Applicant: Theranica Bio-Electronics LTD

Equipment Under Test:

NerivioInfinity Transceiver

Model: FGD000100 FCC ID: 2AOH8-NI

Issued by:

The Standards Institution of Israel Industry Division Electrical & Electronics Laboratory EMC Branch









<u>Test Report No.:</u> 7212322306 Page 2 of 32 Pages <u>Title:</u> Test on Neriviolnfinity Transceiver <u>Model:</u> FGD000100

FCC ID: 2AOH8-NI

Applicant: Theranica Bio-Electronics LTD.

Address: 4 Ha-Omanut St., 4250438, P.O.B 16008,

Netanya 4206001, Israel

Sample for test selected by: The customer

The date of test: November & December 2022

Description of Equipment

under Test (EUT): NerivioInfinity Transceiver

Model: FGD000100

Software version: FW Version 4.0.4.70 **Hardware version:** ELC-PCA-0200-1.0

Manufactured by: Theranica Bio-Electronics LTD.

Reference Documents:

CFR 47 FCC Rules and Regulations: Part 15. Radio frequency devices,

(2020) Subpart C: Intentional radiators.

Section 15.247: Operation within the bands 902 - 928 MHz,

2400 - 2483.5 MHz, 5725 - 5875 MHz

Test Results The EUT was found to be in compliance with the following standard:

CFR47 Part 15 Subpart C

sections: 15.203, 15.205, 15.207, 15.209 and 15.247.

This Test Report contains 32 pages	This Test Report applies only to the specimen tested and may not
and may be used only in its entirety.	be applied to other specimens of the same product.

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1. Summary of Test Results

Transmitter characteristic	Ref. Section
6dB and occupied bandwidth	15.247 (a) (2)
Maximum peak conducted output power	15.247 (b) (3)
Power spectral density	15.247 (e)
Radiated emission in restricted and non-restricted bands	15.247 (d), 15.209, 15.205
Band-edge compliance of RF conducted emission	15.247 (d)
AC power line conducted emission measurements	15.207
Antenna requirement	15. 203

Name: Eng. Yuri Rozenberg Position: Head of Branch Electrical & Electronics Laboratory 26 March 2023

Tested by: Alexander Konkov Position: Testing Engineer

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2. EUT Description

Note: All information in this section was provided by the customer.

2.1. General description:

NerivioInfinity Transceiver(the EUT) is indicated for acute and/or preventive treatment of migraine with or without aura in patients 12 years of age or older. It is a prescription use, self-administered device for use in the home environment at the onset of migraine headache or aura for acute treatment, and/or every other day for preventive treatment. The EUT is a wearable, battery-powered device. It is powered by a non-detachable, non-replaceable, recharge battery and is operated via a mobile application. The device is worn on a user's upper arm and delivers transcutaneous remote electrical neurostimulation ("REN") via weak electrical pulses to achieve migraine pain inhibition via conditional pain modulation (CPM). The NerivioInifinity uses standard BLE 5.0 for communication utilizing off-the-shelf Cypress controller.

The test data contained in this report pertains only to the emissions due to the EUT's BLE transmitter.

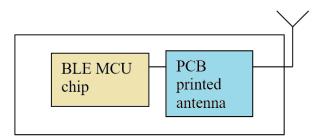


Figure 1. Block diagram



Figure 2. Neriviolnfinity Transceiver

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2.2. Transmitter description:

Type of equipment

Combined equipment (Equipment where the radio part is fully integrated within another type of equipment)

BLE standards B	SLE 5
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Assigned frequency range	from 2400MHz to 2483.5MHz		
Operating frequency range	from 2402MHz to 2480MHz (BLE transceiver)		
RF channel spacing	1 MHz (BLE transceiver)		
Maximum rated output power	Effective radiated power (for equipment with no RF connector)	-2.3 dBm = 0.58 mW	
Declare temperature range:	0°C - 35°C	Normal indoor use	

Antenna information
Antenna MIFA on PCB printed - without temporary RF connector
Manufacturer: Cypress
Antenna gain = 1.6 dBi

Transmitter 99% power bandwidth	
Type of modulation	GFSK
Modulating test signal (baseband)	GFSK

Transmitter power source		
Nominal rated voltage	3.7 VDC	
Type of battery Li-lon		

2.3. Test setup:

The EUT was tested per the guidance ANSI C63.10: 2020.

The test setup is shown in Figures 3 and 4. EUT gets 3.7 V DC power from battery.

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EUT

Spectrum Analyzer

Figure 3. EUT test setup

Auxiliary Equipment

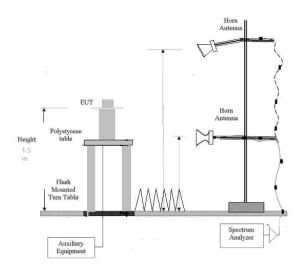


Figure 4. RE test setup above 1 GHz.

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2.4. System test configuration:

Table 1. BLE channels / frequencies

Channel	Frequency MHz	Channel	Frequency MHz
37	2402	18	2442
0	2404	19	2444
1	2406	20	2446
2	2408	21	2448
2	2410	22	2450
4	2412	23	2452
5	2414	24	2454
6	2416	25	2456
7	2418	26	2458
8	2420	27	2460
9	2422	28	2462
10	2424	29	2464
38	2426	30	2466
11	2428	31	2468
12	2430	32	2470
13	2432	33	2472
14	2434	34	2474
15	2436	35	2476
16	2438	36	2478
17	2440	39	2480

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3. Test specification, methods and procedures

❖ CFR 47 FCC Rules and Regulations: Part 15. Radio frequency devices,

Subpart C: Intentional radiators (2020)

American National Standard for Method of Measurement

of Radio Noise Emissions from Low Voltage Electrical and Electronic

Equipment in the Range 9 kHz to 40 GHz.

ANSI C63.10: 2020 American National Standard for Testing of Unlicensed Wireless

Devices

4. Testing Facility:

Laboratory Name: Standards Institution of Israel (SII)

Test site location: 42 Haim Levanon st., Tel-Aviv Israel

Laboratory Accreditation: ANAB: AT-1359

5. Measurement uncertainty

The test equipment has been calibrated according to its recommended procedures and is within the manufacturer's published limit of error.

The laboratory calibrates its standards by a third party (traceable to NIST, USA) on a regular basis according to equipment manufacturer requirements.

Test description	Calculated uncertainty U LAB		
Conducted measurements			
Frequency error 37.6 Hz			
Spurious emission ± 2.98 dB			
Radiated mea	Radiated measurements		
Electric field strength in a SAR at 3 m			
distance	±4.32 dB		
30 MHz – 1.0 GHz			
Electric field strength in a FAR at 3 m			
distance	± 4.47		
1.0 GHz – 18 GHz			
Substitution measurements			
In a FAR at 3 m distance	± 3.41 dB		
1.0 GHz – 18 GHz	± 3.41 ub		

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6. Transmitter characteristics - test results

6.1. Duty Cycle

Limits & methods:

FCC requirements		15.247		
Test procedure		ANSI 63.10 11.6 Duty cycle		
		Radiated Measurement		
Operating mode		BLE, Hight Mid and Low		
Ambient Temperature	23°C	Relative Humidity 49% Air Pressure 1003hPa		

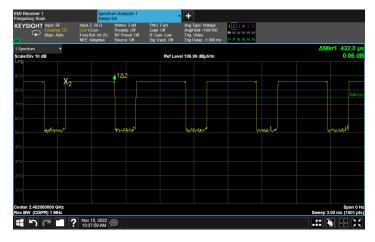
Results:

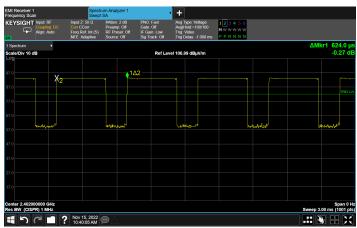
Table 2. Transmitter characteristics - result parameters

Tx On	432	uS
Tx Off	192	uS
Period	624	uS
Duty cycle	69.231	%
D	0.69231	-

Note: duty cycle correction = $[10 \log (1 / D)] = 1.6 dB$

The results are presented in Plots 1 -2.





Plot 1 Plot 2

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6.2. 6dB and Occupied Bandwidth

Limits & methods:

FCC requirements		15.247(a)(2)				
Test procedure		ANSI 63.10 11.8.2 Option 2				
		Radiated Measurement				
Operating mode		BLE, Hight Mid and Low				
Ambient Temperature	23°C	Relative Humidity	49%	Air Pressure	1003hPa	

Limit:

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

Test procedure

The measurements were performed in hopping transmission mode of operation for carrier (channel) frequency at bottom, middle and at the top of 2402MHz to 2480MHz frequency band and maximum transmitting data rate.

Results:

Table 3. 6dB Bandwidth & Occupied Bandwidth Results

Frequency	6dB Bandwidth	Limit	Verdict	Ref. Plot
MHz	kHz	kHz		
2402	624.3	500	Pass	3
2442	638.5	500	Pass	4
2480	642.2	500	Pass	5

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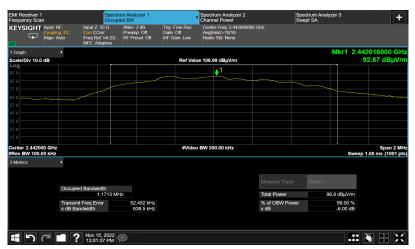
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BLE



Plot 3



Plot 4



Plot 5

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6.3. Maximum Peak Conducted Output Power

Limits & methods:

FCC requirements		15.247(b)(3)				
Test procedure		ANSI 63.10 11.9.2.2.4 Method AVGSA-2				
		Radiated Measurement				
Operating mode		BLE, Hight Mid and Low				
Ambient Temperature	23°C	Relative Humidity 49% Air Pressure 1003hPa				

Limit

The maximum peak conducted output power shall not exceed 1 watt.

Test procedure

The measurements were performed in hopping transmission mode of operation for carrier (channel) frequency at bottom, middle and at the top of 2402 MHz to 2480 MHz frequency band and maximum transmitting data rate.

Results:

Table 4. Maximum Peak Conducted Output Power Results

Freq.	Mesure	Calculated	Limit	Verdict	Plot
MHz	dBm	mWatt	Watt		
2402	-2.31	0.587	1	Pass	6
2442	-2.77	0.528	1	Pass	7
2480	-5.27	0.297	1	Pass	8

Note:

Total power(dBm) = P Measured(dBuV/m) – 95.2 – Antenna Gain(dBi) + Duty Cycle correction(dB)

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BLE



Plot 6



Plot 7



Plot 8

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6.4. Power Spectral Density

Limits & methods:

FCC requirements	15.247(e)				
Test procedure	ANSI 63.10 11.10.5 Method AVGPSD-2				
	Radiated Measurement				
Operating mode	BLE, Hight Mid and Low				
Ambient Temperature 23°C	Relative Humidity 49% Air Pressure 1003hPa				

Limit

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

Test procedure

The measurements were performed in hopping transmission mode of operation for carrier (channel) frequency at bottom, middle and at the top of 2402 MHz to 2480 MHz frequency band and maximum transmitting data rate.

Results:

Table 5. Power Spectral Density Test Results

Freq.	Measure	Limit	Verdict	Plot
MHz	dBm/3kHz	dBm/3kHz		
2402	-2.09	8	Pass	9
2442	-2.44	8	Pass	10
2480	-4.89	8	Pass	11

Note:

PSD (dBm/3kHz) = PSD Measured(dBuV/m) – 95.2 – Antenna Gain(dBi) + Duty Cycle correction(dB) Worst case RBW=100 kHz maximum.

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Plot 9



Plot 10



Plot 11

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6.5. Radiated Emissions in Restricted and non-Restricted bands

Limits & methods:

FCC requirements		15.247(d), 15.209, 15.205				
Test procedure		ANSI 63.10 Sections 6.5, 6.6, 11.11, 11.12				
		Radiated Measurement				
Operating mode		BLE, Hight Mid and Low				
Ambient Temperature	23°C	Relative Humidity 49%		Air Pressure	1009hPa	

Limit

In any 100 kHz 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 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.

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 below)

FREQUENCIES (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

Test procedure

The frequency spectrum was investigated from the lowest radio frequency signal generated in the equipment and up to ten harmonics. The measurements were performed in hopping transmission mode of operation for carrier (channel) frequency at bottom, middle and at the top 2402MHz to 2480MHz frequency band and maximum transmitting data rate.

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Results:

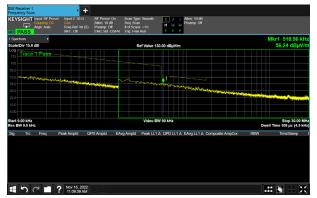
Range: 9 kHz-30 MHz

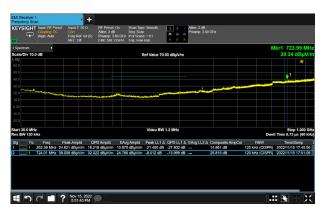
Not found disturbance emission plot 12, plot 20, plot 27.

Range: 30 MHz - 40 GHz:

Table 6. CH1 2402 MHz - modulation PRBS - Results

Frequency	Meas Freq.	Pk Det.	QPk Det.	Limit Pk	Limit QPk	Verdict	Ref. Plot
MHz	MHz	dbuV/m	dbuV/m	dbuV/m	dbuV/m		
	262.39	26.21	18.218	-	46.02	Pass	13
	724.01	38.008	32.022	-	46.02	Pass	13
CH 37			AVG Det. dbuV/m		Limit AVG Det. dbuV/m		
2402	2400	63.87		74	-	Pass	14
	2400	-	33.55	-	54	Pass	14
	2399.972	52.57	-	74	-	Pass	15
	2399.972	-	34.10	-	54	Pass	15
	5676	51.37		74	-	Pass	16
	5676	-	40.34	-	54	Pass	16
	11388	57.06	-	74	-	Pass	17
	11388	-	45.65	-	54	Pass	17
	14310	58.73	-	74	-	Pass	18
	14310	-	46.86	-	54	Pass	18
	25439	57.25	-	74	-	Pass	19
	25439	-	45.53	-	54	Pass	19

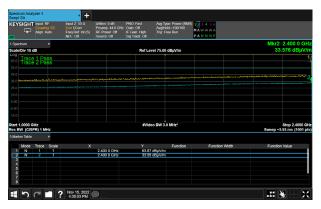




Plot 12 Plot 13

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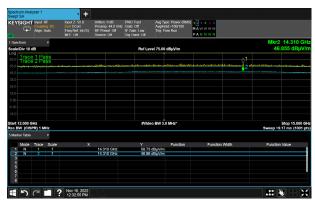


Plot 14

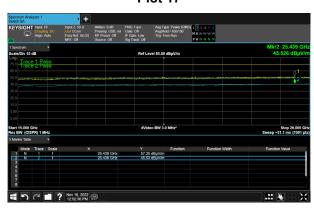
Plot 15



Plot 16



Plot 17



Plot 18 Plot 19

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Table 7. CH6 2442 MHz - modulation PRBS - Results

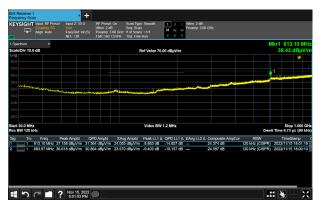
Frequency	Meas Freq.	Pk Det.	QPk Det.	Limit Pk	Limit QPk	Verdict	Ref. Plot
MHz	MHz	dbuV/m	dbuV/m	dbuV/m	dbuV/m		
	613.10	37.15	31.36	-	46.02	Pass	21
	683.97	36.61	30.86	-	46.02	Pass	21
			AVG Det.		Limit AVG Det.		
CH 18			dbuV/m		dbuV/m		
2442	2254.4	49.06	35.61	74	54	Pass	22
	5666	51.70	-	74	-	Pass	23
	5660	-	40.26		54	Pass	23
	10398	57.48	45.34	74	54	Pass	24
	14151	59.10	49.96	74	54	Pass	25
	24625	56.71	45.20	74	54	Pass	26

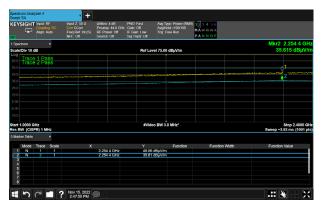


Plot 20

FCC ID: 2AOH8-NI

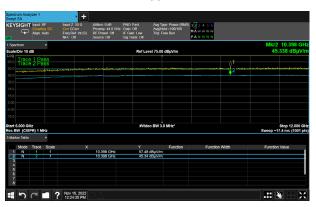
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Plot 21

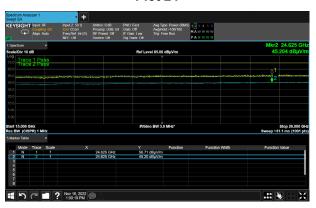
Plot 22



Plot 23



Plot 24



Plot 25 Plot 26

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Table 8. CH11 24802 MHz - modulation PRBS - Results

Frequency	Meas Freq.	Pk Det.	QPk Det.	Limit Pk	Limit QPk	Verdict	Ref. Plot
MHz	MHz	dbuV/m	dbuV/m	dbuV/m	dbuV/m		
	656.44	37.37	31.60	-	46.02	Pass	28
	826.59	38.91	32.57	-	46.02	Pass	28
			AVG Det.		Limit AVG Det.		
CH 39			dbuV/m		dbuV/m		
2480	2247.4	45.11	32.07	74	54	Pass	29
	5982	50.63	39.98	74	54	Pass	30
	11262	57.09	45.47	74	54	Pass	31
	14151	59.10	46.47	74	54	Pass	32
	23415	57.32	44.89	74	54	Pass	33

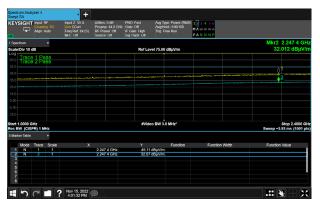


Plot 27

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Plot 28

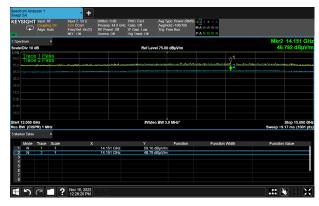
Plot 29

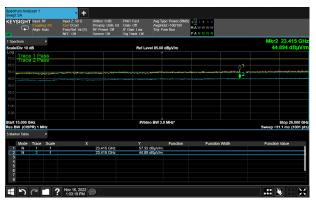




Plot 30

Plot 31





Plot 32 Plot 33

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6.6. Band-edge measurements

Limits & methods:

FCC requirements		15.247(d)				
Test procedure		ANSI 63.10 Section 11.13				
		Radiated Measurement				
Operating mode		BLE, Hight Mid and Low				
Ambient Temperature	23°C	Relative Humidity	49%	Air Pressure	1009hPa	

Limit

In any 100 kHz bandwidth outside the frequency band the radio frequency power shall be at least 20 dB below that in the 100 kHz bandwidth within the band

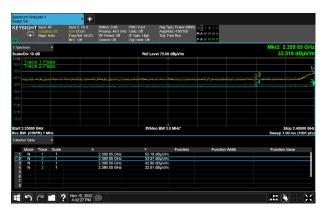
Results:

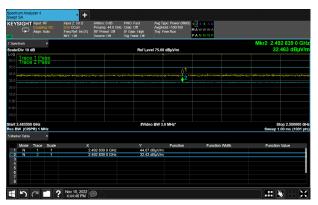
Table 9. Band-edge Results

Channel	Freq MHz	Peak, dBµV/m	Limit 20dBc dBµV/m	Verdict	Plot
CH 37	2399.85	52.18	72.89	Pass	34
2402 MHz	2492.839	44.07	72.89	Pass	35
CH 18	2381.05	44.61	72.43	Pass	36
2442 MHz	2489.918	46.05	72.43	Pass	37
CH 39	2356.70	44.98	69.93	Pass	38
2480 MHz	2486.074	45.21	69.93	Pass	39

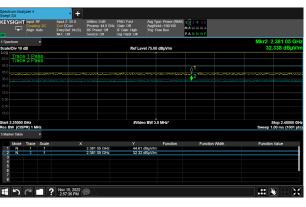
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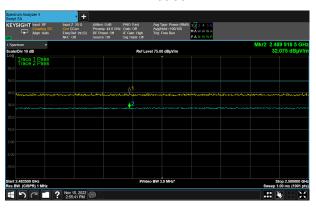




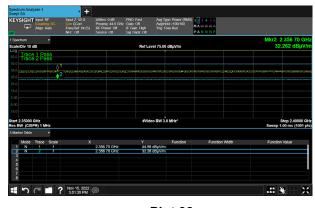
Plot 34



Plot 35



Plot 36



Plot 37



Plot 38 Plot 39

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6.7. AC power line conducted emission measurement

Limits & methods:

FCC requirements		15.207			
Test procedure		ANSI 63.10 Section 6.2			
Ambient Temperature	23°C	Relative Humidity	49%	Air Pressure	1009hPa

Limit:

Frequency,	Class B equipment, dB (μV)			
MHz	QP	AVRG		
0.15 - 0.5	66 - 56*	56 - 46*		
0.5 - 5	56	46		
5 - 30	60	50		

^{*} Decreases linearly with the logarithm of the frequency.

Test Procedure:

EUT was connected to 120VAC main via auxiliary power supply.

The EUT was placed on a table in shielded room at a height 80 cm from floor and 40 cm from the vertical reference plane and at more than 80 cm from any other metal surfaces. The measurements were performed at mains terminals by means of LISN, connected to spectrum analyzer in the frequency range as referred to in the table above. The measurements were made with quasi-peak(CISPR) and average detectors. The position of the EUT cables was varied to determine maximum emission level.

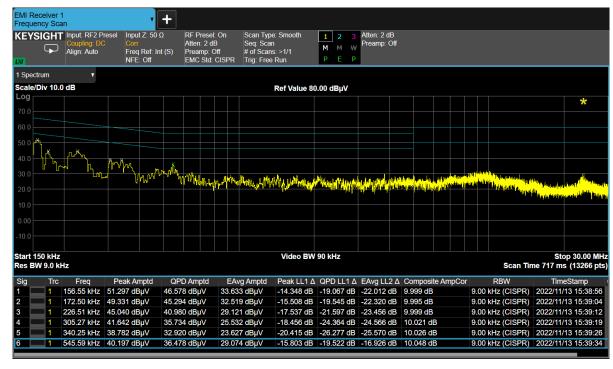
Results:

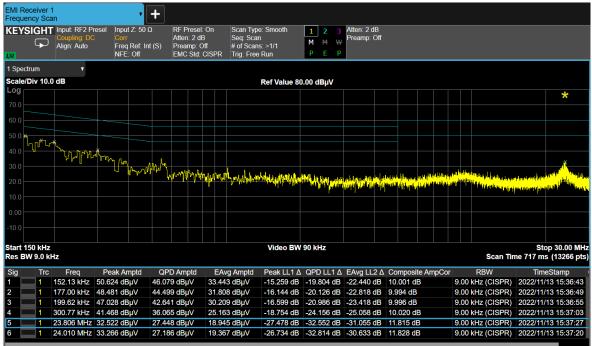
The results are presented in Plots # 40-41.

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Plot 40- Plot 41
Conducted emission on 120VAC mains. Phase & Neutral

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7. Antenna requirements

Excerpt from §15.203 of the FCC Rules/Regulations:

"An intentional radiator antenna shall be designed to ensure that no antenna other than that furnished by the responsible party can 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 antenna of the device is - inside case box and non-detachable antenna. There are no provisions for connection to an external antenna. Antenna MIFA on PCB printed.

Conclusion: The unit complies with the requirement of §15.203.



Figure 5. Antenna of Neriviolnfinity Transceiver

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8. Appendix 1: Test equipment used

All measurements equipment is on SII calibration schedule with a recalibration interval not exceeding one year.

Instrument	Manufacturer	Model	SII No.	Last calibration date	Next calibration date
EMI RECEIVER-MXE 3Hz- 44GHz	Keysight	N9038B	6505208	12/21	12/22
Biconilog Antenna 30 – 6000 MHz	ETS Lindgren	3142D	00146488	04/21	04/23
Double Ridged Waveguide Antenna 1-18 GHz	ETS Lindgren	3115	0143138	07/21	07/23
Semi Anechoic Chamber	ETS-Lindgren	RFSD-F/A-100	5002	N/A	N/A
Multi-Device Positioning Controller	ETS-Lindgren	2090	5002	N/A	N/A
Antenna Tower	ETS-Lindgren	2175	5002	N/A	N/A
Boresight Antenna Tower	ETS-Lindgren	2171B	5002	N/A	N/A
Turntable	ETS-Lindgren	2188	5002	N/A	N/A
MXG Analog Microwave Signal generator 100 KHz - 20 GHz	Agilent	N5183A	6501148	02/22	02/23
Cable Sets 9 kHz-18GHz (7mtr LLEF 142)	-	-	-	02/22	02/23
Cable Sets 9 kHz-6GHz RE Cbl Set (Horn Ant)	-	-	-	02/22	02/23
Cable Up to 18 GHz	SUCOFLEX	104PE	21323	02/22	02/23

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9. Appendix 2: Antenna Factor

Antenna Factor Biconilog Antenna, Model Number: 3142D S/N: 00146488 SII No. 6503046 3 m distance

No.	f / MHz	ACF / dB/m	f / MHz	AF / dB/m
1	30	22.7	200	16.7
2	35	20.4	250	18.0
3	40	17.8	300	19.8
4	45	15.7	400	22.7
5	50	14.2	500	25.8
6	60	13.0	600	27.4
7	70	13.0	700	28.4
8	80	12.4	800	30.0
9	90	13.3	900	31.3
10	100	14.2	1000	32.8
11	120	13.3	1250	35.8
12	140	13.3	1500	42.9
13	160	14.6	1750	36.1
14	180	16.3	2000	34.6

Double Ridged Waveguide Antenna Model Number: 3115 S/N 0143138 3m distance

No.	f / MHz	AF / dB/m	f / MHz	AF / dB/m	f / MHz	AF / dB/m
1	1000	23.6	7000	36.7	13000	39.7
2	1500	25.6	7500	37.3	13500	40.3
3	2000	28.2	8000	37.0	14000	41.0
4	2500	27.8	8500	37.6	14500	41.0
5	3000	29.3	9000	37.8	15000	39.6
6	3500	30.7	9500	38.0	15500	38.8
7	4000	31.8	10000	38.3	16000	39.1
8	4500	32.1	10500	38.6	16500	40.0
9	5000	32.9	11000	38.6	17000	40.9
10	5500	32.9	11500	38.9	17500	42.3
11	6000	34.0	12000	38.8	18000	42.5
12	6500	35.3	12500	38.9		

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10. Appendix 3: Test illustrations





Picture 1 Radiated spurious emission test setup.

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Picture 2 Radiated spurious emission test setup (continuation).



Picture 3. Conducted emission

END OF THE DOCUMENT