Test Report No.7412313969/1

Applicant: **BlueWind Medical Ltd.**

Equipment Under Test:
Revi™ Peripheral Nerve Stimulation System

Product Name: **Revi™ Wearable Device**

Model: **E03 ECU**

Issued by
The Standards Institution of Israel
Electrical & Electronics Laboratory
EMC Branch

ANAB ANSI National Accreditation Board ACCREDITED ISO/IEC 17025 TESTING LABORATORY
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Applicant:	BlueWind Medical Ltd.
Address:	6 Maskit St., Business Park, building B4614002, P.O.B 4101Herzliya, Israel
Sample for test selected by:	The customer
The date of test:	14/7, 17/7/2024

Description of Equipment under Test (EUT):	Revi™ Peripheral Nerve Stimulation System
Name:	Revi™ Wearable Device
Model:	E03 ECU
Serial No:	ECU S/N 3223240600192, Implant S/N 119010312A4
Manufactured by:	BlueWind Medical Ltd.

Reference Standards:

- CFR 47 FCC. Rules and Regulations:
  Part 15. “Radio frequency devices”,
  Subpart B: Unintentional radiators (2020).

Test Result: The EUT was found to be in compliance with the requirements of:

- FCC Part 15 Subpart B Class B

Details see in clause 1.

The presented Test Report #7412313969/1 supersedes the previous one #7412313969. The aim of the revision: a type in the Implant S/N has been corrected (see page 2).	
This Test Report contains 23 pages and may be used only in its entirety.	This Test Report applies only to the specimen tested and may not be applied to other specimens of the same product.

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1. Summary of Test Results

Test Description	Ref. Standard	Class/ line	Test result
Radiated emission Freq. range: 30MHz – 1GHz	FCC Part 15 Subpart B	Class B Operation & Charging mode	Complies
Conducted emission Freq. range:150 kHz - 30 MHz		Class B 120VAC mains	Complies

Electrical & Electronics
Laboratory
12 February 2025

Approved by: Eng. Yuri Rozenberg
Position: Head of Branch

Written by: Galit Gorodetsky
Position: Technical Writer

Tested by: Alex Konkov
Position: Testing Engineer

2. EUT Description

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

2.1. General description

The Equipment under Test (hereinafter: EUT) is an electrical medical equipment incorporate an External Control Unit (ECU) and Implant. The ECU power and control the implantable device intended for indoor/home neurostimulation of the tibial nerve.

The ECU powers and controls the implantable device intended for neurostimulation of the tibial nerve.

The EUT is intended for indoor/home use.

ECU transmits electrical power at frequency 6.78MHz (ISM band).
FCC ID 2BAXD-E02-0.

ECU comprises RF Bluetooth module (BLE) transmitting at 2.4GHz.
BLE module inside the ECU is a certify module FCC ID HSW2832.
BLE module has passed FCC Part 15 Subpart B test and data is available in SII EMC Lab report #7412309734.

After implantation patient receives wall adapter for battery charging and ECU for neurostimulation treatment.

CP intended only for physician use in clinics.

External Control Unit (ECU)

The ECU is comprised of the following:

- Transmitting Antenna
- Electronic Assembly – produces the energy for the Transmitting Antenna, controls treatment, communicates with the Implant, and CP/PC
- Rechargeable battery
- Audible and Visual Indicators (buzzer, LEDs)
- Housing – component which houses the electronic assembly and indicators
- Buttons for Interface (“Power”, “+”, and “-“)
- Charge/Communication interface with USB-C connector

The ECU is designed to be worn around the leg by the patient during treatment or utilized by the physician during the implantation procedure. To accommodate varying leg circumferences, the ECU will have an adjustable closing mechanism (pocket).

Charger

The ECU charging is allowed only with the dedicated charger supplied with the ECU.

The connection between the charger to ECU is done via regular USB-C type cable (supplied with the ECU).

Implant

The Implant consists of an electronic assembly. On the outer surface of the Implant there are two ring electrodes, which provide the stimulation current to the tissue surrounding the Implant.The electrodes are connected electrically to the encapsulated electronic assembly. The electronic assembly comprises of an energy receiving antenna and electronic circuit. The electronic circuit is powered wirelessly using magnetic coupling between the receiving antenna in the Implant and the source antenna in the ECU. The main functions of the electronic circuit are the stimulation current output and communication with the ECU to receive the control commands and send the values of various electrical parameters.

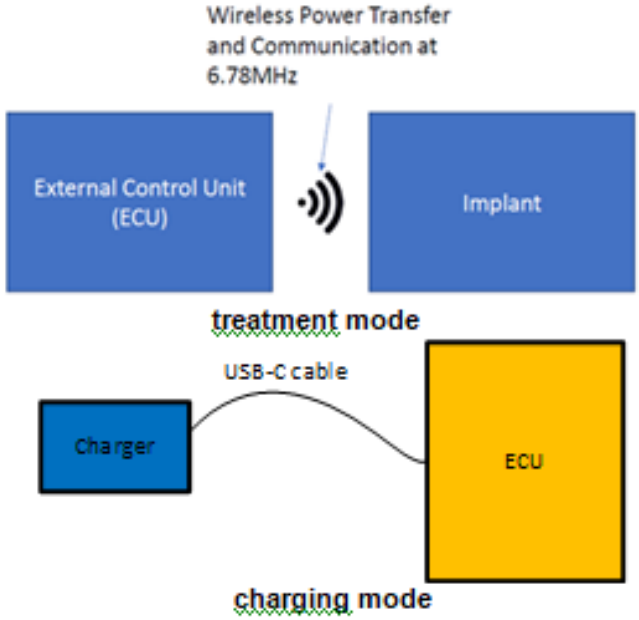
The EUT dimensions:

ECU	36.06 (H) x 48.93 (W) without bar x 96.5 (L) mm approx.
AC Adapter (Charger)	55 x 27 x 55 mm approx.
Implant	30 x 2.7 mm approx.

AC Adapter for Charging: 100V-240V

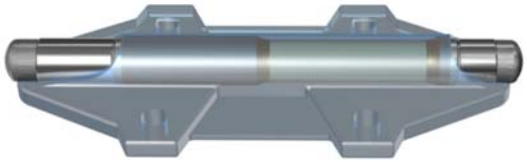
Treatment performed using the internal battery only: 3.6 VDC Li-Ion battery nominal 2350mA.

The EUT block diagram is shown in Picture 1, the components view - in Picture 2.



Picture # 1. EUT block diagram

E03 ECU



Implant

Power adapter and USB-C type cable

Picture # 2.
Revi™ Peripheral Nerve Stimulation System components

2.2. EUT sub-assembling list

Table1. Sub-assemblies list

No.	Description (function)	Manufacturer	Type / Model; P/N
1	External Control Unit (ECU)	BlueWind Medical LTD.	SW version is 7.1.10.196 HW version is based on MA-3000-1300
2	Implant	BlueWind Medical LTD.	Implant SW version – 1.1 Implant HW version – Revision 12
3	Power Adapter 100-240V/5V 1400mA	FRIWO Geratebau GmbH	Type: FW8002.1MUSB/05

2.3. EUT cable / connector list

Table2. Cables and Connectors

No.	Connector's description	Connector's type	Type of Cable	Length (m)	Location	No. of identical connectors
1	AC power	Mains plug (no cable)	No cable	NA	Mains	1
2	USB-C type DC terminal (used for charging of the ECU)	USB-C	Unshielded	<1.5	ECU box	1

2.4. Auxiliary equipment used

Table3. Auxiliary equipment used during the tests

Name	MFR	Model
Jig with circumference of 25cm	BlueWind Medical LTD.	JP-9007 -0931
Digital Oscilloscope 70MHz	Keysight	InfiniiVision DSO-X 2004A
Laptop, Tablet	-	-

2.5. Potential emission sources

Table4. Potential emission sources

Frequency	Location	Remark
13.56MHz	Power Amplifier board of ECU	Power amplifier clock frequency
6.78MHz	Power Amplifier board of ECU	Power amplifier RF transmission frequency
2.4GHz	Main Board of ECU	Bluetooth Module (BLE)
8MHz	Main Board of ECU	ST CPU
3.5MHz to 4.5MHz	Main Board of ECU	DC-DC Auxiliary boost
500kHz 750KHz	USB Board of ECU	DC-DC buck boost for stim
500kHz 750KHz	Main Board of ECU	DC-DC buck boost control
100kHz	Compensation board	DC-DC Fly-back
32.768kHz	Main Board	ECU Real time clock

2.6. EUT setup and operation

Power voltages

120 VAC 50Hz (Charging mode) & Battery (Operation mode)

Tested modes

1. Normal Operation- Treatment at ISM frequency, EUT is powered from the battery.
2. Charging from external Power Adapter. ISM is disabled, BLE enabled.

EUT test setup in charging mode is shown in Picture 3.

Picture # 3. EUT test setup, Charging mode

3. Test specification, Methods and Procedures

CFR 47 FCC.	Rules and Regulations: Part 15. “Radio frequency devices”, Subpart B: Unintentional radiators (2020).
ANSI C63.4:2014	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

4. Additional deviations or exclusions from the test specifications

Not applicable.

5. General conditions

5.1. Location of the Test Site:

All tests were conducted at the EMC Laboratory of the Standards Institution of Israel
Address: 42 Chaim Levanon St., Tel Aviv 6997701 Israel.

5.2. Emission tests:

- For both radiated and conducted measurements, initial scans were made using a peak detector but still using the appropriate CISPR 16 (Quasi-Peak) detector IF bandwidth.
- For conducted emissions, a tolerance limit was set 6 dB below the specification limit. Levels above the tolerance limit were retested using the Quasi-Peak detector or an average detector.
- For radiated emissions, a tolerance limit was set 10 dB below the specification limit. Levels above the tolerance limit were retested using the Quasi-Peak detector.

5.3. Initial visual check and functional test:

Initial visual check and brief built- in- test of the EUT was performed before testing.

The BIT test passed successfully. No external damages were found.

6. Emissions Summary

6.1. Radiated Emission Summary

Tested configurations:

1. Treatment (Operation) mode – EUT is powered from the Battery
   Tx = 6.78MHz (ISM band).
2. Charging mode - EUT is powered from external Power Adapter.

Test procedure:

Power voltage: 120VAC 50 Hz & Battery

The BLE is turned ON during all the tests

The radiated emission measurements were performed as detailed in section 2.6.

The radiated emission measurements were conducted in 3-m semi-anechoic chamber.

The frequency range from 30MHz to 1GHz was investigated.

Antenna used: Biconilog Antenna 20 MHz-6 GHz

The measurements were performed at each frequency where the signal was 10 dB below the limit or less.

The levels were maximized by changing antenna polarization from vertical to horizontal, rotating turntable through 360 degree, varying antenna height from 1m to 4m and rerouting EUT cable.

Measuring equipment settings:

Initial scan:	
Detector type	Peak
Mode	Max hold
Bandwidth	120 kHz (30-1000 MHz)
Step size	Continuous sweep
Sweep time	>1 seconds/MHz

Measurements	
Detector type	Quasi-peak (CISPR)
Bandwidth	120 kHz (30-1000 MHz) 1 MHz (above 1000 MHz)
Observation	>15 seconds
Measurement time	20 seconds/MHz

Test results summary:

Reference standard: FCC Part 15 Subpart B Class B Section 15.109

Power supply/ mode	Freq. range	Polari-zation	Ref. Plot / Table	Result	Remark
Battery (Treatment mode)	30 MHz – 1GHz	V/H	Table 5, Plots 1	**PASS**	All emissions are 5.4dB at least below limits
120 VAC PS (Charging mode)	30 MHz – 1GHz	V/H	Table 6 Plots 2	**PASS**	All QP emissions are 10dB at least below limit

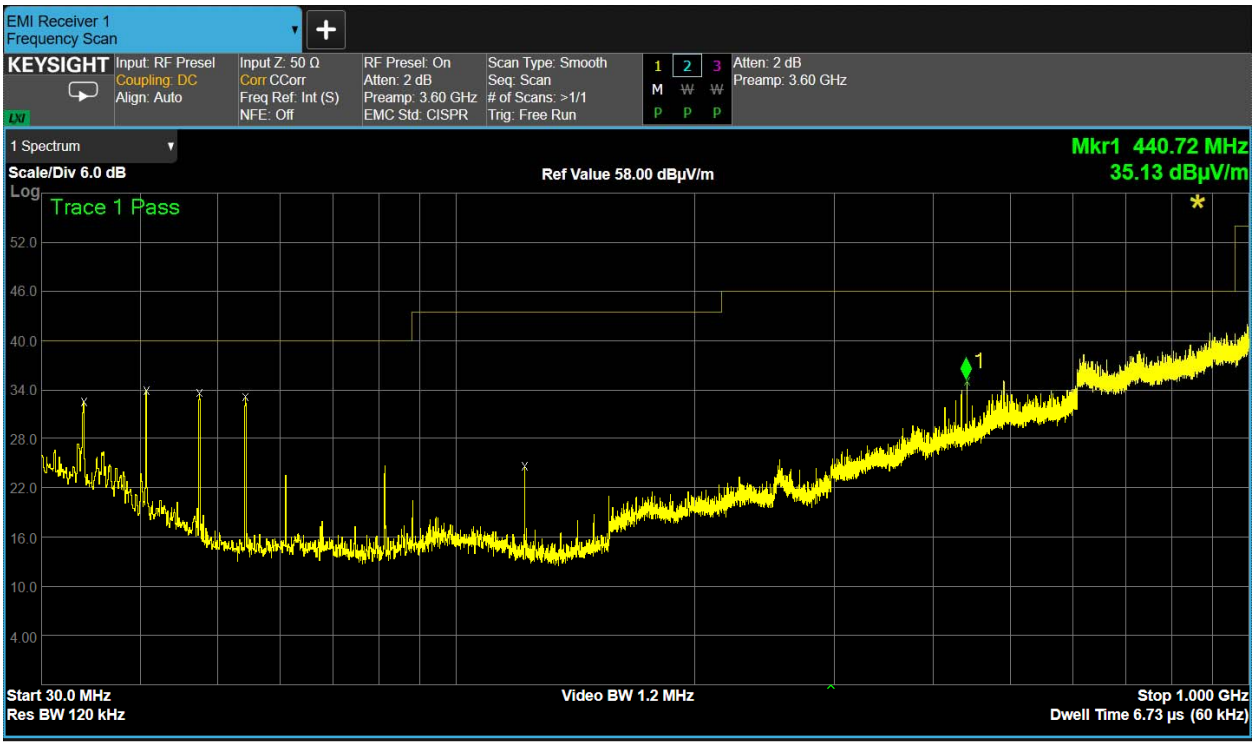
Results:	**Pass**
Specified standard / Class:	FCC Part 15 Subpart B Class B
Frequency range:	30 MHz – 1 GHz
Power supply:	Battery
Measured distance:	3 m
Tested mode:	treatment (operation) mode

Table5. Radiated emission test results

No.	Frequency (MHz)	Antenna Polariz. V/H	Antenna Height (m)	Turn-table Angle (°)	Emission Level (dBµV/m)	Limit @ 3 m (dBµV/m)	Margin (dB)	Result
1	33.9	V	1.0	220	31.9	40.0	-8.1	Pass
2	40.7	V	1.0	217	29.1	40.0	-10.9	Pass
3	47.5	V	1.0	220	34.6	40.0	-5.4	Pass
4	54.2	V	1.0	215	31.5	40.0	-8.5	Pass
5	122.0	V	1.0	200	23.7	43.5	-19.8	Pass
6	440.7	V	1.0	28	29.4	46.0	-16.6	Pass

Note: Emission level = E Reading (dBµV) + Cable loss (dB) + Antenna Factor (dB/m)
For Cable Loss and Antenna Factor refer to Appendix3.

Plot #1. Radiated emission scan



Results:	**Pass**
Specified standard / Class:	FCC Part 15 Subpart B Class B
Frequency range:	30 MHz – 1 GHz
Power supply:	120 VAC
Measured distance:	3 m
Tested mode:	charging

Table6. Radiated emission test results

No.	Frequency (MHz)	Antenna Polariz. V/H	Antenna Height (m)	Turn-table Angle (°)	Emission Level (dBμV/m)	Limit @ 3 m (dBμV/m)	Margin (dB)	Result
1	30.8	V	1.0	227	21.7	40.0	-18.3	Pass
2	42.2	V	1.0	360	23.0	40.0	-17.0	Pass
3	127.9	V	1.0	216	26.2	43.5	-17.3	Pass
4	142.9	V	1.0	246	28.2	43.5	-15.3	Pass
5	187.2	V	1.0	142	26.5	43.5	-17.0	Pass
6	568.6	V	1.0	240	35.2	46.0	-10.8	Pass

Note: Emission level = E Reading (dBμV) + Cable loss (dB) + Antenna Factor (dB/m)
For Cable Loss and Antenna Factor refer to Appendix3.

Plot #2. Radiated emission scan

Sig	Trc	Freq	Peak Amptd	QPD Amptd	EAvg Amptd	Peak LL1 Δ	QPD LL1 Δ	EAvg LL1 Δ	Composite AmpCor	RBW	TimeStamp
1	1	30.777 MHz	27.593 dBμV/m	21.695 dBμV/m	13.902 dBμV/m	-12.407 dB	-18.305 dB	-26.098 dB	16.954 dB	120 kHz (CISPR)	2024/07/15 14:23:26
2	1	42.241 MHz	27.476 dBμV/m	23.031 dBμV/m	14.646 dBμV/m	-12.524 dB	-16.969 dB	-25.354 dB	11.180 dB	120 kHz (CISPR)	2024/07/15 14:57:56
3	1	127.92 MHz	30.610 dBμV/m	26.188 dBμV/m	13.220 dBμV/m	-9.390 dB	-13.812 dB	-26.780 dB	8.008 dB	120 kHz (CISPR)	2024/07/15 14:54:15
4	1	142.92 MHz	33.654 dBμV/m	28.227 dBμV/m	13.478 dBμV/m	-6.346 dB	-11.773 dB	-26.522 dB	8.692 dB	120 kHz (CISPR)	2024/07/15 14:11:08
5	1	187.21 MHz	31.804 dBμV/m	26.531 dBμV/m	17.154 dBμV/m	-8.196 dB	-13.469 dB	-22.846 dB	10.822 dB	120 kHz (CISPR)	2024/07/15 14:55:26
6	1	568.64 MHz	41.297 dBμV/m	35.233 dBμV/m	27.929 dBμV/m	-5.703 dB	-11.767 dB	-19.071 dB	22.500 dB	120 kHz (CISPR)	2024/07/15 14:03:17

6.2. Conducted Emission Summary

Test procedure:

During the measurements EUT was configured and operated as detailed in section 2.6.
Power voltage: 120 VAC 50 Hz Charging mode.

The test was started with an initial scan. Final measurements were performed at the peaks, exceeded the tolerance limit.

Initial scan:	
Detector type	Peak
Mode	Max hold
Bandwidth	9 kHz
Step size	Continuous sweep
Sweep time	>100 msec

Measurements	
Detector type	Quasi-peak (CISPR)
Bandwidth	9 kHz
Observation	>15 seconds

Test results summary:

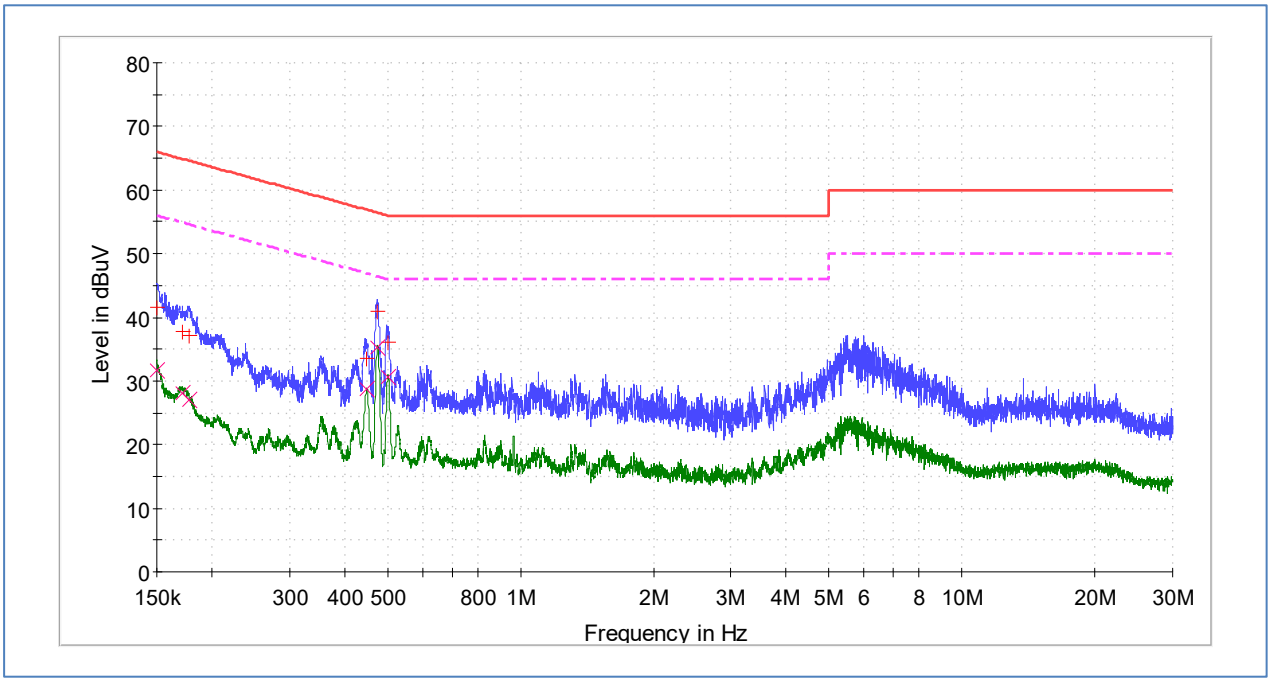
Reference standard : FCC Part 15 Subpart B Class B Section 15.107

Tested line	Meas. equip.	Ref. Plot#	Result	Remarks
120 VAC mains	LISN	#4-5	**PASS**	All emissions are 11dB at least below limit

All measurements were performed with external Power Adapter– Type: FW8002.1 MUSB/05 mfr FRIWO

Results: **Pass**
Specified standard / Class: FCC Part 15 Subpart B Class B
Tested line: 120 VAC mains

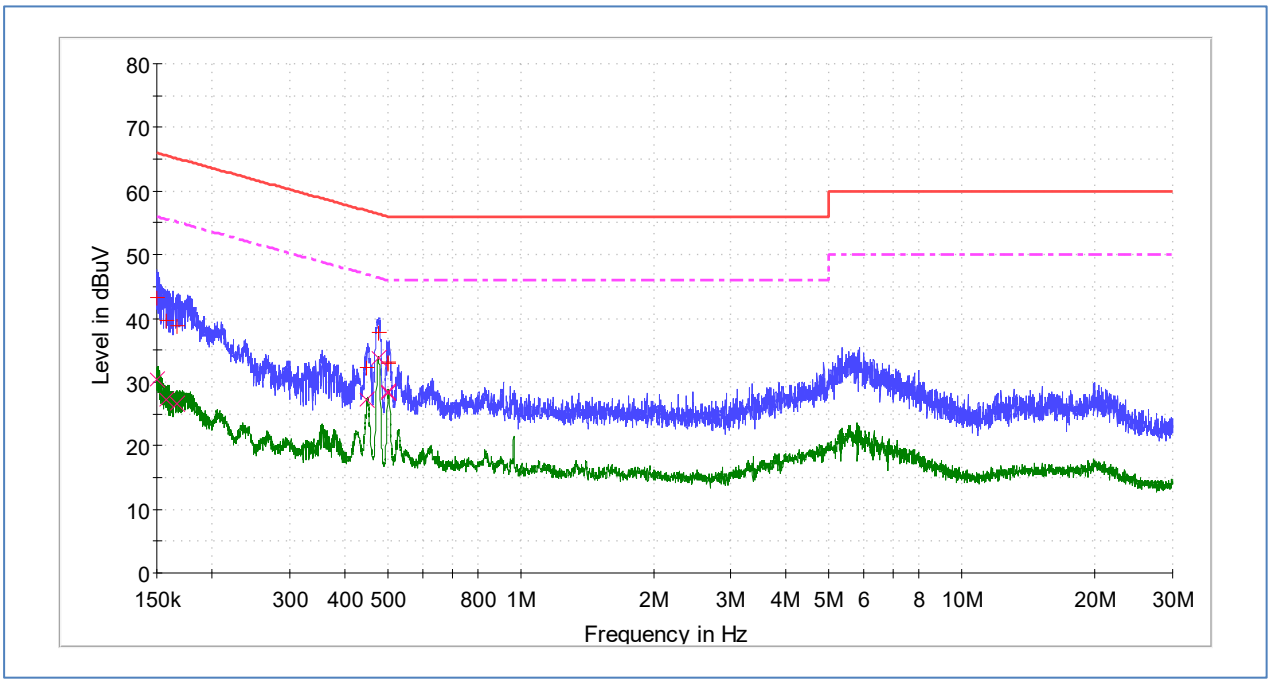
Plot # 3. Conducted emission –Phase



Frequency	Quasi Peak	Average	Margin - QPK	Limit - QPK	Margin - AVG	Limit - AVG	Result
MHz	dBµV	dBµV	dB	dBµV	dB	dBµV	
0.15	41.5	31.7	-24.5	66.0	-24.3	56.0	PASS
0.17	37.7	28.0	-27.2	64.9	-26.9	54.9	PASS
0.18	37.1	27.1	-27.5	64.6	-27.6	54.6	PASS
0.45	33.6	28.7	-23.4	56.9	-18.2	46.9	PASS
0.47	40.9	35.3	-15.6	56.4	-11.1	46.4	PASS
0.50	36.2	30.7	-19.8	56.0	-15.3	46.0	PASS

Results: **Pass**
Specified standard / Class: FCC Part 15 Subpart B Class B
Tested line: 120 VAC mains

Plot # 4. Conducted emission – Neutral



Frequency	Quasi Peak	Average	Margin - QPK	Limit - QPK	Margin - AVG	Limit - AVG	Result
MHz	dBµV	dBµV	dB	dBµV	dB	dBµV	
0.15	43.4	30.5	-22.6	66.0	-25.5	56.0	PASS
0.16	39.7	27.1	-25.9	65.6	-28.5	55.6	PASS
0.17	38.9	26.6	-26.2	65.1	-28.5	55.1	PASS
0.45	32.2	27.1	-24.7	56.9	-19.7	46.9	PASS
0.48	37.9	33.7	-18.5	56.4	-12.7	46.4	PASS
0.50	33.0	28.4	-23.0	56.0	-17.6	46.0	PASS

7. Appendix 1: Test equipment used

Instrument	Manufac-turer	Model	SII No.	Last calibration date	Next calibration date
EMI Test Receiver 3 Hz - 44 GHz	Keysight	N9038B	6505208	03/24	03/25
LISN 9 kHz – 30 MHz	Schwarbeck Mess Elektronik	NSLK 8128	6505753	08/23	08/24
Biconilog Antenna 20 MHz - 6000 MHz	ETS LINDGREN	3142D	6503046	12/23	12/25
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

8. Appendix 2: 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.
In the following table the uncertainty calculation is given.
Calculated uncertainty U_{LAB} are less than U_{CISPR}, therefore compliance is deemed to occur if no measured disturbance level exceeds the disturbance limit.

Type of disturbance Test description	Calculated uncertainty U_{LAB}	U_{CISPR}
Conducted disturbance at mains port (9 kHz to 150 kHz)	3.3 dB	3.8 dB
Conducted disturbance at mains port (150 kHz to 30 MHz)	2.8 dB	3.4 dB
Disturbance power (30 MHz to 300 MHz)	3.3 dB	4.5 dB
Radiated disturbance (electric field strength at an OATS at 10 m distance) (30 MHz to 1 000 MHz)	4.18 dB	6.3 dB
Radiated disturbance (electric field strength in a SAR at 3 m distance) (30 MHz to 1 000 MHz)	4.32 dB	6.3 dB
Radiated disturbance (electric field strength in a FAR) (1 GHz to 6 GHz)	4.47 dB	5.2 dB
Radiated disturbance (electric field strength in a FAR) (6 GHz to 18 GHz)	4.47 dB	5.5 dB

The expanded uncertainty at a level of 95% confidence is obtained by multiplying the combined standard uncertainty by coverage factor of 2.

9. Appendix 3: Antenna Factor and Cable Loss

Cable Loss (SAC, frequency range: 30 MHz-1.0 GHz)

No.	Frequency (MHz)	Attenuation (dB)	Frequency (MHz)	Attenuation (dB)	Frequency (MHz)	Attenuation (dB)
1	28.71	0.4	97.21	1.0	329.17	1.7
2	30.14	0.4	102.07	1.0	345.63	1.8
3	31.65	0.5	107.17	1.0	362.91	1.8
4	33.23	0.5	112.53	1.0	381.06	1.8
5	34.89	0.5	118.15	1.0	400.11	1.9
6	36.64	0.5	124.06	1.1	420.12	2.0
7	38.47	0.5	130.27	1.1	441.12	2.0
8	40.39	0.6	136.78	1.1	463.18	2.1
9	42.41	0.6	143.62	1.1	486.34	2.1
10	44.53	0.6	150.80	1.1	510.66	2.2
11	46.76	0.6	158.34	1.1	536.19	2.2
12	49.10	0.6	166.26	1.1	563.00	2.4
13	51.55	0.6	174.57	1.2	591.15	2.4
14	54.13	0.7	183.30	1.2	620.70	2.5
15	56.83	0.7	192.46	1.3	651.74	2.6
16	59.68	0.7	202.08	1.3	684.33	2.6
17	62.66	0.7	212.19	1.3	718.54	2.8
18	65.79	0.8	222.80	1.4	754.47	2.9
19	69.08	0.8	233.94	1.4	792.19	2.9
20	72.54	0.8	245.63	1.4	831.80	3.0
21	76.16	0.8	257.92	1.5	873.39	3.2
22	79.97	0.9	270.81	1.5	917.06	3.2
23	83.97	0.9	284.35	1.5	962.92	3.3
24	88.17	0.9	298.57	1.6	1011.06	3.4
25	92.58	0.9	313.50	1.6	--	--

Cable Loss (SAC, frequency range: 1.0 GHz – 6.0 GHz)

No.	Frequency (MHz)	Attenuation (dB)	Frequency (MHz)	Attenuation (dB)	Frequency (MHz)	Attenuation (dB)
1	962.92	3.3	1815.72	5.0	3423.81	7.2
2	1011.06	3.4	1906.51	5.1	3595.00	6.8
3	1061.61	3.4	2001.83	5.2	3774.75	7.0
4	1114.70	3.5	2101.92	5.3	3963.49	7.1
5	1170.43	3.7	2207.02	5.4	4161.67	7.6
6	1228.95	3.9	2317.37	5.5	4369.75	7.7
7	1290.4	3.9	2433.24	5.6	4588.24	7.7
8	1354.92	4.0	2554.90	5.9	4817.65	7.8
9	1422.67	4.2	2682.65	5.8	5058.53	8.1
10	1493.80	4.6	2816.78	5.8	5311.46	8.4
11	1568.49	4.7	2957.62	6.3	5577.03	8.6
12	1646.91	4.8	3105.50	6.2	5855.88	9.1
13	1729.26	4.9	3260.77	6.7	6000.00	9.3

Antenna Factor

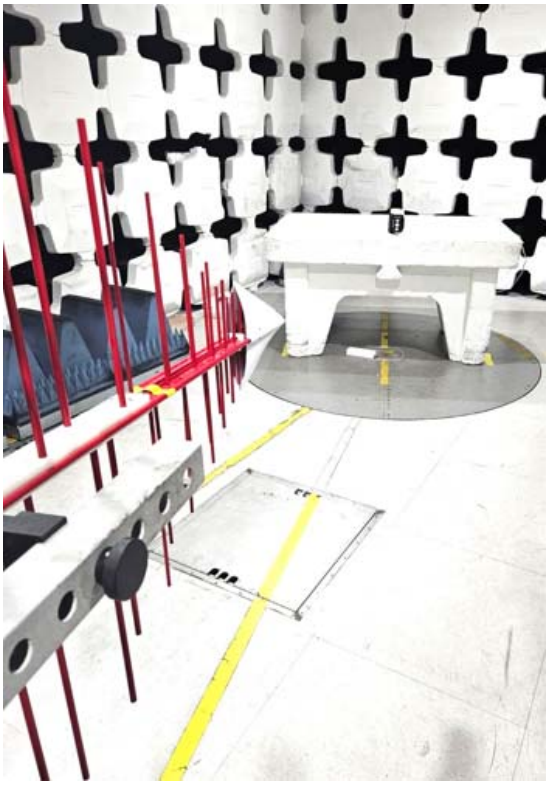
Biconilog Antenna, Model Number: 3142D S/N: 6503046
3 m distance

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

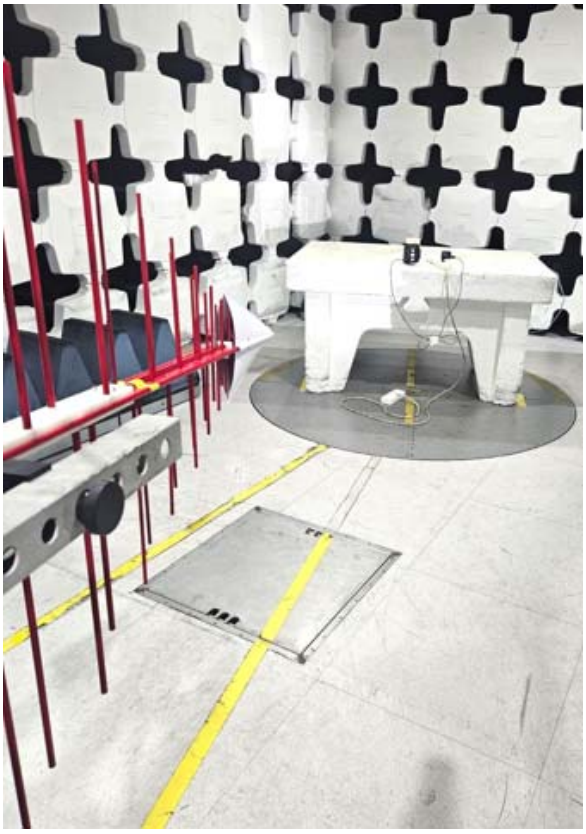
Double Ridged Waveguide Antenna Model Number: 3115 S/N 0143138
3m distance

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	--	--

10. Appendix 4: Test illustrations



Picture # 4.
Radiated emission test setup - Operation mode



Picture # 5.
Radiated emission test setup in Charging mode.
Power Adapter Marking Label

Picture # 6.
Conducted emission test setup.
Revi Wearable peripheral nerve stimulator general view

END OF THE DOCUMENT