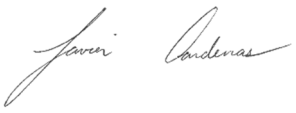
Engineering Test Report No. 2204008-03	
Report Date	March 15, 2023
Manufacturer Name	Cala Health, Inc
Manufacturer Address	1800 Gateway Drive, Suite 300 San Mateo, CA 94404
Product Name Brand/Model No.	SW100 BW100
Date Received	February 8, 2023
Assessment Date	March 15, 2023
Specifications	FCC 47 CFR Part 2.1093 KDB, 447498 D01 OET Bulletin 65:1997 RSS-102 EN 62311 EN 62479 AS/NZS 2772.2 RPS S-1
Test Facility	Elite Electronic Engineering, Inc. 1516 Centre Circle, Downers Grove, IL 60515
Signature	
Tested by	Javier Cardenas
Signature	
Approved by	Raymond J. Klouda, Registered Professional Engineer of Illinois – 44894
PO Number	PO2821

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1. Report Revision History

Revision	Date	Description
–	17 MAR 2023	Initial Release of Engineering Test Report No. 2204008-03

2. Introduction

The FCC, Innovation, Science and Economic Development Canada, European Union and Australia/New Zealand publish standards regarding the evaluation of the RF Exposure hazard of radio communications devices. An evaluation has been performed on a Cala Health, Inc wrist-worn tremor therapy device, Model No. SW100 and the accompanying charging dock, Model No. BW100 pursuant to the relevant requirements.

3. Subject of Investigation

This document presents the demonstration of RF Exposure compliance on a wrist-worn tremor therapy device and charging dock, (hereinafter referred to as the Equipment under Test (EUTs)). The EUTs were identified as follows:

EUT Identification	
EUT #1	
Description	charging dock
Model/Part No.	BW100
S/N	BA00067
Radio Access Technology	BLE, LTE Cat M1 and NFC
EUT #2	
Description	wrist-worn tremor therapy device
Model/Part No.	SW100
S/N	SA00211
Radio Access Technology	BLE

4. Standards and Requirements

The tests were performed to selected portions of, and in accordance with the following specifications.

- 47 CFR Parts 1.1310, 2.1091 and 2.1093 Code of Federal Regulations, Title 47, Telecommunications
- KDB 447498 D01 – “RF Exposure Procedures and Equipment Authorization Polices for Mobile and Portable Devices, General RF Exposure Guidance v06”
- OET Bulletin 65 Edition 97-01:1997 – “Evaluating Compliance with FCC Guidelines for Human Exposure to Radiofrequency Electromagnetic Fields”
- ANSI/IEEE C95.1:1992 – "Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz,"
- RSS-102, Issue 5 Radio Frequency (RF) Exposure Compliance of Radiocommunication Apparatus (All Frequency Bands
- EN 62311:2020 Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz)
- EN 62479:2010 Assessment of the Compliance of Low Power Electronic and Electrical Equipment with the Basic Restrictions Related to Human Exposure to Electromagnetic Fields (10MHz-300GHz)
- 1999/519/EC Council Recommendation on the Limitation of Exposure of The General Public to Electromagnetic fields (0Hz-300GHz)
- AS/NZS 2772.2: 2016 Principles and methods of measurement and computation-3 kHz to 300 GHz

- RSP S-1 Standard for Limiting Exposure to Radiofrequency Fields – 100 kHz to 300 GHz

5. Sample Calculations

The far field power density can be calculated using the following formula:

$$S = \frac{PG}{4\pi R^2} \quad (1)$$

where P is the transmit output power (mW), G is the maximum antenna gain relative to an isotropic antenna (linear) and R is the evaluation distance (cm).

In cases where multiple antennas are utilized for a single signal, the following formula is applied to calculate the maximum antenna gain:

$$Gain\ (dBi) = G + 10 \log \mathrm{N} \quad (2)$$

where N is the number of antennas, G is the gain of a single antenna.

A minimum separation distance can be calculated using the following formulas

$$Minimum\ Seperation\ Distance = \sqrt{\frac{PG}{4\pi(Power\ Density\ Limit)}} \quad (3)$$

where P is the transmit output power (mW) and G is the maximum antenna gain relative to an isotropic antenna (linear).

For sources with frequencies <30MHz

$$Seperation\ Distance = R\left(10^{\frac{(FS_{Limit} - FS_R)}{40}}\right)^{-1} \quad (4)$$

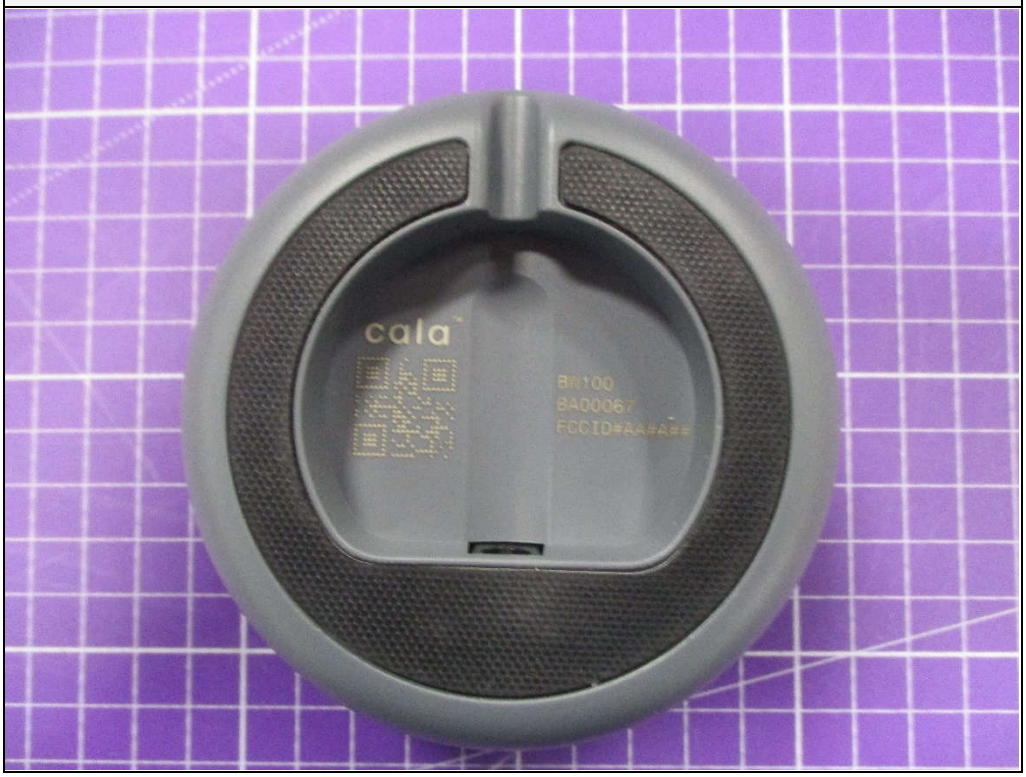
For sources with frequencies >30MHz

$$Seperation\ Distance = R\left(10^{\frac{(FS_{Limit} - FS_R)}{20}}\right)^{-1} \quad (5)$$

where R is the measurement distance, FS_{Limit} is the field strength limit and FS_R is the measured field strength at distance R.

6. Photographs of EUT

BW100



SW100

7. Limits and Requirements

7.1. Requirements mandated by the FCC

Equipment pursuing compliance to the requirements with respect to the limits of human exposure to RF provided in FCC 1.1310, need follow the criteria in FCC 1.1307(b)(1).

Equipment exemption qualification must be demonstrated pursuant to FCC 1.1307(b)(3).

For single RF sources (i.e., any single portable device, mobile device, or fixed RF source): A single RF source is exempt if:

- FCC 1.1307(b)(3)(i)(A) The available maximum time-averaged power is no more than 1 mW, regardless of separation distance.
- FCC 1.1307(b)(3)(i)(B) The available maximum time-averaged power or effective radiated power (ERP), whichever is greater, is less than or equal to the threshold Pth (mW) described in the following formula. This method shall only be used at separation distances (cm) from 0.5 centimeters to 40 centimeters and at frequencies from 0.3 GHz to 6 GHz (inclusive). Pth is given by:

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

With

$$x = -\log_{10}\left(\frac{60}{ERP_{20cm}\sqrt{f}}\right)$$

Where f is in GHz, and

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

- FCC 1.1307(b)(3)(i)(C) 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).

RF Source frequency (MHz)	Threshold ERP (watts)
0.3 – 1.34	1920 R^2
1.34 – 30	3450 R^2 / f^2
30 – 300	3.83 R^2
300 – 1,500	0.0128 R^2
1,500 – 100,000	19.2 R^2

Multiple RF sources are exempt if:

- FCC 1.1307(b)(3)(ii)(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).

- FCC 1.1307(b)(3)(ii)(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 *Pth*, 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.

Pi = 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).

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

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

ERPth,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.

Evaluatedk = 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 Limitk = 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 of this chapter.

If it is determined that the equipment under investigation is not exempt from routine evaluation an assessment must be performed to determine compliance in regards to the RF exposure limits by means of measurement or calculation of the electric field, magnetic field or power density. It may be the case that a minimum separation distance will need to be calculated or measured and maintained from the source of RF to meet the basic restrictions.

In environments where the possibility of simultaneous exposure to fields on different frequencies exists, the

exposure shall be considered to be additive. The fraction of the recommended limit incurred within each frequency should be determined, and the sum of all fractional contributions should not exceed 1.0.

Per 1.1310(e)(1), the power density shall not exceed the levels below:

Limits for Occupational/Controlled Exposure			
Frequency Range (MHz)	Electric Field Strength (V/m)	Magnetic Field Strength (A/m)	Power Density (mW/cm^2)
0.3 - 3.0	614	1.63	*100
3.0 – 30	1842 / f	4.89 / f	*900 / f^2
30 – 300	61.4	0.163	1.0
300 – 1,500	—	—	f / 300
1,500 – 100,000	—	—	5
Limits for General/Uncontrolled Exposure			
Frequency Range (MHz)	Electric Field Strength (V/m)	Magnetic Field Strength (A/m)	Power Density (mW/cm^2)
0.3 – 1.34	614	1.63	*100
1.34 – 30	842 / f	2.19 / f	*180 / f^2
30 – 300	27.5	0.073	0.2
300 – 1,500	—	—	f / 1500
1,500 – 100,000	—	—	1.0
f – Frequency in MHz * – Plane wave Equivalent Power Density			

7.2. Requirements mandated by Innovation, Science and Economic Development Canada

The RF exposure level shall be determined by either measurement or by calculating the power density at an evaluation distance of 0.2m, as specified by ANSI/IEEE C95.1-1992.

If it is found that the product meets the low power exclusion level criteria listed in RSS 102 Section 2.5.2, no further RF exposure evaluation is required. The low power exclusion level criteria are given in the following table (f is given in MHz):

RF Source Frequency (MHz)	Threshold ERP (watts)
$f < 20\ MHz$	$x \leq 1$
$20\ MHz \leq f < 48\ MHz$	$x \leq \frac{4.49}{f^{0.5}}$
$48\ MHz \leq f < 300\ MHz$	$x \leq 0.6$
$300\ MHz \leq f < 6\ GHz$	$x \leq (1.31 * 10^{-2}) * f^{0.6834}$
$6\ GHz \leq f$	$x \leq 5$

If it is determined that the measured or calculated power density does not meet the basic restrictions, a separation distance must be measured or calculated such that the basic restrictions are met.

In environments where the possibility of simultaneous exposure to fields on different frequencies exists, the exposure shall be considered to be additive. The fraction of the recommended limit incurred within each frequency should be determined, and the sum of all fractional contributions should not exceed 1.0. The following formula shall apply:

$$\sum_{i=1}^{n} \frac{S_{C,1}}{S_{L,1}} + \frac{S_{C,2}}{S_{L,2}} + \frac{S_{C,3}}{S_{L,3}} + \cdots \frac{S_{C,n}}{S_{L,n}} \leq 1 \qquad (6)$$

where:

S_C is the measured/calculated power density.
S_L is the RF exposure limit.

Per RSS 102 Section 4, the power density shall not exceed the levels below:

Limits for Occupational/Controlled Exposure			
Frequency Range (MHz)	Electric Field Strength (V/m)	Magnetic Field Strength (A/m)	Power Density (W/m^2)
0.003 – 10*	170	180	—
0.1 – 10*	—	1.6 / f	—
1.29 – 10*	193 / $f^{0.5}$	—	—
10 – 20	61.4	0.163	10
20 – 48	129.8 / $f^{0.25}$	0.3444 / $f^{0.25}$	44.72 / $f^{0.5}$
48 – 100	49.33	0.1309	6.455
100 – 6000	15.60 $f^{0.25}$	0.04138 $f^{0.25}$	0.6455 $f^{0.5}$
6000 – 15000	137	0.364	50
15000 – 150000	137	0.364	50
150000 – 300000	0.354 $f^{0.5}$	$9.40x10^{-4}$ $f^{0.5}$	$3.33x10^{-4}$ f
Limits for General/Uncontrolled Exposure			
Frequency Range (MHz)	Electric Field Strength (V/m)	Magnetic Field Strength (A/m)	Power Density (W/m^2)
0.003 – 10*	83	90	—
0.1 – 10*	—	0.73 / f	—
1.1 – 10*	87 / $f^{0.5}$	—	—
10 – 20	27.46	0.0728	2
20 – 48	58.07 / $f^{0.25}$	0.1540 / $f^{0.25}$	8.944 / $f^{.05}$
48 – 300	22.06	0.05852	1.291
300 – 6000	3.142 $f^{0.3417}$	0.008335 $f^{0.3417}$	0.02619 $f^{0.6834}$
6000 – 15000	61.4	0.163	10
15000 – 150000	61.4	0.163	10
150000 – 300000	0.158 $f^{0.5}$	$4.21x10^{-4}$ $f^{0.5}$	$6.67x10^{-5}$ f
f – Frequency in MHz			

*Limits only apply to Specific Absorption Rate and Nerve Stimulation requirements.

7.3. Requirements mandated by the European Union and outlined in EN 62311

The RF exposure level shall be determined by either measurement or by calculating the power density at an evaluation distance of 0.2m, as specified by ANSI/IEEE C95.1-1992. If it is determined that the measured or calculated power density does not meet the basic restrictions, a separation distance must be measured or calculated such that the basic restrictions are met. If the device output power is less than the low power exclusion level, then the device is deemed to comply with the basic restrictions listed in the 1999/519/EC Council Recommendation.

In environments where the possibility of simultaneous exposure to fields on different frequencies exists, the exposure shall be considered to be additive. The fraction of the recommended limit incurred within each frequency should be determined, and the sum of all fractional contributions should not exceed 1.0. The following formula shall apply:

$$\sum_{i=1}^{n} \frac{S_1}{S_{L,1}} + \frac{S_2}{S_{L,2}} + \frac{S_3}{S_{L,3}} + \cdots \frac{S_n}{S_{L,n}} \leq 1 \qquad (7)$$

where:

S is the measured/calculated power density.
S_L is the power density limit.

Per the 1999/519/EC Council Recommendation, the measured field strength shall not exceed the levels below:

Reference Levels for Maximum Exposure			
Frequency Range	Electric Field Strength (V/m)	Magnetic Field Strength (A/m)	Power Density (W/m^2)
0 – 1Hz	—	3.2×10^4	—
1 – 8Hz	10000	$3.2 \times 10^4 / f^2$	—
8 – 25Hz	10000	4000 / f	—
0.025 – 0.8kHz	250 / f	4 / f	—
0.8 – 3kHz	250 / f	5	—
3 – 150kHz	87	5	—
0.15 – 1MHz	87	0.73 / f	—
1 – 10MHz	$87 / f^{1/2}$	0.73 / f	—
10 – 400MHz	28	0.073	2
400 – 2000MHz	$1.375 f^{0.5}$	$0.0037 / f^{0.5}$	f / 200
2 – 300GHz	61	0.16	10
f as indicated in the frequency range column			

7.4. Requirements mandated by Australia/New Zealand and outlined in AS/NZS 2772.2

As stated in Schedule 5 of RPS 3, S5.2.2, the evaluation of transmitting equipment for compliance with RPS S-1 is not required where the nominal mean power output averaged over 6 minutes does not exceed the levels listed in the table below. For devices exceeding the power levels below, evaluation of transmitting equipment for compliance with this standard is not required where it can be demonstrated that in normal use the mean radiated power output does not exceed the alternative low-power exclusion levels as defined in IEC 62479 (2010).

Exposure Scenario	Low Power Exclusion Level at Frequency, f		
	100 kHz ≤ f ≤ 6 GHz	6 GHz ≤ f ≤ 30 GHz	30 GHz ≤ f ≤ 300 GHz
Occupational	100 mW	40 mW	20 mW
General Public	20 mW	8 mW	4 mW

The RF exposure levels shall be assessed either by measurement or by calculating the power density at an evaluation distance of ??m, as specified by ANSI/IEEE C95.1-1992. If it is determined that the measured or calculated power density does not meet the basic restrictions, a minimum separation distance must be measured or calculated such that the basic restrictions are met. The assessment is based on transmitter power levels, transmit frequency(s) and antenna parameters.

In environments where the possibility of simultaneous exposure to fields on different frequencies exists, the exposure shall be considered to be additive. The fraction of the recommended limit incurred within each frequency should be determined, and the sum of all fractional contributions should not exceed 1.0.

The following formula shall apply:

$$\sum_{i=1}^{n} \frac{S_1}{S_{L,1}} + \frac{S_2}{S_{L,2}} + \frac{S_3}{S_{L,3}} + \cdots \frac{S_n}{S_{L,n}} \leq 1 \qquad (8)$$

where:

S is the measured/calculated power density.
S_L is the MPE limit.

Per RPS 3, the calculated power density shall not exceed the levels below:

Limits for Occupational/Controlled Exposure			
Frequency Range	Electric Field Strength (V/m)	Magnetic Field Strength (A/m)	Power Density (W/m^2)
100kHz – 1MHz	614	1.63 / f	-
1MHz – 10MHz	614 / f	1.63 / f	$1000 / f^2$
10MHz – 400MHz	61.4	0.163	10
400MHz – 2GHz	$3.07 \times f^{0.5}$	$0.00814 / f^{0.5}$	f / 40
2GHz – 300GHz	137	0.364	50
Limits for General/Uncontrolled Exposure			
Frequency Range (MHz)	Electric Field Strength (V/m)	Magnetic Field Strength (A/m)	Power Density (W/m^2)
100kHz – 150kHz	86.8	4.86	-
150KHz – 1MHz	86.8	0.729 / f	-
1MHz – 10MHz	$86.8 / f^{0.5}$	0.729 / f	-
10MHz – 400MHz	27.4	0.0729	2
400MHz – 2GHz	$1.37 \times f^{0.5}$	$0.00364 \times f^{0.5}$	f / 200
2GHz – 300GHz	61.4	0.163	10
f – Frequency in MHz			

8. Assessment Results

8.1. RF Exposure Evaluation Relevant to the Requirements of the FCC

8.1.1. Assessment Results for the Wrist-worn Tremor Therapy Device

BLE conducted output power = 1mW

Per FCC 1.1307(b)(3)(i)(A) the device is exempt from routine evaluation.

8.1.2. Assessment Results for the Charging Dock

BLE fractional contribution:

$ERP_{th\ BLE}$ = 768mW per FCC 1.1307(b)(3)(i)(C) Table 1
ERP_{BLE} = 0.08mW

$$\frac{\mathrm{ERP_{BLE}}}{\mathrm{PER_{th\ BLE}}} = \frac{0.08\mathrm{mW}}{768\mathrm{mW}} = 1.04 \times 10^{-4}$$

LTE Cat M1 fractional contribution:

$ERP_{th\ LTE\ B12}$ = 358mW* per FCC 1.1307(b)(3)(i)(C) Table 1
$ERP_{LTE\ B12}$ = 316mW
*Most stringent ERP value

$$\frac{\mathrm{ERP_{LTE\ B12}}}{\mathrm{PER_{th\ LTE\ B12}}} = \frac{316\mathrm{mW}}{358\mathrm{mW}} = 0.883$$

NFC fractional contribution:

MPE = 60.8V/m per FCC 1.1310(e)(1) Table 1
Electric FS_{20cm} = 0.3V/m
*Most stringent ERP value

$$\frac{\mathrm{Electric\ FS}}{\mathrm{MPE}} = \frac{0.3\mathrm{V/m}}{60.8\mathrm{V/m}} = 0.005$$

Sum of fractional contributions:

$$\sum \frac{\mathrm{ERP_{BLE}}}{\mathrm{PER_{th\ BLE}}} + \frac{\mathrm{ERP_{LTE\ B12}}}{\mathrm{PER_{th\ LTE\ B12}}} + \frac{\mathrm{Electric\ FS}}{\mathrm{MPE}} = \frac{0.08\mathrm{mW}}{768\mathrm{mW}} + \frac{316\mathrm{mW}}{358\mathrm{mW}} + \frac{0.3\mathrm{V/m}}{60.8\mathrm{V/m}} = 0.8881$$

The equipment under investigation is determined to be exempt from routine evaluation, following the guidelines of FCC 1.1307(b)(3)(ii)(B)

8.2. RF Exposure Evaluation Relevant to the Requirements of the ISED

8.2.1.Assessment Results for the Wrist-worn Tremor Therapy Device

BLE conducted output power = 1mW

Per RSS-102 Section 2.5.1 Table 1, the exemption limit at a separation of ≤5mm is equal to 4mW. Given that the device is limb worn the exemption limit is multiplied by 2.5. The exemption threshold power is 10mW.

The equipment under investigation is exempt from routine evaluation.

8.2.2.Assessment Results for the Charging Dock

Radio Access Technology	*f* Transmit Frequency (MHz)	EIRP (dBm)	EIRP (W)
LTE B12*	707.5	25	0.316
BLE	2402	-8.9	0.0001
NFC	13.56	26.2	0.417

Radio Access Technology	*f* Transmit Frequency (MHz)	S_C Calculated Power Density (W/m^2)	S_L Power Density Limit (W/m^2)	S_C:S_L Ratio	∑ S_C:S_L Ratio
LTE B12*	707.5	0.629	2.32	0.271	0.69
BLE	2402	$2.56x10^{-04}$	5.35	$4.79x10^{-05}$	
NFC	13.56	0.829	2.00	0.415	

*Results in highest fractional contribution.

8.3. RF Exposure Evaluation Relevant to the Requirements of the EU

8.3.1.Assessment Results for the Wrist-worn Tremor Therapy Device

The low power exclusion level at 2400-2483.5MHz is 40mW. The power output of the tremor therapy device is 1mW. The device is excluded from further evaluation.

8.3.2.Assessment Results for the Charging Dock

Radio Access Technology	*f* Transmit Frequency (MHz)	EIRP (dBm)	EIRP (W)
LTE B12	707.5	25	0.316
BLE	2402	-8.9	0.0001
NFC	13.56	26.2	0.417

Radio Access Technology	*f* Transmit Frequency (MHz)	S_C Calculated Power Density (W/m^2)	S_L Power Density Limit (W/m^2)	S_C:S_L Ratio	Sum of S_C:S_L Ratio
LTE B12	707.5	0.629	3.54	0.178	0.59
BLE	2402	2.56E-04	10.0	2.56E-05	
NFC	13.56	0.829	2.00	0.415	

8.4. RF Exposure Evaluation Relevant to the Requirements of Australia/New Zealand

8.4.1.Assessment Results for the Wrist-worn Tremor Therapy Device

Per the RPS S-1 Advisory Note, the low power exclusion level at 2400-2483.5MHz is 20mW. The power output of the tremor therapy device is 1mW. The device is excluded from further evaluation.

8.4.2.Assessment Results for the Charging Dock

BLE fractional contribution:

$EIRP_{BLE}$ = 0.13mW
S_{BLE} = $2.56x10^{-4}W/m^{-2}$
$S_{Limit\ BLE}$ = $40W/m^{-2}$

$$\frac{S_{BLE}}{S_{Limit\ BLE}} = \frac{2.56 \times 10^{-4}\mathrm{W/m^{-2}}}{40\mathrm{W/m^{-2}}} = 6.41 \times 10^{-6}$$

LTE Cat M1 fractional contribution:

$EIRP_{LTE\ B12}$ = 316mW
$S_{LTE\ B12}$ = $0.629W/m^{-2}$
$S_{Limit\ LTE\ B12}$ = $16.4W/m^{-2}$
*Results in highest fractional contribution.

$$\frac{S_{LTE\ B12}}{S_{Limit\ LTE\ B12}} = \frac{0.629\mathrm{W/m^{-2}}}{16.4\mathrm{W/m^{-2}}} = 0.04$$

NFC fractional contribution:

Electric FS_{Limit} = 108V/m
Electric FS_{20cm} = 0.346V/m

$$\frac{\text{Electric FS}}{\text{Electric FS}_{\text{Limit}}} = \frac{0.346\mathrm{V/m}}{108\mathrm{V/m}} = 0.003$$

Sum of fractional contributions:

$$\sum \frac{S_{BLE}}{S_{Limit\ BLE}} + \frac{S_{LTE\ B12}}{S_{Limit\ LTE\ B12}} + \frac{\text{Electric FS}}{\text{Electric FS}_{\text{Limit}}} = 6.41 \times 10^{-6} + 0.04 + 0.003 = 0.043$$

9. Statement of Compliance

The Cala Health, Inc wrist-worn tremor therapy device, Model SW100 is in compliance with the FCC, Innovation, Science and Economic Development Canada, European Union and Australia/New Zealand requirements for RF Exposure.

Additionally the Cala Health, Inc charging dock, Model BW100 is in compliance with the FCC, Innovation, Science and Economic Development Canada, European Union and Australia/New Zealand requirements for RF Exposure.

10. Scope of Accreditation

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

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ELECTRICAL

Valid To: June 30, 2023 Certificate Number: 1786.01

In recognition of the successful completion of the A2LA Accreditation Program evaluation process, accreditation is granted to this laboratory to perform the following automotive electromagnetic compatibility and other electrical tests:

Test Technology:	Test Method(s) [1]:
Transient Immunity	ISO 7637-2 (including emissions); ISO 7637-3; ISO 16750-2:2012, Sections 4.6.3 and 4.6.4; CS-11979, Section 6.4; CS.00054, Section 5.9; EMC-CS-2009.1 (CI220); FMC1278 (CI220, CI221, CI222); GMW 3097, Section 3.5; SAE J1113-11; SAE J1113-12; ECE Regulation 10.06 Annex 10
Electrostatic Discharge (ESD)	ISO 10605 (2001, 2008); CS-11979 Section 7.0; CS.00054, Section 5.10; EMC-CS-2009.1 (CI 280); FMC1278 (CI280); SAE J1113-13; GMW 3097 Section 3.6
Conducted Emissions	CISPR 25 (2002, 2008), Sections 6.2 and 6.3; CISPR 25 (2016), Sections 6.3 and 6.4; CS-11979, Section 5.1; CS.00054, Sections 5.6.1 and 5.6.2; GMW 3097, Section 3.3.2; EMC-CS-2009.1 (CE 420); FMC1278 (CE420, CE421)
Radiated Emissions Anechoic	CISPR 25 (2002, 2008), Section 6.4; CISPR 25 (2016), Section 6.5; CS-11979, Section 5.3; CS.00054, Section 5.6.3; GMW 3097, Section 3.3.1; EMC-CS-2009.1 (RE 310); FMC1278 (RE310);

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Test Technology:	Test Method(s) [1]:
Vehicle Radiated Emissions	CISPR 12; CISPR 36; ICES-002; ECE Regulation 10.06 Annex 5
Bulk Current Injection (BCI)	ISO 11452-4; CS-11979, Section 6.1; CS.00054, Section 5.8.1; GMW 3097, Section 3.4.1; SAE J1113-4; EMC-CS-2009.1 (RI112); FMC1278 (RI112); ECE Regulation 10.06 Annex 9
Radiated Immunity Anechoic *(Including Radar Pulse)*	ISO 11452-2; ISO 11452-5; CS-11979, Section 6.2; CS.00054, Section 5.8.2; GMW 3097, Section 3.4.2; EMC-CS-2009.1 (RI114); FMC1278 (RI114); SAE J1113-21; ECE Regulation 10.06 Annex 9
Radiated Immunity Magnetic Field	ISO 11452-8
Radiated Immunity Reverb	ISO/IEC 61000-4-21; GMW 3097, Section 3.4.3; EMC-CS-2009.1 (RI114); FMC1278 (RI114); ISO 11452-11
Radiated Immunity *(Portable Transmitters)*	ISO 11452-9; EMC-CS-2009.1 (RI115); FMC1278 (RI115)
Vehicle Radiated Immunity (ALSE)	ISO 11451-2; ECE Regulation 10.06 Annex 6
Vehicle Product Specific EMC Standards	EN 14982; EN ISO 13309; ISO 13766; EN 50498; EC Regulation No. 2015/208; EN 55012
Electrical Loads	ISO 16750-2
Emissions Radiated and Conducted (3m Semi-anechoic chamber, up to 40 GHz)	47 CFR, FCC Part 15 B (using ANSI C63.4:2014); 47 CFR, FCC Part 18 (using FCC MP-5:1986); ICES-001; ICES-003; ICES-005; IEC/CISPR 11, Ed. 4.1 (2004-06); AS/NZS CISPR 11 (2004); IEC/CISPR 11 Ed 5 (2009-05) + A1 (2010); KN 11 (2008-5) with RRL Notice No. 2008-3 (May 20, 2008); CISPR 11; EN 55011; KS C 9811; CNS 13803 (1997, 2003); CISPR 14-1; EN 55014-1; AS/NZS CISPR 14.1; CISPR 16-2-1 (2008); CISPR 16-2-1; KS C 9814-1; KN 14-1; IEC/CISPR 22 (1997); EN 55022 (1998) + A1(2000); EN 55022 (1998) + A1(2000) + A2(2003); EN 55022 (2006); IEC/CISPR 22 (2008-09); AS/NZS CISPR 22 (2004); AS/NZS CISPR 22, 3rd Edition (2006); KN 22 (up to 6 GHz); CNS 13438 (up to 6 GHz); VCCI V-3 (up to 6 GHz); CISPR 32; EN 55032; KS C 9832; KN 32; ECE Regulation 10.06 Annex 7 (Broadband) ECE Regulation 10.06 Annex 8 (Narrowband) ECE Regulation 10.06 Annex 14 (Conducted)

Test Technology:	Test Method(s) [1]:
Emissions (cont'd)	
Cellular Radiated Spurious Emissions	ETSI TS 151 010-1 GSM; 3GPP TS 51.010-1, Sec 12; ETSI TS 134 124 UMTS; 3GPP TS 34.124; ETSI TS 136 124 LTE; E-UTRA; 3GPP TS 36.124
Current Harmonics	IEC 61000-3-2; EN 61000-3-2; KN 61000-3-2; KS C 9610-3-2; ECE Regulation 10.06 Annex 11
Flicker and Fluctuations	IEC 61000-3-3; EN 61000-3-3; KN 61000-3-3; KS C 9610-3-3; ECE Regulation 10.06 Annex 12
Immunity	
Electrostatic Discharge	IEC 61000-4-2, Ed. 1.2 (2001); IEC 61000-4-2 (1995) + A1(1998) + A2(2000); EN 61000-4-2 (1995); EN 61000-4-2 (2009-05); KN 61000-4-2 (2008-5); RRL Notice No. 2008-4 (May 20, 2008); IEC 61000-4-2; EN 61000-4-2; KN 61000-4-2; KS C 9610-4-2; IEEE C37.90.3 2001
Radiated Immunity	IEC 61000-4-3 (1995) + A1(1998) + A2(2000); IEC 61000-4-3, Ed. 3.0 (2006-02); IEC 61000-4-3, Ed. 3.2 (2010); KN 61000-4-3 (2008-5); RRL Notice No. 2008-4 (May 20, 2008); IEC 61000-4-3; EN 61000-4-3; KN 61000-4-3; KS C 9610-4-3; IEEE C37.90.2 2004
Electrical Fast Transient/Burst	IEC 61000-4-4, Ed. 2.0 (2004-07); IEC 61000-4-4, Ed. 2.1 (2011); IEC 61000-4-4 (1995) + A1(2000) + A2(2001); KN 61000-4-4 (2008-5); RRL Notice No. 2008-5 (May 20, 2008); IEC 61000-4-4; EN 61000-4-4; KN 61000-4-4; KS C 9610-4-4; ECE Regulation 10.06 Annex 15
Surge	IEC 61000-4-5 (1995) + A1(2000); IEC 61000-4-5, Ed 1.1 (2005-11); EN 61000-4-5 (1995) + A1(2001); KN 61000-4-5 (2008-5); RRL Notice No. 2008-4 (May 20, 2008); IEC 61000-4-5; EN 61000-4-5; KN 61000-4-5; KS C 9610-4-5; IEEE C37.90.1 2012; IEEE STD C62.41.2 2002; ECE Regulation 10.06 Annex 16

Test Technology:	Test Method(s) [1]:
Immunity (cont'd)	
Conducted Immunity	IEC 61000-4-6 (1996) + A1(2000); IEC 61000-4-6, Ed 2.0 (2006-05); IEC 61000-4-6 Ed. 3.0 (2008); KN 61000-4-6 (2008-5); RRL Notice No. 2008-4 (May 20, 2008); EN 61000-4-6 (1996) + A1(2001); IEC 61000-4-6; EN 61000-4-6; KN 61000-4-6; KS C 9610-4-6
Power Frequency Magnetic Field Immunity (*Down to 3 A/m*)	IEC 61000-4-8 (1993) + A1(2000); IEC 61000-4-8 (2009); EN 61000-4-8 (1994) + A1(2000); KN 61000-4-8 (2008-5); RRL Notice No. 2008-4 (May 20, 2008); IEC 61000-4-8; EN 61000-4-8; KN 61000-4-8; KS C 9610-4-8
Voltage Dips, Short Interrupts, and Line Voltage Variations	IEC 61000-4-11, Ed. 2 (2004-03); KN 61000-4-11 (2008-5); RRL Notice No. 2008-4 (May 20, 2008); IEC 61000-4-11; EN 61000-4-11; KN 61000-4-11; KS C 9610-4-11
Ring Wave	IEC 61000-4-12, Ed. 2 (2006-09); EN 61000-4-12:2006; IEC 61000-4-12; EN 61000-4-12; KN 61000-4-12; IEEE STD C62.41.2 2002
Generic and Product Specific EMC Standards	IEC/EN 61000-6-1; AS/NZS 61000-6-1; KN 61000-6-1; KS C 9610-6-1; IEC/EN 61000-6-2; AS/NZS 61000-6-2; KN 61000-6-2; KS C 9610-6-2; IEC/EN 61000-6-3; AS/NZS 61000-6-3; KN 61000-6-3; KS C 9610-6-3; IEC/EN 61000-6-4; AS/NZS 61000-6-4; KN 61000-6-4; KS C 9610-6-4; EN 50130-4; EN 61326-1; EN 50121-3-2; EN 12895; EN 50270; EN 50491-1; EN 50491-2; EN 50491-3; EN 55015; EN 60730-1; EN 60945; IEC 60533; EN 61326-2-6; EN 61800-3; IEC/CISPR 14-2; EN 55014-2; AS/NZS CISPR 14.2; KN 14-2; KS C 9814-2; IEC/CISPR 24; AS/NZS CISPR 24; EN 55024; KN 24; IEC/CISPR 35; AS/NZS CISPR 35; EN 55035; KN 35; KS C 9835; IEC 60601-1-2; JIS T0601-1-2
TxRx EMC Requirements	EN 301 489-1; EN 301 489-3; EN 301 489-9; EN 301 489-17; EN 301 489-19; EN 301 489-20

Test Technology:	Test Method(s) [1]:
European Radio Test Standards	ETSI EN 300 086-1; ETSI EN 300 086-2; ETSI EN 300 113-1; ETSI EN 300 113-2; ETSI EN 300 220-1; ETSI EN 300 220-2; ETSI EN 300 220-3-1; ETSI EN 300 220-3-2; ETSI EN 300 330-1; ETSI EN 300 330-2; ETSI EN 300 440-1; ETSI EN 300 440-2; ETSI EN 300 422-1; ETSI EN 300 422-2; ETSI EN 300 328; ETSI EN 301 893; ETSI EN 301 511; ETSI EN 301 908-1; ETSI EN 908-2; ETSI EN 908-13; ETSI EN 303 413; ETSI EN 302 502; EN 303 340; EN 303 345-2; EN 303 345-3; EN 303 345-4
Canadian Radio Tests	RSS-102 (RF Exposure Evaluation [MEAS]); RSS-102 (Nerve Stimulation [MEAS]) (5Hz to 400kHz); SPR-002; RSS-111; RSS-112; RSS-117; RSS-119; RSS-123; RSS-125; RSS-127; RSS-130; RSS-131; RSS-132; RSS-133; RSS-134; RSS-135; RSS-137; RSS-139; RSS-140; RSS-141; RSS-142; RSS-170; RSS-181; RSS-182; RSS-191; RSS-192; RSS-194; RSS-195; RSS-196; RSS-197; RSS-199; RSS-210; RSS-211; RSS-213; RSS-215; RSS-216; RSS-220; RSS-222; RSS-236; RSS-238; RSS-243; RSS-244; RSS-247; RSS-248; RSS-251; RSS-252; RSS-287; RSS-288; RSS-310; RSS-GEN
Mexico Radio Tests	IFT-008-2015; NOM-208-SCFI-2016
Japan Radio Tests	Radio Law No. 131, Ordinance of MPT No. 37, 1981, MIC Notification No. 88:2004, Table No. 22-11; ARIB STD-T66, Regulation 18
Taiwan Radio Tests	LP-0002 (July 15, 2020)
Australia/New Zealand Radio Tests	AS/NZS 4268; Radiocommunications (Short Range Devices) Standard (2014)
Hong Kong Radio Tests	HKCA 1039 Issue 6; HKCA 1042; HKCA 1033 Issue 7; HKCA 1061; HKCA 1008; HKCA 1043; HKCA 1057; HKCA 1073
Korean Radio Test Standards	KN 301 489-1; KN 301 489-3; KN 301 489-9; KN 301 489-17; KN 301 489-52; KS X 3124; KS X 3125; KS X 3130; KS X 3126; KS X 3129
Vietnam Radio Test Standards	QCVN 47:2015/BTTTT; QCVN 54:2020/BTTTT; QCVN 55:2011/BTTTT; QCVN 65:2013/BTTTT; QCVN 73:2013/BTTTT; QCVN 74:2020/BTTTT; QCVN 112:2017/BTTTT; QCVN 117:2020//BTTTT
Vietnam EMC Test Standards	QCVN 18:2014/BTTTT; QCVN 86:2019/BTTTT; QCVN 96:2015/BTTTT; QCVN 118:2018/BTTTT

Test Technology:	Test Method(s) [1]:
Unlicensed Radio Frequency Devices *(3 Meter Semi-Anechoic Room)*	47 CFR FCC Part 15C, 15D, 15E, 15F, 15G, 15H (using ANSI C63.10:2013, ANSI C63.17:2013 and FCC KDB 905462 D02 (v02))
Licensed Radio Service Equipment	47 CFR FCC Parts 20, 22, 24, 25, 27, 30, 73, 74, 80, 87, 90, 95, 96, 97, 101 (using ANSI/TIA-603-E, TIA-102.CAAA-E, ANSI C63.26:2015)
OTA (Over the Air) Performance GSM, GPRS, EGPRS UMTS (W-CDMA) LTE including CAT M1 A-GPS for UMTS/GSM LTS A-GPS, A-GLONASS, SIB8/SIB16 Large Device/Laptop/Tablet Testing Integrated Device Testing WiFi 802.11 a/b/g/n/a	CTIA Test Plan for Wireless Device Over-the-Air Performance (Method for Measurement for Radiated Power and Receiver Performance) V3.8.2; CTIA Test Plan for RF Performance Evaluation of WiFi Mobile Converged Devices V2.1.0
Electrical Measurements and Simulation AC Voltage / Current (1mV to 5kV) 60 Hz (0.1V to 250V) up to 500 MHz (1μA to 150A) 60 Hz DC Voltage / Current (1mV to 15 kV) / (1μA to 10A) Power Factor / Efficiency / Crest Factor (Power to 30kW) Resistance (1mΩ to 4000MΩ) Surge (Up to 10 kV / 5 kA) (Combination Wave and Ring Wave)	FAA AC 150/5345-10H FAA AC 150/5345-43J FAA AC 150/5345-44K FAA AC 150/5345-46E FAA AC 150/5345-47C FAA EB 67D

On the following products and materials:
Telecommunications Terminal Equipment (TTE), Radio Equipment, Network Equipment, Information Technology Equipment (ITE), Automotive Electronic Equipment, Automotive Hybrid Electronic Devices, Maritime Navigation and Radio Communication Equipment and Systems, Vehicles, Boats and Internal Combustion Engine Driven Devices, Automotive, Aviation, and General Lighting Products, Medical Electrical Equipment, Motors, Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment, Household Appliances, Electric Tools, Low-voltage Switchgear and Control gear, Programmable Controllers, Electrical Equipment for Measurement, Control and Laboratory Use, Base Materials, Power and Data Transmission Cables and Connectors

[1] When the date, edition, version, etc. is not identified in the scope of accreditation, laboratories may use the version that immediately precedes the current version for a period of one year from the date of publication of the standard measurement method, per part C., Section 1 of A2LA *R101 - General Requirements- Accreditation of ISO-IEC 17025 Laboratories*.

Testing Activities Performed in Support of FCC Certification in Accordance with 47 Code of Federal Regulations and FCC KDB 974614, Appendix A, Table A.1[2]

Rule Subpart/Technology	Test Method	Maximum Frequency (MHz)
Unintentional Radiators Part 15B	ANSI C63.4:2014	40000
Industrial, Scientific, and Medical Equipment Part 18	FCC MP-5 (February 1986)	40000
Intentional Radiators Part 15C	ANSI C63.10:2013	40000
Unlicensed Personal Communication Systems Devices Part 15D	ANSI C63.17:2013	40000
U-NII without DFS Intentional Radiators Part 15E	ANSI C63.10:2013	40000
U-NII with DFS Intentional Radiators Part 15E	FCC KDB 905462 D02 (v02)	40000
UWB Intentional Radiators Part 15F	ANSI C63.10:2013	40000
BPL Intentional Radiators Part 15G	ANSI C63.10:2013	40000
White Space Device Intentional Radiators Part 15H	ANSI C63.10:2013	40000
Commercial Mobile Services (FCC Licensed Radio Service Equipment) Parts 22 (cellular), 24, 25 (below 3 GHz), and 27	ANSI/TIA-603-E; TIA-102.CAAA-E; ANSI C63.26:2015	40000
General Mobile Radio Services (FCC Licensed Radio Service Equipment) Parts 22 (non-cellular), 90 (below 3 GHz), 95, 97, and 101 (below 3 GHz)	ANSI/TIA-603-E; TIA-102.CAAA-E; ANSI C63.26:2015	40000
Citizens Broadband Radio Services (FCC Licensed Radio Service Equipment) Part 96	ANSI/TIA-603-E; TIA-102.CAAA-E; ANSI C63.26:2015	40000

Testing Activities Performed in Support of FCC Certification in Accordance with 47 Code of Federal Regulations and FCC KDB 974614, Appendix A, Table A.1[2]

Rule Subpart/Technology	Test Method	Maximum Frequency (MHz)
Maritime and Aviation Radio Services		
Parts 80 and 87	ANSI/TIA-603-E; ANSI C63.26:2015	40000
Microwave and Millimeter Bands Radio Services		
Parts 25, 30, 74, 90 (above 3 GHz), 97 (above 3 GHz), and 101	ANSI/TIA-603-E; TIA-102.CAAA-E; ANSI C63.26:2015	40000
Broadcast Radio Services		
Parts 73 and 74 (below 3 GHz)	ANSI/TIA-603-E; TIA-102.CAAA-E; ANSI C63.26:2015	40000
Signal Boosters		
Part 20 (Wideband Consumer Signal Boosters, Provider-specific signal boosters, and Industrial Signal Boosters) Section 90.219	ANSI C63.26:2015	40000

[2] Accreditation does not imply acceptance to the FCC equipment authorization program. Please see the FCC website (https://apps.fcc.gov/oetcf/eas/) for a listing of FCC approved laboratories.

Accredited Laboratory

A2LA has accredited

ELITE ELECTRONIC ENGINEERING INC.

Downers Grove, IL

for technical competence in the field of

Electrical Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (*refer to joint ISO-ILAC-IAF Communiqué dated April 2017*).

Presented this 19th day of May 2021.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 1786.01
Valid to June 30, 2023

For the tests to which this accreditation applies, please refer to the laboratory's Electrical Scope of Accreditation.