

TEST REPORT

Report Number: 102499373MPK-053

Project Number: G102499373

April 21, 2016

**Testing performed on
Orthofix PEMF Device
Model: 5505
FCC ID: 2AHVN-OFIX-5000-001
IC: 21309-5000OFIX001
to**

**FCC Part 15 Subpart C (15.247)
Industry Canada RSS-247 Issue 1**

For

Orthofix, Inc.

Test Performed by:

Intertek

1365 Adams Court

Menlo Park, CA 94025 USA

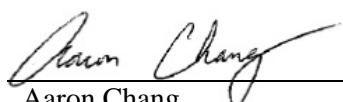
Test Authorized by:

Orthofix, Inc.

3451 Plano Pkwy

Lewisville, TX 75056 USA

Prepared by:



Aaron Chang

Date: April 21, 2016

Reviewed by:



Krishna K Vemuri

Date: April 21, 2016

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Report No. 102499373MPK-053**Equipment Under Test:**

Orthofix PEMF Device

Trade Name:

Orthofix, Inc.

Model Number:

5505

Serial Number:

0260560003

Applicant:

Orthofix, Inc.

Contact:

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Orthofix, Inc.

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PhilipGarman@Orthofix.com

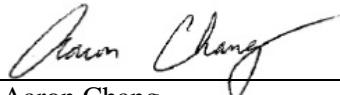
Applicable Regulation:

FCC Part 15 Subpart C (15.247)

Industry Canada RSS-247 Issue 1

Date of Test:

March 21 - 24, 2016

We attest to the accuracy of this report:

Aaron Chang
Project Engineer

Krishna K Vemuri
EMC Engineering Team Lead

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1.0 Summary of Tests

Test	Reference FCC	Reference Industry Canada	Result
RF Output Power	15.247(b)(3)	RSS-247, 5.4.4	Complies
6 dB Bandwidth	15.247(a)(2)	RSS-247, 5.2.1	Complies
Power Density	15.247(e)	RSS-247, 5.2.2	Complies
Out of Band Antenna Conducted Emission	15.247(d)	RSS-247, 5.5	Complies
Transmitter Radiated Emissions	15.247(d), 15.209, 15.205	RSS-247, 5.5	Complies
AC Line Conducted Emission	15.207	RSS-GEN	Not Applicable ¹
Antenna Requirement	15.203	RSS-GEN	Complies (Internal Antenna & Unique connector)
RF Exposure	15.247(i), 2.1093(d)	RSS-102	Complies

¹EUT is battery operated in normal operation.

EUT receive date: March 21, 2016

EUT receive condition: The pre-production version of the EUT was received in good condition with no apparent damage. As declared by the Applicant, it is identical to the production units.

Test start date: March 21, 2016

Test completion date: March 24, 2016

The test results in this report pertain only to the item tested.

2.0 General Information

2.1 Product Description

The Cervical-Stim osteogenesis (bone growth) stimulator is an external device that generates a Pulsed Electromagnetic Field (PEMF) signal as a nonsurgical, prescription treatment to increase the chances of a successful fusion. The device is lightweight, adjustable, and portable, including a rechargeable battery that allows freedom of movement during treatment. A Liquid Crystal Display (LCD) and audible indicators provide important feedback during treatment. Cervical-Stim comes with an optional comfort collar for improved fit and support around the treatment coil. It consists of one Bluetooth 4.0 (BLE) radio.

Information about the Bluetooth 4.0 (BLE) radio is presented below:

For more information, refer to the following product specification, declared by the manufacturer.

Information about the 2.4 GHz radio is presented below:

Applicant	Orthofix, Inc.
Model No.	5505
FCC Identifier	2AHVN-OFIX-5000-001
IC Identifier	21309-5000OFIX001
Type of transmission	Digital Transmission System (DTS)
Rated RF Output	-7.6 dBm (0.174 mW)
Antenna(s) & Gain	PCB antenna, Gain: -3.86 dBi
Frequency Range	2402 – 2480 MHz
Type of modulation/data rate	GFSK / 1Mbit/s
Number of Channel(s)	40
Applicant Name & Address	Orthofix, Inc. 3451 Plano Pkwy Lewisville, TX 75056 USA

2.2 Related Submittal(s) Grants

None.

2.3 Test Facility

The test site used to collect the radiated data is site 1 (10-m semi-anechoic chamber). This test facility and site measurement data have been fully placed on file with the FCC, IC and A2LA accredited.

2.4 Test Methodology

Antenna conducted measurements were performed according to the FCC documents "Guidance for Performing Compliance Measurement on Digital Transmission Systems (DTS) Operating under §15.247" (KDB 558074 D01 DTS Meas Guidance v03r04 January 7, 2016), and RSS-247, RSS-GEN.

Radiated emissions and AC mains conducted emissions measurements were performed according to the procedures in ANSI C63.10-2013. Radiated tests were performed at an antenna to EUT distance of 3 meters, unless stated otherwise in the "Data Sheet" of this report.

2.5 Measurement Uncertainty

Compliance with the limits was based on the results of the measurements and doesn't take into account the measurement uncertainty.

Estimated Measurement Uncertainty

Measurement	Expanded Uncertainty (k=2)		
	0.15 MHz – 1 GHz	1 GHz – 2.5 GHz	> 2.5 GHz
RF Power and Power Density – antenna conducted	-	0.7 dB	-
Unwanted emissions - antenna conducted	1.1 dB	1.3 dB	1.9 dB
Bandwidth – antenna conducted	-	30 Hz	-
Radiated emissions	4.2 dB	3.4 dB	4.4 dB
AC mains conducted emissions	2.4 dB	-	-

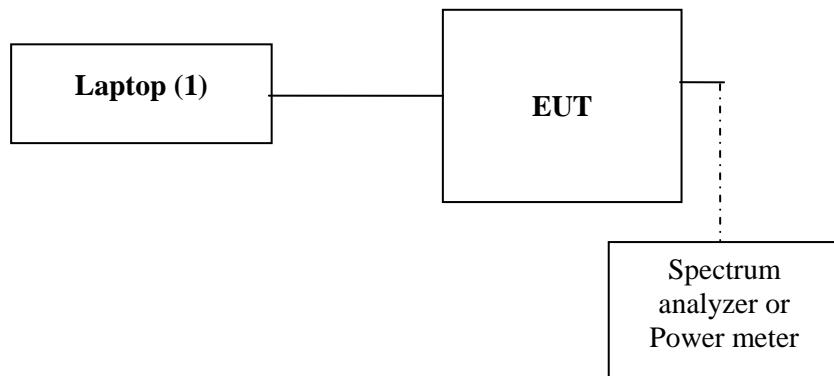
3.0 System Test Configuration

3.1 Support Equipment

Item #	Description	Model No./ Part No.	Serial No.
1	Dell Laptop	Latitude D620	345452

3.2 Block Diagram of Test Setup

Antenna was removed and co-axial connector with a cable was installed for Conducted Measurements.
Laptop was only used to configure the radio.



S = Shielded
U = Unshielded

F = With Ferrite
m = Length in Meters

3.3 Justification

For radiated emission measurements the EUT is placed on a non-conductive table.

3.4 Software Exercise Program

The EUT exercise program used during radiated and conducted testing was provided by Orthofix, Inc..

3.5 Mode of Operation during Test

During transmitter testing, the transmitter was setup to transmit at maximum RF power on low, middle and high frequencies/channels.

3.5 Modifications Required for Compliance

Intertek installed no modifications during compliance testing in order to bring the product into compliance.

3.6 Additions, Deviations and Exclusions from Standards

No additions, deviations or exclusions from the standard were made.

4.0 Measurement Results

4.1 6-dB Bandwidth and Occupied Bandwidth FCC Rule: 15.247(a)(2); RSS-247 A8.2 and RSS-GEN;

4.1.1 Requirement

The minimum 6-dB bandwidth shall be at least 500 kHz

4.1.2 Procedure

A spectrum analyzer was connected to the antenna port of the transmitter.

For FCC 6dB Channel Bandwidth the Procedure described in the FCC Publication 558074 D01 DTS Meas Guidance v03r04 January 7, 2016 was used to determine the DTS occupied bandwidth. Section 8.1 Option 1 was used.

1. Set RBW = 100 kHz.
2. Set the video bandwidth (VBW) $\geq 3 \times$ RBW.
3. Detector = Peak.
4. Trace mode = max hold.
5. Sweep = auto couple.
6. Allow the trace to stabilize.
7. Measure the maximum width of the emission that is constrained by the frequencies associated with the two outermost amplitude points (upper and lower frequencies) that are attenuated by 6 dB relative to the maximum level measured in the fundamental emission.

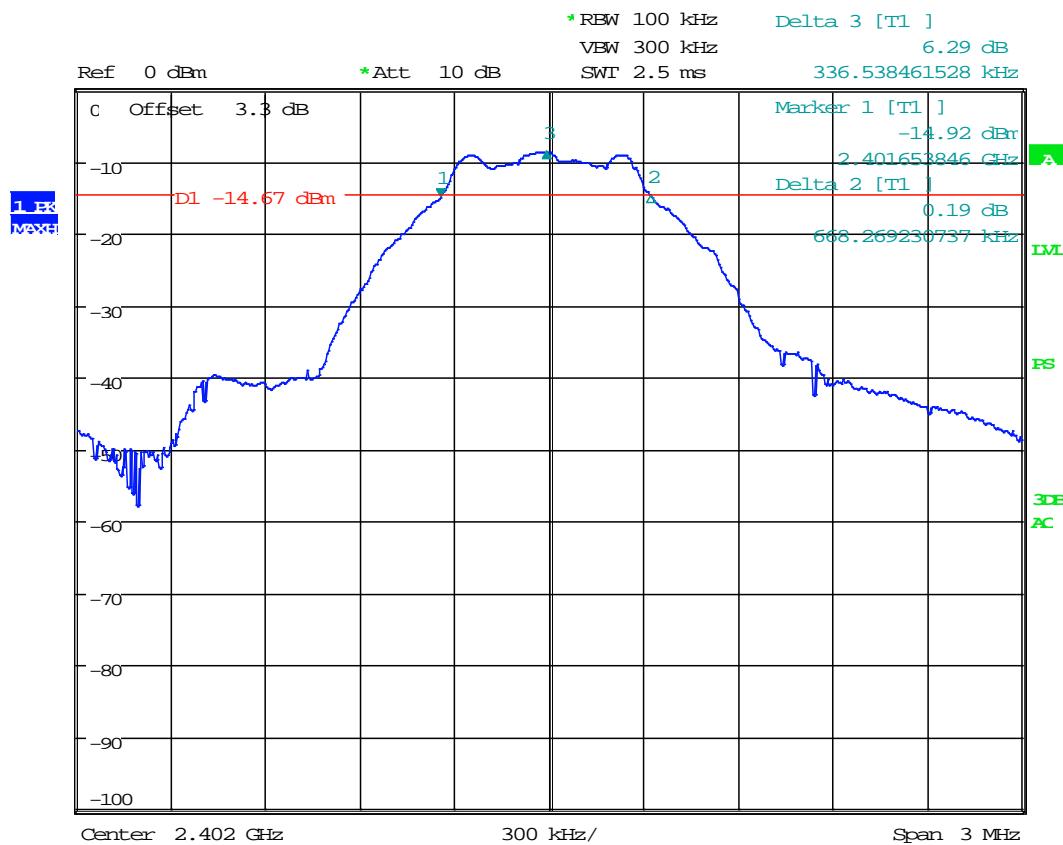
For 99% power bandwidth measurement, the bandwidth was determined by using the built-in 99% occupied bandwidth function of the spectrum analyzer. The resolution bandwidth is set to 1% of the selected span as is without being below 1%. The video bandwidth shall be set to 3 times the resolution bandwidth.

4.1.3 Test Result

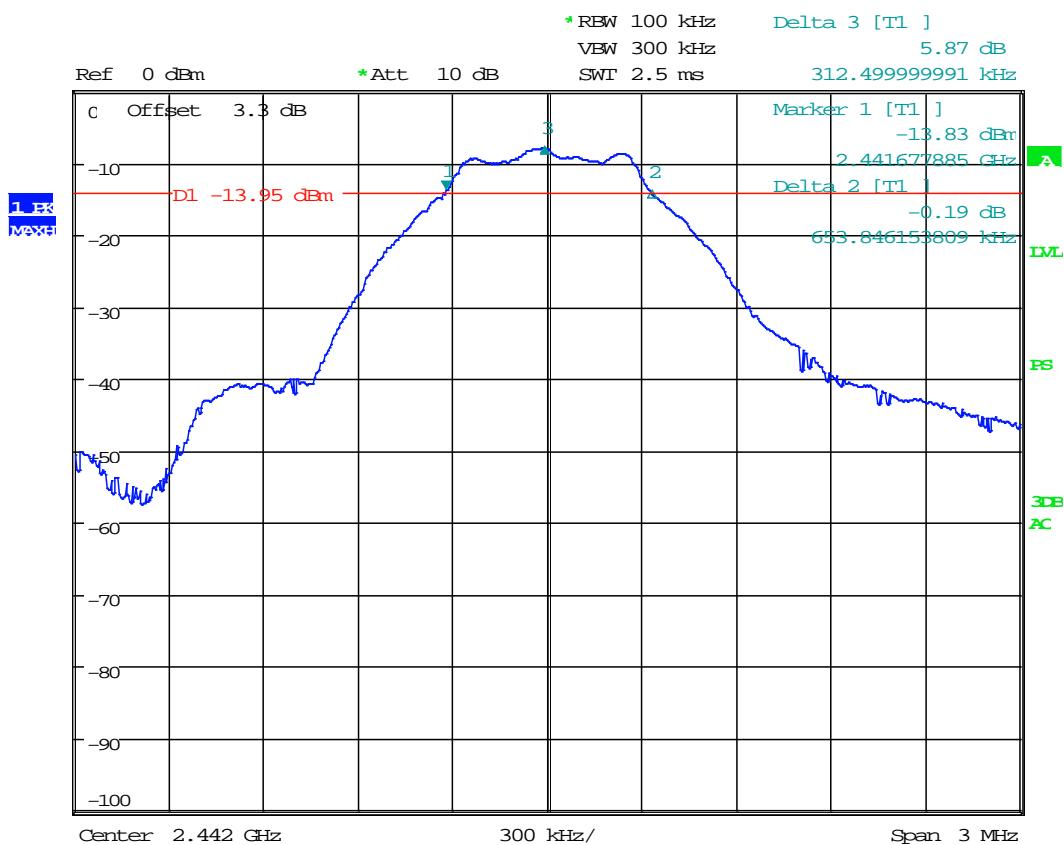
Frequency (MHz)	6-dB bandwidth FCC 15.247 & RSS-GEN, MHz	Occupied bandwidth, RSS-GEN, MHz	Plot
2402	0.668	--	1.1
	--	1.014	1.4
2442	0.654	--	1.2
	--	1.024	1.5
2480	0.644	--	1.3
	--	1.014	1.6

Date of Test:	March 21, 2016
Results	Complies

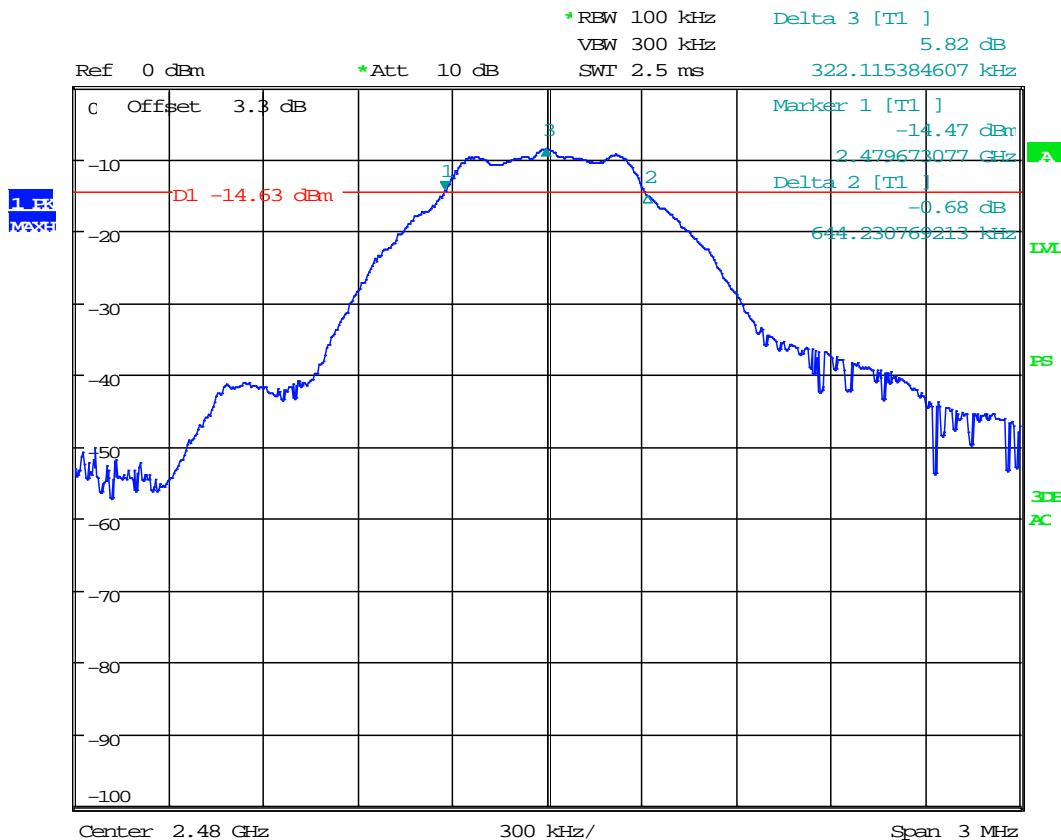
Plot 1. 1



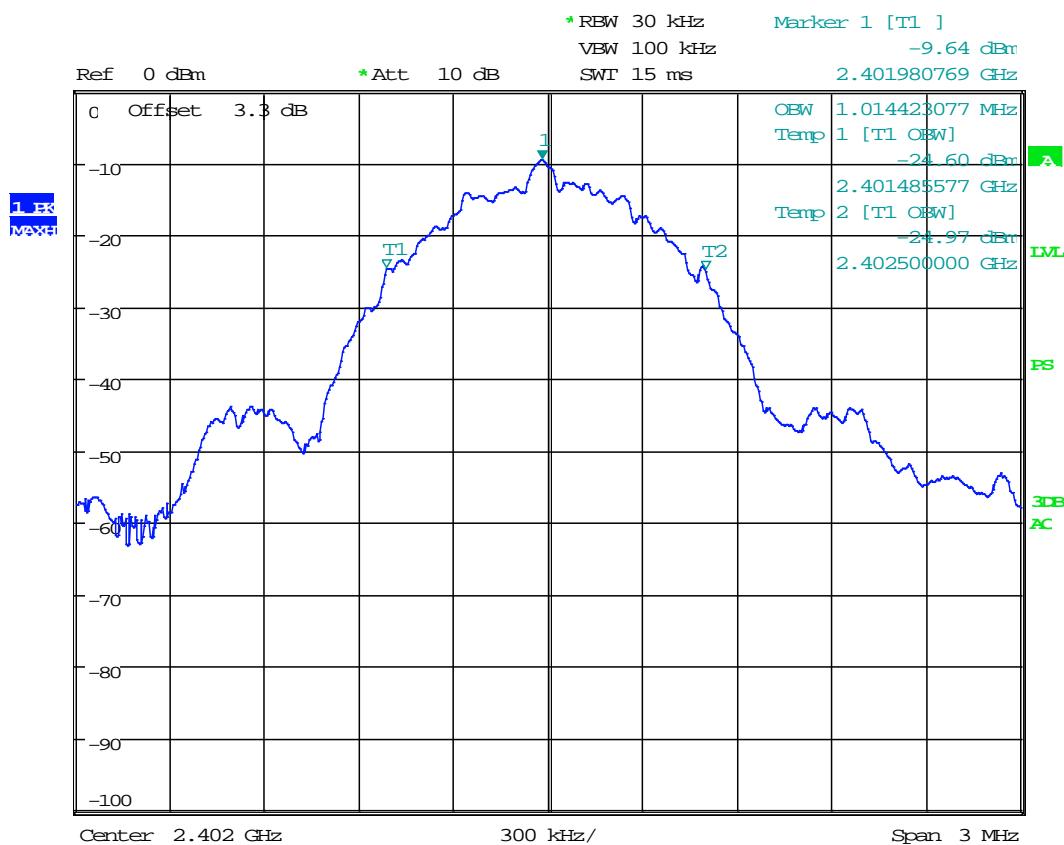
Plot 1. 2



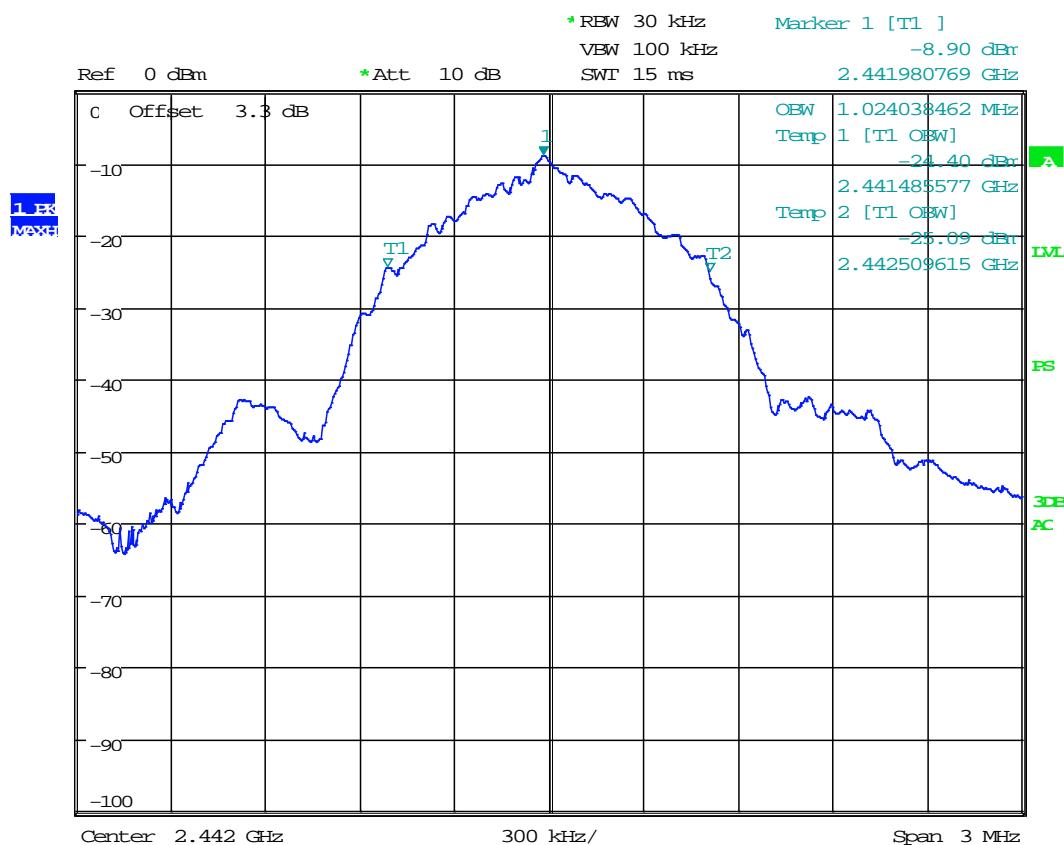
Plot 1. 3



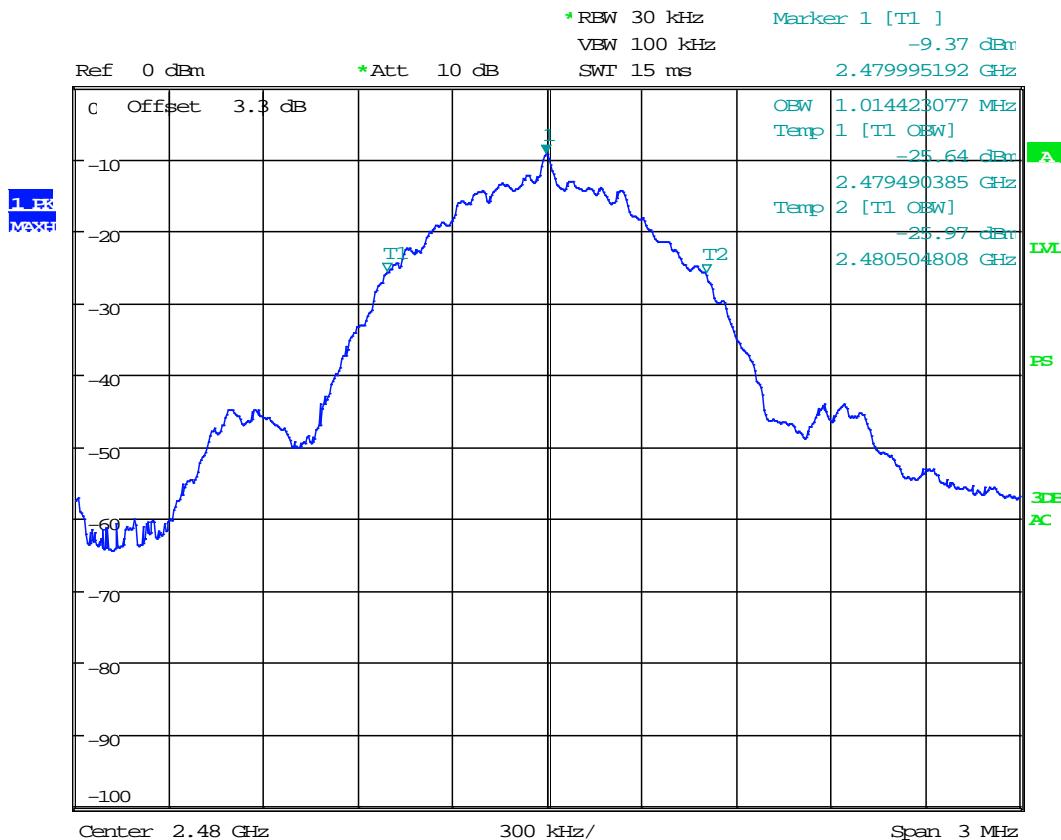
Plot 1.4



Plot 1.5



Plot 1.6



4.2 Maximum Peak Conducted Output Power at Antenna Terminals FCC Rule: 15.247(b)(3); RSS-247 A8.4;

4.2.1 Requirement

For antennas with gains of 6 dBi or less, maximum allowed transmitter output is 1 watt or 30 dBm. For antennas with gains greater than 6 dBi, transmitter output level must be decreased appropriately, by the amount in dB that the directional gain of the antenna exceeds 6 dBi.

4.2.2 Procedure

The procedure described in FCC Publication 558074 D01 DTS Meas Guidance v03r04 January 7, 2016 was used. Specifically, section 9.1.1 RBW \geq DTS Bandwidth was utilized as the spectrum analyzer's resolution bandwidth was greater than the DTS bandwidth.

1. Set the $\text{RBW} \geq \text{DTS Bandwidth}$
2. Set the $\text{VBW} \geq 3 \times \text{RBW}$
3. Set the span $\geq 3 \times \text{RBW}$
4. Detector = Peak
5. Sweep time = Auto couple
6. Trace mode = Max Hold
7. Allow trace to fully stabilize
8. Use peak marker function to determine the peak amplitude level.

A spectrum analyzer was connected to the antenna port of the transmitter.

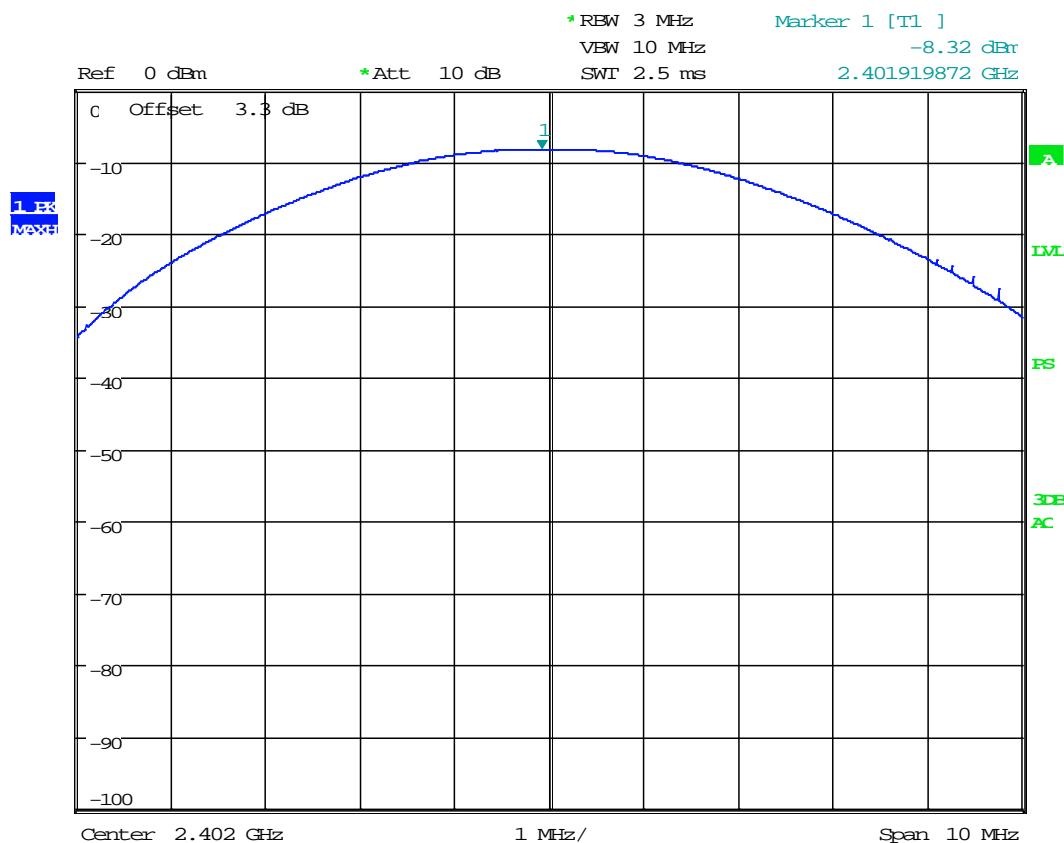
4.3.3 Test Result

Refer to the following plots 2.1 – 2.3 for the test details.

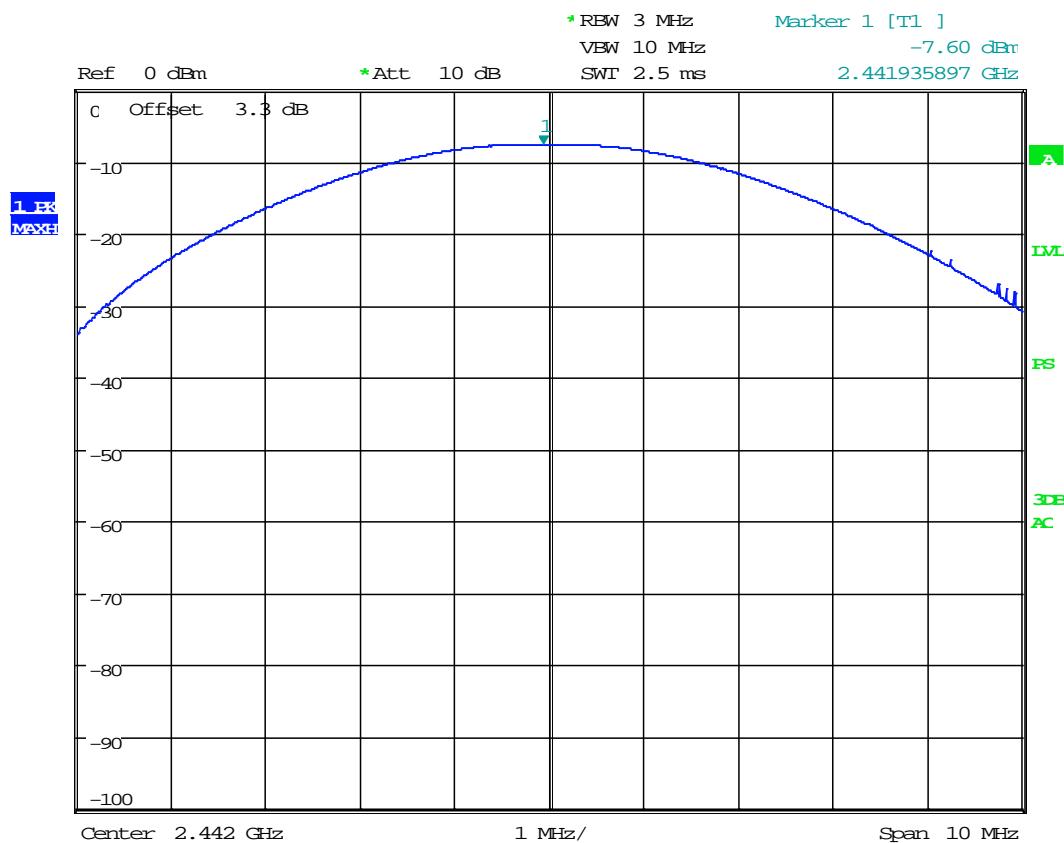
Frequency, MHz	Conducted Power (peak), dBm	Conducted Power (peak), mW	Plot
2402	-8.32	0.147	2.1
2442	-7.60	0.174	2.2
2480	-8.23	0.150	2.3

Date of Test:	March 21, 2016
Results	Complies

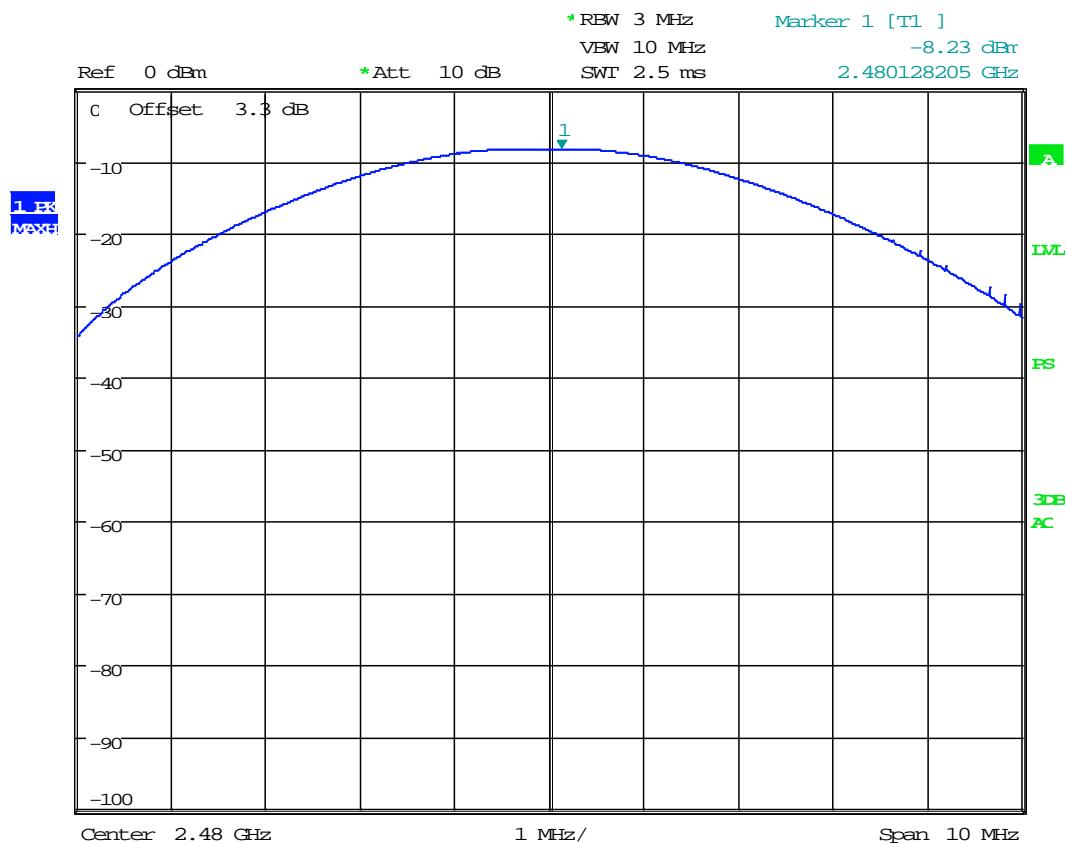
Plot 2. 1



Plot 2.2



Plot 2.3



4.3 Maximum Power Spectral Density FCC: 15.247 (e); RSS-247 A8.2b;

4.3.1 Requirement

For digitally modulated systems, the power spectral density conducted from the intentional radiator to the antenna should not be greater than 8 dBm in any 3 kHz band during any time interval of continuous transmission.

4.3.2 Procedure

A spectrum analyzer was connected to the antenna port of the transmitter.

The procedure described in FCC Publication 558074 D01 DTS Meas Guidance v03r04 January 7, 2016, specifically section 10.2 Method PKPSD (peak PSD).

1. Set analyzer center frequency to DTS channel center frequency.
2. Set the span to 1.5 times the *DTS bandwidth*.
3. Set the RBW to: $3 \text{ kHz} \leq \text{RBW} \leq 100 \text{ kHz}$.
4. Set the VBW $\geq 3 \times \text{RBW}$.
5. Detector = peak.
6. Sweep time = auto couple.
7. Trace mode = max hold.
8. Allow trace to fully stabilize.
9. Use the peak marker function to determine the maximum amplitude level within the RBW.
10. If measured value exceeds limit, reduce RBW (no less than 3 kHz) and repeat.

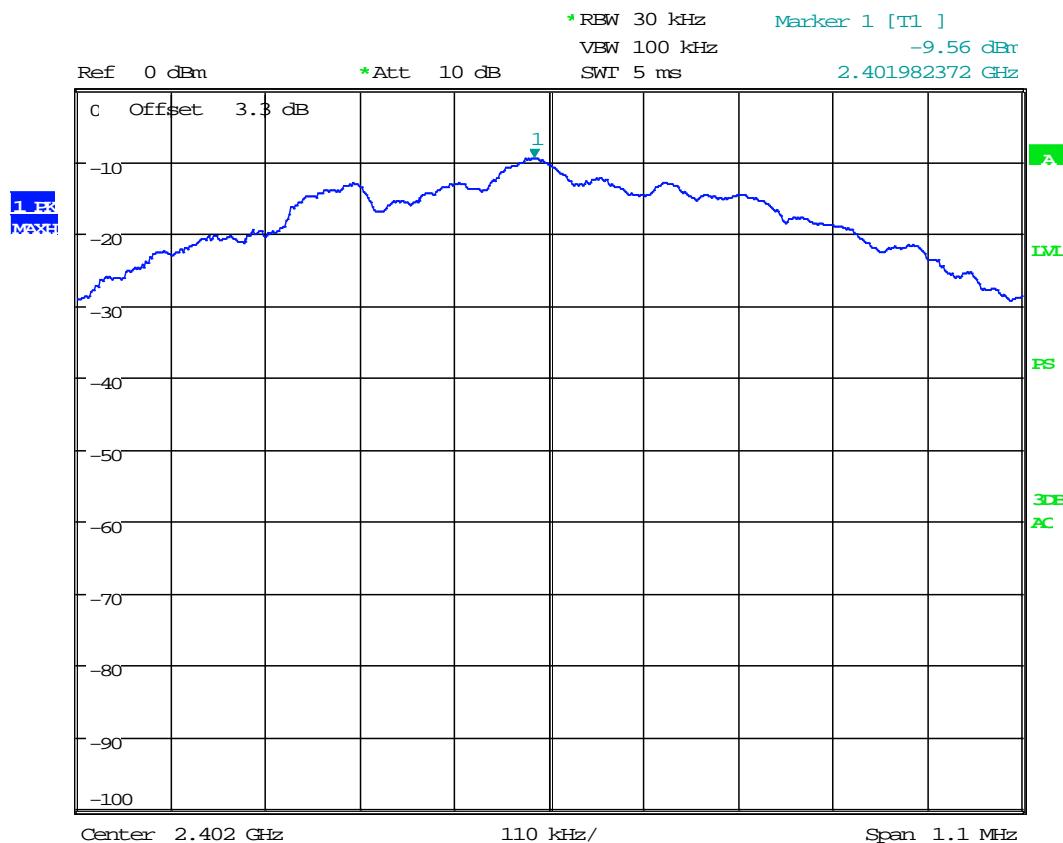
4.3.3 Test Result

Refer to the following plots for the test result

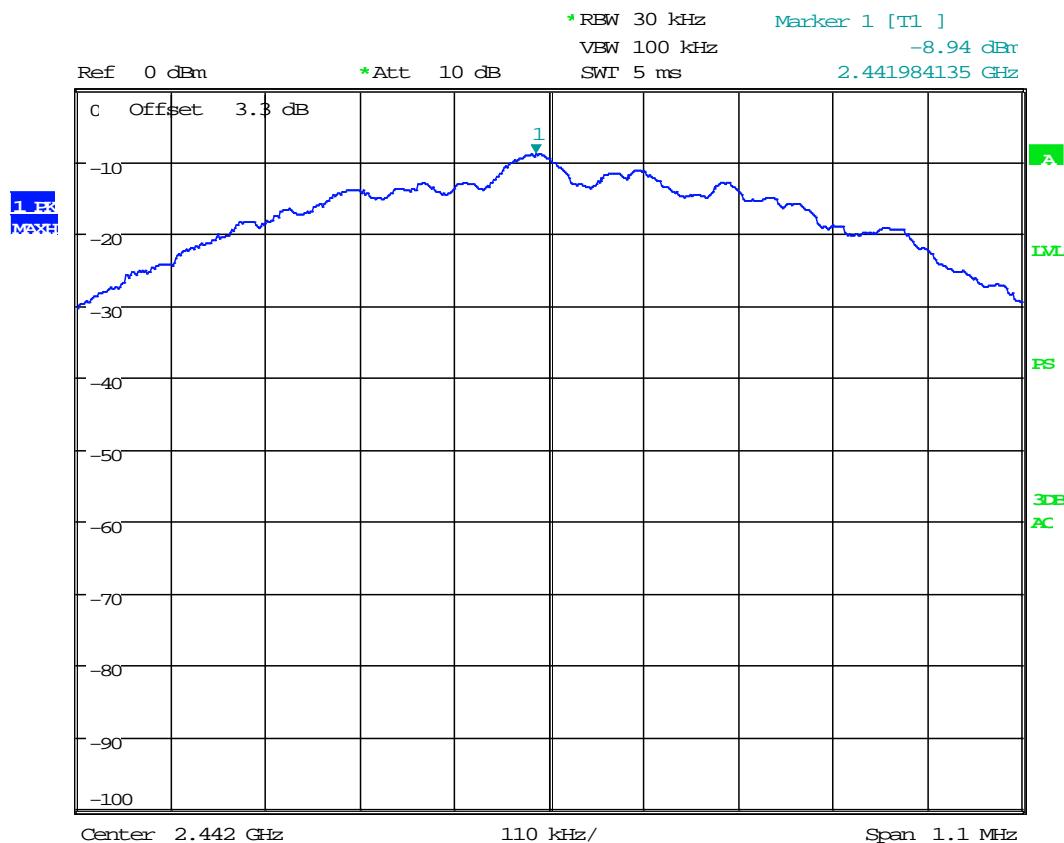
Frequency, MHz	Maximum Power Spectral Density, dBm	Maximum Power Spectral Density Limit, dBm	Margin, dB	Plot
2402	-9.56	8.0	-17.56	3.1
2442	-8.94	8.0	-16.94	3.2
2480	-9.40	8.0	-17.4	3.3

Date of Test:	March 21, 2016
Results	Complies

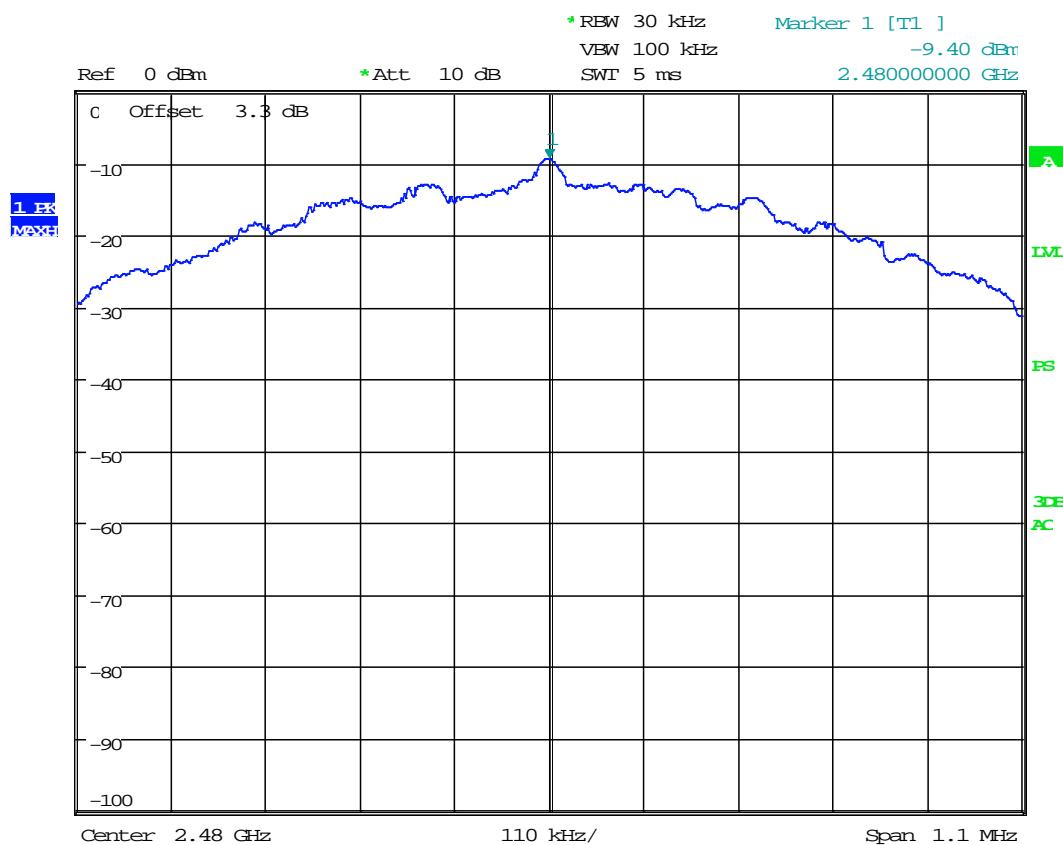
Plot 3. 1



Plot 3. 2



Plot 3.3



4.4 Unwanted Conducted Emissions
FCC: 15.247(d); RSS-247 A8.5;

4.4.1 Requirement

In any 100 kHz bandwidth outside the EUT pass-band, the RF power shall be below the maximum in-band 100 kHz emissions by at least 20 dB (if peak power of in-band emission is measured) or 30 dB (if average power of in-band emission is measured).

In addition, radiated emissions which fall in the restricted bands, as defined in § 15.205(a), must also comply with the radiated emission limits specified in § 15.209(a)

4.4.2 Procedure

The procedure described in FCC Publication 558074 D01 DTS Meas Guidance v03r04 January 7, 2016, specifically section 11.0 Emissions in non-restricted frequency bands.

A spectrum analyzer was connected to the antenna port of the transmitter.

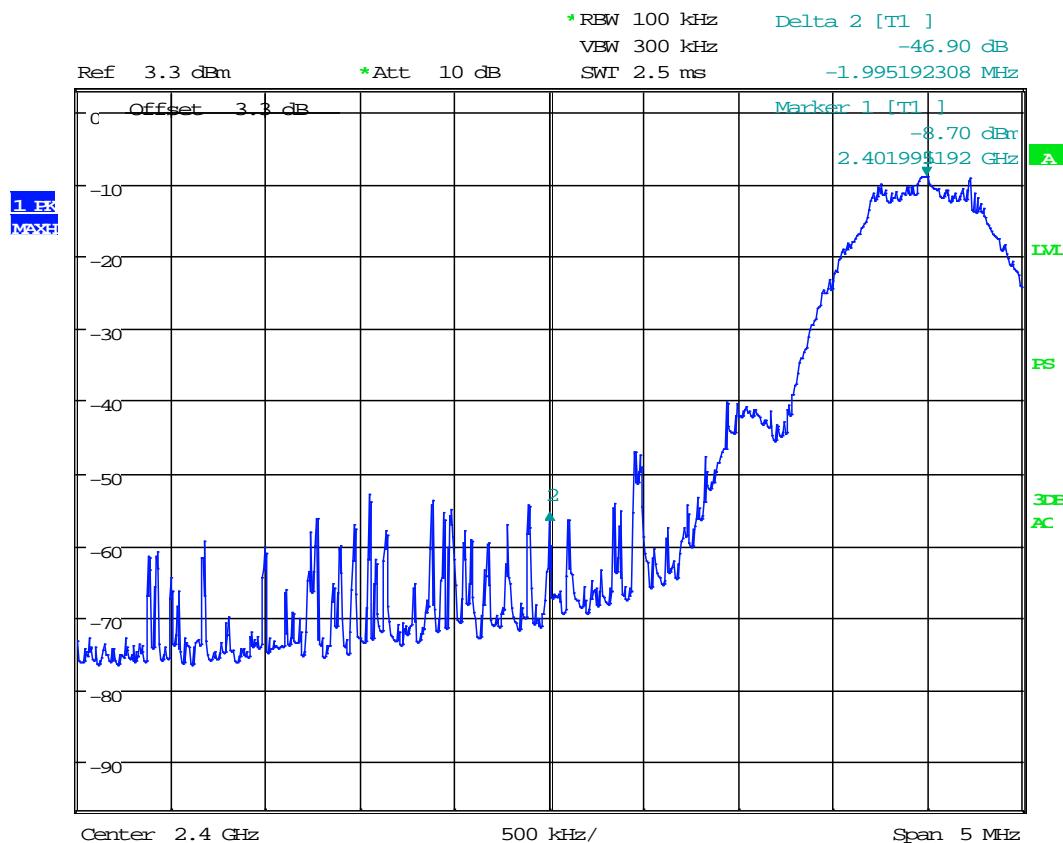
1. Set the RBW = 100 kHz.
2. Set the VBW \geq 3 x RBW.
3. Detector = peak.
4. Sweep time = auto couple.
5. Trace mode = max hold.
6. Allow trace to fully stabilize.
7. Use the peak marker function to determine the maximum amplitude level.

The unwanted emissions were measured from 30 MHz to 25 GHz. Plots below are corrected for cable loss and then compared to the limits.

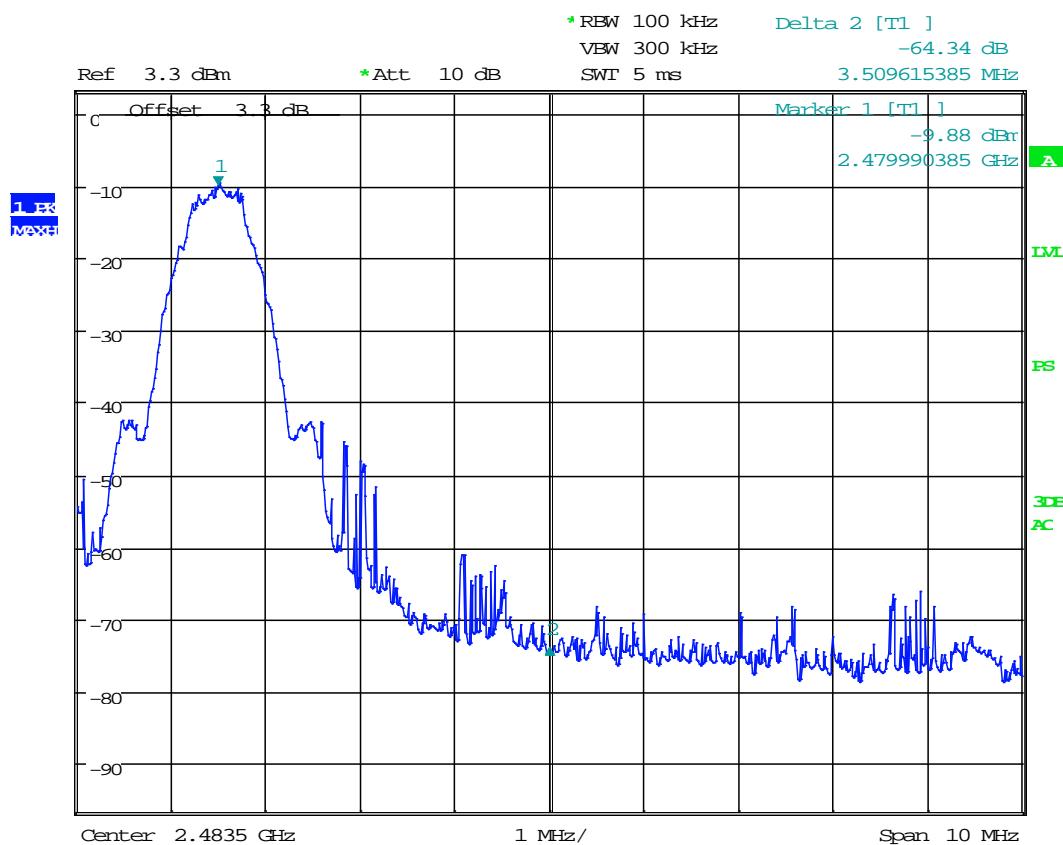
4.4.3 Test Result

Refer to the following plots 4.1 – 4.5 for unwanted conducted emissions. The plot shows -20dB attenuation limit line.

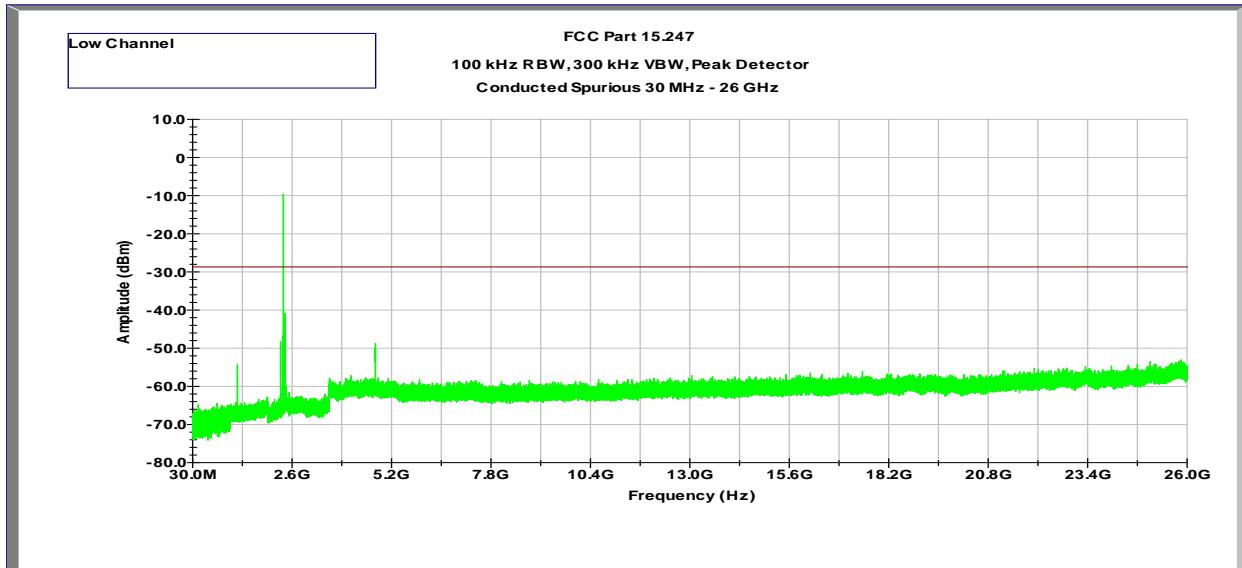
Date of Test:	March 21, 2016
Results	Complies

Tx @ Low Channel, 2400 MHz Band Edge
Plot 4.1

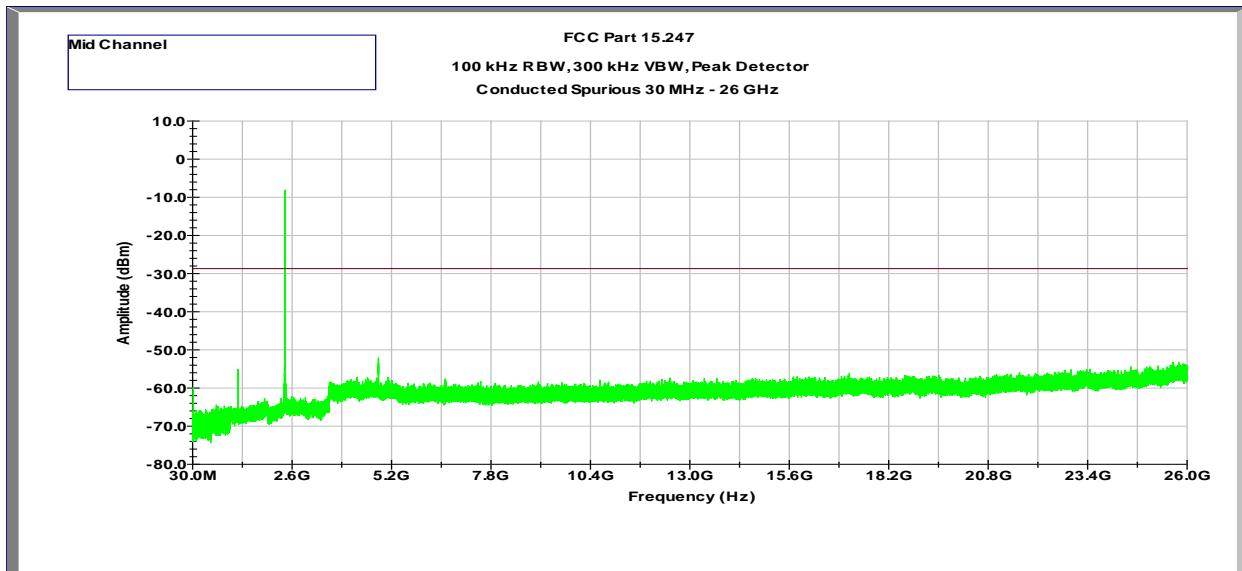
Tx @ Low Channel, 2483.5 MHz Band Edge
Plot 4.2



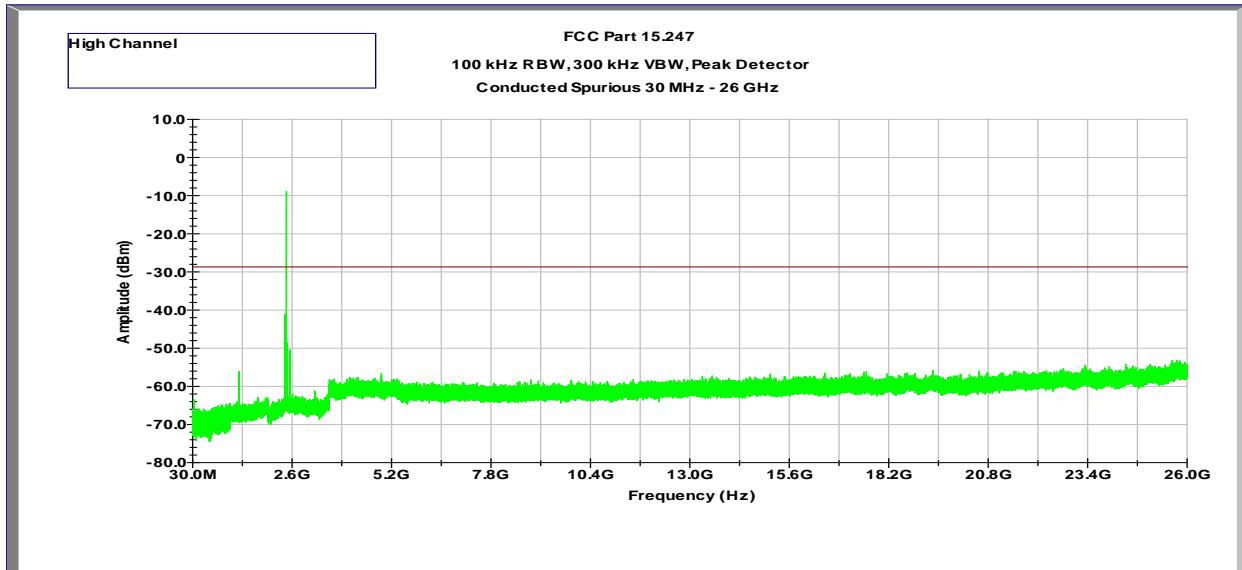
Tx @ Low Channel, 2402 MHz
30MHz -26GHz Conducted Spurious
Plot 4.3



Tx @ Mid Channel, 2442 MHz
30MHz -26GHz Conducted Spurious
Plot 4.4



Tx @ High Channel, 2480 MHz
30MHz -26GHz Conducted Spurious
Plot 4.5



4.5 Transmitter Radiated Emissions

FCC Rules: 15.247(d), 15.209, 15.205; RSS-247;

4.5.1 Requirement

Radiated emissions which fall in the restricted bands, as defined in §15.205(a), must also comply with the radiated emission limits specified in §15.209(a) (see §15.205(c)).

For out of band radiated emissions (except for frequencies in restricted bands), in any 100 kHz bandwidths outside the EUT pass-band, the RF power shall be at least 20dB (peak) or 30 dB (average) below that of the maximum in-band 100 kHz emissions.

4.5.2 Procedure

Radiated emission measurements were performed from 30 MHz to 25 GHz according to the procedure described in ANSI C63.10. Spectrum Analyzer Resolution Bandwidth is 100 kHz or greater for frequencies 30 MHz to 1000 MHz, 1 MHz for frequencies above 1000 MHz. Above 1000 MHz Peak and Average measurements were performed.

The EUT is placed on a plastic turntable that is 80 cm in height for below 1000MHz and 1.5m in height for above 1GHz. If the EUT attaches to peripherals, they are connected and operational (as typical as possible). During testing, all cables were manipulated to produce worst-case emissions. The signal is maximized through rotation. The antenna height and polarization are varied during the search for maximum signal level. The antenna height is varied from 1 to 4 meters.

Radiated emissions are taken at 3 meters for frequencies above 1 GHz and at 10 meters for frequencies below 1 GHz.

Measurements made from 1 GHz to 18GHz had a 2.4-2.5GHz notch filter in place. A preamp was used from 30MHz to 26GHz.

All measurements were made with a Peak Detector and compared to QP limits for 30MHz – 1GHz and Average limits for 1GHz – 26GHz.

Data is included of the worst-case configuration (the configuration which resulted in the highest emission levels).

4.5.3 Field Strength Calculation

Field Strength Calculation

The field strength is calculated by adding the Antenna Factor and Cable Factor, and subtracting the Amplifier Gain (if any) from the measured reading. The basic equation with a sample calculation is as follows:

FS = RA + AF + CF - AG; if measurement is performed at a distance other than specified in the rule, a Distance Correction Factor (DCF) shall be added.

Where FS = Field Strength in dB(μ V/m)

RA = Receiver Amplitude (including preamplifier) in dB(μ V); AF = Antenna Factor in dB(1/m)

CF = Cable Attenuation Factor in dB; AG = Amplifier Gain in dB

Assume a receiver reading of 52.0 dB(μ V) is obtained. The antennas factor of 7.4 dB(1/m) and cable factor of 1.6 dB is added. The amplifier gain of 29 dB is subtracted, giving field strength of 32 dB(μ V/m). This value in dB(μ V/m) was converted to its corresponding level in μ V/m.

RA = 52.0 dB(μ V)

AF = 7.4 dB(1/m)

CF = 1.6 dB

AG = 29.0 dB

$$FS = 52.0 + 7.4 + 1.6 - 29.0 = 32 \text{ dB}(\mu\text{V}/\text{m}).$$

Level in μ V/m = Common Antilogarithm $[(32 \text{ dB}\mu\text{V}/\text{m})/20] = 39.8 \mu\text{V}/\text{m}$.

4.5.4 Antenna-port conducted measurements

Antenna-port conducted measurements may also be used as an alternative to radiated measurements for demonstrating compliance in the restricted frequency bands. If conducted measurements are performed, then proper impedance matching must be ensured and an additional radiated test for cabinet/case spurious emissions is required.

4.5.6 General Procedure for conducted measurements in restricted bands

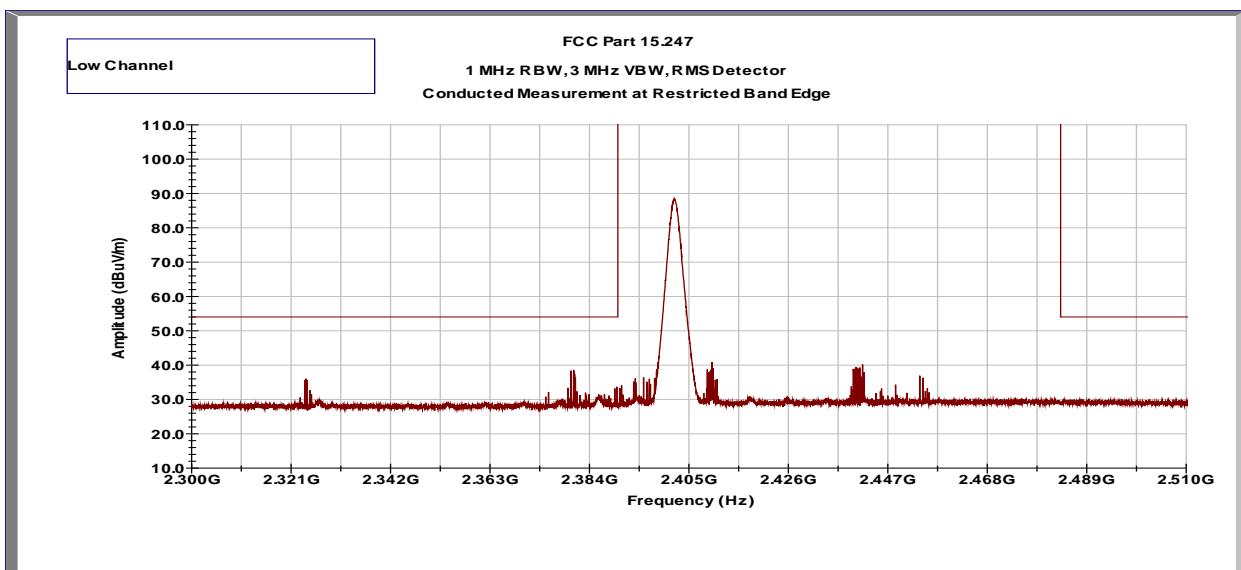
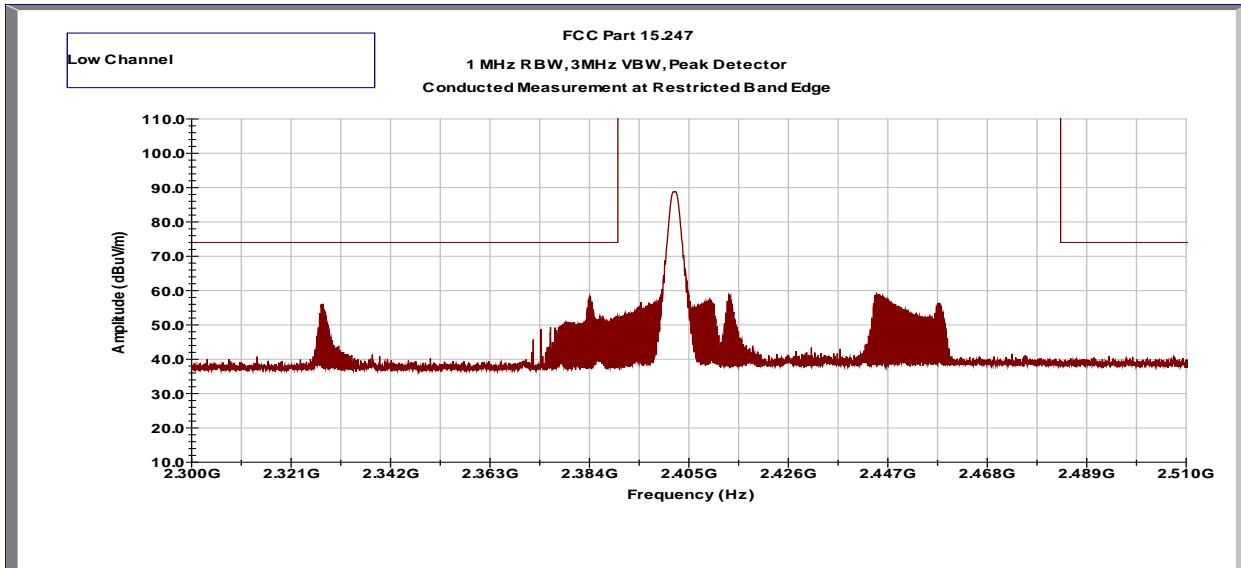
- a) Measure the conducted output power (in dBm) using the detector specified for determining quasi-peak, peak, and average conducted output power, respectively.
- b) Add the maximum transmit antenna gain (in dBi) to the measured output power level to determine the EIRP level (see 12.2.5 for guidance on determining the applicable antenna gain)
- c) Add the appropriate maximum ground reflection factor to the EIRP level (6 dB for frequencies \leq 30 MHz, 4.7 dB for frequencies between 30 MHz and 1000 MHz, inclusive and 0 dB for frequencies $>$ 1000 MHz).
- d) For devices with multiple antenna-ports, measure the power of each individual chain and sum the EIRP of all chains in linear terms (*e.g.*, Watts, mW).
- e) Convert the resultant EIRP level to an equivalent electric field strength using the following relationship:
$$E = EIRP - 20\log D + 104.8$$
where:
E = electric field strength in $\text{dB}\mu\text{V}/\text{m}$,
EIRP = equivalent isotropic radiated power in dBm
D = specified measurement distance in meters.
- f) Compare the resultant electric field strength level to the applicable limit.
- g) Perform radiated spurious emission test

4.5.7 Test Results

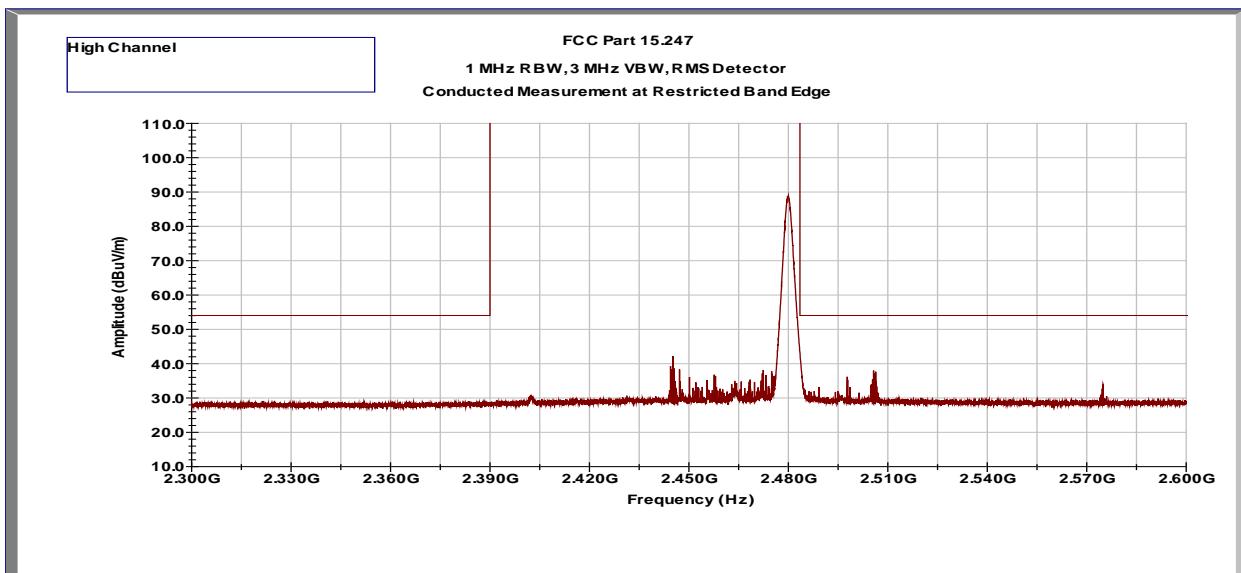
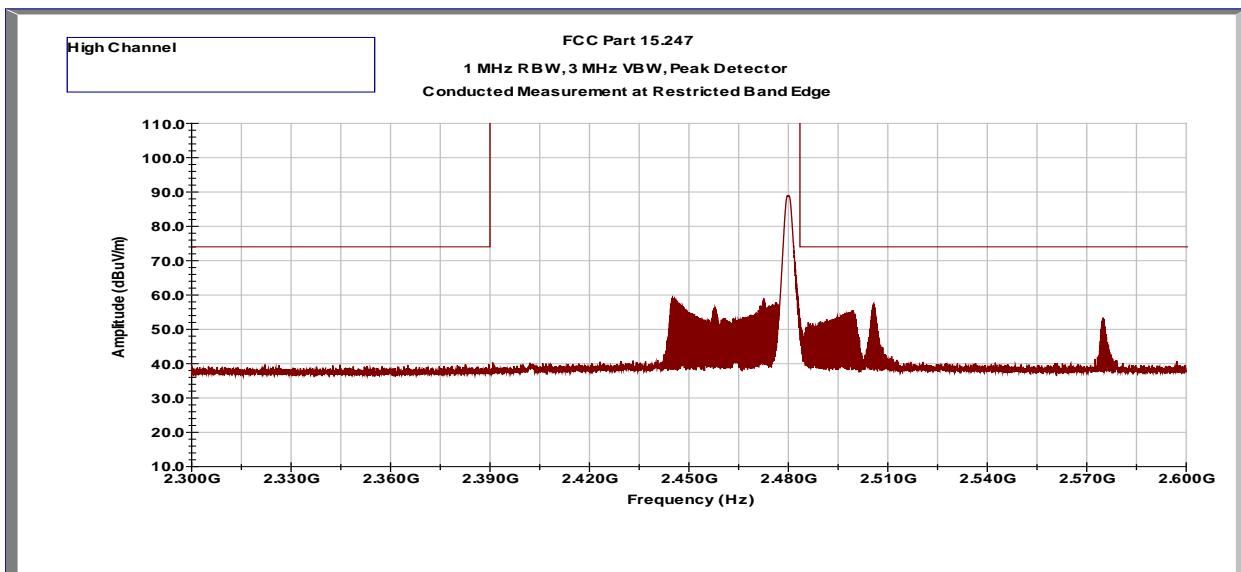
The data on the following pages list the significant emission frequencies, the limit and the margin of compliance where emissions are within 3dB of the limit.

All conducted antenna port plots are corrected with the consideration of a 0 dBi Antenna Gain.

Radiated emission measurements were performed up to 26GHz. No Emissions were identified when scanned from 18-25 GHz.

Test Results: 15.209/15.205 Restricted Band Emissions at Antenna Port**Out-of-Band Spurious Emissions at the Band Edge – Tx @ 2402 MHz**

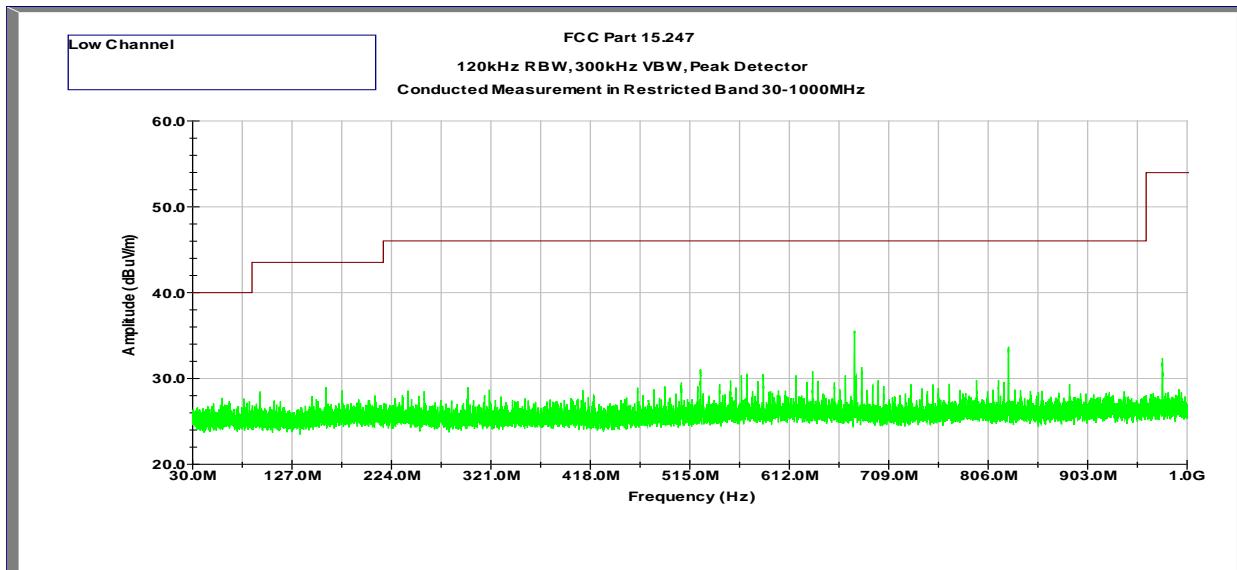
Out-of-Band Spurious Emissions at the Band Edge – Tx @ 2480 MHz



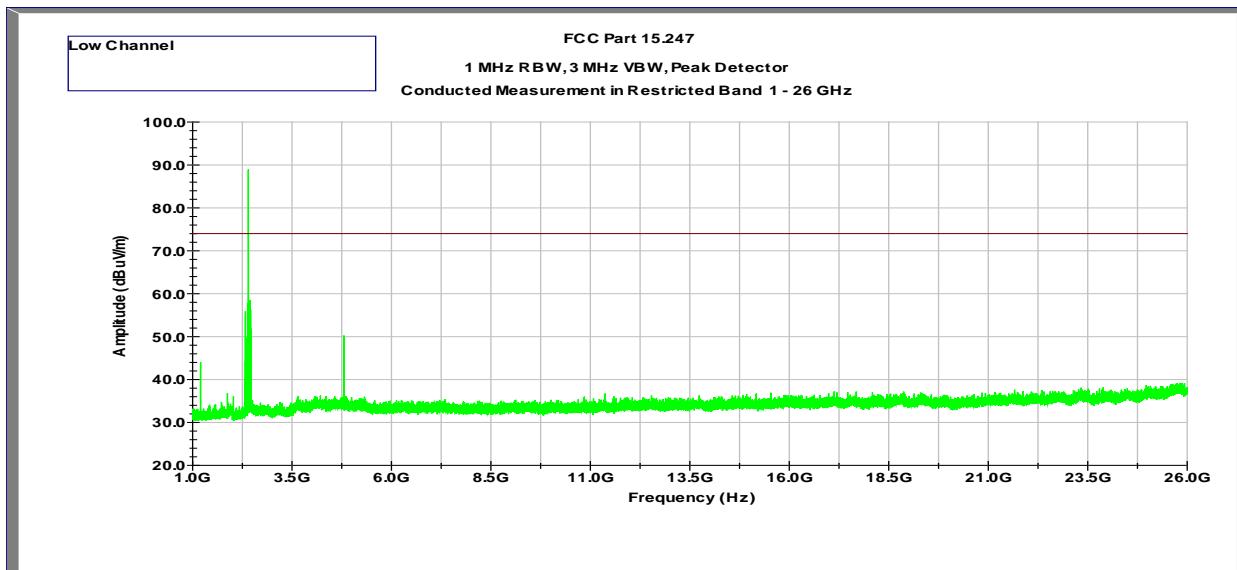
Frequency	Corrected Amplitude	Avg Limit	Margin	Detector	Results
GHz	dB μ V/m	dB μ V/m	dB		
2.4835	43	54	-11.0	RMS	Pass

Out-of-Band Conducted Spurious Emissions (at Antenna Port)**Tx @ 2402MHz**

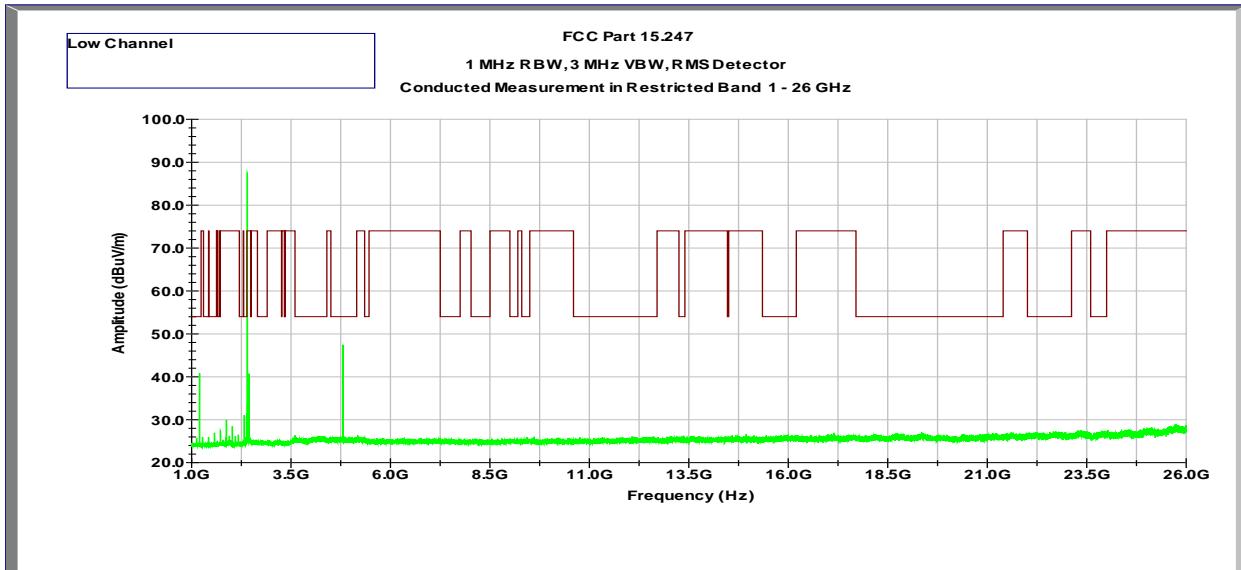
Out-of-Band Spurious Emissions at Antenna Port - 30 MHz to 1 GHz



Out-of-Band Spurious Emissions at Antenna Port – 1 - 26 GHz Peak

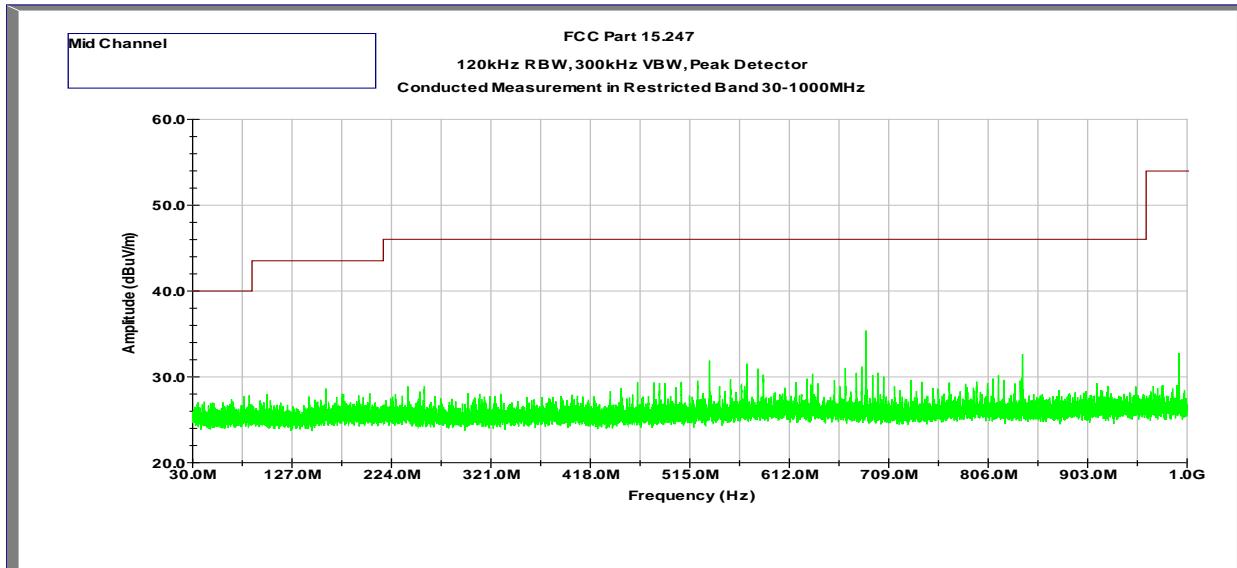


Out-of-Band Spurious Emissions at Antenna Port – 1 - 26 GHz Avg

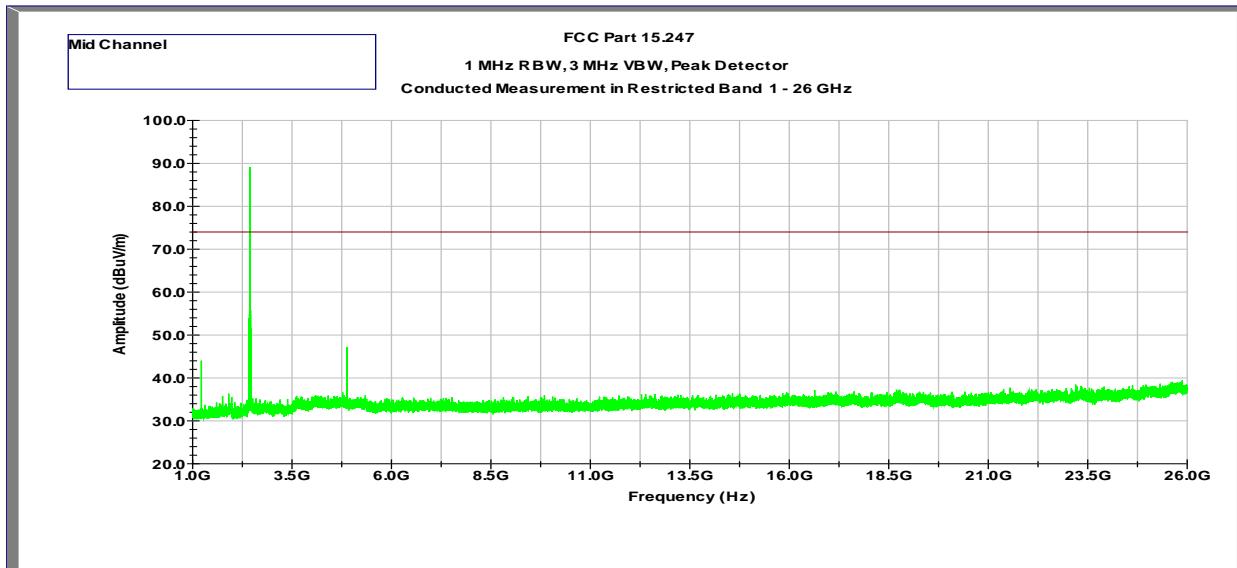


Out-of-Band Conducted Spurious Emissions (at Antenna Port)**Tx @ 2442MHz**

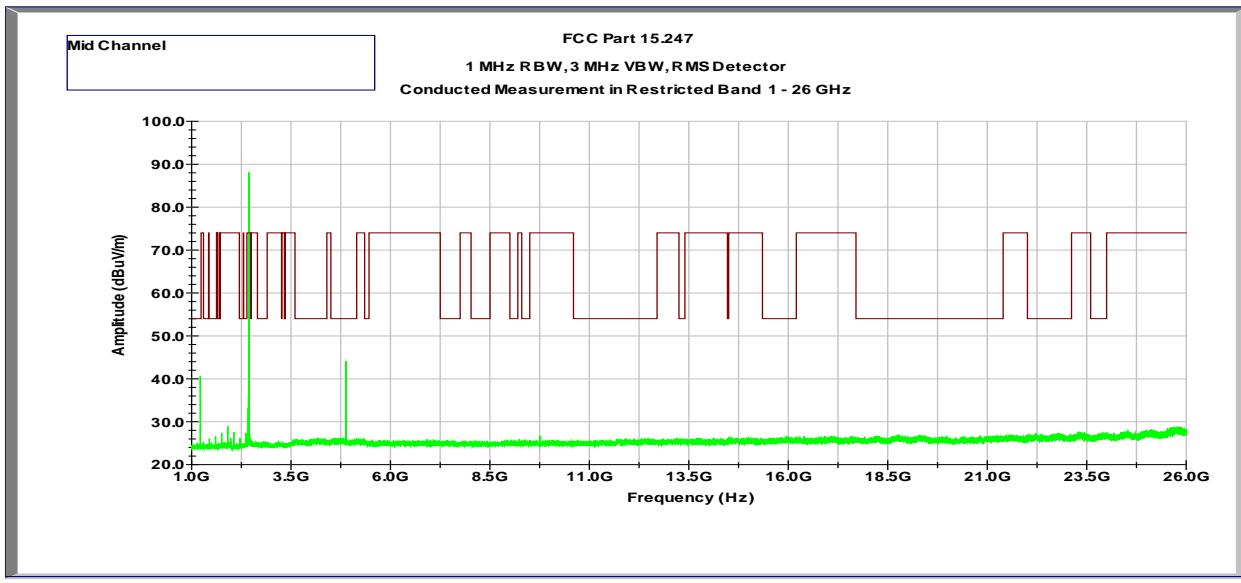
Out-of-Band Spurious Emissions at Antenna Port - 30 MHz to 1 GHz



Out-of-Band Spurious Emissions at Antenna Port – 1 - 26 GHz Peak

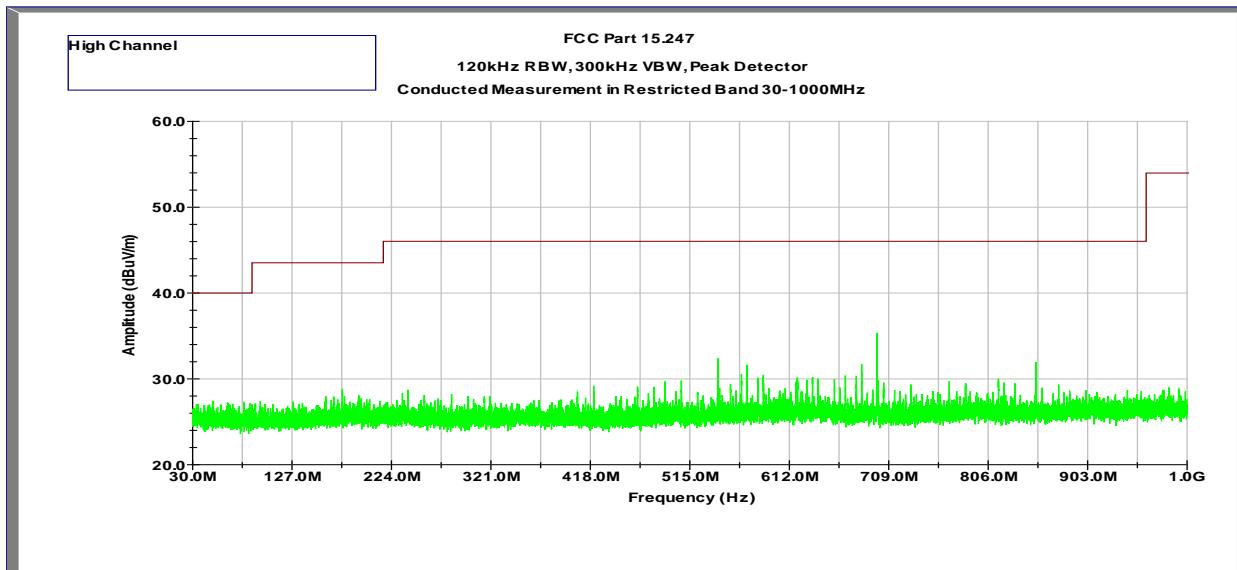


Out-of-Band Spurious Emissions at Antenna Port – 1 - 26 GHz Avg

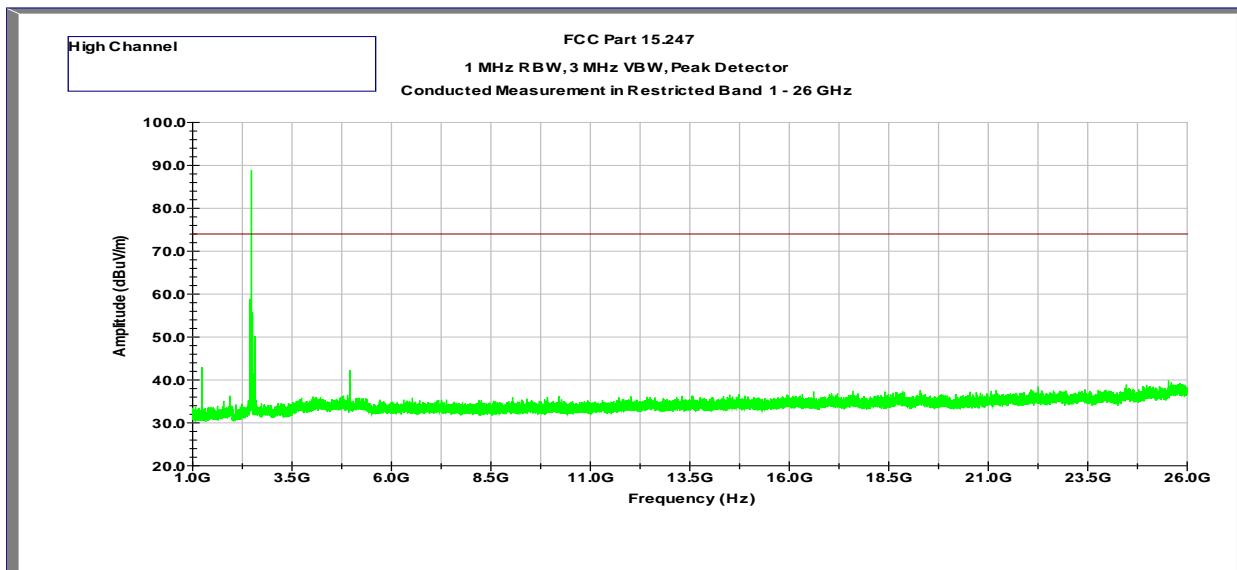


Out-of-Band Conducted Spurious Emissions (at Antenna Port)**Tx @ 2480MHz**

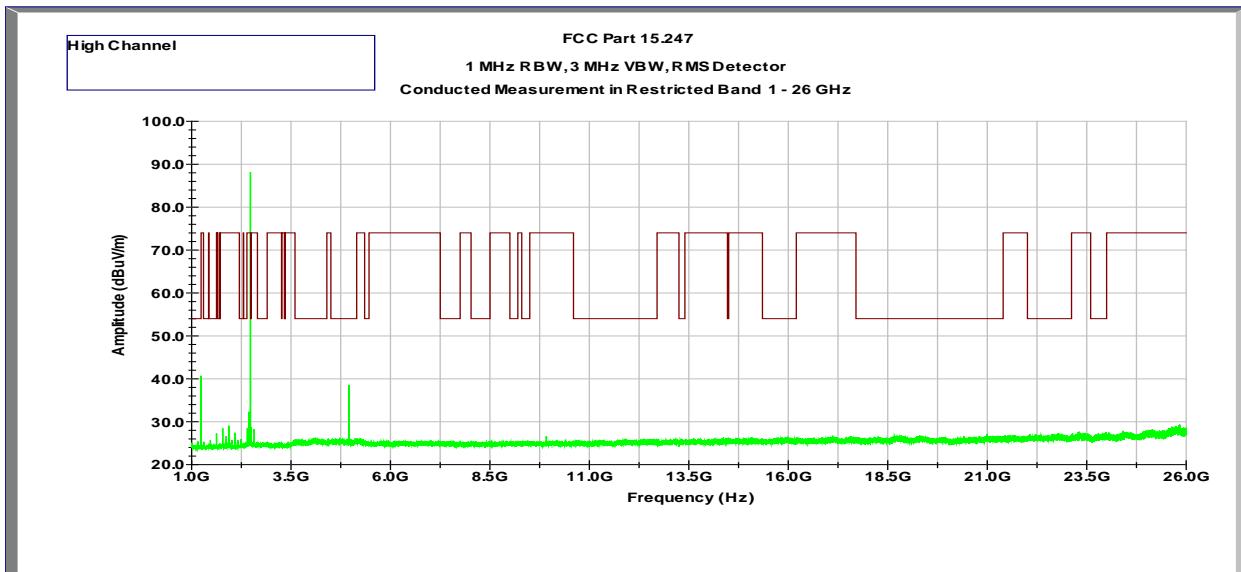
Out-of-Band Spurious Emissions at Antenna Port - 30 MHz to 1 GHz



Out-of-Band Spurious Emissions at Antenna Port – 1 - 26 GHz Peak



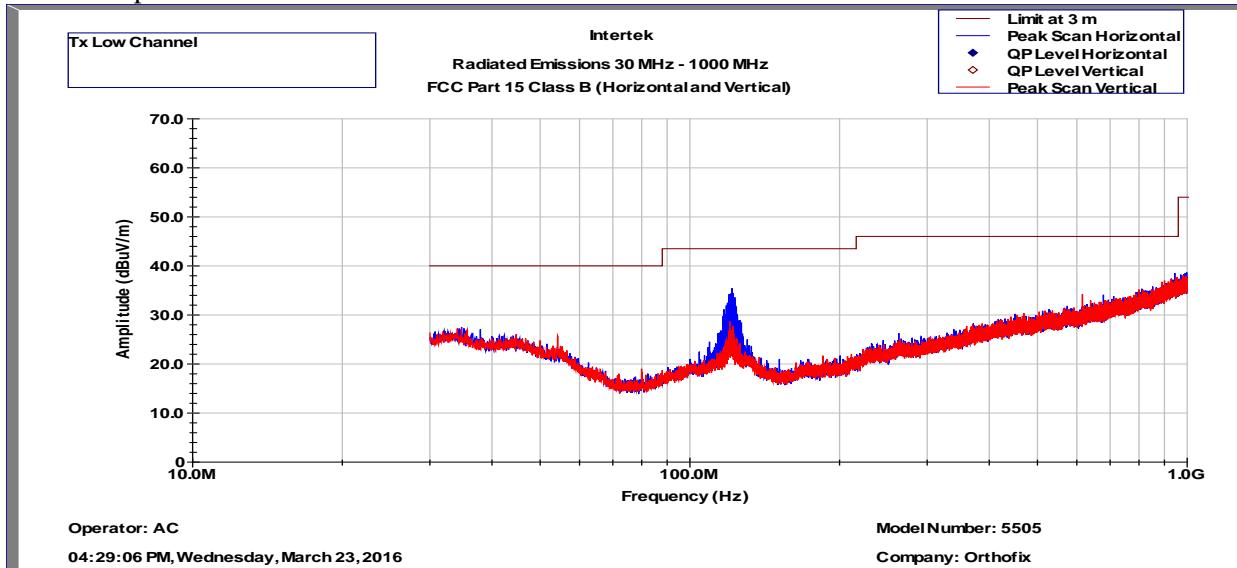
Out-of-Band Spurious Emissions at Antenna Port – 1 - 26 GHz Avg



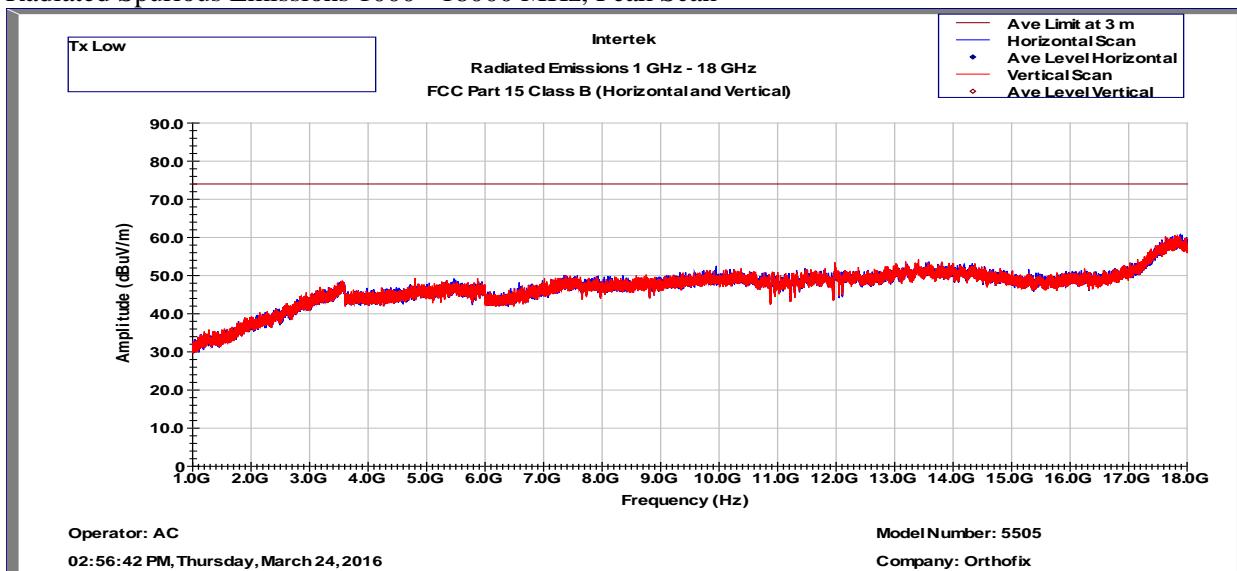
Out-of-Band Radiated Spurious Emissions (Cabinet Radiation)

Test Results: 15.209 Radiated Spurious Emissions Low Channel, Tx at 2402MHz

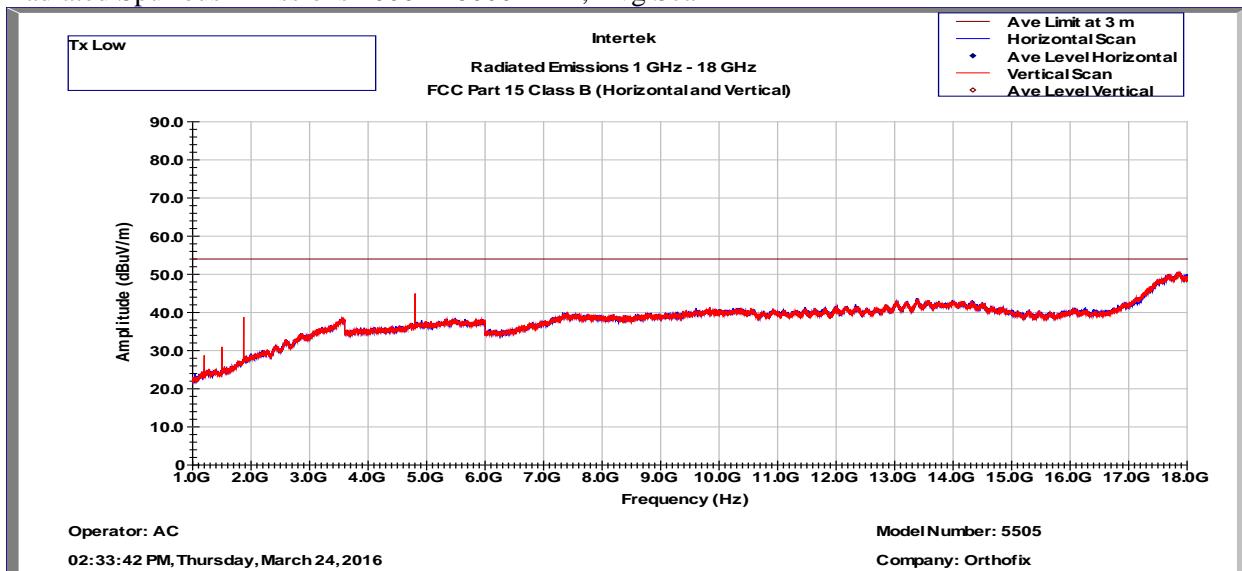
Radiated Spurious Emissions 30 MHz - 1000 MHz



Radiated Spurious Emissions 1000 - 18000 MHz, Peak Scan



Radiated Spurious Emissions 1000 - 18000 MHz, Avg Scan

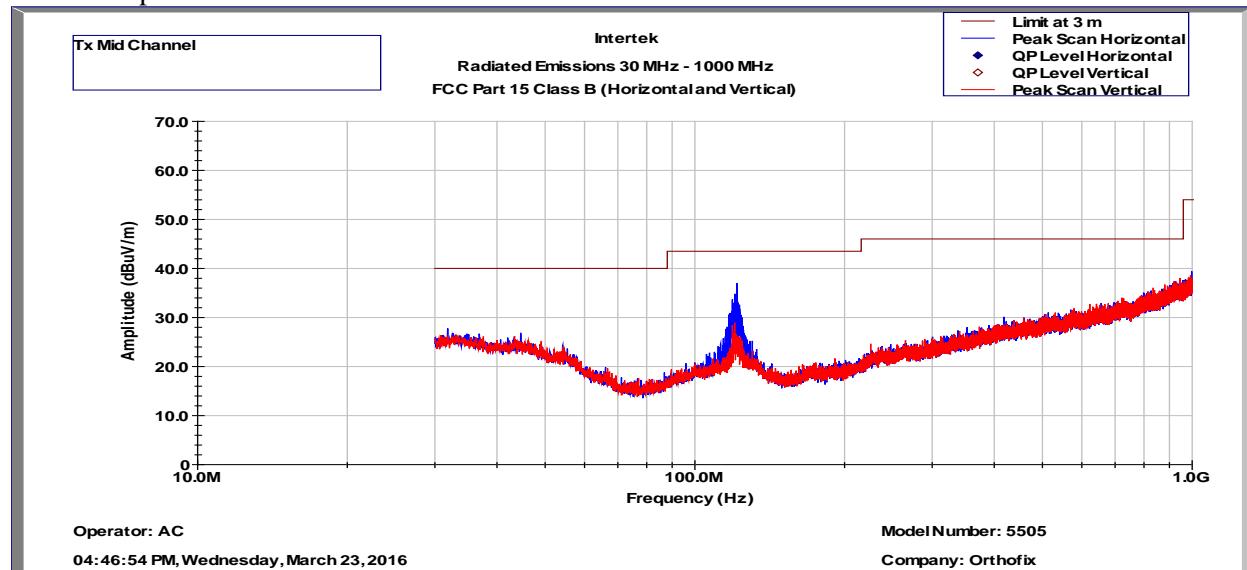


Note: Radiated emission measurements were performed up to 25GHz. No Emissions were identified when scanned from 18-25 GHz

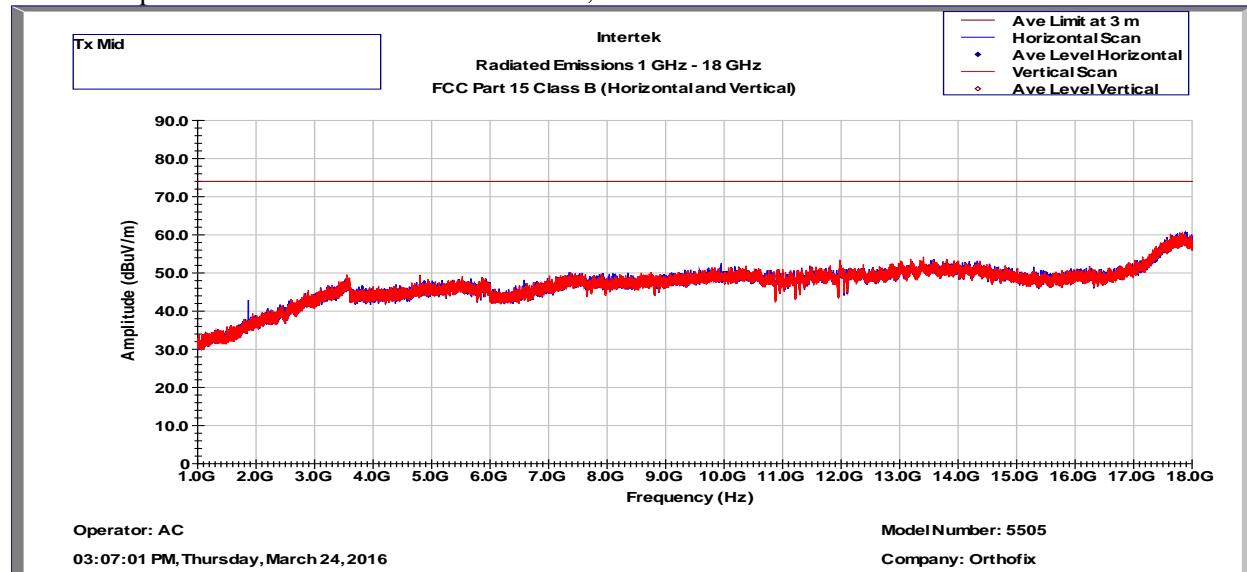
Note: FS@3m = RA + AF + CF - Preamp

Test Results: 15.209 Radiated Spurious Emissions Mid Channel, Tx at 2442MHz

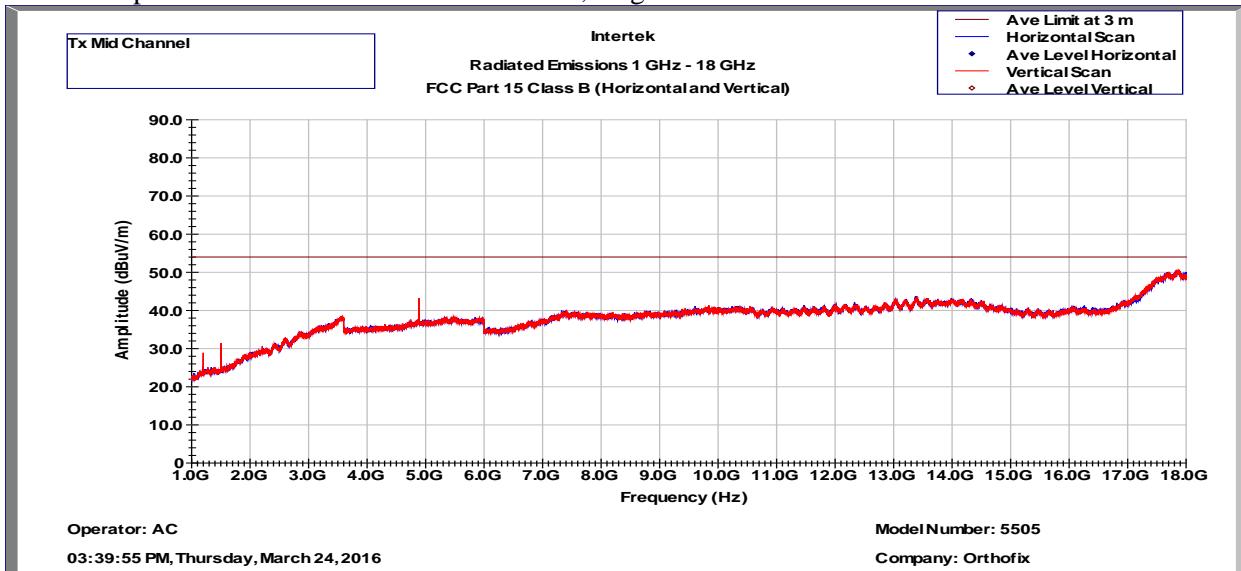
Radiated Spurious Emissions 30 MHz - 1000 MHz



Radiated Spurious Emissions 1000 - 18000 MHz, Peak Scan



Radiated Spurious Emissions 1000 - 18000 MHz, Avg Scan

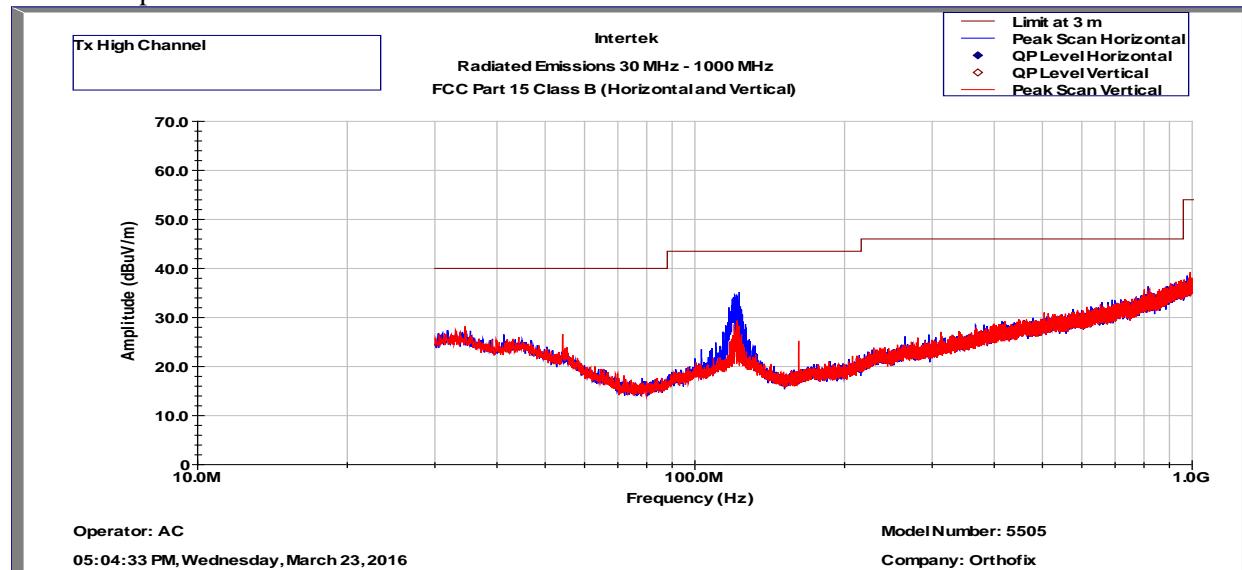


Note: Radiated emission measurements were performed up to 25GHz. No Emissions were identified when scanned from 18-25 GHz

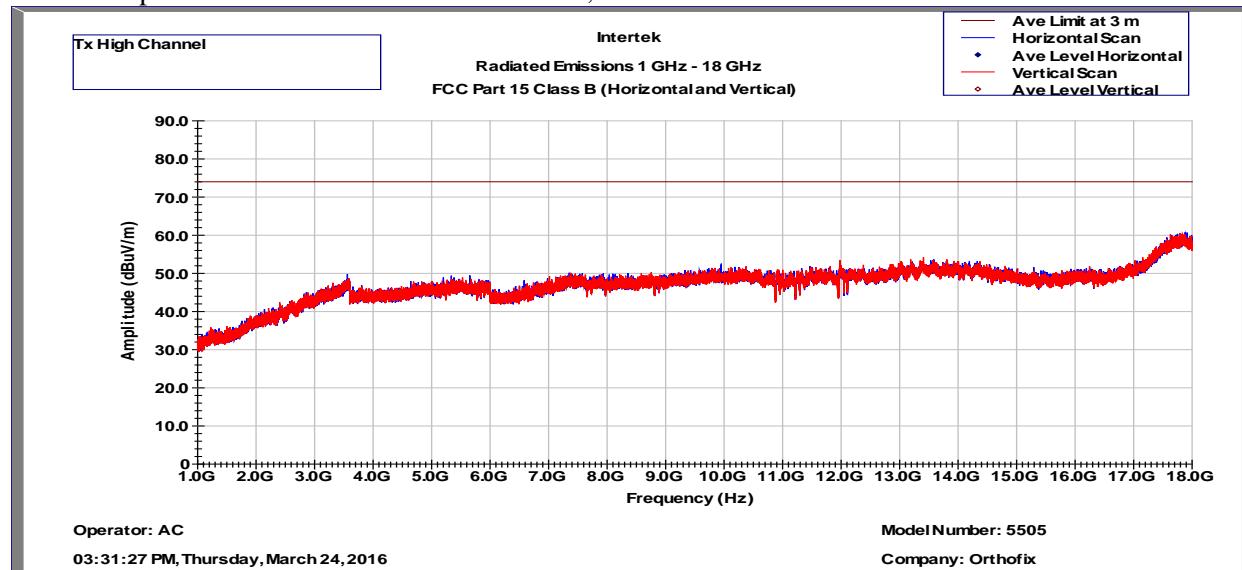
Note: FS@3m = RA + AF + CF - Preamp

Test Results: 15.209 Radiated Spurious Emissions High Channel, Tx at 2480MHz

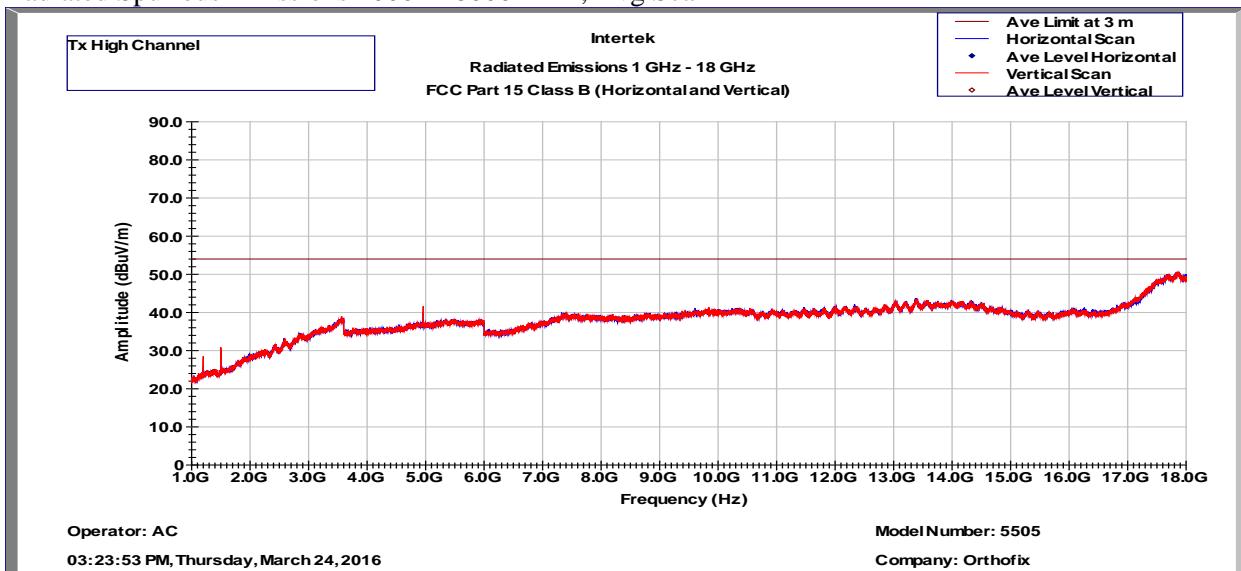
Radiated Spurious Emissions 30 MHz - 1000 MHz



Radiated Spurious Emissions 1000 - 18000 MHz, Peak Scan



Radiated Spurious Emissions 1000 - 18000 MHz, Avg Scan



Note: Radiated emission measurements were performed up to 25GHz. No Emissions were identified when scanned from 18-25 GHz

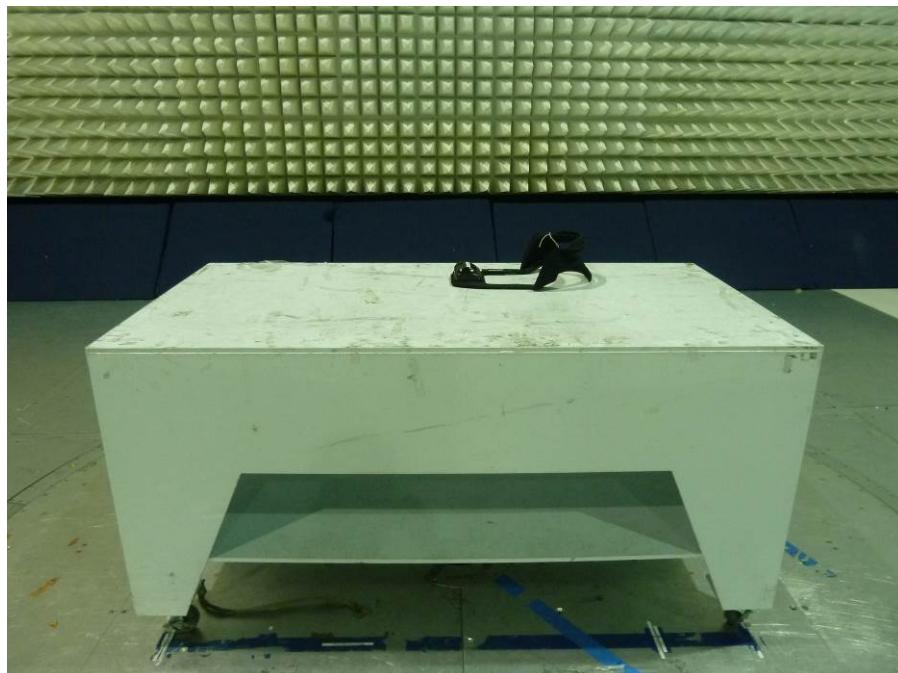
Note: FS@3m = RA + AF + CF - Preamp

Results

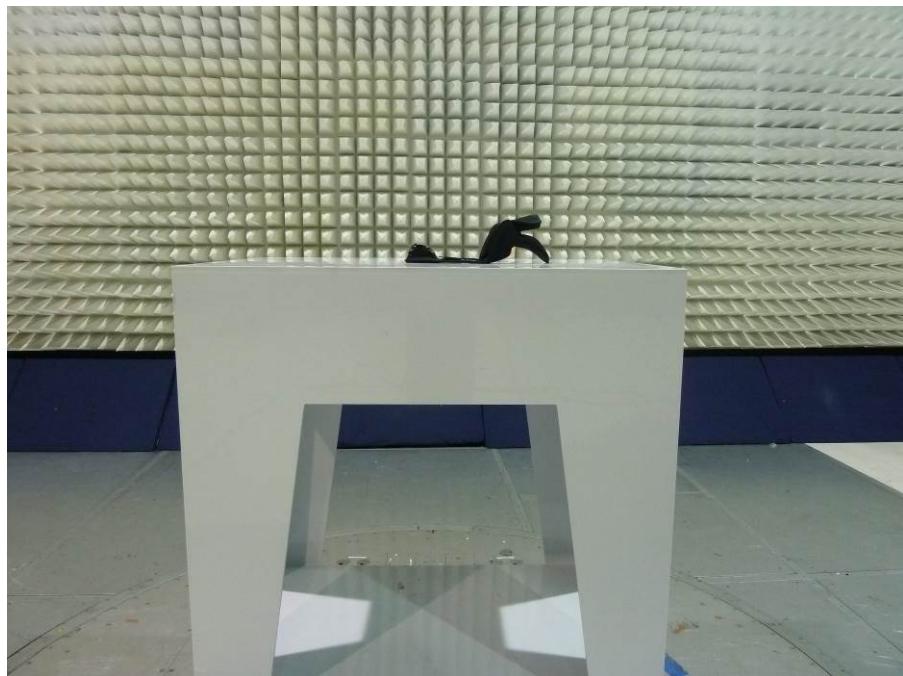
Complies

4.5.8 Test setup photographs

The following photographs show the testing configurations used.



4.5.5 Test setup photographs (Continued)



5.0 RF Exposure Evaluation

MPE Evaluation

SAR test exclusion threshold formula according to FCC KDB 447898 D01 v05r02 is

$$P * \sqrt{f/d} < 3$$

where

P is max. power of channel, including tune-up tolerance, mW

f is operating frequency in GHz

d is min. test separation distance, mm

The maximum Peak EIRP calculated is -7.6 dBm (RF Conducted Power) + -3.86 dBi (Antenna Gain) = -11.46 dBm or 0.0714 mW (P); therefore, to comply with RF Exposure Requirement, the MPE is calculated.

At 5mm distance the condition for SAR exclusion threshold is

$$0.0714 \times \sqrt{2.480 \div 5} = 0.0225 \text{ which is less than 3.}$$

Therefore, SAR testing is not required as the SAR Test Exclusion Threshold condition is satisfied.

SAR Exemption limit according to IC RSS-102 Issue 5, at 5 mm separation distance = 4 mW

Routine evaluation is not required since the higher of the maximum conducted or equivalent isotropically radiated power (e.i.r.p.) source-based, time averaged output power is below the exemption limit.

Date of Test:	March 24, 2016
Results	Complies

6.0 List of Test Equipment

Measurement equipment used for emission compliance testing utilized the equipment on the following list:

Equipment	Manufacturer	Model/Type	Asset #	Cal Int	Cal Due
EMI Receiver	Rohde and Schwarz	ESU	ITS 00961	12	06/02/16
BI-Log Antenna	ARA	LPB-2513/A	ITS 00355	12	09/11/16
Pyramidal Horn Antenna	EMCO	3160-09	ITS00571	#	#
Pre-Amplifier	Sonoma Instrument	310N	ITS 00942	12	01/07/17
Pre-Amplifier (18-40GHz)	Miteq	JSD44-18004000-305P	ITS 00921	12	06/18/16
Active Horn Antenna	ETS-Lindgren	3117-PA	ITS 01365	12	10/15/16

No Calibration required

7.0 Document History

Revision/ Job Number	Writer Initials	Reviewers Initials	Date	Change
1.0 / G102499373	AC	KV	April 21, 2016	Original document