OrthAlign

Lantern Reusable Navigation Unit

FCC 1.1307:2025

FCC 2.1093:2025

802.11 a/n/ac

Bluetooth Low Energy

Report: ORTH0035.0 Rev. 2, Issue Date: January 7, 2025

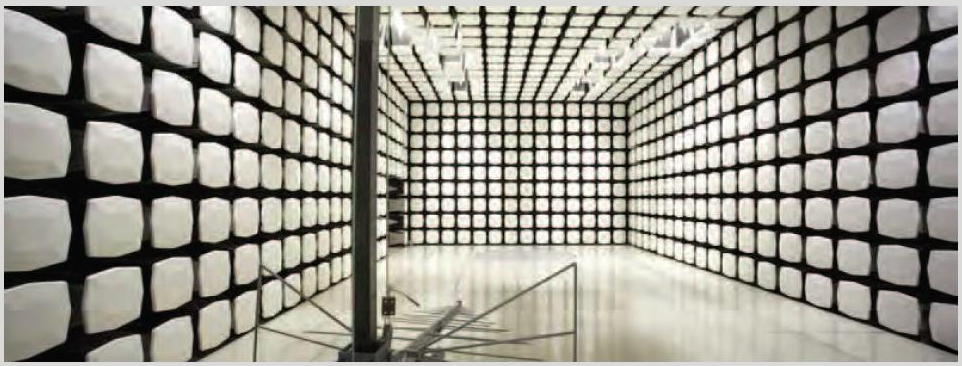


TABLE OF CONTENTS

element
2023.04.17

Section	Page Number

CERTIFICATE OF EVALUATION

Last Date of Evaluation: January 7, 2025
OrthAlign
EUT: Lantern Reusable Navigation Unit

RF Exposure Evaluation

Standards

Specification	Method
FCC 1.1307:2025 FCC 2.1093:2025	FCC 1.1307:2025

Results

Method Clause	Description	Applied	Results	Comments
(b)(3)(i)(A)	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
01	Updated EUT name	2024-11-20	1, 3, 7
	Updated company address	2024-11-20	7
	Updated functional description	2024-11-20	7
02	Updated the assessment using EIRP values	2025-01-07	12
	Updated dates to 2025.	2025-01-07	1, 3

ACCREDITATIONS AND AUTHORIZATIONS

element
2021.09.01

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:

California Minnesota Oregon Texas Washington

FACILITIES

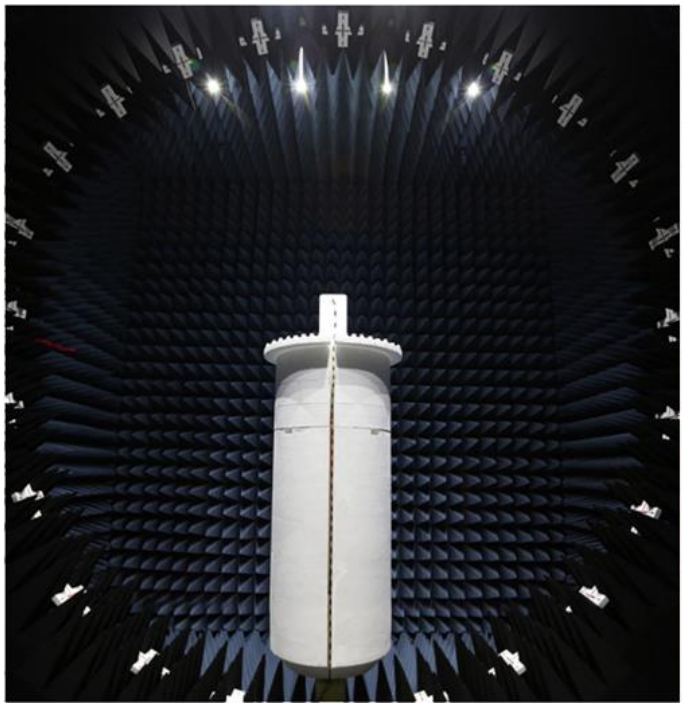
element
2024.09.23

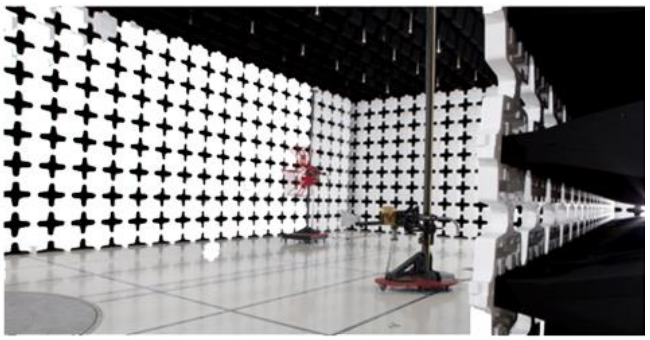
Testing was performed at the following location(s)

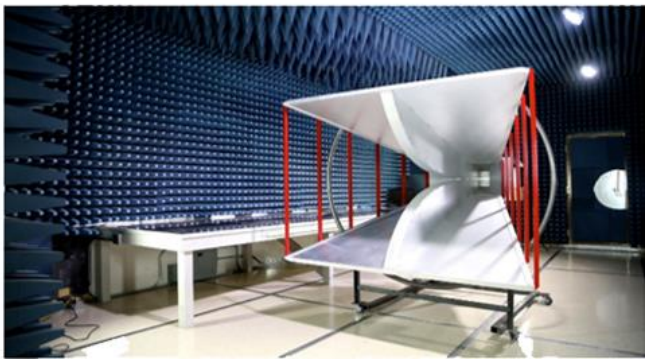
	Location	Labs (1)	Address	A2LA (2)	ISED (3)	BSMI (4)	VCCI (5)	CAB (6)	FDA (7)
☒	California	OC01-17	41 Tesla Irvine, CA 92618 (949) 861-8918	3310.04	2834B	SL2-IN-E-1154R	A-0029	US0158	TL-55
☐	Minnesota	MN01-11	9349 W Broadway Ave. Brooklyn Park, MN 55445 (612) 638-5136	3310.05	2834E	SL2-IN-E-1152R	A-0109	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
☐	Plano Texas	PT01-15	1701 E Plano Pkwy, Ste 150 Plano, TX 75074 (972) 509-2566	214.19	32637	SL2-IN-E-057R	A-0426	US0054	N/A
☐	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

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







PRODUCT DESCRIPTION

Client and Equipment Under Evaluation Information

Company Name:	OrthAlign
Address:	153 Technology Dr, Suite 100
City, State, Zip:	Irvine, CA 92618
Evaluation Requested By:	Kian Gholizadeh
EUT:	Lantern Reusable Navigation Unit
Date of Evaluation:	1/7/2025

Information Provided by the Party Requesting the Evaluation

Functional Description of the Equipment:
Surgical navigation device containing Wi-fi and Bluetooth Low Energy transmitter and receiver.

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

PRODUCT DESCRIPTION

The following duty cycle information was provided by Steven DeVincentis, Dr. Embedded Technology at OrthAlign, Inc.:

ORTH0035 - Wi-fi 5Ghz Time Based Averaging Duty Cycle Calculation			
Worst-Case DC Measurement:			
802.11 a/n HT20	**0.54548%**		
802.11 n HT40	**0.45371%**		
802.11 ac VHT80	**0.32884%**		
Field	**Origin**	**Number**	**Units**
Total Time	**Measured**	**100**	s
Total Bytes Transmitted (100s duration)	Worst Case Condition Measured (802.11 ac VHT80)	2323557	Byte
Bits in Byte	From Standard	8	bit/Byte
Total Bytes Transmitted	**Packet Size * (Bits in Byte)**	**18588456**	bit
Wi-fi Configuration	802.11 a/n MCS0		
Total Bytes Transmitted (100s duration)	Measured	464735	Byte
Bits in Byte	From Standard	8	bit/Byte
Total Bits Transmitted	**Packet Size * (Bits in Byte)**	**3717880**	bit
Transmit Rate	From Standard	6815744	Mb/s
Total Active Time	Actual Transmit Time	0.545484103	s
Duty Cycle	Total Active Time **/ Total Time * 100**	**0.545484103**	%
Wi-fi Configuration	802.11 n MCS0		
Total Bytes Transmitted (100s duration)	Measured	802833	Byte
Bits in Byte	From Standard	8	bit/Byte
Total Bits Transmitted	**Packet Size * (Bits in Byte)**	**6422664**	bit
Transmit Rate	From Standard	14155776	Mb/s
Total Active Time	Actual Transmit Time	0.454	s
Duty Cycle	Total Active Time **/ Total Time * 100**	**0.453713311**	%
Wi-fi Configuration	802.11 ac VHT80 MCS0		
Total Bytes Transmitted (100s duration)	Measured	1262884	Byte
Bits in Byte	From Standard	8	bit/Byte
Total Bits Transmitted	**Packet Size * (Bits in Byte)**	**10103072**	bit
Transmit Rate	From Standard	30723276.8	Mb/s
Total Active Time	Actual Transmit Time	0.328840965	s
Duty Cycle	Total Active Time **/ Total Time * 100**	**0.328840965**	%

ORTH0035 - BTLE 5.0 1Mbps GFSK Time Based Averaging Duty Cycle Calculation			
Worst-Case DC Measurement:	**2.5568%**		
Field	**Origin**	**Number**	**Units**
Total Time	**Measured**	**36.69**	s
# Instances (Transmissions)	**Worst Case Condition Measured**	**243**	
Data Size per Instance	Measured	486	Byte
Header Size	From Standard	10	Byte
Number of Packets per Instance	From Standard	2	
Total Packet Size	Data Size + (Header Size * Number of Packets)	506	Byte
Bits in Byte	From Standard	8	bit/Byte
Total Bits per Instance	**Packet Size * (Bits in Byte)**	**4048**	bit
Transmit Rate	From Standard	1048576	Mb/s
Actual Transmit Time per Instance	**Total Bits per Instance** / Transmit Rate	0.003860474	s
Total Active Time	Actual Transmit Time per Instance *** Instances**	0.938095093	s
Duty Cycle	Total Active Time **/ Total Time * 100**	**2.556814099**	%

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	The device is used at a distance less than 20 cm from the patient.
Radios Contained in the Same Host Device	802.11 a/n/ac Bluetooth Low Energy
Simultaneous Transmitting Radios	None
Body Worn Accessories	None
Environment	General Population/Uncontrolled Exposure

EXEMPTION FROM RF EXPOSURE EVALUATION

element
EXRPT.2023.10.17.0

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

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:

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

Where

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

And

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

(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^2f.
1,500-100,000	19.2R^2.

(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.

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

Where:

a = number of fixed, mobile, or portable RF sources claiming exemption using paragraph (b)(3)(i)(B) of this section for P_{th}, 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).

$P_{th,i}$ = the exemption threshold power (P_{th}) according to paragraph (b)(3)(i)(B) of this section for fixed, mobile, or portable RF source *i.*

ERP_j = the ERP of fixed, mobile, or portable RF source *j.*

$ERP_{th,j}$ = exemption threshold ERP for fixed, mobile, or portable RF source *j,* at a distance of at least λ/2π 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

element
EXRPT.2023.10.17.0

ASSESSMENT

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

Radio	Transmit Frequency (MHz)	Radiated Output Power or Field Strength	Power Tolerance (dB)	Duty Cycle	Antenna Assembly Gain (dBi)	Minimum Separation Distance (cm)	Calculated Conducted Exposure Power (mW)	Limit (mW)	Compliant
802.11a/n/ac: 5745 - 5825	5785	15.9 dBm EIRP	2.0	0.6%	6.5	0.5	0.1	1.0	Yes
802.11a/n/ac: 5150 - 5240	5230	21.8 dBm EIRP	2.0	0.6%	6.5	0.5	0.3	1.0	Yes

The information in the table above was obtained from:

A measured value was used in these calculations. This assessment is based on customer supplied information and Element report ORTH0035.3 Rev. 2

Radio	Transmit Frequency (MHz)	Radiated Output Power or Field Strength	Power Tolerance (dB)	Duty Cycle	Antenna Assembly Gain (dBi)	Minimum Separation Distance (cm)	Calculated Conducted Exposure Power (mW)	Limit (mW)	Compliant
Bluetooth Low Energy: 2402 - 2480 MHz	2442	10.923 dBm EIRP	2.0	2.6%	5	0.5	0.2	1.0	Yes

The information in the table above was obtained from:

A measured value was used in these calculations. This assessment is based on customer supplied information and Element report ORTH0035.2 Rev. 1

Evaluator: Jay Whitworth

End of Test Report