

Test Report # 317245A

Equipment Under Test: Patient Assistant

Test Date(s): 11/2/17 – 11/13/17

Prepared for: ATTN: Ana Santos
Medtronic Inc
710 Medtronic Parkway NE
Minneapolis MN 55432


Report Issued by: Shane Dock, EMC Engineer

Signature:



Date: 2/27/2018

Report Reviewed by: Adam Alger, Quality Systems Engineer

Signature: 

Date: 12/04/2017

Report Constructed by: Shane Dock, EMC Engineer

Signature:



Date: 1/9/2018

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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: 2005 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



Innovation, Science and Economic Development Canada

ISED Site listing of two 3 meter Semi-Anechoic Chambers based on RSS-GEN – Issue 4

File Number: IC 3088A-2

File Number: IC 3088A-3

Company: Medtronic Inc.	Page 3 of 25	Name: Patient Assistant
Report: 317245A		Model: PA97000
Job: C-2837		Serial: See Section 2.1

1 TEST REPORT SUMMARY

During **11/2/17 – 11/13/17** the Equipment Under Test (EUT), **Patient Assistant**, as provided by **Medtronic Inc.** was tested to the following requirements:

Requirement	Description	Specification	Method	Result
FCC: 15.247 (a)(2) IC: RSS-247 5.2 (1)	Digital Modulation System 6 dB bandwidth	500 kHz	FCC KDB 558074	Pass
FCC: 2.1049 IC: RSS-GEN 6.6	Occupied Bandwidth	Reported	ANSI C63.10	Pass
FCC: 15.247 (b)(3) IC: RSS-247 5.4 (4)	Maximum Conducted Output Power	30 dBm	FCC KDB 558074	Pass
FCC: 15.247 (e) IC: RSS-247 5.2 (2)	Digital Modulation System Power Spectral Density	8 dBm / 3 kHz	FCC KDB 558074	Pass
FCC: 15.247 (d) IC: RSS-247 5.5	RF Spurious Emissions at the Transmitter Antenna Terminal	20 dBc	FCC KDB 558074	Pass
FCC: 15.247 (d) IC: RSS-GEN 8.10	Spurious Radiated Emissions in Restricted Bands	FCC 15.209 RSS-GEN 8.9	ANSI C63.10	Pass
FCC: 2.1055 (d) IC: RSS-GEN 6.11	Frequency Stability	Reported	ANSI C63.10	Pass
FCC: 15.207 IC: RSS-GEN 8.8	AC Power Line Conducted Emissions	0.150-30 MHz	ANSI C63.10	N/A (Battery Powered EUT)

Notice:

The results relate only to the item tested and described in this report. Any modifications made to the equipment under test after the specified test date(s) may invalidate the data herein.

If the resulting measurement margin is seen to be within the uncertainty value, as listed in this report, the possibility exists that this unit may not meet the required limit specification if subsequently tested.

2 CLIENT INFORMATION

Company Name	Medtronic Inc
Contact Person	Keely Wagner (Plexus)
Address	Medtronic Inc 710 Medtronic Parkway NE Minneapolis MN 55432

2.1 Equipment Under Test (EUT) Information





The following information has been supplied by the client

Product Name	Patient Assistant
Model Number	PA97000
Serial Number	Conducted RF Testing – MPB000027A Radiated BLE Testing – MPB000028A
FCC/IC ID	FCC: LF5PA97000 IC: 3408D-PA97000

2.2 Product Description

The Activator uses a magnetic dual tone wake up signal which functions as a Tissue Conductance Communication (TCC) sting signal to initiate ICM BLE fast-advertising facilitating BLE connection. After BLE connection a symptom mark command is sent to the Device and the Device responds with an acknowledgement. A successful symptom mark is indicated by an audible tone and an illuminated green LED. The patient assistant activates the data management features in the LINQ II implanted device to initiate recording of cardiac event data in the implanted device memory.

Use of the Patient Assistant

			
Press the symptom button	Blue light will start flashing	Patient holds PA over LINQ II device until the success tone and light occur.	Tone sounds, green light illuminates

2.3 Modifications Incorporated for Compliance

None noted at time of test

Company: Medtronic Inc.	Page 5 of 25	Name: Patient Assistant
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Job: C-2837		Serial: See Section 2.1

2.4 Deviations and Exclusions from Test Specifications

None noted at time of test

2.5 Additional Information

EUT emissions peaked out in three orientations. Unit programmed via button presses, which was configured to cycle through channels. Unit configured to run with a 3 VDC Bench Supply.

2.6 Channel Plan

EUT emissions tested for Low Mid and High Channel.

Low – 2402 MHz

Mid – 2442 MHz

High – 2480 MHz

3 REFERENCES

Publication	Edition	Date
CFR 47 Part 15	-	2017
ANSI C63.10	-	2013
KDB 558074	V4	2017
RSS-247	2	2017
RSS GEN	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

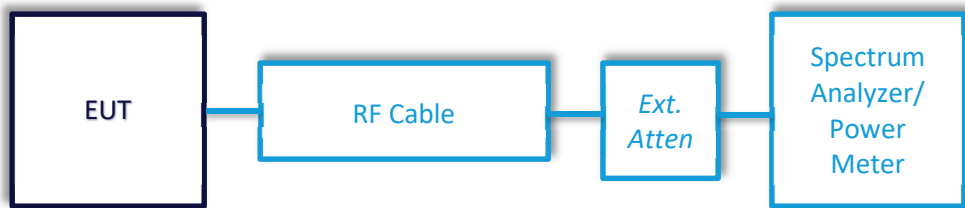
Parameter	ETSI U.C. \pm	U.C. \pm
Radio Frequency, from F0	1×10^{-7}	0.55×10^{-7}
Occupied Channel Bandwidth	5 %	2 %
RF conducted Power (Power Meter)	1.5 dB	1.2 dB
RF conducted emissions (Spectrum Analyzer)	3.0 dB	1.7 dB
All emissions, radiated	6.0 dB	5.3 dB
Temperature	1° C	0.65° C
Humidity	5 %	2.9 %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

5 TEST DATA

5.1 Antenna Port Conducted Emissions

Description of Measurement	<p>The direct measurement of emissions at the antenna port of the EUT is achieved by use of a RF connection to a spectrum analyzer or power meter.</p> <p>The cable and attenuator factors are loaded into the analyzer or power meter allowing for direct measurement readings without the need for further corrections.</p>
Example Calculations	<p>Measurement (dBm) + Cable factor (dB) + External Attenuator (dB) = Corrected Reading (dBm)</p> <p>Margin (dB) = Limit (dBm) – Corrected Reading (dBm)</p>

Block Diagram



5.1.1 Antenna Port Conducted Emissions – Bandwidth

Operator	Shane Dock
Test Date	11/13/17
Location	Conducted RF Measurement Area
Temp. / R.H.	71/42%
Requirement	OBW: FCC: 2.1049 IC: RSS-GEN 6.6 DTS BW: FCC: 15.247 (a)(2) IC: RSS-247 5.2 (1)
Method	ANSI C63.10 Section 6.9.2 FCC KDB 558074 D01 DTS Meas Guidance V04, Section 8

Limits:

6 dB BW (MHz)
> 500

Test Parameters

Frequency	2402, 2442, 2480 MHz
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Tables

Channel	Low	Mid	High
6dB BW (kHz)	740.3	752.5	753.4
99% BW (kHz)	1083.2	1085.6	1083.7

Instrumentation



Date : 3-Nov-2017 Test : Conducted RF BLE Job : C-2837
 PE : Shane Dock Customer : Plexus Quote : 317245

No.	Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due Date	Equipment Status
1	AA 960143	Cable - Phaseflex	Gore	EKD01D01048.0	5546519	6/29/2016	12/31/2017	Active Calibration
2	EE 960087	Analyzer - Spectrum	Agilent	N9010A	MY53400296	12/22/2016	12/22/2017	Active Calibration

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Job: C-2837		Serial: See Section 2.1

Plots



99% BW Low



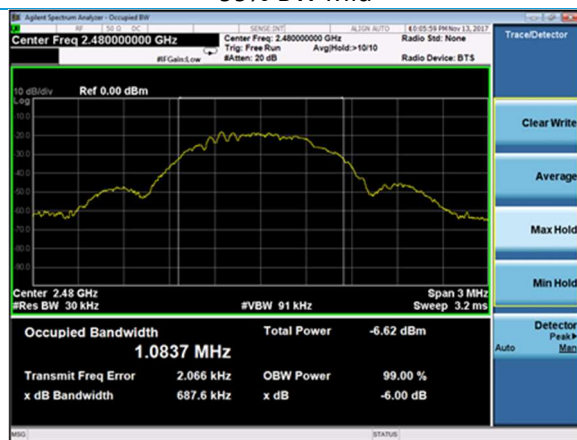
6 dB BW Low



99% BW Mid



6 dB BW Mid



99% BW High



6 dB BW High

5.1.2 Antenna Port Conducted Emissions – Maximum Conducted Output Power

Operator	Shane Dock
Test Date	11/13/17
Location	Conducted RF Measurement Area
Temp. / R.H.	71/42%
Requirement	15.247 (b) (3)
Method	FCC KDB 558074 D01 DTS Meas Guidance V04, section 9.1.1

Limits:

Maximum Conducted Output Power (watts)	Maximum Conducted Output Power (dBm)
1	30

Test Parameters

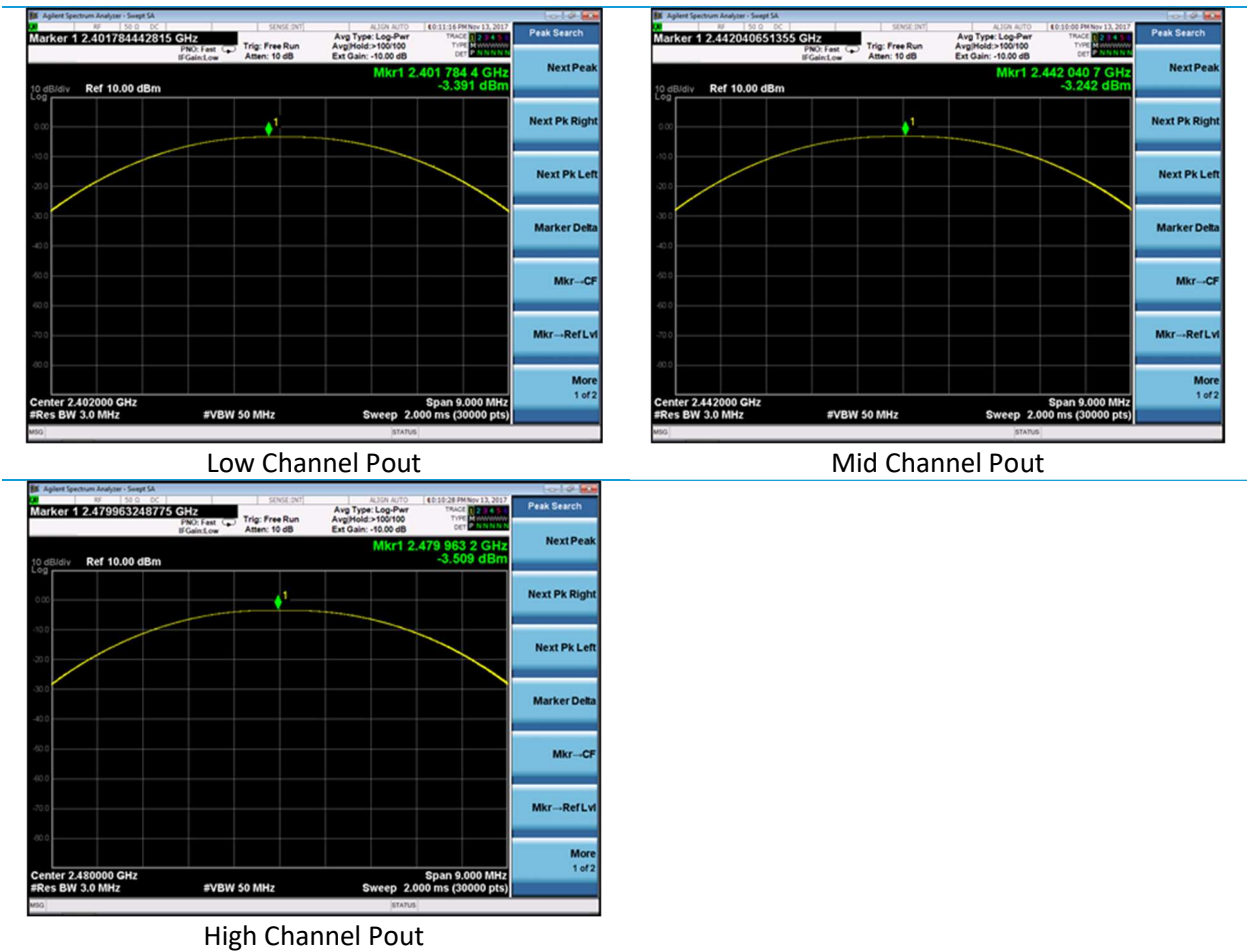
Frequency	2402, 2442, 2480 MHz
RBW	3 MHz

Table

Channel	Low	Mid	High
Pout Conducted (dBm)	-3.391	-3.242	-3.509

Worst Case Margin = 30.000 dBm – (–3.242dBm) = 33.242 dB

Plots



5.1.3 Antenna Port Conducted Emissions – RF Spurious Emissions

Operator	Shane Dock
Test Date	11/13/17
Location	Conducted RF Measurement Area
Temp. / R.H.	71/42%
Requirement	15.247 (d)
Method	FCC KDB 558074 D01 DTS Meas Guidance V04, section 11

Limits:

RF Spurious Limit

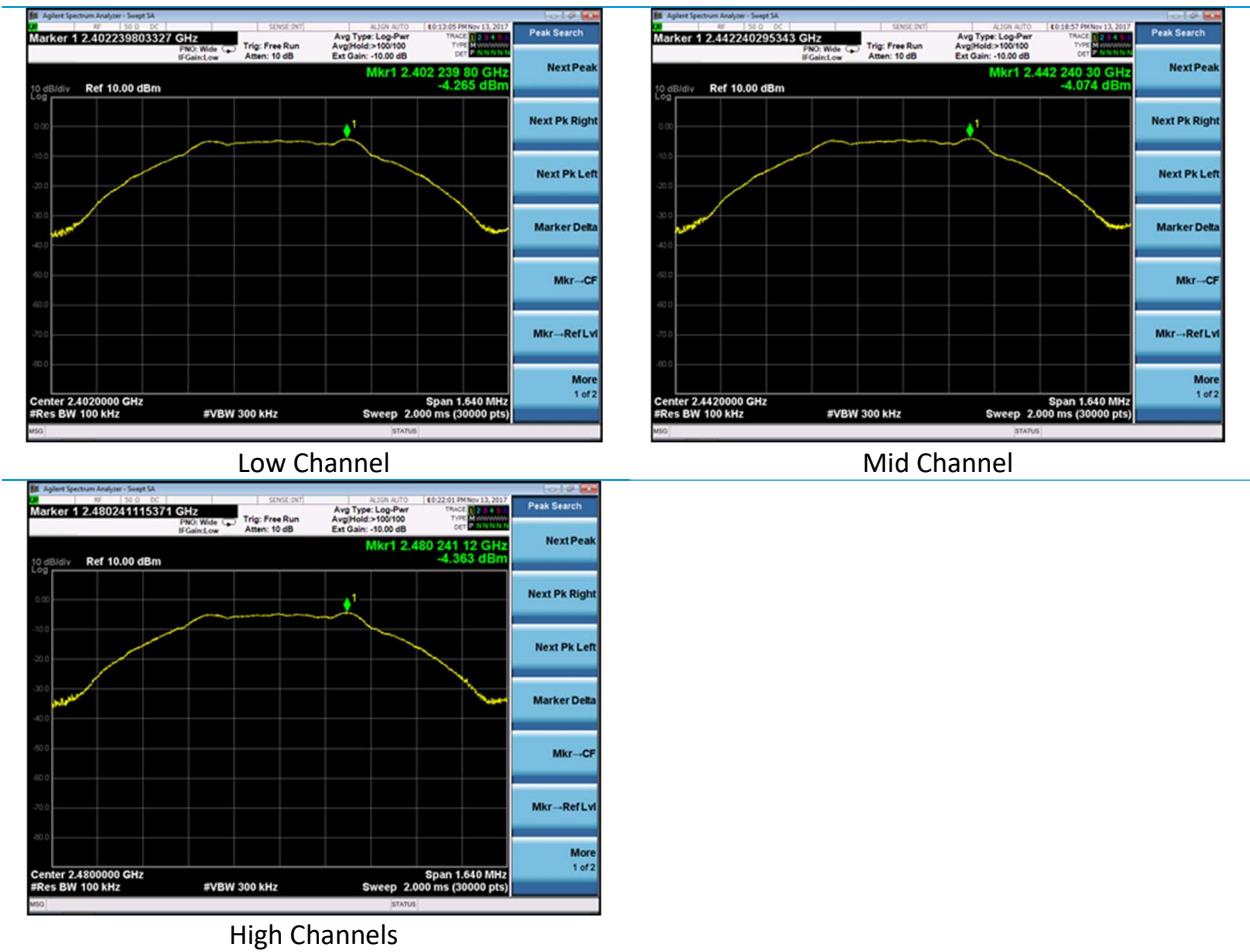
20 dBc

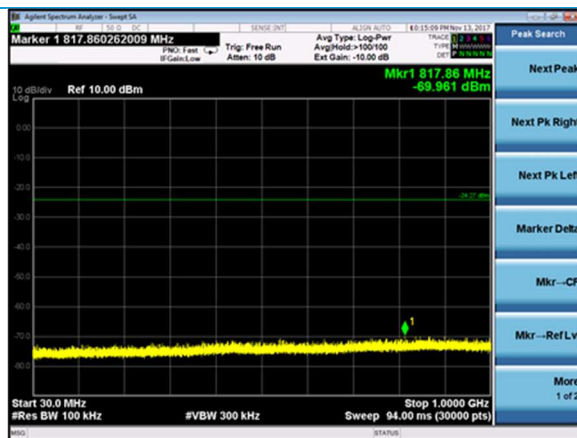
Test Parameters

Frequency	30-25000 MHz
Settings	2402, 2442, 2480 MHz Channels
RBW	100 kHz
VBW	300 kHz
Trace	Max Hold
Detector	Peak
Note	All emissions are >25 dB below the limit.

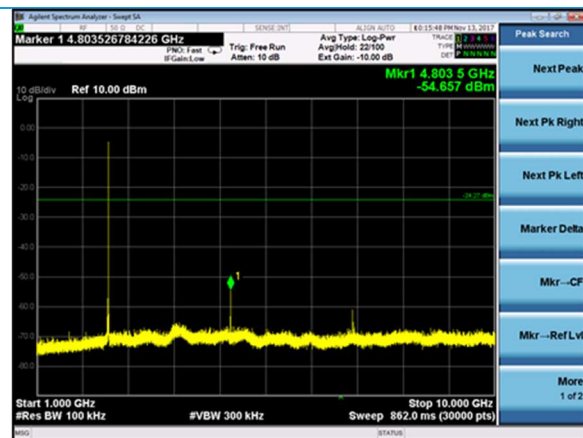
Plots

Reference Levels (Worst-Case Shown)

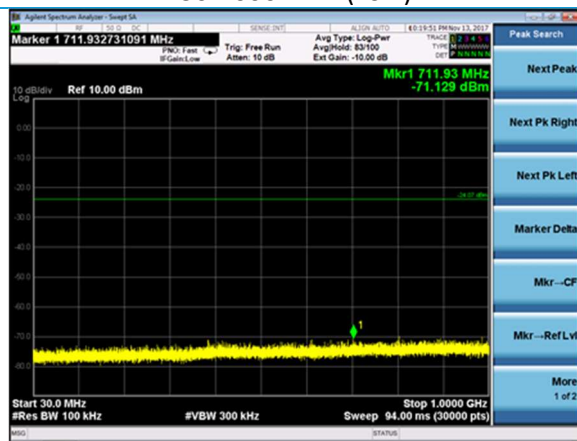




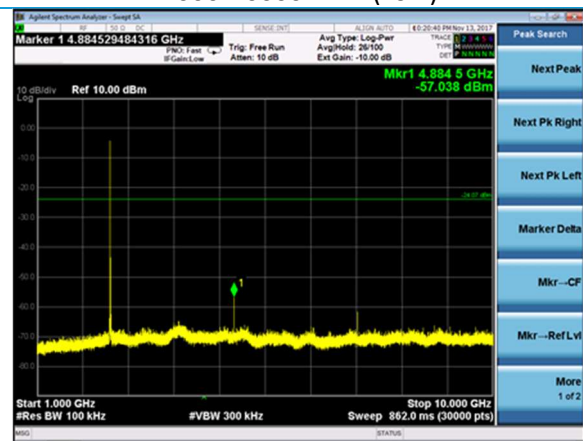
30-1000 MHz (Low)



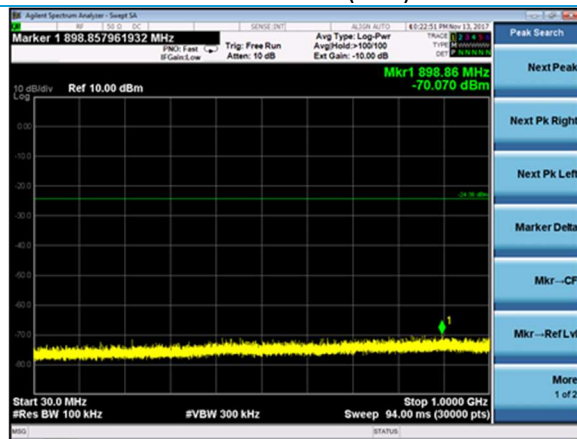
1000-10000 MHz (Low)



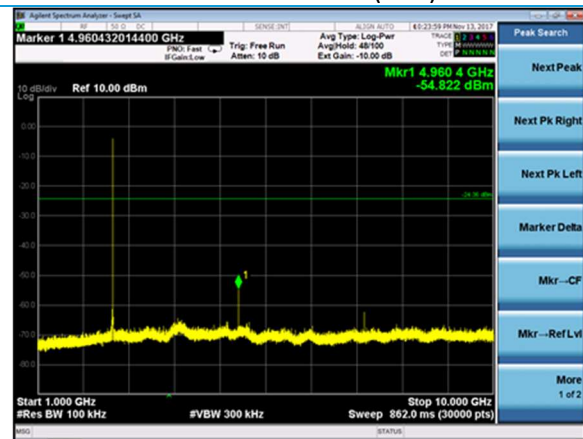
30-1000 MHz (Mid)



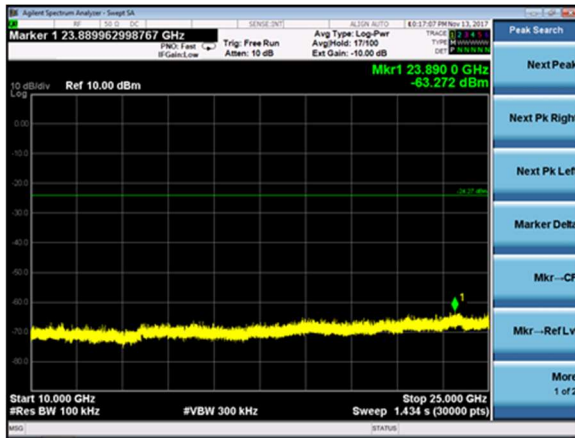
1000-10000 MHz (Mid)



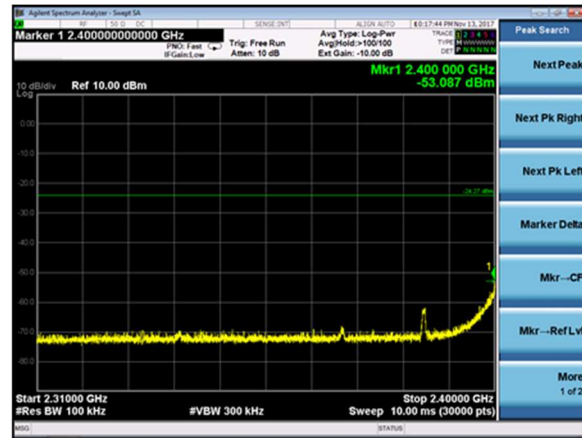
30-1000 MHz (High)



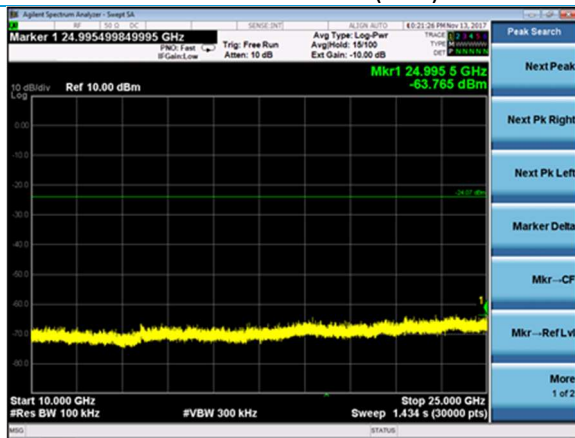
1000-10000 MHz (High)



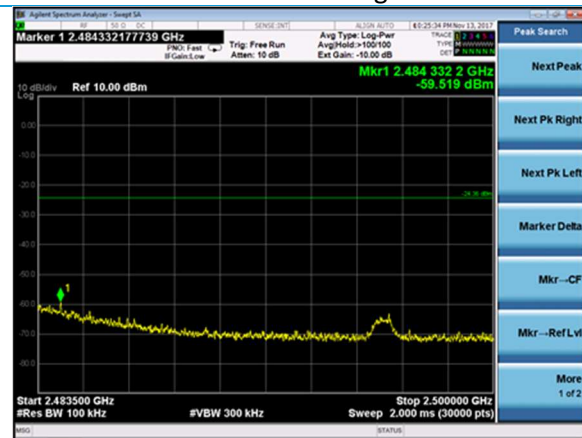
10000-25000 MHz (Low)



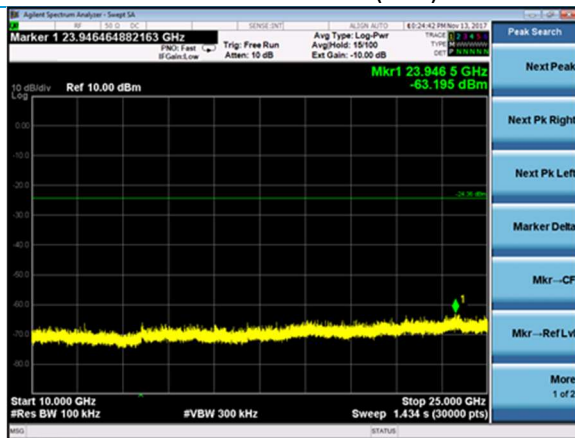
Lower Band Edge



10000-25000 MHz (Mid)



Upper Band Edge



10000-25000 MHz (High)

5.1.4 Antenna Port Conducted Emissions – Power Spectral Density

Operator	Shane Dock
Test Date	11/13/17
Location	Conducted RF Measurement Area
Temp. / R.H.	71/42%
Requirement	15.247 (e)
Method	FCC KDB 558074 D01 DTS Meas Guidance V04, Section 10.2

Limits:

PSD (dBm/3 kHz)
< 8

Test Parameters

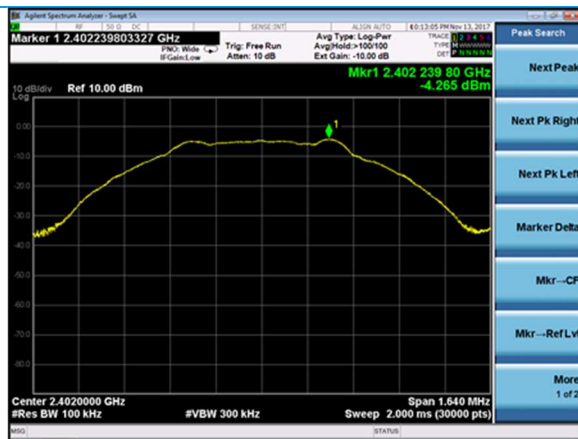
Frequency	2402, 2442, 2480 MHz
RBW	100kHz
VBW	300kHz
Trace	Max Hold
Detector	Peak

Table

Channel	Low	Mid	High
PSD (dBm)	-4.265	-4.074	-4.363

Worst Case Margin = 8.000 dBm – (-4.074dBm) = 12.074 dB

Plots



Low Channel



Mid Channel



High Channels

5.1.5 Antenna Port Conducted Emissions – Frequency Stability

Operator	Shane Dock
Test Date	11/13/17
Location	Conducted RF Measurement Area
Temp. / R.H.	71/42%
Requirement	FCC: 2.1055 (d) IC: RSS-GEN 6.11
Method	ANSI C63.10 Section 6.8

Test Parameters

Frequency	2402, 2442, 2480 MHz
Channels	Low, Mid, High
Frequencies (Nominal)	2402, 2440, 2480 Mhz
Voltages	2.55, 3.00, and 3.10 VDC

Table (Values below listed in Hz at the given voltages)

Channel	2.55 VDC	3.00 VDC	3.10 VDC	Deviation (Hz)
Low	2401991608	2401993841	2401993675	2233
Mid	2441995142	2441994725	2441993941	1201
High	2479995942	2479994741	2479993591	2351

5.2 Radiated Emissions

Description of Measurement	<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>
Example Calculations	<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



5.2.1 Radiated Emissions

Operator	Shane Dock
Test Date	11/2/17 – 11/9/17
Location	Chamber 5
Temp. / R.H.	70/60%
Requirement	FCC: 15.247 (d) IC: RSS-GEN 8.10
Method	ANSI C63.10 Sections 6.5 and 6.6

Limits:

	30-88 MHz	88-216 MHz	216 – 960 MHz	960+ MHz
Field Strength ($\mu\text{V}/\text{m}$)	100	150	200	500
Field Strength ($\text{dB}\mu\text{V}/\text{m}$)	40.0	43.5	46.0	54.0

Test Parameters

Frequency	30-25000
Distance	3M
Settings	Unit tested at Low, Mid, High Channels
Settings	RBW = 120kHz, VBW 1.2 MHz (<1 GHz) RBW = 1 MHz, VBW = 3 MHz (>1 GHz)
Notes	Measurements taken in restricted bands. For measurements above 1 GHz, antenna used with a tilt gear to keep EUT within the cone of radiation. Absorbers were also added to the floor of the chamber while measuring emissions above 1 GHz.
Example Calculation	Limit ($\text{dB}\mu\text{V}$) = $20 * \text{Log}[\text{Limit } (\mu\text{V})]$ $40 = 20 * \text{log}(100)$ Raw Data + Antenna Factor + Cable Factor = Reported Data $19.77 \text{ dB}\mu\text{V} + 12.50 \text{ dB/m} + 0.93 \text{ dB} = 33.20 \text{ dB}\mu\text{V/m}$

Instrumentation



Date : 3-Nov-2017

Test : Tx Spurious Emissions

Job : C-2837

PE : Shane Dock

Customer : Plexus

Quote : 317245

No.	Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due Date	Equipment Status
1	EE 960085	Analyzer - EMI Receiver	Agilent	N9038A	MY 51210148	5/12/2017	5/12/2018	Active Calibration
2	AA 960174	Antenna - Small Horn	ETS Lindgren	3116C-PA	00206880	5/1/2017	5/1/2018	Active Calibration
3	AA 960007	Double Ridge Horn Antenna	EMCO	3115	9311-4138	8/30/2017	8/30/2018	Active Calibration
4	AA 960171	Cable - low loss 6m	A.H. Systems, Inc	SAC-26G-6	386	3/31/2016	12/11/2017	Active Verification
5	AA 960153	Filter - High Pass 2.4 GHz	KWM	HPF-L-14186	7272-04	5/2/2017	5/2/2018	Active Calibration
6	AA 960158	Antenna - Double Ridge Horn	ETS Lindgren	3117	109300	4/12/2017	4/12/2018	Active Calibration
7	AA 960150	Antenna - Biconical	ETS Lindgren	3110B	0003-3346	3/3/2017	3/3/2018	Active Calibration
8	AA 960163	Antenna - Log Periodic	A.H. Systems, Inc	SAS-512-2	500	3/28/2017	3/28/2018	Active Calibration

Table

Frequency (MHz)	Height (Cm)	Azimuth (degree)	Peak Reading (dBμV/m)	Average Reading (dBμV/m)	Peak Limit (dBμV/m)	Average Limit (dBμV/m)	Peak Margin (dBμV/m)	Average Margin (dB)	Antenna Polarity	EUT orientation
4804.00	120.85	198.25	41.5	32.0	74.0	54.0	32.5	22.0	H	V
4804.00	183.00	12.25	41.3	31.1	74.0	54.0	32.7	22.9	V	V
4804.00	212.38	41.50	42.6	31.6	74.0	54.0	31.4	22.4	H	H
4804.00	155.42	161.50	41.7	31.7	74.0	54.0	32.3	22.3	V	H
4804.00	196.90	198.25	41.9	32.1	74.0	54.0	32.1	21.9	H	F
4804.00	319.47	158.75	40.6	30.5	74.0	54.0	33.4	23.5	V	F
4884.00	135.66	198.00	40.8	30.8	74.0	54.0	33.2	23.2	H	F
4960.00	274.04	95.50	41.2	30.7	74.0	54.0	32.8	23.3	H	F

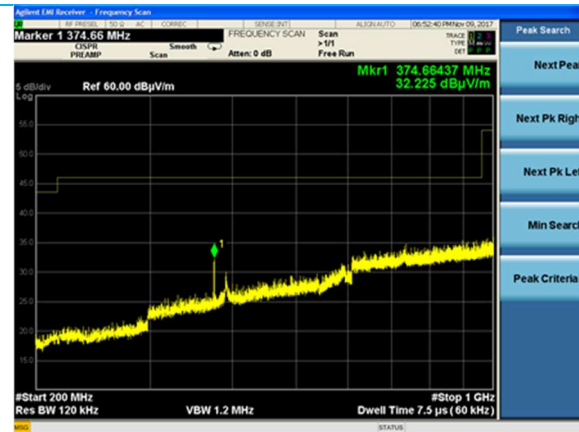
Frequency (MHz)	Height (Cm)	Azimuth (degree)	Quasi Peak Reading (dBμV/m)	Quasi Peak Limit (dBμV/m)	Quasi Peak Margin (dBμV/m)	Antenna Polarity	EUT orientation
102.93	100.23	0.00	18.6	43.5	24.9	V	V
63.69	100.00	200.25	22.5	43.5	21.0	V	V
390.43	100.00	0.00	23.8	46.0	22.2	H	V
374.66	100.00	183.50	30.0	46.0	16.0	V	V

***Note: Emission at 102.93 MHz is not a function of the EUT.**

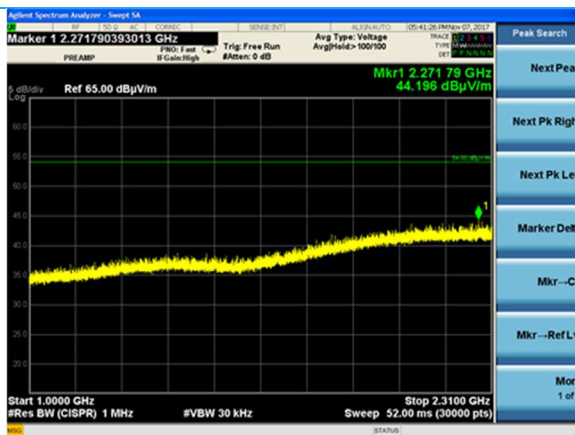
Plots (Worst-Case Shown)



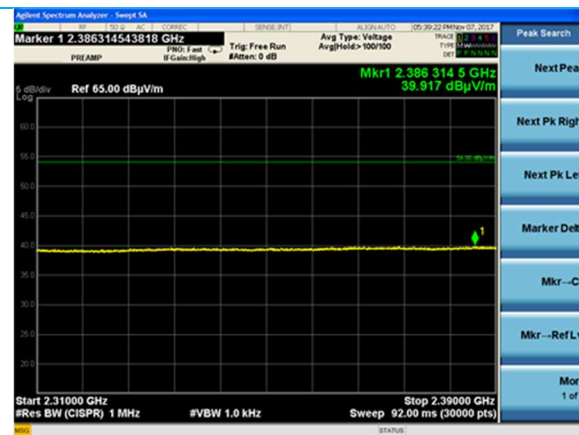
30 – 200 MHz



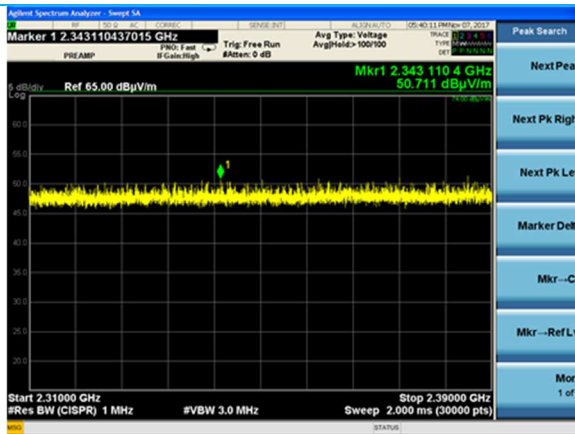
200 – 1000 MHz



1 – 2.31 GHz



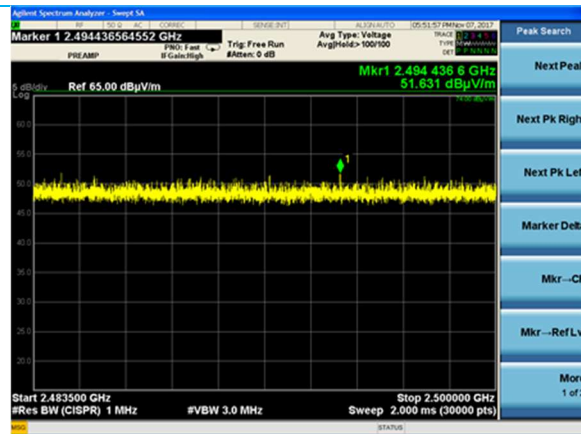
Lower Band Edge (Average)



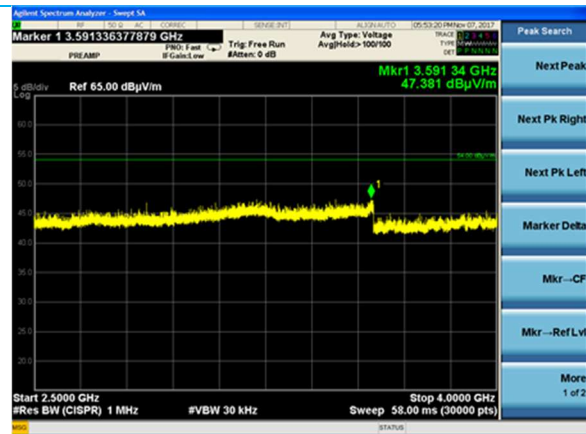
Lower Band Edge (Peak)



Upper Band Edge (Average)



Upper Band Edge (Peak)



2.5 – 4 GHz



4 – 18 GHz



18 – 25 GHz

6 REVISION HISTORY

Version	Date	Notes	Person
V0	11/20/17	First Draft	Shane Dock
V1	11/29/17	Revised Draft	Shane Dock
V2	1/9/18	Final Draft	Shane Dock
V3	2/27/18	Updated Draft	Shane Dock

END OF REPORT