

Galvani Bioelectronics RF Exposure Exemption Report

SCOPE OF WORK

RF Exposure Exemption Evaluation – Implantable Pulse Generator, Model: 21101

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RF Exposure Exemption Evaluation Report (FULL COMPLIANCE)

Report Number: 104106572MPK-001C

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Model(s) Tested: 21101

Standards: FCC Part 1 Subpart I, April 2021

Procedures Implementing the National Environmental Policy Act of 1969

§1.1307 Actions that may have a significant environmental effect, for which Environmental Assessments (EAs) must be prepared.

§1.1307(b)(3)

Tested by:

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1 Introduction and Conclusion

This evaluation report covers for a medical implant device subject to routine environmental evaluation for RF exposure.

The evaluation indicated in section 2.0 were performed on the product constructed as described in section 4.0. The remaining sections are the verbatim text from the actual evaluation during the investigation. These sections include the evaluation name, the specified Method, and Results. No additions, deviations, or exclusions have been made from the standard(s) unless specifically noted.

Based on the results of our investigation, we have concluded the product evaluated **complies** with the requirements of the standard(s) indicated. The results obtained in this report pertain only to the item(s) evaluated. Intertek does not make any claims of compliance for samples or variants which were not evaluated.

2 Evaluation Summary

Section	Test full name	Result
3	Client Information	-
4	Description of Equipment Under Evaluation and Variant Models	-
5	FCC SAR Test Exclusion	Compliant
6	ISED Canada SAR Test Exclusion	Compliant
7	Revision History	-

3 Client Information

This EUT was evaluated at the request of:

Client: Galvani Bioelectronics
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4 Description of Equipment Under Test and Variant Models

Description of Equipment Under Test (provided by client)

The equipment under test (EUT), Galvani Bioelectronics implantable pulse generator (IPG), model: 21101.

The EUT contains a 2.4 GHz Bluetooth Low Energy (BLE) transmitter.

Variant Models:

The following variant models have been identified by the manufacturer as being electrically identical models, depopulated models, or with reasonable similarity to the model(s) tested. Intertek does not make any claims of compliance for samples or variants which were not tested.

➤ None

5 RF Exposure Exemption Evaluation

5.1 Determination of exemption [FCC 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 centimeters to 40 centimeters and at frequencies from 0.3 GHz to 6 GHz (inclusive). P_{th} is given by;

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

Where

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

and

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

d = the separation distance (cm);

- (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

(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} , 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}) 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 of this chapter.

5.2 Exemption Evaluation

Frequency Range (MHz)	RF Conducted Power ¹ (dBm)	Antenna Gain ² (dBi)
2402 - 2480	-2.87	-11.5

1: Power was taken from Intertek 104106572MPK-001 test report

2: Antenna gain was provided by the client. Intertek takes no responsibility for the accuracy of the value

The maximum conducted power of -2.87 dBm (0.5164 mW) is less than 1 mW. According to FCC §1.1307(b)(3)(i), the medical implant device is exempt from evaluation of the human exposure to RF radiation.

5.3 Evaluation Results

The sample evaluated was found to Comply. The maximum conducted power is less than 1 mW.

6 Revision History

Revision Level	Date	Report Number	Prepared By	Reviewed By	Notes
1.0	4/19/2020	104106572MPK-001C	AC	KV	Original Issue
2.0	11/05/2021	104106572MPK-001C	AC	KV	Removed IPG Charger, Model: 31102, from the report. Updated IPG FCC ID to 2AVN4-21101.
3.0	12/14/2021	104106572MPK-001C	SK	KV	Rewrote the report per FCC's PAG comments