Report on the Radio Testing

For

Teva Branded Pharmaceutical Products R&D, Inc.

on

Electronic Inhaler

Report no. TRA-032074-02-45-01C

23rd March 2017

Report Number: TRA-032074-02-45-01C
Issue: B

REPORT ON THE RADIO TESTING OF A

Teva Branded Pharmaceutical Products R&D, Inc.

Electronic Inhaler

WITH RESPECT TO SPECIFICATION
FCC 47CFR 15.247 & IC RSS-247

TEST DATE: From 7/10/2016 to10/10/2016

Written by: A Wong — Alan Wong, Radio Test Engineer

Approved by: Digitally signed by John Charters DN: cn=John Charters, o=Element Materials Technology, ou, email=john.charters@element.com, c=GB Date: 2017.04.04 14:37:25 +01'00' — John Charters, Department Manager

Date: 4th April 2017

Element Materials Technology Warwick Ltd.
Registered in England and Wales. Registered Office: 5 Fleet Place, London, EC4M 7RD
Company Reg No. 02536659

1 Revision Record

Issue Number	*Issue Date*	*Revision History*
A	19th December 2016	Original
B	23rd March 2017	Amended according to TCB comments
C	4th April 2017	Product name change

2 Summary

TEST REPORT NUMBER:	TRA-032074-02-45-01C
WORKS ORDER NUMBER:	TRA-032074-02
PURPOSE OF TEST:	USA: Testing of radio frequency equipment per the relevant authorization procedure of chapter 47 of CFR (code of federal regulations) Part 2, subpart J. Canada: Testing of radio apparatus for TAC (technical acceptance certificate) per subsections 4(2) of the Radiocommunication Act and 21(1) of the Radiocommunication Regulations.
TEST SPECIFICATION(S):	47CFR15.247 & RSS-247
EQUIPMENT UNDER TEST (EUT):	ProAir Digihaler
FCC IDENTIFIER:	2AJVSPDR0000401
EUT SERIAL NUMBER:	Sample numbers S11, S12, S13, S14, S15, S16 and S17
AGENT:	Cambridge Consultants Ltd
ADDRESS:	Science Park Milton Road Cambridge CB4 0DW United Kingdom
CLIENT CONTACT:	Steven Gardner ☎ 392303 ✉ steven.gardner@cambridgeconsultants.com
ORDER NUMBER:	38478/SDG
TEST DATE:	7/10/2016 to10/10/2016
TESTED BY:	Alan Wong Element

2.1 Test Summary

Test Method and Description		*Requirement Clause*		*Applicable to this equipment*	*Result / Note*
		RSS	*47CFR15*		
Radiated spurious emissions (restricted bands of operation and cabinet radiation)		Gen, 8.10	15.205	☒	*PASS*
AC power line conducted emissions		Gen, 8.8	15.207	☐	*N/A*
Occupied bandwidth		247, 5.2 (1)	15.247(a)(2)	☒	*PASS*
Conducted carrier power	Peak	247, 5.4 (4)	15.247(b)(3)	☐	*N/A*
	Max.			☐	
*Radiated carrier power		247, 5.4 (4)	15.247(b)(3)	☒	*PASS*
Conducted / radiated RF power out-of-band		247, 5.5	15.247(d)	☒	*PASS*
Power spectral density, conducted		247, 5.2 (2)	15.247(e)	☒	*PASS*
Calculation of duty correction		-	15.35(c)	☐	*N/A*

Notes:
*Alternative measurement method used because of the lack of antenna port connector.

The results contained in this report relate only to the items tested, in the condition at time of test, and were obtained in the period between the date of initial receipt of samples and the date of issue of the report.

The apparatus was set up and exercised using the configurations, modes of operation and arrangements defined in this report only. Any modifications made are identified in Section 8 of this report.

N/A: Not Applicable, because the EUTs do not have antenna port, and not supplied by AC power line.

Particular operating modes, apparatus monitoring methods and performance criteria required by the standards tested to have been performed except where identified in Section 5.2 of this test report (Deviations from Test Standards).

3 Contents

4 Introduction

This report TRA-032074-02-45-01C presents the results of the Radio testing on a Cambridge Consultants Ltd, Electronic Inhaler to specification 47CFR15 Radio Frequency Devices and RSS-247 Licence-exempt Radio Apparatus (All Frequency Bands): Category I Equipment.

The testing was carried out for Cambridge Consultants Ltd by Element, at the address(es) detailed below.

☒ Element Hull
Unit E
South Orbital Trading Park
Hedon Road
Hull
HU9 1NJ
UK

☐ Element Skelmersdale
Unit 1
Pendle Place
Skemersdale
West Lancashire
WN8 9PN
UK

This report details the configuration of the equipment, the test methods used and any relevant modifications where appropriate.

All test and measurement equipment under the control of the laboratory and requiring calibration is subject to an established programme and procedures to control and maintain measurement standards. The quality management system meets the principles of ISO 9001, and has quality control procedures for monitoring the validity of tests undertaken. Records and sufficient detail are retained to establish an audit trail of calibration records relating to its test results for a defined period. Under control of the established calibration programme, key quantities or values of the test & measurement instrumentation are within specification and comply with the relevant traceable internationally recognised and appropriate standard specifications, which are UKAS calibrated as such where these properties have a significant effect on results. Participation in inter-laboratory comparisons and proficiency testing ensures satisfactory correlation of results conform to Elements own procedures, as well as statistical techniques for analysis of test data providing the appropriate confidence in measurements.

Throughout this report EUT denotes equipment under test.

FCC Site Listing:
Element is accredited for the above sites under the US-EU MRA, Designation number UK0009.

IC Registration Number(s):

Element Hull	3483A
Element North West	3930B

The test site requirements of ANSI C63.4-2014 are met up to 1GHz.

The test site SVSWR requirements of CISPR 16-1-4:2010 are met over the frequency range 1 GHz to 18 GHz.

5 Test Specifications

5.1 Normative References

- FCC 47 CFR Ch. I – Part 15 – Radio Frequency Devices.
- ANSI C63.10-2013 – American National Standard of Procedures for Compliance Testing of Unlicensed Wireless Devices.
- 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 9 kHz to 40 GHz.
- Industry Canada RSS-247, Issue 1, May 2015 – Digital Transmission Systems (DTSs), Frequency Hopping Systems (FHSs) and Licence-Exempt Local Area Network (LE-LAN) Devices
- Industry Canada RSS-Gen, Issue 4, November 2014 – General Requirements for Compliance of Radio Apparatus

5.2 Deviations from Test Standards

There were no deviations from the test standard.

6 Glossary of Terms

§	denotes a section reference from the standard, not this document
AC	Alternating Current
ANSI	American National Standards Institute
BW	bandwidth
C	Celsius
CFR	Code of Federal Regulations
CW	Continuous Wave
dB	decibel
dBm	dB relative to 1 milliwatt
DC	Direct Current
DSSS	Direct Sequence Spread Spectrum
EIRP	Equivalent Isotropically Radiated Power
ERP	Effective Radiated Power
EUT	Equipment Under Test
FCC	Federal Communications Commission
FHSS	Frequency Hopping Spread Spectrum
Hz	hertz
IC	Industry Canada
ITU	International Telecommunication Union
LBT	Listen Before Talk
m	metre
max	maximum
MIMO	Multiple Input and Multiple Output
min	minimum
MRA	Mutual Recognition Agreement
N/A	Not Applicable
PCB	Printed Circuit Board
PDF	Portable Document Format
Pt-mpt	Point-to-multipoint
Pt-pt	Point-to-point
RF	Radio Frequency
RH	Relative Humidity
RMS	Root Mean Square
Rx	receiver
s	second
SVSWR	Site Voltage Standing Wave Ratio
Tx	transmitter
UKAS	United Kingdom Accreditation Service
V	volt
W	watt
Ω	ohm

7 Equipment Under Test

7.1 EUT Identification

- Name: Electronic Inhaler
- Serial Number: Sample numbers S11, S12, S13, S14, S15, S16 and S17
- Model Number: PDR0000401
- Software Revision: Not Applicable
- Build Level / Revision Number: For approval testing

7.2 System Equipment

The EUT does not need any support equipment for testing. Different complete PCB assemblies was provided for receiver, transmitters with top, middle and bottom channels, including modulated and un-modulated carrier modes.

7.3 EUT Mode of Operation

7.3.1 Transmission

The mode of operation for transmitter tests was as follows…
For different channels with fixed power levels, modulation schemes and data rates, different samples was used. Each sample started to transmit as soon as a Lithium power cell was mounted on each of them. The mode of operation was Bluetooth low energy. There is no means to set the EUT to transmit or different mode, channel and power.

7.3.2 Reception

The mode of operation for receiver tests was as follows…

A sample configured to listen, for receiver test was provided. Once the sample was populated with a Lithium power cell, the EUT was placed in the SAR for testing. No external support equipment was required to set it up for testing.

7.4 EUT Radio Parameters

7.4.1 General

Frequency of operation:	2402 – 2480 MHz
Modulation type(s):	Bluetooth LE
Occupied channel bandwidth(s):	1 MHz
Declared output power(s):	2.5 mW
Nominal Supply Voltage:	3.0 V d.c.
Location of notice for license exempt use:	user manual
Duty cycle:	68%

7.4.2 Antennas

Type / Manufacturer:	Integral / Etherthronics 1001312
Frequency range:	2402-2480 MHz
Gain:	-10 dB
Polarisation:	Horizontal
Beam width:	N/A
Connector type:	N/A
Length:	7 mm
Weight:	Negligible
Environmental limits:	N/A
Mounting:	Pre-designed on PCB

7.4.3 Product specific declarations

Multiple antenna configuration(s), e.g. MIMO:	None
Fixed pt-pt operations (yes/no):	No
Fixed pt-mpt operations (yes/no):	No

7.5 EUT Description

The EUT has integrated electronics (eModule) which store and transmit information related to inhaler use via Bluetooth to the App installed on a smart device, or to a PC via a Bluetooth dongle. The system stores and transmits information about inhaler use and helps a patient use their inhaler correctly. In regular use, patients are expected to open the cap, inhale through the mouthpiece, and close the cap to receive an inhalation. It communicates with the patient, tracks inhaler information, and allows the use of other tools created in the application to help engage the patient and better manage their respiratory diseases. The electronic module does not control or interfere with how the users use the inhaler to take their inhalations. The inhaler can be used with or without the App.

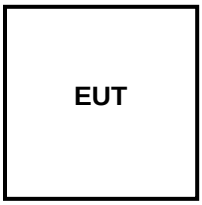
8 Modifications

No modifications were performed during this assessment.

9 EUT Test Setup

9.1 Block Diagram

The EUT operated stand-alone with a 3V d.c. Lithium Coin Cell. For different transmitter channels, different EUT was used. For receiver tests, a receiving EUT was used. No other support equipment was connected.



9.2 General Set-up Photograph

Photographs are held confidential.

10 General Technical Parameters

10.1 Normal Conditions

The E U T was tested under the normal environmental conditions of the test laboratory, except where otherwise stated. The normal power source applied was approx. 3V dc from alkaline batteries.

10.2 Varying Test Conditions

There are no specific frequency stability requirements for the type of device. The results contained in this report demonstrate that the occupied bandwidth is contained within the authorised band and the manufacturer has declared sufficient frequency stability (refer to section 7.4).

Variation of supply voltage is required to ensure stability of the declared output power. During carrier power testing the following variations were made:

	Category	***Nominal***	***Variation***
☐	Mains		85 % and 115 %
☒	Battery	New battery	N/A

11 Radiated emissions

11.1 Definitions

Spurious emissions
Emissions on a frequency or frequencies, which are outside the necessary bandwidth and the level of which may be reduced without affecting the corresponding transmission of information. Spurious emissions include harmonic emissions, parasitic emissions, intermodulation products and frequency conversion products, but exclude out-of-band emissions.

Restricted bands
A frequency band in which intentional radiators are permitted to radiate only spurious emissions but not fundamental signals.

11.2 Test Parameters

Test Location:	Element Hull
Test Chamber:	Lab16
Test Standard and Clause:	ANSI C63.10-2013, Clause 6.5 and 6.6
EUT Channels / Frequencies Measured:	Low / Mid / High
EUT Channel Bandwidths:	1 MHz
Deviations From Standard:	None
Measurement BW:	30 MHz to 1 GHz: 120 kHz Above 1 GHz: 1 MHz
Measurement Detector:	Up to 1 GHz: quasi-peak Above 1 GHz: RMS average and Peak

Environmental Conditions (Normal Environment)

Temperature: 21 °C	+15 ºC to +35 ºC (as declared)
Humidity: 49 % RH	20 % RH to 75 % RH (as declared)
Supply: 3 V ac/dc	±10 % (as declared)

11.3 Test Limit

Unwanted emissions that fall within the restricted frequency bands shall comply with the limits specified:

General Field Strength Limits for License-Exempt Transmitters at Frequencies above 30 MHz

Frequency (MHz)	***Field Strength (µV/m at 3 m)***
30 to 88	100
88 to 216	150
216 to 960	200
Above 960	500

11.4 Test Method

With the EUT setup as per section 9 of this report and connected as per Figure i, the emissions from the EUT were measured on a spectrum analyzer / EMI receiver.

Radiated electromagnetic emissions from the EUT are checked first by preview scans. Preview scans for all spectrum and modulation characteristics are checked, using a peak detector and where applicable worst-case determined for function, operation, orientation, etc. for both vertical and horizontal polarisations. Pre-scan plots are shown with a peak detector and 100 kHz RBW.

If the EUT connects to auxiliary equipment and is table or floor standing, the configurations prescribed in ANSI C63.10 are followed. Alternatively, a layout closest to normal use (as declared by the provider) is employed, (see EUT setup photographs for more detail).

Emissions between 30 MHz and 1 GHz are measured using calibrated broadband antennas. Emissions above 1 GHz are characterized using standard gain horn antennas. Pre-amplifiers and filters are used where required. Care is taken to ensure that test receiver resolution bandwidth, video bandwidth and detector type(s) meet the regulatory requirements.

For both horizontal and vertical polarizations, the EUT is then rotated through 360 degrees in azimuth until the highest emission is detected. At the previously determined azimuth the test antenna is raised and lowered from 1 to 4 m in height until a maximum emission level is detected, this maximum value is recorded.

Power values measured on the test receiver / analyzer are converted to field strength, FS, in dBµV/m at the regulatory distance, using:

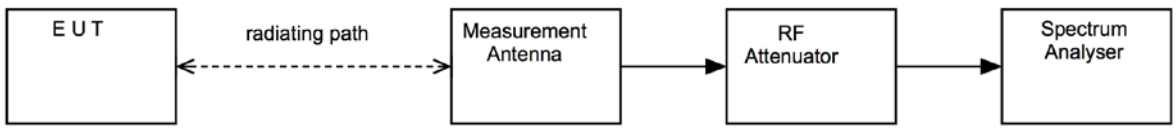
$$FS = PR + CL + AF – PA + DC – CF$$

Where,

PR is the power recorded on the receiver / spectrum analyzer in dBµV;
CL is the cable loss in dB;
AF is the test antenna factor in dB/m;
PA is the pre-amplifier gain in dB (where used);
DC is the duty correction factor in dB (where used, e.g. harmonics of pulsed fundamental);
CF is the distance factor in dB (where measurement distance different to limit distance);

This field strength value is then compared with the regulatory limit.

Figure i Test Setup



11.5 Test Set-up Photograph

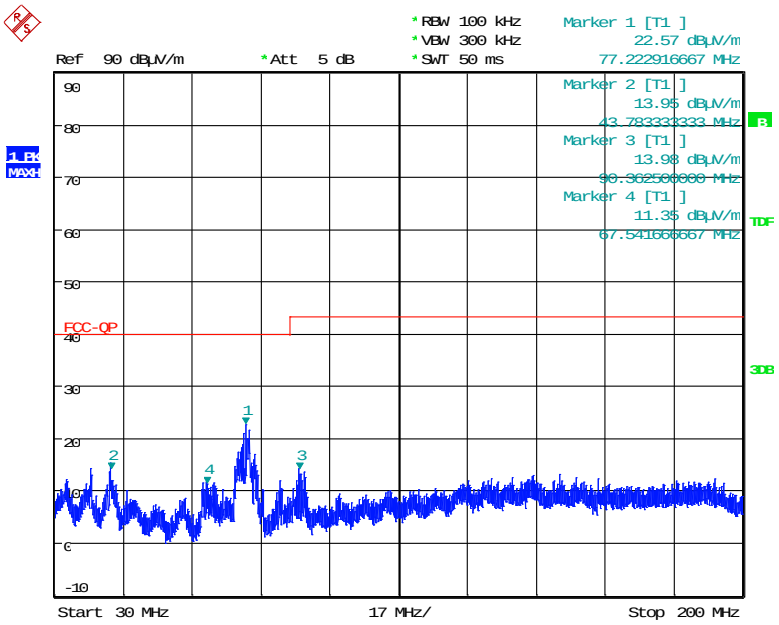
Photographs are held confidential.

11.6 Test Equipment

Equipment Description	*Manufacturer*	*Equipment Type*	*Element No*	*Due For Calibration*
Biconical Antenna	EMCO	3109	RFG095	17/05/2019
Log Periodic Antenna	EMCO	3146	RFG191	17/05/2019
Horn Antenna	EMCO	3115	RFG129	09/02/2018
Spectrum Analyser	R&S	FSU46	REF910	05/07/2017
N-Type RF coaxial cable	Unknown	Cable	REF884	04/12/2016
Pre-Amp (9kHz – 1GHz)	Sonoma	310	REF927	30/06/2018
Short SMA RF Cable	AtlanTec	Cable	REF2165	09/12/2017
Cable	Teledyne	5m 2.92mm	REF919	5/10/2017
Pre-Amp (1 – 26.5GHz)	Agilent	8449B	REF913	02/02/2018

11.7 Test Results

Channel Frequency: 2402 MHz



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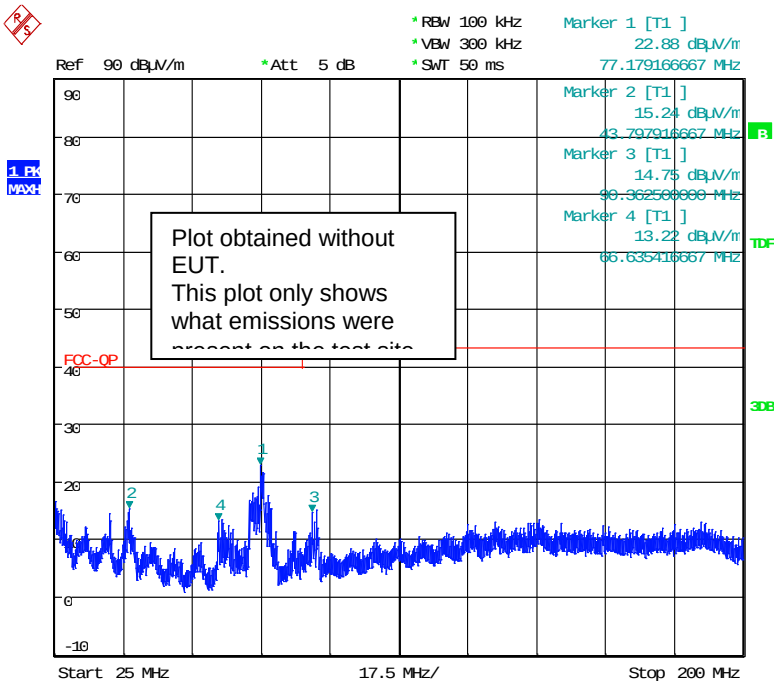

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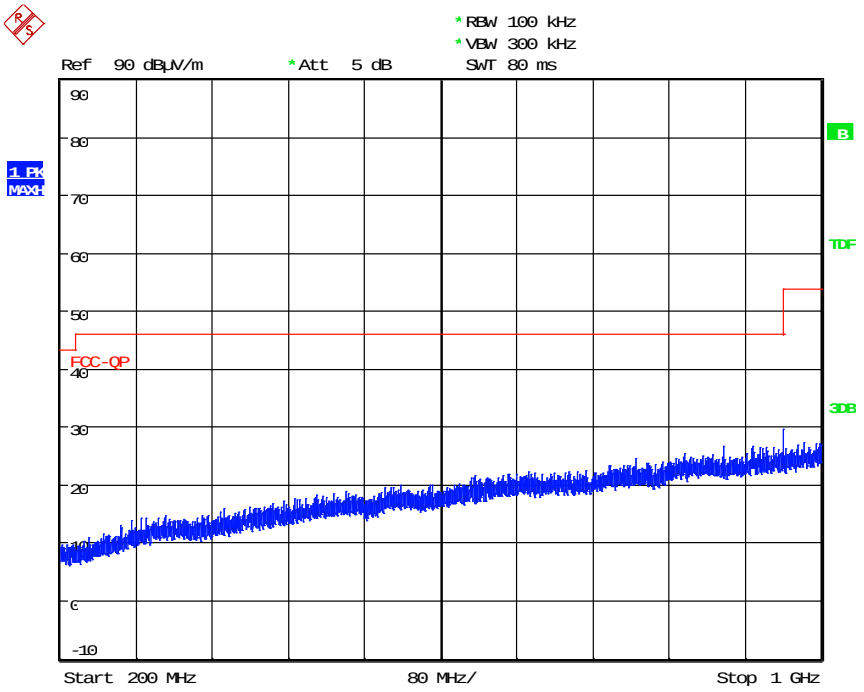

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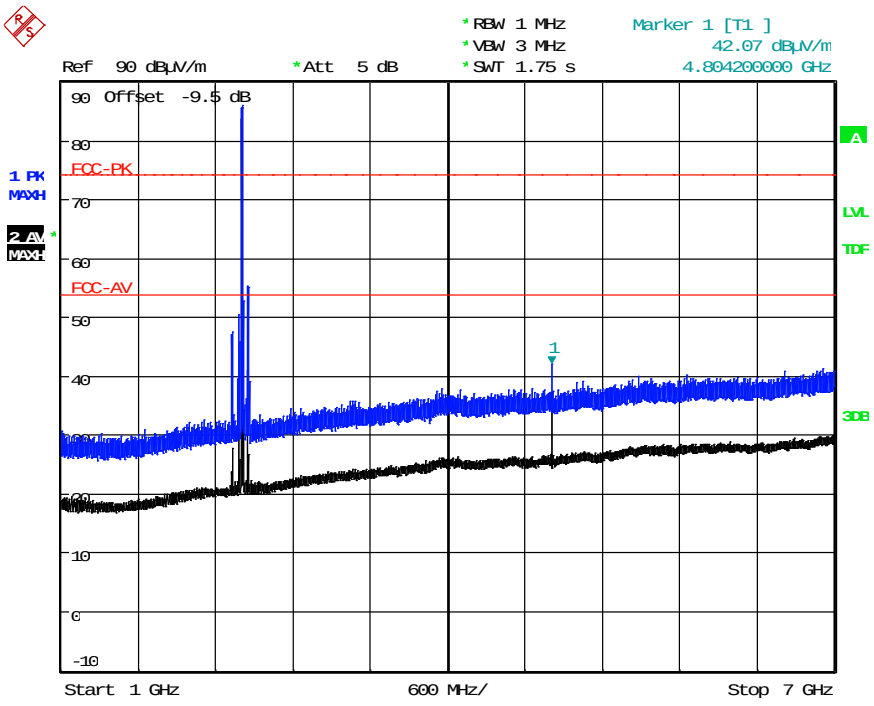

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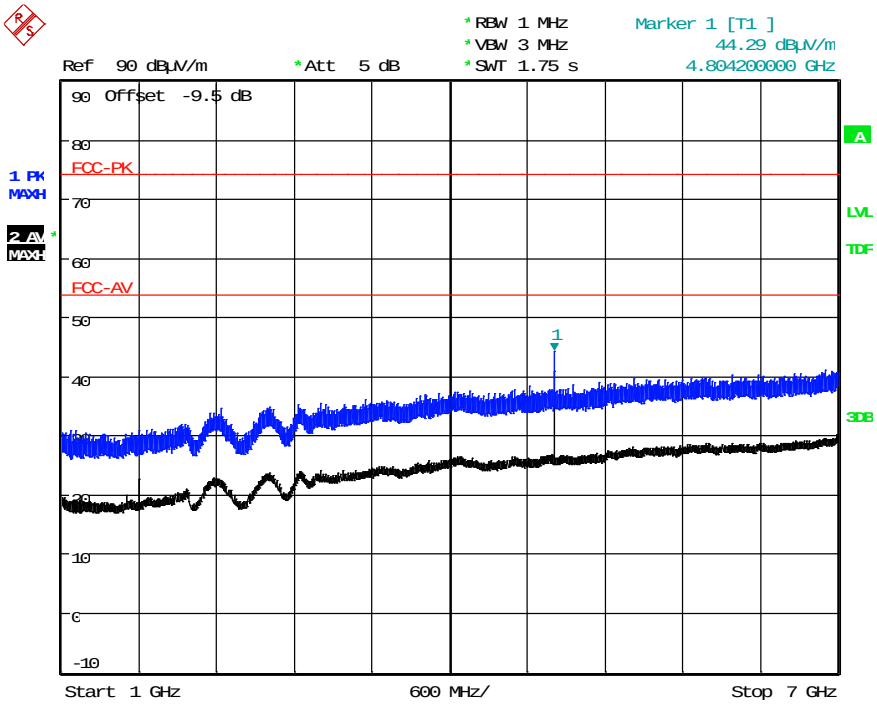
Plot in the above was obtained without filter. Interpolation factor of -9.5 dB is applied for measuring distance at 1 m, instead of the required distance at 3 m.



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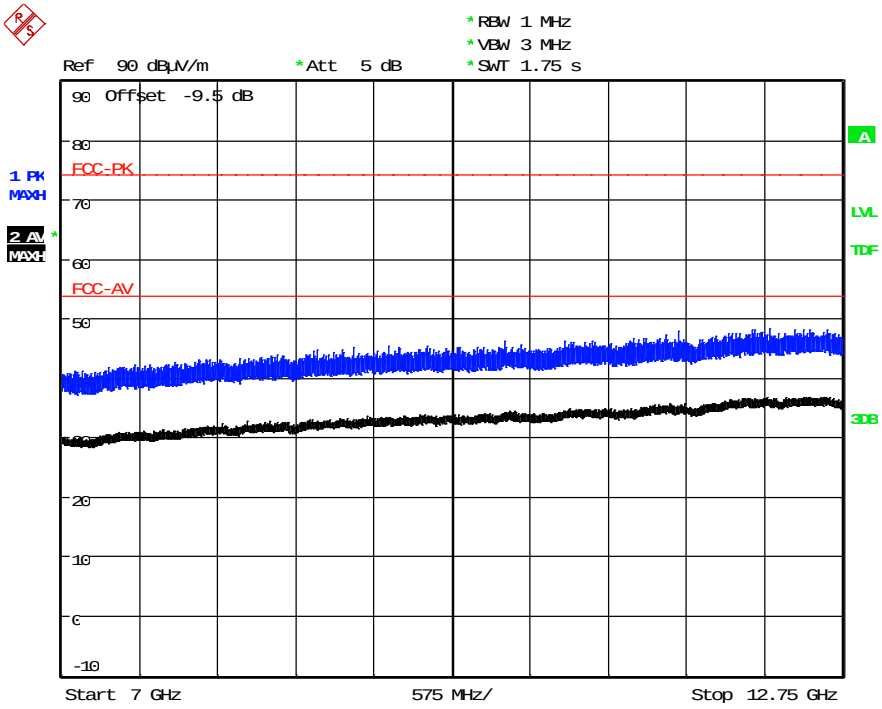

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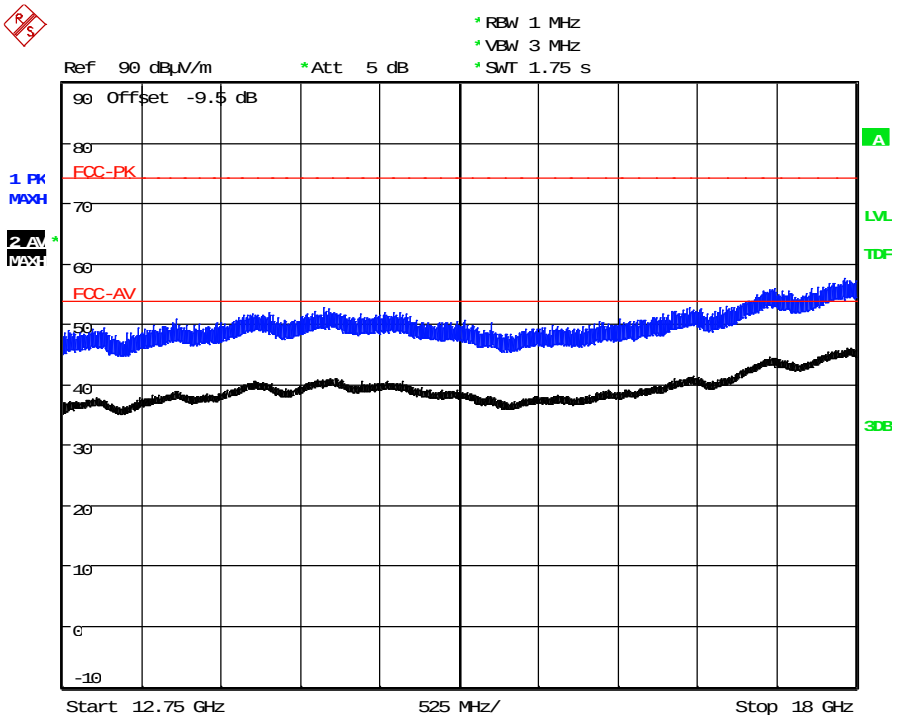

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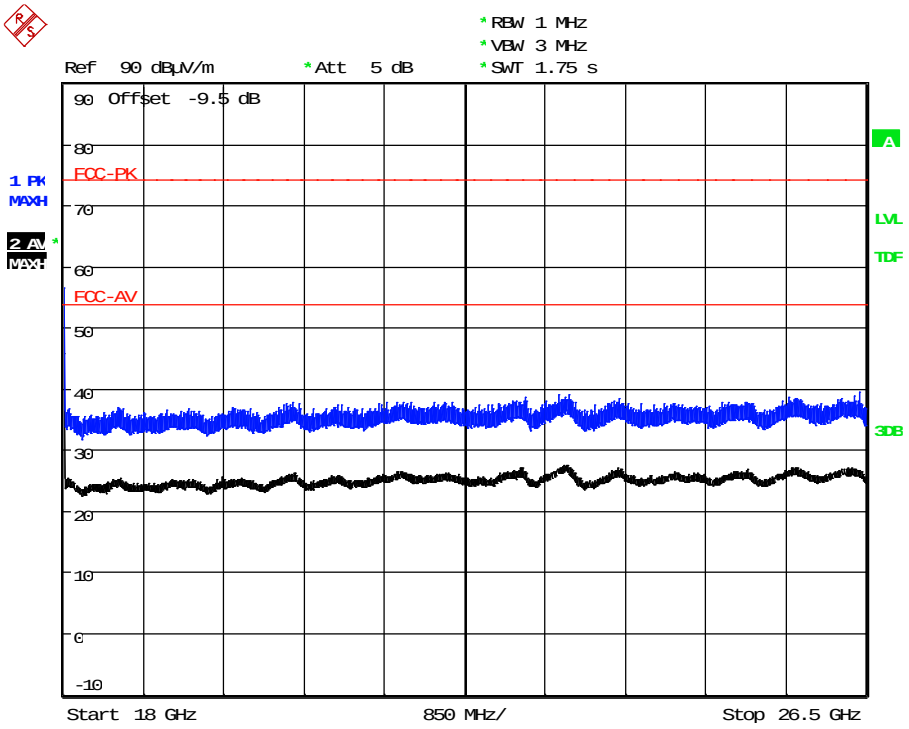
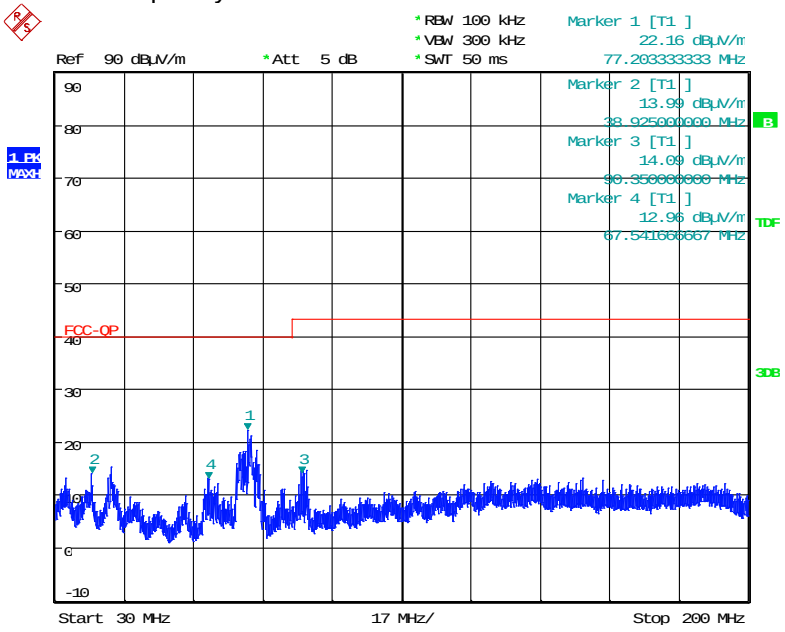


Date: 19.OCT.2016 16:57:00

Full Power; Channel: 2402 MHz										
Detector	***Freq. (MHz)***	***Meas'd Emission (dBµV)***	***Cable Loss (dB)***	***Antenna Factor (dB/m)***	***Pre-amp Gain (dB)***	***Duty Cycle Corr'n (dB)***	***Distance Interp'ltn Factor (dB)***	***Field Strength (dBµV/m)***	***Field Strength (µV/m)***	***Limit (µV/m)***
Peak	4804	52.33	5.6	33.1	34.6	0	-9.5	46.9	221.3	5000
Average	4804	44.91	5.6	33.1	34.6	0	-9.5	39.5	94.4	500
Peak	2382	66.37	3.9	28.4	34.5	0	-9.5	54.6	537.0	5000
Average	2382	35	3.9	28.4	34.5	0	-9.5	23.3	14.6	500

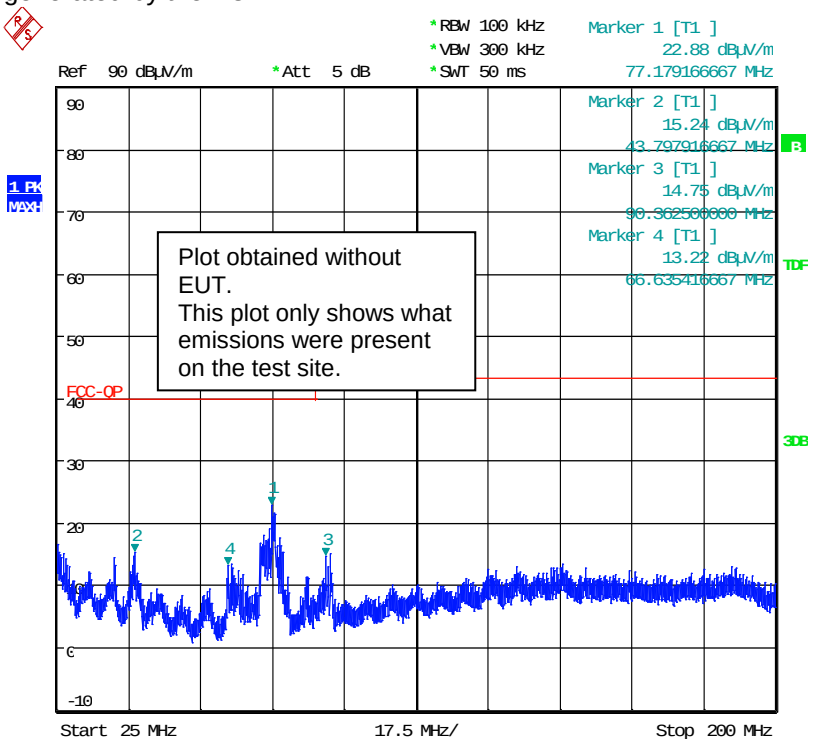
Note: Interpolation factor of -9.5 dB is applied for measuring distance at 1 m, instead of the required distance at 3 m.

Channel frequency: 2442 MHz



Date: 26.OCT.2016 16:07:06

The above plot for prescan with transmitter is the same as the plot below for prescan without transmitter in the SAR, thus proving those emissions peaks on the plot above are not generated by the EUT.



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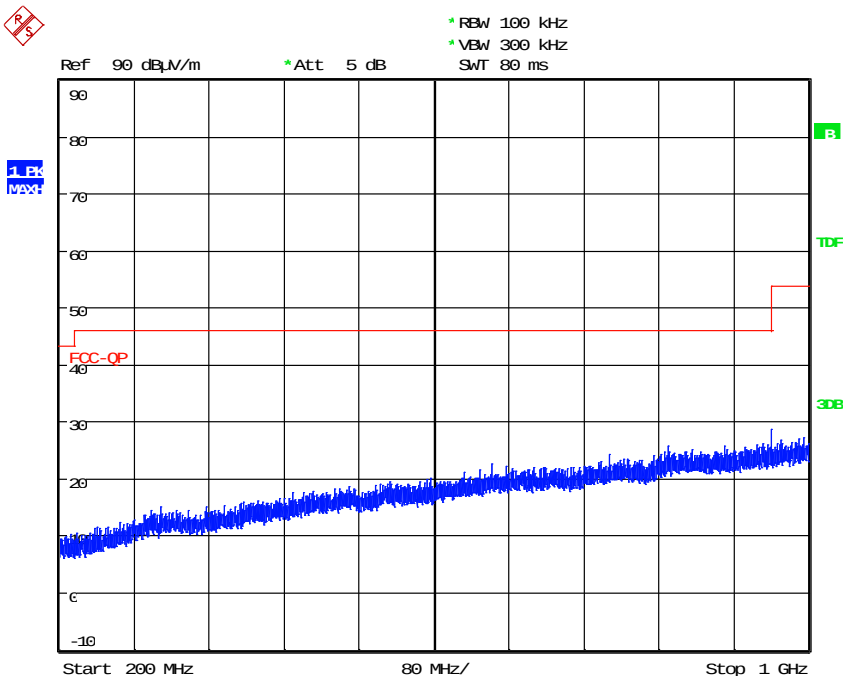

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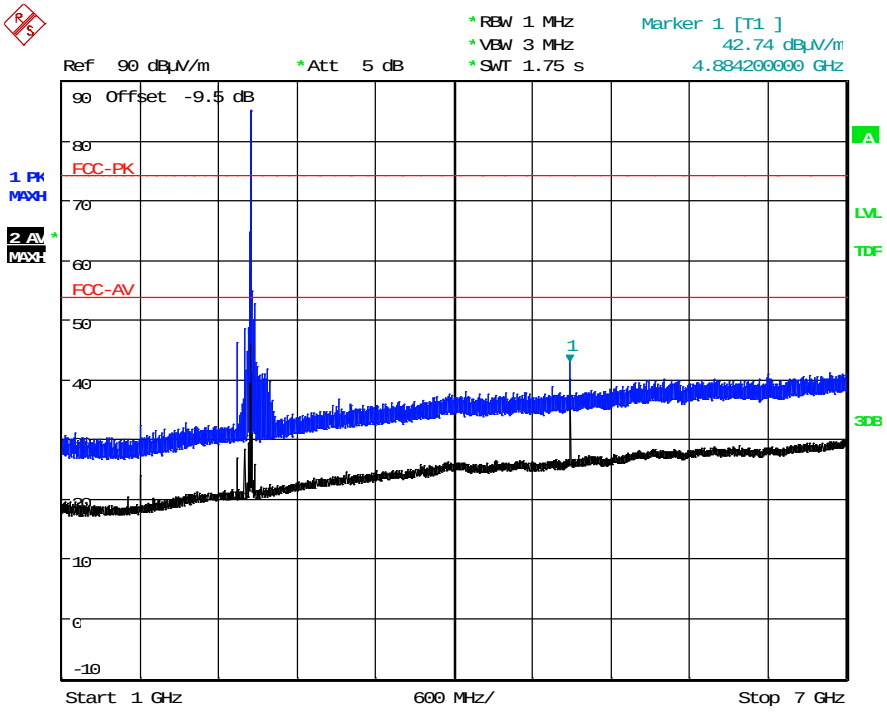

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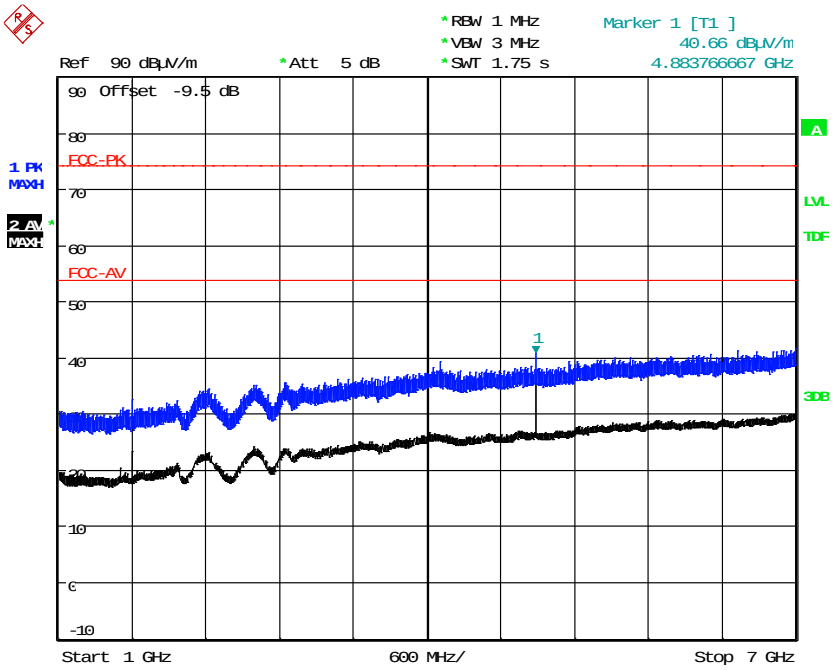

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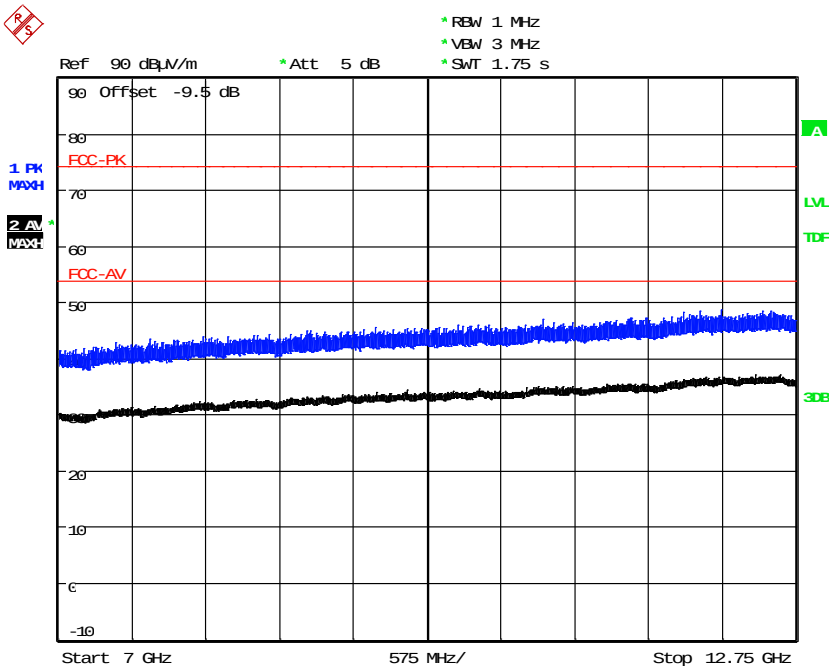

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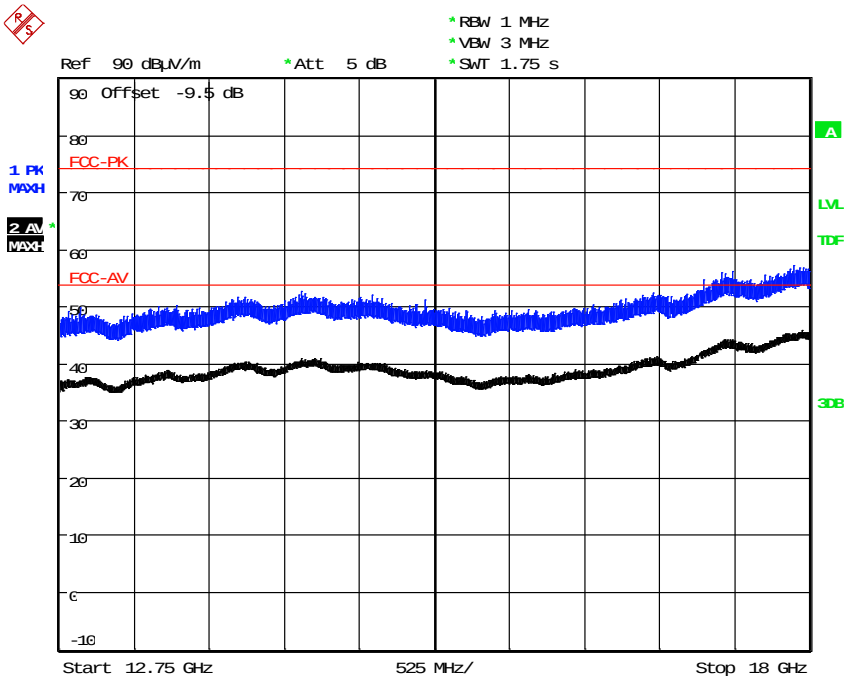
Note: Interpolation factor of -9.5 dB is applied for measuring distance at 1 m, instead of the required distance at 3 m.



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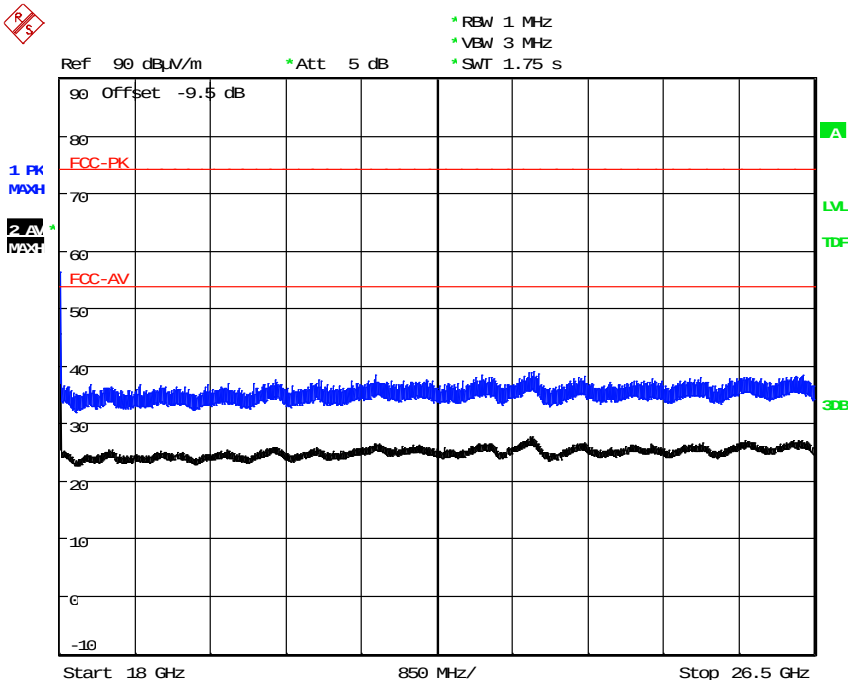


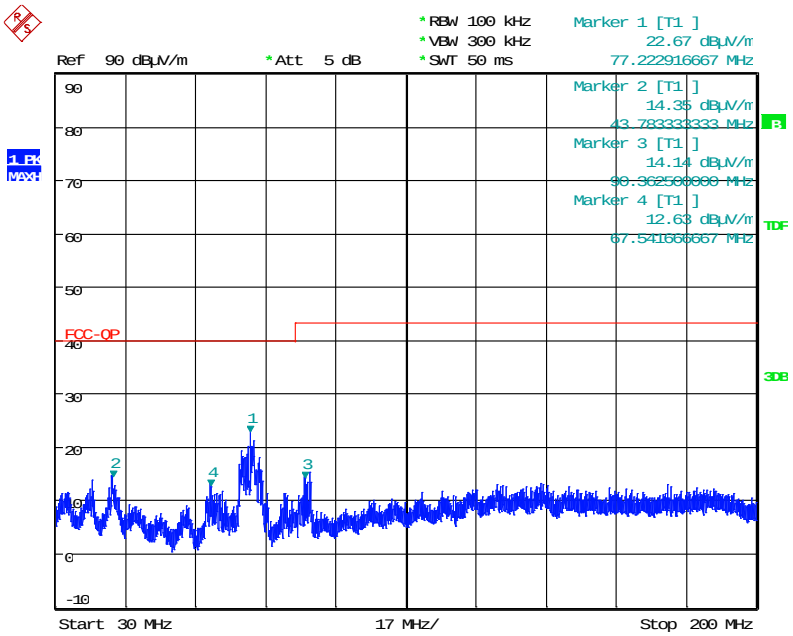
Date: 19.OCT.2016 17:01:05

Note: Interpolation factor of -9.5 dB is applied for measuring distance at 1 m, instead of the required distance at 3 m.

Full Power; Channel: 2442 MHz										
Detector	***Freq. (MHz)***	***Meas'd Emission (dBµV)***	***Cable Loss (dB)***	***Antenna Factor (dB/m)***	***Pre-amp Gain (dB)***	***Duty Cycle Corr'n (dB)***	***Distance Interp'n Factor (dB)***	***Field Strength (dBµV/m)***	***Field Strength (µV/m)***	***Limit (µV/m)***
Peak	4884	54.67	5.6	33.4	34.59	0	-9.5	49.6	302.0	5000
Average	4884	43.55	5.6	33.4	34.59	0	-9.5	38.5	84.1	500

Note: Interpolation factor of -9.5 dB is applied for measuring distance at 1 m, instead of the required distance at 3 m.

Channel Frequency: 2480 MHz



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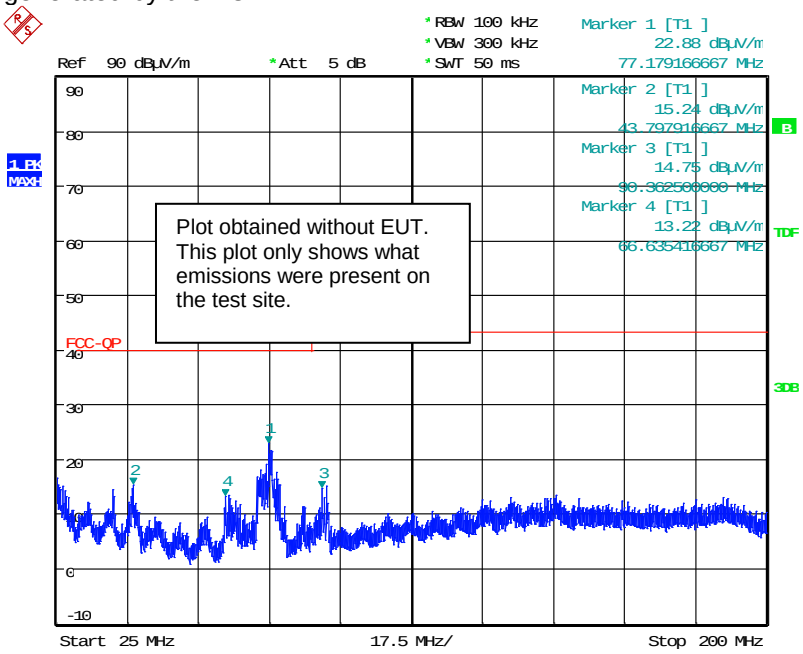
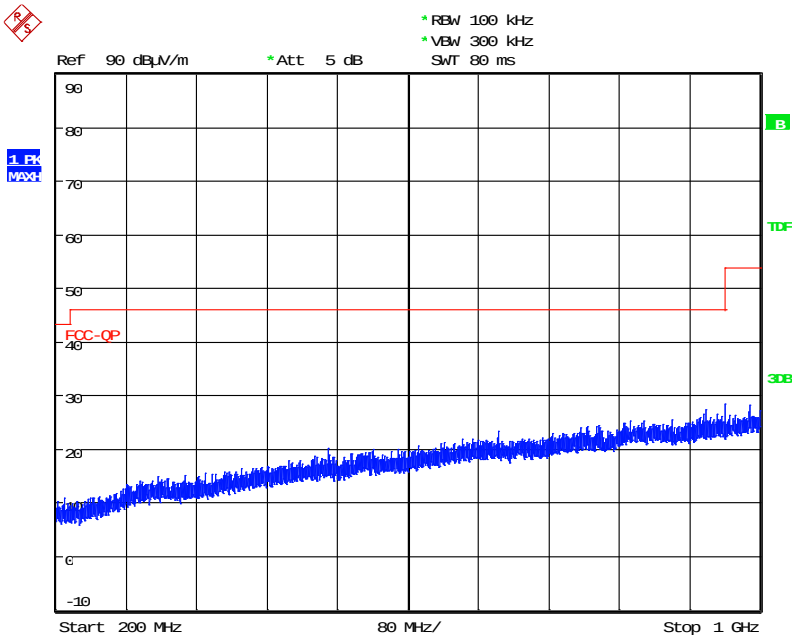
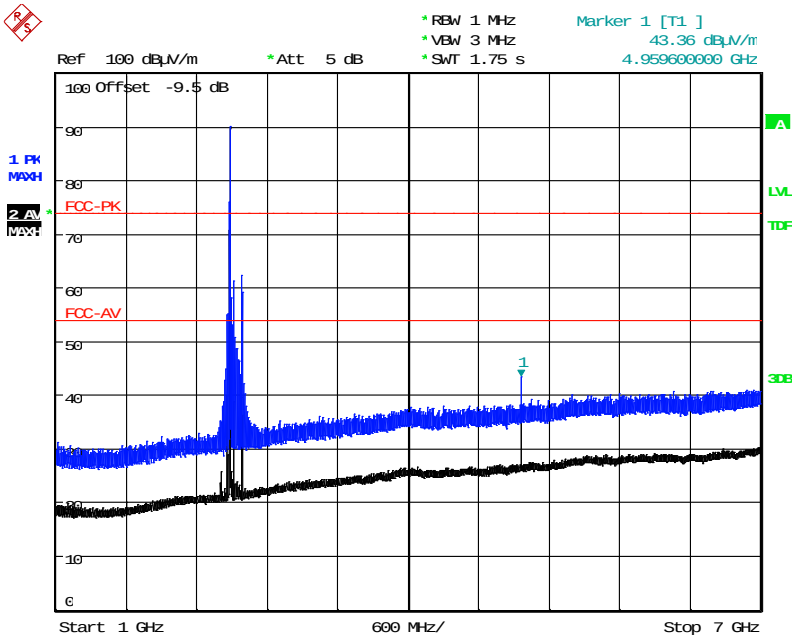
The above plot for prescan with transmitter is the same as the plot below for prescan without transmitter in the SAR, thus proving those emissions peaks on the plot above are not generated by the EUT.



Date: 26.OCT.2016 15:57:33



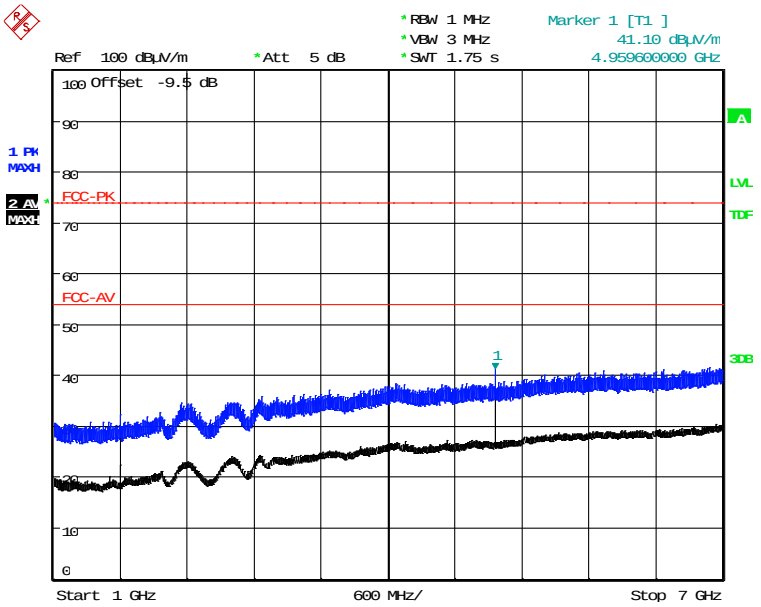
Date: 26.OCT.2016 16:25:07



Date: 19.OCT.2016 17:36:54

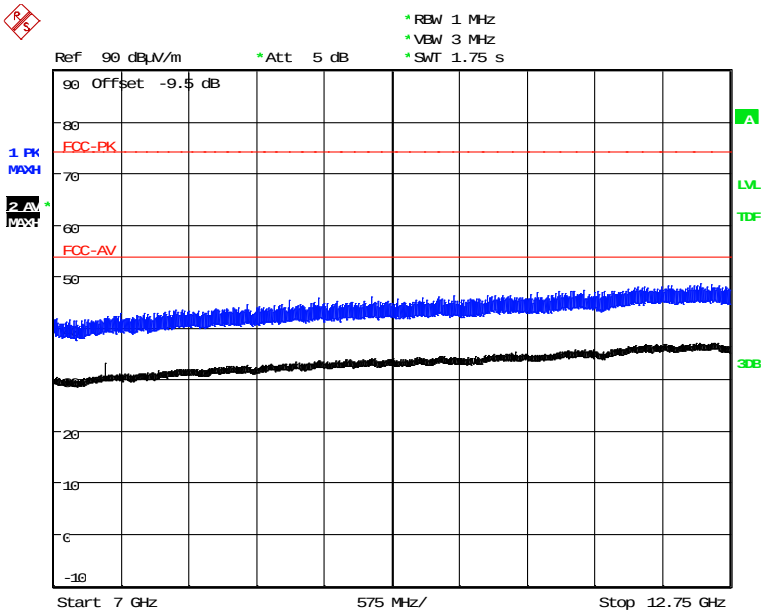
Plot in the above was measured without filter.

Note: Interpolation factor of -9.5 dB is applied for measuring distance at 1 m, instead of the required distance at 3 m.



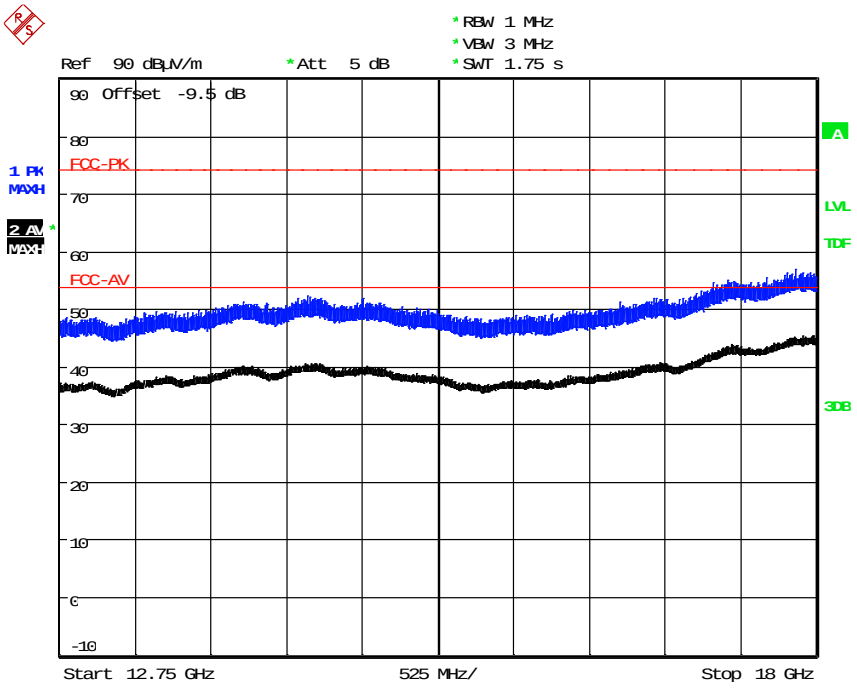
Date: 19.OCT.2016 17:39:34

Plot in the above was measured with a filter.

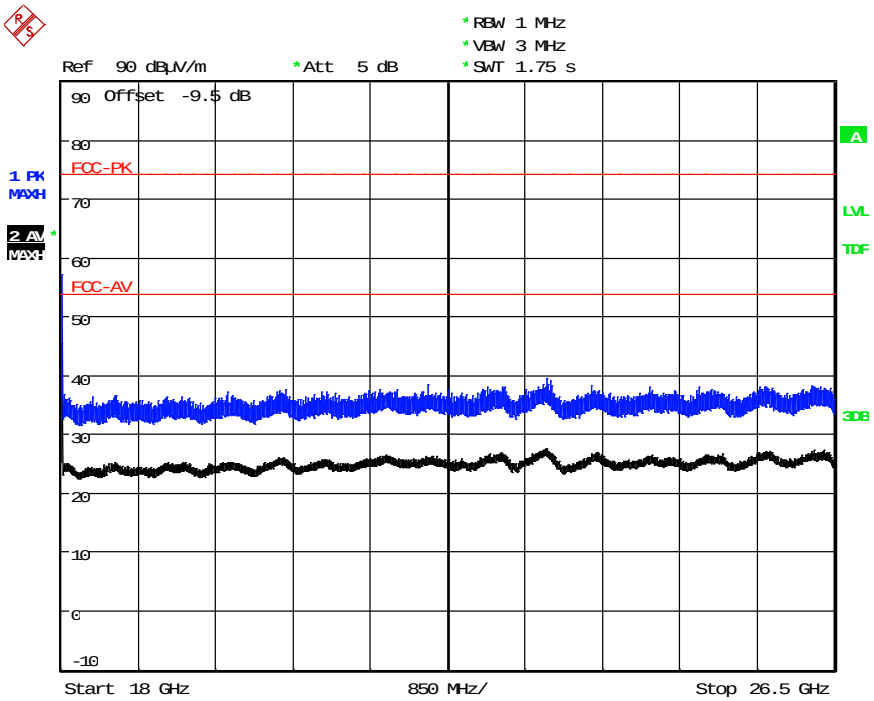


Date: 19.OCT.2016 17:34:40

Note: Interpolation factor of -9.5 dB is applied for measuring distance at 1 m, instead of the required distance at 3 m.



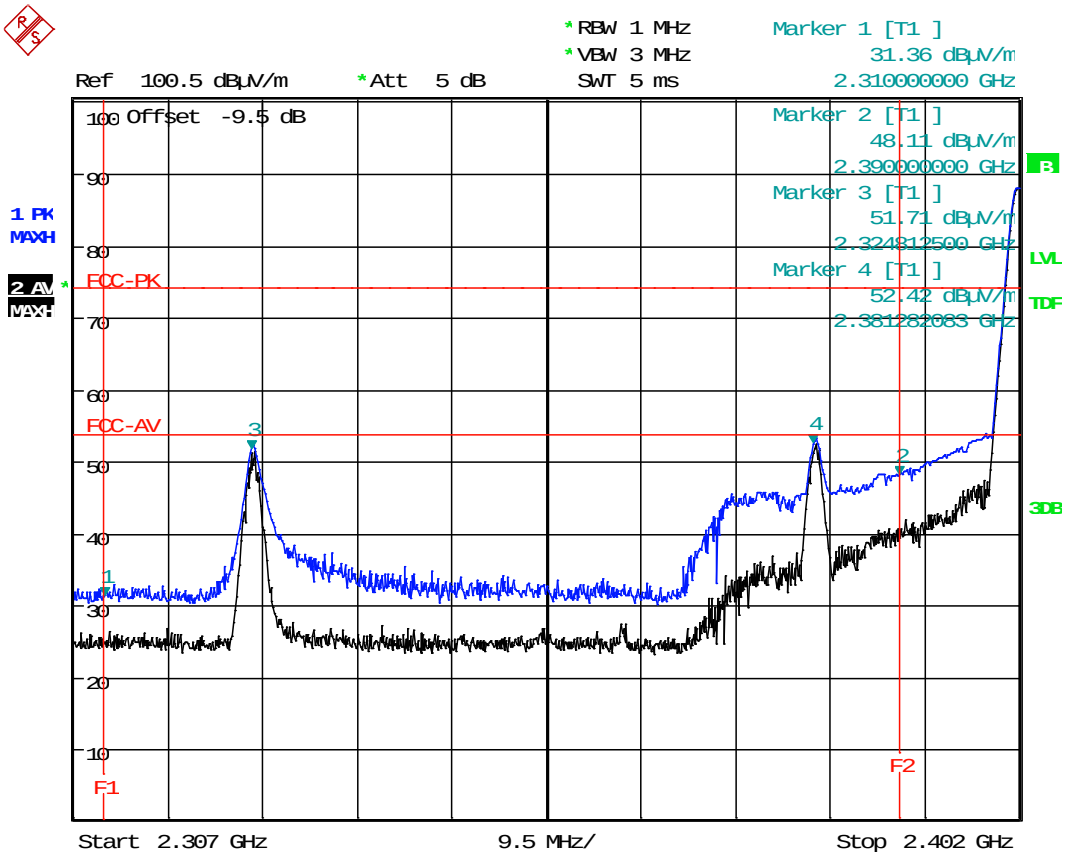
Date: 19.OCT.2016 17:10:33



Date: 19.OCT.2016 16:53:49

Note: Interpolation factor of -9.5 dB is applied for measuring distance at 1 m, instead of the required distance at 3 m.

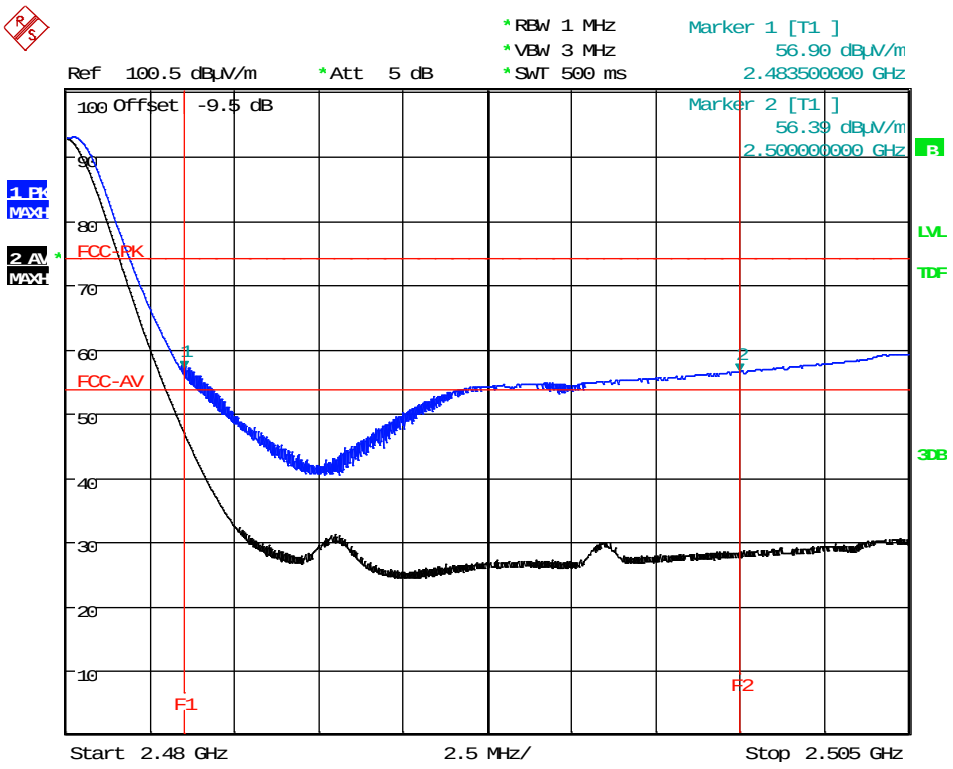
Full Power; Channel: 2480 MHz										
Detector	***Freq. (MHz)***	***Meas'd Emission (dBµV)***	***Cable Loss (dB)***	***Antenna Factor (dB/m)***	***Pre-amp Gain (dB)***	***Duty Cycle Corr'n (dB)***	***Distance Interp'n Factor (dB)***	***Field Strength (dBµV/m)***	***Field Strength (µV/m)***	***Limit (µV/m)***
Peak	4960	51.34	5.6	33.6	34.58	0	-9.5	46.5	211.3	5000
Average	4960	43.59	5.6	33.6	34.58	0	-9.5	38.7	86.1	500



Date: 28.OCT.2016 12:34:17

Lower Band Edge Plot

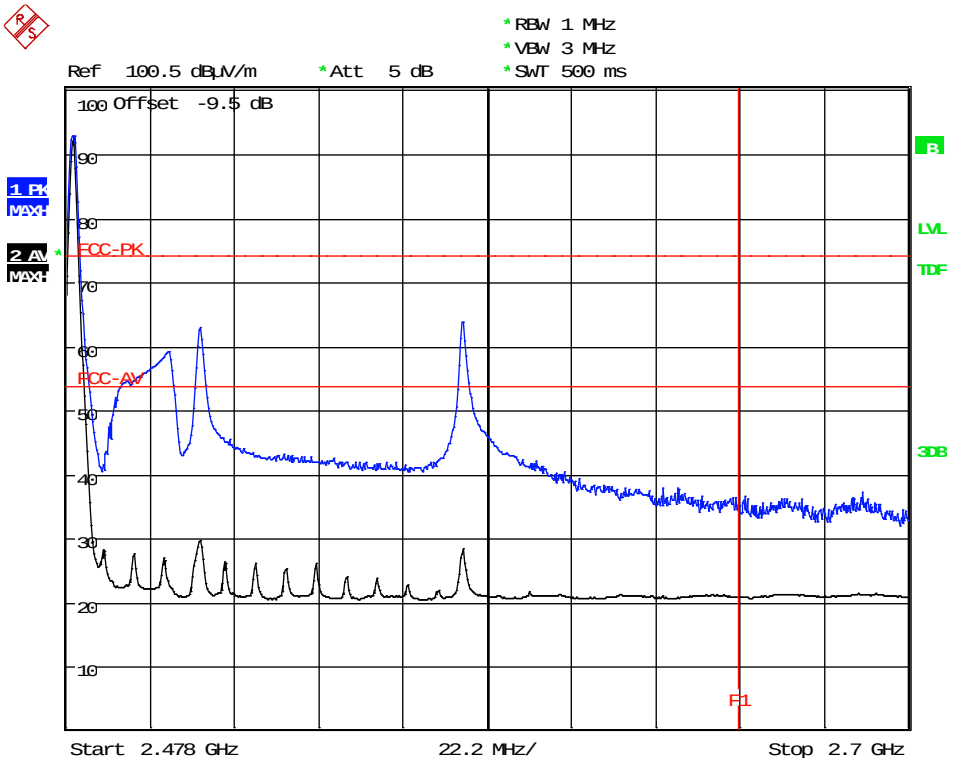
Note: Interpolation factor of -9.5 dB is applied for measuring distance at 1 m, instead of the required distance at 3 m.



Date: 27.OCT.2016 17:32:42

Upper Band Edge Plot

Note: Interpolation factor of -9.5 dB is applied for measuring distance at 1 m, instead of the required distance at 3 m.



Date: 27.OCT.2016 17:35:38

Upper Band Edge Plot for Industry Canada

Note: Interpolation factor of -9.5 dB is applied for measuring distance at 1 m, instead of the required distance at 3 m.

12 Occupied Bandwidth

12.1 Definition

The emission bandwidth (x dB) is defined as the frequency range between two points, one above and one below the carrier frequency, at which the spectral density of the emission is attenuated x dB below the maximum in-band spectral density of the modulated signal.

12.2 Test Parameters

Test Location:	Element Hull
Test Chamber:	Lab16
Test Standard and Clause:	IC: ANSI C63.10-2013, Clause 6.9 FCC: ANSI C63.10-2013, Clause 11.8
EUT Channels / Frequencies Measured:	Low / Mid / High
EUT Channel Bandwidths:	1 MHz
EUT Test Modulations:	Bluetooth Low Energy (BTLE)
Deviations From Standard:	None
Measurement BW: (IC requirement: 1% to 5% OBW; FCC requirement: 100 kHz)	100 kHz
Spectrum Analyzer Video BW: (requirement at least 3x RBW)	300 kHz
Measurement Span: (requirement 2 to 5 times OBW)	3 MHz
Measurement Detector:	Peak

Environmental Conditions (Normal Environment)

Temperature: 21 °C	+15 ºC to +35 ºC (as declared)
Humidity: 49 % RH	20 % RH to 75 % RH (as declared)
Supply: 3 V dc	3 V dc ±10 % (as declared)

12.3 Test Limit

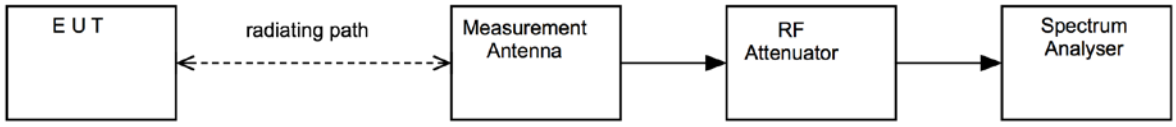
The minimum -6 dB bandwidth shall be at least 500 kHz.

12.4 Test Method

With the EUT setup as per section 9 of this report and connected as per Figure iii, the bandwidth of the EUT was measured on a spectrum analyser.

The measurements were performed with EUT set at its maximum duty. All modulation schemes, data rates and power settings were used to observe the worst-case configuration in each bandwidth.

Figure iii Test Setup

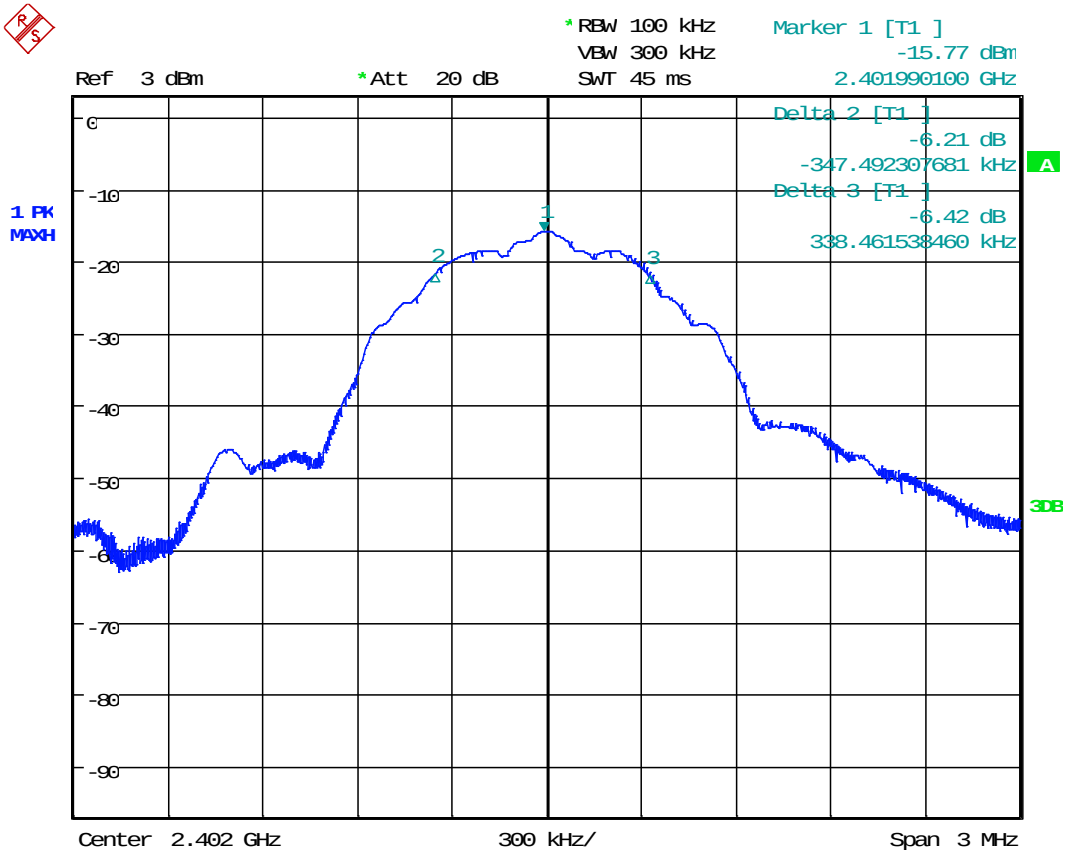


12.5 Test Equipment

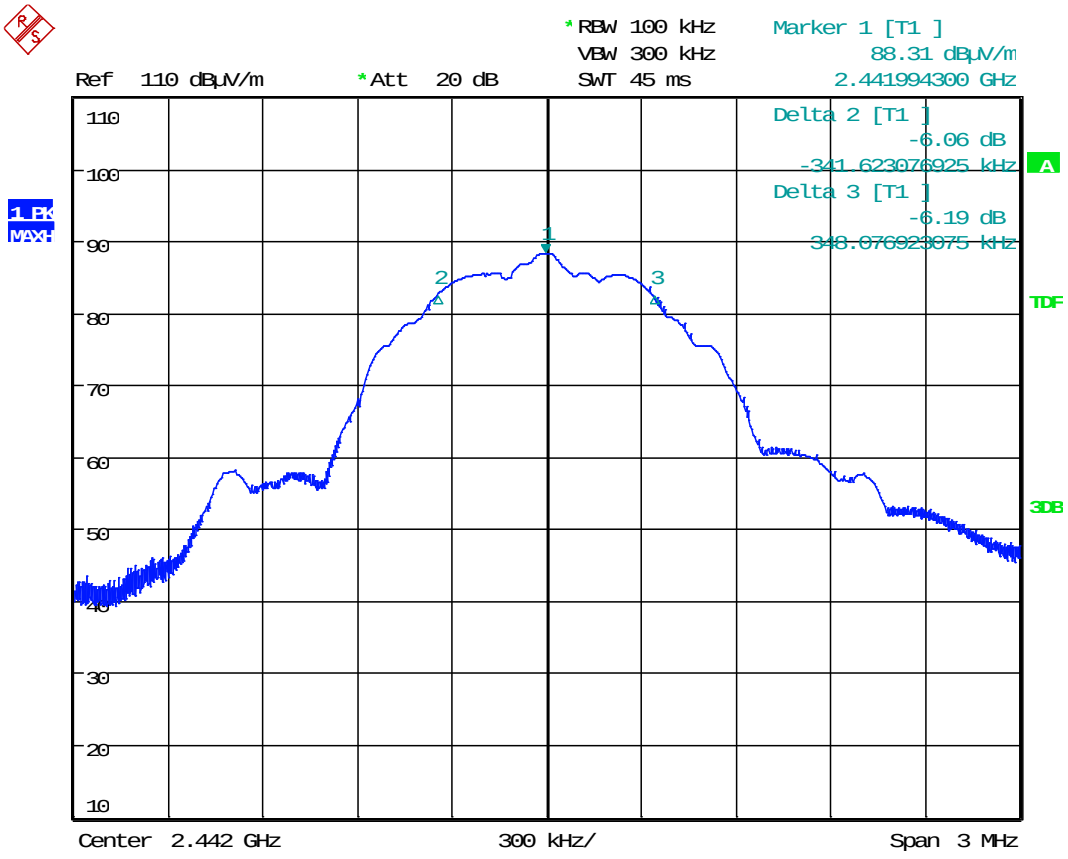
Equipment Description	*Manufacturer*	*Equipment Type*	*Element No*	*Due For Calibration*
Biconical Antenna	EMCO	3109	RFG095	17/05/2019
Log Periodic Antenna	EMCO	3146	RFG191	17/05/2019
Horn Antenna	EMCO	3115	RFG129	09/02/2018
Spectrum Analyser	R&S	FSU46	REF910	05/07/2017
N-Type RF coaxial cable	Unknown	Cable	REF884	04/12/2016
Pre-Amp (9kHz – 1GHz)	Sonoma	310	REF927	30/06/2018
Short SMA RF Cable	AtlanTec	Cable	REF2165	09/12/2017
Cable	Teledyne	5m 2.92mm	REF919	5/10/2017
Pre-Amp (1 – 26.5GHz)	Agilent	8449B	REF913	02/02/2018

12.6 Test Results

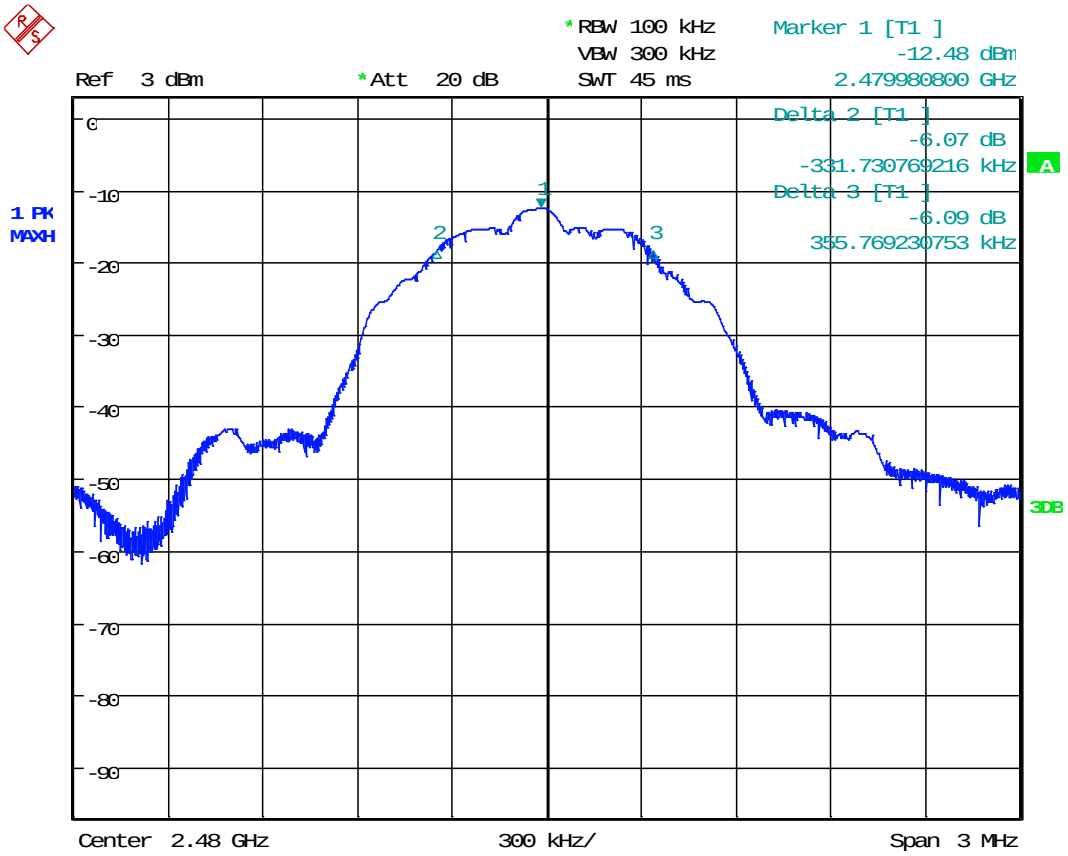
RSS-210. Modulation: BTLE; Data rate: BTLE; Power setting: Full				
Channel Frequency (MHz)	F_L (MHz)	F_H (MHz)	6dB Bandwidth (kHz)	Result
2402	2401.653	2402.339	687	PASS
2442	2441.658	2442.342	690	PASS
2480	2479.649	2480.337	688	PASS



Date: 4.OCT.2016 10:32:13

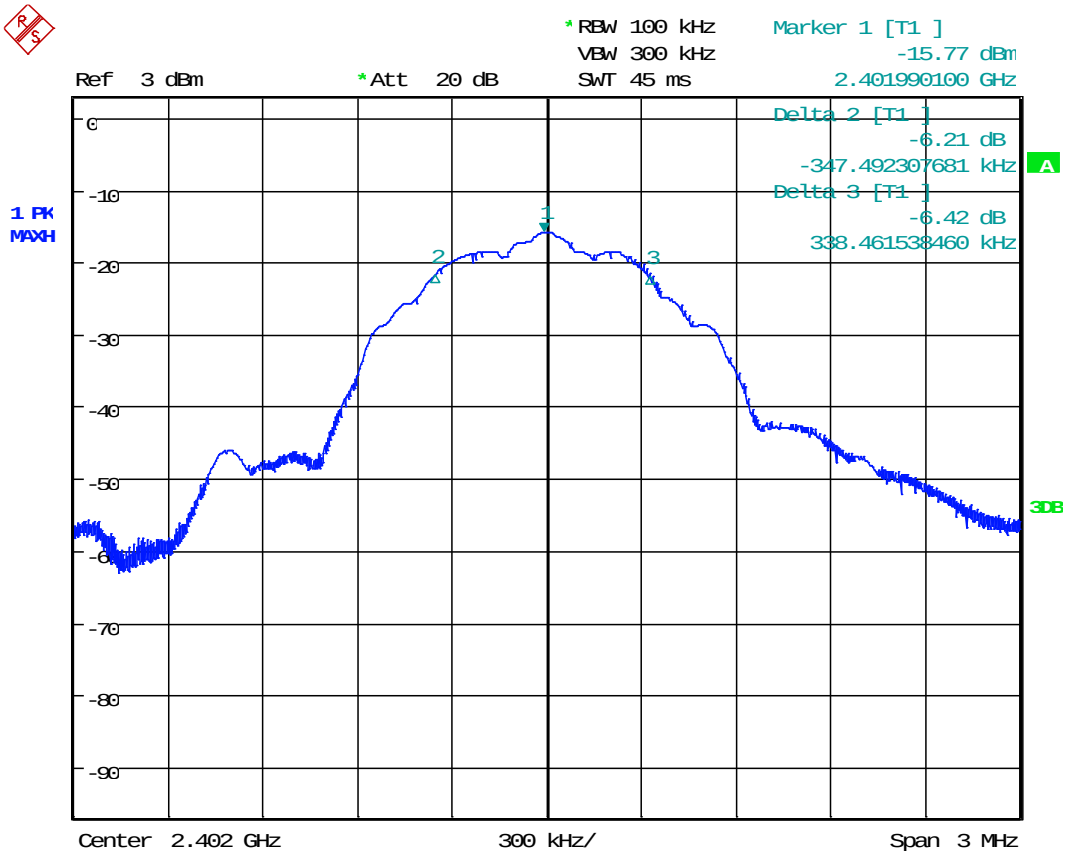


Date: 3.OCT.2016 17:11:31

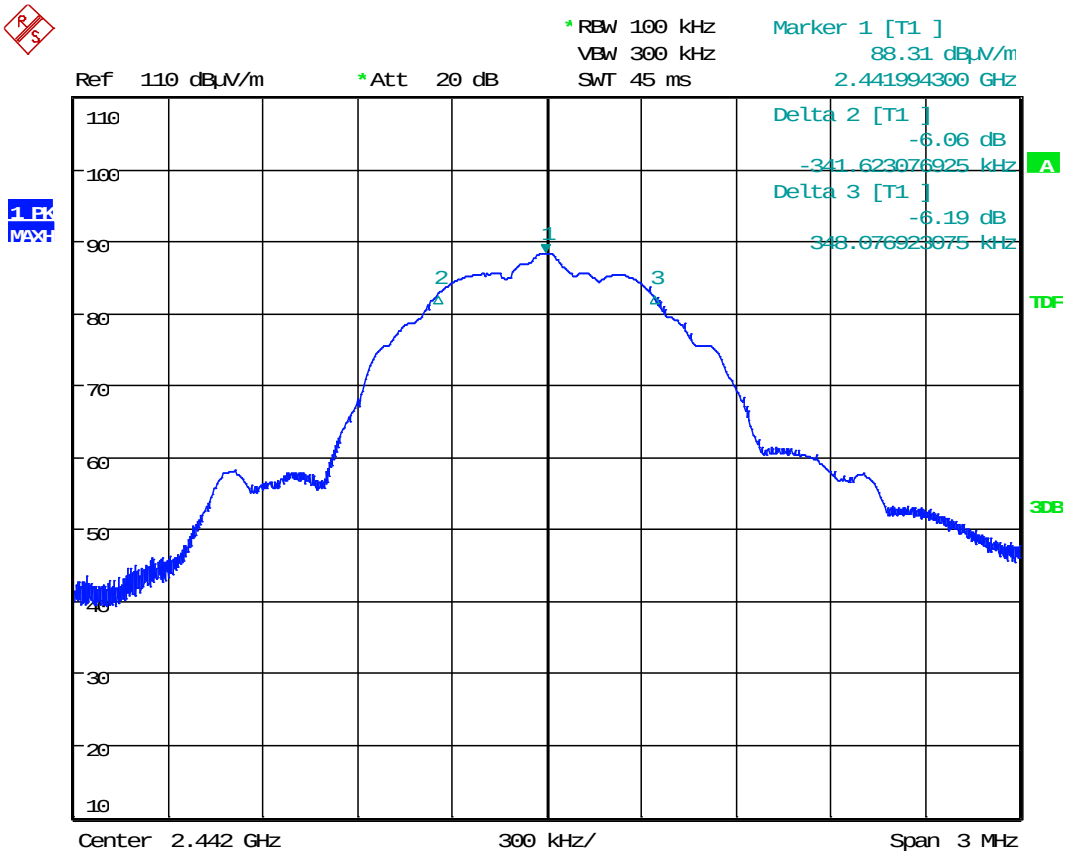


Date: 4.OCT.2016 10:48:36

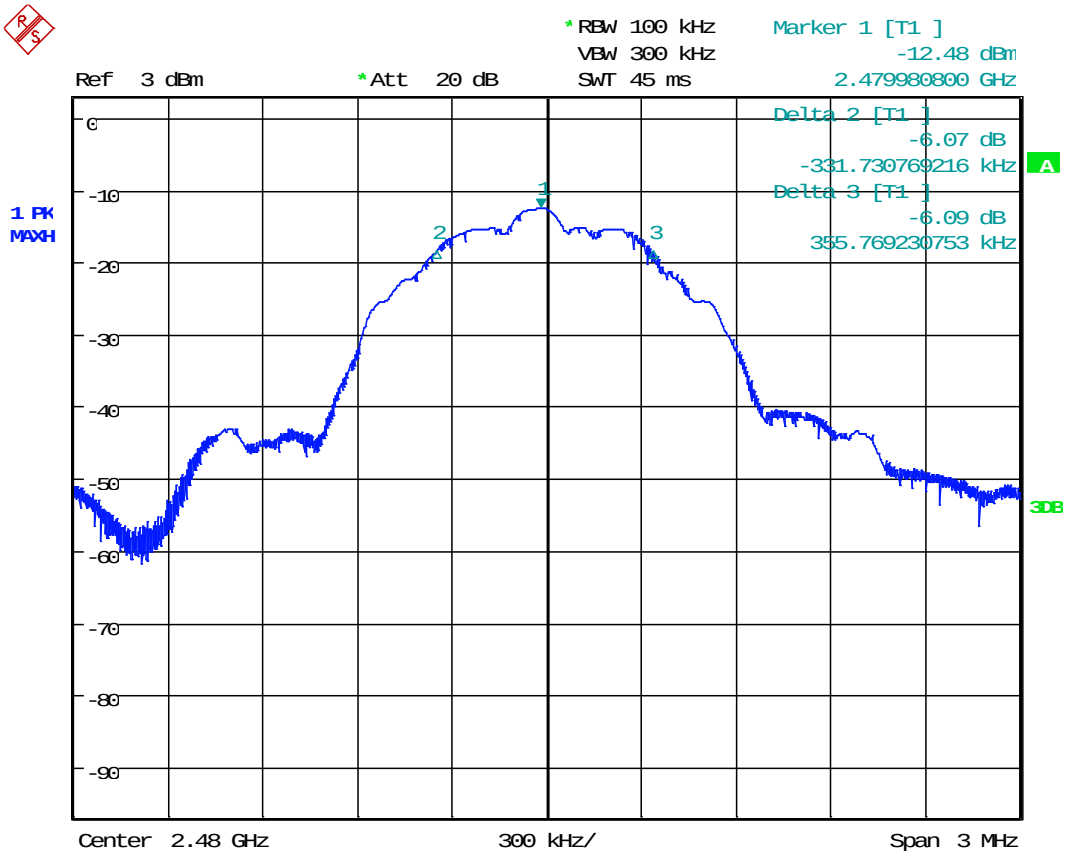
FCC 15.247. Modulation: BTLE; Data rate: BTLE; Power setting: xx				
Channel Frequency (MHz)	***F_L (MHz)***	***F_H (MHz)***	***6dB Bandwidth (kHz)***	***Result***
2402	2401.653	2402.339	687	PASS
2442	2441.658	2442.342	690	PASS
2480	2479.649	2480.337	688	PASS



Date: 4.OCT.2016 10:32:13



Date: 3.OCT.2016 17:11:31



Date: 4.OCT.2016 10:48:36

13 Maximum peak radiated output power

13.1 Definition

The maximum peak radiated output power is defined as the maximum power level measured with a peak detector using a filter with width and shape of which is sufficient to accept the signal bandwidth.

The maximum radiated output power is defined as the total transmit power delivered to all antennas and antenna elements averaged across all symbols in the signaling alphabet when the transmitter is operating at its maximum power control level.

13.2 Test Parameters

Test Location:	Element Hull
Test Chamber:	Lab16
Test Standard and Clause:	ANSI C63.10-2013, Clause 11.9.1
EUT Channels / Frequencies Measured:	Low / Mid / High
EUT Channel Bandwidths:	1 MHz
Deviations From Standard:	None
Measurement BW:	1 MHz
Spectrum Analyzer Video BW: (requirement at least 3x RBW)	3 MHz
Measurement Detector:	Peak
Voltage Extreme Environment Test Range:	Mains Power = 85 % and 115 % of Nominal (FCC only requirement); Battery Power = new battery.

Environmental Conditions (Normal Environment)

Temperature: 21 °C	+15 ºC to +35 ºC (as declared)
Humidity: 45 % RH	20 % RH to 75 % RH (as declared)

13.3 Test Limit

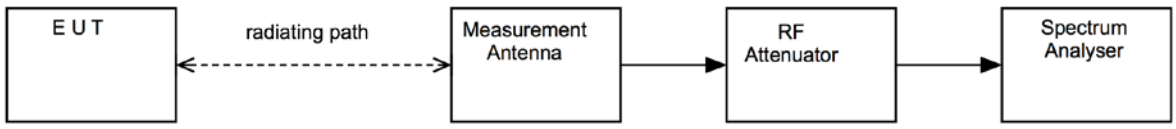
For systems employing digital modulation techniques operating in the bands 902 to 928 MHz, 2400 to 2483.5 MHz and 5725 to 5850 MHz, the maximum peak conducted output power shall not exceed 1 W.

13.4 Test Method

With the EUT setup as per section 9 of this report and connected as per Figure iv, the resolution bandwidth of the spectrum analyser was increased above the EUT occupied bandwidth and the peak emission data noted.

The measurements were performed with EUT set at its maximum duty. All modulation schemes, data rates and power settings were used to observe the worst-case configuration in each bandwidth.

Figure iv Test Setup



13.5 Test Equipment

Equipment Type	Manufacturer	Equipment Description	Element No	Due For Calibration
3115	EMCO	Horn Antenna	RFG129	09/02/2018
FSU46	R&S	Spectrum Analyser	REF910	05/07/2017
Cable	AtlanTec	Short SMA RF Cable	REF2165	09/12/2017
5m 2.92mm	Teledyne	Cable	REF919	5/10/2017
8449B	Agilent	Pre-Amp (1 – 26.5GHz)	REF913	02/02/2018
RPR3006W	DARE	Power Meter	REF2083	17/11/2016

13.6 Test Results

The following formula may be used to convert field strength (FS) in volts/metre to transmitter output power (TP) in watts:

$$TP = (FS \times D)^2 / 30$$

where D is the distance in metres between the two antennas and G is the antenna numerical gain referenced to isotropic gain.

Modulation: BTLE; Data rate: BTLE; Power setting: Full				
Channel Frequency (MHz)	***FS (V/m)***	***Distance (m)***	***Transmitter Power (mW)***	***Result***
2402	0.0270	3	0.22	PASS
2442	0.0255	3	0.20	PASS
2480	0.0395	3	0.47	PASS

14 Out-of-band and radiated spurious emissions

14.1 Definition

Out-of-band emission.
Emission on a frequency or frequencies immediately outside the necessary bandwidth that results from the modulation process but excluding spurious emissions.

Spurious emission.
Emission on a frequency or frequencies that are outside the necessary bandwidth and the level of which may be reduced without affecting the corresponding transmission of information. Spurious emissions include harmonic emissions, parasitic emissions, intermodulation products, and frequency conversion products, but exclude out-of-band emissions.

14.2 Test Parameters

Test Location:	Element Hull
Test Chamber:	Lab16
Test Standard and Clause:	ANSI C63.10-2013, Clause 11.11
EUT Channels / Frequencies Measured:	Low / Mid / High
EUT Channel Bandwidths:	1 MHz
Deviations From Standard:	None
Measurement BW:	100 kHz
Spectrum Analyzer Video BW: (requirement at least 3x RBW)	300 kHz
Measurement Detector:	Peak
Measurement Range:	30 MHz to 26.5 GHz

Environmental Conditions (Normal Environment)

Temperature: 21 °C	+15 ºC to +35 ºC (as declared)
Humidity: 45 % RH	20 % RH to 75 % RH (as declared)
Supply: 3 V dc	New Lithium power cell

14.3 Test Limit

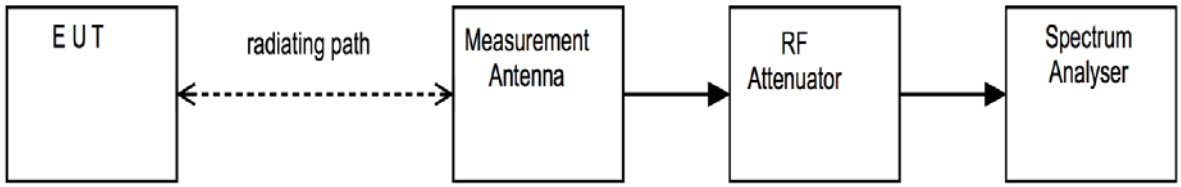
In any 100 kHz bandwidth outside the frequency band in which the spread spectrum or digitally modulated device is operating, the RF power that is produced shall be at least 20 dB below that in the 100 kHz bandwidth within the band that contains the highest level of the desired power, based on either an RF conducted or a radiated measurement, provided that the transmitter demonstrates compliance with the peak conducted power limits. If the transmitter complies with the conducted power limits based on the use of root-mean-square averaging over a time interval, the attenuation required shall be 30 dB instead of 20 dB. Attenuation below the general field strength limits specified in FCC 47CFR15.209(a) / RSS-Gen is not required.

14.4 Test Method

With the EUT setup as per section 9 of this report and connected as per Figure v, the emissions from the EUT were measured on a spectrum analyser.

The measurements were performed with EUT set at its maximum duty. All modulation schemes, data rates and power settings were used to observe the worst case configuration in each bandwidth.

Figure v Test Setup



14.5 Test Equipment

Equipment Type	Manufacturer	Equipment Description	Element No	Due For Calibration
FSU46	R&S	Spectrum Analyser	REF910	05/07/2017
310	Sonoma	Pre-Amp (9kHz – 1GHz)	REF927	30/06/2018
8449B	Agilent	Pre-Amp (1 – 26.5GHz)	REF913	02/02/2018
Cable	AtlanTec	Short SMA RF Cable	REF2165	09/12/2017
Cable	Unknown	N-Type RF coaxial cable	REF884	04/12/2016
5m 2.92mm	Teledyne	Cable	REF919	5/10/2017
3109	EMCO	Biconical Antenna	RFG095	17/05/2019
3146	EMCO	Log Periodic Antenna	RFG191	17/05/2019
3115	EMCO	Horn Antenna	RFG129	09/02/2018
Horn	Q-Par	Horn Antenna	RFG629	30/09/2017

13.6 Test Results

Channel: 2402 MHz; Modulation: BTLE; Data rate: BTLE; Power setting: Full						
Emission Frequency (MHz)	***Peak Field Strength (dBµV/m)***	***Distance (m)***	***Power (dBm)***	***Limit (dBm)***	***Margin (dB)***	***Result***
No significant emission detected.						PASS

Channel: 2442 MHz; Modulation: BTLE; Data rate: BTLE; Power setting: Full						
Emission Frequency (MHz)	***Peak Field Strength (dBµV/m)***	***Distance (m)***	***Power (dBm)***	***Limit (dBm)***	***Margin (dB)***	***Result***
No significant emission detected.						PASS

Channel: 2480 MHz; Modulation: BTLE; Data rate: BTLE; Power setting: Full						
Emission Frequency (MHz)	***Peak Field Strength (dBµV/m)***	***Distance (m)***	***Power (dBm)***	***Limit (dBm)***	***Margin (dB)***	***Result***
No significant emission detected.						PASS

15 Power spectral density

15.1 Definition

The power per unit bandwidth.

15.2 Test Parameters

Test Location:	Element Hull
Test Chamber:	Lab 16
Test Standard and Clause:	ANSI C63.10-2013, Clause 11.10
EUT Channels / Frequencies Measured:	Low / Mid / High
EUT Channel Bandwidth:	1 MHz
Deviations From Standard:	None
Measurement BW:	3 kHz
Spectrum Analyzer Video BW: (requirement at least 3x RBW)	10 kHz
Measurement Span: (requirement 1.5 times Channel BW)	3 MHz
Measurement Detector:	Peak

Environmental Conditions (Normal Environment)

Temperature: 21 °C	+15 ºC to +35 ºC (as declared)
Humidity: 45 % RH	20 % RH to 75 % RH (as declared)
Supply: 3 V dc	New Lithium power cell

15.3 Test Limit

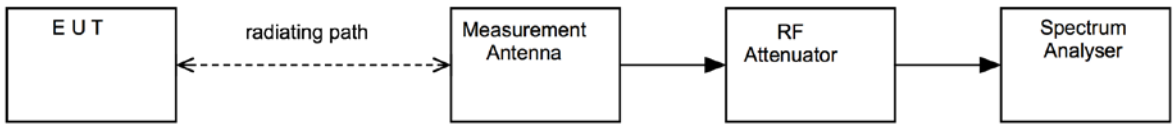
The transmitter power spectral density conducted from the transmitter to the antenna shall not be greater than 8 dBm in any 3 kHz band during any time interval of continuous transmission.

15.4 Test Method

With the EUT setup as per section 9 of this report and connected as per Figure vi, the peak emission of the EUT was measured on a spectrum analyser, with path losses taken into account.

The measurements were performed with EUT set at its maximum duty. All modulation schemes, data rates and power settings were used to observe the worst case configuration in each bandwidth.

Figure vi Test Setup



15.5 Test Equipment

Equipment Type	Manufacturer	Equipment Description	Element No	Due For Calibration
FSU46	R&S	Spectrum Analyser	REF910	05/07/2017
RPR3006W	DARE	Power Meter	REF2112	23/03/2017
5m 2.92mm	Teledyne	Cable	REF919	5/10/2017
8449B	Agilent	Pre-Amp (1 – 26.5GHz)	REF913	02/02/2018

15.6 Test Results

The following formula may be used to convert field strength (FS) in volts/metre to transmitter output power (TP) in watts:

$$TP = (FS \times D)^2 / 30$$

where D is the distance in metres between the two antennas and G is the antenna numerical gain referenced to isotropic gain.

Modulation: BTLE; Data rate: BTLE; Power setting: Full				
Channel Frequency (MHz)	***FS (V/m)***	***Distance (m)***	***TP (mW)***	***Result***
2402	0.0083	3	0.021	PASS
2442	0.0082	3	0.020	PASS
2480	0.0119	3	0.043	PASS

16 Measurement Uncertainty

Calculated Measurement Uncertainties

All statements of uncertainty are expanded standard uncertainty using a coverage factor of 1.96 to give a 95 % confidence:

[1] Radiated spurious emissions

Uncertainty in test result (30 MHz to 1 GHz) = **4.6 dB**
Uncertainty in test result (1 GHz to 18 GHz) = **4.7 dB**

[2] AC power line conducted emissions

Uncertainty in test result = **3.4 dB**

[3] Occupied bandwidth

Uncertainty in test result = **15.5 %**

[4] Conducted carrier power

Uncertainty in test result (Power Meter) = **1.08 dB**

[5] Conducted / radiated RF power out-of-band

Uncertainty in test result – up to 8.1 GHz = **3.31 dB**
Uncertainty in test result – 8.1 GHz to 15.3 GHz = **4.43 dB**
Uncertainty in test result (30 MHz to 1 GHz) = **4.6 dB**
Uncertainty in test result (1 GHz to 18 GHz) = **4.7 dB**

[6] Power spectral density

Uncertainty in test result (Spectrum Analyser) = **2.48 dB**

17 RF Exposure: General SAR test reduction and exclusion guidance

KDB 447498

Section 4.3 General SAR test reduction and exclusion guidance

For Standalone SAR exclusion consideration, when SAR Exclusion Threshold requirement in KDB 447498 is satisfied, standalone SAR evaluation for general population exposure conditions by measurement or numerical simulation is not required.

In the frequency range between 100 MHz and 6 GHz and test separation distance <50 mm, the SAR Test Exclusion Threshold for operation in the 2400 – 2483.5 MHz band will be determined as follows

SAR Exclusion Threshold (SARET)

SAR Exclusion Threshold = Step 1 + Step 2

Step 1

$$NT = [(MP/TSD^{A}) * \sqrt{f_{GHz}}]$$

NT	=	Numeric Threshold (3.0 for 1-g SAR and 7.5 for 10-g SAR)
MP	=	Max Power of channel (mW) (inc tune up)
TSD^{A}	=	Min Test separation Distance or 50mm (whichever is lower) = 5mm

According to KDB447498 section 4.3.1 (a), when the minimum test separation distance is <5 mm, a distance of 5 mm is applied to determine SAR test exclusion.

We can transpose this formula to allow us to find the maximum power of a channel allowed and compare this to the measured maximum power.

$$= [(NT \times TSD^{A}) / \sqrt{f_{GHz}}]$$

Since the Min test separation is less than 50mm, there is no need for Step 2.

Calculations:

Operating Frequency 2.402 GHz
SARET = [(3.0 x 5) / √2.402]
SARET = 9.7 mW

Operating Frequency 2.440 GHz
SARET = [(3.0 x 5) / √2.442]
SARET = 9.6 mW

Operating Frequency 2.480 GHz
SARET = [(3.0 x 5) / √2.480]
SARET = 9.5 mW

Channel Frequency (MHz)	EIRP (mW)	SAR Exclusion Threshold (mW)	SAR Evaluation
2402	0.22	9.7	Not Required
2442	0.20	9.6	Not Required
2480	0.47	9.5	Not Required

Remarks:
Max. EIRP power of 0.47mW is below the SARET, exempted from stand-alone SAR test.

Therefore standalone SAR evaluation for general population exposure conditions by measurement or numerical simulation is not required.

At a distance of 5 mm, which is the usual distance for using the inhaler, it is the distance between the transmitter and the user skin, separated by gaps between the antenna, housing and thickness of material.

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2.5.1 Exemption Limits for Routine Evaluation — SAR Evaluation

SAR evaluation is required if the separation distance between the user and/or bystander and the antenna and/or radiating element of the device is less than or equal to 20 cm, except when the device operates at or below the applicable output power level (adjusted for tune-up tolerance) for the specified separation distance defined in **§**Table 1.

Results

Prediction Frequency (MHz)	Maximum Radiated Power EIRP (dBm)	Antenna Gain (dBi)	Maximum EIRP (mW)	Exemption Limit at separation distance ≤ 5mm (mW)
2402	-6.6	-10	0.22	4
2442	-7.1	-10	0.20	4
2480	-3.3	-10	0.47	4

The maximum e.i.r.p. of the device at the top, middle and low channels are well below the limits as shown in the table above. So it meets the exemption limits to operate without SAR evaluation is required.