratory:	Nemko

Observations: Not a voice communication.

Test Results: Passed