Axonics Modulation Technologies, Inc.

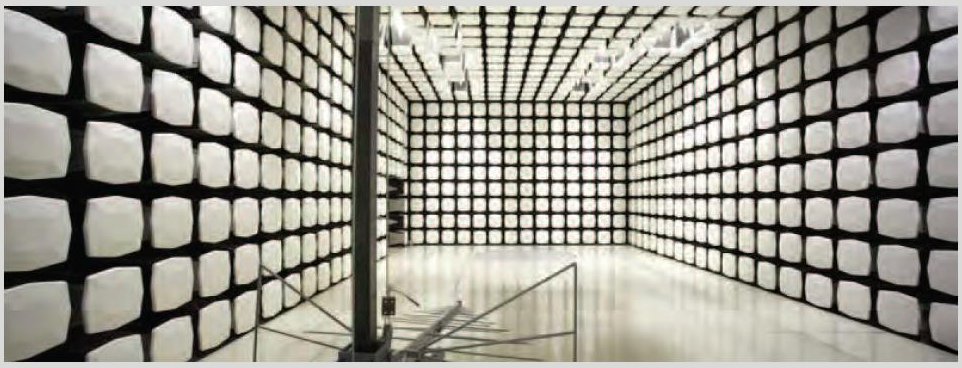
Clinician Programmer (CP) Model: 2501 (MICS/MEDS/MedRadio)

FCC 2.1093:2018

MedRadio

MICS Radio

Report # AXON0097.8



NVLAP Lab Code: 200630

CERTIFICATE OF EVALUATION

Last Date of Evaluation: Tuesday, March 13, 2018
Axonics Modulation Technologies, Inc.
Clinician Programmer (CP) Model: 2501 (MICS/MEDS/MedRadio)

RF Exposure Evaluation

Standards

Specification	Method
FCC 2.1093:2018	FCC 447498 D01 General RF Exposure Guidance v06

Results

Method Clause	Description	Applied	Results	Comments
4.3.1	SAR Test Exclusion	Yes	Pass	

Deviations From Evaluation Standards

None

Approved By:

Donald Facteau, Systems Architect

This report must not be used to claim product certification, approval, or endorsement by NVLAP, NIST, or any agency of the federal government of the United States of America.

Product compliance is the responsibility of the client, therefore the evaluation and equipment modes of operation represented in this report were agreed upon by the client, prior to evaluating. This Report may only be duplicated in its entirety. The results of this evaluation pertain only to the sample(s) evaluated. The specific description is noted in each of the individual sections of the evaluation report supporting this certificate of evaluation. This report reflects only those evaluations from the referenced standards shown in the certificate of evaluation. It does not include inspection or verification of labels, identification, marking or user information.

RF Exposure Condition

2017-1-25

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	A tablet computer (battery operated and wall outlet) used by a clinician to program the EPG/IPG
Radios Contained in the Same Host Device	MedRadio MICS Radio
Simultaneous Transmitting Radios	None
Body Worn Accessories	N/A
Environment	General Population/Uncontrolled Exposure

REVISION HISTORY

Revision Number	Description	Date	Page Number
00	None		

ACCREDITATIONS AND AUTHORIZATIONS

2018.2.20

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 - Accredited by A2LA to ISO / IEC 17065 as a product certifier. This allows Element to certify transmitters to FCC and IC specifications.

NVLAP - Each laboratory is accredited by NVLAP to ISO 17025

Canada

ISED - Recognized by Innovation, Science and Economic Development Canada as a Certification Body (CB). Certification chambers and Open Area Test Sites are filed with ISED.

European Union

European Commission – Within Element, we have a EU Notified Body validated for the EMCD and RED Directives.

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.

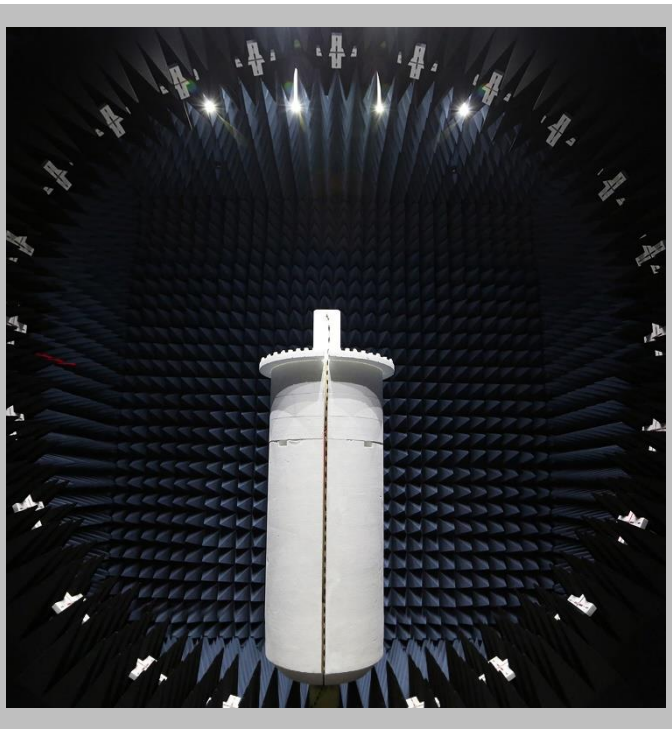
SCOPE

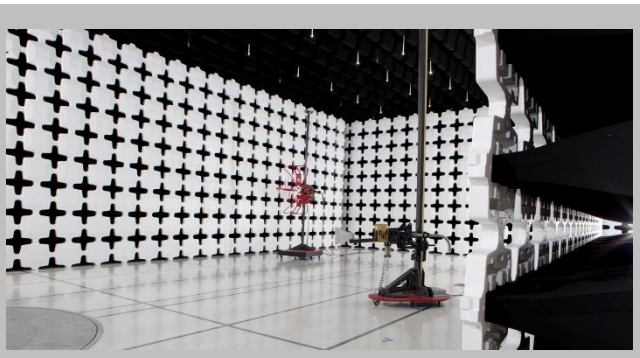
For details on the Scopes of our Accreditations, please visit:
http://portlandcustomer.element.com/ts/scope/scope.htm
http://gsi.nist.gov/global/docs/cabs/designations.html

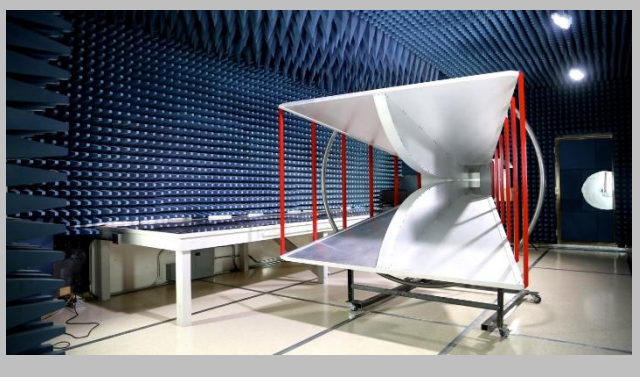
FACILITIES

2017.9.15

California	Minnesota	New York	Oregon	Texas	Washington
Labs OC01-17 41 Tesla Irvine, CA 92618 (949) 861-8918	Labs MN01-10 9349 W Broadway Ave. Brooklyn Park, MN 55445 (612)-638-5136	Labs NY01-04 4939 Jordan Rd. Elbridge, NY 13060 (315) 554-8214	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
NVLAP					
NVLAP Lab Code: 200676-0	NVLAP Lab Code: 200881-0	NVLAP Lab Code: 200761-0	NVLAP Lab Code: 200630-0	NVLAP Lab Code:201049-0	NVLAP Lab Code: 200629-0
Innovation, Science and Economic Development Canada					
2834B-1, 2834B-3	2834E-1, 2834E-3	N/A	2834D-1, 2834D-*2*	2834G-1	2834F-1
BSMI					
SL2-IN-E-1154R	SL2-IN-E-1152R	N/A	SL2-IN-E-1017	SL2-IN-E-1158R	SL2-IN-E-1153R
VCCI					
A-0029	A-0109	N/A	A-0108	A-0201	A-0110
Recognized Phase I CAB for ACMA, BSMI, IDA, KCC/RRA, MIC, MOC, NCC, OFCA					
US0158	US0175	N/A	US0017	US0191	US0157







PRODUCT DESCRIPTION

Client and Equipment Under Evaluation Information

Company Name:	Axonics Modulation Technologies, Inc.
Address:	7575 Irvine Center Drive Suite 200
City, State, Zip:	Irvine, CA 92618
Evaluation Requested By:	Franklin Portillo
Model:	Clinician Programmer (CP) Model: 2501 (MICS/MEDS/MedRadio)
Date of Evaluation:	Tuesday, March 13, 2018

Information Provided by the Party Requesting the Evaluation

Functional Description of the Equipment:
Clinician Programmer (CP): a tablet computer (battery operated and wall outlet) used by a clinician to program the EPG/IPG The CP generates stimulation pulses which are transferred to the region of therapy by foramen needle via a J-clip or by a Quadripolar tined lead via a Stimulation Test cable.

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

SAR TEST EXCLUSION

EXRPT.2017.10.02

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

"Portable devices that operate in the Cellular Radiotelephone Service pursuant to part 22 of this chapter; the Personal Communications Service (PCS) pursuant to part 24 of this chapter; the Satellite Communications Services pursuant to part 25 of this chapter; the Miscellaneous Wireless Communications Services pursuant to part 27 of this chapter; the Maritime Services (ship earth station devices only) pursuant to part 80 of this chapter; the Specialized Mobile Radio Service, the 4.9 GHz Band Service, and the 3650 MHz Wireless Broadband Service pursuant to part 90 of this chapter; the Wireless Medical Telemetry Service (WMTS) and the Medical Device Radiocommunication Service (MedRadio), pursuant to subparts H and I of part 95 of this chapter, respectively, unlicensed personal communication service, unlicensed NII devices and millimeter wave devices authorized under §§15.253(f), 15.255(g), 15.257(g), 15.319(i), and 15.407(f) of this chapter; and the Citizens Broadband Radio Service pursuant to part 96 of this chapter are subject to routine environmental evaluation for RF exposure prior to equipment authorization or use. All other portable transmitting devices are categorically excluded from routine environmental evaluation for RF exposure prior to equipment authorization or use, except as specified in §§1.1307(c) and 1.1307(d) of this chapter. Applications for equipment authorization of portable transmitting devices subject to routine environmental evaluation must contain a statement confirming compliance with the limits specified in paragraph (d) of this section. Technical information showing the basis for this statement must be submitted to the Commission upon request."

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).

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

EXRPT.2017.10.02

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 MHz 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

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:

[(max. power of channel, including tune-up tolerance, mW)/(min. test separation distance, mm)] · [vf(GHz)] = 3.0 for 1-g SAR and = 7.5 for 10-g extremity SAR,
where

- f(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 in the step b below

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.

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

Radio	Transmit Frequency (MHz)	Measured Conducted Output Power (mW)	Duty Cycle	Minimum Separation Distance (mm)	Exclusion Threshold	Limit	Compliant
MICS Radio	403.5	2.577	1	5	0.327	3.0	Yes

The information in the table above was obtained from:

Report No AXON0097.2 and client provided information

Radio	Transmit Frequency (MHz)	Measured Conducted Output Power (mW)	Duty Cycle	Minimum Separation Distance (mm)	Exclusion Threshold	Limit	Compliant
MEDS Radio	401.55	2.507	1	5	0.318	3.0	Yes

The information in the table above was obtained from:

Report No AXON0097.2 and client provided information