

TEST REPORT

FCC Part 15 Subpart C Section 15.209 IC RSS-210 Issue 8 Amendment 1 IC RSS-Gen Issue 4

MANUFACTURER	Inspire Medical Systems, Inc. 9700 63rd Ave. North – Suite 200 Maple Grove MN 55369 USA
PRODUCT NAME	Inspire Sleep Remote
MODEL NUMBER	2500
SERIAL NUMBER TESTED	SLP002008N
DESCRIPTION	Patient Programmer for Implantable Pulse Generator with 175 kHz Transmitter
TEST REPORT NUMBER	NC72109305.1
TEST DATE(S)	02 October 2015

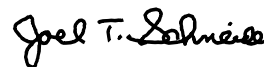
TÜV SÜD America Inc, as an independent testing laboratory, declares that the equipment tested as specified above conforms to the applicable EMC requirements of FCC Part 15 Subpart C Section 15.209 "Radiated emission limits; general requirements" and Industry Canada RSS-210 Issue 8 with Amendment 1 "Licence-exempt Radio Apparatus (All Frequency Bands): Category I Equipment" and Industry Canada RSS-Gen Issue 4 "General Requirements and Information for the Certification of Radio Apparatus".

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: 09 October 2015



Greg S Jakubowski
EMC Test Engineer



Joel T Schneider
Senior EMC Engineer

Not Transferable

EMC TEST REPORT

Test Report No. NC72109305.1 Date of issue: 09 October 2015

Product Name Inspire Sleep Remote

Model 2500

Serial number tested SLP002008N

Description Patient Programmer for Implantable Pulse Generator. 175 kHz transmitter

Test Date 02 October 2015

Manufacturer Inspire Medical Systems, Inc.
9700 63rd Ave. North – Suite 200
Maple Grove MN 55369 USA

Issuing Laboratory TÜV SÜD America Inc
1775 Old Highway 8 NW, Suite 104
New Brighton MN 55112-1891 USA
Phone: 651 631 2487 / Fax: 651 638 0285

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 New Brighton and Taylors Falls Labs maintain 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	09 October 2015	Initial Release



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EMC TEST REGULATIONS:

The tests were performed according to the following regulations:

FCC Part 15 Subpart C §15.209
IC RSS-210 Issue 8 Amendment 1
IC RSS-Gen Issue 4

LAB ACCREDITATION:

TÜV SÜD America's New Brighton and Taylors Falls Labs maintain A2LA accreditation to ISO/IEC 17025 for the specific tests listed in A2LA Certificate #2955.11 as Electrical Testing Laboratories located at the following addresses:

Physical Location: 1775 Old Highway 8 NW, Suite 104
New Brighton MN 55112-1891 USA
Satellite Location 19333 Wild Mountain Road
Taylors Falls MN 55084 USA

ENVIRONMENTAL CONDITIONS IN THE LAB

	<u>Actual</u>
Temperature:	: 23°C
Atmospheric pressure	: 100kPa
Relative Humidity	: 54-61%

POWER SUPPLY UTILIZED

Power supply system :3.0 VDC

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. 175kHz fundamental transmit signal

FCC 15.209(a), FCC 15.209(c), IC RSS-210 2.5, RSS-Gen 7.2.5

Test summary

The requirements are: ■ - MET □ - NOT MET

Testing was performed in accordance with the test procedure of ANSI C63.10: 2013

Test location

TÜV SÜD America Inc, Taylors Falls, Large Test Site (Open Area Test Site)

Test distances

- - 1 meters
- - 3 meters
- - 10 meters

Test equipment

TUV ID	Model	Manufacturer	Description	Serial	Cal Date	Cal Due
WRLE02418	6502	Electro-Mechanics (EMCO)	Loop Antenna	2215	03-Sep-15	03-Sep-16
WRLE02534	ESHS-20	Rohde & Schwarz	EMI Receiver 9kHz-30MHz	837055/003	26-Aug-15	26-Aug-16

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

Test limit

13.7µV/m or 22.7dBµV/m at 300m average

137µV/m or 42.7dBµV/m at 300m peak

Test Data

DUT rotated through 360 degrees in 3 orthogonal axes
Highest fundamental field strength with DUT standing upright, bottom side parallel with loop antenna

FREQ	LEVEL (dBuV)	CABLE / ANT / PREAMP / ATTN (dB)	FINAL (dBuV / m)
1 meter distance			
175.0 kHz	113.3 Pk	0.0 / 12.38 / 0.0 / 0.0	125.68
175.0 kHz	99.2 Av	0.0 / 12.38 / 0.0 / 0.0	111.58
3m			
175.0 kHz	87.32 Pk	0.0 / 12.38 / 0.0 / 0.0	99.7
175.0 kHz	73.75 Av	0.0 / 12.38 / 0.0 / 0.0	86.13
10m			
175.0 kHz	60.03 Pk	0.0 / 12.38 / 0.0 / 0.0	72.41
175.0 kHz	47.05 Av	0.0 / 12.38 / 0.0 / 0.0	59.43

Frequency (MHz)	Detector	Distance 1 m dBµV/m	Distance 3 m dBµV/m	Distance 10 m dBµV/m	Distance 300 m dBµV/m	Distance 300 m µV/m	Limit dBµV/m 300 m	Limit µV/m 300 m
0.175	AV	111.58	86.13	59.43	-0.57*	0.936*	22.7	13.7
0.175	PK	125.68	99.7	72.41	12.41*	4.17*	42.7	137

* Extrapolated value using 40 dB per decade fall off as indicated by measurements

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.

General field strength limits 0.009 – 30 MHz. Spurious emissions

FCC 15.209(a), FCC 15.209(c), IC RSS-210 2.5, RSS-Gen 7.2.5

Test summary

The requirements are: ■ - MET □ - NOT MET

Testing was performed in accordance with the test procedure of ANSI C63.10: 2013

No unwanted emissions exceed the level of the fundamental.

Test location

TÜV SÜD America Inc, Taylors Falls, Large Test Site (Open Area Test Site)

Test distances

- - 1 meters
- - 3 meters
- - 10 meters

Test equipment

TUV ID	Model	Manufacturer	Description	Serial	Cal Date	Cal Due
WRLE02418	6502	Electro-Mechanics (EMCO)	Loop Antenna	2215	03-Sep-15	03-Sep-16
WRLE02534	ESHS-20	Rohde & Schwarz	EMI Receiver 9kHz-30MHz	837055/003	26-Aug-15	26-Aug-16

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

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. The provisions in §§15.31, 15.33, and 15.35 for measuring emissions at distances other than the distances specified in the above table, determining the frequency range over which radiated emissions are to be measured, and limiting peak emissions apply to all devices operated under this part.

Test Data

(see following page)

Quasi-Peak detector

Frequency (kHz)	Field strength (dB μ V/m@1m)	Field strength (dB μ V/m@3m)	Field strength (dB μ V/m@10m)	Field strength (dB μ V/m@30m)	Field strength (μ V/m@30m)	Limit (μ V/m@30m)	Result (pass/fail)
525	86.96	61.19	NF	21.19*	11.468*	45.714	Pass
875	80.83	55.23	NF	15.23*	5.774*	27.429	Pass
1225	66.25	41.95	NF	1.95*	1.252*	19.592	Pass
1575	62.49	38.22	NF	-1.78*	0.815*	15.238	Pass
1925	55.83	NF	---	-4.17*	0.619*	30.000	Pass
2275	60.2	35.5	NF	-4.50*	0.596*	30.000	Pass
2625	56.57	NF	---	-3.43*	0.674*	30.000	Pass
2975	48.21	NF	---	-11.79*	0.257*	30.000	Pass
3325	50.87	NF	---	-9.13*	0.350*	30.000	Pass
3675	43.27	NF	---	-16.73*	0.146*	30.000	Pass

NF Noise floor

* Extrapolated using 40 dB/decade falloff.

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.

General field strength limits above 30 MHz

FCC 15.209(c), FCC 15.209(f), IC RSS-210 2.5, RSS-Gen 7.2.5

Test summary

The requirements are: ■ - MET □ - NOT MET

Testing was performed in accordance with the test procedure of ANSI C63.10: 2013.

Test location

TÜV SÜD America Inc, Taylors Falls, Large Test Site (Open Area Test Site)

Test distance

3 meters

Test Equipment

TUV ID	Model	Manufacturer	Description	Serial	Cal Date	Cal Due
OWLE03202	EM-6917B	Electro-Metrics	Biconicallog Periodic	101	16-Oct-14	16-Oct-15
WRLE10897	ZHL-1042J	Mini-Circuits	Amplifier Broadband AMP/ SMA QA1148002	NA	Code B 06-Feb-15	Code B 06-Feb-16
WRLE03294	8566B	Hewlett-Packard	Spectrum Analyzer	2349A03098	15 Sep 15	15 Sep 16
WRLE02680	85650A	Hewlett-Packard	Quasi-Peak Adapter	2043A00343	15 Sep 15	15 Sep 16
WRLE02673	85662A	Hewlett-Packard	Analyzer Display	2152A03687	15 Sep 15	15 Sep 16
WRLE10863	N/A	TÜV SÜD America Inc	Test Companion Software Version 3.4.71	N/A	Code Y	Code Y

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

Test limit

Frequency (MHz)	Field strength (μ V/m)	Field strength (dB μ V/m)	Measurement distance (m)
30 - 88	100	40	3
88 - 216	150	43.5	3
216 - 960	200	46	3
Above 960	500	54	3

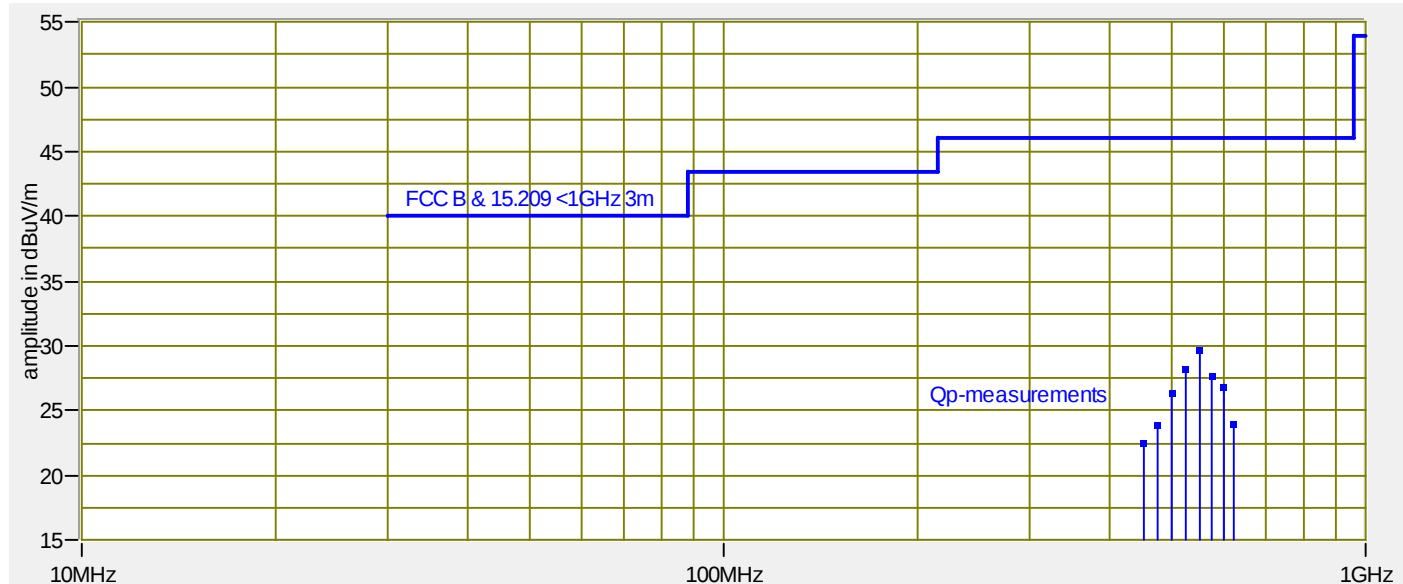
The emission limits shown in the above tables are based on measurements employing a CISPR quasi-peak detector except for the frequency bands 9–90 kHz, 110–490 kHz and above 1000 MHz. Radiated emission limits in these three bands are based on measurements employing an average detector. When average radiated 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.

Test Data

(see following page)

Measurement summary for limit1: FCC B & 15.209 <1GHz 3m (Qp)

FREQ	LEVEL (dBuV)	CABLE / ANT / PREAMP / ATTEN (dB)	FINAL (dBuV / m)	POL / HGT / AZ (m)(DEG)	DELTA1 FCC B & 15.209 <1GHz 3m
550.0 MHz	33.17 Qp	2.66 / 24.1 / 30.17 / 0.0	29.76	V / 1.00 / 325	-16.24
525.0 MHz	32.18 Qp	2.58 / 23.5 / 30.18 / 0.0	28.08	V / 1.00 / 325	-17.92
575.0 MHz	30.81 Qp	2.74 / 24.25 / 30.11 / 0.0	27.69	V / 1.00 / 325	-18.31
600.0 MHz	29.57 Qp	2.82 / 24.54 / 30.19 / 0.0	26.74	V / 1.00 / 325	-19.26
500.0 MHz	30.98 Qp	2.5 / 23.0 / 30.16 / 0.0	26.32	V / 1.00 / 325	-19.68
625.0 MHz	26.04 Qp	2.9 / 25.26 / 30.27 / 0.0	23.92	V / 1.00 / 325	-22.08
475.0 MHz	29.06 Qp	2.42 / 22.54 / 30.13 / 0.0	23.88	V / 1.00 / 325	-22.12
450.0 MHz	28.06 Qp	2.34 / 22.08 / 30.11 / 0.0	22.37	V / 1.00 / 325	-23.63



Occupied bandwidth

RSS-Gen 4.6.1

Test summary

The requirements are: ■ - MET □ - NOT MET

Test was performed in accordance with the article "The Measurement of Occupied Bandwidth" by Industry Canada's certification bureau. Occupied bandwidth is 21.7649 kHz

Test location

TÜV SÜD America Inc, Taylors Falls, Large Test Site (Open Area Test Site)

Test equipment

TUV ID	Model Number	Manufacturer	Description	Serial Number	Cal Date	Cal Due
WRLE03371	E4440A	Agilent	Spectrum Analyzer	MY43362222	28-Oct-14	28-Oct-15

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

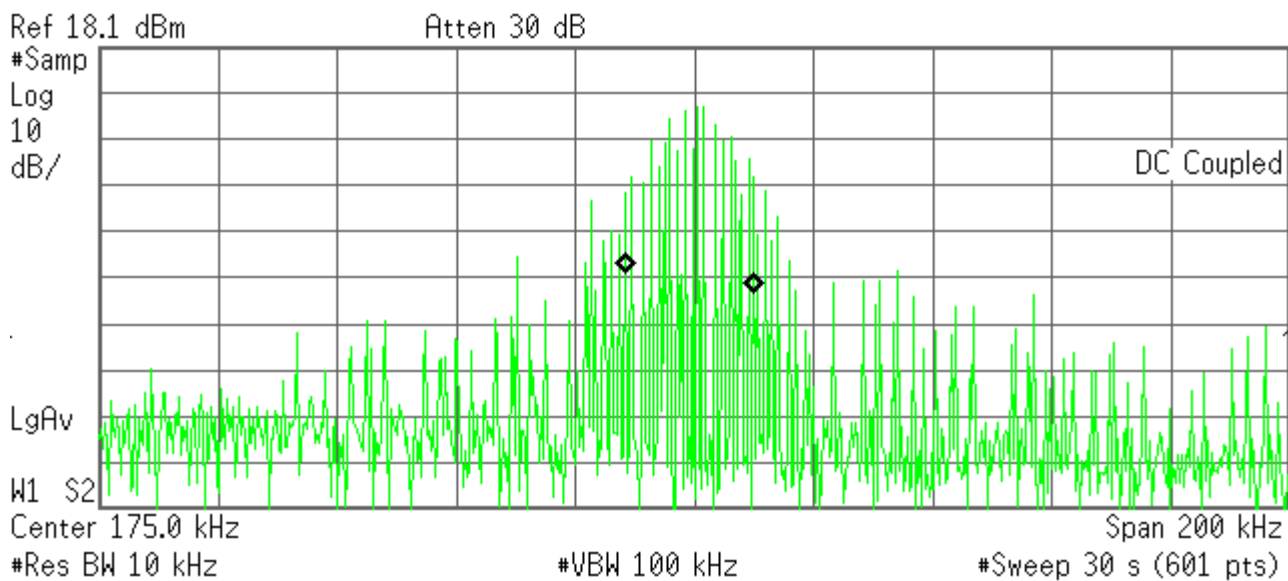
Test limit

Not specified

Test data

✱ Agilent 13:36:07 Oct 2, 2015

L



Occupied Bandwidth
21.7649 kHz

Occ BW % Pwr 99.00 %
x dB -26.00 dB

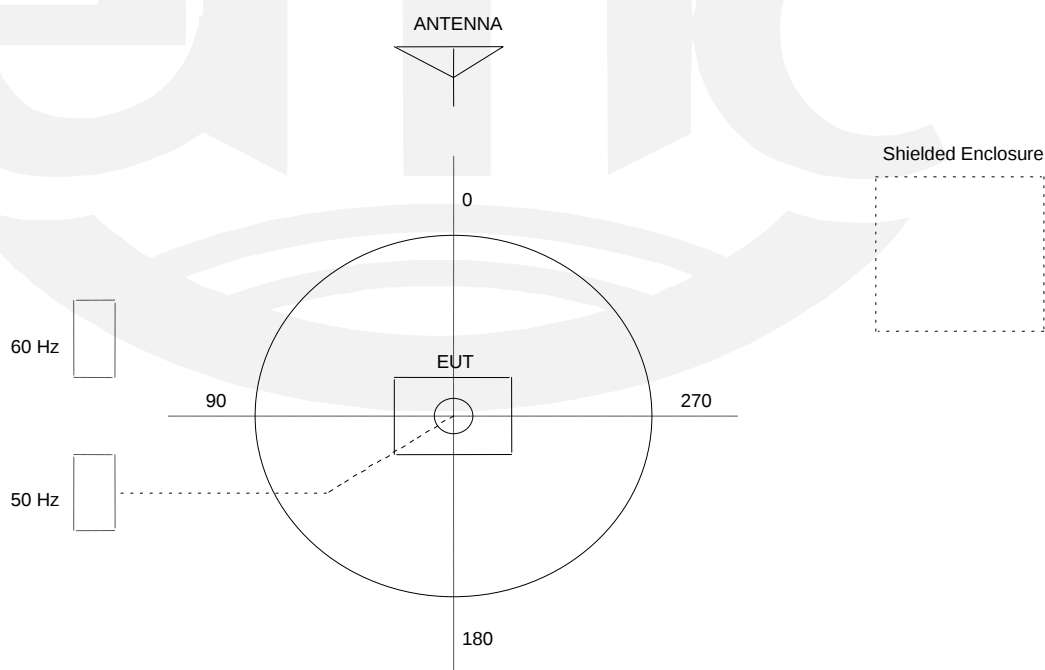
Transmit Freq Error -718.061 Hz
x dB Bandwidth 31.773 kHz*

TEST SETUP FOR EMISSIONS TESTING

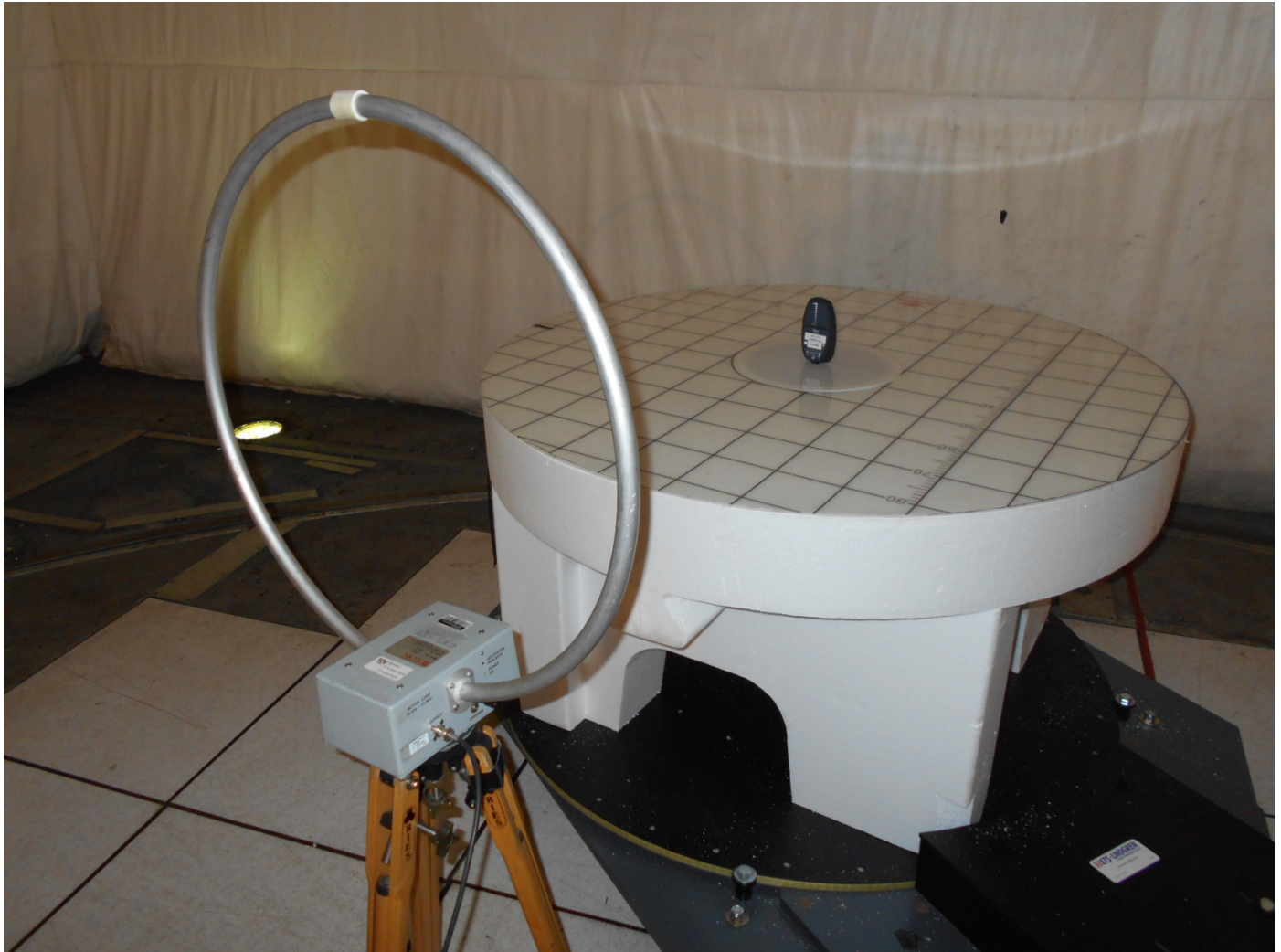
TÜV SÜD America Inc, Taylors Falls
Large Test Site

Notes:

1. Items shown in dotted lines are located on the floor below the test area. It is 5 meters vertically from the ground floor to the test area.
2. 50 Hz and 60 Hz are power panels for alternating current.
3. The antenna may be positioned horizontally 3 and 10 meters from the center of the turntable.
4. The circle is either a 6.7 meter or 1.2 meter diameter turntable.
5. A ground plane is in the plane of this sheet.
6. The test sample is shown in the azimuthal position representing zero degrees.



Test-setup photo(s):



Test-setup photo(s):



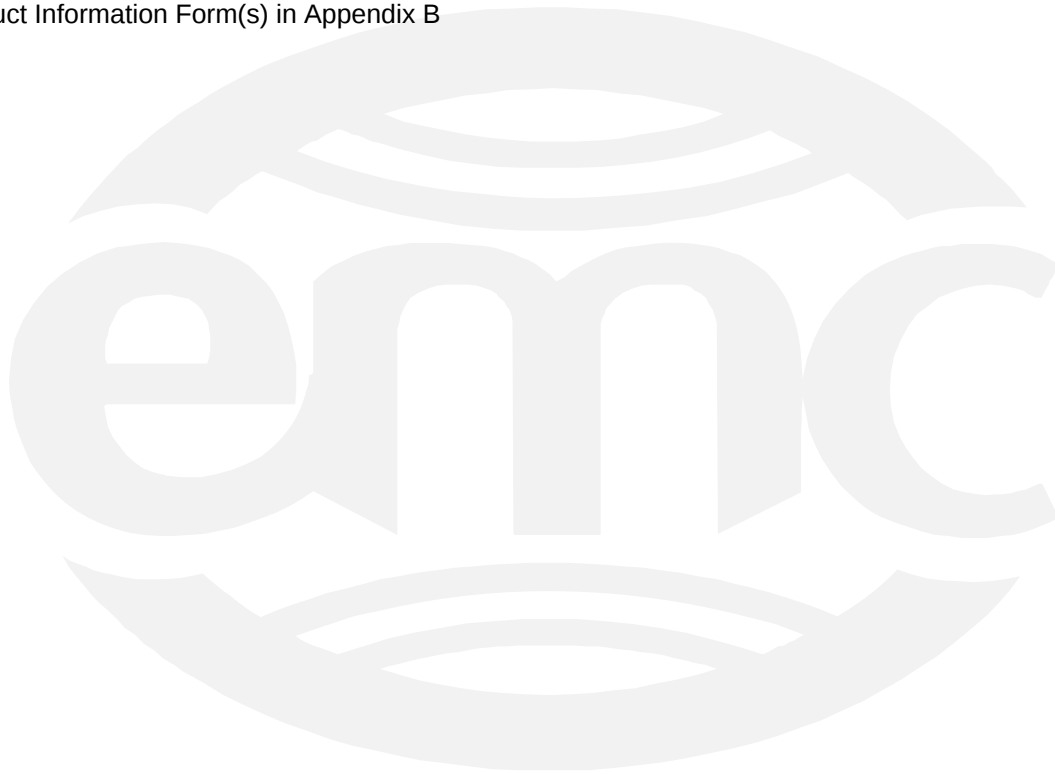
Equipment Under Test (EUT) Test Operation Mode:

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

- ☐ - Normal operating mode
- ☒ - Continuous transmit 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: 02 October 2015
Condition of EUT: Normal
Testing Start Date: 02 October 2015
Testing End Date: 02 October 2015

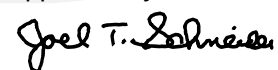
TÜV SÜD AMERICA INC

Tested by:



Greg S Jakubowski
EMC Test Engineer

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: Inspire Medical Systems, Inc.
 Address: 9700 63rd Ave. North
Suite 200
Maple Grove, MN 55369
 Contact: Dave Dieken Position: Principal Systems Engineer
 Phone: 612-242-6506 Fax: 763-537-4310
 E-mail Address: davedieken@inspiresleep.com

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

EUT Description Patient Programmer for Implantable Pulse Generator
 EUT Name Inspire Sleep Remote
 Model No.: 2500 Serial No.: SLP002005N, SLP002006N,
SLP002007N, SLP002008N,
SLP002009N
 Product Options: N/A
 Configurations to be tested: Normal firmware (installed on SLP002005N, SLP002007N,
SLP002008N)
Test mode firmware (installed on SLP002006N, SLP002009N)

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: N/A
 Modifications made during test: N/A

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

Form



EMC Test Plan and Constructional Data Form

EUT Interface Ports and Cables													
Type	Analog	Digital	During Test		Qty	Shielding		Termination	Connector Type	Port Termination	Length tested (in meters)	Removable	Permanent
			Active	Passive		Yes	No						
EXAMPLE:													
RS232	☐	☒	☒	☐	2	☒	☐	Foil over braid	Coaxial	Metallized 9-pin D-Sub	Characteristic Impedance	6	☒ ☐
Micro USB	☐	☒	☐	☒	1	☒	☐	Foil	USB	USB		1	☒ ☐
	☐	☐	☐	☐		☐	☐						☐ ☐
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Form



EMC Test Plan and Constructional Data Form

EUT Software.

Revision Level: 0.6.4 (Normal functionality), 0.1.1 (Test mode functionality)

Description:

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. Normal mode
2. Test modes: Continuous Operation Mode (for electrical safety testing), Continuous Telemetry Mode (for radiated immunity testing), Continuous Transmit Mode (for intentional radiator testing), Continuous Status Mode (for radiated emissions testing)
- 3.

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 #

Form



EMC Test Plan and Constructional Data Form

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 #
Inspire Implantable Pulse Generator	3024	NCR200726H, NCR200003H, NCR000040H	
Inspire Physician Programmer	2740	LAB009	

Oscillator Frequencies

Manufacturer	Frequency	Derived Frequency	Component # / Location	Description of Use
Abrakon	32.768kHz	48MHz	Y2/PCBA	Main oscillator for microprocessor and telemetry
Abrakon	32.768kHz	32.768kHz	Y3/PCBA	Real time clock

Power Supply

Manufacturer	Model #	Serial #	Type
N/A			☐ Switched-mode: (Frequency) _____ ☐ Linear ☐ Other: _____
			☐ Switched-mode: (Frequency) _____ ☐ Linear ☐ Other: _____

Power Line Filters

Manufacturer	Model #	Location in EUT
N/A		

Form



EMC Test Plan and Constructional Data Form

Critical EMI Components (Capacitors, ferrites, etc.)

<i>Description</i>	<i>Manufacturer</i>	<i>Part # or Value</i>	<i>Qty</i>	<i>Component # / Location</i>
N/A				

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

N/A

PLEASE ENTER NAMES BELOW (INSERT ELECTRONIC SIGNATURE IF POSSIBLE)

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

Dave Dieken

2Oct2015

 Customer authorization to perform tests
 according to this test plan.

 Date

Dave Dieken

2Oct2015

 Test Plan/CDF Prepared By (please print)

 Date