



OrthAlign

Lantern Refresh Surgical Assistant (LSA)

FCC 2.1093:2026

Bluetooth Low Energy

FCC: 2.1091:2026

802.11b/g/n

Report: ORTH0042.5 Rev 01, Issue Date: June 25, 2026



This report must not be used to claim product certification, approval, or endorsement by A2LA, NIST, or any agency of the U.S. Government. This Report shall not be reproduced, except in full without written approval of the laboratory.

This report is Blockchain Verified. To verify the report's authenticity, please visit <https://www.blockchain-verified.com/> or by clicking the logo to the right.



TABLE OF CONTENTS



Section	Page Number
Certificate of Evaluation	3
Revision History	4
Facilities	5
Product Description	6
Exposure Condition	7
SAR Test Exclusion	8
Maximum Permissible Exposure	10
End of Report	13

CERTIFICATE OF EVALUATION

Last Date of Evaluation: June 4, 2026
 OrthAlign
 EUT: Lantern Refresh Surgical Assistant (LSA)

RF Exposure Evaluation

Standards

Specification	Method
FCC 2.1091:2026	FCC 447498 D01 General RF Exposure Guidance v06
FCC 2.1093:2026	FCC 447498 D01 General RF Exposure Guidance v06

Results

Method Clause	Description	Applied	Results	Comments
4.3.1	SAR Test Exclusion	Yes	Compliant	None
7.1	Maximum Permissible Exposure	Yes	Compliant	None

SAR Test Exclusion for BLE Compliance Distance: 5 mm

Maximum Permissible Exposure for 802.11b/g/n Compliance Distance: 20 cm

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	Revised Report Number of SRE and MPE	06-25-2026	9, 12
01	Removed Second Row for MPE and removed footnote	06-25-2026	12

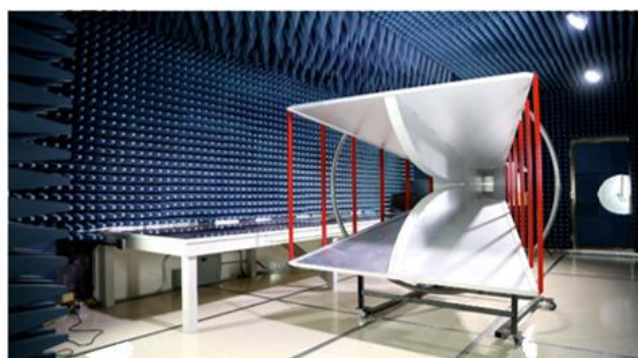
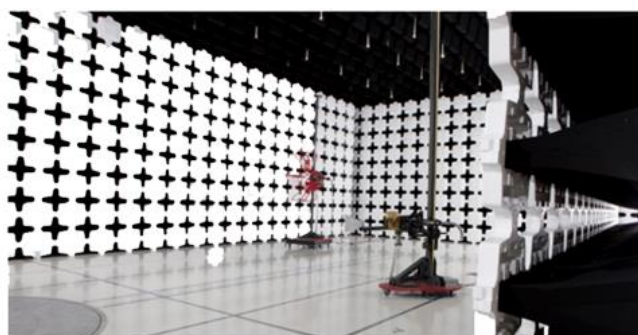
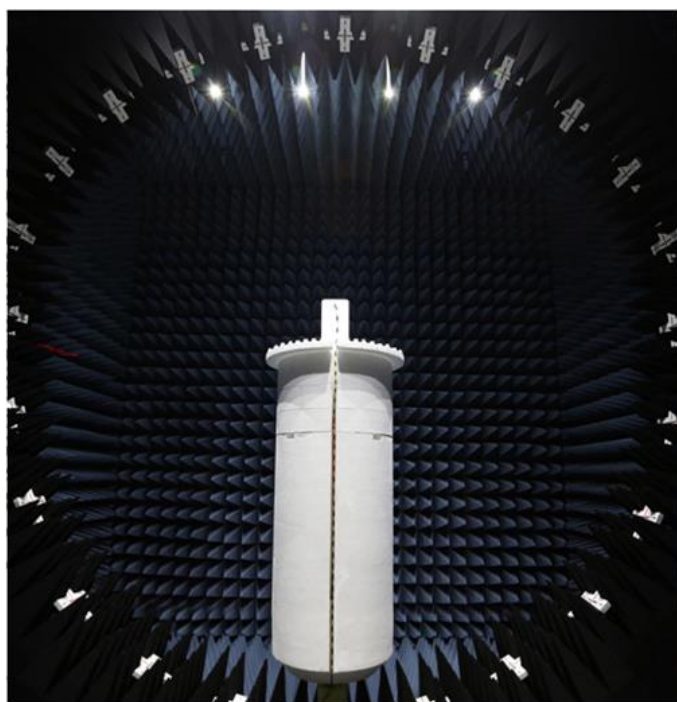
FACILITIES

Testing was performed at the following location(s)

	Location	Labs ⁽¹⁾	Address	A2LA ⁽²⁾	ISED ⁽³⁾	BSMI ⁽⁴⁾	VCCI ⁽⁵⁾	CAB	FDA ⁽⁶⁾
☒	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
☐	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) FDA ASCA No.



PRODUCT DESCRIPTION

Client and Equipment Under Evaluation Information

Company Name:	OrthAlign
Address:	153 Technology Drive, Suite 100
City, State, Zip:	Irvine, CA 92618
Evaluation Requested By:	Larry Varnado
EUT:	Lantern Refresh Surgical Assistant (LSA)
Date of Evaluation:	6/4/2026

Information Provided by the Party Requesting the Evaluation

Functional Description of the Equipment:

Simple and efficient joint technology for total hip, total knee, revision knee, and partial knee replacements.
FCC ID: 2AVMS- 406012

The Bluetooth Low Energy is used to communicate with the Femur Sensor and Reference Sensor.

The 802.11b/g/n is only used to program the firmware onto the EUT at the factory and will not be used by the end user.

HT20 is the 802.11n for the 20 MHz Bandwidth.

HT40 is the 802.11n for the 40 MHz Bandwidth

Objective:

To demonstrate compliance with FCC RF exposure requirements for 2.1093 portable devices for BLE.

To demonstrate compliance with FCC requirements for RF exposure for 2.1091 mobile/fixed devices for Wi-Fi.

RF EXPOSURE CONDITION



The following RF Exposure conditions were used for the assessment documented in this report:	
Intended Use	Bluetooth Low Energy: Portable 802.11b/g/n: Mobile
Location on Body (if applicable)	Head/Torso
How is the Device Used	Bluetooth Low Energy: The Lantern Surgical Assistant is used at a distance of 5 mm from the user 802.11b/g/n: The Lantern Surgical Assistant is used at a distance of 20 cm or greater from the user
Radios Contained in the Same Host Device	Bluetooth Low Energy 802.11 b/g/n
Simultaneous Transmitting Radios	None
Body Worn Accessories	N/A
Environment	General Population/Uncontrolled Exposure

SAR TEST EXCLUSION

OVERVIEW

Human exposure to RF emissions from portable devices (47 CFR §2.1093) used with the radiating antenna closer than 20 cm to the user requires Specific Absorption Rate (SAR) to evaluate the environmental impact of human exposure to radiofrequency (RF) radiation.

COMPLIANCE WITH FCC REQUIREMENTS IN 47 CFR §2.1093

The EUT will be used with a separation distance of less than 20 centimeters between the radiating antenna and the body of the user or nearby persons and must therefore be considered a portable transmitter per 47 CFR 2.1093(b).

47 CFR §2.1093

“(b) For purposes of this section, the definitions in §1.1307(b)(2) of this chapter shall apply. A portable device is defined as a transmitting device designed to be used in other than fixed locations and to generally be used in such a way that the RF source’s radiating structure(s) is/are within 20 centimeters of the body of the user.”

COMPLIANCE WITH FCC KDB 447498 D01 GENERAL RF EXPOSURE GUIDANCE V06

“KDB 447498 D01 General RF Exposure Guidance v06” provides the procedures, requirements, and authorization policies for mobile and portable devices.

Standalone radio SAR test exclusion is covered under section 4.3.1. Unless specifically required by the published RF exposure KDB procedures, standalone 1-g head or body and 10-g extremity SAR evaluation for general population exposure conditions, by measurement or numerical simulation, is not required when the corresponding SAR Test Exclusion Thresholds are met as shown in the Limits section below.

Simultaneous transmission SAR test exclusion is covered under section 4.3.2. SAR test exclusion is determined for each operating configuration and exposure condition according to the reported standalone SAR of each applicable simultaneously transmitting antenna. When the sum of 1-g or 10-g SAR of all simultaneously transmitting antennas in an operating mode and exposure condition combination is within the SAR limit, SAR test exclusion applies to that simultaneous transmission configuration.

SAR TEST EXCLUSION

LIMITS

Limits for General Population /Uncontrolled Exposure: 47 CFR §1.1310 (c)

The SAR limits for general population/uncontrolled exposure are 0.08 W/kg, as averaged over the whole body, and a peak spatial-average SAR of 1.6 W/kg, averaged over any 1 gram of tissue (defined as a tissue volume in the shape of a cube). Exceptions are the parts of the human body treated as extremities, such as hands, wrists, feet, ankles, and pinnae, where the peak spatial-average SAR limit is 4 W/kg, averaged over any 10 grams of tissue (defined as a tissue volume in the shape of a cube). Exposure may be averaged over a time period not to exceed 30 minutes to determine compliance with general population/uncontrolled SAR limits.

For 100 kHz to 6 GHz and test separation distances ≤ 50 mm, the SAR test exclusion thresholds are 1-g for head and body SAR and 10-g SAR for extremity SAR.

ASSESSMENT (KDB 447498 D01 GENERAL RF EXPOSURE GUIDANCE V06)

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:

$$\left[\frac{(\text{max. power of channel, including tune-up tolerance, mW})}{(\text{min. test separation distance, mm})} \right] \cdot [\sqrt{f(\text{GHz})}] = \begin{matrix} 3.0 \text{ for 1-g SAR} \\ 7.5 \text{ for 10-g extremity SAR} \end{matrix}$$

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
- 3.0 and 7.5 are referred to as the numeric thresholds

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 < 5 mm, a distance of 5 mm according to 4.1f) is applied to determine SAR test exclusion.

ASSESSMENT

By operating below the SAR Test Exclusion Threshold, the standalone radio is compliant with the requirements of 47 CFR §1.1310. If applicable, collocated radios are further assessed later in this document. The SAR Test Exclusion Threshold is summarized in the following table(s):

Radio	Frequency Range (MHz)	Conducted Output Power	Power Tolerance (dB)	Duty Cycle	Antenna Assembly Gain (dBi)	Minimum Separation Distance (mm)	Exclusion Threshold	Limit	Compliant
Bluetooth Low Energy: 2.4 GHz	2402-2480	5.85 dBm	1.0	100.0%	4	5	1.5	3.0	yes

The information in the table above was obtained from:

A measured value was used in these calculations. The rated value was used in these calculations. From Customer Supplied Information and Element Report Number: ORTH0042.0 Rev. 2

Evaluator: Kyle Fujimoto

MAXIMUM PERMISSIBLE EXPOSURE (MPE)



OVERVIEW

Human exposure to RF emissions from mobile devices (47 CFR §2.1091) may be evaluated based on the MPE limits adopted by the FCC for electric and magnetic field strength and/or power density, as appropriate, since exposures are assumed to occur at distances of 20 cm or more from persons. IEEE C95.1:2019 specifies a minimum separation distance of 20 cm for performing reliable field measurements to determine adherence to MPE limits. If the minimum separation distance between a transmitter and nearby persons is more than 20 cm under normal operating conditions, compliance with MPE limits may be determined at such distance from the transmitter. The field strength and power density limits adopted by the FCC are based on whole-body averaged exposure and the assumption of RF field levels relate most accurately to estimating whole-body averaged SAR. This means some local values of exposures exceeding the stated field strength and power density limits may not necessarily imply non-compliance if the spatial average of spatially averaged RF fields over the exposed portions of a person's body does not exceed the limits.

COMPLIANCE WITH FCC REQUIREMENTS IN 47 CFR §2.1091

47 CFR §2.1091

"A mobile device is defined as a transmitting device designed to be used in other than fixed locations and to generally be used in such a way that a separation distance of at least 20 centimeters is normally maintained between the RF source's radiating structure(s) and the body of the user or nearby persons. In this context, the term "fixed location" means that the device is physically secured at one location and is not able to be easily moved to another location while transmitting. Transmitting devices designed to be used by consumers or workers that can be easily re-located, such as wireless devices associated with a personal desktop computer, are considered to be mobile devices if they meet the 20-centimeter separation requirement."

The device will only be used with a separation distance between the antenna and the body of the user or nearby persons as shown in the table below and can therefore be considered a mobile transmitter per 47 CFR 2.1091(b).

COMPLIANCE WITH FCC KDB 447498 D01 General RF Exposure Guidance v06

"KDB 447498 D01 General RF Exposure Guidance v06" provides the procedures, requirements, and authorization policies for mobile and portable devices.

Devices operating in standalone mobile device exposure conditions may contain a single transmitter or multiple transmitters that do not transmit simultaneously are covered in section 7.1. Devices containing multiple transmitters capable of simultaneous transmissions are covered in section 7.2.

By meeting the requirements in sections 7.1 and 7.2, as applicable, mobile equipment meets the requirements of 47 CFR §1.1310.

LIMITS

Limits for General Population /Uncontrolled Exposure: 47 CFR §1.1310

Frequency Range (MHz)	Electric Field Strength (V/m)	Magnetic Field Strength (A/m)	Power Density (mW/cm ²)	Averaging Time (minutes)
0.3 - 1.34	614	1.63	*(100)	30
1.34 - 30	824/f	2.19/f	*(180/f ²)	30
30 - 300	27.5	0.073	0.2	30
300 - 1500			f/1500	30
1500 - 100000			1	30

f = frequency in MHz

* = Plane-wave equivalent power density

MAXIMUM PERMISSIBLE EXPOSURE (MPE)

POWER DENSITY

The exposure level for the radio is evaluated at a 20 cm distance from the radio's transmitting antenna using the general equation:

$$S = \frac{P * G}{4 * \pi * R^2}$$

Where: S = power density (mW/cm²)

P = power input to the antenna (mW)

G = numeric power gain relative to an isotropic radiator

R = distance to the center of the radiation of the antenna (20 cm = limit for MPE estimates)

P*G = EIRP

Solving for S, the maximum power density 20 cm from the transmitting antenna is determined. This level is then compared to the applicable limit for the transmit frequency. If limits were not met at the 20 cm boundary the evaluation distance is increased until the limit is met as shown in the table below.

For co-located radios, the ratio of the calculated level to the limit is determined. The ratios for each co-located radio are summed. If the sum is less than or equal to one, then the device is excluded from testing and is deemed compliant.

MAXIMUM PERMISSIBLE EXPOSURE (MPE)



ASSESSMENT

The standalone MPE and summed MPE ratios are summarized in the following table(s):

Radio	Frequency Range (MHz)	Max Rated Output Power	Duty Cycle	Antenna Assembly Gain (dBi)	Minimum Separation Distance (cm)	Calculated Power Density (mW/cm ²)	Limit (mW/cm ²)	Compliant
802.11 b/g/n	2412-2462	11.5 dBm	100.0%	4	20	0.0	1.0	yes

The information in the table above was obtained from:

The rated value was used in these calculations. From Customer Supplied Information and Element Report Number: ORTH0042.2 Rev. 2

Evaluator: Kyle Fujimoto

End of Test Report