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Element Materials Technology

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#400

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FCC ID: PX2-GMCHG1

Charger Model 16000

To whom it may concern,

We, Abbott Laboratories (Neuromodulation Division 6901 Preston Road, Plano, TX 75024), are providing this RF Exposure Assessment letter to show compliance to the FCC 1.1310 rule part. This summary uses data from Element Report “ABBO0075.1” and Abbott Report “90976808” to satisfy FCC 47 CFR 1.1307(b)(3)(ii)(B) for multiple RF sources operating in the same time-averaging period.

#### EUT Use-Cases and key RF exposure conditions

SUMMARY: The following RF Exposure conditions are used for the assessment documented in this report	
Intended Use	Portable
Location on Body	Torso
How is the Device Used	< 20cm, on the body
Radios	WPT (266kHz-320kHz) Bluetooth Low Energy (2402 – 2483.5 MHz)
Body Worn Accessories	The charging apparel (model 16750 or 16760) are intended to secure the Gemini Charger (model 16000) at the pulse generator implant location. The accessories are made of spandex and fabric and do not include any RF shielding.
Environment	General Population/Uncontrolled Exposure

## Overview

With respect to the limits on human exposure to RF emissions provided in 47 CFR 1.1310, if the equipment can be shown to qualify for an exemption pursuant to 47 CFR 1.1307(b)(3)(ii)(B) for multiple RF sources, additional 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  $\lambda$  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 ( $P_r$ ) 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).

## Assessment

Computational SAR per FCC 2.1093 and FCC KDB Inquiry values were used in these calculations.

Radio	Transmit Frequency (kHz)	Duty Cycle	Worse Case Separation	Computational SAR Exposure (W/kg)	Limit (W/kg)	Ratio
WPT: 266-320kHz	280	100%	0.32	0.11	1.6	0.07
Max Ratio						0.07

The rated values were used in these calculations. The rated power was provided by Abbott in the RF Exposure documentation. Duty Cycle is limited by design. See operational description for Low Duty Cycle Analysis included with submission.

Radio	Transmit Frequency (MHz)	Conducted Output Power (dBm)	Power Tolerance (dB)	Duty Cycle	Antenna Assembly Gain	Minimum Separation Distance (cm)	Calculated Radiated Exposure Power (mW) ERP	Calculated Conducted Exposure Power (mW)	Limit (mW)	Ratio
BTLE: 2402 – 2483.5	2402	0	4	14.1	2	0.32	0.3	0.4	2.8	0.13
Max Ratio										0.13

Sum of Maximum Ratios	Limit	Compliant
0.20	1	Yes

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