

Test Report # 318326 B

Equipment Under Test: NIM Vital Console and PIU

Test Date(s): 21, 29-30 January, 2019
22 August, 2019


Prepared for: Medtronic
Attn: Patrick Richart
6743 Southpoint Drive North
Jacksonville, FL 33216

Report Issued by: Jeysson P. Gonzalez, EMC Engineer I

Signature: 

Date: 23 August 2019

Report Reviewed by: Laura Zehnder, Certification Engineer

Signature: 

Date: 23 August 2019

Report Constructed by: Jeysson Gonzalez, EMC Engineer I

Signature: 

Date: 22 August 2019

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CONTENTS

Contents.....	2
Laird Technologies Test Services in Review	3
1 Test Report Summary	4
2 Client Information.....	5
2.1 Equipment Under Test (EUT) Information.....	5
2.2 Product Description	5
2.3 Modifications Incorporated for Compliance	6
2.4 Deviations and Exclusions from Test Specifications	6
2.5 Power source	6
3 References.....	6
4 Uncertainty Summary.....	7
5 Test Data	8
5.1 Simultaneous Transmission	8
6 Revision History	40

Laird Technologies Test Services in Review

The Laird Technologies, Inc. laboratory located at W66 N220 Commerce Court Cedarburg, Wisconsin, 53012 USA is recognized through the following organizations:



A2LA – American Association for Laboratory Accreditation

Accreditation based on ISO/IEC 17025: 2017 with Electrical (EMC) Scope

A2LA Certificate Number: 1255.01

Scope of accreditation includes all test methods listed herein, unless otherwise noted.



Federal Communications Commission (FCC) – USA

Accredited recognition of two 3 meter Semi-Anechoic Chambers

Accredited Test Firm Registration Number: 953492



**Government
of Canada**

Innovation, Science and Economic Development Canada

Accredited U.S. Identification Number: US0218

Recognition of two 3-meter Semi-Anechoic chambers

1 TEST REPORT SUMMARY

During **21, 29-30 January 2019** the Equipment Under Test (EUT), **NIM Vital Console and PIU**, as provided by **Medtronic** was tested to the following requirements:

CFR 47(15.247)

Requirements	Description	Method
15.247	Operation within the bands kof 902-928 MHz, 2400-2483.5 MHz, and 5725-5850 MHz	ANS C63.10

Note: the requirements listed above are intended to cover the scope of general product emissions as well as evaluation for simultaneous transmission emissions (of two radios with full modular certification) against the requirements within FCC 15.247.

Notice:

The results relate only to the item tested as configured and described in this report. Any additional configurations, modes of operation, or modifications made to the equipment under test after the specified test date(s) are at the decision of the client and may not apply to the data seen in this test report.

The decision rule for Pass / Fail assessment to the specification or standard listed in this test report has been agreed upon by the client and laboratory to be as follows:

Measurement Type	Rule
Emissions – Amplitude	0.1 dB below specified limit
Emissions – Frequency	1% less than the specification
Immunity	Tested at specified level

2 CLIENT INFORMATION

Company Name	Medtronic
Contact Person	Patrick Richart
Address	6743 Southpoint Drive North Jacksonville, FL 33216

2.1 Equipment Under Test (EUT) Information

The following information has been supplied by the client

Product Name	NIM Vital Console NIM Vital Patient Interface
Model Number	NIM4CM01 NIM4CPB1
Serial Number	X08122218 PV004
EUT Software	Console GUI: 4.0.0 (0edc57) Console CRM Rev B firmware: January 14 (0edc576cdd) Console EIC Rev B w/ESD modifications firmware: January 14 (0edc576cdd) Console PMB Rev C firmware: January 14 (5aa9fbbb8) Mainboard Rev B firmware: January 14 (0edc576cdd)
Wifi + Bluetooth radio	FCC ID: PD98265NG IC ID: 1000M-8265NG
Bluetooth radio	FCC ID: SQGBL652 IC ID: 3147A-BL652
PIU Bluetooth radio	FCC ID: SQGBL652 IC ID: 3147A-BL652

2.2 Product Description

The NIM Vital System system is an EMG monitor for intraoperative use during surgeries in which a motor or motor-sensory nerve is at risk. The NIM 4.0 records electromyography (EMG) activity from the muscles innervated by the affected nerve. The system assists in early nerve identification by providing the surgeon with tools to help locate and identify the particular nerve at risk within the surgical field. The system monitors EMG activity from the muscles innervated by the nerve at risk, alerting the surgeon when a particular nerve has been activated. The system also allows an option for Automatic Periodic Stimulation (APS), allowing for EMG monitoring nerve activity trending and alerts

2.3 Modifications Incorporated for Compliance

Removed ferrites on PIU to console cable

2.4 Deviations and Exclusions from Test Specifications

None noted at time of test

2.5 Power source

100-240VAC 50/60Hz

2.6 Equipment and Accessories

ID	Description	CFN
A03	CONN CABLE NIM4CPB2 PAT INTFC NIM 4.0	NIM4CPB2
A04	BATTERY NIM4CB01 NIM 4.0 CONSOLE	NIM4CB01
A05	VIDEO/AUD REC ADPT KIT NIM4CAV1 NIM 4.0	NIM4CAV1
A06	POWER CORD NIMCPCUS US 6 METER	NIMCPCUS
A08	POWER ISOLATOR NIM4CC02 NIM 4.0 PRINTER	NIM4CC02
A09	CABLE NIM4CLAN ETHERNET NIM 4.0	NIM4CLAN
A10	MODULE NIM4CD01 WIRELESS DISPLAY NIM 4.0	NIM4CD01
A11	INTFC ADAPTOR NIM4CAM1 MUTE PROBE	NIM4CAM1
A12	INTFC ADAPTOR NIMCAD400 NIM 4.0 INCREMT	NIMCAD400
A13	4ft power cord (Tripp Lite Model: P004-004)	N/A
A14	Cart power strip (Schurter Minibloc 4747)	N/A
A15	POWER ISOL NIM4CC03 NIM 4.0 PRINTER INTL	NIM4CC03
A16	POWER CORD NIMCPCUK UK 6 METER	NIMCPCUK
A17	POWER CORD NIMCPCEU EU 6 METER	NIMCPCEU

Legacy NIM disposables

ID	CFN	Description	QTY provided
D02	8225401	PROBE, SIDE BY SIDE BIPOL. STIM. 5/PK	1
D22	8225825E	PROBE 8225825E INCREMENT STD PRASS TIP	1
D36	8229306	EMG TUBE REINFORCED 6MM/PRO PIN 1/EA	1
D92	8227412	ELECTRODE SET, PRD. SUBDERM.,8CH 1/EA	1
D111	8228053	ELECTRODE 8228053 APS 3MM	1

3 REFERENCES

Publication	Edition	Date	AMD 1
CFR 47 Part 15	-	2019	-
ANSI C63.10	-	2013	-
ANSI C63.4		2014	

4 UNCERTAINTY SUMMARY

Using the guidance of the following publications the calculated measurement uncertainty represents an expanded uncertainty expressed at approximately the 95 % confidence level, using a coverage factor of $k = 2$.

References	Version / Date
CISPR 16-4-1	Ed. 2 (2009-02)
CISPR 16-4-2	Ed. 2 (2011-06)
CISPR 32	Ed. 1 (2012-01)
ANSI C63.23	2012
A2LA P103	February 4, 2016
A2LA P103c	August 10, 2015
ETSI TR 100-028	V1.3.1 (2001-03)

Measurement Type	Configuration	Uncertainty \pm
Radiated Emissions	Biconical Antenna	5.0 dB
Radiated Emissions	Log Periodic Antenna	5.3 dB
Radiated Emissions	Horn Antenna	4.7 dB
AC Line Conducted Emissions	Artificial Mains Network	3.4 dB
Telecom Conducted Emissions	Asymmetric Artificial Network	4.9 dB
Disturbance Power Emissions	Absorbing Clamp	4.1 dB
Radiated Immunity	3 Volts/meter	2.2 dB
Conducted Immunity	CDN/EM/BCI	2.4/3.5/3.4 dB
EFT Burst/Surge	Peak pulse voltage	164 volts
ESD Immunity	15 kV level	1377 Volts

Parameter	ETSI U.C. \pm	U.C. \pm
Radio Frequency, from F0	1×10^{-7}	0.55×10^{-7}
Occupied Channel Bandwidth	5 %	2 %
RF conducted Power (Power Meter)	1.5 dB	1.2 dB
RF conducted emissions (Spectrum Analyzer)	3.0 dB	1.7 dB
All emissions, radiated	6.0 dB	5.3 dB
Temperature	1° C	0.65° C
Humidity	5 %	2.9 %
Supply voltages	3 %	1 %

5 TEST DATA

5.1 Simultaneous Transmission

<p>Description of Measurement</p>	<p>The frequency spectrum is investigated for intentional and / or unintentional signals emanating from the EUT by use of a standardized test site and measurement antenna.</p> <p>The antenna, cable, pre-amp, and other necessary measurement system correction factors are loaded onto the EMI receiver / spectrum analyzer when the measurements are performed allowing the data to be gathered and reported as corrected values.</p> <p>The maximum emissions from the EUT are determined by turn-table azimuth rotation (360°) and scanning of the measurement antenna. Maximized levels are noted at degree values of azimuth, measurement antenna height, and measurement antenna polarity.</p>
<p>Example Calculations</p>	<p>Measurement (dBμV) + Cable factor (dB) + Other (dB) + Antenna Factor (dB/m) = Corrected Reading (dBμV/m)</p> <p>Margin (dB) = Limit (dBμV/m) - Corrected Reading (dBμV/m)</p> <p>Example at 4000 MHz: Reading = 40 dBμV + 3.4 dB + 0.9 dB + 6.5 dB/m = 50.8 dBμV/m Average Limit = 20 log (500) = 54 dBμV/m Margin = 54 dBμV/m - 50.8 dBμV/m = 3.2 dB</p>

Block Diagram



5.1.1 Radiated – Simultaneous Transmission

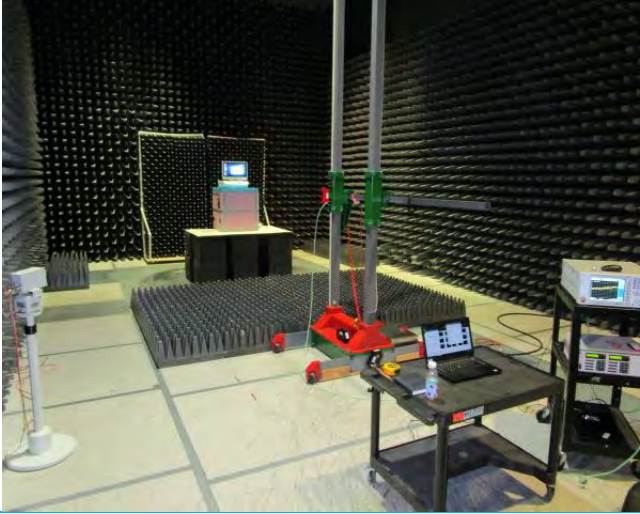
Operator	Braden Smith Jon Dilley	QA	Zach Wilson Jeysson Gonzalez
Temperature	23.5°	R.H.	26.3%
Test Date	2/7/2019	Location	Chamber 5
Requirement	FCC 15.247	Method	ANSI C63.10

Evaluation/Limits:

Spurious emissions generated by any colocation transmission are subject to the following limits:

Frequency (MHz)	Field Strength (μV/m)	Field Strength (dBμV/m)
30 – 88	100	40.0
88 – 216	150	43.5
216 – 960	200	46.0
Above 960	500	54.0

	BLE 1 (6674)	BLE 2 (8795)	BT	WLAN	Identity
Frequency/Rate	2402/BR	2440/BR	2480/BR	3F (2422) 802.11b HT40 (MCS0) Low Channel Transmit Chain A	Configuration 1
	2480/BR	2440/BR	2402/BR	11F (2462) 802.11b HT40 (MCS0) Low Channel Transmit Chain A	Configuration 2
	2440/BR	2402/BR	2480/BR	7F (2442) 802.11b HT40 (MCS0) Low Channel Transmit Chain A	Configuration 3
	2440/BR	2480/BR	2402/BR	7F (2442) 802.11b HT40 (MCS0) Low Channel Transmit Chain A	Configuration 4



18 – 25 GHz

Plots

Configuration 1



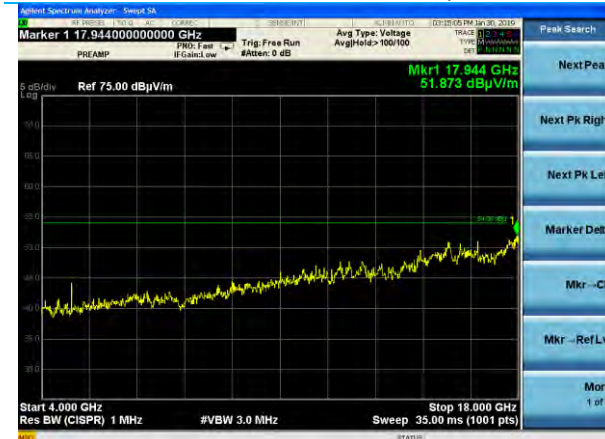
2.4-2.4835 GHz, 30dB Att. Horizontal pol.

2.4-2.4835 GHz, 30dB Att. Vertical pol.



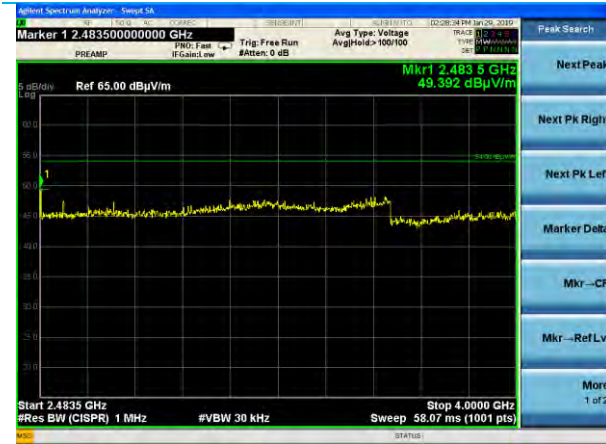
2.4835-4 GHz, Horizontal pol.

2.4835-4 GHz, Vertical pol.



4-18 GHz, Horizontal pol.

4-18 GHz, Vertical pol.



2.4835-4 GHz, Horizontal pol. 30kHz VBW



2.4835-4 GHz, Vertical pol. 30kHz VBW



4-18 GHz, Horizontal pol. 30kHz VBW

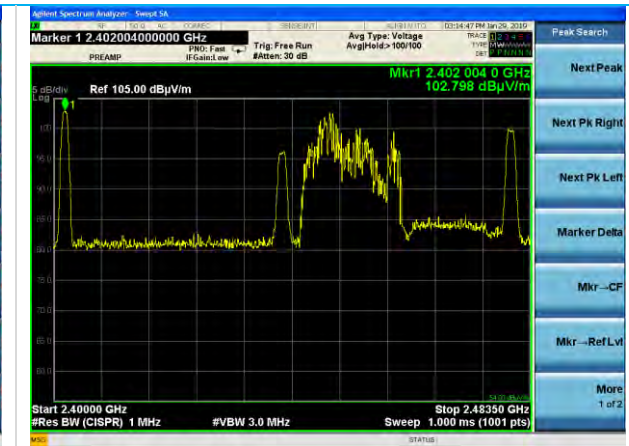


4-18 GHz, Vertical pol. 30kHz VBW

Configuration 2



2.4-2.4835 GHz, 30dB Att. Horizontal pol.



2.4-2.4835 GHz, 30dB Att. Vertical pol.



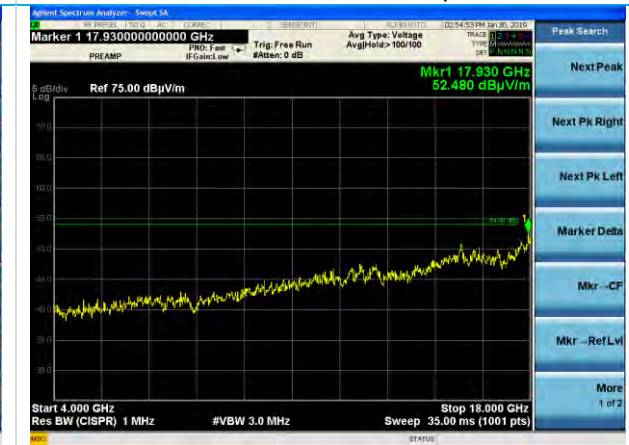
2.4835-4 GHz, Horizontal pol.



2.4835-4 GHz, Vertical pol.



4-18 GHz, Horizontal pol.



4-18 GHz, Vertical pol.



2.4835-4 GHz, Horizontal pol. 30kHz VBW



2.4835-4 GHz, Vertical pol. 30kHz VBW



4-18 GHz, Horizontal pol. 30kHz VBW



4-18 GHz, Vertical pol. 30kHz VBW

Configuration 3



2.4-2.4835 GHz, 30dB Att. Horizontal pol.



2.4-2.4835 GHz, 30dB Att. Vertical pol.



2.4835-4 GHz, Horizontal pol.



2.4835-4 GHz, Vertical pol.



4-18 GHz, Horizontal pol.



4-18 GHz, Vertical pol.



2.4835-4 GHz, Horizontal pol. 30kHz VBW



2.4835-4 GHz, Vertical pol. 30kHz VBW

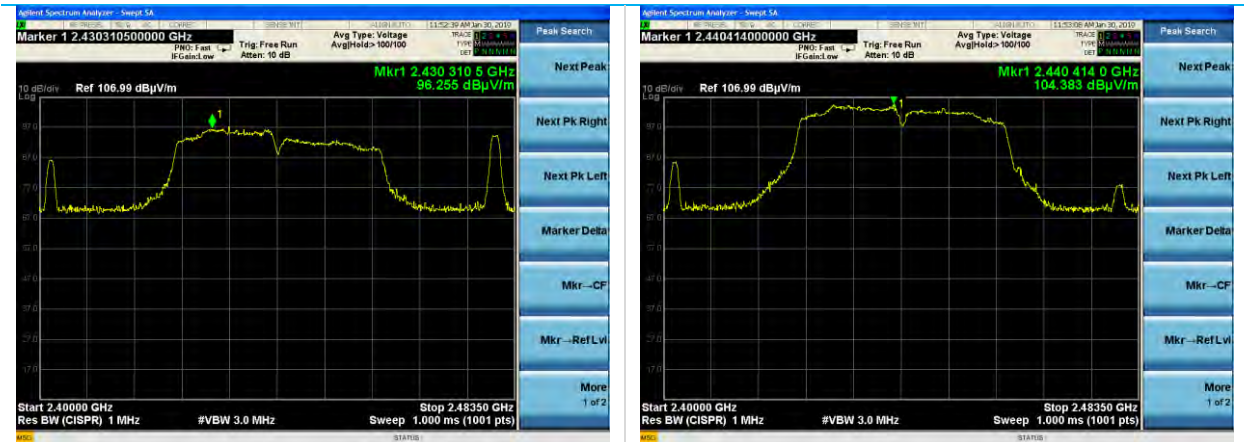


4-18 GHz, Horizontal pol. 30kHz VBW



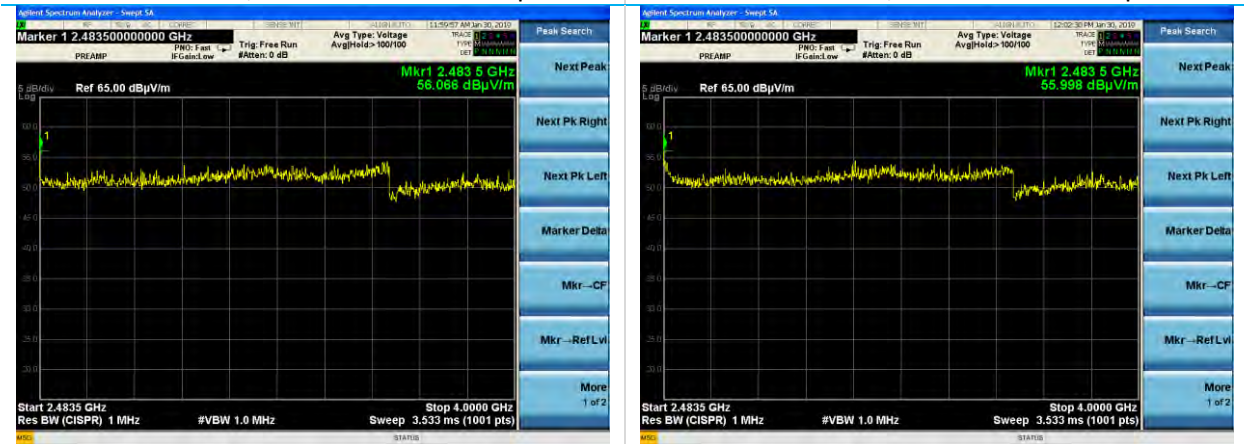
4-18 GHz, Vertical pol. 30kHz VBW

Configuration 4



2.4-2.4835 GHz, 30dB Att. Horizontal pol.

2.4-2.4835 GHz, 30dB Att. Vertical pol.



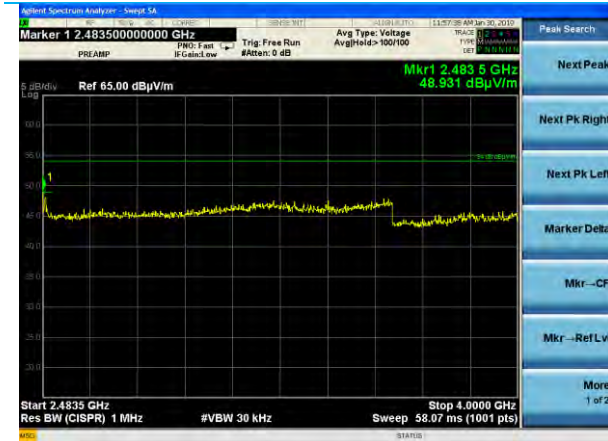
2.4835-4 GHz, Horizontal pol.

2.4835-4 GHz, Vertical pol.

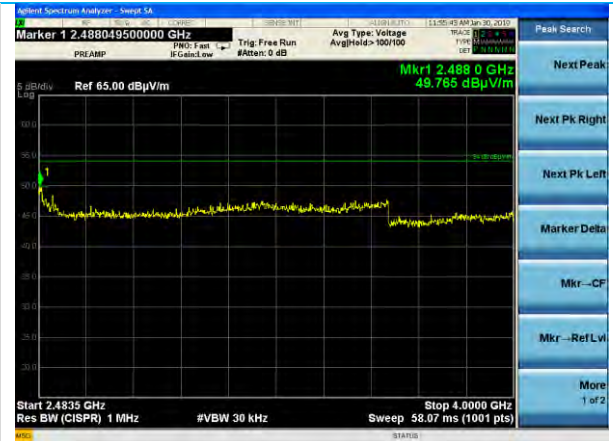


4-18 GHz, Horizontal pol.

4-18 GHz, Vertical pol.



2.4835-4 GHz, Horizontal pol. 30kHz VBW



2.4835-4 GHz, Vertical pol. 30kHz VBW



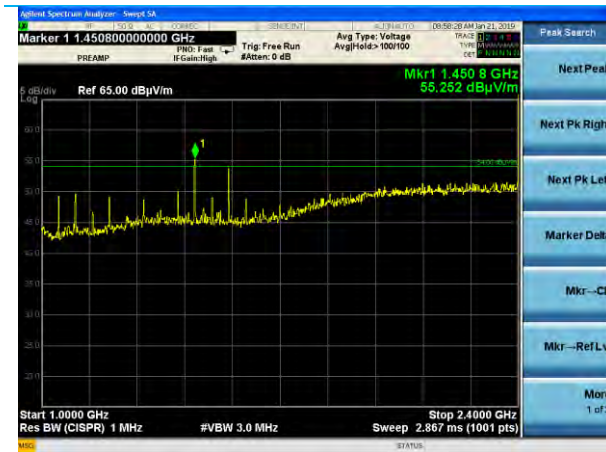
4-18 GHz, Horizontal pol. 30kHz VBW



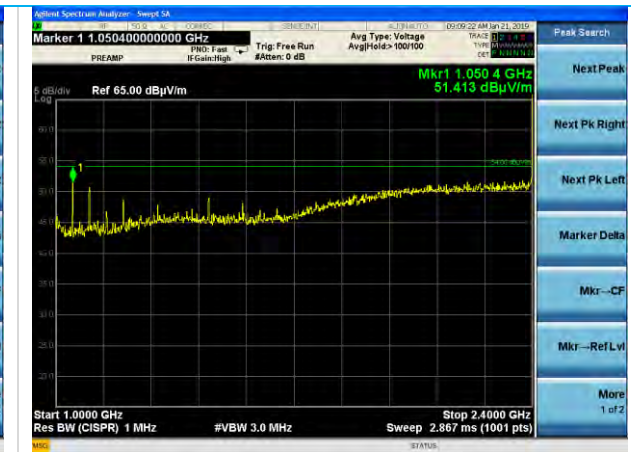
4-18 GHz, Vertical pol. 30kHz VBW

Individual Radio plots

Intel Bluetooth Low channel 2402MHz EDR1



1 – 2.4 GHz Horizontal pol.



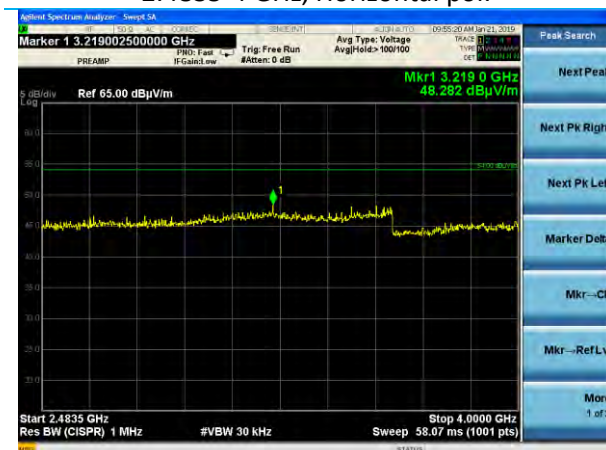
1 – 2.4 GHz Vertical pol.



2.4835-4 GHz, Horizontal pol.



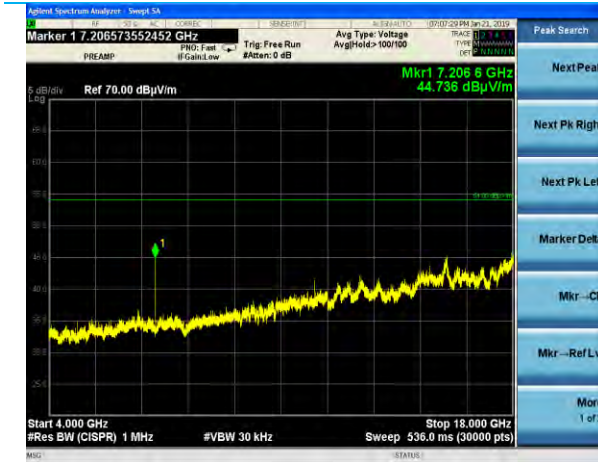
2.4835-4 GHz, Vertical pol.



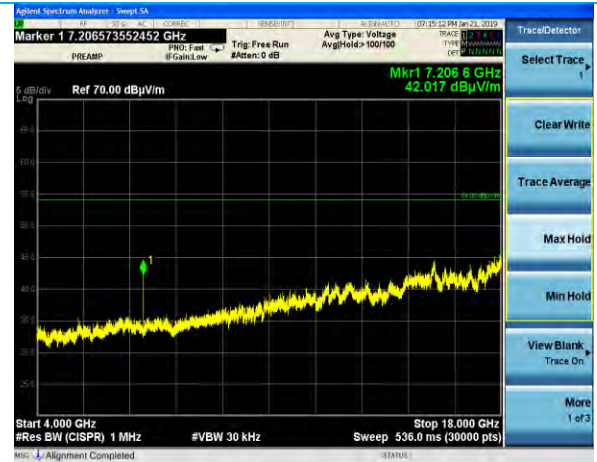
2.4835 – 4 GHz, Horizontal pol. VBW=30kHz



2.4835 – 4 GHz, Vertical pol. VBW=30kHz

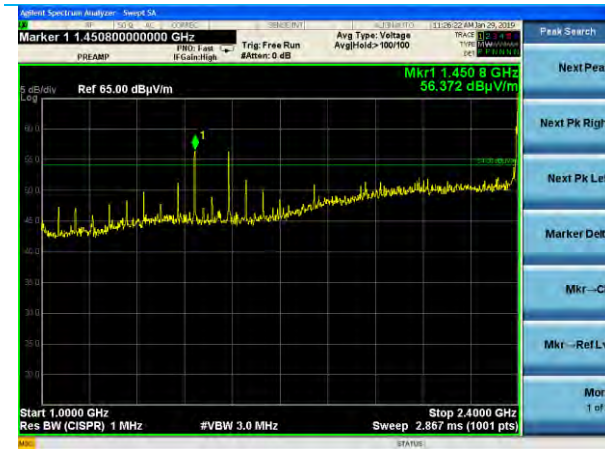


4-18 GHz, Horizontal pol. VBW=30kHz



4-18 GHz, Vertical pol. VBW=30kHz

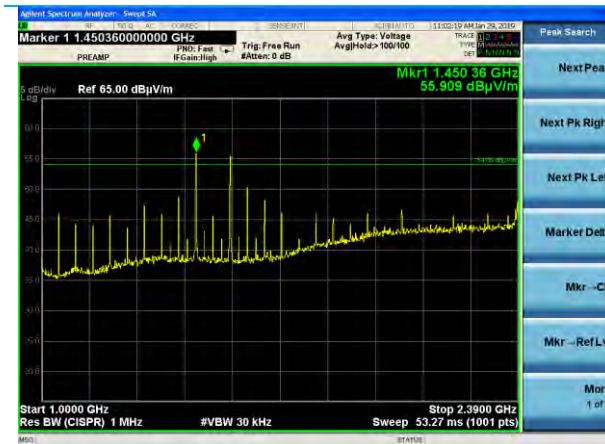
Intel WLAN 802.11b, HT40(MCS0), Low channel (2412MHz), 40MHz BW, Trasmist chain A



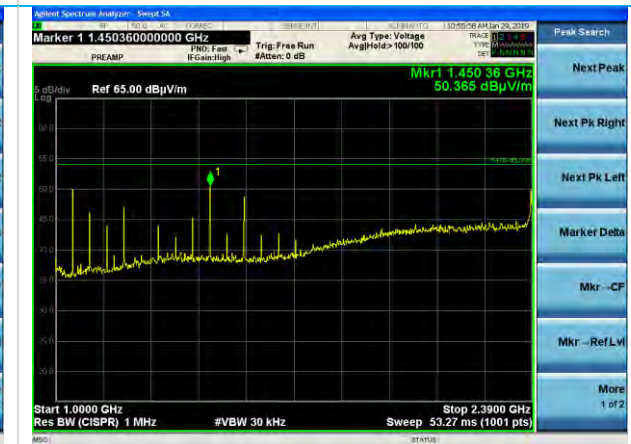
1 – 2.4GHz Horizontal Pol.



1 – 2.4GHz Pertical Pol.



1 – 2.4GHz Horizontal Pol. VBW=30kHz



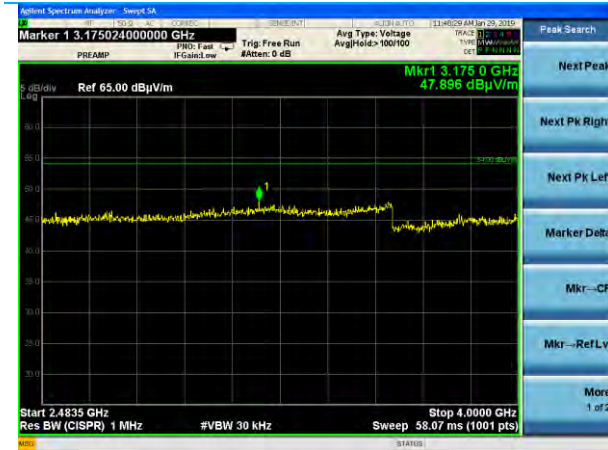
1 – 2.4GHz Pertical Pol. VBW=30kHz



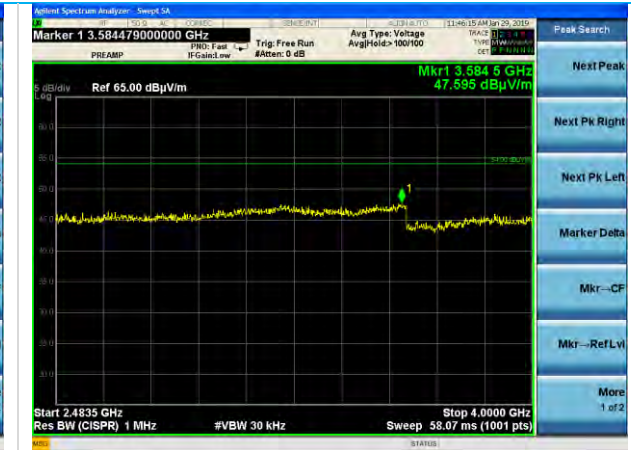
2.4835-4 GHz, Horizontal pol.



2.4835-4 GHz, Vertical pol.



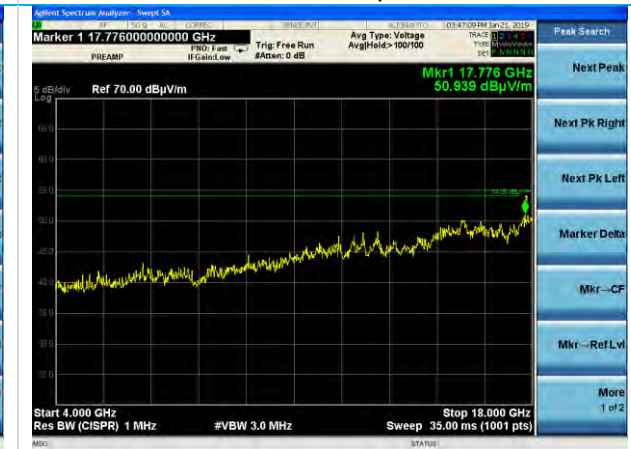
2.4835 – 4 GHz, Horizontal pol. VBW=30kHz



2.4835 – 4 GHz, Vertical pol. VBW=30kHz

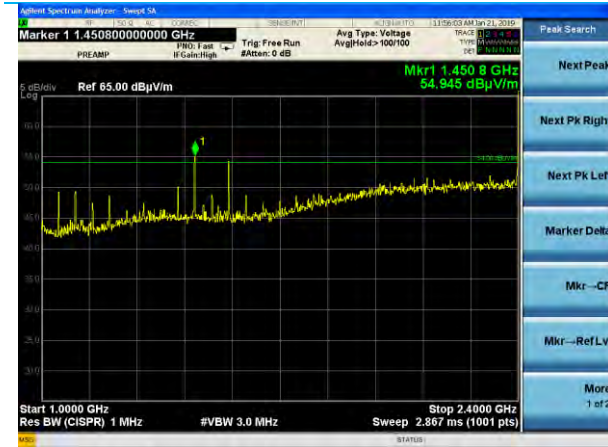


4-18 GHz, Horizontal pol.

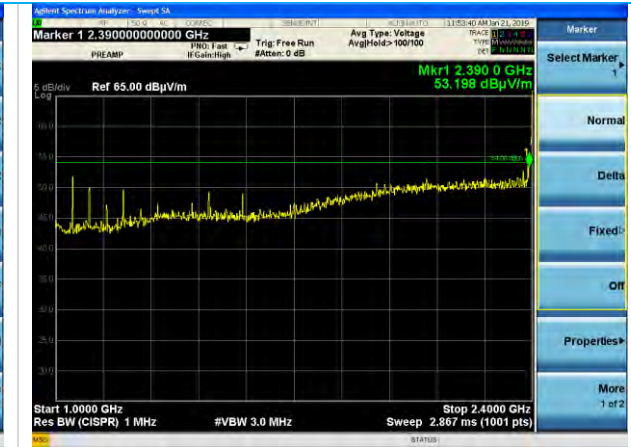


4-18 GHz, Vertical pol.

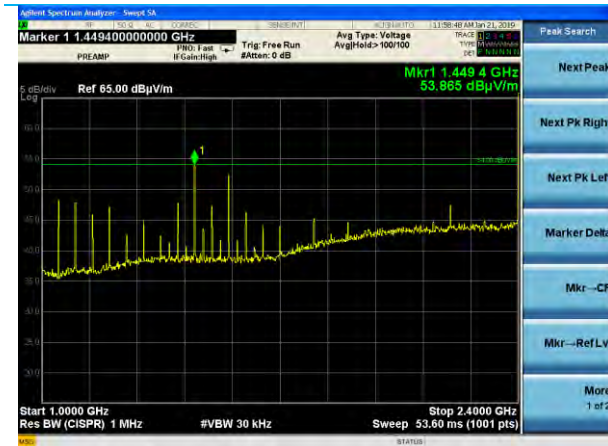
Laird BL652 (MTD2360308795), Low channel (2402MHz), 1Mbps



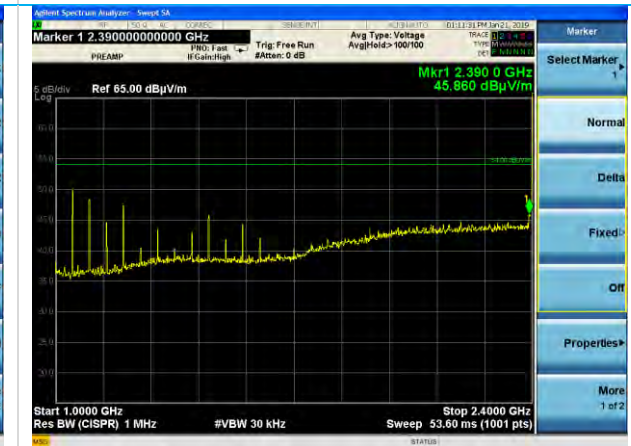
1 – 2.4GHz Horizontal Pol.



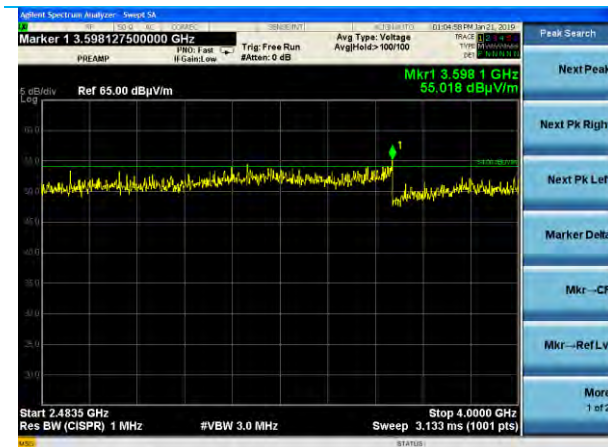
1 – 2.4GHz Vertical Pol.



1 – 2.4GHz Horizontal Pol. VBW=30kHz



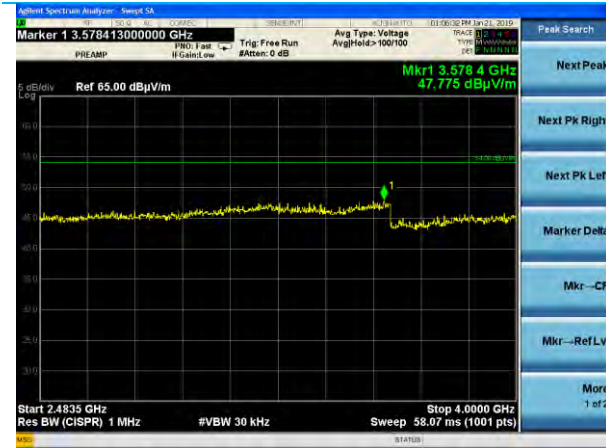
1 – 2.4GHz Vertical Pol. VBW=30kHz



2.4835-4 GHz, Horizontal pol.



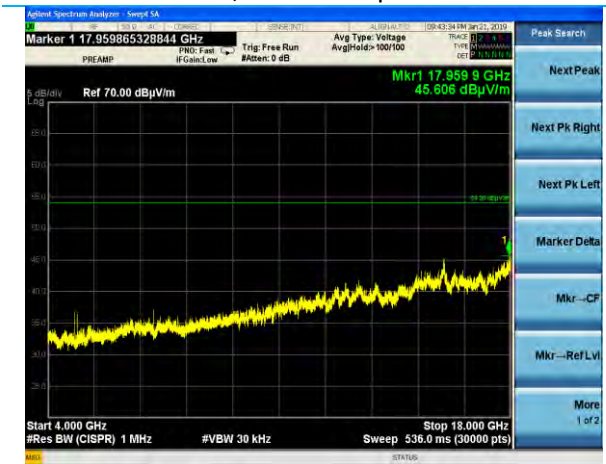
2.4835-4 GHz, Vertical pol.



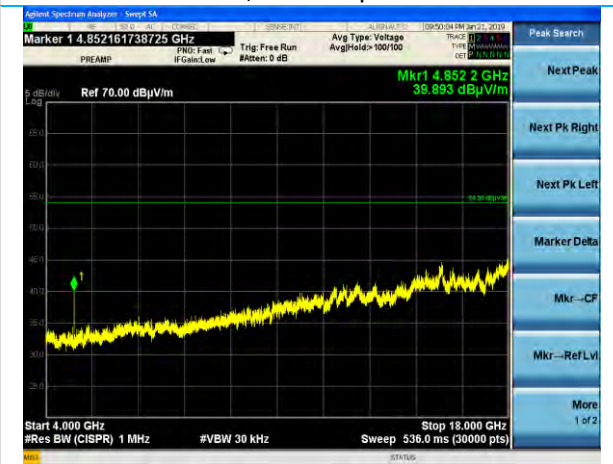
2.4835 – 4 GHz, Horizontal pol. VBW=30kHz



2.4835 – 4 GHz, Vertical pol. VBW=30kHz

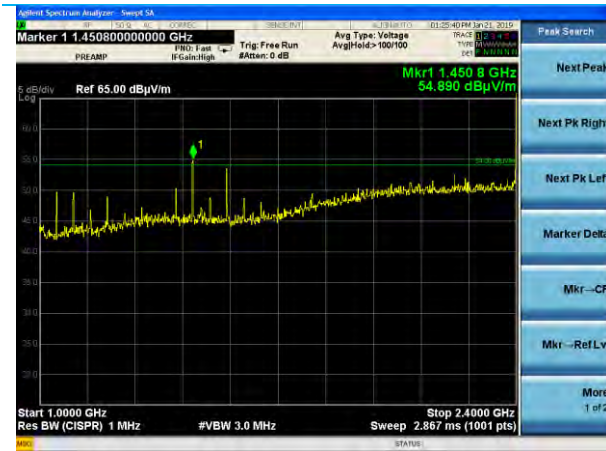


4-18 GHz, Horizontal pol. VBW=30kHz

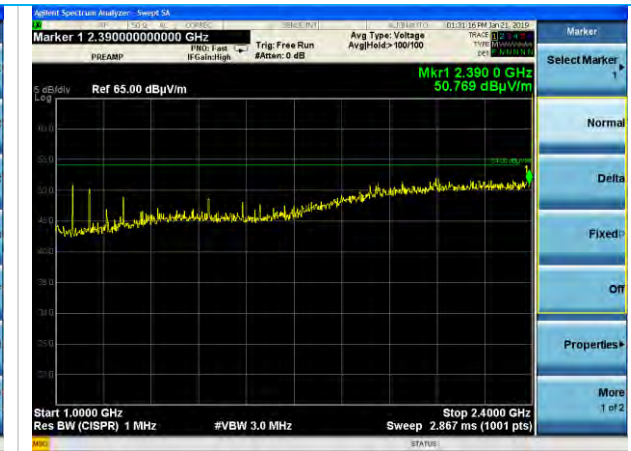


4-18 GHz, Vertical pol. VBW=30kHz

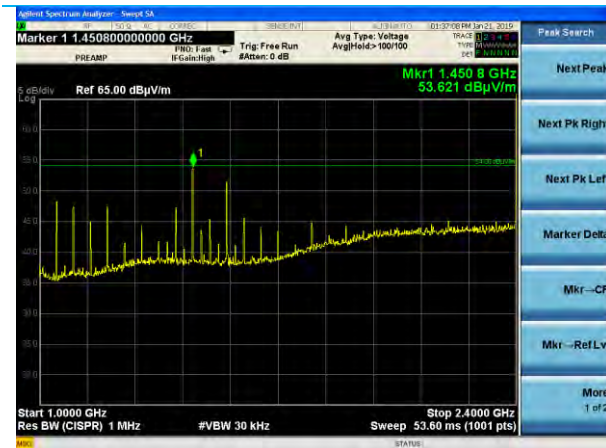
Laird BL652 (MDT3067136674), Low channel (2402MHz), 1Mbps



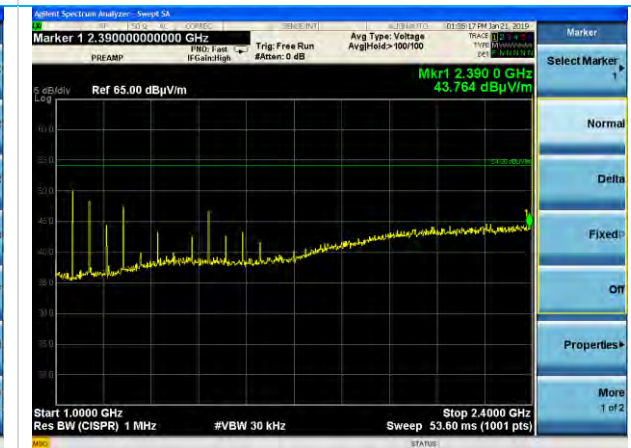
1 – 2.4GHz Horizontal Pol.



1 – 2.4GHz Vertical Pol.



1 – 2.4GHz Horizontal Pol. VBW=30kHz



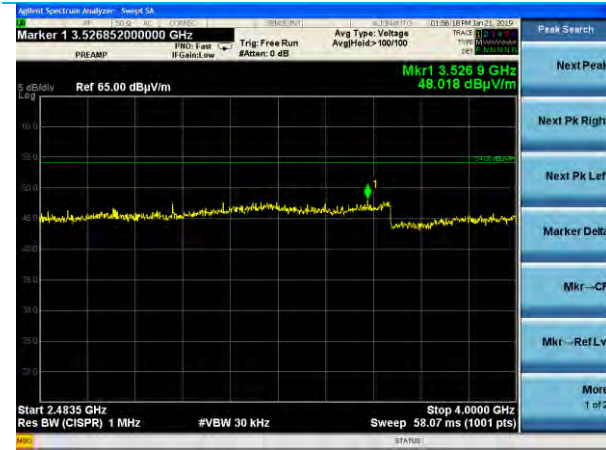
1 – 2.4GHz Vertical Pol. VBW=30kHz



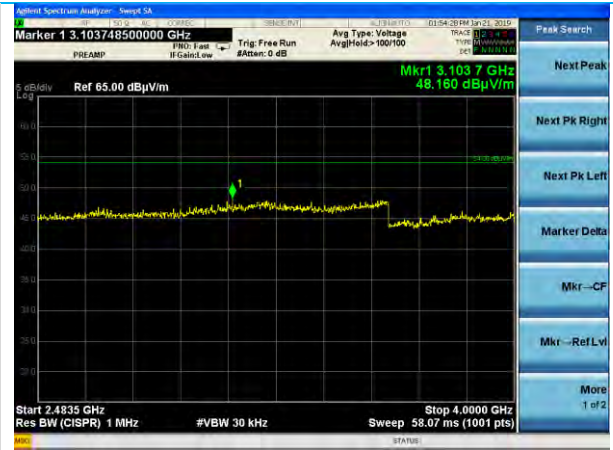
2.4835-4 GHz, Horizontal pol.



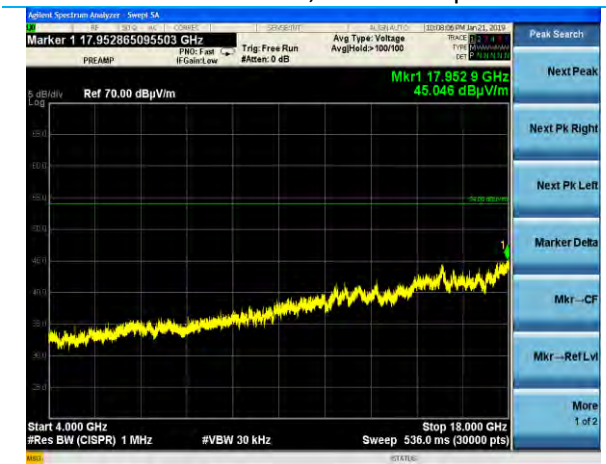
2.4835-4 GHz, Vertical pol.



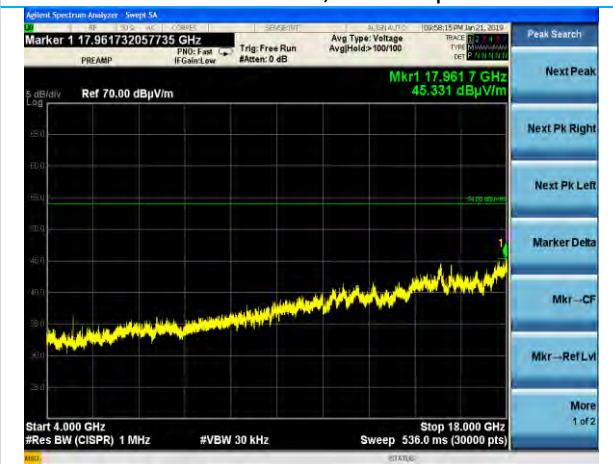
2.4835 – 4 GHz, Horizontal pol.



2.4835 – 4 GHz, Vertical pol.

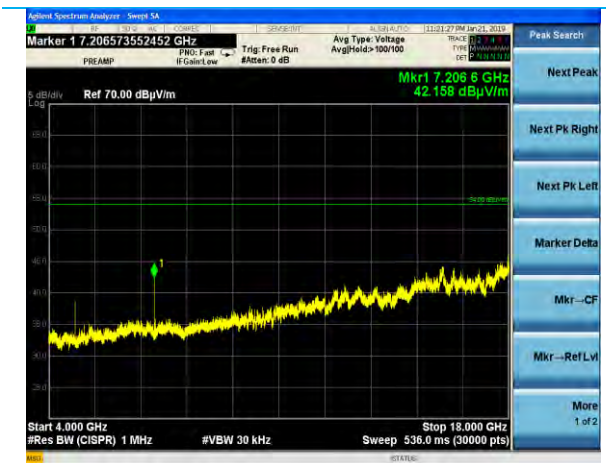


4-18 GHz, Horizontal pol.

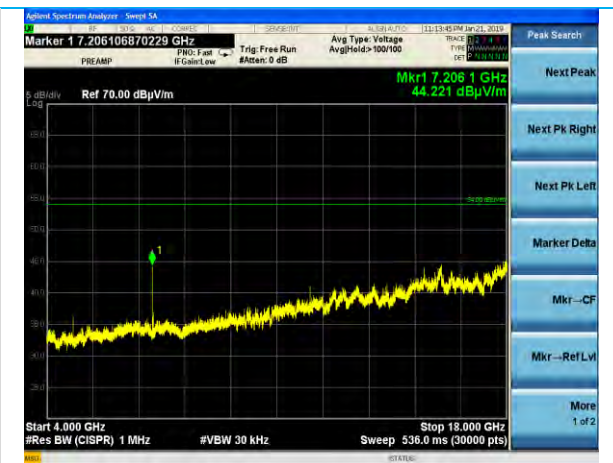


4-18 GHz, Vertical pol.

All radios on low channel Tx mode



4 – 18 GHz, Horizontal pol.



4 – 18 GHz, Vertical pol.

Company: Medtronic	Page 27 of 40	Name: NIM Vital Console
Report: TR 318326 B		Model: NIM4CM01; NIM4CPB1
Job: C-3142		Serial: X08122218; PV004
Page 27 of 40		10944155DOC Rev B - Attachment B

Data tables

Frequency (GHz)	Height (cm)	Antenna Polarity	Peak reading (dBμV/m)	Average reading (dBμV/m)	Peak Limit (dBμV/m)	Average Limit (dBμV/m)	Peak Margin (dB)	Average Margin (dB)	Config
17.96	150	H	52.72	44.26	74.0	54.0	21.3	9.7	4
17.75	150	V	52.29	44.68	74	54	21.7	9.3	4
7.21	150	H	-	44.74	-	54	-	9.3	Intel BLE only
7.21	150	H	-	42.16	-	54	-	11.8	All radios on

5.1.2 Radiated – Simultaneous Transmission Band Edge

Operator	Jeysson Gonzalez	QA	Laura Zehnder
Temperature	26.7°	R.H.	38.6%
Test Date	8/22/2019	Location	Chamber 5
Requirement	FCC 15.247	Method	ANSI C63.10

Evaluation/Limits:

Spurious emissions generated by any colocation transmission are subject to the following limits:

Frequency (MHz)	Peak Limit (dBμV/m)	Average Limit (dBμV/m)
2310 – 2390	74	54
2483.5 – 2500	74	54

Test Parameters

Frequency	2.4835 – 18 GHz	Distance	3 m
Detector(s)	Peak	Table height	150 cm
RBW	1 MHz	VBW	30 kHz for averaged measurement 3 MHz for peak measurement
Notes	Console position at 150 cm from reference ground. No intermodulations were detected. PIU positioned at 80 cm from reference ground.		

EUT Parameters

Input Power	120VAC/60Hz	Mode	Parotid Ch4
Notes	No printer, external monitor, no Ethernet cable PIU cable has 2 ferrites		

Instrumentation

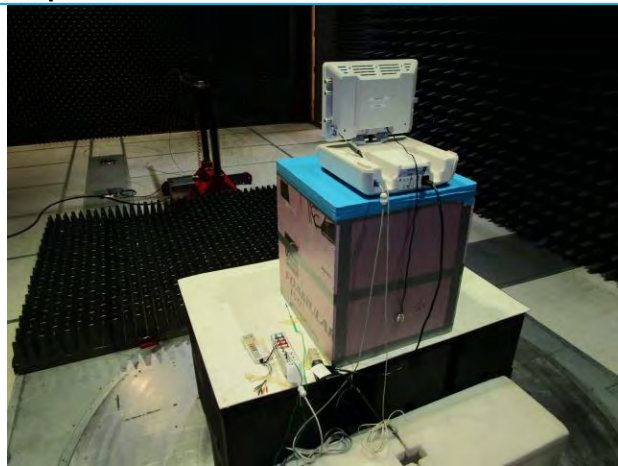
Date : 21-Jan-2019 Test : Simultaneous Transmission Job : C-3142
 PE : Jeysson Gonzalez Customer : Medtronic- Surgical Technologies Quote : 318326

No.	Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due Date	Equipment Status
1	EE 960085	Analyzer - EMI Receiver	Agilent	N9038A	MY51210148	4/24/2019	4/24/2020	Active Calibration
2	AA 960154	Filter - High Pass 2.4 GHz	KWM	HPF-L-14186	7272-02	4/22/2019	4/22/2020	Active Calibration
3	AA 960173	Cable	A.H. Systems, Inc.	SAC-26G-1	388	6/4/2018	6/4/2020	Active Verification
4	AA 960158	Antenna - Double Ridge Horn	ETS Lindgren	3117	109300	3/26/2018	3/26/2020	Active Calibration
5	EE 960159	Antenna - Low Noise Amplifier	Mini-Circuits	ZVA-213X-S+	691801732	3/26/2018	3/26/2020	Active Calibration
6	AA 960176	Cable	A.H. Systems, Inc.	SAC-26G-6	395	6/4/2018	6/4/2020	Active Verification

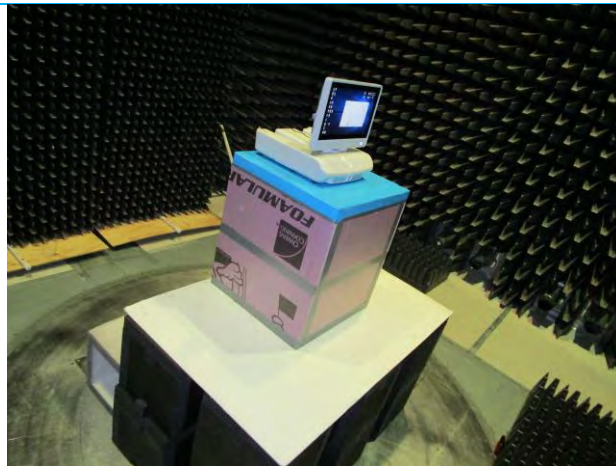
Date : 21-Aug-2019 Test : Simultaneous Transmission Job : C-3142
 PE : Jeysson Gonzalez Customer : Medtronic- Surgical Technologies Quote : 318326

No.	Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due Date	Equipment Status
1	AA 960007	Antenna - Double Ridge Horn	EMCO	3115	9311-4138	9/12/2018	9/12/2019	Active Calibration
2	EE 960085	Analyzer - EMI Receiver	Agilent	N9038A	MY51210148	4/24/2019	4/24/2020	Active Calibration

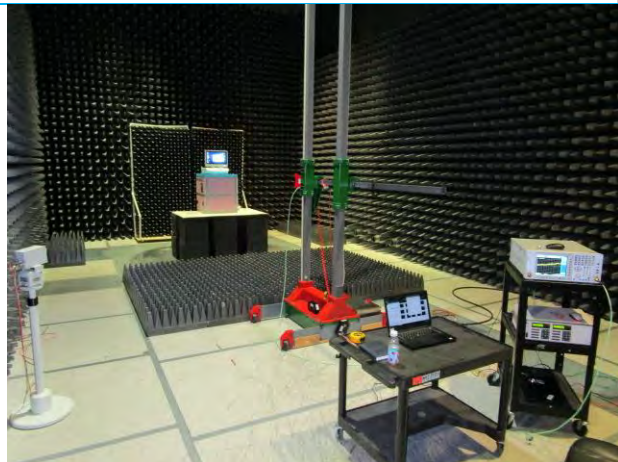
Setup Photos



4-18 GHz



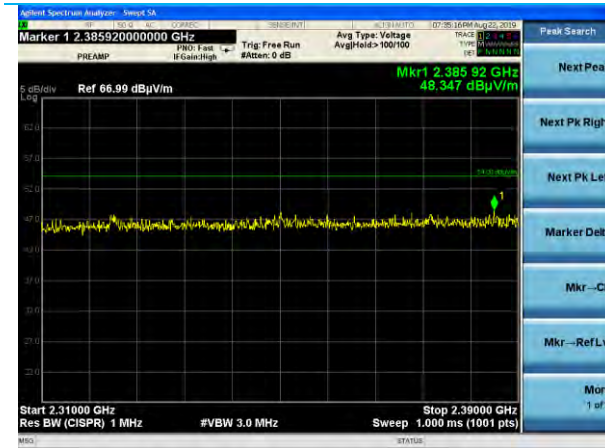
4 – 18 GHz



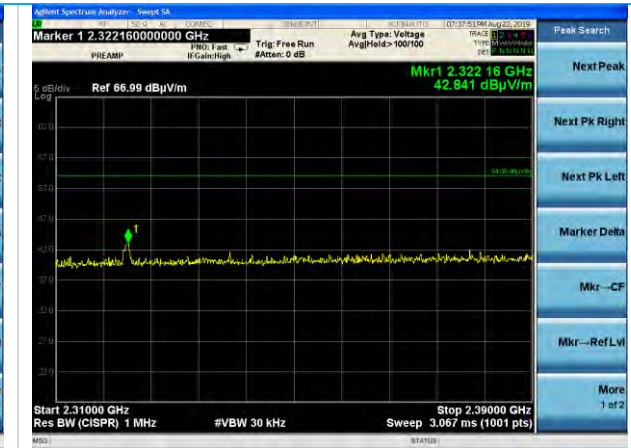
18 – 25 GHz

Individual Radio plots

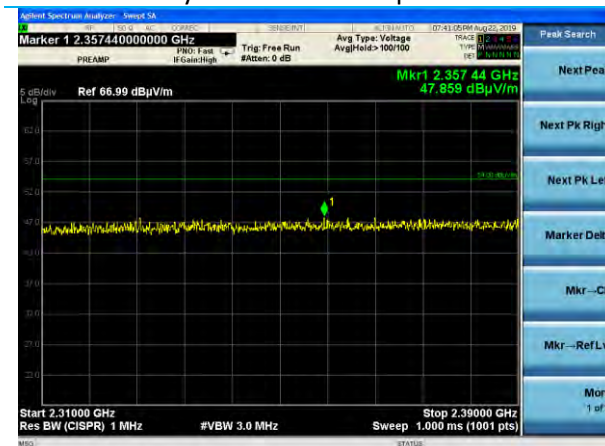
Intel Bluetooth LE 2402MHz



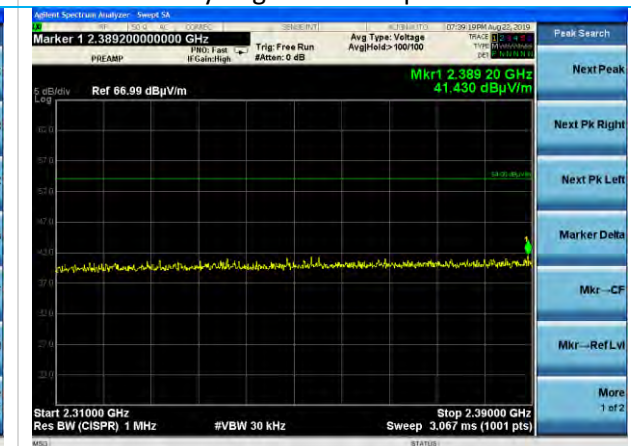
BLE only Peak Horizontal polarization



BLE only Avg Horizontal polarization

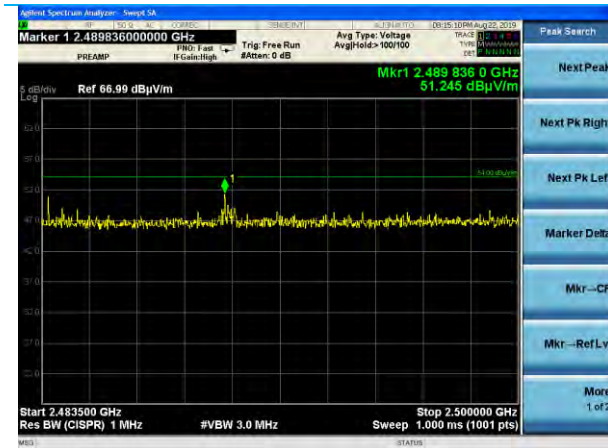


BLE only Peak Vertical polarization

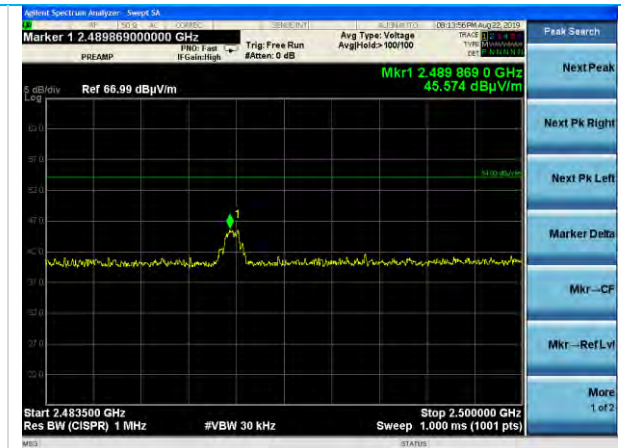


BLE only Avg Vertical polarization

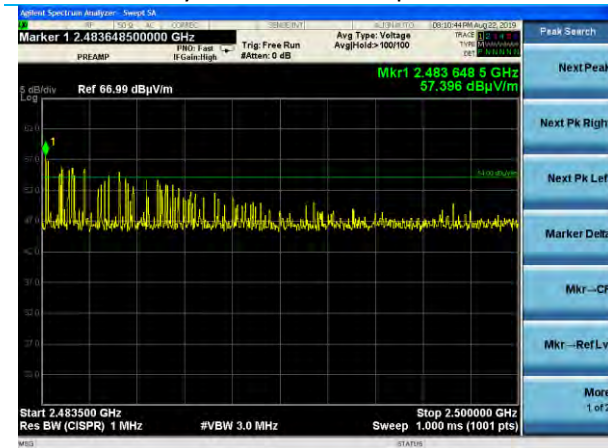
Intel Bluetooth LE 2480MHz



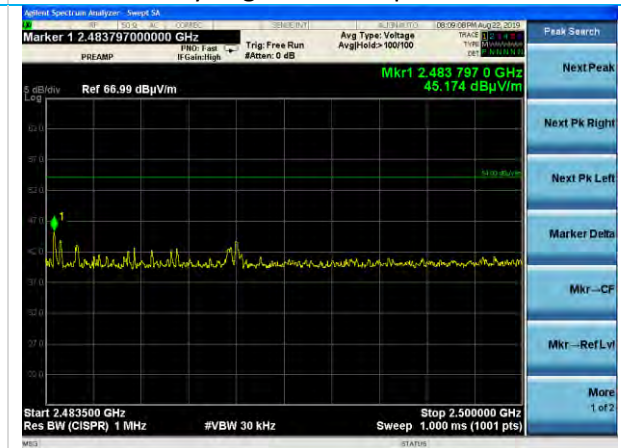
BLE only Peak Horizontal polarization



BLE only Avg Horizontal polarization

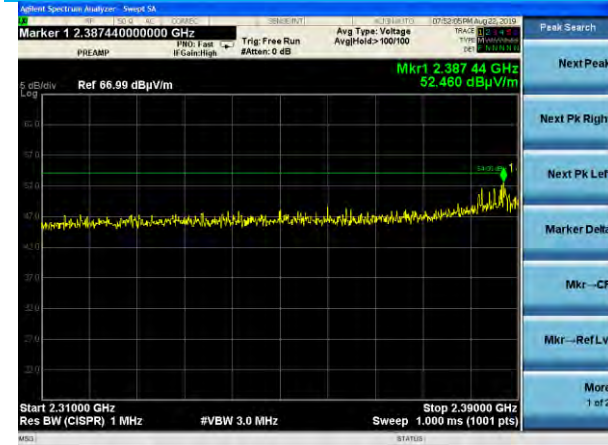


BLE only Peak Vertical polarization

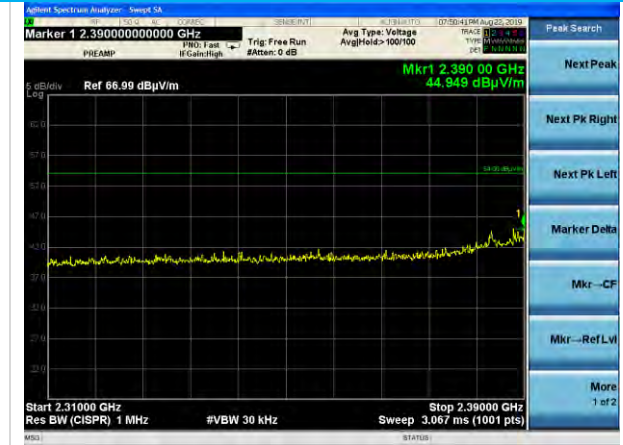


BLE only Avg Vertical polarization

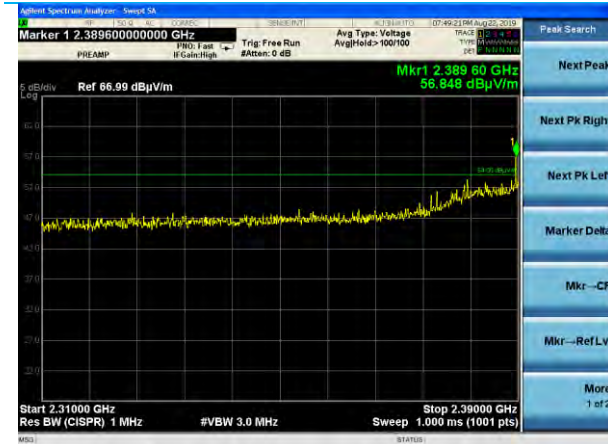
Intel WLAN 802.11b, 3F/2422MHz, 40MHz BW, Trasmist chain A



BLE only Peak Horizontal polarization



BLE only Avg Horizontal polarization

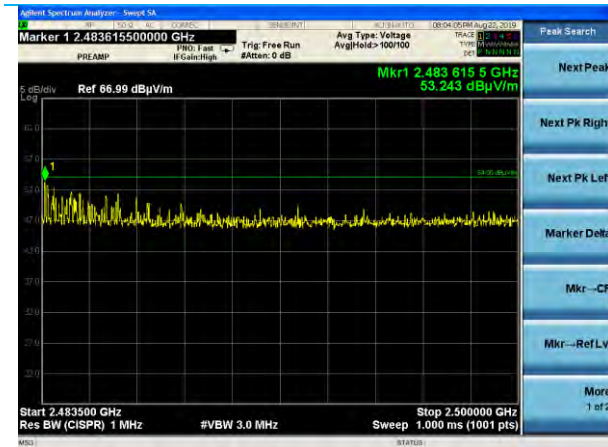


BLE only Peak Vertical polarization

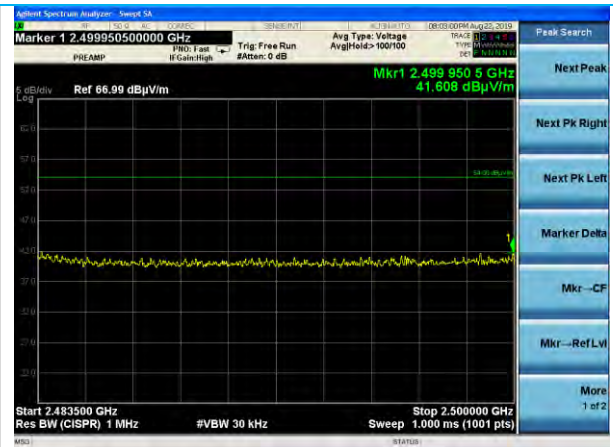


BLE only Avg Vertical polarization

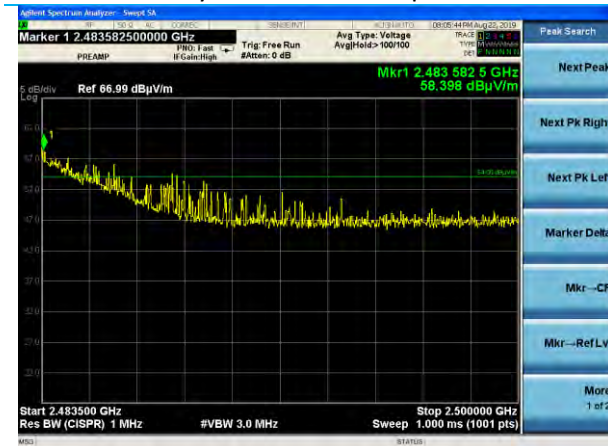
Intel WLAN 802.11b, 11F/2462MHz, 40MHz BW, Trasmitt chain A



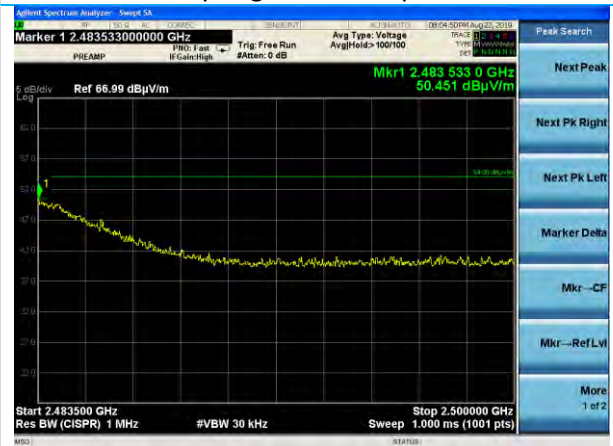
WLAN only Peak Horizontal polarization



WLAN only Avg Horizontal polarization

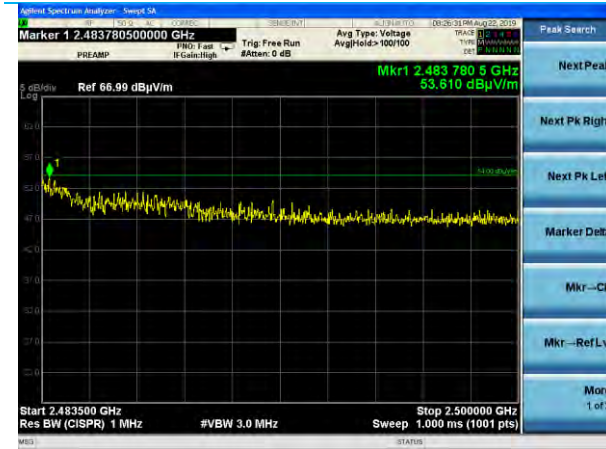


WLAN only Peak Vertical polarization

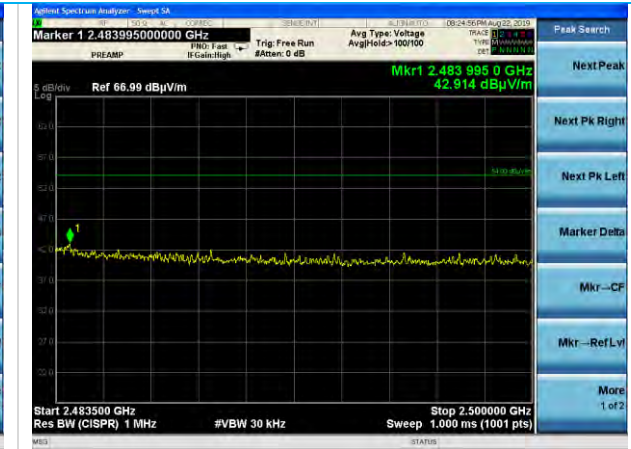


WLAN only Avg Vertical polarization

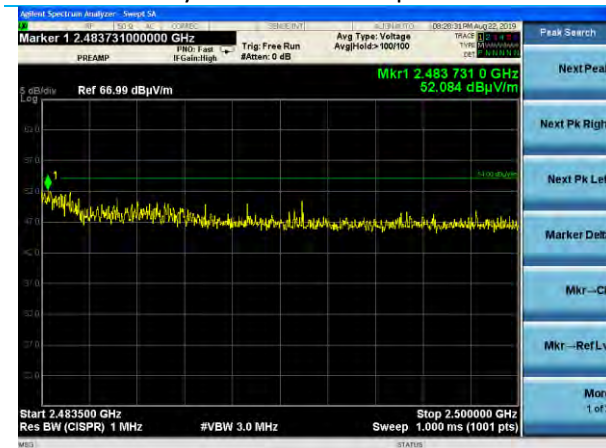
Laird BL652 (MTD2360308795), High channel (2480MHz), 1Mbps



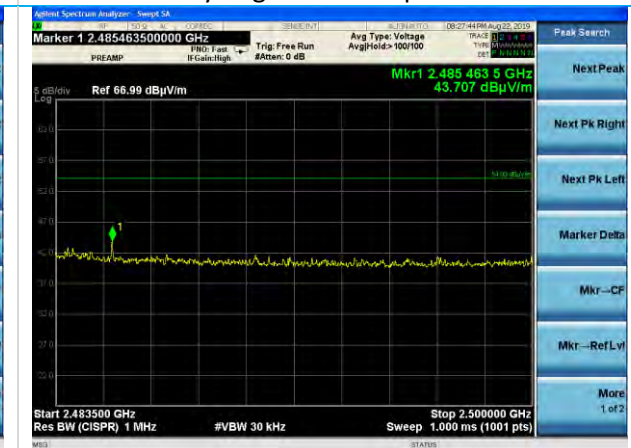
BLE only Peak Horizontal polarization



BLE only Avg Horizontal polarization

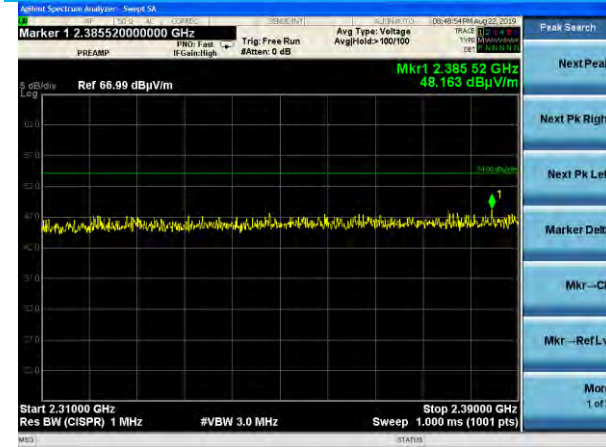


BLE only Peak Vertical polarization

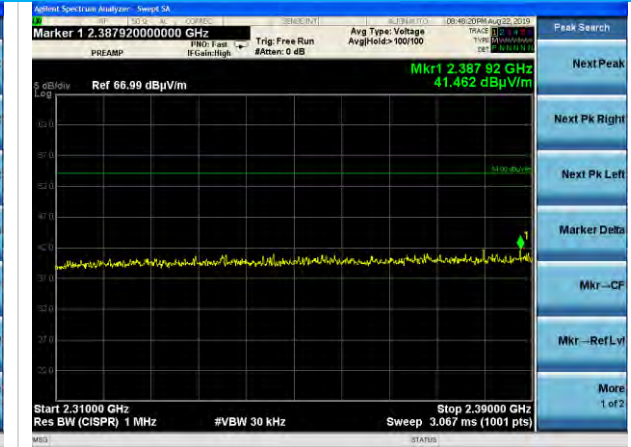


BLE only Avg Vertical polarization

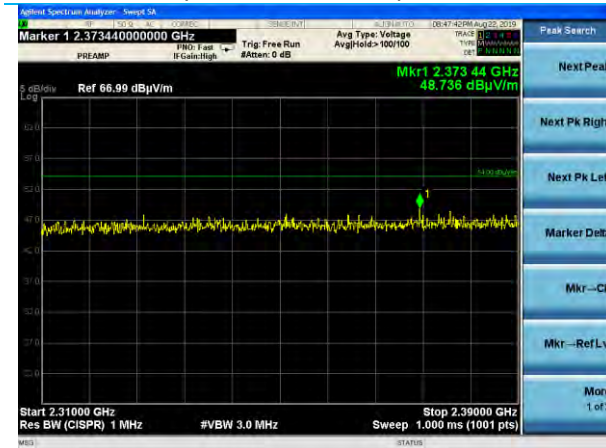
Laird BL652 (MDT3067136674), Low channel (2402MHz), 1Mbps



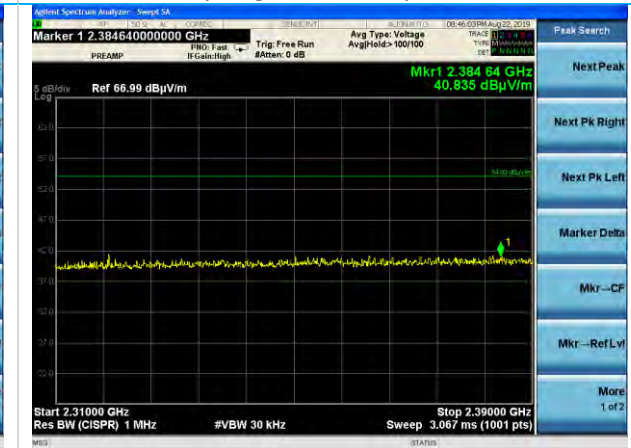
BLE only Peak Horizontal polarization



BLE only Avg Horizontal polarization

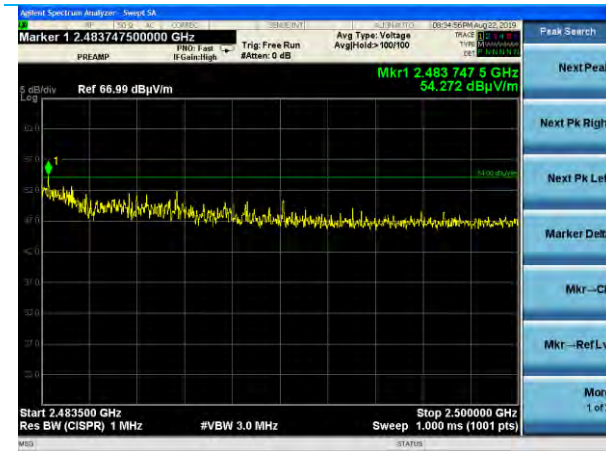


BLE only Peak Vertical polarization

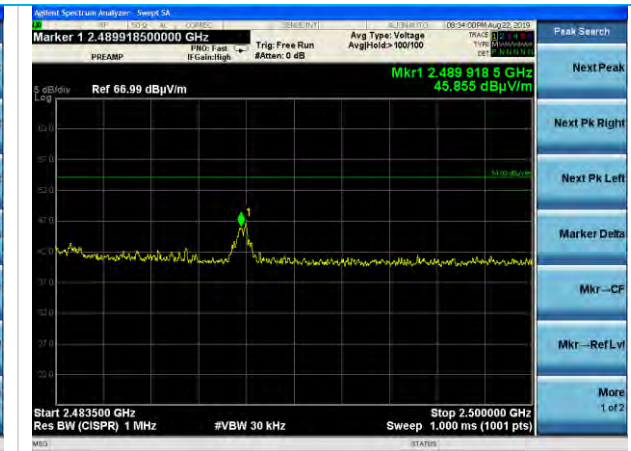


BLE only Avg Vertical polarization

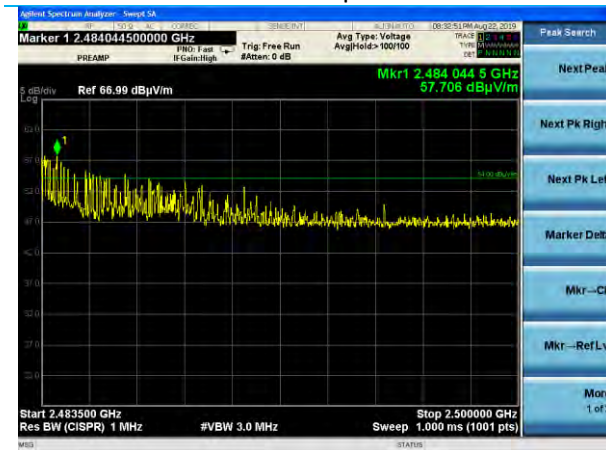
BLE2 and Intel BLE on High channel



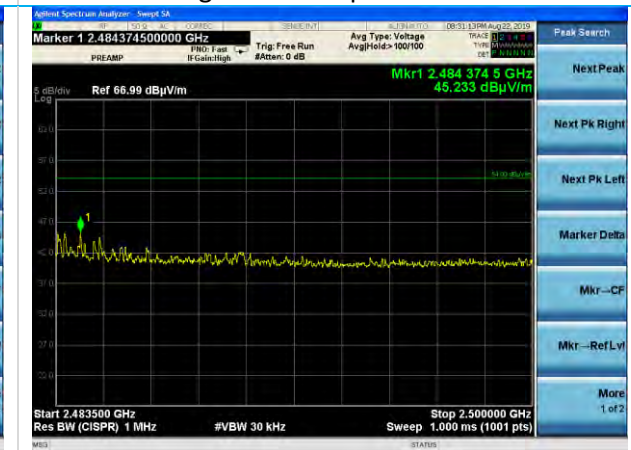
Peak Horizontal polarization



Avg Horizontal polarization

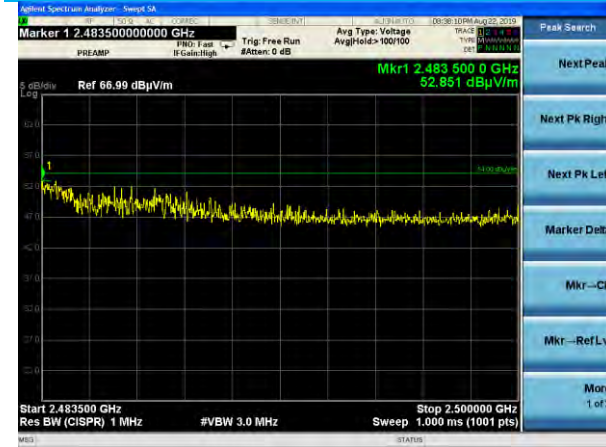


Peak Vertical polarization

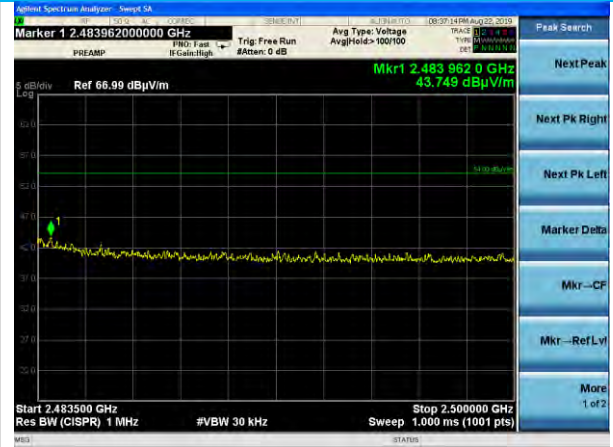


Avg Vertical polarization

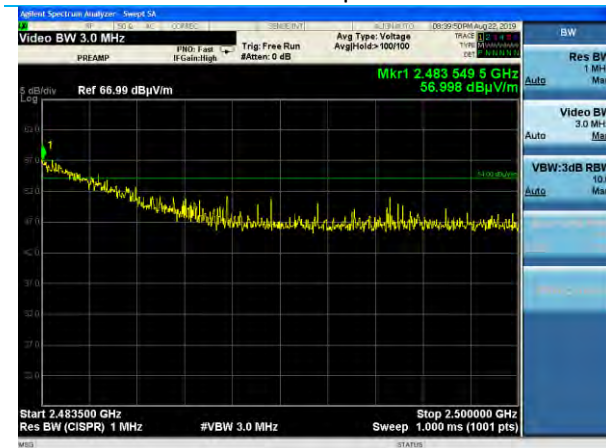
BLE2 and Intel WLAN on High channel



Peak Horizontal polarization



Avg Horizontal polarization

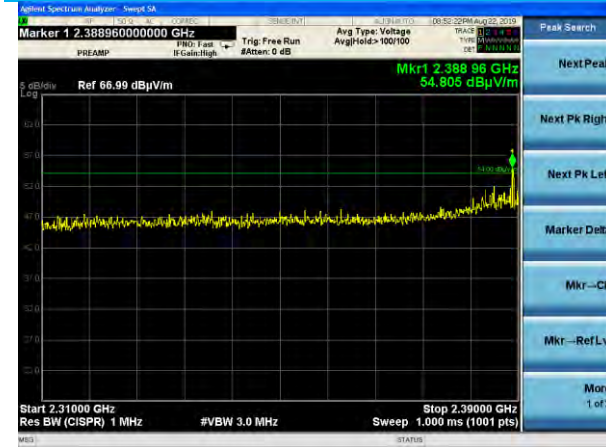


Peak Vertical polarization

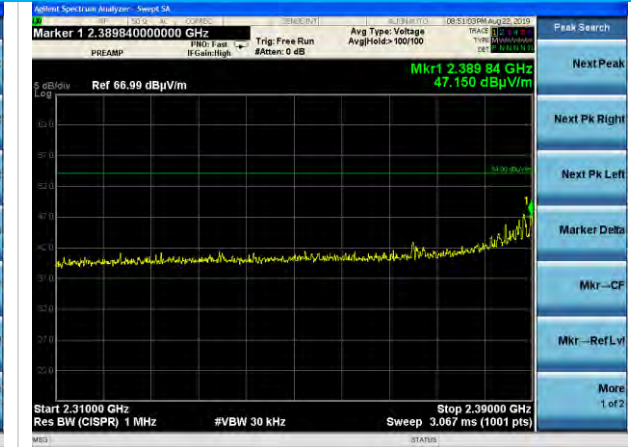


Avg Vertical polarization

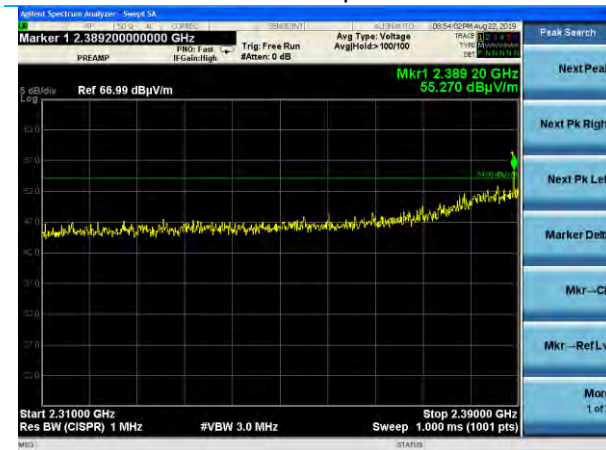
BLE1 and Intel WLAN on Low channel



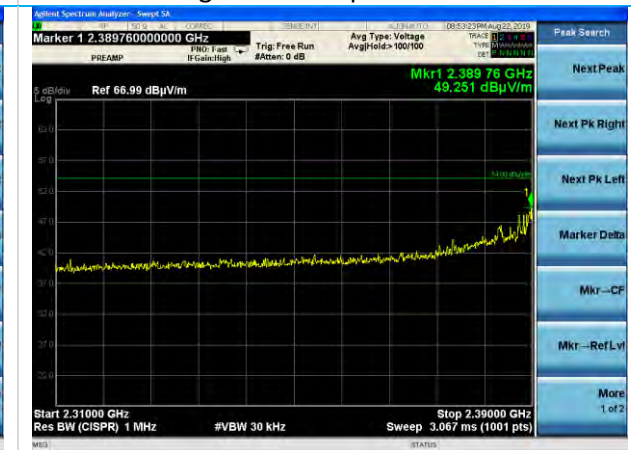
Peak Horizontal polarization



Avg Horizontal polarization



Peak Vertical polarization



Avg Vertical polarization

Note: when both radios transmit simultaneously, there are no additional intermodulation spurious emissions present.

6 REVISION HISTORY

Version	Date	Notes	Person
1	07 August, 2019	Initial released	Jeysson Gonzalez
2	23 August, 2019	Updated section 2, 2.6	Jeysson Gonzalez

END OF REPORT