



element

ShiraTronics Inc.

RIP-CM System (CommHub)

FCC 2.1093:2023

Bluetooth Low Energy

Report: SHIR0003.0, Issue Date: May 12, 2023



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CERTIFICATE OF EVALUATION



Last Date of Evaluation: May 12, 2023
ShiraTronics Inc.
EUT: RIP-CM System (CommHub)

RF Exposure Evaluation

Standards

Specification	Method
FCC 2.1093:2023	FCC 447498 D01 General RF Exposure Guidance v06

Results

Method Clause	Description	Applied	Results	Comments
4.3.1	SAR Test Exclusion	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
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

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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.

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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

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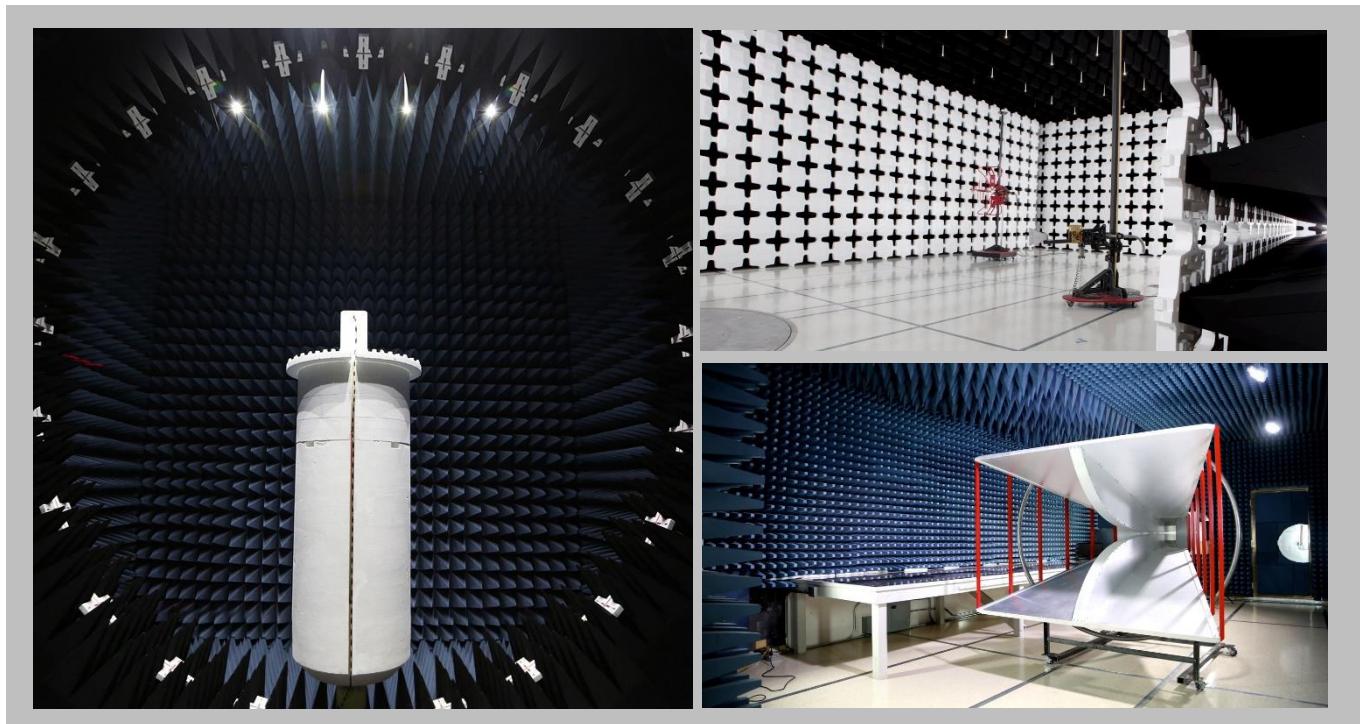
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FACILITIES



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:	ShiraTronics Inc.
Address:	9210 Wyoming Ave North Suite 275
City, State, Zip:	Brooklyn Park, MN 55445
Evaluation Requested By:	Scott Lambert
EUT:	RIP-CM System (CommHub)
Date of Evaluation:	5/12/2023

Information Provided by the Party Requesting the Evaluation

Functional Description of the Equipment:

The RIP-CM system is a head-located peripheral nerve neuromodulation system that provides pain relief through stimulation of peripheral nerves in the head. The System is intended for the treatment of headache pain, specifically chronic migraine. The therapy utilizes electrical pulses to create an electrical energy field that provides peripheral neural stimulation to interrupt or change the transmission of pain signals to the brain. RIP-CM has two identical Implantable Pulse Generators (IPG), one for each side of the head. Each IPG has a lead for the Occipital nerve and a lead for the Supraorbital nerve. Each lead array has eight contacts driven by independent current sources.

The patient interacts with the system through a Bluetooth-enabled iPad device. The iPad device provides the patient with an app to control the stimulation in the IPG, read logs, and control charging. The app also provides the clinician a means to program stimulation and fully control the IPGs. The app will store programs for the patient.

The CommHub is either affixed to the hip with belt clip or carried in a pocket.

The largest dimension of the CommHub enclosure is 136.25 mm.

Objective:

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

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 RIP-CM system is used at a distance of less than 20 cm from the user.
Radios Contained in the Same Host Device	Bluetooth Low Energy
Simultaneous Transmitting Radios	None
Body Worn Accessories	None
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 2.1093

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.

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 \leq 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 \leq 50 mm, the 1-g and 10-g SAR test exclusion thresholds are determined by the following:

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

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 \leq 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.

The SAR Test Exclusion Threshold is summarized in the following table(s):

Radio	Transmit Frequency (MHz)	Radiated Output Power or Field Strength	Duty Cycle	Minimum Separation Distance (mm)	Exclusion Threshold	Limit	Compliant
Bluetooth Low Energy	2402	10 dBm EIRP	100.0%	5	2.0	3.0	Yes

The information in the table above was obtained from:

The rated value was used in these calculations. The power tolerance is included in the rated output power. Customer supplied information. FCC ID: 2A3O3NINAB31

Evaluator: Jay Whitworth



End of Test Report