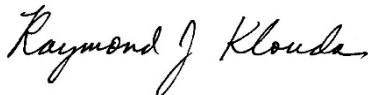




Engineering Test Report No. 2203581-03

Report Date	April 19, 2023
Manufacturer Name	Etymotic Research Inc
Manufacturer Address	61 Martin Ln Elk Grove Village, IL 60007
Product Name Model No.	TALA Bluetooth Hearing Aids Tala
Date Received	March 20, 2023
Assessment Dates	March 23 and 24, 2023
Specifications	FCC 47 CFR Part 2.1093 KDB 447498 D01 OET Bulletin 65:1997 RSS-102
Test Facility	Elite Electronic Engineering, Inc. 1516 Centre Circle, Downers Grove, IL 60515
Signature	
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Signature	
Approved by	Raymond J. Klouda, Registered Professional Engineer of Illinois – 44894
PO Number	PO-007-0003697

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1. Report Revision History

Revision	Date	Description
–	27 APR 2023	Initial Release of Engineering Test Report No. 2203581-03

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 the Etymotic Research Inc TALA Bluetooth Hearing Aids (Model No. Tala) pursuant to the relevant requirements.

3. Subject of Investigation

This document presents the demonstration of RF Exposure compliance on a TALA Bluetooth Hearing Aids (hereinafter referred to as the Equipment under Test (EUT)).

The EUT was identified as follows:

EUT Identification	
Description	TALA Bluetooth Hearing Aids
Model/Part No.	Tala
Serial No.	(LEFT) 003A (RIGHT) 008B (CHARGER) 005
Radio Access Technology	BLE
Band of Operation	2400 – 2483.5MHz
EIRP	-14.13dBm (0.0000386W)
Antenna Gain	0dB

4. Standards and Requirements

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

- 47 CFR Parts 1.1307, 1.1310, 2.1091 and 2.1093 Code of Federal Regulations, Title 47, Telecommunications
- KDB 447498 D01 – “RF Exposure Procedures and Equipment Authorization Policies 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)”

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:

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

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

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

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

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

For sources with frequencies >30MHz

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

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

Photo removed for confidentiality purposes.

Photo removed for confidentiality purposes.

Photo removed for confidentiality purposes.

Photo removed for confidentiality purposes.

7. Limits and Requirements

7.1. Requirements mandated by the FCC

Equipment pursuing compliance with 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 P_{th} (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). P_{th} is given by:

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

With

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

Where f is in GHz, and

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

- 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 $\lambda/2\pi$, 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 $\lambda/4$ 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	$19.2 R^2$

If it is determined that the equipment under investigation is not exempt from routine evaluation an assessment must be performed to determine compliance in regard 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.

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 separation distance between the user and/or bystander and the antenna and/or radiated element of the device is less than 0.2m criteria, per RSS-102 Section 2.5.1, the unit is exempt when it operates at or below the applicable output power level. The exemption limit criteria are given in the following table:

Frequency (MHz)	Exemption Limits (mW) at Separation Distances									
	≤ 5mm	10mm	15mm	20mm	25mm	30mm	35mm	40mm	45mm	≥ 50mm
≤ 300	71	101	132	162	193	223	254	284	315	345
450	52	70	88	106	123	141	159	177	195	213
835	17	30	42	55	67	80	92	105	117	130
1900	7	10	18	34	60	99	153	225	316	431
2450	4	7	15	30	52	83	123	173	235	309
3500	2	6	16	32	55	86	124	170	225	290
5800	1	6	15	27	41	56	71	85	97	106

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)
$f < 20 \text{ MHz}$	$x \leq 1$
$20 \text{ MHz} \leq f < 48 \text{ MHz}$	$x \leq \frac{4.49}{f^{0.5}}$
$48 \text{ MHz} \leq f < 300 \text{ MHz}$	$x \leq 0.6$
$300 \text{ MHz} \leq f < 6 \text{ GHz}$	$x \leq (1.31 \times 10^{-2}) * f^{0.6834}$
$6 \text{ GHz} \leq f$	$x \leq 5$

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.

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 ^{0.5}
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.			

8. Assessment Results

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

Radio Access Technology	f Transmit Frequency (MHz)	ERP/P (dBm)	ERP/P (mW)	ERP/P Exemption Threshold (mW)	Exempt /Not Exempt
BLE	2402	-15.04	0.031332857	1.0	Exempt - (A)
	2440	-14.18	0.038194427	1.0	Exempt - (A)
	2480	-14.13	0.038636698	1.0	Exempt - (A)

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

Radio Access Technology	f Transmit Frequency (MHz)	EIRP (dBm)	EIRP (W)	SAR Exemption Threshold (W)	Exempt /Not Exempt
BLE	2402	-15.04	0.00003133	0.004	Exempt
	2440	-14.18	0.00003819	0.004	Exempt
	2480	-14.13	0.00003864	0.002	Exempt

9. Statement of Compliance

The Etymotic Research Inc TALA Bluetooth Hearing Aids (Model Tala) is in compliance with the FCC and Innovation, Science and Economic Development Canada requirements for RF Exposure and is determined to be exempt from routine evaluation.