Electromagnetic Compatibility
Test Report

Tested to FCC Part 15C & RSS-210 Issue 9

On

VERASENSE for Zimmer Biomet Persona

Model: CR C-D/3-9 LEFT, ZBH-PSNCRCD39-L, CR G-H/7-12 Left, ZBH-PSNCRGH712-L

ORTHOSENSOR®

1855 Griffin Rd, St A-310

Dania Beach, FL 33044-2401 USA

Prepared by:

TUV Rheinland of North America, Inc.

Client:	OrthoSensor 1855 Griffin Rd, St A-310 Dania Beach, FL 33044-2401 USA	Joshua Gardner Ph: (954) 577-7770 Fax: (954) 790-6744 joshua.gardner@orthosensor.com	
Identification:	VERASENSE for Zimmer Biomet Persona	***Serial No.:***	247020019, 247020021, 247020026, 247020027, 247020030, 247020096, 247020160, 247020256
Test item:	Model: CR C-D/3-9 LEFT, ZBH-PSNCRCD39-L, CR G-H/7-12 Left, ZBH-PSNCRGH712-L	***Date tested:***	06 December 2017
Testing location:	TUV Rheinland of North America 762 Park Avenue Youngsville, NC 27596-9470 U.S.A.	Tel: (919) 554-3668 Fax: (919) 554-3542	
Test specification:	**Emissions:** FCC Part 15, Subpart C, RSS-210 Issue 9: FCC Parts 15.207(a):2017 and RSS-GEN I4 clause 8.8, FCC Parts 15.249(d), 15.209, 15.215(c), RSS-210 I9 clause B.10, RSS-GEN I4 clauses 8.9 and 8.10, FCC Part 15.249:2017 and RSS-210 Annex B.10, FCC Parts 15.249(a):2017, 15.249(c):2017, RSS-210 B.10(a), FCC Part 2.1093:2017 and RSS-102, Issue 4		
Test Result	**The above product was found to be Compliant to the above test standard(s)**		
tested by: Mark Ryan		***reviewed by:*** David Spencer	
13 June 2018 ***Signature***		13 June 2018 ***Signature***	
Other Aspects:	**None**		

Abbreviations: OK, Pass, Compliant, Complies = passed
Fail, Not Compliant, Does Not Comply = failed
N/A = not applicable

FC	ilac-MRA A2LA ACCREDITED	ISED Canada
90552 and 100881	**Testing Cert #3331.05**	**2932H-1 and 2932H-2**

TABLE OF CONTENTS

1 General Information

1.1 Scope

This report is intended to document the status of conformance with the requirements of the standard(s), based on the results of testing performed on 06 December 2017 on the VERASENSE for Zimmer Biomet Persona, Model No. CR C-D/3-9 LEFT, ZBH-PSNCRCD39-L, CR G-H/7-12 Left, ZBH-PSNCRGH712-L, manufactured by OrthoSensor This report only applies to the specific samples tested under the stated test conditions. It is the responsibility of the manufacturer to assure that additional production units of this model are manufactured with identical or EMI equivalent electrical and mechanical components. This report is further intended to document changes and modifications to the EUT throughout its life cycle. All documentation will be included as a supplement.

1.2 Purpose

Testing was performed to evaluate the EMC performance of the EUT (Equipment Under Test) in accordance with the applicable requirements, procedures, and criteria defined in the application of regulations and application of standards listed in this report.

1.3 Revision History

Rev.	Date	Description of Revision
.001	12June2018	Initial Release

1.1 *Summary of Test Results*

Applicant	OrthoSensor 1855 Griffin Rd, St A-310 Dania Beach, FL 33044-2401 USA	**Tel**	(954) 577-7770	**Contact**	Joshua Gardner
		Fax	(954) 790-6744	**e-mail**	joshua.gardner@orthosensor.com

Description	VERASENSE for Zimmer Biomet Persona	**Model**	CR C-D/3-9 LEFT, ZBH-PSNCRCD39-L and CR G-H/7-12 LEFT, ZBH-PSNCRGH712-L
Serial Number	247020019, 247020021, 247020026, 247020027, 247020030, 247020096, 247020160, 247020256	**Test Voltage/Freq.**	3 V DC Lithium battery
Test Date Completed:	06 December 2017	**Test Engineer**	Mark Ryan

Standards	Description	Severity Level or Limit	Worst-case Values	Test Result
FCC Part 15, Subpart C Standard	Radio Frequency Devices-Subpart C: Intentional Radiators	See called out parts below	See Below	**Complies**
RSS-210 Issue 9 Standard	Low-Power Licence-exempt Radiocommunication Devices Category I Equipment	See called out parts below	See Below	**Complies**
FCC Part 15.249:2017 and RSS-210 Annex B.10	Operation within the band 2400 to 2483.5 MHz	See called out parts below	See Below	Complies
FCC Parts 15.249(a):2017, 15.249(c):2017, RSS-210 B.10(a)	Radiated Output Power for Fundamental and Harmonic Frequencies	Fund: Shall not exceed 50 mV/m at 3m Harmonics: Shall not exceed 500µV/m (0.5 mV/m) at 3m, (unresticted bands)	Below Limit	Complies
FCC Parts 15.249(d):2017, 15.209, 15.215(c):2017, RSS-210 I9 clause B.10, RSS-GEN I4 clauses 8.9 and 8.10	Out-of-Band Spurious Emissions and Band Edges (EUT in Transmit Mode)	Below the applicable limits	Below Limit	Complies
FCC Parts 15.207(a):2017 and RSS-GEN I4 clause 8.8	Conducted Emissions on AC Mains	NA, The EUT is battery operated only	Below Limit	NA
RSS-GEN I4 clause 6.6	Occupied Bandwidth	99% BW ≤ 0.5% of center freq.	Below Limit	Complies
FCC Part 2.1093:2017 and RSS-102, Issue 4	RF Exposure and Antenna Gain Calulation	SAR or MPE Requirements	Below Limit	Complies

2 Laboratory Information

2.1 Accreditations

2.1.1 US Federal Communications Commission

TUV Rheinland of North America located at 762 Park Avenue, Youngsville, NC 27596-9470 is accredited by the commission for performing testing services for the general public on a fee basis. This laboratory test facilities have been fully described in reports submitted to and accepted by the FCC (Registration No 90552 and 100881). The laboratory scope of accreditation includes: Title 47 CFR Part 15, and 18. The accreditation is updated every 3 years.

2.1.2 ILAC / A2LA

The laboratory has been assessed and accredited by A2LA in accordance with ISO Standard 17025:2005 (Certificate Number: 3331.05, Master Code: 134288). The scope of laboratory accreditation includes emission and immunity testing. The accreditation is updated annually.

2.1.3 Innovation, Science and Economic Development Canada (ISED)

Registration No.: 2932H-1 The OATS has been accepted by ISED to perform testing to 3 and to 10 meters, based on the test procedures described in ANSI C63.4-2014.

Registration No.: 2932H-2 The 5 meter chamber has been accepted by ISED to perform testing to 3 meters, based on the test procedures described in ANSI C63.4-2014.

2.1.4 Japan – VCCI

The Voluntary Control Council for Interference by Information Technology Equipment (VCCI) is a group that consists of Information Technology Equipment (ITE) manufacturers and EMC test laboratories. The purpose of the Council is to take voluntary control measures against electromagnetic interference from Information Technology Equipment, and thereby contribute to the development of a socially beneficial and responsible state of affairs in the realm of Information Technology Equipment in Japan. TUV Rheinland at the 762 Park Ave. Youngsville, N.C 27596 address has been assessed and approved in accordance with the Regulations for Voluntary Control Measures. (Laboratory Registration No: A-0034).

2.1.5 Sample Calculation – radiated & conducted emissions

The field strength is calculated by subtracting the Amplifier Gain and adding the Cable Loss and Antenna Correction Factor to the measured reading. The basic equation is as follows:

Field Strength (dBμV/m) = RAW - AMP + CBL + ACF

Where: RAW = Measured level before correction (dBμV)

AMP = Amplifier Gain (dB)

CBL = Cable Loss (dB)

ACF = Antenna Correction Factor (dB/m)

$$\mu V/m = 10^{\frac{dB\mu V/m}{20}}$$

Sample radiated emissions calculation @ 30 MHz

Measurement +Antenna Factor–Amplifier Gain+Cable loss=Radiated Emissions (dBuV/m)

25 dBuV/m + 17.5 dB – 20 dB + 1.0 dB = 23.5 dBuV/m

2.2 Expanded Measurement Uncertainty

The accumulated measurement uncertainties of the test system in use for the parameters measured were expected not exceed the values given in the following tables.

Per CISPR 16-4-2:2011	U_{95}
Radiated Disturbance @ 3m, 10m	
30 MHz – 1,000 MHz (Horizontal Polarity)	3m = 4.52 dB,
1.0 GHz – 6.0 GHz	3m = 4.25 dB
> 6.0 GHz	3m = 4.93 dB

U_{95}= Expanded Uncertainty.

Note:
Expanded measurement uncertainty numbers are shown in the table above. Compliance criteria are not based on measurement uncertainty. The expanded uncertainty at a level of 95% confidence is obtained by multiplying the combined standard uncertainty by a coverage factor of 2 (U_{96}).

Per ETSI TR 100 028 and ETSI TR 100 273	U_{95}
Frequency Accuracy	
30 MHz – 1000 MHz (Band 1)	1.44 Hz
1.0 GHz – 6.0 GHz (Band 2)	1.78 Hz
> 6.0 GHz (Band 3)	3.13 Hz
Carrier Power Measurement	
Total	1.59 dB
Adjacent Channel Power Measurement	
Total	1.47 dB
Conducted Spurious Emissions Measurement	
Total	4.01 dB
Frequency Deviation Measurement	
Total	1.30 dB
Total Response Measurement	
Total	0.46 dB

U_{95}= Expanded Uncertainty.

Notes: Expanded measurement uncertainty numbers are shown in the table above. The given uncertainty figures are valid to a confidence level of 95 % (k=2), calculated according to the methods described in ETSI TR 100 028 and ETSI TR 100 273.

2.3 Calibration Traceability

All measurement instrumentation is traceable to the National Institute of Standards and Technology (NIST). Measurement method complies with ANSI/NCSL Z540-1-1994 and ISO Standard 17025:2005. Equipment calibration records are kept on file at the test facility.

2.4 Measurement Equipment Used

Equipment	Manufacturer	Model #	Serial/Inst #	Last Cal dd/mm/yy	Next Cal dd/mm/yy
Radiated Emissions (5 Meter Chamber)					
Receiver, EMI	Rohde & Schwarz	ESIB40	100043	08-Aug-17	08-Aug-18
Amplifier, preamp	Agilent Technologies	8449B	3008A01480	11-Aug-17	11-Aug-19
Ant. BiconiLog	Chase	CBL6140A	1108	06-Oct-15	06-Oct-18
Antenna Horn 1-18GHz	EMCO	3115	5770	23-Mar-17	23-Mar-18
Notch Filter: 2.4-2.4835GHz	Micro-Tronics	BRM50702	049	17-Nov-17	17-Nov-18
Cable, Coax	MicroCaox	MKR300C-0-0-1200-500500	002	17-Aug-16	17-Aug-18
Cable, Coax	MicroCaox	MKR300C-0-1968-500310	005	17-Aug-16	17-Aug-18
Cable, Coax	MicroCaox	UFB29C-1-5905-50U-50U	009	17-Aug-16	17-Aug-18
Cable, Coax	Andrew	FSJ1-50A	045	17-Aug-16	17-Aug-18
General Laboratory Equipment					
Meter, Multi	Fluke	233	12430137	10-Aug-17	10-Aug-18

3 Product Information

3.1 Product Description

VERASENSE is indicated for any medical condition in which primary or revision Total Knee Arthroplasty (TKA) would be indicated. For use as a tool for adjustment of the femoral knee implant to reduce instability from flexion gap asymmetry. The VERASENSE is sterile, for single patient use and with a Bluetooth Low-Energy (BLE) The model is CR C-D/3-9 LEFT, ZBH-PSNCRCD39-L and CR G-H/7-12 LEFT, ZBH-PSNCRGH712-L.

Two sets of each EUT were provided for testing. One is a normal configuration for unintentional cabinet radiation. The second was modified with test firmware to allow the low, medium and high hopping channels to continuously transmit with modulation. External batteries were not included on the modified devices to allow long-term transmissions. Fresh batteries were installed frequently.

3.2 Equipment Modifications

No modifications were needed to bring product into compliance.

3.3 Equivalent Models

No additional models covered by test report.

3.4 Test Plan

The EUT product information, test configuration, mode of operation, test types, test procedures, test levels, pass/failure criteria, in this report were carried out per the product test plan located in appendix A of this report.

4 Radiated Emissions in Transmit mode

4.1 Radiated emissions - FCC Parts 15.249, RSS-210 B.10

The field strength of emissions from intentional radiators operated within these frequency bands shall comply with the following limits:
Fundamental Frequency: 2400 to 2483.5 MHz – 50 mV/m (94 dB µV/m) at 3m.
Harmonic Frequencies: 500 µV/m (54 dB µV/m) at 3m, except for emissions in a restricted band.
Spurious Emissions: To the limits of FCC Part 15.209 and RSS-GEN 7.2.1.

4.1.1 Over View of Test

Results	**Complies** (as tested per this report)				**Date**	15 November 2017	
Standard	FCC Parts 15.205, 15.209, 15.215(c), 15.249(a), 15.249(c), 15.249(d) RSS-210 A2.9, and RSS-GEN						
Product Model	CR C-D/3-9 LEFT, ZBH-PSNCRCD39-L and CR G-H/7-12 LEFT, ZBH-PSNCRGH712-L			**Serial#**	247020019, 247020021, 247020026, 247020027, 247020030, 247020096, 247020160, 247020256		
Test Set-up	Tested in a 5m Semi Anechoic chamber, placed on a 1.0m x 1.5m non-conductive table 80cm above the ground plane on a turn-table.						
EUT Powered By	3.0 V DC Lithium battery	**Temp**	73º F	**Humidity**	31%	**Pressure**	1003 mbar
Perf. Criteria	(Below Limit)		**Perf. Verification**		Readings Under Limit		
Mod. to EUT	None		**Test Performed By**		Mark Ryan		

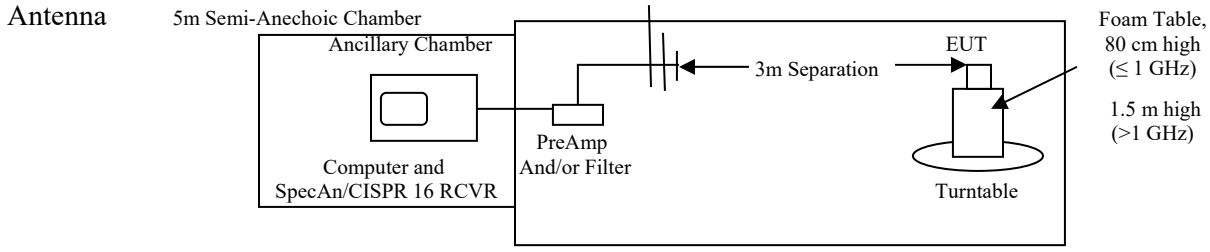
4.1.2 Test Procedure

Testing was performed in accordance with 47 CFR Part 15, ANSI C63.10:2013, RSS-GEN Issue 4. These test methods are listed under the laboratory's A2LA Scope of Accreditation. This test measures the levels emanating from the EUT, thus evaluating the potential for the EUT to cause radio frequency interference to other electronic devices.

4.1.3 Deviations

Since all emissions outside the band are within the limits of FCC Part 15.209 and RSS-GEN 7.2.1, the emissions shown below are also compliant with FCC Parts 15.205, 15.209, 15.215(c), 15.249(d), RSS-210 B.10, and RSS-GEN 7.2.1.

4.1.4 Test Setup Block Diagram



4.1.5 Final Test

All final radiated spurious emissions measurements were below (in compliance) the limits.

4.1.5.1 Worst Case Emissions inside the Frequency Band

Emission Freq (MHz)	ANT Polar (H/V)	ANT Pos (m)	Table Pos (deg)	FIM Value (dBuV)	Amp Gain (dB)	Cable Loss (dB)	ANT Factor (dB/m)	E-Field Value (dBuV/m)	Equivalent EiRP level (mV/m)	Spec Limit (mV/m)
Orientation A:										
2402	H	2	195	33.47	33.99	8.52	28.43	36.44	0.07	50
2402	V	1.4	139	32.15	33.99	8.52	28.43	35.12	0.06	50
2402	H	2	195	70.04	33.99	8.52	28.43	73.01	4.476	70
2402	V	1.4	139	66.94	33.99	8.52	28.43	69.91	3.13	70
2440	H	2.1	347	30.54	34.06	8.59	28.31	33.38	0.047	50
2440	H	2.1	347	67.44	34.06	8.59	28.31	70.28	3.27	70
2480	H	2.2	217	31.73	34	8.66	28.35	34.74	0.057	50
2480	H	2.2	217	65.93	34	8.66	28.35	68.94	2.80	70
Orientation B:										
2402	H	2.1	0	33.57	33.99	8.52	28.43	36.54	0.07	50
2402	V	1.9	84	32.65	33.99	8.52	28.43	35.62	0.06	50
2402	H	2.1	0	69.54	33.99	8.52	28.43	72.51	4.22	70
2402	V	1.9	84	66.94	33.99	8.52	28.43	69.91	3.13	70
2440	H	2	7	31.67	34.06	8.59	28.31	34.51	0.05	50
2440	H	2	7	66.94	34.06	8.59	28.31	69.78	3.08	70
2480	H	2.2	210	31.78	34	8.66	28.35	34.79	0.05	50
2480	H	2.2	210	66.18	34	8.66	28.35	69.19	2.88	70
Orientation C:										
2402	H	2	8	33.14	33.99	8.52	28.43	36.11	0.06	50
2402	V	2	28	32.15	33.99	8.52	28.43	35.12	0.06	50
2402	H	2	8	69.65	33.99	8.52	28.43	72.62	4.28	70
2402	V	2	28	66.81	33.99	8.52	28.43	69.78	3.08	70
2440	H	2.1	322	29.95	34.06	8.59	28.31	32.79	0.04	50
2440	H	2.1	311	67.55	34.06	8.59	28.31	70.39	3.31	50
2480	H	2.2	34	32.17	34	8.66	28.35	35.18	0.06	50
2480	H	2.2	34	66.34	34	8.66	28.35	69.35	2.93	50

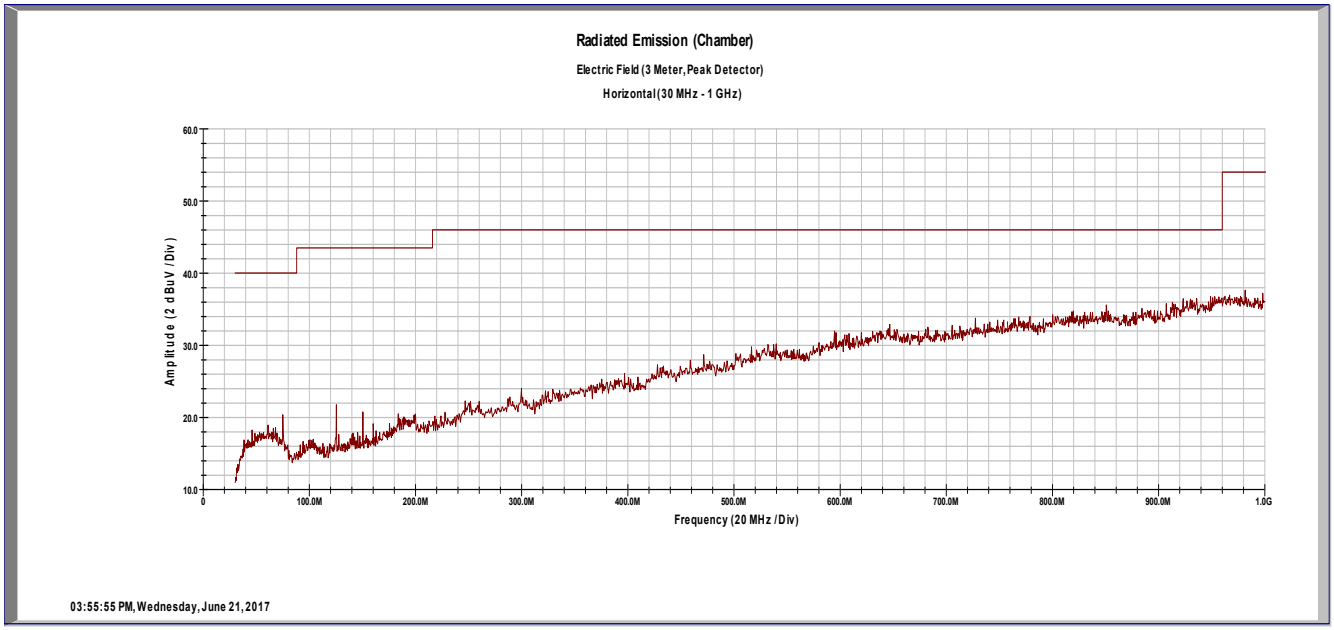
Spec Margin = E-Field Value - Limit, E-Field Value = FIM Value - Amp Gain + Cable Loss + ANT Factor

Notes: **GREEN = Average Detector, Blue = Peak Detector**
The Limit using the Peak Detector is 20dB higher than the Average Detector limit.
EUT in Orientation A is worst case as shown.
This highlighted frequency and orientation was Highest Emission (2402 MHz, Orientation A).

In all cases, the Peak Values are below the 50mV/m (94dBµV/m) average limit. Therefore, compliance is demonstrated.

4.1.5.2 Emissions Outside the Frequency Band:

Radiated Emissions – 30 MHz to 1000 MHz
Horizontal



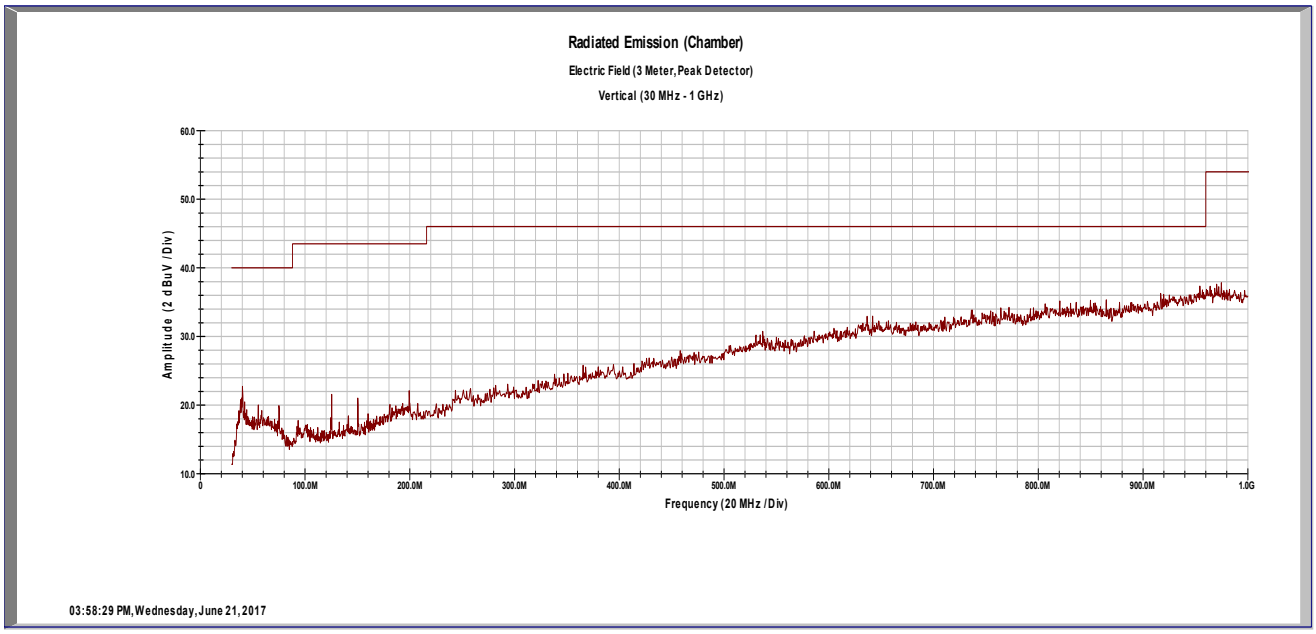
Emission Freq (MHz)	ANT Polar (H/V)	ANT Pos (m)	Table Pos (deg)	FIM Value (dBuV)	Amp Gain (dB)	Cable Loss (dB)	ANT Factor (dB/m)	E-Field Value (dBuV/m)	Spec Limit (dBuV/m)	Spec Margin (dB)

Spec Margin = E-Field Value - Limit, E-Field Value = FIM Value - Amp Gain + Cable Loss + ANT Factor

Notes: The remaining two channels gave very similar results.
The signals shown below 200 MHz are anomalies in the preamp of the measuring instrument.
A notch filter at the transmitter fundamental frequency was not used.

Radiated Emissions – 30 MHz to 1000 MHz

Vertical



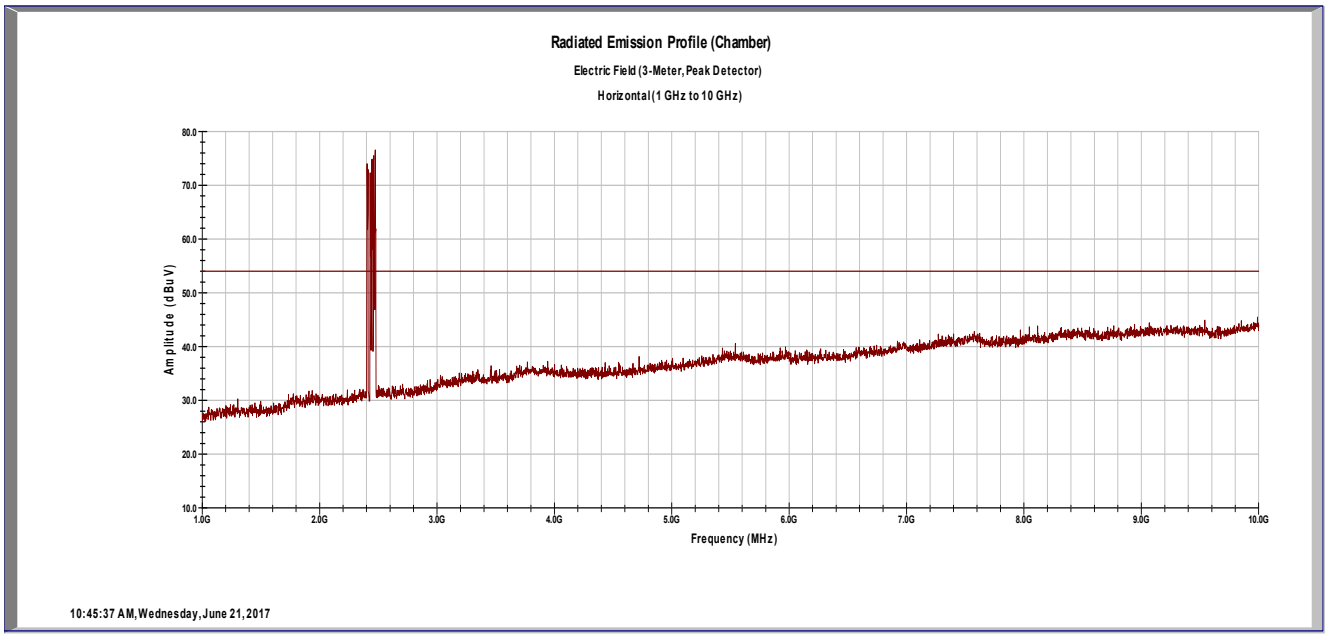
Emission Freq (MHz)	ANT Polar (H/V)	ANT Pos (m)	Table Pos (deg)	FIM Value (dBuV)	Amp Gain (dB)	Cable Loss (dB)	ANT Factor (dB/m)	E-Field Value (dBuV/m)	Spec Limit (dBuV/m)	Spec Margin (dB)

Spec Margin = E-Field Value - Limit, E-Field Value = FIM Value - Amp Gain + Cable Loss + ANT Factor

Notes: The signals shown below 200 MHz are anomalies in the preamp of the measuring instrument.
A notch filter at the transmitter fundamental frequency was not used.

Worst Case Radiated Emissions – 1 to 10 GHz

Horizontal



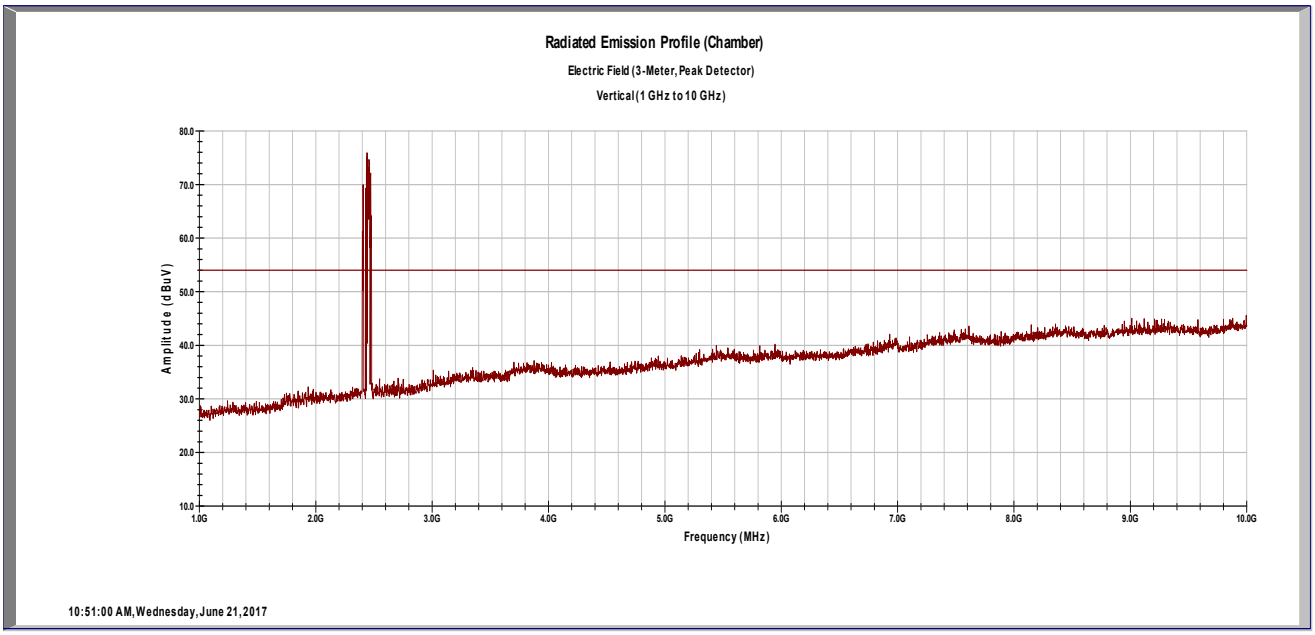
Emission Freq (MHz)	ANT Polar (H/V)	ANT Pos (m)	Table Pos (deg)	FIM Value (dBuV)	Amp Gain (dB)	Cable Loss (dB)	ANT Factor (dB/m)	E-Field Value (dBuV/m)	Spec Limit (dBuV/m)	Spec Margin (dB)
1204.00	H	1	0	12.18	35.04	5.99	24.79	7.92	54.00	-46.08
1204.00	H	1	0	26.08	35.04	5.99	24.79	21.82	74.00	-52.18
4804.00	H	1	0	12.20	33.84	12.55	33.03	23.94	54.00	-30.06
4804.00	H	1	0	25.96	33.84	12.55	33.03	37.70	74.00	-36.30

Spec Margin = E-Field Value - Limit, E-Field Value = FIM Value - Amp Gain + Cable Loss + ANT Factor

Notes: The Emissions from the transmitter was low enough that a filter was not required.

Worst Case Radiated Emissions - 1 to 10 GHz

Vertical



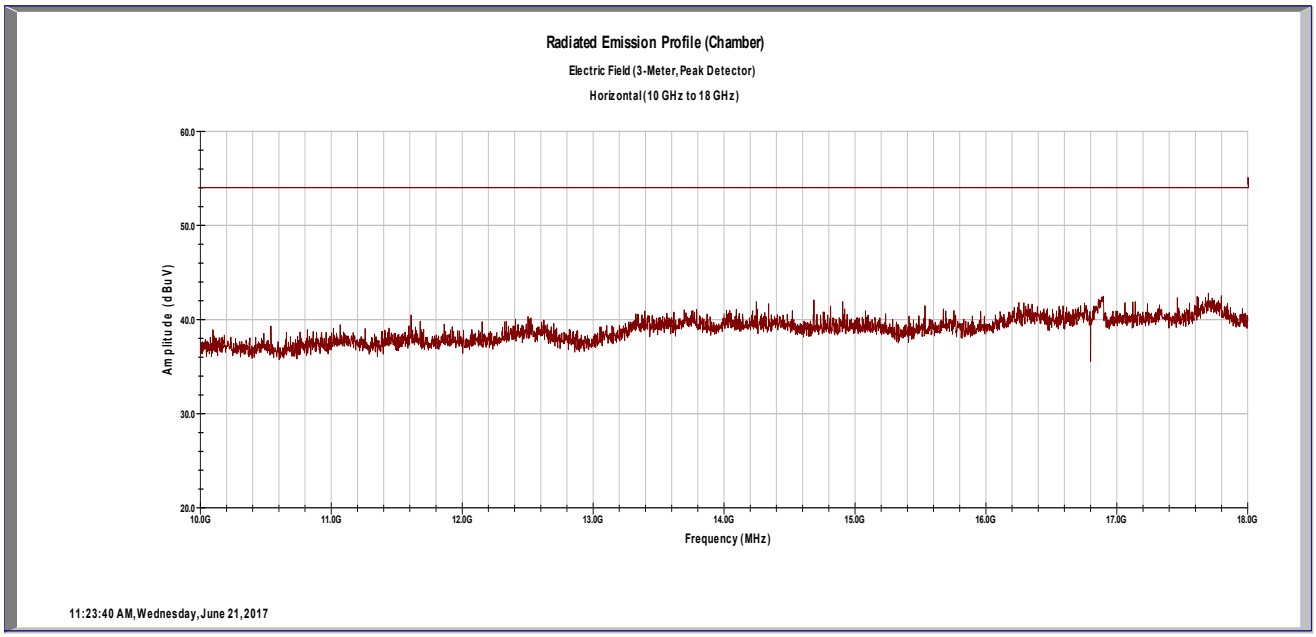
Emission Freq (MHz)	ANT Polar (H/V)	ANT Pos (m)	Table Pos (deg)	FIM Value (dBuV)	Amp Gain (dB)	Cable Loss (dB)	ANT Factor (dB/m)	E-Field Value (dBuV/m)	Spec Limit (dBuV/m)	Spec Margin (dB)
7206.00	V	1	0	14.89	33.61	14.51	36.07	31.86	54.00	-22.14
7206.00	V	1	0	28.01	33.61	14.51	36.07	44.98	74.00	-29.02
9608.00	V	1	0	14.02	34.18	16.88	37.93	34.65	54.00	-19.35
9608.00	V	1	0	27.23	34.18	16.88	37.93	47.86	74.00	-26.14

Spec Margin = E-Field Value - Limit, E-Field Value = FIM Value - Amp Gain + Cable Loss + ANT Factor

Notes: The Emissions from the transmitter was low enough that a filter was not required.
The Emissions shown is **GREEN** are using the Average Detector.
The Emissions shown in **BLUE** are using the Peak Detector.
The highest Harmonic emission is 34.65 dBµV/m or 54.0 µV/m.

Radiated Emissions – 10 to 18 GHz

Horizontal



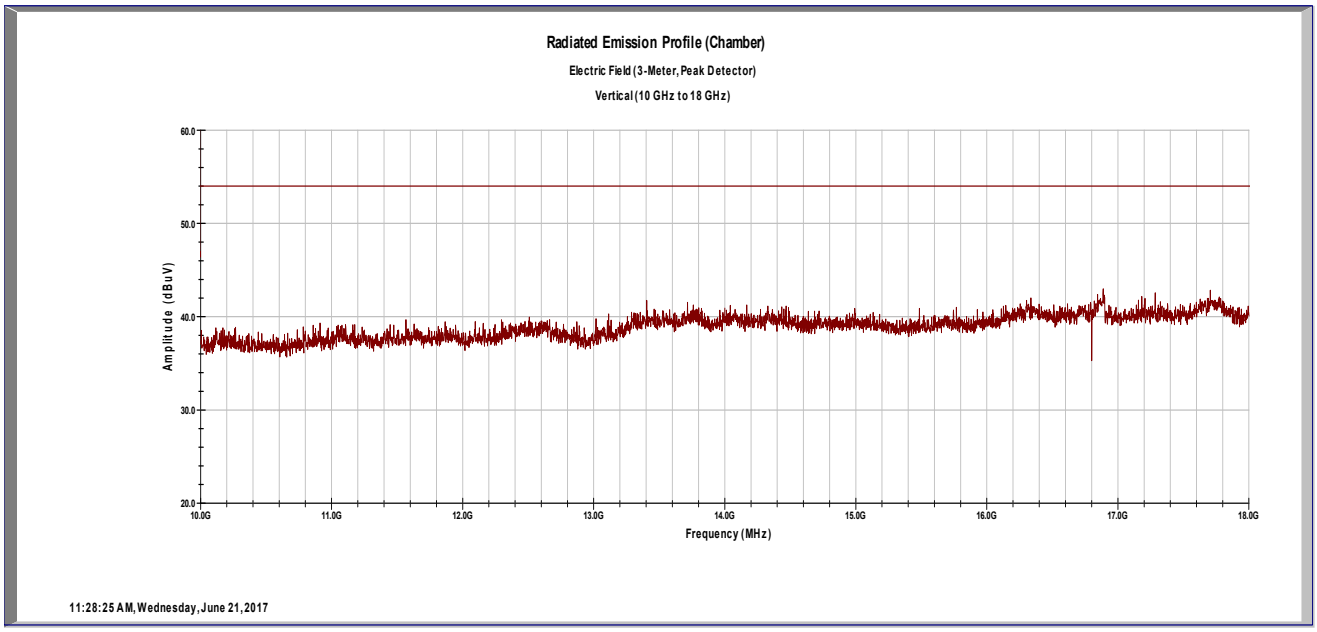
Emission Freq (MHz)	ANT Polar (H/V)	ANT Pos (m)	Table Pos (deg)	FIM Value (dBuV)	Amp Gain (dB)	Cable Loss (dB)	ANT Factor (dB/m)	E-Field Value (dBuV/m)	Spec Limit (dBuV/m)	Spec Margin (dB)
12010.00	H	1	0	14.73	33.30	20.59	39.32	41.34	54.00	-12.66
12010.00	H	1	0	27.52	33.30	20.59	39.32	54.13	74.00	-19.87

Spec Margin = E-Field Value - Limit, E-Field Value = FIM Value - Amp Gain + Cable Loss + ANT Factor

Notes: The Emissions from the transmitter was low enough that a filter was not required.
The Emissions shown is **GREEN** are using the Average Detector.
The Emissions shown in **BLUE** are using the Peak Detector.

Radiated Emissions – 10 to 18 GHz

Vertical



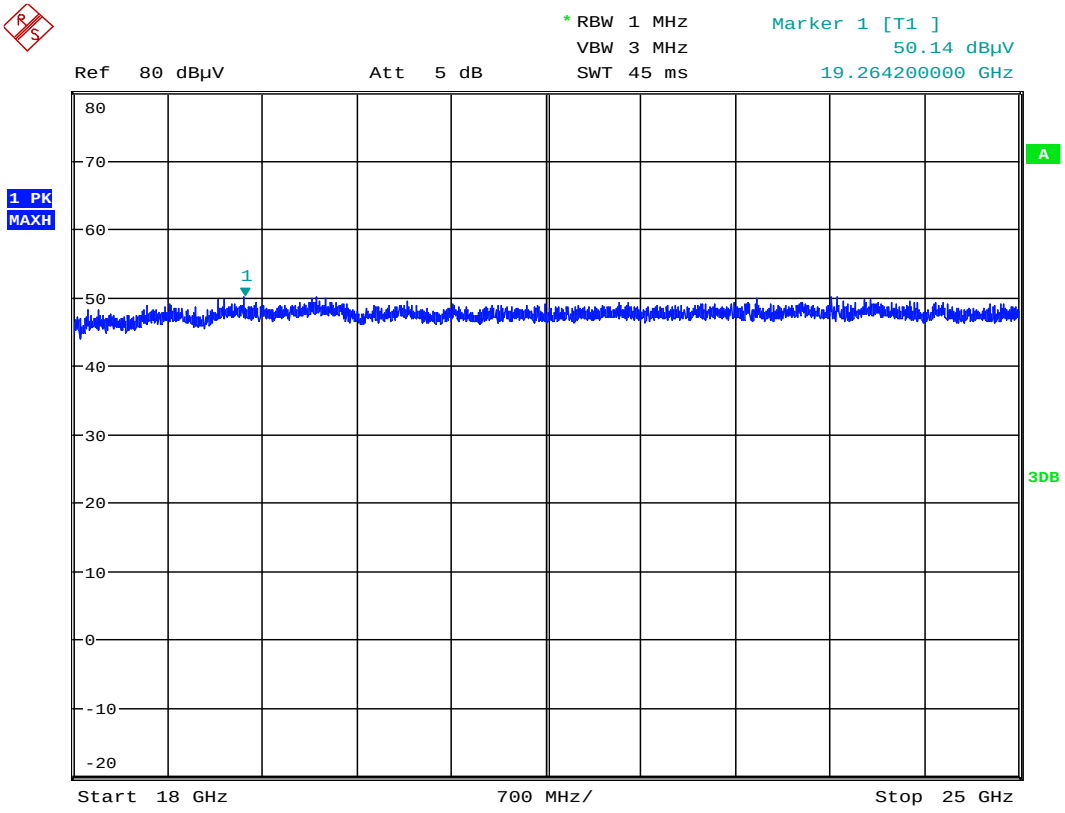
Emission Freq (MHz)	ANT Polar (H/V)	ANT Pos (m)	Table Pos (deg)	FIM Value (dBuV)	Amp Gain (dB)	Cable Loss (dB)	ANT Factor (dB/m)	E-Field Value (dBuV/m)	Spec Limit (dBuV/m)	Spec Margin (dB)
16814.00	V	1	0	14.10	32.04	24.40	39.30	45.76	54.00	-8.24
16814.00	V	1	0	27.60	32.04	24.40	39.30	59.26	74.00	-14.74

Spec Margin = E-Field Value - Limit, E-Field Value = FIM Value - Amp Gain + Cable Loss + ANT Factor

Notes: The Emissions from the transmitter was low enough that a filter was not required.
The Emissions shown is **GREEN** are using the Average Detector.
The Emissions shown in **BLUE** are using the Peak Detector.

Radiated Emissions Ch 2 – 18 to 25 GHz

Horizontal



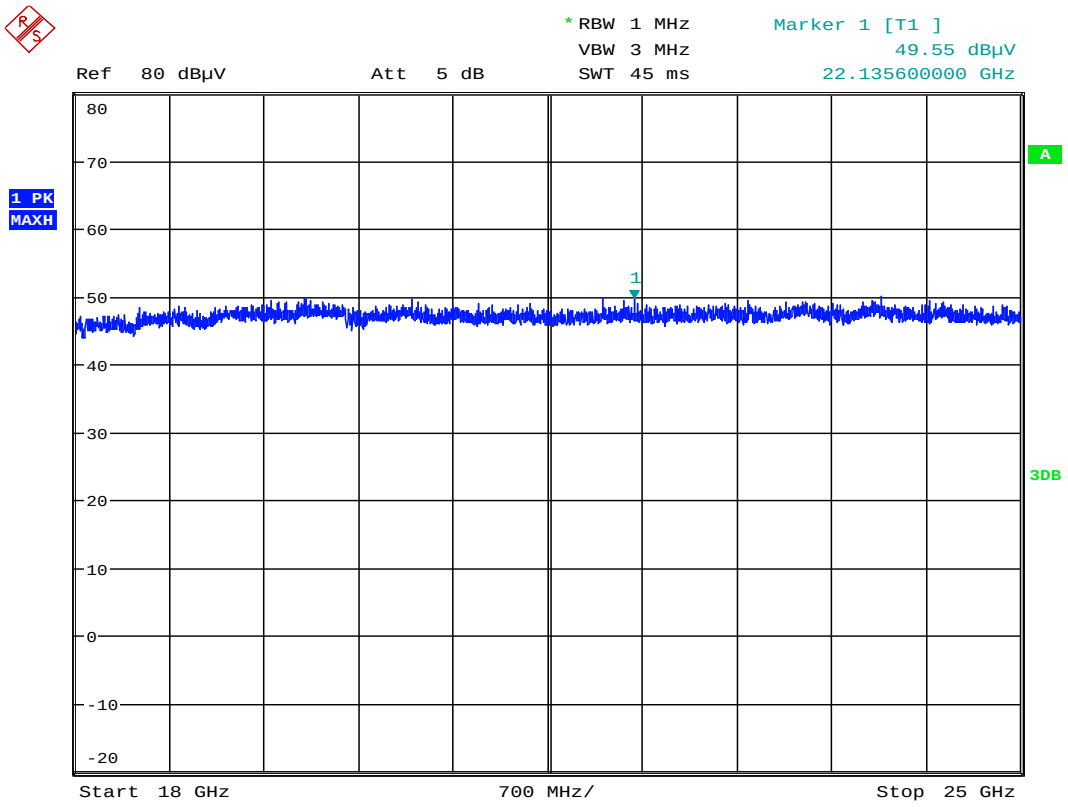
Emission Freq (MHz)	ANT Polar (H/V)	ANT Pos (m)	Table Pos (deg)	FIM Value (dBuV)	Amp Gain (dB)	Cable Loss (dB)	ANT Factor (dB/m)	E-Field Value (dBuV/m)	Spec Limit (dBuV/m)	Spec Margin (dB)

Spec Margin = E-Field Value - Limit, E-Field Value = FIM Value - Amp Gain + Cable Loss + ANT Factor

Notes: No measureable emissions were noted.
No correction factors were used for the above graph. The number of Sweep Points was increased to 8000.
The Measuring distance was decreased to 1 meter.
No notch filter was used for this frequency range.

Radiated Emissions Ch 2 – 18 to 25 GHz

Vertical



Emission Freq (MHz)	ANT Polar (H/V)	ANT Pos (m)	Table Pos (deg)	FIM Value (dBuV)	Amp Gain (dB)	Cable Loss (dB)	ANT Factor (dB/m)	E-Field Value (dBuV/m)	Spec Limit (dBuV/m)	Spec Margin (dB)

Spec Margin = E-Field Value - Limit, E-Field Value = FIM Value - Amp Gain + Cable Loss + ANT Factor

Notes: No measureable emissions were noted.
No correction factors were used for the above graph. The number of Sweep Points was increased to 8000.
The Measuring distance was decreased to 1 meter.
No notch filter was used for this frequency range.

4.2 Band Edge requirements - FCC Part 15.249(d), RSS-GEN

4.2.1 Test Over View

Results	**Complies** (as tested per this report)				**Date**	15 November 2017	
Standard	FCC Part 15.249(d), RSS-GEN						
Product Model	CR C-D/3-9 LEFT, ZBH-PSNCRCD39-L and CR G-H/7-12 LEFT, ZBH-PSNCRGH712-L			**Serial#**	247020019, 247020021, 247020026, 247020027, 247020030, 247020096, 247020160, 247020256		
Test Set-up	Direct Measurement from antenna port						
EUT Powered By	3.0 V DC Lithium battery	**Temp**	73º F	**Humidity**	35%	**Pressure**	998 mbar
Perf. Criteria	(Below Limit)		**Perf. Verification**		Readings Under Limit		
Mod. to EUT	None		**Test Performed By**		Mark Ryan		

4.2.2 Test Procedure

Emissions radiated outside of the specified frequency bands, except for harmonics, shall be attenuated by at least 50 dB below the level of the fundamental or to the general radiated emission limits in Sec. 15.209, whichever is the lesser attenuation.

4.2.3 Deviations

There were no deviations from the test methodology listed in the test plan.

RBW of 100 kHz was chosen as it is within 1% to 5% of the total span. (4.8%)

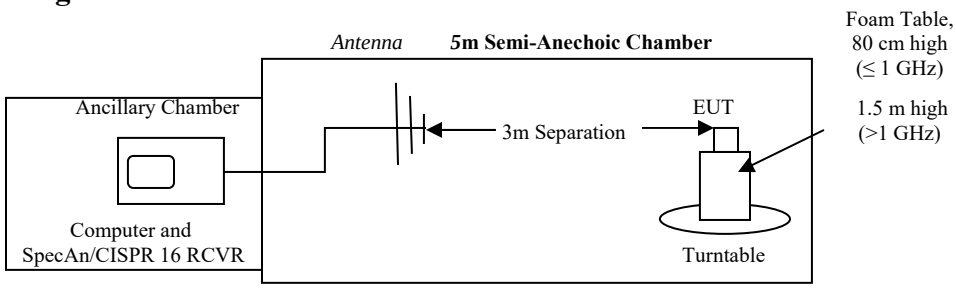
The VBW of 300 kHz was chosen as it is 3 times the 100 kHz RBW.

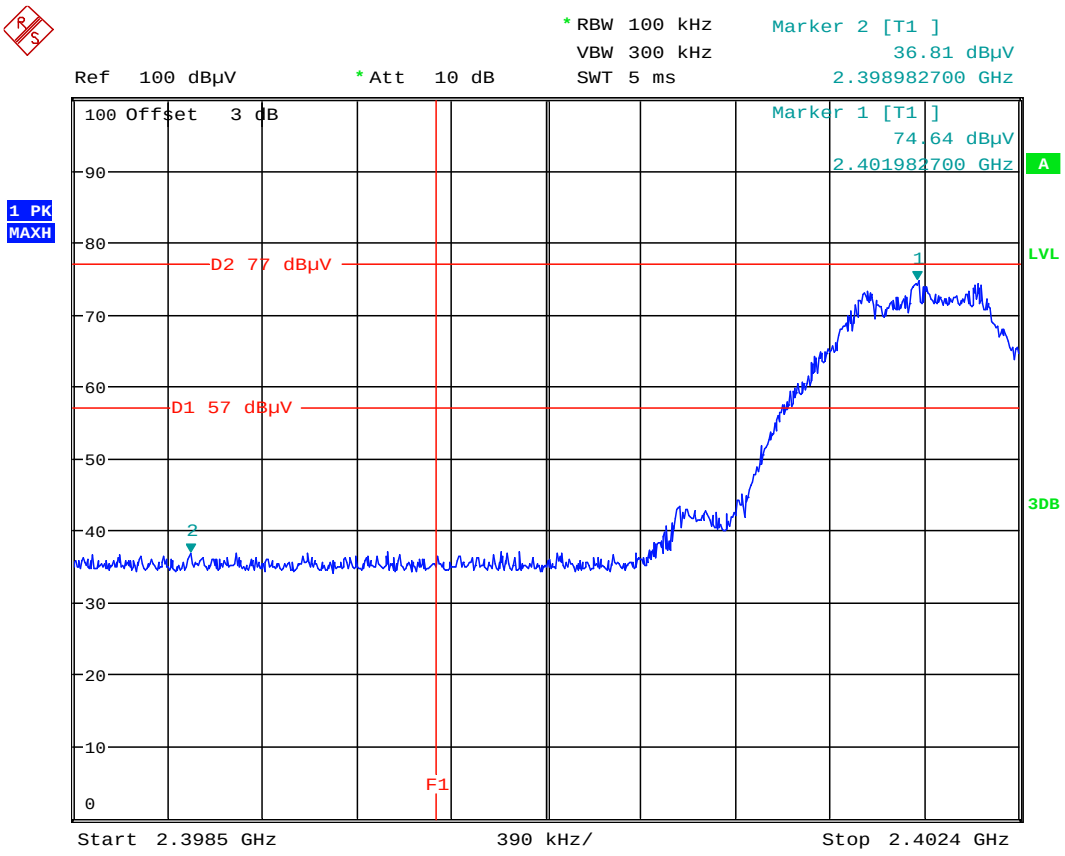
The Sweep time was set to Auto.

4.2.4 Final Test

The EUT met the performance criteria requirement as specified in the standards.

4.2.5 Test Setup Block Diagram



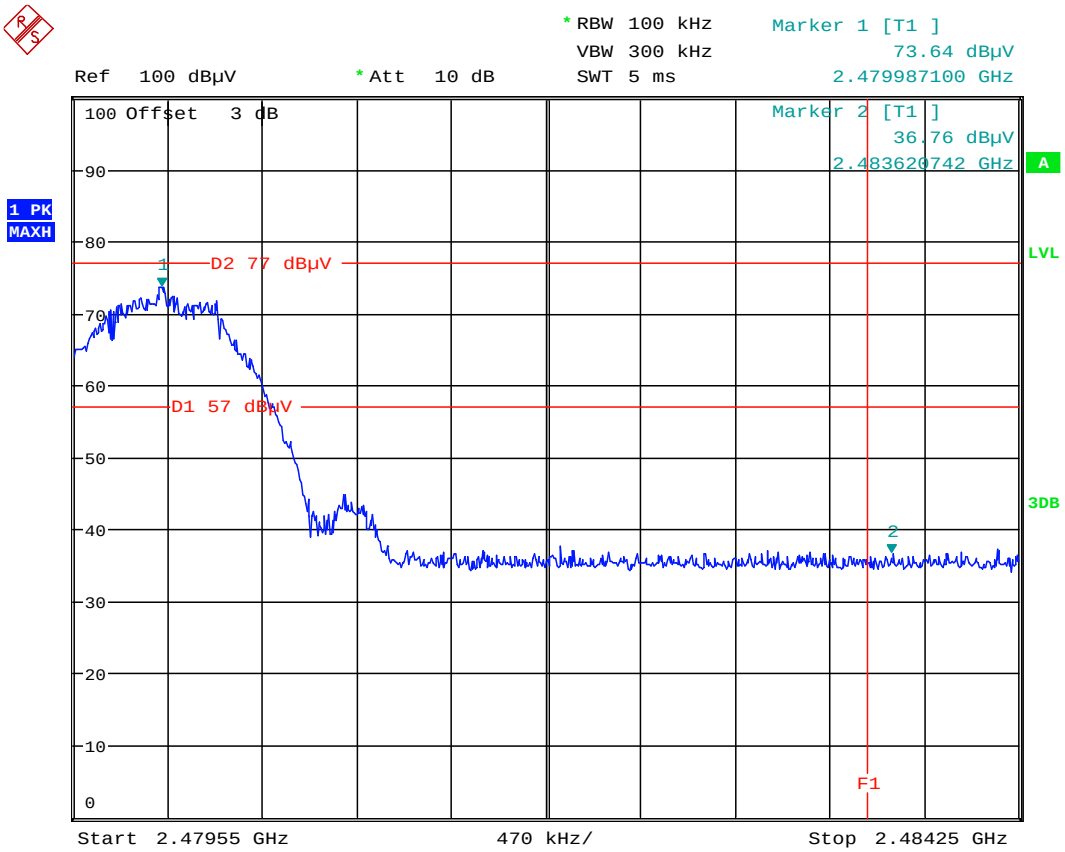


Notes: Measured using the Peak detector. The Peak level is below the Average Limit Band Edge is at 2.4 GHz (Line F1).

The nearest restricted band (2390MHz) is 10 MHz below the band edge

The Highest frequency outside the band is at 38.07 dBµV/m (using the Peak Detector) which is below the Average restricted-band limits)

Figure 1: Lower Band Edge Measurement (Radiated Emission)



Note: Measured using the Peak detector. Band Edge is at 2.483.5 MHz (Line F1).

Band edge at 2483.5 MHz is also the start of a restricted band, so the restricted band rules apply.

The Highest frequency outside the band is at 38.02 dBµV/m (using the Peak Detector) which is below the Average restricted-band limits)

Figure 2: Upper Band Edge Measurement (Radiated Emission)

The EUT is compliant with the rules.

4.3 Conducted Emissions on AC Mains – FCC 207(a) and RSS-GEN 8.8

This test measures the electromagnet levels of spurious signals generated by the EUT on the AC power line that may affect the performance of other nearby electronic equipment.

4.3.1 Over View of Test

Results	**NA** EUT is battery operated only					**Date**	11/20/2018
Standard	FCC Parts 15.207(a):2017 and RSS-GEN I4 clause 8.8						
Product Model	CR C-D/3-9 LEFT, ZBH-PSNCRCD39-L and CR G-H/7-12 LEFT, ZBH-PSNCRGH712-L			**Serial#**	NA		
Test Set-up	Tested in shielded room. EUT placed on table, see test plans for details						
EUT Powered By	3.0 V DC Lithium battery	**Temp**	NA	**Humidity**	NA	**Pressure**	NA
Frequency Range	150 kHz – 30 MHz						
Perf. Criteria	(Below Limit)	**Perf. Verification**	Readings Under Limit for L1 & Neutral				
Mod. to EUT	None	**Test Performed By**	NA				

4.3.2 Test Procedure

Conducted emissions tests were performed using the procedures of 47 CFR Part 15, ANSI C63.10:2013, RSS-GEN Issue 4, including methods for signal maximizations and EUT configuration. The photos included with the report show the EUT in its maximized configuration.

4.3.3 Deviations

The Test sample is battery operated only. It does not have provision for external power of any kind.

4.3.4 Final Test

This test is not applicable for the device submitted for testing

4.4 99% Power Bandwidth

When the occupied bandwidth limit is not stated in the applicable RSS or reference measurement method, the transmitted signal bandwidth shall be reported as the 99% emission bandwidth, as calculated or measured.

4.4.1 Test Over View

Results	**Complies** (as tested per this report)				**Date**	11/20/2018	
Standard	RSS-GEN Issue 4, Clause 6.6						
Product Model	CR C-D/3-9 LEFT, ZBH-PSNCRCD39-L and CR G-H/7-12 LEFT, ZBH-PSNCRGH712-L		**Serial#**	247020019, 247020021, 247020026, 247020027, 247020030, 247020096, 247020160, 247020256			
Test Set-up	Direct Measurement from antenna port						
EUT Powered By	3 V DC Lithium battery	**Temp**	73º F	**Humidity**	50%	**Pressure**	999 mbar
Perf. Criteria	(Below Limit)		**Perf. Verification**	Readings Under Limit			
Mod. to EUT	None		**Test Performed By**	Mark Ryan			

4.4.2 Test Procedure

Using the procedures of RSS-GEN section 6.6;
• The transmitter shall be operated at its maximum carrier power measured under normal test conditions.
• The span of the analyzer shall be set to capture all products of the modulation process, including the emission skirts.
• The resolution bandwidth (RBW) shall be in the range of 1% to 5% of the occupied bandwidth (OBW) and video bandwidth (VBW) shall be approximately 3x RBW.

4.4.3 Deviations

There were no deviations from the test methodology.

4.4.4 Final Results

The highest measured 99% bandwidth is 1058.09 kHz.

The EUT met the performance criteria requirement as specified in the test plan of this report and in the standards.

Frequency (MHz)	99% BW (kHz)
2402	1046
2440	1052
2480	1048

99% Power Band Width.

4.4.5 Final Data

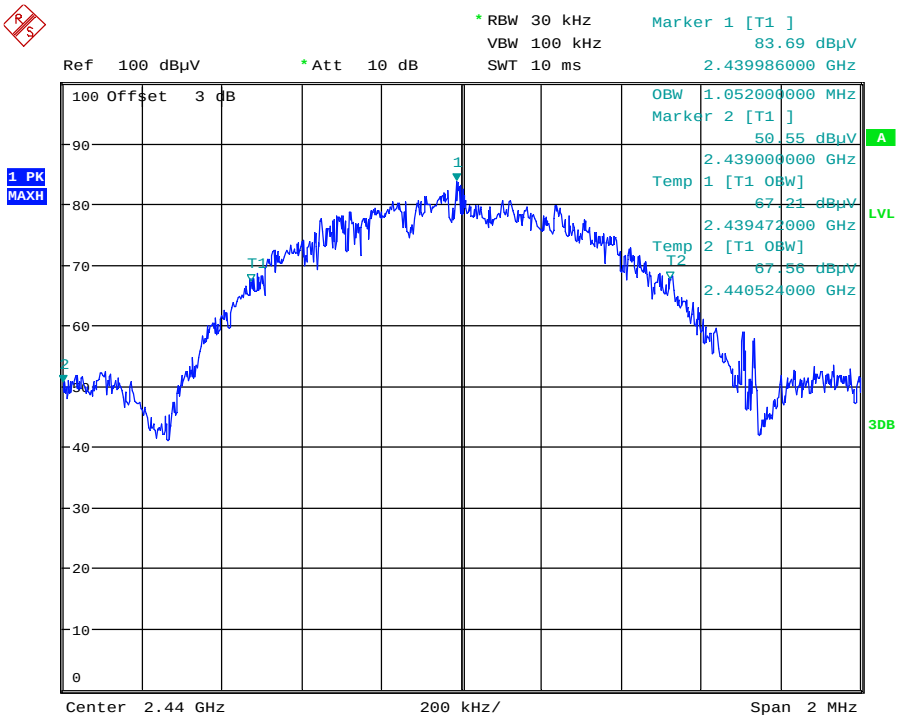


Figure 3 – 99% Power Bandwidth = 1052 kHz. The Worst-Case shown.

Span = 2MHz, RBW = 30 kHz (1% of Span), VBW = 100 kHz (≥ 3x RBW)

The EUT is compliant to the requirements of RSS-GEN 6.6

Appendix A

5 Test Documentation Requirements - Transmitters

This test report is intended to follow this test plan outlined below unless otherwise stated in this report or quote agreement. The following test plan will give details on product information, test set ups, and product configurations.

5.1 General Information

Client	OrthoSensor
Address	1855 Griffin Rd, St A-310
Address	Dania Beach, FL 33004-2401 USA
Contact Person	Joshua Gardner
Telephone	(954) 790-6744
Fax	
e-mail	joshua.gardner@orthosensor.com

5.1.1 Product Name

VERASENSE for Zimmer Biomet Persona

5.1.2 Model(s) Name

CR C-D/3-9 LEFT, ZBH-PSNCRCD39-L and CR G-H/7-12 LEFT, ZBH-PSNCRGH712-L

5.1.3 Equipment Under Test (EUT) Description

VERASENSE is indicated for any medical condition in which primary or revision Total Knee Arthroplasty (TKA) would be indicated. For use as a tool for adjustment of the femoral knee implant to reduce instability from flexion gap asymmetry. The VERASENSE is sterile, for single patient use.

The VERASENSE is intended to be temporally implanted during an Arthroplasty surgical procedure. It is removed and discarded by the surgeon when the proper knee alignment is achieved.

The EUT contains a transmitter that operates in the 2.4 to 2.4835 GHz ISM band.
The transmitter is a low power 40 channel BLE (Bluetooth Low Energy) FHSS device that uses the BLE protocol and operates from 2402 to 2480 MHz. The EUT utilizes an internal wire antenna.

Sizes:

Three sizes exist a Small, Medium, and Large, denoted as CD, EF, and GH respectively.

Symmetry:

Each size is offered for a left or right knee orientation denoted as “Left” or “Right” on the product box, respectively. The internal components, including the intentional radiator, are identical in both variants.

Note: The plastic housing of the device denotes an “L” on one side, and an “R” on the flip side. As stated above, The EUTs tested per this report were of the “Left” or “L” configuration. While some images throughout may show the plastic housing marked with “R”, it is not to be confused with a “Right” configured device.

The internal electrical components of all models are identical. The size and symmetry are the only differences, a total of 6 models exist which belong to the VERASENSE Zimmer Biomet Persona system, see external photo document for examples:

- VERASENSE for Zimmer Biomet Persona CR C-D/3-9 Left, ZBH-PSNCRCD39-L
- VERASENSE for Zimmer Biomet Persona CR C-D/3-9 Right, ZBH-PSNCRCD39-R
- VERASENSE for Zimmer Biomet Persona CR E-F/3-11 Left, ZBH-PSNCREF311-L
- VERASENSE for Zimmer Biomet Persona CR E-F/3-11 Right, ZBH-PSNCREF311-R
- VERASENSE for Zimmer Biomet Persona CR G-H/7-12 Left, ZBH-PSNCRGH712-L
- VERASENSE for Zimmer Biomet Persona CR G-H/7-12 Right, ZBH-PSNCRGH712-R

Appendix B

6 Manufacturer's Statement – Attestation

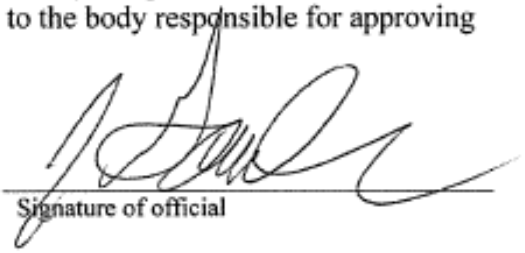
The manufacturer; OrthoSensor, as the responsible party for the equipment tested, hereby affirms:

a) Reviewed and concurs that the test shown in this report are reflective of the operational characteristics of the device for which certification is sought;

b) That the device in this test report will be representative of production units;

c) That all changes (in hardware and software/firmware) to the subject device will be reviewed.

d) That any changes impacting the attributes, functionality or operational characteristics documented in this report will be communicated to the body responsible for approving (certifying) the subject equipment.

Joshua Gardner	
Printed name of official	Signature of official
OrthoSensor 1855 Griffin Rd, St A-310 Dania Beach, FL 33044-2401 USA	24 April 2018
Address	Date
(954) 577-7770	joshua.gardner@orthosensor.com
Telephone number	Email address of official