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SAR Exposure Report

Test Report Number	AXN-22061451-LC-FCC-SAR Exclusion
FCC ID	2AEEGS
Applicant	Axonics Modulation Technologies, Inc.
Applicant Address	7575 Irvine Center Drive Suite 200, Irvine, CA 92618
Product Name	Implantable Pulse Generator (IPG)
Model (s)	5101
Date of Receipt	10/10/2022
Date of Test	10/10/2022- 10/13/2022
Report Issue Date	10/21/2022
Test Standards	47 CFR §2.1093 447498 D04 Interim General RF Exposure Guidance v01
Test Result	**PASS**

Issued by:

Vista Compliance Laboratories
1261 Puerta Del Sol, San Clemente, CA 92673 USA
www.vista-compliance.com

Devin Tai (Test Engineer)

David Zhang (Technical Manager)

REVISION HISTORY

Report Number	Version	Description	Issued Date
AXN-22061451-LC-FCC-SAR Exclusion	01	Initial report	10/21/2022

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1 General Information

1.1 Applicant

Applicant	Axonics Modulation Technologies, Inc.
Applicant address	7575 Irvine Center Drive Suite 200, Irvine, CA 92618
Manufacturer	Axonics Modulation Technologies, Inc.
Manufacturer Address	7575 Irvine Center Drive Suite 200, Irvine, CA 92618

1.2 Product information

Product Name	Implantable Pulse Generator (IPG)
Model Number	5101
Family Models	N/A
Serial Number	AX9H150423
Frequency Band	MedRadio (MICS) 402-405 MHz, 300KHz channel spacing
Type of modulation	2-FSK
Equipment Type	Medical Devices
Equipment Class	TNT
Radio type	MedRadio (MICS), implant
Antenna Information	Integral Antenna
Clock Frequencies	N/A
Input Power	Internal battery 3.65V (nominal)
Power Adapter Manufacturer/Model	N/A
Power Adapter SN	N/A
Hardware version	N/A
Software version	N/A
Additional Info	N/A

1.3 Test standard and method

Test standard	47 CFR §1.1310 47 CFR §2.1093
Test method	47 CFR §1.1310 47 CFR §2.1093 447498 D04 Interim General RF Exposure Guidance v01

2 Test Site Information

Lab performing tests	Vista Laboratories, Inc.
Lab Address	1261 Puerta Del Sol, San Clemente, CA 92673 USA
Phone Number	+1 (949) 393-1123
Website	www.vista-compliance.com

Test Condition	Temperature	Humidity	Atmospheric Pressure
RF Testing	23.2°C	57.5%	996 mbar
Radiated Emission Testing	23.2°C	57.5%	996 mbar

3 SAR Evaluation

3.1 Test Exemption

Per KDB 447498 D04 Interim General RF Exposure Guidance v01

1. 1-mW Test Exemption

   Per § 1.1307(b)(3)(i)(A), a single RF source is exempt RF device (from the requirement to show data demonstrating compliance to RF exposure limits, as previously mentioned) if the available maximum time-averaged power is no more than 1 mW, regardless of separation distance.

   This exemption applies to all operating configurations and exposure conditions, for the frequency range 100 kHz to 100 GHz, regardless of fixed, mobile, or portable device exposure conditions. This is a standalone exemption, and it cannot be applied in conjunction with any other test exemption

2. SAR-Based Exemption

   A more comprehensive exemption, considering a variable power threshold that depends on both the separation distance and power, is provided in § 1.1307(b)(3)(i)(B). This exemption is applicable to the frequency range between 300 MHz and 6 GHz, with test separation distances between 0.5 cm and 40 cm, and for all RF sources in fixed, mobile, and portable device exposure conditions. Accordingly, a RF source is considered an RF exempt device if its available maximum time averaged (matched conducted) power or its effective radiated power (ERP), whichever is greater, are below a specified threshold. This exemption threshold was derived based on general population 1-g SAR requirements and is detailed in Appendix C.

4 SAR Test Exclusion Threshold Results

Freq. (MHz)	Max. Conducted Power (dBm)	Duty Cycle in 6-min time-averaging period (%)	Time-averaged Max. Power (mW)	Measured EIRP (dBm) / (mW)	SAR test exemption limit for implant (mW)	Result
402.3	5.055	9.3	0.298	-34.42 / 0.00036	1	Pass

EUT is exempted for SAR test.

Note: Maximum output power please refer to RF test report: AXN-22061451-LC-FCC IC-TNT

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FCC– Low Duty Factor – Analysis – using a conservative transmission duty factor estimation

The Axonics IPG model 5101 is a medical device implanted in user that utilizes the MedRadio band (402-405 MHz) and complies with Part 95i.

The IPG (5101) does not initiate any communications. Also, the IPG does not decide which data to transmit. The IPG only transmits data (non-voice) that is requested by the Axonics Clinician Programmer device. These transmissions, and their on-off durations, are inherently controlled by the device software and the user only initiates the "Connect" request. Therefore, the Axonics system is source-based, as the device inherently controls the transmissions and there is no need for specific user behavior over time to maintain compliance.

Maximum (worst-case) IPG transmitter duty ratios occur when one (1) diagnostic data file is retrieved from the IPG. The Clinician Programmer is the only device that can request such data file from the IPG (5101). Furthermore, the file's data length transmitted is short (~42 kB max file size) and of fixed data length (it never varies). The typical use of the Clinician Programmer is intermittent, used when user visits their urologist physician that is responsible for the system. This doctor visit is typically about twice a year. A user may experience the worst-case scenario in the event that retrieving of system diagnostic logs are required for analyzing detailed IPG behavior. This event is extremely rare, less than 1 in 5000 (0.02%), physician visits. The Axonics IPG (5101) has a worst-case low duty factor of **23.2%**, details are described below.

The details of the transmitted data by the IPG (5101) are discussed below. These transmission estimates are conservative.

Transmit bit rate: 19.2 kbit/s (2.4 kB/s)	
% Distribution	
Max data size (kB)	**Tx-ON time (ms)**
41.672 kB – Fixed size (diagnostic log)	17363 ms
2.242 kB – Fixed size (Therapy parameters)	934 ms

All transmissions have been included, based on worst-case scenario (*most conservative*), where diagnostic logs (largest file) are accessed.

Events are in sequence. Events cannot be requested in parallel	**Duration: Tx-ON plus Tx-OFF (ms)**	**Tx-ON time (ms)**
Initiate Wake-up, Preamble response (once per session)	16000 ms	35 ms
Initiate Connect, included retrieving Therapy parameters (once per session)	14220 ms	1458 ms
Download ***diagnostic file*** (log) - Authorized Access Required (password protected) (once per session)	45334 ms	17363 ms
Initiate Stimulation (ON/OFF)	1000 ms	48 ms
Ping while Connected	5000 ms	60 ms
Initiate Disconnect (once per session)	379 ms	57 ms
Total time	**81933 ms**	**19021 ms**
Final composite Tx Duty Factor	19021 / 81933 = ***23.2%***	

The following worst-case scenario is based on *6-min time-averaging* period:

Events are in sequence. Events cannot be requested in parallel	**Duration: Tx-ON plus Tx-OFF (ms)**	**Tx-ON time (ms)**
Initiate Wake-up, Preamble response (once per session)	16000 ms	35 ms
Initiate Connect, included retrieving Therapy parameters (once per session)	14220 ms	1458 ms
Retrieve diagnostic log (file-fixed size) - Authorized Access Required (password protected) (once per session)	45334 ms	17363 ms
Initiate Stimulation (ON/OFF) – repeat every 1 sec, until **6-min session** ends. (this would not be a common user behavior, used to prove worst-case)	360000 ms	17280 ms
Ping while Connected (repeat every 5 sec, until **6-min session** ends)	Included in the 6-min for stimulation. conservative	4320 ms
Initiate Disconnect at the end of 6 min session (once per session)	379 ms	57 ms
Total time	**435,933 ms**	**40513 ms**
Final 6-min time-average Tx Duty Factor	40513 / 435933 = ***9.3%***	

The following worst-case scenario is based on *30-min time-averaging* period:

Events are in sequence. Events cannot be requested in parallel	**Duration: Tx-ON plus Tx-OFF (ms)**	**Tx-ON time (ms)**
Initiate Wake-up, Preamble response (once per session)	16000 ms	35 ms
Initiate Connect, included retrieving Therapy parameters (once per session)	14220 ms	1458 ms
Retrieve diagnostic log (file-fixed size) - Authorized Access Required (password protected) (once per session)	45334 ms	17363 ms
Initiate Stimulation (ON/OFF) – repeat every 1 sec, until 30-min session ends. (this would not be a common user behavior, used to prove worst-case)	1800000 ms	86400 ms
Ping while Connected (repeat every 5 sec, until 30-min session ends)	Included in the 30-min for stimulation.	21600 ms
Initiate Disconnect at the end of 6 min session (once per session)	379 ms	57 ms
Total time	**1875933 ms**	**126913 ms**
Final 30-min time-average Tx Duty Factor	126913 / 1875933 = ***6.8%***	

The following worst-case scenario is based on *common use* (does not include diagnostic file):

Events are in sequence. Events cannot be requested in parallel	**Duration: Tx-ON plus Tx-OFF (ms)**	**Tx-ON time (ms)**
Initiate Wake-up, Preamble response (once per session)	16000 ms	35 ms
Initiate Connect, included retrieving Therapy parameters (once per session)	14220 ms	1458 ms
Initiate Stimulation (ON/OFF)	1000 ms	48 ms
Ping while Connected	5000 ms	60 ms
Initiate Disconnect (once per session)	379 ms	57 ms

Events are in sequence. Events cannot be requested in parallel	**Duration: Tx-ON plus Tx-OFF (ms)**	**Tx-ON time (ms)**
Total time	**36599 ms**	**1658 ms**
Final Common Use composite Tx Duty Factor	1658 / 36599 = ***4.5%***	

Conclusion

Based on this analysis, we can conclude that the Axonics IPG (5101) has a worst-case low duty factor of **23.2%**. This scenario represents the worst-case. Furthermore, this scenario is considered extremely rare and requires special privileges to access the log file request. The 6-minute average worst-case low duty factor is **9.3%**. The 30-minute average worst-case low duty factor is **6.8%.** The more common conservative scenario would have a low duty factor of **4.5%**, which does not include the diagnostic log file.

Type of Worst-Case Scenario	**Low Duty Factor**
Worst Single Session	23.2%
6-min Average	9.3%
30-min Average	6.8%
Common Use conservative	4.5%

Based on this analysis it can be concluded that the source-based Axonics IPG (5101) system has a worst-case low duty factor of 23.2%.