



ISED LISTED
REGISTRATION NUMBER
4621A-2

Test report No:
NIE: 57186RRF.004

Test report

USA FCC Part 15.249, 15.209

CANADA RSS-210, RSS-Gen

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

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 15.249 10-1-17 Edition: Operation within the bands 902 - 928 MHz, 2400 -2483.5 MHz, 5725 - 5875 MHz, and 24.0 – 24.25 GHz. USA FCC Part 15.209 10-1-17 Edition: Radiated emission limits; general requirements. CANADA RSS-210 Issue 9 (August 2016). CANADA RSS-Gen Issue 5 (April 2018). ANSI C63.10-2013: American National Standard for Testing Unlicensed Wireless Devices.
Approved by (name / position & signature)	A. Llamas RF Lab. Manager
Date of issue	2019-02-21
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

1. This report is only referred to the item that has undergone the test.
2. This report does not constitute or imply on its own an approval of the product by the Certification Bodies or competent Authorities.
3. This document is only valid if complete; no partial reproduction can be made without previous written permission of DEKRA Testing and Certification S.A.U.
4. This test report cannot be used partially or in full for publicity and/or promotional purposes without previous written permission of DEKRA Testing and Certification S.A.U. and the Accreditation Bodies.

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 Nº	Description	Model	Serial Nº	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 Nº	Description	Model	Serial Nº	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
	☒	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.004	2019-02-21	First release

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, Francisco José Alcaide, 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. RF Pre-amplifier, G>48dB, 18-40GHz NARDA JS44-18004000-33-8P	2018/02	2020/02
9. Broadband Horn antenna 1-18 GHz SCHWARZBECK MESS-ELEKTRONIK BBHA 9120 D	2016/11	2019/11
10. Broadband Horn antenna 18 - 40 GHz SCHWARZBECK MESS-ELEKTRONIK BBHA 9170	2018/07	2021/07

Testing verdicts

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

Summary

1. Proprietary protocol 2.4 GHz

FCC PART 15 PARAGRAPH / RSS-210			
Requirement – Test case		Verdict	Remark
Occupied bandwidth		P	
Section 15.249 Subclause (a) / RSS-210 B.10. (a)	Field strength of fundamental	P	
Section 15.249 Subclause (d) / RSS-210 B.10.(b)	Emission limitations radiated	P	
<u>Supplementary information and remarks:</u> None.			

Appendix A: Test results. Proprietary protocol 2.4 GHz

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TEST CONDITIONS

POWER SUPPLY (V):

Vnominal: 1.45 Vdc

Type of power supply: DC voltage from battery.

Type of antenna: Integral antenna.

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.

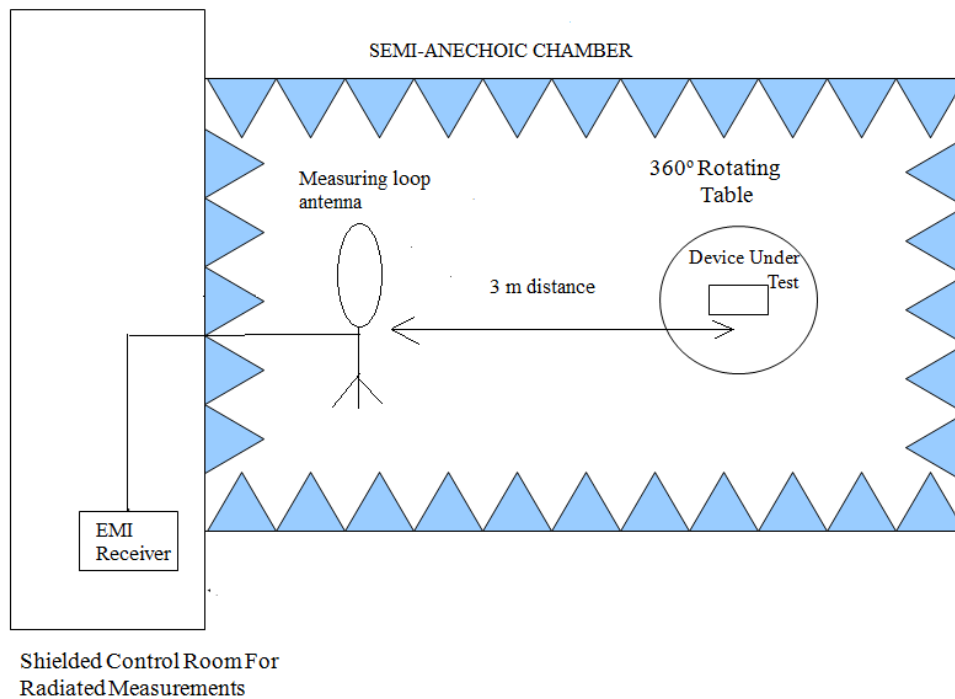
The equipment under test was set up on a non-conductive platform above the ground plane and the situation and orientation was varied to find the maximum radiated emission. It was also rotated 360° and the antenna height (Bilog antenna and Double ridge horn antenna) was varied from 1 to 4 meters to find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

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

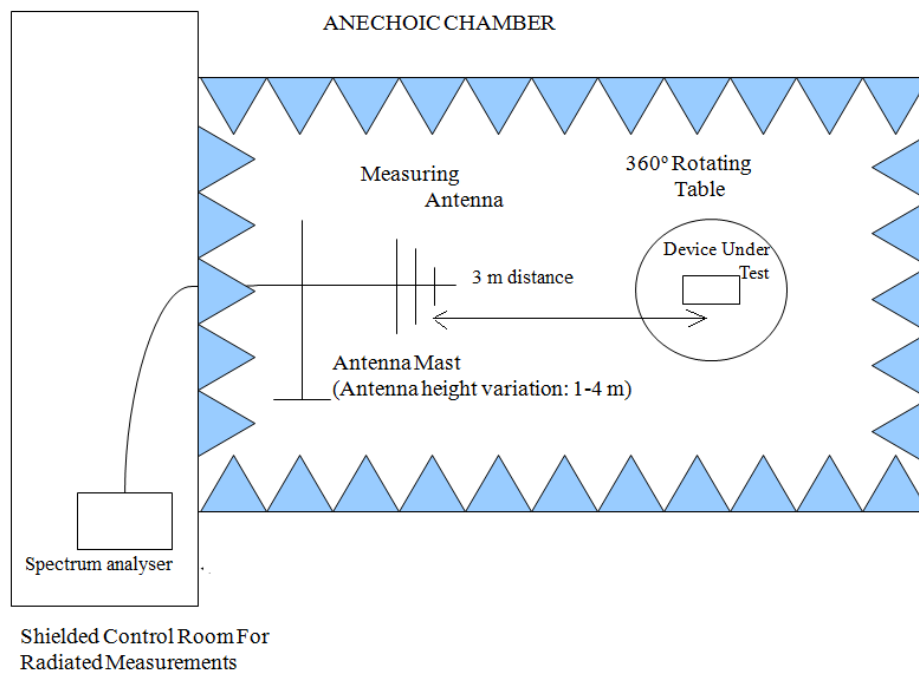
In the range between 9 kHz and 30 MHz the measurements were made in the three different orientation planes of the loop antenna to determine the maximum received field.

The test was performed with the equipment transmitting first with only the Proprietary protocol 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.

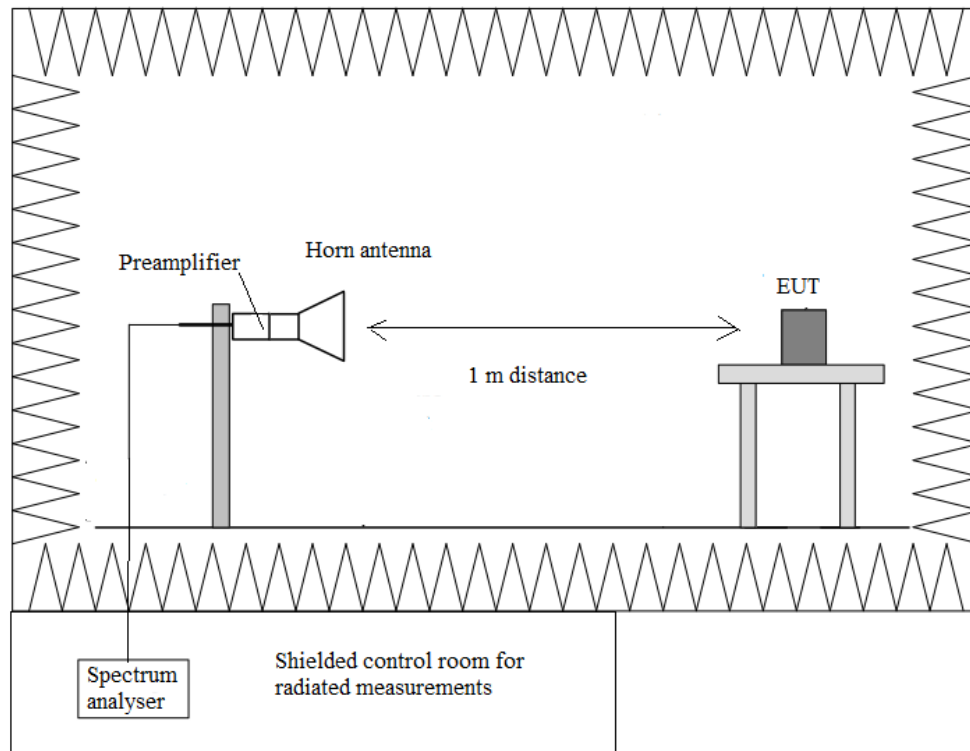
Radiated measurements setup from 9 kHz to 30 MHz:



Radiated measurements setup $f < 1$ GHz:



Radiated measurements setup $f > 1$ GHz:

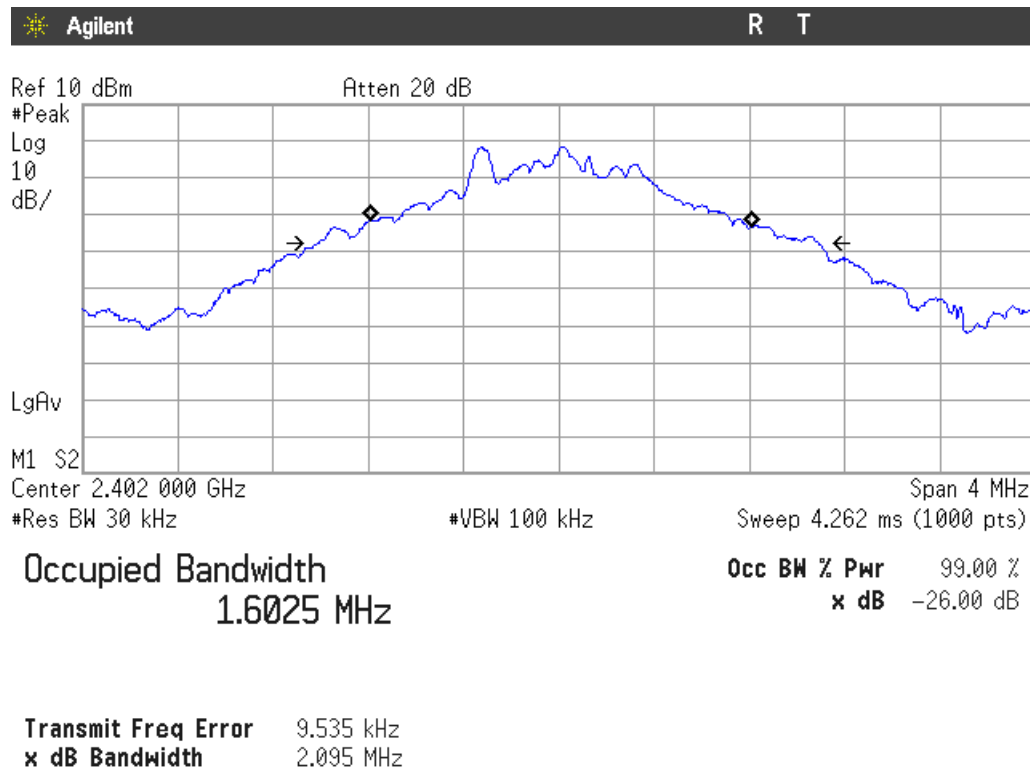


Occupied Bandwidth

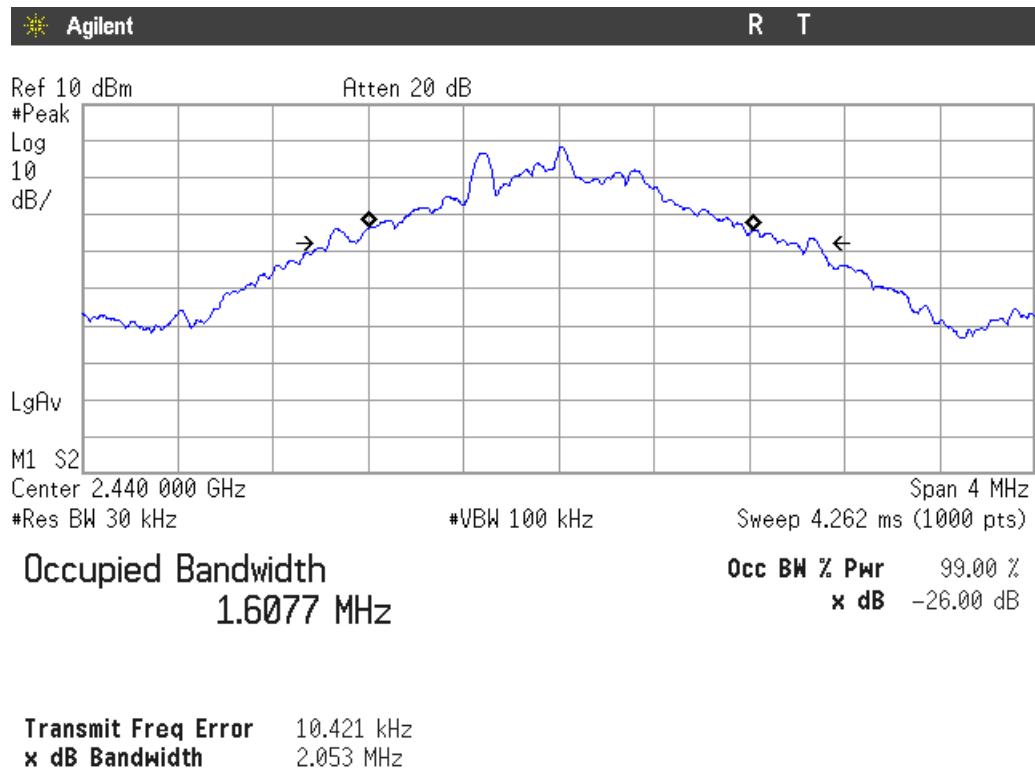
RESULTS:

	Low Channel 2402 MHz	Middle Channel 2440 MHz	High Channel 2480 MHz
99% Bandwidth (MHz)	1.6025	1.6077	1.5942
-26 dBc Bandwidth (MHz)	2.0950	2.0530	2.0420
Measurement Uncertainty (kHz)	<±5.00		

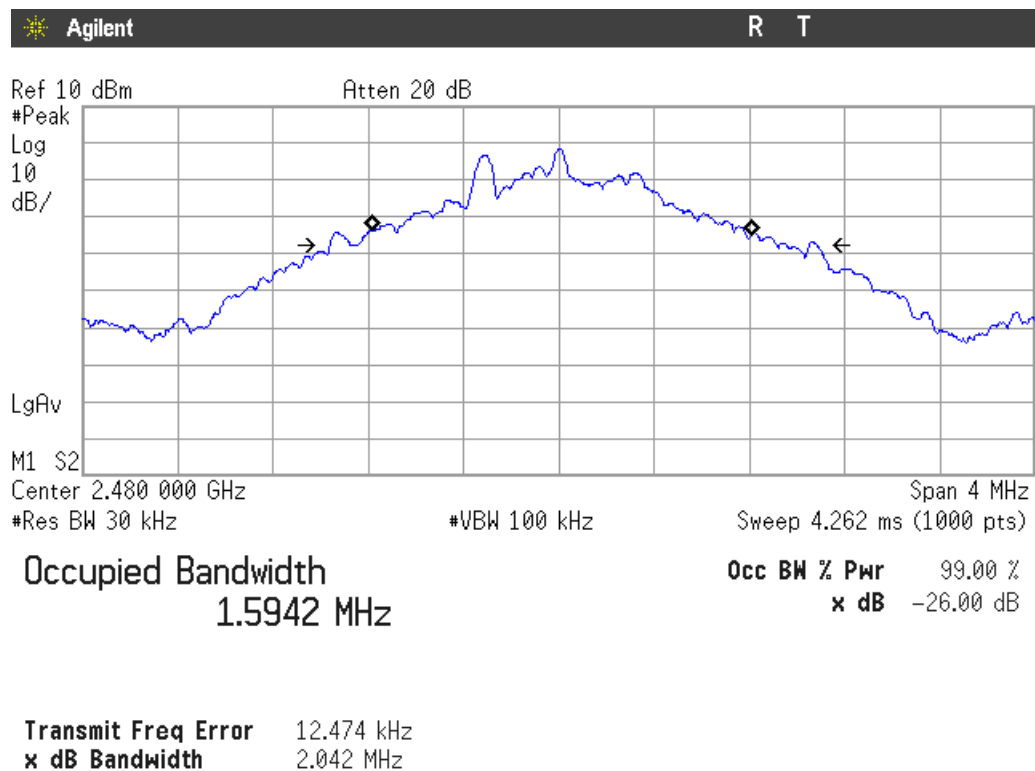
- Low Channel:



- Middle Channel:



- High Channel:



Section 15.249 Subclause (a) / RSS-210 B.10 (a). Field strength of Fundamental

SPECIFICATION:

The field strength of emissions from intentional radiators shall comply with the following

Fundamental frequency (MHz)	Field strength of fundamental (mV/m)	Field strength (dB μ V/m)	Measurement distance (m)
902 - 928	50	93.98	3
2400 – 2483.5	50	93.98	3
5725 - 5875	50	93.98	3
24000-24250	250	107.96	3

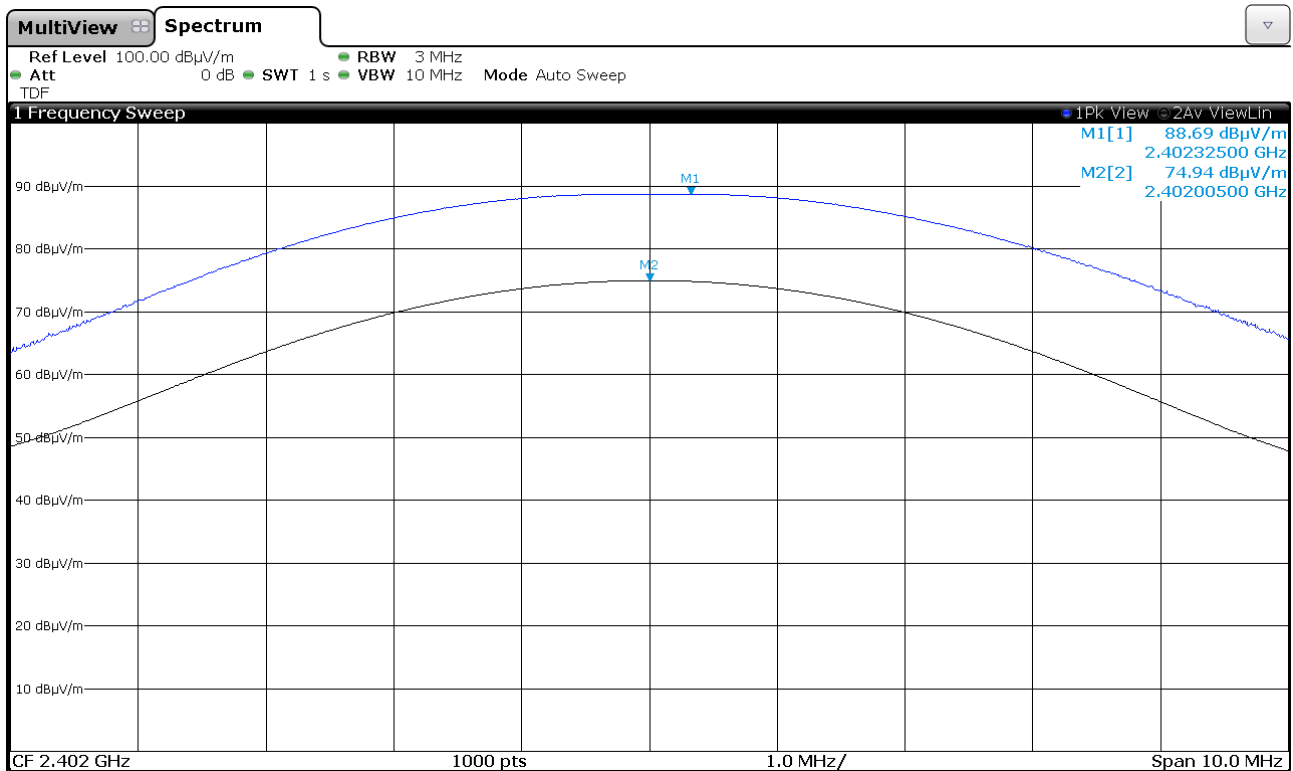
For frequencies above 1000 MHz, the above field strength limits are based on average limits. However, the peak field strength of any emission shall not exceed the maximum permitted average limits specified above by more than 20 dB under any condition of modulation.

RESULTS:

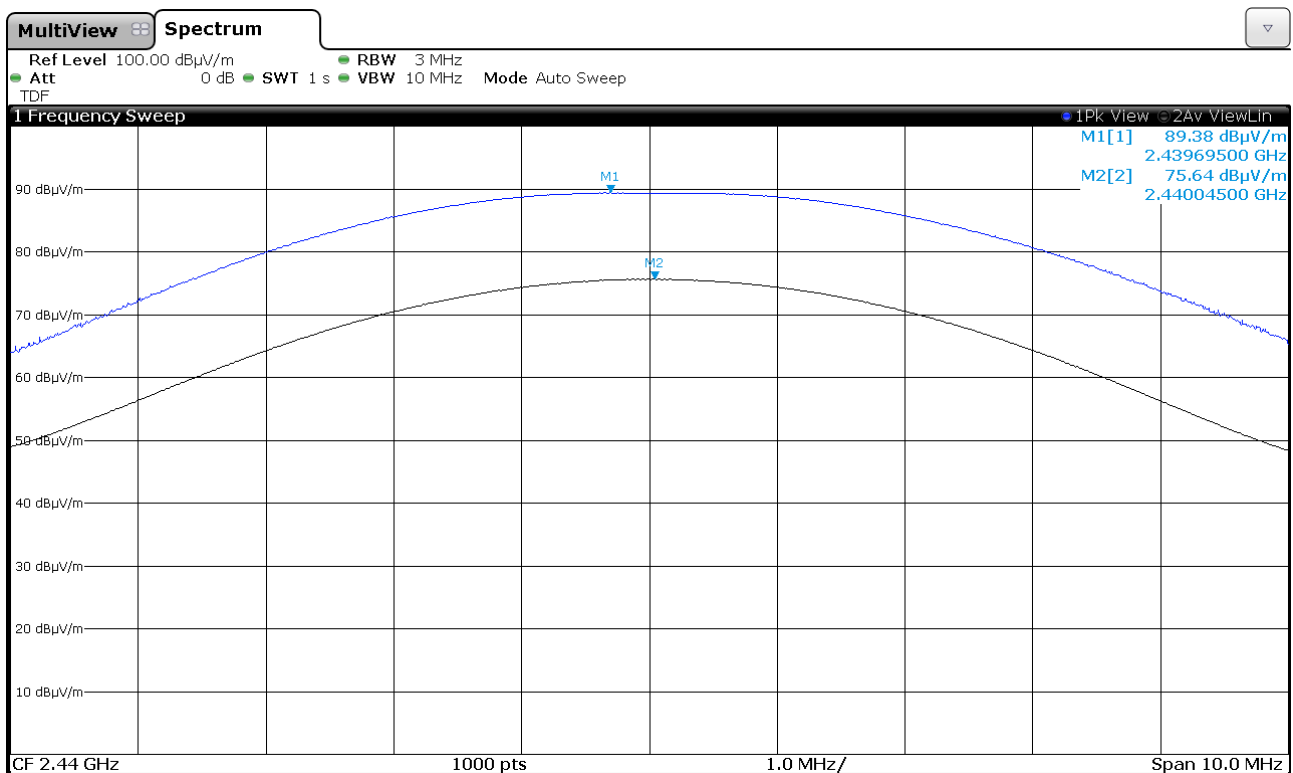
	Low Channel 2402 MHz	Middle Channel 2440 MHz	High Channel 2480 MHz
Average Field Strength (dB μ V/m)	74.94	75.64	72.39
Peak Field Strength (dB μ V/m)	88.69	89.38	86.13
Measurement Uncertainty (dB)	< $\pm$ 3.70		

Verdict: PASS

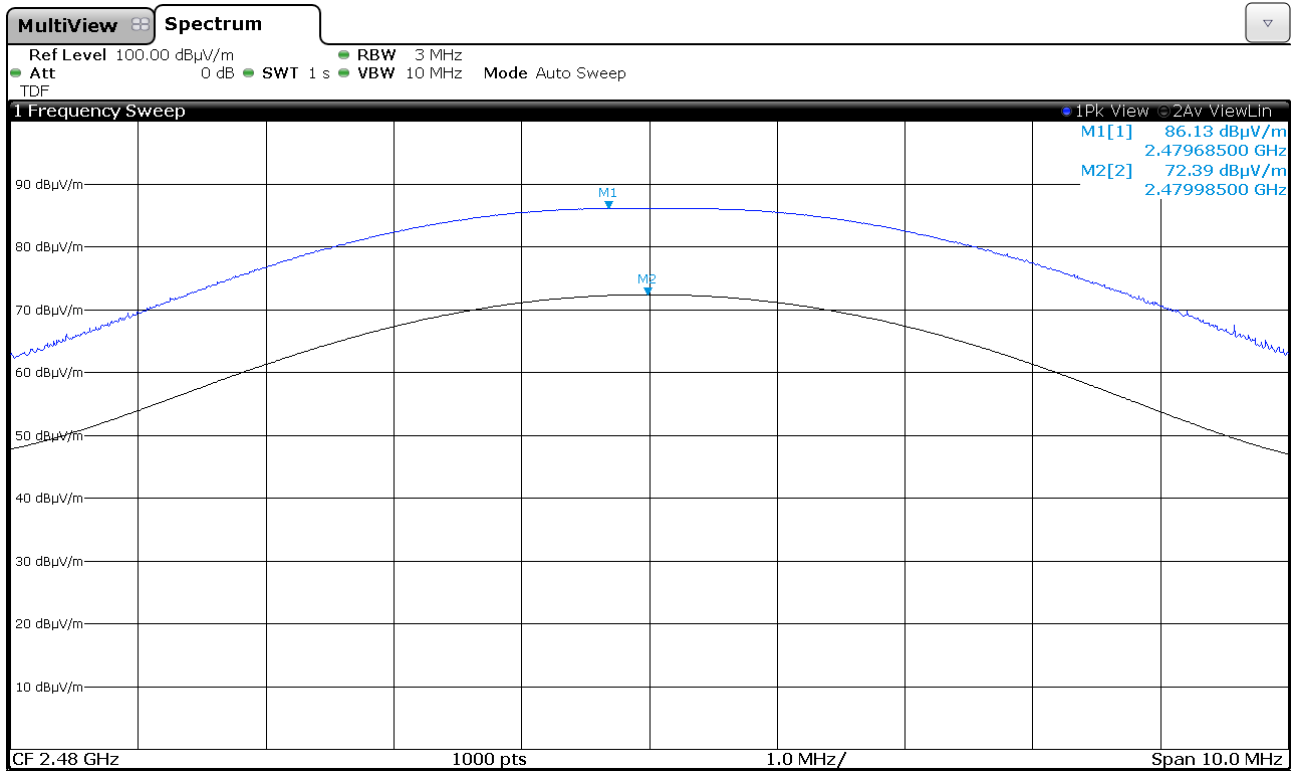
- Low Channel:



- Middle Channel:



- High Channel:



Section 15.249 Subclause (a) and (d) / RSS-210 B.10 (b). Emission limitations radiated (Transmitter)

SPECIFICATION:

The field strength of harmonics from intentional radiators shall comply with the following

Fundamental frequency (MHz)	Field strength of harmonics ($\mu\text{V/m}$)	Field strength of harmonics ($\text{dB}\mu\text{V/m}$)	Measurement distance (m)
902 - 928	500	54	3
2400 – 2483.5	500	54	3
5725 - 5875	500	54	3
24000-24250	2500	67.96	3

Emissions radiated outside of the specific frequency bands, except for harmonics, shall be attenuated by at least 50 dB below the level of fundamental or to the general radiated emission limits specified in section 15.209:

Frequency Range (MHz)	Field strength ($\mu\text{V/m}$)	Field strength ($\text{dB}\mu\text{V/m}$)	Measurement distance (m)
0.009-0.490	$2400/F(\text{kHz})$	-	300
0.490-1.705	$24000/F(\text{kHz})$	-	30
1.705 - 30.0	30	-	30
30 - 88	100	40	3
88 - 216	150	43.5	3
216 - 960	200	46	3
960 - 25000	500	54	3

Whichever is the lesser attenuation.

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 30 MHz-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)
179.99433	Quasi peak	29.6	H	<± 3.88
260.01933	Quasi peak	32.7	H	<± 3.88
460.03330	Quasi peak	29.1	H	<± 3.88
465.01266	Quasi peak	29.4	H	<± 3.88

Frequency range 1 - 25 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 (see next plots).

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 (2402 MHz). Spurious signals closest to the limit:

Spurious frequency (GHz)	Detector	Emission Level (dBμV/m)	Polarization	Measurement Uncertainty (dB)
1.04377	Peak	53.50	V	<±3.70
2.33063	Peak	53.49	H	<±3.70
2.38649	Peak	55.26	H	<±3.70
	Average	41.71		<±3.70
4.80390	Peak	44.80	H	<±3.70

- Middle Channel (2440 MHz). Spurious signals closest to the limit:

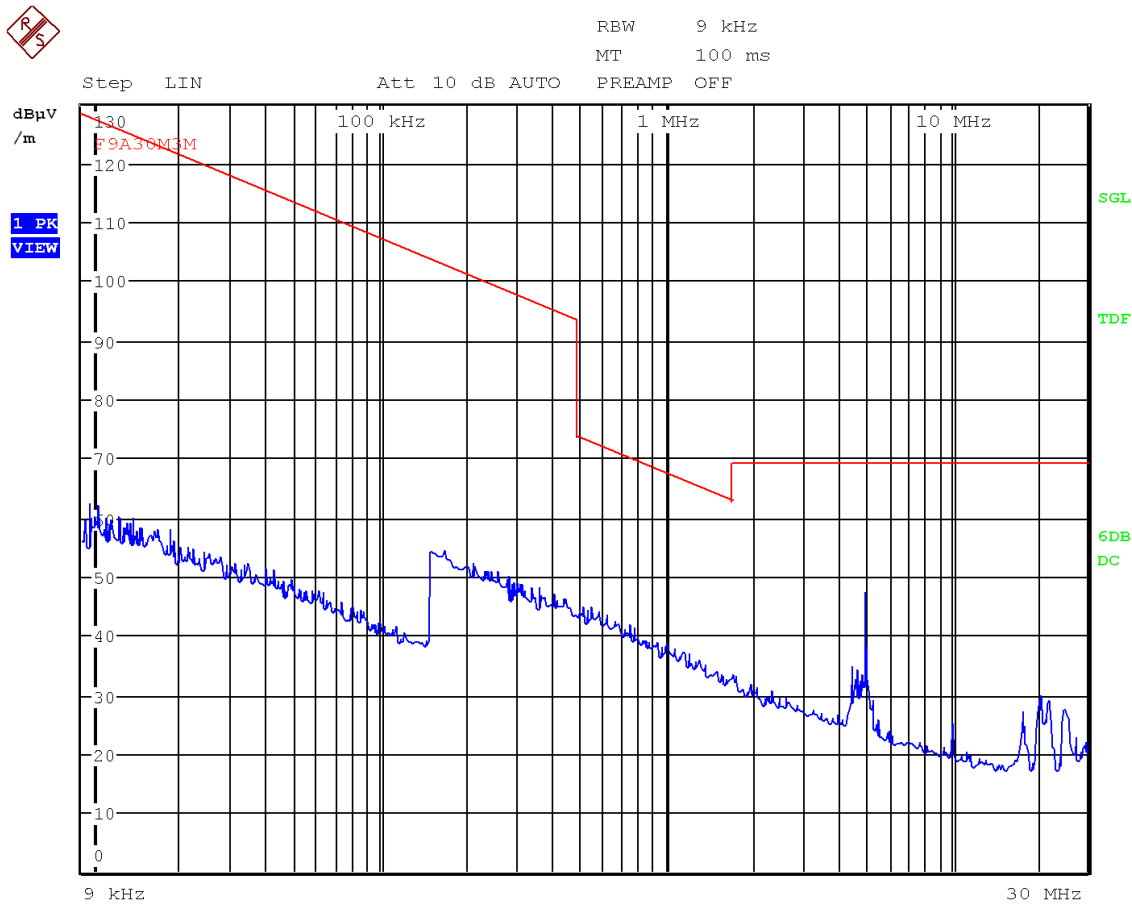
Spurious frequency (GHz)	Detector	Emission Level (dBμV/m)	Polarization	Measurement Uncertainty (dB)
2.33016	Peak	52.57	H	<±3.70
2.38646	Peak	56.62	H	<±3.70
	Average	42.11		<±3.70
2.41617	Peak	55.49	H	<±3.70
	Average	40.93		<±3.70
4.88043	Peak	46.78	H	<±3.70
7.32110	Peak	50.39	V	<±3.70
10.53130	Peak	55.49	V	<±3.70
	Average	48.84		<±3.70

- High Channel (2480 MHz). Spurious signals closest to the limit:

Spurious frequency (GHz)	Detector	Emission Level (dBμV/m)	Polarization	Measurement Uncertainty (dB)
2.44710	Peak	56.30	H	<±3.70
	Average	45.48		<±3.70
2.49965	Peak	53.78	H	<±3.70
2.50850	Peak	54.35	H	<±3.70
	Average	42.42		<±3.70
2.57837	Peak	54.77	H	<±3.70
	Average	40.51		<±3.70
4.95930	Peak	42.62	H	<±3.70
7.44010	Peak	44.49	V	<±3.70

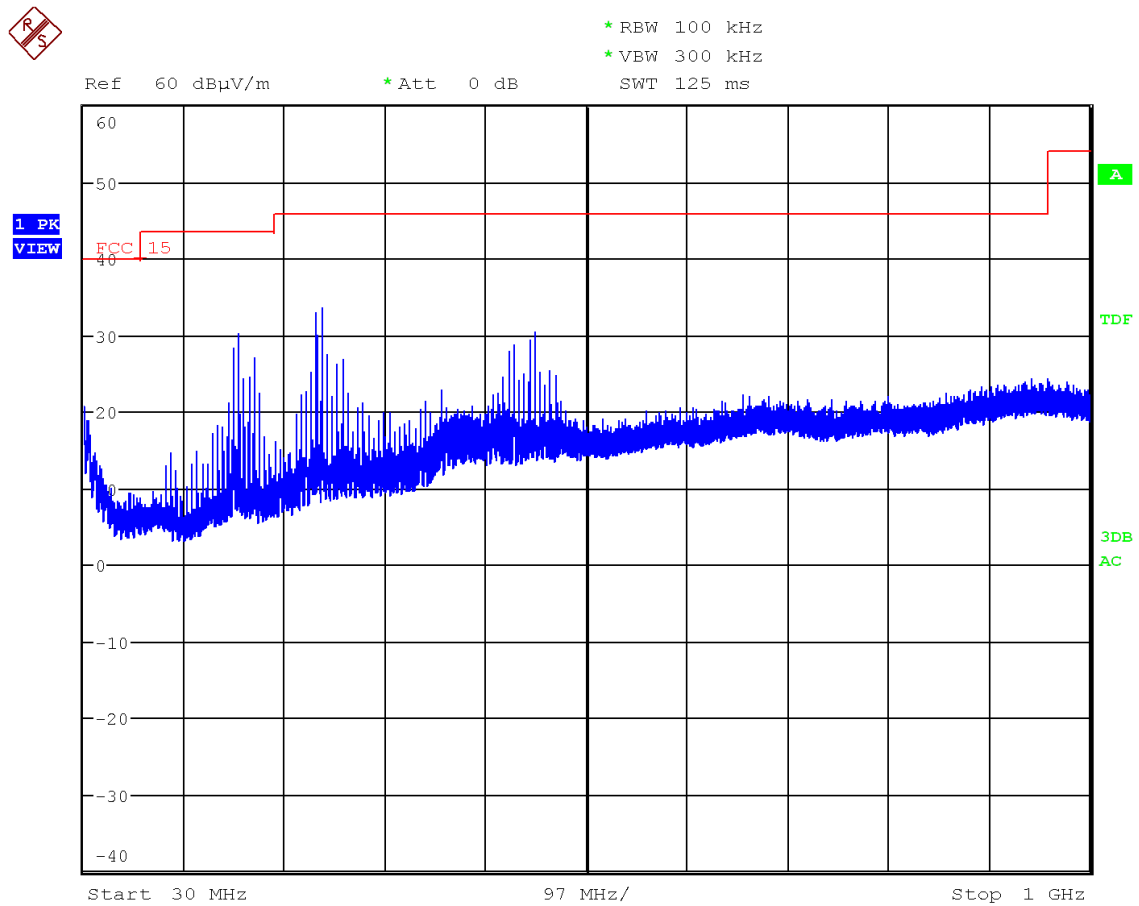
Verdict: PASS

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.

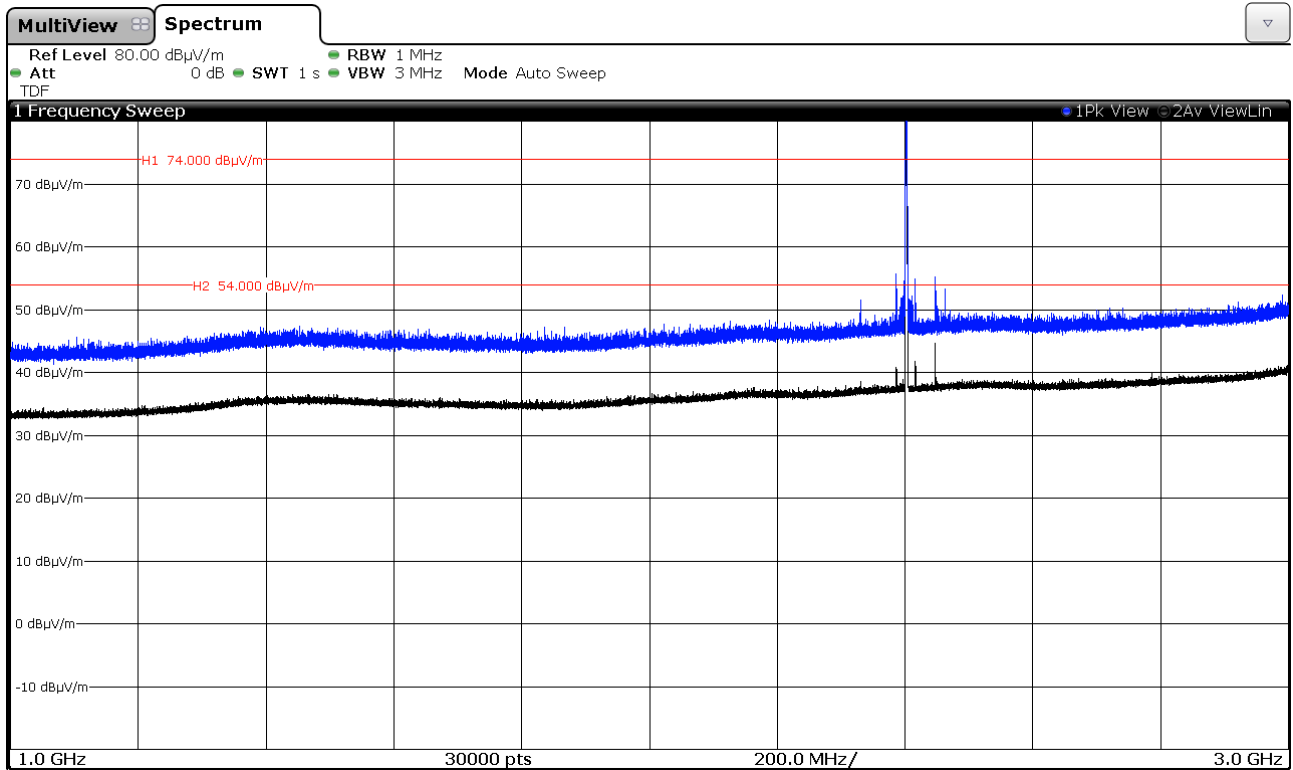
FREQUENCY RANGE 30 MHz - 1 GHz:



Note: This plot is valid for all three channels.

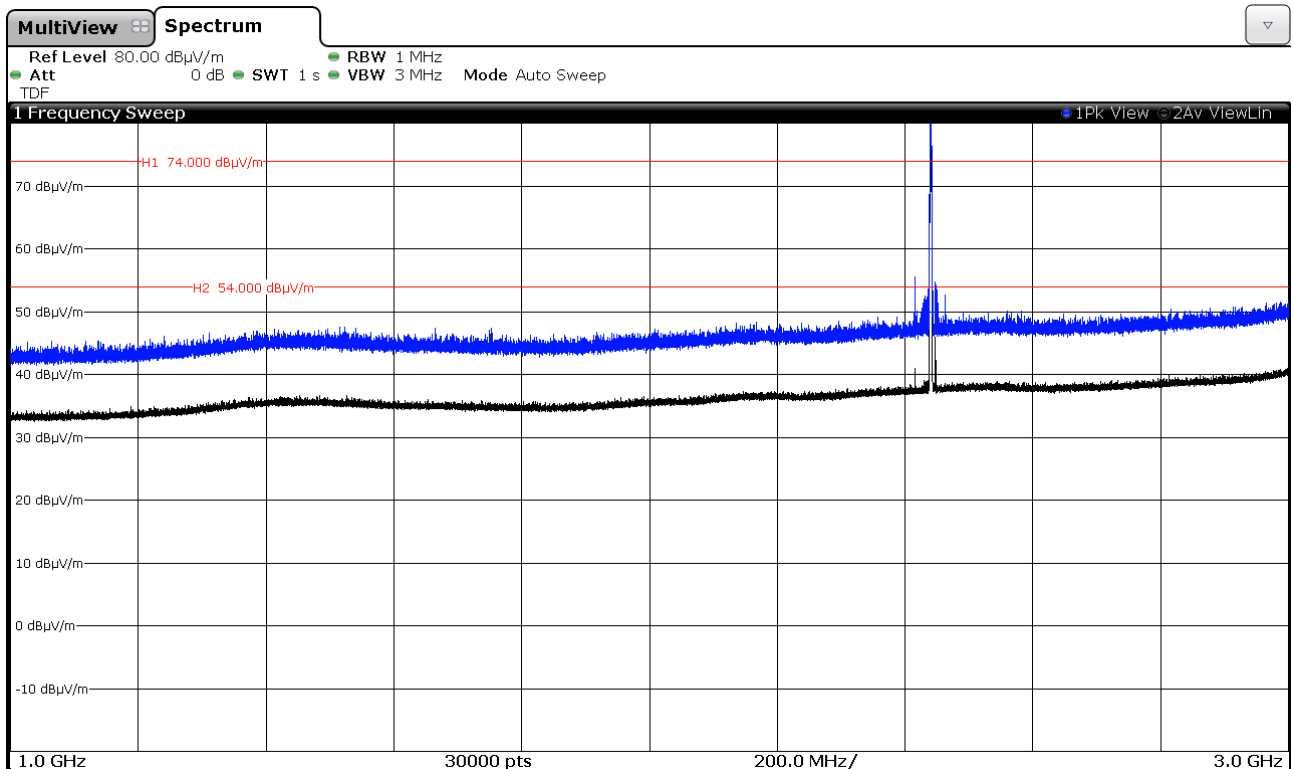
FREQUENCY RANGE 1 - 3 GHz

- Low Channel:



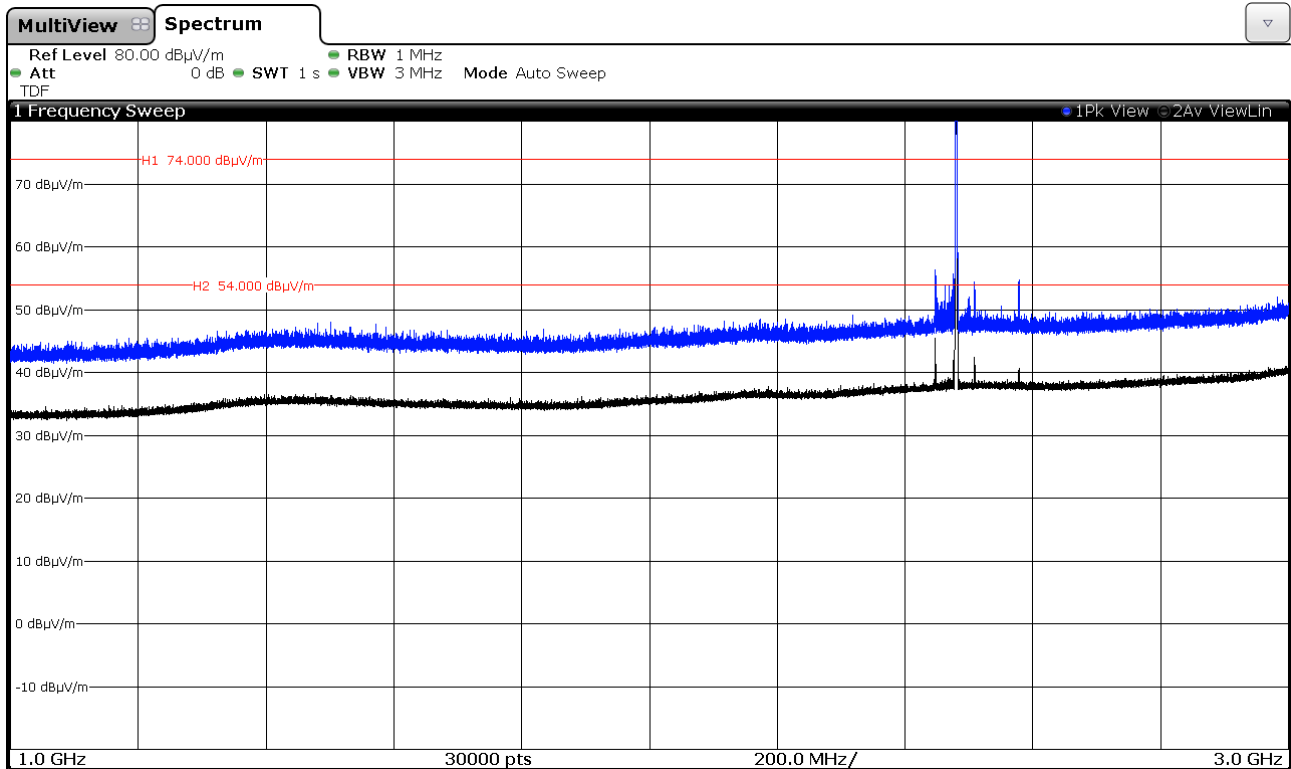
Note: The peak shown in the plot above the limit is the carrier frequency.

- Middle Channel:



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

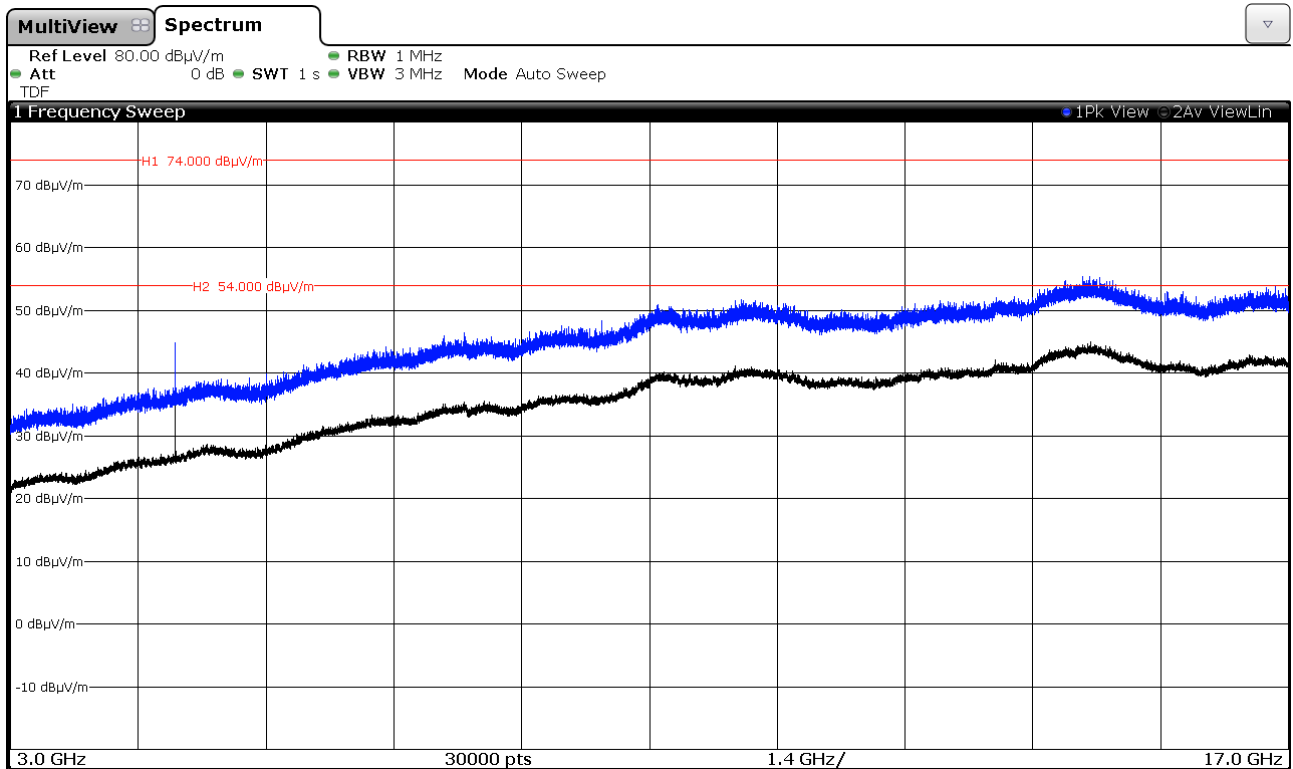
- High Channel:



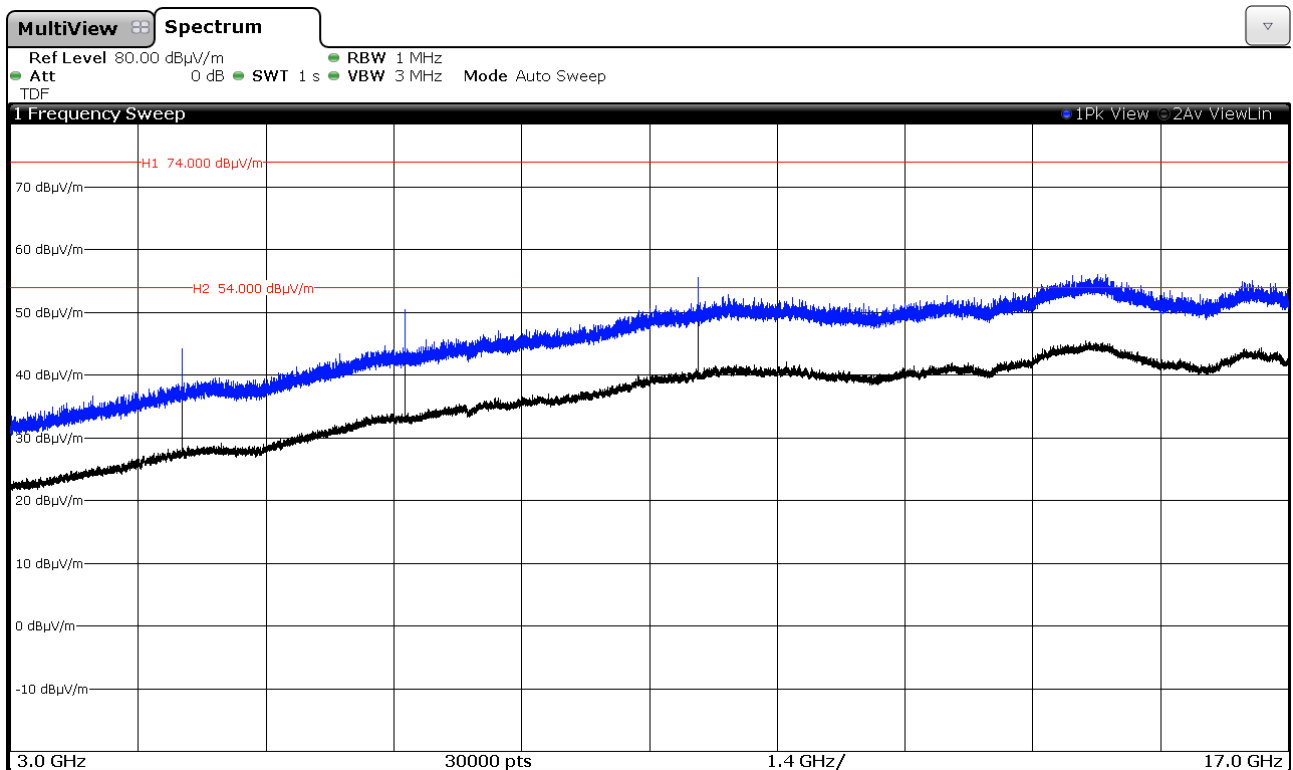
Note: The peak shown in the plot above the limit is the carrier frequency.

FREQUENCY RANGE 3 - 17 GHz

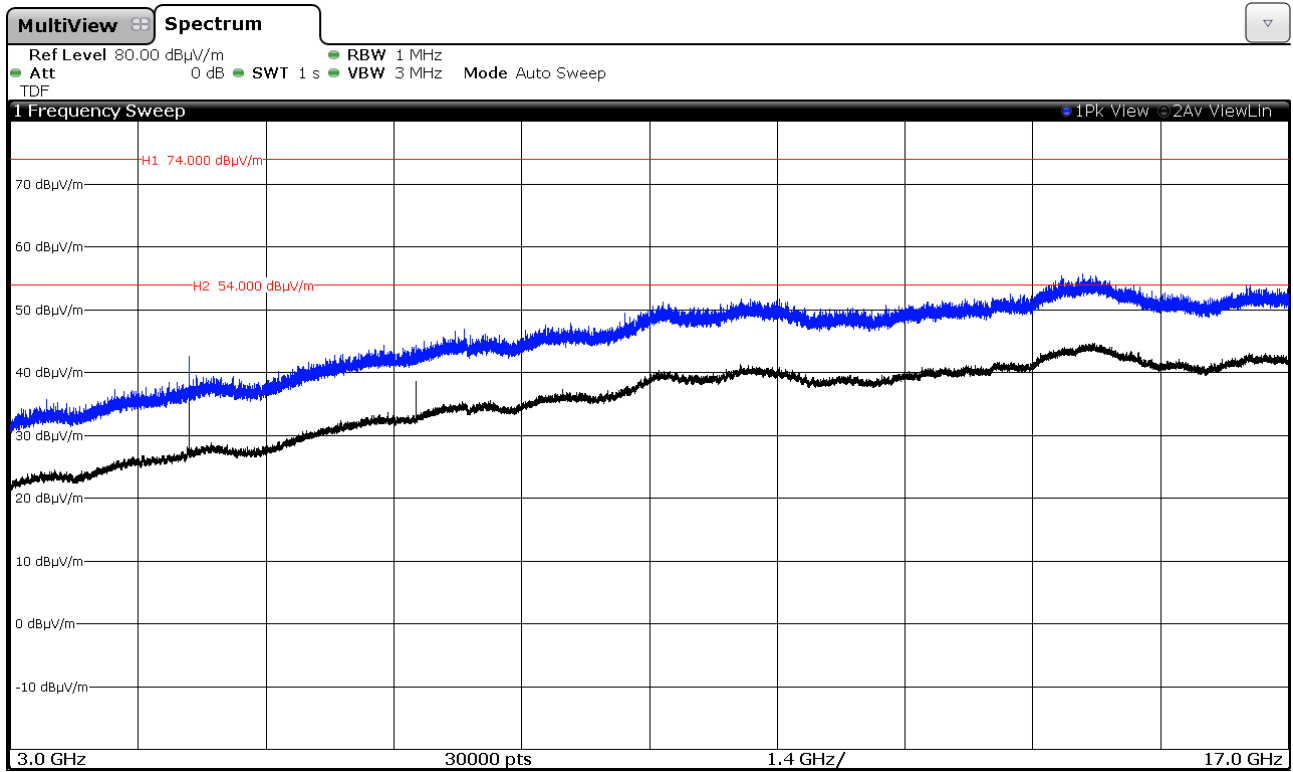
- Low Channel:



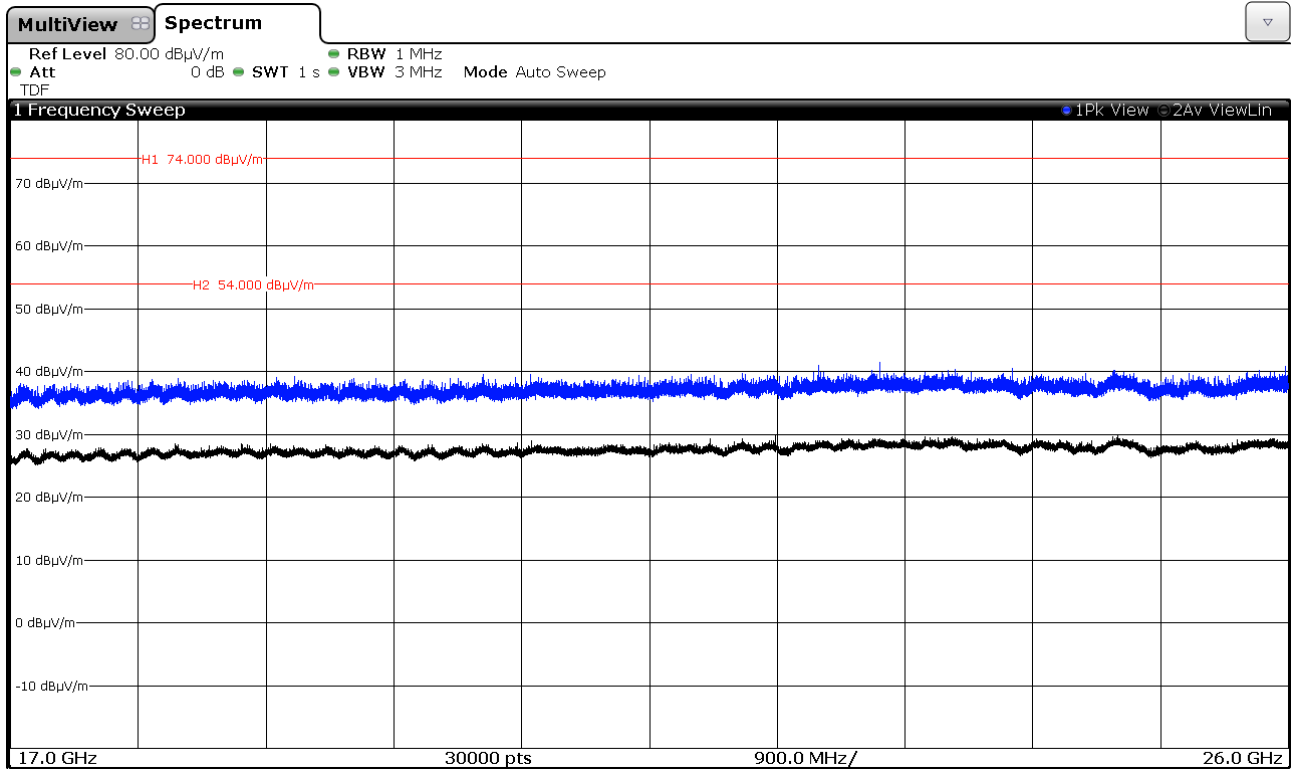
- Middle Channel:



- High Channel:



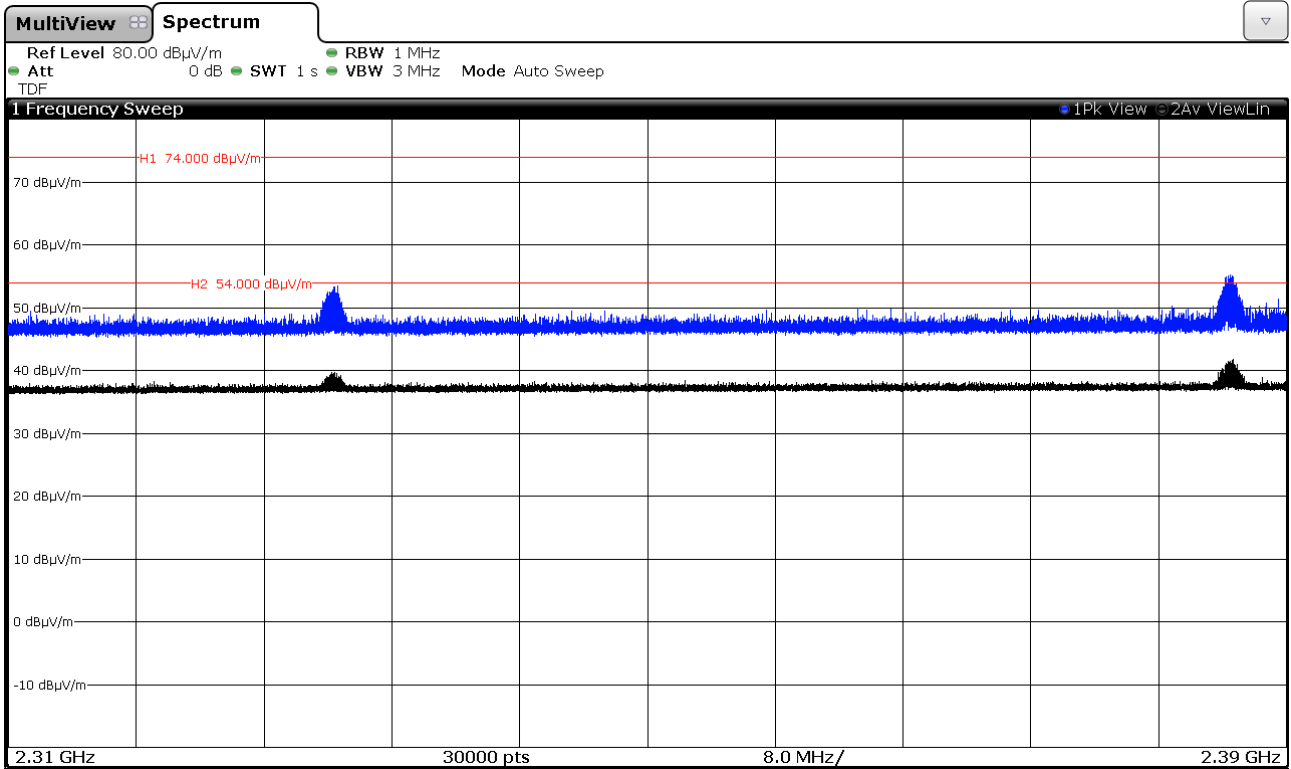
FREQUENCY RANGE 17 - 26 GHz



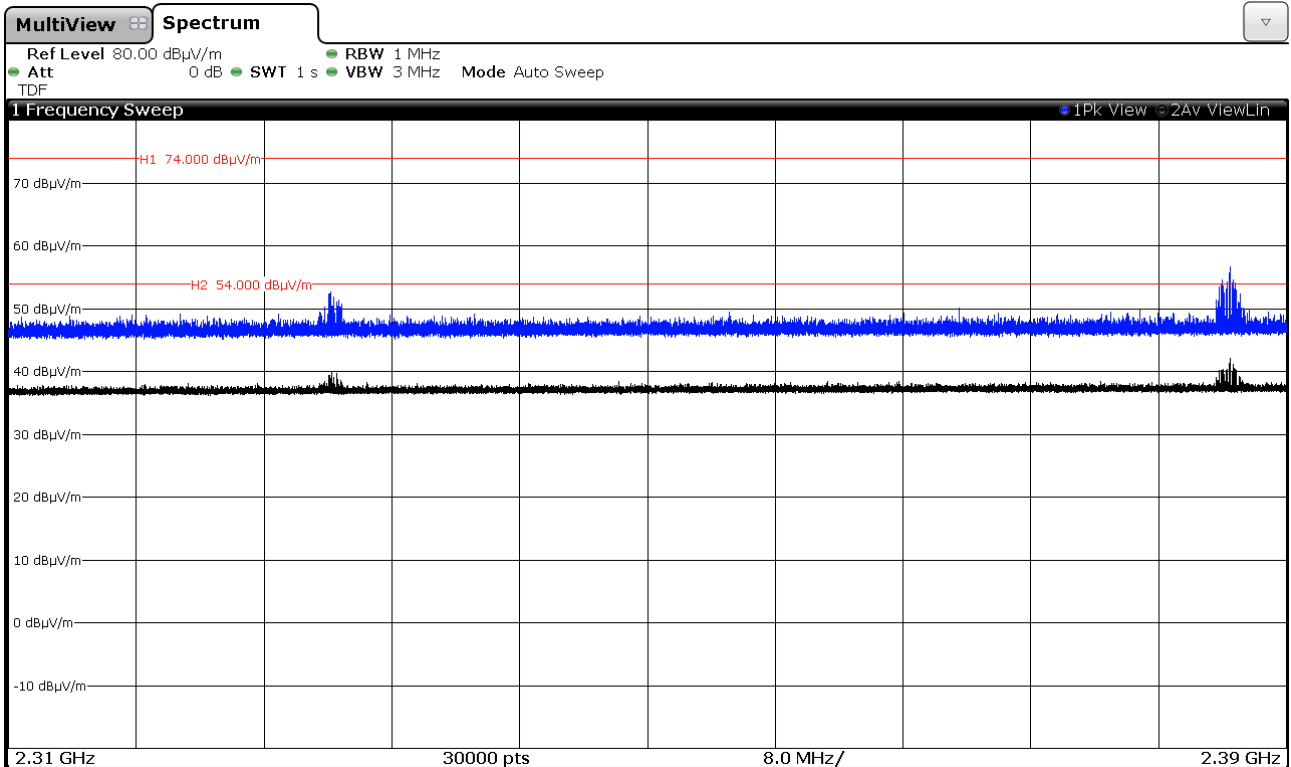
Note: This plot is valid for all three channels.

FREQUENCY RANGE 2.31 - 2.39 GHz (RESTRICTED BAND)

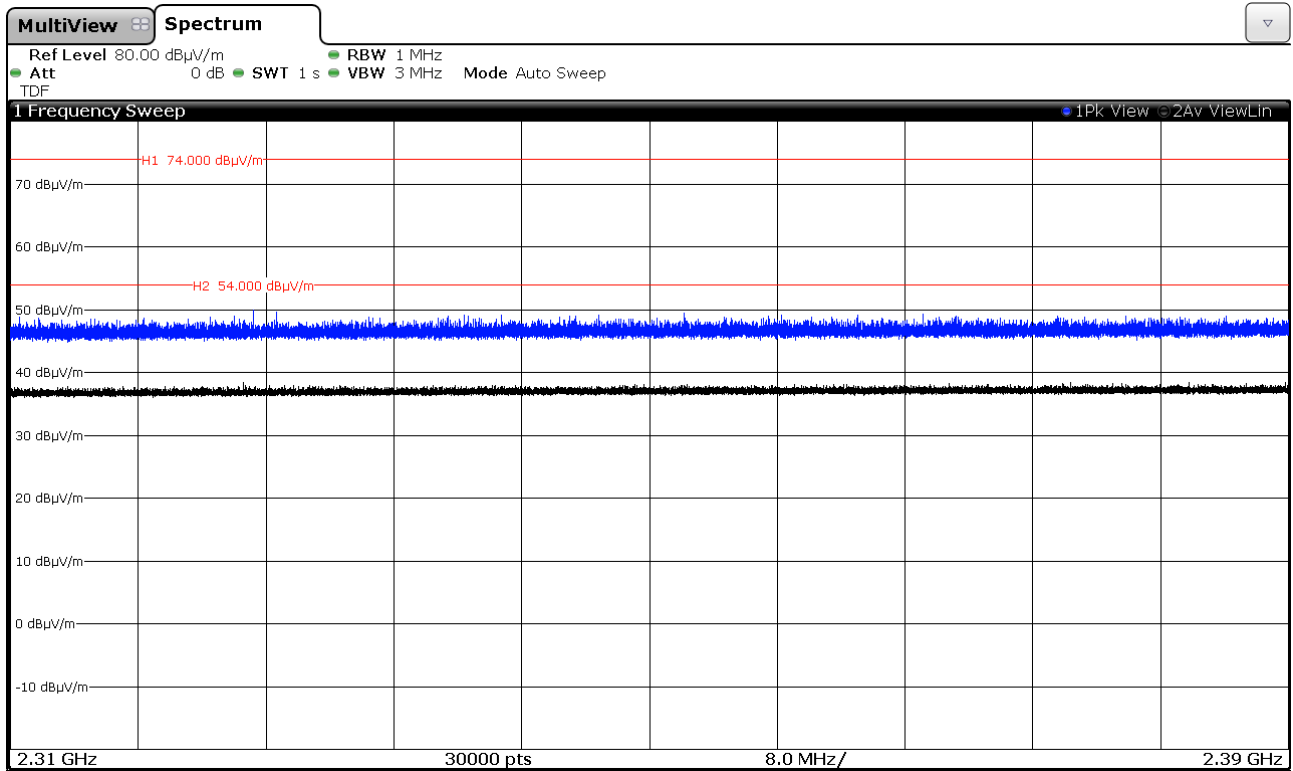
- Low Channel:



- Middle Channel:

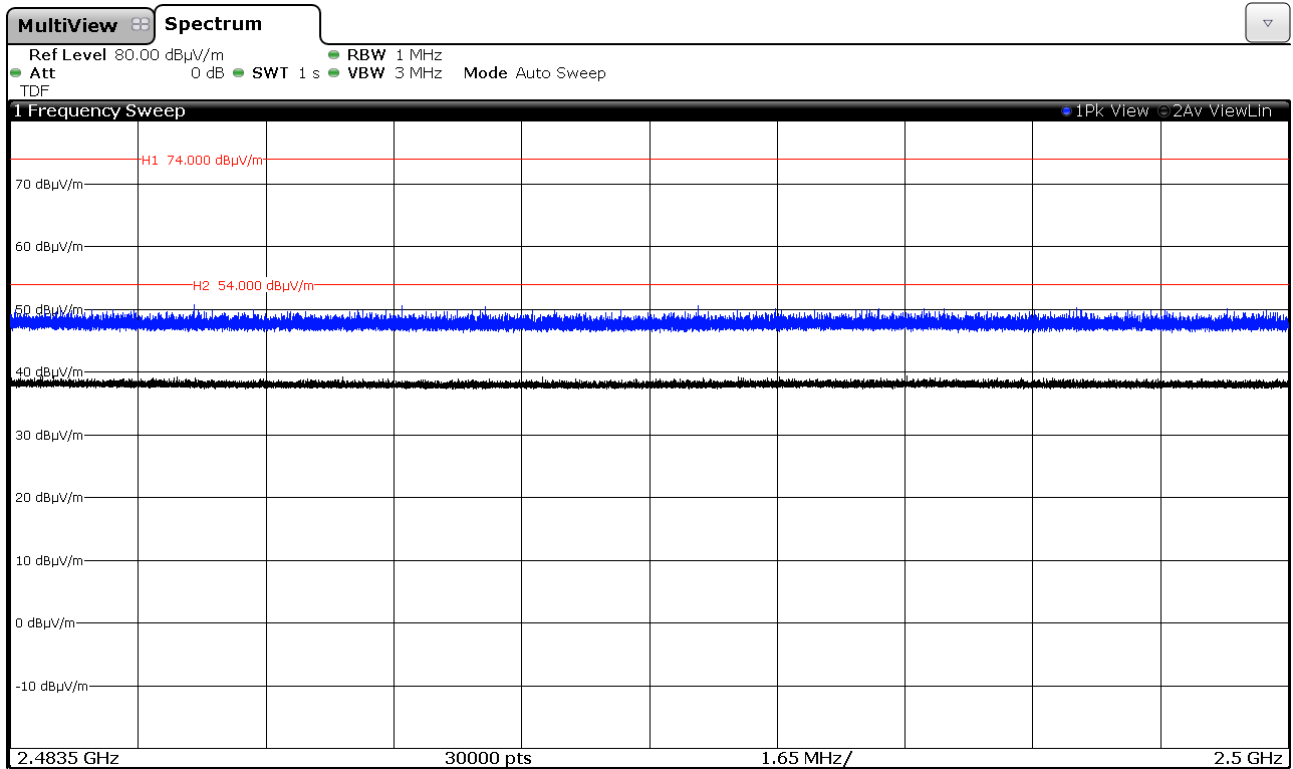


- High Channel:

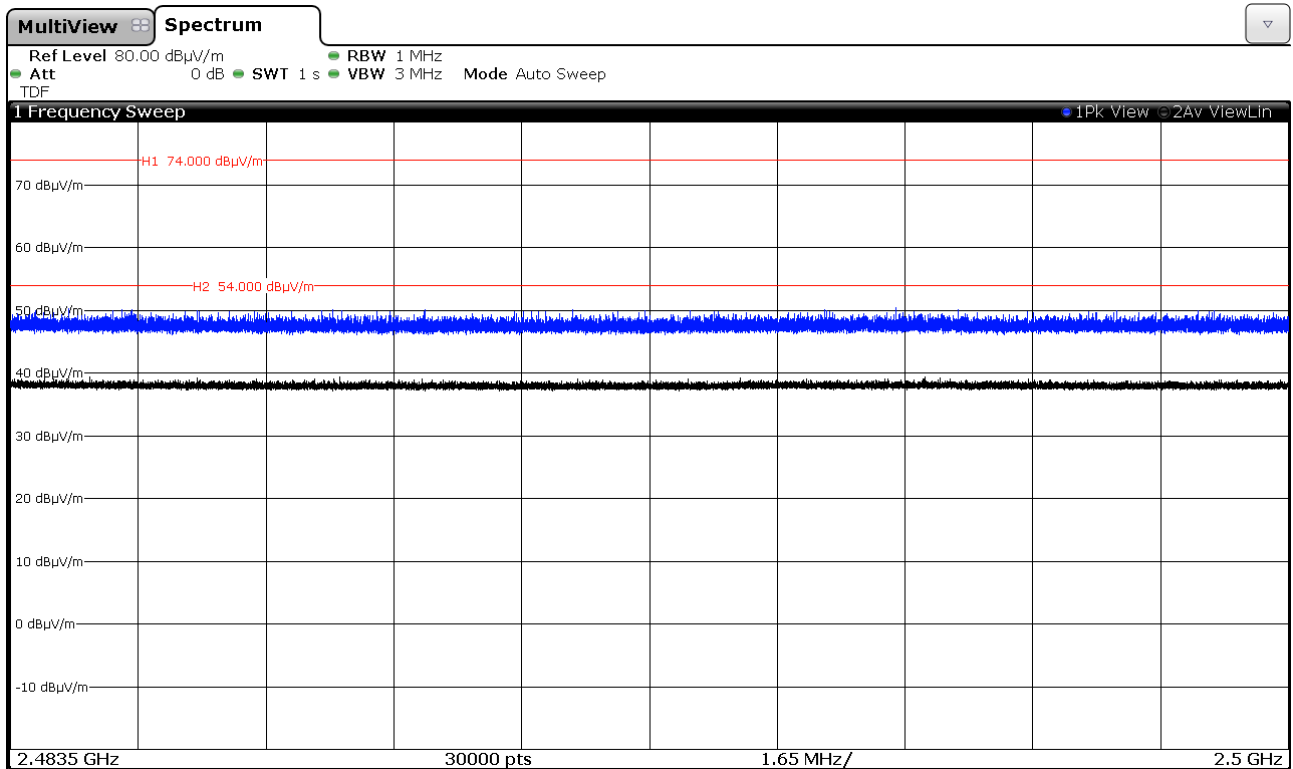


FREQUENCY RANGE 2.4835 - 2.5 GHz (RESTRICTED BAND)

- Low Channel:



- Middle Channel:



- High Channel:

