TEST REPORT

FCC Part 15 Subpart C Section 15.209

MANUFACTURER'S NAME	EnteroMedics Inc 2800 Patton Road St. Paul MN 55113 USA
PRODUCT NAME	Maestro® Rechargeable System

MODEL NUMBER(S) TESTED

Description	Model #	Serial #
Neuroregulator	2002	003007
Transmit Coil	2403-60	10596
Anterior Lead	2200A-47E	021316
Posterior Lead	2200P-47E	021314
Mobile Charger	2402	D05010
Clinician Programmer	2502/Dell E5420 Latitude PC	CP502Z
CP Power Supply	DA65NM111-00	CN-0N6M8J-48661-25H-GG03-A02

PRODUCT DESCRIPTION	Implantable pulse generator with leads for delivering blocking signals to vagus nerve
TEST REPORT NUMBER	NC1309532.1 Rev C
TEST DATE(S)	04 October 2013

TÜV SÜD America Inc, as an independent testing laboratory, declares that the equipment tested as specified above conforms to the applicable EMC requirements of FCC Part 15 Subpart C Section 15.209 “Radiated emission limits; general requirements”, with consideration to DA 09-2425 FCC Waiver granted to EnteroMedics.

It is the manufacturer's responsibility to assure that additional production units of this model are manufactured with identical electrical and mechanical characteristics. Any modifications necessary for compliance made during testing on the above mentioned date(s) must be implemented in all production units for compliance to be maintained.

Issue Date: 24 July 2014

Greg Jakubowski
Senior EMC Technician

Joel T Schneider
Senior EMC Engineer

Not Transferable

EMC TEST REPORT

Test Report No. NC1309532.1 Rev C Date of issue: 24 July 2014

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Product Description Implantable pulse generator with leads for delivering blocking signals to vagus nerve

Manufacturer

EnteroMedics Inc
2800 Patton Road
St. Paul, MN 55113
USA

Test Result ■ **Positive** ☐ **Negative**

TÜV SÜD America Inc reports apply only to the specific samples tested under stated test conditions. It is the manufacturer's responsibility to assure that additional production units of this model are manufactured with identical electrical and mechanical components. TÜV SÜD America Inc shall have no liability for any deductions, inferences or generalizations drawn by the client or others from TÜV SÜD America Inc issued reports.

This report is the confidential property of the client. As a mutual protection to our clients, the public and ourselves, extracts from the test report shall not be reproduced except in full without our written approval. TÜV SÜD America's Wild River Lab maintains A2LA accreditation to ISO/IEC 17025 for the specific tests listed in A2LA Certificate #2955.11 as an Electrical Testing Laboratory.

TÜV SÜD America Inc and its professional staff hold government and professional organization certifications and are members of AAMI, ACIL, AEA, ANSI, IEEE, NARTE, and VCCI.

REVISION RECORD

REVISION	TOTAL NUMBER OF PAGES	DATE	DESCRIPTION
	22	14 November 2013	Initial Release
A	23	03 March 2014	Page 1 and corresponding Test Result Summary: adding details regarding model /serial number and EUT description per revised Test Plan/CDF in Appendix B. Page 5: Corrected 63.1 μV/m to 63.3 μV/m. Page 9: Added data from 30-1000 MHz with PC.
B	23	13 June 2014	Page 1 and corresponding Test Result Summary: Changing Maestro™ Rechargeable System to Maestro® Rechargeable System per revised Test Plan/CDF in Appendix B Test Plan/CDF: Correcting Posterior Lead Serial number from 021214 to 021314. Throughout report: Various template updates.
C	23	24 July 2014	Appendix A: replaced Test Plan/CDF with revised document received from the manufacturer with more details included regarding the EUT tested.

DIRECTORY

Contents

EMC TEST REGULATIONS:
The tests were performed according to the following regulations:
FCC Part 15 Subpart C §15.209

ENVIRONMENTAL CONDITIONS IN THE LAB

	Actual
Temperature:	: 22° C
Atmospheric pressure	: 99 kPa
Relative Humidity	: 65%

POWER SUPPLY UTILIZED
Power supply system : 4 VDC battery

TEST EQUIPMENT
All measurement instrumentation is traceable to the National Institute of Standards and Technology and is calibrated according to internal procedure.

MEASUREMENT UNCERTAINTY
The test system for conducted emissions is defined as the LISN, tuned receiver or spectrum analyzer, and coaxial cable. The test system has a measurement uncertainty of ±1.8 dB. The test system for radiated emissions is defined as the antenna, the pre-amplifier, the spectrum analyzer and the coaxial cable. The test system has a measurement uncertainty of ±4.8 dB. All measurement instrumentation is traceable to the National Institute of Standards and Technology and is calibrated according to internal procedure.

SIGN EXPLANATIONS
☐ - not applicable
■ - applicable

General field strength limits 0.009 – 30 MHz
FCC 15.209(a), FCC 15.209(c)

Test summary
The requirements are: ■ - MET ☐ - NOT MET
Testing was performed in accordance with the test procedure of ANSI C63.4 2009, clause 8.2.2.
Maximum field strength of the fundamental is 32.5 dBμV/m or 42.2 μV/m at 30 meters at 6.78 MHz.
Maximum field strength of spurious emissions is -12.5 dBμV/m or 0.237 μV/m at 30 meters at 13.56 MHz.
No unwanted emissions exceed the level of the fundamental.

Test location
■ - Wild River Lab Large Test Site (Open Area Test Site)
☐ - Wild River Lab Small Test Site (Open Area Test Site)

Test distance
■ - 1 meters
■ - 3 meters
■ - 10 meter

Test equipment

TUV ID	Model	Manufacturer	Description	Serial	Cal Due
WRLE02418	6502	EMCO	Loop Antenna	2215	16 Aug 14
WRLE02534	ESHS-20	Rohde & Schwarz	EMI Receiver 9kHz-30MHz	837055/003	15 Jul 14
WRLE10863	N/A	TÜV SÜD America Inc	Test Companion Software Version 3.4.71	N/A	Code Y

Cal Code B = Calibration verification performed internally.

Test limit

Frequency (MHz)	Field strength μV/m	Measurement distance (m)
0.009-0.490	2400/F(kHz)	300
0.490 - 1.705	24000/F(kHz)	30
1.705 - 30	30	30

The emission limits shown in the above table are based on measurements employing a CISPR quasi-peak detector except for the frequency bands 9–90 kHz, 110–490 kHz and above 1000 MHz. Radiated emission limits in these three bands are based on measurements employing an average detector, with consideration to DA 09-2425 FCC Waiver granted to EnteroMedics. Relaxed fundamental limit is 36.02 dBμV/m, 63.3 μV/m at 30 meters. The implantable is tested in human simulator.

Test Data
See following page

Frequency (MHz)	Field strength dBμV/m – 1m	Field strength dBμV/m – 3m	Field strength dBμV/m– 10m	Field strength dBμV/m– 30m	Field strength μV/m– 30m	Limit w/waiver μV/m– 30m
6.78	104.2	79.1	55.8	32.5*	42.2	63.3
13.56		34.1	Noise floor	-12.5*	0.237	30

***extrapolated using 46.6 dB/decade falloff as indicated by the measurements**

FREQ	LEVEL (dBuV)	CABLE / ANT / PREAMP / ATTEN (dB)	FINAL (dBuV / m)	POL / HGT / AZ (m)(DEG)	DELTA1	DELTA2
4cm spacing						
Fundamental on						
1m						
6.78 MHz	93.29 Qp	0.3 / 10.68 / 0.0 / 0.0	104.27	V / 1.00 / 0	n/a	n/a
3m						
6.78 MHz	68.15 Qp	0.3 / 10.68 / 0.0 / 0.0	79.13	V / 1.00 / 0	n/a	n/a
13.561 MHz	22.89 Qp	0.5 / 10.75 / 0.0 / 0.0	34.14	V / 1.00 / 0	n/a	n/a
Fundamental off, noise floor						
6.78 MHz	15.97 Qp	0.3 / 10.68 / 0.0 / 0.0	26.95	V / 1.00 / 0	n/a	n/a
13.561 MHz	8.07 Qp	0.5 / 10.75 / 0.0 / 0.0	19.32	V / 1.00 / 0	n/a	n/a
Fundamental on						
10m						
6.78 MHz	44.77 Qp	0.3 / 10.68 / 0.0 / 0.0	55.75	V / 1.00 / 0	n/a	n/a
13.56 MHz	5.59 Qp	0.5 / 10.75 / 0.0 / 0.0	16.84	V / 1.00 / 0	n/a	n/a
noise floor						
No other significant emissions detected 9kHz – 30MHz						
30m extrapolation						
6.78 MHz fundamental;						
Field strength delta from 3m to 10m = 79.1 dBuV/m - 55.8 dBuV/m = 23.3 dB						
55.8 dBuV/m @ 10m - 23.3 dB = 32.5 dBuV/m @ 30m						
Limit per FCC DA 09-2425 = 36 dBuV/m @ 30m						
At 13.56 MHz harmonic;						
34.1 dBuV/m @ 3m - (2 x 23.3 dB) = -12.5 dBuV/m @ 30m						
Limit = 29.5 dBuV/m @ 30m						

Radiated emissions in the frequency range of 10 kHz to 30 MHz, including the fundamental transmit signal, are measured using a receiver capable of quasi-peak/average/peak measurements and a magnetic loop antenna. The transmitter and loop antenna are rotated through 3 orthogonal axes in order to determine the maximum emission levels. If the signal cannot be measured at the specified limit distance, measurements are recorded at multiple distances nearer to the device and the final level mathematically extrapolated. Measurements between 150 kHz and 30 MHz are made with a 9 kHz resolution bandwidth. Measurements between 9 kHz and 150 kHz are made with a 200 Hz resolution bandwidth.

Radiated Emissions 30 - 1000 MHz

FCC 15.209(c), FCC 15.209(f)

Test summary

The requirements are: ■ - MET ☐ - NOT MET

Testing was performed in accordance with the test procedure of ANSI C63.4 2009, clause 8.3.

Maximum spurious emission is 29.6 dBμV/m (30.2 μV/m) at 3 meters at 379.71 MHz.

Test location

Wild River Lab Large Test Site (Open Area Test Site)

Test distance

10 meters

Test Equipment

TUV ID	Model	Manufacturer	Description	Serial	Cal Due
WRLE03204	EM-6917B	Electro-Metrics	Biconicalog Periodic-6 dB	102	30-May-14
WRLE02683	85650A	Hewlett-Packard	Quasi-Peak Adapter	2811A01127	22 Apr 14
WRLE02689	8566B	Hewlett-Packard	Spectrum Analyzer	2416A00321	22 Apr 14
WRLE03295	85662A	Hewlett-Packard	Analyzer Display	2152A03687	22 Apr 14
WRLE02670	8447D	Hewlett-Packard	Preamplifier	2443A03954	Code B 11 Jan 14
WRLE10863	N/A	TÜV SÜD America Inc	Test Companion Software Version 3.4.71	N/A	Code Y

Code B = Calibration verification performed internally. Code Y = Calibration not required when used with other calibrated equipment

Limit

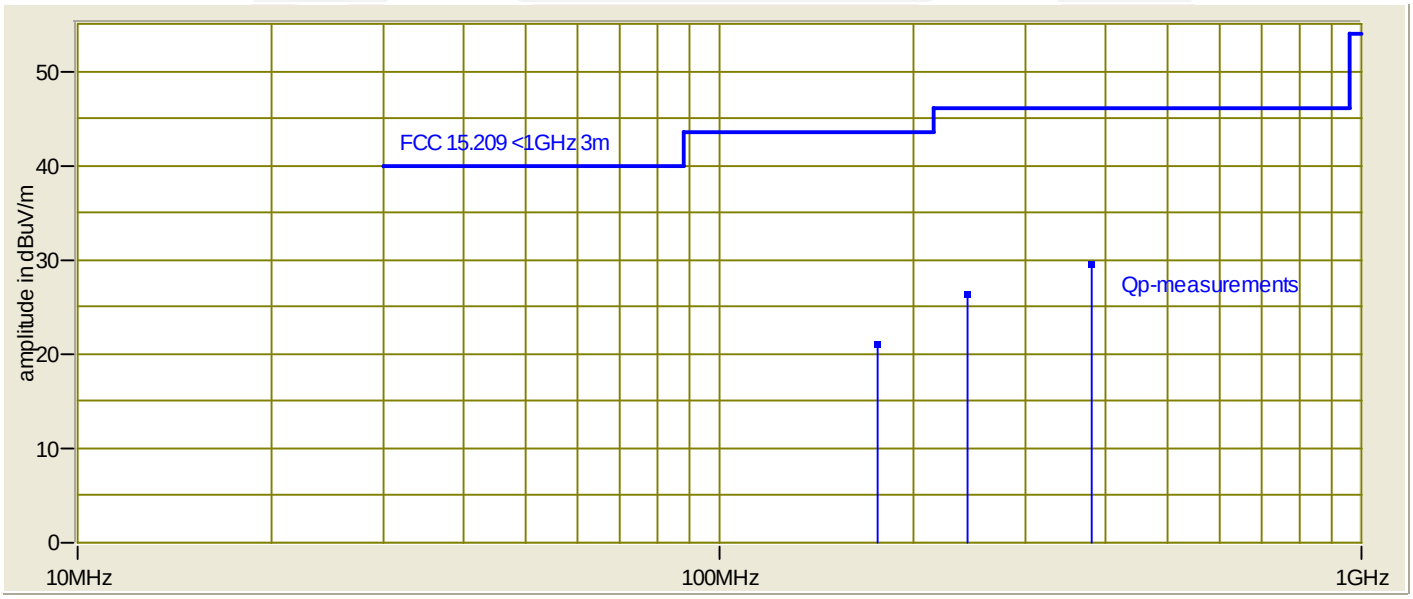
Frequency (MHz)	Field strength (μV/m)	Measurement distance (m)
30 - 88	100	3
88 - 216	150	3
216 - 960	200	3
Above 960	500	3

The emission limits shown in the above tables are based on measurements employing a CISPR quasi-peak detector except for the frequency bands 9–90 kHz, 110–490 kHz and above 1000 MHz. Radiated emission limits in these three bands are based on measurements employing an average detector. When average radiated emission measurements are specified in this part, including average emission measurements below 1000 MHz, there also is a limit on the peak level of the radio frequency emissions. Unless otherwise specified, *e.g.*, see §§ 15.250, 15.252, 15.255, and 15.509–15.519, the limit on peak radio frequency emissions is 20 dB above the maximum permitted average emission limit applicable to the equipment under test. Radiated emissions from the EUT are measured in the frequency range of 30 to 1000 MHz using a spectrum analyzer and appropriate broadband linearly polarized antennas. Measurements between 30 MHz and 1000 MHz are made with a 120 kHz / 6 dB bandwidth and quasi-peak detection and measurements above 1000 MHz are made with a 1 MHz RBW/VBW / 6 dB bandwidth and peak detection, 1 MHz RBW/ 10 Hz VBW for average detection. Table top equipment is placed on a non-conductive support 80 cm above the ground plane. Interface cables that are closer than 40 centimeters to the ground plane are bundled in the center in a serpentine fashion so they are at least 40 centimeters from the ground plane. Cables to simulators/testers (if used in this test) are routed through the center of the table and to a screen room located outside the test area. The antenna is positioned 3, 10 or 30 meters horizontally from the EUT. To locate maximum emissions from the test sample the antenna is varied in height from 1 to 4 meters, measurement scans are made with both horizontal and vertical antenna polarizations and the EUT is rotated 360 degrees. When performing measurements at a distance other than that specified, the results shall be extrapolated to the specified distance using an extrapolation factor of 20 dB / decade (inverse linear-distance for field strength measurements).

Test data

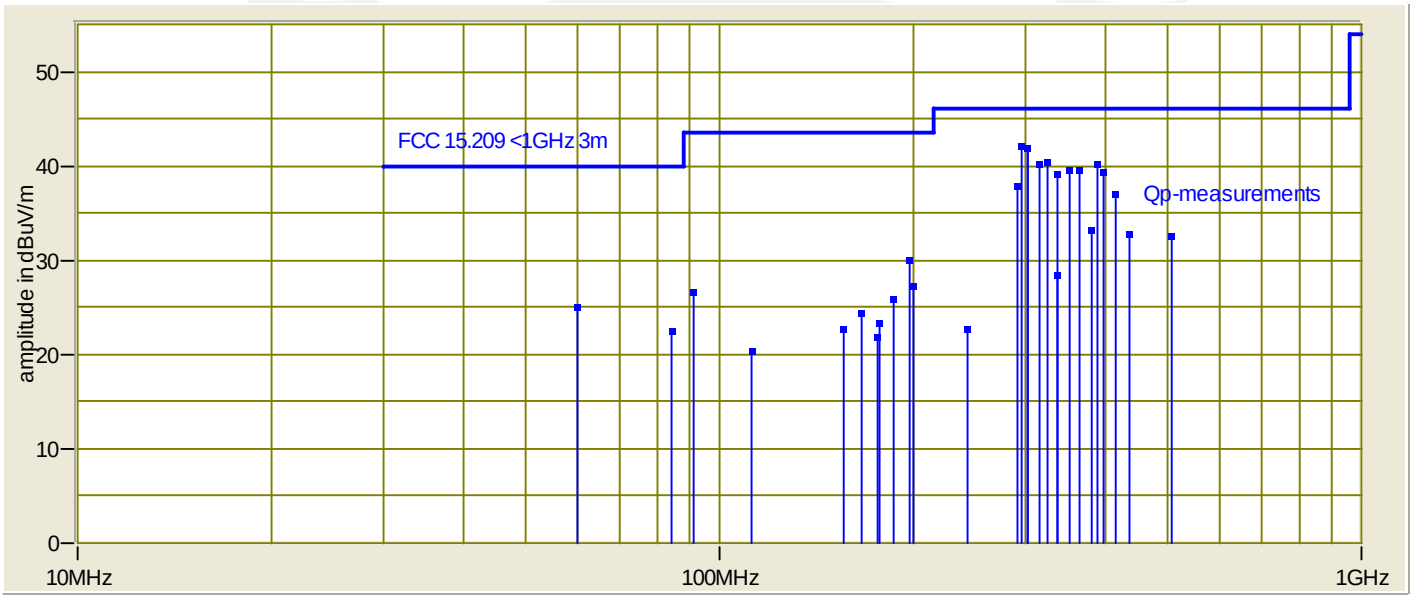
See next page.

FREQ	LEVEL (dBuV)	CABLE / ANT / PREAMP / ATTEN (dB)	FINAL (dBuV / m)	POL / HGT / AZ (m)(DEG)	DELTA1 FCC 15.209 <1GHz 3m	DELTA2
No PC						
176.3 MHz	32.1 Qp	1.19 / 15.11 / 27.42 / 0.0	20.98	V / 1.00 / 270	-22.52	n/a
244.1 MHz	31.5 Qp	1.44 / 17.28 / 27.27 / 0.0	22.96	H / 1.00 / 270	-23.04	n/a
379.71 MHz	27.64 Qp	1.83 / 21.31 / 27.29 / 0.0	23.49	H / 1.00 / 270	-22.51	n/a
379.71 MHz	31.65 Qp	1.83 / 21.31 / 27.29 / 0.0	27.5	H / 1.80 / 0	-18.5	n/a
244.1 MHz	34.9 Qp	1.44 / 17.28 / 27.27 / 0.0	26.36	H / 1.80 / 90	-19.64	n/a
379.71 MHz	33.15 Qp	1.83 / 21.31 / 27.29 / 0.0	29.0	H / 1.80 / 180	-17.0	n/a
maximized						
379.71 MHz	33.75 Qp	1.83 / 21.31 / 27.29 / 0.0	29.6	H / 3.11 / 91	-16.4	n/a
End scan 30 - 1000 MHz						



With PC

FREQ	LEVEL (dBuV)	CABLE / ANT / PREAMP / ATTEN (dB)	FINAL (dBuV / m)	POL / HGT / AZ (m)(DEG)	DELTA1 FCC 15.209 <1GHz 3m
296.122 MHz	48.53 Qp	1.59 / 19.23 / 27.29 / 0.0	42.06	H / 1.20 / 227	-3.94
301.09 MHz	48.2 Qp	1.6 / 19.35 / 27.28 / 0.0	41.88	H / 1.20 / 227	-4.12
302.088 MHz	48.15 Qp	1.61 / 19.38 / 27.28 / 0.0	41.86	H / 1.20 / 227	-4.14
323.947 MHz	46.0 Qp	1.67 / 19.92 / 27.23 / 0.0	40.37	H / 1.20 / 227	-5.63
314.004 MHz	46.05 Qp	1.64 / 19.68 / 27.25 / 0.0	40.12	H / 1.20 / 227	-5.88
388.543 MHz	44.25 Qp	1.86 / 21.24 / 27.28 / 0.0	40.07	H / 1.20 / 227	-5.93
362.695 MHz	44.05 Qp	1.78 / 20.95 / 27.26 / 0.0	39.52	H / 1.20 / 227	-6.48
350.767 MHz	44.25 Qp	1.75 / 20.64 / 27.23 / 0.0	39.41	H / 1.20 / 227	-6.59
397.483 MHz	43.05 Qp	1.88 / 21.6 / 27.25 / 0.0	39.28	H / 1.20 / 227	-6.72
335.869 MHz	44.4 Qp	1.71 / 20.24 / 27.2 / 0.0	39.15	H / 1.20 / 227	-6.85
291.161 MHz	44.6 Qp	1.58 / 19.01 / 27.29 / 0.0	37.89	H / 1.20 / 227	-8.11
414.367 MHz	40.2 Qp	1.93 / 22.0 / 27.21 / 0.0	36.93	H / 1.20 / 227	-9.07
379.71 MHz	37.35 Qp	1.83 / 21.31 / 27.29 / 0.0	33.2	H / 1.00 / 270	-12.8
435.247 MHz	35.9 Qp	1.99 / 22.01 / 27.28 / 0.0	32.62	H / 1.20 / 227	-13.38
504.805 MHz	34.35 Qp	2.2 / 23.31 / 27.29 / 0.0	32.56	H / 1.00 / 270	-13.44
198.328 MHz	39.5 Qp	1.31 / 16.47 / 27.37 / 0.0	29.91	H / 1.80 / 270	-13.59
60.012 MHz	35.3 Qp	0.57 / 16.95 / 27.67 / 0.0	25.14	V / 1.00 / 180	-14.86
200.734 MHz	36.9 Qp	1.31 / 16.41 / 27.36 / 0.0	27.27	H / 1.80 / 270	-16.23
90.8 MHz	39.75 Qp	0.73 / 13.77 / 27.6 / 0.0	26.65	V / 1.00 / 270	-16.85
186.322 MHz	35.9 Qp	1.25 / 16.22 / 27.39 / 0.0	25.98	V / 1.00 / 270	-17.52
84.469 MHz	36.44 Qp	0.7 / 12.94 / 27.62 / 0.0	22.46	V / 1.00 / 0	-17.54
336.006 MHz	33.7 Qp	1.71 / 20.25 / 27.2 / 0.0	28.45	H / 1.00 / 180	-17.55
166.0 MHz	36.25 Qp	1.14 / 14.56 / 27.44 / 0.0	24.51	V / 1.00 / 0	-18.99
176.884 MHz	34.5 Qp	1.2 / 15.14 / 27.41 / 0.0	23.42	H / 1.80 / 270	-20.08
156.004 MHz	34.45 Qp	1.08 / 14.6 / 27.46 / 0.0	22.67	V / 1.00 / 0	-20.83
176.3 MHz	33.05 Qp	1.19 / 15.11 / 27.42 / 0.0	21.93	H / 1.80 / 270	-21.57
112.291 MHz	31.8 Qp	0.85 / 15.27 / 27.56 / 0.0	20.36	V / 1.00 / 270	-23.14
244.112 MHz	31.35 Qp	1.44 / 17.28 / 27.27 / 0.0	22.81	H / 1.00 / 270	-23.19



Equipment Under Test (EUT) Test Operation Mode:

The device under test was operated under the following conditions during immunity testing :

☐ - Standby

☐ - Test program (H - Pattern)

☐ - Test program (color bar)

☐ - Test program (customer specific)

☐ - Practice operation

■ - Normal operating mode

Configuration of the device under test:

■ - See Appendix A and test setup photos

☐ - See Product Information Form(s) in Appendix B

DEVIATIONS FROM STANDARD:
None.

GENERAL REMARKS:
None

Modifications required to pass:
■ None
☐ As indicated on the data sheet(s)

Test Specification Deviations: Additions to or Exclusions from:
■ None
☐ As indicated in the Test Plan

SUMMARY:
The requirements according to the technical regulations are
■ - met and the device under test does fulfill the general approval requirements.
☐ - **not** met and the device under test does **not** fulfill the general approval requirements..

EUT Received Date: 04 October 2013
Condition of EUT: Normal
Testing Start Date: 04 October 2013
Testing End Date: 04 October 2013

TÜV SÜD AMERICA INC

Tested by:
Greg Jakubowski
Senior EMC Technician

Approved by:
Joel T Schneider
Senior EMC Engineer

Appendix A

Constructional Data Form

Form

EMC Test Plan and Constructional Data Form

PLEASE COMPLETE THIS DOCUMENT IN FULL, ENTERING N/A IF THE FIELD IS NOT APPLICABLE. IF TESTING RESULTS IN MODIFICATIONS TO THE EQUIPMENT, PLEASE SUBMIT A REVISED TP/CDF INDICATING THOSE MODIFICATIONS.
NOTE: This information will be input into your test report as shown below. Press the F1 key at any time to get HELP for the current field selected.

Company:	EnteroMedics Inc		
Address:	2800 Patton Road		
	St. Paul, MN 55113		
	USA		
Contact:	Scott Lambert	Position:	Engineering Director
Phone:	651-270-4487	Fax:	651-634-3212
E-mail Address:	slambert@entermedics.com		

General Equipment Description -- ***NOTE: This information will be input into your test report as shown below.***

EUT Description	Implantable pulse generator with leads for delivering blocking signals to vagus nerve		
EUT Name	Maestro Rechargeable System		
Model No.:	2002 2402 2403-60 2200A-47E 2200P-47E 2502 1600	Serial No.:	003007 D05010 10596 021316 021314 CP502Z Lot 11672-1638
Product Options:			
Configurations to be tested:	Low Power / Normal		

Equipment Modification (*If applicable, indicate modifications since EUT was last tested. If modifications are made during this testing, submit revised TP/CDF after testing is complete.)*

Modifications since last test:	Not Applicable
Modifications made during test:	Not Applicable

Test Objective(s): ***Please indicate the tests to be performed, entering the applicable standard(s) where noted.***

- ☐ EMC Directive 2004/108/EC (EMC)
  Std: FCC Part 15 Subpart C Section 15.209
- ☐ Machinery Directive 89/392/EEC (EMC)
  Std:
- ☐ Medical Device Directive 93/42/EEC (EMC)
  Std:
- ☐ Vehicle Directive - 2004/104/EC (EMC)
  ☐ Other Vehicle Std:
- ☐ FDA Reviewers Guidance for Premarket Notification Submissions (EMC)
- ☒ FCC: Class ☐ A ☐ B Part 15
- ☐ VCCI: Class ☐ A ☐ B
- ☐ BSMI: Class ☐ A ☐ B (Separate Report)
- ☐ Canada: Class ☐ A ☐ B
- ☐ Australia: Class ☐ A ☐ B
- ☐ Other:
- ☐ Ag Directive *2009/64/EC (EMC)

Form

EMC Test Plan and Constructional Data Form

Third Party Certification (contact TÜV for quote), if applicable (*Signature on last page required).	
☐ Attestation of Compliance (AoC)*	☐ EMC Certification (used with Octagon Mark)*
☐ Statement of Compliance (SoC, previously CoC)* - All aspects of the essential requirements were assessed	
Protection Class (Req'd for AoC, SoC, EMC Cert. N/A for vehicles) ☐ Class I ☐ Class II ☐ Class III (Press **F1** when field is selected to show additional information on Protection Class.)	
☒ FCC / TCB Certification	☐ Taiwan Certification
☐ Industry Canada / FCB Certification	☐ Korean Certification
☐ e-Mark Certification	

Attendance

Test will be: ☒ Attended by the customer ☐ Unattended by the customer

Failure - *Complete this section if testing will not be attended by the customer.*

If a failure occurs, TÜV SÜD America should:

☐ Call contact listed above, if not available then stop testing. (After hrs phone): _____

☐ Continue testing to complete test series.

☐ Continue testing to define corrective action.

☐ Stop testing.

EUT Specifications and Requirements

Length: Multiple Devices Under Test Width: _____ Height: _____ Weight: _____

Power Requirements

Regulations require testing to be performed at typical power ratings in the countries of intended use. (i.e., European power is typically 230 VAC 50 Hz or 400 VAC 50 Hz, single and three phase, respectively)

Voltage: 4.0 VDC (MC and RNR battery) (If battery powered, make sure battery life is sufficient to complete testing.)

# of Phases: NA

Current (Amps/phase(max)): 1000 mA maximum current

Current (Amps/phase(nominal)): 200 mA nominal current

Other _____

Other Special Requirements

Typical Installation and/or Operating Environment

(ie. Hospital, Small Business, Industrial/Factory, etc.)
Home and hospital

Form

EMC Test Plan and Constructional Data Form

EUT Power Cable

☐ Permanent OR ☐ Removable Length (in meters): _____
☐ Shielded OR ☐ Unshielded
☒ Not Applicable

EUT Interface Ports and Cables

Type	Analog	Digital	During Test: Active	During Test: Passive	Qty	Shielding: Yes	Shielding: No	Shielding: Type	Termination	Connector Type	Port Termination	Length tested (in meters)	Removable	Permanent
EXAMPLE:										*Metallized 9-pin D-Sub*	*Characteristic Impedance*			
RS232	☐	☒	☒	☐	*2*	☒	☐	*Foil over braid*	*Coaxial*			*6*	☒	☐
Two bipolar leads with IS1 type connectors	☒	☐	☐	☒	2	☐	☒	7 x 7 filar	Dual side by side	3.2 mm pin and sleeve	15 ohms	0.5m	☒	☐
Transmit Coil Cable	☒	☐	☒	☐	1	☒	☐	braid	Coaxial	Lemo RF connector	50 ohms	0.6m	☒	☐
Programmer Cable	☐	☒	☒	☐	1	☒	☐	4 conductor microphone cable	USB on one end, ttl on the other	USB/ODU 5 pin		1m	☒	☐
Mobile Charger (MC)	☒	☐	☒	☐	1	☐	☒	#26 zip cord	Coaxial	Lemo miniature RF connector			☐	☐
Laptop power supply cable assy	☒	☐	☒	☐	1	☐	☒		Coaxial	Custom	NA		☐	☐
	☐	☐	☐	☐		☐	☐						☐	☐
	☐	☐	☐	☐		☐	☐						☐	☐
	☐	☐	☐	☐		☐	☐						☐	☐
	☐	☐	☐	☐		☐	☐						☐	☐
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	☐	☐	☐	☐		☐	☐						☐	☐

Form

EMC Test Plan and Constructional Data Form

EUT Interface Ports and Cables

Type	Analog	Digital	During Test: Active	During Test: Passive	Qty	Shielding: Yes	Shielding: No	Shielding: Type	Termination	Connector Type	Port Termination	Length tested (in meters)	Removable	Permanent
	☐	☐	☐	☐		☐	☐						☐	☐

EUT Software.

Revision Level: RNR Model 2002 Rev 2.19 MC Model 2402 Rev MC2A v F5.07 for Emissions Test

Description: MC firmware modified to send continuous telemetry test downlinks to the implant on command. SerialTool script MCTelemEmissions via the CP and programming cable will control the downlink command and monitor communication. Note the fw file is named F5.07 but when queried the MC will state the fw to be 245.0.7.

Equipment Under Test (EUT) Operating Modes to be Tested -- list the operating modes to be used during test. It is recommended the equipment be tested while operating in a typical operation mode. FCC testing of personal computers and/or peripherals requires that a simple program generate a complete line of upper case H's. Provide a general description of all software, firmware, and PLD algorithms used in the equipment. List all code modules as described above, with the revision level used during testing. Consult with your TÜV Product Service Representative if additional assistance is required.

1. FCC Part 15 Subpart C Section 15.209 -A special PC program is used to setup continous low power communications between the CP, MC and RNR. The RNR is linked to the MC via the transmit coil and the MC is linked to the CP via the programmer cable. The RNR and leads shall be placed in a 1.9ppt saline solution. The RNR shall be spaced 4cm from the transmiit coil. The entire frequency range shall be performed with this configuration.
2. An additional test shalll be performed as above but without the CP and programmer cable, for the frequency range of 30 - 1000MHZ
3.

Form

EMC Test Plan and Constructional Data Form

Equipment Under Test (EUT) System Components -- List and describe all components which are part of the EUT. For FCC & Taiwan testing a minimum configuration is required. (ie. Mouse, Printer, Monitor, External Disk Drive, Motherboard, etc)

Description	Model #	Serial #	FCC ID #
Neuroregulator	2002	003007	None
Transmit Coil	2403-60	10596	None
Anterior Lead	2200A-47E	021316	None
Posterior Lead	2200P-47E	021314	None
Mobile Charger	2402	D05010	None

Support Equipment -- List and describe all support equipment which is not part of the EUT. (i.e. peripherals, simulators, etc) This information is required for FCC & Taiwan testing.

Description	*Model #*	*Serial #*	*FCC ID #*
Programmer Cable	1600		None
AC Recharger	452240-01062	Prototype#1	None
Clinician Programmer	2502/ Dell E5420 Latitude PC	CP502Z	None
CP Power Supply	DA65NM111-00	CN-0N6M8J-48661-25H-GG03-A02	None

Oscillator Frequencies

Manufacturer	*Frequency*	*Derived Frequency*	*Component # / Location*	*Description of Use*
6.78 MHz				Inductive coupling between transmit coil and neuroregulator

Form

EMC Test Plan and Constructional Data Form

Power Supply			
Manufacturer	***Model #***	***Serial #***	***Type***
Dell	DA65NM111-00	CN-0N6M8J-48661-25H-GG03-A02	☒ Switched-mode: (Frequency) ☐ Linear ☐ Other:
			☐ Switched-mode: (Frequency) ☐ Linear ☐ Other:

Power Line Filters		
Manufacturer	***Model #***	***Location in EUT***

Critical EMI Components (Capacitors, ferrites, etc.)				
Description	***Manufacturer***	***Part # or Value***	***Qty***	***Component # / Location***

EMC Critical Detail -- Describe other EMC Design details used to reduce high frequency noise.

PLEASE ENTER NAMES BELOW (INSERT ELECTRONIC SIGNATURE IF POSSIBLE)

Authorization (Signature Required if a Third Party Certification is checked on pg 1)

Customer authorization to perform tests according to this test plan. — Date

Test Plan/CDF Prepared By (please print) — Date