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Report On

Application for Grant of Equipment Authorization of the
ImThera Medical, Inc.
aura6000 RCC Remote Control and Charger

FCC Part 95 Subpart I § 95.627
IC RSS-243 Issue 3 February 2010

Report No. SD72112017-1215B Rev.1 December 2015

REPORT ON	Radio Testing of the ImThera Medical, Inc. Remote Control and Charger
TEST REPORT NUMBER	SD72112017-1215B Rev.1
PREPARED FOR	ImThera Medical, Inc. 12555 High Bluff Drive, Suite 310 San Diego, CA 92130-2056
CONTACT PERSON	Paul Meadows VP-R&D, CTO (858) 259-2980 x11 pmeadows@imtheramedical.com
PREPARED BY	Ferdinand S. Custodio **Name** Authorized Signatory Title: EMC/Senior Wireless Test Engineer
APPROVED BY	Chip R. Fleury **Name** Authorized Signatory
DATED	March 03, 2016

TÜV SÜD AMERICA INC 10040 Mesa Rim Road San Diego, CA 92121-2912 Phone: 858 678 1400 FAX: 858 546 0364

Revision History

SD72112017-1215B Rev.1 ImThera Medical, Inc. aura6000 RCC Remote Control and Charger					
DATE	OLD REVISION	NEW REVISION	REASON	PAGES AFFECTED	APPROVED BY
03/03/2016	Initial Release				Chip R. Fleury
03/17/2016	Initial Release	Rev. 1	Corrected High Channel frequency on Section 2.1.8 from 500MHz to 405MHz	16	Ferdie Custodio
			Included Attestation Letter provided by the manufacturer for frequency monitoring requirements	17,18,43 and 42	

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SECTION 1

REPORT SUMMARY

Radio Testing of the
ImThera Medical, Inc.
Remote Control and Charger

1.1 INTRODUCTION

The information contained in this report is intended to show verification of the ImThera Medical, Inc. aura6000 RCC Remote Control and Charger to the requirements of FCC Part 95 Subpart I § 95.627 and IC RSS-243 Issue 3 February 2010.

Objective	To perform Radio Testing to determine the Equipment Under Test's (EUT's) compliance with the Test Specification, for the series of tests carried out.
Manufacturer	ImThera Medical, Inc.
Model Number(s)	500.0100
FCC ID Number	2AGS5-RCC
IC Number	20934-RCC
Serial Number(s)	F114120904649; F3150706024
Number of Samples Tested	2
Test Specification/Issue/Date	• FCC Part 95 Subpart I § 95.627 (October 1, 2014). • IC RSS-243 Issue 3 February 2010. Medical Devices Operating in the 401-406 MHz Frequency Band • RSS-Gen - General Requirements for Compliance of Radio Apparatus (Issue 4, November 2014). • KDB 412172 D01 Determining ERP And EIRP V01r01 (August 07, 2015) Guidelines For Determining The Effective Radiated Power (ERP) and Equivalent Isotropically Radiated Power (EIRP) of an RF Transmitting System
Start of Test	December 07, 2015
Finish of Test	December 14, 2015
Name of Engineer(s)	Ferdinand Custodio
Related Document(s)	None. Supporting documents for EUT certification are separate exhibits.

1.2 BRIEF SUMMARY OF RESULTS

A brief summary of the tests carried out in accordance with FCC Part 95 Subpart I § 95.627 with cross-reference to the corresponding IC RSS standard is shown below.

Section	FCC Part 95 Spec Clause	RSS	Test Description	Result	Comments/ Base Standard
2.1	§95.639(f)(1)	RSS-243 Section 5.4	Transmitter Output Power	Compliant	
2.2	§95.627(a)(1) to (4)	RSS-243 Section 5.7.2	Frequency Monitoring	Manufacturer Declaration*	
2.3		RSS-Gen 8.8	Conducted Emissions	Compliant	
2.4		RSS-Gen 6.6	99% Emission Bandwidth	Compliant	
2.5	§95.635(d)(4)	RSS-243 Section 5.5(b)	Emission Mask	Compliant	
2.6	§95.633(e)	RSS-243 Section 5.1	Emission Bandwidth	Compliant	
2.7	§95.628(d)	RSS-243 Section 5.3	Frequency Stability	Compliant	
2.8	§95.635(d)(1)(i)	RSS-243 Section 5.5	Transmitter Unwanted Emissions	Compliant	
2.9		RSS-243 Section 5.6	Receiver Spurious Emissions	Compliant	

* *See Attestation Letter provided with this filing*

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1.3 PRODUCT INFORMATION

1.3.1 Technical Description

The Equipment Under Test (EUT) was an ImThera Medical, Inc. aura6000 RCC Remote Control and Charger as shown in the photograph below. The EUT is a remote control and charger for Implantable Neurostimulator for the treatment of Obstructive Sleep Apnea.

Equipment Under Test

EUT Charge Antenna

EUT Battery Charger

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1.3.2 EUT General Description

EUT Description	Remote Control and Charger
Model Name	aura6000 RCC
Model Number(s)	500.0100
Rated Voltage	Internal 3.6VDC Nickel Metal Hydride rechargeable battery (2000mAh). Battery charger is Advanced Power Solutions M/N GS2U-015-075-M P/N 5607-010 (7.5VDC 2000mA).
Mode Verified	MedRadio 401.01 MHz to 405.81 MHz
Capability	MedRadio 401.01 MHz to 405.81 MHz
Transmitter Output Power	13.386 µW (EIRP)
Primary Unit (EUT)	☒ Production
	☐ Pre-Production
	☐ Engineering
Antenna Type	AntennaFactor by Linx surface mount quarter-wave/monopole antenna
Antenna Part Number	ANT-403-SP

1.4 EUT TEST CONFIGURATION

1.4.1 Test Configuration Description

Test Configuration	Description
Default	Telemetry Mode. The EUT FW was replaced with a special version of the FW that, when the RCC is in its idle state with the LCD display off, and when the Up arrow button is pressed the RCC will begin to broadcast packets of data continuously on the center channel of the MedRadio band until a button is pressed on the RCC.

1.4.2 EUT Exercise Software

None. There is no special test software used during verification. The firmware however was modified as detailed above to enable continuous transmit mode.

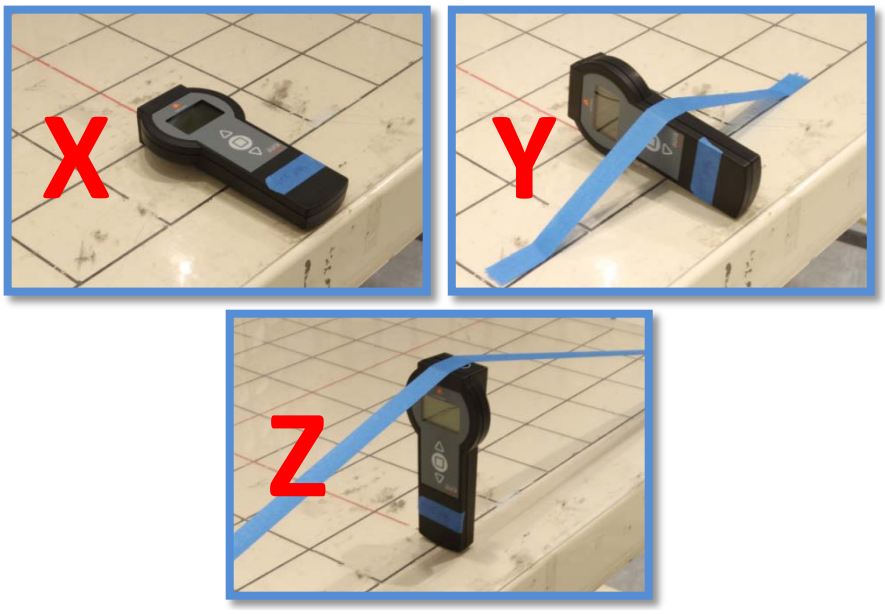
1.4.3 Support Equipment and I/O cables

Manufacturer	Equipment/Cable	Description
-	-	-

Note: *EUT verified on a standalone configuration.*

1.4.4 Worst Case Configuration

EUT is a mobile device. For radiated measurements, the EUT was verified on all three (3) orthogonal axes. Worst case axis was "Z".



1.5 DEVIATIONS FROM THE STANDARD

No deviations from the applicable test standards or test plan were made during testing.

1.6 MODIFICATION RECORD

Description of Modification	Modification Fitted By	Date Modification Fitted
Serial Number F114120904649 and F3150706024		
N/A		

The table above details modifications made to the EUT during the test programme. The modifications incorporated during each test (if relevant) are recorded on the appropriate test pages.

1.7 TEST METHODOLOGY

All measurements contained in this report were conducted with ANSI C63.4-2014, American National Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the range of 9 kHz to 40 GHz.
For conducted and radiated emissions the equipment under test (EUT) was configured to measure its highest possible emission level. This level was based on the maximized cable configuration from exploratory testing per ANSI C63.4-2014. The test modes were adapted according to the Operating Instructions provided by the manufacturer/client.

1.8 TEST FACILITY LOCATION

1.8.1 TÜV SÜD America Inc. (Mira Mesa)

10040 Mesa Rim Road, San Diego, CA 92121-2912 (32.901268,-117.177681). Phone: 858 678 1400 FAX: 858-546 0364

1.8.2 TÜV SÜD America Inc. (Rancho Bernardo)

Sony Electronics Inc., Building #8 16530 Via Esprillo, San Diego, CA 92127-1708 (33.018644,-117.092409). Phone: 858 942 5542 FAX: 858-546 0364

1.9 TEST FACILITY REGISTRATION

1.9.1 FCC – Registration No.: US1146

TUV SUD America Inc. (San Diego), is an accredited test facility with the site description report on file and has met all the requirements specified in §2.948 of the FCC rules. The acceptance letter from the FCC is maintained in our files and the Registration is US1146.

1.9.2 **Industry Canada (IC) Registration No.: 3067A**

The 10m Semi-anechoic chamber of TUV SUD America Inc. (San Diego) has been registered by Certification and Engineering Bureau of Industry Canada for radio equipment testing with Registration No. 3067A.

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SECTION 2

TEST DETAILS

Radio Testing of the
ImThera Medical, Inc.
Remote Control and Charger

2.1 TRANSMITTER OUTPUT POWER

2.1.1 Specification Reference

Part 95 Subpart E §95.639(f)(1) and RSS-243 Section 5.4

2.1.2 Standard Applicable

(1) For transmitters operating in the 401-406 MHz band that are not excepted under §95.627(b) from the frequency monitoring requirements of §95.627(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 §95.627(b) from the frequency monitoring requirements of §95.627(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, 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 the power radiated by any station operating in 401.85-402 MHz shall not exceed 25 microwatts in the 150 kHz bandwidth. See §§95.633(e).

2.1.3 Equipment Under Test and Modification State

Serial No: F114120904649 and F3150706024/ Default Test Configuration

2.1.4 Date of Test/Initial of test personnel who performed the test

December 07, 2015/FSC

2.1.5 Test Equipment Used

The major items of test equipment used for the above tests are identified in Section 3.1.

2.1.6 Environmental Conditions/ Test Location

Test performed at TÜV SÜD America Inc. Rancho Bernardo facility

Ambient Temperature	22.4 °C
Relative Humidity	29.2 %
ATM Pressure	98.9 kPa

2.1.7 Additional Observations

- EIRP was calculated using Field Strength Approach (linear terms) of KDB 412172.

$$EIRP = \frac{(\mathrm{E\ x\ d})^2}{30}$$

Where: E = electric field strength in V/m
d = measurement distance in meters

- Only the worst case axis presented.
- Field Strength measurements were from Section 2.7 of this test report.
- Electric Field Strength was calculated from the formula:

$$V/m = 10^{\left(\frac{\left(db\mu\frac{V}{m}\right)-120}{20}\right)}$$

2.1.8 **Test Results (Calculation)**

Channel	Frequency (MHz)	Field Strength @ 3 meters (dbµV/m)	Electric Field Strength (V/m)	EIRP (mW)	EIRP Limit (mW)	Compliance
Low	401.85	76.5	0.00668	0.013386	0.025	Complies
High	405.00	72.0	0.00398	0.004752	0.025	Complies

2.2 FREQUENCY MONITORING

2.2.1 Specification Reference

Part 95 Subpart E §95.627(a)(1) to (4) and RSS-243 Section 5.7.2

2.2.2 Standard Applicable

(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.

2.2.3 Equipment Under Test and Modification State

Test not performed. Manufacturer provided Attestation Letter to justify compliance.

2.2.4 Test Results (Monitoring System Bandwidth)

Not performed. See Annex A for details.

2.2.5 Test Results (Minimum Channel Monitoring Period)

Not performed. See Annex A for details.

2.2.6 Test Results (System Threshold Power Levels)

Not performed. See Annex A for details.

2.2.7 Test Results (Scan Cycle Time)

Not performed. See Annex A for details.

2.2.8 Test Results (Channel Access)

Not performed. See Annex A for details.

2.2.9 Test Results (Discontinuation of a MedRadio Session)

Not performed. See Annex A for details.

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2.3 CONDUCTED EMISSIONS

2.3.1 Specification Reference

RSS Gen. 8.8

2.3.2 Standard Applicable

A radio apparatus that is designed to be connected to the public utility (AC) power line shall ensure that the radio frequency voltage, which is conducted back onto the AC power line on any frequency or frequencies within the band 150 kHz-30 MHz, shall not exceed the limits in the Table below.

Unless the requirements applicable to a given device state otherwise, for any radio apparatus equipped to operate from the public utility AC power supply either directly or indirectly (such as with a battery charger), the radio frequency voltage of emissions conducted back onto the AC power lines in the frequency range of 0.15 MHz to 30 MHz shall not exceed the limits shown in the below. The more stringent limit applies at the frequency range boundaries.

The conducted emissions shall be measured in accordance with the reference publication mentioned in Section 3 of RSS-Gen.

Frequency of emission (MHz)	Conducted limit (dBµV)	
	Quasi-peak	Average
0.15–0.5	66 to 56*	56 to 46*
0.5–5	56	46
5–30	60	50

**Decreases with the logarithm of the frequency.*

2.3.3 Equipment Under Test and Modification State

N/A (Not Applicable). The EUT is not designed to transmit while in charging mode.

2.4 99% EMISSION BANDWIDTH

2.4.1 Specification Reference

RSS-Gen Clause 6.6

2.4.2 Standard Applicable

The emission bandwidth (x dB) is defined as the frequency range between two points, one above and one below the carrier frequency, at which the spectral density of the emission is attenuated x dB below the maximum in-band spectral density of the modulated signal. Spectral density (power per unit bandwidth) is to be measured with a detector of resolution bandwidth in the range of 1% to 5% of the anticipated emission bandwidth, and a video bandwidth at least 3x the resolution bandwidth.
When the occupied bandwidth limit is not stated in the applicable RSS or reference measurement method, the transmitted signal bandwidth shall be reported as the 99% emission bandwidth, as calculated or measured.

- The transmitter shall be operated at its maximum carrier power measured under normal test conditions.
- The span of the analyzer shall be set to capture all products of the modulation process, including the emission skirts.
- The resolution bandwidth (RBW) shall be in the range of 1% to 5% of the occupied bandwidth (OBW) and video bandwidth (VBW) shall be approximately 3x RBW.

Note: Video averaging is not permitted.
A peak, or peak hold, may be used in place of the sampling detector as this may produce a wider bandwidth than the actual bandwidth (worst-case measurement). Use of a peak hold may be necessary to determine the occupied bandwidth if the device is not transmitting continuously.
The trace data points are recovered and are directly summed in linear power level terms. The recovered amplitude data points, beginning at the lowest frequency, are placed in a running sum until 0.5% of the total is reached and that frequency recorded. The process is repeated for the highest frequency data points (starting at the highest frequency, at the right side of the span, and going down in frequency). This frequency is then recorded.
The difference between the two recorded frequencies is the 99% occupied bandwidth.

2.4.3 Equipment Under Test and Modification State

Serial No: F114120904649 and F3150706024 / Default Test Configuration

2.4.4 Date of Test/Initial of test personnel who performed the test

December 10, 2015/FSC

2.4.5 Test Equipment Used

The major items of test equipment used for the above tests are identified in Section 3.1.

2.4.6 Environmental Conditions/ Test Location

Test performed at TÜV SÜD America Inc. Rancho Bernardo facility

Ambient Temperature	23.6 °C
Relative Humidity	37.3.%
ATM Pressure	99.1 kPa

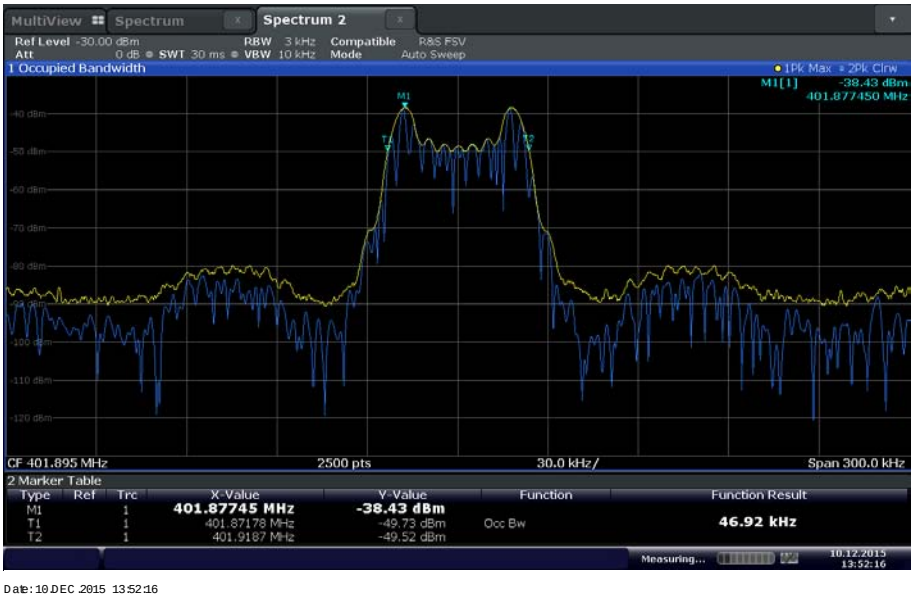
2.4.7 Additional Observations

- This is a radiated test.
- Span is wide enough to capture the channel transmission.
- RBW is 1% of the span.
- VBW is 3X RBW.
- Sweep is auto.
- Detector is peak.
- The % Power Bandwidth setting in the spectrum analyzer was set to 99% (default).
- The Channel Bandwidth measurement function of the spectrum analyzer was used for this test.

2.4.8 Test Results (For reporting purposes only)

Channel	Measured 99% EBW (kHz)
Low (401.85 MHz)	46.92
High (405 MHz)	47.00

2.4.9 Test Results Plots



Date: 10.DEC.2015 13:52:16

Low Channel

Date: 10.DEC.2015 13:49:25

High Channel

2.5 EMISSION MASK

2.5.1 Specification Reference

Part 95 Subpart E §95.635(d)(4)

2.5.2 Standard Applicable

(4) For devices designed to operate in the 402-405 MHz band: Emissions within the band more than 150 kHz away from the center frequency of the spectrum the transmission is intended to occupy and emissions 250 kHz or less below 402 MHz or above 405 MHz band will be attenuated below the maximum permitted output power by at least 20 dB.

2.5.3 Equipment Under Test and Modification State

Serial No: F114120904649 and F3150706024/ Default Test Configuration

2.5.4 Date of Test/Initial of test personnel who performed the test

December 11, 2015/FSC

2.5.5 Test Equipment Used

The major items of test equipment used for the above tests are identified in Section 3.1.

2.5.6 Environmental Conditions/ Test Location

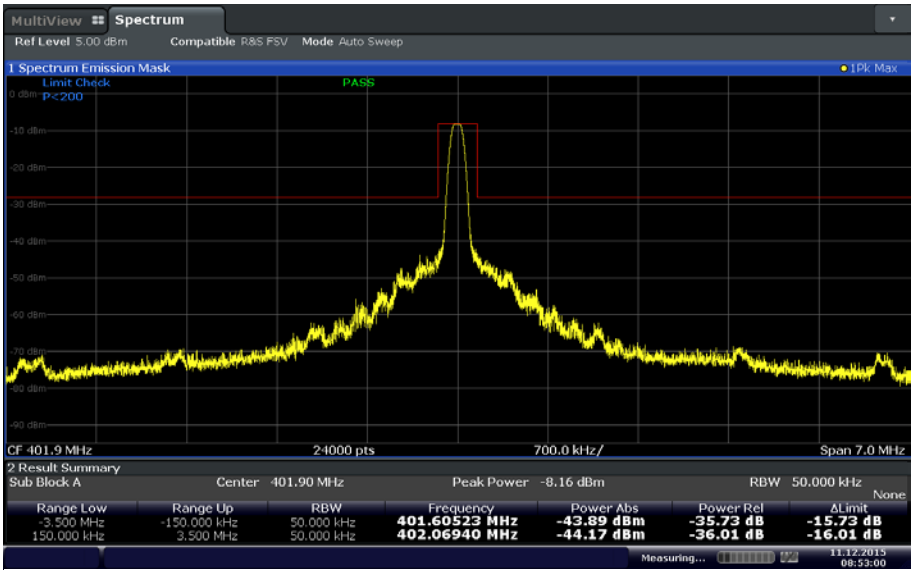
Test performed at TÜV SÜD America Inc. Rancho Bernardo facility

Ambient Temperature	24.4 °C
Relative Humidity	44.1.%
ATM Pressure	98.7 kPa

2.5.7 Additional Observations

- This is a radiated test.
- Span was adjusted to always show frequency range between 401.75 MHz and 405.25 MHz.
- RBW is set to approximately 1% to 5% of the span (worst case).
- VBW is ≥3X RBW.
- Detector is peak.
- The Spectrum Emission Mask function of the spectrum analyzer was used for this test.
- Mask was set to 20dBc more than 150kHz away from the center frequency.

2.5.8 **Test Results Plots**



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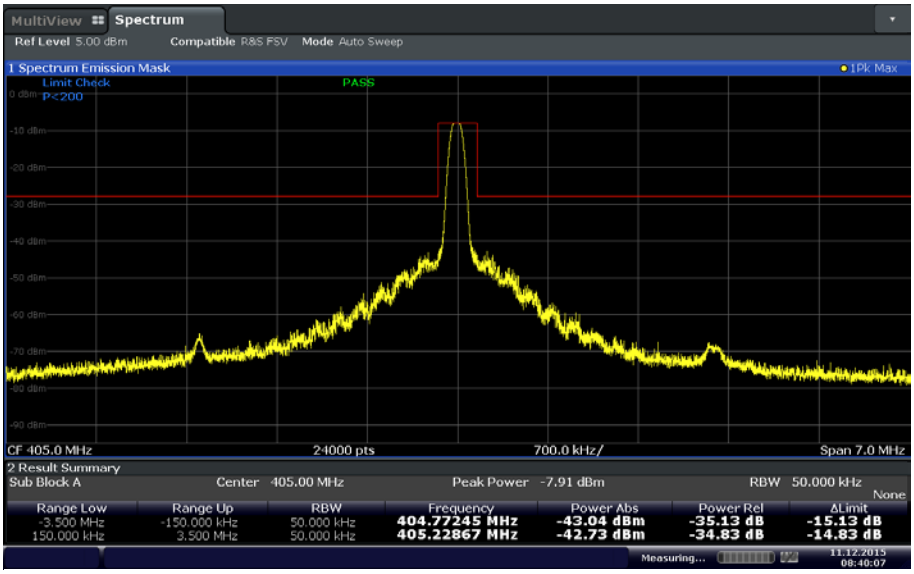
Low Channel



Date: 11.DEC.2015 08:40:07

High Channel

2.6 EMISSION BANDWIDTH

2.6.1 Specification Reference

Part 95 Subpart E §95.633(e)

2.6.2 Standard Applicable

(1) For stations operating in 402-405 MHz, the maximum authorized emission bandwidth is 300 kHz. For stations operating in 401-401.85 MHz or 405-406 MHz, the maximum authorized emission bandwidth is 100 kHz. For stations operating in 401.85-402 MHz, the maximum authorized emission bandwidth is 150 kHz. For stations operating in 413-419 MHz, 426-432 MHz, 438-444 MHz, or 451-457 MHz, the maximum authorized emission bandwidth is 6 megahertz. For stations operating in 2360-2400 MHz, the maximum authorized emission bandwidth is 5 megahertz.

(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

2.6.3 Equipment Under Test and Modification State

Serial No: F114120904649 and F3150706024/ Default Test Configuration

2.6.4 Date of Test/Initial of test personnel who performed the test

December 10, 2015/FSC

2.6.5 Test Equipment Used

The major items of test equipment used for the above tests are identified in Section 3.1.

2.6.6 Environmental Conditions/ Test Location

Test performed at TÜV SÜD America Inc. Rancho Bernardo facility

Ambient Temperature	23.6 °C
Relative Humidity	37.3.%
ATM Pressure	99.1 kPa

2.6.7 Additional Observations

- This is a radiated test.
- Span is between 2X and 5X of the OBW.
- RBW is set to approximately 1% to 5% of the OBW.
- VBW is ≥3X RBW.
- Sweep is auto.

- Detector is peak.
- The “n” dB down marker function of the spectrum analyzer was used for this test.

2.6.8 Test Results

Channel	Measured Emission Bandwidth (kHz)	Maximum Authorized Emission Bandwidth (kHz)	Compliance
Low (401.85 MHz)	50.60	100	Complies
High (405.00 MHz)	50.70	300	Complies

2.6.9 Test Results Plots

Date: 10.DEC.2015 13:52:57

Low Channel

Date: 10.DEC.2015 13:48:04

High Channel

2.7 FREQUENCY STABILITY

2.7.1 Specification Reference

Part 95 Subpart E §95.628(d) and RSS-243 Section 5.3

2.7.2 Standard Applicable

Each transmitter in the MedRadio service must maintain a frequency stability of ±100 ppm of the operating frequency over the range:

(1) 25 °C to 45 °C in the case of medical implant transmitters; and
(2) 0 °C to 55 °C in the case of MedRadio programmer/control transmitters and Medical body-worn transmitters

2.7.3 Equipment Under Test and Modification State

Serial No: F114120904649 and F3150706024/ Default Test Configuration

2.7.4 Date of Test/Initial of test personnel who performed the test

December 10, 2015/FSC

2.7.5 Test Equipment Used

The major items of test equipment used for the above tests are identified in Section 3.1.

2.7.6 Environmental Conditions/ Test Location

Test performed at TÜV SÜD America Inc. Rancho Bernardo facility

Ambient Temperature	23.6 °C
Relative Humidity	37.3.%
ATM Pressure	99.1 kPa

2.7.7 Additional Observations

- The EUT is a MedRadio programmer/control transmitter. Temperature range verified was from 0 °C to 55 °C.
- The EUT is a hand carried, battery powered equipment, the primary supply voltage was reduced to the battery operating end point specified by the manufacturer during testing.
- Both Low and High channels verified, only High channel presented.
- Since the fundamental frequency is modulated, the center frequency was calculated by using OBW measurement function of the spectrum analyzer and the following formula:

$$Center\ Frequency = \frac{T1 + T2}{2}$$

Where: T1 = Lower OBW edge
T2 = Upper OBW edge

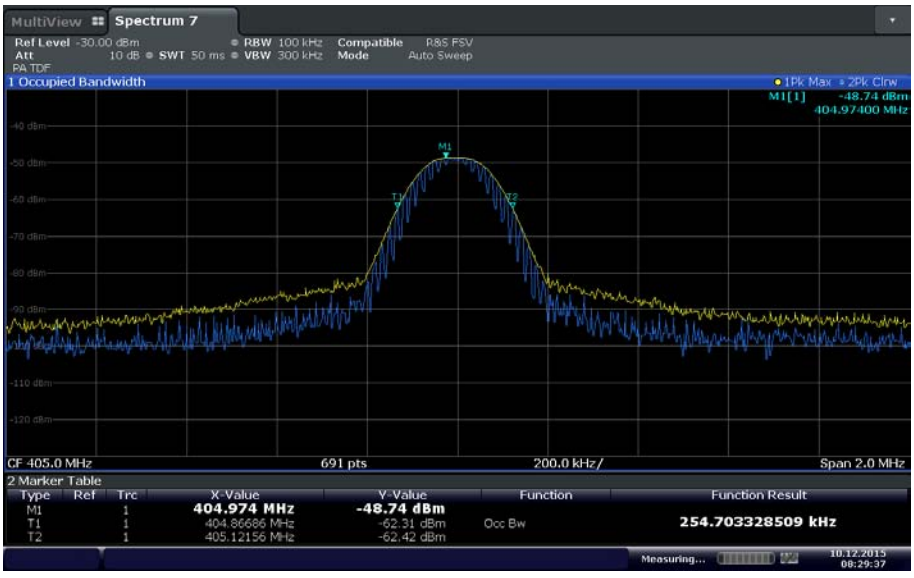
- The limit is ±100 ppm. Reference fundamental frequency at 25°C is 404.991315 MHz, therefore calculated deviation limit is ±40.499 kHz.

2.7.8 Test Results

Complies. See attached table and plots.

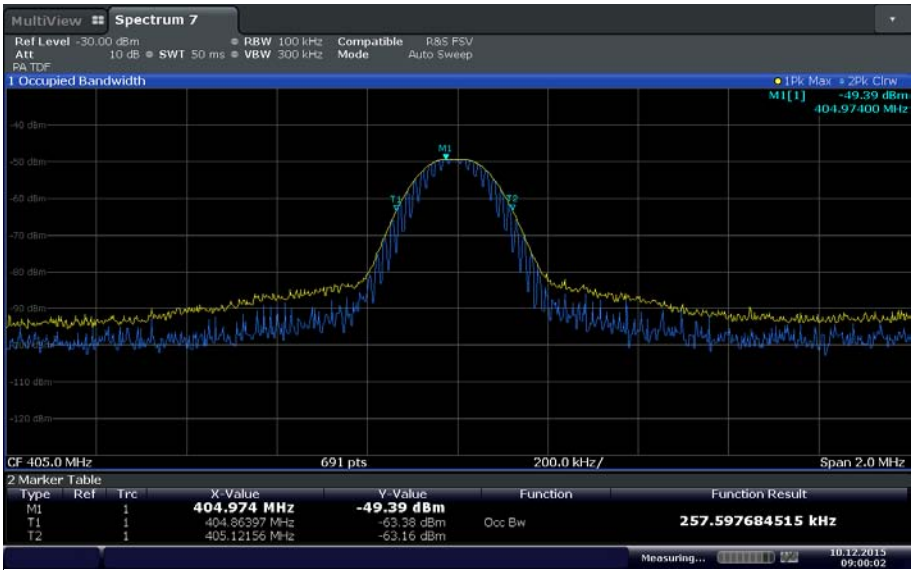
Voltage (%)	Power (VDC)	Temp (°C)	Frequency (MHz)	Max. Frequency Deviation (kHz)	Deviation Limit (kHz)
100	Voltage variation not performed. Instead, voltage close to battery operating end point was supplied to the EUT.	0	404.994210	-2.895	±40.499
		+10	404.992765	-1.450	
		+20	404.992765	-1.450	
		+25	404.991315	-	
		+35			
		+45			
		+55			
115		+25	-	-	
85		+25	-	-	

2.7.9 Test Plots



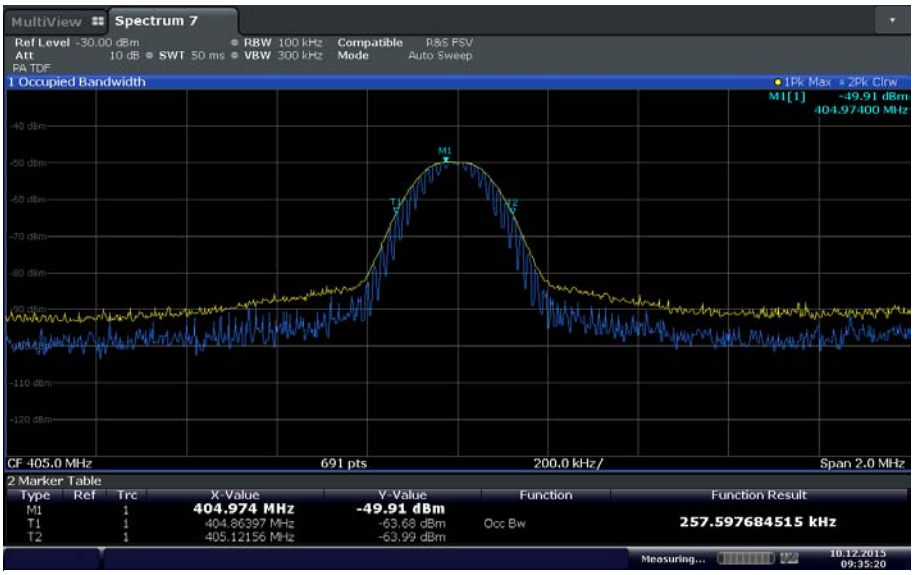
Date: 10.DEC.2015 08:29:37

High Channel @ 0°C



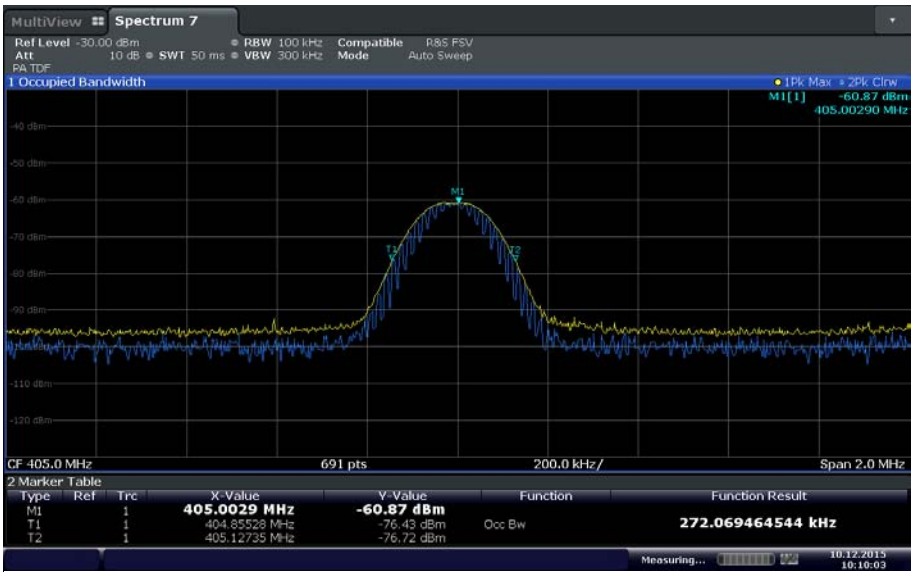
Date: 10.DEC.2015 09:00:02

High Channel @ 10°C



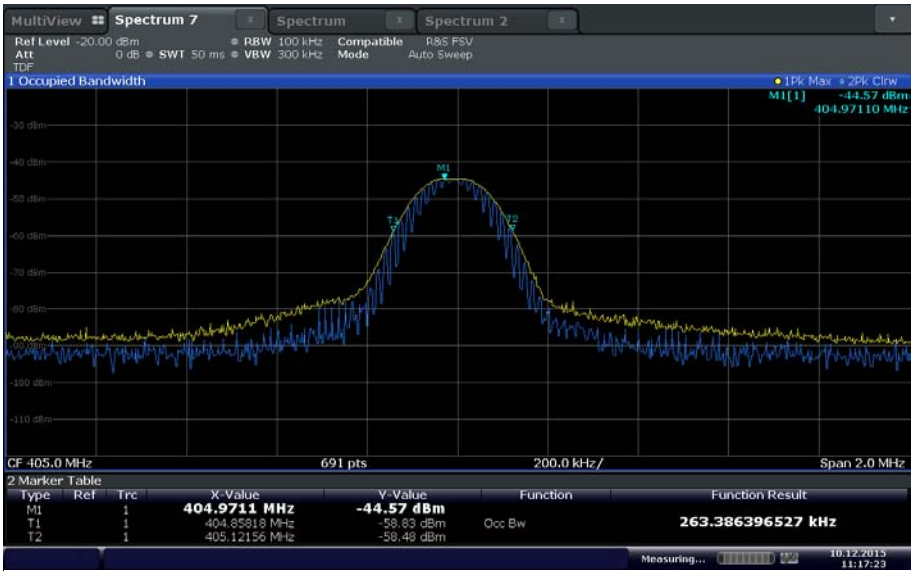
Date: 10.DEC.2015 09:35:20

High Channel @ 20°C



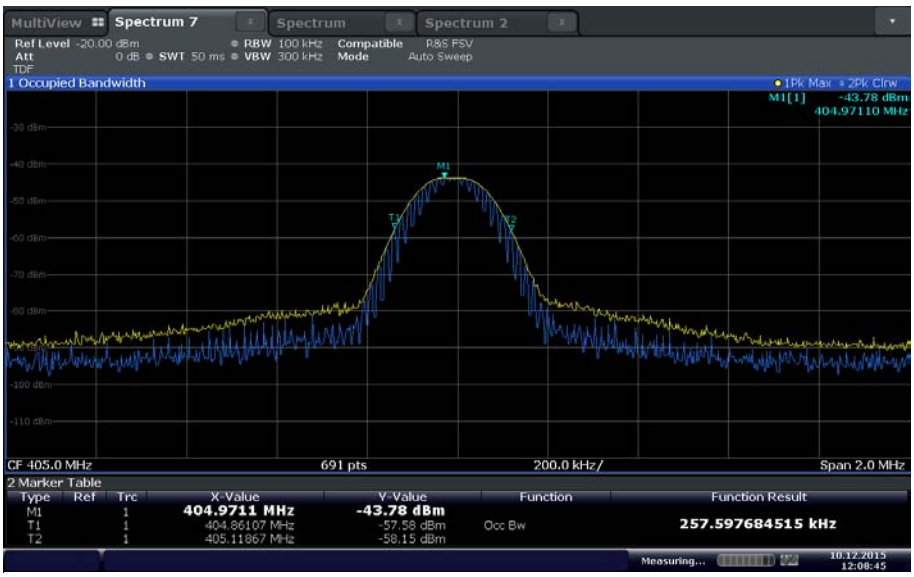
Date: 10.DEC.2015 10:10:03

High Channel @ 25°C (Reference)



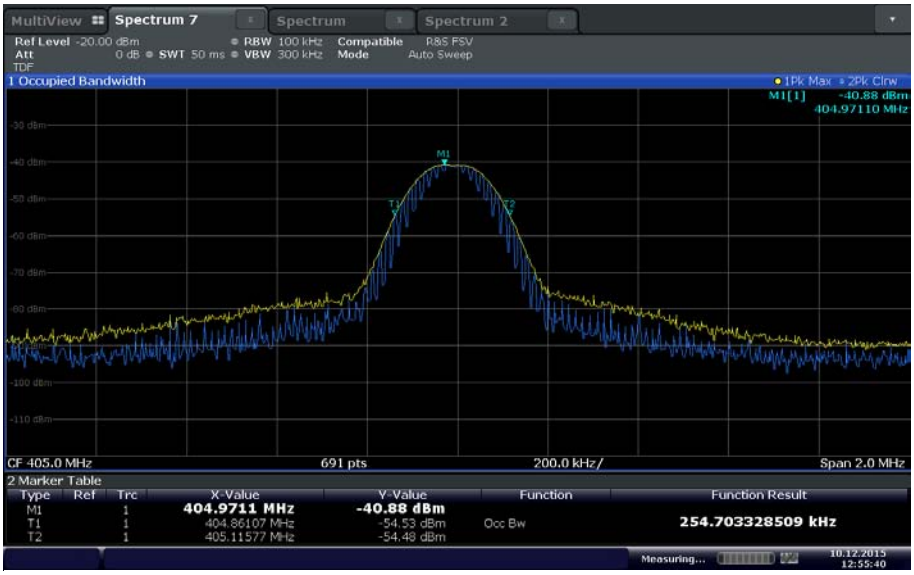
Date: 10.DEC.2015 11:17:23

High Channel @ 35°C



Date: 10.DEC.2015 12:08:45

High Channel @ 45°C



Date: 10.DEC.2015 12:55:40

High Channel @ 55°C

2.8 TRANSMITTER UNWANTED EMISSIONS

2.8.1 Specification Reference

Part 95 Subpart E §95.635(d)(1)(i) and RSS-243 Section 5.5

2.8.2 Standard Applicable

(d) For transmitters designed to operate in the MedRadio service, emissions shall be attenuated in accordance with the following:

(1) Emissions from a MedRadio transmitter shall be attenuated to a level no greater than the field strength limits shown in the following table when they:

(i) Are more than 250 kHz outside of the 402-405 MHz band (for devices designed to operate in the 402-405 MHz band);

Frequency (MHz)	Field Strength (µV/m)	Measurement Distance (meters)
30-88	100	3
88-216	150	3
216-960	200	3
960 and above	500	3

2.8.3 Equipment Under Test and Modification State

Serial No: F3150706024 / Default Test Configuration

2.8.4 Date of Test/Initial of test personnel who performed the test

December 07, 2015/FSC

2.8.5 Test Equipment Used

The major items of test equipment used for the above tests are identified in Section 3.1.

2.8.6 Environmental Conditions/ Test Location

Test performed at TÜV SÜD America Inc. Rancho Bernardo facility

Ambient Temperature	22.4 °C
Relative Humidity	29.2 %
ATM Pressure	98.9 kPa

2.8.7 Additional Observations

- This is a radiated test. The spectrum was searched from 30MHz to the 10th harmonic.
- Limits used were from §15.209 which are identical with §95.635(d)(1)(i) limits.

- Only noise floor measurements observed above 18GHz.
- Measurement was done using EMC32 automated software. Reported level is the actual level with all the correction factors factored in. Correction Factor column is for informational purposes only. See Section 2.8.8 for sample computation.

2.8.8 Sample Computation (Radiated Emission)

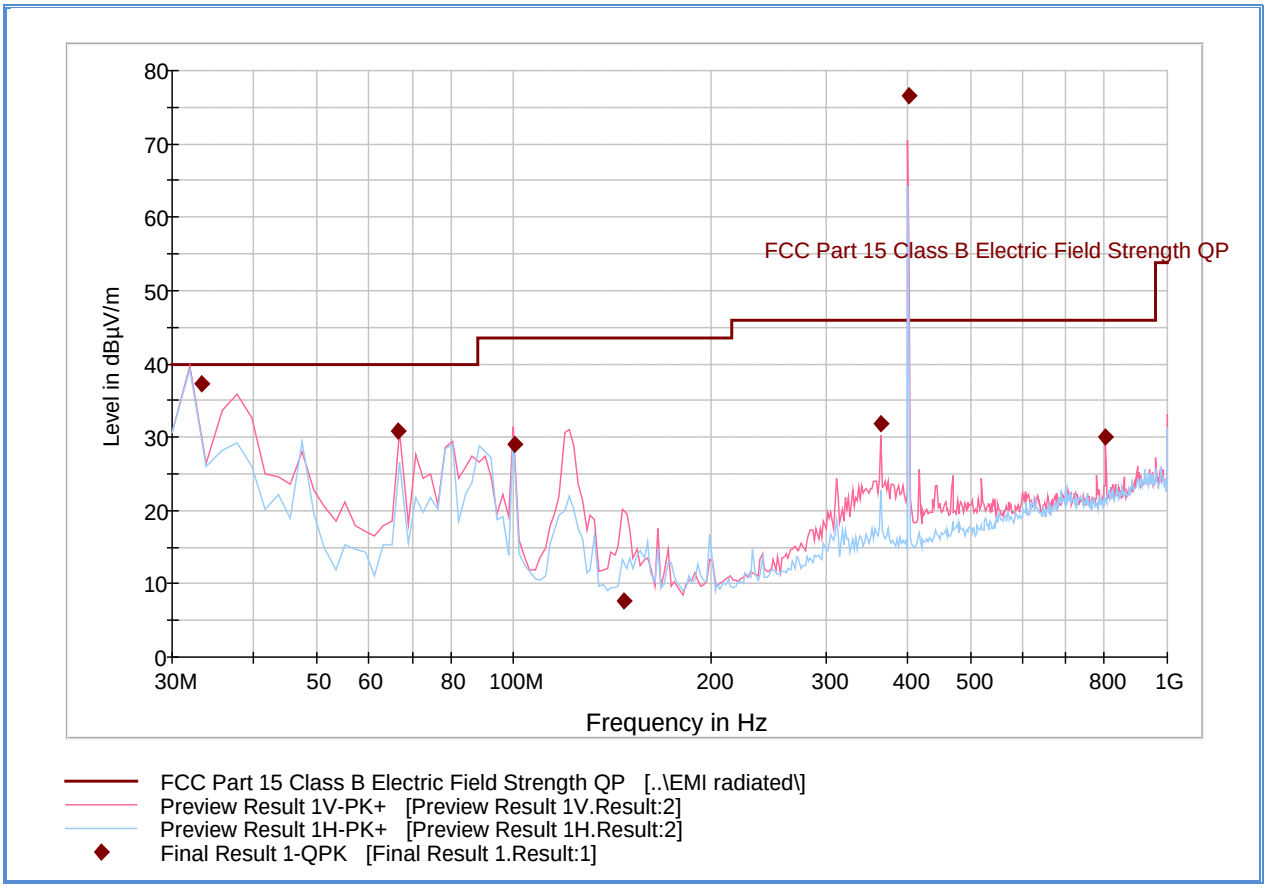
Measuring equipment raw measurement (dbµV) @ 30 MHz			24.4
Correction Factor (dB)	Asset# 1066 (cable)	0.3	-12.6
	Asset# 1172 (cable)	0.3	
	Asset# 1016 (preamplifier)	-30.7	
	Asset# 1175(cable)	0.3	
	Asset# 1002 (antenna)	17.2	
Reported QuasiPeak Final Measurement (dbµV/m) @ 30MHz			**11.8**

2.8.9 Test Results

See attached plots.

TÜV SÜD AMERICA INC 10040 Mesa Rim Road San Diego, CA 92121-2912 Phone: 858 678 1400 FAX: 858 546 0364

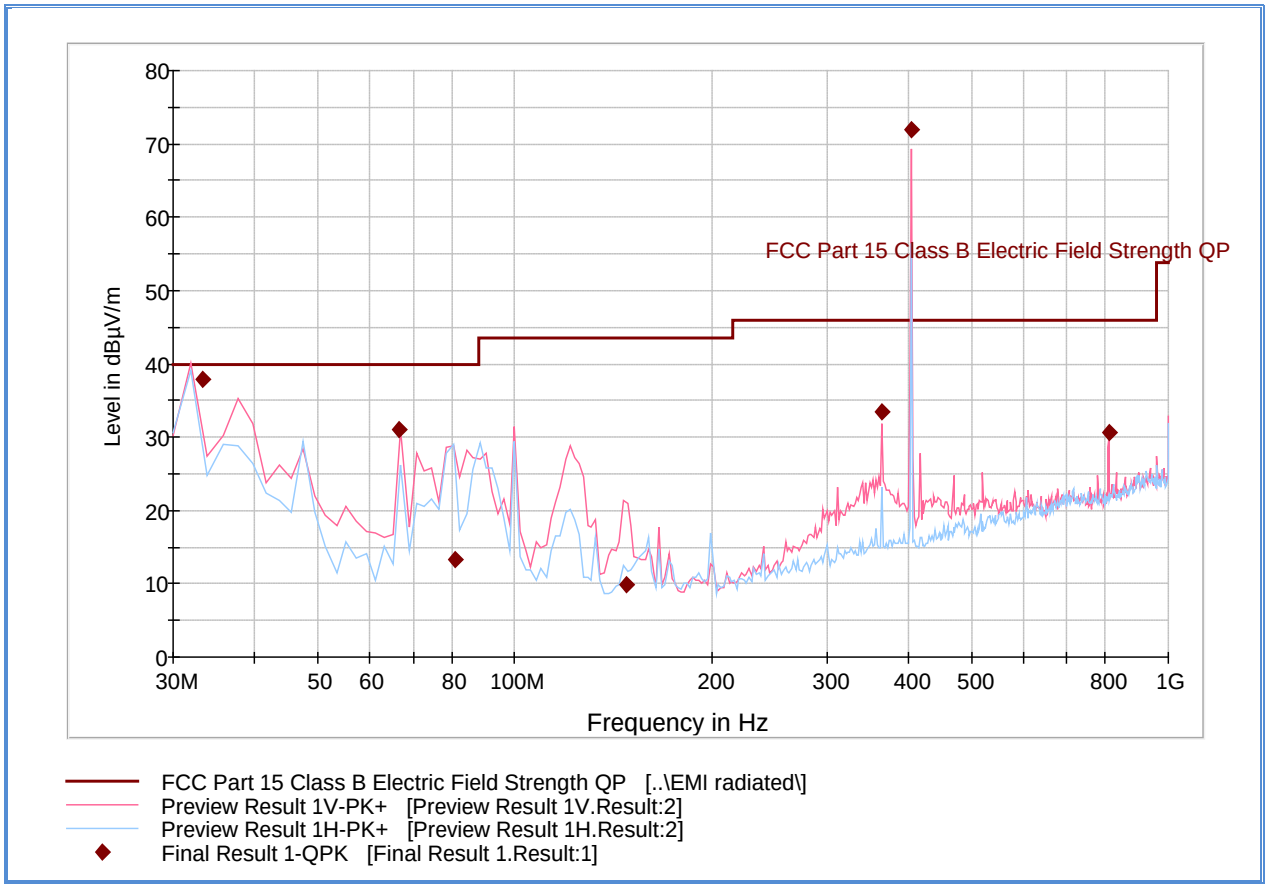
2.8.10 Test Results Below 1GHz (Worst Case Axis – Low Channel)



Quasi Peak Data

Frequency (MHz)	QuasiPeak (dBµV/m)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Polarization	Azimuth (deg)	Corr. (dB)	Margin (dB)	Limit (dBµV/m)
33.280000	37.2	1000.0	120.000	102.0	V	213.0	-13.2	2.8	40.0
66.573868	30.8	1000.0	120.000	102.0	V	213.0	-22.3	9.2	40.0
100.259960	29.0	1000.0	120.000	102.0	V	73.0	-19.8	14.5	43.5
147.433267	7.7	1000.0	120.000	103.0	V	-3.0	-19.2	35.8	43.5
364.028697	31.9	1000.0	120.000	139.0	V	299.0	-10.1	14.1	46.0
401.922565	76.5	1000.0	120.000	114.0	V	-8.0	-9.1	Fundamental	
803.851222	30.0	1000.0	120.000	110.0	V	269.0	-1.4	16.0	46.0

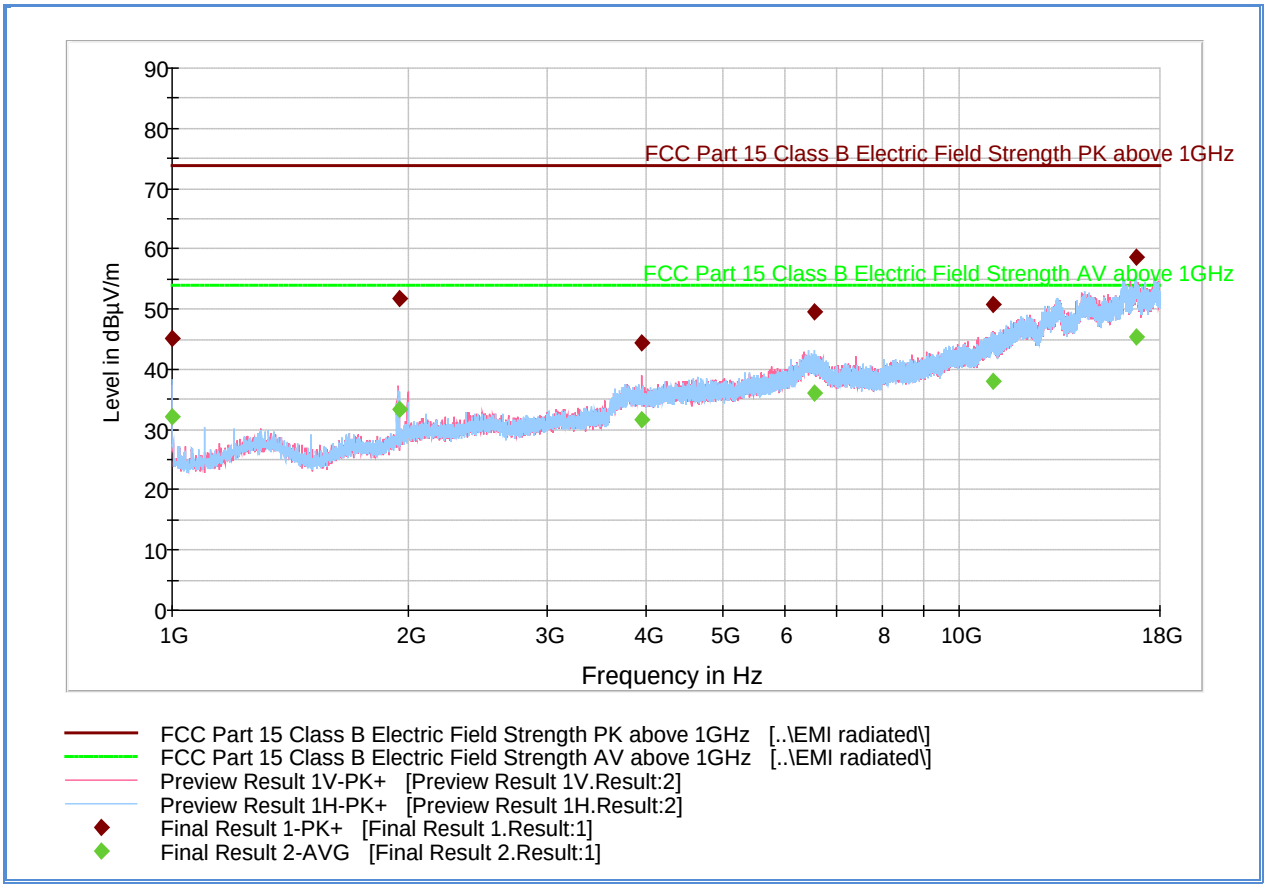
2.8.11 Test Results Below 1GHz (Worst Case Axis – High Channel)



Quasi Peak Data

Frequency (MHz)	QuasiPeak (dBµV/m)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Polarization	Azimuth (deg)	Corr. (dB)	Margin (dB)	Limit (dBµV/m)
33.320000	37.9	1000.0	120.000	100.0	V	144.0	-13.2	2.1	40.0
66.573868	30.9	1000.0	120.000	100.0	V	230.0	-22.3	9.1	40.0
81.228858	13.3	1000.0	120.000	150.0	V	355.0	-21.9	26.7	40.0
148.353267	9.8	1000.0	120.000	100.0	V	3.0	-19.1	33.7	43.5
364.028697	33.5	1000.0	120.000	150.0	V	188.0	-10.1	12.5	46.0
405.010341	72.0	1000.0	120.000	115.0	V	198.0	-9.2	Fundamental	
810.042886	30.5	1000.0	120.000	112.0	V	125.0	-1.1	15.5	46.0

2.8.12 Test Results Above 1GHz (Worst Case Axis – Low Channel)



Peak Data

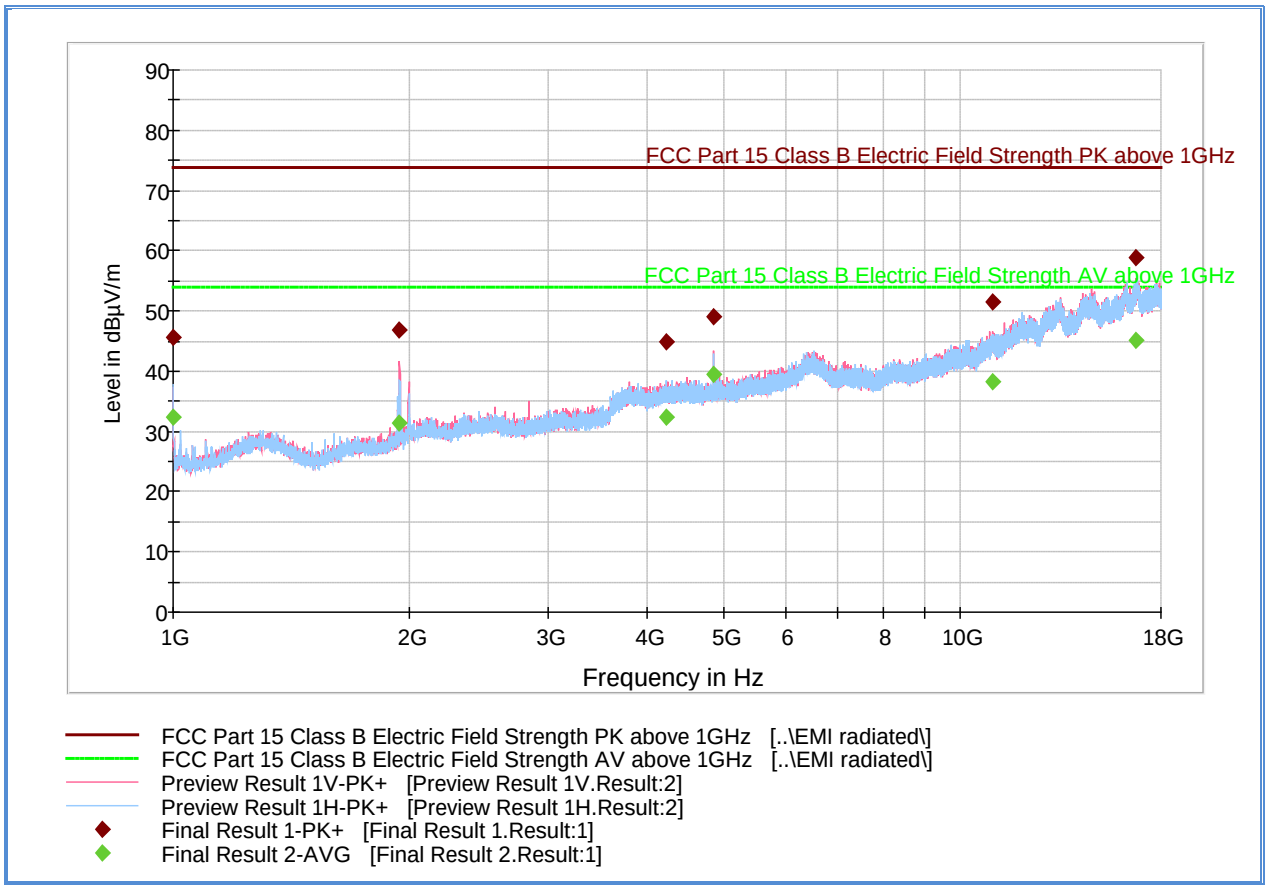
Frequency (MHz)	MaxPeak (dBµV/m)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Polarization	Azimuth (deg)	Corr. (dB)	Margin (dB)	Limit (dBµV/m)
1000.000000	45.2	1000.0	1000.000	218.4	H	142.0	-7.2	28.7	73.9
1941.066667	51.6	1000.0	1000.000	245.3	V	141.0	-2.3	22.3	73.9
3949.866667	44.3	1000.0	1000.000	191.5	V	184.0	5.2	29.6	73.9
6547.100000	49.5	1000.0	1000.000	389.1	H	270.0	11.5	24.4	73.9
11027.40000	50.7	1000.0	1000.000	345.1	V	291.0	15.5	23.3	73.9
16768.86666	58.5	1000.0	1000.000	401.7	H	231.0	24.6	15.4	73.9

Average Data

Frequency (MHz)	Average (dBµV/m)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Polarization	Azimuth (deg)	Corr. (dB)	Margin (dB)	Limit (dBµV/m)
1000.000000	32.2	1000.0	1000.000	218.4	H	142.0	-7.2	21.7	53.9
1941.066667	33.3	1000.0	1000.000	245.3	V	141.0	-2.3	20.6	53.9
3949.866667	31.6	1000.0	1000.000	191.5	V	184.0	5.2	22.3	53.9
6547.100000	35.9	1000.0	1000.000	389.1	H	270.0	11.5	18.0	53.9
11027.40000	37.9	1000.0	1000.000	345.1	V	291.0	15.5	16.0	53.9
16768.86666	45.5	1000.0	1000.000	401.7	H	231.0	24.6	8.4	53.9

Test Notes: No significant emissions observed above 3GHz.

2.8.13 Test Results Above 1GHz (Worst Case Axis – High Channel)



Peak Data

Frequency (MHz)	MaxPeak (dBµV/m)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Polarization	Azimuth (deg)	Corr. (dB)	Margin (dB)	Limit (dBµV/m)
1000.000000	45.6	1000.0	1000.000	216.5	H	239.0	-7.2	28.3	73.9
1940.466667	46.9	1000.0	1000.000	331.2	V	-15.0	-2.3	27.0	73.9
4226.433333	45.0	1000.0	1000.000	171.6	H	20.0	5.4	28.9	73.9
4860.333333	49.0	1000.0	1000.000	117.7	V	341.0	6.0	24.9	73.9
11008.33333	51.5	1000.0	1000.000	377.1	V	302.0	15.6	22.4	73.9
16722.96666	58.9	1000.0	1000.000	301.5	V	185.0	24.3	15.0	73.9

Average Data

Frequency (MHz)	Average (dBµV/m)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Polarization	Azimuth (deg)	Corr. (dB)	Margin (dB)	Limit (dBµV/m)
1000.000000	32.4	1000.0	1000.000	216.5	H	239.0	-7.2	21.5	53.9
1940.466667	31.3	1000.0	1000.000	331.2	V	-15.0	-2.3	22.6	53.9
4226.433333	32.3	1000.0	1000.000	171.6	H	20.0	5.4	21.6	53.9
4860.333333	39.6	1000.0	1000.000	117.7	V	341.0	6.0	14.3	53.9
11008.33333	38.3	1000.0	1000.000	377.1	V	302.0	15.6	15.6	53.9
16722.96666	45.1	1000.0	1000.000	301.5	V	185.0	24.3	8.8	53.9

Test Notes: No significant emissions observed above 5GHz.

2.9 RECEIVER SPURIOUS EMISSIONS

2.9.1 Specification Reference

RSS-243 Section 5.6

2.9.2 Standard Applicable

Receiver spurious emissions shall comply with the limits specified in RSS-Gen.

2.9.3 Equipment Under Test and Modification State

Serial No: F3150706024 / Default Test Configuration (Idle Mode)

2.9.4 Date of Test/Initial of test personnel who performed the test

December 07, 2015/FSC

2.9.5 Test Equipment Used

The major items of test equipment used for the above tests are identified in Section 3.1.

2.9.6 Environmental Conditions/ Test Location

Test performed at TÜV SÜD America Inc. Rancho Bernardo facility

Ambient Temperature	22.4 °C
Relative Humidity	29.2 %
ATM Pressure	98.9 kPa

2.9.7 Additional Observations

- This is a radiated test. The spectrum was searched from 30MHz to the 3rd harmonic (up to 10th performed).
- In RX mode, data from the whole system when verified is presented.
- Measurement was done using EMC32 automated software. Reported level is the actual level with all the correction factors factored in. Correction Factor column is for informational purposes only. See Section 2.9.8 for sample computation.

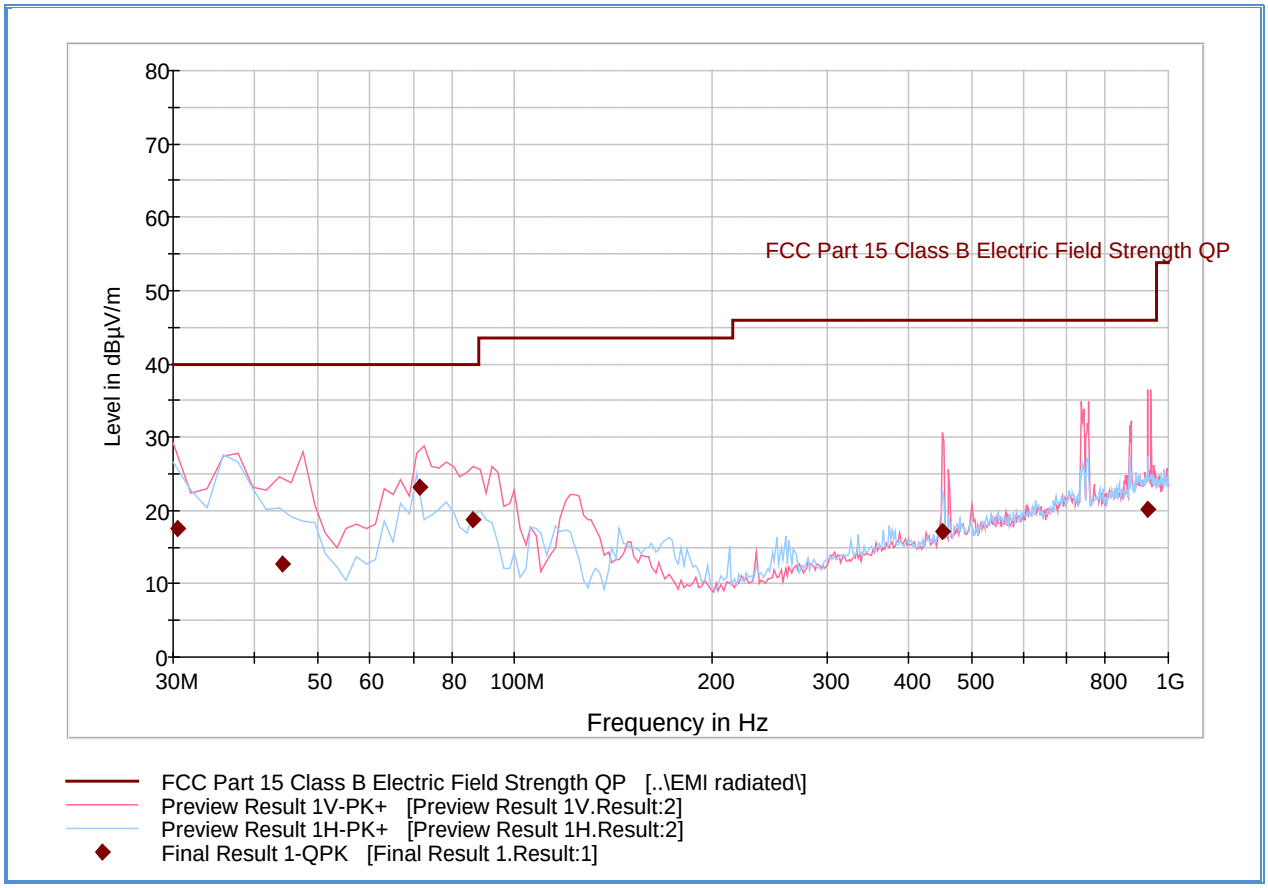
2.9.8 Sample Computation (Radiated Emission)

Measuring equipment raw measurement (dbµV) @ 2400 MHz			53.9
Correction Factor (dB)	Asset# 1153 (cable)	3.4	-0.4
	Asset# 8628(preamplifier)	-36.5	
	Asset#7575 (antenna)	32.7	
Reported Max Peak Final Measurement (dbµV/m) @ 2400 MHz			**53.5**

2.9.9 Test Results

See attached plots.

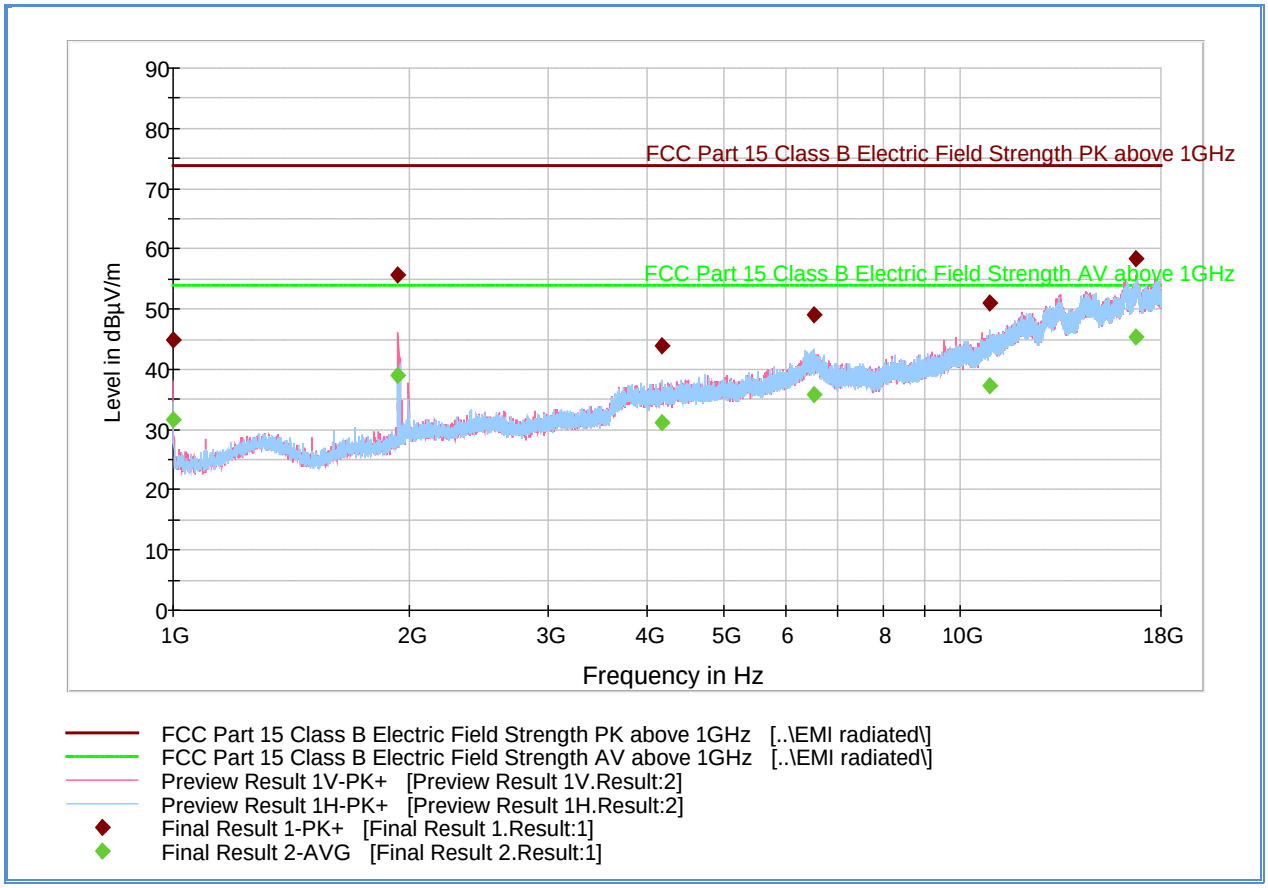
2.9.10 Test Results Below 1GHz



Quasi Peak Data

Frequency (MHz)	QuasiPeak (dBµV/m)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Polarization	Azimuth (deg)	Corr. (dB)	Margin (dB)	Limit (dBµV/m)
30.400000	17.4	1000.0	120.000	108.0	V	15.0	-11.7	22.6	40.0
44.134990	12.7	1000.0	120.000	102.0	V	314.0	-18.3	27.3	40.0
71.605531	23.1	1000.0	120.000	100.0	V	62.0	-22.4	16.9	40.0
86.372745	18.7	1000.0	120.000	123.0	V	223.0	-21.4	21.3	40.0
451.943647	17.1	1000.0	120.000	108.0	V	61.0	-8.1	28.9	46.0
932.100040	20.2	1000.0	120.000	108.0	V	15.0	1.4	25.8	46.0

2.9.11 Test Results Above 1GHz



Peak Data

Frequency (MHz)	MaxPeak (dBµV/m)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Polarization	Azimuth (deg)	Corr. (dB)	Margin (dB)	Limit (dBµV/m)
1000.000000	44.8	1000.0	1000.000	155.6	V	314.0	-7.2	29.1	73.9
1932.366667	55.8	1000.0	1000.000	202.3	V	247.0	-2.3	18.1	73.9
4176.133333	43.9	1000.0	1000.000	343.1	H	182.0	5.3	30.0	73.9
6528.600000	49.1	1000.0	1000.000	181.6	H	160.0	11.5	24.8	73.9
10906.03333	51.0	1000.0	1000.000	402.5	H	280.0	15.1	22.9	73.9
16718.63333	58.4	1000.0	1000.000	227.4	V	247.0	24.3	15.5	73.9

Average Data

Frequency (MHz)	Average (dBµV/m)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Polarization	Azimuth (deg)	Corr. (dB)	Margin (dB)	Limit (dBµV/m)
1000.000000	31.7	1000.0	1000.000	155.6	V	314.0	-7.2	22.2	53.9
1932.366667	38.9	1000.0	1000.000	202.3	V	247.0	-2.3	15.0	53.9
4176.133333	31.1	1000.0	1000.000	343.1	H	182.0	5.3	22.8	53.9
6528.600000	35.7	1000.0	1000.000	181.6	H	160.0	11.5	18.2	53.9
10906.03333	37.4	1000.0	1000.000	402.5	H	280.0	15.1	16.5	53.9
16718.63333	45.3	1000.0	1000.000	227.4	V	247.0	24.3	8.6	53.9

Test Notes: No significant emissions observed above 3GHz.

2.10 ANNEX A – ATTESTATION LETTER FOR FREQUENCY MONITORING

IMTHERA

Date (23-Feb-2016)

TUV SUD BABT TCB/FCB
Octagon House,
Segensworth Road,
Fareham,
Hampshire,
PO15 5RL

Dear Sir or Madam,

We, *ImThera Medical, Inc., 12555 High Bluff Drive, Suit 310, San Diego, California 92130 USA,* hereby declare that the aura6000 Implantable Pulse Generator (ID: 2AGS5-IPG) complies with the requirements of Part 95 Subpart E §95.627(a)(1) to (4) as detailed below:

(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. We comply with this requirement by having the Remote Control and Charger (RCC, Master in this paired MedRadio telemetry system, the IPG being the Slave device) set its center frequency control registers to each of the 17 MedRadio Channel Frequencies in turn (401.01MHz, 401.31MHz, and every 300kHz higher through 405.85MHz), and its bandwidth control registers to 100kHz.

(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. We comply with this requirement by having the Remote Control and Charger (RCC, Master in this paired MedRadio telemetry system, the IPG being the Slave device), set its center frequency control register to the first channel of the MedRadio Channel Frequencies, 401.01MHz. The RCC monitors this frequency for a minimum of 10ms and records the peak value of the received signal strength as measured by the transceiver (CC1101) RSSI register. The RCC then sets its center frequency to the next MedRadio Channel, 300kHz higher than the last frequency at 401.31MHz, and repeats this process until all 17 channels have been monitored.

(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. We comply with this requirement by having the IPG and RCC set their power levels via control registers in the telemetry transceiver (CC1101) to values determined by tested performance by TUV to be compliant with this regulation.

12555 High Bluff Drive, Suite 310 • San Diego, CA 92130 • USA
Phone: +1.858.259.2980 • Fax: +1.858.259.2981
www.imtheramedical.com

IMTHERA

(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. We comply with this requirement by monitoring the MedRadio Band as described above, analyzing the RSSI data for the 17 MedRadio Channels, and the first channel in the MedRadio band that meets the requirements for Clear Channel status is selected and the RCC instructs the IPG to continue communication on this new channel.

Sincerely,

Company Officer: Paul Meadows, VP R&D, CTO

Telephone Number: +1-858-259-2980 ext. 11

Email: PMeadows@ImTheraMedical.com

12555 High Bluff Drive, Suite 310 • San Diego, CA 92130 • USA
Phone: +1.858.259.2980 • Fax: +1.858.259.2981
www.imtheramedical.com

SECTION 3

TEST EQUIPMENT USED

3.1 TEST EQUIPMENT USED

List of absolute measuring and other principal items of test equipment.

ID Number (SDGE/SDRB)	Test Equipment	Type	Serial Number	Manufacturer	Cal Date	Cal Due Date
Conducted Emissions						
1024	1024	1024	1024	1024	1024	1024
7567	7567	7567	7567	7567	7567	7567
8822	8822	8822	8822	8822	8822	8822
8824	8824	8824	8824	8824	8824	8824
Radiated Emission						
1002	Bilog Antenna	3142C	00058717	ETS-Lindgren	01/30/14	01/30/16
7575	Double-ridged waveguide horn antenna	3117	00155511	EMCO	04/27/15	04/27/16
8628	Pre-amplifier	QLJ 01182835-JO	8986002	QuinStar Technologies Inc.	03/20/15	03/20/16
1153	High-frequency cable	SucoFlex 100 SX	N/A	Suhner	04/03/15	04/03/16
1040	EMI Test Receiver	ESIB40	100292	Rhode & Schwarz	09/29/15	09/29/16
1049	EMI Test Receiver	ESU	100133	Rhode & Schwarz	03/11/15	03/11/16
1016	Pre-amplifier	PAM-0202	187	PAM	12/10/14	12/10/15
Miscellaneous						
	Test Software	EMC32	V8.53	Rhode & Schwarz	N/A	
6792	Multimeter	3478A	2911A70964	Hewlett Packard	08/14/15	08/14/16
7560	Barometer/Temperature/Humidity Transmitter	iBTHX-W	1240476	Omega	10/19/15	10/19/16

3.2 MEASUREMENT UNCERTAINTY

For a 95% confidence level, the measurement uncertainties for defined systems are:

3.2.1 Radiated Measurements (Below 1GHz)

	Contribution	Probability Distribution Type	Probability Distribution x_i	Standard Uncertainty $u(x_i)$	$[u(x_i)]^2$
1	Receiver/Spectrum Analyzer	Rectangular	0.45	0.26	0.07
2	Cables	Rectangular	0.50	0.29	0.08
3	Preamp	Rectangular	0.50	0.29	0.08
4	Antenna	Rectangular	0.75	0.43	0.19
5	Site	Rectangular	2.70	1.56	2.43
6	EUT Setup	Rectangular	1.00	0.58	0.33
				Combined Uncertainty (u_c):	1.78
				Coverage Factor (k):	2
				Expanded Uncertainty:	3.57

3.2.2 Radiated Measurements (Above 1GHz)

	Contribution	Probability Distribution Type	Probability Distribution x_i	Standard Uncertainty $u(x_i)$	$[u(x_i)]^2$
1	Receiver/Spectrum Analyzer	Rectangular	0.57	0.33	0.11
2	Cables	Rectangular	0.70	0.40	0.16
3	Preamp	Rectangular	0.50	0.29	0.08
4	Antenna	Rectangular	0.37	0.21	0.05
5	Site	Rectangular	2.70	1.56	2.43
6	EUT Setup	Rectangular	1.00	0.58	0.33
				Combined Uncertainty (u_c):	1.78
				Coverage Factor (k):	2
				Expanded Uncertainty:	3.57

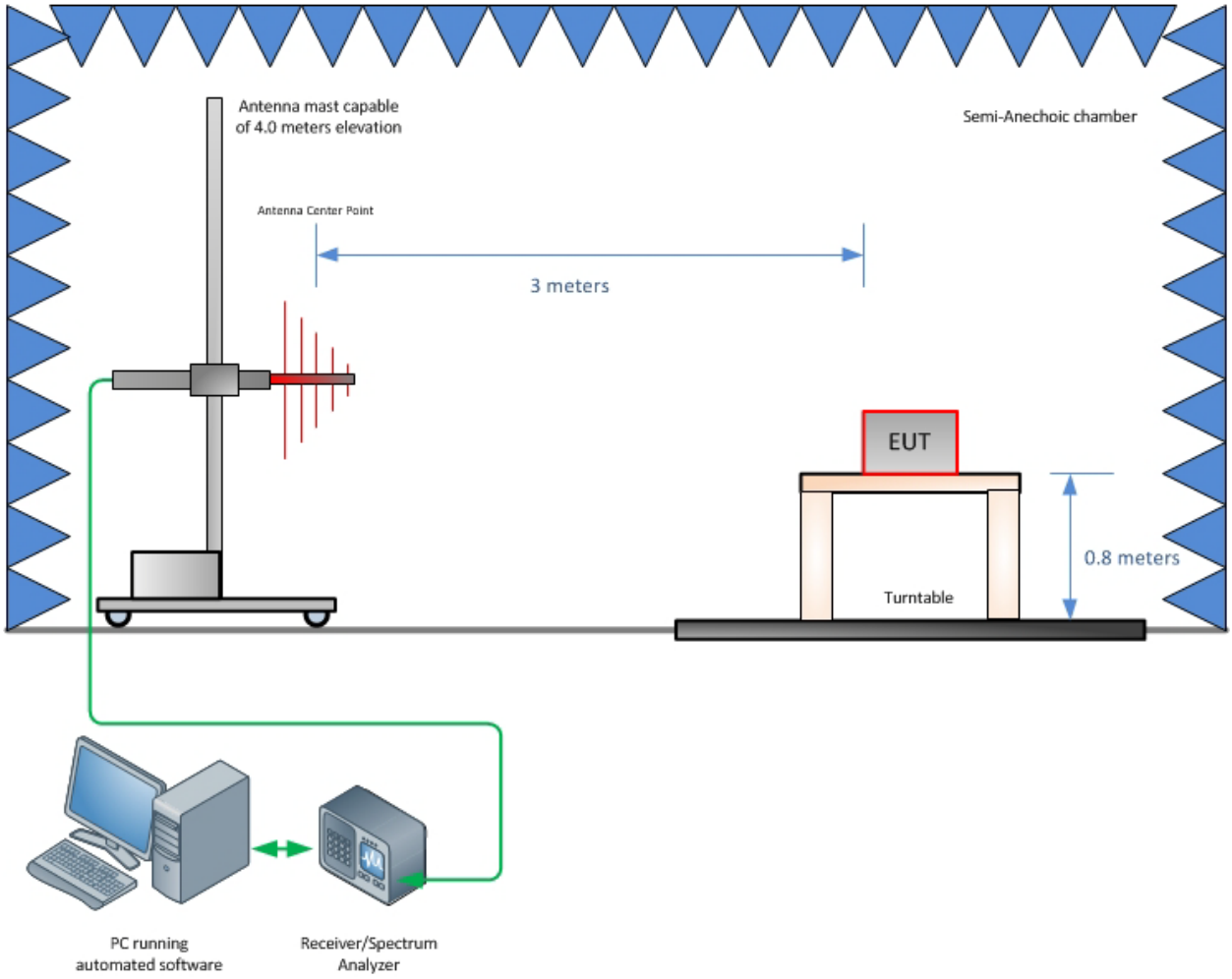
3.2.1 AC Conducted Measurements

	Contribution	Probability Distribution Type	Probability Distribution x_i	Standard Uncertainty $u(x_i)$	$[u(x_i)]^2$
1	Receiver/Spectrum Analyzer	Rectangular	0.36	0.21	0.04
2	Cables	Rectangular	0.50	0.29	0.08
3	LISN	Rectangular	0.66	0.38	0.15
4	Attenuator	Rectangular	0.30	0.17	0.03
5	EUT Setup	Rectangular	1.00	0.58	0.33
				Combined Uncertainty (u_c):	0.80
				Coverage Factor (k):	2
				Expanded Uncertainty:	1.59

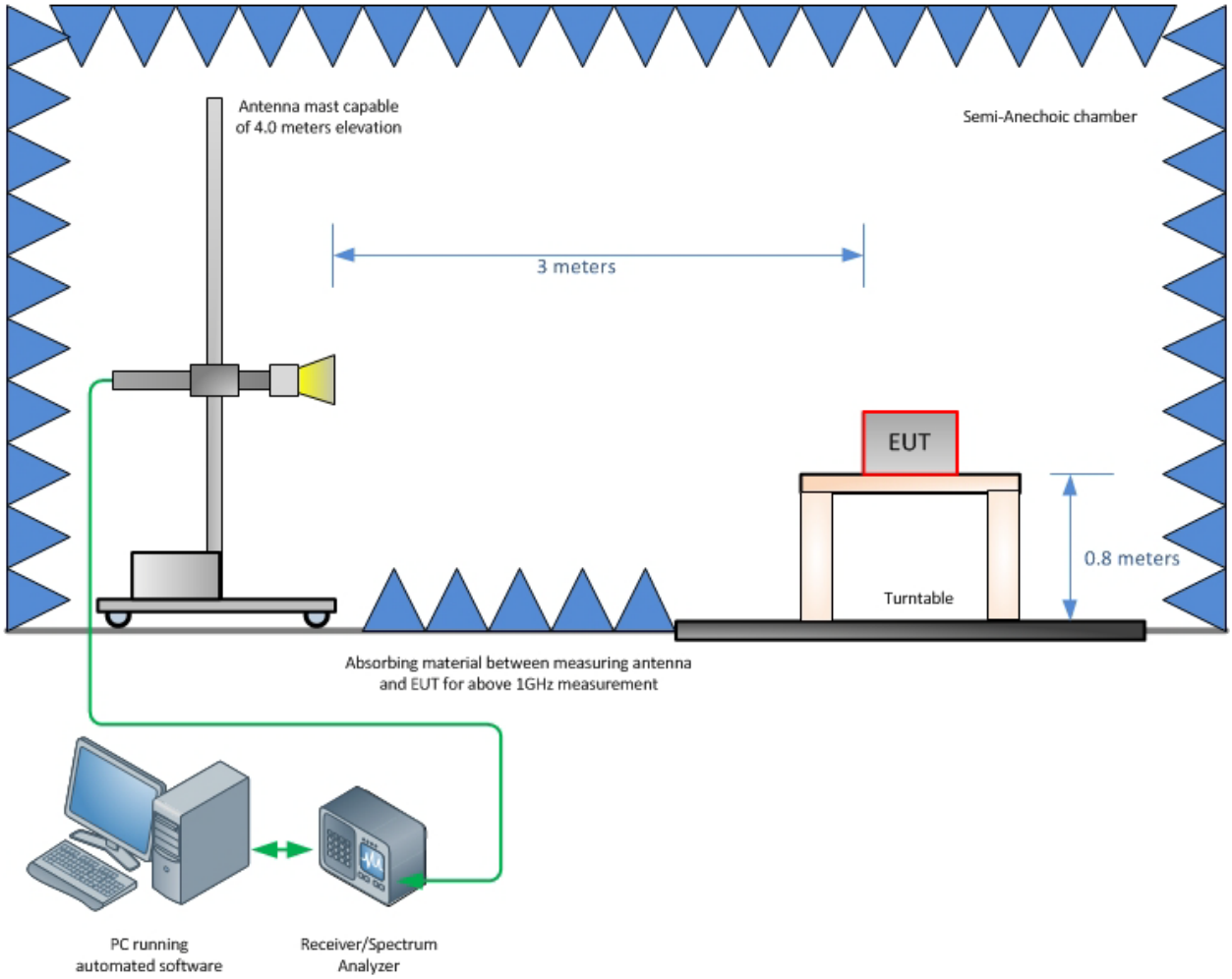
SECTION 4

DIAGRAM OF TEST SETUP

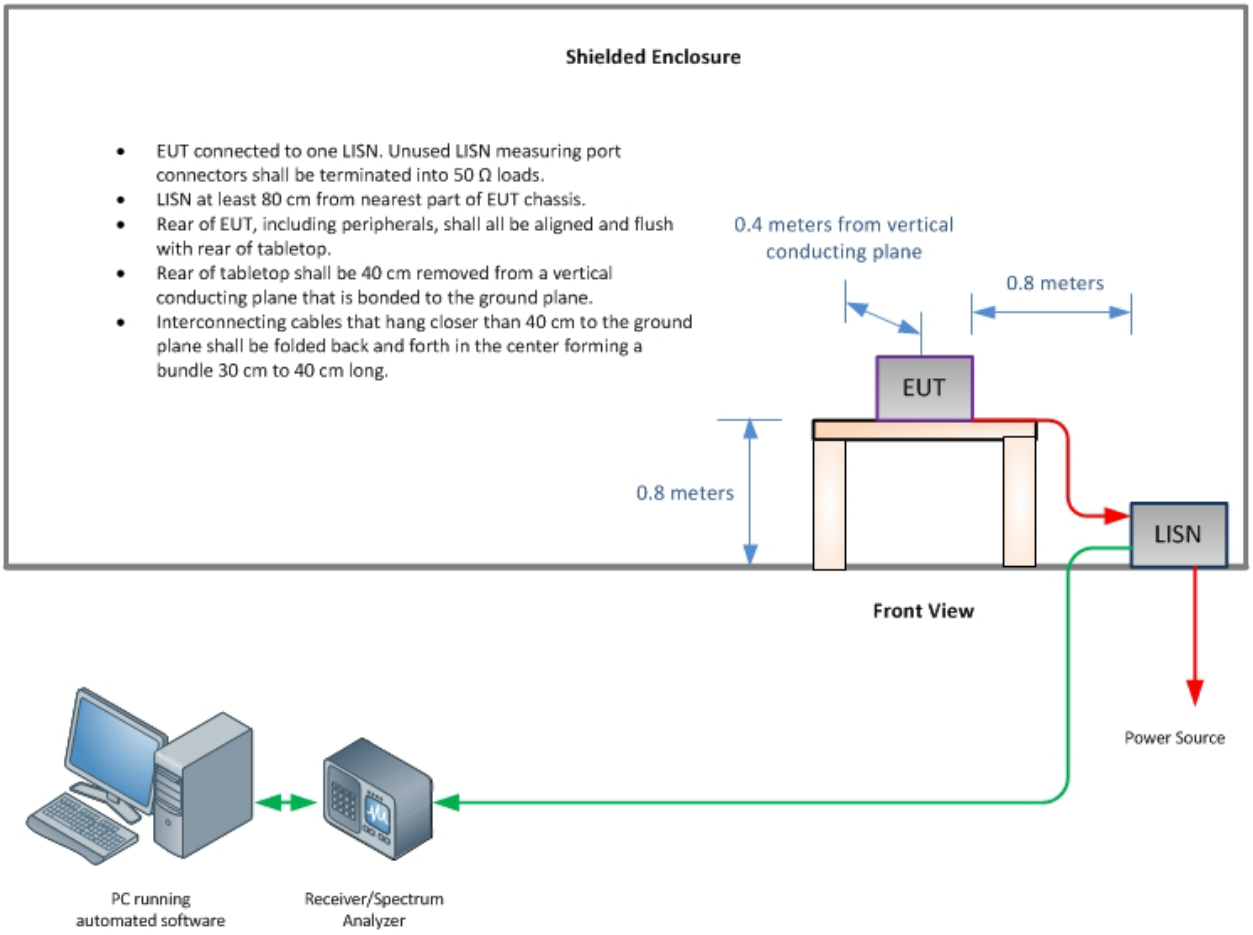
4.1 TEST SETUP DIAGRAM



Radiated Emission Test Setup (Below 1GHz)



Radiated Emission Test Setup (Above 1GHz)



Conducted Emission Test Setup

SECTION 5

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5.1 ACCREDITATION, DISCLAIMERS AND COPYRIGHT

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