Compliance Testing, LLC
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Test Report

Prepared for: OrthoSensor, Inc.

Model: Biomet Vanguard Knee Balancer

Description: Intra-Operative Knee Arthroplasty Device Used for Soft Tissue Balancing & Alignment

To

FCC Part 95

Date of Issue: January 31, 2013

On the behalf of the applicant:	**OrthoSensor, Inc.** **1560 Sawgrass Corporate Pkwy** **4th Floor4th Floor** **Sunrise, FL 33323**
Attention of:	**Erik Herrmann, Director of Product Development** **Ph: (602)692-7678** **E-Mail: eherrmann@orthosensor.com**

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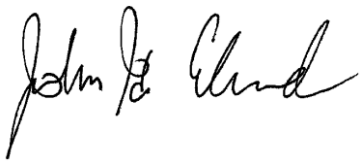
Project No: p1310007



John Erhard
Project Test Engineer

Test Report Revision History

Revision	Date	Revised By	Reason for Revision
1.0	January 31, 2013	John Erhard	Original Document

Table of Contents

ILAC / A2LA

Compliance Testing, LLC, has been accredited in accordance with the recognized International Standard ISO/IEC 17025:2005. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer joint ISO-ILAC-IAF Communiqué dated January 2009)

The tests results contained within this test report all fall within our scope of accreditation, unless noted below.

Please refer to http://www.compliancetesting.com/labscope.html for current scope of accreditation.

Testing Certificate Number: **2152.01**

FCC OATS Reg, #933597

IC Reg. #2044A-1

Non-accredited tests contained in this report:

N/A

The Applicant has been cautioned as to the following:

15.21: **Information to the User**

The user's manual or instruction manual for an intentional radiator shall caution the user that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

15.27(a): **Special Accessories**

Equipment marketed to a consumer must be capable of complying with the necessary regulations in the configuration in which the equipment is marketed. Where special accessories, such as shielded cables and/or special connectors are required to enable an unintentional or intentional radiator to comply with the emission limits in this part, the equipment must be marketed with, i.e. shipped and sold with, those special accessories. However, in lieu of shipping or packaging the special accessories with the unintentional or intentional radiator, the responsible party may employ other methods of ensuring that the special accessories are provided to the consumer, without an additional charge.

Information detailing any alternative method used to supply the special accessories for a grant of equipment authorization or retained in the verification records, as appropriate. The party responsible for the equipment, as detailed in § 2.909 of this chapter, shall ensure that these special accessories are provided with the equipment. The instruction manual for such devices shall include appropriate instructions on the first page of text concerned with the installation of the device that these special accessories must be used with the device. It is the responsibility of the user to use the needed special accessories supplied with the equipment.

Test and Measurement Data
Sub-part
2.1033(c)(14):

All tests and measurement data shown were performed in accordance with FCC Rules and Regulations, Volume II, Part 2, Sub-part J, Sections 2.947, 2.1033(c), 2.1041, 2.1046, 2.1047, 2.1079, 2.1051, 2.1053, 2.1055, 2.1057, and the following individual Parts: 95.

Standard Test Conditions and Engineering Practices

Except as noted herein, the following conditions and procedures were observed during the testing.

In accordance with ANSI/C63.4-2009, and unless otherwise indicated in the specific measurement results, the ambient temperature of the actual EUT was maintained within the range of 10° to 40°C (50° to 104°F) unless the particular equipment requirements specify testing over a different temperature range. Also, unless otherwise indicated, the humidity levels were in the range of 10% to 90% relative humidity.

Environmental Conditions		
Temp (ºC)	**Humidity (%)**	**Pressure (mbar)**
20.0	31.9	978.4

Measurement results, unless otherwise noted, are worst-case measurements.

EUT Description

Model: Biomet Vanguard Knee Balancer
Description: Intra-Operative Knee Arthroplasty Device Used for Soft Tissue Balancing & Alignment
Firmware: N/A
Software: N/A

Additional Information

N/A

EUT Operation during Tests

The EUT was in a normal operating condition and placed between representative replacement knee metal components.

Accessories: None

Cables: None

Modifications: None

Test Result Summary

Specification	Test Name	Pass, Fail, N/A	Comments
95.628(c)(4)	Radiated Output Power	Pass	
95.628(c)(4)	Radiated Spurious Emissions	Pass	
95.628(d)	Transmitter Occupied Bandwidth	Pass	
95.628(e)	Frequency Stability	Pass	

Radiated Output Power

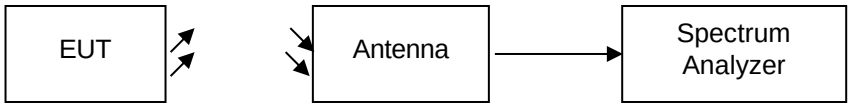
Name of Test: Radiated Output Power **Engineer:** John Erhard

Test Equipment Utilized: i00267, i00379 **Test Date:** 1/30/2013

Test Procedure

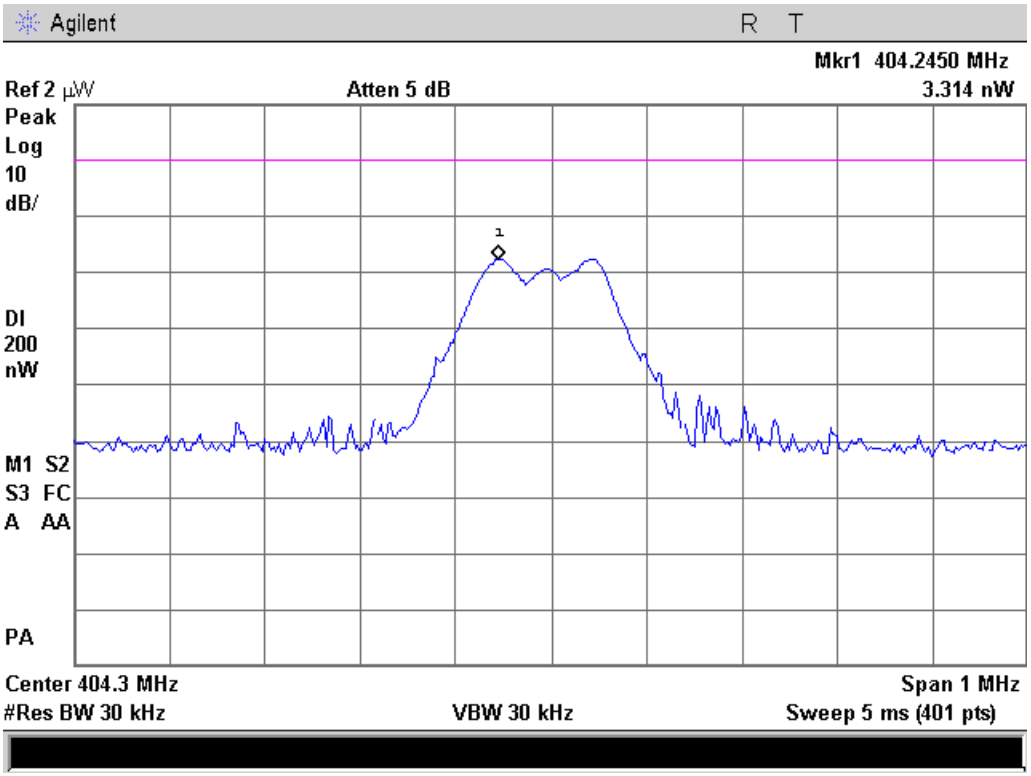
The EUT was tested in an Open Area Test Site (OATS) set 3m from the receiving transducer. A spectrum analyzer was used to verify that the EUT met the requirements for Radiated Output Power. The EUT was tested by rotating it 360° with the antennas in both the vertical and horizontal orientation and was raised from 1 to 4 meters to ensure the TX signal levels were maximized

Test Setup



Transmitter Peak Output Power

Tuned Frequency (MHz)	Recorded Measurement (Watts)	Limit (Watts)	Result
404.3	3.314 nW	200 nW	Pass



Radiated Spurious Emissions

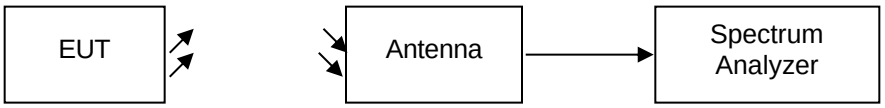
Name of Test: Radiated Spurious Emissions **Engineer:** John Erhard

Test Equipment Utilized: i00103, i00267, i00379 **Test Date:** 1/31/2013

Test Procedure

The EUT was tested in an Open Area Test Site (OATS) set 3m from the receiving transducer. A spectrum analyzer was used to verify that the EUT met the requirements for Radiated spurious Emissions. The EUT was tested by rotating it 360° with the antennas in both the vertical and horizontal orientation and was raised from 1 to 4 meters to ensure the TX signal levels were maximized. All emission from 30 MHz to the 10th harmonic of the fundamental transmitter were examined. All detectable emission were plotted and recorded in the results tables. The limits were converted from µV to a common form of measurement for ease of comparison to the limit.

Test Setup



Transmitter Spurious Emissions 402.35 MHz Test Table

Measured Frequency (MHz)	Recorded Level	Limit	Result
808.5	35.81	857 pW	Pass
1212.9	38.67	54 dB/µV	Pass
1617.2	40.54	54 dB/µV	Pass

No other emissions were detected.

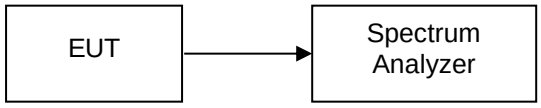
Transmitter Occupied Bandwidth

Name of Test:	Transmitter Occupied Bandwidth	**Engineer:** John Erhard
Test Equipment Utilized:	i00331	**Test Date:** 1/29/2013

Test Procedure

A conducted Sample of the EUT was connected to a spectrum analyzer and the 20 dB bandwidth was measured.

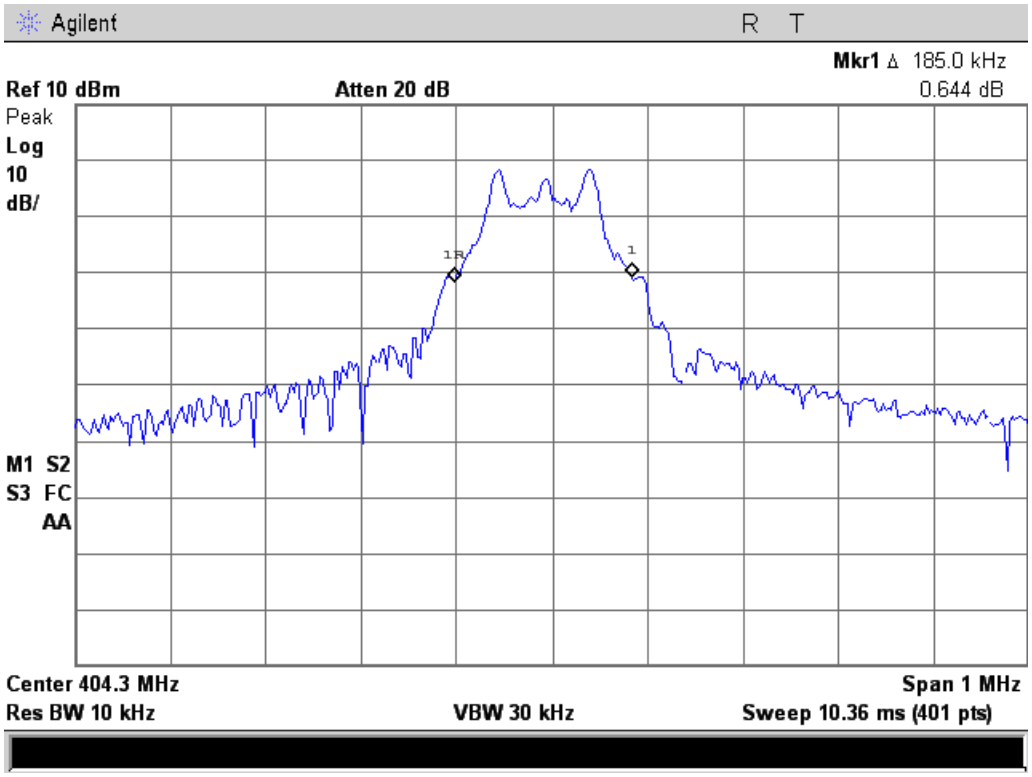
Test Setup



Emissions Bandwidth Results Table

Tuned Frequency MHz	Recorded Measurement
404.30	**185.0 kHz**

Emissions Bandwidth Test Plots



Frequency Stability

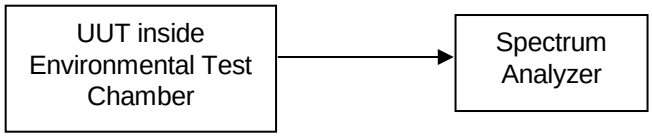
Name of Test: Frequency Stability
Engineer: John Erhard
Test Equipment Utilized: i00027, i00331, i00343
Test Date:1/25/2013

Test Procedure

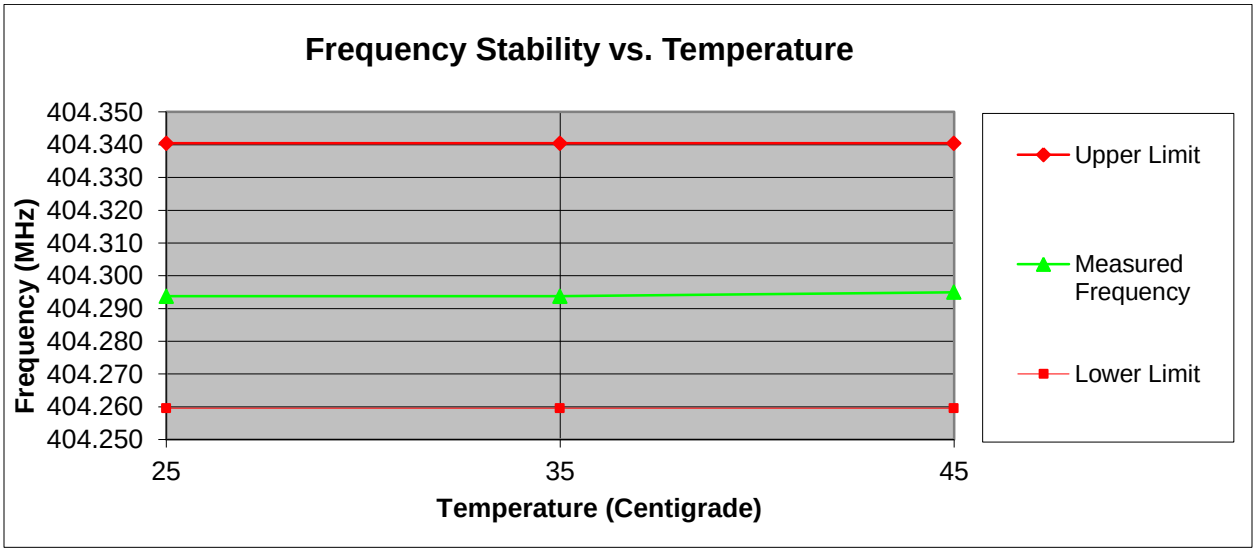
A conducted sample of the EUT was placed inside of an environmental test chamber. The temperature was varied from 25ºC to 45ºC in 10ºC increments. At each temperature the EUT was given sufficient time for temperature stabilization. The frequency was measured with a spectrum analyzer set to a very narrow span and resolution bandwidth to ensure accurate measurements were obtained. The data was plotted and compared to the limit as indicated in the following graph.

Tuned Frequency = 404.3 MHz
Limit = 100 PPM
Upper Limit = 404.340430 MHz
Lower Limit = 404.259570 MHz

Test Setup



Test Results



Test Equipment Utilized

Description	Manufacturer	Model Number	CT Asset #	Last Cal Date	Cal Due Date
Temperature Chamber	Tenney	Tenney Jr	i00027	Verified on: 1/25/13	
Horn Antenna	EMCO	3115	i00103	12/11/12	12/11/14
Bi-Log Antenna	Schaffner	CBL611C	i00267	12/19/11	12/19/13
Humidity / Temp Meter	Newport	IBTHX-W-5	i00282	12/4/12	12/4/13
Spectrum Analyzer	Agilent	E4407B	i00331	4/20/12	4/20/13
Data Logger	Fluke	Hydra Data Bucket	i00343	12/19/12	12/19/13
EMI Analyzer	Agilent	E7405A	i00379	4/20/12	4/20/13

In addition to the above listed equipment standard RF connectors and cables were utilized in the testing of the described equipment. Prior to testing these components were tested to verify proper operation.

END OF TEST REPORT