

RF Exposure Report

EUT Name: Stryker Triathlon GEN 4
Model No.: VERASENSE
FCC ID: XNL-ORTHOSNSR10

Prepared for:

OrthoSensor, Inc.
1855 Griffin Road Suite A-310
Dania FL 33004
USA

Prepared by:

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Statement of Compliance

Manufacturer: OrthoSensor, Inc.
1855 Griffin Road Suite A-310
Dania FL 33004

Name of Equipment: Stryker Triathlon GEN 4
Model No. VERASENSE
Application of Regulations: CFR 47 Part 2.1093

Guidance Documents:

FCC Part 2.1091

Test Methods:

FCC Part 1.1310, KDB 447498 D01

The electromagnetic compatibility test and documented data described in this report has been performed and recorded by TUV Rheinland, in accordance with the standards and procedures listed herein. As the responsible authorized agent of the EMC laboratory, I hereby declare that the equipment described above has been shown to be compliant with the EMC requirements of the stated regulations and standards based on these results. If any special accessories and/or modifications were required for compliance, they are listed in this report.

This report must not be used to claim product endorsement by A2LA or any agency of the U.S. Government. This report shall not be reproduced except in full, without the written authorization of TUV Rheinland of North America.



Rachana Khanduri August 5, 2020

Test Engineer Date



Richard Decker August 5, 2020

Laboratory Signatory Date



Test Cert. # 3331.02

1 Product Specifications

1.1 Product Description

1.2 Product Specifications

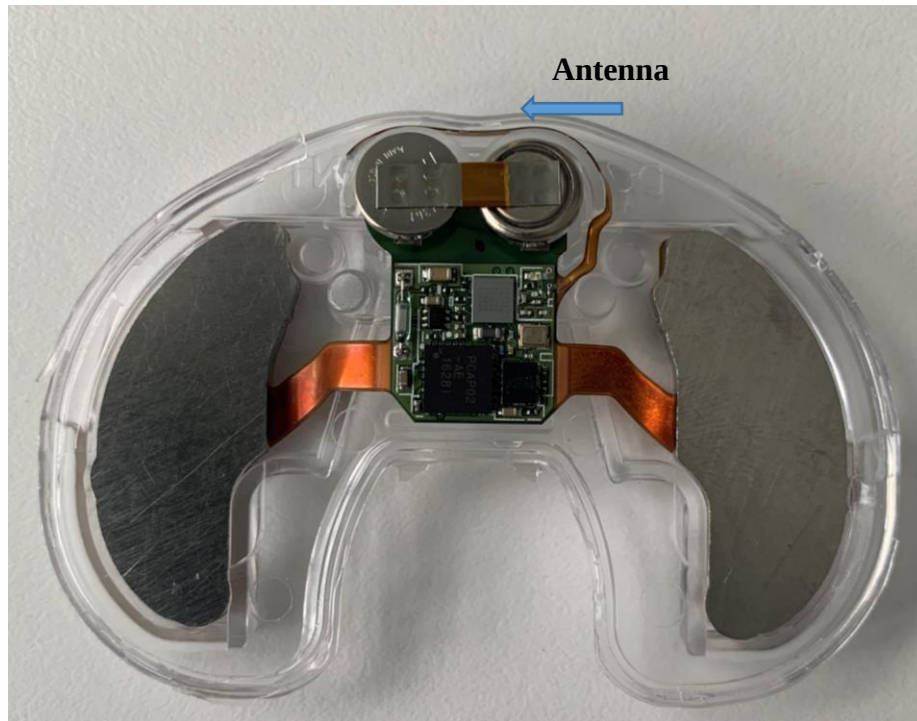
EUT Specifications	
Exposure Type	☒ General Population / Uncontrolled ☐ Occupational / Controlled
Multiple Antenna Feeds:	☐ Yes and how many ☒ No
Note:	

1.3 Air Interfaces

Air Interface	Supported Capabilities	Modulation	Maximum Duty Cycle	Band	Frequency Range (MHz)	Maximum Output Power Including Tolerance (dBm)
Bluetooth	• Low Energy	• GFSK	100%	N/A	2400 – 2483.5	3.95

1.4 Test Separation Distance

The minimum RF exposure distance between the device antenna and the user is less than 10mm apart. The value of 10mm is therefore used as required by KDB 447498. OrthoSensor's VERASENSE delivers evidence-based data wirelessly to an intra-operative monitor that enables surgeons to make informed decisions on soft tissue balance and implant position in real time. It has wireless capability, Bluetooth, operating in the band 2.4 GHz.



2 Stand-Alone SAR Evaluation Exclusion

2.1 Purpose

This report will demonstrate the compliance of RF exposure to the human body of the Stryker Triathlon GEN 4 according to FCC rule part 2.1091. All transmitters, regardless if it is categorically excluded, are assessed to ensure the product can operate in manners that meet or exceed the minimum test separation distance as required by KDB 447498.

2.2 SAR Exclusion Limits and Calculation

For 100 MHz to 6 GHz and *test separation distances* ≤ 50 mm, the 1-g and 10-g SAR *test exclusion thresholds* are determined by the following:

$$[(\text{max. power of channel, including tune-up tolerance, mW}) / (\text{min. test separation distance, mm})] \cdot [\sqrt{f(\text{GHz})}] \leq 3.0 \text{ for 1-g SAR, and } \leq 7.5 \text{ for 10-g extremity SAR,}$$

Where,

- $f(\text{GHz})$ is the RF channel transmit frequency in GHz
- Power and distance are rounded to the nearest mW and mm before calculation
- The result is rounded to one decimal place for comparison

The test exclusions are applicable only when the minimum *test separation distance* is ≤ 50 mm, and for transmission frequencies between 100 MHz and 6 GHz. When the minimum *test separation distance* is < 10 mm, a distance of 10 mm is applied to determine SAR test exclusion.

2.3 Assessment Calculation

The maximum output power and antenna gain is declared by the manufacturer and used in this assessment. The minimum RF exposure distance during normal operation is 10mm.

Stand Alone Analysis

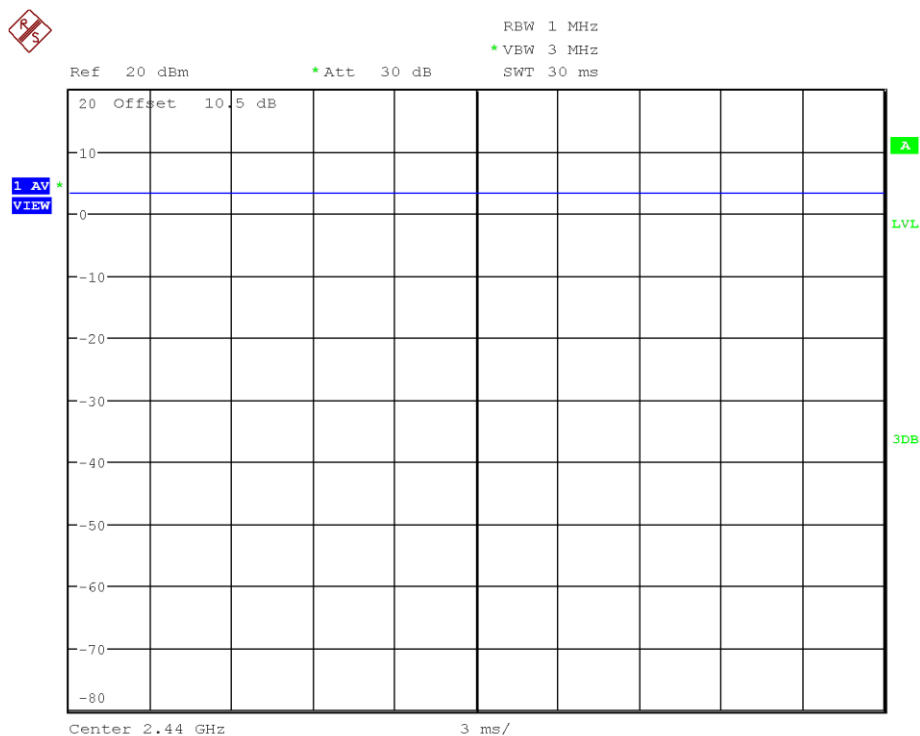
Frequency Band	Frequency of Max Power (GHz)	Max Conducted Power (dBm)	Conducted Power (mW)	Test Separation Distance (mm)	1-g ≤ 3.0	Result
2.4 GHz BLE	2.402	3.95	2.48	10	0.384	Pass

2.4 Conclusion

The EUT was found to be compliant to the requirements of FCC part 1.1310 and part 2.1091 with a separation distance of 10mm.

3 Duty Cycle Measurement

The maximum duty cycle for the Bluetooth Low Energy transmitter contained within this device is 100%



Date: 28.JAN.2020 10:28:37

END OF REPORT