

Prüfbericht - Nr.: 19660333 001		Seite 1 von 32	
<i>Test Report No.:</i>		<i>Page 1 of 32</i>	
Auftraggeber: <i>Client:</i>		Vios Medical Inc. 7300 Hudson Blvd N Ste 140 Oakdale Minnesota USA 55128	
Gegenstand der Prüfung: <i>Test item:</i>		Vios Monitoring System	
Bezeichnung: <i>Identification:</i>	CS2050	Serien-Nr.: <i>Serial No.</i>	Engineering Sample
Wareneingangs-Nr.: <i>Receipt No.:</i>	1803244730	Eingangsdatum: <i>Date of receipt:</i>	25.07.2017
Prüfart: <i>Testing location:</i>		Refer Page 4 of 32 for test facilities	
Prüfgrundlage: <i>Test specification:</i>		FCC Part 15 Subpart C: 15.247 ANSI C63.10-2013	
Prüfergebnis: <i>Test Result:</i>		Der Prüfgegenstand entspricht oben genannter Prüfgrundlage(n). <i>The test items passed the test specification(s).</i> FCC Test Firm Registration No.: 176555	
Prüflaboratorium: <i>Testing Laboratory:</i>		TÜV Rheinland (India) Pvt. Ltd. 82/A, 3rd Main, West Wing, Electronic City Phase 1 Hosur Road, Bangalore – 560 100. India	
geprüft / tested by:		kontrolliert / reviewed by:	
23.08.2017	Shrikanth S Naik Senior Engineer	31.08.2017	Saibaba Siddapur Assistant Manager
Datum <i>Date</i>	Name/Stellung <i>Name/Position</i>	Datum <i>Date</i>	Name/Stellung <i>Name/Position</i>
	Unterschrift <i>Signature</i>		Unterschrift <i>Signature</i>
Sonstiges / Other Aspects: FCC ID:2ANL9CS2050			
Abkürzungen:		Abbreviations:	
P(ass) = entspricht Prüfgrundlage		P(ass) = passed	
F(ail) = entspricht nicht Prüfgrundlage		F(ail) = failed	
N/A = nicht anwendbar		N/A = not applicable	
N/T = nicht getestet		N/T = not tested	
Dieser Prüfbericht bezieht sich nur auf das o.g. Prüfmuster und darf ohne Genehmigung der Prüfstelle nicht auszugsweise vervielfältigt werden. Dieser Bericht berechtigt nicht zur Verwendung eines Prüfzeichens. <i>This test report relates to the a. m. test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts.</i> <i>This test report does not entitle to carry any safety mark on this or similar products.</i>			

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1 TEST RESULT SUMMARY

Table 1: Test result summary

Test Item	Clause	Result
Maximum Peak Conducted Output Power	FCC 15.247(b) (3)	Pass
DTS Bandwidth	FCC 15.247(a) (2)	Pass
Maximum Power Spectral Density	FCC 15.247(e)	Pass
Emissions in non-restricted frequency bands	FCC 15.247(d)	Pass
Radiated Spurious Emissions and Restricted Bands of Operation	FCC 15.209 / FCC 15.205	Pass
Conducted Emissions on A.C Power Lines	FCC Part 15.107	Pass

Note: Conducted measurements are done according to the procedure given in KDB No. **558074 D01 DTS Meas Guidance v04**

2 TEST SITES

2.1 Testing Facilities

TUV Rheinland (India) Private Limited
108 , Beside ISBR Business School,
Electronic city Phase I
Bangalore - 560 100.

2.2 List of Test and Measurement Instruments

Table 2: List of Test and Measurement Instruments

Equipment	Manufacturer	Model Name	Serial Number	Calibration Due Date	Periodicity	Used for Test Items
EMI Test Receiver	Rohde & Schwarz	ESU 40	100288	29.10.2017	Yearly	Radiated Spurious Emissions
Bicorcal Antenna	Schwarzbeck mess-elektronik	VHBB-9124 / BBA-9106	9124-656	09.01.2018	Yearly	
Log Periodic Antenna	Schwarzbeck mess-elektronik	VUSLP-9111B	9111B-111	10.01.2018	Yearly	
Active Loop Antenna	Frankonia	LAX-10	LAX-10-800	22.12.2017	Yearly	
Broadband Horn Antenna	Frankonia	HAX-18	HAX18-802	16.03.2018	Yearly	
Double-Ridged Waveguide Horn Antenna	ETS Lindgren	116706	00107323	02.11.2017	Yearly	
Anechoic Chamber	Frankonia	-	-		-	
Spectrum Analyser	Agilent Technologies	E4407B	US41192772	13.02.2018	Yearly	Antenna - Port Conducted Tests
LISN	Rohde & Schwarz	ENV216	100022	07.09.2017	Yearly	Conducted Emission test on AC power lines
EMI Receiver	Rohde & Schwarz	ESR7	101133	10.12.2017	Yearly	

3 GENERAL PRODUCT INFORMATION

3.1 Product Function and Intended Use

The Vios Monitoring System (VMS) is intended for use by medically qualified personnel for physiological vital signs monitoring of adult (18+) patients in healthcare facilities. It is indicated for use in monitoring of ECG, heart rate, respiratory rate, pulse rate, functional oxygen saturation of arterial hemoglobin, and patient posture and activity. VMS allows for the input of body temperature, and can display data from peripheral devices. VMS can generate alerts when rate-based cardiac arrhythmias are detected and when physiological vital signs fall outside of selected parameters.

3.2 Ratings and System Details

Table 3: Ratings and System Details

Operating Frequency Range	2400MHz – 2483.50MHz
Radio Protocol	BLE
No. of channels	40
RF Output Power (Conducted mode)	-5.56dBm /0.2775 mW
Channel Spacing	2 MHz
Modulation	GFSK
Number of antennas	One
Antenna Gain & Type	1.7 dBi & Ceramic chip
Supply Voltage to Product	Internal Battery Pack -> 4.2V
Environmental conditions	Storage: -40° to + 70° C Operating: 10°C to +40° C

Environmental conditions:

Temperature: +24 ° C RH: 62%

3.3 Measurement Uncertainty:

Table 4: Measurement Uncertainty

Parameter	Uncertainty
Occupied Channel Bandwidth	±5 %
RF output power, conducted	±1.5 dB
Power Spectral Density, conducted	±3 dB
Unwanted Emissions, conducted	±3 dB
All emissions, radiated	±6 dB
Temperature	±3 °C
Supply Voltages	±3 %
Time	±5 %

4 OPERATIONAL DESCRIPTIONS

The Vios Monitoring System includes:

- Chest Sensor: A plastic encased, Bluetooth-enabled reusable sensor. The Chest Sensor is used in conjunction with the Adapter and BSM to monitor heart rate, respiratory rate, pulse rate, SpO2, and patient posture.
- Adapter: A plastic encased, reusable adapter with four (4) patient ECG cables and a one (1) pulse oximetry cable. The Adapter is used in conjunction with the Chest Sensor and BSM to monitor heart rate, respiratory rate, pulse rate, SpO2, and patient posture.

The Adaptor is placed on the patient chest using electrodes, the cables are attached to the respective points on the body. The Chest Sensor is powered on and placed in the socket of the Adaptor. The Chest Sensor is now ready for being discovered by the Vios Bed Side Monitor application

Note: The Wi-Fi module has been disabled through software for end application wi-fi will not be used.

AC-DC adaptor will be used for only charging for EUT, during Charging EUT will not be functional.

5 TEST SET-UP AND OPERATION MODE

5.1 Principle of Configuration Selection

Continuous transmission was enabled on low, mid and high channel. Switch on the device was used to enable the transmission on different channels.

5.2 Test Operation and Test Software

- None

5.3 Special Accessories and Auxiliary Equipment

- None

5.4 Countermeasures to achieve EMC Compliance

- None

Test sample used for testing:

Conducted mode: Serial # G200005817

Radiated mode: Serial # G200004617

Table 5: List of Centre Frequencies

Frequency Band (MHz)	Channel No.	Channel Frequency (MHz)
2400 – 2483.5	0	2402
	1	2404
	2	2406
	3	2408
	:	:
	:	:
	18	2438
	19	2440
	20	2437
	:	:
	:	:
	36	2474
	37	2476
	38	2478
	39	2480

6 TEST METHODOLOGY

6.1 Radiated Emission Test

The radiated emission measurement was performed according to the procedures in ANSI C63.10-2013. The equipment under test (EUT) was placed at the middle of the 80 cm high turntable for below 1 GHz & 1.5 m height for above 1 GHz measurement, and the EUT is 3 meters far from the measuring antenna.

The turntable was rotated 360° for obtaining the maximum emission. The height of the measuring antennas was scanned between 1 m and 4 m, and the antenna rotated to repeat the measurements for both the horizontal and vertical antenna polarizations. Repeat the measurement steps until the maximum emissions were obtained. The measurement above 1000 MHz was performed by horn antenna, The measurement below 30 MHz was performed by loop antenna.

The EUT was rotated around the X-, Y-, and Z-Axis and the results from worst case axis are recorded.

6.1.1 Test Setup Configuration

Figure 1: Frequency Range 9 KHz -30 MHz

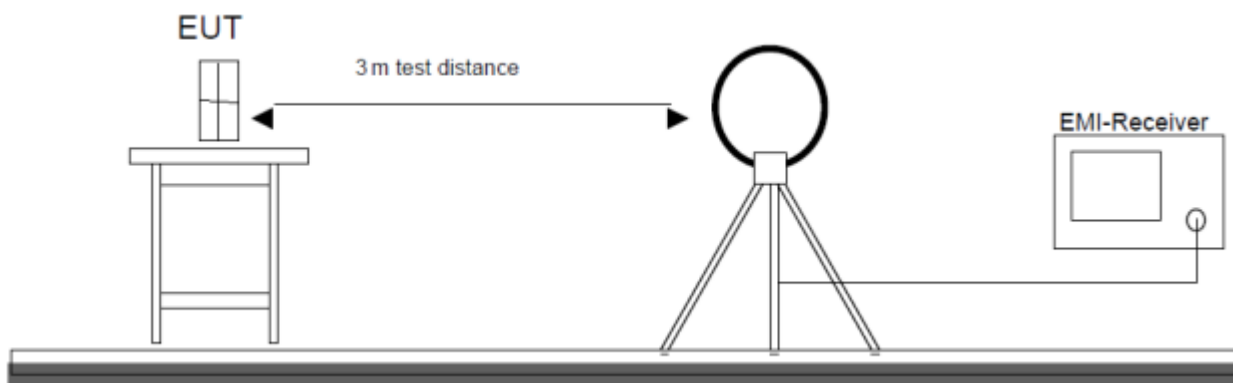


Figure 2: Frequency Range 30 MHz - 1 GHz

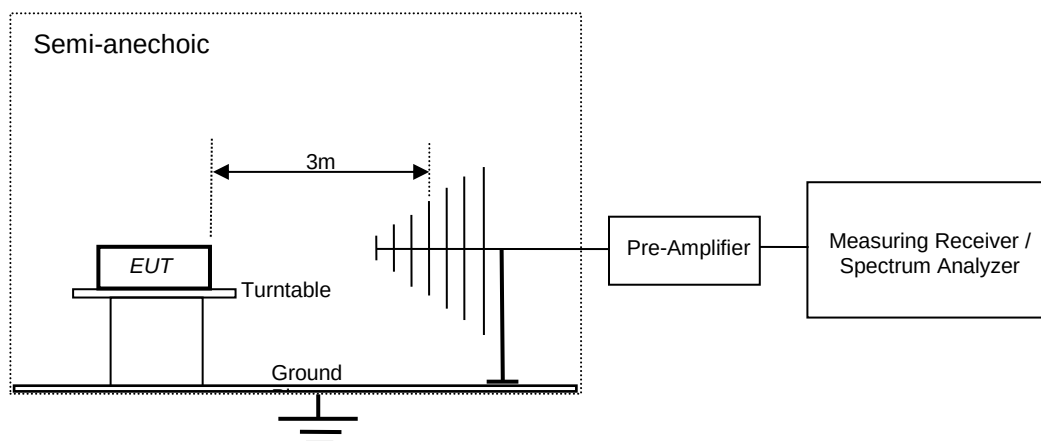
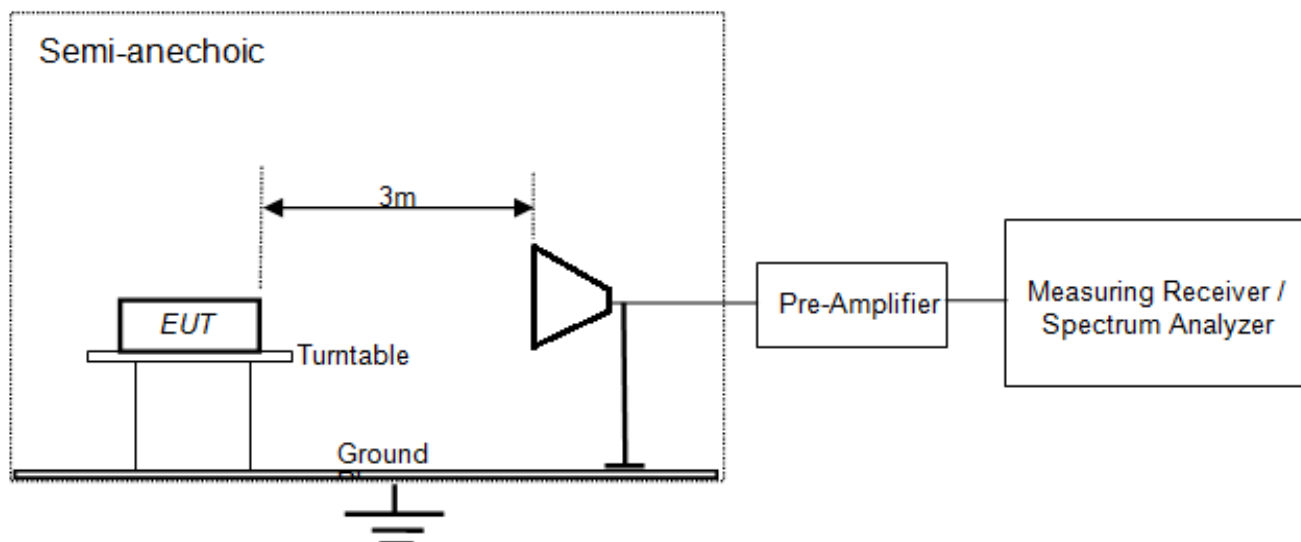


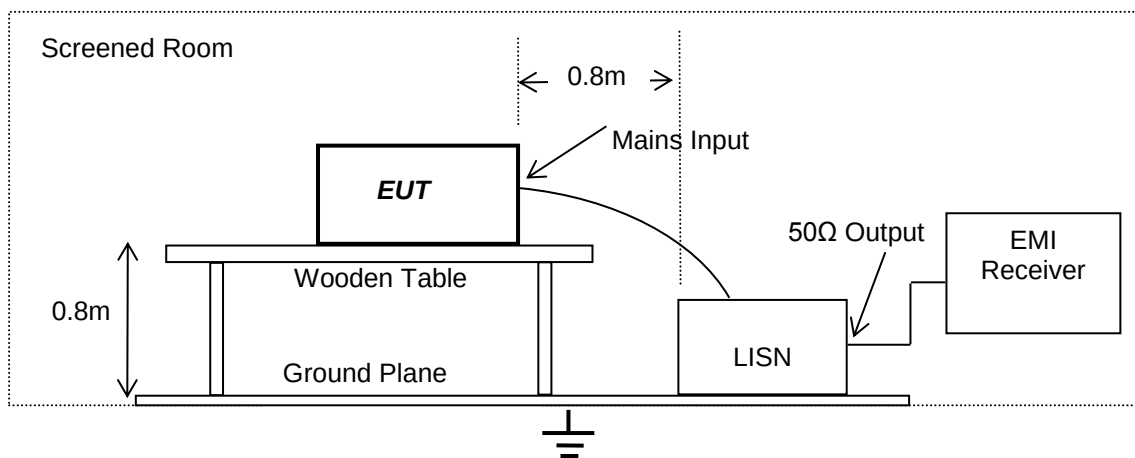
Figure 3: Frequency above 1 GHz



6.2 Conducted Emission Test on A.C. mains line

The equipment under test (EUT) was placed on a wooden table 80cm above the ground plane, the LISN was placed 80cm away from the EUT. The test was performed in accordance with ANSI C63.10 - 2013, with the following: an initial measurement was performed in peak and average detection mode on the live and neutral lines. The pre-scan was performed by peak detection on both live and neutral conductors. Any emissions recorded within 20dB of the relevant limit line were re-measured using quasi-peak and average detections, the 6 worst cases were recorded in the table of results.

Figure 4: Conducted Emission Test Setup



7 TEST RESULTS

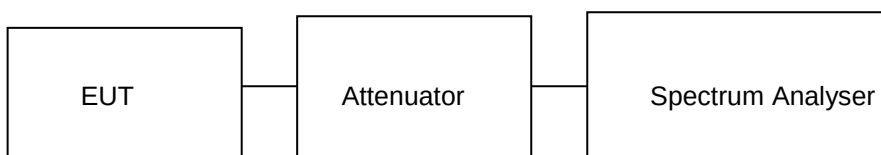
7.1 Maximum Peak Conducted Output Power

Result

Pass

Test Specification FCC Part 15.247(b)(3)
Measurement
Bandwidth (RBW) 1MHz
Requirement ≤ 1 watt (30dBm).

Test Method:

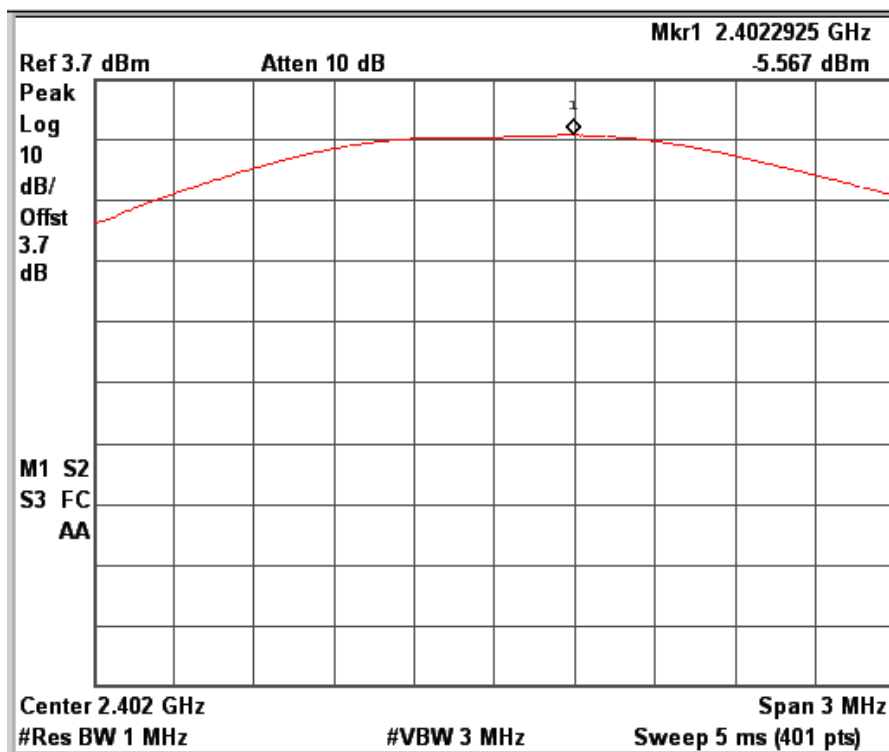


Cable Loss & attenuation values are considered in the test results

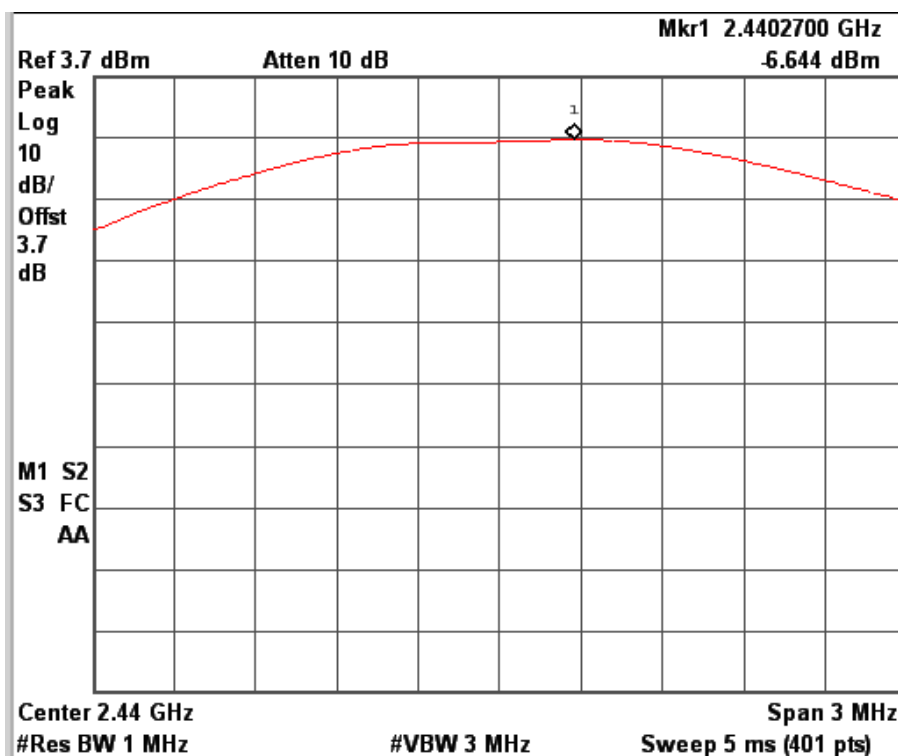
Test Result:

Table 6: Maximum Peak Conducted Output Power

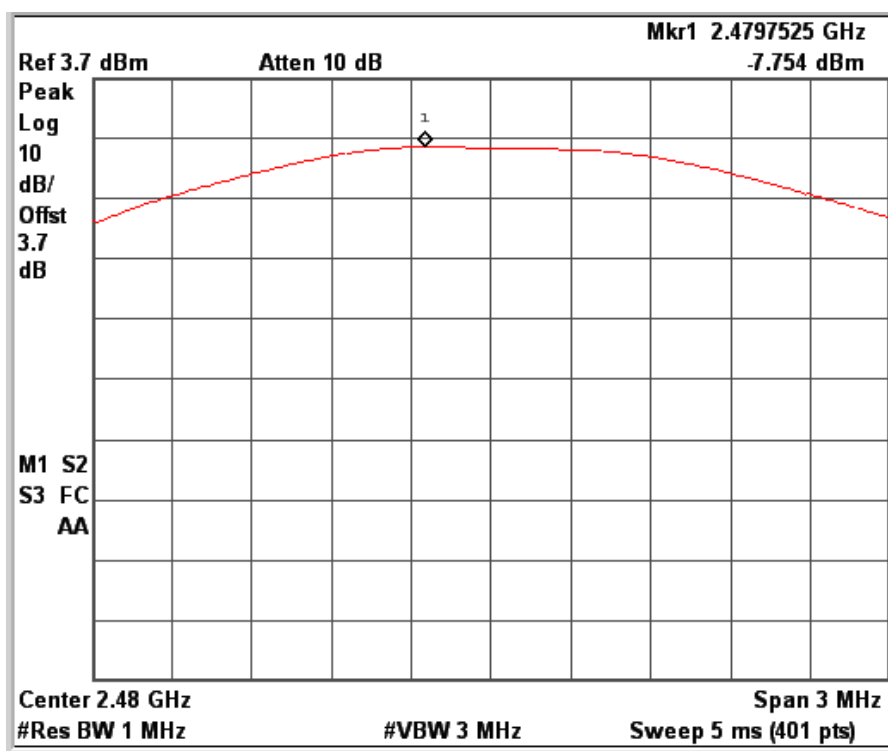
Channel Frequency (MHz)	Total Power (dBm)	Limit (dBm)	Margin (dB)
2402.00	-5.56	30.00	-35.56
2440.00	-6.64	30.00	-36.64
2480.00	-7.75	30.00	-37.75



Channel Frequency: 2402 MHz



Channel Frequency: 2440 MHz



Channel Frequency: 2480 MHz

7.2 Maximum Power Spectral Density

Result

Pass

Test
Specification

FCC Part 15.247 (e)

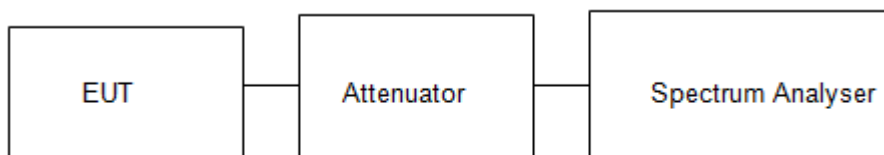
Detector
Function

Peak

Requirement

For digitally modulated systems, the power spectral density conducted from the intentional radiator to the antenna shall not be greater than 8 dBm.

Test Method:

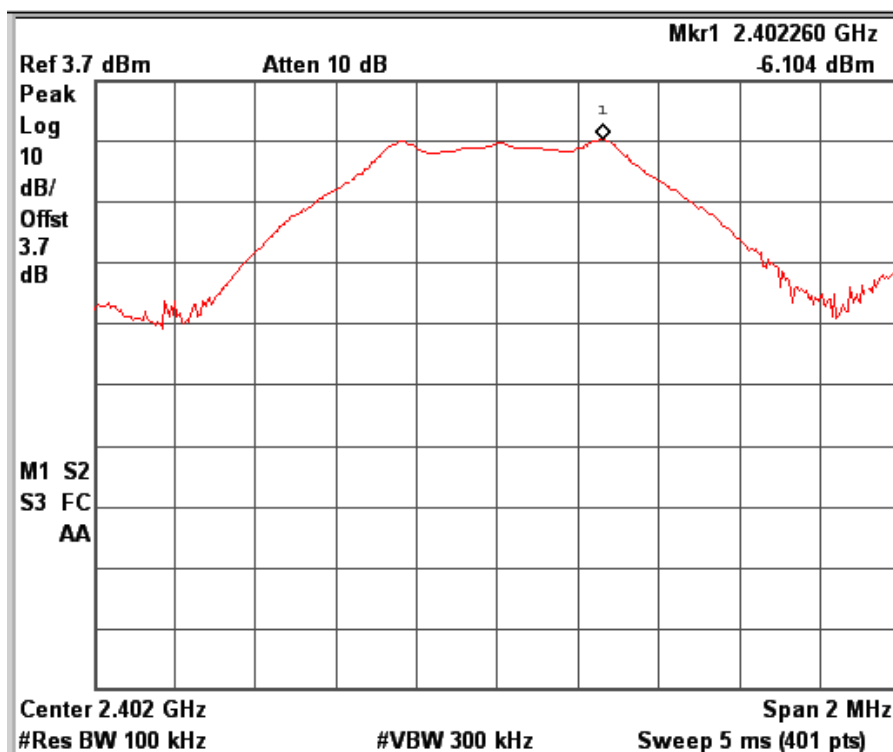


Cable Loss & attenuation values are considered in the test results

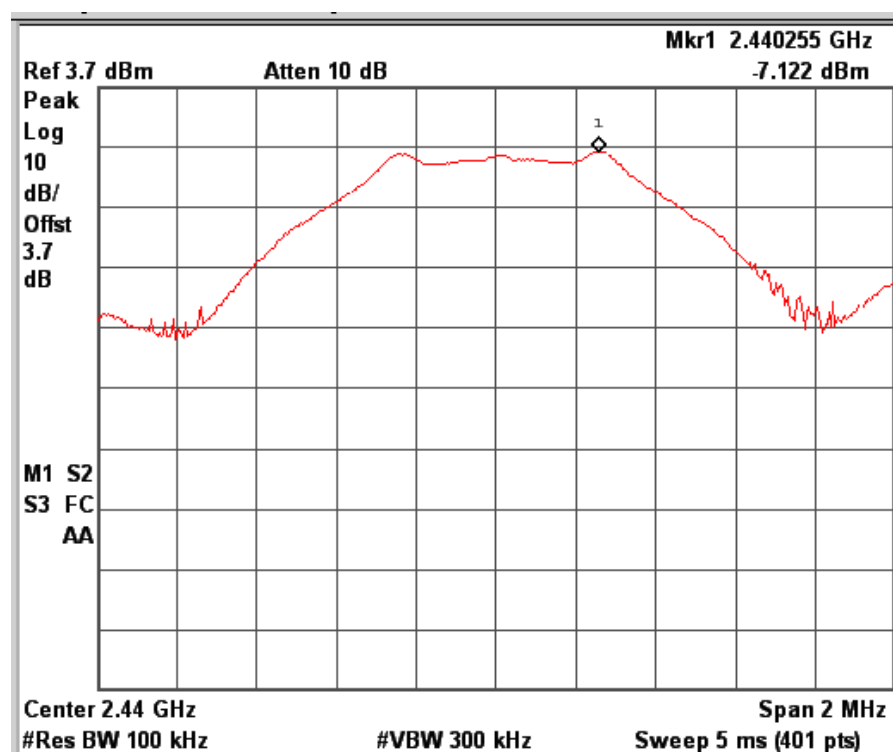
Test Result:

Table 7: Maximum Power Spectral Density

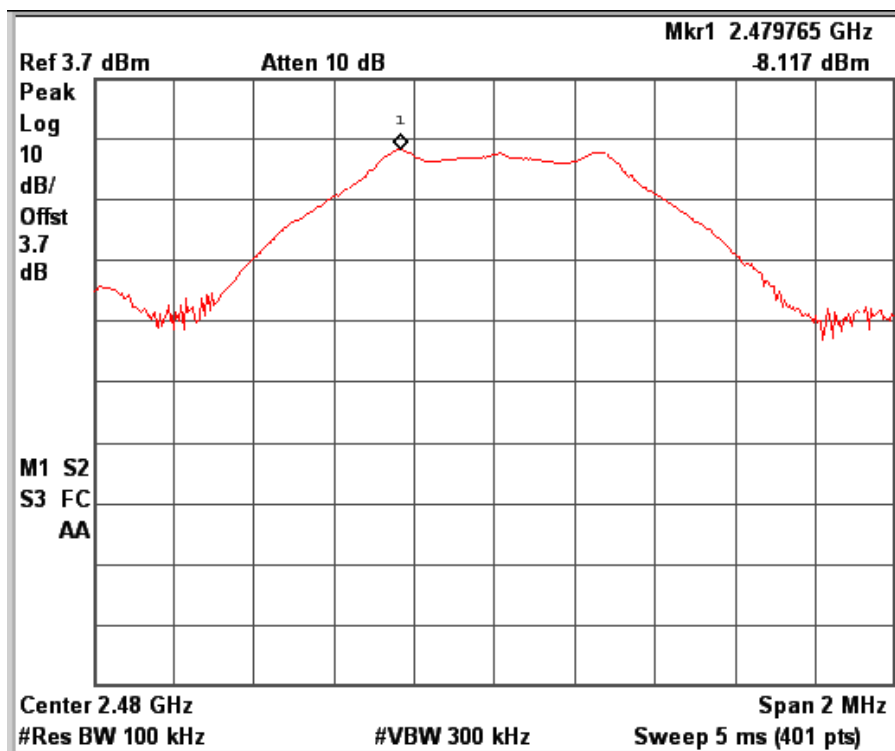
Channel Frequency (MHz)	Total PSD (dBm)	Limit (dBm)	Margin (dB)
2402.00	-6.10	8.00	-14.10
2440.00	-7.12	8.00	-15.12
2480.00	-8.11	8.00	-16.11



Channel Frequency: 2402 MHz



Channel Frequency: 2440 MHz



Channel Frequency: 2480 MHz

7.3 DTS Bandwidth

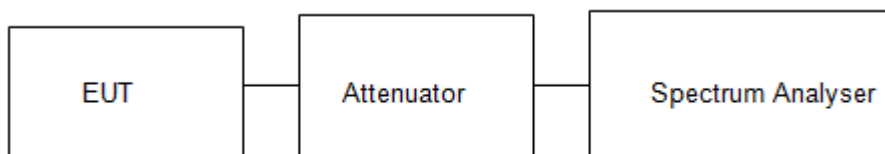
Result

Pass

Test Specification FCC Part 15.247 (a) (2)

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

Test Method:

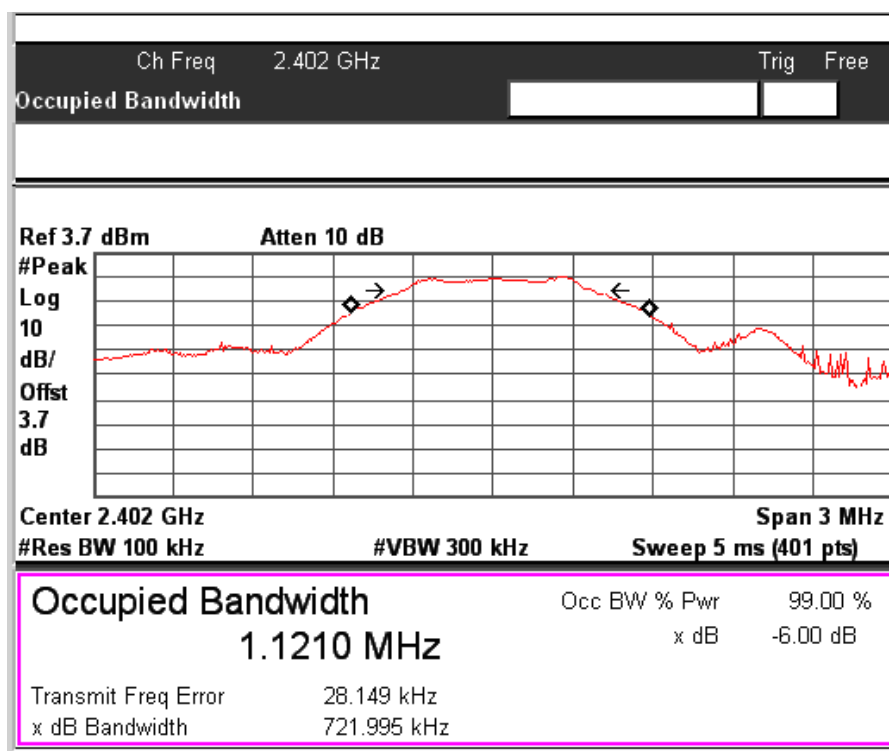


Cable Loss & attenuation values are considered in the test results

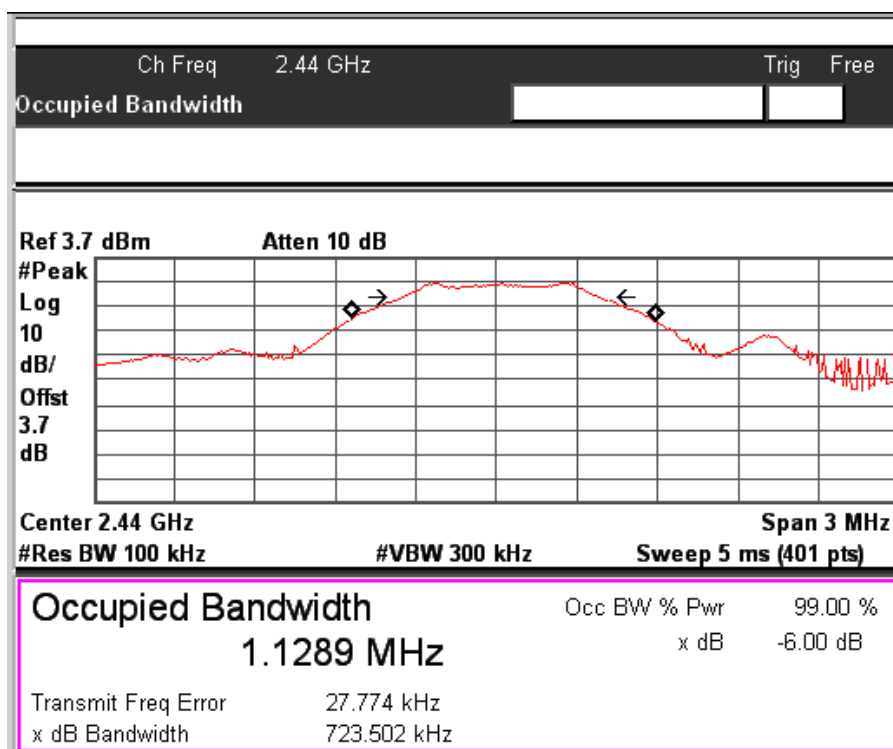
Test Result:

Table 8: DTS Bandwidth

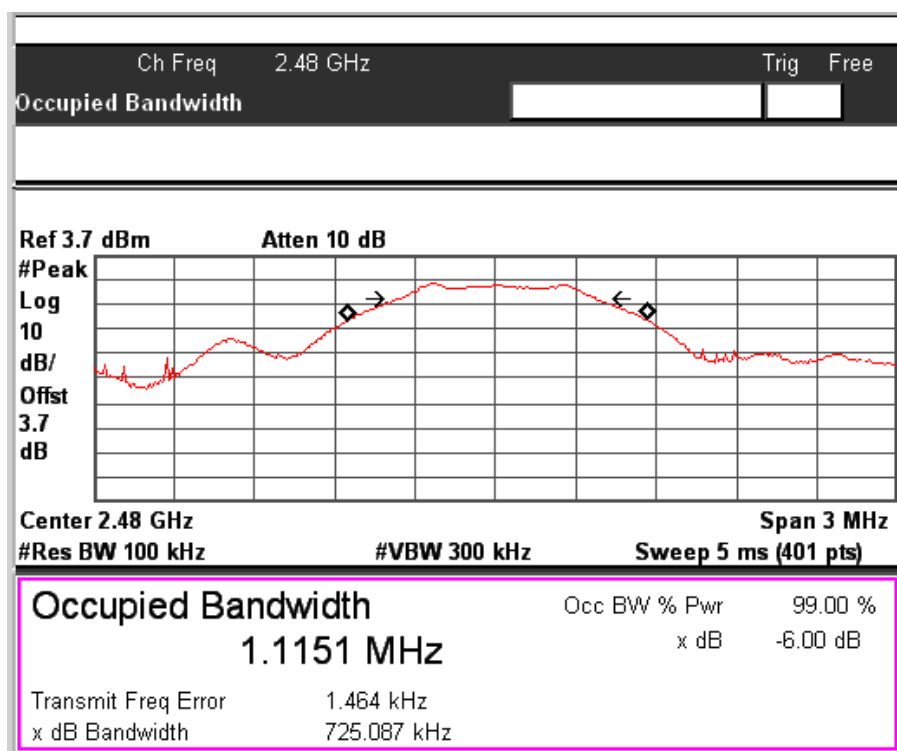
Channel Frequency (MHz)	6 dB Bandwidth (kHz)	99% OBW (MHz)
2402.00	721.99	01.12
2440.00	723.50	01.12
2480.00	725.08	01.11



Channel Frequency: 2402 MHz



Channel Frequency: 2440 MHz



Channel Frequency: 2480 MHz

7.4 Emissions in non-restricted frequency bands

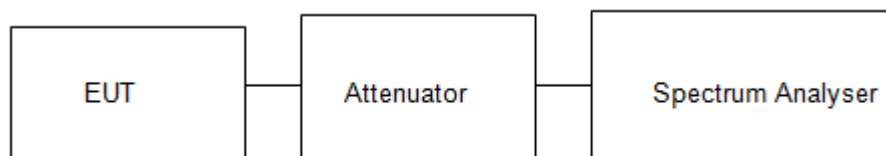
Result

Pass

Test Specification
Detector Function
FCC Part 15.247(d)
Peak

Requirement
In any 100kHz bandwidth outside the frequency band in which the spread spectrum or digitally modulated intentional radiator is operating, the radio frequency power that is produced by the intentional radiator shall be at least 20dB below that in the 100kHz bandwidth within the band that contains the highest level of the desired power, based on either an RF conducted or a radiated measurement, provided the transmitter demonstrates compliance with the peak conducted power limits.

Test Method:

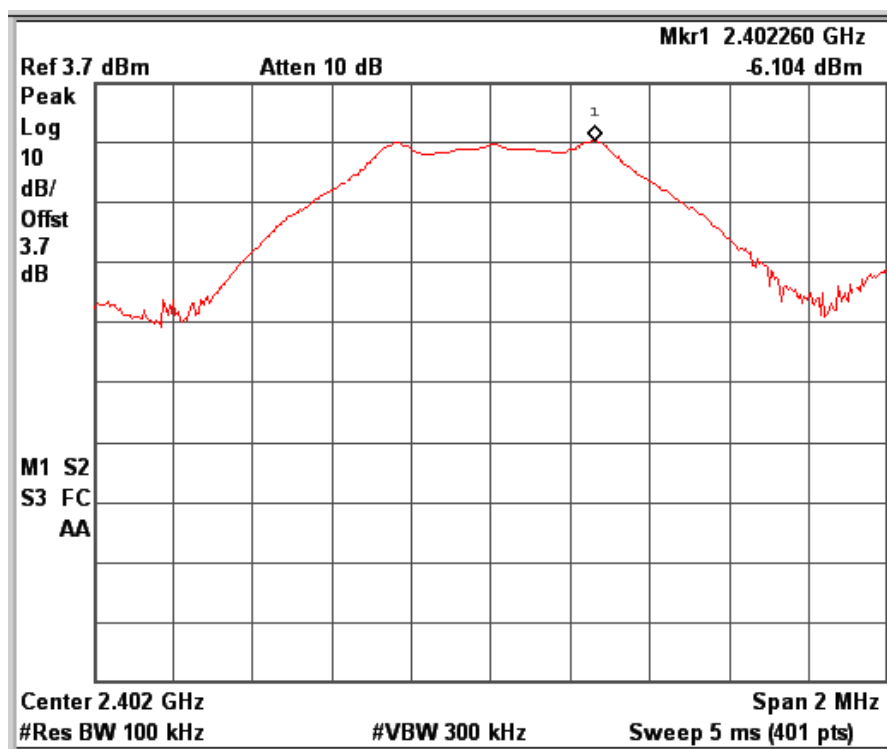


Cable Loss & attenuation values are considered in the test results

Test Result:

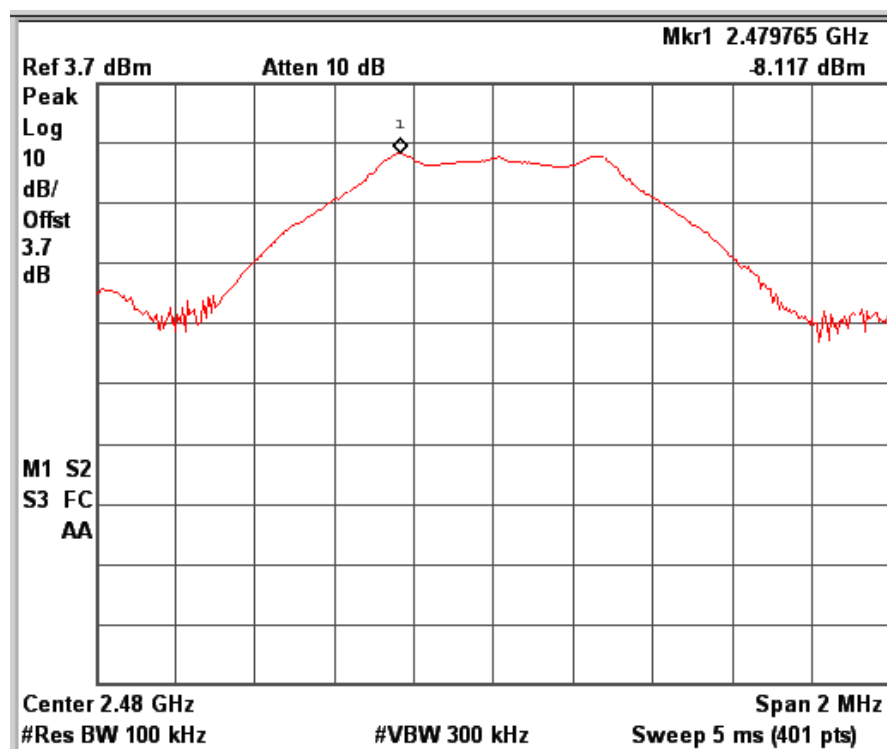
Table 9: Emissions in non-restricted frequency bands

Channel Frequency (MHz)	Value at Band Edge		Reference PSD Value B (dBm)	Band Edge Value A~B (dBc)	Limit (dBc)
	Frequency (MHz)	Value A (dBm)			
2402	2400	-40.98	-06.10	47.08	20.00
2480	2483.5	-49.56	-08.11	57.67	20.00



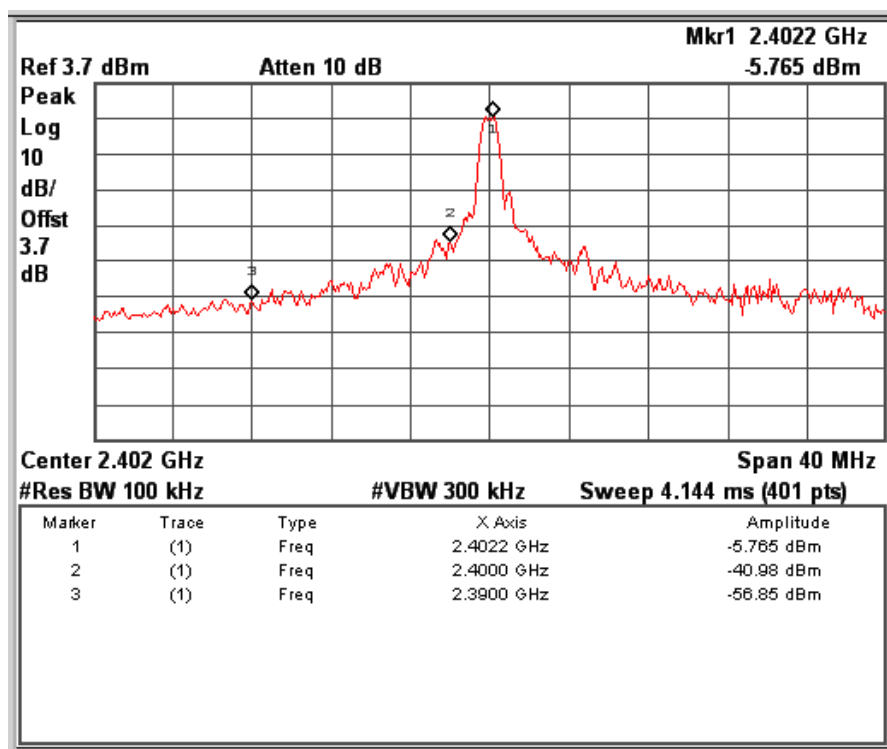
Reference Level Plot

Channel Frequency: 2402MHz

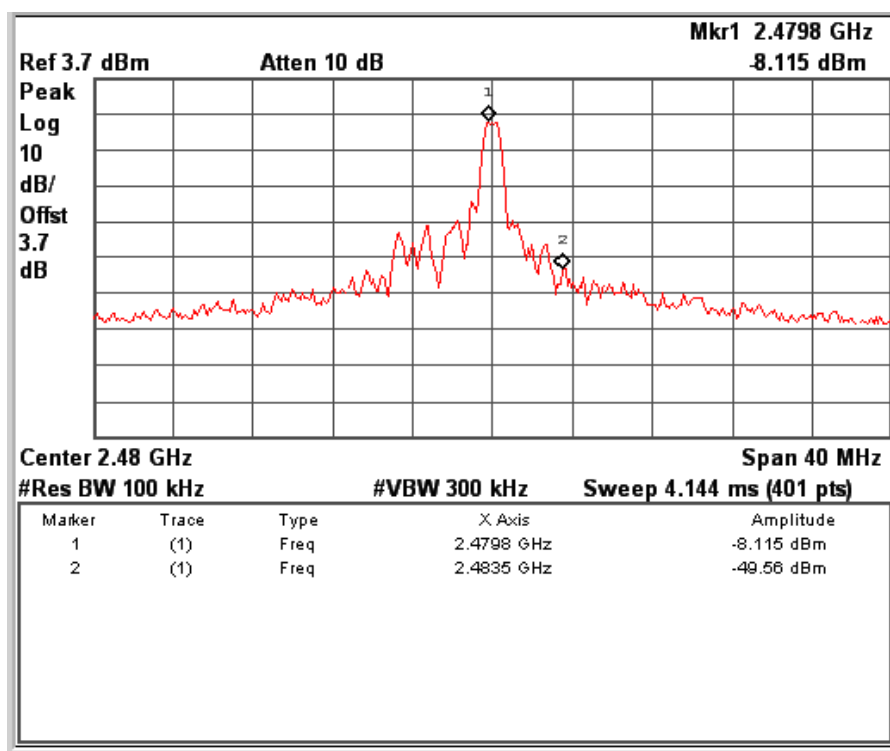


Reference Level Plot

Channel Frequency: 2480MHz

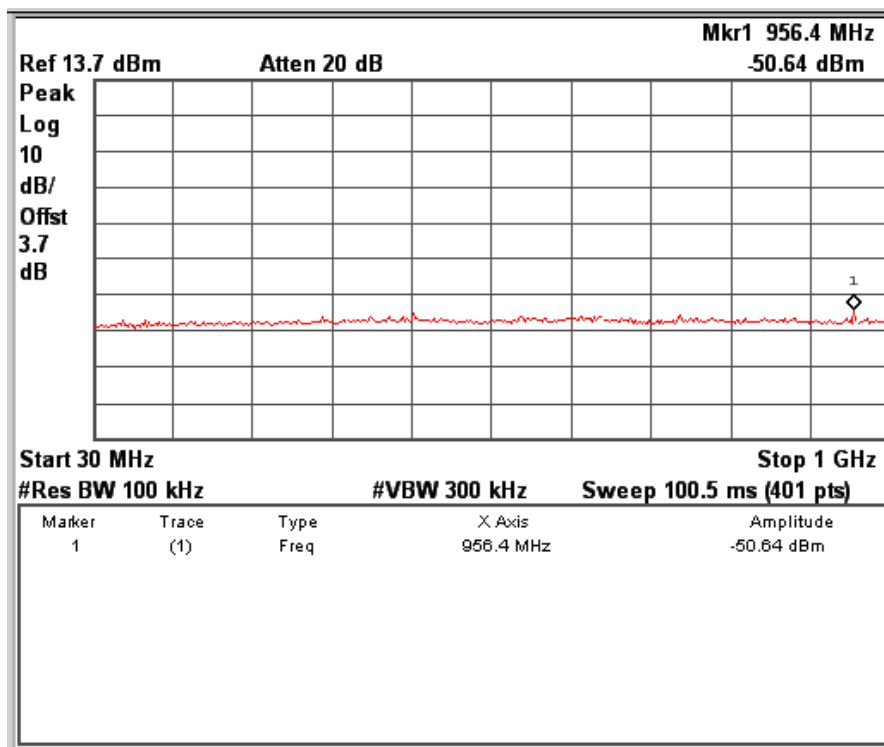


Channel Frequency 2402 MHz

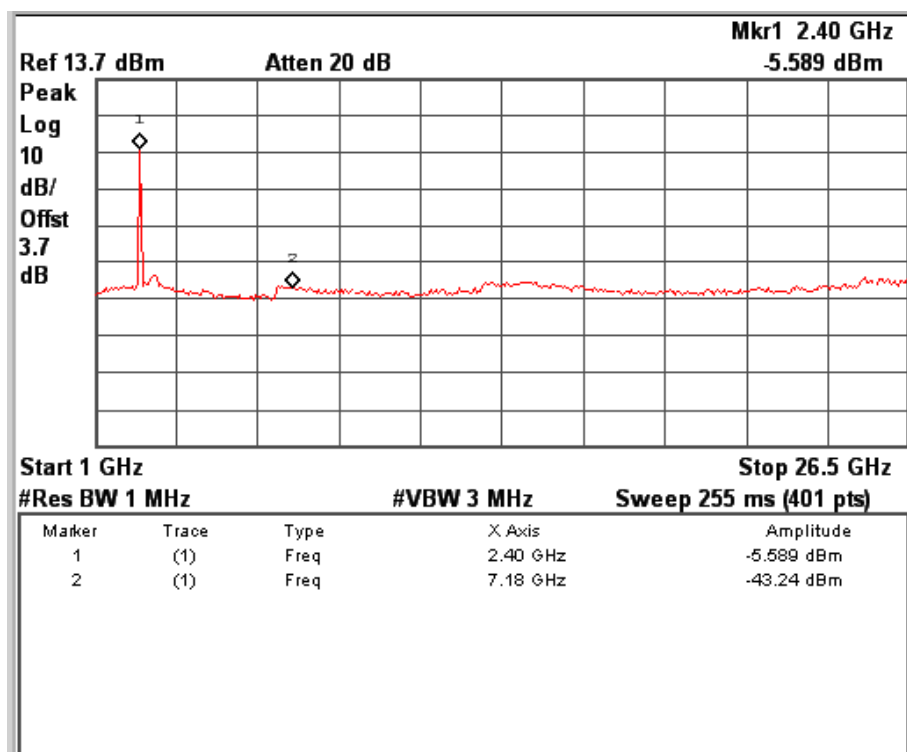


Channel Frequency 2480 MHz

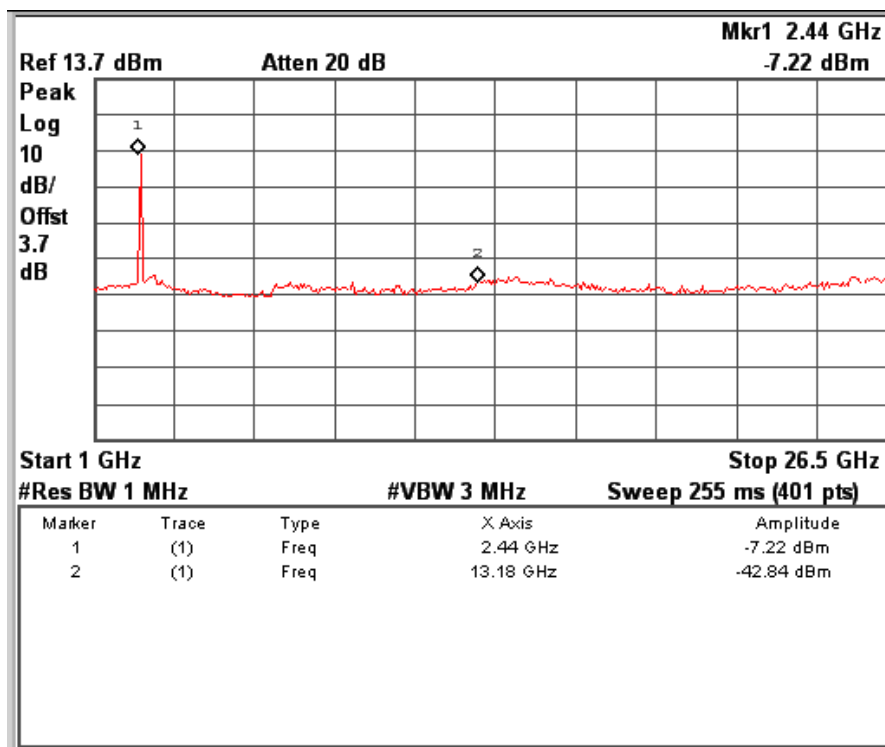
Conducted Spurious Emission



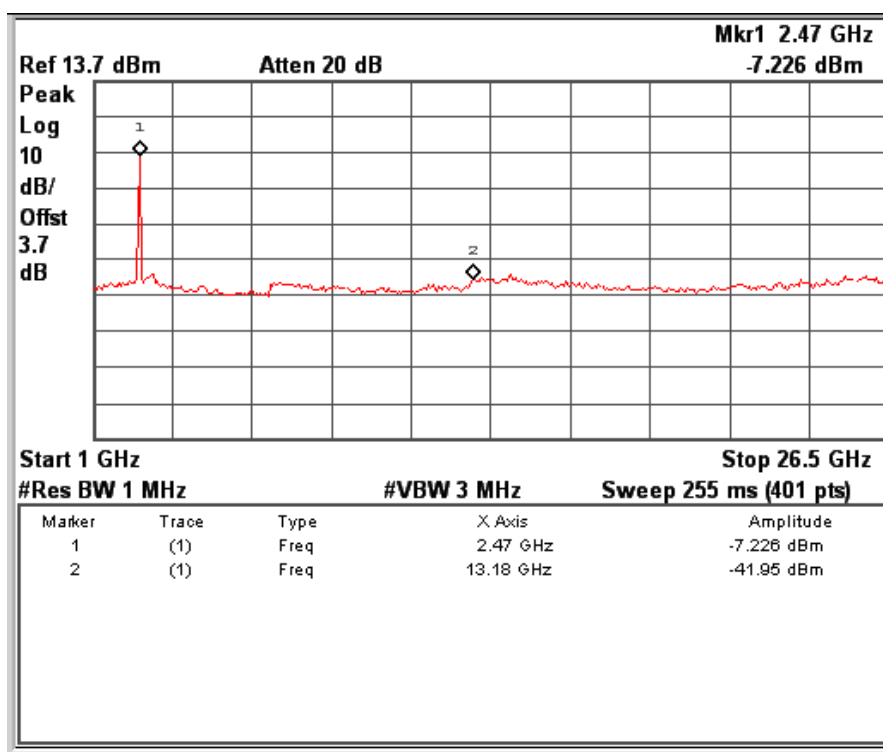
Frequency below 1GHz



Channel Frequency 2402 MHz



Channel Frequency 2440 MHz



Channel Frequency 2480 MHz

7.5 Radiated Spurious Emissions & Restricted Bands of Operation
Result

Pass

Test Specification	FCC 15.205, FCC 15.209
Test Method	ANSI C63.10-2013
Measurement Location	Semi Anechoic Chamber
Measuring Frequency Range	9 KHz to 40 GHz (Up to 10 th harmonic of the highest fundamental frequency)
Measuring Distance	3 m
Detection	QP for frequency below 1 GHz, Peak, Average for frequency above 1 GHz
Requirement	As per the limits mentioned in the below table

Table 10: Limit for radiated emission measurement 15.209

Frequency (MHz)	Field strength (μV/m)	Field strength (dBμV/m)	Distance of Measurement (m)
0.009 – 0.490	2400/F (KHz)	48.50 – 13.80	300*
0.490 – 1.705	24000/F (KHz)	33.80 – 23.00	30*
1.705 - 30	30	29.54	30*
30 - 88	100	40.0	3
88 - 216	150	43.5	3
216 - 960	200	46.0	3
Above 960	500	54.0	3

Remark: * The limit shows in the table above of frequency range 0.009 – 0.490, 0.490 – 1.705 MHz and 1.705-30 MHz is at 300 meter, 30 meter and 30 meter range respectively, which corresponds to 88.50 – 53.80, 53.80 – 43.00 and 49.5 dBμV/m at 3 m range by extrapolation calculation and the measurement of loop antenna.

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

Test results:

For Frequency Range 9kHz – 30MHz

--No Spurious Emission found.

For Frequency Range 30MHz – 1GHz

--No Spurious Emission found

Table 11: Test results for frequency range 1 GHz to 26.5 GHz

Channel	Polarization	Frequency (MHz)	Spurious Emission (dBµV/m)	Limit (dBµV/m)	Margin (dB)
Low	V	2390(Pk)	41.28	74	-32.72
		2390(Av)	28.16	54	-25.84
		2402(Pk)	71.82	*	-
		2402(Av)	70.62	*	-
		4804(Pk)	49.67	74	-24.33
		4804(Av)	38.91	54	-15.09
	H	2390(pk)	41.54	74	-32.46
		2390(Av)	28.79	54	-25.21
		2402(Pk)	85.01	*	-
		2402(Av)	83.75	*	-
		4804(Pk)	50.74	74	-23.26
		4804(Av)	40.56	54	-13.44
Mid	V	2440(Pk)	71.42	*	-
		2440(Av)	70.27	*	-
		4880(Pk)	50.34	74	-23.66
		4880(Av)	39.07	54	-14.93
	H	2440(Pk)	86.79	*	-
		2440(Av)	85.59	*	-
		4880(Pk)	51.65	74	-22.35
		4880(Av)	41.6	54	-12.4
High	V	2483.5(Pk)	43.45	74	-30.55
		2483.5(Av)	29.97	54	-24.03
		2480(Pk)	73.19	*	-
		2480(Av)	72.01	*	-
		4960(Pk)	50.69	74	-23.31
		4960(Av)	37.07	54	-16.93
	H	2483.5(Pk)	56.5	74	-17.5
		2483.5(Av)	39.95	54	-14.05
		2480(Pk)	87.23	*	-
		2480(Av)	85.94	*	-
		4960(Pk)	50.81	74	-23.19
		4960(Av)	36.99	54	-17.01

7.6 Conducted Emission Test on A.C. Power Line
Result

Pass

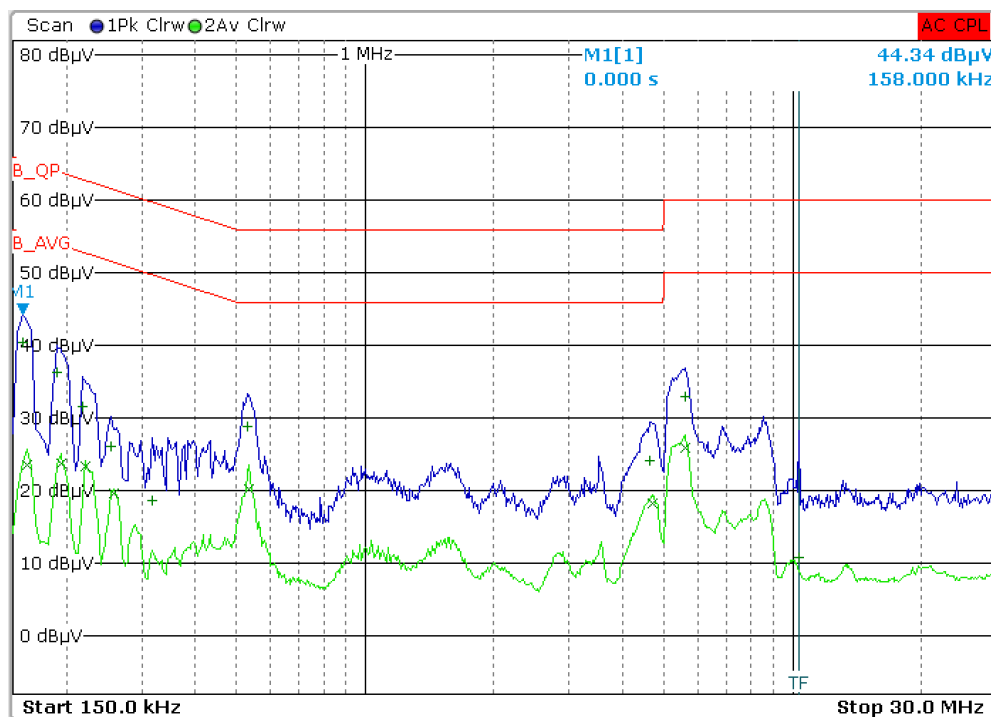
Test Specification : FCC Part 15 Section 15.107
Test Method : ANSI C63.10-2013
Testing Location : Screened room
Measurement Bandwidth : 9kHz
Frequency Range : 150kHz – 30MHz
Supply Voltage : 120VAC,60Hz

Table 12: Limit of section 15.107

Frequency of emission	QP Limit	AV Limit
(MHz)	(dBμV)	(dBμV)
0.15 – 0.5	66 – 56*	56 – 46*
0.5 – 5	56	46
5 – 30	60	50

* Decreases with the logarithm of the frequency

Test Result:

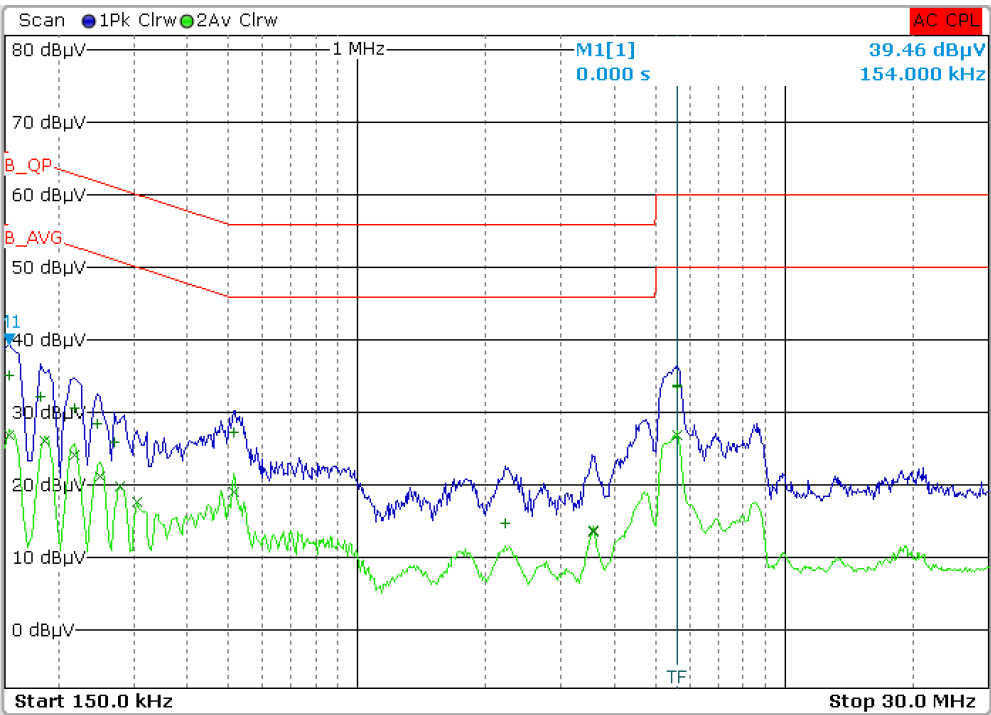


Line Graph

Final Results

Meas Time	1.0 s				
Margin	6.0 dB				
Peaks	25				
Trace	Frequency	Level (dBμV)	Phase	Detector	Delta Limit/dB
2	5.602000000 MHz	25.88		Average	-24.12
1	158.000000000 kHz	40.37		Quasi Peak	-25.20
2	534.000000000 kHz	20.25		Average	-25.75
1	530.000000000 kHz	28.90		Quasi Peak	-27.10
1	5.602000000 MHz	32.90		Quasi Peak	-27.10
2	4.686000000 MHz	18.37		Average	-27.63
1	190.000000000 kHz	36.22		Quasi Peak	-27.82
2	222.000000000 kHz	23.42		Average	-29.32
2	194.000000000 kHz	23.69		Average	-30.17
1	218.000000000 kHz	31.63		Quasi Peak	-31.26
1	4.626000000 MHz	24.21		Quasi Peak	-31.79
2	162.000000000 kHz	23.53		Average	-31.83
2	258.000000000 kHz	19.66		Average	-31.84
1	254.000000000 kHz	26.12		Quasi Peak	-35.51
1	318.000000000 kHz	18.76		Quasi Peak	-41.00
1	10.358000000 MHz	10.79		Quasi Peak	-49.21

Line Table



Neutral Graph

Final Results

Meas Time	1.0 s				
Margin	6.0 dB				
Peaks	25				
Trace	Frequency	Level (dBμV)	Phase	Detector	Delta Limit/dB
2	5.618000000 MHz	26.88		Average	-23.12
1	5.614000000 MHz	33.86		Quasi Peak	-26.14
1	5.614000000 MHz	33.53		Quasi Peak	-26.47
2	514.000000000 kHz	19.11		Average	-26.89
2	186.000000000 kHz	26.11		Average	-28.10
1	514.000000000 kHz	27.23		Quasi Peak	-28.77
2	218.000000000 kHz	24.08		Average	-28.81
2	154.000000000 kHz	26.93		Average	-28.85
2	250.000000000 kHz	21.17		Average	-30.59
1	154.000000000 kHz	35.04		Quasi Peak	-30.74
2	278.000000000 kHz	19.75		Average	-31.13
1	218.000000000 kHz	30.70		Quasi Peak	-32.19
1	182.000000000 kHz	32.18		Quasi Peak	-32.21
2	3.558000000 MHz	13.68		Average	-32.32
2	3.558000000 MHz	13.65		Average	-32.35
2	306.000000000 kHz	17.62		Average	-32.46
1	246.000000000 kHz	28.44		Quasi Peak	-33.45
1	270.000000000 kHz	25.99		Quasi Peak	-35.13
1	2.218000000 MHz	14.72		Quasi Peak	-41.28
1	2.218000000 MHz	14.65		Quasi Peak	-41.35

Neutral Table

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