



ISED LISTED
REGISTRATION
NUMBER 4621A-2

Test report No:
NIE: 57186RRF.003A1

Test report

USA FCC Part 15.247, 15.209

CANADA RSS-247, RSS-Gen

Radio Frequency Devices. Operation within the bands 902 - 928 MHz, 2400 - 2483.5 MHz, and 5725 - 5850 MHz.

Digital Transmission Systems (DTSs), Frequency Hopping Systems (FHSs) and Licence-Exempt Local Area Network (LE-LAN) Devices.

General Requirements and Information for the Certification of Radio Apparatus.

Identification of item tested	General Medical Devices (Bone anchored sound processor).
Trademark	Cochlear
Model and /or type reference	Osia 2 Sound Processor
Other identification of the product	FCC ID: QZ3OSIA2 IC: 8039C-OSIA2 HW Version: EP4 SW Version: Osia2-NPC.0.8.5
Features	Bluetooth LE, Proprietary protocol 2.4 GHz ISM band, SRD 5 MHz.
Applicant	COCHLEAR BONE ANCHORED SOLUTIONS AB Konstruktionsvägen 14, 43533 Mölnlycke, SWEDEN
Test method requested, standard	USA FCC Part 15.247 10-1-17 Edition: Operation within the bands 902 - 928 MHz, 2400 - 2483.5 MHz, and 5725 - 5850 MHz. USA FCC Part 15.209 10-1-17 Edition: Radiated emission limits; general requirements. CANADA RSS-247 Issue 2 (February 2017). CANADA RSS-Gen Issue 5 (April 2018). Guidance for Performing Compliance Measurements on Digital Transmission System, Frequency Hopping Spread Spectrum System, and Hybrid Systems Devices Operating Under Section 15.247 of the FCC Rules. 558074 D01 Meas Guidance v05 dated August 24, 2018. ANSI C63.10-2013: American National Standard for Testing Unlicensed Wireless Devices.
Summary	IN COMPLIANCE

Approved by (name / position & signature)	Jose Carlos Luque RF Lab. Supervisor
Date of issue	2019-09-03
Report template No	FDT08_21

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Competences and guarantees

DEKRA Testing and Certification S.A.U. is a testing laboratory accredited by the National Accreditation Body (ENAC -Entidad Nacional de Acreditación), to perform the tests indicated in the Certificate No. 51/LE 147.

DEKRA Testing and Certification is a FCC-recognized accredited testing laboratory with appropriate scope of accreditation that include testing performed in this test report.

DEKRA Testing and Certification S.A.U. is a laboratory with a measurement site in compliance with the requirements of RSS 212, Issue 1 (Provisional) and has been added to the list of filed sites of the Canadian Certification and Engineering Bureau. Reference File Number: ISED 4621A-2.

In order to assure the traceability to other national and international laboratories, DEKRA Testing and Certification S.A.U. has a calibration and maintenance program for its measurement equipment.

DEKRA Testing and Certification S.A.U. guarantees the reliability of the data presented in this report, which is the result of the measurements and the tests performed to the item under test on the date and under the conditions stated on the report and, it is based on the knowledge and technical facilities available at DEKRA Testing and Certification S.A.U. at the time of performance of the test.

DEKRA Testing and Certification S.A.U. is liable to the client for the maintenance of the confidentiality of all information related to the item under test and the results of the test.

The results presented in this Test Report apply only to the particular item under test established in this document.

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General conditions

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Uncertainty

Uncertainty (factor $k=2$) was calculated according to the DEKRA Testing and Certification S.A.U. internal document PODT000.

Data provided by the client

The Cochlear Osia System uses bone conduction to transmit sounds to the cochlear (inner ear) with the purpose of enhancing hearing. The Osia 2 Sound Processor is intended to be used as a part of the Cochlear Osia System to pick up surrounding sound and transfer it to the implant through a digital inductive link.

DEKRA Testing and Certification S.A.U. declines any responsibility with respect to the information provided by the client and that may affect the validity of results.

Usage of samples

Samples undergoing test have been selected by: The client.

- Sample S/01 is composed of the following elements:

Control N°	Description	Model	Serial N°	Reception
57186B/001	General Medical Devices (Bone anchored sound processor)	Osia 2 Sound Processor	1170020010597	2018/11/19
57186B/009	Water tank	--	--	2018/11/19
57186B/015	OSI100 implant	--	--	2018/11/19

Sample S/01 has undergone the following test(s): All RADIATED tests indicated in Appendix A.

- Sample S/02 is composed of the following elements:

Control N°	Description	Model	Serial N°	Reception
57186B/014	General Medical Devices (Bone anchored sound processor)	Osia 2 Sound Processor	1170020012560	2018/11/19
57186B/005	Speedlink	--	--	2018/11/19
57187B/006	USB cable	--	--	2018/11/19
57187B/007	Programming cable	--	--	2018/11/19

Sample S/02 has undergone the following test(s): All CONDUCTED tests indicated in Appendix A.

Test sample description

Ports..... :	Port name and description	Cable			
		Specified max length [m]	Attached during test	Shielded	Coupled to patient ⁽³⁾
	Antenna (for 2.4GHz ISM band)		☐	☐	☐
	Coil (for 5 MHz inductive link)		☐	☐	☒
Supplementary information to the ports..... :					

Rated power supply	Voltage and Frequency		Reference poles				
			L1	L2	L3	N	PE
	☒	DC:1.45 V					
Rated Power							
Clock frequencies	16 MHz, 40MHz						
Other parameters.....							
Software version	Drop 4.1, Osia2-NPC.0.8.5						
Hardware version.....	EP4						
Dimensions in cm (W x H x D).....							
Mounting position.....	☒	Other: Body-worn equipment					
Modules/parts	Module/parts of test item			Type		Manufacturer	
Accessories (not part of the test item)	Description			Type		Manufacturer	
	Bone conduction implant			OSI100		Cochlear	
	MiniMic			SM-2P		Cochlear	
	Skull simulator			TU 1000		Cochlear	
Documents as provided by the applicant.....	Description			File name		Issue date	

⁽³⁾ Only for Medical Equipment

Identification of the client

COCHLEAR BONE ANCHORED SOLUTIONS AB
Konstruktionsvägen 14, 43533 Mölnlycke, SWEDEN

Testing period and place

Test Location	DEKRA Testing and Certification S.A.U.
Date (start)	2018-11-19
Date (finish)	2018-11-29

Document history

Report number	Date	Description
57186RRF.003	2019-02-21	First release
57186RRF.003A1	2019-09-03	On the cover sheet, the RSS 210 is modified to correct version. The correct version is RSS 247 and not RSS 210.

Environmental conditions

In the control chamber, the following limits were not exceeded during the test:

Temperature	Min. = 15 °C Max. = 35 °C
Relative humidity	Min. = 20 % Max. = 75 %
Shielding effectiveness	> 100 dB
Electric insulation	> 10 kΩ
Reference resistance to earth	< 1 Ω

In the semianechoic chamber, the following limits were not exceeded during the test.

Temperature	Min. = 15 °C Max. = 35 °C
Relative humidity	Min. = 20 % Max. = 75 %
Air pressure	Min. = 860 mbar Max. = 1060 mbar
Shielding effectiveness	> 100 dB
Electric insulation	> 10 kΩ
Reference resistance to earth	< 1 Ω
Normal site attenuation (NSA)	< ±4 dB at 10 m distance between item under test and receiver antenna, (30 MHz to 1000 MHz)
Field homogeneity	More than 75% of illuminated surface is between 0 and 6 dB (26 MHz to 1000 MHz).

In the chamber for conducted measurements, the following limits were not exceeded during the test:

Temperature	Min. = 15 °C Max. = 35 °C
Relative humidity	Min. = 20 % Max. = 35 %
Air pressure	Min. = 860 mbar Max. = 1060 mbar
Shielding effectiveness	> 100 dB
Electric insulation	> 10 kΩ
Reference resistance to earth	< 1 Ω

Remarks and comments

The tests have been performed by the technical personnel: Ignacio Cabra, Juan Carlos Fuentes, Carolina Postigo, Miguel Ángel Torres.

Used instrumentation:

Conducted Measurements:

	Last Calibration	Due Calibration
1. Spectrum Analyzer PSA 3Hz-26.5 GHz AGILENT TECHNOLOGIES E4440A	2017/10	2019/10
2. DC Power Supply, 30V, 5A KEYSIGHT TECHNOLOGIES U8002A	---	---
3. Multimeter Fluke 179	2018/06	2019/06

Radiated Measurements:

	Last Calibration	Due Calibration
1. Semianechoic Absorber Lined Chamber ETS LINDGREN FACT 3 200 STP	N.A.	N.A.
2. Shielded Room ETS LINDGREN S101	N.A.	N.A.
3. EMI Receiver ROHDE AND SCHWARZ ESU40	2018/06	2020/06
4. RF Pre-amplifier, 38 dB, 30 MHz-6 GHz BONN ELEKTRONIK BLNA 0360-01N	2018/07	2019/07
5. Biconical/Log Antenna ETS LINDGREN 3142E	2017/04	2020/04
6. Spectrum Analyzer ROHDE AND SCHWARZ FSW50	2018/02	2020/02
7. Pre-amplifier G>30dB, 1-18GHz BONN ELEKTRONIK BLMA 0118-3A	2018/03	2019/03
8. Broadband Horn antenna 1-18 GHz SCHWARZBECK MESS-ELEKTRONIK BBHA 9120 D	2016/11	2019/11
9. Broadband Horn antenna 18 - 40 GHz SCHWARZBECK MESS-ELEKTRONIK BBHA 9170	2018/07	2021/07
10. RF Pre-amplifier, G>48dB, 18-40GHz NARDA JS44-18004000-33-8P	2018/02	2020/02

Testing verdicts

Not applicable:	N/A
Pass:	P
Fail:	F
Not measured:	N/M

Summary

1. Bluetooth Low Energy

FCC PART 15 PARAGRAPH / RSS-247			
Requirement – Test case		Verdict	Remark
Section 15.247 Subclause (a) (2) / RSS-247 5.2. (a)	6 dB Bandwidth	P	
Section 15.247 Subclause (b) / RSS-247 5.4. (d)	Maximum output power and antenna gain	P	
Section 15.247 Subclause (d) / RSS-247 5.5	Emission limitations conducted (Transmitter)	P	
Section 15.247 Subclause (d) / RSS-247 5.5.	Band-edge emissions compliance (Transmitter)	P	
Section 15.247 Subclause (e) / RSS-247 5.2. (b)	Power spectral density	P	
Section 15.247 Subclause (d) / RSS-247 5.5.	Emission limitations radiated (Transmitter)	P	
<u>Supplementary information and remarks:</u>			
None.			

Appendix A: Test results. Bluetooth Low Energy

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TEST CONDITIONS

POWER SUPPLY (V):

V_{nominal} : 1.45 Vdc

Type of power supply: DC voltage from battery.

Type of Antenna: Integral antenna.

Maximum declared antenna Gain: -1.7 dBi.

TEST FREQUENCIES:

Low Channel: 2402 MHz

Middle Channel: 2440 MHz

High Channel: 2480 MHz

CONDUCTED MEASUREMENTS

The equipment under test was set up in a shielded room and it is directly connected to the spectrum analyzer.



RADIATED MEASUREMENTS

All radiated tests were performed in a semi-anechoic chamber. The measurement antenna (Loop antenna for the range between 9 kHz to 30 MHz and Bilog antenna for the range between 30 MHz to 1000 MHz) is situated at a distance of 3 m and at a distance of 1m for the frequency range 1 GHz-26 GHz (1 GHz-18 GHz Double ridge horn antenna and 18 GHz-40 GHz horn antenna).

For radiated emissions in the range 9 kHz to 30 MHz that is performed at a distance closer than the specified distance, an inverse proportionality factor of 40 dB per decade is used to normalize the measured data for determining compliance.

For radiated emissions in the range 1 GHz-26 GHz that is performed at a distance closer than the specified distance, an inverse proportionality factor of 20 dB per decade is used to normalize the measured data for determining compliance.

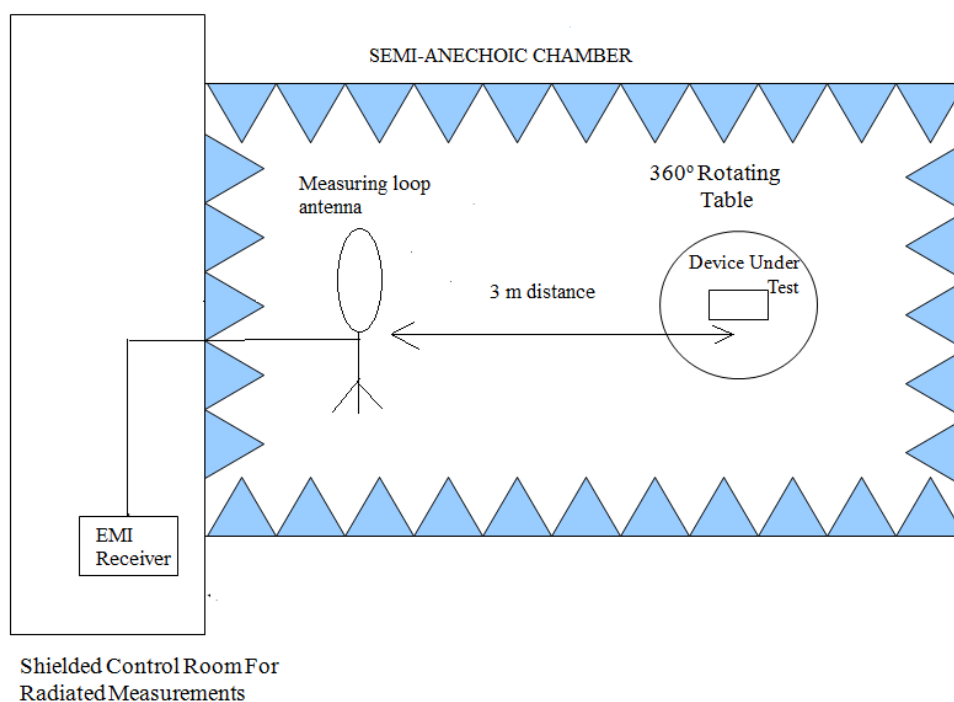
The equipment under test was set up on a non-conductive platform above the ground plane and the situation and orientation was varied to find the maximum radiated emission. It was also rotated 360° and the antenna height (Bilog antenna and Double ridge horn antenna) was varied from 1 to 4 meters to find the maximum radiated emission.

Measurements were made in both horizontal and vertical planes of polarization.

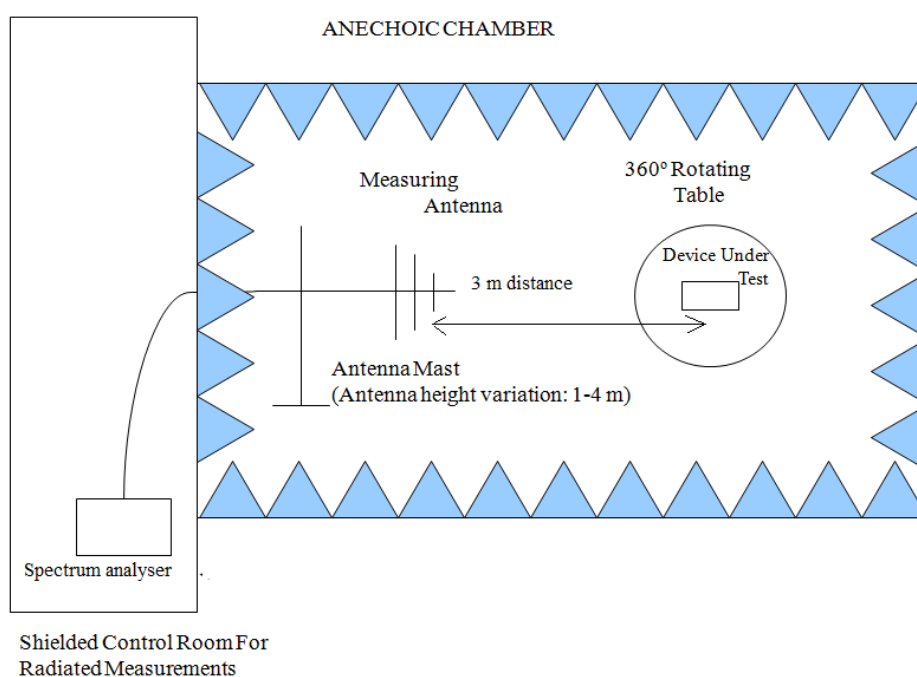
In the range between 9 kHz and 30 MHz the measurements were made in the three different orientation planes of the loop antenna to determine the maximum received field.

The test was performed with the equipment transmitting first with only the Bluetooth Low Energy 2.4 GHz radio and repeated with 5 MHz radio transmitting simultaneously to check the impact of the co-location of the other radio interfaces. The results and plots below show the worst results obtained.

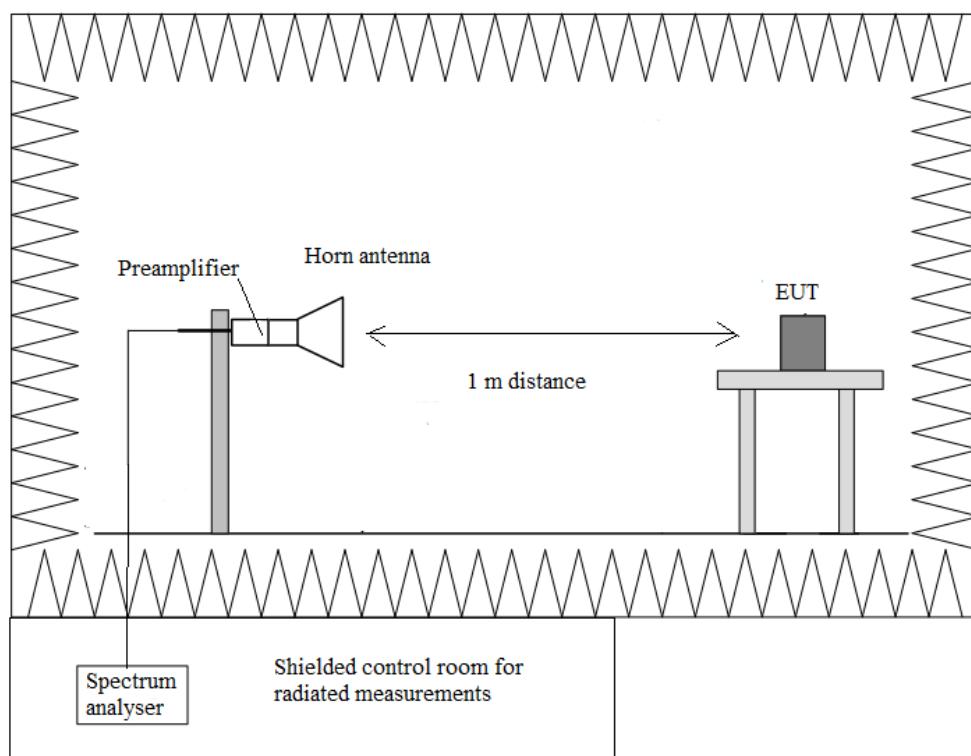
Radiated measurements setup from 9 kHz to 30 MHz:



Radiated measurements setup from 30 MHz to 1 GHz:



Radiated measurements setup $f > 1$ GHz:

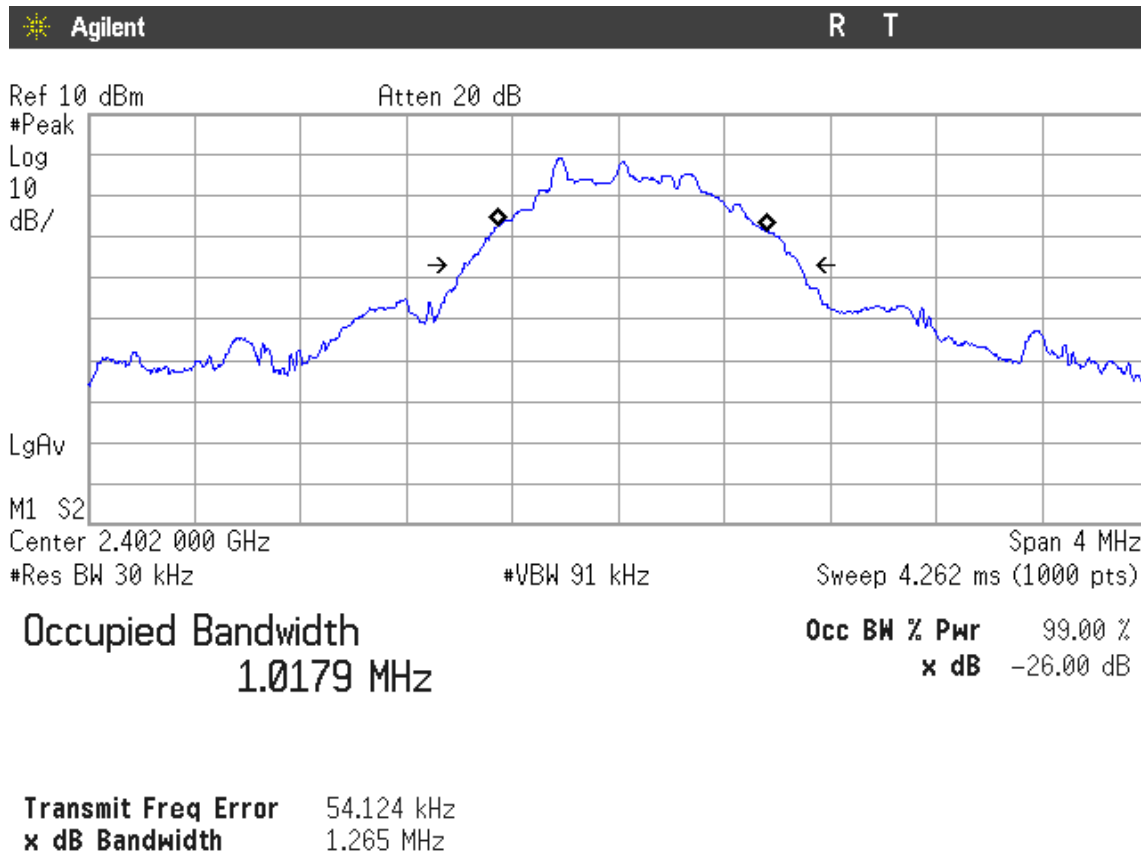


Occupied Bandwidth

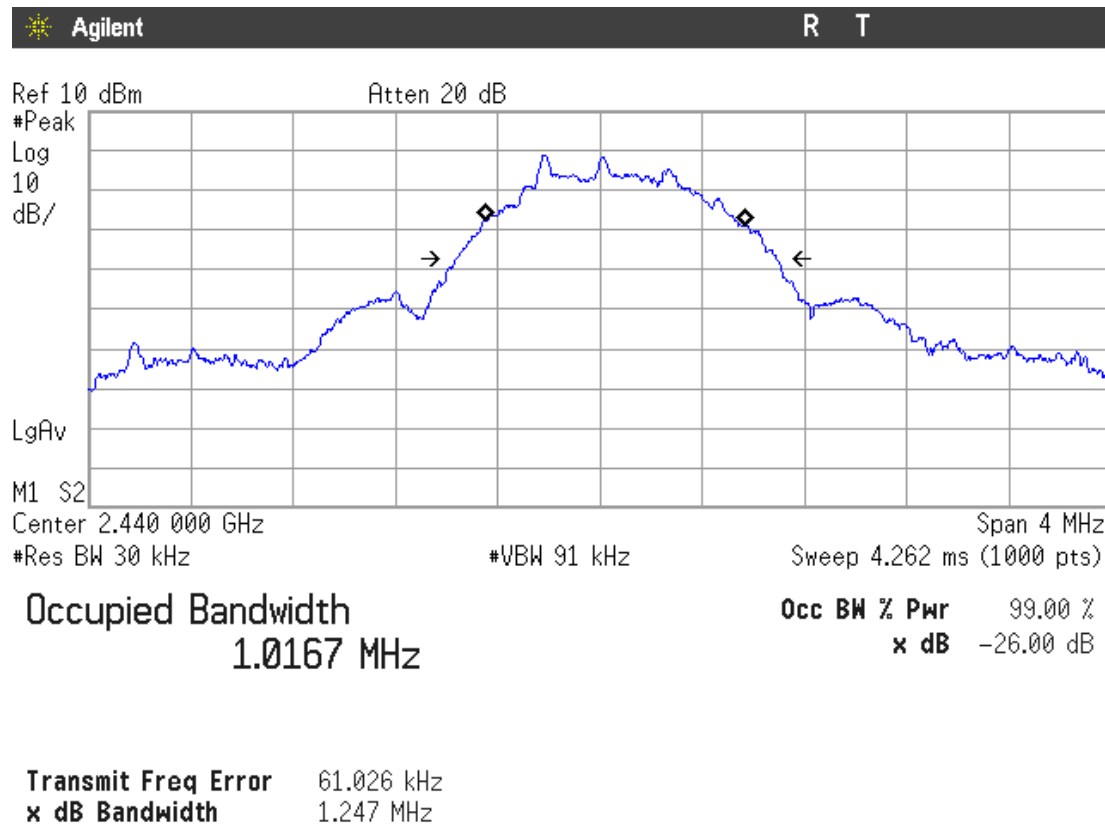
RESULTS:

	Low Channel 2402 MHz	Middle Channel 2440 MHz	High Channel 2480 MHz
99% bandwidth (MHz)	1.0179	1.0167	0.9977
-26 dBc bandwidth (MHz)	1.265	1.247	1.238
Measurement uncertainty (kHz)	<± 5.00		

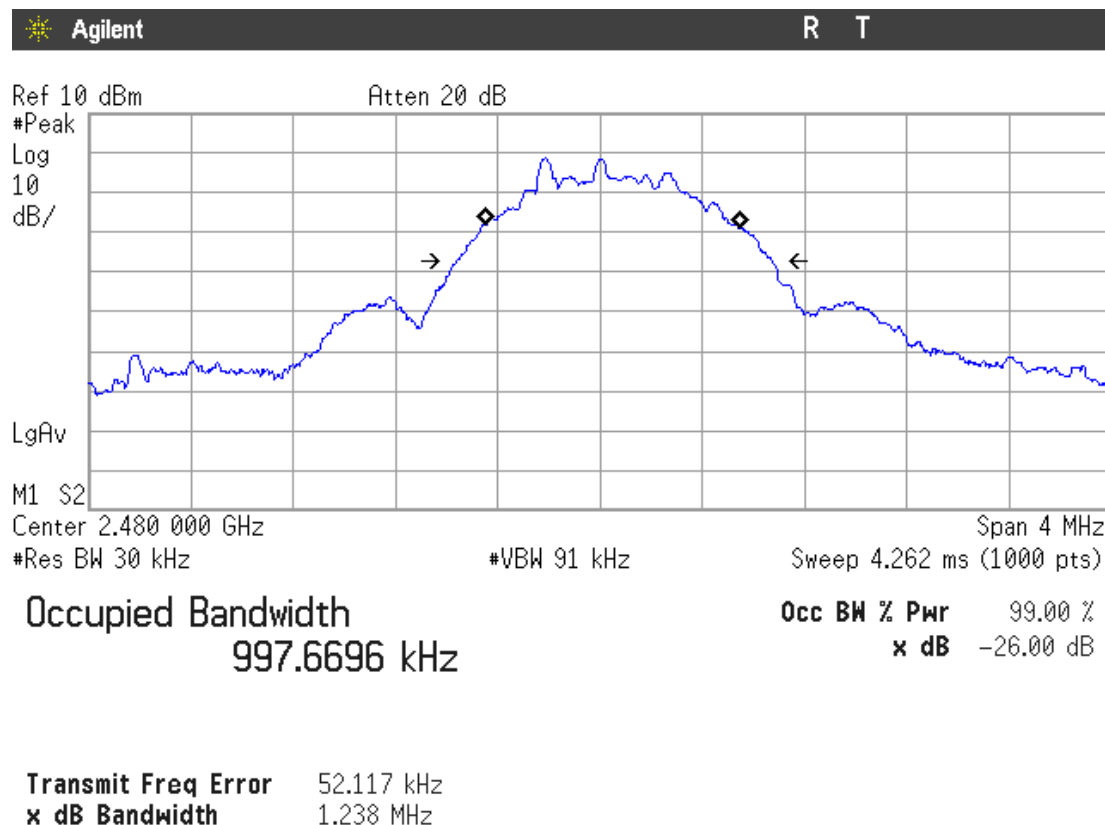
- Low Channel:



- Middle Channel:



- High Channel:



FCC Section 15.247 Subclause (a) (2) / RSS-247 Clause 5.2 (a) 6 dB Bandwidth.

SPECIFICATION:

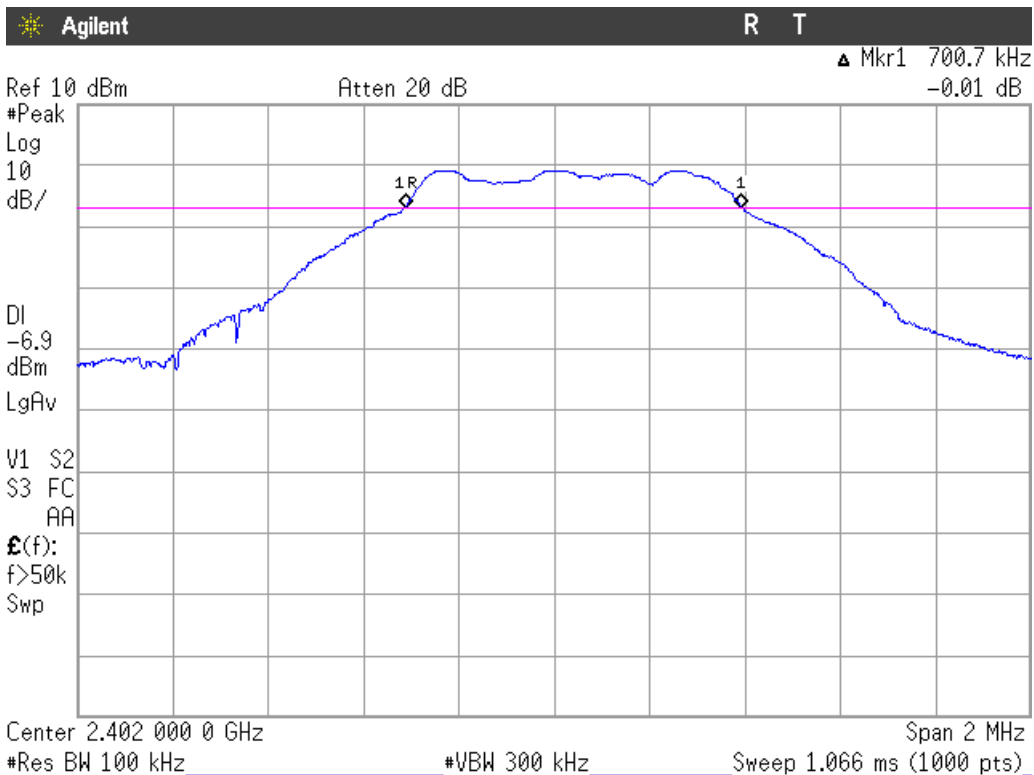
The minimum 6 dB bandwidth shall be at least 500 kHz.

RESULTS:

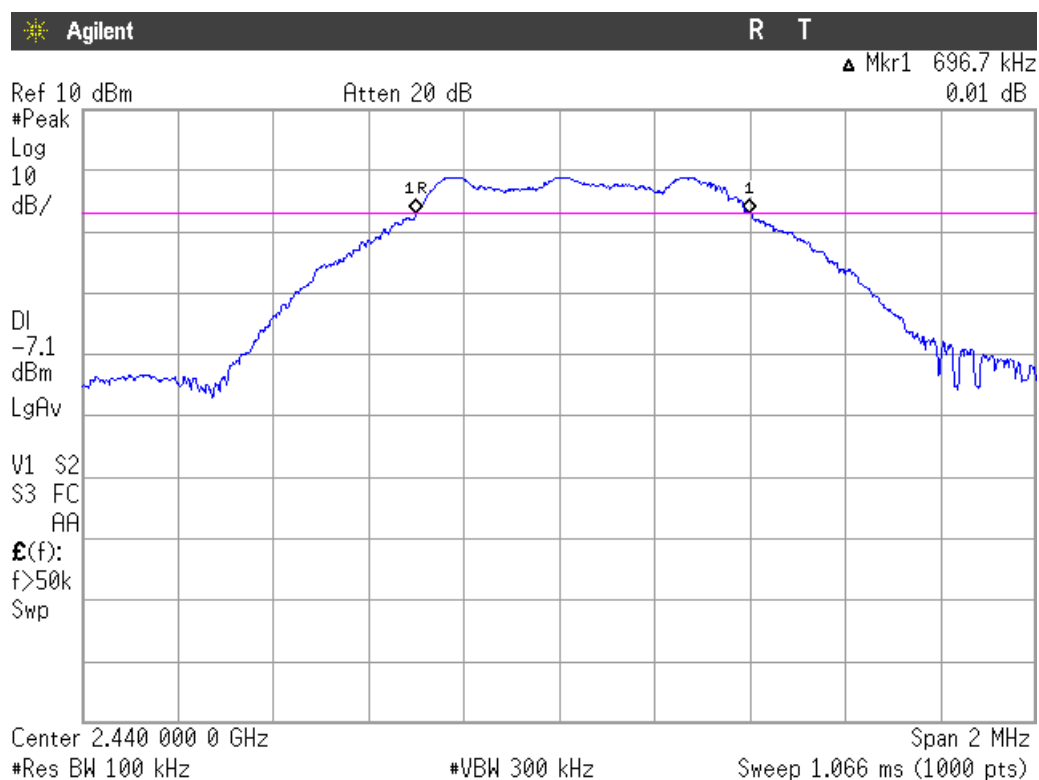
	Low Channel 2402 MHz	Middle Channel 2440 MHz	High Channel 2480 MHz
6 dB Spectrum bandwidth (kHz)	700.7	696.7	680.7
Measurement uncertainty (kHz)	<±11.0		

Verdict: PASS

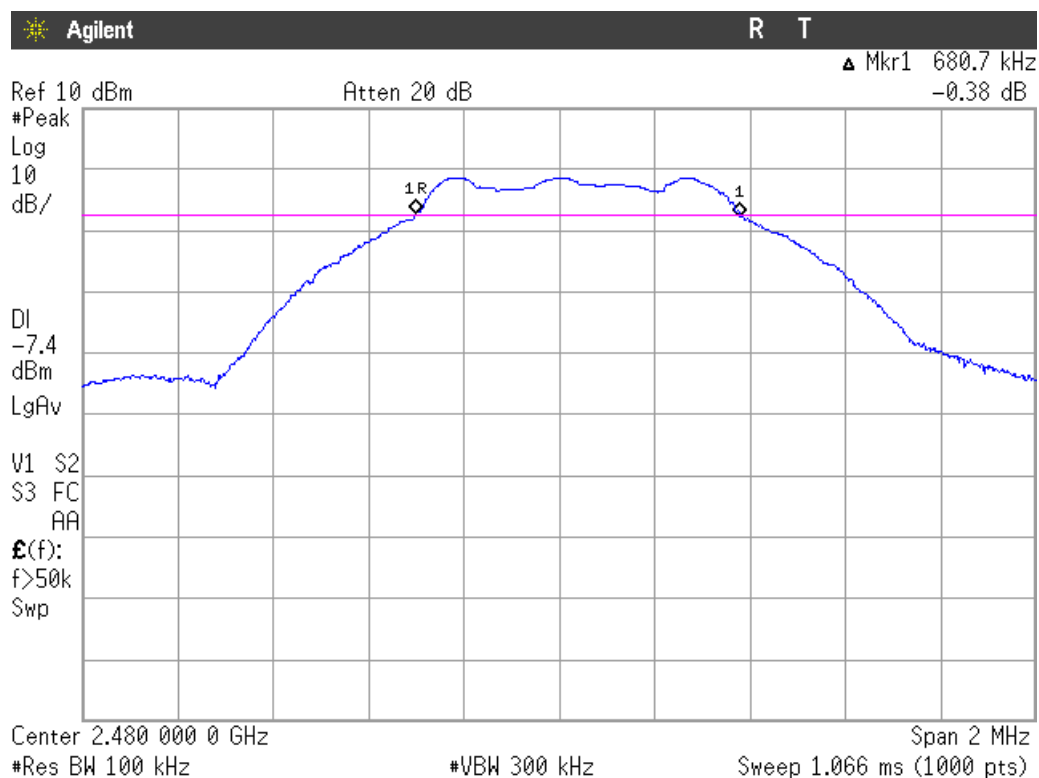
- Low Channel:



- Middle Channel:



- High Channel:



FCC Section 15.247 Subclause (b) / RSS-247 Clause 5.4 (d) Maximum output power and antenna gain

SPECIFICATION:

For systems using digital modulation in the 2400-2483.5 MHz band: 1 watt (30 dBm).

The e.i.r.p. shall not exceed 4 W (36 dBm) (Canada).

RESULTS:

The maximum peak conducted output power was measured using the method according to point 9.1.1. of Guidance for Performing Compliance Measurements on Digital Transmission Systems (DTS) Operating Under Section 15.247 558074 D01 DTS Meas Guidance v04 dated 04/05/2017.

The EIRP power (dBm) is calculated by adding the declared maximum antenna gain to the measured conducted power.

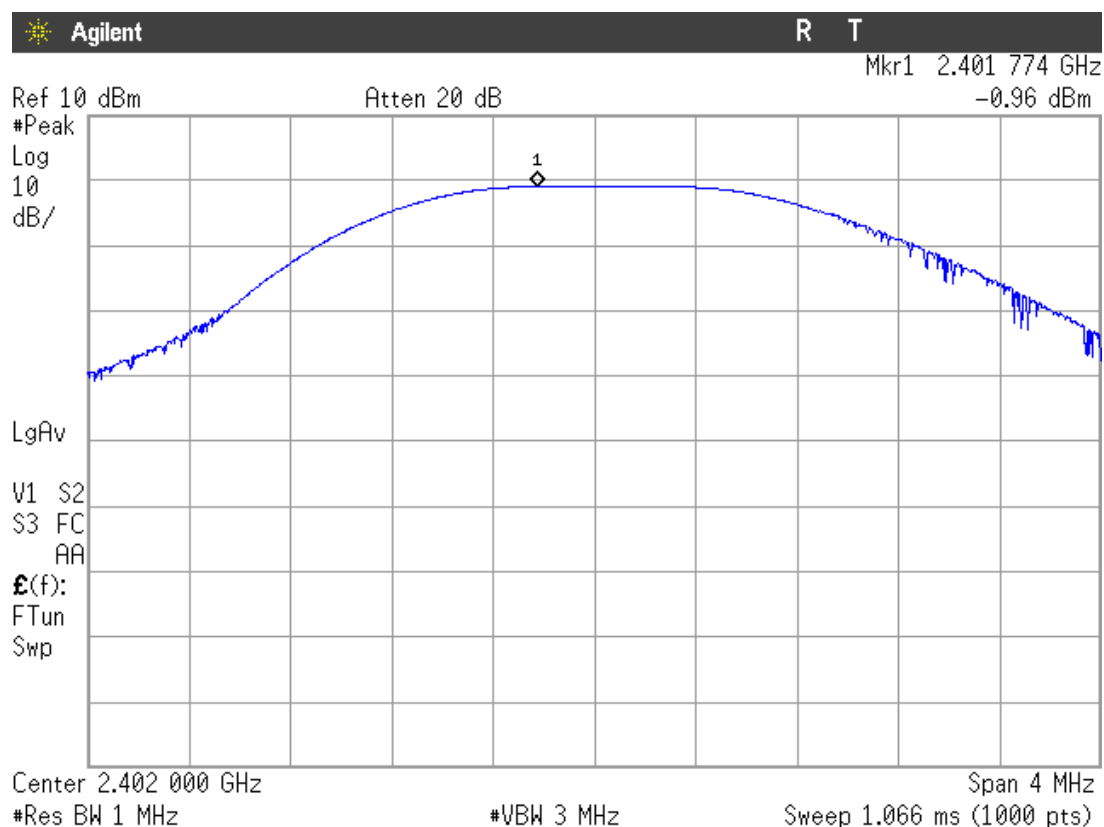
Maximum declared antenna gain: -1.7 dBi.

	Low Channel 2402 MHz	Middle Channel 2440 MHz	High Channel 2480 MHz
Maximum Conducted Power (dBm)	-0.96	-1.10	-1.38
Maximum EIRP Power (dBm)	-2.66	-2.80	-3.08
Measurement uncertainty (dB)	<±0.78		

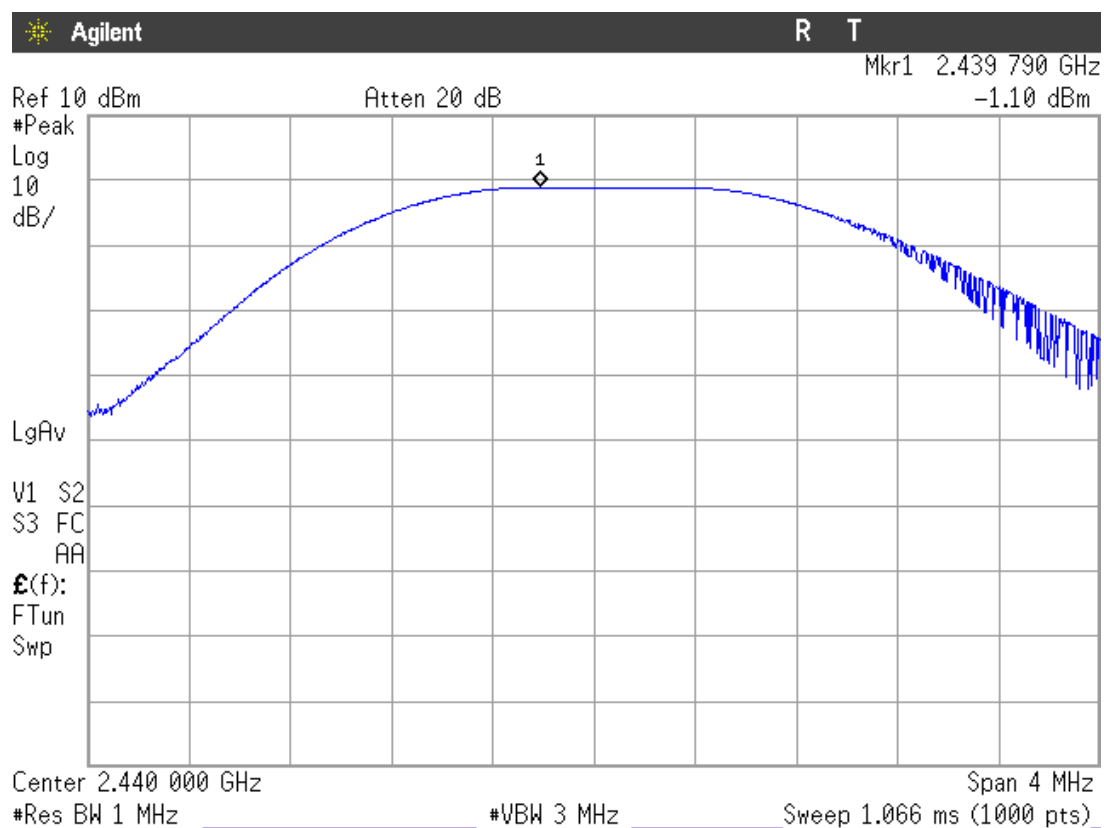
The maximum directional gain of the antenna is less than 6 dBi and therefore the maximum output power is not required to be reduced from the stated values.

Verdict: PASS

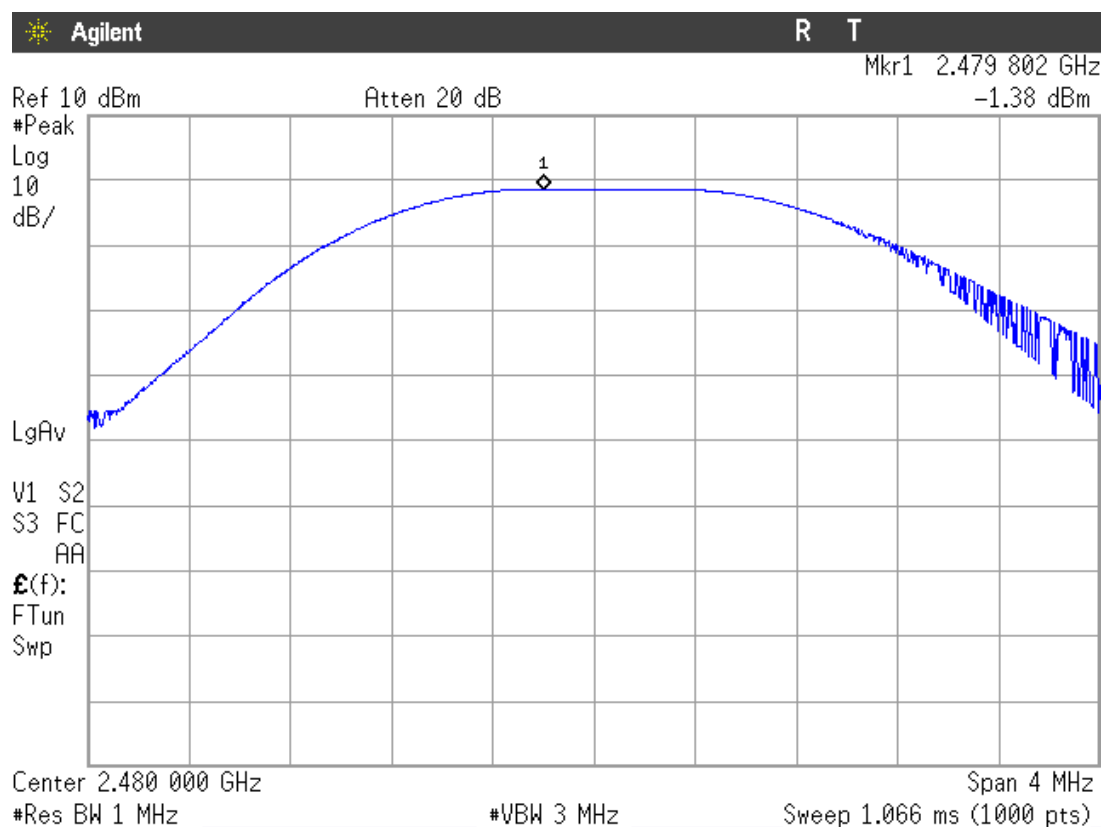
- Low Channel:



- Middle Channel:



- High Channel:



FCC Section 15.247 Subclause (d) / RSS-247 Clause 5.5. Emission limitations conducted (Transmitter)

SPECIFICATION:

In any 100 kHz bandwidths outside the frequency band in which the intentional radiator is operating, the radio frequency power that is produced by the intentional radiator shall be at least 20 dB below that in the 100 kHz 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. If the transmitter complies with the conducted power limits based on the use of RMS averaging over a time interval, the attenuation required under this paragraph shall be 30 dB instead of 20 dB.

RESULTS:

	Low Channel 2402 MHz	Middle Channel 2440 MHz	High Channel 2480 MHz
Reference Level Measurement (dBm)	-1.00	-1.15	-1.55
Measurement uncertainty (dB)	<±0.78		

- Low Channel:

No spurious peaks found at less than 20 dB respect to the limit.

- Middle Channel:

No spurious peaks found at less than 20 dB respect to the limit.

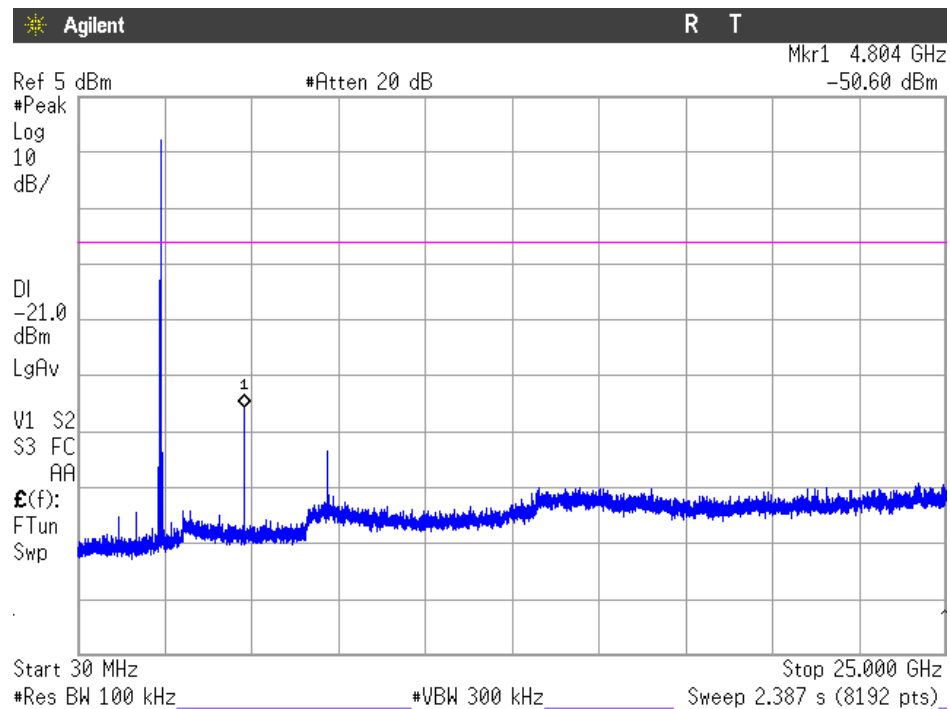
- High Channel:

No spurious peaks found at less than 20 dB respect to the limit.

Measurement uncertainty (dB)	<±2.03
------------------------------	--------

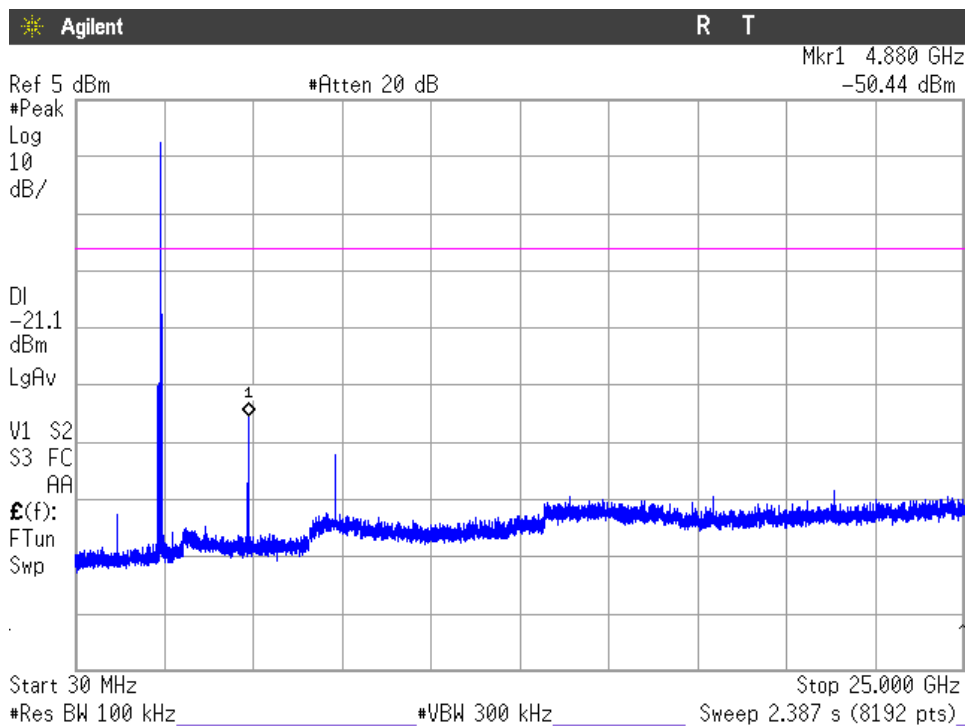
Verdict: PASS

- Low Channel:



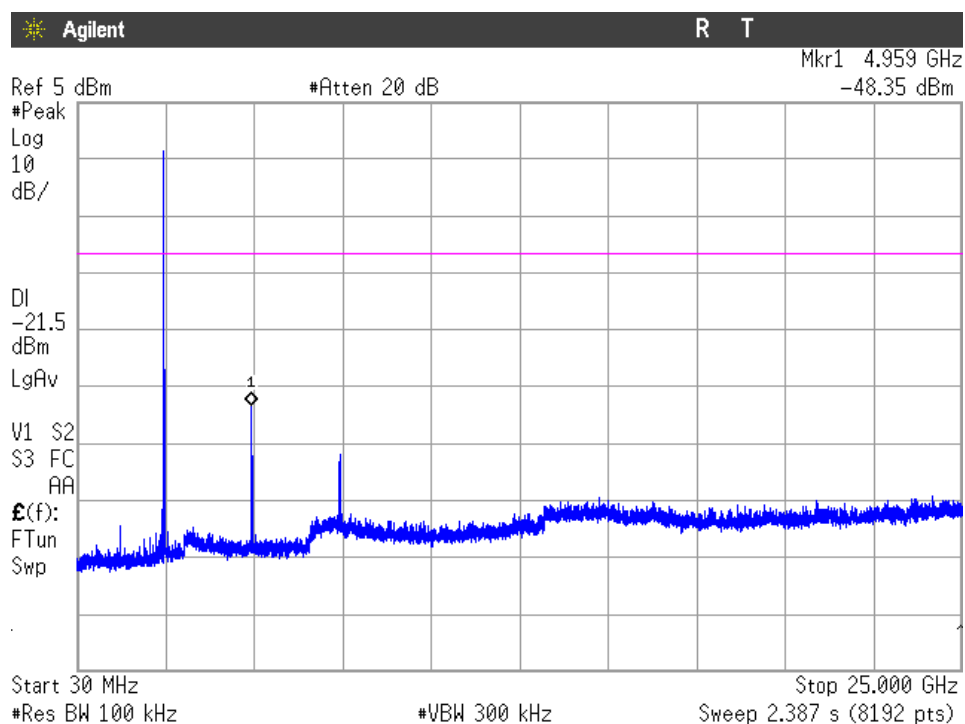
The peak shown in the plot above the limit is the carrier frequency.

- Middle Channel:



The peak shown in the plot above the limit is the carrier frequency.

- High Channel:



The peak shown in the plot above the limit is the carrier frequency.

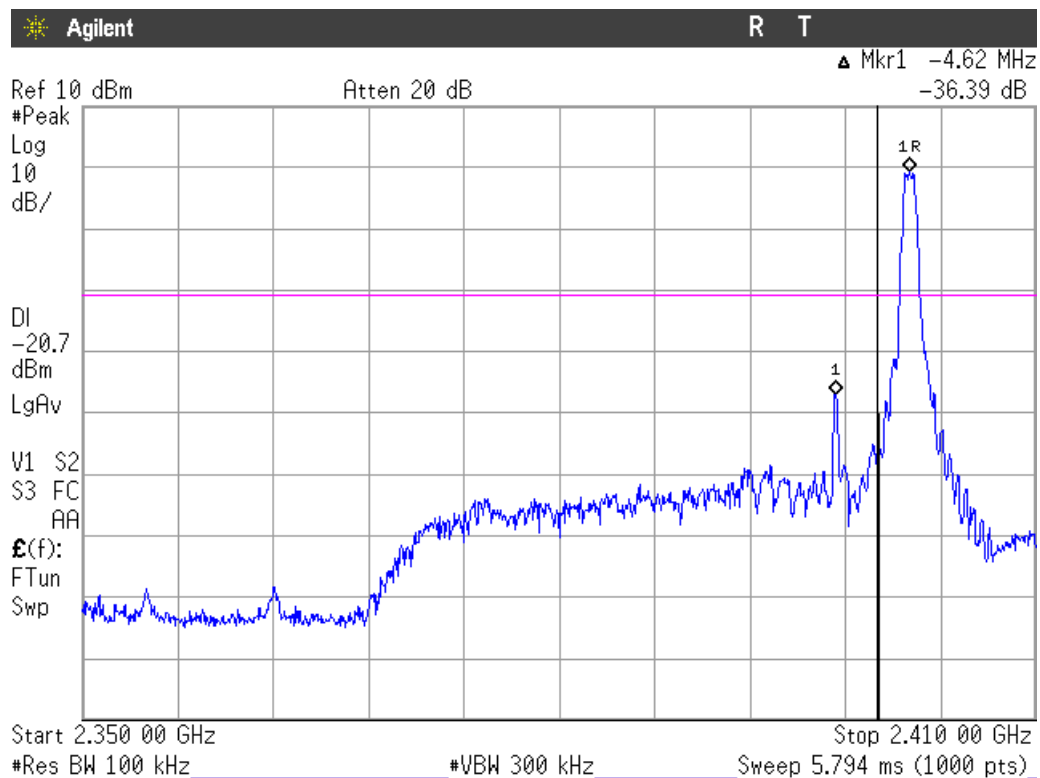
FCC Section 15.247 Subclause (d) / RSS-247 Clause 5.5. Band-edge emissions compliance (Transmitter)

SPECIFICATION:

In any 100 kHz bandwidths outside the frequency band in which the intentional radiator is operating, the radio frequency power that is produced by the intentional radiator shall be at least 20 dB below that in the 100 kHz 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. If the transmitter complies with the conducted power limits based on the use of RMS averaging over a time interval, the attenuation required under this paragraph shall be 30 dB instead of 20 dB.

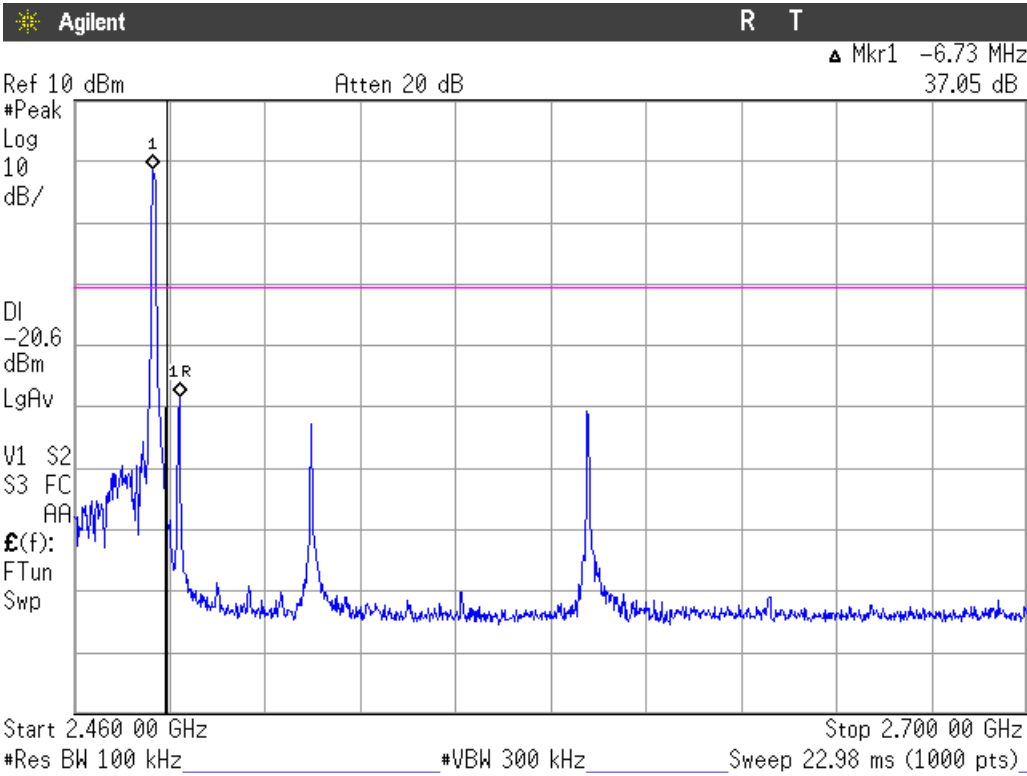
RESULTS:

1. LOW CHANNEL.



Verdict: PASS

2. HIGH CHANNEL.



Verdict: PASS

Measurement uncertainty (dB)	<±2.03
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FCC Section 15.247 Subclause (e) / RSS-247 5.2. (b) Power spectral density

SPECIFICATION:

For digitally modulated systems, 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.

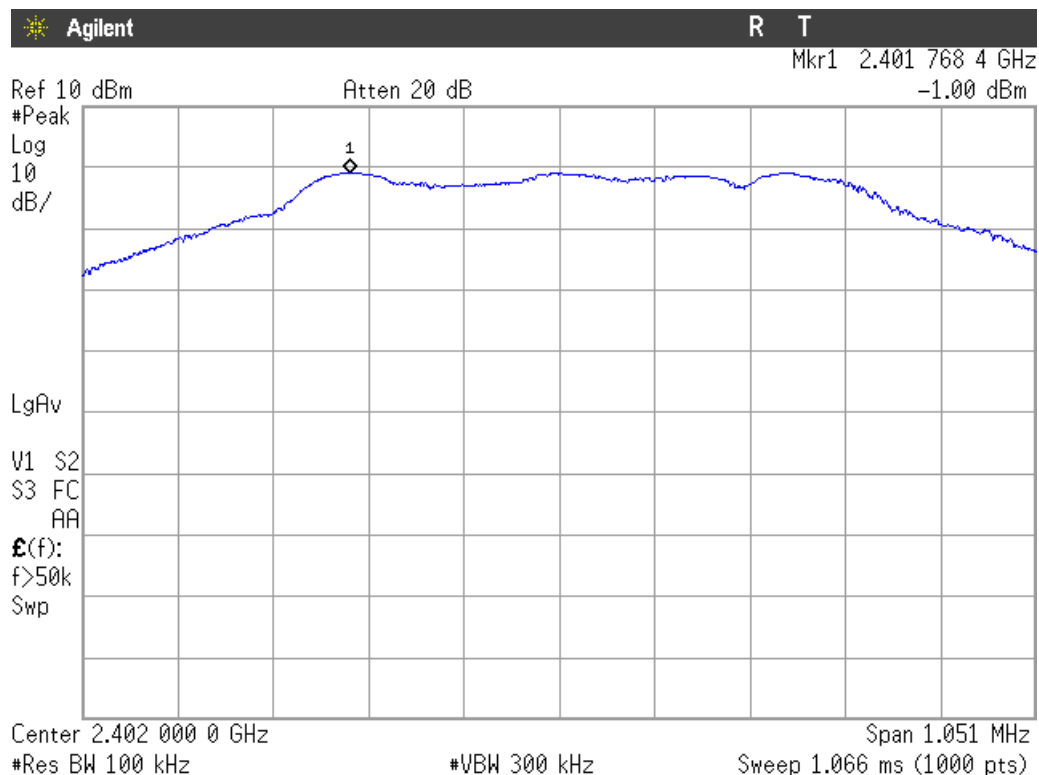
RESULTS:

The maximum power spectral density level in the fundamental emission was measured using the method PKPSD (Peak PSD) according to point 10.2. of Guidance for Performing Compliance Measurements on Digital Transmission Systems (DTS) Operating Under Section 15.247 558074 D01 DTS Meas Guidance v04 dated 04/05/2017.

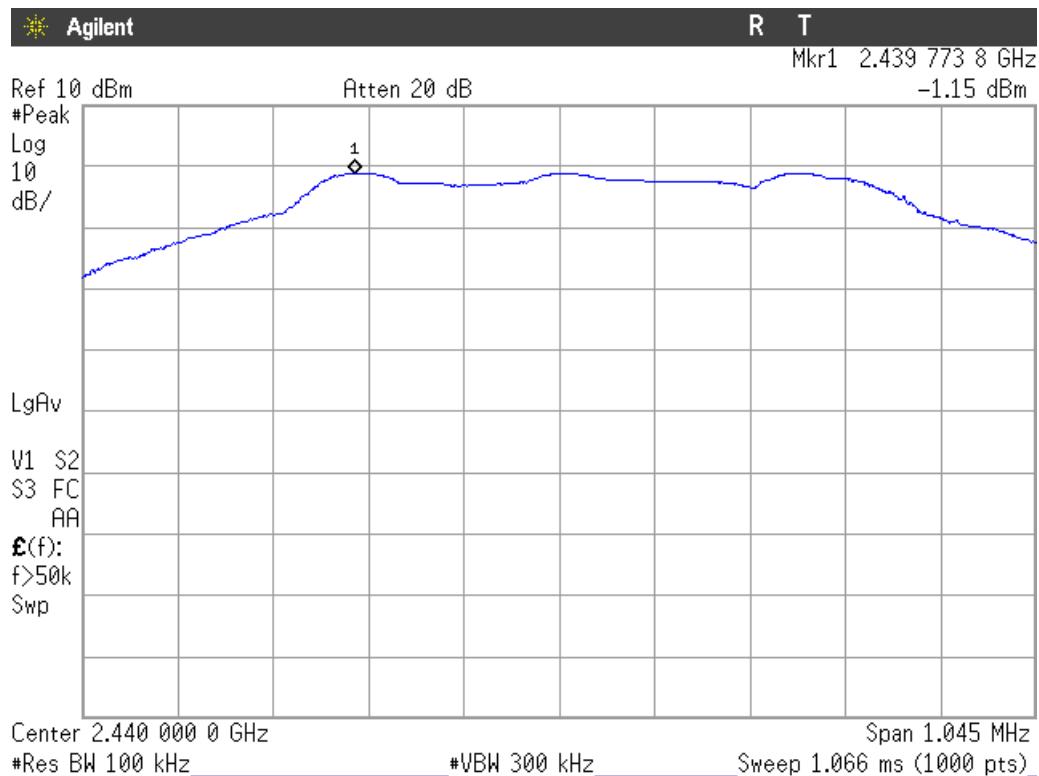
	Low Channel 2402 MHz	Middle Channel 2440 MHz	High Channel 2480 MHz
Power Spectral Density (dBm)	-1.00	-1.15	-1.55
Measurement uncertainty (dB)	<±1.20		

Verdict: PASS

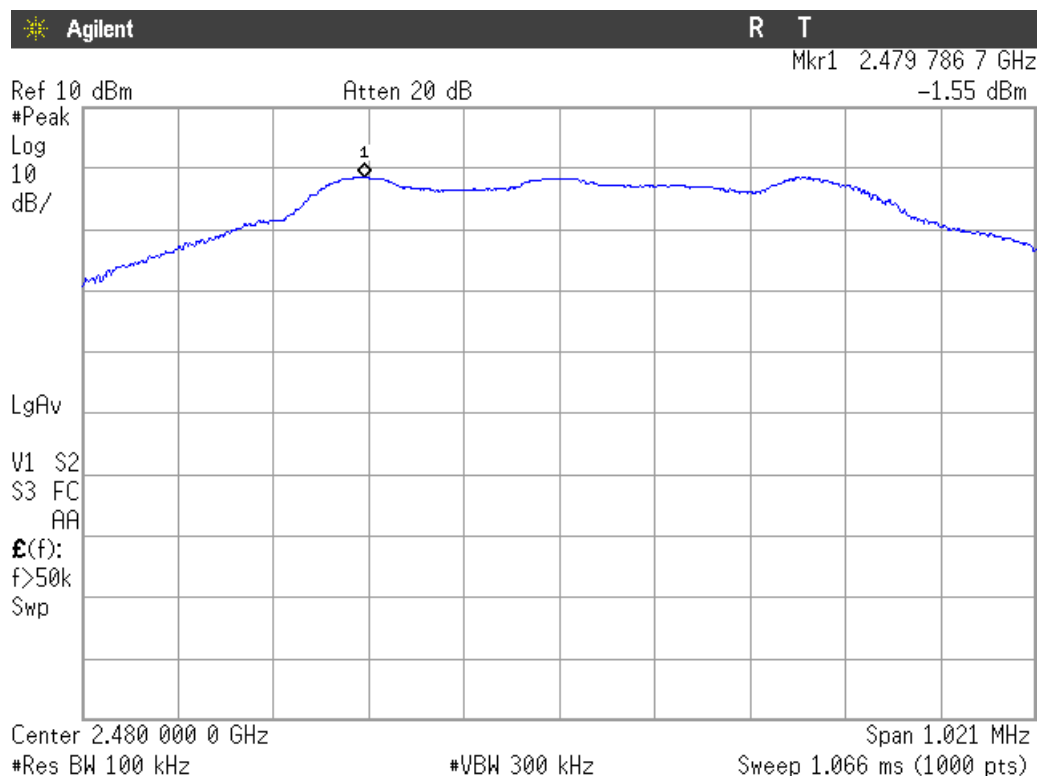
- Low Channel:



- Middle Channel:



- High Channel:



FCC Section 15.247 Subclause (d) / RSS-247 Clause 5.5. Emission limitations radiated (Transmitter)

SPECIFICATION:

Radiated emissions which fall in the restricted bands, as defined in Section 15.205(a), must also comply with the radiated emission limits specified in Section 15.209(a) (see Section 15.205(c)/RSS-Gen):

Frequency Range (MHz)	Field strength ($\mu\text{V/m}$)	Field strength ($\text{dB}\mu\text{V/m}$)	Measurement distance (m)
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	40	3
88 - 216	150	43.5	3
216 - 960	200	46	3
960 - 10000	500	54	3

The emission limits shown in the above table are based on measurements employing 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.

For average radiated emission measurements above 1000 MHz, there is also a limit corresponding to 20 dB above the indicated values in the table is specified when measuring with peak detector function.

RSS-247: Attenuation below the general field strength limits specified in RSS-Gen is not required.

RESULTS:

The situation and orientation was varied to find the maximum radiated emission. It was also rotated 360° and the antenna height was varied from 1 to 4 meters to find the maximum radiated emission.

Measurements were made in both horizontal and vertical planes of polarization.

All tests were performed in a semi-anechoic chamber at a distance of 3 m for the frequency range 9 kHz-1000 MHz and at distance of 1m for the frequency range 1 GHz-26 GHz.

The field strength is calculated by adding correction factor to the measured level from the spectrum analyzer. This correction factor includes antenna factor, cable loss and pre-amplifiers gain.

Frequency range 9 kHz - 30 MHz:

The spurious signals detected do not depend on the operating channel.

No peaks were found at less than 20 dB respect to the limit.

Frequency range 30 MHz - 1 GHz:

The spurious signals detected do not depend on the operating channel.

Spurious signals closest to the limit:

Spurious frequency (MHz)	Detector	Emission Level (dBμV/m)	Polarization	Measurement Uncertainty (dB)
30.3880	Quasi peak	17.1	V	<± 3.88
180.0105	Quasi peak	29.5	H	<± 3.88
254.9915	Quasi peak	32.4	H	<± 3.88
460.0010	Quasi peak	27.4	V	<± 3.88
464.9965	Quasi peak	29.3	H	<± 3.88

Frequency range 1 - 26 GHz:

The results in the next tables show the maximum measured levels in the 1-26 GHz range including the restricted bands 2.31-2.39 GHz and 2.4835-2.5 GHz.

Spurious signals with peak levels above the average limit (54 dBμV/m at 3 m) are measured with average detector for checking compliance with the average limit.

- LOW CHANNEL. Spurious signals closest to the limit:

Spurious frequency (GHz)	Detector	Emission Level (dBμV/m)	Polarization	Measurement Uncertainty (dB)
1.37843	Peak	50.94	V	<± 3.70
2.33029	Peak	53.61	H	<± 3.70
2.38630	Peak	55.45	H	<± 3.70
	Average	41.31		<± 3.70
2.44683	Peak	54.91	H	<± 3.70
	Average	45.38		<± 3.70
4.80390	Peak	43.59	H	<± 3.70

- MIDDLE CHANNEL. Spurious signals closest to the limit:

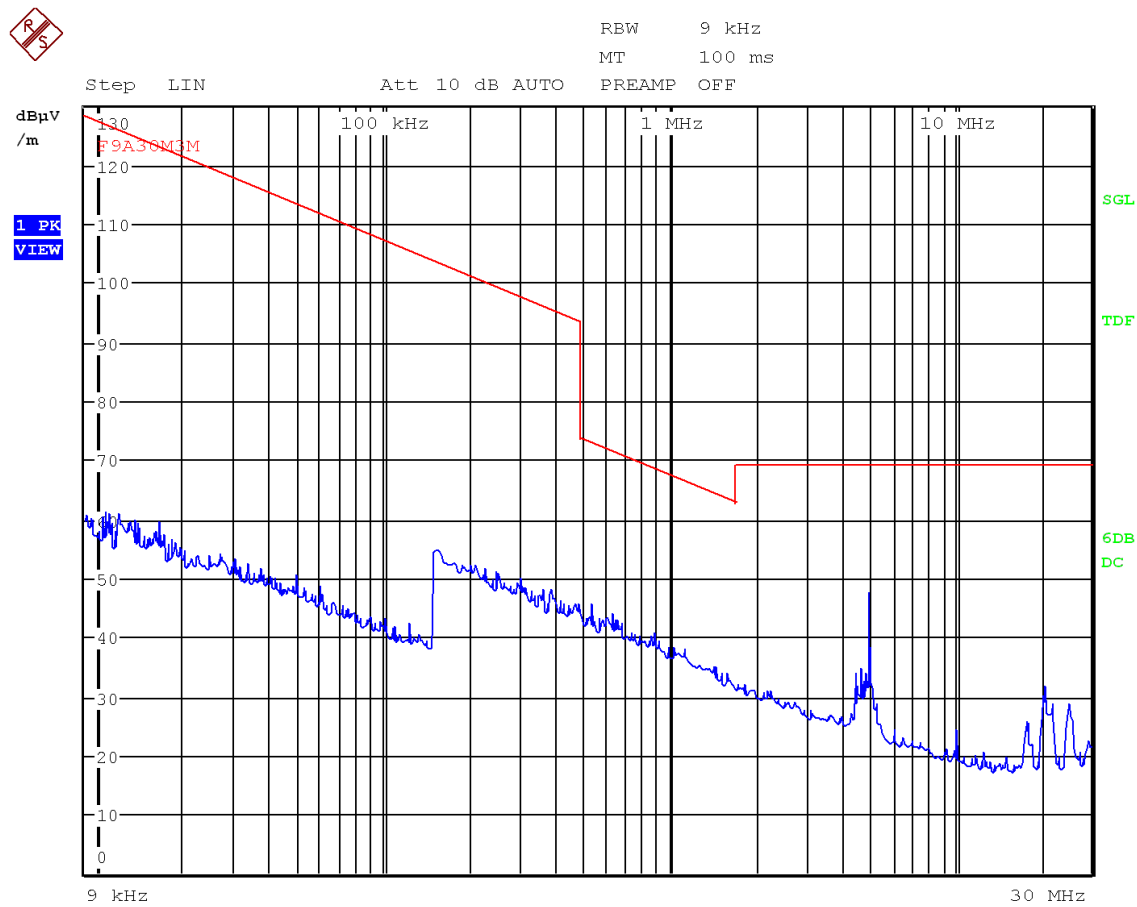
Spurious frequency (GHz)	Detector	Emission Level (dBμV/m)	Polarization	Measurement Uncertainty (dB)
2.38663	Peak	53.16	H	<± 3.70
2.41610	Peak	55.67	H	<± 3.70
	Average	38.7		<± 3.70
4.88043	Peak	44.56	V	<± 3.70
7.32063	Peak	49.39	V	<± 3.70
10.53083	Peak	55.76	V	<± 3.70
	Average	46.91		<± 3.70

- HIGH CHANNEL. Spurious signals closest to the limit:

Spurious frequency (MHz)	Detector	Emission Level (dBμV/m)	Polarization	Measurement Uncertainty (dB)
4.95977	Peak	44.83	H	<± 3.70
7.44010	Peak	46.95	V	<± 3.70

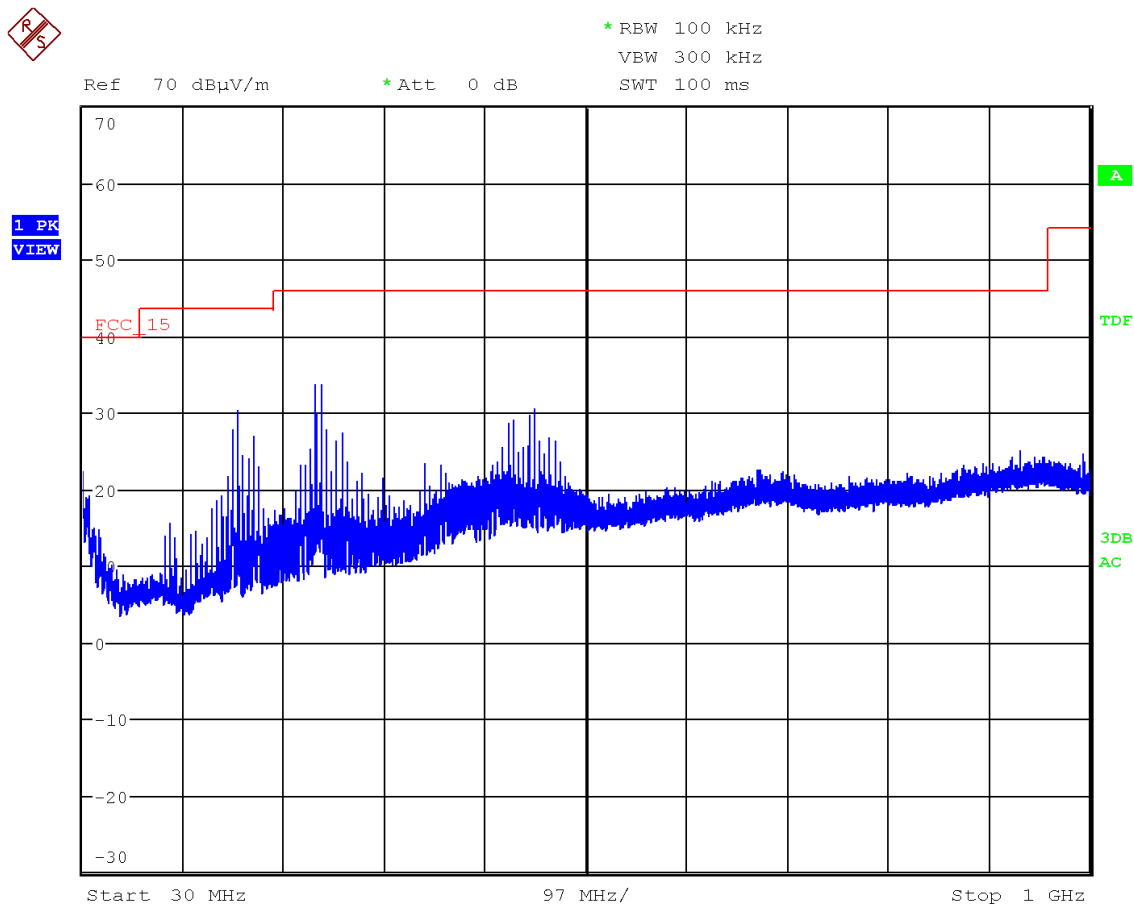
Verdict: PASS

FREQUENCY RANGE 9 kHz - 30 MHz:



Note: This plot is valid for all three channels. The highest peak shown is the 5 MHz carrier frequency.

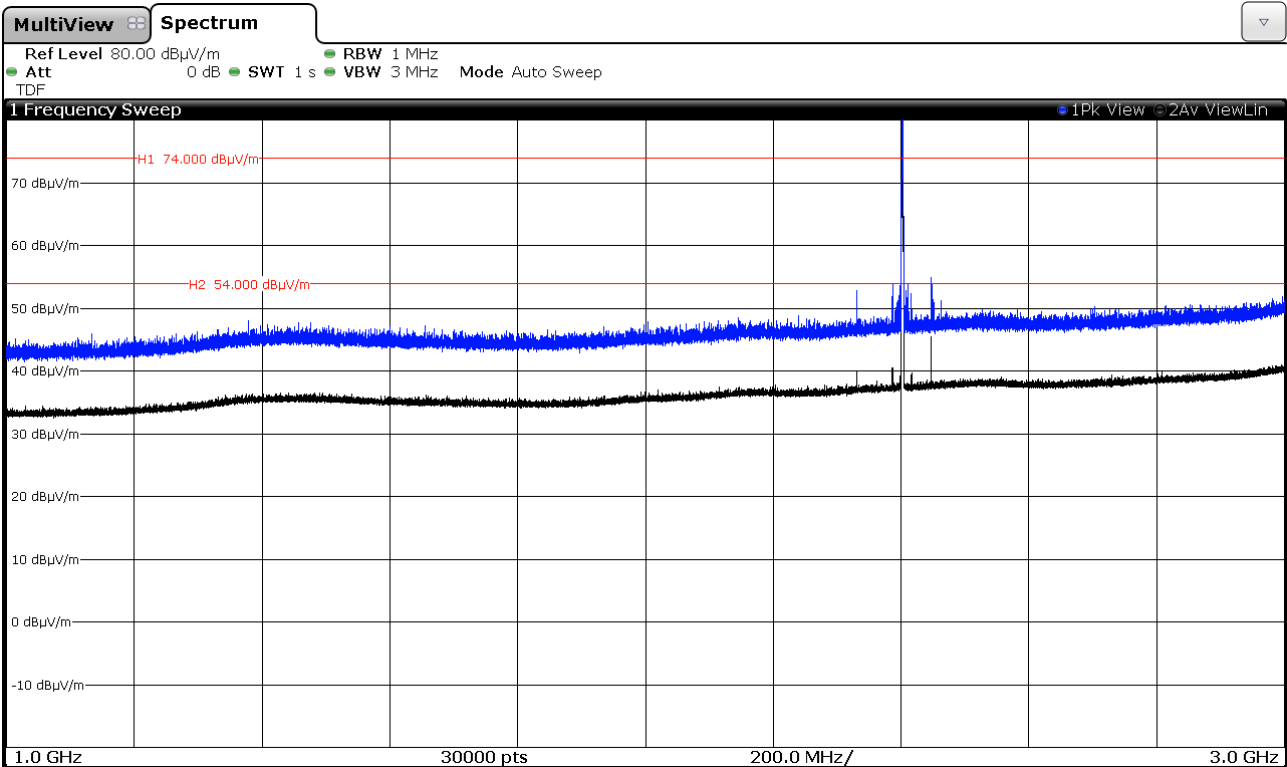
FREQUENCY RANGE 30 MHz - 1 GHz:



Note: This plot is valid for all three channels.

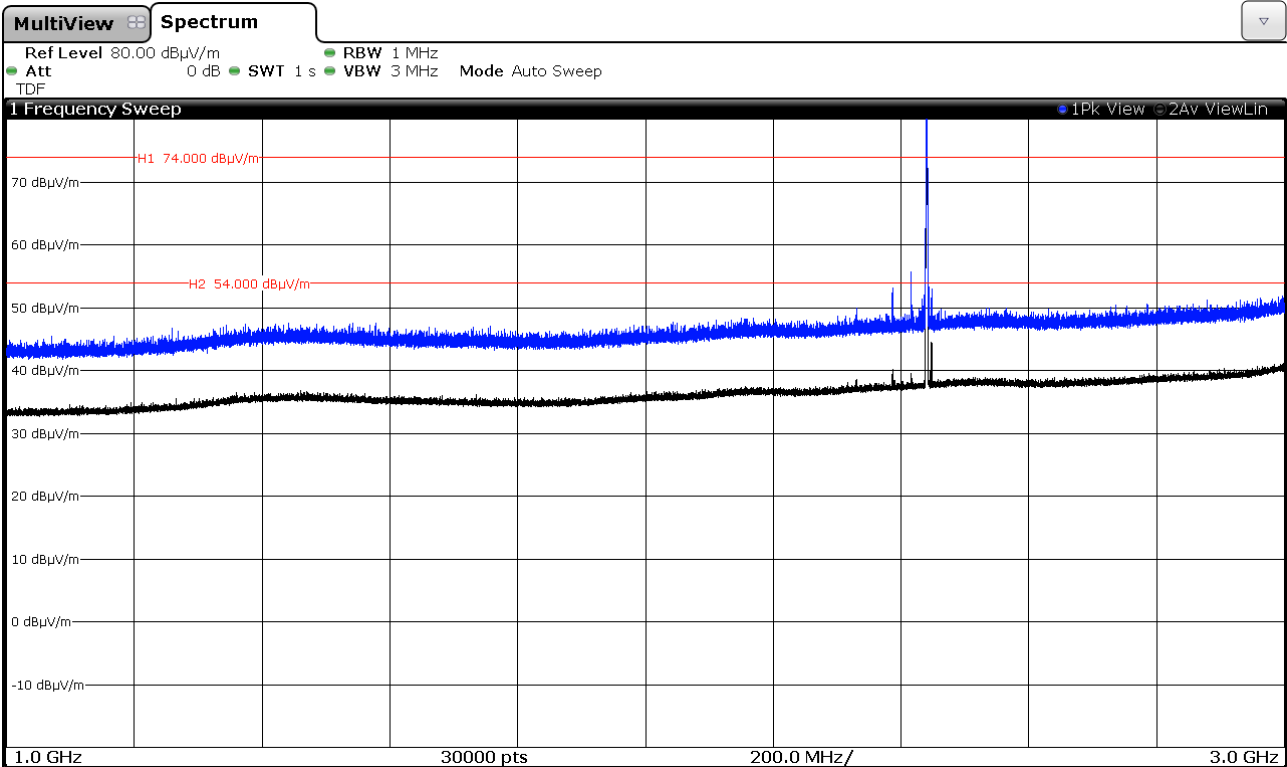
FREQUENCY RANGE 1 - 3 GHz:

- Low Channel:



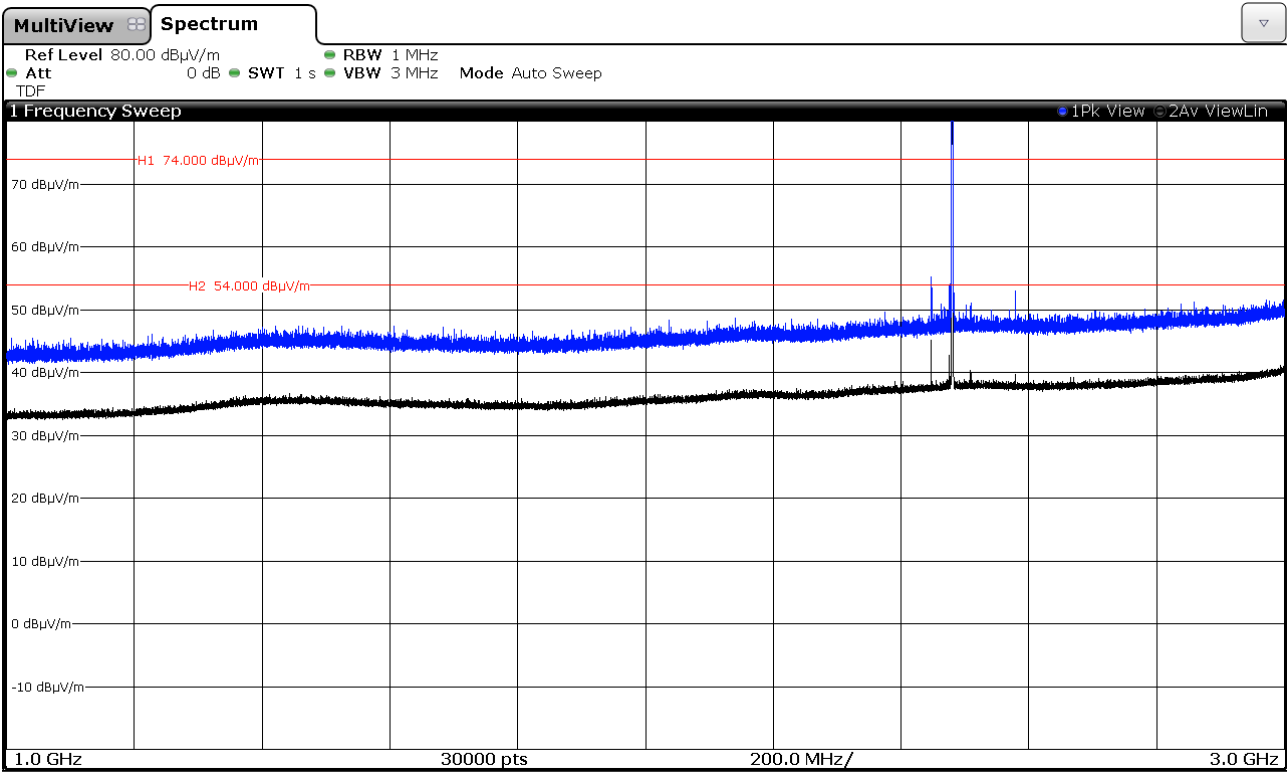
Note: The peak shown in the plot above the limit is the carrier frequency.

- Middle Channel:



Note: The peak shown in the plot above the limit is the carrier frequency.

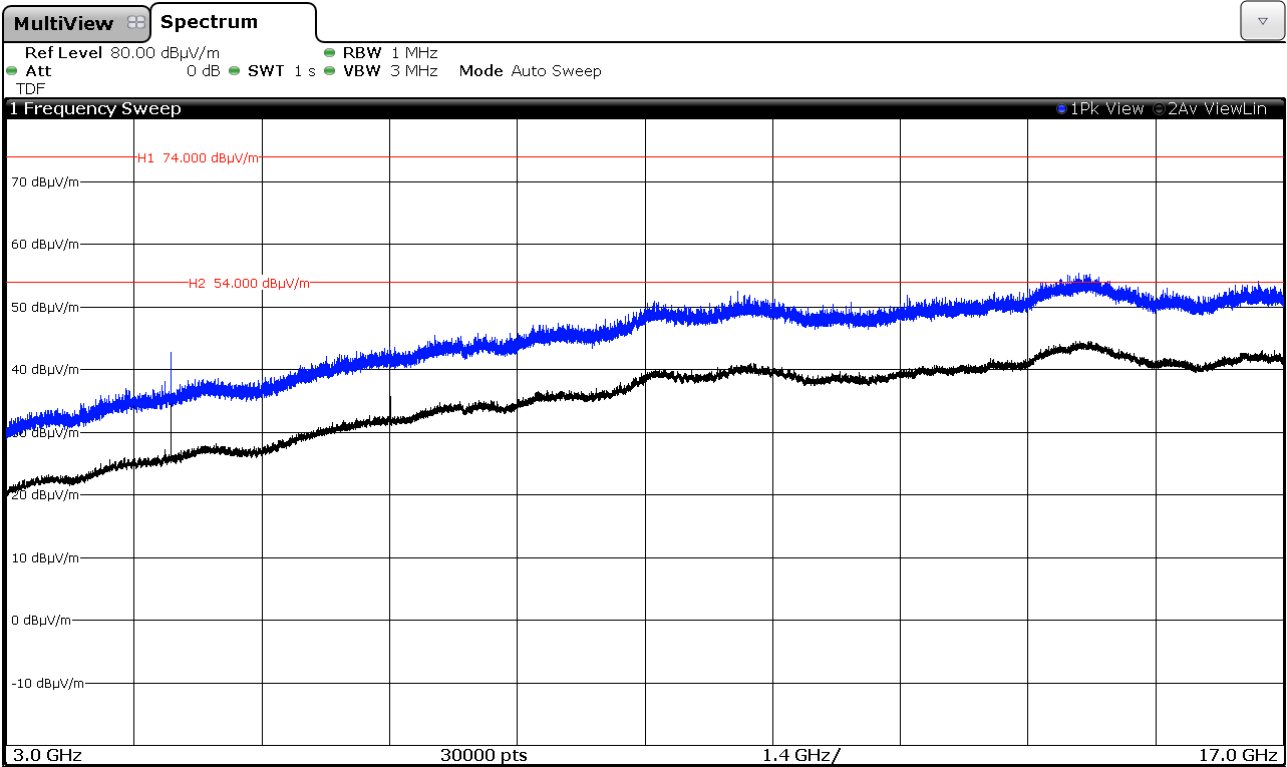
- High Channel:



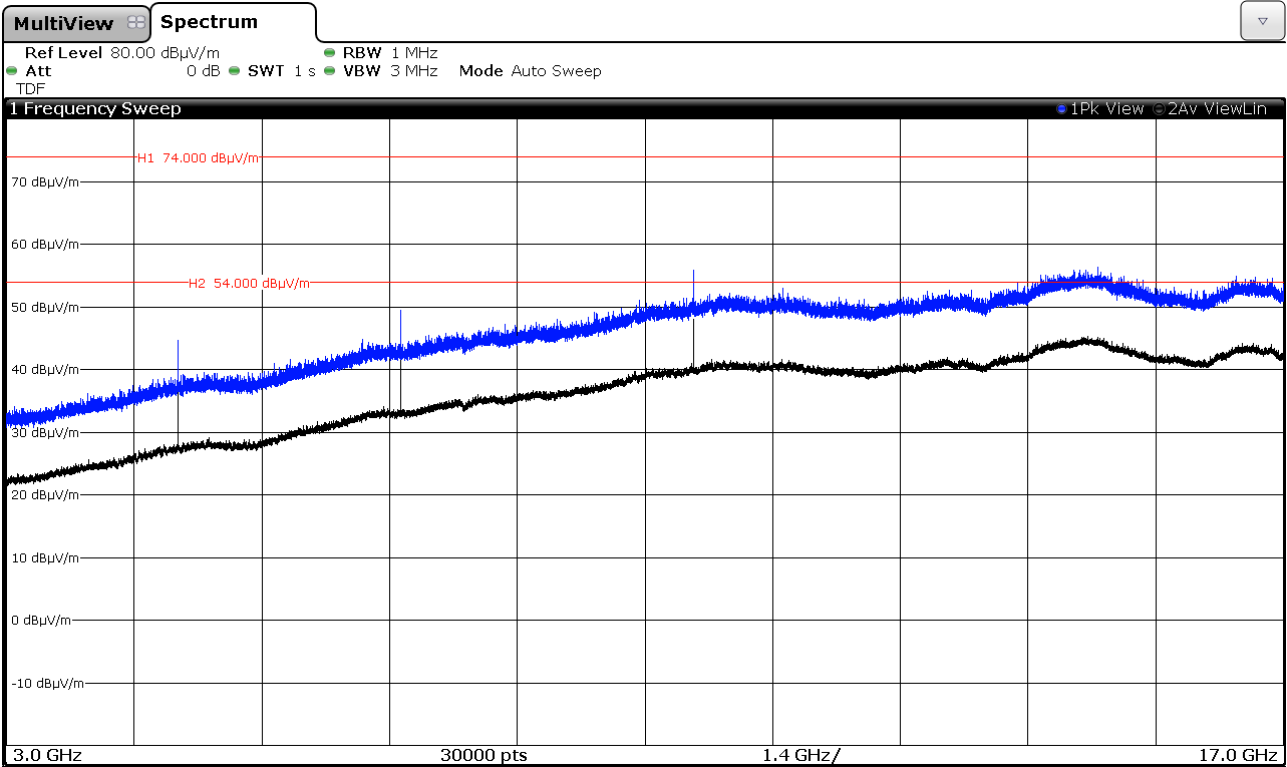
Note: The peak shown in the plot above the limit is the carrier frequency.

FREQUENCY RANGE 3 - 17 GHz:

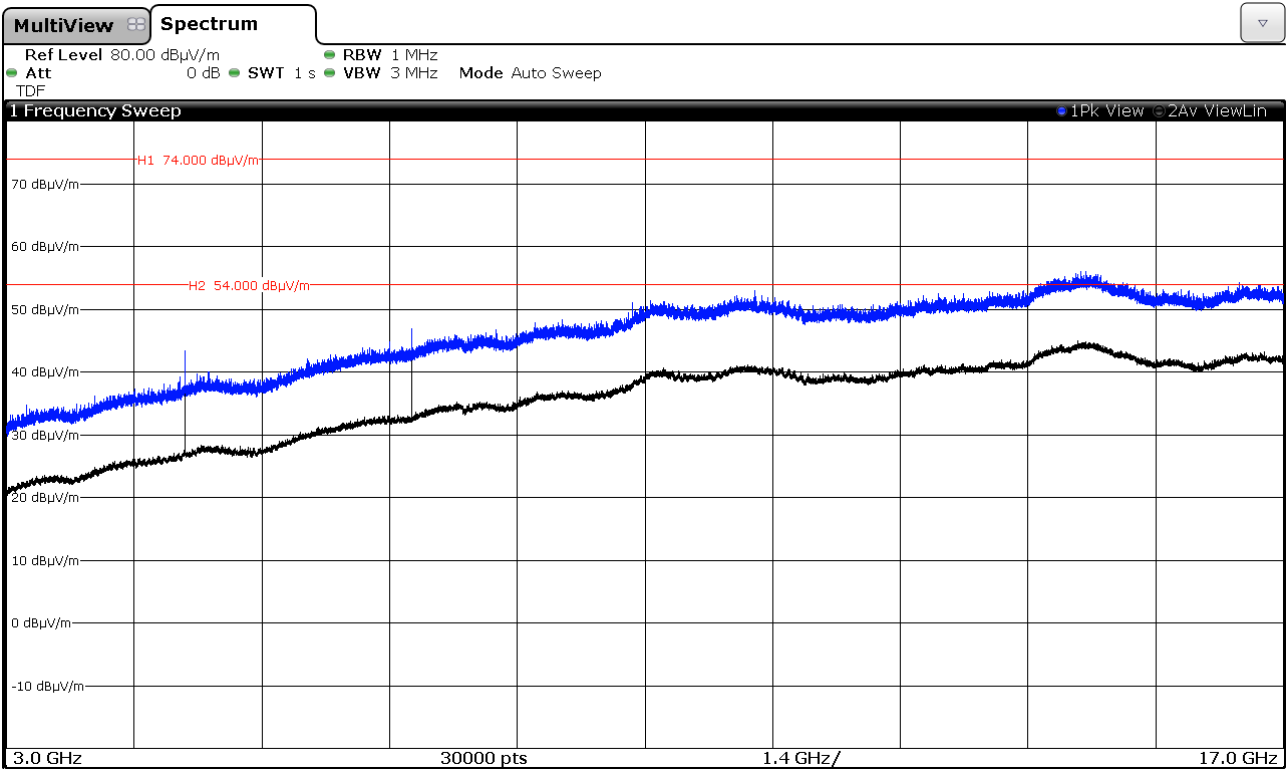
- Low Channel:



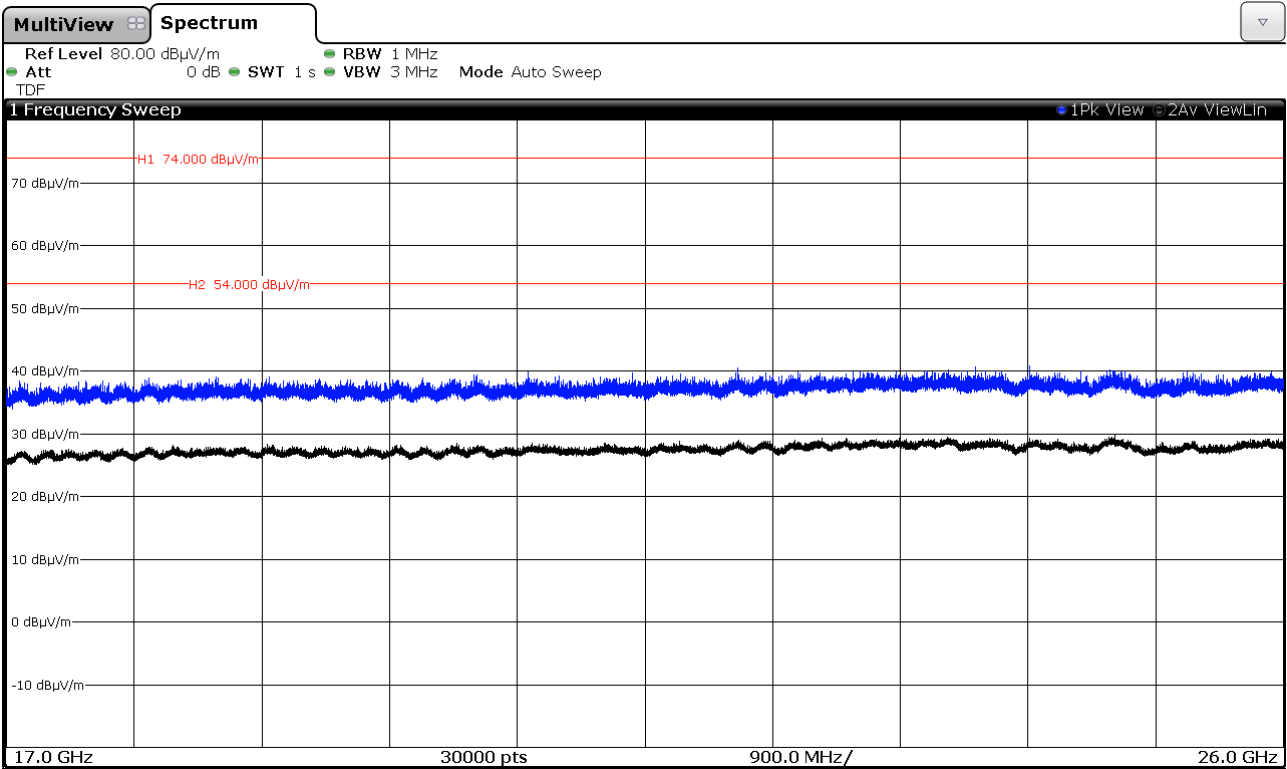
- Middle Channel:



- High Channel:



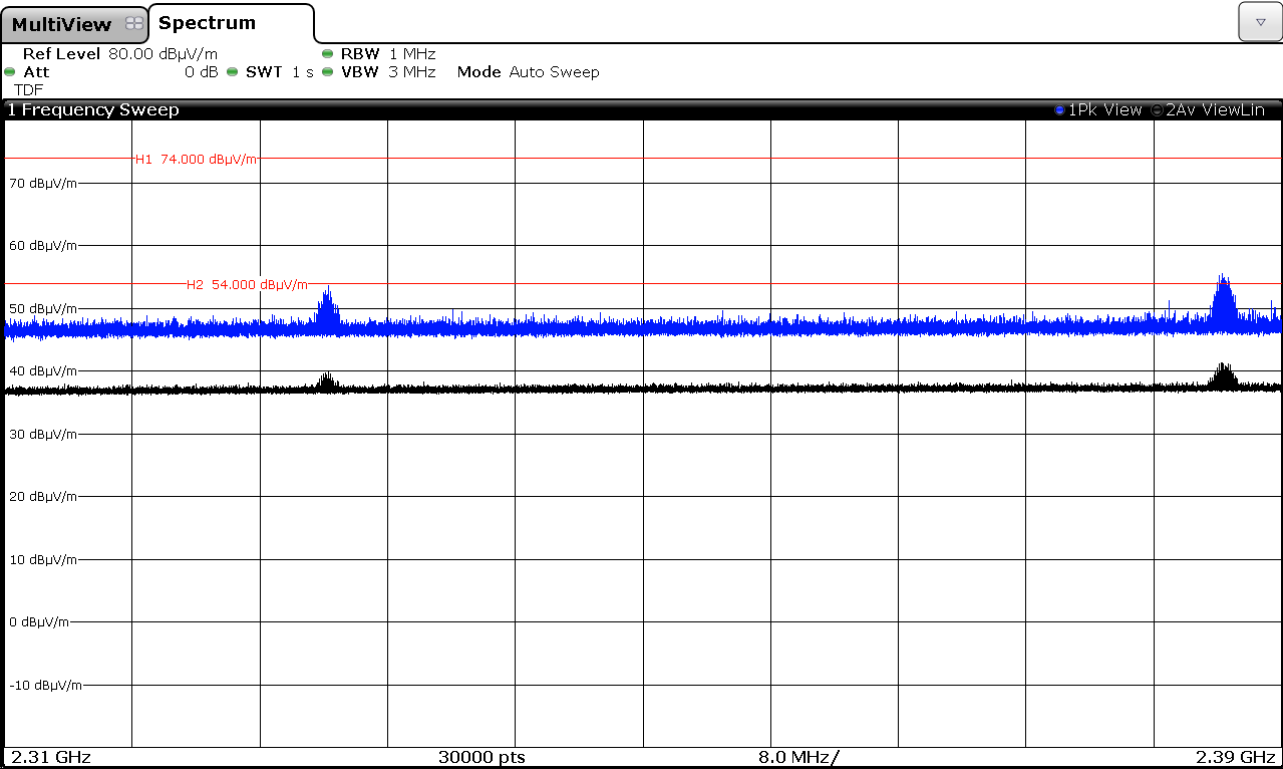
FREQUENCY RANGE 17 - 26 GHz:



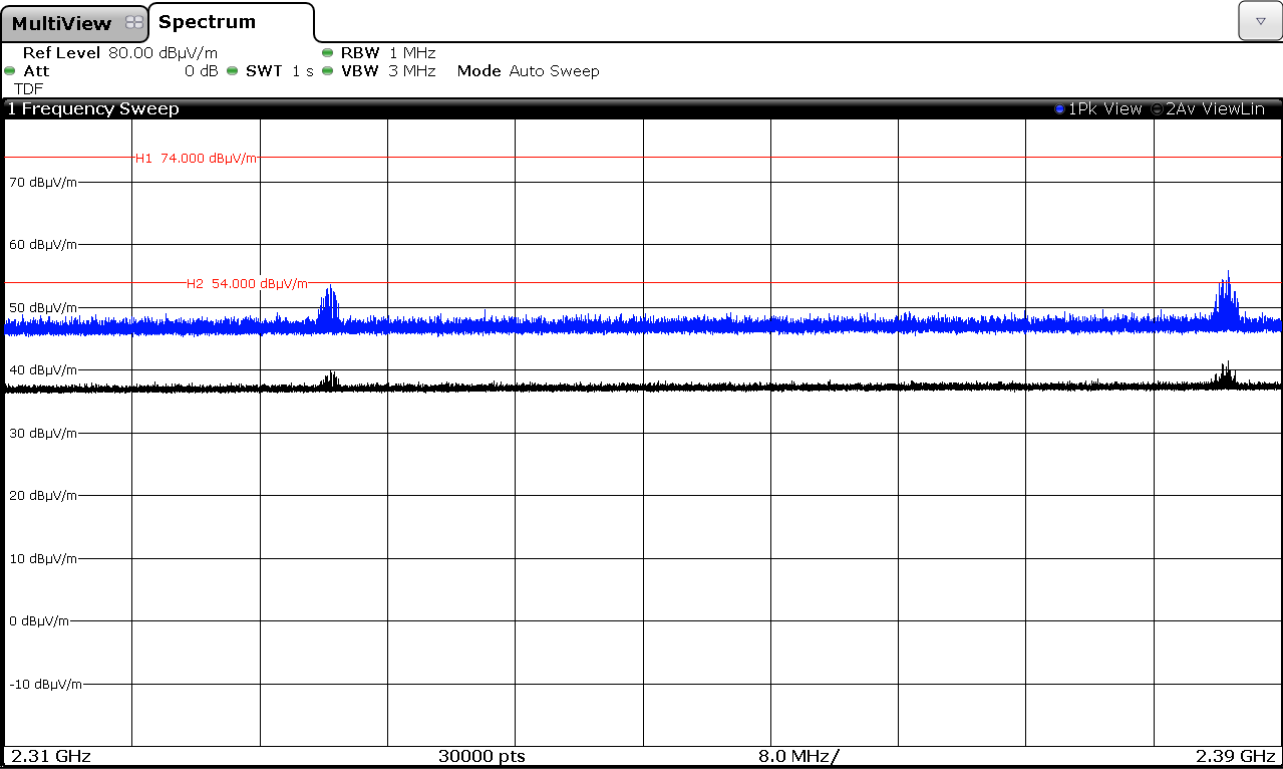
Note: This plot is valid for all three channels.

FREQUENCY RANGE 2.31-2.39 GHz (Restricted Band):

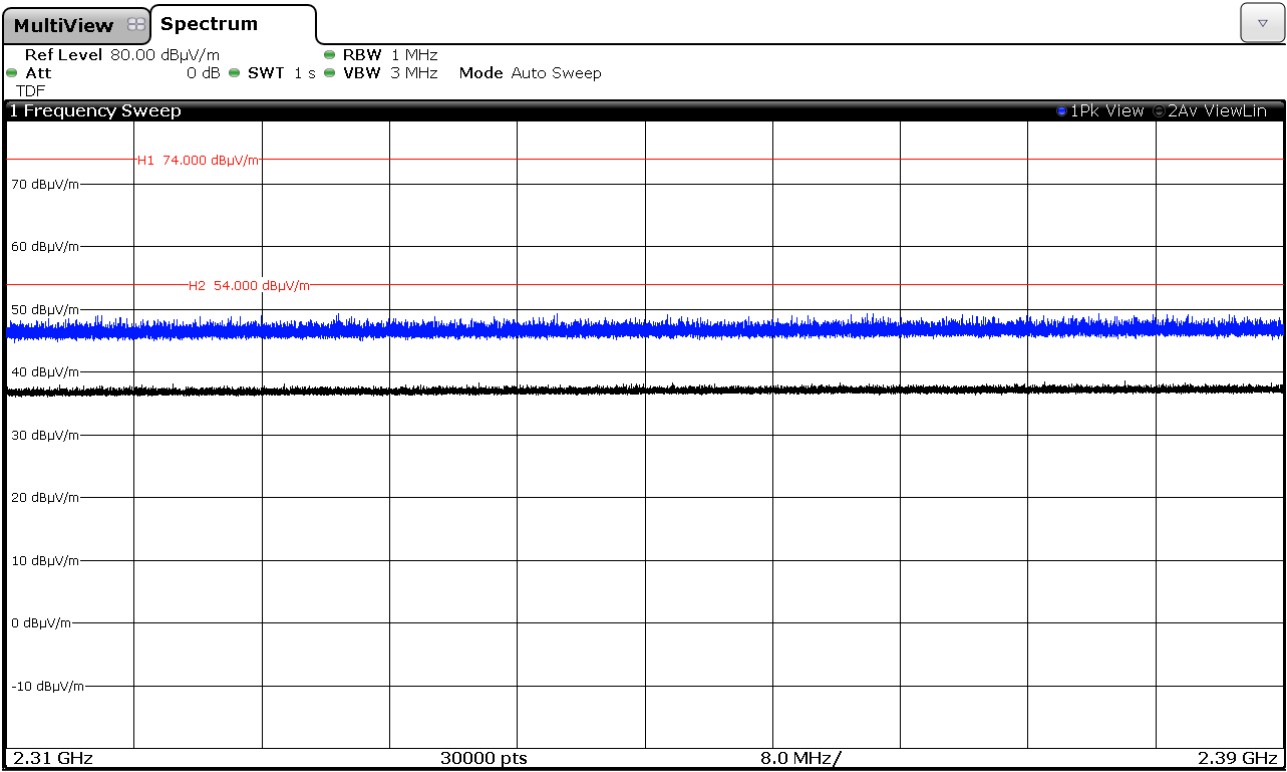
- Low Channel:



- Middle Channel:

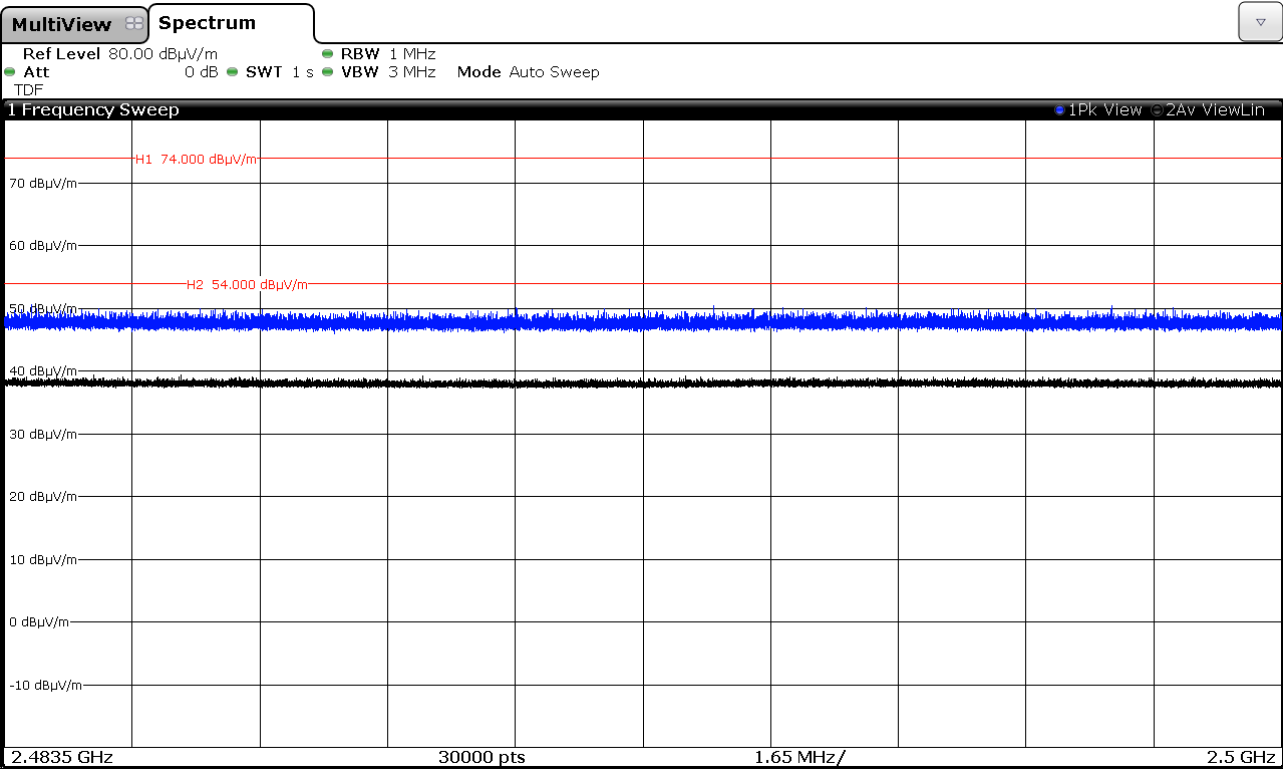


- High Channel:

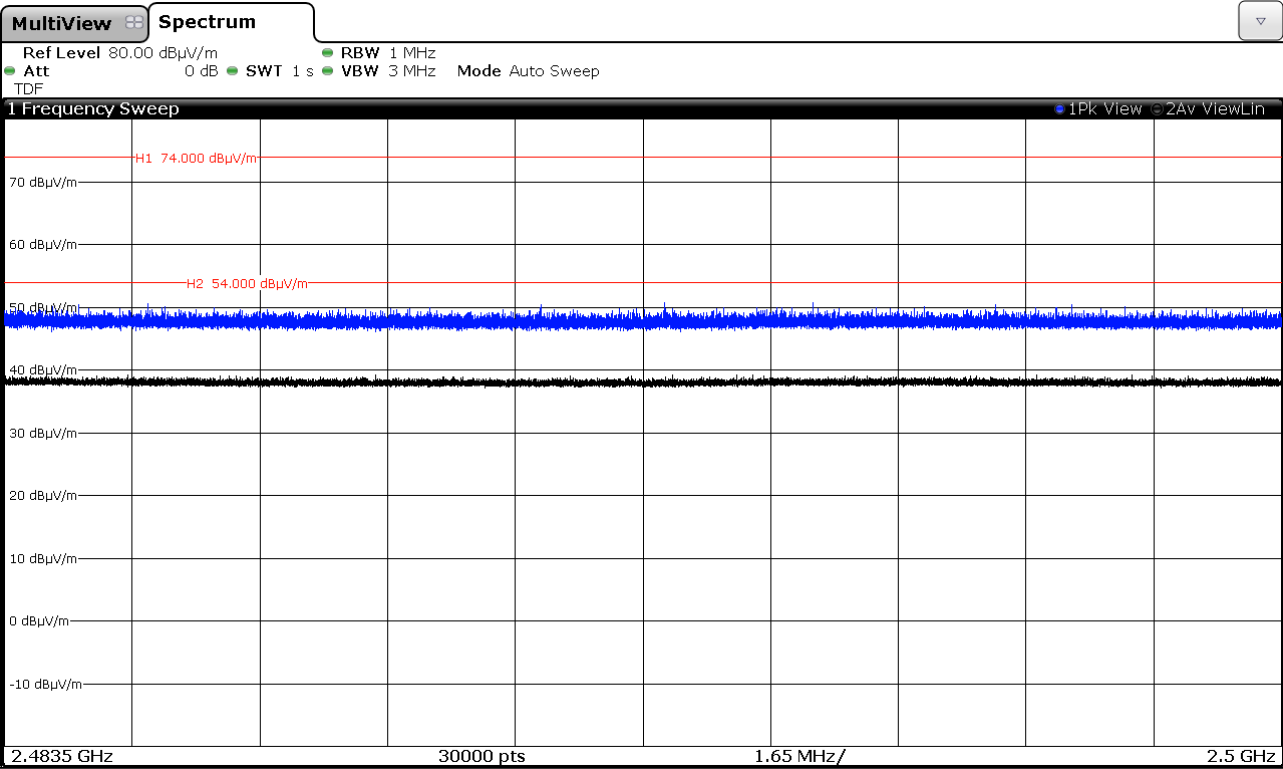


FREQUENCY RANGE 2.4835-2.5 GHz (Restricted Band):

- Low Channel:



- Middle Channel:



- High Channel:

