



FCC/IC Test Report

Brand:

Smith & Nephew Medical Limited

Model:

66803126

Marketing name:

RENASYS 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

FCC ID: 2AWH9-EDGE

IC: 26135-EDGE

Applied Rules and Standards:

47 CFR Parts: 15B, and ICES-003 Issue 7

REPORT #: EMC_SMITH_063_25001_FCC_15B_Rev2

DATE: 2025-04-29



A2LA Accredited

IC recognized #
3462B-2

CETECOM Inc.

411 Dixon Landing Road • Milpitas, CA 95035 • U.S.A.

Phone: + 1 (408) 586 6200 • Fax: + 1 (408) 586 6299 • E-mail: contact@cetecom.com • <http://www.cetecom.com>

CETECOM Inc. is a Delaware Corporation with Corporation number: 2905571

TABLE OF CONTENTS

1	ASSESSMENT.....	3
2	ADMINISTRATIVE DATA.....	4
2.1	IDENTIFICATION OF THE TESTING LABORATORY ISSUING THE EMC TEST REPORT	4
2.2	IDENTIFICATION OF THE CLIENT	4
2.3	IDENTIFICATION OF THE MANUFACTURER.....	4
3	EQUIPMENT UNDER TEST (EUT).....	5
3.1	EUT SPECIFICATIONS	5
3.2	EUT SAMPLE DETAILS.....	6
3.3	ACCESSORY EQUIPMENT (AE) DETAILS.....	6
3.4	TEST SAMPLE CONFIGURATION	6
3.5	MODE OF OPERATION DETAILS	6
4	SUBJECT OF INVESTIGATION	7
4.1	DATE OF TESTING:.....	7
4.2	MEASUREMENT UNCERTAINTY	7
4.3	ENVIRONMENTAL CONDITIONS DURING TESTING:.....	7
4.4	DECISION RULE:.....	7
5	MEASUREMENT PROCEDURES.....	8
5.1	RADIATED MEASUREMENT.....	8
5.2	SAMPLE CALCULATIONS FOR FIELD STRENGTH MEASUREMENTS	10
6	MEASUREMENT RESULTS SUMMARY	11
7	TEST RESULT DATA	12
7.1	RADIATED EMISSIONS MEASUREMENT ACCORDING TO CFR 47 PART 15.109 AND ICES-003, 3.2.2.....	12
7.2	AC POWER LINE CONDUCTED EMISSIONS ACCORDING TO CFR 47 PART 15.107 AND ICES-003 §3.2.1	16
8	TEST SETUP PHOTOS.....	19
9	TEST EQUIPMENT AND ANCILLARIES USED FOR TESTING	19
10	REVISION HISTORY	20

1 Assessment

The following device as further described in section 3 of this report was evaluated against the applicable criteria specified in the Code of Federal Regulations Title 47 parts 15B and ICES-003 Issue 7.

Radiated and conducted Emission tests are carried out to show that the EUT complies with FCC 15.107; FCC 15.109 and ICES-003, §3.2.1; §3.2.2 limits for Class B device.

No deficiencies were ascertained.

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

Report Reviewer:

Alvin Ilarina

(Senior Manager Regulatory

2025-04-29 Compliance Services)

Date	Section	Name	Signature

Responsible for the Report:

Cheng Song

(EMC Engineer)

2025-04-29 Compliance

Date	Section	Name	Signature

The test results of this test report relate exclusively to the test item specified in Section3.

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.

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
Senior Manager Regulatory Services:	Alvin Ilarina
Responsible Project Leader:	Ruby Hall

2.2 Identification of the Client

Client Firm/Name:	Smith & Nephew Medical Limited
Street Address:	101 Hessle Road
City/Zip Code	Hull England HU3 2BN
Country	United Kingdom

2.3 Identification of the Manufacturer

Manufacturer's Name:	
Manufacturers Address:	Same as Client
City/Zip Code	
Country	

3 Equipment Under Test (EUT)

3.1 EUT Specifications

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.
Model:	66803126
Marketing Name:	RENASYS EDGE
HW Version:	1000026187 Rev E
SW Version:	1000026850 Version 1.6.1
FCC-ID:	2AWH9-EDGE
IC:	26135-EDGE
Radio Information as declared:	Bluetooth: Bluetooth 5 LE Nordic nRF52840 SoC NFC: NXP SLRC61003HNY – Frequency 13.56 MHz
Antenna Information as declared:	Max Gain: 2.13 dBi
Power Supply/ Rated Operating Voltage Range	Low 10.8V; Norm12; High 13.2V
Operating Temperature Range	Low: -5 °C Norm 25 °C High 40 °C
Sample Revision	<input checked="" type="checkbox"/> Production <input type="checkbox"/> Pre-Production
EUT Dimensions	150mm x 150mm x 100mm
Weight	1000 grams
EUT Diameter	<input checked="" type="checkbox"/> < 60 cm <input type="checkbox"/> Other _____
Note: The EUT specifications listed in the table above were provided by the client.	

3.2 EUT Sample details

EUT #	Serial Number	HW Version	SW Version	Comments
1	66803126	1000026187 Rev E	1000026850 Version 1.6.1	-

3.3 Accessory Equipment (AE) details

AE #	Type	Model	Manufacturer	Comments
1	Medical Power Supply	ME40A1200C03	SL Power Electronics	-

3.4 Test Sample Configuration

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

3.5 Mode of Operation details

Mode of Operation	Description of Operating modes	Additional Information
Op. 1	Idle	The EUT is operating in its fully functional mode, with all radio components set to idle.

4 Subject of Investigation

The objective of the measurements done by CETECOM Inc. was to evaluate the compliance of the EUT against the relevant requirements specified in section 1.

4.1 Date of Testing:

3/3/2025 – 3/5/2025

4.2 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=2.

Measurement System		EMC 1	EMC 2
Conducted emissions (mains port)	150 kHz – 30 MHz	2.47 dB	N/A
Radiated emissions	9 kHz – 30 MHz	2.68 dB	2.53 dB
	30 – 100 MHz	4.39 dB	3.85 dB
	100 MHz – 1 GHz	5.65 dB	5.24 dB
	1 – 6 GHz	5.0 dB	4.88 dB
	6 – 18 GHz	4.76 dB	4.58 dB
	18 – 40 GHz	4.65 dB	4.61 dB

4.3 Environmental Conditions during Testing:

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

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

Deviating test conditions are indicated at individual test description where applicable.

4.4 Decision Rule:

Cetecom advanced follows ILAC G8:2019 chapter 4.2.1 (Simple Acceptance Rule).

Only the measured values related to their corresponding limits will be used to decide whether the equipment under test meets the requirements of the test standards listed in chapter 3. The measurement uncertainty is mentioned in this test report, See chapter 9, but is not taken into account – neither to the limits nor to the measurement results. Measurement results with a smaller margin to the corresponding limits than the measurement uncertainty have a potential risk of more than 5% that the decision might be wrong.

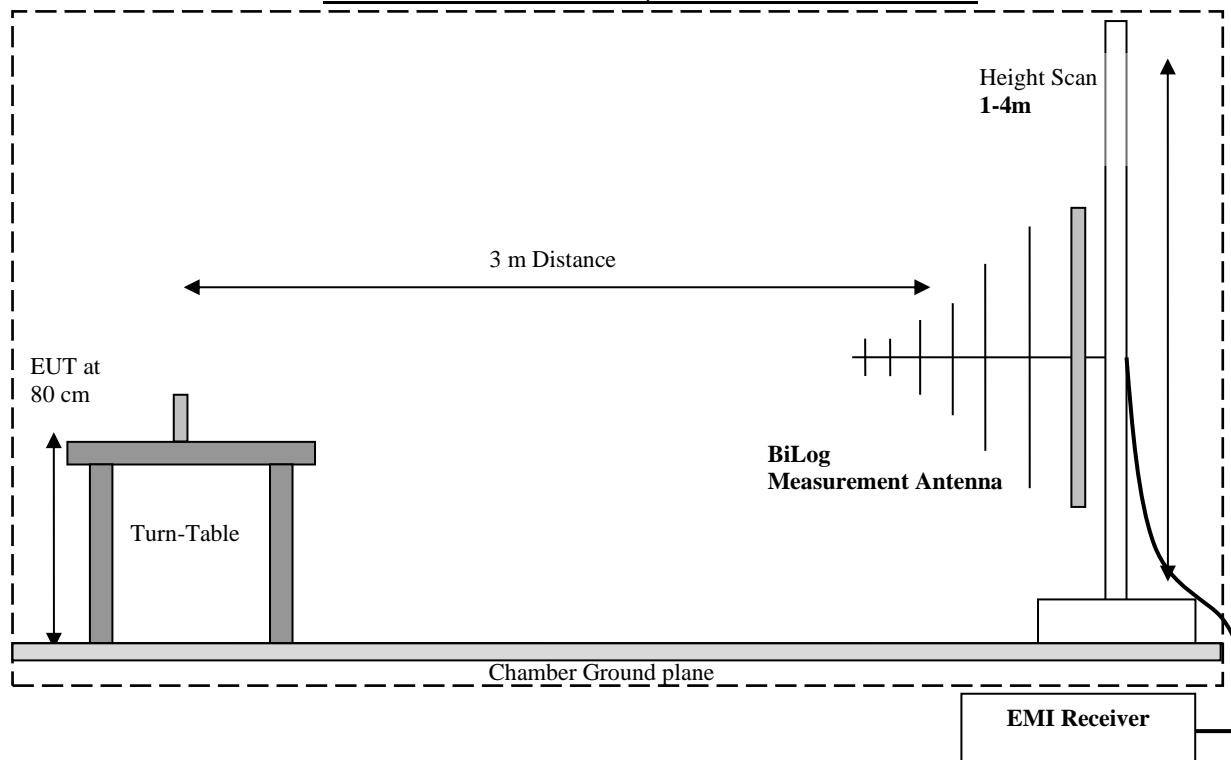
5 Measurement Procedures

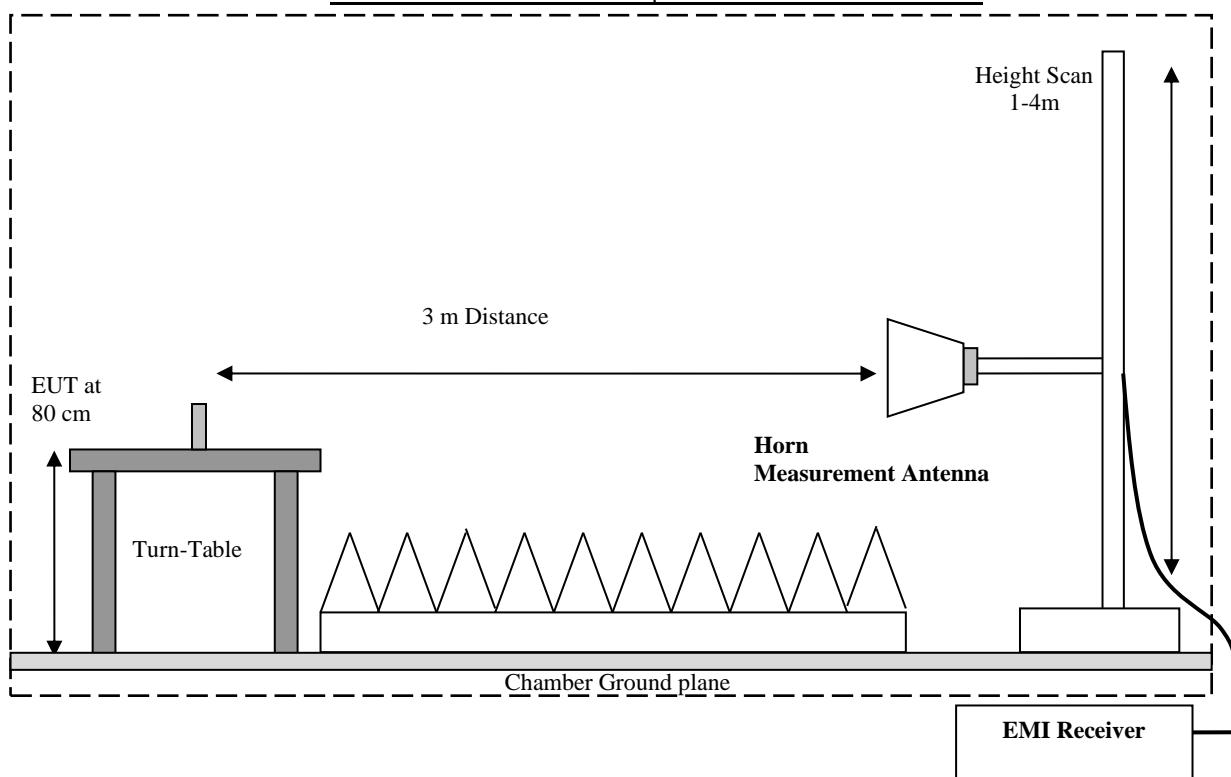
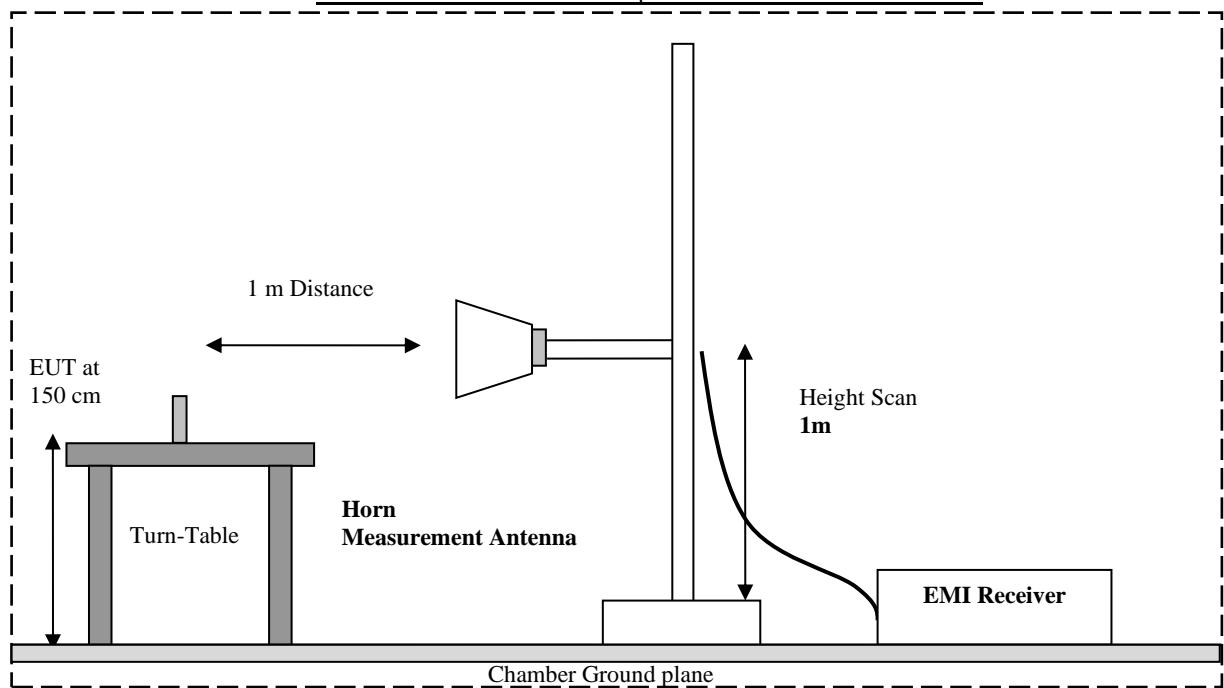
Testing is performed according to the guidelines provided in ANSI C63.4-2014 American National Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 30 MHz to 40 GHz

5.1 Radiated Measurement

- The exploratory measurement is accomplished by running a matrix of sweeps over the required frequency range with R&S Test-SW EMC32, 360° continuous measurement of the turntable, two orthogonal positions of the EUT and both antenna polarizations, at 1, 1.5, and 2 meters. 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 sweeps and saves the settings for each point of this trace. The maximum trace is part of the test report.
- The 6 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.

Radiated Emissions Test Setup 30MHz-1GHz Measurements



Radiated Emissions Test Setup 1GHz-18GHz MeasurementsRadiated Emissions Test Setup 18GHz-40GHz Measurements

5.2 Sample Calculations for Field Strength Measurements

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

- Measured reading in dB μ V
- Cable Loss between the receiving antenna and SA in dB and
- 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

6 Measurement Results Summary

Test Specification	Test Case	Temperature and Voltage Conditions	Mode	Pass	Fail	NA	NP	Result
FCC §15.109 ICES-003, §3.2.2	Radiated Emissions	Nominal	Op. 1	■	□	□	□	Complies
FCC §15.107 ICES-003, §3.2.1	Conducted Emissions	Nominal	Op. 1	■	□	□	□	Complies

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

7 Test Result Data

7.1 Radiated Emissions Measurement according to CFR 47 Part 15.109 and ICES-003, 3.2.2

Spectrum Analyzer settings		
Sweep Frequency Range	30 MHz – 1 GHz	1 GHz – 40 GHz
Resolution Bandwidth	120 kHz	1 MHz
Detector (Exploratory Measurements)	Peak	Peak, Average
Detector (Final Measurements)	Quasi-Peak	Peak, Average
Trace Mode	Max Hold	Max Hold
Step Size	40 kHz	800 kHz
Measurement Time (Exploratory Measurements)	2 ms	2 ms
Measurement Time (Final Measurements)	100 ms	100 ms

7.1.1 Limits:

Class A Limits		
Frequency of emission (MHz)	Field Strength @ 10 m (µV/m)	Field Strength @ 3 m (dBµV/m)
30-88	90	49.5
88-216	150	54
216-960	210	56.9
Above 960	300	60

Class B Limits		
Frequency of emission (MHz)	Field Strength @ 3 m (µV/m)	Field Strength @ 3 m (dBµV/m)
30-88	100	40
88-216	150	43.5
216-960	200	46
Above 960	500	54

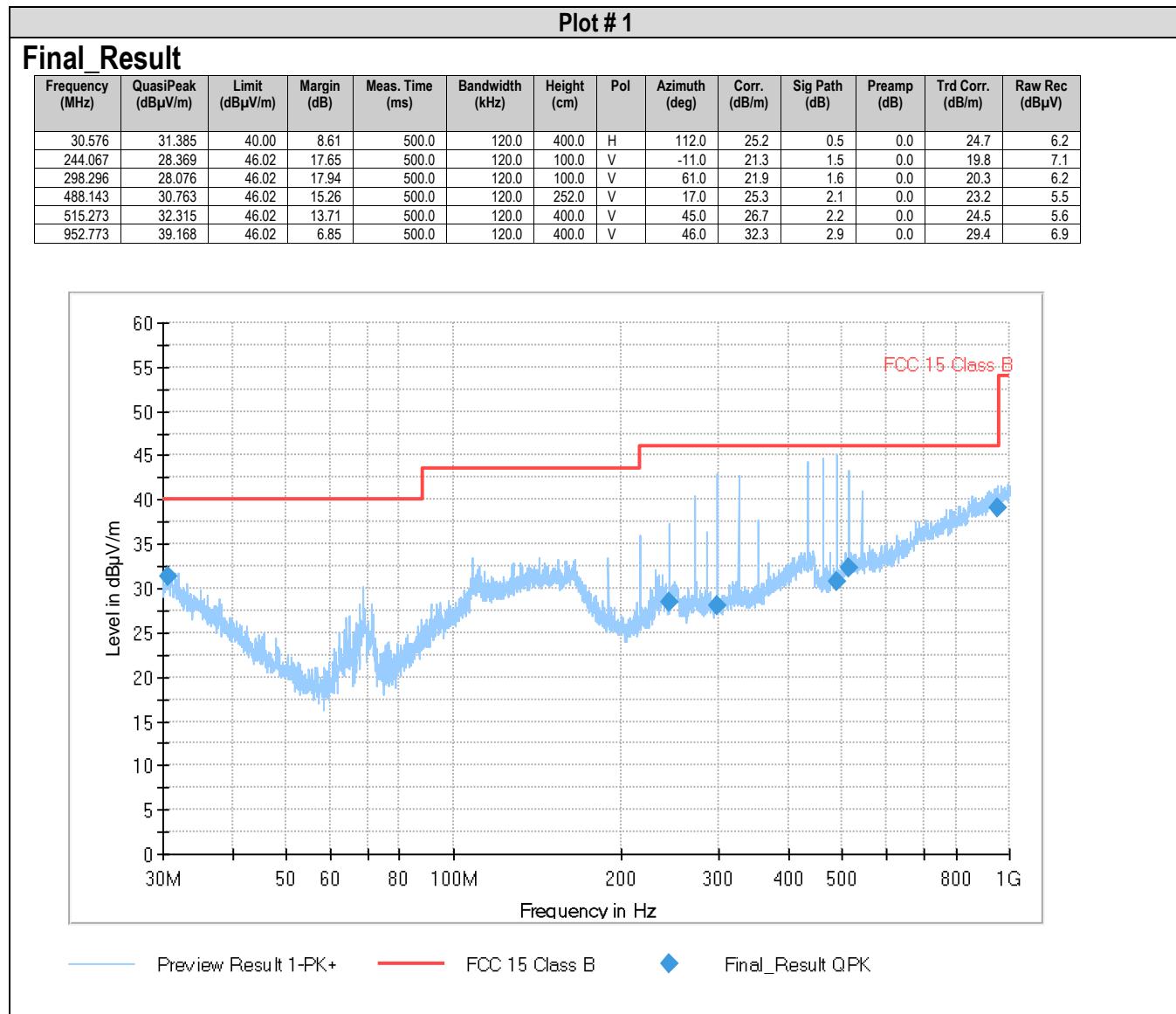
Note: For measurements below 1 GHz, the limits above use a quasi-peak detector. For measurements above 1 GHz, the limits above use an average detector.

7.1.2 Test Summary:

Environmental Conditions	
Ambient Temperature:	24.6°C
Relative Humidity:	45.1%
Atmospheric Pressure:	1010 mbar

Test Results						
Plot #	EUT Set-Up #	EUT operating mode	Scan Frequency	Power Supply Input	Comments	Result
1 - 3	1	Op. 1	30 MHz – 18 GHz	120 VAC	Final measurement	Pass

7.1.3 Measurement Plots:



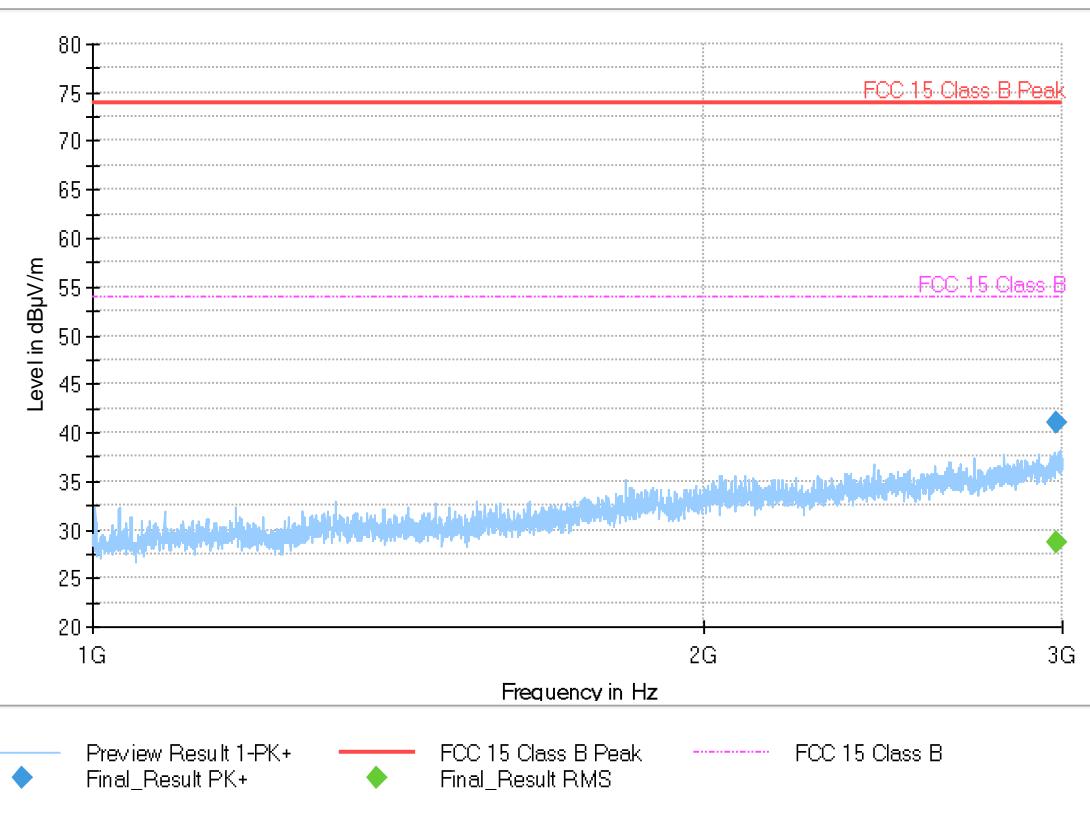
Plot # 2

Final_Result

Frequency (MHz)	MaxPeak (dB μ V/m)	RMS (dB μ V/m)	Limit (dB μ V/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol	Azimuth (deg)	Corr. (dB/m)	Sig Path (dB)	Preamp (dB)	Trd Corr. (dB/m)
2982.816	---	28.667	53.98	25.31	500.0	1000.0	131.0	H	214.0	0.6	-29.3	0.0	29.9
2982.816	41.054	---	73.98	32.93	500.0	1000.0	131.0	H	214.0	0.6	-29.3	0.0	29.9

(continuation of the "Final_Result" table from column 19 ...)

Frequency (MHz)	Raw Rec (dB μ V)
2982.816	28.1
2982.816	40.5



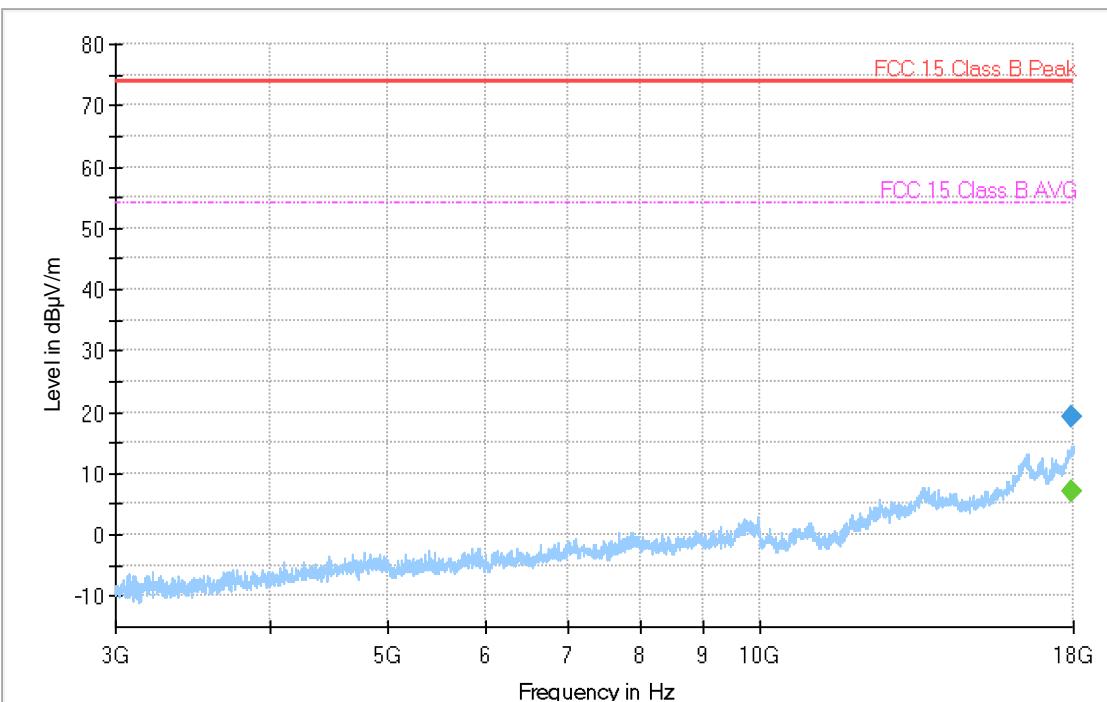
Plot # 3

Final_Result

Frequency (MHz)	MaxPeak (dB μ V/m)	RMS (dB μ V/m)	Limit (dB μ V/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol	Azimuth (deg)	Corr. (dB/m)	Sig Path (dB)	Preamp (dB)	Trd Corr. (dB/m)
17907.464	---	7.172	53.98	46.81	500.0	1000.0	100.0	V	89.0	-10.8	-9.7	-42.7	41.6
17907.464	19.190	---	73.98	54.79	500.0	1000.0	100.0	V	89.0	-10.8	-9.7	-42.7	41.6

(continuation of the "Final_Result" table from column 19 ...)

Frequency (MHz)	Raw Rec (dB μ V)
17907.464	18.0
17907.464	30.0



◆ Preview Result 1-PK+ Final_Result PK+ — FCC 15 Class B Peak Final_Result RMS - - - FCC 15 Class B AVG

7.2 AC Power line Conducted Emissions according to CFR 47 Part 15.107 and ICES-003 §3.2.1

Spectrum Analyzer Setting	
Frequency band	150 kHz – 30 MHz
Resolution Bandwidth	9 kHz
Detector (Exploratory Measurements)	Peak, Average
Detector (Final Measurements)	Quasi-Peak, Average
Trace Mode	Max Hold
Step Size	4 kHz
Measurement Time	20 ms

7.2.1 Measurement Procedure:

- The EUT and accessories are placed on a non-conducting table 80 cm above the horizontal ground plane and 40 cm from the vertical ground plane.
- Cables that hang closer than 40 cm to the ground plane are gathered into a 30 cm to 40 cm long bundle.
- The power cable of the EUT is connected to the LISN.
- The 6 highest emissions within 20 dB of the limit are noted.

7.2.2 Limits:

Class A Limits		
Frequency of emission (MHz)	Conducted Limit (dB μ V)	
	Quasi-peak	Average
0.15-0.5	79	66
0.5-30	73	60

Class B Limits		
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

7.2.3 Test Summary:

Environmental Conditions	
Ambient Temperature:	22° C
Relative Humidity:	40.4%
Atmospheric Pressure:	1010 mbar

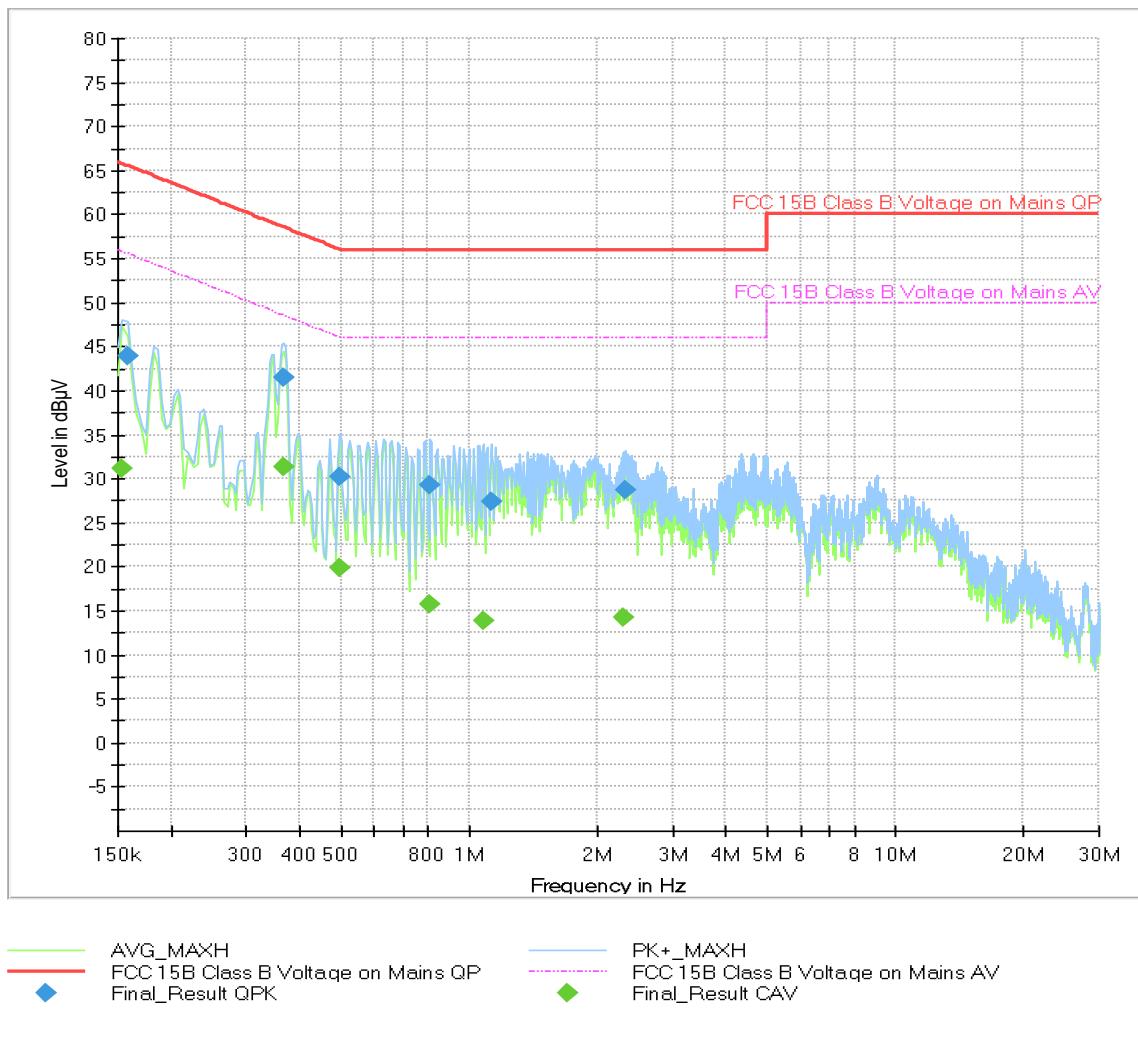
Test Results							
Plot #	EUT Set-Up #	EUT operating mode	Detector (Peak / AVG / QP)	Line Under Test	Power Supply Input	Comments	Result
1	1	Op. 1	QP & AVG	Line & Neutral	120 VAC	Final measurement	Pass

7.2.4 Measurement Plots:

Plot # 1

Final_Result

Frequency (MHz)	QuasiPeak (dB μ V)	CAverage (dB μ V)	Limit (dB μ V)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Line	PE	Corr. (dB)
0.154	---	31.13	55.78	24.65	1000.0	9.0	L1	GND	10.1
0.158	43.92	---	65.57	21.64	1000.0	9.0	L1	GND	10.1
0.368	---	31.40	48.55	17.15	1000.0	9.0	L1	GND	9.9
0.368	41.45	---	58.55	17.10	1000.0	9.0	L1	GND	9.9
0.497	---	19.81	46.05	26.24	1000.0	9.0	L1	GND	9.9
0.497	30.19	---	56.05	25.86	1000.0	9.0	L1	GND	9.9
0.812	29.20	---	56.00	26.80	1000.0	9.0	L1	GND	9.9
0.812	---	15.74	46.00	30.26	1000.0	9.0	L1	GND	9.9
1.078	---	13.82	46.00	32.18	1000.0	9.0	N	GND	9.9
1.126	27.42	---	56.00	28.58	1000.0	9.0	L1	GND	9.9
2.308	---	14.19	46.00	31.81	1000.0	9.0	L1	GND	9.9
2.336	28.80	---	56.00	27.20	1000.0	9.0	L1	GND	9.9



8 Test setup photos

Setup photos are included in supporting file name: "EMC_SMITH_063_25001_FCC_15B_Setup_Photos"

9 Test Equipment and Ancillaries Used for Testing

Equipment Type	Manufacturer	Model	Serial #	Calibration Cycle	Last Calibration Date
BILOG ANTENNA	A.H. SYSTEMS	BiLA2G	569	3 Years	10/30/2023
HORN ANTENNA	EMCO	3115	00035111	3 Years	10/26/2023
HORN ANTENNA	ETS LINDGREN	3117-PA	00167061	3 Years	9/25/2023
ESW.EMI TEST RECEIVER	ROHDE & SCHWARZ	ESW44	101715	3 Years	10/24/2023
DIGITAL THERMOMETER	Control Company	4410,90080-03	230712972	3 Years	10/18/2023
Multimeter	Fluke	115	56090717MV	3 Years	09/26/2023
Software	EMC32	Version 10.50.40	-	-	-

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.

10 Revision History

Date	Report Name	Changes to report	Prepared by
2025-03-05	EMC_SMITH_058_24001_FCC_15B	Initial Version	Cheng Song
2025-04-22	EMC_SMITH_063_25001_FCC_15B_Rev1	Updated the report to reflect the latest HW version.	Cheng Song
2025-04-29	EMC_SMITH_063_25001_FCC_15B_Rev2	Updated the report to reflect the latest HW version.	Cheng Song

<<< The End >>>