



Abbott Laboratories

Gemini System (IPG)

FCC 1.1307:2022

Bluetooth Low Energy (BTLE)

Report: ABBO0075.13 Rev. 1, Issue Date: January 13, 2022



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CERTIFICATE OF EVALUATION



Last Date of Evaluation: January 4, 2022
Abbott Laboratories
EUT: Gemini System (IPG)

RF Exposure Evaluation

Standards

Specification	Method
FCC 1.1307:2022	FCC 1.1307:2022

Results

Method Clause	Description	Applied	Results	Comments
1.1307(b)(3)(i)(A)	Exemption From RF Exposure Evaluation	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
01	Updated Operational Description in Appendix.	2022-01-13	12-15

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

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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.

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

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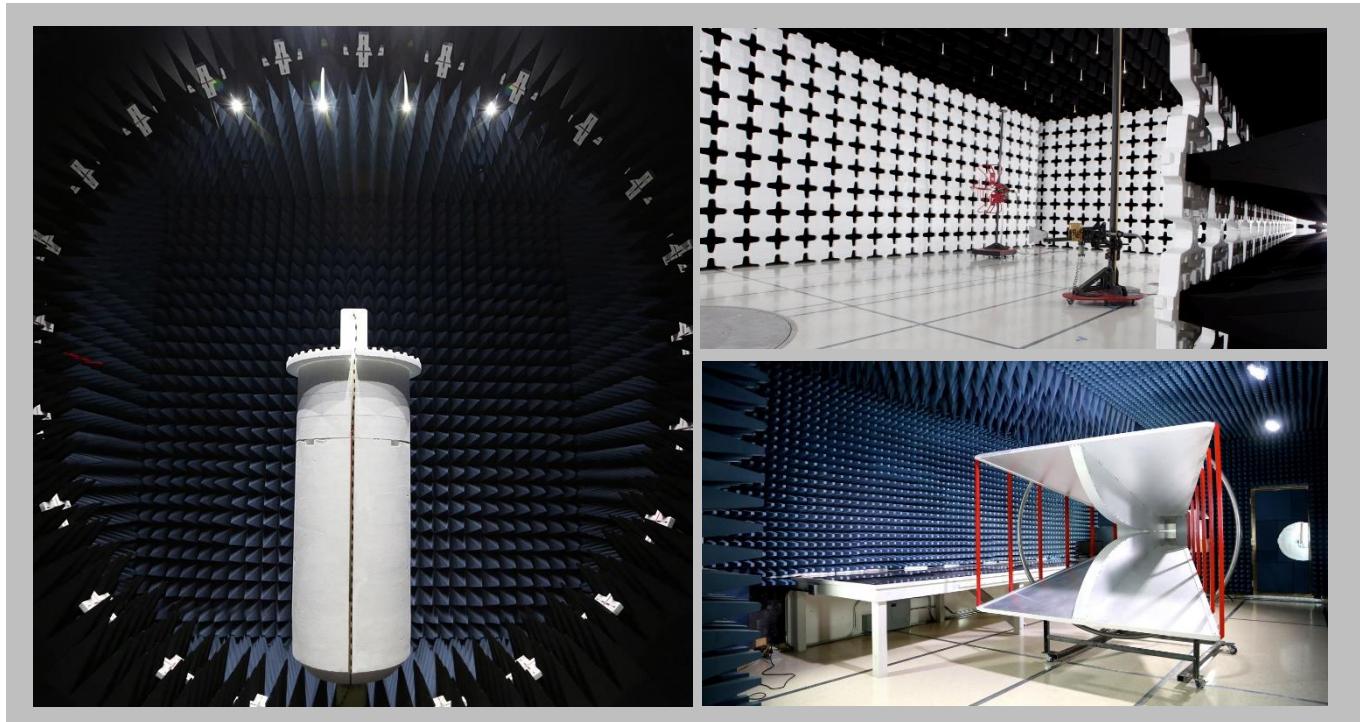
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FACILITIES



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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:	Abbott Laboratories
Address:	6901 Preston Rd
City, State, Zip:	Plano, TX 75024
Evaluation Requested By:	Jeremiah Darden
EUT:	Gemini System (IPG)
Date of Evaluation:	January 4, 2022

Information Provided by the Party Requesting the Evaluation

Functional Description of the Equipment:

Implantable Pulse Generator used to provide nerve therapy. Bluetooth Low Energy (BTLE) radio is used to communicate with commercial off the shelf devices (i.e. Apple iPhones). See attached "Operational Description IPG.docx" for further details.

Largest Product Dimension: 1.9 inches

Objective:

To demonstrate compliance with FCC Requirements for RF exposure for 1.1307 RF exempt 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	< 20cm, in the body
Radios Contained in the Same Host Device	Bluetooth Low Energy (BTLE)
Simultaneous Transmitting Radios	None
Body Worn Accessories	N/A
Environment	General Population/Uncontrolled Exposure

EXEMPTION FROM RF EXPOSURE EVALUATION



OVERVIEW

With respect to the limits on human exposure to RF emissions provided in 47 CFR §1.1310, if equipment can be shown to qualify for an exemption pursuant to 47 CFR §1.1307(b)(3), an evaluation is not required.

COMPLIANCE WITH FCC 1.1310

Per 1.1307(b)(3), (i) For single RF sources (*i.e.*, any single fixed RF source, mobile device, or portable device, as defined in paragraph (b)(2) of this section): A single RF source is exempt if:

- (A) The available maximum time-averaged power is no more than 1 mW, regardless of separation distance. This exemption may not be used in conjunction with other exemption criteria other than those in paragraph (b)(3)(ii)(A) of this section. Medical implant devices may only use this exemption and that in paragraph (b)(3)(ii)(A);
- (B) Or 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 cm to 40 cm and at frequencies from 0.3 GHz to 6 GHz (inclusive). P_{th} is given by:

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

Where

$$x = -\log_{10}\left(\frac{60}{ERP_{20\text{ cm}}\sqrt{f}}\right) \text{ and } f \text{ is in GHz;}$$

And

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

- (C) Or 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).

TABLE 1 TO §1.1307(b)(3)(i)(C)—SINGLE RF SOURCES SUBJECT TO ROUTINE ENVIRONMENTAL EVALUATION

RF Source frequency (MHz)	Threshold ERP (watts)
0.3-1.34	$1,920 R^2$.
1.34-30	$3,450 R^2/f^2$.
30-300	$3.83 R^2$.
300-1,500	$0.0128 R^2 f$.
1,500-100,000	$19.2 R^2$.

EXEMPTION FROM RF EXPOSURE EVALUATION



(ii) For multiple RF sources: Multiple RF sources are exempt if:

(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). This exemption may not be used in conjunction with other exemption criteria other than those in paragraph (b)(3)(i)(A) of this section. Medical implant devices may only use this exemption and that in paragraph (b)(3)(i)(A).

(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 $P_{th,i}$, 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.

P_i = 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).

$P_{th,i}$ = the exemption threshold power ($P_{th,i}$) according to paragraph (b)(3)(i)(B) of this section for fixed, mobile, or portable RF source i .

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

$ERP_{th,j}$ = exemption threshold ERP for fixed, mobile, or portable RF source j , at a distance of at least $\lambda/2\pi$ according to the applicable formula of paragraph (b)(3)(i)(C) of this section.

$Evaluated_k$ = 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.

$Exposure\ Limit_k$ = 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

The relationship between EIRP and ERP is:

$$ERP\ (dBm) = EIRP\ (dBm) - 2.14\ dB$$

Where EIRP is the sum of the conducted power (dBm) and the antenna gain (dBi).

EXEMPTION FROM RF EXPOSURE EVALUATION



ASSESSMENT

The exemption from RF exposure evaluation is summarized in the following table(s):

Radio	Transmit Frequency (MHz)	Conducted Output Power	Power Tolerance (dB)	Duty Cycle	Antenna Assembly Gain (dBi)	Minimum Separation Distance (cm)	Calculated Conducted Exposure Power (mW)	Limit (mW)	Compliant
BTLE: 2402-2483.5MHz	2402	6 dBm	1.6	14.1%	-2.92	0.5	0.8	1.0	Yes

The information in the table above was obtained from:

The rated value was used in these calculations. The values presented herein were derived from a client provided RF exposure document and attached technical operational description received via email.

Evaluator: Brandon Hobbs

APPENDIX

Operational Description (IPG)

FCC ID: PX2-GMIPG1

This device is an implantable pulse generator and operates in the 2.4GHz band for data communication with smartphones. The maximum data rate could be up to 2 Mbit/s as limited by the Bluetooth Low Energy protocol. It uses up to 40 2-MHz channels. Within a channel, data is transmitted using frequency-shift keying modulation. The transmitter of the EUT is powered by an internal rechargeable battery (during compliance testing a USB FTDI cable operating at 5VDC is used to control the radio functions of the IPG via the serial interface (i.e changing channels, data rates, etc), but the IPG still operates on the internal 3.7VDC battery and is not powered by the USB port). Modulated signals are used to transfer patient or settings data. Voice and video are not transmitted. The device only uses one integral custom monopole antenna that is permanently attached and cannot be changed by the user. Stabilization and monitoring of clocks are outlined within the clock control block diagram figure. A matching network is used at the output to the antenna to reduce spurious harmonics. For additional details, please see the user's manual.

The power settings employed for this application: 0 dBm (Advertising) and +6dBm (Packet Transfer)

Power accuracy: +1.5dB / -1.5dB

Rated power delivered to the antenna : +6 dBm

Antenna Gain: -2.92 dBi

Frequency of operation: 2402 – 2480 MHz

Non product software is used to manually control the radio for compliance testing. To match the production firmware, the power settings used for the product software are referenced within the Interface Communications Document and the matching power settings are used.

Duty cycle – 100% duty cycle is used for all compliance testing for the listed rule part. In normal operation, duty cycle is 14.8% over a 100mS period or 14.1% over a 6min or 30min period. (see Page 3 for duty cycle derivation).

Battery voltage – 3.7 VDC

Data Rates – 1Mbit/s and 2Mbit/s

Modulation: Gaussian Frequency Shift Keying (data only, no video or audio)

Channel access protocol – Bluetooth 5 LE

Modulation Index: Limited by SIG Bluetooth Protocol. 0.45 – 0.55

Largest Product Dimension: 1.9 inches



Abbott Laboratories

Neuromodulation

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Jeremiah Darden

A handwritten signature in blue ink that reads "J Darden".

Senior Development Quality Engineer

BLE Low Duty Cycle Analysis

The following low duty cycle justification provided below is based on the limitations and specifications within the Bluetooth Low Energy (BLE) v4.2 and v5.0 Specifications as required by Bluetooth SIG (Special Interest Group [Core Specifications | Bluetooth® Technology Website](#)). The Gemini product supports up to 2mbps data rate, but all calculations will be done using 1mbps since this produces a longer transmit time and increases duty cycle.

Background: There is a mandatory connection interval for BLE where the radio transmission must stop and wait for the next appropriate time to transmit. The shortest interval time allowed that provides the most transmitter on time is 15milliseconds (ms) when paired with off the shelf commercial hardware that is compatible with the Gemini system (i.e. Apple iPhone and iPads). This will be used for all calculations.

Also, during each connection, there is a mandatory Inter Frame Space (T_IFS) of 0.150 ms that occurs twice. There is also a 0.08 ms wait time for the receiving companion device to respond with its own transmissions. Below is a summary of all actions that impact the transmission time.

Connection Interval (ms) = 15

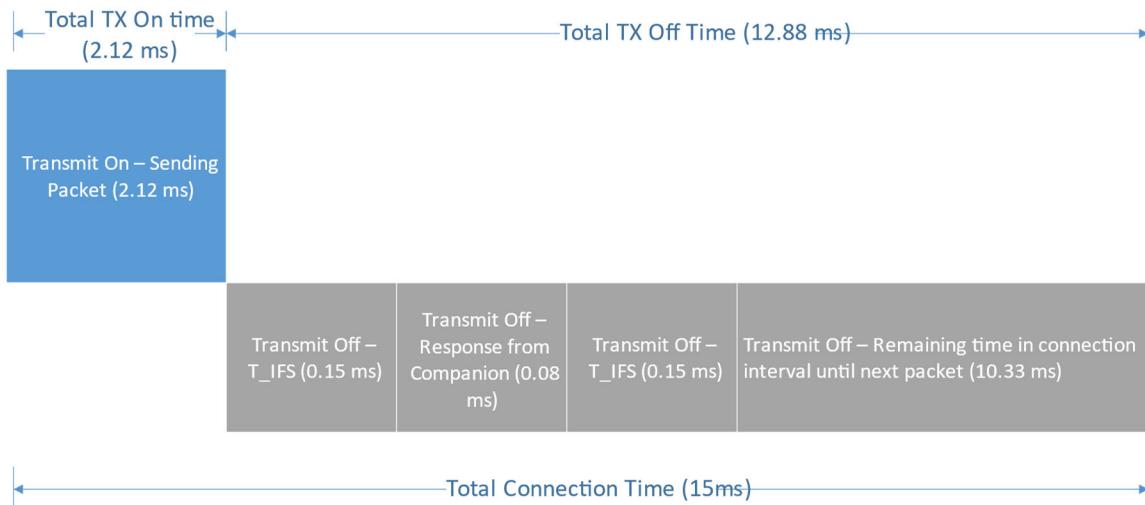
T_IFS (ms) = 0.15 (x2)

Companion Response time (ms) = 0.08

Maximum Transmit on Time (ms) = Packet size in bytes x 8bits/byte x 1Mbps = 2.12

(Transmit time is based on the packet size. The maximum packet size for BLE 1mbps is 265 bytes)

From the perspective of the Gemini device acting as a transmitter, the following is a block diagram of the maximum time the radio transmits and the time when it is not transmitting due to the required frame spaces, connectional interval and waiting for the companion device to respond.



Duty Cycle Calculation: $2.12\text{mS} / 15\text{mS} = 0.141 = 14.1\%$ over one interval. $14.84\text{mS} / 100\text{mS} = 0.148 = 14.8\%$ in a 100mS window. The 15mS interval of 14.1% duty cycle can be extrapolated to 6min or 30min time frame as needed but the duty cycle would be the same if using an uninterrupted connection interval with maximum packet size.

In real world situations, due to companion device limitations, path loss, and interference, this would reduce the packet sizes and increase connectional intervals times so the duty cycle may be further reduced. However, for worse case conditions, the hardware maximums were used to indicate the highest available duty cycle at the rated power and tolerance.