

RADIO PERFORMANCE TEST REPORT

Test Report No. : OT-21D-RWD-048

Reception No. : 2112005204

Applicant : Tianjin Empecs Medical Device Co., Ltd.

Address : No.35 and 37, Yingcheng Street, Hangu, Binhai New Area, Tianjin, China

Manufacturer : Tianjin Empecs Medical Device Co., Ltd.

Address : No.35 and 37, Yingcheng Street, Hangu, Binhai New Area, Tianjin, China

Type of Equipment : Blood Beta-Ketone Monitoring System

FCC ID. : 2AFE8K21BT

Model Name : KT21 BT

Multiple Model Name : N/A

Serial number : N/A

Total page of Report : 31 pages (including this page)

Date of Incoming : December 10, 2021

Date of issue : December 22, 2021

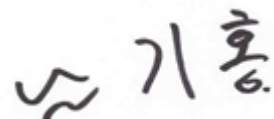
SUMMARY

The equipment complies with the regulation; *FCC PART 15 SUBPART C Section 15.247*

This test report only contains the result of a single test of the sample supplied for the examination.

It is not a generally valid assessment of the features of the respective products of the mass-production.





Tested by
/Su-Min You / Assistant Manager
ONETECH Corp.

Reviewed by
/ Tae-Ho, Kim / Senior Manager
ONETECH Corp.

Approved by
/ Ki-Hong, Nam / General Manager
ONETECH Corp.

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Revision History

Rev. No.	Issue Report No.	Issued Date	Revisions	Section Affected
0	OT-21D-RWD-048	December 22, 2021	Initial Release	All

1. VERIFICATION OF COMPLIANCE

Applicant : Tianjin Empecs Medical Device Co., Ltd.
 Address : No.35 and 37, Yingcheng Street, Hangu, Binhai New Area, Tianjin, China
 Contact Person : Dongeon Cho / Senior Research Engineer
 Telephone No. : 82(0)70-7124-0476
 FCC ID : 2AFE8K21BT
 Model Name : KT21 BT
 Brand Name : Medisign
 Serial Number : N/A
 Date : December 22, 2021

EQUIPMENT CLASS	DTS – DIGITAL TRNSMISSION SYSTEM
E.U.T. DESCRIPTION	Blood Beta-Ketone Monitoring System
THIS REPORT CONCERNS	Original Grant
MEASUREMENT PROCEDURES	ANSI C63.10: 2020
TYPE OF EQUIPMENT TESTED	Pre-Production
KIND OF EQUIPMENT AUTHORIZATION REQUESTED	Certification
EQUIPMENT WILL BE OPERATED UNDER FCC RULES PART(S)	FCC PART 15 SUBPART C Section 15.247 KDB 558074 D01 15.247 Meas Guidance v05r02
Modifications on the Equipment to Achieve Compliance	None
Final Test was Conducted On	3 m, Semi Anechoic Chamber

-. The above equipment was tested by ONETECH Corp. for compliance with the requirement set forth in the FCC Rules and Regulations. This said equipment in the configuration described in this report, shows the maximum emission levels emanating from equipment are within the compliance requirements.

2. TEST SUMMARY

2.1 Test items and results

SECTION	TEST ITEMS	RESULTS
15.247 (a) (2)	Minimum 6 dB Bandwidth	Met the Limit / PASS
15.247 (b) (3)	Maximum Peak Conducted Output Power	Met the Limit / PASS
15.247 (d)	100 kHz Bandwidth Outside the Frequency Band	Met the Limit / PASS
15.247 (d)	Radiated Emission which fall in the Restricted Band	Met the Limit / PASS
15.247 (e)	Peak Power Spectral Density	Met the Limit / PASS
15.209	Radiated Emission Limits	Met the Limit / PASS
15.207	Conducted Limits	N/A (See Note)
15.203	Antenna Requirement	Met requirement / PASS

Note.: As the EUT is operated by DC battery, this test item is not required.

2.2 Additions, deviations, exclusions from standards

No additions, deviations or exclusions have been made from standard.

2.3 Related Submittal(s) / Grant(s)

Original submittal only

2.4 Purpose of the test

To determine whether the equipment under test fulfills the requirements of the regulation stated in FCC PART 15 SUBPART C Section 15.247.

2.5 Test Methodology

Both conducted and radiated testing was performed according to the procedures in ANSI C63.10: 2020. Radiated testing was performed at a distance of 3 m from EUT to the antenna.

2.6 Test Facility

The Onetech Corp. has been designated to perform equipment testing in compliance with ISO/IEC 17025.

The Electromagnetic compatibility measurement facilities are located at 43-14, Jinsaegol-gil, Chowol-eup, Gwangju-si, Gyeonggi-do, 12735, Korea.

-. Site Filing:

VCCI (Voluntary Control Council for Interference) – Registration No. R-20122/ C-14617/ G-10666/ T-11842

ISED (Innovation, Science and Economic Development Canada) – Registration No. Site# 3736A-3

KOLAS (Korea Laboratory Accreditation Scheme) - Accreditation NO. KT085

FCC (Federal Communications Commission) - Accreditation No. KR0013

RRA (Radio Research Agency) – Designation No. KR0013

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3. GENERAL INFORMATION

3.1 Product Description

The Tianjin Empecs Medical Device Co., Ltd., Model KT21 BT (referred to as the EUT in this report) is a Blood Beta-Ketone Monitoring System. The product specification described herein was obtained from product data sheet or user's manual.

Device Type	Blood Beta-Ketone Monitoring System
Operating Frequency	2 402 MHz ~ 2 480 MHz
RF Output Power	-1.59 dBm
Modulation Type	GFSK
Antenna Type	PCB Antenna
Antenna Gain	-4.34 dBi
Rated Supply Voltage	DC 3.0 V
List of each Osc. or crystal Freq.(Freq. >= 1 MHz)	32 MHz

3.2 Alternative type(s)/model(s); also covered by this test report.

-. None

4. EUT MODIFICATIONS

-. None

5. SYSTEM TEST CONFIGURATION

5.1 Justification

This device was configured for testing in a typical way as a normal customer is supposed to be used. During the test, the following components were installed inside of the EUT.

DEVICE TYPE	MANUFACTURER	MODEL/PART NUMBER	FCC ID
Main Board	Tianjin Empecs Medical Device Co., Ltd.	N/A	N/A

5.2 Peripheral equipment

Defined as equipment needed for correct operation of the EUT, but not considered as tested:

Model	Manufacturer	Description	Connected to
KT21 BT	Tianjin Empecs Medical Device Co., Ltd.	Blood Beta-Ketone Monitoring System (EUT)	-

5.3 Mode of operation during the test

For the testing, software used to control the EUT for staying in continuous transmitting is programmed.

For final testing, the EUT was set at 2 402 MHz, 2 440 MHz, and 2 480 MHz to get a maximum emission levels from the EUT. The EUT was moved throughout the XY, XZ, and YZ planes and the worst case is “XY” axis, but the worst data was recorded in this report.

- . Frequency / Channel Operations

Channel	Frequency
0	2 402
19	2 440
39	2 480

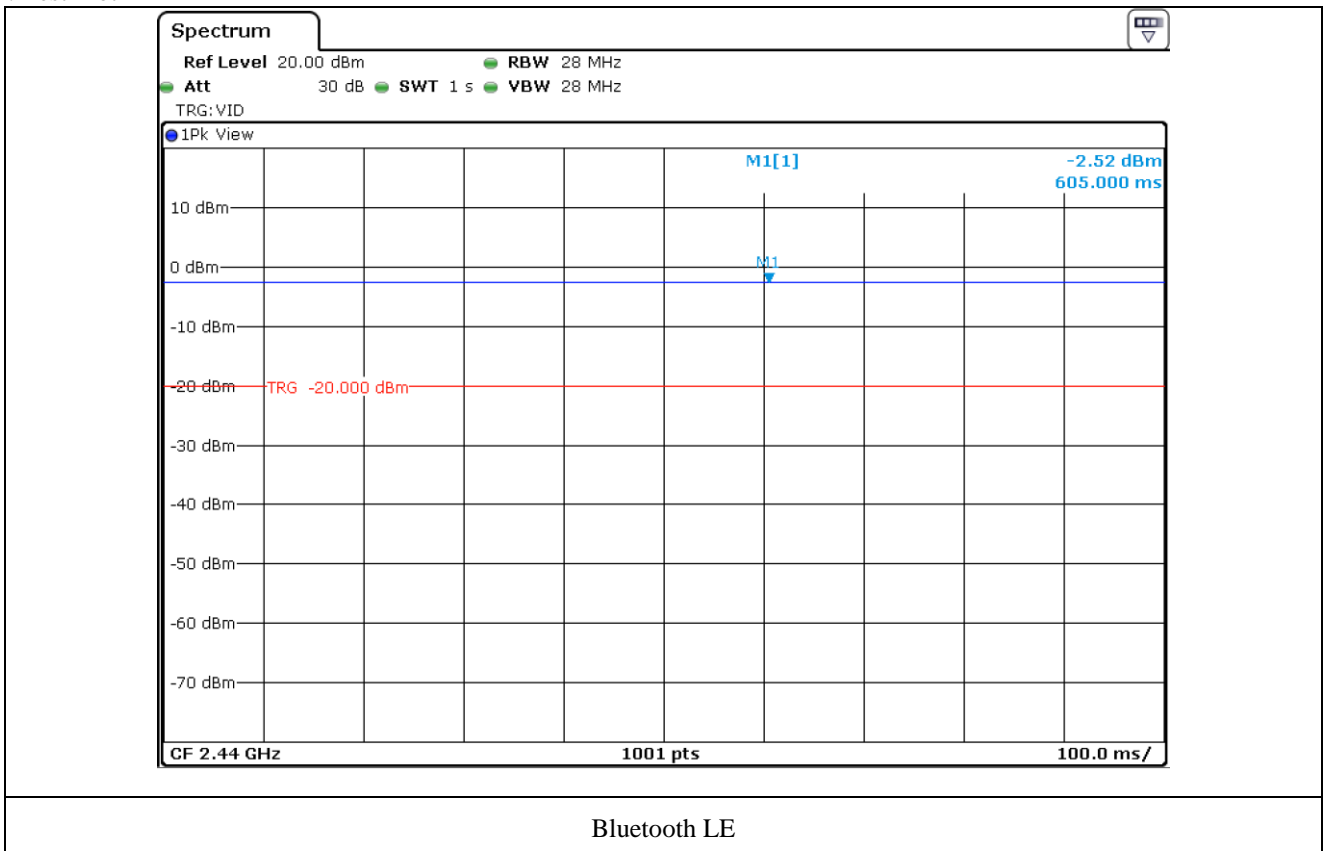
- Duty Cycle

Mode	Tx On Time [ms]	Tx Off Time [ms]	Duty Cycle [%]	Correction Factor [dB]
Bluetooth LE	-	-	100	0.00

Note – Duty Cycle : (Tx On Time / (Tx On Time + Tx Off Time)) * 100

Correction Factor : 10 * Log(1 / (Duty Cycle / 100))

- Test Plot



Bluetooth LE

5.4 Configuration of Test System

Line Conducted Test: As This product is only using DC power, AC conducted emission test has not been performed

Radiated Emission Test: Preliminary radiated emissions test were conducted using the procedure in ANSI C63.10: 2020 to determine the worse operating conditions. Final radiated emission tests were conducted at 3 meter Semi Anechoic Chamber.

The turntable was rotated through 360 degrees and the EUT was tested by positioned three orthogonal planes to obtain the highest reading on the field strength meter. Once maximum reading was determined, the search antenna was raised and lowered in both vertical and horizontal polarization.

5.5 Antenna Requirement

For intentional device, according to section 15.203, an intentional radiator shall be designed to ensure that no antenna other than that furnished by the responsible party shall be used with the device.

Antenna Construction:

The antenna of the EUT is PCB Antenna on the main board in the EUT, so no consideration of replacement by the user.

6. PRELIMINARY TEST

6.1 AC Power line Conducted Emissions Tests

As This product is only using DC power, AC conducted emission test has not been performed

6.2 General Radiated Emissions Tests

During Preliminary Test, the following operating mode was investigated.

Operation Mode	The Worse operating condition (Please check one only)
Transmitting Mode	X

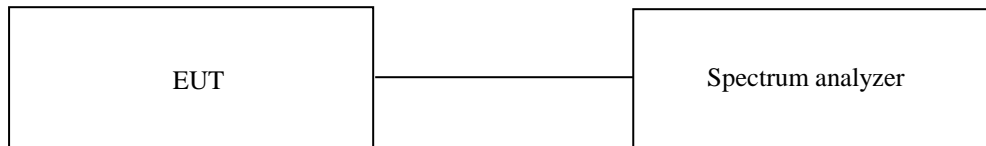
7. MINIMUM 6 dB BANDWIDTH

7.1 Operating environment

Temperature : 21 °C
 Relative humidity : 42 % R.H.

7.2 Test set-up

The antenna output of the EUT was connected to the spectrum analyzer. The resolution bandwidth is set to 100 kHz, and peak detection was used. The 6 dB bandwidth is defined as the total spectrum over which the power is higher than the peak power minus 6 dB.



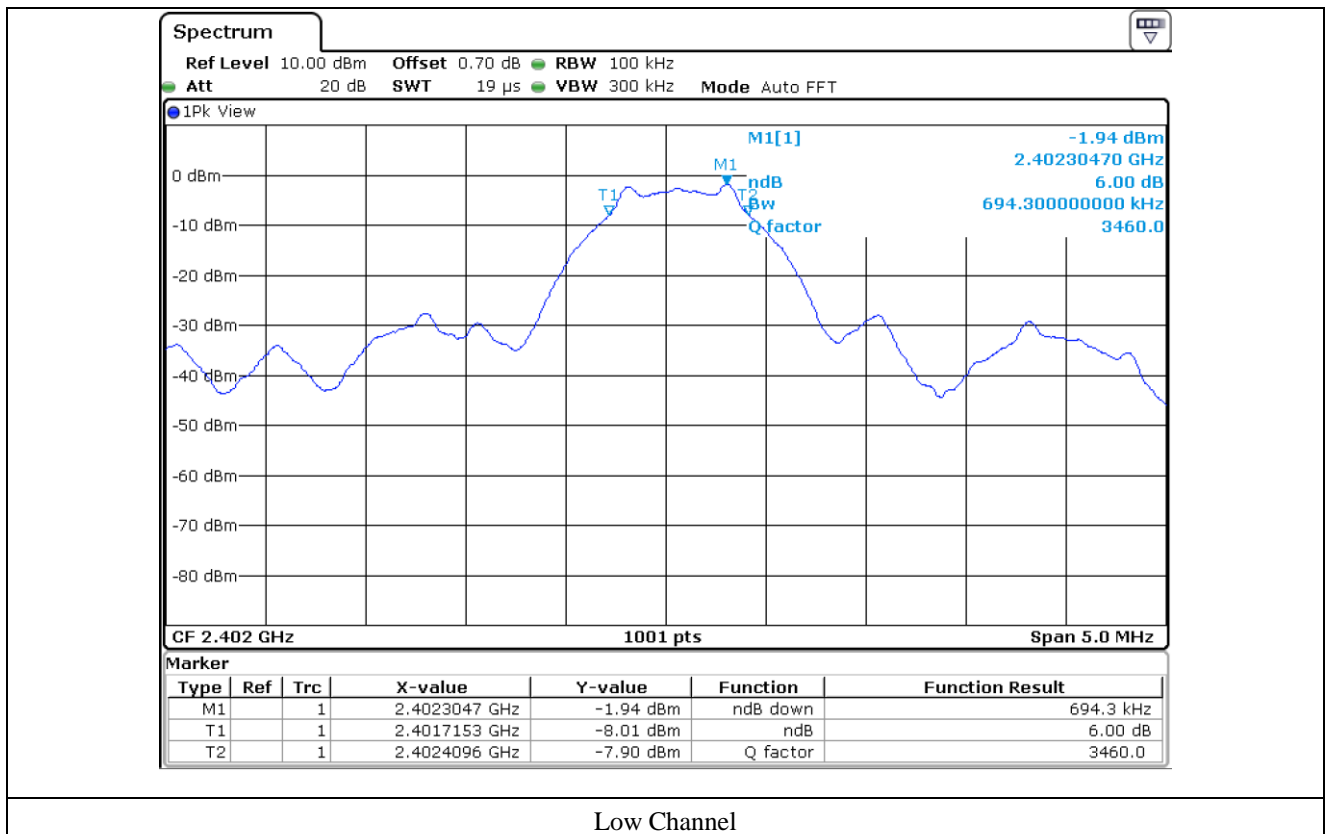
7.3 Test Date

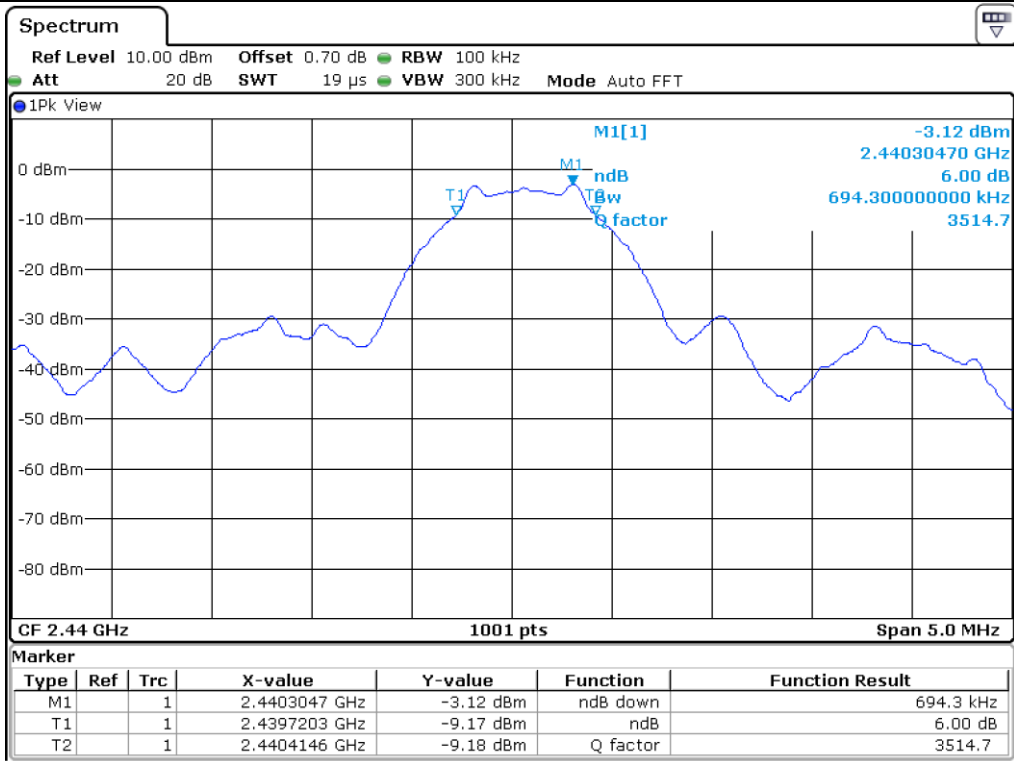
December 10, 2021 ~ December 21, 2021

7.4 Test data

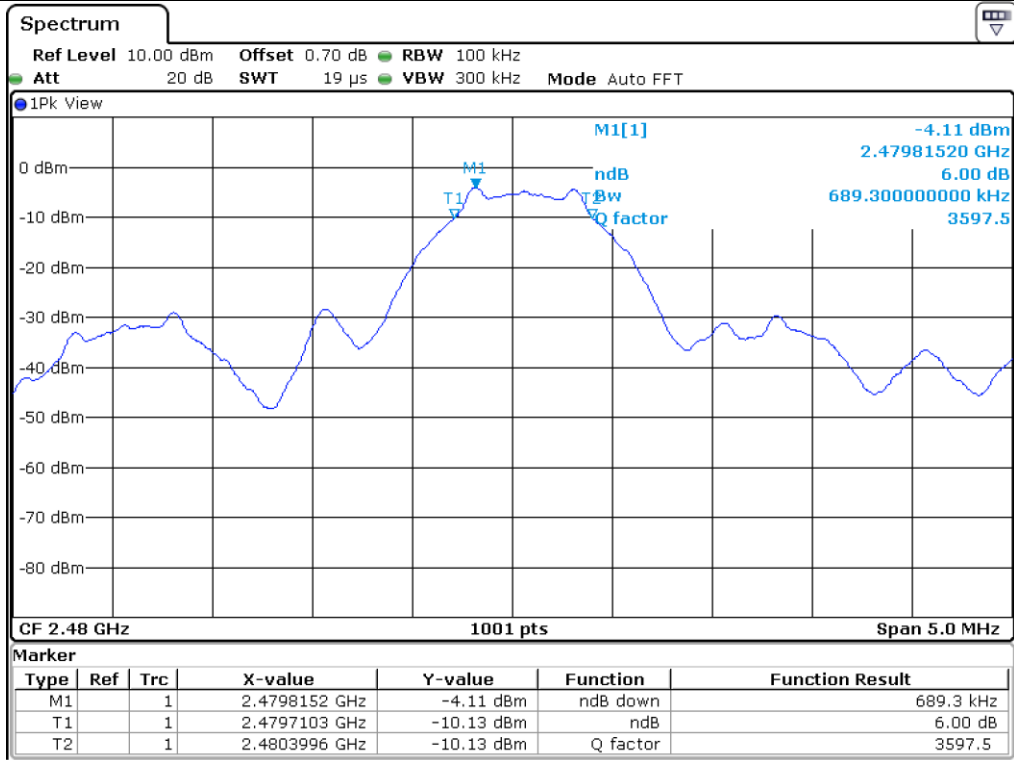
Channel	Frequency (MHz)	Measured Value (kHz)	Limit (kHz)	Margin (kHz)
Low	2 402.00	694.30	500.00	194.30
Middle	2 440.00	694.30	500.00	194.30
High	2 480.00	689.30	500.00	189.30

Remark. Margin = Measured Value - Limit





Middle Channel



High Channel

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8. MAXIMUM PEAK OUTPUT POWER

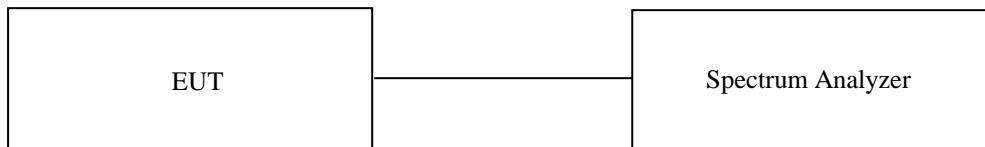
8.1 Operating environment

Temperature : 21 °C
Relative humidity : 42 % R.H.

8.2 Test set-up

The antenna output of the EUT was connected to the spectrum analyzer.

The resolution bandwidth is set to \geq DTS Bandwidth, the video bandwidth is set to 3 times the resolution bandwidth.



8.3 Test Date

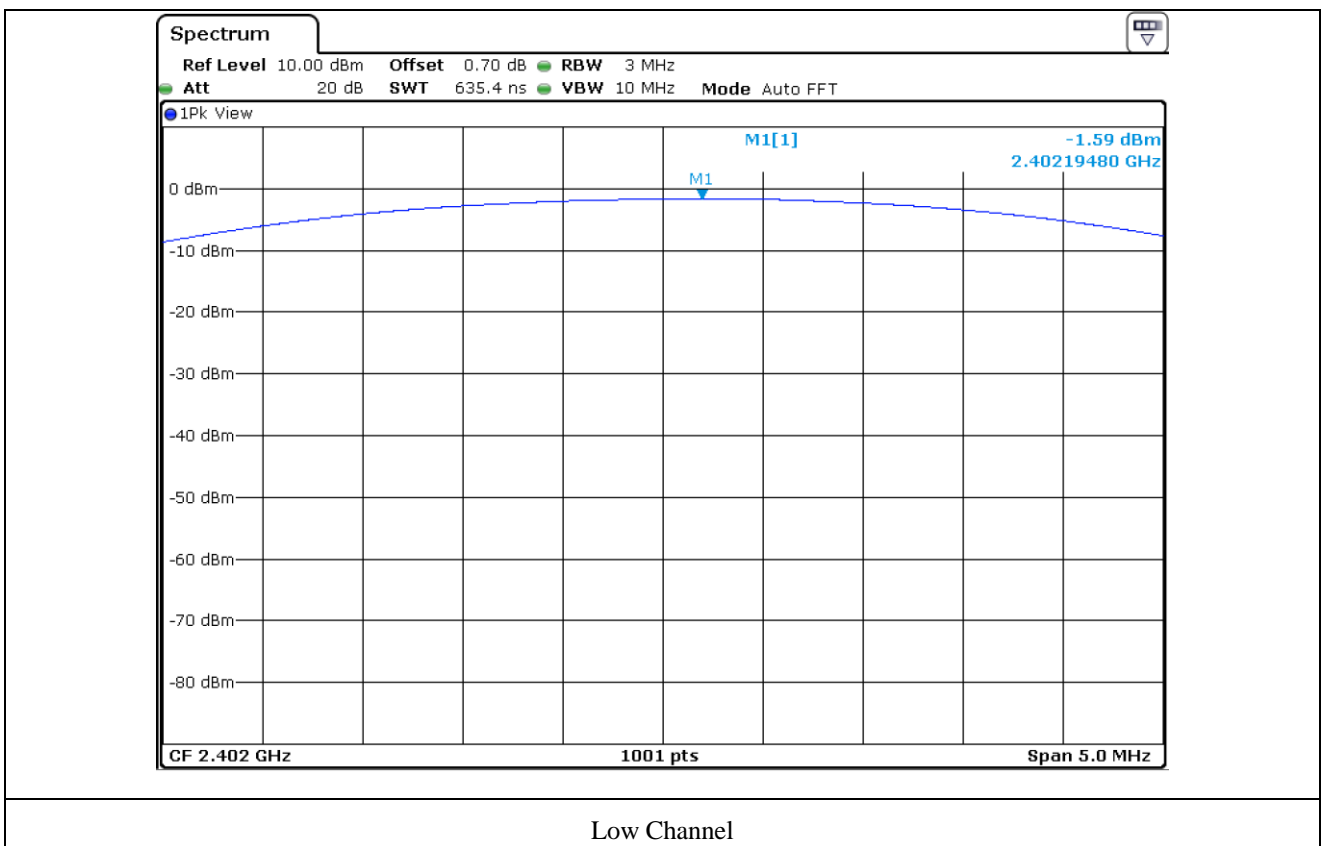
December 10, 2021 ~ December 21, 2021

8.4 Test data

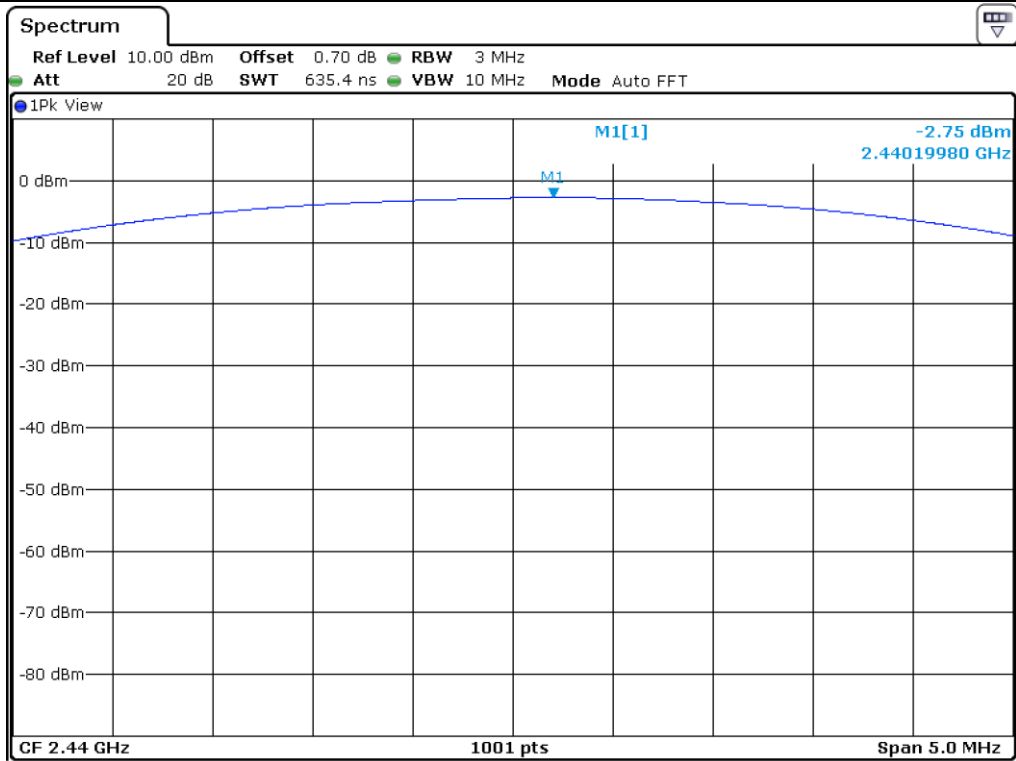
-. Test Result : Pass

Channel	Frequency (MHz)	6 dB Bandwidth (kHz)	Measured Value (dBm)	Limit (dBm)	Margin (dB)
Low	2 402.00	694.30	-1.59	30.00	31.59
Middle	2 440.00	694.30	-2.75	30.00	32.75
High	2 480.00	689.30	-3.81	30.00	33.81

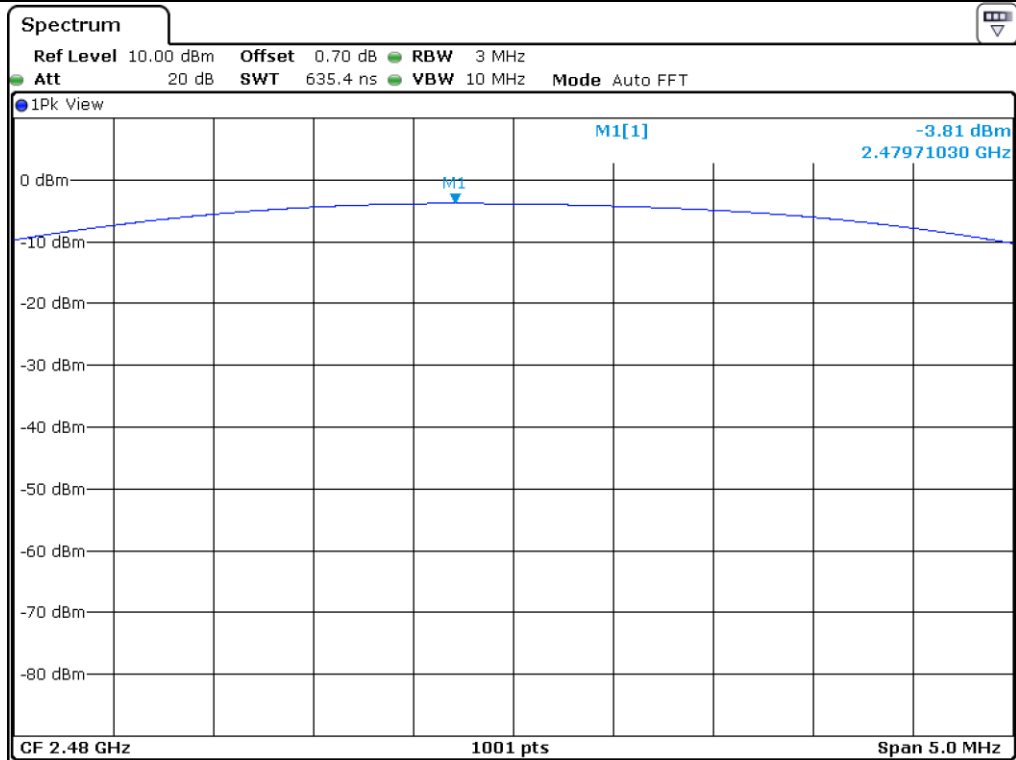
Remark. Margin = Limit – Measured value (=Receiver Reading + Cable Loss)



Low Channel



Middle Channel



High Channel

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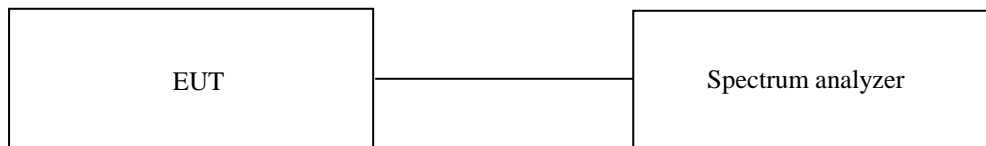
9. 100 kHz BANDWIDTH OUTSIDE THE FREQUENCY BAND

9.1 Operating environment

Temperature : 21 °C
 Relative humidity : 42 % R.H.

9.2 Test set-up for conducted measurement

The antenna output of the EUT was connected to the spectrum analyzer. The resolution bandwidth is set to 100 kHz, the video bandwidth is set to 3 times the resolution bandwidth and peak detection was used.



9.3 Test set-up for radiated measurement

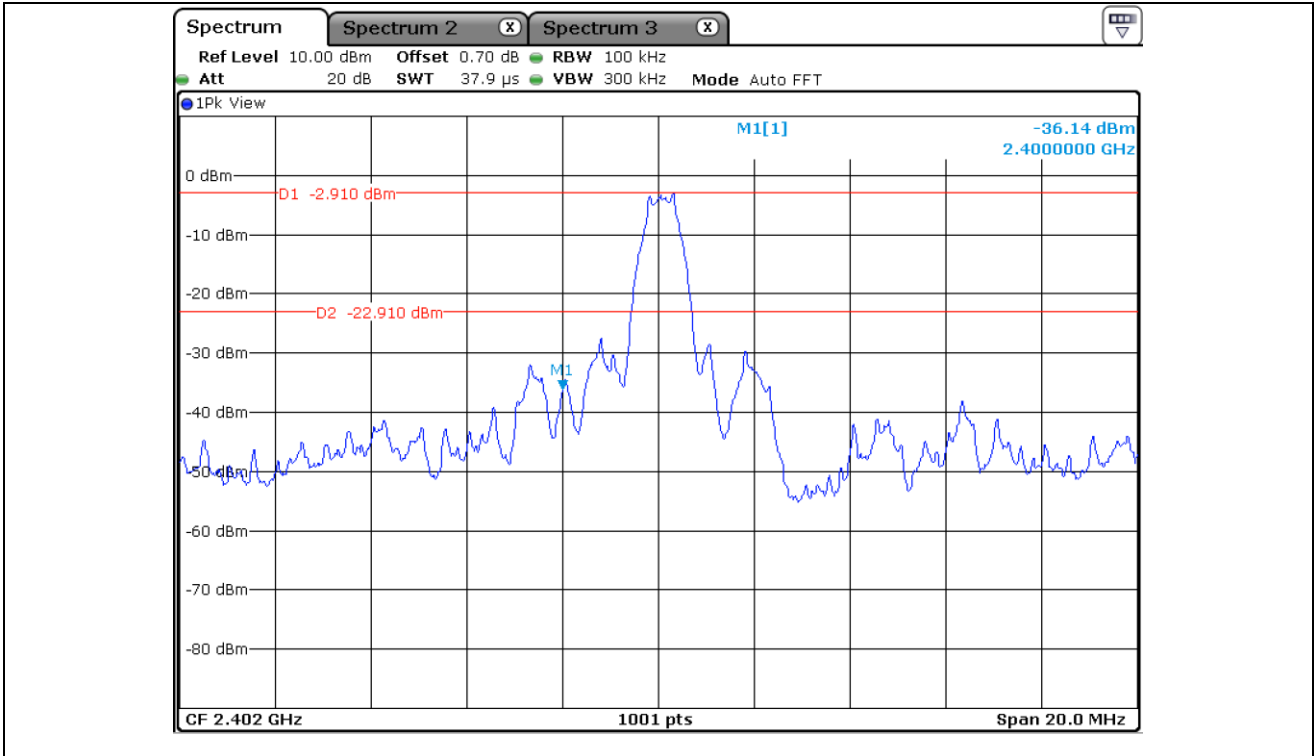
The radiated emissions measurements were performed on the 3 m semi anechoic chamber. The EUT was placed on turntable approximately 1.5 m above the ground plane.

The frequency spectrum from 30 MHz to 26.5 GHz was scanned and maximum emission levels at each frequency recorded. The system was rotated 360°, and the antenna was varied in the height between 1.0 m and 4.0 m in order to determine the maximum emission levels. This procedure was performed for horizontal and vertical polarization of the receiving antenna.

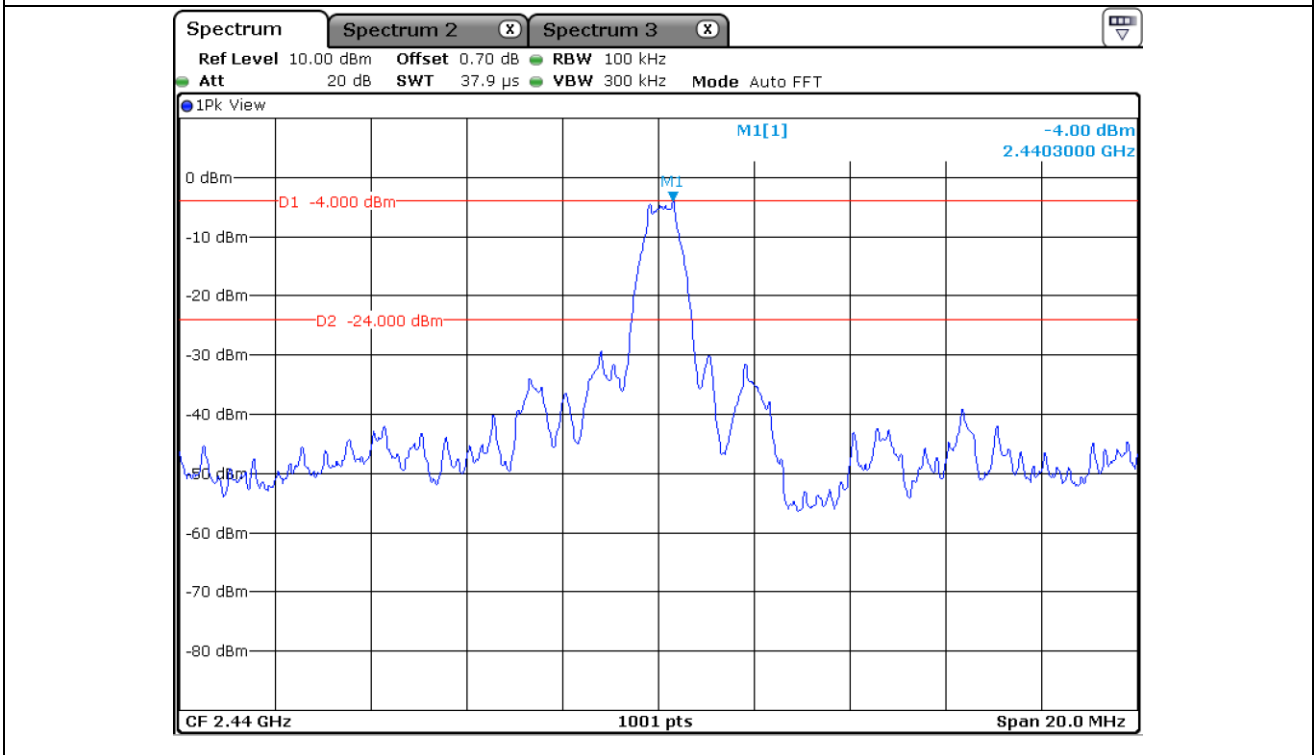
9.4 Test Date

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9.5 Test data for conducted emission



Low Channel

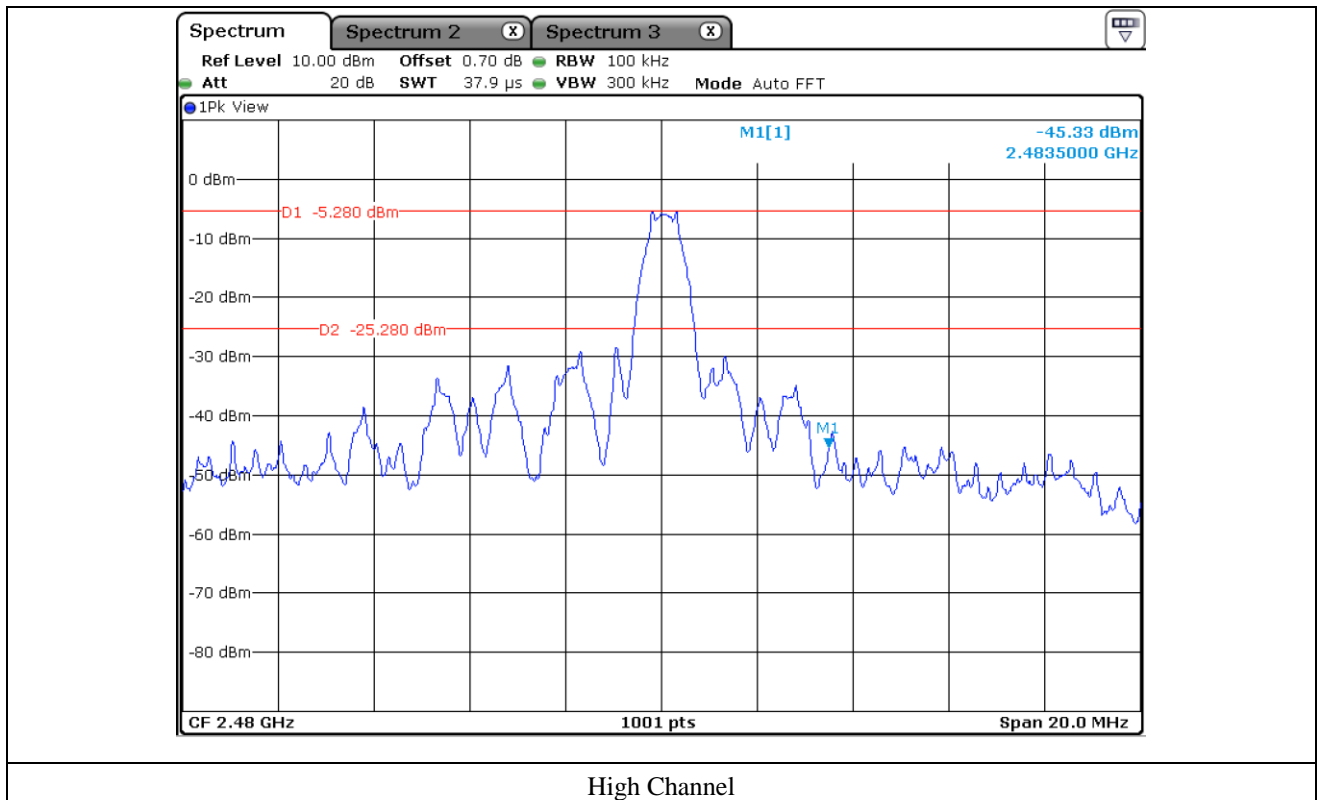


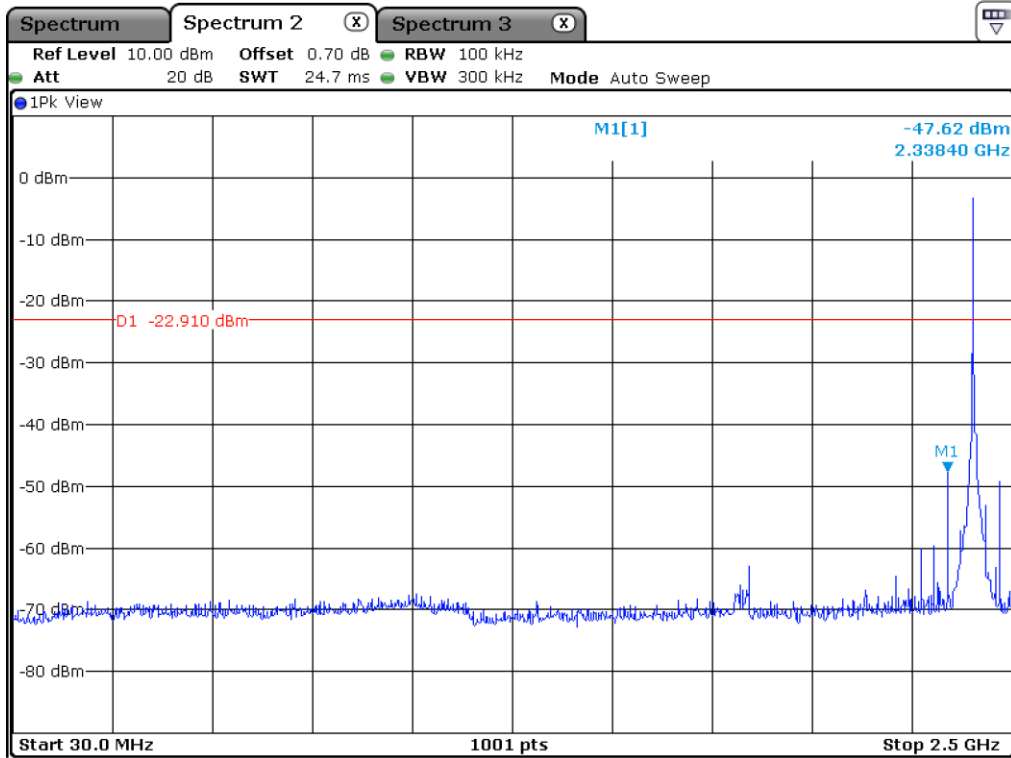
Middle Channel

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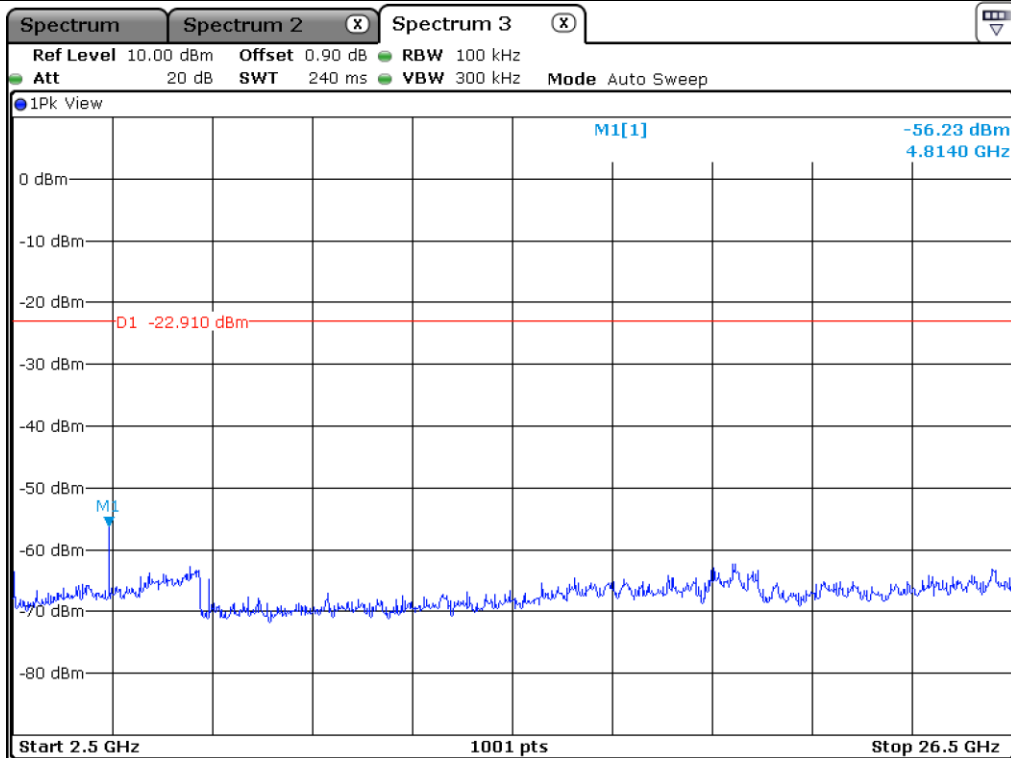
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Low Channel

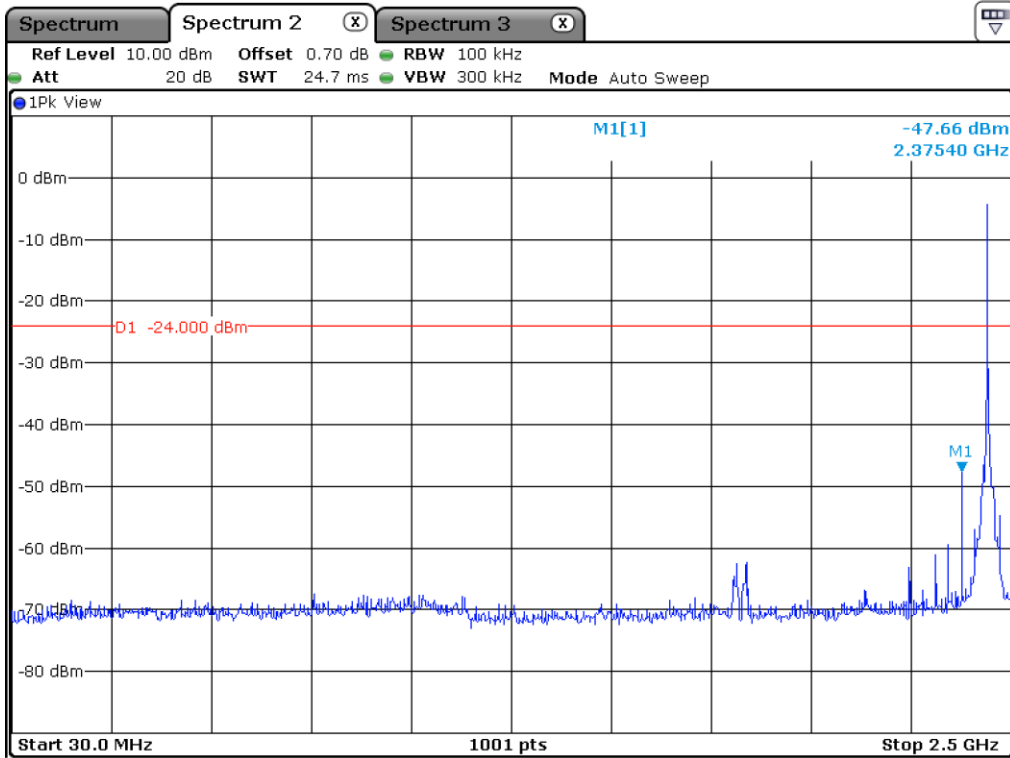


Low Channel

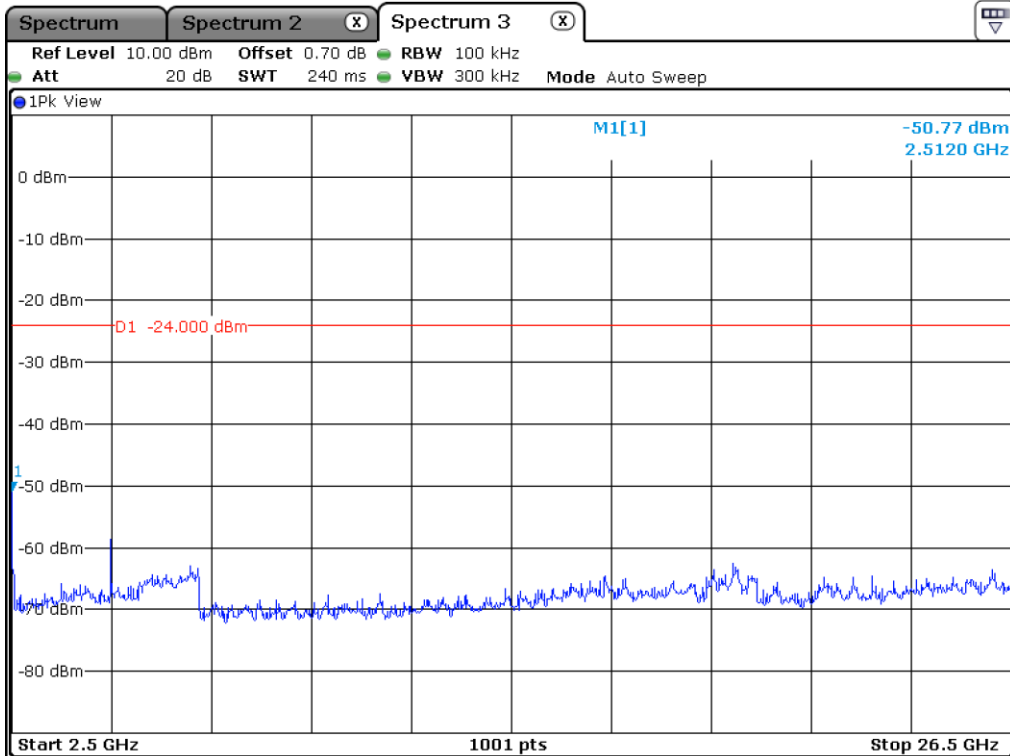
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Middle Channel

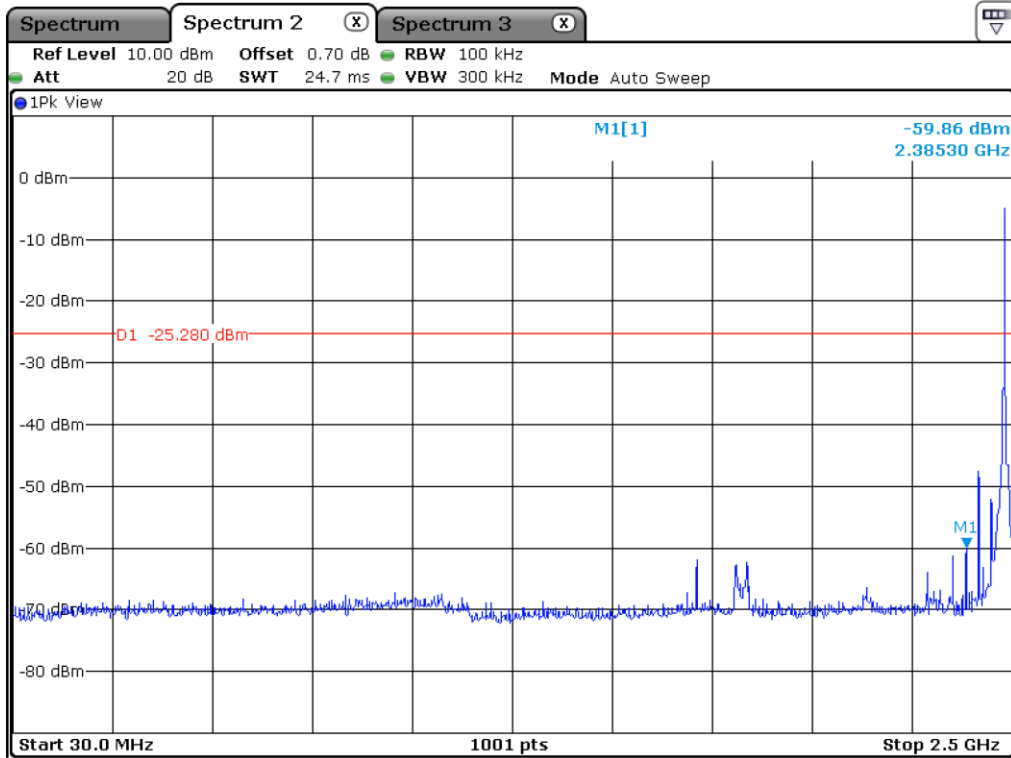


Middle Channel

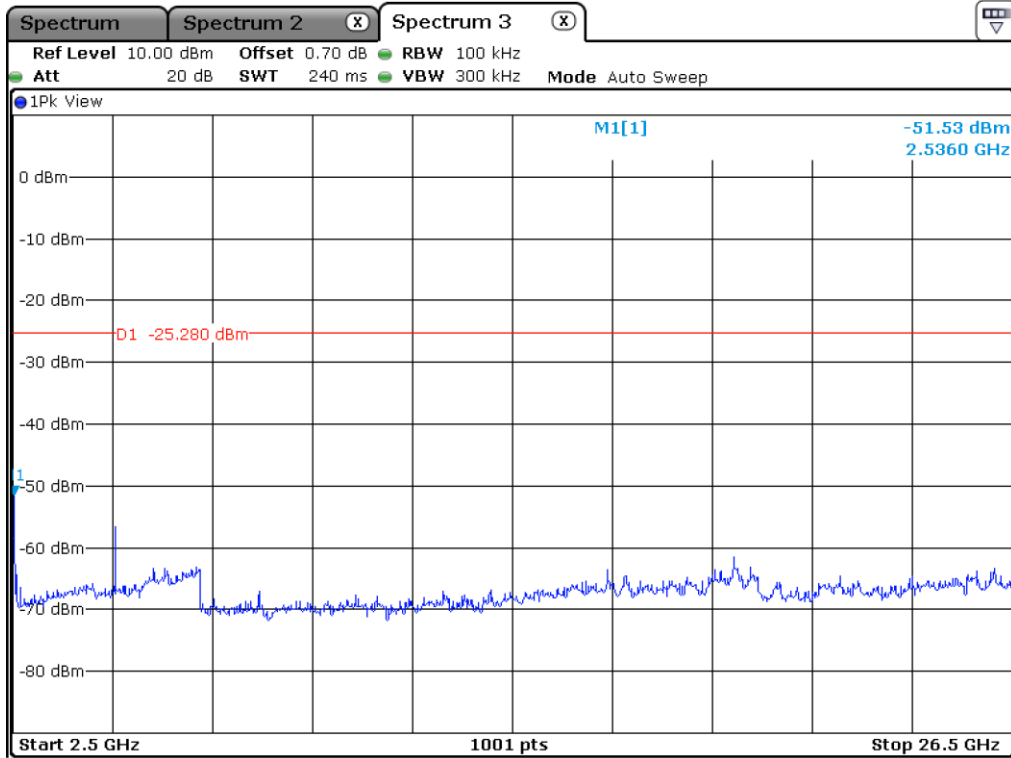
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High Channel



High Channel

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9.6 Test data for radiated emission

9.6.1 Radiated Emission which fall in the Restricted Band

- Resolution bandwidth : 1 MHz and Peak Detector for Peak Mode
1 MHz and RMS Detector for Average Mode
- Video bandwidth : 3 MHz for Peak and Average Mode
- Measurement distance : 3 m
- Duty Cycle : 100 %
- Result : PASSED

Frequency (MHz)	Reading (dBμV)	Detector Mode	Ant. Pol. (H/V)	Ant. Factor	Cable Loss	AMP Gain	Duty Factor (dB)	Total (dBμV/m)	Limits (dBμV/m)	Margin (dB)
Test Data for Low Channel										
2 338.01	57.47	Peak	H	28.30	8.20	46.15	-	47.82	74.00	26.18
2 338.10	50.41	Average	H	28.30	8.20	46.15	0.00	40.76	54.00	13.24
2 337.65	56.97	Peak	V	28.30	8.20	46.15	-	47.32	74.00	26.68
2 338.11	49.61	Average	V	28.30	8.20	46.15	0.00	39.96	54.00	14.04
Test Data for High Channel										
2 483.50	58.92	Peak	H	28.80	8.33	46.15	-	49.90	74.00	24.10
2 483.50	51.34	Average	H	28.80	8.33	46.15	0.00	42.32	54.00	11.68
2 485.98	56.62	Peak	V	28.80	8.33	46.15	-	47.60	74.00	26.40
2 483.50	47.79	Average	V	28.80	8.33	46.15	0.00	38.77	54.00	15.23

Tabulated test data for Restricted Band

Remark: “H”: Horizontal, “V”: Vertical

$$\text{Margin (dB)} = \text{Limits (dB}\mu\text{V/m)} - \text{Total Level (dB}\mu\text{V/m)}$$

$$\text{Total Level} = \text{Reading} + \text{Antenna Factor} + \text{Cable Loss} + \text{Duty Factor} - \text{AMP Gain}$$

9.6.2 Spurious & Harmonic Radiated Emission

- Resolution bandwidth : 1 MHz for Peak and Average Mode for the emissions fall in restricted band,
1 MHz for Peak Mode for the emissions outside restricted band
- Video bandwidth : 3 MHz for Peak and Average Mode
- Frequency range : 1 GHz ~ 26.5 GHz
- Measurement distance : 3 m
- Duty Cycle : 100 %
- Result : PASSED

Frequency (MHz)	Reading (dBμV)	Detector Mode	Ant. Pol. (H/V)	Ant. Factor	Cable Loss	AMP Gain	Duty Factor (dB)	Total (dBμV/m)	Limits (dBμV/m)	Margin (dB)
Test Data for Low Channel										
4 804.00	54.96	Peak	H	33.40	11.21	45.89	-	53.68	74.00	20.32
4 804.00	48.76	Average	H	33.40	11.21	45.89	0.00	47.48	54.00	6.52
4 804.00	53.40	Peak	V	33.40	11.21	45.89	-	52.12	74.00	21.88
4 804.00	45.93	Average	V	33.40	11.21	45.89	0.00	44.65	54.00	9.35
Test Data for Middle Channel										
4 880.00	55.76	Peak	H	33.30	11.23	45.89	-	54.40	74.00	19.60
4 880.00	50.20	Average	H	33.30	11.23	45.89	0.00	48.84	54.00	5.16
4 880.00	54.55	Peak	V	33.30	11.23	45.89	-	53.19	74.00	20.81
4 880.00	47.71	Average	V	33.30	11.23	45.89	0.00	46.35	54.00	7.65
Test Data for High Channel										
4 960.00	55.84	Peak	H	33.60	11.31	45.89	-	54.86	74.00	19.14
4 960.00	50.49	Average	H	33.60	11.31	45.89	0.00	49.51	54.00	4.49
4 960.00	53.61	Peak	V	33.60	11.31	45.89	-	52.63	74.00	21.37
4 960.00	47.04	Average	V	33.60	11.31	45.89	0.00	46.06	54.00	7.94

Remark: "H": Horizontal, "V": Vertical

$$\text{Margin (dB)} = \text{Limits (dB}\mu\text{V/m)} - \text{Total Level (dB}\mu\text{V/m)}$$

$$\text{Total Level} = \text{Reading} + \text{Antenna Factor} + \text{Cable Loss} + \text{Duty Factor} - \text{AMP Gain}$$

10. PEAK POWER SPECTRAL DENSITY

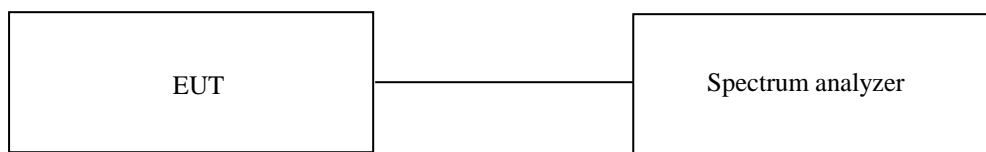
10.1 Operating environment

Temperature : 21 °C
 Relative humidity : 42 % R.H.

10.2 Test set-up

The antenna output of the EUT was connected to the spectrum analyzer.

The resolution bandwidth is set to $3 \text{ kHz} \leq \text{RBW} \leq 100 \text{ kHz}$, the video bandwidth is set to 3 times the resolution bandwidth.



10.3 Test Date

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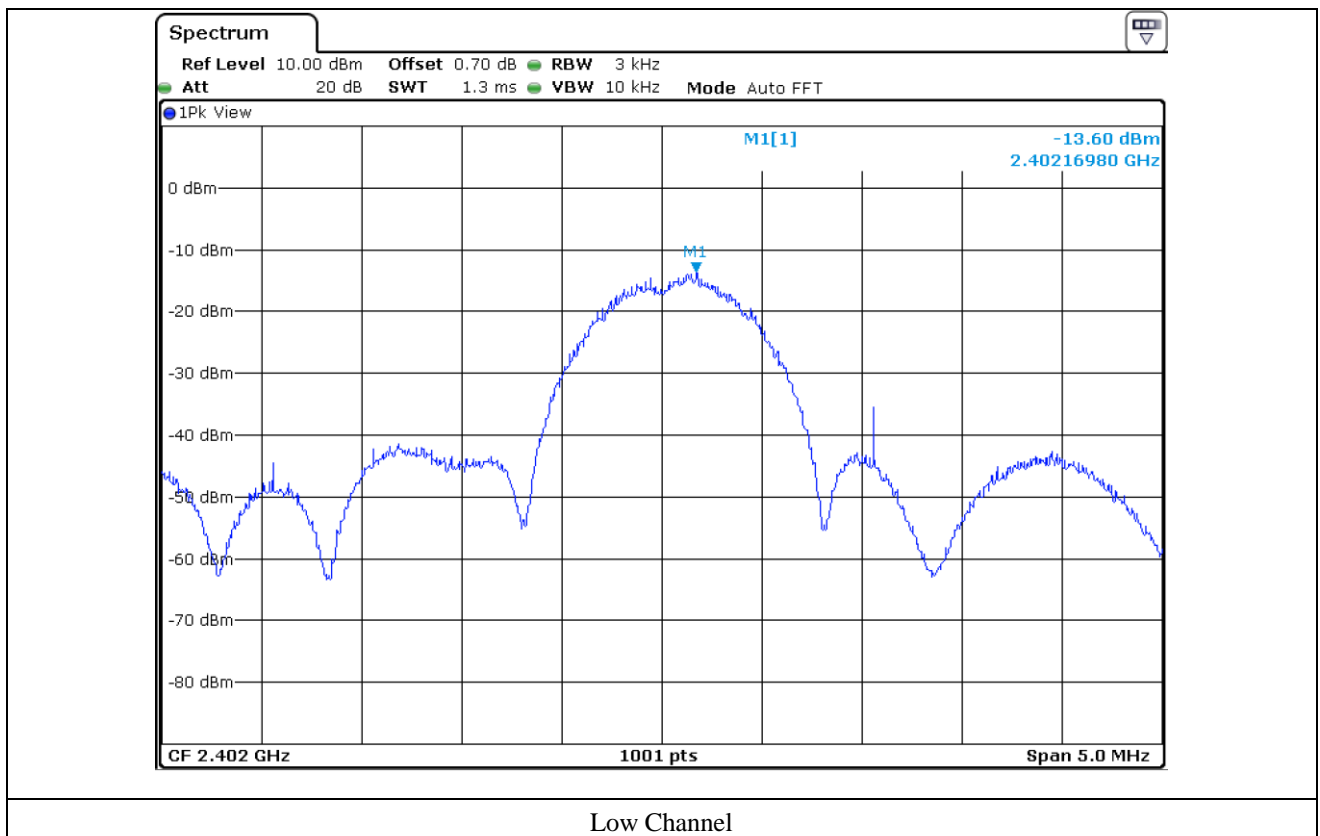
10.4 Test data

- Test Result : Pass

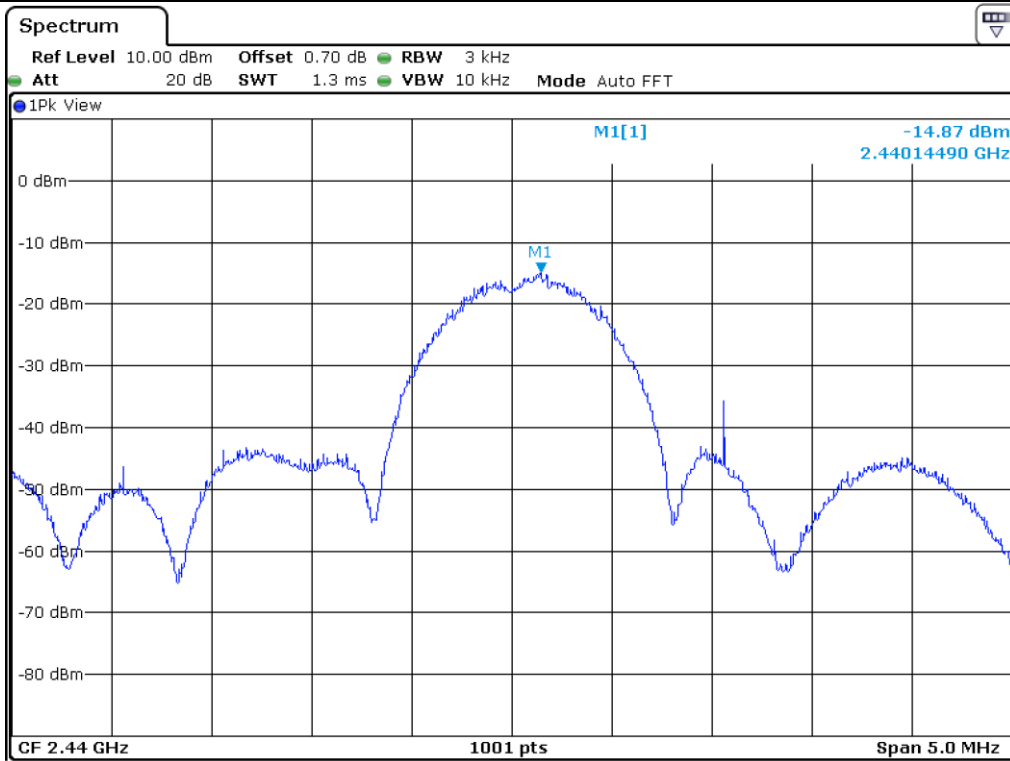
- Operating Condition : Continuous transmitting mode

Channel	Frequency (MHz)	Measured Value (dBm)	Limit (dBm)	Margin (dB)
Low	2 402.00	-13.60	8.00	21.60
Middle	2 440.00	-14.87	8.00	22.87
High	2 480.00	-15.92	8.00	23.92

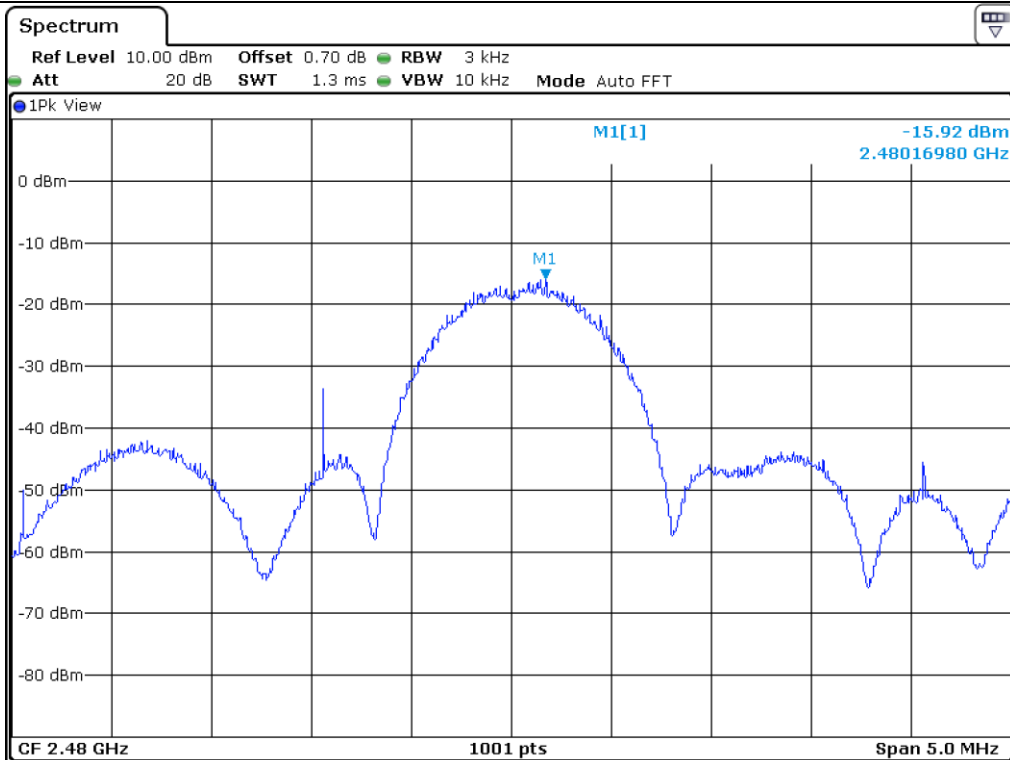
Remark. Margin = Limit – Measured value (=Receiver Reading + Cable Loss)



Low Channel



Middle Channel



High Channel

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11. RADIATED EMISSION TEST

11.1 Operating environment

Temperature : 21 °C
Relative humidity : 42 % R.H.

11.2 Test set-up

The radiated emissions measurements were on the 3 m semi anechoic chamber. The EUT and other support equipment were placed on a non-conductive turntable above the ground plane. The interconnecting cables from outside test site were inserted into ferrite clamps at the point where the cables reach the turntable.

The frequency spectrum from 30 MHz to 26.5 GHz was scanned and emission levels maximized at each frequency recorded. The system was rotated 360°, and the antenna was varied in height between 1.0 m and 4.0 m in order to determine the maximum emission levels. This procedure was performed for both horizontal and vertical polarization of the receiving antenna.

11.3 Test Date

December 10, 2021 ~ December 21, 2021

11.4 Test data

11.4.1 Test data for 30 MHz ~ 1000 MHz

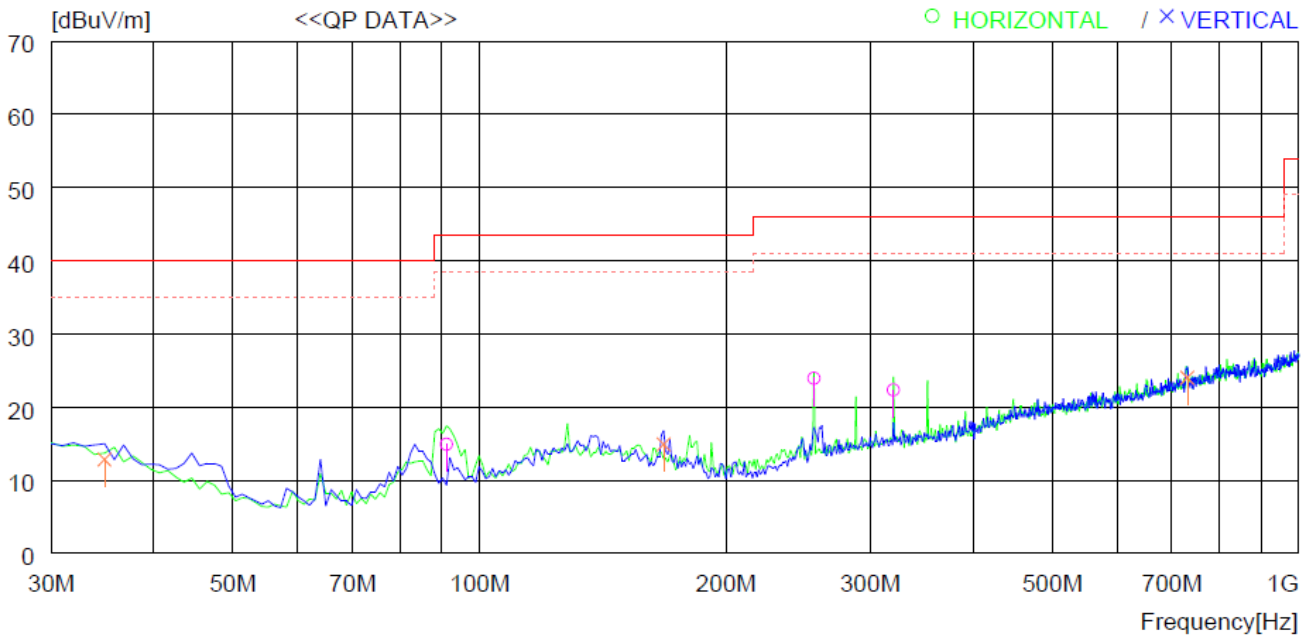
Humidity Level : 42 % R.H. Temperature: 21 ° C

Limits apply to : FCC CFR 47, PART 15, SUBPART C, SECTION 15.247

Result : PASSED

EUT : Blood Beta-Ketone Monitoring System

Detector : CISPR Quasi-Peak (6 dB Bandwidth: 120 kHz)



No.	FREQ [MHz]	READING QP [dBuV]	ANT FACTOR [dB]	LOSS [dB]	GAIN [dB]	RESULT [dBuV/m]	LIMIT [dBuV/m]	MARGIN [dB]	ANTENNA [cm]	TABLE [DEG]
----- Horizontal -----										
1	91.110	32.0	13.6	1.8	32.5	14.9	43.5	28.6	300	359
2	256.010	35.2	17.9	3.2	32.4	23.9	46.0	22.1	100	102
3	320.030	31.7	19.5	3.5	32.4	22.3	46.0	23.7	100	359
----- Vertical -----										
4	34.850	25.1	19.2	1.1	32.6	12.8	40.0	27.2	100	145
5	167.740	27.4	17.5	2.5	32.5	14.9	43.5	28.6	200	6
6	731.304	25.1	26.1	5.3	32.5	24.0	46.0	22.0	200	59

11.4.2 Test data for Below 30 MHz

- . Resolution bandwidth : 200 Hz (from 9 kHz to 0.15 MHz), 9 kHz (from 0.15 MHz to 30 MHz)
- . Frequency range : 9 kHz ~ 30 MHz
- . Measurement distance : 3 m
- . Operating mode : Transmitting mode

Frequency (MHz)	Reading (dBμV)	Ant. Pol. (H/V)	Ant. Height (m)	Angle (°)	Ant. Factor (dB/m)	Cable Loss	Emission Level(dBμV/m)	Limits (dBμV/m)	Margin (dB)
Emission from the EUT more than 20 dB below the limit in each frequency range.									

11.4.3 Test data for above 1 GHz

- . Resolution bandwidth : 1 MHz for Peak and Average Mode
- . Video bandwidth : 3 MHz for Peak and Average Mode
- . Frequency range : 1 GHz ~ 26.5 GHz
- . Measurement distance : 3 m
- . Operating mode : Transmitting mode

Frequency (MHz)	Reading (dBμV)	Ant. Pol. (H/V)	Ant. Height (m)	Angle (°)	Ant. Factor (dB/m)	Cable Loss	Emission Level(dBμV/m)	Limits (dBμV/m)	Margin (dB)
Emission from the EUT more than 20 dB below the limit in each frequency range.									

13. LIST OF TEST EQUIPMENT

Model Number	Manufacturer	Description	Serial Number	Last Cal.(Interval)
FSV40-N	Rohde & Schwarz	Signal Analyzer	102177	Apr. 16, 2021 (1Y)
ESW	Rohde & Schwarz	EMI Test Receiver	101851	Mar. 23, 2021 (1Y)
310N	Sonoma Instrument	Pre-Amplifier	312544	Mar. 16, 2021 (1Y)
SCU40A	Rohde & Schwarz	Signal Conditioning unit	100436	Feb. 28, 2021 (1Y)
SCU18	Rohde & Schwarz	Signal Conditioning unit	10041	Oct. 14, 2021 (1Y)
DT3000-3t	Innco System	Turn Table	DT3000/093	N/A
CO3000	Innco System	Controller	1026/40960617/P	N/A
MA-4000XPET	Innco System	Antenna Master	MA4000/509	N/A
HLP-2008	TDK RF Solutions	Hybrid Antenna	131316	Feb. 27, 2020 (2Y)
AH-118	Com-Power	Horn Antenna	10050061	Oct. 15, 2021 (1Y)
BBHA9170	Schwarzbeck	Horn Antenna	BBHA9170178	Jan. 07, 2021(1Y)
FMZB 1513	Schwarzbeck	Loop Antenna	1513-235	Mar. 24, 2020 (2Y)
HPF 3GHz	Rohde & Schwarz	High Pass Filter	N/A	Feb. 08, 2021 (1Y)