

Prüfbericht-Nr.: <i>Test report no.:</i>	50349154 001	Auftrags-Nr.: <i>Order no.:</i>	238133832	Seite 1 von 36 Page 1 of 36
Kunden-Referenz-Nr.: <i>Client reference no.:</i>	N/A	Auftragsdatum: <i>Order date:</i>	03-Feb-2020	
Auftraggeber: <i>Client:</i>	BIONIME CORPORATION No. 100, Sec. 2, Daqing St., South Dist., Taichung City 40242 Taiwan			
Prüfgegenstand: <i>Test item:</i>	RIGHTEST Continuous Glucose Monitoring System (CGMS)			
Bezeichnung / Typ-Nr.: <i>Identification / Type no.:</i>	HM312			
Auftrags-Inhalt: <i>Order content:</i>	FCC Part 15C Test report (BLE)			
Prüfgrundlage: <i>Test specification:</i>	FCC 47CFR Part 15: Subpart C Section 15.247			
Wareneingangsdatum: <i>Date of sample receipt:</i>	19-Feb-2020			
Prüfmuster-Nr.: <i>Test sample no.:</i>	A001062564-001 A001062564-002			
Prüfzeitraum: <i>Testing period:</i>	19-Feb-2020 – 17-Mar-2020			
Ort der Prüfung: <i>Place of testing:</i>	EMC/RF Laboratory Taipei			
Prüflaboratorium: <i>Testing laboratory:</i>	TUV Rheinland Taiwan Ltd.			
Prüfergebnis*: <i>Test result*:</i>	Pass			
überprüft von: <i>reviewed by:</i>	genehmigt von <i>authorized by:</i>			
Datum: 13-Oct-2020 <i>Date:</i>			Datum: 13-Oct-2020 <i>Date:</i>	
Stellung / Position:	Mars Lin/Senior Project Engineer		Stellung / Position:	Brenda Chen/Senior Project Manager
Sonstiges / Other:				
Zustand des Prüfgegenstandes bei Anlieferung: <i>Condition of the test item at delivery:</i>		Prüfmuster vollständig und unbeschädigt <i>Test item complete and undamaged</i>		
* Legende:	1 = sehr gut P(ass) = entspricht o.g. Prüfgrundlage(n)	2 = gut F(ail) = entspricht nicht o.g. Prüfgrundlage(n)	3 = befriedigend N/A = nicht anwendbar	4 = ausreichend N/T = nicht getestet
* Legend:	1 = very good P(ass) = passed a.m. test specification(s)	2 = good F(ail) = failed a.m. test specification(s)	3 = satisfactory N/A = not applicable	4 = sufficient N/T = not tested
Dieser Prüfbericht bezieht sich nur auf das o.g. Prüfmuster und darf ohne Genehmigung der Prüfstelle nicht auszugsweise vervielfältigt werden. Dieser Bericht berechtigt nicht zur Verwendung eines Prüfzeichens. <i>This test report only relates to the a. m. test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any test mark.</i>				

TEST SUMMARY

5.1.1 ANTENNA REQUIREMENT

RESULT: Passed

5.1.2 PEAK OUTPUT POWER

RESULT: Passed

5.1.3 6dB BANDWIDTH AND 99% BANDWIDTH

RESULT: Passed

5.1.4 POWER DENSITY

RESULT: Passed

5.1.5 CONDUCTED SPURIOUS EMISSIONS AND FREQUENCY BAND EDGE MEASURED IN 100kHz BANDWIDTH

RESULT: Passed

5.1.6 SPURIOUS EMISSION

RESULT: Passed

5.2.1 MAINS CONDUCTED EMISSIONS

RESULT: Passed

6.1.1 ELECTROMAGNETIC FIELDS

RESULT: Passed

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1. General Remarks

1.1 Complementary Materials

The following attachments are integral parts of this test report:

Appendix P: Photo Documentation internal view
(File Name: 50349154 001, 50354184 001 APPENDIXP)

Appendix D: Test Result of Radiated Emissions
(File Name: 50349154 001 APPENDIXD)

Test Specifications

The following standards were applied.

Table 1: Applied Standard and Test Levels

Radio
FCC 47CFR Part 15: Subpart C Section 15.247 FCC 47CFR Part 2: Subpart J Section 2.1091 ANSI C63.10:2013 KDB558074 D01 DTS Meas Guidance v05r02 KDB447498 D01 General RF Exposure Guidance v06

1.2 Decision Rule of conformity

The decision rule of conformity of this test report is following the requirements of the requested standard in the quotation, and agreed among testing laboratory and manufacturer (applicant) to exclude the consideration of Measurement Uncertainty, unless it is required by the specific standard.

2. Test Sites

2.1 Test Laboratory

TUV Rheinland Taiwan Ltd.

11F. No.758, Sec. 4, Bade Rd., Songshan Dist.
Taipei City 105
Taiwan (R.O.C.)

2.2 Test Facility

TUV Rheinland Taiwan Ltd.

AC Mains Conduction / Radiated Test:
11F. No.758, Sec. 4, Bade Rd., Songshan Dist.
Taipei City 105
Taiwan (R.O.C.)
FCC Registration No.: 180491
IC Canada Registration No.: 9465A

Conducted Test:
No. 458-18, Sec 2, Fenliao., Linkou Dist.
New Taipei City 244
Taiwan (R.O.C.)
FCC Registration No.: 226631
IC Canada Registration No.: 25563

TAF Accredited NCC Test Lab. No.:3567
TAF ISO17025 Certification effective period: 6th-May-2019 to 05th-May-2022



2.3 List of Test and Measurement Instruments

Table 2: List of Test and Measurement Equipment

Equipment	Manufacturer	Model No.	Serial No.	Cal. Date	Cal. Due Date
EMI Test Receiver	R&S	ESR7	102109	2019/4/17	2020/4/16
Spectrum Analyzer	R&S	FSV40	101112	2019/10/15	2020/10/15
Pre-Amplifier	Agilent	8447D	2727A05146	2020/2/17	2021/2/16
Pre-Amplifier	EMCI	EMC051845SE	980635	2020/2/11	2021/2/10
Pre-Amplifier	EMCI	EMC184045SE	980656	2020/2/11	2021/2/10
Bilog Antenna	SCHWARZBECK	VULB-9168	00950	2020/1/20	2021/1/19
Horn Antenna	ETS-Lindgren	3117	00218929	2019/11/27	2020/11/26
Horn Antenna	SCHWARZBECK	BBHA 9170	00890	2019/4/12	2020/4/11
Loop Antenna	EMCI	LPA600	287	2019/12/20	2020/12/19
Test Software	Audix	e3	Ver. 9	N/A	N/A
Test Cable	HUBER+SUHNER	SUCOFLEX 104EA	800057/4EA	2019/4/11	2020/4/10
Test Cable	HUBER+SUHNER	SUCOFLEX 104	802244/4	2019/4/11	2020/4/10
Test Cable	HUBER+SUHNER	SUCOFLEX 104	MY37203/4	2019/4/11	2020/4/10
Test Cable	HUBER+SUHNER	SUCOFLEX 102EA	800897/2EA	2019/4/11	2020/4/10
Test Cable	HUBER+SUHNER	SUCOFLEX 102EA	800902/2EA	2019/4/11	2020/4/10
Test Cable	HUBER+SUHNER	SUCOFLEX 102EA	801026/2EA	2019/4/11	2020/4/10
Thermo Chamber	Giant Force	GHT-150-40-CP-SD	MAA1902-010	2020/2/1	2021/2/1
Signal Generator	R&S	SMB100A03	181335	2020/1/23	2021/1/23
Power Meter	Anritsu	ML2495A	1901008	2019/4/29	2020/4/28
Power Sensor	Anritsu	MA2411B	1725269	2019/4/29	2020/4/28
EXG-B RF Analog Signal Generator	Agilent	N5171B	MY53050377	2019/04/22	2020/04/21
MXG-B RF Vector Signal Generator	Agilent	N5182B	MY53050524	2019/04/22	2020/04/21
EMI Test Receiver	Rohde & Schwarz	ESR 7	101062	2019/10/15	2020/10/15
Two-Line V-Network (for EUT)	Rohde & Schwarz	ENV216	101243	2019/06/23	2020/06/23
Two-Line V-Network	Rohde & Schwarz	ENV216	101262	2019/07/16	2020/07/16
Telecom ISN 4 Line	Fischer Custom Communications	FFCC-TLISN-T4-02-09	101168	2020/02/03	2021/02/03
Impedance Stabilization Network (for Conduction)	TESEQ	ISN T800	51949	2019/02/25	2020/02/25
				2020/02/25	2021/02/25
Pulse Limiter	Rohde & Schwarz	ESH3-Z2	0357.8810.54-102102-HN	2019/07/25	2020/07/25
Wireless Tester	Rohde & Schwarz	CMW270	101929	2020/01/18	2021/01/17
Test Software	Audix	e3	Ver. 9	N/A	N/A

2.4 Traceability

All measurement equipment calibrations are traceable to NML(Taiwan)/NIST(USA) or where calibration is performed outside Taiwan, to equivalent nationally recognized standards organizations.

2.5 Calibration

Equipment requiring calibration is calibrated periodically in a suitably accredited Calibration Lab. Additionally all equipment is verified for proper performance on a regular schedule using in house standards or comparisons.

2.6 Measurement Uncertainty

The estimated combined standard uncertainty for radiated emissions and conducted emissions measurements .

Table 3: Emission Measurement Uncertainty

Parameter	Uncertainty
Radio Frequency	$\pm 1 \times 10^{-7}$
RF power, conducted	± 1.5 dB
RF power density, conducted	± 3 dB
spurious emissions, conducted	± 3 dB
all emissions, radiated	± 6 dB
Temperature	± 1 °C
Humidity	± 5 %

3. General Product Information

3.1 Product Function and Intended Use

The EUT is a RIGHTEST Continuous Glucose Monitoring System (CGMS). It contains a Bluetooth compatible module enabling the user to communicate data through a Wireless interface.
For details refer to the User Guide, Data Sheet and Circuit Diagram.

3.2 System Details and Ratings

Table 4: Basic Information of EUT

Item	EUT information
Kind of Equipment/Test Item	RIGHTEST Continuous Glucose Monitoring System (CGMS)
Type Designation	HM312
FCC ID	ADU-HM312

Table 5: Technical Specification of EUT

Technical Specification	Value
Operating Frequencies	2402~2480MHz
Channel number	40
Operation Voltage	3.7 Vdc from Battery, 5Vdc from USB charger
Modulation	GFSK
Antenna gain	2dBi

3.3 Independent Operation Modes

Basic operation modes are:

- A. Transmitting
- B. Normal link

3.4 Noise Generating and Noise Suppressing Parts

Refer to the Circuit Diagram.

3.5 Submitted Documents

- Circuit Diagram
- Block Diagram
- Rating Label
- Technical Description

4. Test Set-up and Operation Modes

4.1 Principle of Configuration Selection

The equipment under test (EUT) was configured to measure its maximum power level.

During testing, Channel and Power Controlling Software provided by the customer was used to control the operating channel as well as the output power level. The RF output power selection is for the setting of RF output power expected by the customer and is going to be fixed on the firmware of the final end product.

Table 6: Table for Parameters of Test Software Setting

Mode	Channel Frequency		
	2402 MHz	2440 MHz	2480 MHz
GFSK	Default	Default	Default

4.2 Test Operation and Test Software

The sample was provided with Direct Test Mode F/W to connect with CMW270 through UART for testing.

The samples were used as follows:

A001062564-001 (Radiated)

A001062564-002 (Conducted)

Full test was applied on all test modes, but only worst case was shown

4.3 Special Accessories and Auxiliary Equipment

The product has been tested together with the following additional accessories:

Accessory of EUT

No.	Product	Brand	Model	Description
A	USB Charger	BIONIME	TRANSMITTER CHARGER	-
1	AC Adapter	SWITCHING	UES06WNCPU-050100SPA	I/P: 100-240 Vac, 50/60 Hz, O/P: 5.0 Vdc, 1.0 A
B	USB Cable	-	-	2m

Support Unit

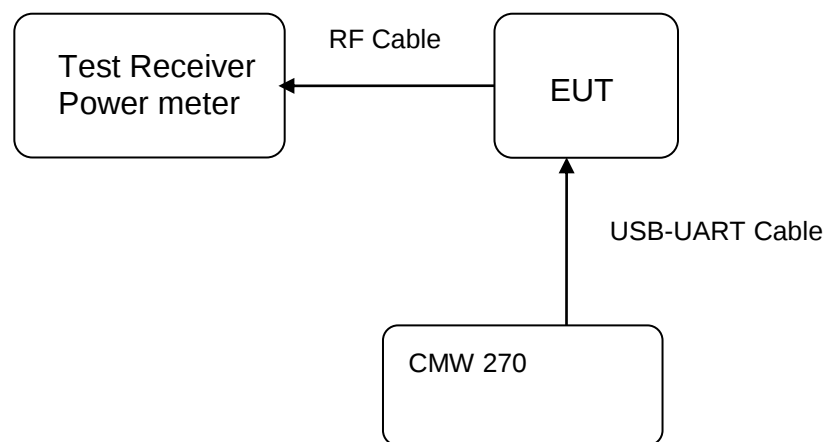
Support Unit					
No.	Description	Brand	Model	S/N	Remark
2	UART	Silicon	CP2102	-	USB to TTL

4.4 Countermeasures to achieve EMC Compliance

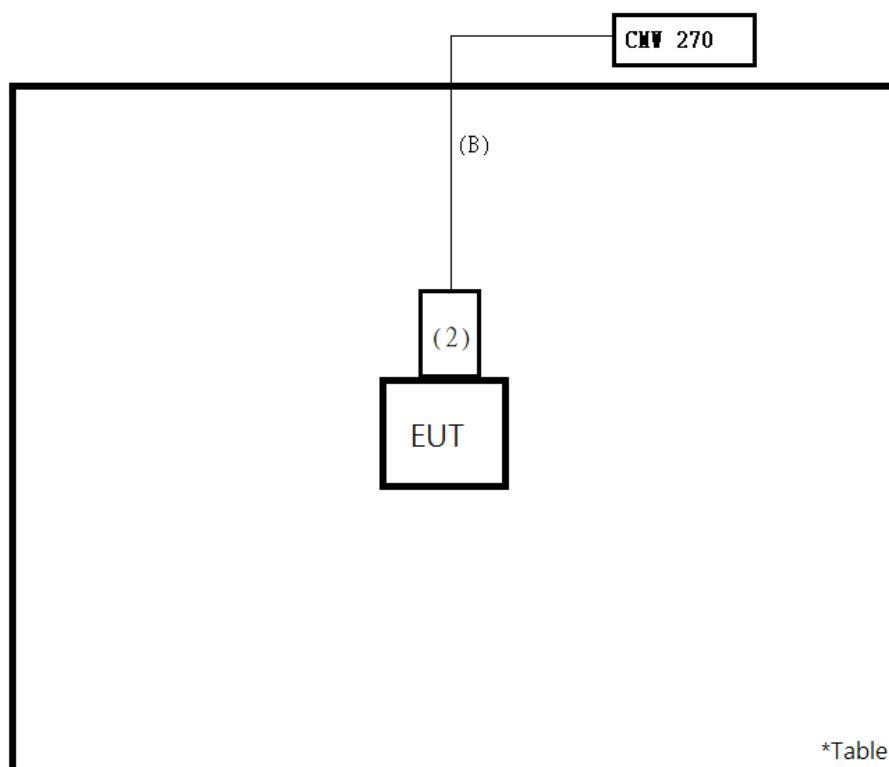
The test sample which has been tested contained the noise suppression parts as described in the Constructional Data Form or the Technical Construction File. No additional measures were employed to achieve compliance.

4.5 Test Setup Diagram

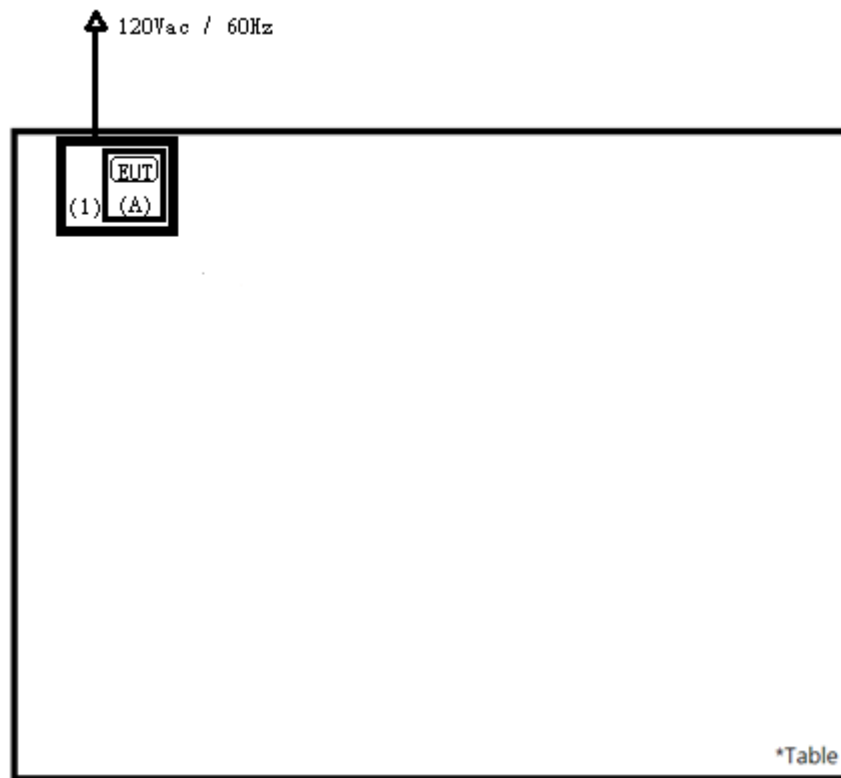
<Diagram of Measurement Equipment Configuration for Conducted Transmitter Measurement>



< Diagram of Measurement Equipment Configuration for Radiated Spurious Emissions>



< Diagram of Measurement Equipment Configuration for Mains Conducted Emission mode >



5. Test Results

5.1 Transmitter Requirement & Test Suites

5.1.1 Antenna Requirement

RESULT:**Passed**

Test standard : FCC Part 15.247(b)(4), Part 15.203

Requirement : use of approved antennas only with directional gains that do not exceed 6 dBi

According to the manufacturer declaration, the EUT has an antenna with Max directional gain of 2dBi. The antenna is a chip antenna with no possibility of replacement with a non-approved antenna by the end-user. Therefore, the EUT is considered to comply with this provision.

Refer to EUT photo for details.

5.1.2 Peak output power

RESULT:**Passed**

Test standard : FCC Part 15.247(b)(3)
Basic standard : ANSI C63.10:2013, KDB558074(8.3.1.3)
Limit : 1 Watt
Kind of test site : Shielded room

Test setup

Test Channel : Low/ Middle/ High
Operation Mode : A

Ambient temperature : 24.1°C
Relative humidity : 64.9%
Atmospheric pressure : 100-103 kPa

Table 7: Test result of Peak output power

Channel	Channel Frequency (MHz)	Output Power		Average Output Power	Limit
		(dBm)	(W)	(mW)	(W)
Low Channel	2402	-5.37	0.00029	0.287	1
Middle Channel	2440	-5.53	0.00028	0.268	1
High Channel	2480	-6.23	0.00024	0.229	1

5.1.3 6dB Bandwidth and 99% Bandwidth

RESULT:
Passed

Test standard : FCC Part 15.247(a)(2),
 Basic standard : ANSI C63.10:2013, KDB558074
 Kind of test site : Shielded room

Test setup

Test Channel : Low/ Middle/ High
 Operation Mode : A

Ambient temperature : 24.1°C
 Relative humidity : 64.9%
 Atmospheric pressure : 100-103 kPa

Table 8: Test result of 6dB Bandwidth

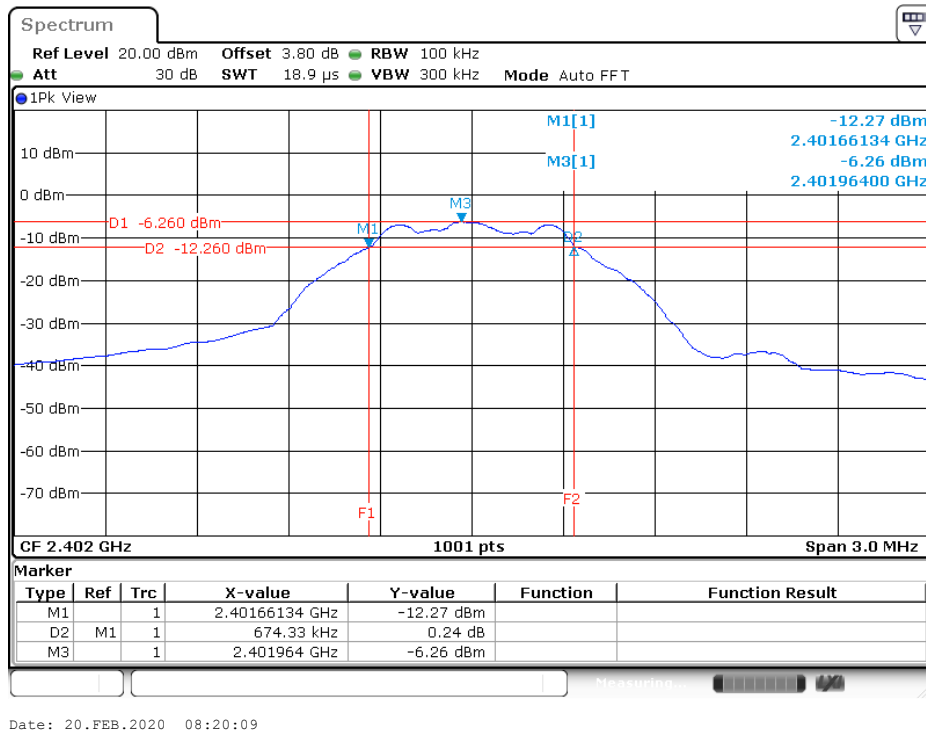
Channel	Channel Frequency (MHz)	6dB Bandwidth (kHz)	Limit (kHz)	Result
Low Channel	2402	674.33	>500	Pass
Mid Channel	2440	671.33	>500	Pass
High Channel	2480	692.31	>500	Pass

Table 9: Test result of 99% Bandwidth

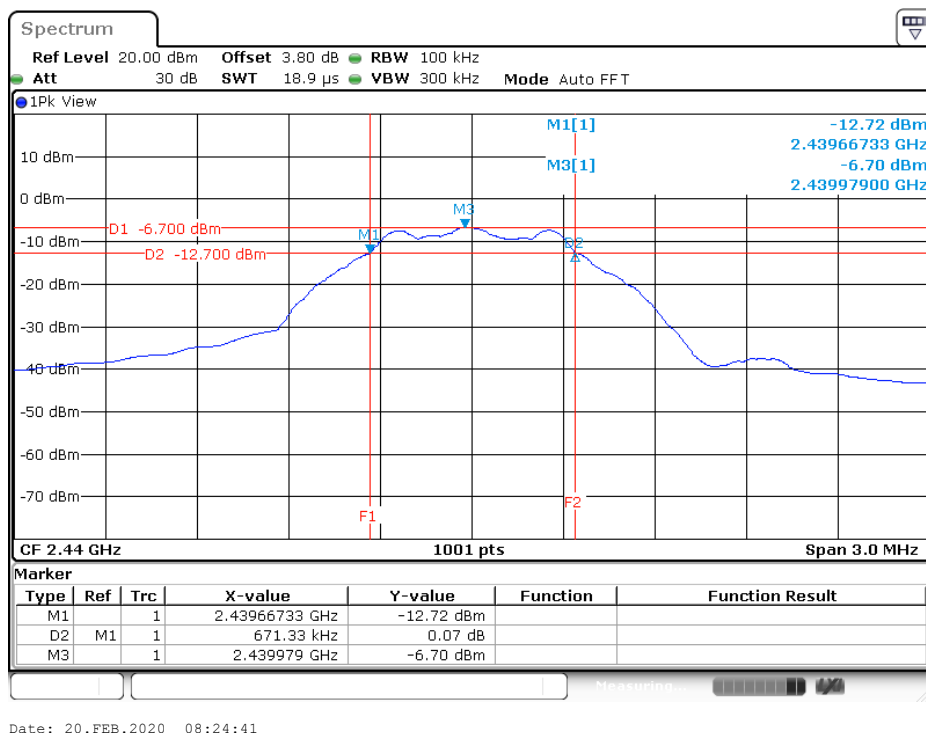
Channel	Channel Frequency (MHz)	99% Bandwidth (MHz)
Low Channel	2402	1.028
Mid Channel	2440	1.025
High Channel	2480	1.028

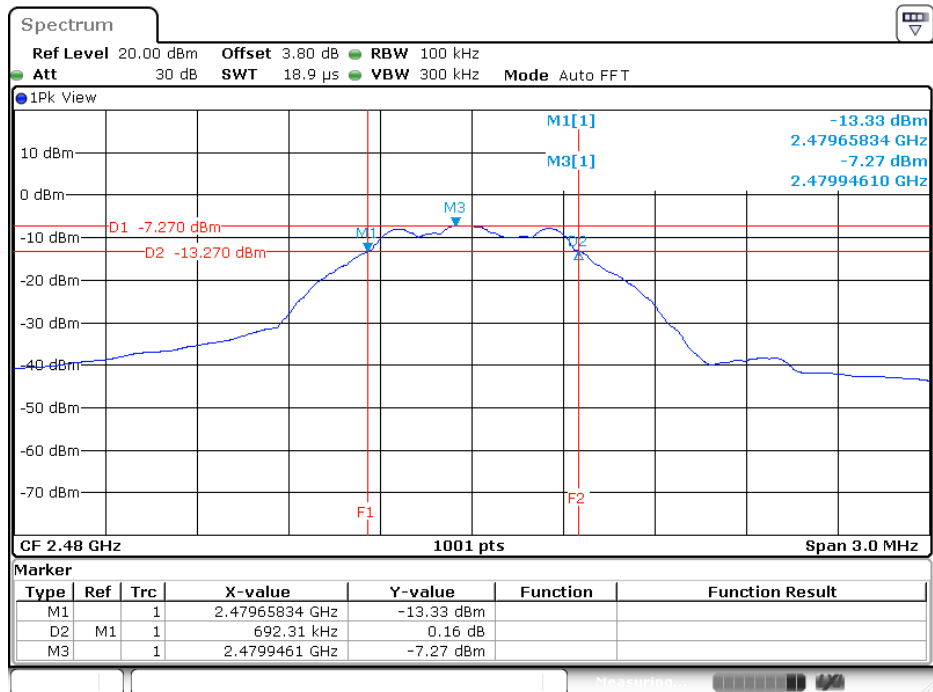
Test Plot of 6dB Bandwidth

Low Channel



Middle Channel

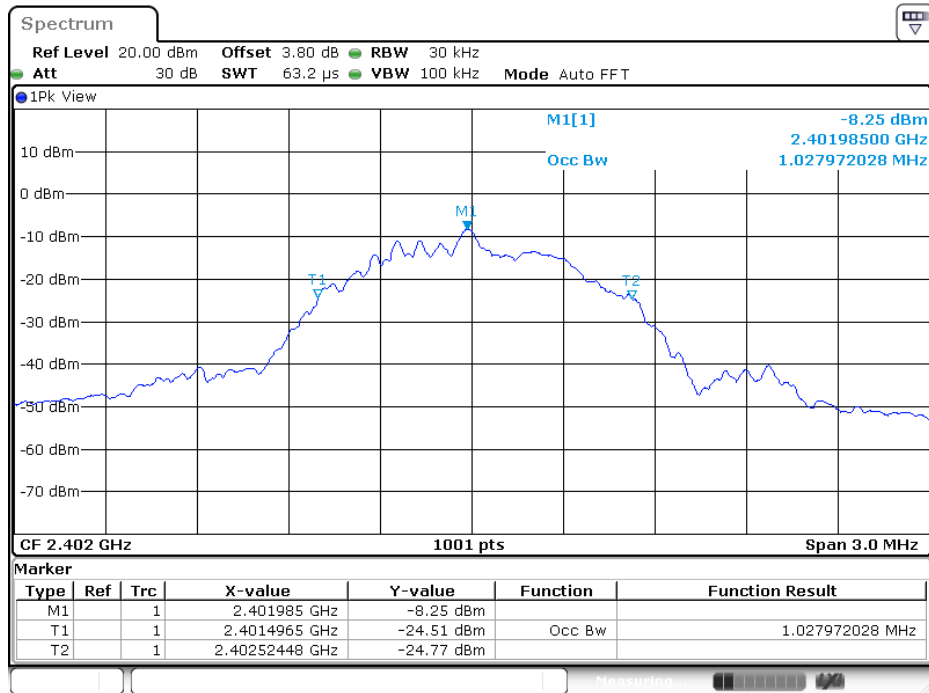


High Channel


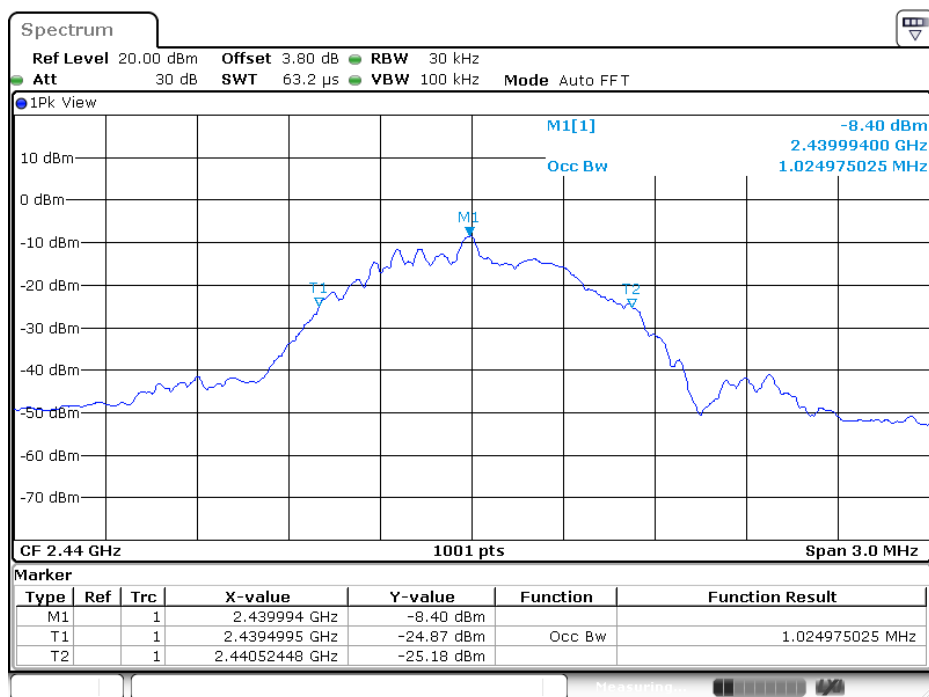
Date: 20.FEB.2020 08:26:24

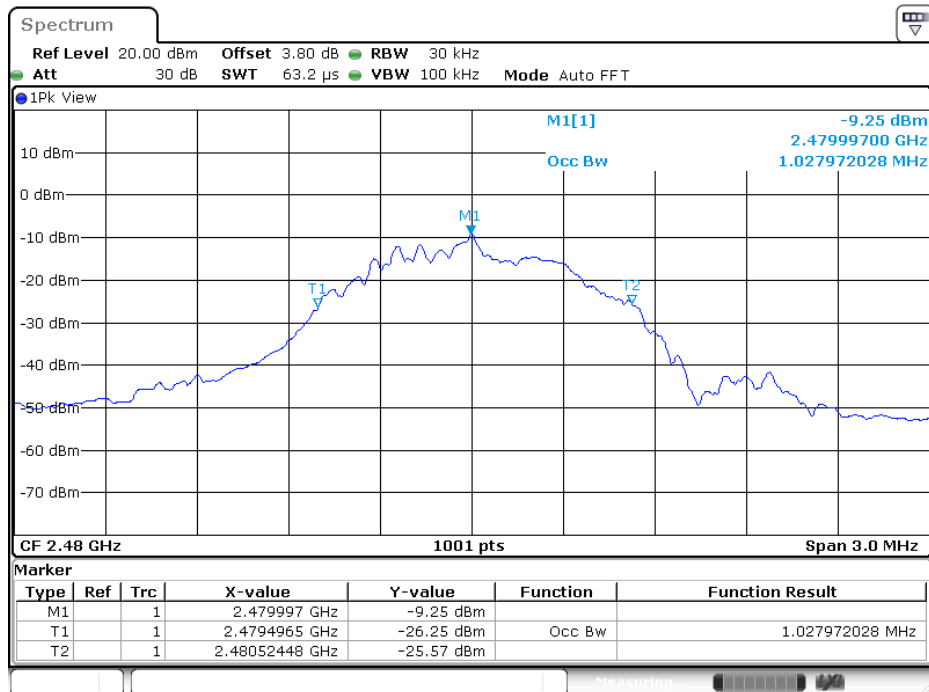
Test Plot of 99% Bandwidth

Low Channel



Middle Channel



High Channel


Date: 20.FEB.2020 08:26:42

5.1.4 Power Density

RESULT:**Passed**

Test standard : FCC Part 15.247(e)
Basic standard : ANSI C63.10:2013, KDB558074
Kind of test site : Shielded room

Test setup

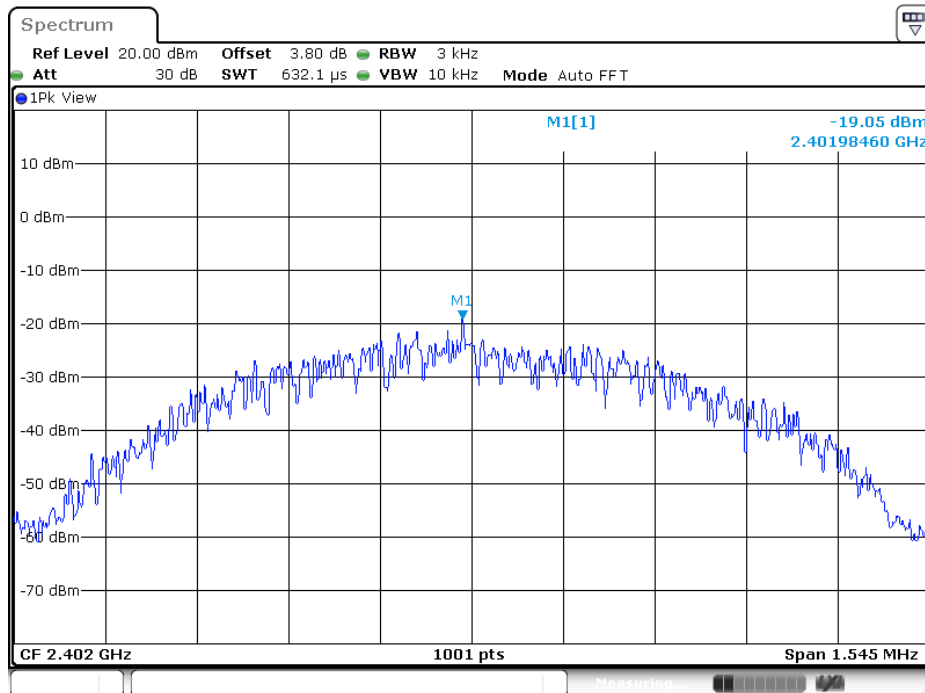
Test Channel : Low/ Middle/ High
Operation Mode : A
Ambient temperature : 24.1°C
Relative humidity : 64.9%
Atmospheric pressure : 100-103 kPa

Table 10: Test result of Power Density

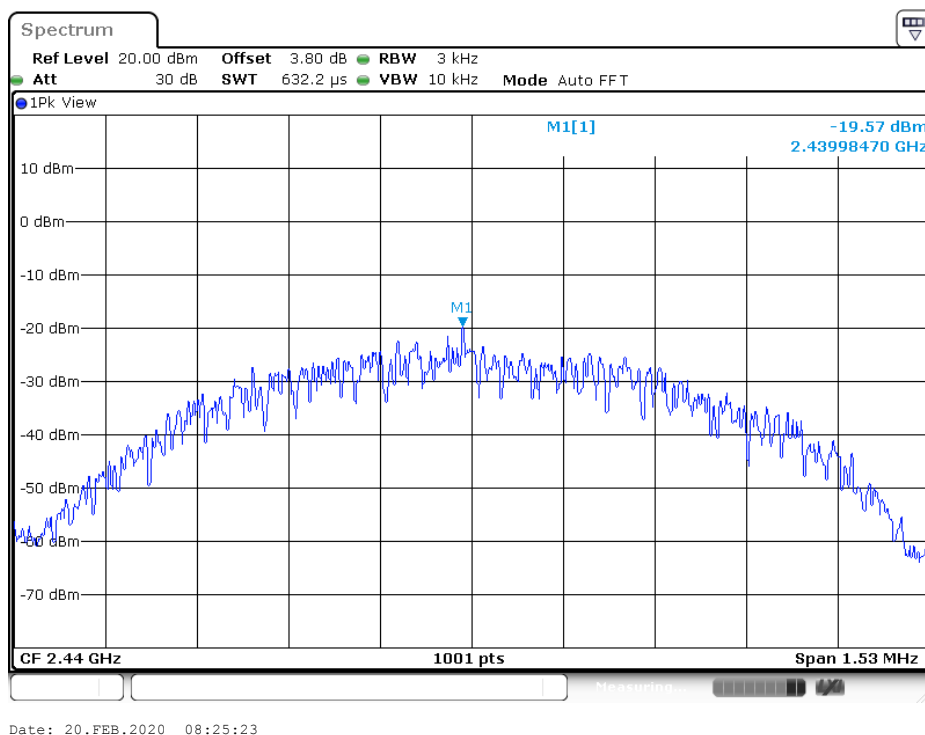
Channel	Channel Frequency (MHz)	Power Density	Limit
		(dBm)	(dBm)
Low Channel	2402	-19.05	8
Middle Channel	2440	-19.57	8
High Channel	2480	-20.15	8

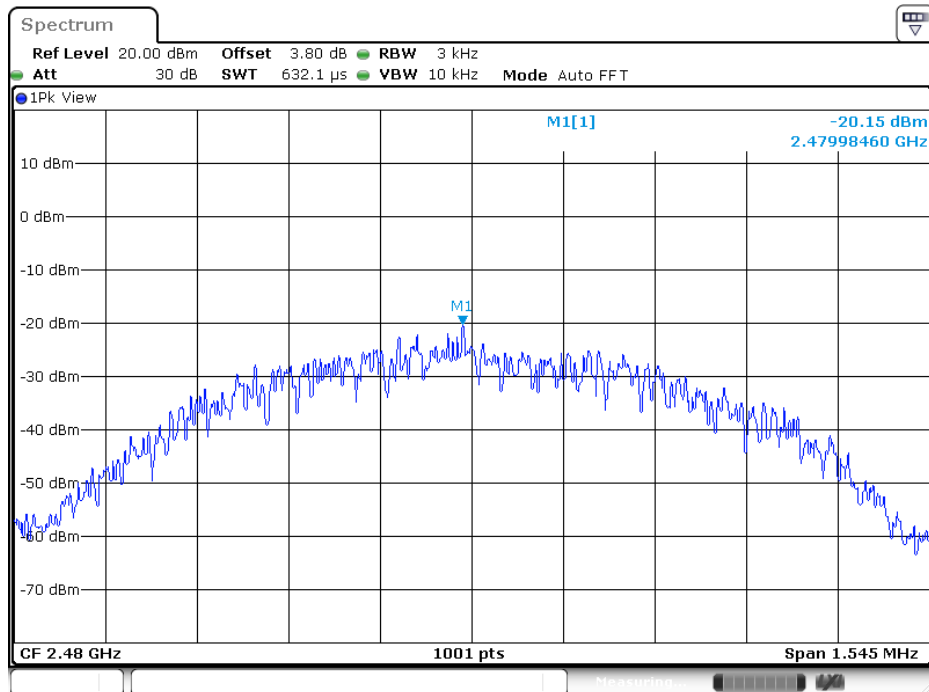
Test Plot of Power Density

Low Channel



Middle Channel



High Channel


Date: 20.FEB.2020 08:27:27

5.1.5 Conducted spurious emissions and Frequency Band Edge measured in 100kHz Bandwidth

RESULT:**Passed**

Test standard	:	FCC part 15.247(d)
Basic standard	:	ANSI C63.10:2013, KDB558074
Limit	:	20dB (below that in the 100kHz bandwidth within the band that contains the highest level of the desired power)
Kind of test site	:	Shielded room

Test setup

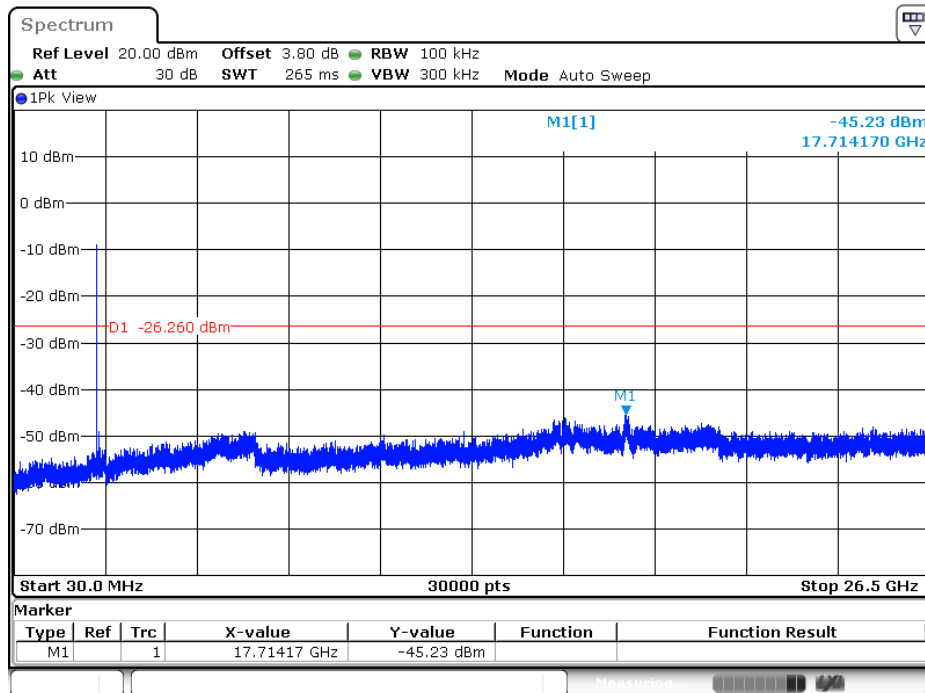
Test Channel	:	Low/ Mid/ High for spurious, Low/ High for Band Edge
Operation mode	:	A
Ambient temperature	:	24.1°C
Relative humidity	:	64.9%
Atmospheric pressure	:	100-103 kPa

All emissions are more than 20dB below fundamental, details refer to following test plot, and compliance is achieved as well.

Due to the small size of the product and that there are no inductive components of significant size, 9kHz to 30MHz frequency range is not tested based on technical judgment.

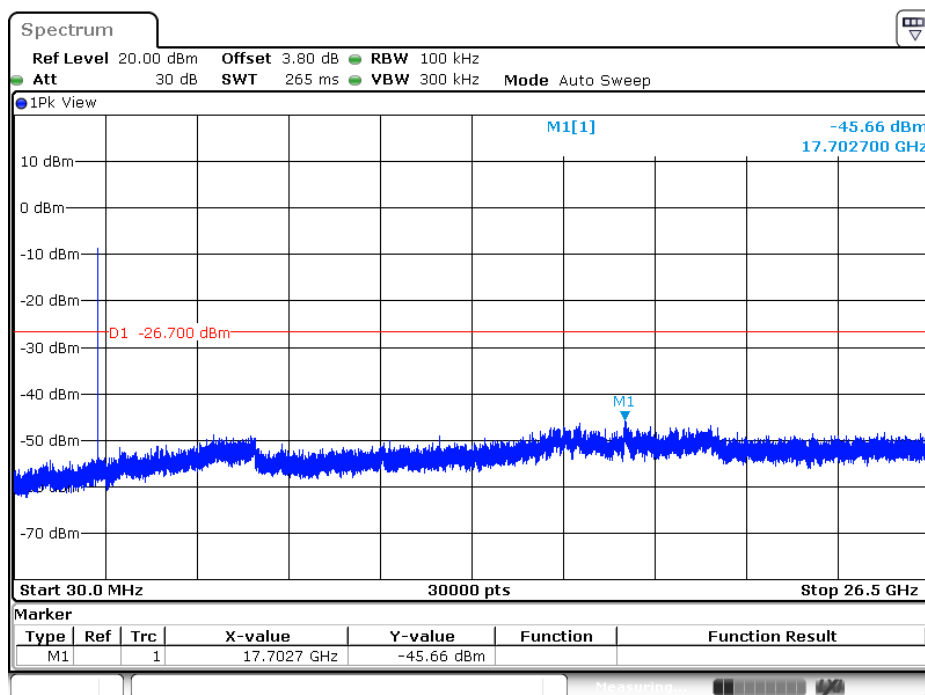
Test Plot 100kHz Conducted Emissions

Low Channel

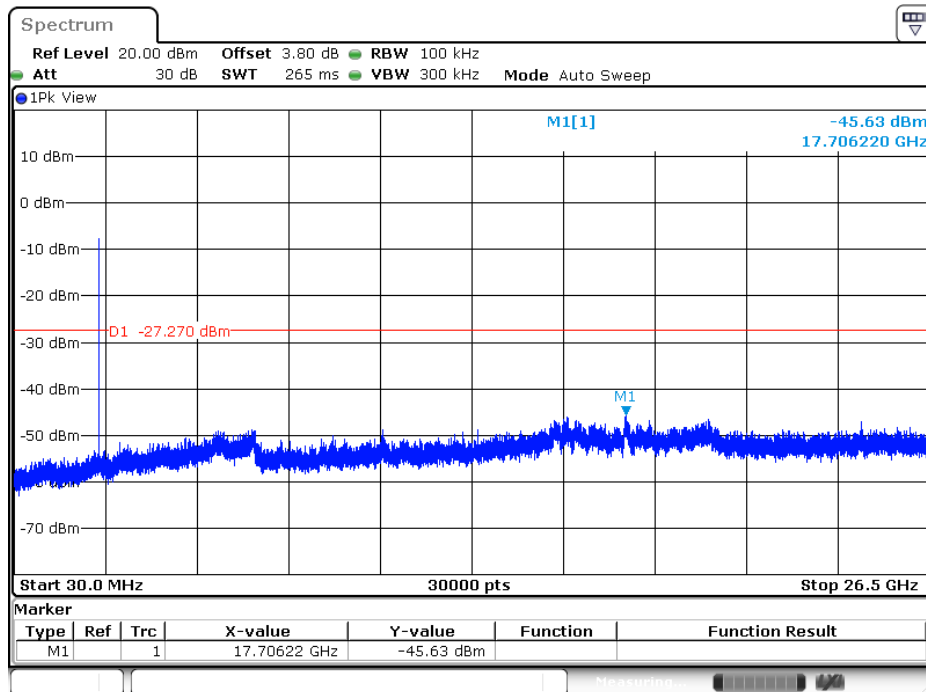


Date: 20.FEB.2020 08:23:42

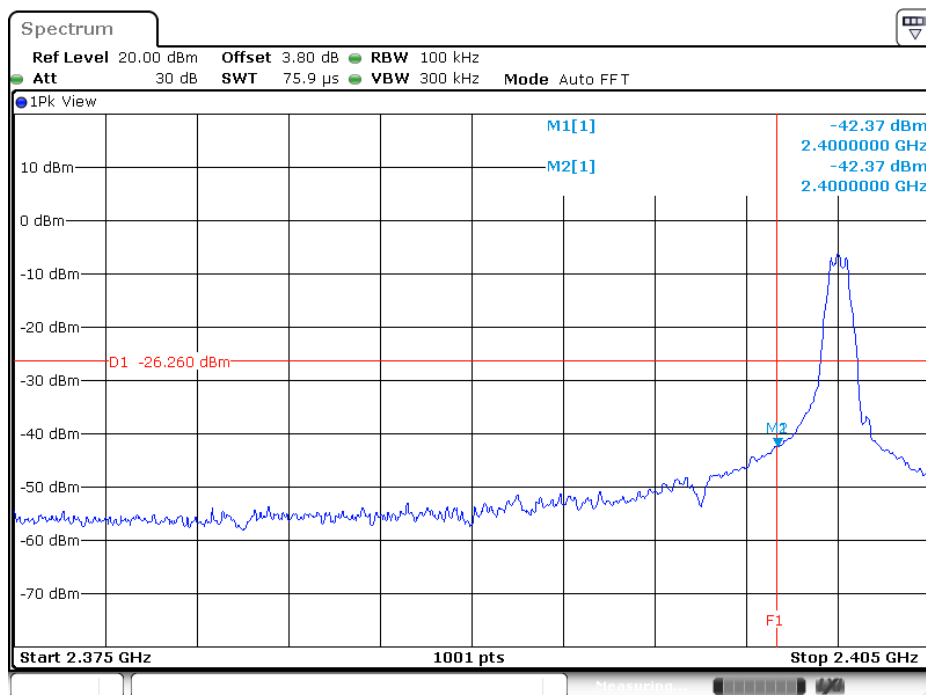
Middle Channel



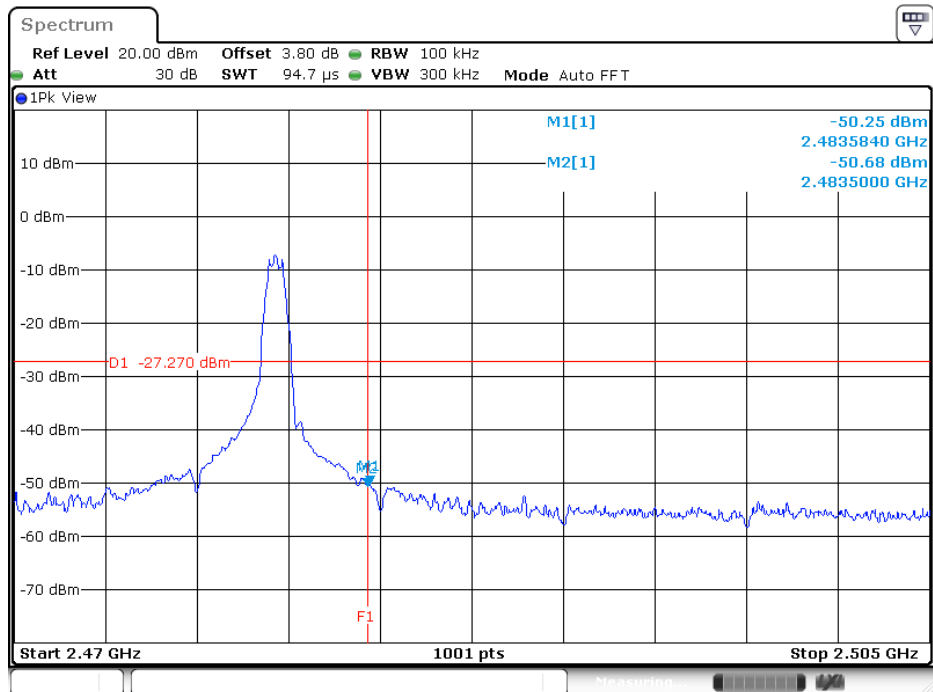
Date: 20.FEB.2020 08:25:42

High Channel


Date: 20.FEB.2020 08:28:35

Test Plot 100kHz RBW of Band Edge
Low Channel


Date: 20.FEB.2020 08:22:00

High Channel


Date: 20.FEB.2020 08:28:07

5.1.6 Spurious Emission

RESULT:**Passed**

Test standard : FCC part 15.247(d), FCC 15.205, FCC 15.209
Basic standard : ANSI C63.10: 2013
Limits : Radiated emissions which fall in the restricted bands, as defined in FCC 15.205(a), must comply with the radiated emission limits specified in FCC 15.209(a).
Emission radiated outside the specified frequency bands must comply with the radiated emission limits specified in FCC 15.209(a).

Kind of test site : 3m Semi-Anechoic Chamber

Test setup

Test Channel : Low/ Middle/ High
Operation mode : A

Ambient temperature : 24.7 °C
Relative humidity : 58.9 %
Atmospheric pressure : 100-103 kPa

For details refer to Appendix D.

The Radiated Emissions testing was performed in the X, Y and Z axis orientation. The worst-case Axis orientation is recorded in this test report.

Factor (dB/m)=Antenna Factor(dB/m)+Cable loss (dB)
Level(dBuV/m)=Reading(dBuV)+ Factor(dB/m)

5.2 Mains Emissions

5.2.1 Mains Conducted Emissions

RESULT:**Passed**

Test standard	:	FCC Part 15.207 FCC Part 15.107
Limits	:	Mains Conducted emissions as defined in above test standards must comply with the mains conducted emission limits specified
Kind of test site	:	Shielded Room

Test setup

Operation mode	:	B
Ambient temperature	:	21.1 °C
Relative humidity	:	43 %
Atmospheric pressure	:	100-103 kPa

Remark: For details refer to Appendix D.

6. Safety Human exposure

6.1 Radio Frequency Exposure Compliance

6.1.1 Electromagnetic Fields

RESULT:**Passed**

Test standard : FCC KDB Publication 447498 D01 v06
47CFR 1.1310
47CFR 2.1091

FCC:

Therefore the maximum output power of the transmitter is $0.29\text{mW} < 10\text{mW}$ (Distance: 5 mm), hence the EUT is excluded from SAR evaluation according to FCC KDB publication 447498 D01: Mobile Portable RF Exposure.

7. Photographs of the Test Set-Up

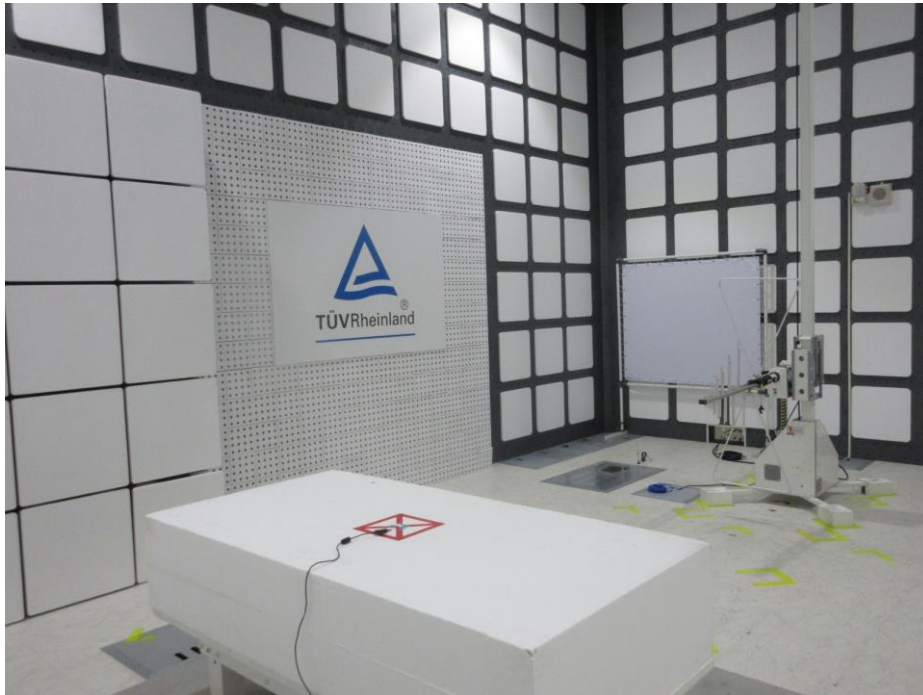
Photograph 1: Set-up for Spurious Emissions (Front View 1)



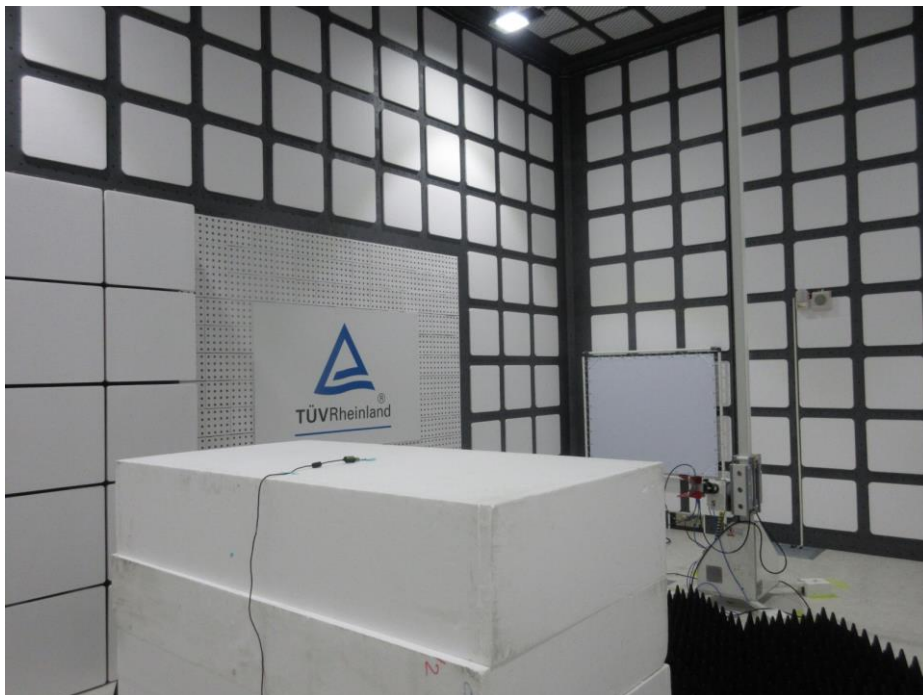
Photograph 2: Set-up for Spurious Emissions (Front View 2)



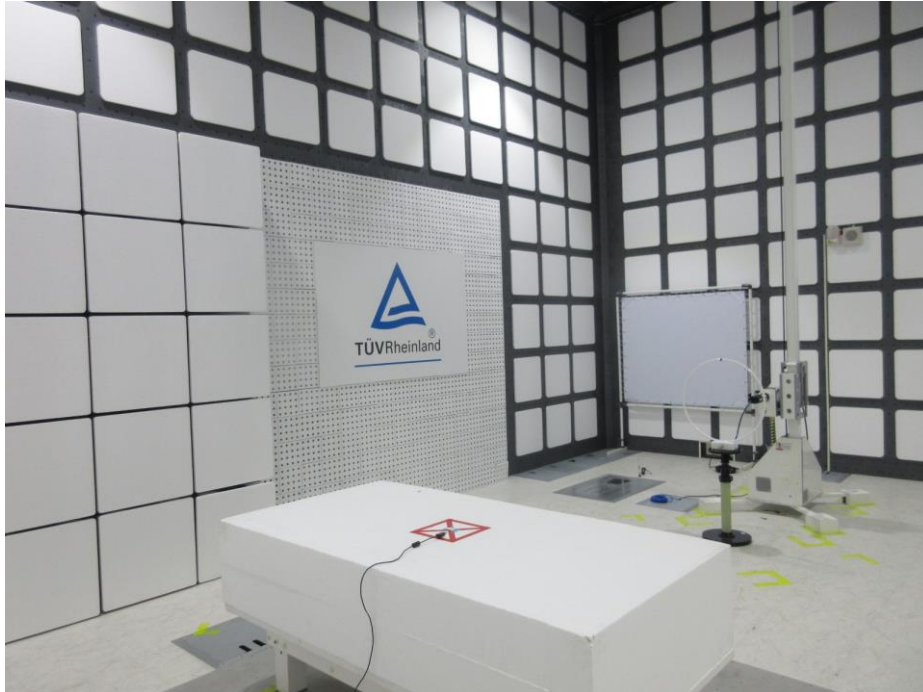
Photograph 3: Set-up for Spurious Emissions (Back View 1)



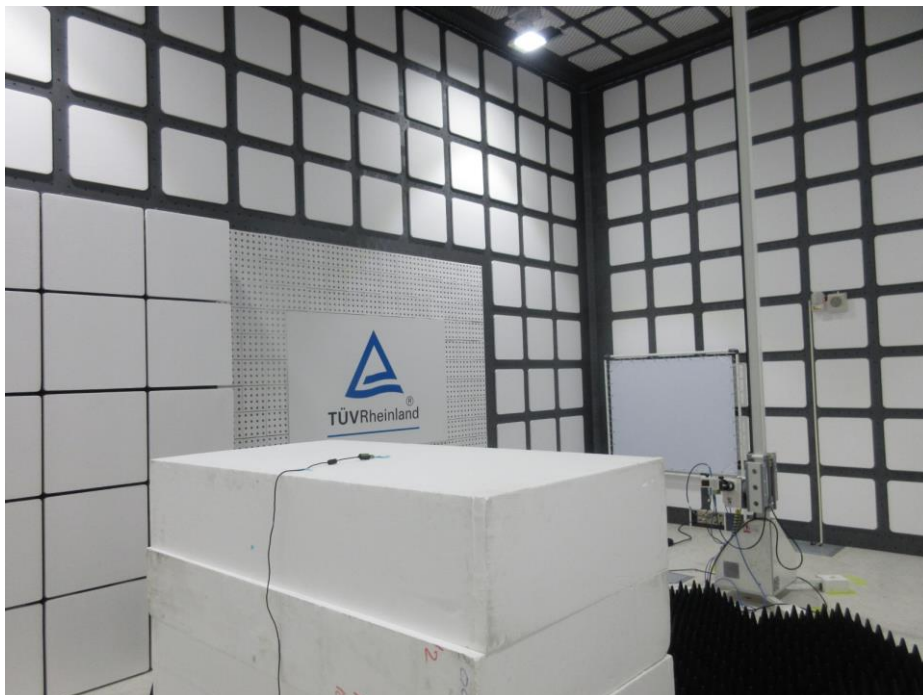
Photograph 4: Set-up for Spurious Emissions (Back View 2)



Photograph 5: Set-up for Spurious Emissions (Back View 3)



Photograph 6: Set-up for Spurious Emissions (Back View 4)



Photograph 7: Set-up for Mains Conducted testing (Front View)



Photograph 8: Set-up for Mains Conducted testing (Back View)



8. List of Tables

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