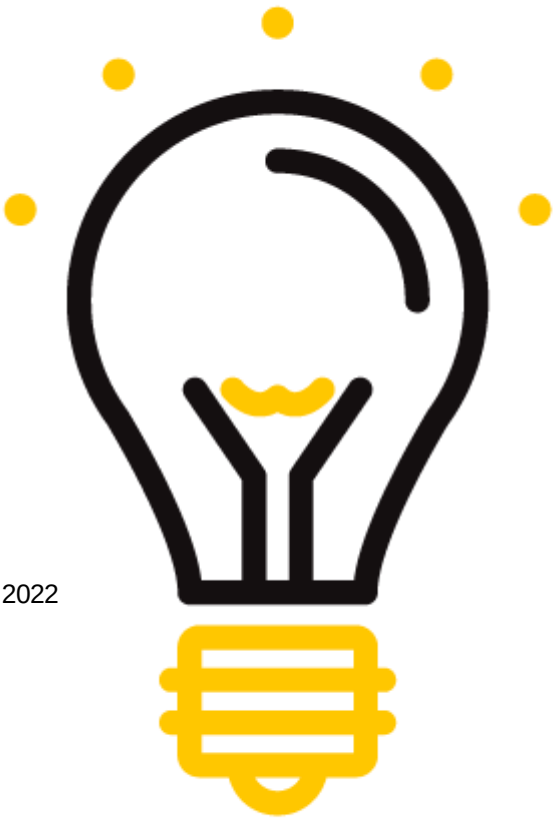
NEUROS MEDICAL INC

TEST REPORT

SCOPE OF WORK
EMC TESTING – THE ALTIUS SYSTEM (IMPLANTABLE)

REPORT NUMBER
105246853BOX-011.FCC

ISSUE DATE
September 16, 2024



DOCUMENT CONTROL NUMBER
IEC 60601-1-2 ed 4.1 EMC Report Shell Rev. October 2022

EMC TEST REPORT

(FULL COMPLIANCE)

Report Number: 105246853BOX-011.FCC
Project Number: G105246853

Report Issue Date: 09/16/2024

Model(s) Tested: THE ALTIUS SYSTEM
Model(s) Partially Tested: None
Model(s) Not Tested but declared equivalent by the client: None

Standards: FCC 47CFR Part 15 Subpart B: 01/2023
FCC 47CFR Part 15.209 Subpart C: 01/2023

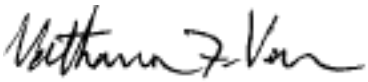
Tested by:
Intertek
70 Codman Hill Road
Boxborough, MA 01719
USA

Client:
Neuros Medical Inc
35010 Chardon Road, Suite 210
Willoughby, OH 44094
USA

Report prepared by:

Kouma Sinn / Sr. EMC Staff Engineer

Report reviewed by:



Vathana Ven / Sr. EMC Staff Engineer

Table of Contents

1 Introduction and Conclusion

The tests indicated in section 2.0 were performed on the product constructed as described in section 4.0. The remaining test sections are the verbatim text from the actual data sheets used during the investigation. These test sections include the test name, the specified test Method, a list of the actual Test Equipment Used, documentation Photos, Results and raw Data. No additions, deviations, or exclusions have been made from the standard(s) unless specifically noted in the relevant section of this report.

Based on the results of our investigation, we have concluded the product tested **complies** with the requirements of the standard(s) indicated. The results obtained in this test report pertain only to the item(s) tested. Intertek does not make any claims of compliance for samples or variants which were not tested.

2 Test Summary

Section	Test full name	Result
3	Client Information	--
4	Description of Equipment Under Test and Variant Models	--
5	System Setup and Method	--
6	Radiated Emissions FCC 47CFR Part 15 Subpart B: 01/2023 FCC 47CFR Part 15.209 Subpart C: 01/2023	Pass

3 Client Information

This EUT was tested at the request of:

Client: Neuros Medical Inc
35010 Chardon Road, Suite 210
Willoughby, OH 44094
USA

Contact: Raymond Zackowski
Telephone: 4805161383
Email: rzackowski@neurosmedical.com

4 Description of Equipment Under Test and Variant Models

Manufacturer: Neuros Medical Inc
35010 Chardon Road, Suite 210
Willoughby, OH 44094
USA

Equipment Under Test			
Description	Manufacturer	Model Number	Serial Number
Patient Controller	Neuros Medical	FG-604-000	0331, 0332,0333
Programmer Wand	Neuros Medical	FG-606-000	0765, 0757, 0761
Altius IPG	Neuros Medical	FG-601-000	0326,0383,0388

Receive Date:	01/10/2023
Received Condition:	Good
Type:	Production

Description of Equipment Under Test (provided by client)
The equipment under test is a patient controller and programmer wand that are intended to be used with the Altius system for treating residual limb pain and phantom pain in lower limb amputees. The Implanted system consists of an implanted IPG (Implantable Pulse Generator) and one or two cuff electrodes.

Equipment Under Test Power Configuration			
Rated Voltage	Rated Current	Rated Frequency	Number of Phases
5VDC USB	N/A	DC	N/A

Operating modes of the EUT:

No.	Descriptions of EUT Exercising
1	Patient controller continuous transmitting at 20 kHz
2	Programmer wand continuous transmitting at 20 kHz. Altius IPG transmitting at 19kHz.

Software used by the EUT:

No.	Descriptions of EUT Exercising
1	Patient controller 0.2
2	Programmer wand 1.0.0.9 or 1.0.1.0
3	Altius IPG Software used by EUT: Altius IPG 1.3-1.3 or 1.5-1.5

Variant Models:

The following variant models were not tested as part of this evaluation; but have been identified by the manufacturer as being electrically identical models, depopulated models, or with reasonable similarity to the model(s) tested. Intertek does not make any claims of compliance for samples or variants which were not tested.

None

5 System Setup and Method

Cables					
ID	Description	Length (m)	Shielding	Ferrites	Termination
1	AC Mains to AC/DC Adapter	1.5	None	None	AC Mains Source

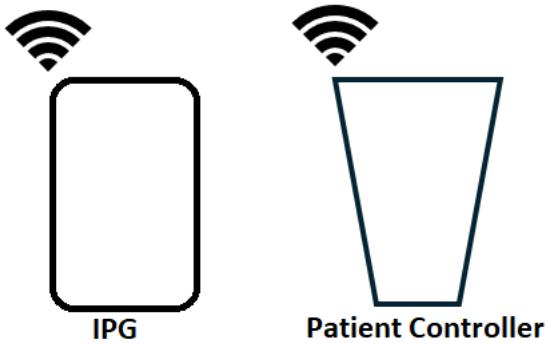
Support Equipment			
Description	Manufacturer	Model Number	Serial Number
PAPC	Lenovo	FG-608-000	PF12Y4CJ, PF12Y2GB, PF12Y2H5

5.1 Method:

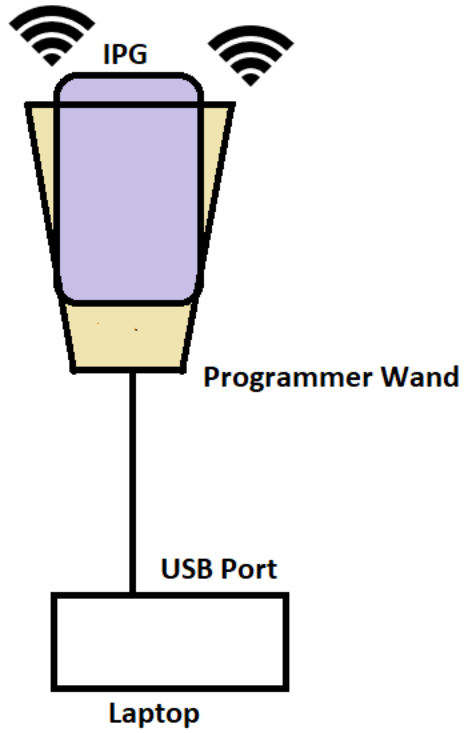
Tests are performed in accordance with ANSI C63.10:2013 and ANSI C63.4:2014.

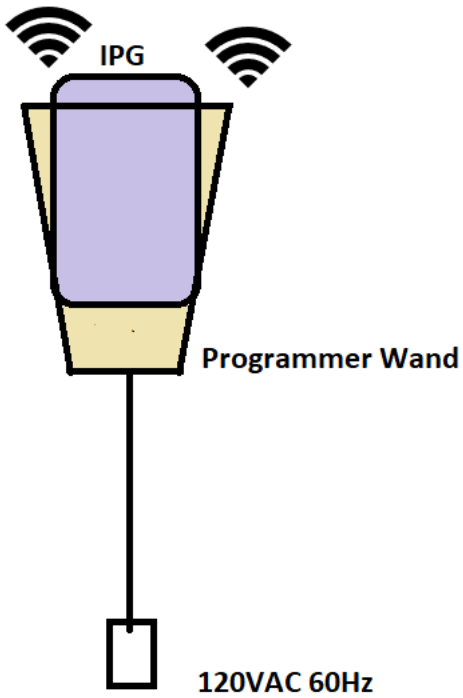
5.2 EUT Block Diagram:

Patient Controller Block Diagram



Programmer Wand Block Diagram





6 Radiated Emissions

6.1 Method

Tests are performed in accordance with ANSI C63.10:2013 and ANSI C63.4:2014.

TEST SITE: 10m ALSE

The 10m ALSE is 13m (Length) x 21m (Depth) x 10m (Height) with the effective size in terms of space from the tips of the absorber is 12m (Length) x 20m (Depth) x 8.5m (Height). This chamber achieves broadband performance using a unique arrangement of hybrid and ferrite tile absorber. This chamber has a built in 3m diameter turntable (Embedded type). The metal structure of the table makes electrical connection around the entire circumference of the turntable to the ground plane with a metal brush type connection. The turntable is located on one end of the chamber and the antennas are mounted 3 and 10 meters away at the other end of the chamber on the adjustable an Antenna Mast. The antenna mast is a non-conductive bore sighted type with remote control of antenna height and polarization. The Antenna Mast and the turntable can be remotely controlled through the controller located in the adjacent Control room. A Styrofoam table 80 cm high is used for table-top equipment.

Measurement Uncertainty

Measurement	Frequency Range	Expanded Uncertainty (k=2)	Ucispr
Radiated Emissions, 10m	30-1000 MHz	4.9 dB	6.3 dB
Radiated Emissions, 3m	30-1000 MHz	4.5 dB	6.3 dB
Radiated Emissions, 3m	1-6 GHz	4.4 dB	5.2 dB
Radiated Emissions, 3m	6-15 GHz	5.2 dB	5.5 dB
Radiated Emissions, 3m	15-18 GHz	4.8 dB	5.5 dB
Radiated Emissions, 3m	18-40 GHz	4.8 dB	N/A

As shown in the table above our radiated emissions U_{lab} is less than the corresponding U_{CISPR} reference value in CISPR 16-4-2 Table 1, hence the compliance of the product is only based on the measured value, and no measurement uncertainty correction is required, based on CISPR 22 and CISPR 11 (for 2006 and later revisions) Clause 11.

Sample Calculation

The field strength is calculated by adding the Antenna Factor and Cable Factor, and subtracting the Amplifier Gain (if any) from the measured reading. The basic equation with a sample calculation is as follows:

FS = RA + AF + CF - AG
Where FS = Field Strength in dBμV/m
RA = Receiver Amplitude (including preamplifier) in dBμV
CF = Cable Attenuation Factor in dB
AF = Antenna Factor in dB/m
AG = Amplifier Gain in dB

In the following table(s), the reading shown on the data table reflects the preamplifier gain. An example for the calculations in the following table is as follows.

Assume a receiver reading of 52.0 dBμV is obtained. The antenna factor of 7.4 dB/m and cable factor of 1.6 dB is added. The amplifier gain of 29 dB is subtracted, giving a field strength of 32 dBμV/m. This value in dBμV/m was converted to its corresponding level in μV/m.

RA = 52.0 dBμV
AF = 7.4 dB/m
CF = 1.6 dB
AG = 29.0 dB
FS = 32 dBμV/m

To convert from dBμV to μV or mV the following was used:

$UF = 10^{(NF / 20)}$ where UF = Net Reading in μV
NF = Net Reading in dBμV

Example:

FS = RA + AF + CF – AG = 52.0 + 7.4 + 1.6 – 29.0 = 32.0
$UF = 10^{(32\ dB\mu V / 20)}$ = 39.8 μV/m

Alternately, when BAT-EMC Emission Software is used, the "Level" includes all losses and gains and is compared directly in the "Margin" column to the "Limit". The "Correction" includes Antenna Factor, Preamp, and Cable Loss. These are already accounted for in the "Level" column.

6.2 Test Equipment Used:

Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due
DAV007'	Weather Station Vantage Vue	Davis	6250	MS191212003	03/08/2022	03/08/2023
145108'	EMI Test Receiver (20Hz - 40GHz)	Rohde & Schwarz	ESIB40	100209	06/23/2022	06/23/2023
145-420'	Receiver to floor cable	Utiflex	UFB311A-2-0591-70070	145-420	02/21/2022	02/21/2023
HS003'	10m under floor cable	Huber-Schuner	10m-1	HS003	02/15/2022	02/15/2023
145-422'	10Amp Pre-amp to under floor	Utiflex	UFB311A-0-2756-70070	145-422	02/21/2022	02/21/2023
145-424'	9kHz to 40GHz Cable	Huber and Suhner	Sucoflex	145-424	02/15/2022	02/15/2023
PRE10'	30-1000MHz pre-amp	ITS	PRE10	PRE10	02/15/2022	02/15/2023
145145'	Broadband Hybrid Antenna 30 MHz - 3 GHz	Sunol Sciences Corp.	JB3	A122313	06/16/2022	06/16/2023
145-414'	Cable 145-414	Huber + Suhner	3m Track A cable	145-414	07/14/2022	07/14/2023
CBL2014-1'	RG58C/U, BNC (M)	Pomona	2249-C-180	CBL2014-1	02/10/2022	02/10/2023
ETS003'	9kHz-30MHz Active Loop Antenna	ETS Lindgren	6502	00143396	09/06/2022	09/06/2023

Software Utilized:

Name	Manufacturer	Version
BAT-EMC	Nexio	3.18.0.16

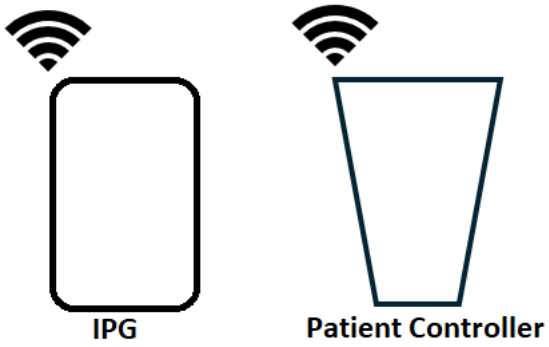
6.3 Results:

The sample tested was found to Comply.

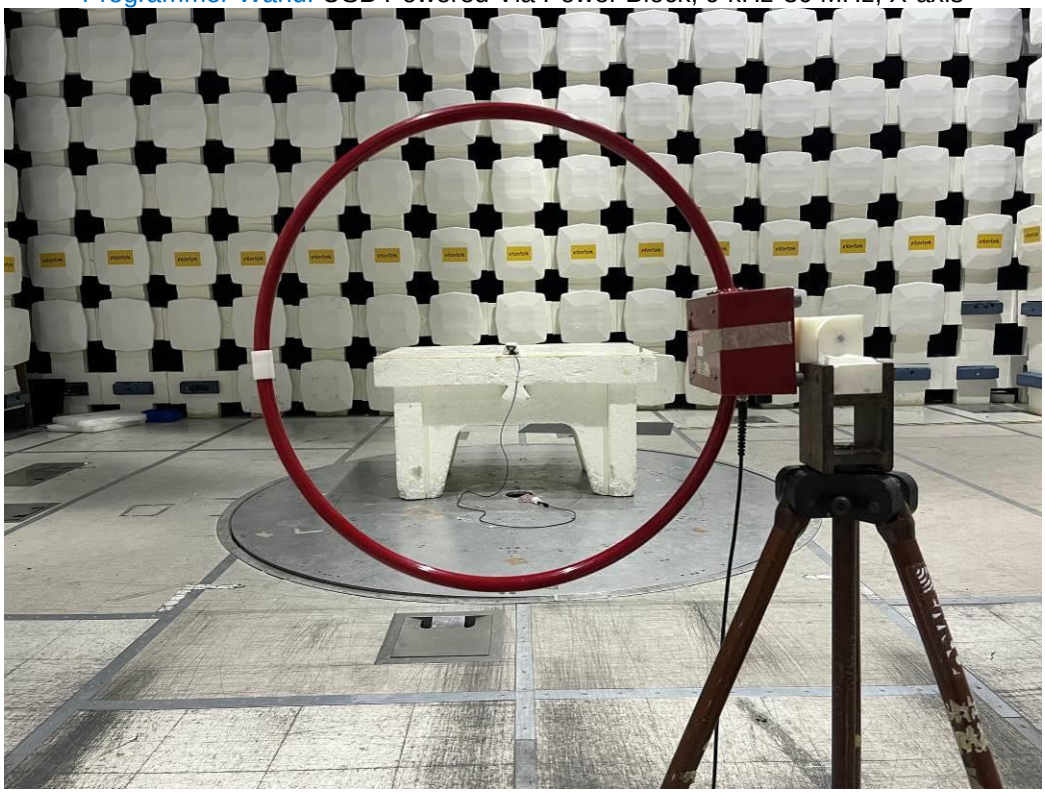
6.4 Setup Photographs:

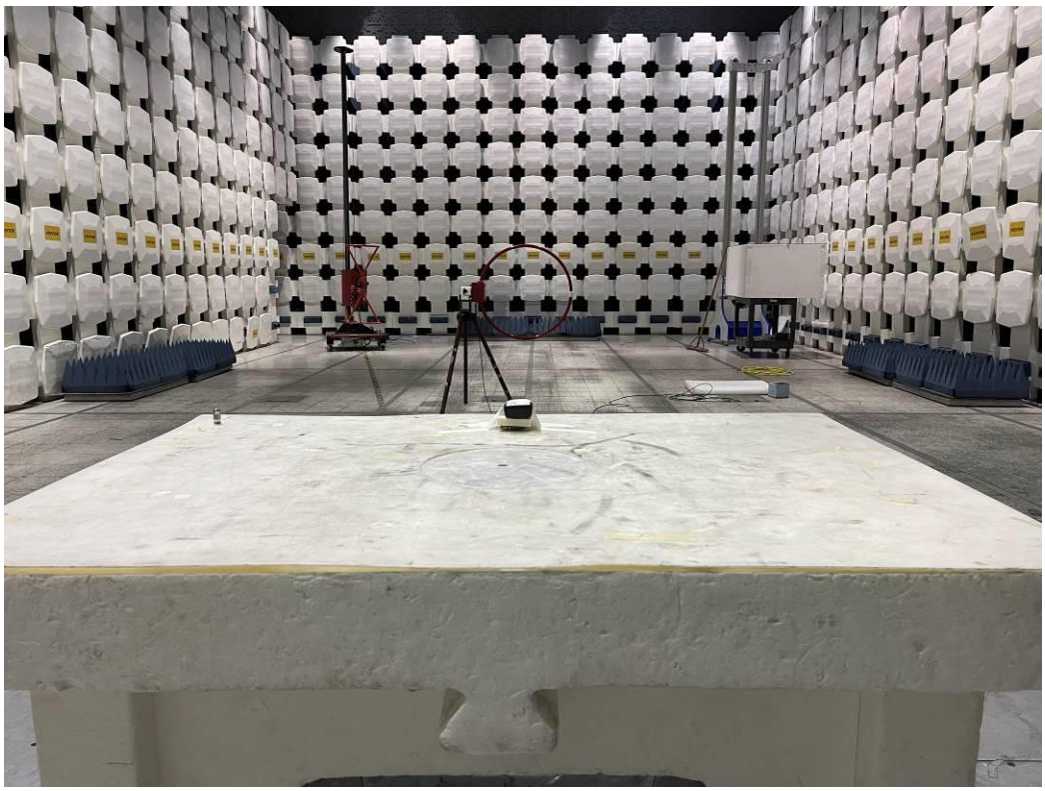
– Photos not available –

The EUT was set up as below with 10cm separation and was placed at the edge of the foam table.

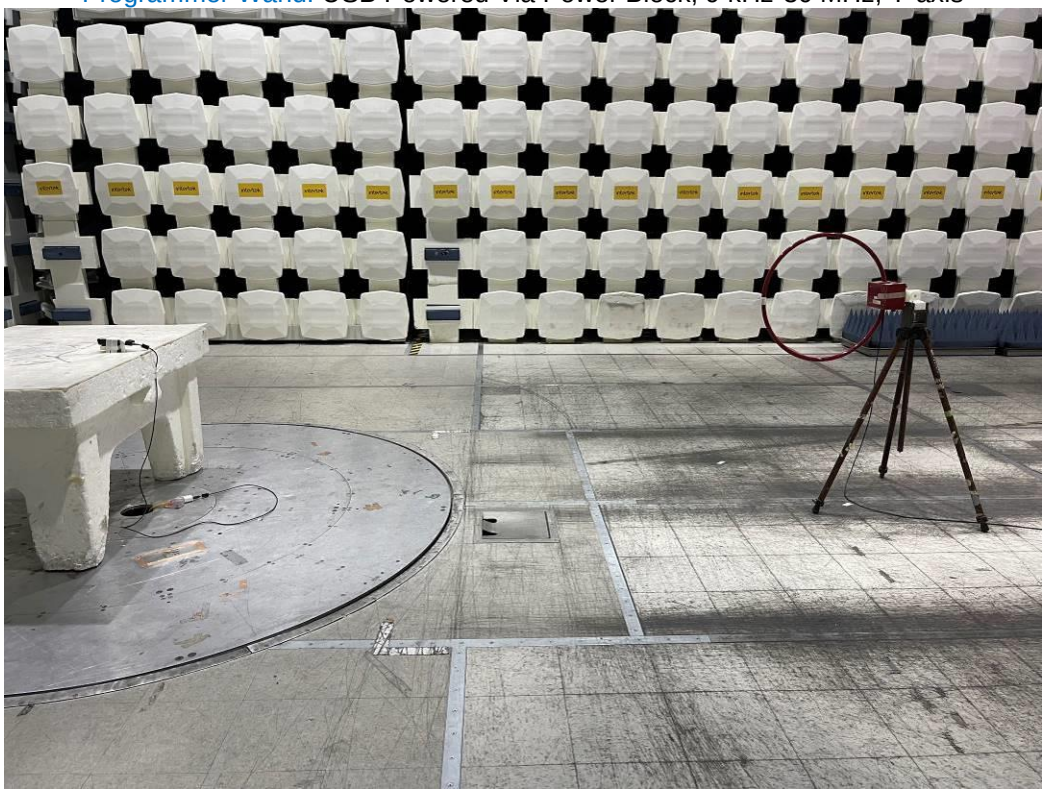


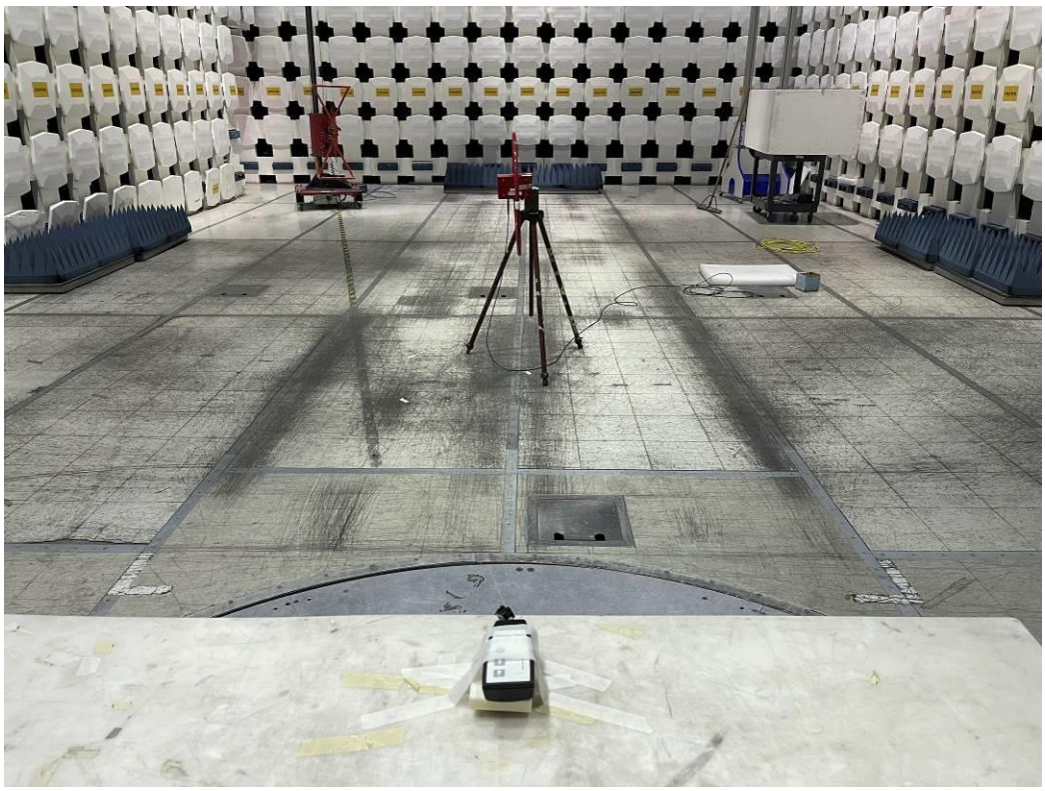
Programmer Wand: USB Powered Via Power Block, 9 kHz-30 MHz, X-axis



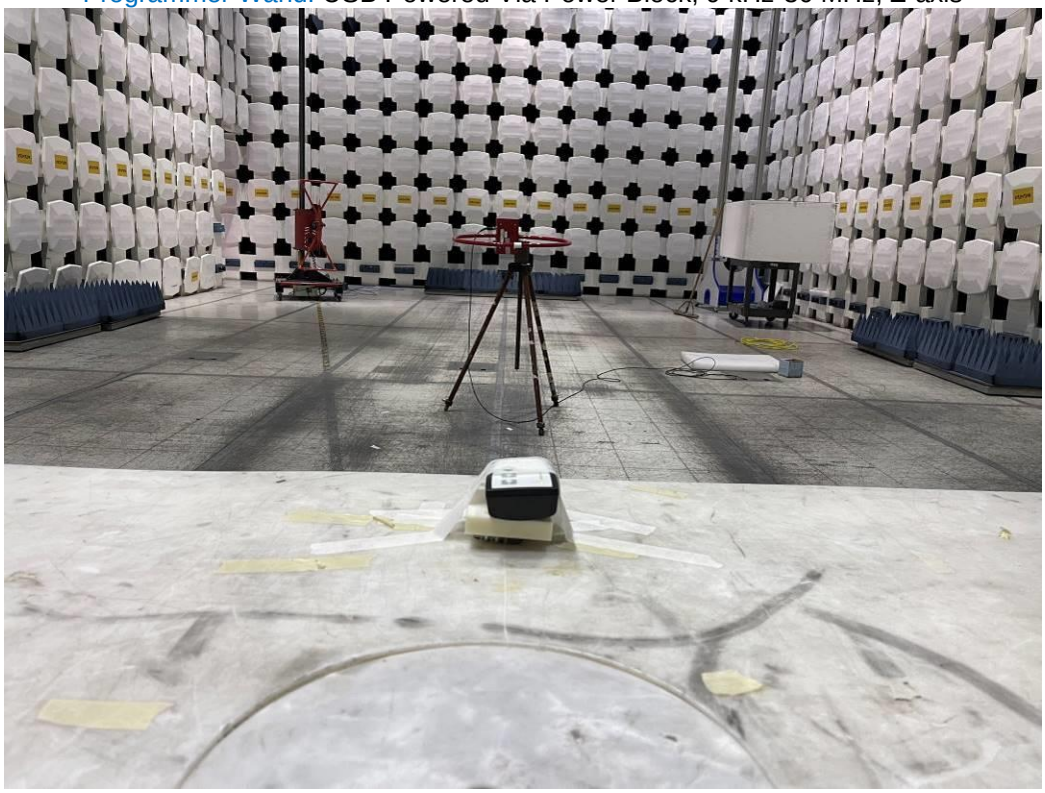


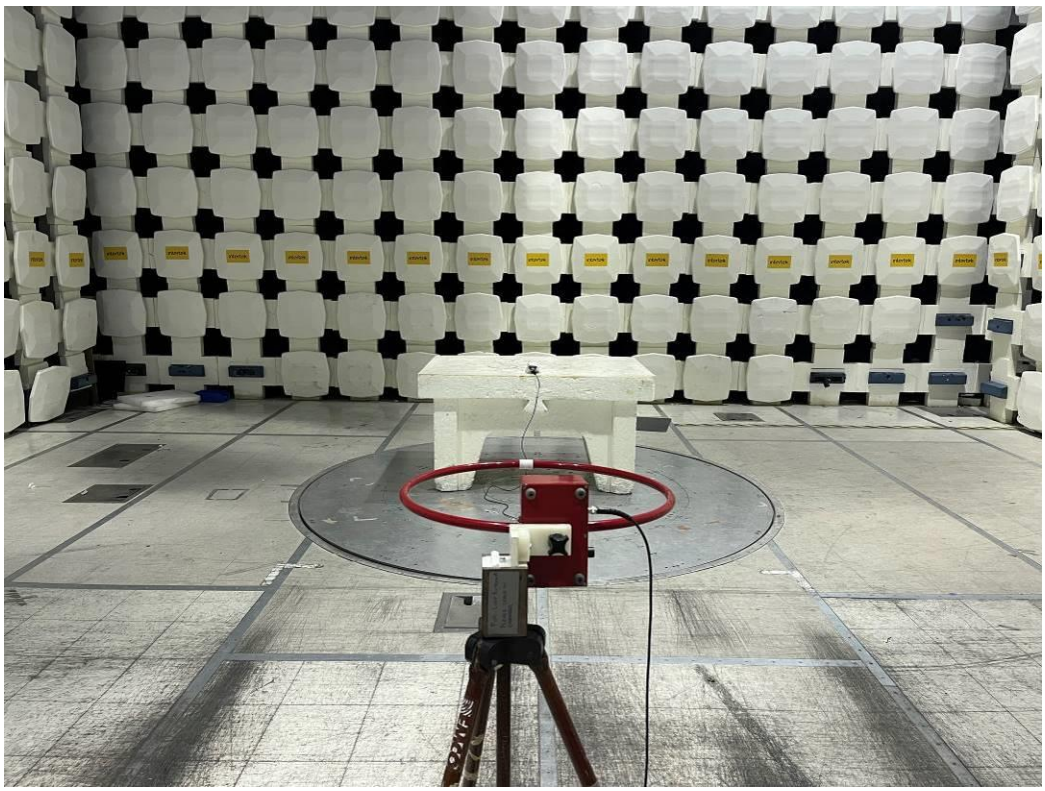
Programmer Wand: USB Powered Via Power Block, 9 kHz-30 MHz, Y-axis





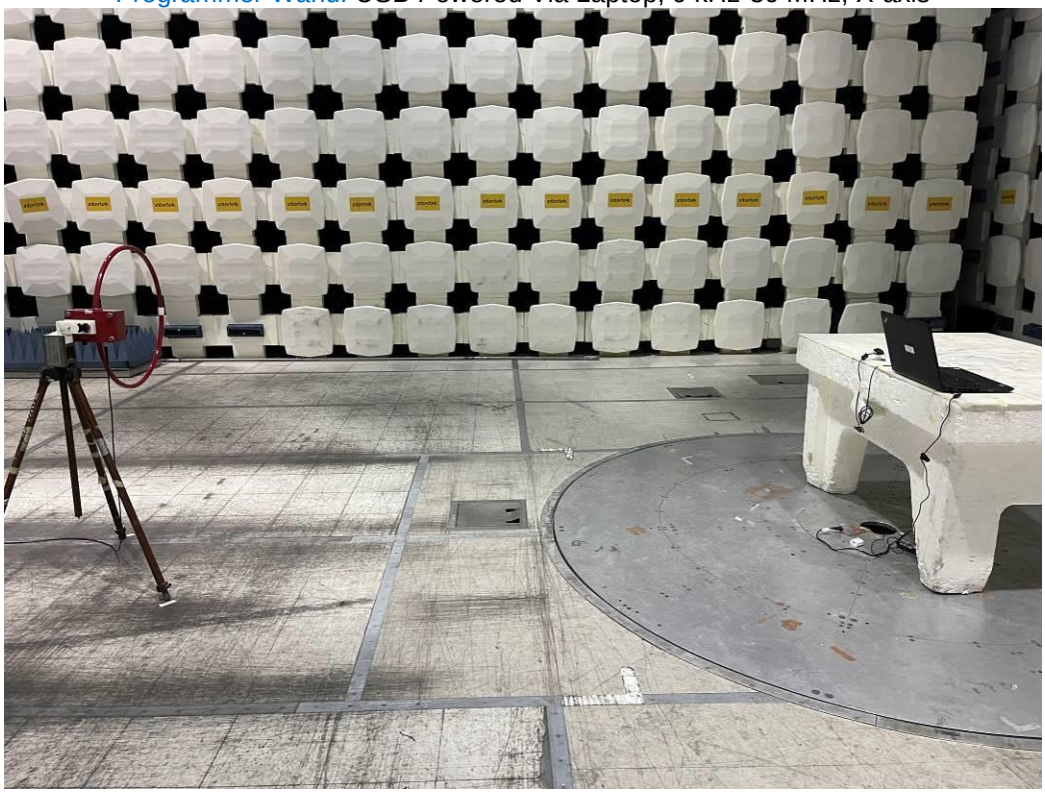
Programmer Wand: USB Powered Via Power Block, 9 kHz-30 MHz, Z-axis

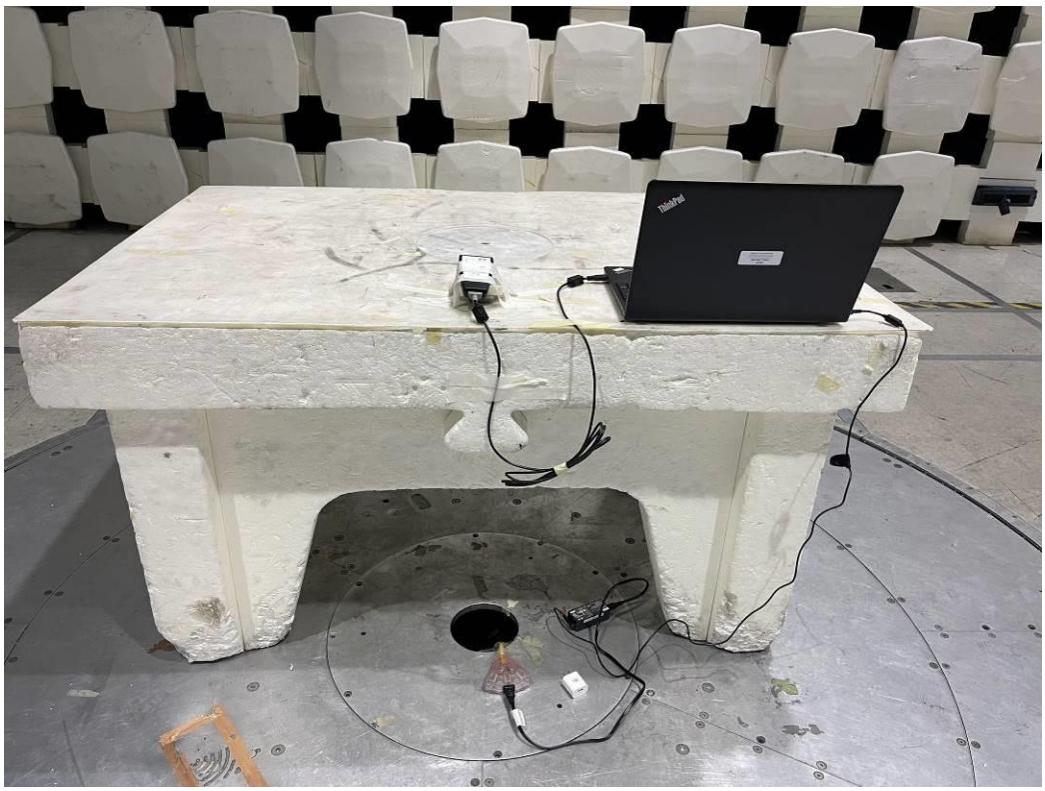




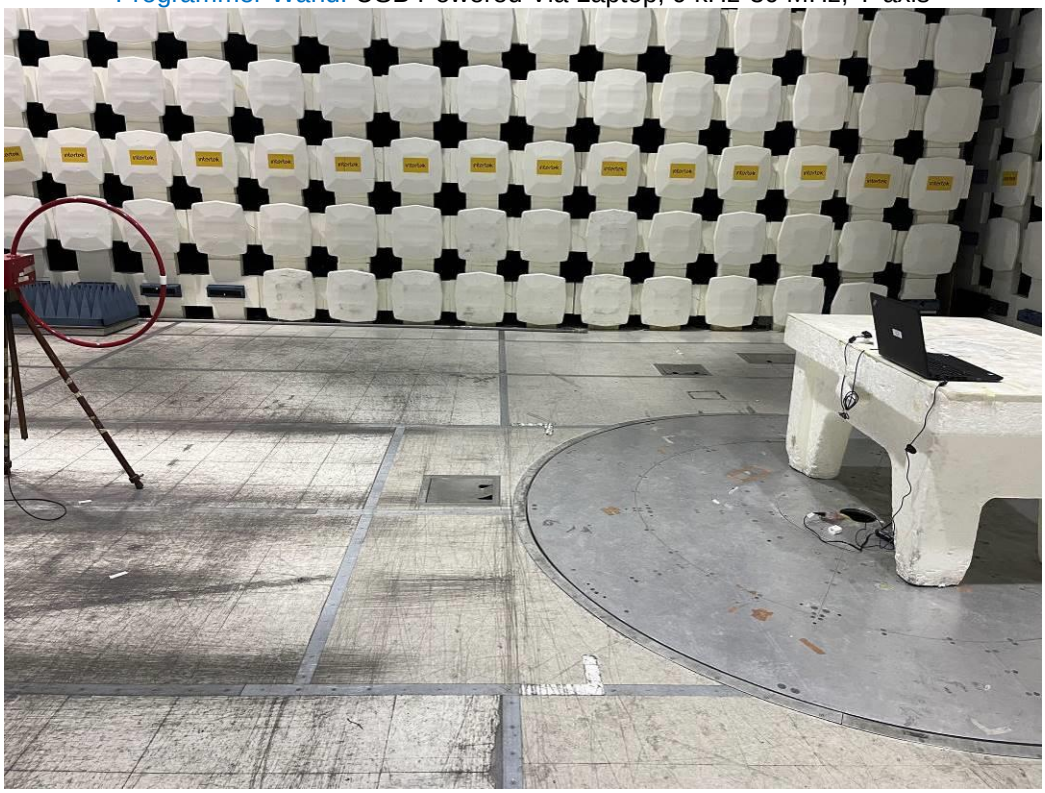
Programmer Wand: USB Powered Via Power Block, 30-1000 MHz

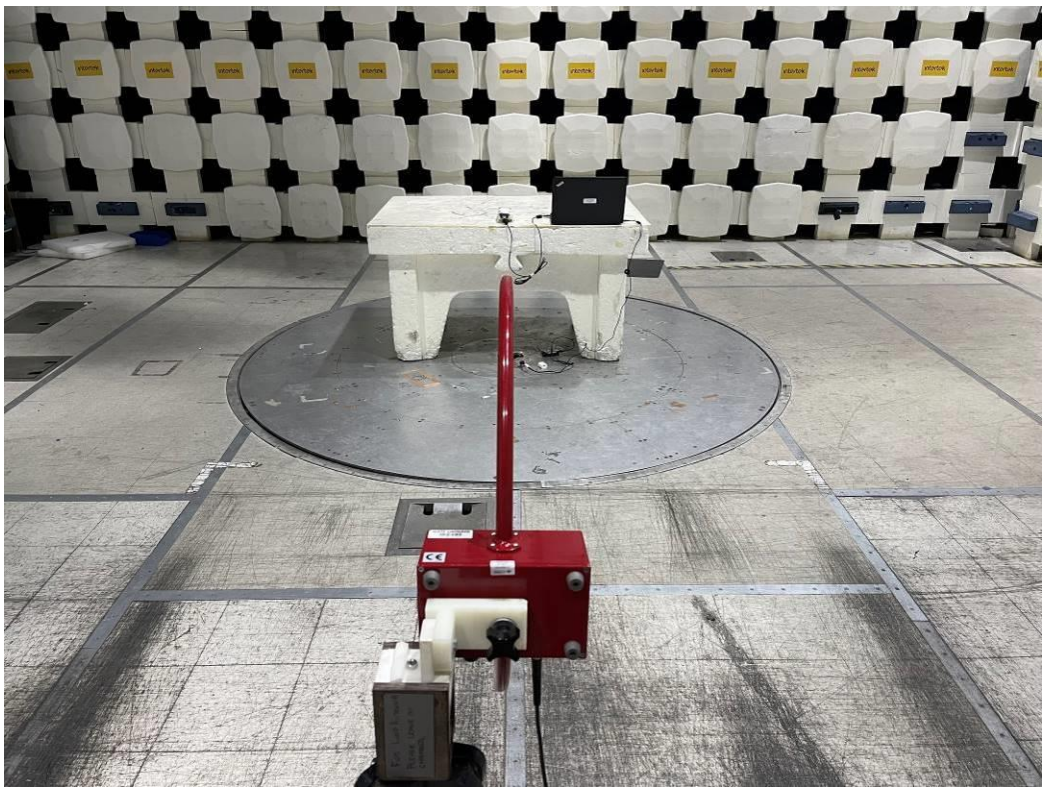
Programmer Wand: USB Powered Via Laptop, 9 kHz-30 MHz, X-axis



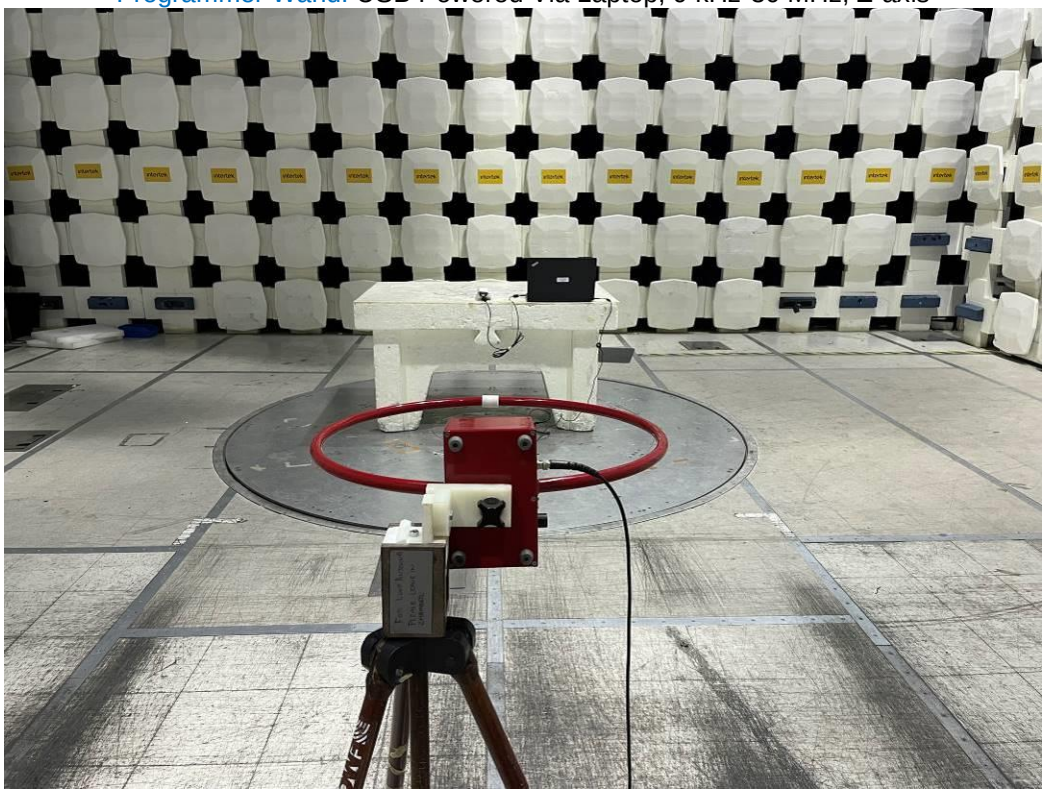


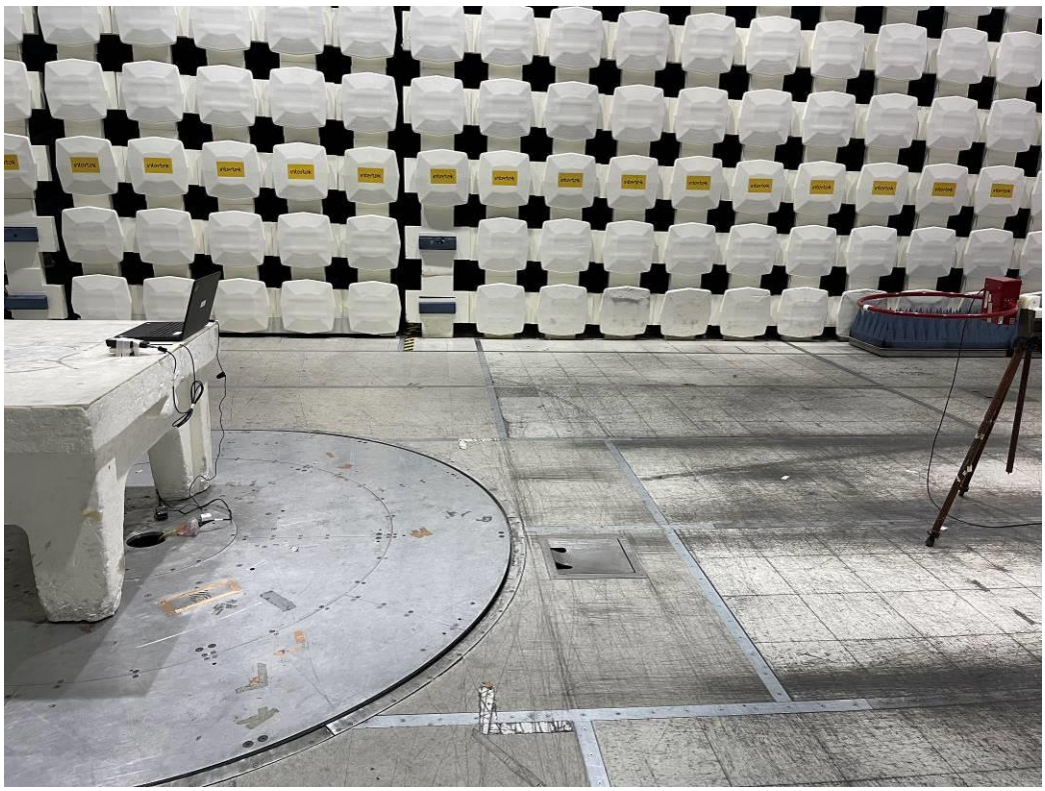
Programmer Wand: USB Powered Via Laptop, 9 kHz-30 MHz, Y-axis



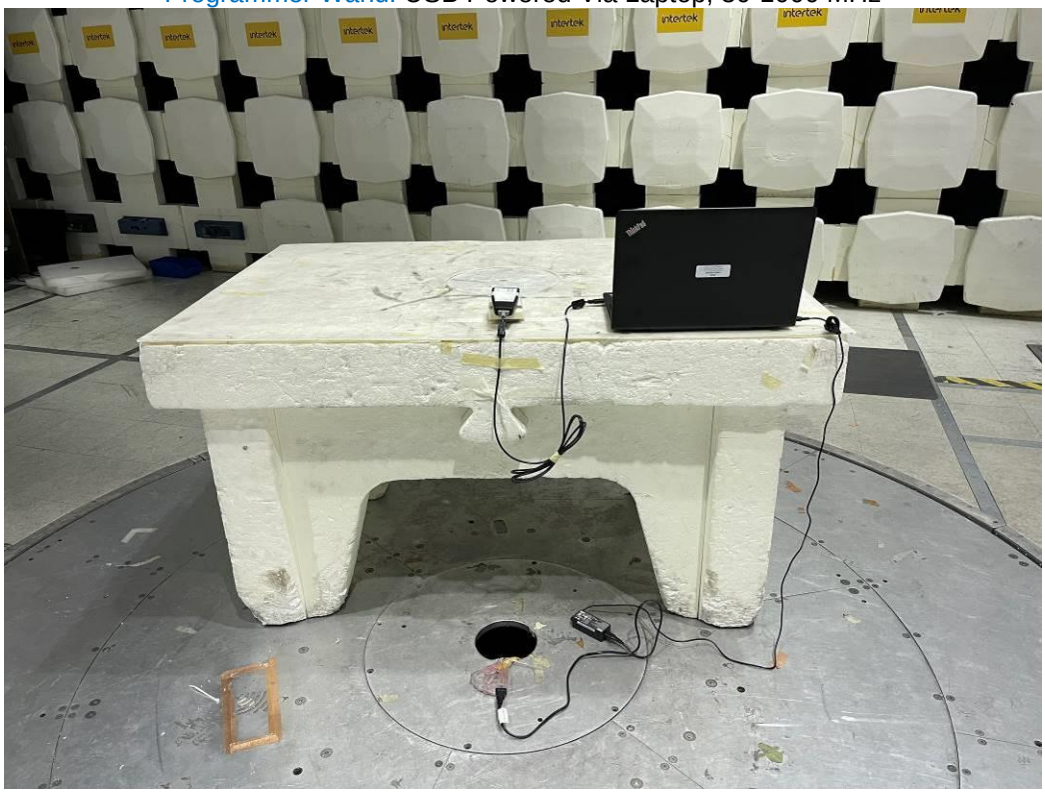


Programmer Wand: USB Powered Via Laptop, 9 kHz-30 MHz, Z-axis





Programmer Wand: USB Powered Via Laptop, 30-1000 MHz



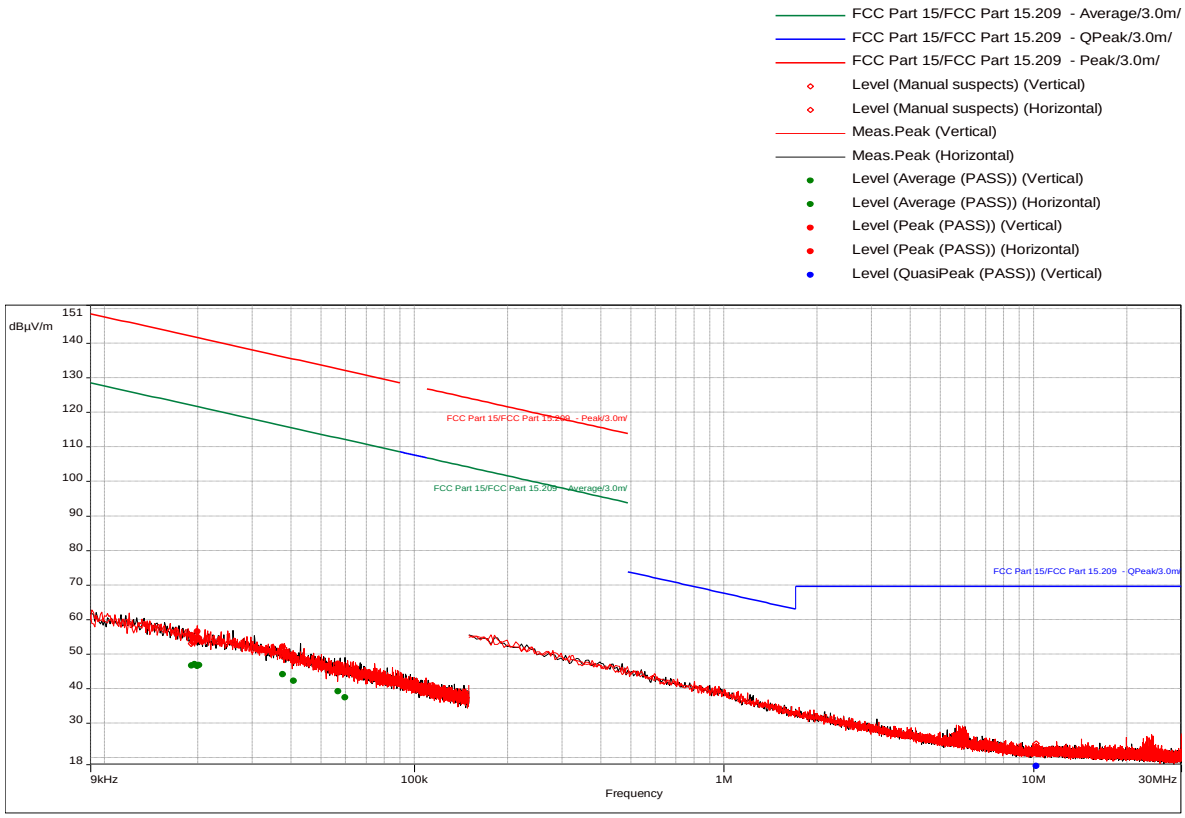
6.5 Plots/Data:

Patient Controller: Internal Battery Powered, RE 9 kHz-30 MHz, 3 meters

Test Information:

Date and Time	1/12/2023 3:16:54 PM
Client and Project Number	Neuros _ G105246853 Config 3
Engineer	William Young
Comments	Patient Controller: Internal Battery Powered, RE 9 kHz-30 MHz, 3 meters

Graph:



Results:

QuasiPeak (PASS) (1)

Frequency (MHz)	Level (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Azimuth (°)	Height (m)	Pol.	RBW (Hz)	Correction (dB)
10.20797368	15.36	69.54	-54.18	0.00	1.00	Vertical	9000.00	11.38

Peak (PASS) (9)

Frequency (MHz)	Level (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Azimuth (°)	Height (m)	Pol.	RBW (Hz)	Correction (dB)
0.01947368421	54.75	141.80	-87.06	177.00	1.00	Vertical	200.00	14.84
0.02021052632	54.60	141.50	-86.90	121.00	1.00	Vertical	200.00	14.53
0.03763157895	52.10	136.10	-84.00	39.00	1.00	Vertical	200.00	13.05
0.04073157895	49.70	135.41	-85.71	200.00	1.00	Vertical	200.00	12.68
10.20797368	21.38	69.54	-48.16	0.00	1.00	Vertical	9000.00	11.38
0.01910526316	55.37	141.98	-86.61	43.00	1.00	Horizontal	200.00	15.04
0.01988421053	56.57	141.63	-85.06	301.00	1.00	Horizontal	200.00	14.61
0.05684210526	47.27	132.52	-85.25	189.00	1.00	Horizontal	200.00	11.75
0.05984210526	44.73	132.07	-87.34	65.00	1.00	Horizontal	200.00	11.75

Average (PASS) (8)

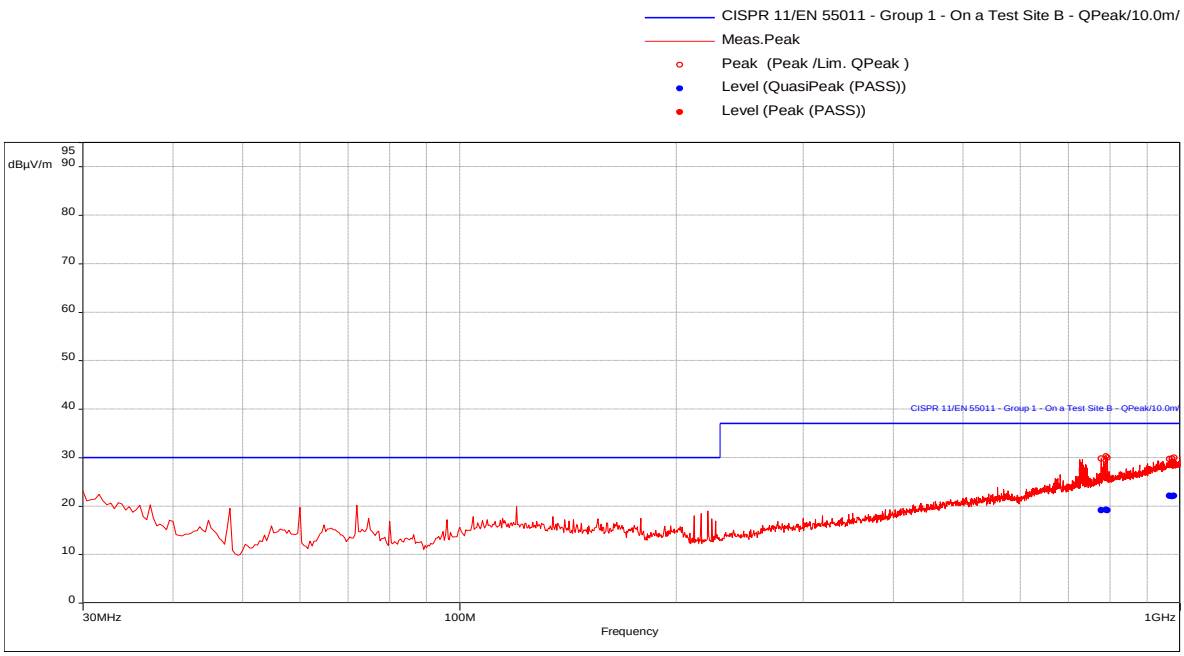
Frequency (MHz)	Level (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Azimuth (°)	Height (m)	Pol.	RBW (Hz)	Correction (dB)
0.01947368421	47.07	121.80	-74.73	177.00	1.00	Vertical	200.00	14.84
0.02021052632	46.82	121.50	-74.68	121.00	1.00	Vertical	200.00	14.53
0.03763157895	44.16	116.10	-71.94	39.00	1.00	Vertical	200.00	13.05
0.04073157895	42.29	115.41	-73.12	200.00	1.00	Vertical	200.00	12.68
0.01910526316	46.71	121.98	-75.28	43.00	1.00	Horizontal	200.00	15.04
0.01988421053	46.57	121.63	-75.06	301.00	1.00	Horizontal	200.00	14.61
0.05684210526	39.19	112.52	-73.33	189.00	1.00	Horizontal	200.00	11.75
0.05984210526	37.43	112.07	-74.64	65.00	1.00	Horizontal	200.00	11.75

Patient Controller: Internal Battery Powered, RE 30-1000 MHz, 10 meters

Test Information:

Date and Time	1/12/2023 10:05:00 AM
Client and Project Number	Neuros _ G105246853 Config 3
Engineer	William Young
Comments	Patient Controller: Internal Battery Powered, RE 30-1000 MHz, 10 meters

Graph:



Results:

QuasiPeak (PASS) (6)

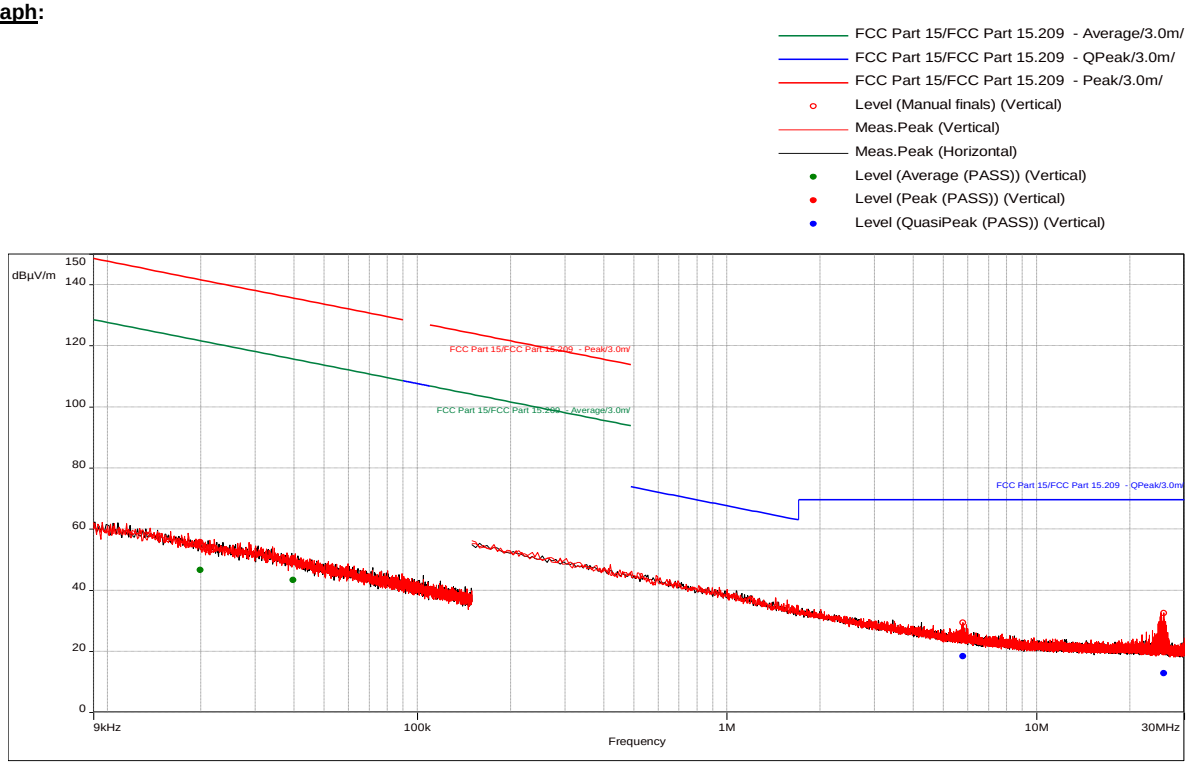
Frequency (MHz)	Level (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Azimuth (°)	Height (m)	Pol.	RBW (Hz)	Correction (dB)
777.2	19.12	37.00	-17.88	24.00	1.43	Vertical	120000.00	-7.53
789.0736842	19.21	37.00	-17.79	309.00	3.64	Vertical	120000.00	-7.44
793.0736842	19.17	37.00	-17.83	227.00	2.57	Vertical	120000.00	-7.41
966.4	22.18	37.00	-14.82	88.00	1.79	Horizontal	120000.00	-4.06
975.2631579	22.05	37.00	-14.95	169.00	3.71	Vertical	120000.00	-4.11
981.3789474	22.16	37.00	-14.84	207.00	2.52	Vertical	120000.00	-4.08

Programmer Wand: USB Powered Via Power Block -120VAC 60Hz, RE 9kHz-30MHz, 3 meters

Test Information:

Date and Time	1/18/2023 10:49:22 AM
Client and Project Number	Neuros Medical
Engineer	Kouma Sinn
Temperature	22 C
Humidity	27 %
Atmospheric Pressure	993 mbar
Comments	Programmer Wand: USB Powered Via Power Block -120VAC 60Hz, RE 9kHz-30MHz, 3 meters

Graph:



Results:

QuasiPeak (PASS) (2)

Frequency (MHz)	Level (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Azimuth (°)	Height (m)	Pol.	RBW (Hz)	Correction (dB)
5.774289474	18.36	69.54	-51.18	3.00	1.00	Vertical	9000.00	11.46
25.78223684	12.86	69.54	-56.68	125.00	1.00	Vertical	9000.00	10.46

Peak (PASS) (4)

Frequency (MHz)	Level (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Azimuth (°)	Height (m)	Pol.	RBW (Hz)	Correction (dB)
0.01989473684	55.74	141.63	-85.89	285.00	1.00	Vertical	200.00	14.60
5.774289474	24.78	69.54	-44.76	3.00	1.00	Vertical	9000.00	11.46
25.78223684	19.70	69.54	-49.84	125.00	1.00	Vertical	9000.00	10.46
0.03968421053	50.46	135.63	-85.17	111.00	1.00	Vertical	200.00	12.79

Average (PASS) (2)

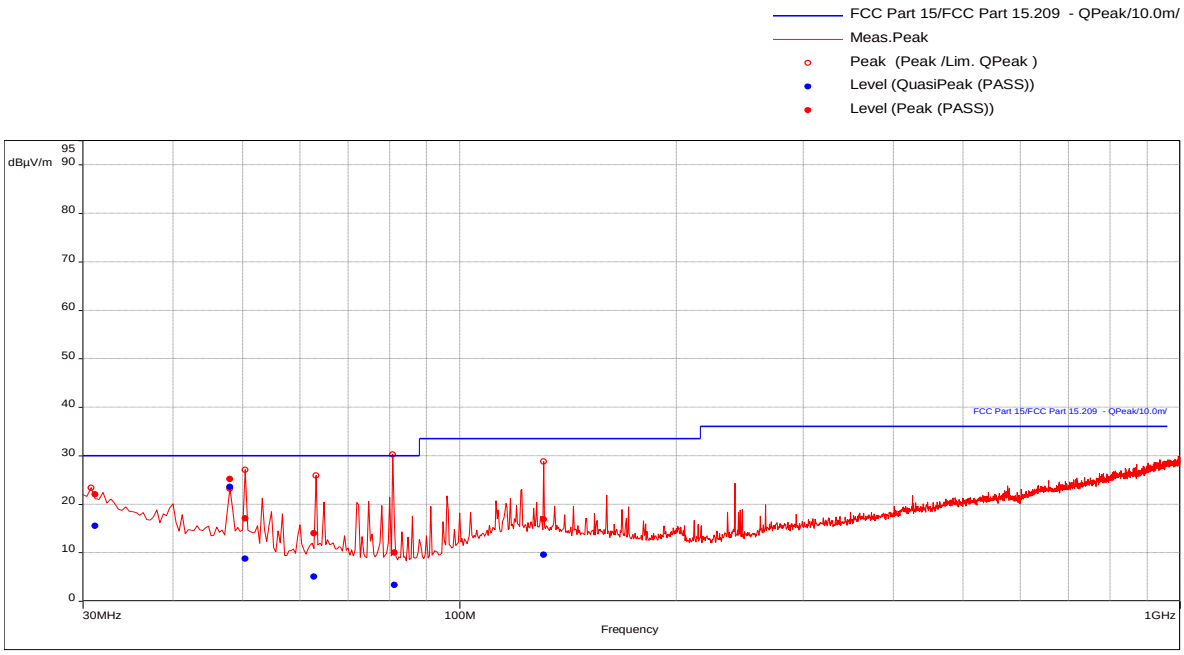
Frequency (MHz)	Level (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Azimuth (°) (dB)	Height (m) (dB)	Pol. (dB)	RBW (dB)	Correction (dB)
0.01989473684	46.60	121.63	-75.03	285.00	1.00	Vertical	200.00	14.60
0.03968421053	43.36	115.63	-72.27	111.00	1.00	Vertical	200.00	12.79

Programmer Wand: USB Powered Via Power Block -120VAC 60Hz, RE 30-1000 MHz, 10 meters

Test Information:

Date and Time	1/18/2023 9:02:40 AM
Client and Project Number	Neuros Medical
Engineer	Kouma Sinn
Temperature	22 C
Humidity	27 %
Atmospheric Pressure	993 mbar
Comments	Programmer Wand: USB Powered Via Power Block -120VAC 60Hz, 30-1000 MHz, 10 meters

Graph:



Results:

QuasiPeak (PASS) (6)

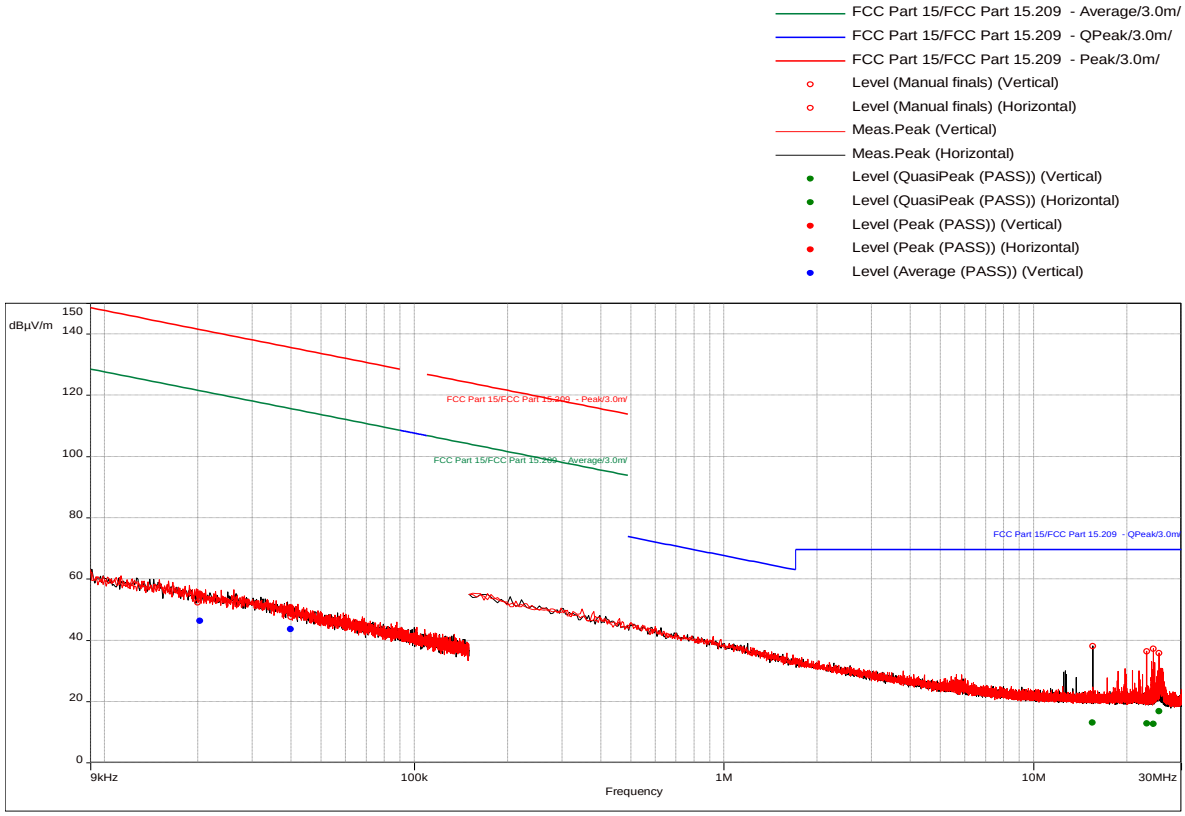
Frequency (MHz)	Level (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Azimuth (°)	Height (m)	Pol.	RBW (Hz)	Correction (dB)
31.08421053	15.57	30.00	-14.43	242.00	3.47	Vertical	120000.00	-13.17
48	23.56	30.00	-6.44	228.00	1.98	Vertical	120000.00	-24.31
50.4	8.78	30.00	-21.22	39.00	1.42	Vertical	120000.00	-25.09
62.97894737	5.08	30.00	-24.92	235.00	2.00	Vertical	120000.00	-25.11
81.05263158	3.39	30.00	-26.61	97.00	3.71	Vertical	120000.00	-25.07
130.9263158	9.57	33.50	-23.93	242.00	3.52	Vertical	120000.00	-18.38

Programmer Wand: USB Powered Via Laptop -120VAC 60Hz, RE 9kHz-30MHz, 3 meters

Test Information:

Date and Time	1/18/2023 2:45:36 PM
Client and Project Number	Neuros Medical
Engineer	Kouma Sinn
Temperature	22 C
Humidity	27 %
Atmospheric Pressure	993 mbar
Comments	Programmer Wand: USB Powered Via Laptop -120VAC 60Hz, RE 9kHz-30MHz, 3 meters

Graph:



Results:

Average (PASS) (2)

Frequency (MHz)	Level (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Azimuth (°)	Height (m)	Pol.	RBW (Hz)	Correction (dB)
0.02031578947	46.31	121.45	-75.15	309.00	1.00	Vertical	200.00	14.53
0.03984210526	43.60	115.61	-72.01	33.00	1.00	Vertical	200.00	12.77

Peak (PASS) (6)

Frequency (MHz)	Level (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Azimuth (°)	Height (m)	Pol.	RBW (Hz)	Correction (dB)
24.40689474	20.24	69.54	-49.30	24.00	1.00	Vertical	9000.00	10.68
0.02031578947	55.20	141.45	-86.26	309.00	1.00	Vertical	200.00	14.53
0.03984210526	50.84	135.61	-84.77	33.00	1.00	Vertical	200.00	12.77
23.19710526	20.37	69.54	-49.17	24.00	1.00	Vertical	9000.00	10.82
25.46013158	23.04	69.54	-46.50	18.00	1.00	Vertical	9000.00	10.54
15.50992105	20.81	69.54	-48.73	67.00	1.00	Horizontal	9000.00	11.42

QuasiPeak (PASS) (4)

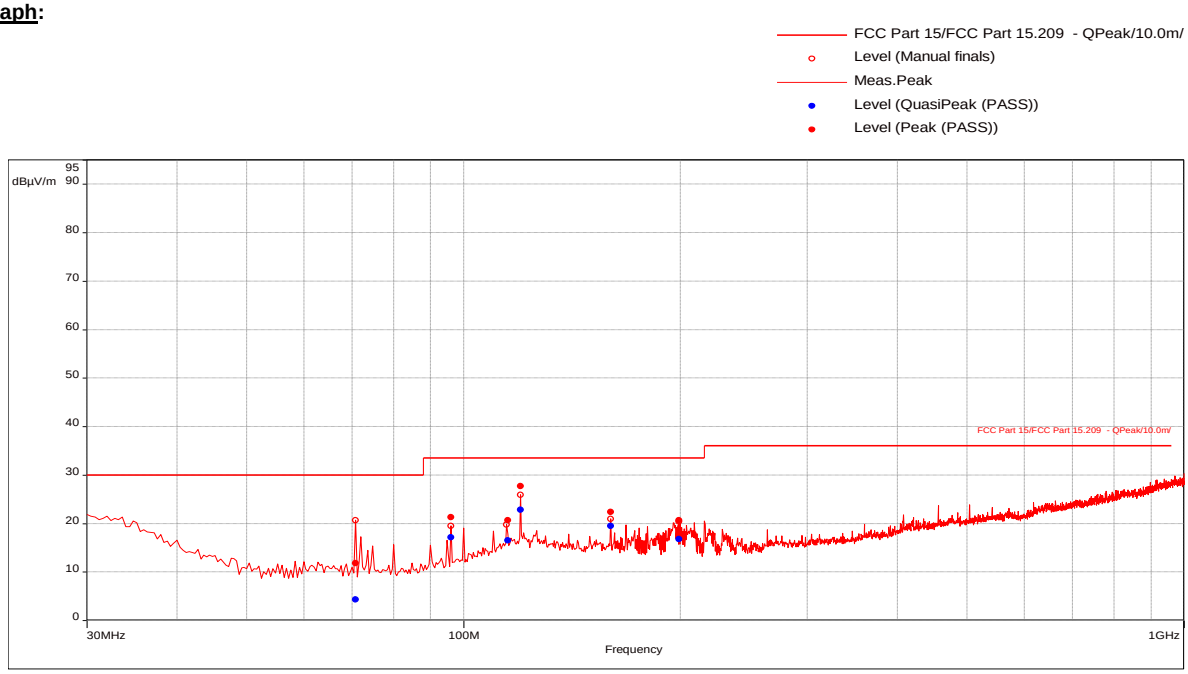
Frequency (MHz)	Level (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Azimuth (°)	Height (m)	Pol.	RBW (Hz)	Correction (dB)
24.40689474	12.72	69.54	-56.82	24.00	1.00	Vertical	9000.00	10.68
23.19710526	12.86	69.54	-56.68	24.00	1.00	Vertical	9000.00	10.82
25.46013158	16.80	69.54	-52.74	18.00	1.00	Vertical	9000.00	10.54
15.50992105	13.08	69.54	-56.46	67.00	1.00	Horizontal	9000.00	11.42

Programmer Wand: USB Powered Via Laptop -120VAC 60Hz, RE 30-1000 MHz, 10 meters

Test Information:

Date and Time	1/19/2023 4:36:49 PM
Client and Project Number	Neuros 01/19/2023
Engineer	Kouma Sinn
Temperature	21 C
Humidity	29 %
Atmospheric Pressure	1003 mbar
Comments	Programmer Wand: USB Powered Via Laptop -120VAC 60Hz, RE 30-1000 MHz, 10 meters

Graph:



Results:

QuasiPeak (PASS) (6)

Frequency (MHz)	Level (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Azimuth (°) (dB)	Height (m) (dB)	Pol. (dB)	RBW (dB)	Correction (dB)
70.67368421	4.31	30.00	-25.69	351.00	3.12	Vertical	120000.00	-24.69
96.03157895	17.13	33.50	-16.37	339.00	1.34	Vertical	120000.00	-23.16
115.0210526	16.54	33.50	-16.96	292.00	2.23	Vertical	120000.00	-18.92
120	22.88	33.50	-10.62	323.00	1.29	Vertical	120000.00	-18.38
160	19.48	33.50	-14.02	192.00	1.40	Vertical	120000.00	-19.59
199.1052632	16.83	33.50	-16.67	126.00	1.35	Vertical	120000.00	-19.20

Product Standard: FCC 47CFR Part 15.209 and FCC 47CFR Part 15 Subpart B				Limit applied: All Class B Pretest Verification w/BB source: Yes			
Test Date	Test Personnel/ Initials	Supervising Engineer/ Initials	Input Voltage	Mode	Atmospheric Data		
					Temp C°	Relative Humidity %	Atmospheric Pressure mbar
01/12/2023	William Young	N/A	Internal Battery	Patient Controller	22	20	1015
01/18/2023	Kouma Sinn	N/A	USB Block Powered, Laptop USB Powered	Program Wand	22	27	993
01/19/2023	Kouma Sinn	N/A	Laptop USB Powered	Program Wand	21	29	1003

Deviations, Additions, or Exclusions:

7 Revision History

Revision Level	Date	Report Number	Prepared By	Reviewed By	Notes
0	09/16/2024	105246853BOX-011.FCC	KPS	VFV	Original Issue