



FCC / ISED Test Report

For:

Smith & Nephew Medical, Ltd.

Model No:

66803126

Product Description:

The RENASYS EDGE is a Negative Pressure Wound Therapy device that has wireless interfaces to a user smartphone/tablet and the device canister.

FCC ID: 2AWH9-EDGE

IC ID: 26135-EDGE

Applied Rules and Standards:

47 CFR Part 15.209 and 15.225

RSS-210 Issue 10 & RSS-Gen Issue 5

REPORT #: EMC_SMITH-015-21001_FCC_15.225_Rev3

DATE: 2022-03-15



A2LA Accredited

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3462B-1

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1 Assessment

The following device was evaluated against the applicable radiated emissions criteria specified in FCC rules Parts 15.209, and 15.225 of Title 47 of the Code of Federal Regulations and the relevant ISED Canada standard RSS-210 Issue 10, and RSS-Gen Issue 5.

Company	Description	Model #
Smith & Nephew Medical, Ltd.	The RENASYS EDGE is a Negative Pressure Wound Therapy device that has wireless interfaces to a user smartphone/tablet and the device canister.	66803126

Responsible for Testing Laboratory:

2022-03-15	Compliance	Kevin Wang (EMC Lab Manager)	
Date	Section	Name	Signature

Responsible for the Report:

2022-03-15	Compliance	Cheng Song (EMC Engineer)	
Date	Section	Name	Signature

The test results of this test report relate exclusively to the test item specified in Section 3.
CETECOM Inc. USA does not assume responsibility for any conclusions and generalizations drawn from the test results with regard to other specimens or samples of the type of the equipment represented by the test item. The test report may only be reproduced or published in full. Reproduction or publication of extracts from the report requires the prior written approval of CETECOM Inc. USA.

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2 **Administrative Data**

2.1 Identification of the Testing Laboratory Issuing the EMC Test Report

Company Name:	CETECOM Inc.
Department:	Compliance
Street Address:	411 Dixon Landing Road
City/Zip Code	Milpitas, CA 95035
Country	USA
Telephone:	+1 (408) 586 6200
Fax:	+1 (408) 586 6299
EMC Lab Manager:	Kevin Wang
Responsible Project Leader:	Cathy Palacios

2.2 Identification of the Client

Client's Name:	Smith & Nephew Medical, Ltd.
Street Address:	101 Hessle Road
City/Zip Code	Hull, HU3 2BN
Country	United Kingdom

2.3 Identification of the Manufacturer

Manufacturer's Name:	Plexus Corp
Manufacturers Address:	Pinnacle Hill Industrial Estate
City/Zip Code	Kelso, TD5 8XX, Scotland
Country	United Kingdom

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3 Equipment Under Test (EUT)

3.1 EUT Specifications

Model No:	66803126
HW Version :	1000026187 REV A.2
SW Version :	1000026850 REV 1.3.1
FCC ID:	2AWH9-EDGE
IC ID:	26135-EDGE
Product Description:	The RENASYS EDGE is a Negative Pressure Wound Therapy device that has wireless interfaces to a user smartphone/tablet and the device canister.
Radio Information:	<u>NFC:</u> • NXP SLRC61003HNY • Frequency of Operating: 13.56 MHz <u>Bluetooth:</u> • Nordic nRF52840 SoC • Frequency of Operating: 2402 MHz - 2480 MHz
Antenna Information:	<u>NFC:</u> • PCB Loop Antenna <u>Bluetooth:</u> • PCB Antenna
Power Supply/ Rated Operating Voltage Range:	Vmin: 10.8 V, Vmax: 13.2 V, Vnom: 12 V
Operating Temperature Range	Tmin: 5 °C , Tmax: 40 °C, Tnom: 25 °C
Sample Revision	☐ Prototype Unit; ☐ Production Unit; ☒ Pre-Production

3.2 EUT Sample details

EUT #	Serial Number	HW Version	SW Version	Notes/Comments
1	21PEDL210020	1000026187 REV A.2	1000026850 REV 1.3.1	-

3.3 Accessory Equipment (AE) details

AE #	Type	Manufacturer	Serial Number
1	AC / DC Adapter	SL Power Electronics	-
2	Canister (300ml or 800 ml)	Smith & Nephew Medical, Ltd.	-
3	Carry Bag	Smith & Nephew Medical, Ltd.	-

3.3 Test Sample Configuration

EUT Set-up #	EUT / AE used for set-up	Comments
1	EUT#1 + AE#1 + AE#2	-

3.4 Mode of Operation details

Mode of Operation	Description	Details
Op. 1	RFID	-

3.5 Justification for Worst Case Mode of Operation

During the testing process, the EUT was tested with transmitter sets on low, mid and high channels, and highest possible duty cycle possible. For radiated measurements, all data in this report shows the worst case between horizontal and vertical antenna polarizations and for all orientations of the EUT.

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4 Subject of Investigation

The objective of the measurements done by CETECOM Inc. was to assess the performance of the EUT according to the relevant radiated emissions requirements specified in FCC rules part 15.209 and 15.225 of Title 47 of the Code of Federal Regulations and Radio Standard Specification RSS-210 Issue 10 of ISED Canada.

5 Measurement Results Summary

Test Specification	Test Case	Temperature and Voltage Conditions	Mode	PASS	NA	NP	Result
§15.225(d); §15.209 RSS-210 I10; RSS-Gen I5 8.9	TX Spurious emissions- Radiated	Nominal	RFID	■	□	□	Complies
§15.225(a,b,c); RSS-210 I10 B6 a;	Field strength in band mask	Nominal	RFID	■	□	□	Complies
§15.225(e); RSS-210 I10 B6 b);	Frequency stability	Nominal and Extreme Voltage and Temperature	RFID	■	□	□	Complies
§15.207(a) RSS Gen I5 8.8	AC Conducted Emissions	Nominal	RFID	■	□	□	Complies

Note 1: NA= Not Applicable; NP= Not Performed.

6 **Measurement Uncertainty**

Where relevant, the following measurement uncertainty levels have been estimated for tests performed on the apparatus, with 95% confidence interval (in dB delta to result), based on a coverage factor k=1.

Measurement System	EMC 1	EMC 2
Conducted Emissions (mains port)	1.12 dB	0.46 dB
Radiated Emissions		
(<30 MHz)	3.66 dB	3.88 dB
(30 MHz – 1 GHz)	3.17 dB	3.34 dB
(1 GHz – 3 GHz)	5.01 dB	4.45 dB
(> 3 GHz)	4.0 dB	4.79 dB

RF conducted measurement ± 0.5 dB

6.1 **Environmental Conditions During Testing:**

The following environmental conditions were maintained during the course of testing:

- Ambient Temperature: 20-25° C
- Relative humidity: 40-60%

6.2 **Dates of Testing:**

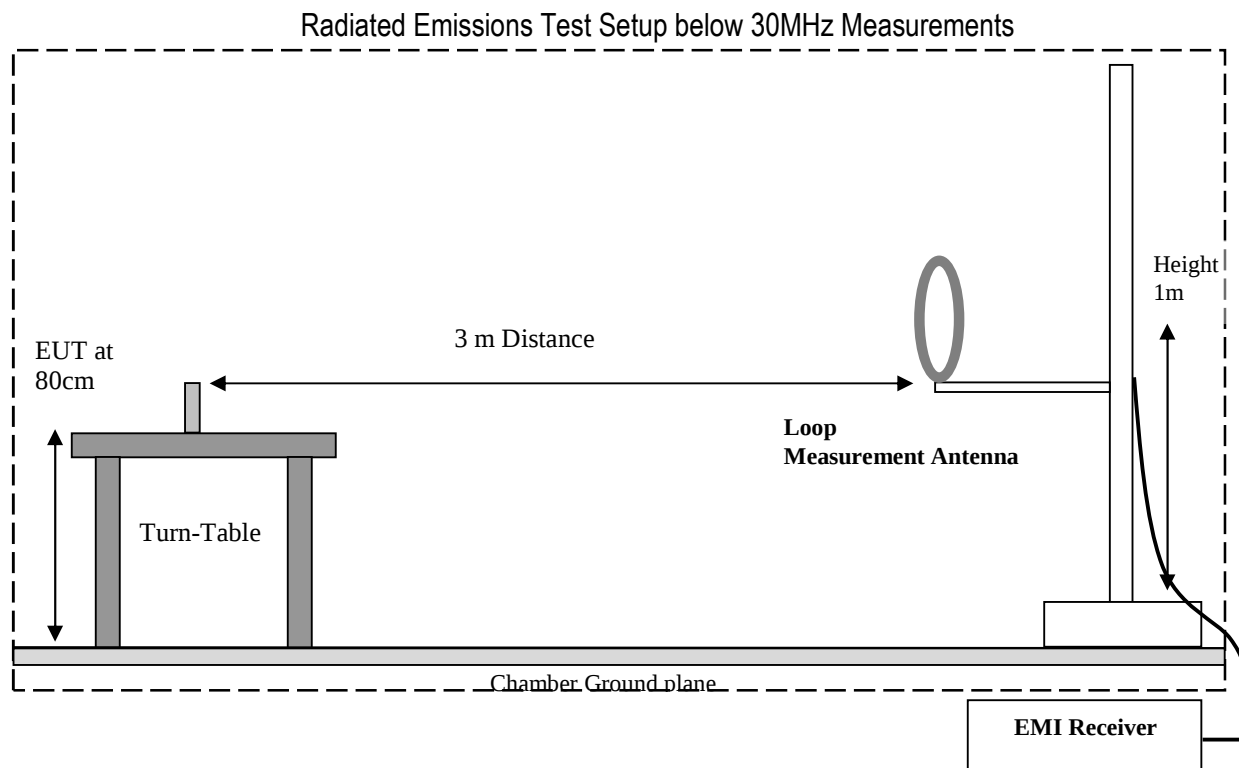
12/17/2021 - 01/12/2022

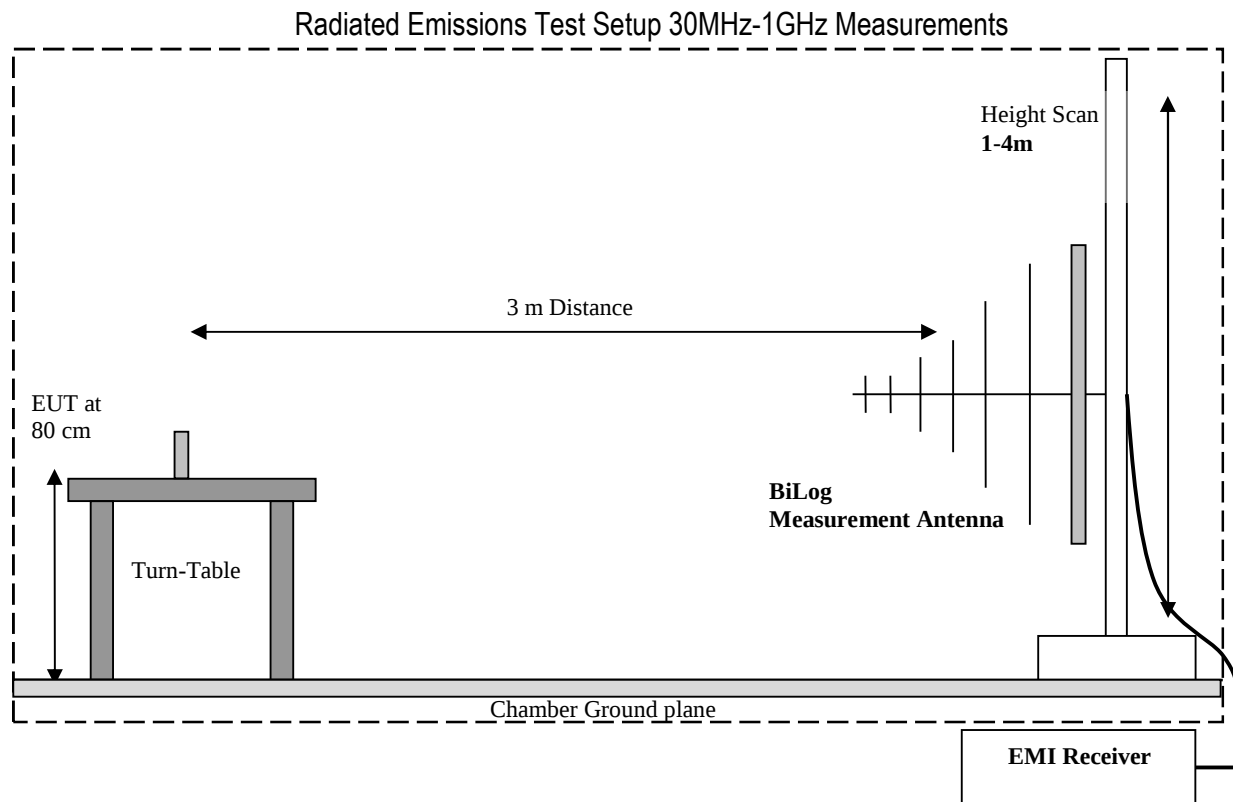
7 Measurement Procedures

7.1 Radiated Measurement

The radiated measurement is performed according to ANSI C63.10 (2013)

- The exploratory measurement is accomplished by running a matrix of 16 sweeps over the required frequency range with R&S Test-SW EMC32 for 4 positions of the turntable, two orthogonal positions of the EUT and both antenna polarizations. This procedure exceeds the requirement of the above standards to cover the 3 orthogonal axis of the EUT. A max peak detector is utilized during the exploratory measurement. The Test-SW creates an overall maximum trace for all 12 sweeps and saves the settings for each point of this trace. The maximum trace is part of the test report.
- The 10 highest emissions are selected with an automatic algorithm of EMC32 searching for peaks in the noise floor and ensuring that broadband signals are not selected multiple times.
- The maxima are then put through the final measurement and again maximized in a 90deg range of the turntable, fine search in frequency domain and height scan between 1m and 4m.
- The above procedure is repeated for all possible ways of power supply to EUT and for all supported modulations.
- In case there are no emissions above noise floor level only the maximum trace is reported as described above.
- The results are split up into up to 4 frequency ranges due to antenna bandwidth restrictions. A magnetic loop is used from 9 kHz to 30 MHz, a Biconilog antenna is used from 30 MHz to 1 GHz, and two different horn antennas are used to cover frequencies up to 40 GHz.





7.1.1 Sample Calculations for Field Strength Measurements

Field Strength is calculated from the Spectrum Analyzer/ Receiver readings, taking into account the following parameters:

1. Measured reading in dB μ V
2. Cable Loss between the receiving antenna and SA in dB and
3. Antenna Factor in dB/m

All radiated measurement plots in this report are taken from a test SW that calculates the Field Strength based on the following equation:

$$FS \text{ (dB}\mu\text{V/m)} = \text{Measured Value on SA (dB}\mu\text{V)} + \text{Cable Loss (dB)} + \text{Antenna Factor (dB/m)}$$

Example:

Frequency (MHz)	Measured SA (dB μ V)	Cable Loss (dB)	Antenna Factor Correction (dB)	Field Strength Result (dB μ V/m)
1000	80.5	3.5	14	98.0

8 Test Result Data

8.1 Radiated Transmitter Spurious Emissions and Restricted Bands

8.1.1 Measurement according to ANSI C63.10

Spectrum Analyzer Settings:

- Frequency = 9 KHz – 30 MHz
- RBW = 9 KHz
- Detector: Peak

- Frequency = 30 MHz – 1 GHz
- Detector = Peak / Quasi-Peak
- RBW= 120 KHz (<1GHz)

- Radiated spurious emissions shall be measured for the transmit frequencies, transmit power, and data rate for the lowest, middle and highest channel in each frequency band of operation and for the highest gain antenna for each antenna type, and using the appropriate parameters and test requirements.
- The highest (or worst-case) data rate shall be recorded for each measurement.
- For testing frequencies below 30 MHz at distance other than the specified in the standard, the limit conversion is calculated by using the FCC materials for the ANSI 63 committee issued on January, 27 1991.

8.1.2 Limits:

FCC §15.225

- The field strength of any emissions appearing outside of the 13.110-14.010 MHz band shall not exceed the general radiated emission limits in §15.209.

FCC §15.209 & RSS-210 / RSS-Gen 8.9

- 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:

Frequency of emission (MHz)	Field strength (μV/m)	Measurement Distance (m)	Field strength @ 3m (dBμV/m)
0.009–0.490	2400/F(kHz) / -----	300	-
0.490–1.705	24000/F(kHz) / -----	30	-
1.705–30.0	30 / (29.5)	30	-
30–88	100	3	40 dBμV/m
88–216	150	3	43.5 dBμV/m
216–960	200	3	46 dBμV/m
Above 960	500	3	54 dBμV/m

FCC §15.205 & RSS-Gen 8.10

- Except as shown in paragraph (d) of this section, only spurious emissions are permitted in any of the frequency bands listed below:

MHz	MHz	MHz	GHz
0.090-0.110	16.42-16.423	399.9-410	4.5-5.15
10.495-0.505	16.69475-16.69525	608-614	5.35-5.46
2.1735-2.1905	16.80425-16.80475	960-1240	7.25-7.75
4.125-4.128	25.5-25.67	1300-1427	8.025-8.5
4.17725-4.17775	37.5-38.25	1435-1626.5	9.0-9.2
4.20725-4.20775	73-74.6	1645.5-1646.5	9.3-9.5
6.215-6.218	74.8-75.2	1660-1710	10.6-12.7
6.26775-6.26825	108-121.94	1718.8-1722.2	13.25-13.4
6.31175-6.31225	123-138	2200-2300	14.47-14.5
8.291-8.294	149.9-150.05	2310-2390	15.35-16.2
8.362-8.366	156.52475-156.52525	2483.5-2500	17.7-21.4
8.37625-8.38675	156.7-156.9	2690-2900	22.01-23.12
8.41425-8.41475	162.0125-167.17	3260-3267	23.6-24.0
12.29-12.293	167.72-173.2	3332-3339	31.2-31.8
12.51975-12.52025	240-285	3345.8-3358	36.43-36.5
12.57675-12.57725	322-335.4	3600-4400	Above 38.6
13.36-13.41			

- Radiated emissions which fall in the restricted bands, as defined in §15.205(a), must also comply with the radiated emission limits specified in §15.209(a) (see §15.205(c)).

*PEAK LIMIT= 74 dBμV/m

*AVG. LIMIT= 54 dBμV/m

8.1.3 Test conditions and setup:

Ambient Temperature	EUT Set-Up #	EUT operating mode	Power Input
22° C	1	RFID	120 VAC

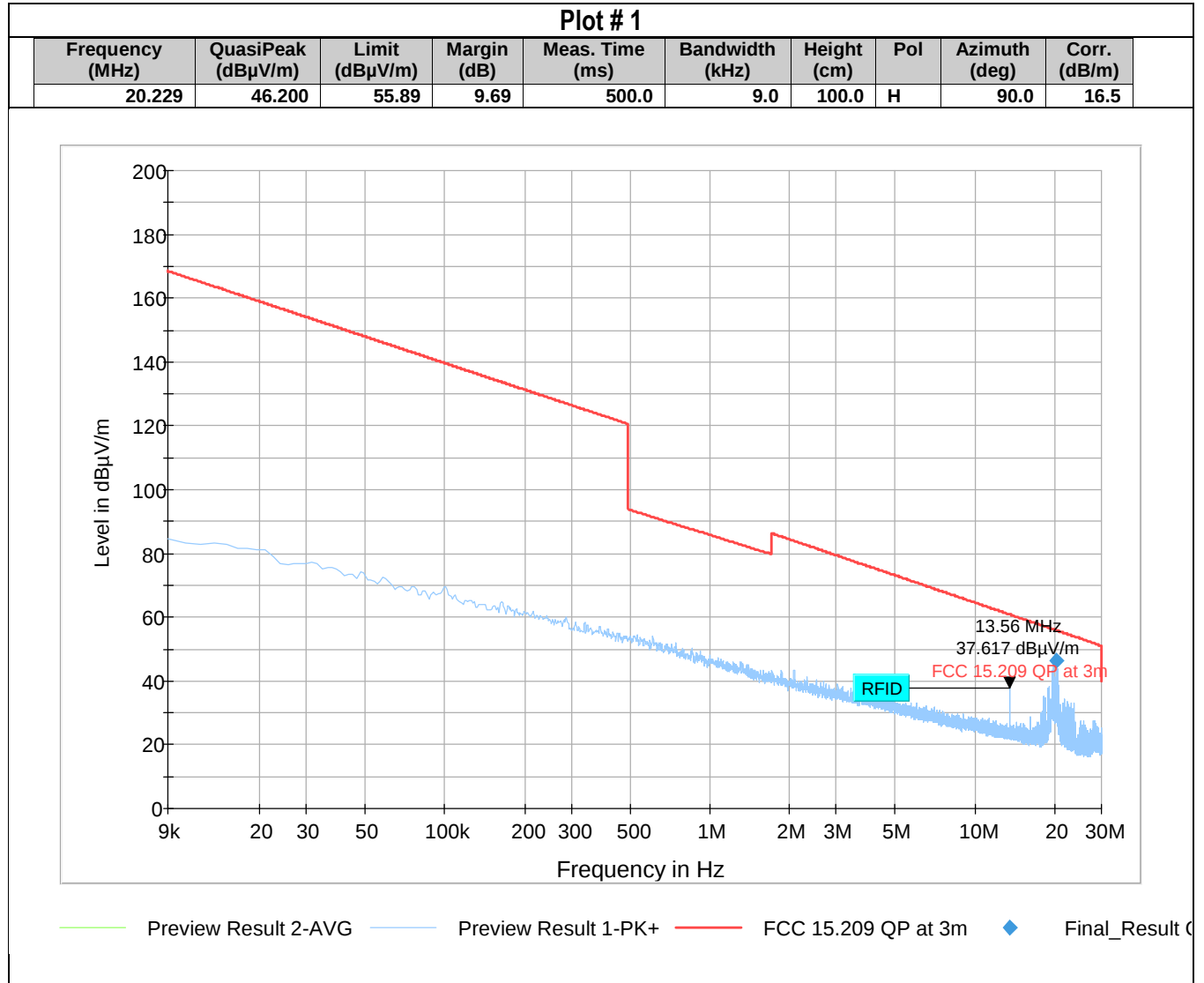
8.1.4 Measurement result:

Plot #	Operating Mode	Scan Frequency	Limit	Result
1	RFID	9 kHz – 30 MHz	See section 8.1.2	Pass
2	RFID	30 MHz – 1 GHz	See section 8.1.2	Pass
3	RFID	13.11 – 14.01 MHz	13.553-13.567 MHz:15,848 uV/m @ 30 m 13.410-13.553 MHz: 334 uV/m @ 30 m 13.567-13.710 MHz: 334 uV/m @ 30 m 13.110-13.410 MHz: 106 uV/m @ 30 m 13.710-14.010 MHz: 106 uV/m @ 30 m	Pass

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8.1.5 Measurement Plots:

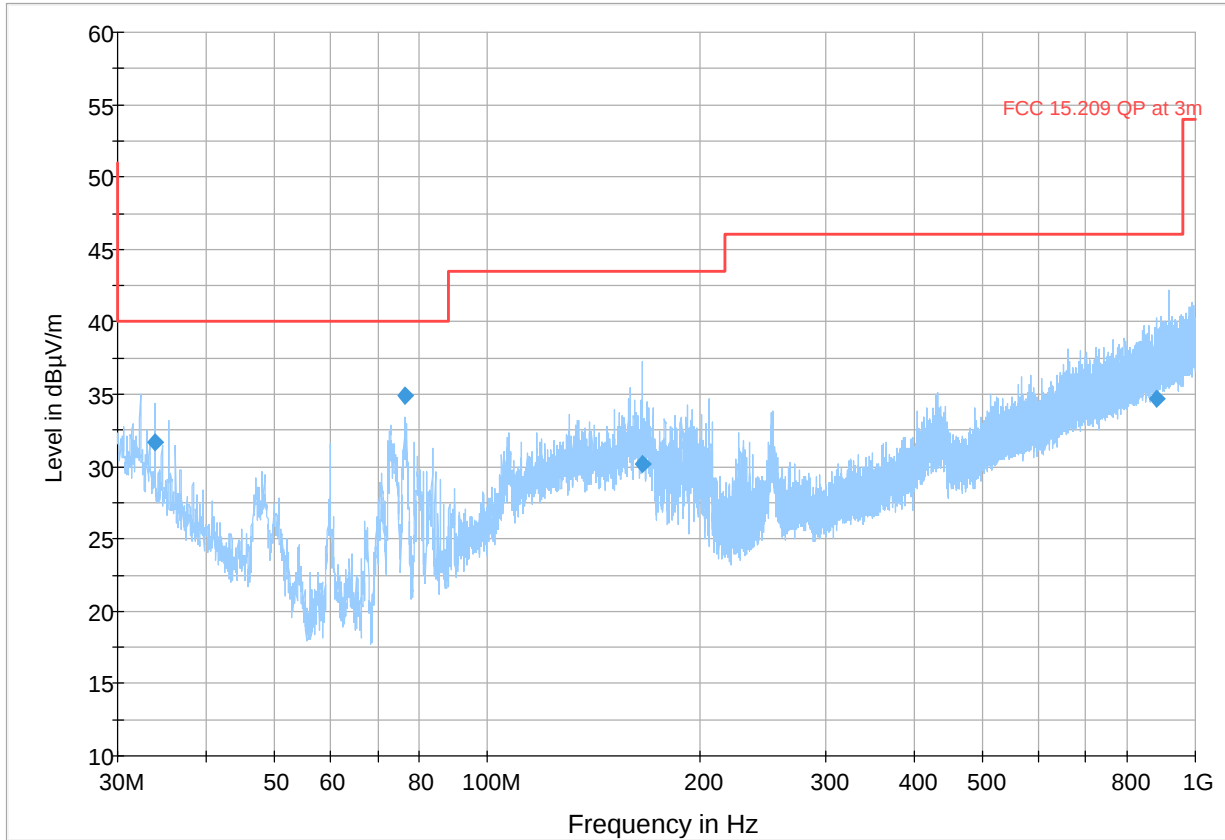


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Plot # 2

Frequency (MHz)	QuasiPeak (dBμV/m)	Limit (dBμV/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol	Azimuth (deg)	Corr. (dB/m)
33.848	31.656	40.00	8.34	500.0	120.0	100.0	V	166.0	22.1
76.237	34.903	40.00	5.10	500.0	120.0	169.0	V	148.0	14.8
165.412	30.175	43.50	13.32	500.0	120.0	100.0	V	149.0	25.2
881.078	34.645	46.02	11.38	500.0	120.0	184.0	H	121.0	31.4



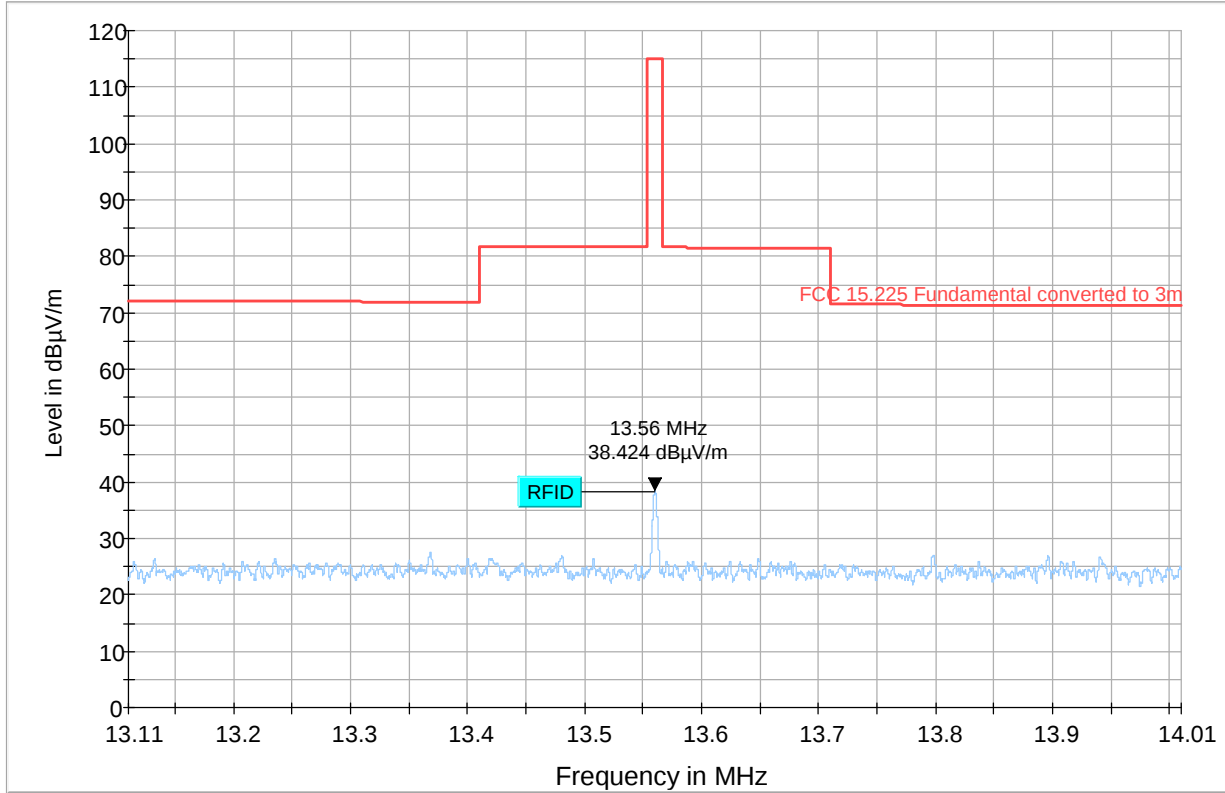
Preview Result 2-AVG Preview Result 1-PK+ FCC 15.209 QP at 3m Final_Result C

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Plot # 3

Frequency	MaxPeak (dBμV/m)	QuasiPeak	Limit (dBμV/m)	Margin	Measurement	Bandwidth	Height	Polarization	Azimuth	Correction (dB/m)	Comments
---	---	---	---	---	---	---	---	---	---	---	---



— Preview Result 1-PK+ * Critical Freqs PK+
— FCC 15.225 Fundamental converted to 3m ◆ Final_Result PK+
◆ Final_Result QPK

8.2 AC Power Line Conducted Emissions

8.2.1 Measurement according to ANSI C63.4

Analyzer Settings:

- RBW = 9 KHz (CISPR Bandwidth)
- Detector: Peak / Average for Pre-scan
- Quasi-Peak/Average for Final Measurements

8.2.2 Limits:

FCC §15.207(a) & RSS-Gen 8.8

- Except as shown in paragraphs (b) and (c) of this section of the CFR, for an intentional radiator that is designed to be connected to the public utility (AC) power line, the radio frequency voltage that is conducted back onto the AC power line on any frequency or frequencies, within the band 150 kHz to 30 MHz, shall not exceed the limits in the following table (1), as measured using a 50 μ H/50 ohms line impedance stabilization network (LISN). Compliance with the provisions of this paragraph shall be based on the measurement of the radio frequency voltage between each power line and ground at the power terminal. The lower limit applies at the boundary between frequency ranges.

Frequency of emission (MHz)	Conducted limit (dB μ V)	
	Quasi-peak	Average
0.15–0.5	66 to 56*	56 to 46*
0.5–5	56	46
5–30	60	50

*Decreases with the logarithm of the frequency.

8.2.3 Test conditions and setup:

Ambient Temperature $^{\circ}$ C	EUT Set-Up #	EUT operating mode	Power line (L1, L2, L3, N)	Power Input
22 $^{\circ}$ C	1	RFID	Line & Neutral	120 VAC

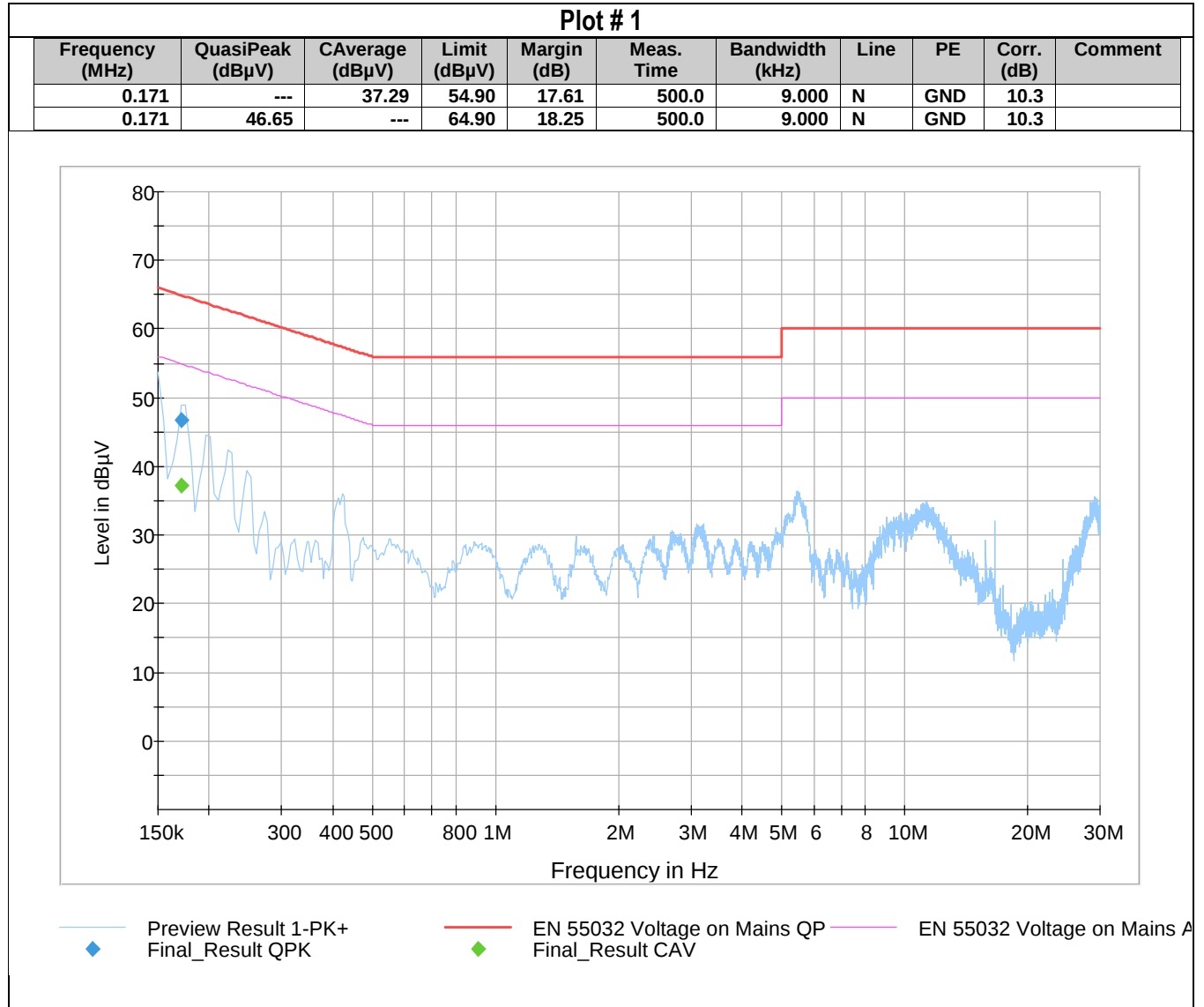
8.2.4 Measurement Result:

Plot #	Port	EUT Set-Up #:	EUT operating mode	Scan Frequency	Result
1	AC Mains	1	RFID	150 kHz – 30 MHz	Pass

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8.2.5 Measurement Plots:



8.3 Frequency Stability

8.3.1 Measurement according to ANSI C63.10

8.3.2 Limits:

Deviation: 0.01%

8.3.3 Test conditions and setup:

Ambient Temperature	EUT Set-Up #	EUT operating mode	Power Input
22° C	1	RFID	120 VAC

8.3.4 Measurement Result:

Temp (°C)	Measured Frequency (MHz)	Test Voltage (V AC)	Frequency Error (Hz)	Limit (+/- Hz)	Result
20	13.560303	120	303	1356	Pass
20	13.560305	102	305	1356	Pass
20	13.560303	138	303	1356	Pass
-20	13.560311	120	311	1356	Pass
-10	13.560305	120	305	1356	Pass
0	13.560304	120	304	1356	Pass
10	13.560303	120	303	1356	Pass
30	13.560303	120	303	1356	Pass
40	13.560303	120	303	1356	Pass
50	13.560305	120	305	1356	Pass

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9 Test setup photos

Setup photos are included in supporting file name: "EMC_SMITH-015-21001_FCC_Setup_Photos_Rev3.pdf"

10 Test Equipment And Ancillaries Used For Testing

Equipment Name/Type	Manufacturer	Model	Serial #	Calibration Cycle	Last Calibration Date
Biconilog Antenna	A.H. Systems	BiLA2G	569343	2 years	12/01/2020
Active Loop Antenna	ETS Lindgren	6507	161344	2 years	10/30/2020
Spectrum Analyzer	R&S	ESU40	100251	2 years	09/13/2021
LISN	FCC	FCC-LISN-50-25-2-08	8014	2 years	08/31/2021
Thermometer Humidity Monitor	CONTROL COMPANY	36934-164	191871986	2 years	10/20/2021
Temperature Humidity Chamber	TestEquity	123H	246902000003	-	-

Note: Equipment used meets the measurement uncertainty requirements as required per applicable standards for 95% confidence levels. Calibration due dates, unless defined specifically, falls on the last day of the month. Items indicated "N/A" for cal status either do not specifically require calibration or is internally characterized before use.

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11 History

Date	Template Revision	Changes to report	Prepared by
2022-01-28	EMC_SMITH-015-21001_FCC_15.225	Initial Version	Cheng Song
2022-02-11	EMC_SMITH-015-21001_FCC_15.225_Rev1	Updated software version	Cheng Song
2022-02-24	EMC_SMITH-015-21001_FCC_15.225_Rev2	Corrected applied standard in section 8.3 Updated supporting setup photos file name in section 9	Cheng Song
2022-03-14	EMC_SMITH-015-21001_FCC_15.225_Rev3	Updated Section 8.3.4 testing temp Updated section 10 temperature humidity chamber	Cheng Song

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