



element

Alcon Laboratories, Inc.

Unity VCS

FCC 2.1091:2023

802.11ac

802.15.4

Bluetooth Low Energy

RFID

Report: ALCO0421.17, Issue Date: December 41, 2023

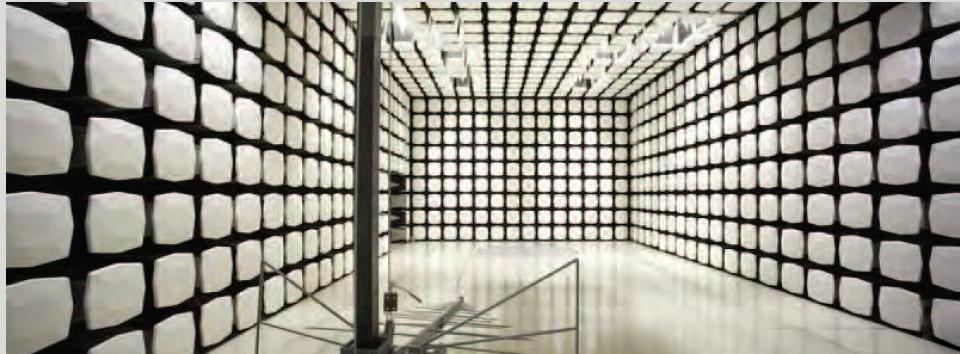


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CERTIFICATE OF EVALUATION



Last Date of Evaluation: December 1, 2023
Alcon Laboratories, Inc.
EUT: Unity VCS

RF Exposure Evaluation

Standards

Specification	Method
FCC 2.1091:2023	FCC 447498 D01 General RF Exposure Guidance v06

Results

Method Clause	Description	Applied	Results	Comments
7.1	Maximum Permissible Exposure	Yes	Pass	N/A

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
00	None		

ACCREDITATIONS AND AUTHORIZATIONS

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](#)

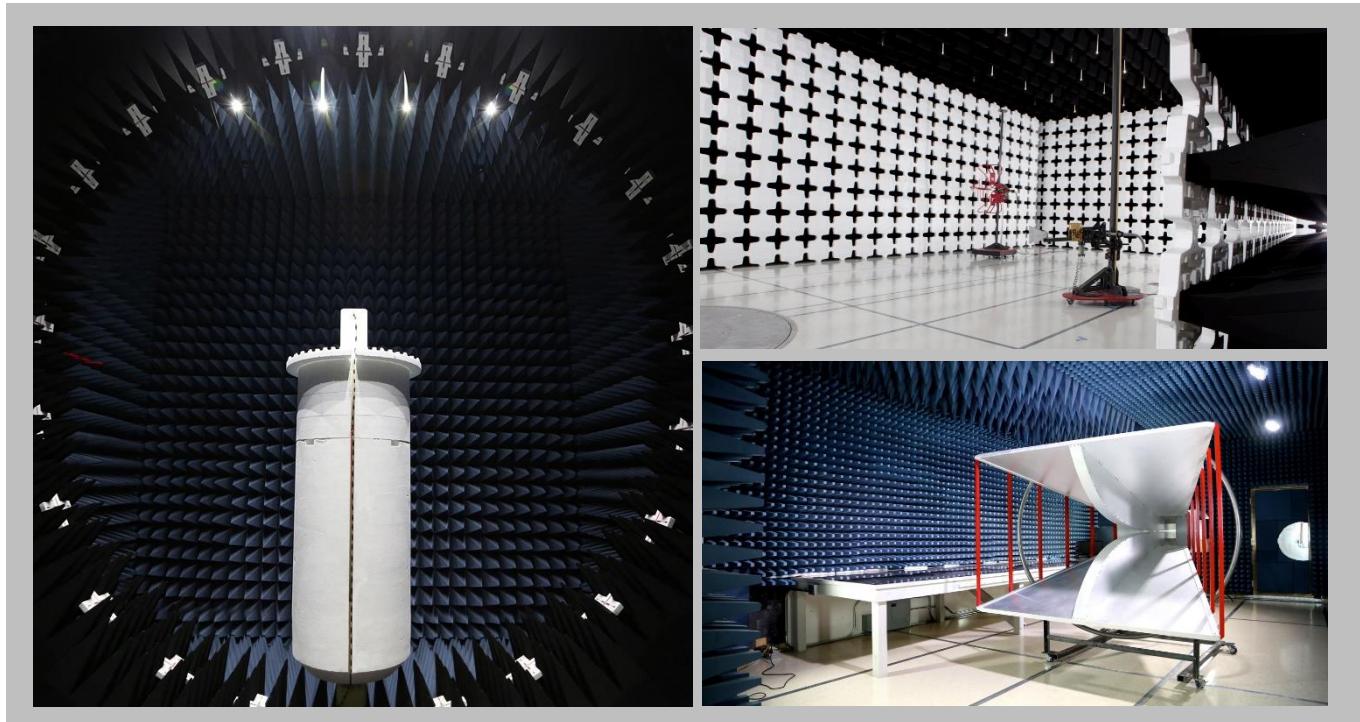
[Texas](#)

[Washington](#)

FACILITIES



California	Minnesota	Oregon	Texas	Washington
Labs OC01-17 41 Tesla Irvine, CA 92618 (949) 861-8918	Labs MN01-11 9349 W Broadway Ave. Brooklyn Park, MN 55445 (612) 638-5136	Labs EV01-12 6775 NE Evergreen Pkwy #400 Hillsboro, OR 97124 (503) 844-4066	Labs TX01-09 3801 E Plano Pkwy Plano, TX 75074 (469) 304-5255	Labs NC01-05 19201 120th Ave NE Bothell, WA 98011 (425) 984-6600
A2LA				
Lab Code: 3310.04	Lab Code: 3310.05	Lab Code: 3310.02	Lab Code: 3310.03	Lab Code: 3310.06
Innovation, Science and Economic Development Canada				
2834B-1, 2834B-3	2834E-1, 2834E-3	2834D-1	2834G-1	2834F-1
BSMI				
SL2-IN-E-1154R	SL2-IN-E-1152R	SL2-IN-E-1017	SL2-IN-E-1158R	SL2-IN-E-1153R
VCCI				
A-0029	A-0109	A-0108	A-0201	A-0110
Recognized Phase I CAB for ISED, ACMA, BSMI, IDA, KCC/RRA, MIC, MOC, NCC, OFCA				
US0158	US0175	US0017	US0191	US0157



PRODUCT DESCRIPTION



Client and Equipment Under Evaluation Information

Company Name:	Alcon Laboratories, Inc.
Address:	15800 Alton Parkway
City, State, Zip:	Irvine, CA 92618-3818
Evaluation Requested By:	Hakan Gokdogan
EUT:	Unity VCS
Date of Evaluation:	12/1/2023

Information Provided by the Party Requesting the Evaluation

Functional Description of the Equipment:

The Unity VCS/CS system is a multifunctional surgical instrument for use in anterior and posterior segment ophthalmic surgeries.

Unity VCS/CS incorporates several wireless devices

1. RFID - operated at frequency 13.56 MHz and used to identify Alcon RFID enabled probes and handpieces.
2. Wi-Fi radio operates at 2.4 and 5 GHz ranges for communication between console and hospital network and UVO (accessory to Unity VCS/CS system).
3. BLE operates at 2.4 GHz for communication with remote control.
4. 802.15.4 operated at 2.4 GHz for communication with foot control.
5. Wireless charger operated at 50 kHz to charge foot control battery.

None of these radios are co-located (distance between antennas are more than 20 cm).

The largest system dimension is 65".

Objective:

To demonstrate compliance with FCC requirements for RF exposure for 2.1091 mobile/fixed devices

RF EXPOSURE CONDITION



The following RF Exposure conditions were used for the assessment documented in this report:

Intended Use	Mobile
Location on Body (if applicable)	NA
How is the Device Used	Device is used at a distance greater than 20cm.
Radios Contained in the Same Host Device	802.11ac 802.15.4 Bluetooth Low Energy RFID
Simultaneous Transmitting Radios	None
Body Worn Accessories	N/A
Environment	General Population/Uncontrolled Exposure

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. ANSI C95.1:2005 + Amd 1:2010 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. When applicable, operation instructions and prominent warning labels may be used to alert the exposed persons to maintain a specified distance from the transmitter or to limit their exposure durations and usage conditions to ensure compliance. If the use of warning labels on a transmitter is not effective or desirable, the alternative of performing SAR evaluation with the device at its closest range to persons under normal operating conditions may be used. 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 2.1091

47 CFR §1.1307

“(b)(1) Requirements. (i) With respect to the limits on human exposure to RF provided in §1.1310 of this chapter, applicants to the Commission for the grant or modification of construction permits, licenses or renewals thereof, temporary authorities, equipment authorizations, or any other authorizations for radiofrequency sources must either:

(A) Determine that they qualify for an exemption pursuant to §1.1307(b)(3);

(B) Prepare an evaluation of the human exposure to RF radiation pursuant to §1.1310 and include in the application a statement confirming compliance with the limits in §1.1310; or

(C) Prepare an Environmental Assessment if those RF sources would cause human exposure to levels of RF radiation in excess of the limits in §1.1310.

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.

MAXIMUM PERMISSIBLE EXPOSURE (MPE)



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.

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

ASSESSMENT

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.

When the transmitted power is measured as a field strength value (dB μ V/m), this value is converted to a power level using the following derivation (assuming the field strength value has been distance corrected to 3 m, see notes below table):

Step 1 – Per ANSI C63.10:2013 section 10.3.9 equation (34), the relationship between EIRP and field strength is as follows:

$$EIRP_{meas} = E_{meas} - 95.3$$

Where:

EIRP_{meas} is the equivalent isotropically radiated power in dBm as converted from a measured value

E_{meas} is the field strength at a 3 m measurement distance in dB μ V/m. To convert from the specification measurement distance to 3 m, a 40 dB/decade adjustment was applied.

MAXIMUM PERMISSIBLE EXPOSURE (MPE)



Step 2 – If a power tolerance or a tune-up value is provided, the reported power should be scaled accordingly:

$$EIRP = EIRP_{meas} + Tolerance$$

Where:

EIRP is the maximum equivalent isotropically radiated power in dBm

EIRP_{meas} is the equivalent isotropically radiated power in dBm as converted from a measured value

Tolerance is either the tolerance provided in dB or the positive tune-up tolerance range in dB

Step 3 – Convert the EIRP value to linear terms

$$EIRP(mW) = 10^{\frac{EIRP(dBm)}{10}}$$

Where:

EIRP is the maximum equivalent isotropically radiated power, in terms of either mW or dBm

This value can then be compared against the limit to determine compliance.

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.

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

Radio	Transmit Frequency (MHz)	Radiated Output Power or Field Strength	Power Tolerance (dB)	Duty Cycle	Minimum Separation Distance (cm)	Power Density (mW/cm ²)	Limit (mW/cm ²)	Compliant
RFID: Unity VCS RFID (Laser module)	13.56	16.6 dBuV/m @ 30m	2.0	100.0%	20	0.0	1.0	Yes
RFID: Unity VCS RFID (Illuminator module)	13.56	22.6 dBuV/m @ 30m	2.0	100.0%	20	0.0	1.0	Yes
RFID: Unity CS RFID (Pneumatic module)	13.56	23.2 dBuV/m @ 30m	2.0	100.0%	20	0.0	1.0	Yes

The information in the table above was obtained from:

A measured value was used in these calculations. From client supplied information and Element test report # ALCO0421.21. The assessment of the Unity VCS/CS system is the worst case of the two model variants. The device contains FCC ID VMC-NGPVID.

Radio	Transmit Frequency (MHz)	Radiated Output Power or Field Strength	Power Tolerance (dB)	Duty Cycle	Minimum Separation Distance (cm)	Power Density (mW/cm ²)	Limit (mW/cm ²)	Compliant
802.11ac: Laird SU60-SOMC	5150	17 dBm EIRP	0.0	100.0%	20	0.0	1.0	Yes
802.11ac: Laird SU60-SOMC	2412	17 dBm EIRP	0.0	100.0%	20	0.0	1.0	Yes

The information in the table above was obtained from:

The rated value was used in these calculations. From client supplied information. The device contains FCC ID SQG-SU60SOMC.

MAXIMUM PERMISSIBLE EXPOSURE (MPE)



Radio	Transmit Frequency (MHz)	Radiated Output Power or Field Strength	Power Tolerance (dB)	Duty Cycle	Minimum Separation Distance (cm)	Power Density (mW/cm ²)	Limit (mW/cm ²)	Compliant
Bluetooth Low Energy: Laird BL654	2402	8 dBm EIRP	0.0	100.0%	20	0.0	1.0	Yes

The information in the table above was obtained from:

The rated value was used in these calculations. From client supplied information. Device contains FCC ID SQGBL654.

Radio	Transmit Frequency (MHz)	Radiated Output Power or Field Strength	Power Tolerance (dB)	Duty Cycle	Minimum Separation Distance (cm)	Power Density (mW/cm ²)	Limit (mW/cm ²)	Compliant
802.15.4: Laird 802.15.4	2405	8 dBm EIRP	0.0	100.0%	20	0.0	1.0	Yes

The information in the table above was obtained from:

The rated value was used in these calculations. From client supplied information. Device contains FCC ID VMCBL654.

Evaluator: Chuck Heller



End of Test Report