

Athena GTX, Inc.

WVSM Pro

FCC 1.1307:2024

WVSM Pro (BLE): BMD 300 module

WVSM Pro (BLE): BMD 340 module

WVSM Pro (BLE): BMD 341 module

WVSM Pro (WFD): b/g/n WVSM Pro (Xbee): b/g/n

Report: AGTX0059.6 Rev. 1, Issue Date: May 22, 2024

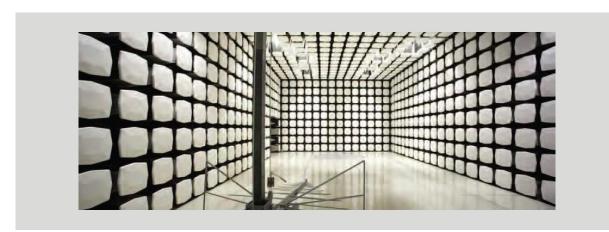


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CERTIFICATE OF EVALUATION



Last Date of Evaluation: May 22, 2024 Athena GTX, Inc. EUT: WVSM Pro

RF Exposure Evaluation

Standards

Specification	Method
FCC 1.1307:2024	FCC 1.1307:2024

Results

Method Clause	Description		Results	Comments
(b)(3)(ii)(B)	Exemption From RF Exposure Evaluation	Yes	Pass	None

Deviations From Evaluation Standards

None

Approved By:

Donald Facteau, Process Architect

Product compliance is the responsibility of the client; therefore, the tests and equipment modes of operation represented in this report were agreed upon by the client, prior to testing. The results of this test pertain only to the sample(s) tested. The specific description is noted in each of the individual sections of the test report supporting this certificate of test. This report reflects only those tests from the referenced standards shown in the certificate of test. It does not include inspection or verification of labels, identification, marking or user information. As indicated in the Statement of Work sent with the quotation, Element's standard process is to always use the latest published version of the test methods even when earlier versions are cited in the test specification. Issuance of a purchase order was de facto acceptance of this approach. Otherwise, the client would have advised Element in writing of the specific version of the test methods they wanted applied to the subject testing

REVISION HISTORY



Revision Number	Description	Date (yyyy-mm-dd)	Page Number
	Corrected errors in table headers	2024-05-22	11
01	Recalculated assessment with 0dB tolerance for WiFi radios	2024-05-22	11

ACCREDITATIONS AND AUTHORIZATIONS



United States

FCC - Designated by the FCC as a Telecommunications Certification Body (TCB). Certification chambers, Open Area Test Sites, and conducted measurement facilities are listed with the FCC.

A2LA - Each laboratory is accredited by A2LA to ISO / IEC 17025, and as a product certifier to ISO / IEC 17065 which allows Element to certify transmitters to FCC and IC specifications.

Canada

ISED - Recognized by Innovation, Science and Economic Development Canada as a Certification Body (CB) and as a CAB for the acceptance of test data.

European Union

European Commission - Recognized as an EU Notified Body validated for the EMCD and RED Directives.

United Kingdom

BEIS - Recognized by the UK as an Approved Body under the UK Radio Equipment and UK EMC Regulations.

Australia/New Zealand

ACMA - Recognized by ACMA as a CAB for the acceptance of test data.

Korea

MSIT / RRA - Recognized by KCC's RRA as a CAB for the acceptance of test data.

Japan

VCCI - Associate Member of the VCCI. Conducted and radiated measurement facilities are registered.

Taiwan

BSMI – Recognized by BSMI as a CAB for the acceptance of test data.

NCC - Recognized by NCC as a CAB for the acceptance of test data.

Singapore

IDA - Recognized by IDA as a CAB for the acceptance of test data.

Israel

MOC - Recognized by MOC as a CAB for the acceptance of test data.

Hong Kong

OFCA - Recognized by OFCA as a CAB for the acceptance of test data.

Vietnam

MIC - Recognized by MIC as a CAB for the acceptance of test data.

SCOPE

For details on the Scopes of our Accreditations, please visit:

<u>California</u> <u>Minnesota</u> <u>Oregon</u> <u>Texas</u> <u>Washington</u>

FACILITIES

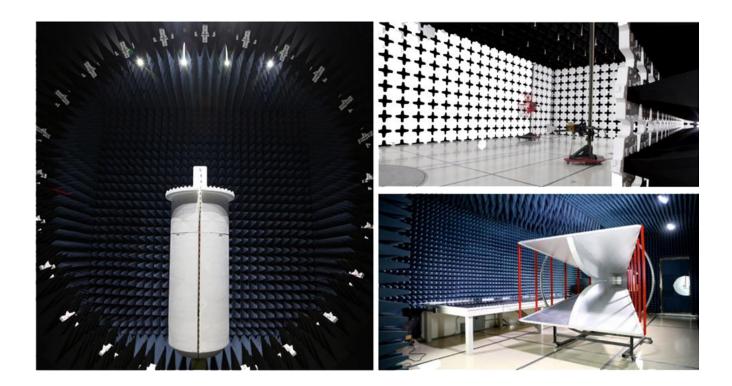


Testing was performed at the following location(s)

Location	Labs (1)	Address	A2LA (2)	ISED (3)	BSMI (4)	VCCI (5)	CAB (6)	FDA (7)
California	OC01-17	41 Tesla Irvine, CA 92618 (949) 861-8918	3310.04	2834B	SL2-IN-E-1154R	A-0029	US0158	TL-55
Minnesota	MN01-11	9349 W Broadway Ave. Brooklyn Park, MN 55445 (612) 638-5136	3310.05	2834E	SL2-IN-E-1152R	A-0109	US0175	TL-57
Oregon	EV01-12	6775 NE Evergreen Pkwy #400 Hillsboro, OR 97124 (503) 844-4066	3310.02	2834D	SL2-IN-E-1017	A-0108	US0017	TL-56
Texas	TX01-09	3801 E Plano Pkwy Plano, TX 75074 (469) 304-5255	3310.03	2834G	SL2-IN-E-1158R	A-0201	US0191	TL-54
Washington	NC01-05	19201 120th Ave NE Bothell, WA 98011 (425) 984-6600	3310.06	2834F	SL2-IN-E-1153R	A-0110	US0157	TL-67
Offsite	N/A	See Product Description	N/A	N/A	N/A	N/A	N/A	N/A

See data sheets for specific labs

- The lab designations denote individual rooms within each location. (OC01, OC02, OC03, etc.)
 A2LA Certificate No.
 ISED Company No.
 BSMI No.
 VCCI Site Filing No.
 CAB Identifier. Recognized Phase I CAB for ISED, ACMA, BSMI, IDA, KCC/RRA, MIC, MOC, NCC, OFCA FDA ASCA No. (1) (2) (3) (4) (5) (6) (7)



PRODUCT DESCRIPTION



Client and Equipment Under Evaluation Information

Company Name:	Athena GTX, Inc.
Address:	5900 NW 86th Street Suite 300
City, State, Zip:	Johnston, IA 50131
Evaluation Requested By:	Cesar Gradilla
EUT:	WVSM Pro
Date of Evaluation:	5/22/2024

Information Provided by the Party Requesting the Evaluation

Functional Description of the Equipment:

WVSM Pro is intended to be used as an adult, pediatric, and neonatal patient vital signs measuring instrument for single measurement spot checking or continuous monitoring from point of injury through transport to an emergency department and into surgery / sedation applications. It is indicated for individual or simultaneous measurement of SpO2, EtCO2, respiration rate, heart rate, 12 lead ECG, temperature, NIBP, as well as for the display of ECG, Plethysmograph, and Capnography waveforms. WVSM Pro is intended for use in pre-hospital, emergency room, inpatient care facilities, healthcare facilities, emergency medical applications, during transport, outpatient care, and other related healthcare scenarios. The WVSM Pro provides display capability and will also have provision for wired and wireless communications to a PC, laptop, tablet, or smartphone. The patient monitor is intended to be used by trained healthcare providers by prescription only.

Objective:

To demonstrate compliance with FCC Requirements for RF exposure for 1.1307 RF exempt devices

RF EXPOSURE CONDITION



The following RF Exposure conditions were used for the assessment documented in this report:								
Intended Use	Portable							
Location on Body (if applicable)	Head/Torso							
How is the Device Used	Device is used at a distance less than 20cm from the user							
Radios Contained in the Same Host Device	WVSM Pro (BLE): BMD 300 module							
	WVSM Pro (BLE): BMD 340 module							
	WVSM Pro (BLE): BMD 341 module							
	WVSM Pro (WFD): b/g/n							
	WVSM Pro (Xbee): b/g/n							
Simultaneous Transmitting Radios	None							
Body Worn Accessories	n/a							
Environment	General Population/Uncontrolled Exposure							

EXEMPTION FROM RF EXPOSURE EVALUATION



OVERVIEW

Section 1.3 of KDB 44798 D04 v01 states that, "Under the new rules, all radio services and operations are subject to Routine Evaluation [§§ 1.1307(b)(1), 2.1033(f), etc.], unless shown to qualify under the exemptions provided in the rules and OET Lab policies for equipment authorization."

The glossary of KDB 447498 D04 v01 specifies that an exempt RF device is defined "solely from the obligation to perform a routine environmental evaluation to demonstrate compliance with the RF exposure limits in § 1.1310; it is not exemption from the equipment authorization procedures described in 47 CFR Part 2, not exemption from general obligations of compliance with the RF exposure limits in § 1.1310 of this chapter, and not exemption from determination of whether there is no significant effect on the quality of the human environment under § 1.1306." Compliance with the exemption criteria defined in 1.1307(b) confirm compliance with the limits in § 1.1310.

COMPLIANCE WITH FCC 1.1310

Where

And

Per 1.1307(b)(3), (i) For single RF sources (*i.e.*, any single fixed RF source, mobile device, or portable device, as defined in paragraph (b)(2) of this section): A single RF source is exempt if:

- (A) The available maximum time-averaged power is no more than 1 mW, regardless of separation distance. This exemption may not be used in conjunction with other exemption criteria other than those in paragraph (b)(3)(ii)(A) of this section. Medical implant devices may only use this exemption and that in paragraph (b)(3)(ii)(A):
- (B) Or the available maximum time-averaged power or effective radiated power (ERP), whichever is greater, is less than or equal to the threshold *P*_{th} (mW) described in the following formula. This method shall only be used at separation distances (cm) from 0.5 cm to 40 cm and at frequencies from 0.3 GHz to 6 GHz (inclusive). *P*_{th} is given by:

$$P_{th}(mW) = \begin{cases} ERP_{20 cm} (d/20 cm)^{x} & d \le 20 cm \\ ERP_{20 cm} & 20 cm < d \le 40 cm \end{cases}$$

$$x = -\log_{10} \left(\frac{60}{ERP_{20 cm} \sqrt{f}}\right) \text{ and } f \text{ is in } GHz;$$

$$(2040 f 0.3 GHz \le f \le 1.5 GHz)$$

$$ERP_{20\ cm}(mW) = \begin{cases} 2040f & 0.3\ GHz \le f < 1.5\ GHz \\ 3060 & 1.5\ GHz \le f \le 6\ GHz \end{cases}$$

(C) Or using Table 1 and the minimum separation distance (R in meters) from the body of a nearby person for the frequency (f in MHz) at which the source operates, the ERP (watts) is no more than the calculated value prescribed for that frequency. For the exemption in Table 1 to apply, R must be at least λ/2π, where λ is the free-space operating wavelength in meters. If the ERP of a single RF source is not easily obtained, then the available maximum time-averaged power may be used in lieu of ERP if the physical dimensions of the radiating structure(s) do not exceed the electrical length of λ/4 or if the antenna gain is less than that of a half-wave dipole (1.64 linear value).

Table 1 to §1.1307(b)(3)(i)(C)—Single RF Sources Subject to Routine Environmental Evaluation

RF Source frequency (MHz)	Threshold ERP (watts)
0.3-1.34	1,920 R ² .
1.34-30	3,450 R ² /f ² .
30-300	3.83 R ² .
300-1,500	0.0128 R ² f.
1,500-100,000	19.2R ² .

EXEMPTION FROM RF EXPOSURE EVALUATION



- (ii) For multiple RF sources: Multiple RF sources are exempt if:
- (A) The available maximum time-averaged power of each source is no more than 1 mW and there is a separation distance of two centimeters between any portion of a radiating structure operating and the nearest portion of any other radiating structure in the same device, except if the sum of multiple sources is less than 1 mW during the time-averaging period, in which case they may be treated as a single source (separation is not required). This exemption may not be used in conjunction with other exemption criteria other than those is paragraph (b)(3)(i)(A) of this section. Medical implant devices may only use this exemption and that in paragraph (b)(3)(i)(A).
- (B) in the case of fixed RF sources operating in the same time-averaging period, or of multiple mobile or portable RF sources within a device operating in the same time averaging period, if the sum of the fractional contributions to the applicable thresholds is less than or equal to 1 as indicated in the following equation.

$$\sum_{i=1}^{a} \frac{P_i}{P_{th,i}} + \sum_{j=1}^{b} \frac{ERP_j}{ERP_{th,j}} + \sum_{k=1}^{c} \frac{Evaluated_k}{Exposure\ Limit_k} \le 1$$

Where:

- a = number of fixed, mobile, or portable RF sources claiming exemption using paragraph (b)(3)(i)(B) of this section for P_m , including existing exempt transmitters and those being added.
- b = number of fixed, mobile, or portable RF sources claiming exemption using paragraph (b)(3)(i)(C) of this section for Threshold ERP, including existing exempt transmitters and those being added.
- *c* = number of existing fixed, mobile, or portable RF sources with known evaluation for the specified minimum distance including existing evaluated transmitters.
- P_i = the available maximum time-averaged power or the ERP, whichever is greater, for fixed, mobile, or portable RF source i at a distance between 0.5 cm and 40 cm (inclusive).
- P_{mi} = the exemption threshold power (P_m) according to paragraph (b)(3)(i)(B) of this section for fixed, mobile, or portable RF source i.
- ERP_i = the ERP of fixed, mobile, or portable RF source *j*.
- $ERP_{n,j}$ = exemption threshold ERP for fixed, mobile, or portable RF source j, at a distance of at least $\lambda/2\pi$ according to the applicable formula of paragraph (b)(3)(i)(C) of this section.
- Evaluated_k = the maximum reported SAR or MPE of fixed, mobile, or portable RF source *k* either in the device or at the transmitter site from an existing evaluation at the location of exposure.
- Exposure $Limit_k$ = either the general population/uncontrolled maximum permissible exposure (MPE) or specific absorption rate (SAR) limit for each fixed, mobile, or portable RF source k, as applicable from §1.1310

The relationship between EIRP and ERP is:

$$ERP(dBm) = EIRP(dBm) - 2.14 dB$$

Where EIRP is the sum of the conducted power (dBm) and the antenna gain (dBi).

EXEMPTION FROM RF EXPOSURE EVALUATION



ASSESSMENT

The exemption from RF exposure evaluation is summarized in the following table(s):

Radio	Transmit Frequency (MHz)	Conducted Output Power	Power Tolerance (dB)	Duty Cycle	Antenna Assembly Gain (dBi)	Minimum Separation Distance (cm)	Calculated Radiated Exposure Power (mW) ERP	Calculated Conducted Exposure Power (mW)	Limit (mW)	Compliant
WVSM Pro (Xbee): n	2412	28.75 dBm	0.0	13.0%	1.5	5.3	83.7	97.2	245.8	Yes
WVSM Pro (Xbee): g	2412	28.52 dBm	0.0	14.0%	1.5	5.3	86.0	99.9	245.8	Yes
WVSM Pro (Xbee): b	2412	26.81 dBm	0.0	3.5%	1.5	5.3	14.6	17.0	245.8	Yes

The information in the table above was obtained from:

The rated value was used in these calculations. The maximum output (worst-case) rated value was used in these calculations. FCC ID: 2AVRK-XBS6BTH

Radio	Transmit Frequency (MHz)	Conducted Output Power	Power Tolerance (dB)	Duty Cycle	Antenna Assembly Gain (dBi)	Minimum Separation Distance (cm)	Calculated Radiated Exposure Power (mW) ERP	Calculated Conducted Exposure Power (mW)	Limit (mW)	Compliant
WVSM Pro (WFD): n	2412	17.3 dBm	0.0	0.9%	-0.2	5	0.3	0.5	220.1	Yes
WVSM Pro (WFD): g	2412	17.3 dBm	0.0	1.0%	-0.2	5	0.3	0.5	220.1	Yes
WVSM Pro (WFD): b	2412	18 dBm	0.0	6.1%	-0.2	5	2.3	3.9	220.1	Yes

The information in the table above was obtained from:

The rated value was used in these calculations. The maximum output (worst-case) rated value was used in these calculations. FCC ID: 2AVRK-CC3200WFD

Radio	Transmit Frequency (MHz)	Conducted Output Power	Power Tolerance (dB)	Duty Cycle	Antenna Assembly Gain (dBi)	Minimum Separation Distance (cm)	Calculated Radiated Exposure Power (mW) ERP	Calculated Conducted Exposure Power (mW)	Limit (mW)	Compliant
WVSM Pro (BLE): BMD 341 module	2402	11 dBm	0.0	100.0%	-1	5	6.1	12.6	220.3	Yes
WVSM Pro (BLE): BMD 340 module	2402	8 dBm	0.0	100.0%	-1	5	3.1	6.3	220.3	Yes
WVSM Pro (BLE): BMD 300 module	2402	4 dBm	0.0	100.0%	-1	5	1.2	2.5	220.3	Yes

The information in the table above was obtained from:

The rated value was used in these calculations. The maximum output (worst-case) rated value was used in these calculations. FCC ID: 2AVRK-2AA9B04

Evaluator: Chuck Heller

Addendum to the RF Exposure Report Information

WVSM Pro is a multi-parameter vital sign monitor that measures electrocardiogram (ECG), Heart Rate (HR), Pulse-OX (SpO2/PR), capnography (etCO2, FiCO2, RR), blood pressure (NIBP) and temperature. HsPro can be attached to the blood pressure cuff on the patient or to an IV pole.

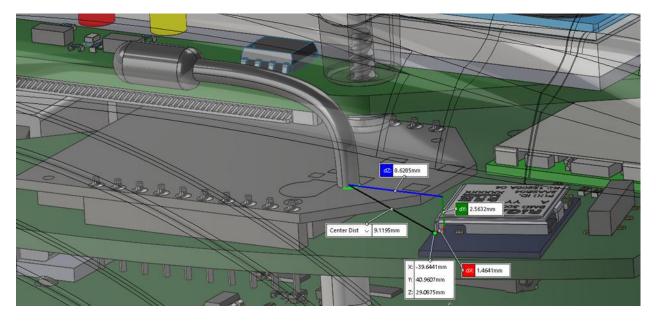
WVSM Pro connects to applicable companion software called the Athena Device Management Suite (ADMS) on a PC, Android, or iOS device via wireless radio communications: WiFi (802.11) or Bluetooth Low energy (BLE).

NOTE Only a single radio module is transmitting at a time.

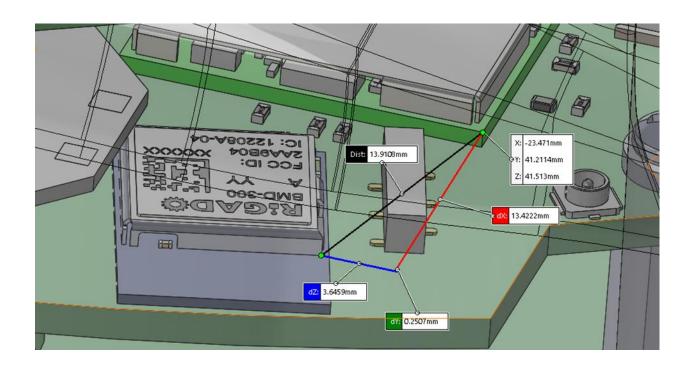
Maximum dimensions are: 2.75" x 4.45" x 5.9"

Co-location Separation

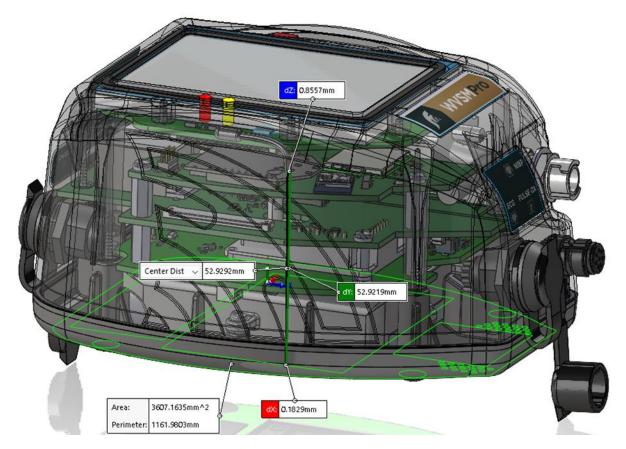
Xbee to BLE: 9.12 mm



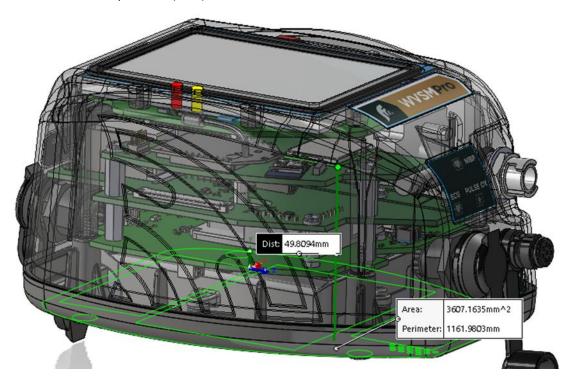
CC3200 to BLE: 13.91 mm



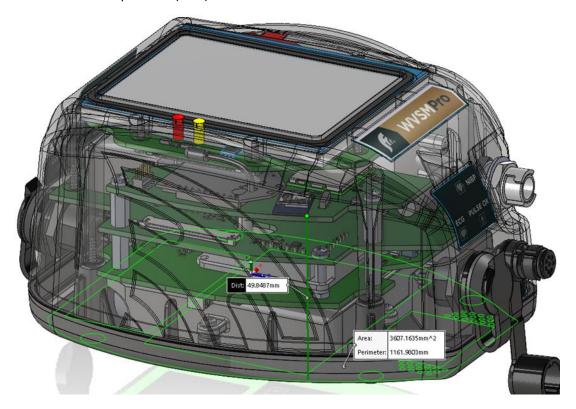
Antenna – Skin Separation (Arm): XBEE: 52.93 mm



Antenna – Skin Separation (Arm): CC3200: 49.81 mm



Antenna – Skin Separation (Arm): BLE: 49.85 mm



Calculations of WVSM Pro duty cycles:

WVSM Pro transmits multiple packets every 1 second and can be a combination of Live and Historical data. A data transmission duty cycle analysis was completed and is fully documented in Athena test report: 230-0008-02R WVSM Pro RF Wireless Technology Test Report Rev 2 with Results. The relevant results are summarized below.

AP and AdHoc Modes (Xbee Module):

Bytes/Sec	bits/Byte	Xbee Minimum (bits/sec)	Sec	Duty Cycle	/Sec	Typical Power (dBm)	FCC Peak (dBm)
4431	8	1000000	35.4E-3	3.545%	b	16	26.81
105300	8	6000000	140.4E-3	14.040%	g	16	28.52
105300	8	6500000	129.6E-3	12.960%	n	15	28.75

WFD Mode (CC3200 Module):

Bytes/Sec	bits/Byte	CC3200 Minimum (bits/sec)	Sec	Duty Cycle/Sec		Typical Power (dBm)	FCC Peak (dBm)
7659	8	1000000	61.3E-3	6.127%	b	16	18
7659	8	6000000	10.2E-3	1.021%	g	16	17.3
7659	8	6500000	9.4E-3	0.943%	n	15	17.3
* Data rate stays the same since in WFD mode - we do not use AP mode for this radio							

BLE Mode (BLE Module):

We are assuming 100% duty cycle for this mode with a FCC Peak output of

- 4 dBm for the BMD 300 module
- 8 dBm for the BMD 340 module
- 11 dBm for the BMD 341 module

SAR Test Exclusion Threshold Calculation

SAR Exclusion Limits (per KDB 447498 D04 Interim General RF Exposure Guidance v01 pg. 39-40)

- Wi-Fi (Xbee) Distance is 53 mm
- Wi-Fi (WFD) Distance is 50 mm
- BLE Distance is 50 mm

ERP20cm 3060 mW	I ERPZUCI	3060	l mW		
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d	5	cm	50	mm	
F	2.45	GHz			
х	1.902153218				
Pth (d<=20cm)	219.03	mW	WiFi Limit 1-g Head/Torso		
2.5	547.58		WiFi Limit 10-g Limb		

	Antenna	Max				
	(dBi)	dBm	mW	Duty Cycle *	mW	Pass/Fail
WVSM Pro (Xbee)	1.5	26.81	479.7	3.545%	17.01	Pass
	1.5	28.52	711.2	14.040%	99.85	Pass
	1.5	28.75	749.9	12.960%	97.19	Pass
WVSM Pro (WFD)	-0.2	18	63.1	6.127%	3.87	Pass
	-0.2	17.3	53.7	1.021%	0.55	Pass
	-0.2	17.3	53.7	0.943%	0.51	Pass
WVSM Pro (BLE)	-1	4	2.5	100.000%	2.512	Pass
	-1	8	6.3	100.000%	6.31	Pass
	2.5	11	12.6	100.000%	12.59	Pass

^{*} at Minimum Tx data rate of b= 1 Mbps, g = 6 Mbps and n = 6.5 Mbps



End of Test Report