

RADIO PERFORMANCE TEST REPORT

Test Report No. : OT-204-RWD-081

AGR No. : A203A-132

Applicant : Tianjin Empecs Medical Device Co., Ltd.

Address : No.35 and 37, Yingcheng Street, Hangu, Binhai New Area, 300480 Tianjin, China

Manufacturer : Tianjin Empecs Medical Device Co., Ltd.

Address : No.35 and 37, Yingcheng Street, Hangu, Binhai New Area, 300480 Tianjin, China

Type of Equipment : Blood Beta-Ketone Monitoring System

FCC ID. : 2AFE8BKABT

Model Name : MediKeto 82 BT

Multiple Model Name : MediKeto 83 BT, MediKeto 82, MediKeto 83

Serial number : N/A

Total page of Report : 29 pages (including this page)

Date of Incoming : April 02, 2020

Date of issue : April 08, 2020

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.

Reviewed by:



Ha-Ram Lee / Manager
ONETECH Corp.

Approved by:



Jae-Ho Lee / Chief Engineer
ONETECH Corp.

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Revision History

Rev. No.	Issue Report No.	Issued Date	Revisions	Section Affected
0	OT-204-RWD-081	April 08, 2020	Initial Issue	All

1. VERIFICATION OF COMPLIANCE

Applicant : Tianjin Empecs Medical Device Co., Ltd.
Address : No.35 and 37, Yingcheng Street, Hangu, Binhai New Area, 300480 Tianjin, China
Contact Person : Dongeon Cho / Senior Research Engineer
Telephone No. : 82(0)70-7124-0476
FCC ID : 2AFE8BKABT
Model Name : MediKeto 82 BT
Brand Name : Medisign
Serial Number : N/A
Date : April 08, 2020

EQUIPMENT CLASS	DTS – DIGITAL TRNSMISSION SYSTEM
KIND OF EQUIPMENT	Blood Beta-Ketone Monitoring System
THIS REPORT CONCERNS	Original Grant
MEASUREMENT PROCEDURES	ANSI C63.10: 2013
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
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 requirement to be performed.

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: 2013. 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-4112/ C-14617/ G-10666 / T-1842

-. Lab Accreditation:

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

3. GENERAL INFORMATION

3.1 Product Description

The Tianjin Empecs Medical Device Co., Ltd., Model MediKeto 82 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	-8.25 dBm
NUMBER OF CHANNEL	40 Channels
MODULATION TYPE	GFSK(Bluetooth LE)
ANTENNA TYPE	PCB pattern Antenna
ANTENNA GAIN	-4.34 dBi
LIST OF EACH OSC. OR CRYSTAL. FREQ.(FREQ.>=1 MHz)	32.768 kHz, 32MHz
RATED SUPPLY VOLTAGE	DC 3.0 V

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

-. The following lists consist of the added model and their differences.

Model Name	Differences	Tested
MediKeto 82 BT	Basic Model	☒
MediKeto 83 BT	This model is identical to the basic model except for appearance of top case.	☐
MediKeto 82		☐
MediKeto 83		☐

Note: 1. Applicant consigns only basic model to test. Therefore, this test report just guarantees the units, which have been tested.

2. The Applicant/manufacture is responsible for the compliance of all variants.

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	N/A	N/A	-
Display Board	N/A	N/A	-

5.2 Peripheral equipment

-None

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.

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: 2013 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 a PCB pattern 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 Tests, the following operating modes were investigated

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

7. MINIMUM 6 dB BANDWIDTH

7.1 Operating environment

Temperature : 24 °C
Relative humidity : 48 % 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 equipment used

	Model Number	Manufacturer	Description	Serial Number	Last Cal.
■ -	FSV30	Rohde & Schwarz	Signal Analyzer	101200	Jul. 24, 2019 (1Y)

All test equipment used is calibrated on a regular basis.

7.4 Test data

-. Test Date : April 02, 2020

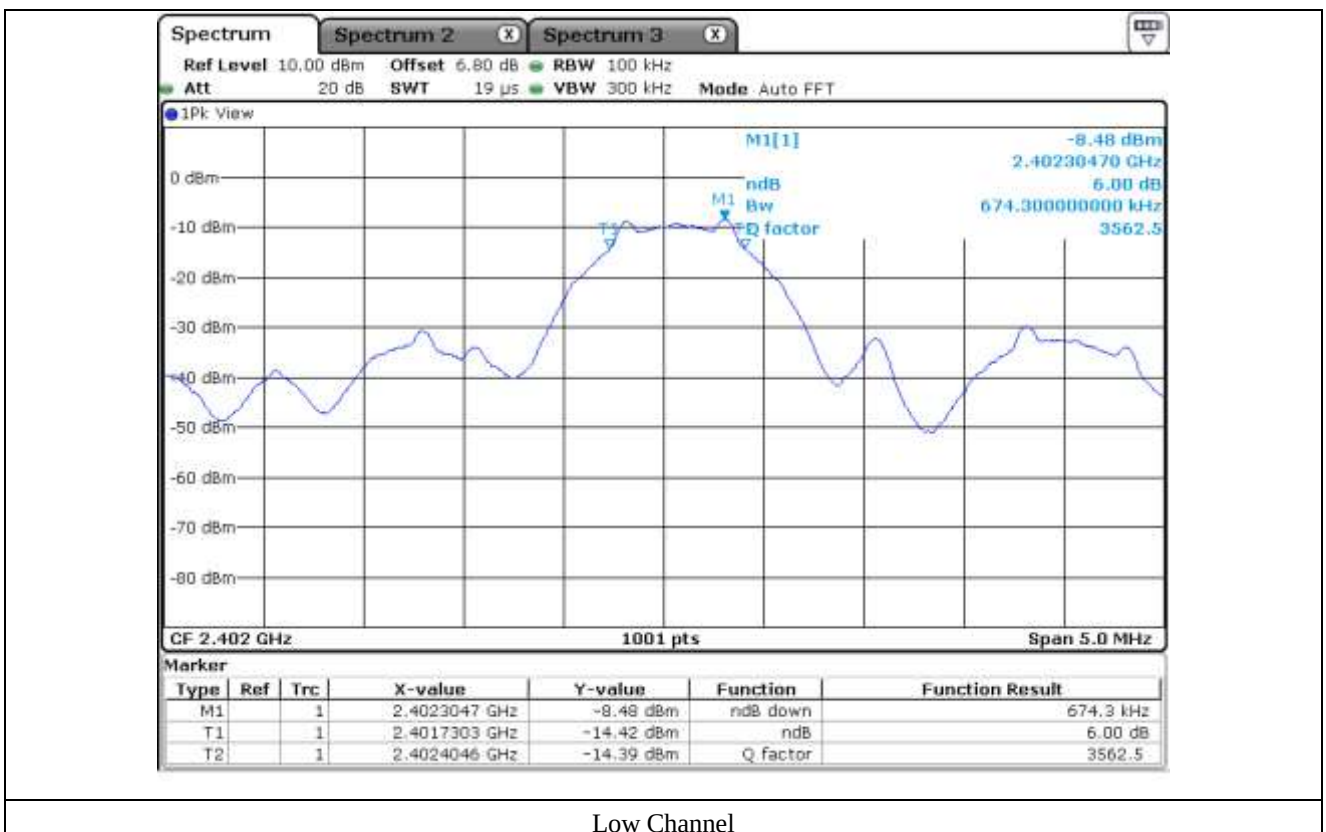
-. Test Result : Pass

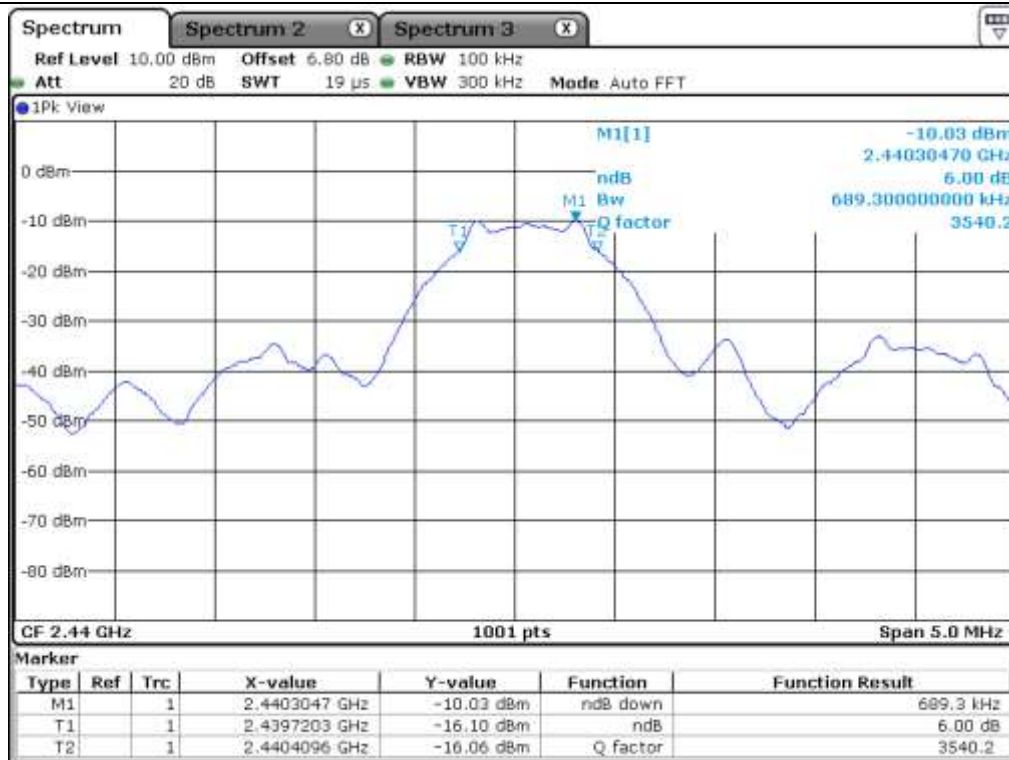
CHANNEL	FREQUENCY(MHz)	MEASURED VALUE (kHz)	LIMIT (kHz)	MARGIN (kHz)
Low	2 402.00	674.30	500	174.30
Middle	2 440.00	689.30	500	189.30
High	2 480.00	679.30	500	179.30

Remark. Margin = Measured Value – Limit

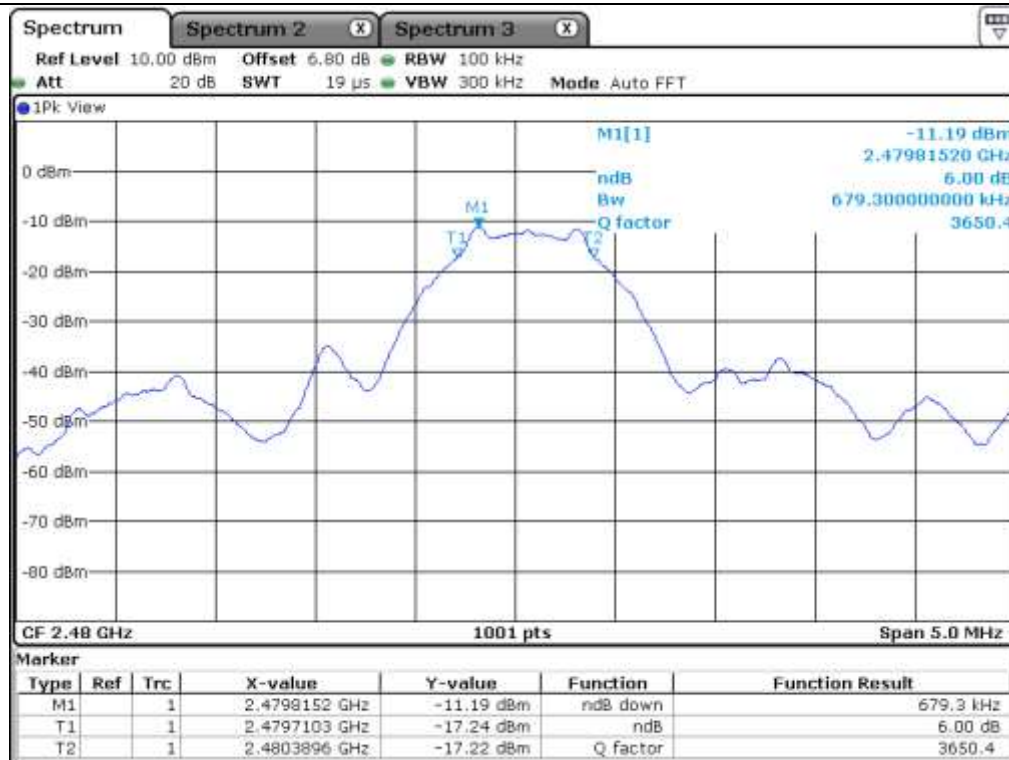


Tested by: Yu-Seog Sim / Assistant Manager





Middle Channel



High Channel

8. MAXIMUM PEAK OUTPUT POWER

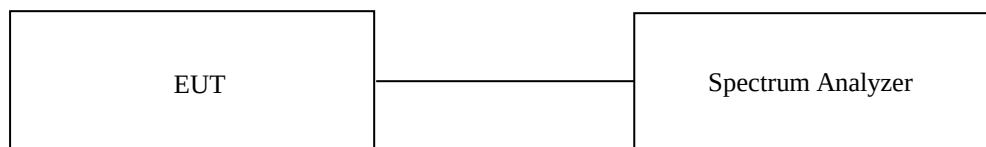
8.1 Operating environment

Temperature : 24 °C
Relative humidity : 48 % 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 equipment used

Model Number	Manufacturer	Description	Serial Number	Last Cal.
■ - FSV30	Rohde & Schwarz	Signal Analyzer	101200	Jul. 24, 2019 (1Y)

All test equipment used is calibrated on a regular basis.

8.4 Test data

-. Test Date : April 02, 2020

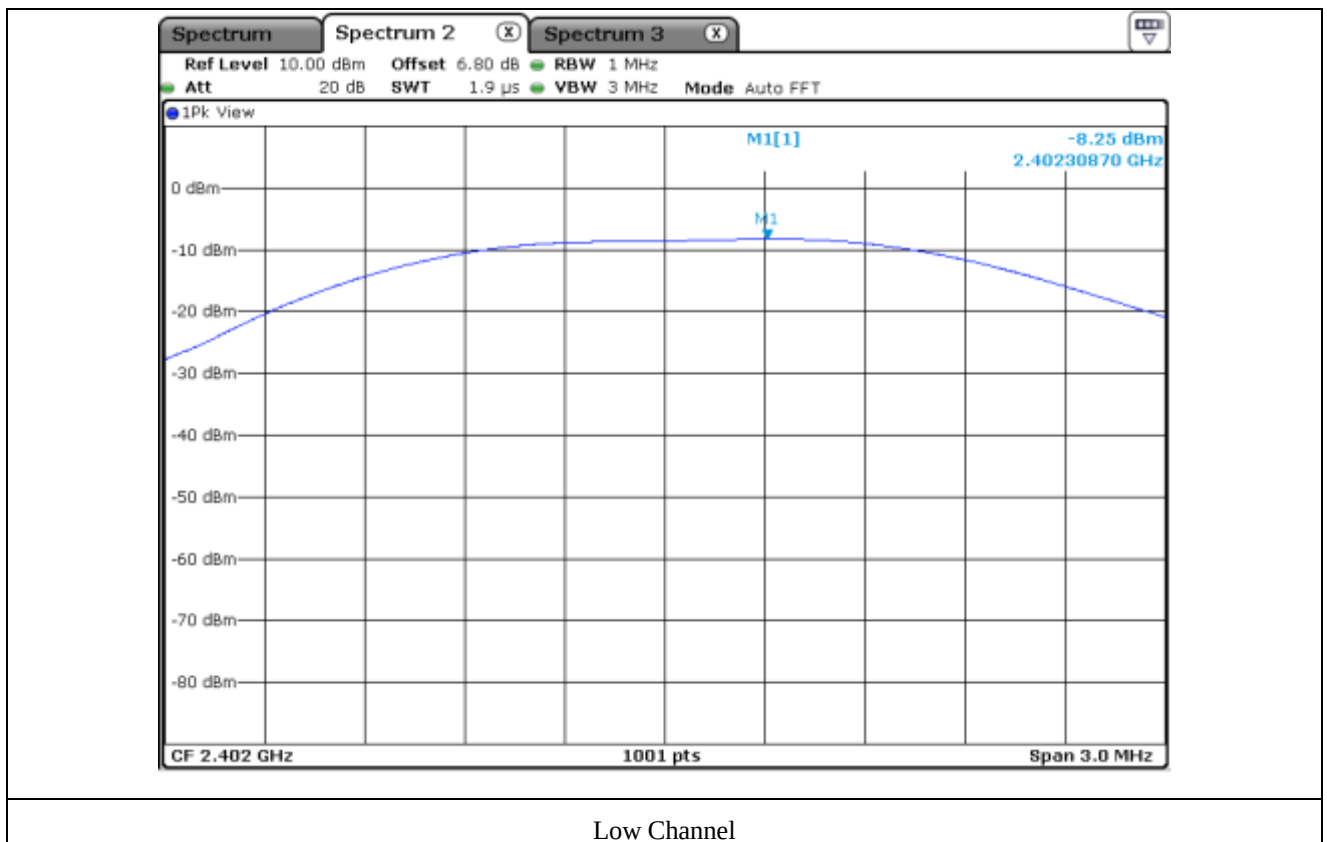
-. Test Result : Pass

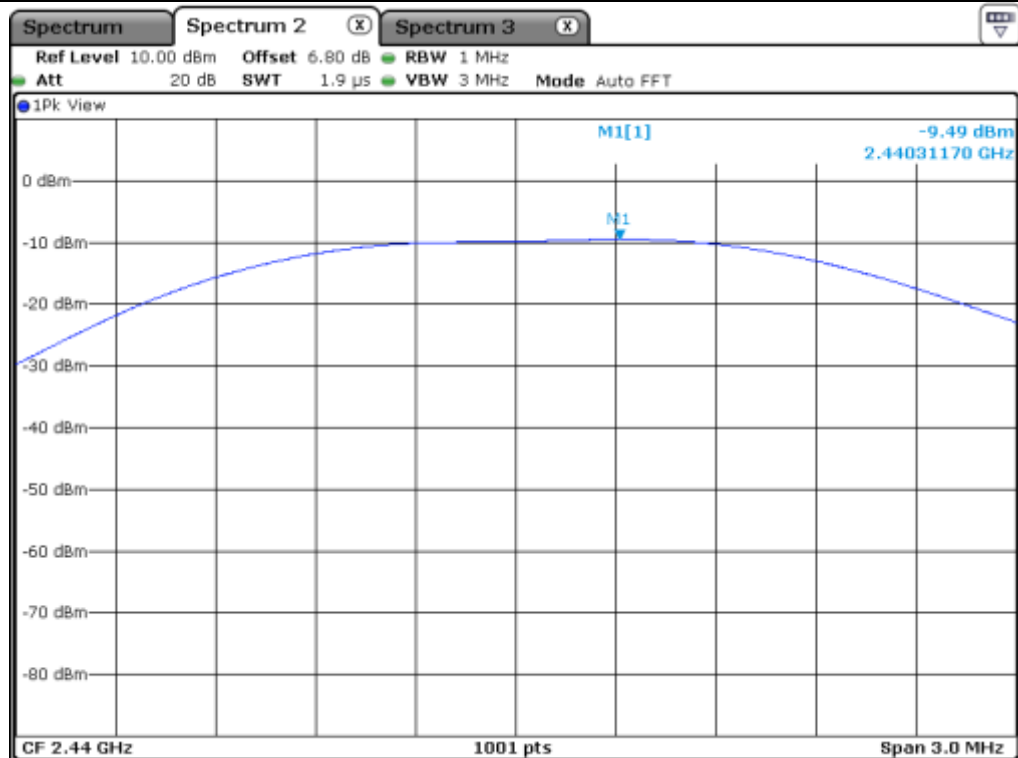
CHANNEL	FREQUENCY (MHz)	MEASURED VALUE (dBm)	LIMIT (dBm)	MARGIN (dB)
LOW	2 402.00	-8.25	30.00	38.25
MIDDLE	2 440.00	-9.49	30.00	39.49
HIGH	2 480.00	-10.97	30.00	40.97

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

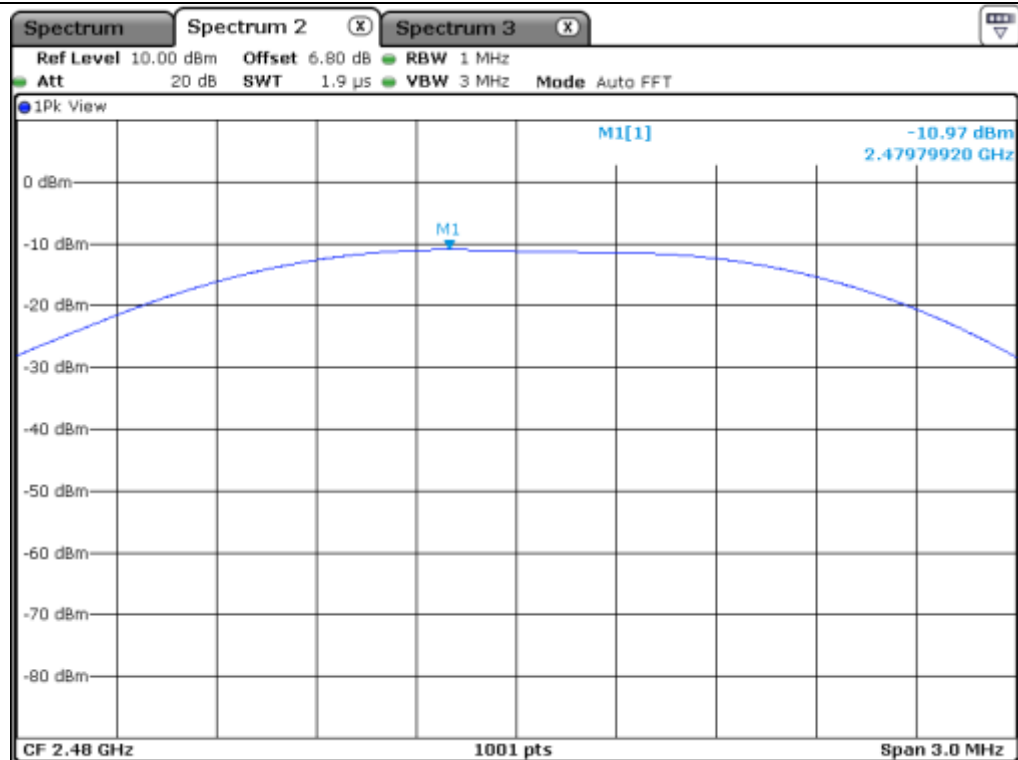


Tested by: Yu-Seog Sim / Assistant Manager





Middle Channel



High Channel

9. 100 kHz BANDWIDTH OUTSIDE THE FREQUENCY BAND

9.1 Operating environment

Temperature : 24 °C
Relative humidity : 48 % R.H.

9.2 Test set-up for conducted measurement

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

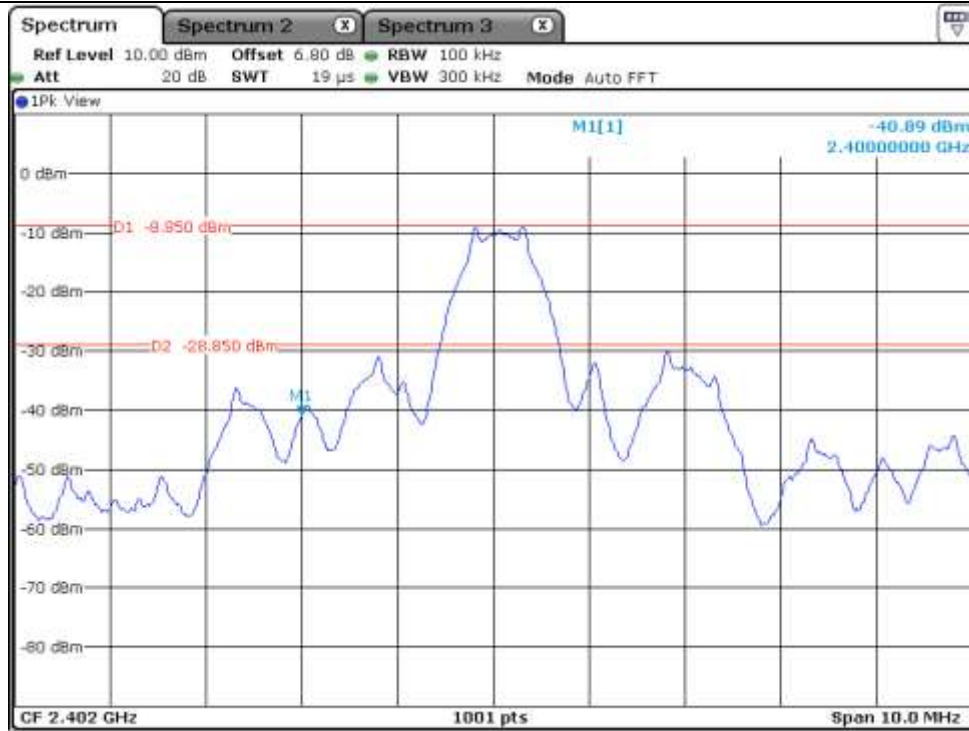
The frequency spectrum from 30 MHz to 26.5 GHz was scanned and maximum emission levels at each frequency recorded. The system was rotated 360°, and the antenna was varied in the height between 1.0 m and 4.0 m in order to determine the maximum emission levels. This procedure was performed for horizontal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

9.4 Test equipment used

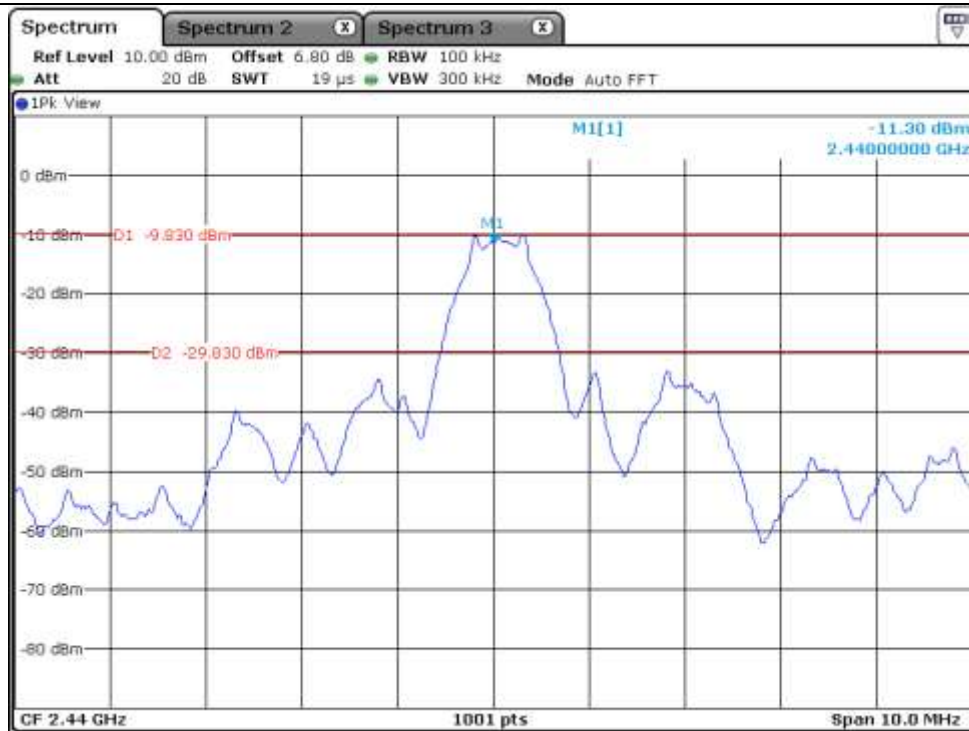
	Model Number	Manufacturer	Description	Serial Number	Last Cal. (Interval)
■ -	ESW44	Rohde & Schwarz	EMI Test Receiver	101851	Aug. 07, 2019 (1Y)
■ -	310N	Sonoma Instrument	AMPLIFIER	312545	Mar. 16, 2020 (1Y)
■ -	FSV30	Rohde & Schwarz	Signal Analyzer	101200	Jul. 24, 2019 (1Y)
■ -	SCU-18F	Rohde & Schwarz	Pre-Amplifier	180117	Jul. 11, 2019 (1Y)
■ -	MA240	HD GmbH	Antenna Master	N/A	N/A
■ -	HD100	HD GmbH	Position Controller	HD1000202261	N/A
■ -	DS420S	HD GmbH	Turn Table	N/A	N/A
■ -	FMZB 1513	Schwarzbeck	LOOP ANTENNA	1513-235	May. 13, 2018 (2Y)
■ -	VULB9163	Schwarzbeck	TRILOG Broadband Antenna	9163-255	Jun. 05, 2018 (2Y)
■ -	BBHA9120D	Schwarzbeck	Horn Antenna	1366	Jul. 16, 2019 (2Y)
■ -	BBHA9170	Schwarzbeck	Horn Antenna	BBHA9170178	Jan. 07, 2020 (1Y)
■ -	SCU40A	Rohde & Schwarz	Pre-Amplifier	100436	Feb. 20, 2020 (1Y)

All test equipment used is calibrated on a regular basis.

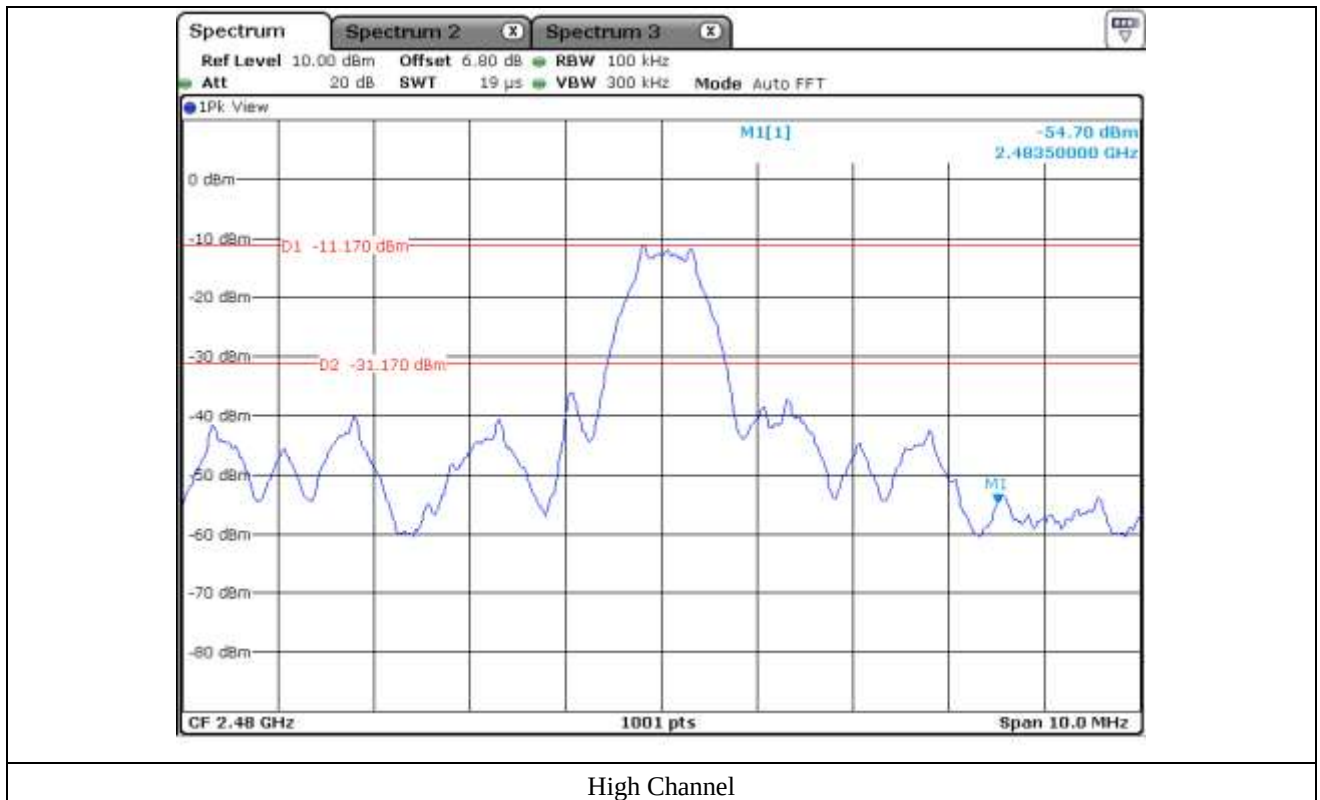
9.5 Test data for conducted emission

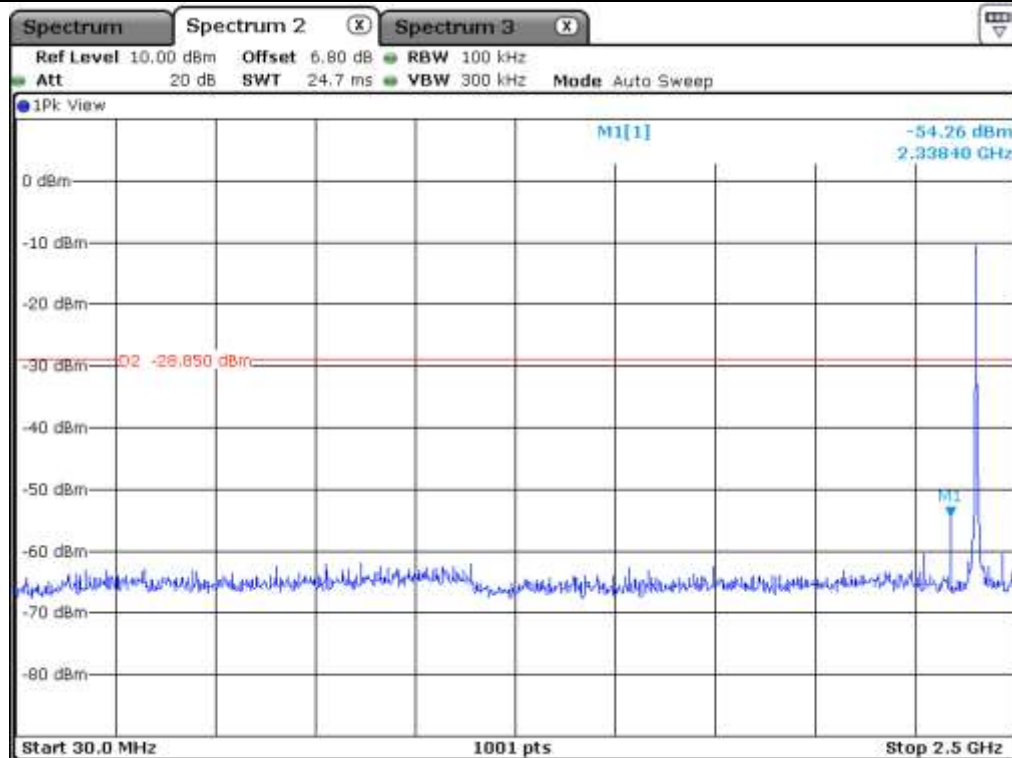


Low Channel

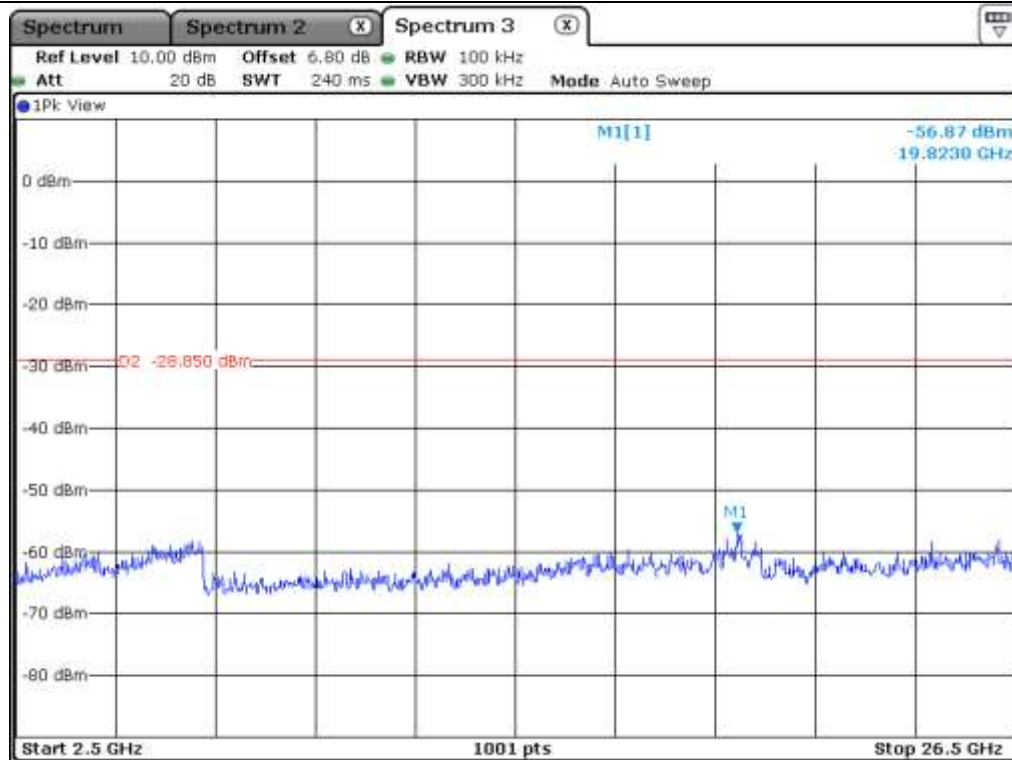


Middle Channel

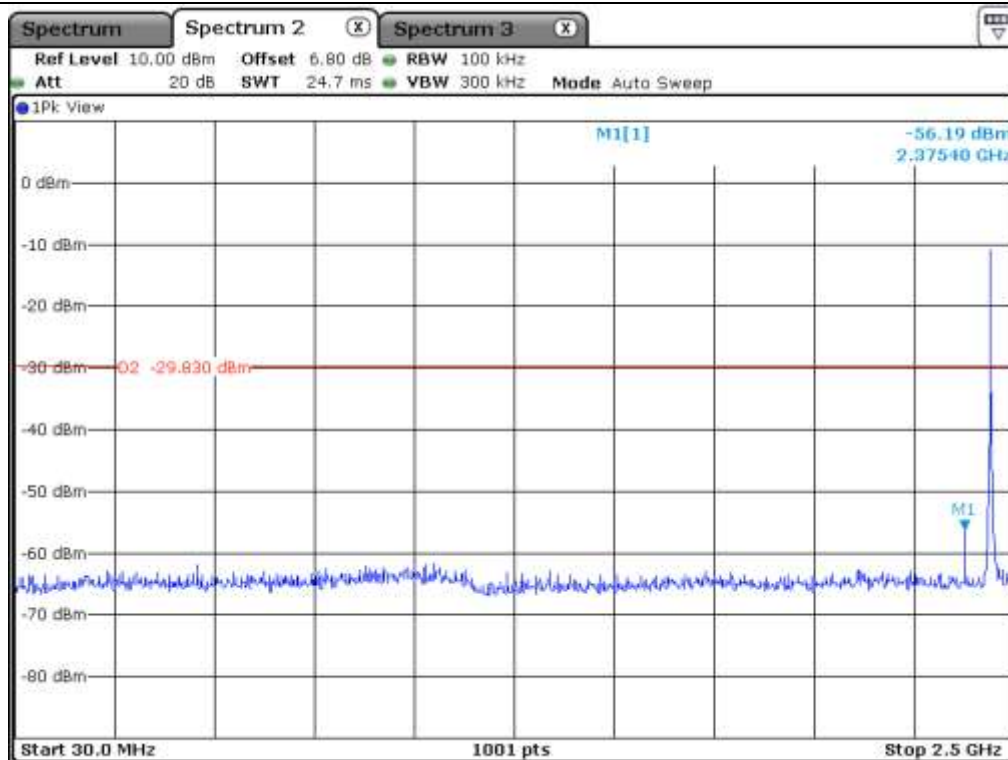




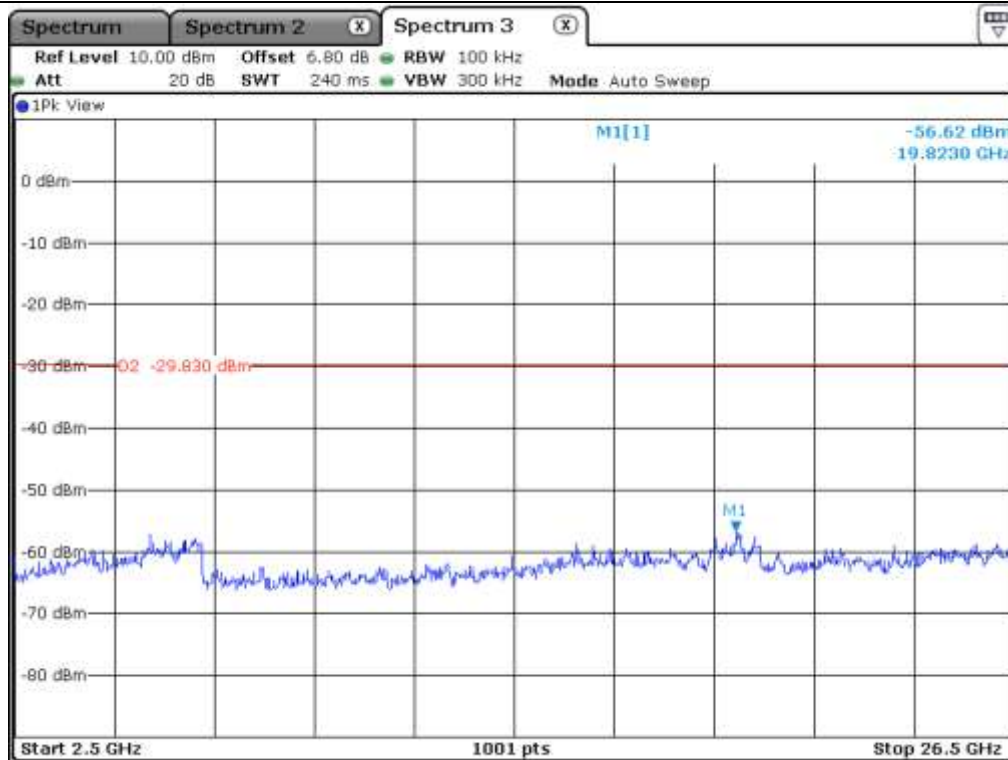
Low Channel



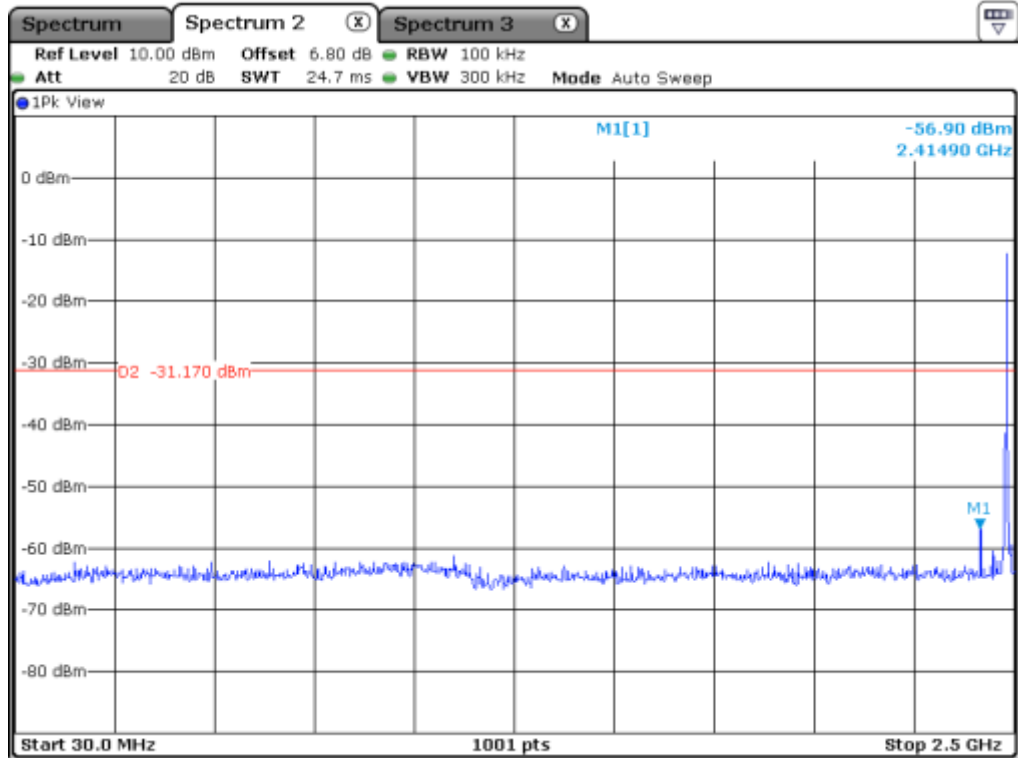
Low Channel



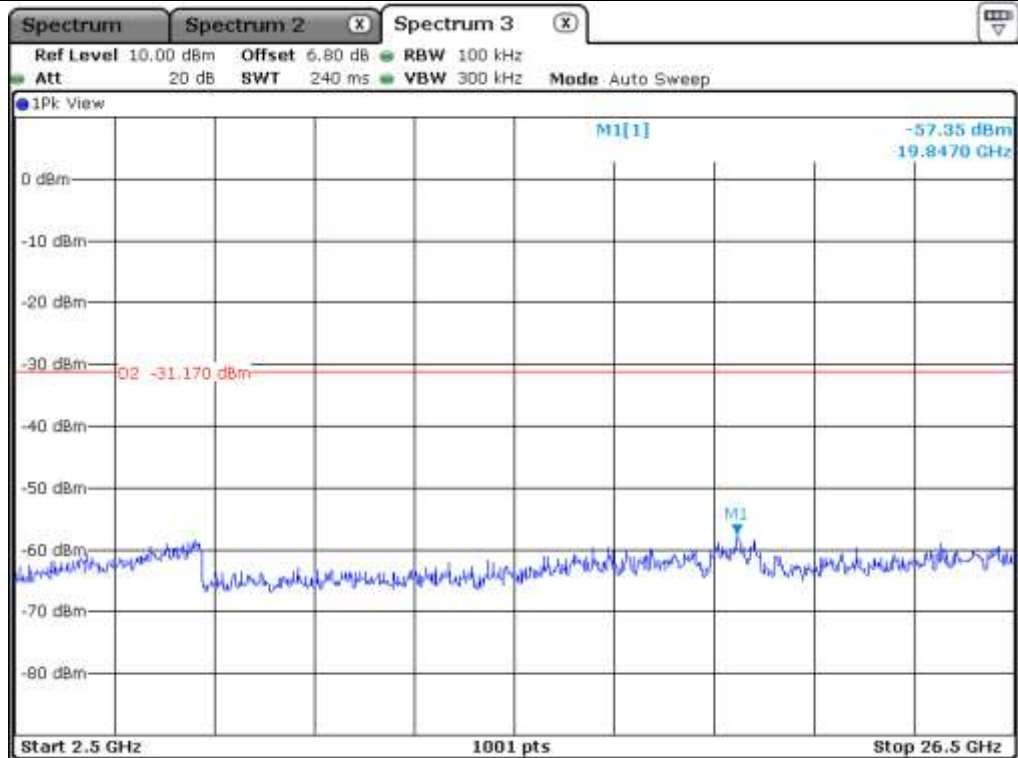
Middle Channel



Middle Channel



High Channel



High Channel

9.6 Test data for radiated emission

9.6.1 Radiated Emission which fall in the Restricted Band

- . Test Date : April 02, 2020
- . Resolution bandwidth : 1 MHz for Peak and Average Mode
- . Video bandwidth : 3 MHz for Peak and Average Mode
- . Detector : Peak Mode(Peak), Average Mode(RMS)
- . Measurement distance : 3 m
- . Result : PASSED

Frequency (MHz)	Reading (dBμV)	Detector Mode	Ant. Pol. (H/V)	Ant. Factor	Cable Loss	Amp Gain	Total (dBμV/m)	Limits (dBμV/m)	Margin (dB)
Test Data for Low Channel									
2 344.01	15.83	Peak	H	27.60	2.91	-	46.34	74.00	27.66
2 337.61	5.00	Average	H				35.51	54.00	18.49
2 332.98	14.34	Peak	V				44.85	74.00	29.15
2 345.37	5.02	Average	V				35.53	54.00	18.47
Test Data for High Channel									
2 497.09	14.55	Peak	H	27.50	3.02	-	45.07	74.00	28.93
2 495.97	4.85	Average	H				35.37	54.00	18.63
2 493.43	14.23	Peak	V				44.75	74.00	29.25
2 489.26	4.79	Average	V				35.31	54.00	18.69

Tabulated test data for Restricted Band

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

Margin (dB) = Limits (dBμV/m) - Total Level (dBμV/m)

Total Level = Reading + Antenna Factor + Cable Loss



Tested by: Yu-Seog Sim / Assistant Manager

9.6.2 Spurious & Harmonic Radiated Emission

- . Test Date : April 02, 2020
- . Resolution bandwidth : 1 MHz for Peak and Average Mode
- . Video bandwidth : 3 MHz for Peak and Average Mode
- . Detector : Peak Mode(Peak), Average Mode(RMS)
- . Frequency range : 1 GHz ~ 26.5 GHz
- . Measurement distance : 3 m
- . Result : PASSED

Frequency (GHz)	Reading (dBμV)	Detector Mode	Ant. Pol. (H/V)	Ant. Factor	Cable Loss	Amp Gain	Total (dBμV/m)	Limits (dBμV/m)	Margin (dB)
Test Data for Low Channel									
4 804.00	16.60	Peak	H	31.20	4.65	-	52.45	74.00	21.55
	6.51	Average	H				42.36	54.00	11.64
	14.65	Peak	V				50.50	74.00	23.50
	6.44	Average	V				42.29	54.00	11.71
Test Data for Middle Channel									
4 880.00	16.00	Peak	H	31.40	4.72	-	52.12	74.00	21.88
	6.17	Average	H				42.29	54.00	11.71
	15.60	Peak	V				51.72	74.00	22.28
	6.73	Average	V				42.85	54.00	11.15
Test Data for High Channel									
4 960.00	16.44	Peak	H	31.70	4.86	-	53.00	74.00	21.00
	6.70	Average	H				43.26	54.00	10.74
	15.36	Peak	V				51.92	74.00	22.08
	6.42	Average	V				42.98	54.00	11.02

Tabulated test data for Restricted Band

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

Margin (dB) = Limits (dBμV/m) - Total Level (dBμV/m)

Total Level = Reading + Antenna Factor + Cable Loss



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10. PEAK POWER SPECTRAL DENSITY

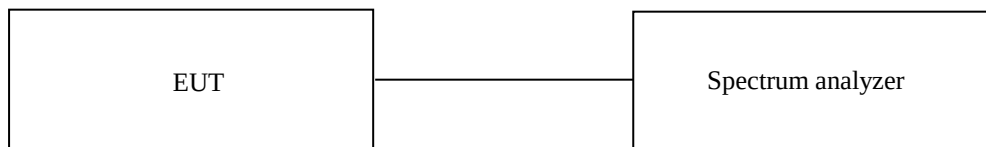
10.1 Operating environment

Temperature : 24 °C
Relative humidity : 48 % 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 equipment used

	Model Number	Manufacturer	Description	Serial Number	Last Cal.
■ -	FSV30	Rohde & Schwarz	Signal Analyzer	101200	Jul. 24, 2019 (1Y)

All test equipment used is calibrated on a regular basis.

10.4 Test data

-. Test Date : April 02, 2020

-. Test Result : Pass

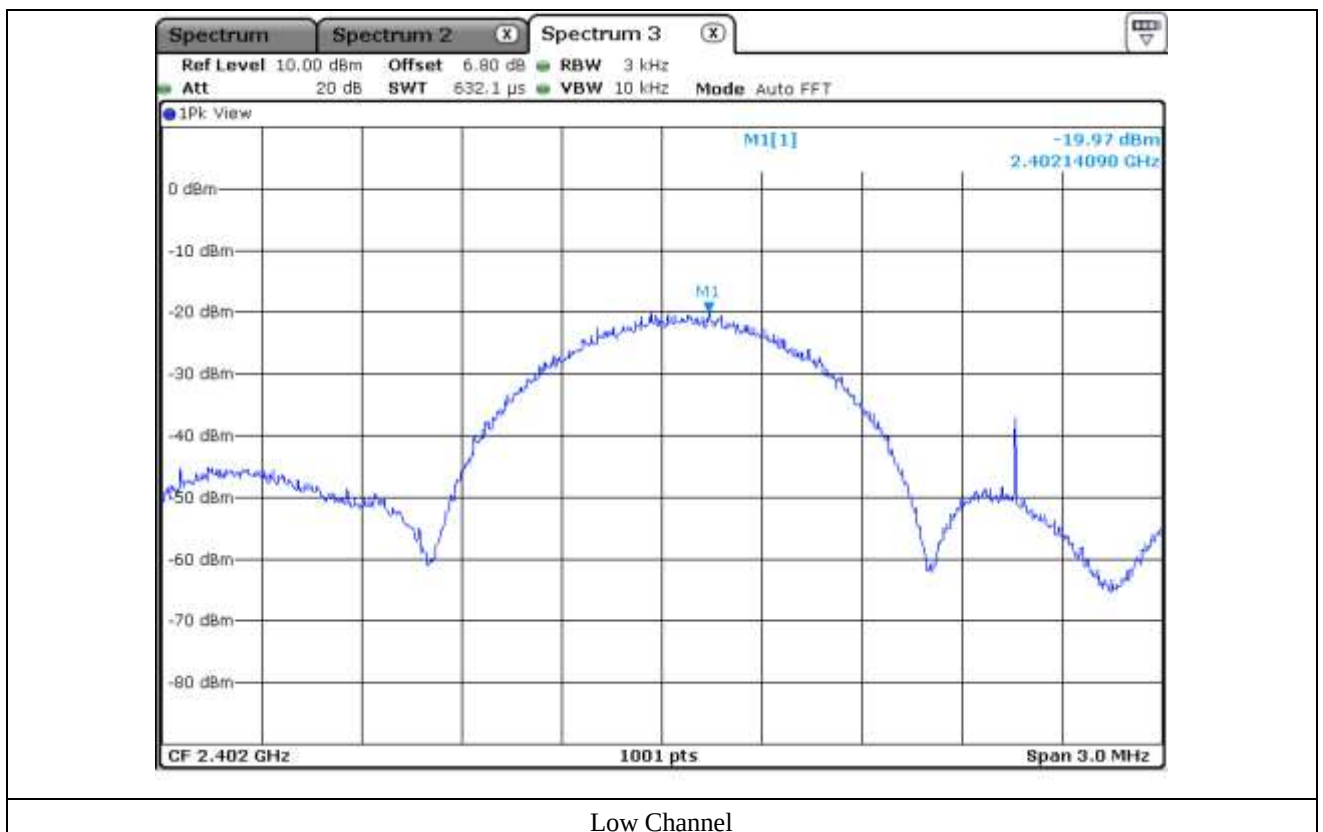
-. Operating Condition : Continuous transmitting mode

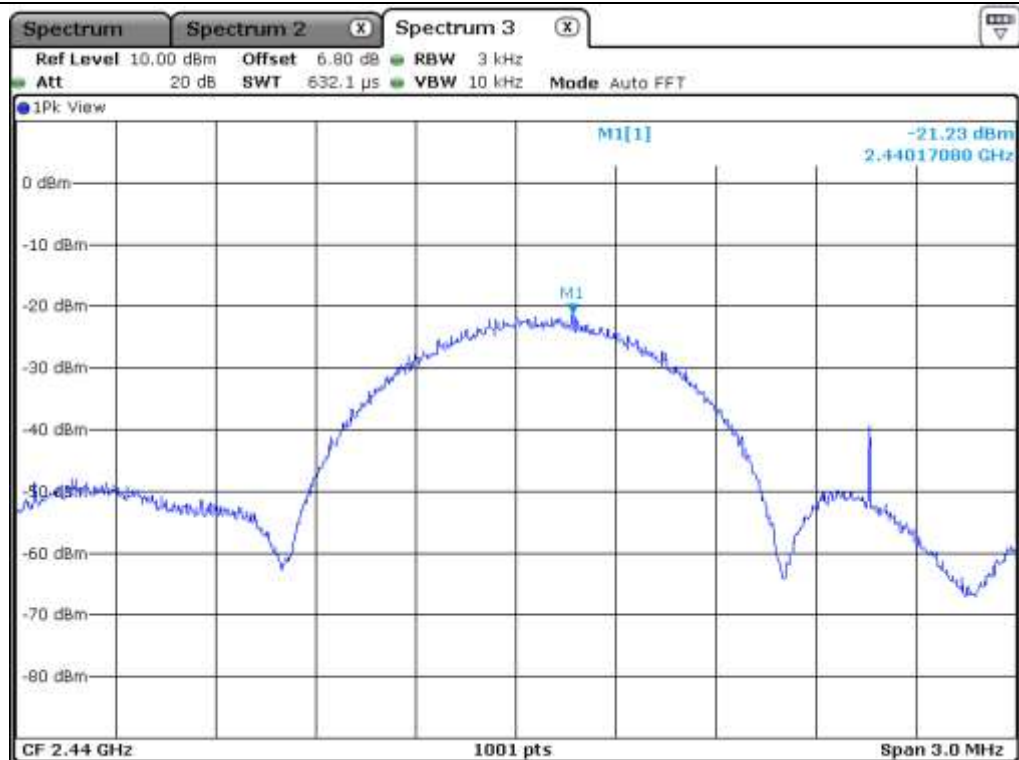
CHANNEL	FREQUENCY(MHz)	MEASURED VALUE (dBm)	LIMIT (dBm)	MARGIN (dB)
Low	2 402.00	-19.97	8.00	27.97
Middle	2 440.00	-21.23	8.00	29.23
High	2 480.00	-23.01	8.00	31.01

Remark. Margin = Limit – Measured value

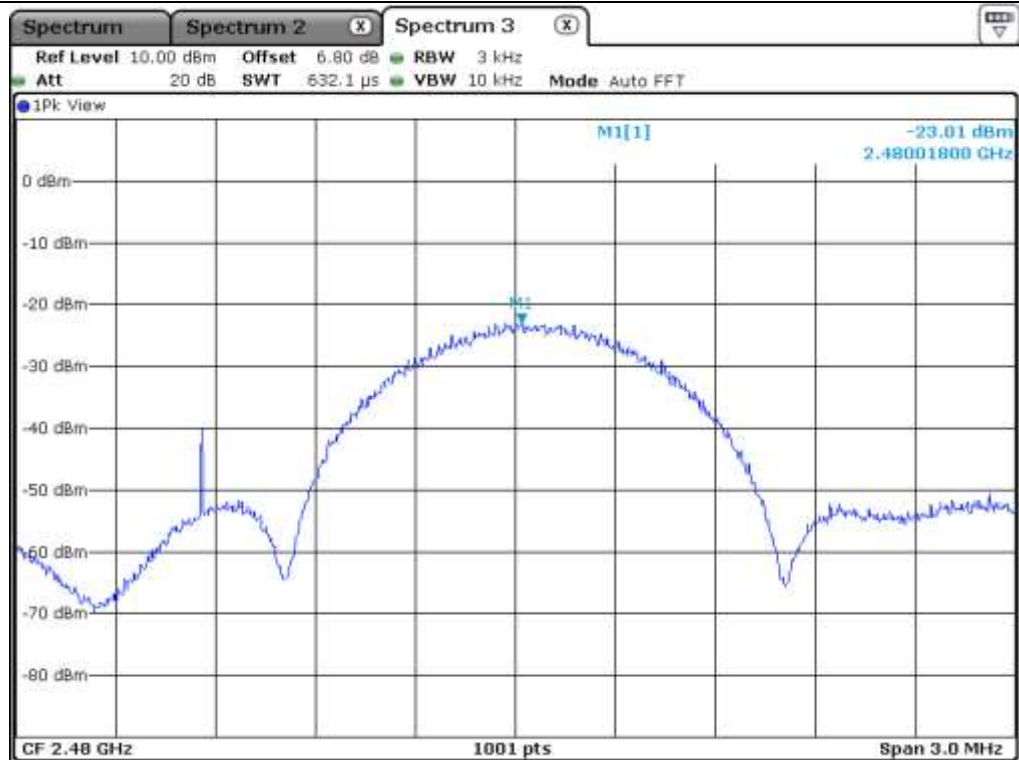


Tested by: Yu-Seog Sim / Assistant Manager





Middle Channel



High Channel

11. RADIATED EMISSION TEST

11.1 Operating environment

Temperature : 24 °C
Relative humidity : 48 % 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 equipment used

	Model Number	Manufacturer	Description	Serial Number	Last Cal. (Interval)
■ -	ESW44	Rohde & Schwarz	EMI Test Receiver	101851	Aug. 07, 2019 (1Y)
■ -	310N	Sonoma Instrument	AMPLIFIER	312545	Mar. 16, 2020 (1Y)
■ -	SCU-18F	Rohde & Schwarz	Pre-Amplifier	180117	Jul. 11, 2019 (1Y)
■ -	MA240	HD GmbH	Antenna Master	N/A	N/A
■ -	HD100	HD GmbH	Position Controller	HD1000202261	N/A
■ -	DS420S	HD GmbH	Turn Table	N/A	N/A
■ -	FMZB 1513	Schwarzbeck	LOOP ANTENNA	1513-235	Mar. 24, 2020 (2Y)
■ -	VULB9163	Schwarzbeck	TRILOG Broadband Antenna	9163-255	Jun. 05, 2018 (2Y)
■ -	BBHA9120D	Schwarzbeck	Horn Antenna	1366	Jul. 16, 2019 (2Y)
■ -	BBHA9170	Schwarzbeck	Horn Antenna	BBHA9170178	Jan. 07, 2020 (1Y)
■ -	SCU40A	Rohde & Schwarz	Pre-Amplifier	100436	Feb. 20, 2020 (1Y)

All test equipment used is calibrated on a regular basis.

11.4 Test data for Transmitting Mode

11.4.1 Test data for 30 MHz ~ 1 GHz

Humidity Level : 48 % R.H.

Temperature: 24 °C

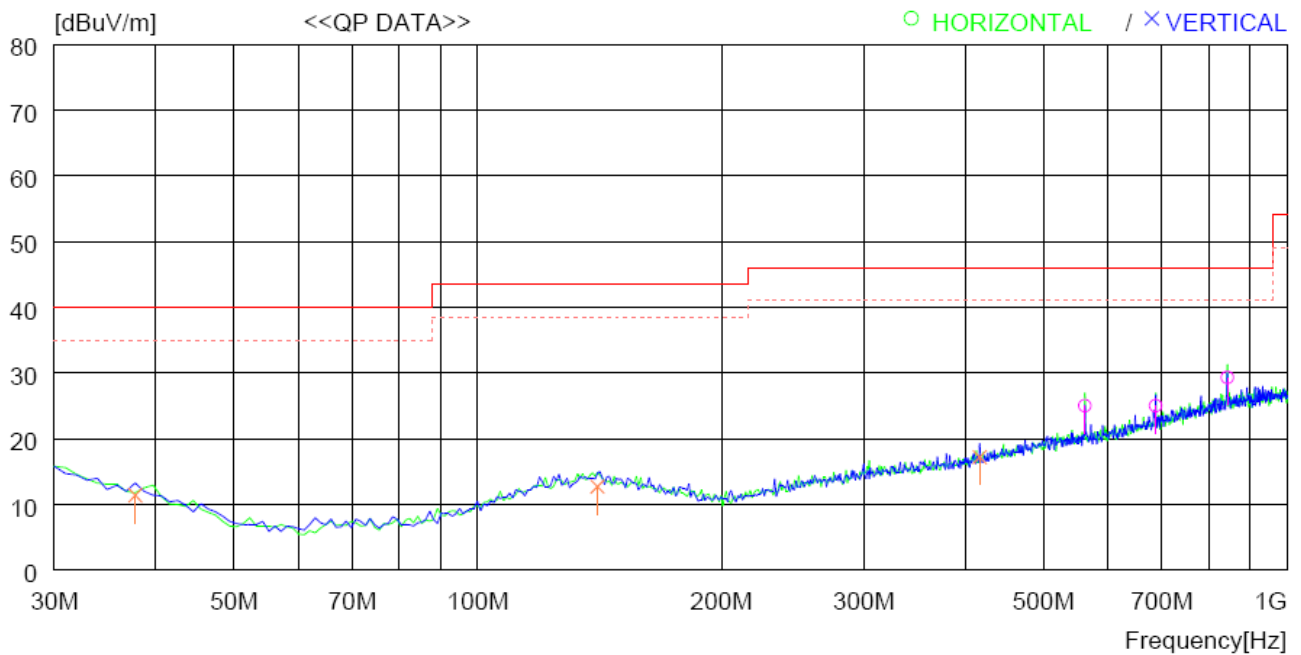
Limits apply to : FCC CFR 47, PART 15, SUBPART C, SECTION 15.247

Result : PASSED

EUT : Blood Beta-Ketone Monitoring System

Date: April 02, 2020

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



No.	FREQ	READING	ANT	LOSS	GAIN	RESULT	LIMIT	MARGIN	ANTENNA	TABLE
	[MHz]	QP	FACTOR	[dB]	[dB]	[dBuV/m]	[dBuV/m]	[dB]	[cm]	[DEG]
		[dBuV]	[dB]							
----- Horizontal -----										
1	562.529	31.3	23.8	2.9	33.0	25.0	46.0	21.0	100	359
2	687.655	29.1	25.4	3.4	32.9	25.0	46.0	21.0	300	359
3	843.821	30.1	27.3	4.2	32.3	29.3	46.0	16.7	200	0
----- Vertical -----										
4	37.760	25.1	18.1	0.9	32.7	11.4	40.0	28.6	100	0
5	140.580	24.5	19.5	1.4	32.7	12.7	43.5	30.8	400	211
6	417.031	26.4	21.1	2.4	32.7	17.2	46.0	28.8	300	0


Tested by: Yu-Seog Sim / Assistant Manager

11.4.2 Test data for Below 30 MHz

- . Test Date : April 02, 2020
- . 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)
All emissions observed were 20dB below the limit.									

11.4.3 Test data for above 1 GHz

- . Test Date : April 02, 2020
- . Resolution bandwidth : 1 MHz for Peak and Average Mode
- . Video bandwidth : 1 MHz for Peak Mode, 10 Hz for 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)
All emissions observed were 20dB below the limit.									



Tested by: Yu-Seog Sim / Assistant Manager