

		ISED LISTED REGISTRATION NUMBER 4621A-2	Test report No: NIE: 57186RRF.005
Test report USA FCC Part 15.209 CANADA RSS-Gen Issue 5			
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 15.209 (10–1–17 Edition): Radiated emission limits, general requirements. CANADA RSS-Gen Issue 5 (April 2018). General Requirements for Compliance of Radio Apparatus. ANSI C63.10-2013: American National Standard for Testing Unlicensed Wireless Devices.		
Summary	IN COMPLIANCE		
Approved by (name / position & signature)	A. Llamas RF Lab. Manager		
Date of issue	2019-02-21		
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Competences and guarantees

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DEKRA Testing and Certification S.A.U. 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.

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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.
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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
	☒	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)	2018-11-20
Date (finish)	2019-01-18

Document history

Report number	Date	Description
57186RRF.005	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: Juan Carlos Fuentes, Carolina Postigo, Francisco José Alcaide.

Used instrumentation:

Conducted Measurements:

	Last Calibration	Due Calibration
1. Signal and spectrum analyzer R&S FSV40	2017/07	2019/07
2. DC power supply R&S NGPE 40/40	2018/02	2021/02

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. Active Loop Antenna Hewlett Packard 11966A	2018/06	2020/06
5. Biconical/Log Antenna ETS LINDGREN 3142E	2017/04	2020/04
6. RF Pre-amplifier, 38 dB, 30 MHz-6 GHz BONN ELEKTRONIK BLNA 0360-01N	2018/07	2019/07

Testing verdicts

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

Summary

1. SRD 5 MHz

FCC PART 15.209 / RSS-Gen PARAGRAPH		
Requirement – Test case	Verdict	Remark
Occupied bandwidth	P	
15.209 Subclause (a) / RSS-Gen Clause 8.9. Transmitter emission limits	P	
<u>Supplementary information and remarks:</u> None.		

Appendix A: Test results

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TEST CONDITIONS

POWER SUPPLY (V):

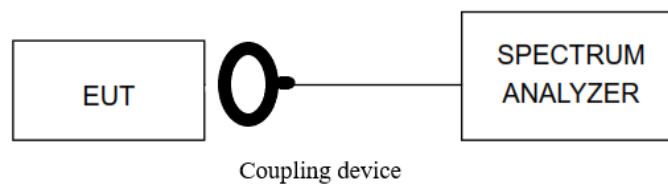
Vnominal: 1.45 Vdc
Type of power supply: DC voltage from battery.
Type of antenna: Integral antenna (inductive coil).

TEST FREQUENCIES:

Nominal Operating Frequency: 5 MHz

CONDUCTED MEASUREMENTS

The equipment under test EUT was set up in a shielded room and it is connected to the spectrum analyzer through a RF cable and a coupling device.



RADIATED MEASUREMENTS

All radiated tests were performed in a semi-anechoic chamber. The measurement antenna is situated at a distance of 3 m (Loop antenna for the range between 9 kHz to 30 MHz and Bilog antenna for 30 MHz to 60 MHz).

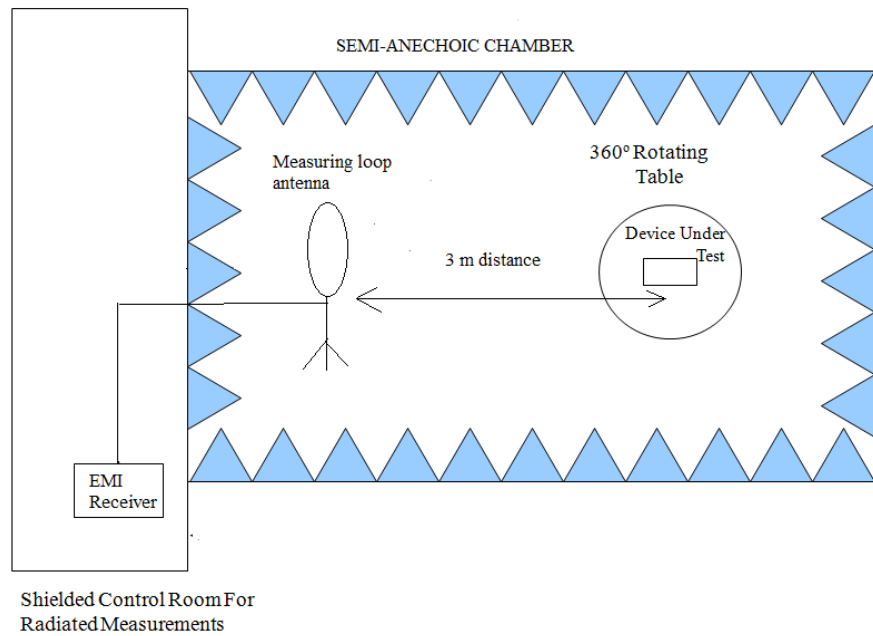
For radiated emissions in the range 9 kHz to 30 MHz that is performed at a distance closer than the specified distance, an inverse proportionality factor of 40 dB per decade is used to normalize the measured data for determining compliance.

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 was varied from 1 to 4 meters to find the maximum radiated emission.

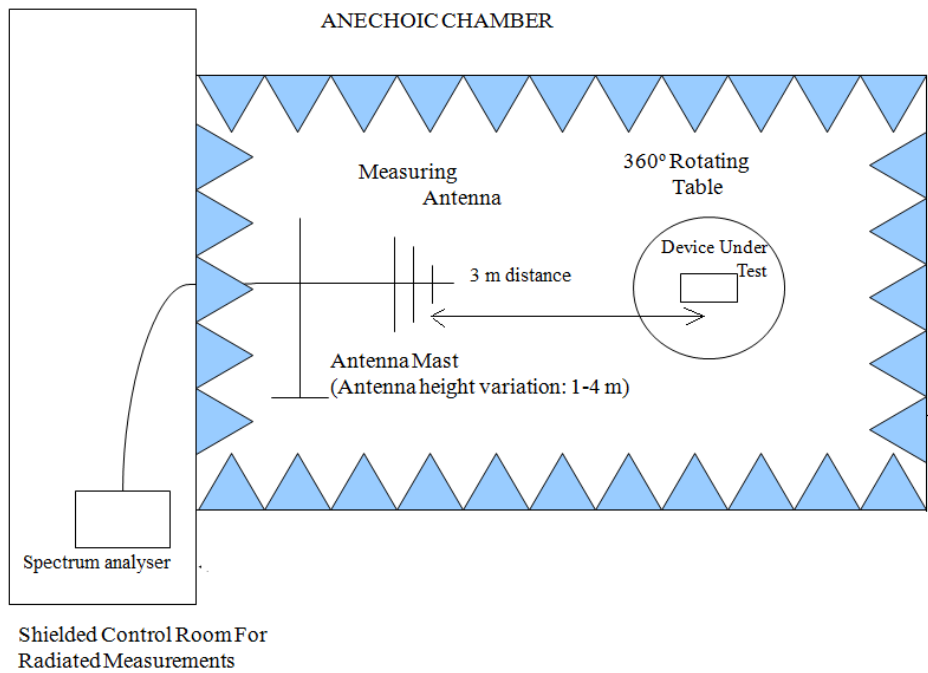
In the range between 9 kHz and 30 MHz the measurements were made in the three different orientation planes of the loop antenna to determine the maximum received field. Measurements above 30 MHz up to 60 MHz were made in both horizontal and vertical planes of polarization.

The test was performed with the equipment transmitting first with only the 5 MHz radio and repeated with the Bluetooth Low Energy 2.4 GHz radio and then the Proprietary protocol 2.4 GHz 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 $f < 30$ MHz:



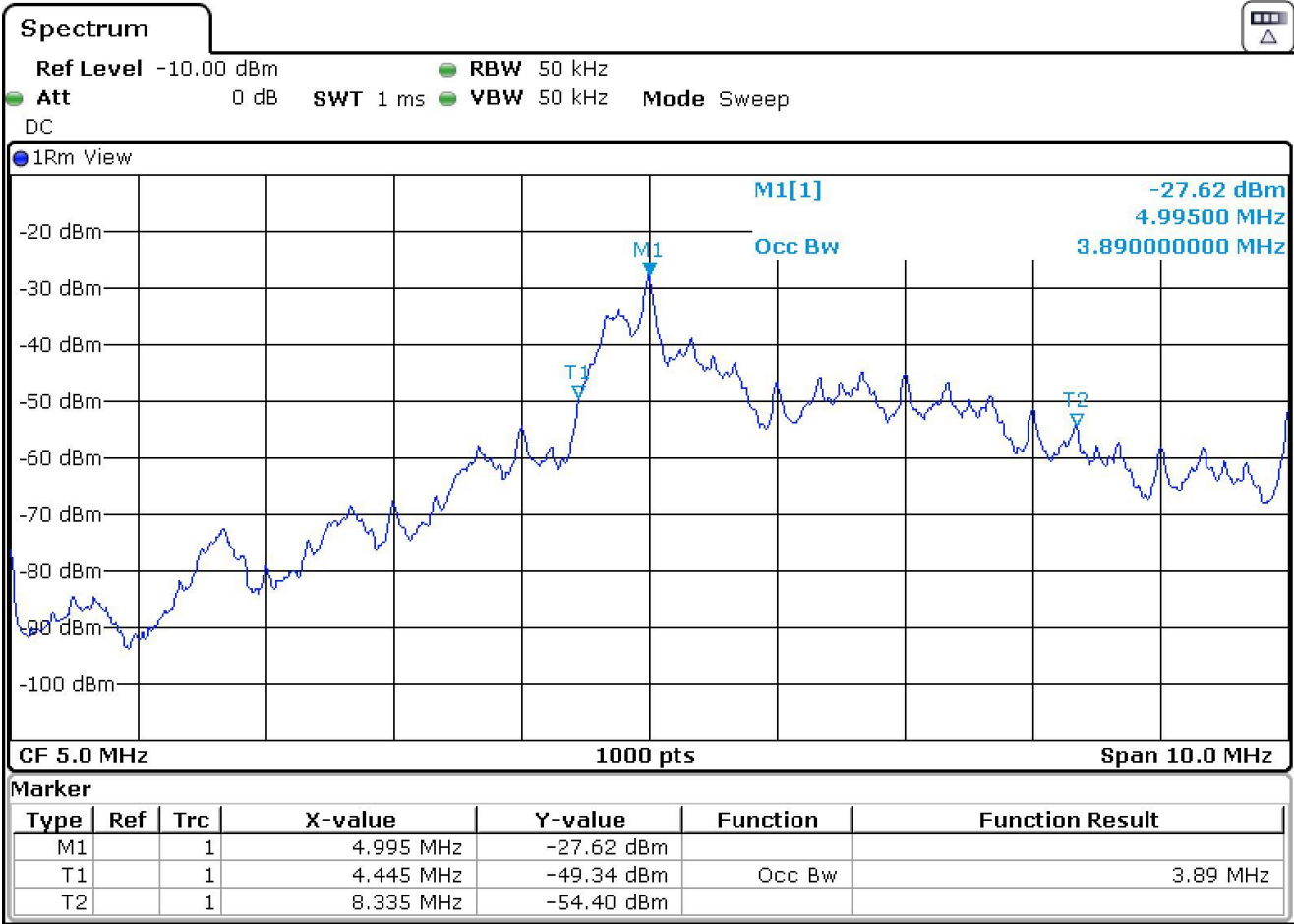
Radiated measurements setup $f > 30$ MHz up to 60 MHz:



Occupied Bandwidth

RESULTS:

99% bandwidth (MHz)	3.89
Measurement uncertainty (kHz)	<±5.51



Section 15.209 Subclause (a) / RSS-Gen Clause 8.9. Transmitter emission limits

SPECIFICATION:

Except as provided elsewhere in this subpart, the emissions from an intentional radiator shall not exceed the field strength levels specified in the following table (see §15.205(c) / RSS-Gen):

Frequency Range (MHz)	Field strength (µV/m)	Field strength (dBµV/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	29.54	30
30 - 88	100	40	3
88 - 216	150	43.5	3
216 - 960	200	46	3
Above 960	500	54	3

RESULTS:

All tests were performed in a semi-anechoic chamber at a distance of 3 m.

The spectrum was inspected from 9 kHz to 60 MHz searching for spurious signals.

The field strength is calculated by adding correction factor to the measured level from the spectrum analyser. This correction factor includes antenna factor and cable loss.

Frequency range 9 kHz - 30 MHz

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

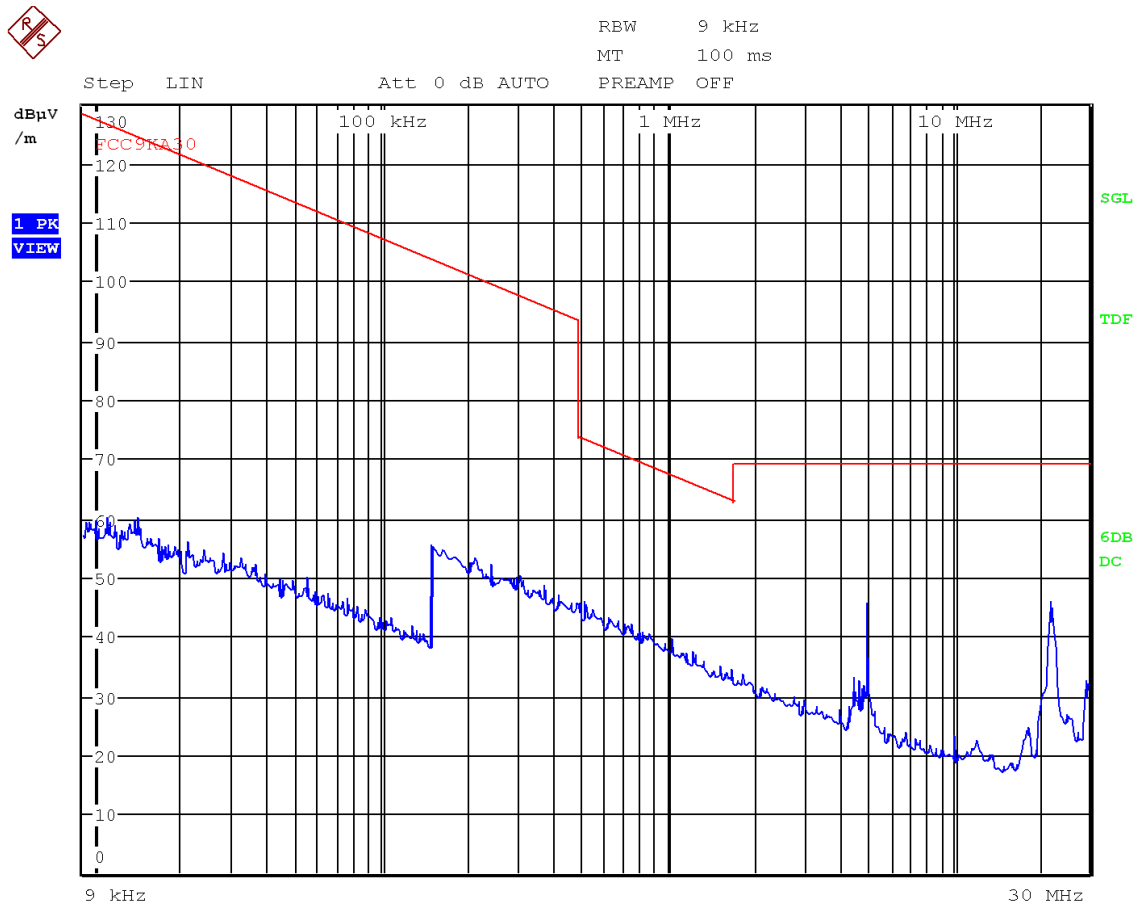
Verdict: PASS

Frequency range 30 - 60 MHz

Spurious frequency (MHz)	Detector	Emission Level (dBµV/m)	Polarization	Measurement Uncertainty (dB)
30.5615	Quasi peak	28.8	V	<± 3.88

Verdict: PASS

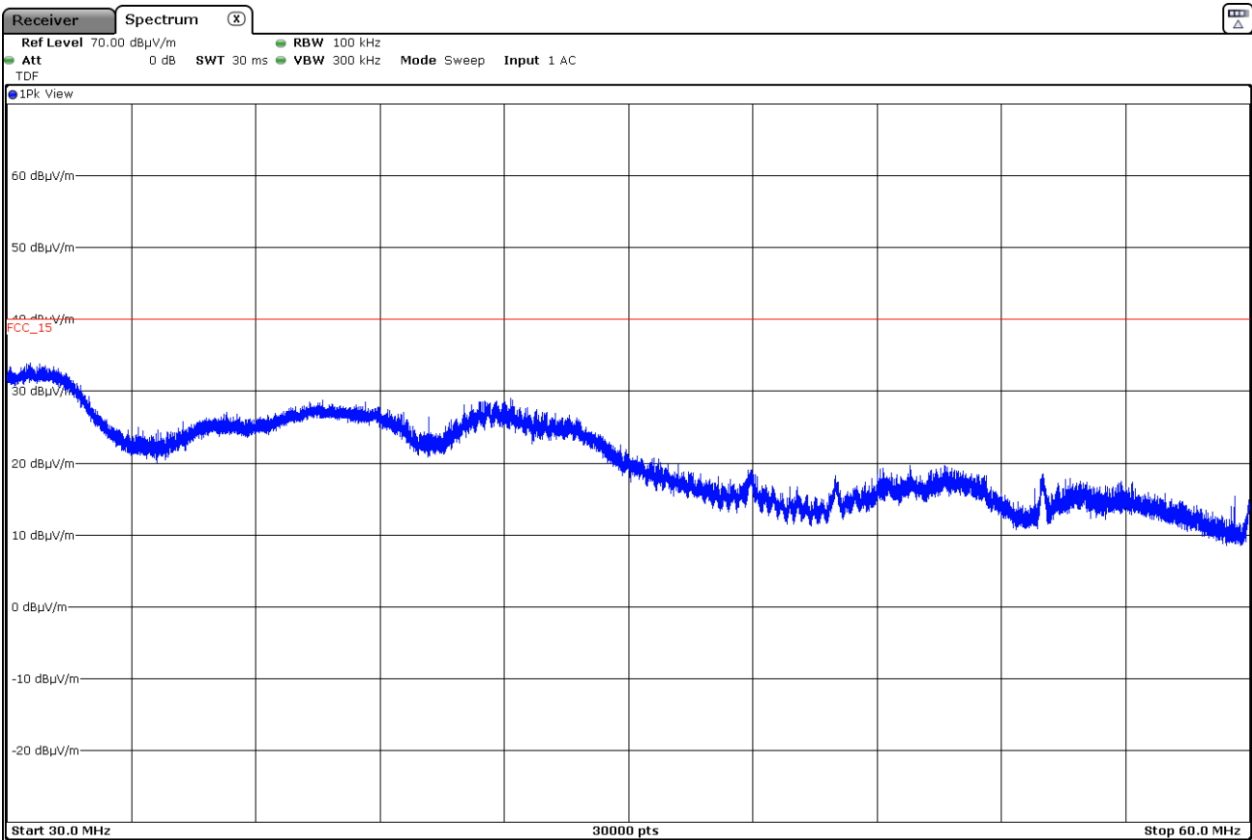
FREQUENCY RANGE 9 kHz-30 MHz



Resolution bandwidth:
 200 Hz for $9 \text{ kHz} \leq f \leq 150 \text{ kHz}$
 9 kHz for $150 \text{ kHz} \leq f \leq 30 \text{ MHz}$

Note: The scan is performed with a peak detector.
 The limits shown in the above plot are extrapolated to 3 meters.

FREQUENCY RANGE 30 - 60 MHz



Note: The scan is performed with a peak detector.