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Emissions
Test Report

EUT Name: Stryker Triathlon GEN 4

Model Name: VERASENSE

CFR 47 Part 15.247: 2019 and RSS 247: 2017

Prepared for:

Orthosensor, Inc
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FL 33004 U.S.A.

Prepared by:

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Project Number: 234116190

Revisions

Revision No.	Date MM/DD/YYYY	Reason for Change	Author
0	02/06/2020	Original Document	RK
1	02/18/2020	Updated Antenna Type	RK
2	08/05/2020	TCB Review	RK

Note: Latest revision report will replace all previous reports.

Statement of Compliance

Manufacturer:	Orthosensor, Inc 1855 Griffin Rd, Ste. A-310, Dania FL 33004
Requester / Applicant:	Orthosensor, Inc
Name of Equipment:	Stryker Triathlon GEN 4
Model Name.	VERASENSE
Type of Equipment:	Intentional Radiator
Application of Regulations:	CFR 47 Part 15.247: 2019 and RSS 247: 2017
Test Dates:	January 20, 2020 to January 30, 2020

Guidance Documents:

Emissions: ANSI C63.10-2013, KDB 558074 D01 DTS Measurement Guidance v05r02, KDB 662911 D01 Multiple Transmitter Output v02r01

Test Methods:

Emissions: ANSI C63.10-2013, KDB 558074 D01 DTS Measurement Guidance v05r02, KDB 662911 D01 Multiple Transmitter Output v02r01

The electromagnetic compatibility test and documented data described in this report has been performed and recorded by TUV Rheinland, in accordance with the standards and procedures listed herein. As the responsible authorized agent of the EMC laboratory, I hereby declare that the equipment described above has been shown to be compliant with the EMC requirements of the stated regulations and standards based on these results. If any special accessories and/or modifications were required for compliance, they are listed in the Executive Summary of this report.

This report must not be used to claim product endorsement by A2LA or any agency of the U.S. Government. This report shall not be reproduced except in full, without the written authorization of TUV Rheinland of North America.

Rachana Khanduri		Richard Decker	
Test Engineer	Date August 5, 2020	A2LA Signatory	Date August 5, 2020

Testing Cert #3331.02 **US1131** **2932D**

1 Executive Summary

1.1 Scope

This report is intended to document the status of conformance with the requirements of the CFR 47 Part 15.247: 2019 and RSS 247: 2017 based on the results of testing performed from January 20, 2020 through January 30, 2020, on the Stryker Triathlon GEN 4 Model Name VERASENSE manufactured by Orthosensor, Inc. This report only applies to the specific samples tested under the stated test conditions. It is the responsibility of the manufacturer to assure that additional production units of this model are manufactured with identical or EMI equivalent electrical and mechanical components. This report is further intended to document changes and modifications to the EUT throughout its life cycle. All documentation will be included as a supplement.

1.2 Purpose

Testing was performed to evaluate the EMC performance of the EUT in accordance with the applicable requirements, procedures, and criteria defined in the application of regulations and application of standards listed in this report. The 2402 MHz to 2480 MHz frequency band for Bluetooth, Low Energy is covered in this document.

1.3 Summary of Test Results

Table 1: Summary of Test Results

Test	Test Method ANSI C 63.10 & C63.4	Worse Case (Measured)	Result
Maximum Output Power	CFR47 15.247 (b), RSS 247 Sect. 5.4 (d)	3.95 dBm @ 2402MHz Channel, 1Mbps	**Complied**
DTS Bandwidth (6dB)	CFR47 15.247 (a)(2), RSS 247 Sect. 5.2 (a)	0.769MHz @ 2440MHz Channel, 1Mbps	**Complied**
Peak Power Spectral Density	CFR47 15.247 (e), RSS 247 Sect. 5.2 (b)	-8.98 dBm/ kHz @ 2402MHz channel, 1Mbps	**Complied**
Out of Band Emissions: Non-Restricted	CFR47 15.247 (d), RSS 247 Sect.5.5	-46.08 dBc @ 2399.96 MHz, Lower Band Edge	**Complied**
Out of Band Emissions: Restricted	CFR47 15.247 (d), RSS 247 Sect.5.5	-17.30dB margin @ 2338.012 MHz, Average	**Complied**
Transmitter Spurious Emissions	CFR47 15.247 (d), RSS 247 Sect.5.5	-0.7dB Margin @ 98.17 MHz, Quasi Max	**Complied**
AC Power Conducted Emission	CFR47 15.207, RSS-GEN Sect.8.8	Class B	**N/A**

Note 1: This test report covers 2400 MHz to 2480 MHz band. * = summed power.

Note 2: Class B limits were applied where applicable.

1.4 Special Accessories

No special accessories were necessary in order to achieve compliance.

1.5 Equipment Modifications

None

2 Laboratory Information

2.1 Accreditations & Endorsements

2.1.1 US Federal Communications Commission

TUV Rheinland of North America EMC test facilities located at 1279 Quarry Lane, Ste. A, Pleasanton, CA, 94566, and 5015 Brandin Ct, Fremont, CA. 94538, are recognized by the Commission for performing testing services for the general public on a fee basis. These laboratory test facilities have been fully described in reports submitted to and accepted by the FCC (Pleasanton Registration No. US1131, Fremont Registration No. US1131). The laboratory Scopes of Accreditation include Title 47 CFR Parts 15, 18 and 90. The accreditations are updated every three years.

2.1.2 A2LA

TUV Rheinland of North America EMC test facilities are accredited by the American Association for Laboratory Accreditation (A2LA). The laboratories have been assessed and accredited by A2LA in accordance with ISO Standard 17025:2017 (Testing Certificate #3331.02). The Scope of Laboratory Accreditation includes emission and immunity testing. The accreditations are updated annually.

2.1.3 Industry Canada

The Pleasanton 5-meter Semi-Anechoic Chamber, Registration No. 2932M-1, has been accepted by Industry Canada to perform testing to 3 and 5 meters based on the test procedures described in ANSI C63.4-2014. The Fremont 10-meter Semi-Anechoic Chamber, Registration No. 2932D-1, has been accepted by Industry Canada to perform testing to 3 and 10 meters based on the test procedures described in ANSI C63.4-2014.

2.1.4 Japan – VCCI

The Voluntary Control Council for Interference by Information Technology Equipment (VCCI) is a group that consists of Information Technology Equipment (ITE) manufacturers and EMC test laboratories. The purpose of the Council is to take voluntary control measures against electromagnetic interference from Information Technology Equipment, and thereby contribute to the development of a socially beneficial and responsible state of affairs in the realm of Information Technology Equipment in Japan. TUV Rheinland of North America EMC test facilities located at 1279 Quarry Lane, Ste. A, Pleasanton, CA, 94566, and 5051 Brandin Ct, Fremont, CA. 94538, have been assessed and approved in accordance with the Regulations for Voluntary Control Measures.

VCCI Registration No. for Pleasanton: A-0326

VCCI Registration No. for Fremont: A-0327

2.1.5 Acceptance by Mutual Recognition Arrangement

The United States has an established agreement with specific countries under the Asia Pacific Laboratory Accreditation Corporation (APLAC) Mutual Recognition Arrangement. Under this agreement, all TUV Rheinland at 1279 Quarry Ln, Pleasanton, CA 94566 test results and test reports within the scope of the laboratory NIST / A2LA accreditation will be accepted by each member country.

2.2 Test Facilities

Test facilities are located at 5015 Brandin Ct, Fremont, California, 94538, USA and 1279 Quarry Lane, Pleasanton, California 94566, USA (Fremont is the Pleasanton Annex).

2.2.1 Emission Test Facility

The Semi-Anechoic Chambers and AC Line Conducted measurement facilities used to collect radiated and conducted emissions data have been constructed in accordance with ANSI C63.7:1992. The Fremont 10 meter semi-anechoic chamber has been measured in accordance with and verified to comply with the theoretical volumetric normalized site attenuation of ANSI C63.4:2014 and SVSWR requirements of CISPR 16-1-4 Consol. Ed. 3.0 (2010-04), at test distances of 3 and 10 meters. This site has been described in reports dated November 1st, 2006, submitted to the FCC, and accepted by letter dated November 28, 2006. The site is listed with the FCC and accredited by A2LA (Testing Certificate #3331.02). The Pleasanton 5 meter semi-anechoic chamber has been verified to comply with the theoretical volumetric normalized site attenuation of ANSI C63.4:2009 and SVSWR requirements of CISPR 16-1-4 Consol. Ed. 3.0 (2010-04) at a test distance of 3 meters. This site has been described in reports dated November 1st, 2006, submitted to the FCC, and accepted by letter dated November 28, 2006. The site is listed with the FCC and accredited by A2LA (Testing Certificate #3331.02).

2.3 Measurement Uncertainty

Two types of measurement uncertainty are expressed in this report, per *ISO Guide To The Expression Of Uncertainty In Measurement*, 1st Edition, 1995.

The Combined Standard Uncertainty is the standard uncertainty of the result of a measurement when that result is obtained from the values of a number of other quantities; it is equal to the positive square root of the sum of the variances or co-variances of these other quantities, weighted according to how the measurement result varies with changes in these quantities. The term *standard uncertainty* is the result of a measurement expressed as a standard deviation.

The Expanded Uncertainty defines an interval about the result of a measurement that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the measurement and the fraction may be viewed as the coverage probability or level of confidence of the interval.

2.3.1 Sample Calculation – radiated & conducted emissions

The field strength is calculated by subtracting the Amplifier Gain and adding the Cable Loss and Antenna Correction Factor to the measured reading. The basic equation is as follows:

Field Strength (dBμV/m) = RAW - AMP + CBL + ACF

Where: RAW = Measured level before correction (dBμV)

AMP = Amplifier Gain (dB)

CBL = Cable Loss (dB)

ACF = Antenna Correction Factor (dB/m)

$$\mu V/m = 10^{\frac{dB\mu V/m}{20}}$$

Sample radiated emissions calculation @ 30 MHz

Measurement +Antenna Factor–Amplifier Gain+Cable loss=Radiated Emissions (dBuV/m)

25 dBuV/m + 17.5 dB – 20 dB + 1.0 dB = 23.5 dBuV/m

2.3.2 Measurement Uncertainty

Per CISPR 16-4-2	**U_{lab}**	**U_{cispr}**
Radiated Disturbance @ 10 meters		
30 – 1,000 MHz	2.25 dB	4.51 dB
Radiated Disturbance @ 3 meters		
30 – 1,000 MHz	2.26 dB	4.52 dB
1 – 6 GHz	2.12 dB	4.25 dB
6 – 18 GHz	2.47 dB	4.93 dB
Conducted Disturbance @ Mains Terminals		
150 kHz – 30 MHz	1.09 dB	2.18 dB
Disturbance Power		
30 MHz – 300 MHz	3.92 dB	4.3 dB

2.4 Calibration Traceability

All measurement instrumentation is traceable to the National Institute of Standards and Technology (NIST). Measurement method complies with ANSI/NCSL Z540-1-1994 and ISO Standard 17025:2017. Equipment calibration records are kept on file at the test facility.

3 Product Information

3.1 Product Description

Model VERASENSE delivers evidence-based data wirelessly to an intra-operative monitor that enables surgeons to make informed decisions on soft tissue balance and implant position in real time. Stryker Triathlon GEN 4, Model VERASENSE utilizing Bluetooth. The EUT will be in compliance with regulatory standards of regions it will be operating in.

3.2 Equipment Configuration

A description of the equipment configuration is given in the Test Plan Section. The EUT was tested as called for in the test standard and was configured and operated in a manner consistent with its intended use. The EUT was connected to rated power and allowed to reach intended operating conditions. The placement of the EUT system components was guided by the test standard and selected to represent typical installation conditions.

In the case of a EUT that can operate in more than one configuration, preliminary testing was performed to determine the configuration that produced maximum radiation.

The final configuration was selected to produce the worst case radiation for emissions testing and to place the EUT in the most susceptible state for immunity testing.

3.3 Operating Mode

A description of the operation mode is given in the Test Plan Section. In the case of a EUT that can operate in more than one state, preliminary testing was performed to determine the operating mode that produced maximum radiation.

The final operating mode was selected to produce the worst case radiation for emissions testing.

3.4 Unique Antenna Connector

An intentional radiator shall be designed to ensure that no antenna other than that furnished by the responsible party shall be used with the device. The use of a permanently attached antenna or of an antenna that uses a unique coupling to the intentional radiator shall be considered sufficient to comply with the provisions of this Section. The manufacturer may design the unit so that a broken antenna can be replaced by the user, but the use of a standard antenna jack or electrical connector is prohibited. This requirement does not apply to carrier current devices or to devices operated under the provisions of CFR47 Parts 15.211, 15.213, 15.217, 15.219, or 15.221.

3.4.1 Results

The Stryker Triathlon GEN 4 has 1 trace antenna dedicated Bluetooth antenna that has maximum gain of – 5.1 dBi. The antenna connection is permanent and inside a plastic housing where the user cannot access it.

Refer to Table 11 for additional antenna information.

3.5 Duty Cycle

Duty cycles were measured by the spectrum analyzer used for measurements in section 4.1 of this report.

Mode	Measured Duty Cycle (%)	Duty Cycle Correction Factor (dB)
BLE	100%	0
Note: EUT configured and measured for the duty cycle. All measurements use 100% duty cycle.		

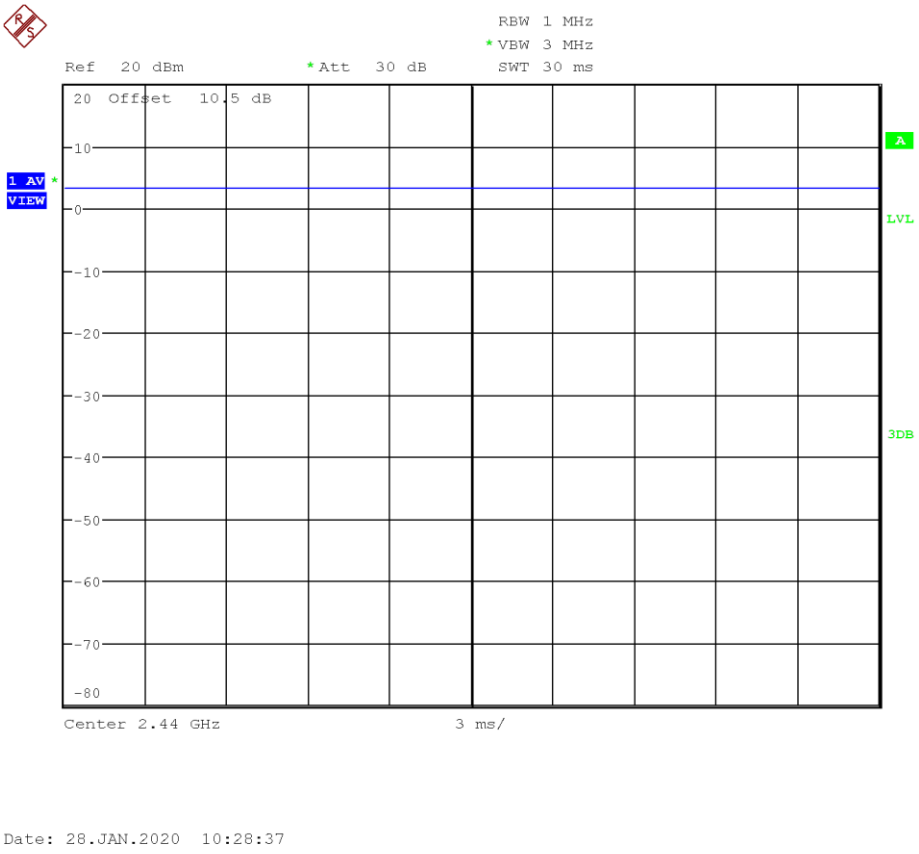


Figure 1: Duty Cycle for BLE

4 Emissions

Testing was performed in accordance with CFR 47 Part 15.247: 2019 and RSS 247: 2017. These test methods are listed under the laboratory's A2LA Scope of Accreditation. This test measures the levels emanating from the EUT, thus evaluating the potential for the EUT to cause radio frequency interference to other electronic devices. Procedures described in section 8 of the standard were used.

4.1 Output Power Requirements

The maximum output power requirement is the maximum equivalent isotropic radiated power delivering at the transmitting antenna under specified conditions of measurements in the presence of modulation.

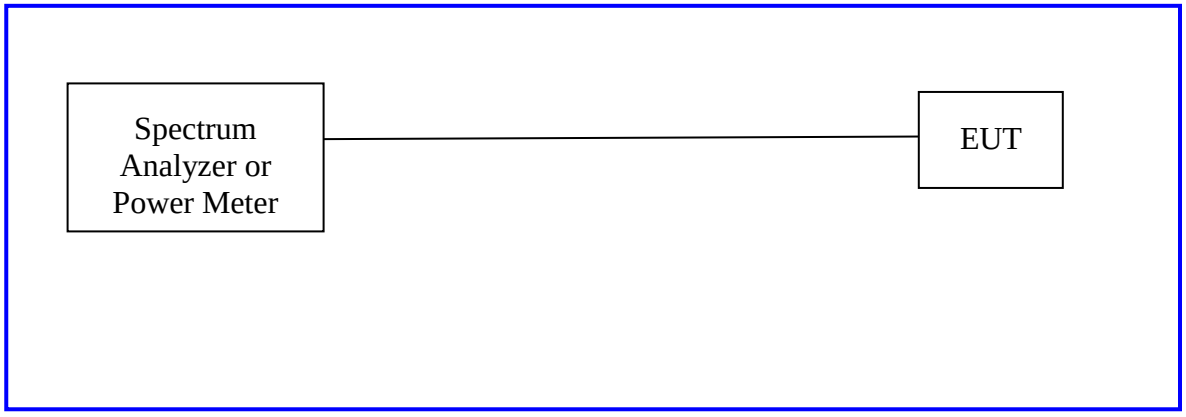
The maximum output power and harmonics shall not exceed CFR47 Part 15.247 (b) and RSS 247 5.4 (d).

The maximum transmitted power in the band 2400-2483.5 MHz: 1 W

4.1.1 Test Method

Conducted method was used to measure the channel power output. The worst findings were conducted on 3 channels in each operating range per CFR47 Part 15.247(b) and RSS 247 Sect. 5.4(d); 2400 MHz to 2483.5 MHz The worst mode results indicated below.

4.1.2 Test Setup:

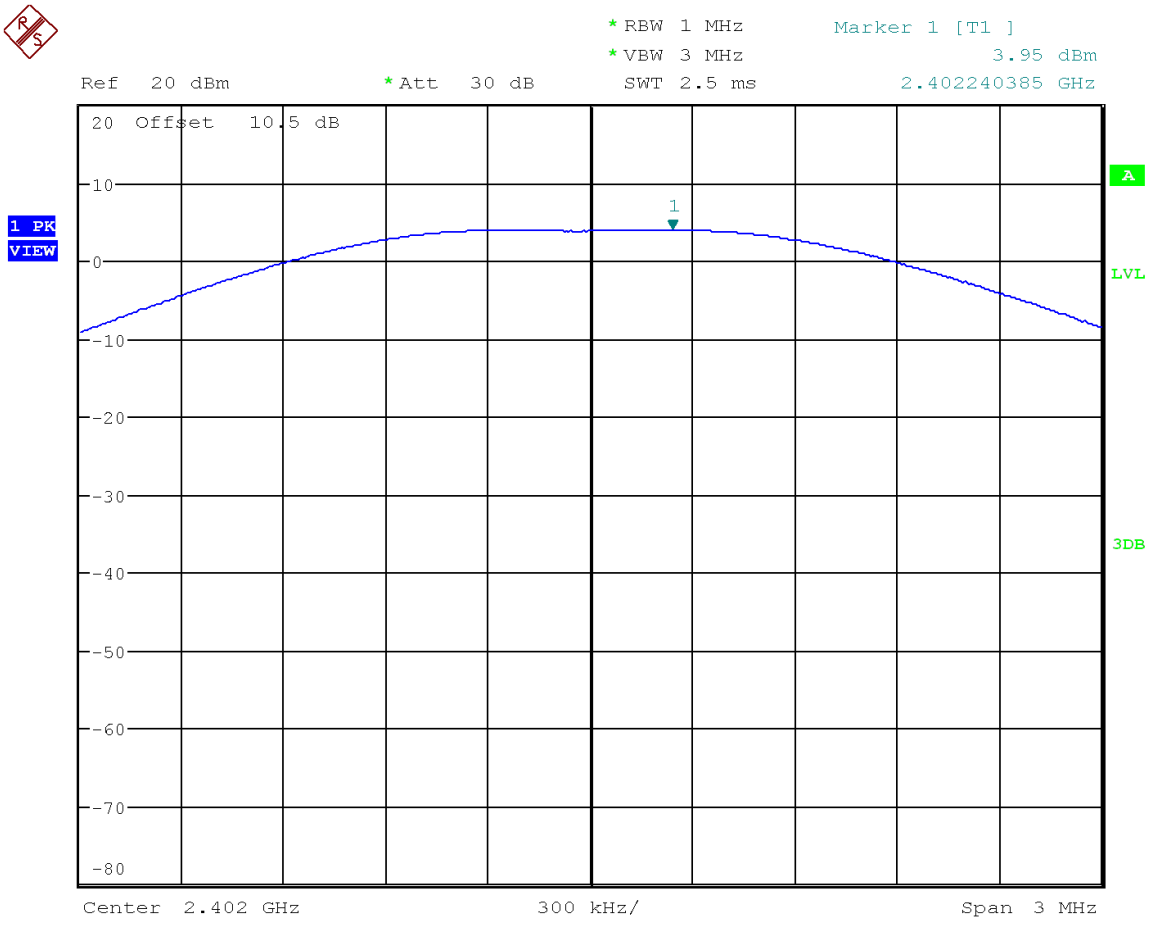


4.1.3 Results

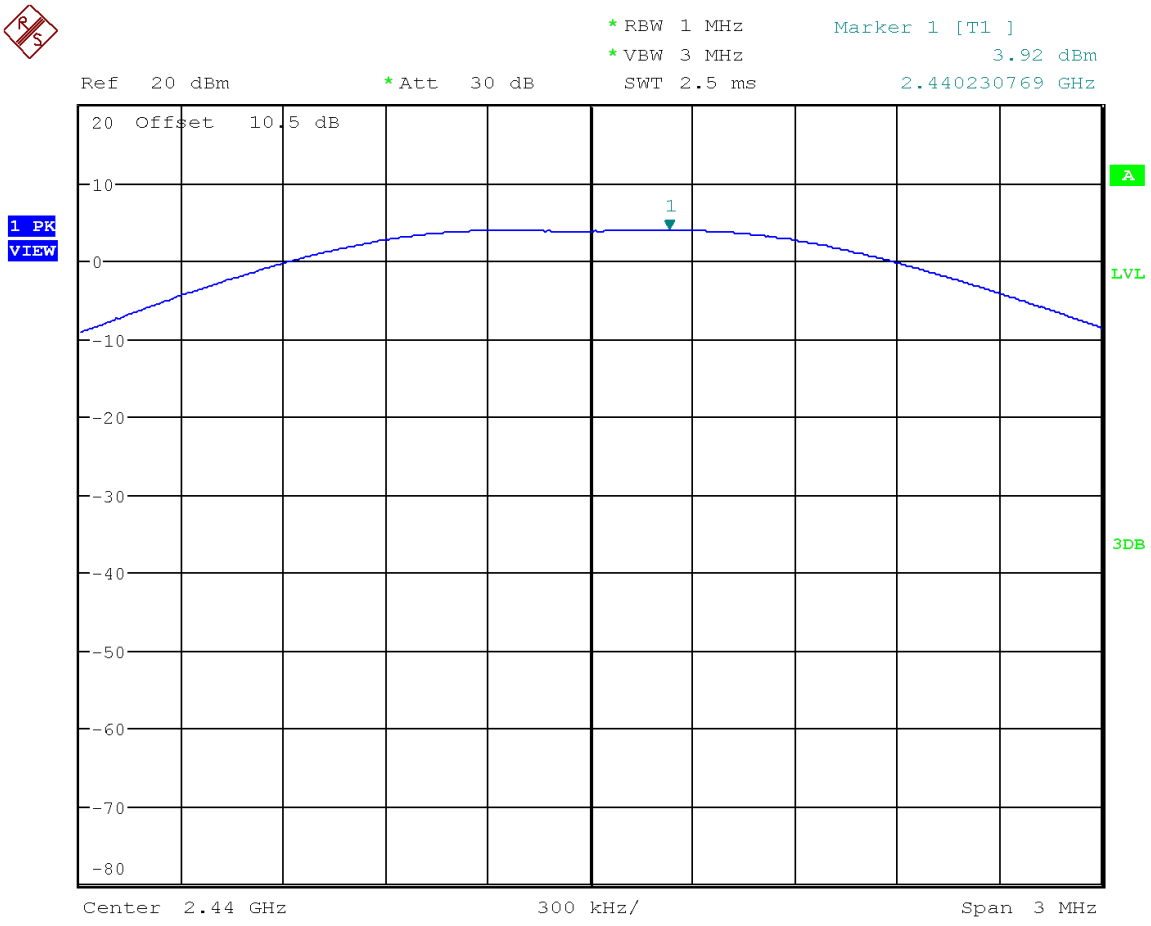
As originally tested, the EUT was found to be compliant to the requirements of the test standard(s). Worse case data for each mode reported below. Plots of highest power included for low, medium, and high channels.

Table 2: RF Output Power at the Antenna Port – Test Results

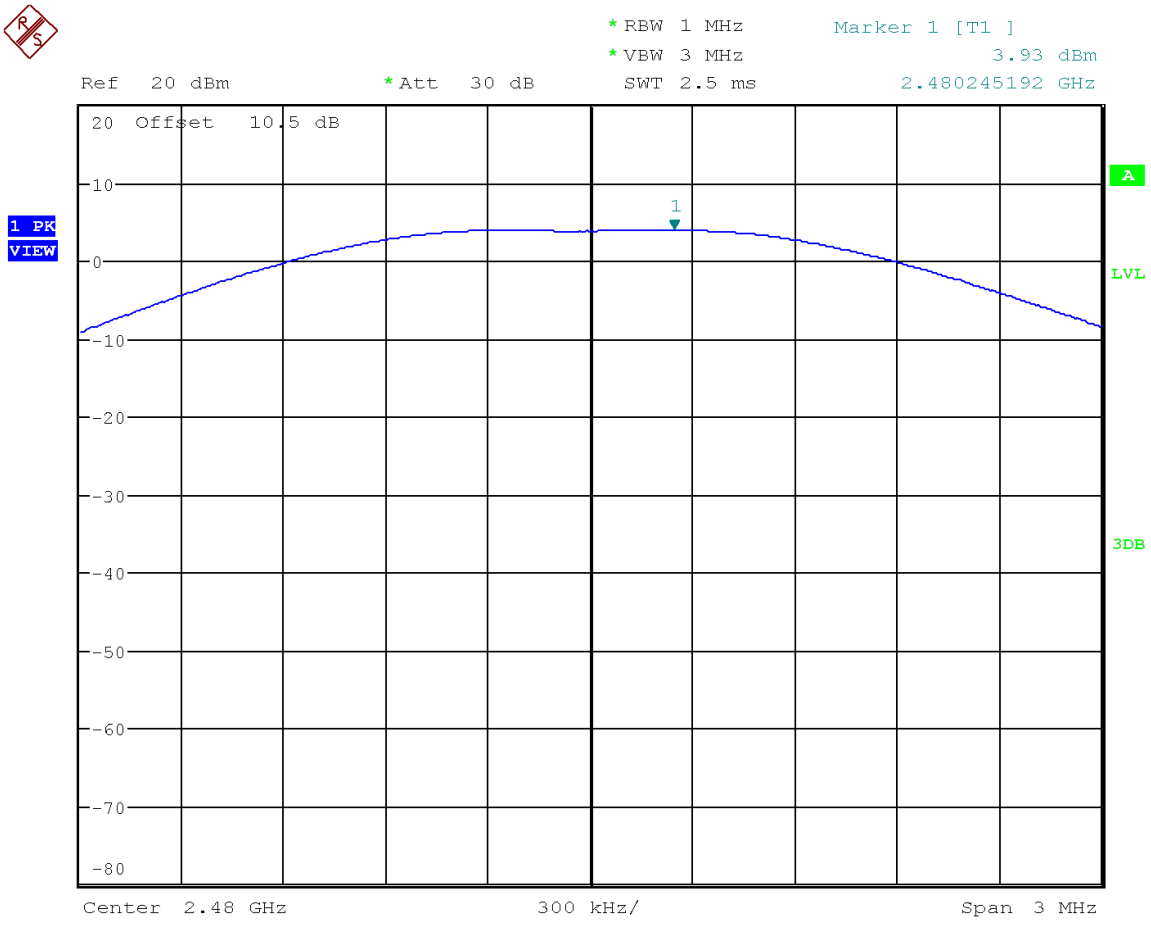
Test Conditions: Conducted Measurement, Normal Temperature			
Antenna Type: Trace Antenna			
Max. Antenna Gain: -5.1 dBi			
Test Performed by: Rachana Khanduri			
Operating Channel (MHz)	**Limit [dBm]**	**Total Power [dBm]**	**Margin [dB]**
2402.00	30.00	3.95	-26.05
2440.00	30.00	3.92	-26.08
2480.00	30.00	3.93	-26.07



Plot 1. Maximum Conducted Power, BLE-2402MHz



Plot 2. Maximum Conducted Power, BLE-2440MHz



Plot 3. Maximum Conducted Power, BLE-2480MHz

4.2 DTS Bandwidth (6dB) and Occupied Bandwidth

The occupied bandwidth is measured at an amplitude level reduced from the reference level by a specified ratio. The reference level is the level of the highest amplitude signal observed from the transmitter at the fundamental frequency.

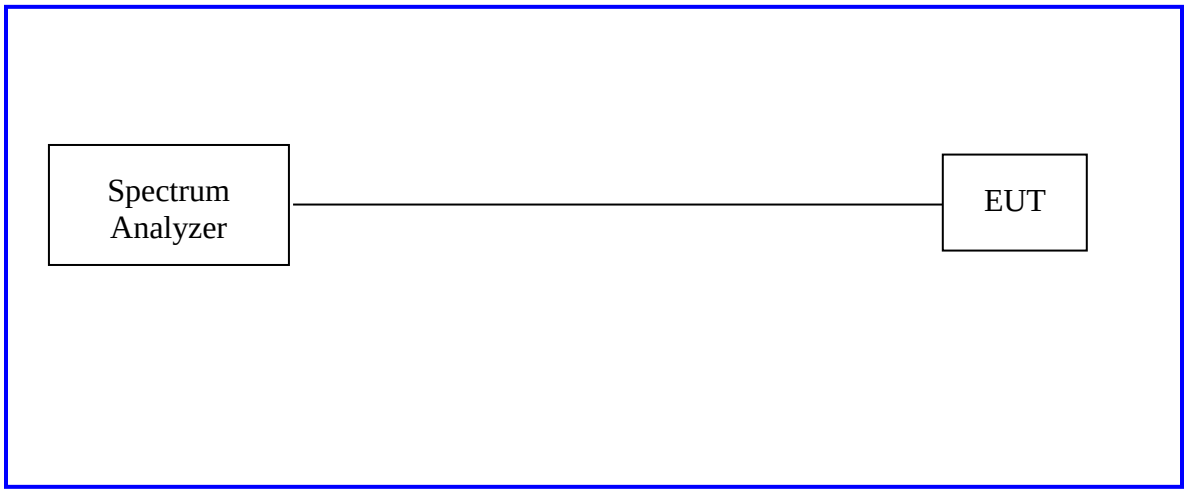
The 99% bandwidth is the bandwidth in which 99% of the transmitted power occupied.

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

4.2.1 Test Method

The conducted method was used to measure the occupied bandwidth according to ANSI C63.10:2013 Section 11.8. The measurement was performed with modulation per CFR47 15.247 (a) (2) and RSS Gen Sect. 6.6. Measurements were performed on the low, middle and high channels of the operating frequency range; 2400 MHz to 2483.5 MHz.

4.2.2 Test Setup:

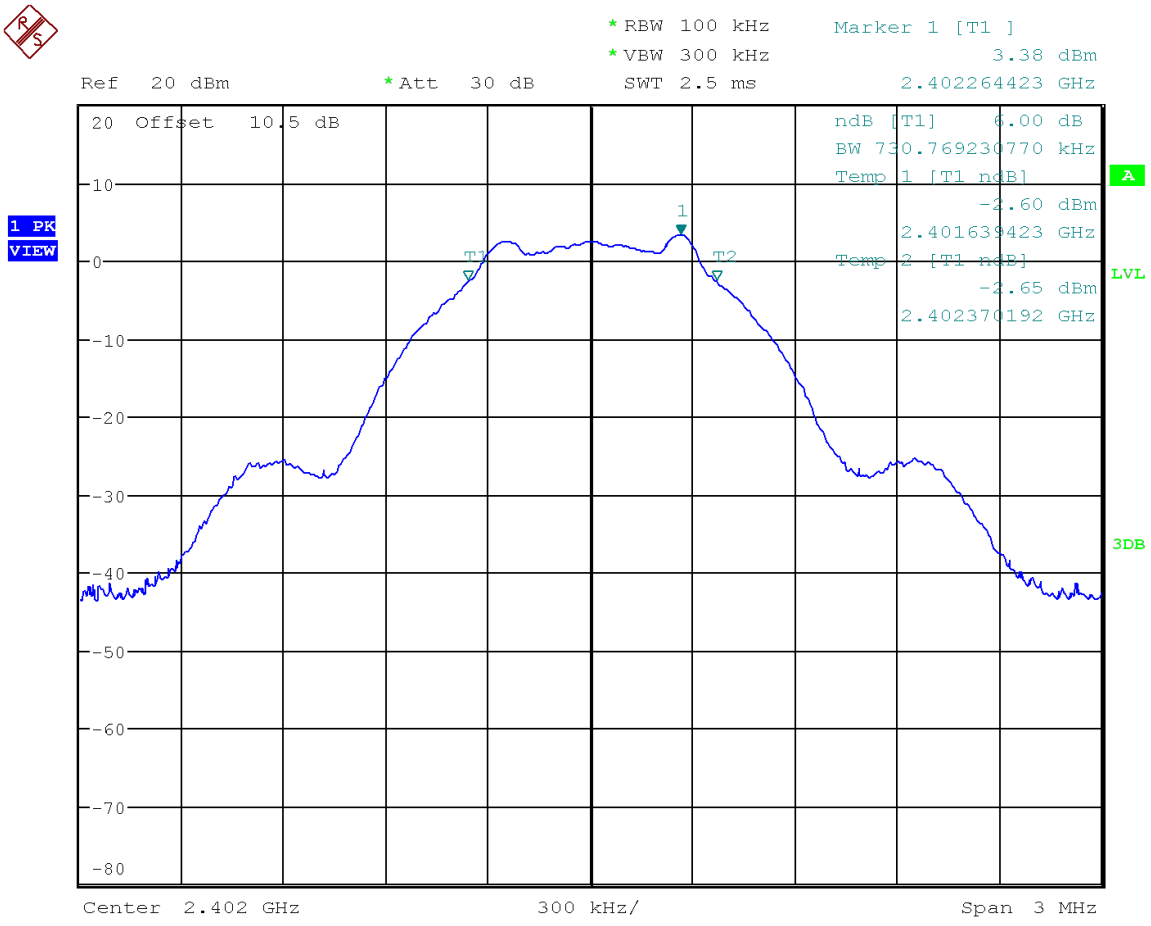


4.2.3 Results

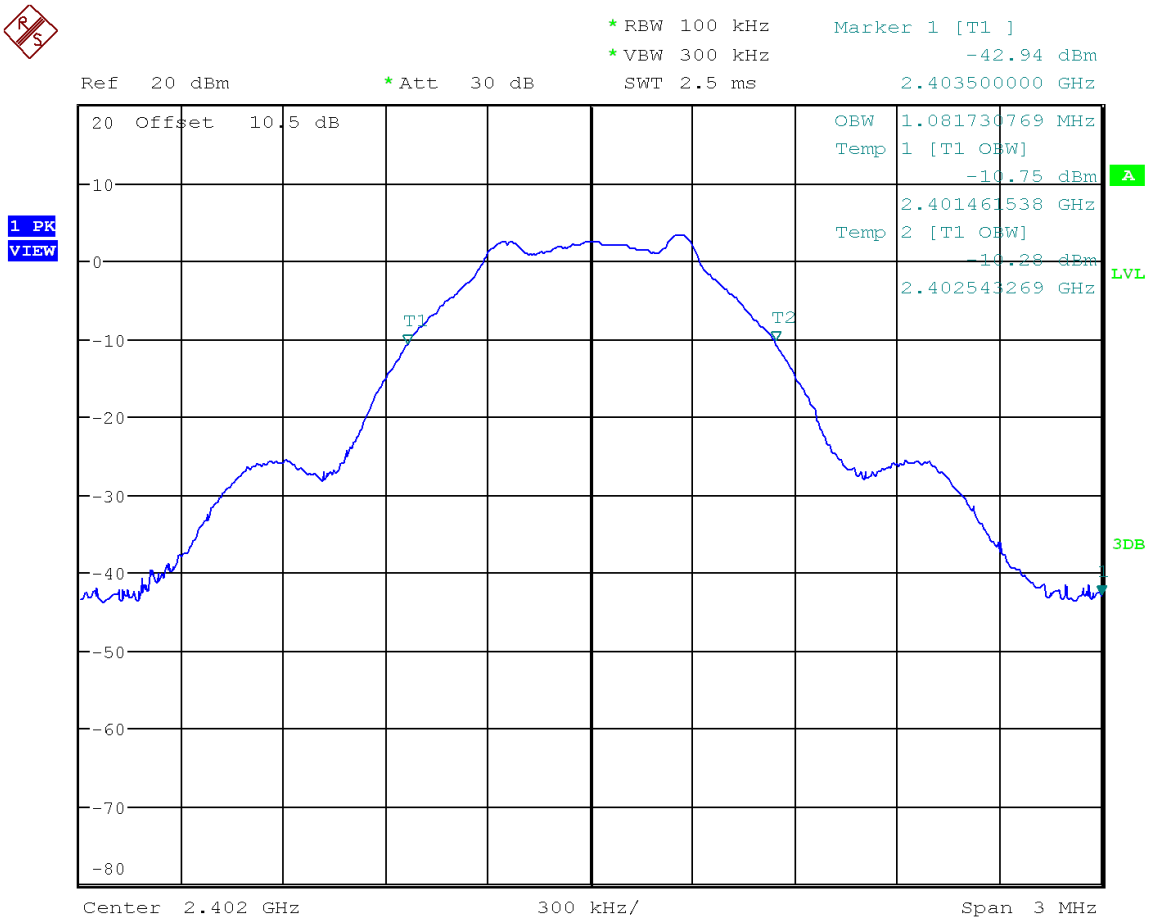
As originally tested, the EUT was found to be compliant to the requirements of the test standard(s).

Table 3: Occupied Bandwidth – Test Results

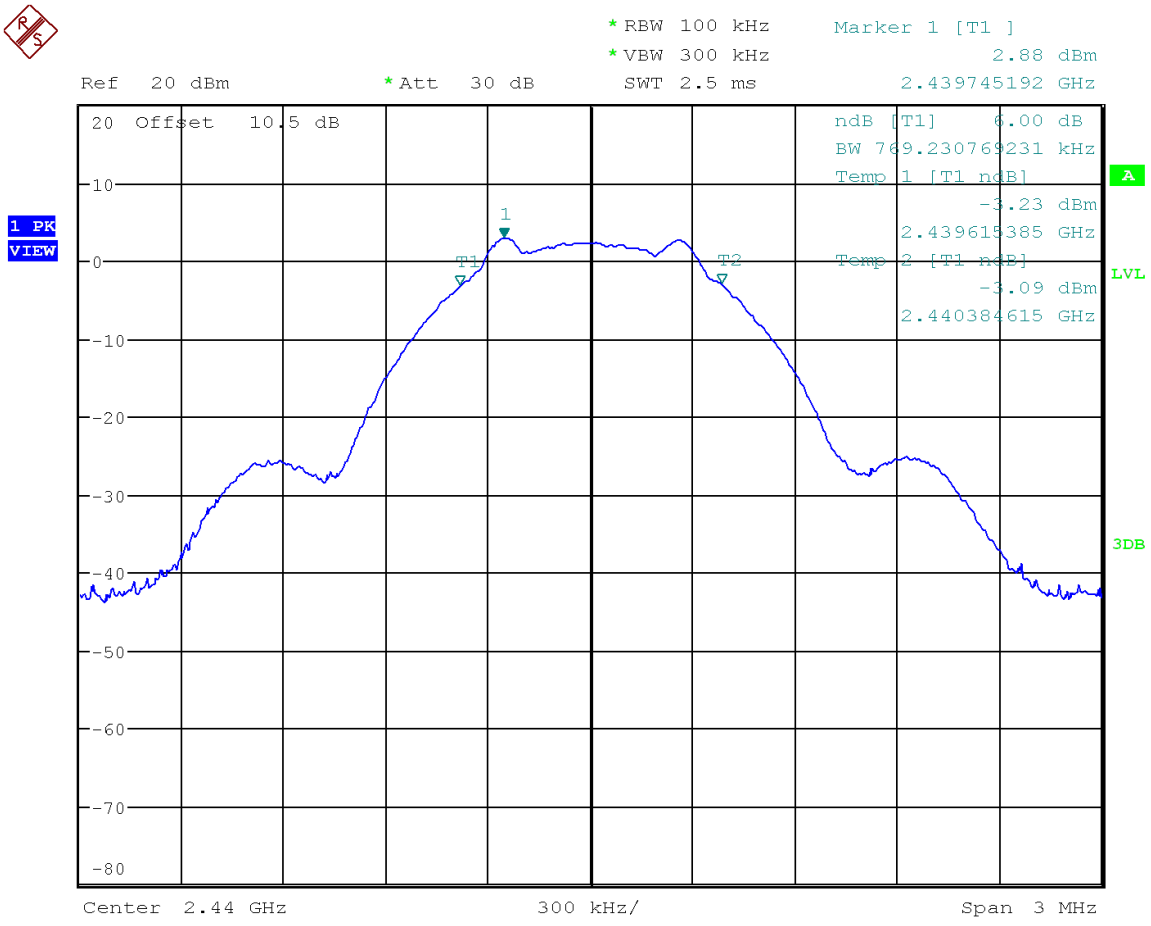
Test Conditions: Conducted Measurement, Normal Temperature		
Antenna Type: Trace Antenna		
Max. Antenna Gain: -5.1 dBi		
Test Performed by: Rachana Khanduri		
Operating Channel (MHz)	**99% Bandwidth (MHz)**	**6dB (DTS) Bandwidth (MHz)**
2402.00	1.082	0.731
2440.00	1.087	0.769
2480.00	1.091	0.760



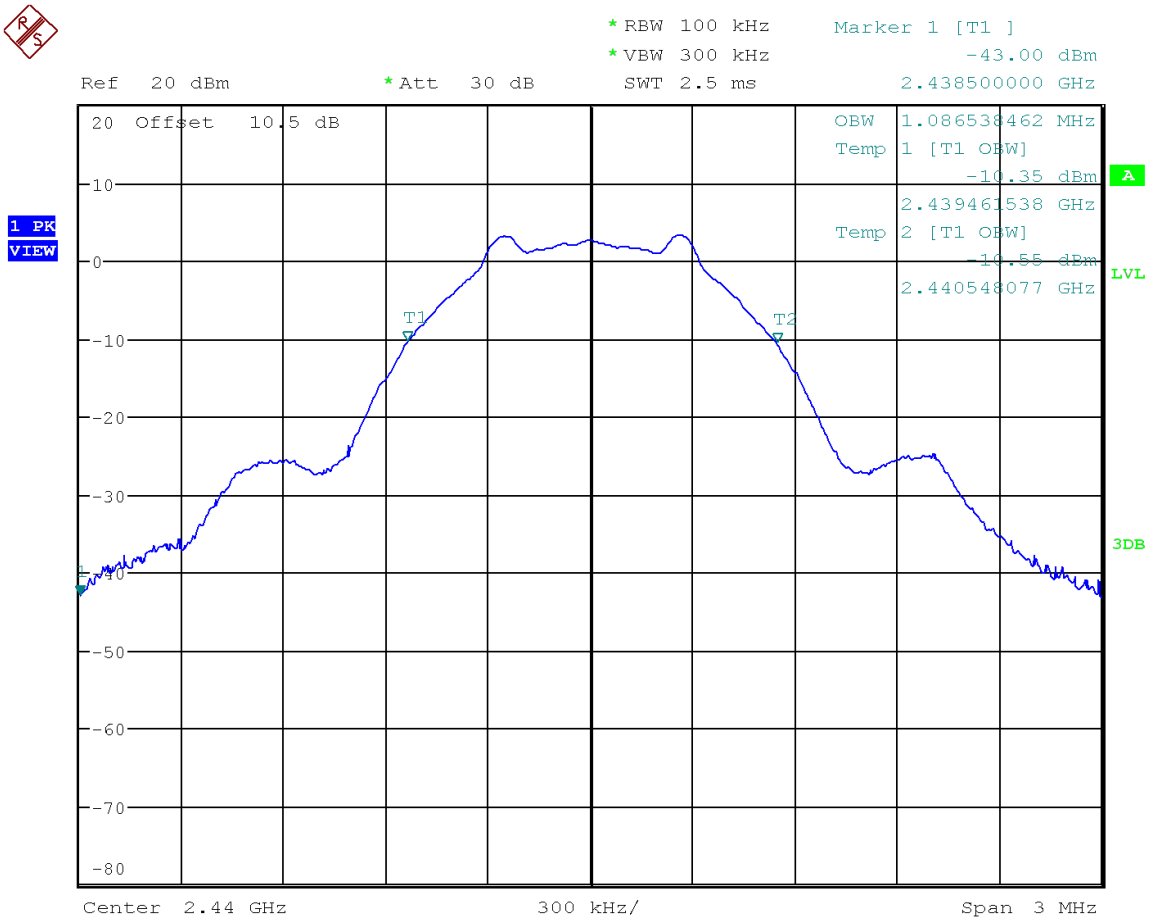
Plot 4. BLE-2402MHz, 6dB Bandwidth



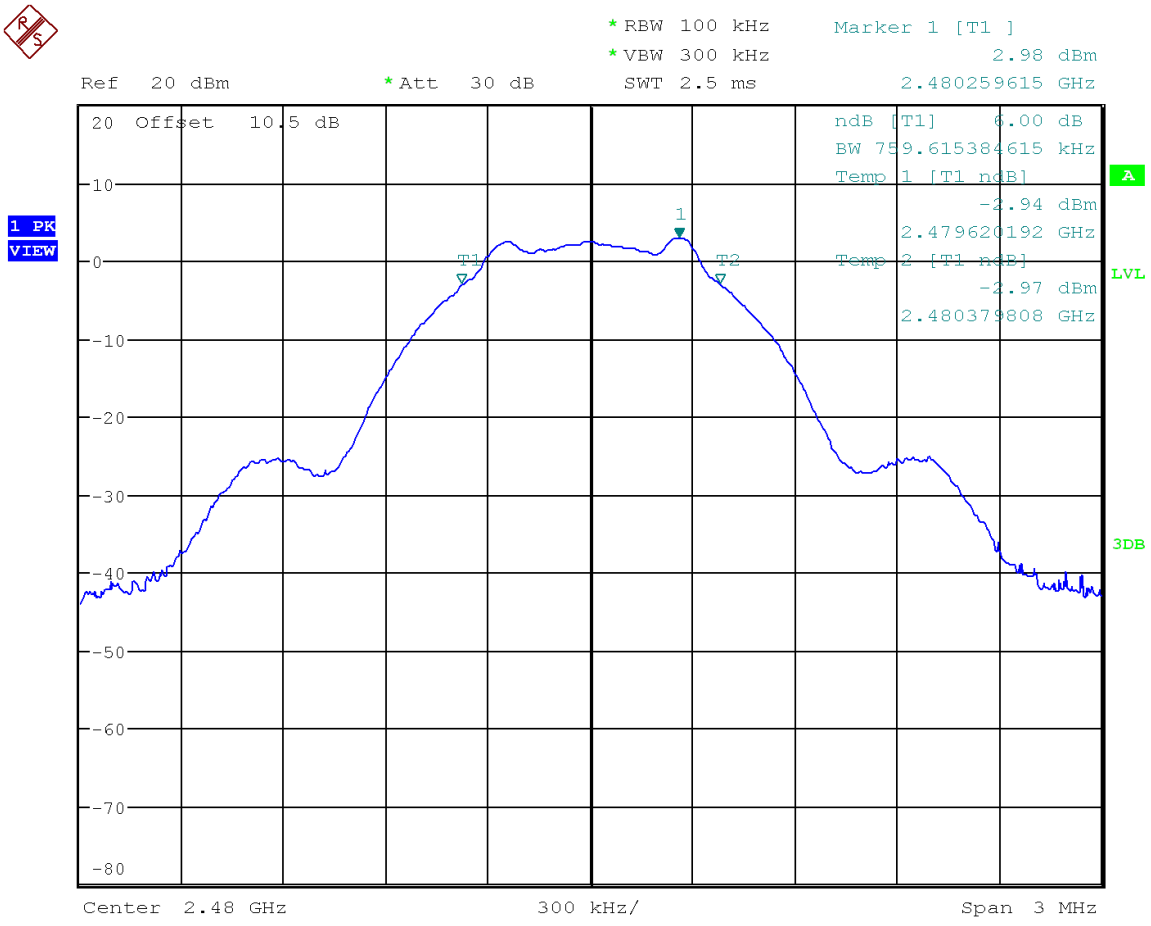
Plot 5. BLE-2402MHz, 99% Bandwidth



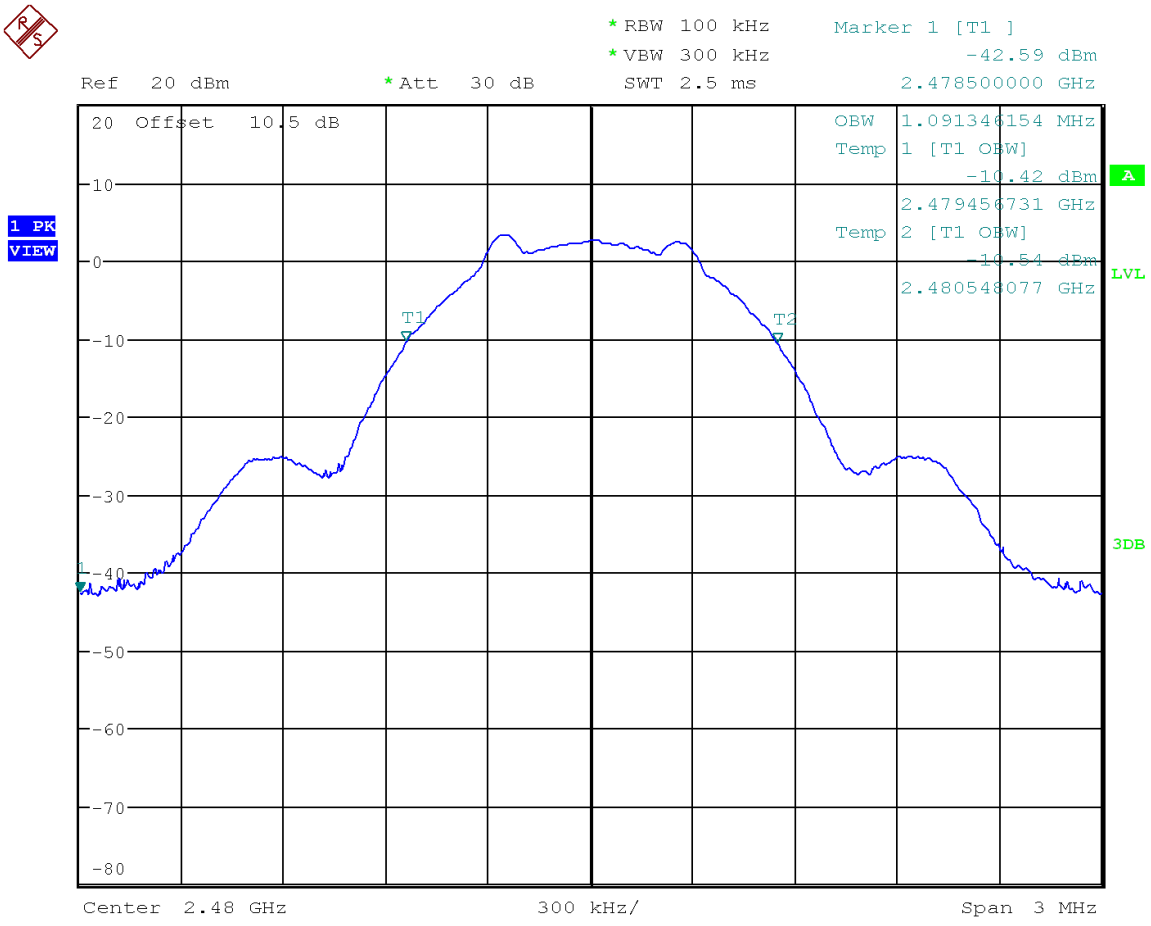
Plot 6. BLE-2440MHz, 6dB Bandwidth



Plot 7. BLE-2440MHz, 99% Bandwidth



Plot 8. BLE-2480MHz, 6dB Bandwidth



Plot 9. BLE-2480MHz, 99% Bandwidth

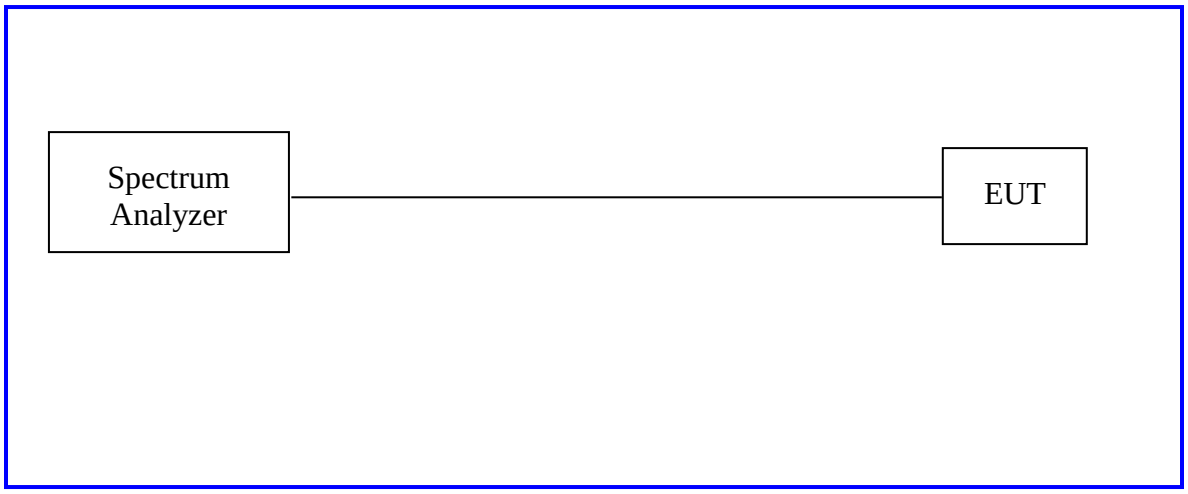
4.3 Peak Power Spectral Density

According to the CFR47 Part 15.247 (e) and RSS 247 Sect.5.2 (b), the power spectral density conducted from the intentional radiator to the antenna shall not be greater than 8 dBm in any 3 kHz band during any time interval of continuous transmission.

4.3.1 Test Method

The conducted method was used to measure the channel power output per ANSI C63.10-2013 Section 11.10.2. The measurement was performed with modulation per CFR47 Part 15.247 (e) and RSS 247 Sect.5.2 (b). The worst findings were conducted on 3 channels in each operating frequency range of 2400 MHz to 2483.5 MHz.

4.3.2 Test Setup:



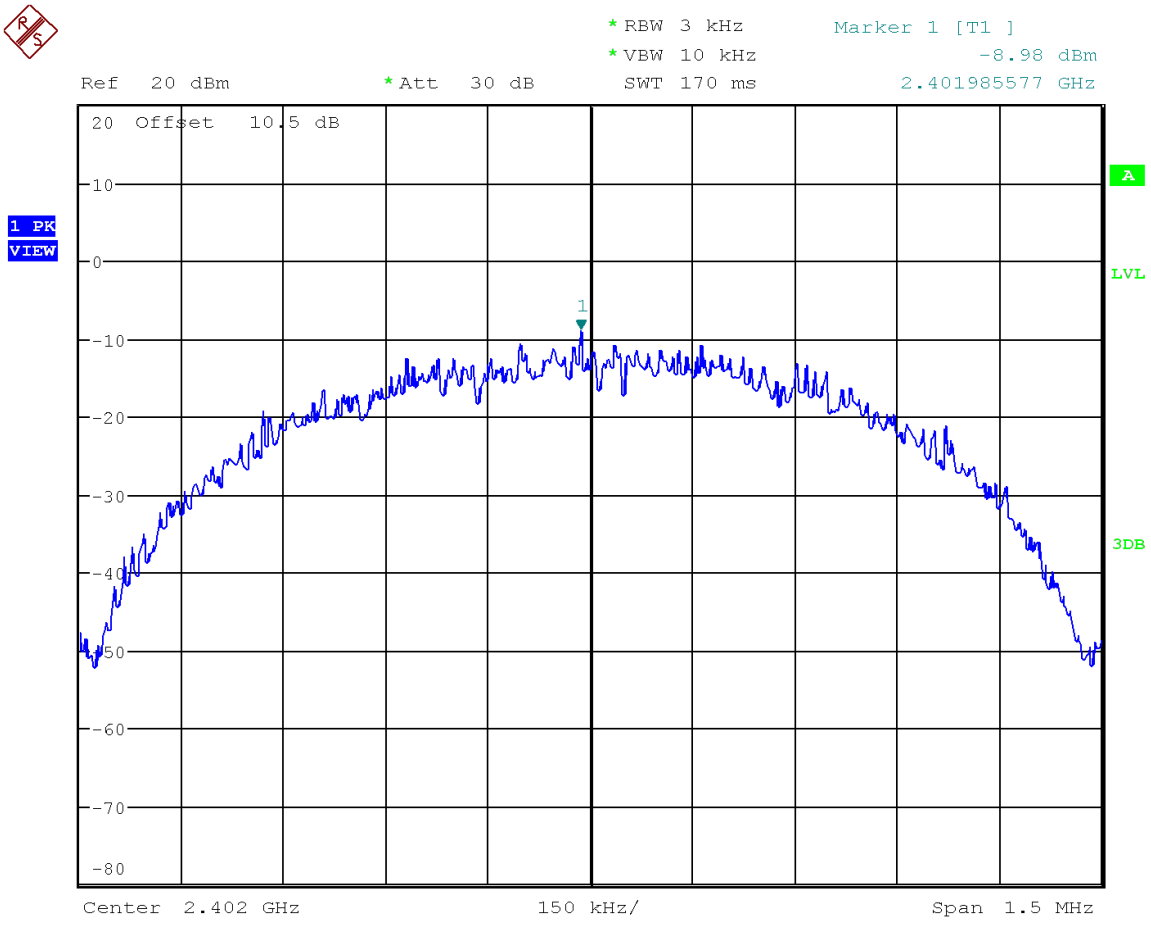
Method PKPSD of "KDB 558074 – DTS Measurement Guidance v04" was used.

4.3.3 Results

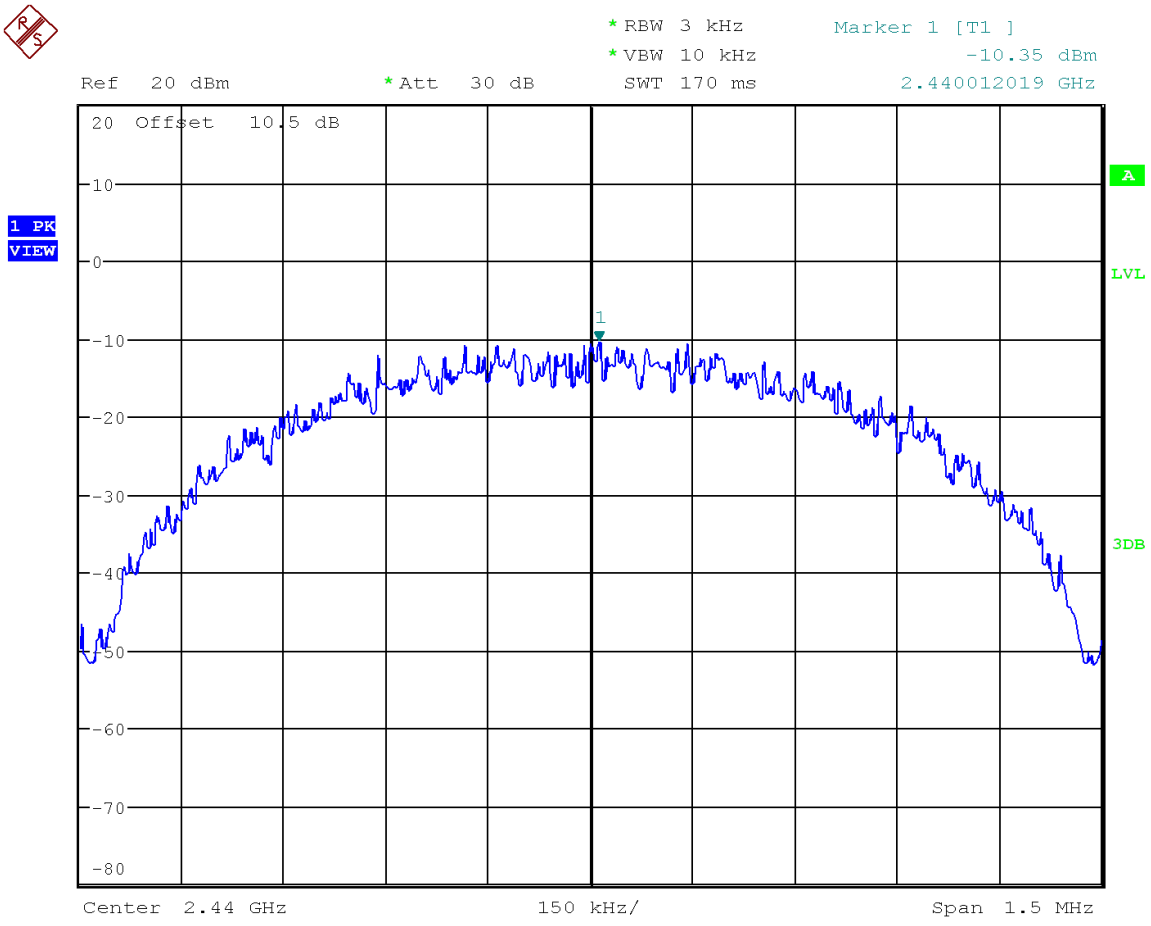
As originally tested, the EUT was found to be compliant to the requirements of the test standard(s).

Table 4: Peak Power Spectral Density – Test Results

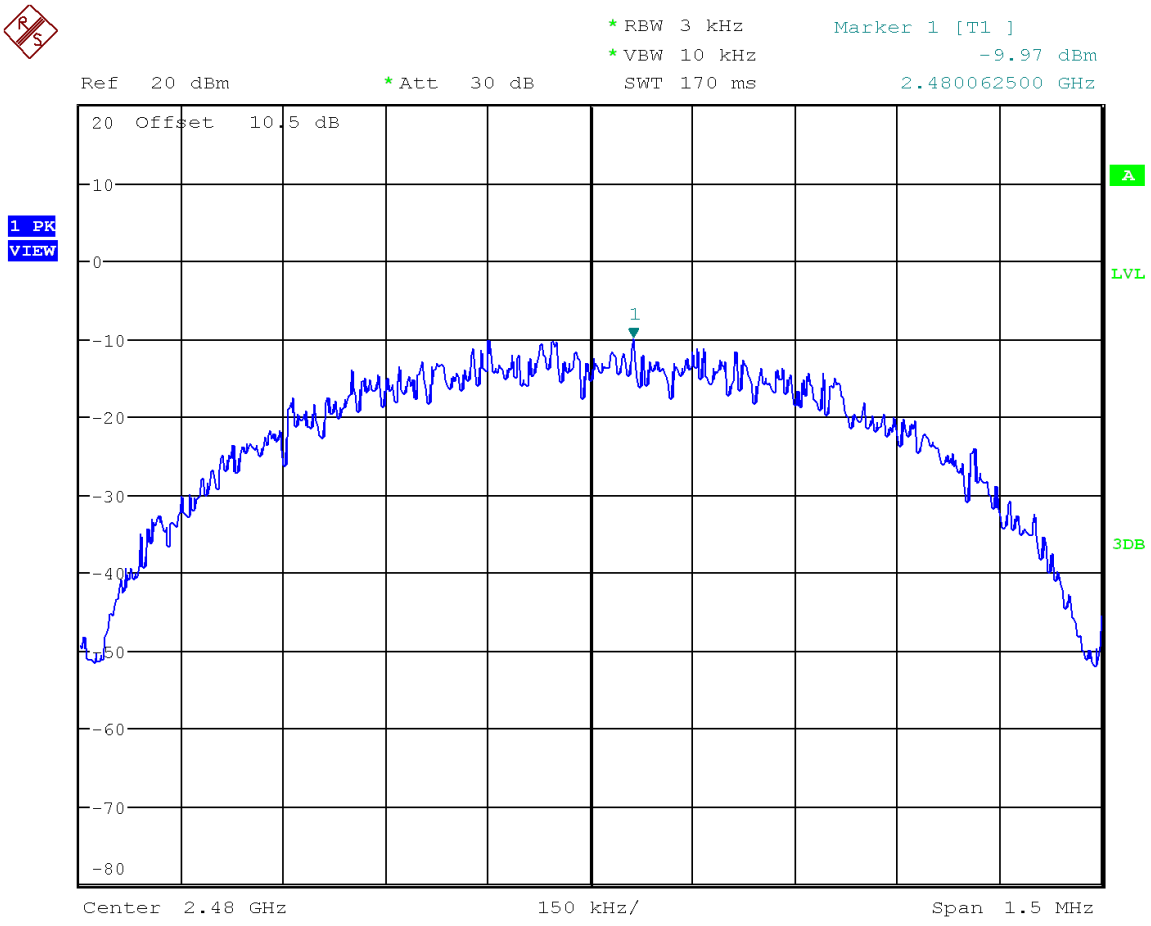
Test Conditions: Conducted Measurement, Normal Temperature			
Antenna Type: Trace Antenna			
Max. Antenna Gain: -5.1 dBi			
Test Performed by: Rachana Khanduri			
Operating Channel (MHz)	**Total PSD [dBm]**	**Limit [dBm/3kHz]**	**Margin [dB]**
2402.00	-8.98	8.0 dBm /3 kHz	-16.98
2440.00	-10.35	8.0 dBm /3 kHz	-18.35
2480.00	-9.97	8.0 dBm /3 kHz	-17.97
Note: None			



Plot 10. BLE-2402MHz PSD



Plot 11. BLE-2440MHz PSD



Plot 12. BLE-2480MHz PSD

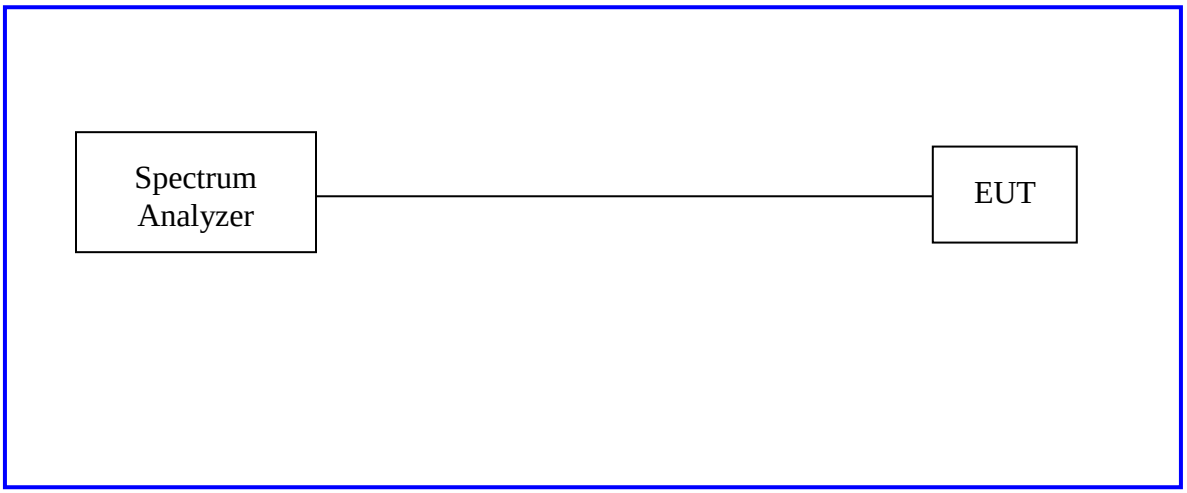
4.4 Out of Band Emissions: Non-Restricted Bands

Transmitter spurious emissions are emissions outside the frequency range of the equipment when the equipment is in transmitting mode; per requirement of CFR47 15.205, 15.209, 15.247(d), RSS-247 Sect. 5.5, RSS-GEN Sect. 8.9 and 8.10.

4.4.1 Test Method

Conducted measurements per ANSI C63.10-2013 Sections 6.10, 11.11, 14.3.3 were used to measure the undesirable emission requirement in non-restricted bands. The measurement was performed with modulation. The measurement was conducted from 30MHz to 26.5GHz on 3 channels in each mode on the EUT. Reference level was established on the channel with highest measured PSD (2402MHz) as stated in ANSI C63.10-2013 Section 11.11.2. Band edge tests were conducted on the low and high channel of each mode. The worst case measurement of each mode is recorded in this report.

4.4.2 Test Setup:

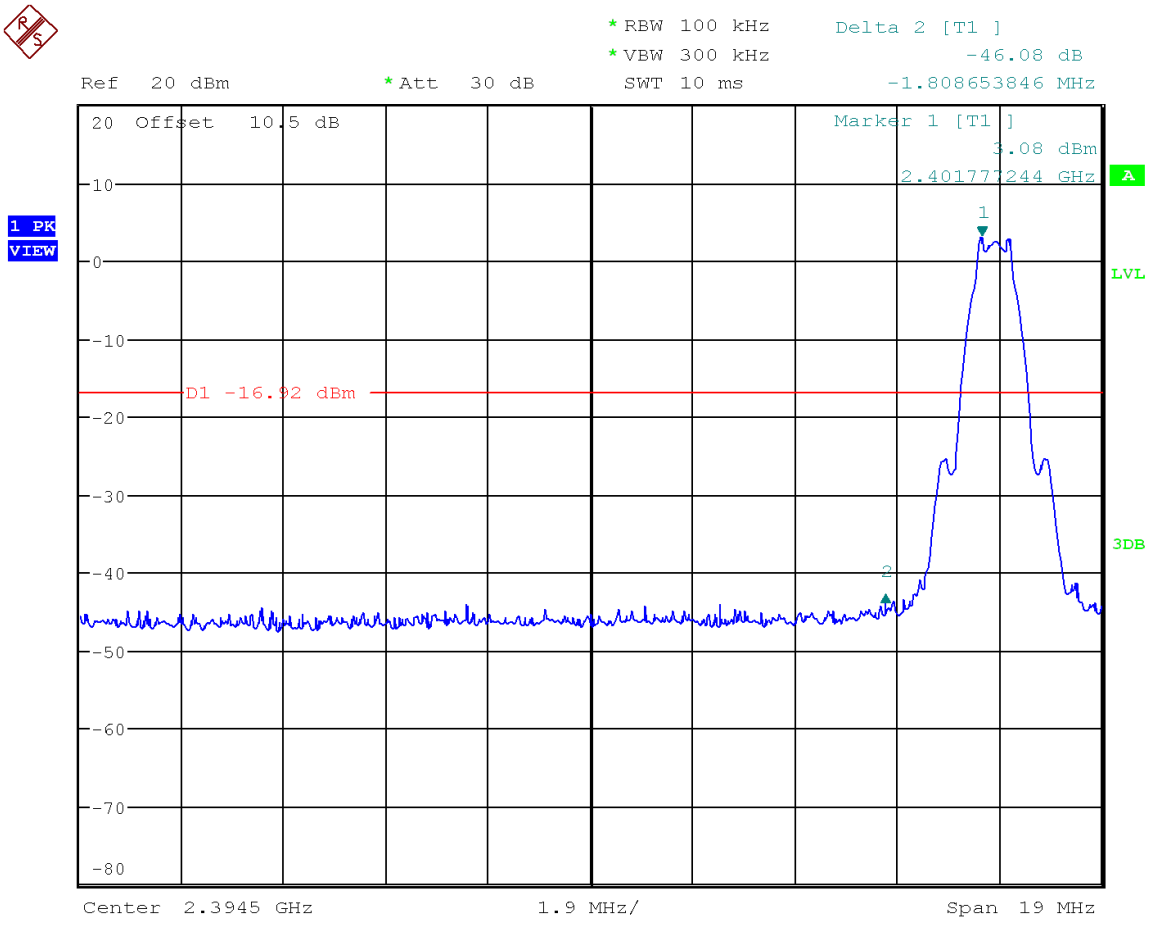


4.4.3 Results

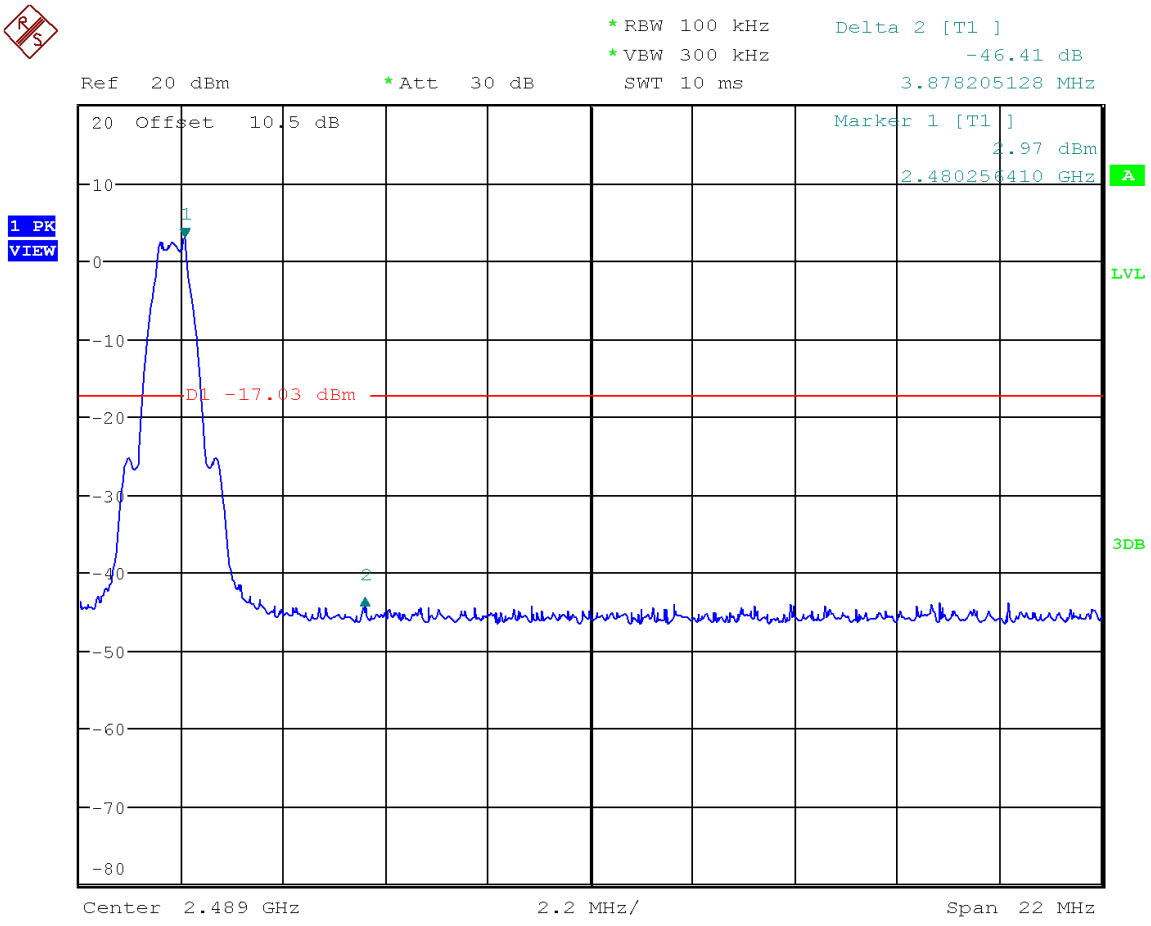
As originally tested, the EUT was found to be compliant to the requirements of the test standard(s).

Table 5: Emissions at the Band-Edge – Test Results

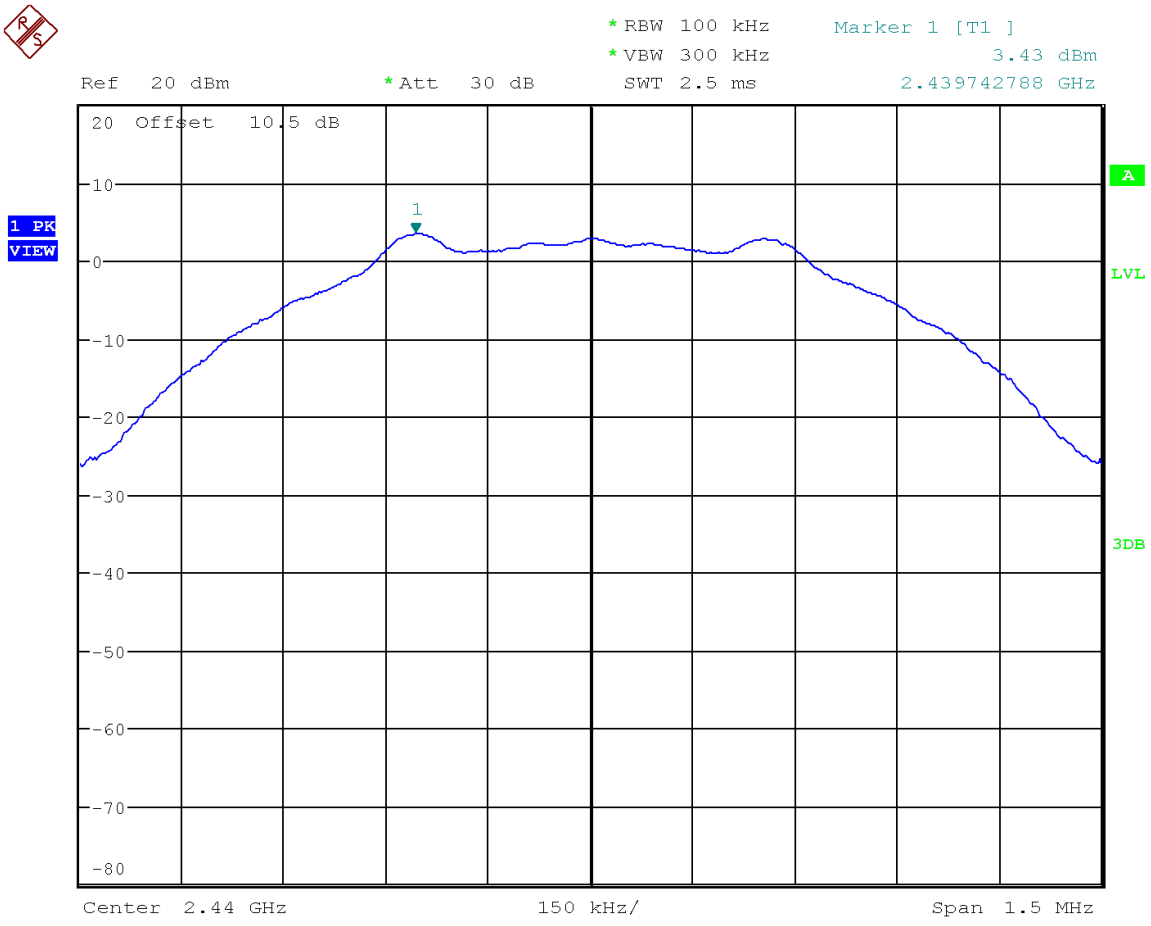
Test Conditions: Conducted Measurement, Normal Temperature and Voltage only					
Antenna Type: Trace Antenna					
Max. Antenna Gain: -5.1 dBi					
Test Performed by: Rachana Khanduri					
Non-Restricted Frequency Band Edge Emissions – Worse Case					
Band Edge	**Center Freq (MHz)**	**Measured (dBc)**	**Limit (dBc)**	**Freq (MHz)**	**Results**
Low	2402	-46.08	20	2399.96	Pass
High	2480	-46.41	20	2484.13	Pass
Note: None					



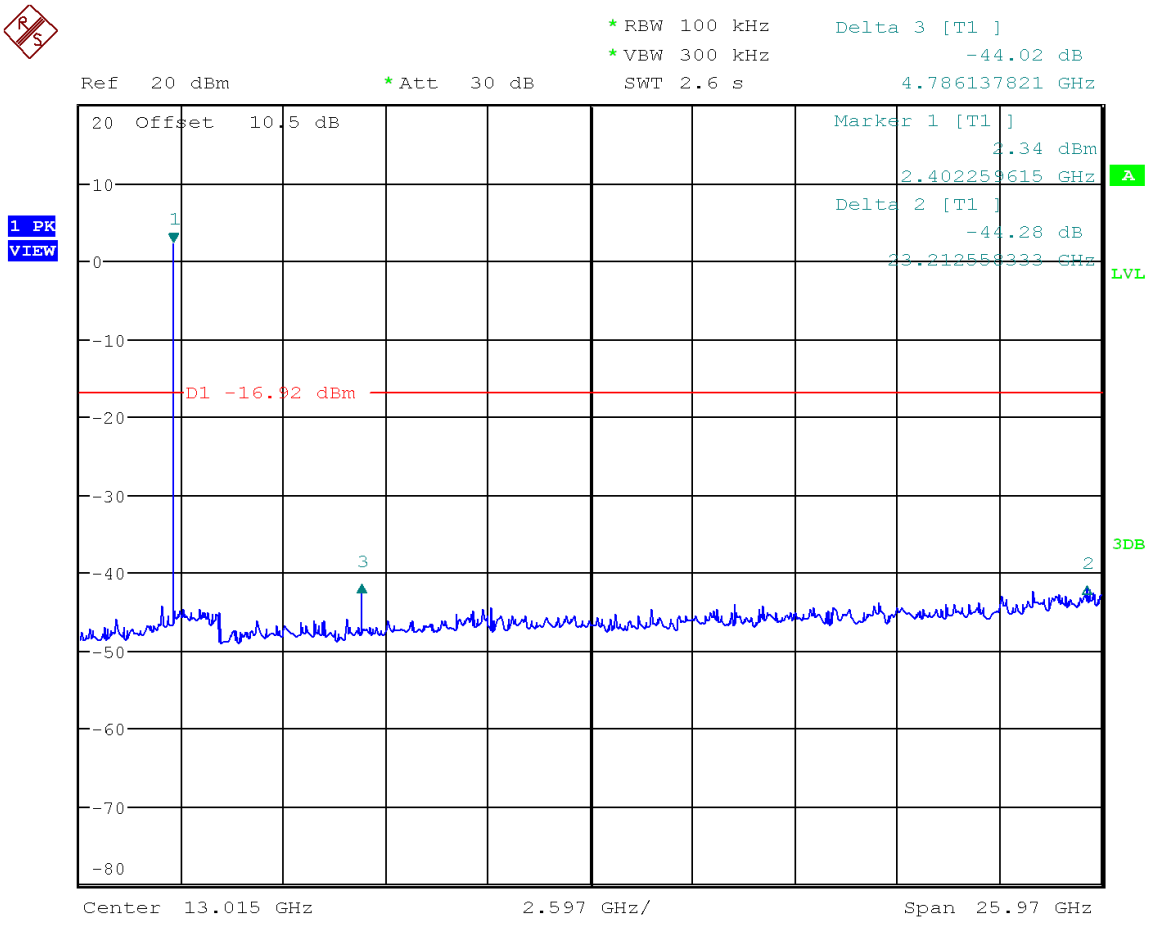
Plot 13. BLE-2402MHz Lower Band Edge



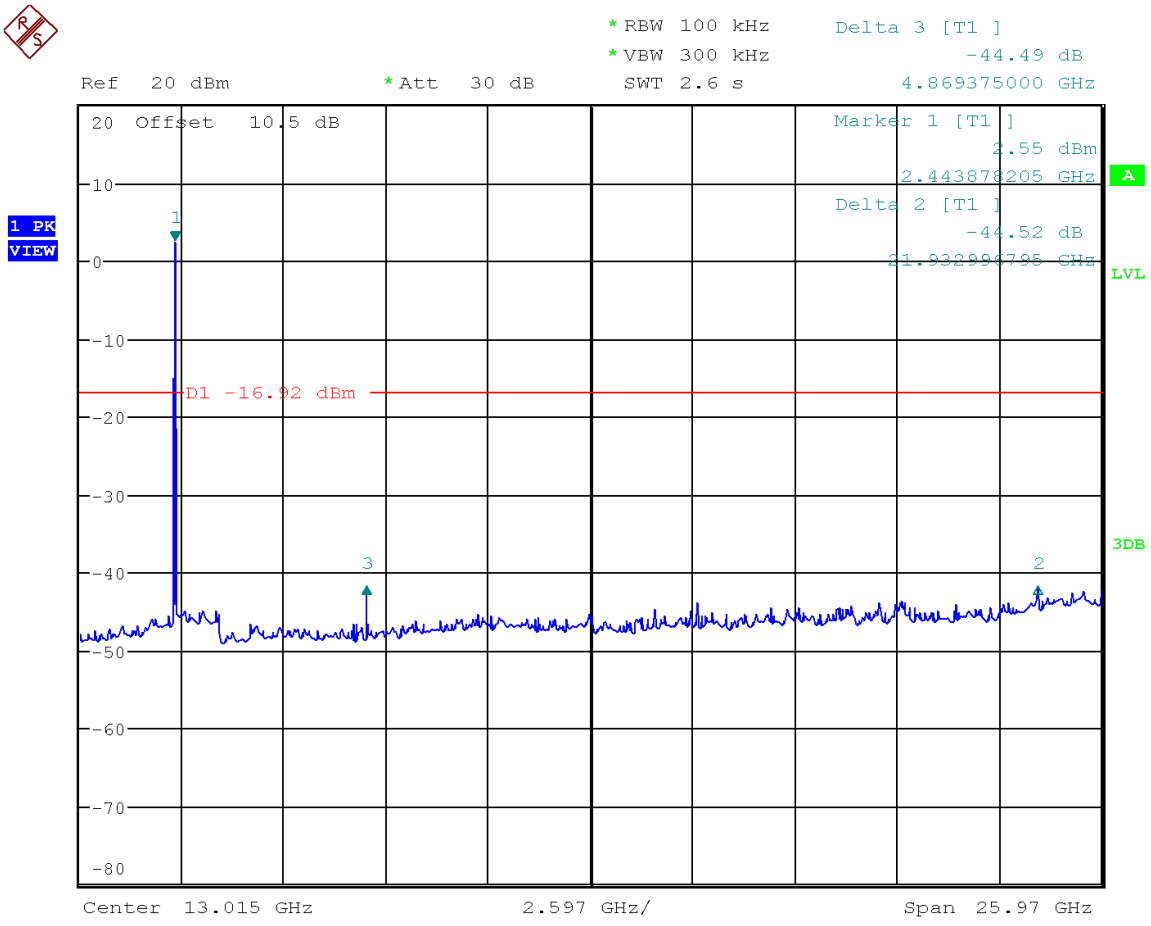
Plot 14. BLE-2480MHz Upper Band Edge



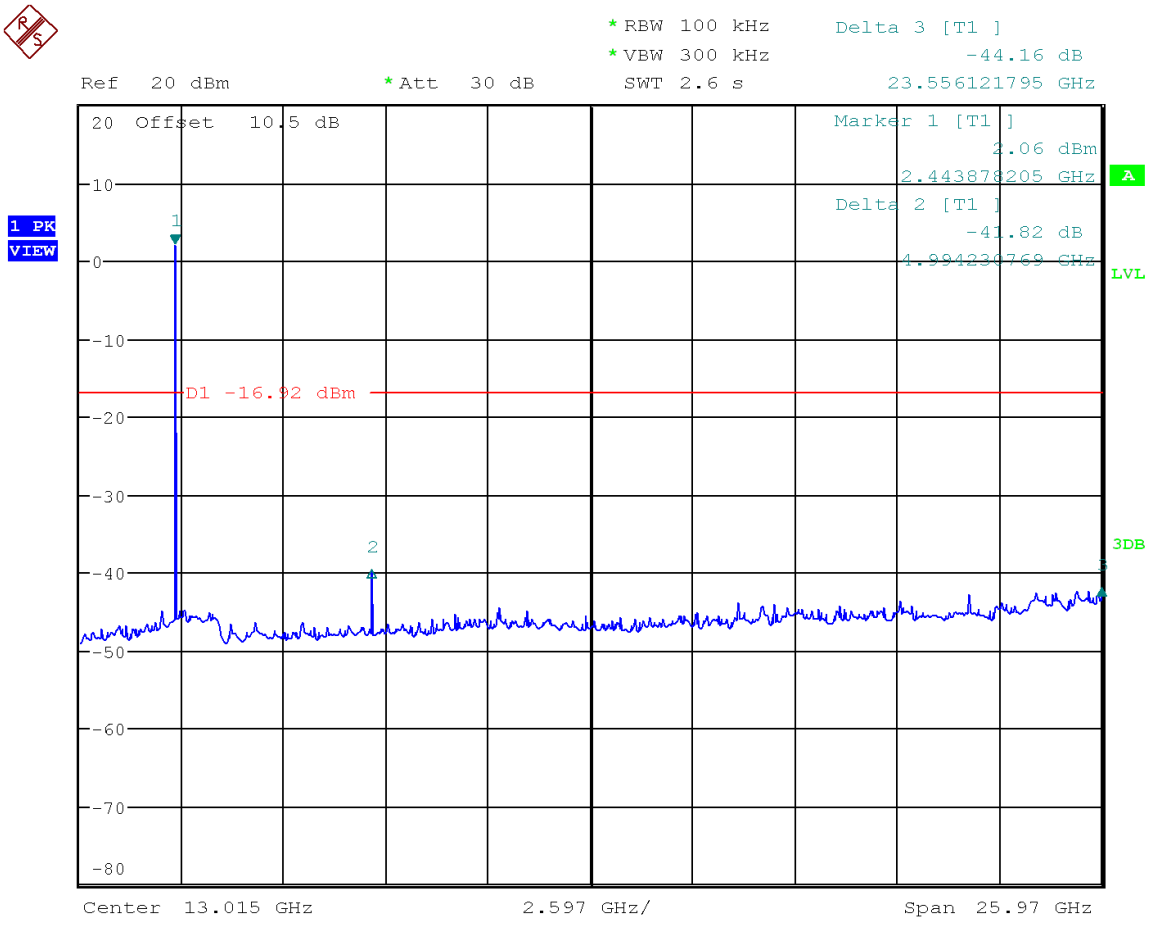
Plot 15. BLE-Non-Restricted Reference Measurement, 2440MHz



Plot 16. BLE-2402MHz 30MHz-26GHz Spurious



Plot 17. BLE-2440MHz 30MHz-26GHz Spurious



Plot 18. BLE-2480MHz 30MHz-26GHz Spurious

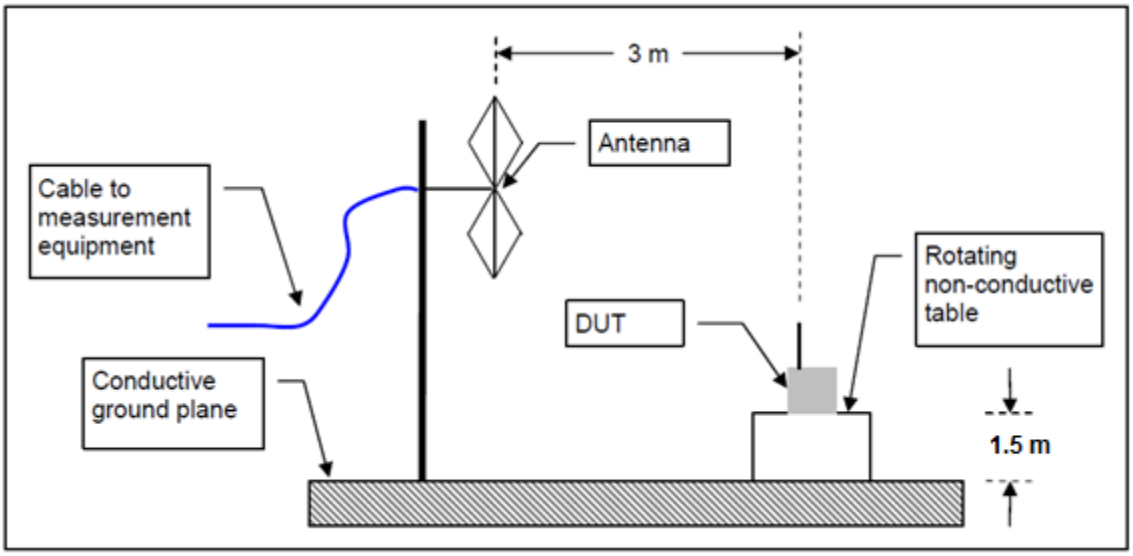
4.5 Out of Band Emissions: Restricted Band Edge

Transmitter spurious emissions are emissions outside the frequency range of the equipment when the equipment is in transmitting mode; per requirement of CFR47 15.205, 15.209, 15.247(d), RSS-247 Sect. 5.5, RSS-GEN Sect. 8.9 and 8.10.

4.5.1 Test Method

Radiated measurements per ANSI C63.10-2013 Section 6.10.5 were used to measure the undesirable emission requirement in restricted bands. Peak points were found and RMS Average was taken for each point found. The measurement was performed with modulation. This test was conducted on 3 channels in each mode on the EUT. The worst case measurement of each channel is recorded in this report. All channels were tested at highest power settings.

Test Setup

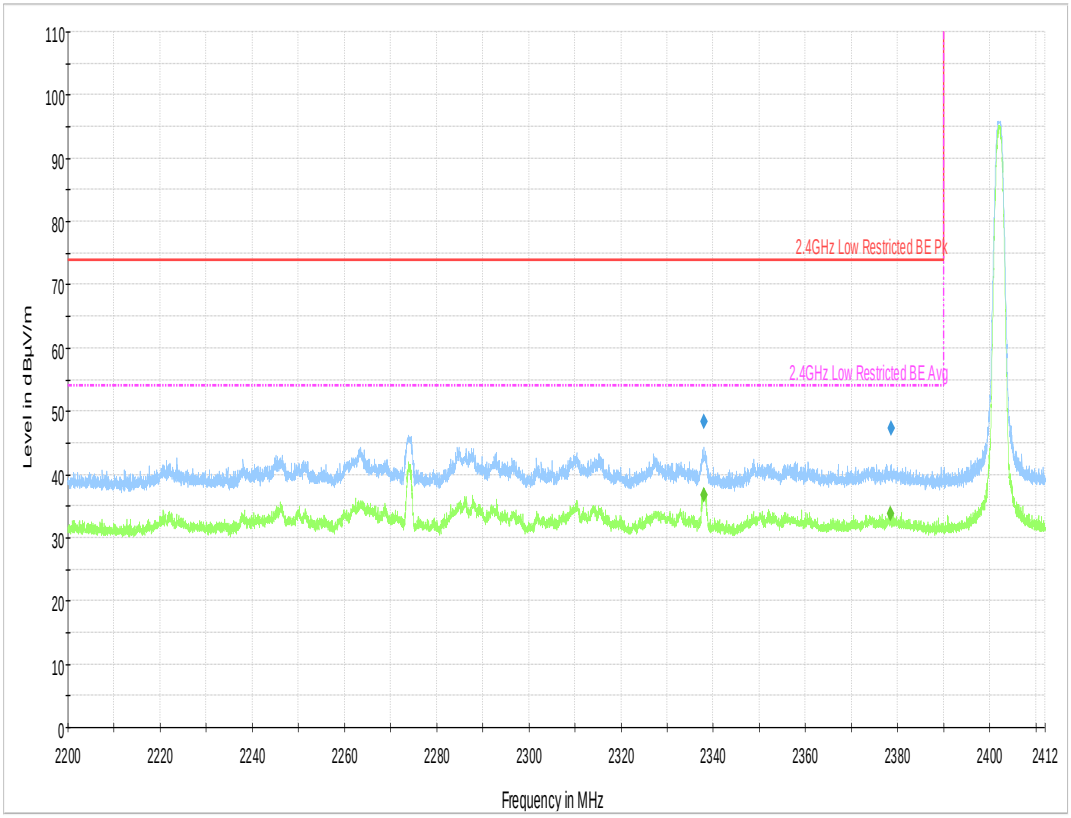


The DUT was stimulated by manufacturer provided test software that is not available to the end user.

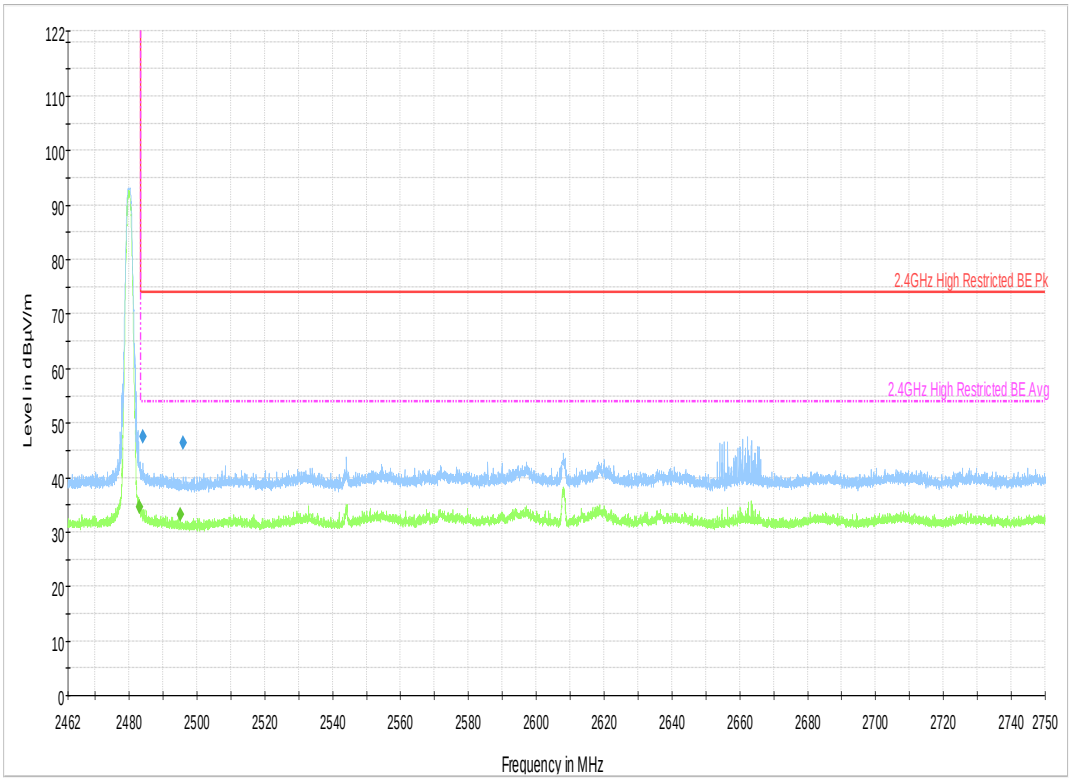
4.5.2 Test Results

Table 6: Emissions at the Band-Edge – Test Results

Test Conditions: Radiated Measurement, Normal Temperature and Voltage							
Antenna Type: Trace Antenna							
Max. Antenna Gain: -5.1 dBi							
Test Performed by: Rachana Khanduri							
Lower Restricted Band Edge							
Freq. (MHz)	**Mode**	**Center Freq (MHz)**	**Detector (Average/Peak)**	**Measured (dBuV/m)**	**Limit (dBuV/m)**	**Margin**	**Results**
2338.012	BLE GFSK 1Mbps	2402	Average	36.70	54	-17.30	Pass
2337.991	BLE GFSK 1Mbps	2402	Peak	48.28	74	-25.72	Pass
Upper Restricted Band Edge							
Freq. (MHz)	**Mode**	**Center Freq (MHz)**	**Detector (Average/Peak)**	**Measured (dBuV/m)**	**Limit (dBuV/m)**	**Margin**	**Results**
2495.062	BLE GFSK 1Mbps	2480	Average	33.28	54	-20.72	Pass
2495.926	BLE GFSK 1Mbps	2480	Peak	47.57	74	-26.43	Pass
Note: 1. The DCCF (Average Detector) is included in this table, the following plots are of peak values							



Plot 19. BLE-2402MHz, Lower Band Edge, Restricted



Plot 20. BLE-2480MHz, Upper Band Edge, Restricted

4.6 Transmitter Spurious Emissions

Transmitter spurious emissions are emissions outside the frequency range of the equipment when the equipment is in transmit mode; per requirement of CFR47 15.205, 15.209, 15.247(d), RSS 247 Sect.5.5, RSS-GEN Sect. 8.9 and 8.10.

4.6.1 Test Methodology

4.6.1.1 Preliminary Test

A test program that controls instrumentation and data logging was used to automate the preliminary RF emission test procedure. The frequency range of interest was divided into sub-ranges to yield a frequency resolution of approximately 120 kHz and provide a reading at each frequency for no more than 12° of turntable rotation. For each frequency sub-range the turntable was rotated 360° while peak emission data was recorded and plotted over the frequency range of interest in horizontal and vertical antenna polarization's.

Preliminary emission profile testing was performed inside the anechoic chamber. The EUT was placed on a 1.0m x 1.5m non-conductive table 80cm (<1 GHz) and 150cm (>1 GHz) above the floor. The EUT was positioned as shown in the setup photographs. The receiving antenna was placed at a distance of 3m at a fixed height of 1m. Measurement equipment was located outside of the chamber. A video camera was placed inside the chamber to view the EUT.

Pre-scans were performed to determine the worst data rate / chains.

4.6.1.2 Final Test

For each frequency measured, the peak emission was maximized by manipulating the receiving antenna from 1 to 4 meters above the ground plane and placing it at the position that produced the maximum signal strength reading. The turntable was then rotated through 360° while observing the peak signal and placing the EUT at the position that produced maximum radiation. The six highest emissions relative to the limit were measured unless such emissions were more than 20 dB below the limit. If less than six emissions are within 20 dB of the limit, than the noise level of the receiver is measured at frequencies where emissions are expected. Multiples of all oscillator and microprocessor frequencies were also checked.

Final testing was performed on an NSA compliant test site. The EUT was placed on a 1.0m x 1.5m non-conductive table 80cm (<1 GHz) and 150cm (>1 GHz) above the ground plane. The placement of EUT and cables were the same as for preliminary testing and is shown in the setup photographs.

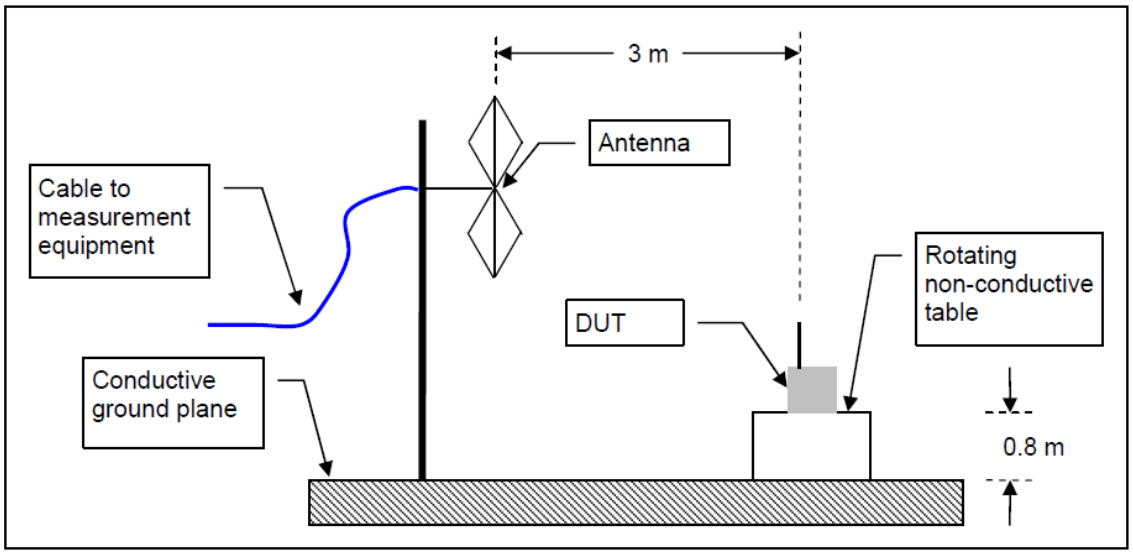
4.6.1.3 Deviations

None.

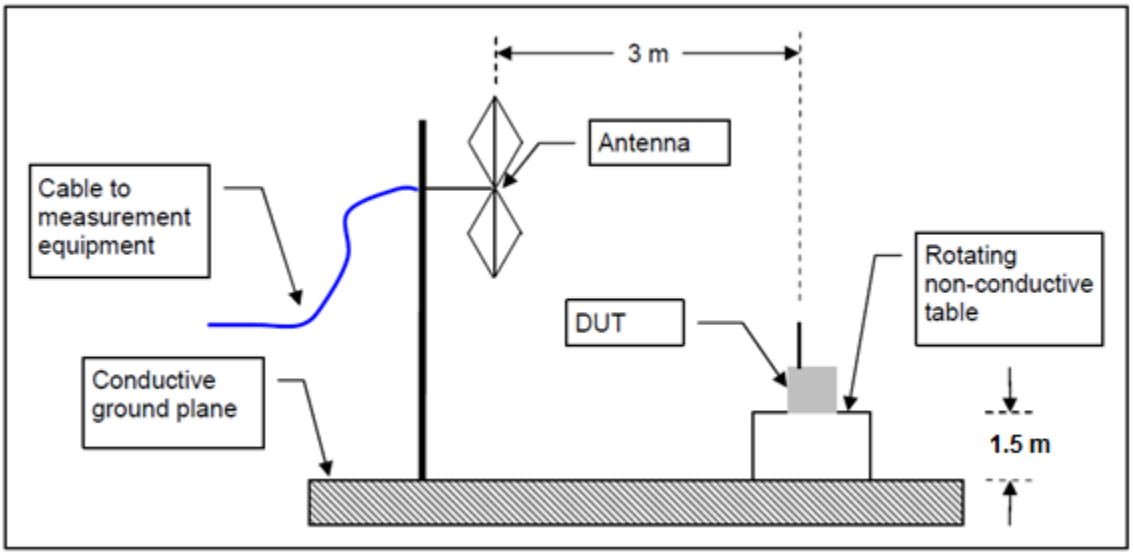
4.6.2 Test Setup:

All tests were conducted at full power on low, middle, and high channels. The DUT was stimulated by manufacturer provided test software that is not available to the end user.

30MHz-1GHz



1-26GHz



4.6.3 Transmitter Spurious Emission Limit

The spurious emissions of the transmitter shall not exceed the values in CFR47 Part 15.205, 15.209: 2015 and RSS Gen Sect. 8.9 and 8.10: 2014.

Frequency (MHz)	Field strength (microvolts/meter)	Measurement distance (meters)
0.009-0.490.....	2400/F(kHz)	300
0.490-1.705.....	24000/F(kHz)	30
1.705-30.0.....	30	30
30-88.....	100 **	3
88-216.....	150 **	3
216-960.....	200 **	3
Above 960.....	500	3

4.6.4 Test Results

The final measurement data was taken under the worst case operating modes, configurations, and/or cable positions. It also reflects the results including any modifications and/or special accessories listed in Sections 1.4 and test plan.

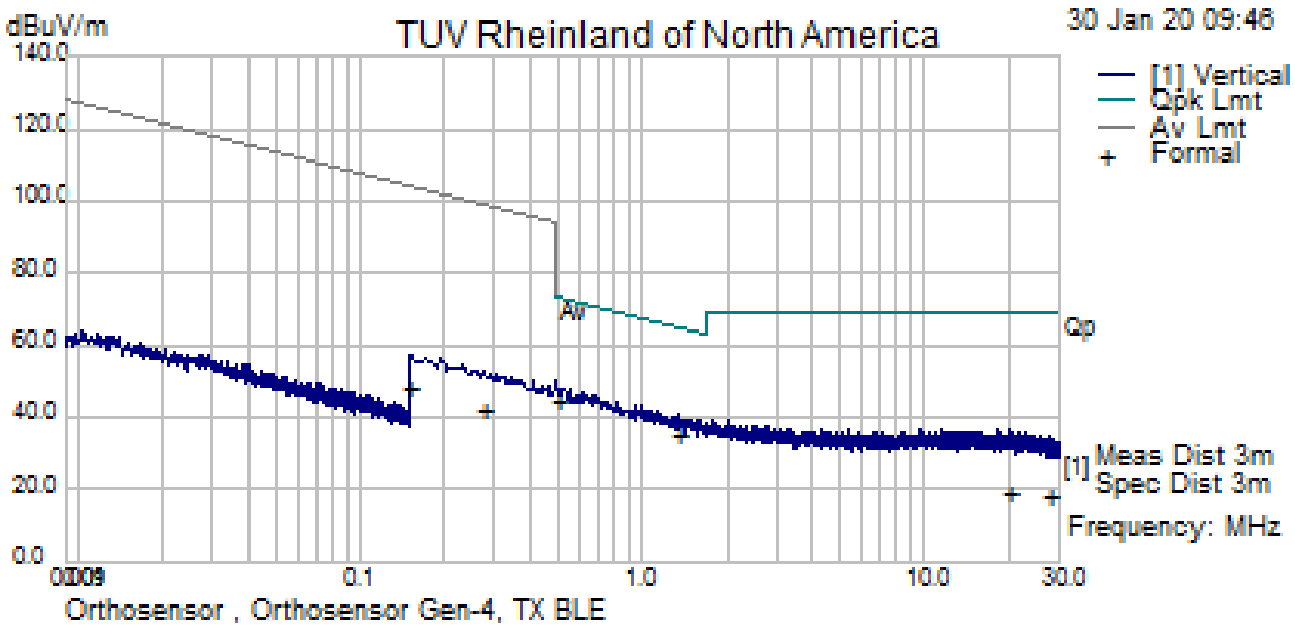
As originally tested, the EUT was found to be compliant to the requirements of the test standard(s).

Note: The 2.4 GHz notch filter was used to protect the front end of the pre-amp.

4.6.4.1 Plots

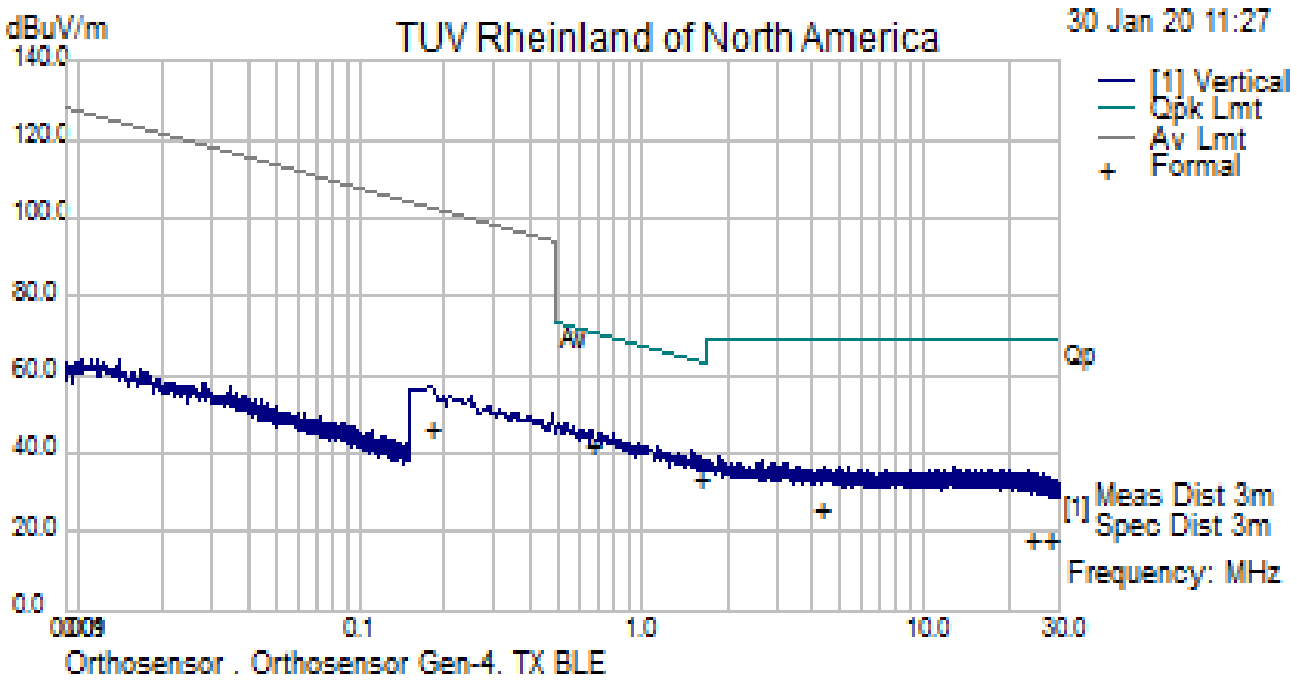
Test Conditions: Radiated Measurement, Normal Temperature and Voltage
Antenna Type: Trace Antenna
Max. Antenna Gain: -5.1 dBi
Test Performed by: Rachana Khanduri

Frequency MHz	Raw dBuV/m	Cable Loss	AF dB	Level dBuV/m	Measurement Type	Pol	Hgt cm	Azt Deg	Limit dBuV/m	Margin dB	Pass /Fail
0.15	35.25	2.19	10.38	47.82	Average Max	0	100	316	104.08	-56.26	Pass
0.27	30.06	2.22	10.22	42.5	Average Max	0	100	336	98.84	-56.34	Pass
0.49	31.75	2.26	10.39	44.39	Quasi Max	0	100	86	73.71	-29.32	Pass
1.34	21.88	2.31	10.60	34.80	Quasi Max	0	100	102	65.09	-30.29	Pass
20.03	5.98	2.47	10.40	18.84	Quasi Max	0	100	94	69.50	-50.66	Pass
28.06	6.74	2.49	8.48	17.71	Quasi Max	0	100	-8	69.50	-51.79	Pass



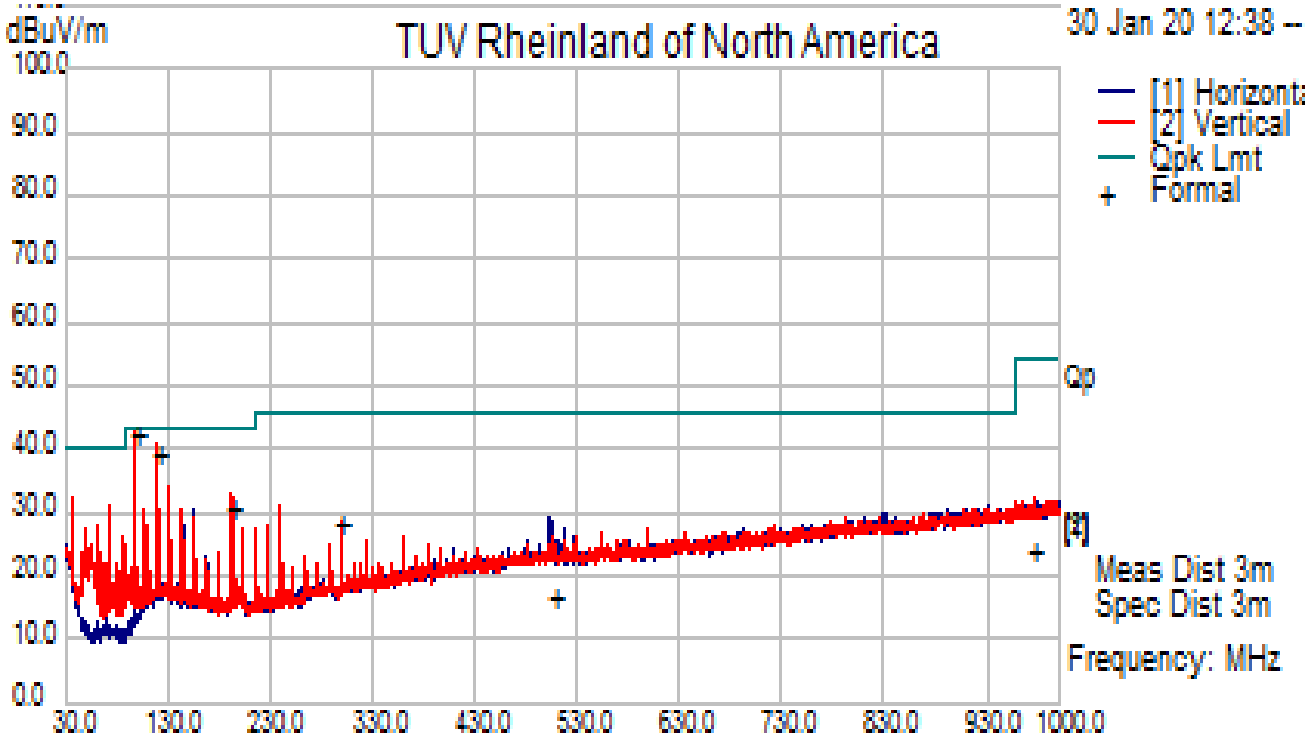
Plot 21. 9 kHz-30MHz, BLE-2402MHz 0 Degree

Frequency MHz	Raw dBuV/m	Cable Loss	AF dB	Level dBuV/m	Measurement Type	Degree (0/90)	Hgt cm	Azt Deg	Limit dBuV/m	Margin dB	Pass /Fail
0.18	33.97	2.20	10.33	46.50	Average Max	90	100	152	102.61	-56.11	Pass
0.66	29.42	2.27	10.40	42.10	Quasi Max	90	100	142	71.27	-29.17	Pass
1.58	20.64	2.32	10.60	33.56	Quasi Max	90	100	62	63.63	-30.07	Pass
4.30	12.64	2.38	10.70	25.72	Quasi Max	90	100	182	69.50	-43.78	Pass
23.57	6.16	2.48	9.78	18.42	Quasi Max	90	100	202	69.50	-51.08	Pass
28.03	6.90	2.49	8.49	17.88	Quasi Max	90	100	306	69.50	-51.62	Pass



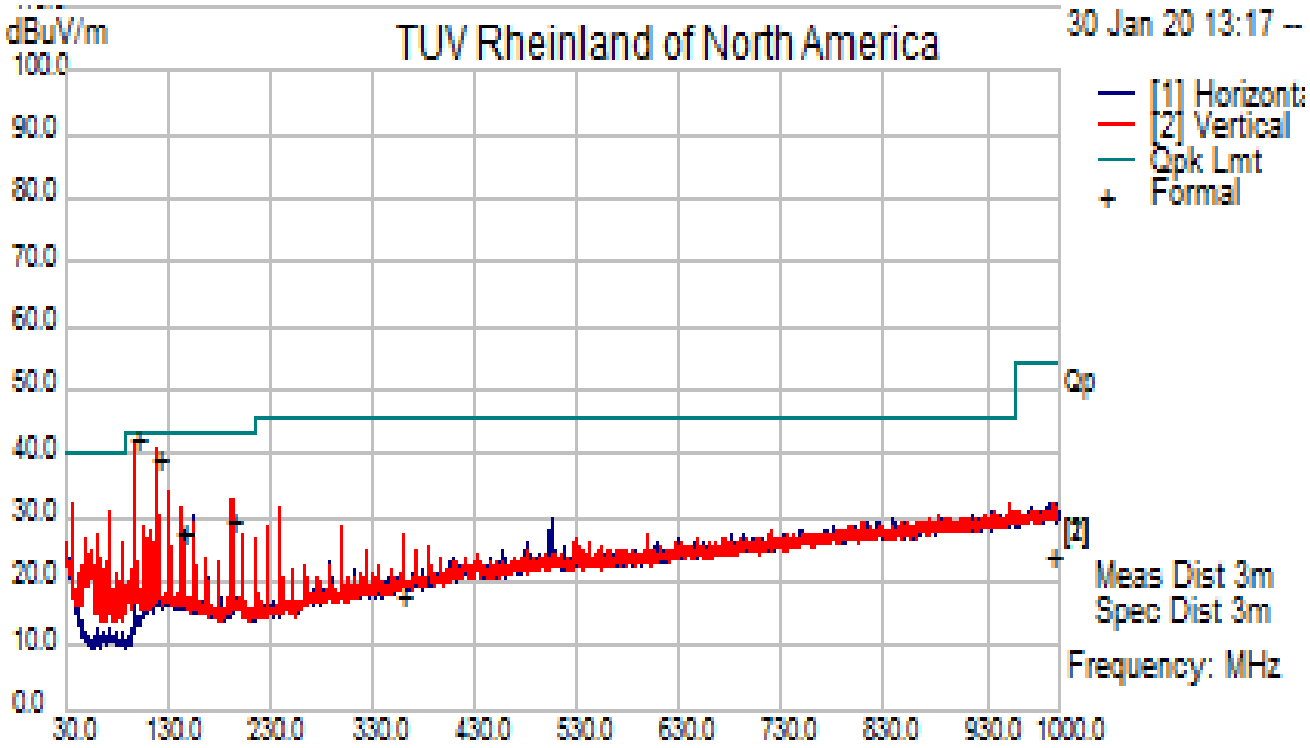
Plot 22. 9 kHz-30MHz, BLE-2402MHz 90 Degree

Frequency MHz	Raw dBuV/m	Cable Loss	AF dB	Level dBuV/m	Measurement Type	Pol (V/H)	Hgt cm	Azt Deg	Limit dBuV/m	Margin dB	Pass /Fail
98.17	57.73	2.87	-18.41	42.19	Quasi Max	V	106	222	43.5	-1.31	Pass
192.43	43.71	3.26	-16.33	30.64	Quasi Max	V	107	24	43.5	-12.86	Pass
300.01	38.96	3.6	-14.07	28.49	Quasi Max	V	103	336	46	-17.51	Pass
505.88	22.63	4.14	-10	16.77	Quasi Max	V	205	180	46	-29.23	Pass
120.00	50.31	2.98	-14.34	38.95	Quasi Max	V	102	360	43.5	-4.55	Pass
976.34	21.51	5.08	-2.8	23.79	Quasi Max	V	225	164	54	-30.21	Pass



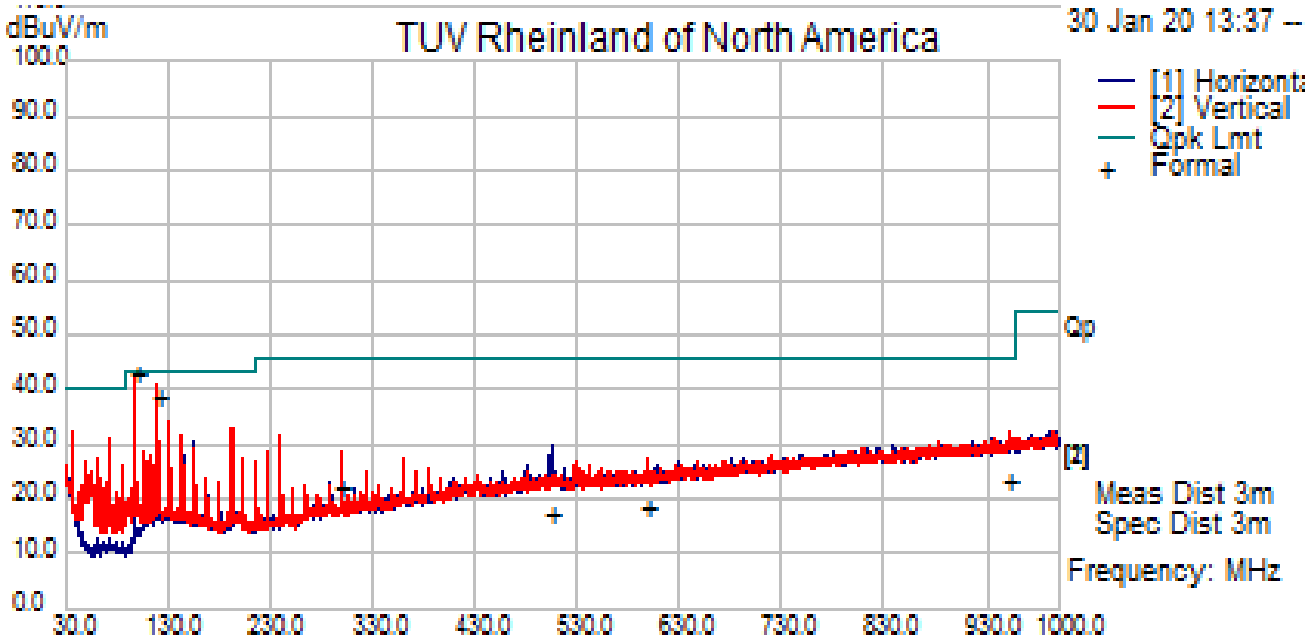
Plot 23. 30MHz-1GHz, BLE-2402MHz

Frequency MHz	Raw dBuV/m	Cable Loss	AF dB	Level dBuV/m	Measurement Type	Pol (V/H)	Hgt cm	Azt Deg	Limit dBuV/m	Margin dB	Pass /Fail
98.17	57.99	2.87	-18.41	42.46	Quasi Max	V	110	344	43.50	-1.04	Pass
120.00	50.51	2.98	-14.34	39.15	Quasi Max	V	108	352	43.50	-4.35	Pass
192.91	42.65	3.26	-16.28	29.63	Quasi Max	V	107	16	43.50	-13.87	Pass
143.99	39.65	3.08	-15.31	27.42	Quasi Max	V	132	224	43.50	-16.08	Pass
360.02	26.71	3.75	-12.54	17.92	Quasi Max	V	278	108	46.00	-28.08	Pass
993.78	21.51	5.14	-2.43	24.22	Quasi Max	V	100	168	54.00	-29.78	Pass



Plot 24. 30MHz-1GHz, BLE-2440MHz

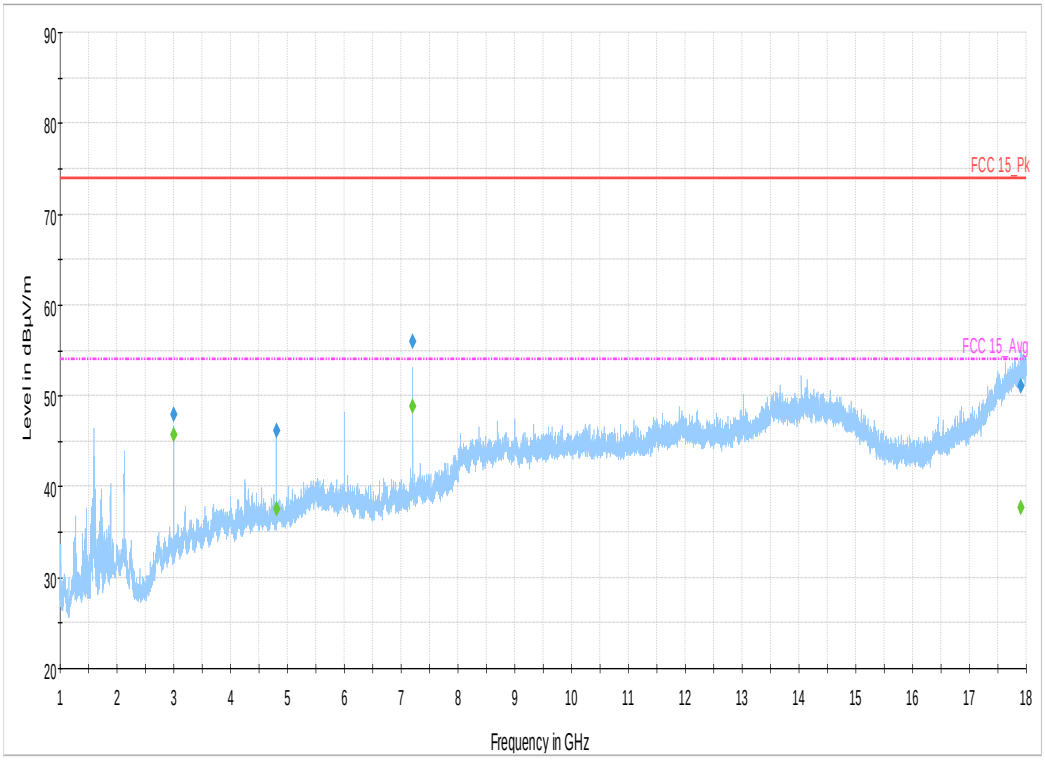
Frequency MHz	Raw dBuV/m	Cable Loss	AF dB	Level dBuV/m	Measurement Type	Pol (V/H)	Hgt cm	Azt Deg	Limit dBuV/m	Margin dB	Pass /Fail
98.17	58.34	2.87	-18.41	42.80	Quasi Max	V	128	356	43.5	-0.70	Pass
120.01	50.18	2.98	-14.34	38.82	Quasi Max	V	109	364	43.5	-4.68	Pass
952.12	21.61	5.05	-3.31	23.35	Quasi Max	V	135	178	46	-22.65	Pass
504.73	23.16	4.14	-10.00	17.29	Quasi Max	V	231	6	46	-28.71	Pass
299.97	32.65	3.60	-14.07	22.18	Quasi Max	V	208	338	46	-23.82	Pass
598.99	22.42	4.39	-8.69	18.12	Quasi Max	V	168	288	46	-27.88	Pass



Plot 25. 30MHz-1GHz, BLE-2480MHz

Final Result

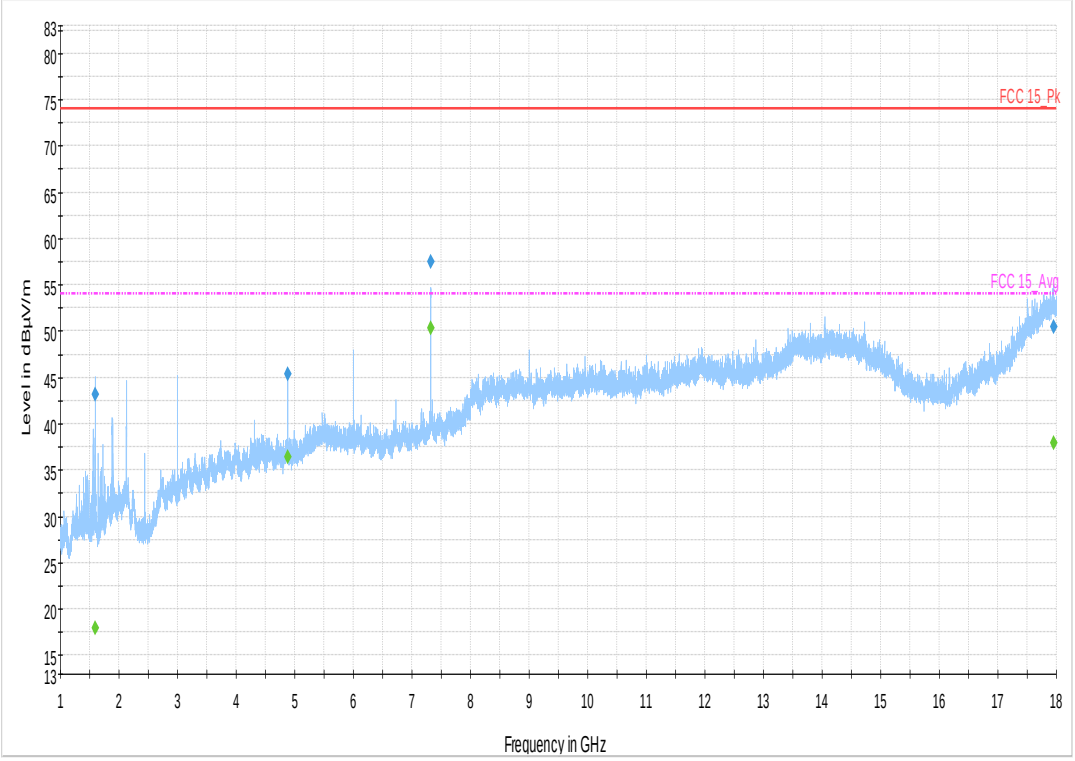
Frequency (MHz)	MaxPeak (dBµV/m)	Average (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol	Azimuth (deg)	Corr. (dB/m)	Comment
3000.040500	---	45.76	54.00	8.24	1000.0	1000.000	100.0	V	154.0	-28.1	
3000.040500	47.98	---	74.00	26.02	1000.0	1000.000	100.0	V	154.0	-28.1	
4804.547000	46.10	---	74.00	27.90	1000.0	1000.000	101.0	H	60.0	-24.2	
4804.547000	---	37.51	54.00	16.49	1000.0	1000.000	101.0	H	60.0	-24.2	
7205.326500	55.90	---	74.00	18.10	1000.0	1000.000	100.0	V	-2.0	-20.4	
7205.326500	---	48.82	54.00	5.18	1000.0	1000.000	100.0	V	-2.0	-20.4	
17906.739500	---	37.67	54.00	16.33	1000.0	1000.000	201.0	V	150.0	-7.1	
17906.739500	51.11	---	74.00	22.89	1000.0	1000.000	201.0	V	150.0	-7.1	



Plot 26. 1-18GHz, BLE-2402MHz

Final Result

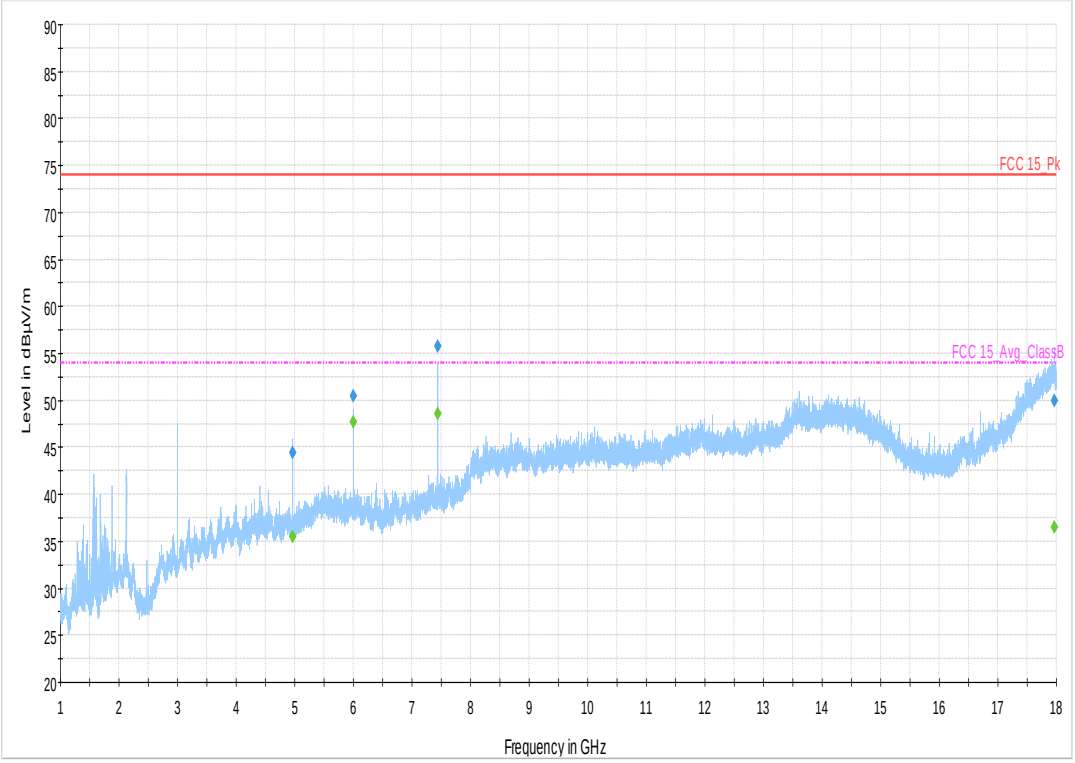
Frequency (MHz)	MaxPeak (dBµV/m)	Average (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol	Azimuth (deg)	Corr. (dB/m)	Comment
1598.143500	---	17.91	54.00	36.09	1000.0	1000.000	200.0	V	-180.0	-34.6	
1598.143500	43.21	---	74.00	30.79	1000.0	1000.000	200.0	V	-180.0	-34.6	
4880.555500	45.42	---	74.00	28.58	1000.0	1000.000	101.0	H	-140.0	-24.0	
4880.555500	---	36.43	54.00	17.57	1000.0	1000.000	101.0	H	-140.0	-24.0	
7319.286000	57.54	---	74.00	16.46	1000.0	1000.000	100.0	V	4.0	-19.6	
7319.286000	---	50.28	54.00	3.72	1000.0	1000.000	100.0	V	4.0	-19.6	
17950.289000	---	38.00	54.00	16.00	1000.0	1000.000	202.0	V	-81.0	-6.9	
17950.289000	50.43	---	74.00	23.57	1000.0	1000.000	202.0	V	-81.0	-6.9	



Plot 27. 1-18GHz, BLE-2440MHz

Final Result

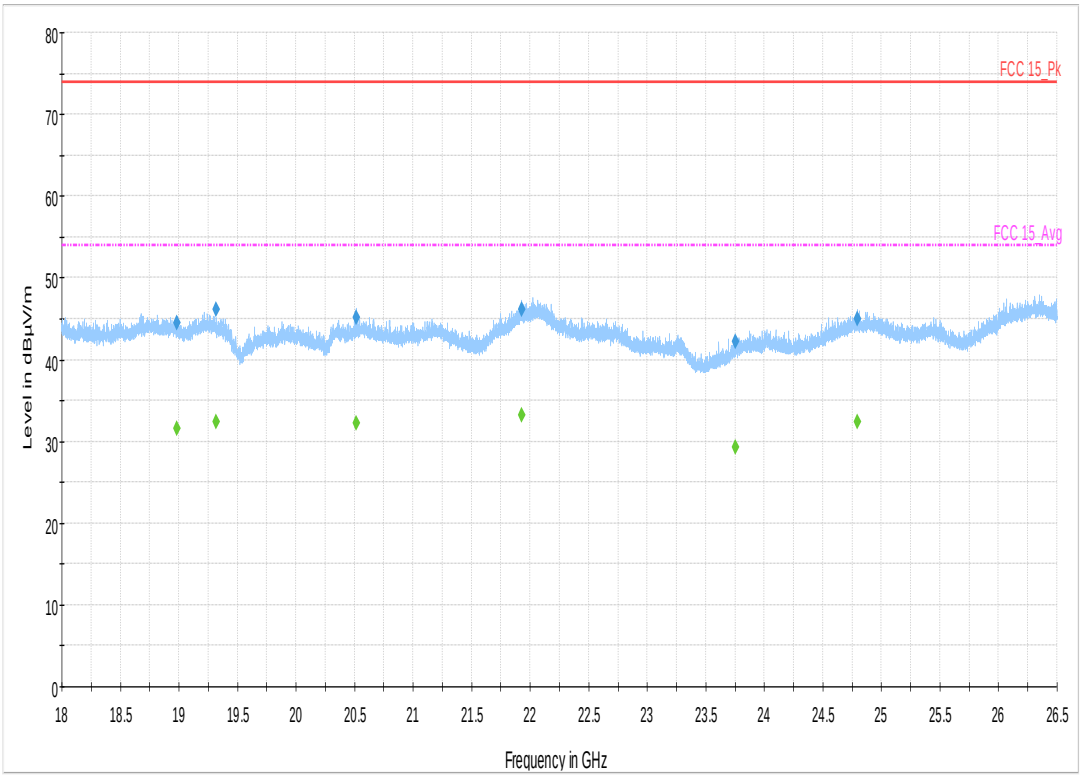
Frequency (MHz)	MaxPeak (dBµV/m)	Average (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol	Azimuth (deg)	Corr. (dB/m)	Comment
4960.533000	44.41	---	74.00	29.59	1000.0	1000.000	202.0	V	94.0	-23.9	
4960.533000	---	35.52	54.00	18.48	1000.0	1000.000	202.0	V	94.0	-23.9	
5999.858000	---	47.68	54.00	6.32	1000.0	1000.000	200.0	V	-163.0	-20.9	
5999.858000	50.49	---	74.00	23.51	1000.0	1000.000	200.0	V	-163.0	-20.9	
7440.723500	---	48.63	54.00	5.37	1000.0	1000.000	100.0	V	15.0	-19.2	
7440.723500	55.74	---	74.00	18.26	1000.0	1000.000	100.0	V	15.0	-19.2	
17959.711000	49.92	---	74.00	24.08	1000.0	1000.000	202.0	V	-150.0	-6.8	
17959.711000	---	36.55	54.00	17.45	1000.0	1000.000	202.0	V	-150.0	-6.8	



Plot 28. 1-18GHz, BLE-2480MHz

Final Result

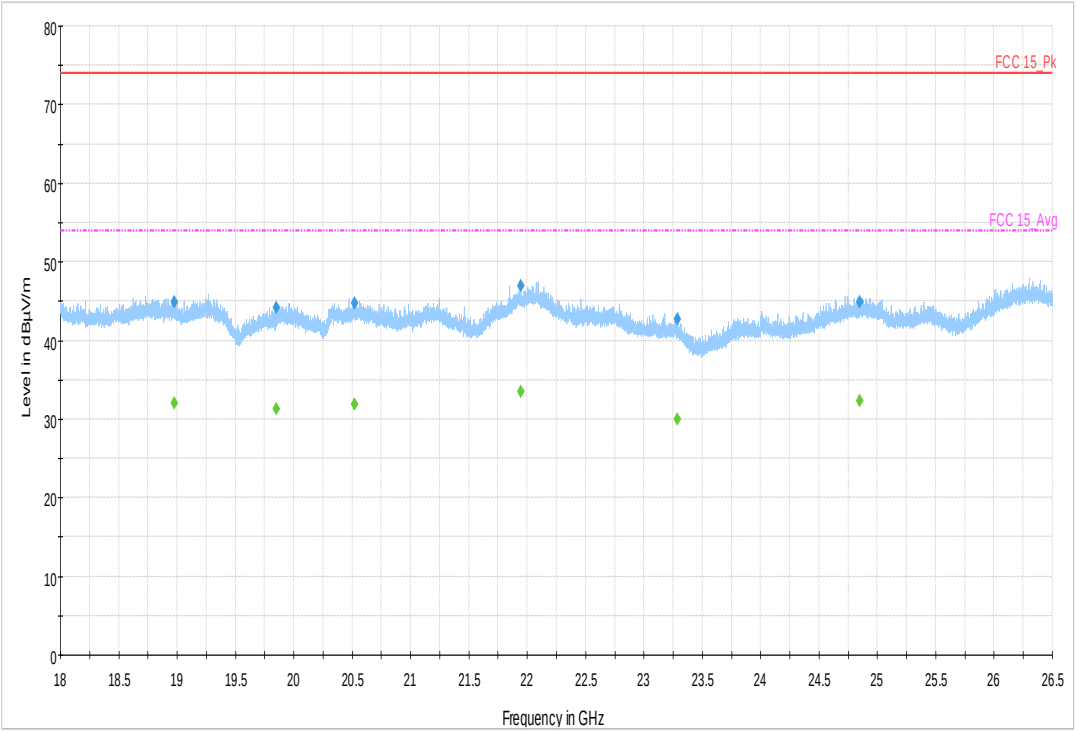
Frequency (MHz)	MaxPeak (dBµV/m)	Average (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol	Azimuth (deg)	Corr. (dB/m)	Comment
18980.670625	44.55	---	74.00	29.45	1000.0	1000.000	125.0	H	-94.0	11.4	
18980.670625	---	31.65	54.00	22.35	1000.0	1000.000	125.0	H	-94.0	11.4	
19315.011250	46.10	---	74.00	27.90	1000.0	1000.000	126.0	H	28.0	11.9	
19315.011250	---	32.44	54.00	21.56	1000.0	1000.000	126.0	H	28.0	11.9	
20515.458125	45.15	---	74.00	28.85	1000.0	1000.000	166.0	H	180.0	11.9	
20515.458125	---	32.18	54.00	21.82	1000.0	1000.000	166.0	H	180.0	11.9	
21926.390625	---	33.23	54.00	20.77	1000.0	1000.000	167.0	V	72.0	12.3	
21926.390625	46.19	---	74.00	27.81	1000.0	1000.000	167.0	V	72.0	12.3	
23753.049375	42.15	---	74.00	31.85	1000.0	1000.000	175.0	V	122.0	11.8	
23753.049375	---	29.33	54.00	24.67	1000.0	1000.000	175.0	V	122.0	11.8	
24793.136875	45.02	---	74.00	28.98	1000.0	1000.000	125.0	V	-105.0	12.1	
24793.136875	---	32.31	54.00	21.69	1000.0	1000.000	125.0	V	-105.0	12.1	



Plot 29. 18-26.5GHz, BLE-2402MHz

Final Result

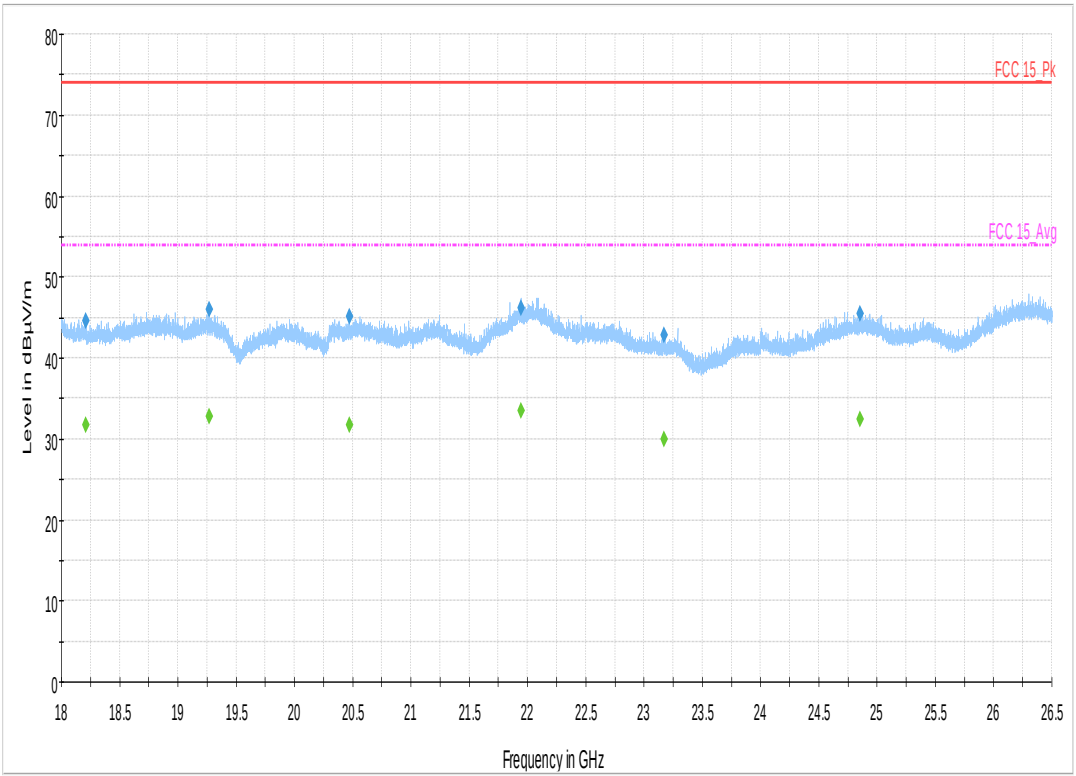
Frequency (MHz)	MaxPeak (dBµV/m)	Average (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol	Azimuth (deg)	Corr. (dB/m)	Comment
18976.415625	44.95	---	74.00	29.05	1000.0	1000.000	175.0	V	23.0	11.5	
18976.415625	---	32.00	54.00	22.00	1000.0	1000.000	175.0	V	23.0	11.5	
19849.967500	---	31.23	54.00	22.77	1000.0	1000.000	125.0	V	180.0	11.7	
19849.967500	44.20	---	74.00	29.80	1000.0	1000.000	125.0	V	180.0	11.7	
20517.148125	---	31.95	54.00	22.05	1000.0	1000.000	140.0	V	-180.0	12.0	
20517.148125	44.71	---	74.00	29.29	1000.0	1000.000	140.0	V	-180.0	12.0	
21943.751875	46.93	---	74.00	27.07	1000.0	1000.000	152.0	V	73.0	12.3	
21943.751875	---	33.45	54.00	20.55	1000.0	1000.000	152.0	V	73.0	12.3	
23284.947500	42.77	---	74.00	31.23	1000.0	1000.000	125.0	V	-180.0	12.0	
23284.947500	---	29.94	54.00	24.06	1000.0	1000.000	125.0	V	-180.0	12.0	
24846.671875	44.85	---	74.00	29.15	1000.0	1000.000	166.0	V	-180.0	12.1	
24846.671875	---	32.28	54.00	21.72	1000.0	1000.000	166.0	V	-180.0	12.1	



Plot 30. 18-26.5GHz, BLE-2440MHz

Final Result

Frequency (MHz)	MaxPeak (dBµV/m)	Average (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol	Azimuth (deg)	Corr. (dB/m)	Comment
18212.440000	44.51	---	74.00	29.49	1000.0	1000.000	126.0	V	-3.0	10.5	
18212.440000	---	31.70	54.00	22.30	1000.0	1000.000	126.0	V	-3.0	10.5	
19268.509375	---	32.78	54.00	21.22	1000.0	1000.000	175.0	V	-180.0	11.8	
19268.509375	46.08	---	74.00	27.92	1000.0	1000.000	175.0	V	-180.0	11.8	
20469.325000	---	31.67	54.00	22.33	1000.0	1000.000	140.0	V	180.0	12.0	
20469.325000	45.12	---	74.00	28.88	1000.0	1000.000	140.0	V	180.0	12.0	
21942.140625	46.18	---	74.00	27.82	1000.0	1000.000	175.0	V	73.0	12.3	
21942.140625	---	33.51	54.00	20.49	1000.0	1000.000	175.0	V	73.0	12.3	
23174.236875	42.79	---	74.00	31.21	1000.0	1000.000	140.0	V	23.0	12.2	
23174.236875	---	30.03	54.00	23.97	1000.0	1000.000	140.0	V	23.0	12.2	
24855.333125	45.38	---	74.00	28.62	1000.0	1000.000	140.0	V	-180.0	12.1	
24855.333125	---	32.37	54.00	21.63	1000.0	1000.000	140.0	V	-180.0	12.1	



Plot 31. 18-26.5GHz, BLE-2480MHz

5 Test Equipment List

5.1 Equipment List

Equipment	Manufacturer	Model #	Serial/Inst #	Last Cal mm/dd/yyyy	Next Cal mm/dd/yyyy
EMI Receiver	Rohde & Schwarz	ESW44	309096881	07/06/2018	07/06/2020
Spectrum Analyzer	Rohde Schwarz	FSL	100169	02/16/2019	02/16/2021
Preamplifier, 9 kHz – 1 GHz	Sonoma	310N	213221	01/16/2019	01/16/2021
Active Loop Antenna	EMCO	6502	00062531	07/01/2019	07/01/2021
Bilog Antenna	Sunol Sciences	JB3	A060502	05/27/2018	05/27/2020
Amplifier	Miteq	TTA1800-30-HG	1842452	01/16/2019	01/16/2021
Horn Antenna	Sunol Sciences	DRH-118	A040806	03/05/2019	03/05/2020
Horn/Amplifier 18 - 26.5 GHz	Rohde & Schwarz	TS-PR26	100011	03/04/2019	03/04/2021
RF Notch Filter 2.4GHz	MICRO-TRONICS	BRM50702	009	01/16/2019	01/16/2021
DC Power Supply	HP	6286A	3001A-11686	N/A (See Note)	
DC Power Supply	Agilent	E3634A	MY40004331	N/A (See Note)	
Note: Equipment is characterized before use.					

6 EMC Test Plan

6.1 Introduction

This section provides a description of the Equipment Under Test (EUT), configurations, operating conditions, and performance acceptance criteria. It is an overview of information provided by the manufacturer so that the test laboratory may perform the requested testing.

6.2 Customer

Table 7: Customer Information

Company Name	Orthosensor, Inc
Address	1855 Griffin Rd, Ste. A-310
City, State, Zip	Dania, FL 33004
Country	United States of America

Table 8: Technical Contact Information

Name	Yaxel Tablada
E-mail	yaxel.tablada@orthosensor.com
Phone	(945) 577 - 7770

6.3 Equipment Under Test (EUT)

The information provided in the following table should be listed as it should appear in the final report. For those products that have only a model name, list the model number as *non-applicable* and vice-versa.

Table 9: EUT Designation

Product Name	Stryker Triathlon GEN 4
Model Name	VERASENSE
System Name	NA
Product Description	OrthoSensor's VERASENSE delivers evidence-based data wirelessly to an intra-operative monitor that enables surgeons to make informed decisions on soft tissue balance and implant position in real time. It has wireless capability, Bluetooth, operating in the band 2.4 GHz.

6.4 Product Specifications

Table 10: EUT Specifications

EUT Specifications	
DC Input	3. 1 VDC (powered by battery)
Environment	Indoor
Operating Temperature Range:	15°C - 35°C
Multiple Feeds:	☐ Yes and how many ☒ No
Product Marketing Name (PMN)	VERASENSE
Hardware Version Identification Number (HVIN)	N/A
Firmware Version Identification Number (FVIN)	3.1.24
RF Test Software Version	3.1.24
Operating Modes	BT Low Energy, 1Mbps
Transmitter Frequency Band	2.4 GHz – 2.480 GHz
Power Setting @ Operating Channel	+4dBm
Bluetooth Antenna Information	☒ Internal ☐ External Type: Trace Antenna Maximum Peak Gain: -5.1 dBi
Modulation	GFSK
TX/RX Chain (s)	N/A
Type of Equipment	☒ Table Top ☐ Wall-mount ☐ Floor standing cabinet ☐ Other:
Note: EUT will be on / transmitted at all times with the highest power levels and antenna gains per channel.	

Table 11: Antenna Information

Number	Antenna Type	Description	Max Gain (dBi)
-	Trace antenna	Bluetooth Low Energy	-5.1

Table 12: Interface Specifications

Interface Type	Cabled with what type of cable?	Is the cable shielded?	Maximum potential length of the cable?	Metallic (M), Coax (C), Fiber (F), or Not Applicable?
USB	6 pin connector cable	Yes	< 3m	M

Table 13: Accessory Equipment

Equipment	Manufacturer	Model	Serial	Comment
N/A	N/A	N/A	N/A	N/A

Table 14: Ancillary Equipment (used for test purposes only)

Equipment	Manufacturer	Model	Serial	Used for
Laptop	HP	17-bs011dx	8CG7240ZPD	Setup EUT operating modes/ channels via a USB connection to pins in EUT
Note: None.				

Table 15: Description of Sample used for Testing

Sample Number	Device	Serial Number	Configuration	Used For
1	Stryker Triathlon GEN 4	480048017	Radiated Sample	TX Spurious Emissions, Band edge
2	Stryker Triathlon GEN 4	480048024	Conducted Sample	All other conducted Measurements
Note: None.				

Table 16: Description of Test Configuration used for Radiated Measurement.

Device	Antenna	Mode	Setup Description
Stryker Triathlon GEN 4	Trace Antenna	Transmit	EUT positioned vertical, worst case.
Note:			

6.5 Test Specifications

Table 17: Test Specifications

Emissions and Immunity	
Standard	**Requirement**
CFR 47 Part 15.247: 2019	All
RSS 247 Issue 2, 2017	All

END OF REPORT