

#### **Intentional Radiator Test Report**

For the

OrthoSensor, Inc.

#### **VERASENSE Mako Restoris PKA**

Tested under

The FCC Rules contained in Title 47 of the CFR, Part 95 for

Personal Radio Service

December 23, 2013

**Prepared for:** 

OrthoSensor, Inc.

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#### **Prepared By:**

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Cert # ATL-0062-E

Engineering Statement: The measurements shown in this report were made in accordance with the procedure indicated, and the emissions from this equipment were found to be within the limits applicable. I assume full responsibility for the accuracy and completeness of these measurements, and for the qualifications of all persons taking them. It is further stated that upon the basis of the measurement made, the equipment tested is capable of operation in accordance with the requirements of Part 95 of the FCC Rules under normal use and maintenance.



# **Report Status Sheet**

Revision #	Report Date	Reason for Revision
Ø	December 23, 2013	Initial Issue
1	January 13, 2014	Updated EIRP value



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### **EXECUTIVE SUMMARY**

# 1. Testing Summary

These tests were conducted on a sample of the equipment for the purpose of demonstrating compliance with Part 95. All tests were conducted using measurement procedure from ANSI TIA/EIA-603-A-2004 as appropriate.

Test Name	Test	Result	Comments
	Method/Standard		
RF Output Power	2.1046	Pass	
Occupied Bandwidth	2.1049; 95.627(a)(1)	Pass	
Spurious Emissions at	2.1051; 95.627(c)	Pass	
Antenna Terminals			
Field Strength of	§95.639	Pass	
Fundamental			
Radiated Spurious	2.1053; 95.627(c)	Pass	
Emissions			
Frequency Stability over	2.1055(a)(1);	Pass	
Temperature Variations	95.627(e)		
Frequency Stability over	2.1055(d); 95.627(e)	Pass	
Voltage Variations			



### **EQUIPMENT CONFIGURATION**

#### 1. Overview

H.B Compliance Solutions was contracted by OrthoSensor to perform testing on the VERASENSE under the purchase order number 071361.

This document describes the test setups, test methods, required test equipment, and the test limit criteria used to perform compliance testing of the OrthoSensor, Inc., VERASENSE.

The tests were based on FCC Part 95 Rules. The tests described in this document were formal tests as described with the objective of the testing was to evaluate compliance of the Equipment Under Test (EUT) to the requirements of the aforementioned specifications. OrthoSensor, Inc. should retain a copy of this document and it should be kept on file for at least five years after the manufacturing of the EUT has been permanently discontinued. The results obtained relate only to the item(s) tested.

Product Name:	VERASENSE Knee System device		
	·		
Model(s) Tested:	VERASENSE Mako		
FCC ID:	XNL-ORTHOSNSR6		
Supply Voltage Input:	Primary Power : 3.10 Vdc		
Frequency Range:	404.3MHz		
No. of Channels:	Single Chanel		
Necessary Bandwidth	213.12kHz		
Type(s) of Modulation:	GFSK		
Range of Operation Power:	0.000016W EIRP		
Voltage into final Transistor	3.0 volts		
<b>Current into final Transistor</b>	16mA		
Emission Designator:	213KF1D		
Channel Spacing(s)	None		
Test Item:	Pre-Production		
Type of Equipment :	Fixed		
Antenna:	PCB		
Environmental Test	Temperature: 15-35°C		
Conditions:	Humidity: 30-60%		
	Barometric Pressure: 860-1060 mbar		
Modification to the EUT:	None		
Evaluated By:	Staff at Emerson Network & H.B. Compliance Solutions		
Test Date(s):	12/04/13 till 12/20/13		



### 2. Test Facility

All radiated testing was performed at Emerson Network Power. This facility is located at 2900 S. Diablo Way, Suite 190, Tempe, AZ 85282.

Test facility at Emerson Network power is an A2LA accredited test site. The A2LA certificate number is 2716.01. The scope of accreditation covers the FCC Method - 47 CFR Part 15, ICES-003, CISPR 22, AS/NZS 3548 and VCCI

All other tests were performed at H.B. Compliance Solutions. This facility is located at 5005 S. Ash Avenue, Suite # A-10, Tempe, AZ 85282. All equipment used in making physical determination is accurate and bears recent traceability to the National Institute of Standards and Technology.

Radiated Emissions measurements were performed in a semi-anechoic chamber (equivalent to an Open Area Test Site). In accordance with §2.948(a)(3), a complete site description is contained at Emerson Network Power.

### 3. Description of Test Sample

The OrthoSensor, Verasense Knee System provides a means to dynamically balance the knee during Total Knee Arthroplasty. It is an intelligent disposable tibial insert that measures dynamic loads in the medical and lateral compartments of the knee and wirelessly transmits the measured load data to the OrthoSensor LinkStation for surgeon visualization. The components are contained in a plastic enclosure.

### 4. Equipment Configuration

Ref. ID	Name / Description	Model Number	Serial Number
# 1	VERASENSE Knee System device	VERASENSE	N/A

**Table 1. Equipment Configuration** 

### 5. Support Equipment

All support equipment supplied is listed in the following Support Equipment List.

Ref ID	Name / Description	Manufacturer	Model #	Serial #
#2	Receiver	Orthosensor	N/A	07359
#3	Laptop Computer	Toshiba	Satellite C655D-	0031039
			S5303	

**Table 2. Support Equipment** 



### 6. Ports and Cabling Information

Ref ID	Port name	Cable Description	Qty.	Length (m)	Shielded? (Y/N)	Termination Box ID & Port ID
N/A	-	-	-	-	-	-

**Table 3. Ports and Cabling Information** 

### 7. Method of Monitoring EUT Operation

A test receiver will be used to monitor the data transmission from the EUT.

#### 8. Mode of Operation

The EUT will be configured to transmit at maximum power level. Customer provided test software to set the device in continuous transmission mode. These settings were created for testing purpose only.

#### 9. Modifications

#### 9.1 Modifications to EUT

No modifications were made to the EUT

#### 9.2 Modifications to Test Standard

No Modifications were made to the test standard.

### 10. Disposition of EUT

The test sample including all support equipment submitted to H.B Compliance Solutions for testing will be returned to OrthoSensor, LLC upon completion of testing & certification



### **Criteria for Intentional Radiators**

## 1. RF Power Output

Test Requirement(s):	§2.1046	Test Engineer(s):	Hoosam B.
Test Results:	Pass	Test Date(s):	12/18/13

**Test Procedures:** 

As required by 47 CFR 2.1046, RF Power output measurements were made at the RF output terminals of the EUT.

Customer provided a test mode internal to the EUT to control the RF modulation, and frequency channel. The EUT was connected through an

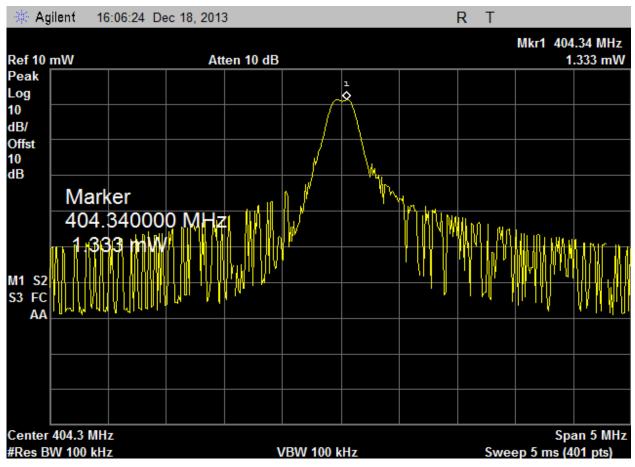
attenuator to a Spectrum Analyzer capable of making power measurements. FCC Part 95 has no test limit for conducted output

power.

Frequency (MHz)	Measured Conducted Power	Test Limit
404.3	1.33mW	N/A

**Table 4 - RF Power Output, Test Results** 





Plot 1 – Output Power



### 2. Emission Bandwidth

Test	2.1049 and §95.633(e)(1)	Test Engineer(s):	Hoosam B.
Requirement(s):			
Test Results:	Pass	Test Date(s):	12/18/13

#### **Test Procedure:**

As required by 47 CFR 2.1049, occupied bandwidth measurements were made at the output terminals of the EUT.

Customer provided a test mode internal to the EUT to control the RF modulation, and frequency channel. The EUT was connected through an attenuator to a Spectrum Analyzer. The measured highest peak power was set relative to zero dB reference. The RBW of the Spectrum Analyzer was set to at least 1% of the channel bandwidth.

Frequency (MHz)	Recorded	Specification Limit
	Measurement	
404.3	213.129 kHz	300 KHz

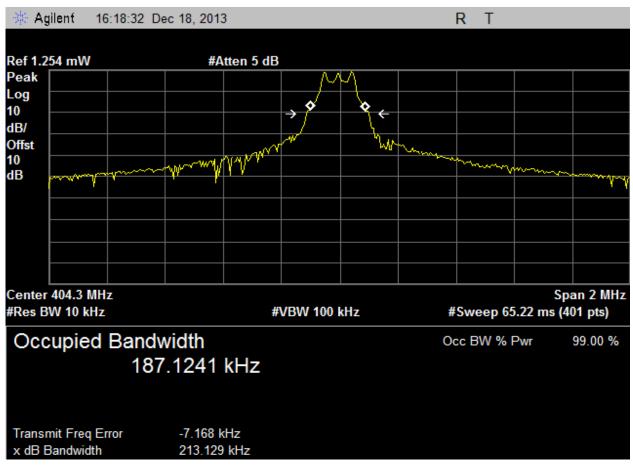
Table 5 - Occupied Bandwidth Summary, Test Results

Frequency (MHz)	Recorded	Specification
	Measurement	Limit
404.3	187.12 kHz	None

Table 6 - 99% Bandwidth, Test Results

The following pages show measurements of Emission Bandwidth plot:





Plot 2 - Emission Bandwidth



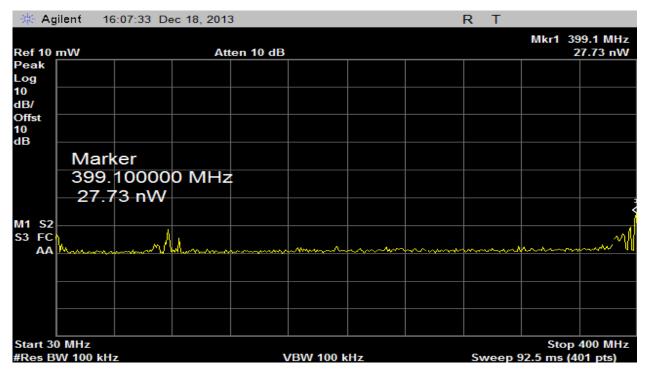
### 3. Spurious Emissions at Antenna Terminals

Test	§2.1051 and 95.635(d)	Test Engineer(s):	Hoosam B.
Requirement(s):			
Test Results:	Pass	Test Date(s):	12/18/13

#### **Test Procedures:**

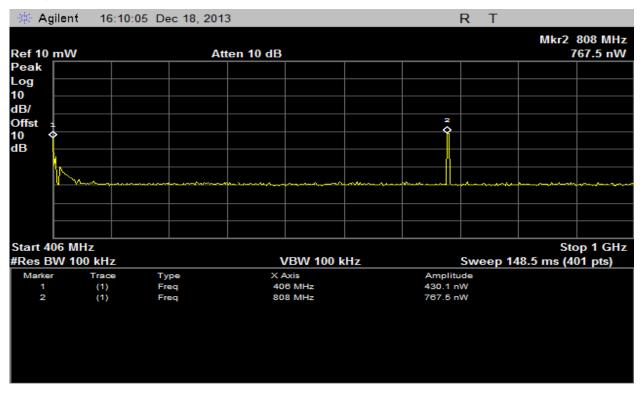
As required by 47 CFR 2.1051, spurious emissions at antenna terminal measurements were made at the RF output antenna terminal of the EUT.

Customer provided a test mode internal to the EUT to control the RF modulation, and frequency channel. The EUT was connected through an attenuator to a Spectrum Analyzer. The Spectrum Analyzer was set to sweep from 30MHz up to 10<sup>th</sup> harmonic of the fundamental or 40GHz whichever is the lesser. Measurements were made at the low, mid and high frequency of the transmit band.

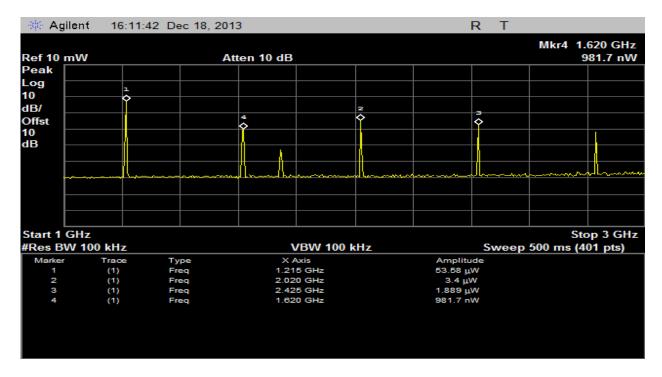


Plot 3 -30MHz to 400MHz





Plot 4 – 406MHz to 1GHz



Plot 5 - 1GHz to 3 GHz



### 4. Field Strength of Fundamental

Test	§95.639	Test Engineer(s):	Frank F.
Requirement(s):			
Test Results:	Pass	Test Date(s):	12/20/2013

#### **Test Procedures:**

As required by 47 CFR 2.1053, field strength of radiated spurious measurements were made in accordance with the procedures of the TIA/EIA-603-A-2004.

The EUT was placed on a wooden table inside a 3 meter semi-anechoic chamber. The EUT was transmitting into a non-radiating load which was directly connected to the EUT antenna port.

The measurement antenna was placed at a distance of 3 meters from the EUT. During the tests, the antenna height and polarization as well as EUT azimuth were varied in order to identify the maximum level of emissions from the EUT. The test was performed by placing the EUT on 3 orthogonal axis. The frequency range up to the 10<sup>th</sup> harmonic was investigated.

Frequency (MHz)	Measured Amplitude (dBuV/m)	Antenna Polarity	Limit (dBuV/m)	Margin (dB)	Comment
404.29	67.27	Vertical	85.2	17.9	Fundamental

Table 7 - Fundamental Radiated Emission Data

NOTE: EIRP limit expressed as 18.2mV/m per 95.627(g)(3) is equivalent to 85.2dBuV/m at 3m.

85.2 = 20\*Log(18.2 \* 1000)



### 5. Radiated Spurious Emissions

Test	§2.1053 and 95.635(d)	Test Engineer(s):	Frank F.
Requirement(s):			
Test Results:	Pass	Test Date(s):	12/20/2013

#### **Test Procedures:**

As required by 47 CFR 2.1053, field strength of radiated spurious measurements were made in accordance with the procedures of the TIA/EIA-603-A-2004.

The EUT was placed on a wooden table inside a 3 meter semi-anechoic chamber. The EUT was transmitting into a non-radiating load which was directly connected to the EUT antenna port.

The measurement antenna was placed at a distance of 3 meters from the EUT. During the tests, the antenna height and polarization as well as EUT azimuth were varied in order to identify the maximum level of emissions from the EUT. The test was performed by placing the EUT on 3 orthogonal axis. The frequency range up to the 10<sup>th</sup> harmonic was investigated.

Frequency (MHz)	Peak Measurement @ 3m (dBuV/m)	Antenna Polarity (H/V)	Average Amplitude (dBuV/m)	FCC Average/QP Limit (dBuV/m)	FCC Peak Limit (dBuV/m)	Average Margin (dB)	Peak Margin (dB)	Comment
808.6	49.7	Н	31.7	53	73	-21.3	23.3	
1212.9	48.4	V	30.07	53	73	-22.93	-24.6	
1617.2	50.57	V	31.57	53	73	-21.43	-22.43	
2021.5	56.2	V	40.3	53	73	-12.7	-16.8	

Table 8 - Radiated Spurious Emission Data – 30MHz – 5GHz



## 6. Frequency Stability vs Temperature

Test	§2.1055 and 95.627(e)	Test Engineer(s):	Jerry M.
Requirement(s):			
Test Results:	Pass	Test Date(s):	12/04/2013

#### **Test Procedures:**

As required by 47 CFR 2.0155, Frequency Stability measurements were made at the RF antenna output terminals of the EUT.

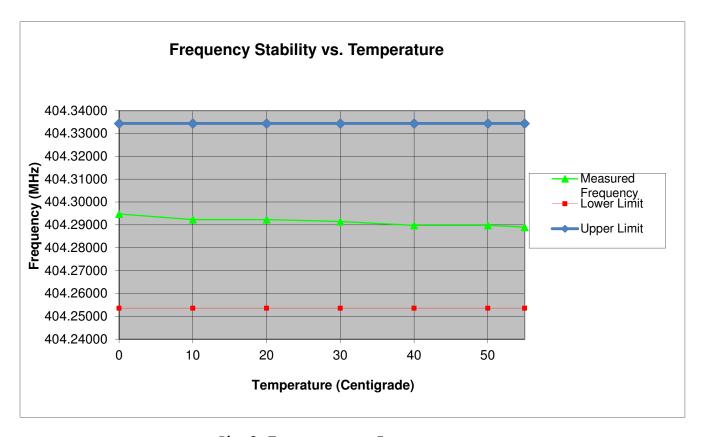
The EUT was placed in an Environmental Chamber with all the support equipment outside the chamber. The EUT was set to transmit a modulated carrier. The reference frequency at 20°C was observed and noted down. The frequency drift was investigated for every 10°C increment until the unit was stabilized then recorded the reading in tabular format with the temperature range of 0°C to 55°C.

Reference Frequency: 404.29MHz

Temperature centigrade	Measured Frequency (MHz)	Upper Margin (MHz)	Lower Margin (MHz)
0	404.29480	-0.03963	0.04123
10	404.29230	-0.04213	0.03873
20	404.29230	-0.04213	0.03873
30	404.29150	-0.04293	0.03793
40	404.28980	-0.04463	0.03623
50	404.28980	-0.04463	0.03623
55	404.28900	-0.04543	0.03543

**Table 9 – Temperature vs Frequency Test Result** 





Plot 6- Temperature vs Frequency



# 7. Frequency Stability vs Voltage

Test	§2.1055	Test Engineer(s):	Jerry M.
Requirement(s):			
Test Results:	Pass	Test Date(s):	12/04/2013

#### **Test Procedures:**

As required by 47 CFR 2.0155, Frequency Stability measurements were made at the RF antenna output terminals of the EUT.

The EUT was connected to a variable DC source. The frequency was measured at both the nominal 3.10 Vdc of the EUT and at the extreme ±15% of nominal which is 85% level or 2.64Vdc and at the 115% level or 3.57Vdc

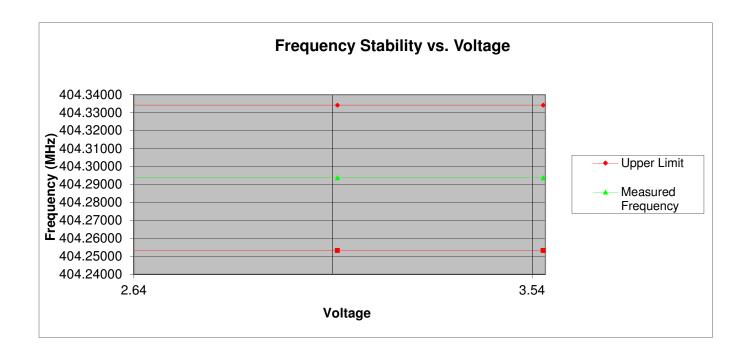
With the voltage set to a measurement point, the transmitted signal was captured by the spectrum analyzer and the frequency value determined. The frequencies are compared to the tuned frequency. All data for these measurements are found in the table 6.

Reference Frequency: 404.29 at 3.10VdC at 25°C

Input Voltage (Vdc)	Measured Frequency (MHz)	Upper Margin (MHz)	Lower Margin (MHz)
2.64	404.29380	-0.04043	0.04043
3.10	404.29380	-0.04043	0.04043
3.57	404.29380	-0.04043	0.04043

Table 10. Temperature vs. Voltage Test Result





Plot 7 – Temperature vs Voltage



# **Test Equipment**

Equipment	Manufacturer	Model	Serial #	Last Cal Date	Cal Due Date
Power Supply	Hewlett Packard	E3610A	KR83021468	NCR	None
Digital Multimeter	Fluke	77111	72550270	Jan/22/13	Jan/22/14
Spectrum Analyzer	Hewlett Packard	E4402B	US41192757	Dec/10/13	Dec/10/14
Notch Filter	K & L	3TNF- 00008	634	NCR	None
Spectrum Analyzer	Hewlett Packard	8563E	3821A09316	Sep/11/13	Sep/11/14
Temp Chamber	Thermotron	SM-3.5S mini Max	12817	Aug/29/13	Aug/29/14
Temperature Meter	Control Company	4184	122670346	Nov/15/13	Nov/15/14
Attenuator 10dB	Huber+Suhner	6810.17.A	747300	NCR	None
EMI Receiver	Rohde & Schwarz	ESCS-30	828985/007	May/16/13	May/16/14
Signal Generator	Rohde & Schwarz	SMY02	1062.5502.12	NCR	None
Attenuator 20dB	Mini Circuits	CAT-20	10012	NCR	None
Horn Antenna	Com-Power	AHA-118	071150	Sep/13/13	Sep/13/14
Bilog Antenna	Chase	CBL6140	1040	Jan/04/13	Jan/04/14

Table 11- Test Equipment List

# **END OF TEST REPORT**

<sup>\*</sup>Statement of Traceability: Test equipment is maintained and calibrated on a regular basis. All calibrations have been performed by a 17025 accredited test facility, traceable to National Institute of Standards and Technology (NIST)