1.0 PURPOSE

The purpose of this document is to show compliance with FCC MPE/SAR requirements for relevant parts of the Guardio Charger System in accordance with 47 CFR 1.1310, 2.1091, 2.1093, and 95.2585 for FCC parts 15 and 95.

2.0 INTERNAL REFERENCES PROVIDED TO FCC

2.1 NTS_FCCPart15_Rev0_GDCH

2.2 NTS_FCCPart95_Rev0_GDCH

2.3 Guardio Charger LTE SAR Report

2.4 PD_RPT_1467 Rev 00 SAR Considerations for WPT for Guardio-Vesta Chargers

3.0 EXTERNAL REFERENCES

3.1 47 CFR Chapter I – Federal Communications Commission

3.2 FCC OET KDB Document 447498 D01 – RF Exposure Procedures and Equipment Authorization Policies for Mobile and Portable Devices

3.3 FCC OET KDB Document 680106 D01 – RF Exposure Considerations for Low Power Consumer Wireless Power Transfer Applications

4.0 ACRONYMS

4.1	FCC	Federal Communications Commission
4.2	KDB	Knowledge Data Base
4.3	IPG	Implantable Pulse Generator
4.4	GDCH	Guardio Charger System
4.5	MPE	Maximum Permissible Exposure
4.6	SAR	Specific Absorption Rate
4.7	ULP-AMI	Ultra-Low Power Active Medical Implant
4.8	MICS	Medical Implant Communication Service

5.0 BACKGROUND INFORMATION

The Impulse Dynamics Guardio Charger System is a peripheral for use with an ULP-AMI. The GDCH charges and communicates with compatible Impulse Dynamics IPGs for home use by patients. The GDCH contains three relevant intentional RF emitters for SAR/MPE consideration; a 402-405MHz MICS MedRadio that uses a ZL70103 transceiver, a custom recharge channel protocol for a low data rate key exchange operating via a near-field inductive link at the ISM frequency of 13.56 MHz, and a 4G/LTE modem manufactured by Quectel Wireless, the EG25-G.

The first RF emitter, the MICs radio is covered by part 95I. The second RF emitter is an ISM near-field inductive link operating at 13.56MHz. This link has multiple modes of operation; first as a method for wireless power transfer to charge compatible IPGs and second using a custom recharge channel protocol for a low data rate key exchange to communicate to the implant. In accordance with KDB 680106, the wireless power transfer portion of the ISM RF emitter requires compliance with FCC Part 18 while the communications link meets required compliance with FCC Part 15. The WPT RF exposure reporting is covered by FCC Part 18 SDoC and is outside the scope of this report. The communications portion is

subject to FCC Part 15C certification, and thus its compliance with RF exposure will be analyzed in this report. The final RF emitter, the 4G modem, is instantiated as a modular device inside the GDCH and RF exposure compliance was evaluated as part of a class II permissive change and can be found under FCC ID 2AY43-EG25G.

6.0 ANTENNA INFORMATION

The GUARDIO Charger contains three antennas:

1. 4G Antenna for cellular service.
2. A 402-405 MHz antenna for MICS to communicate with the ULP-AMI
3. 13.56 MHz antenna for encryption key exchange and charging the ULP-AMI

The 4G module is certified under FCC ID 2AY43-EG25G. This module does not co-transmit with the other transmitters and is therefore outside the scope of this report.

There are several configurations of active radiation configurations for this device. Each of the antennas operate as single Tx sources, with the 402-405 MHz and 13.56 MHz antennas covered in the table in section 8.0 to show standalone compliance. The co-Tx condition involves the use of the 402-405 MHz antenna being active with the 13.56 MHz antenna while charging the ULP-AMI to communicate charge data.

7.0 CALCULATED LIMITS

In accordance with FCC KDB 447498 D01 section 4.3.1, the SAR test exclusion threshold can be calculated for each frequency of interest at a specified test separation distance. As the GDCH is a body-worn device and will have possible operating distance <5mm, according to section 4.1 (f), a distance of 5mm will be applied to the exclusion threshold calculation. For the MICS system in the GDCH, the operating frequency is 0.402 to 0.405 GHz. Therefore, the equation for SAR exclusion must be calculated according to section 4.3.1(a) to be:

$$P_{SAR\ Exclusion} \leq 3.0 \cdot \frac{d_{test\ separation}}{\sqrt{f_{GHz}}}$$

For the 13.56MHz ISM communications system in the GDCH, the operating frequency is 13.56 MHz, therefore, the equation for SAR exclusion must be calculated according to section 4.3.1(c)(2) to be:

$$P_{SAR\ Exclusion} \leq \frac{1}{2} * \left[\left(1 + log\left(\frac{100}{f_{MHz}}\right)\right) * 474\right]$$

$$Where\ 474\ is\ the\ value\ from\ 4.3.1\ (b)\ per\ Appendix\ B$$

The limits as calculated per the above equations are 24 mW or 13.8 dBm for the 402-405 MHz antenna, and 442.6 mW or 26.5 dBm for the 13.56 MHz antenna.

8.0 RESULTS

Microsemi ZL70103 MICS-Band RF Miniaturized Standard Implant Module used as the transmitter module for the Guardio charger has a specified transmission power of -3.5dBm (0.45 mW) when supplied at 3V. Therefore, the conducted power to the 402-405 MHz antenna is below the SAR exclusion threshold.

The 13.56 MHz antenna is used to exchange encryption keys with the ULP-AMI. The conducted current to the class D amplifier used to drive the 13.56 MHz antenna peaks at 750 mW, this power level is used as part of searching and lasts for 6.7 seconds. The other power levels during search also have a duration of 6.7 seconds, with the conducted power to the class D amplifier at 83 mW and 326 mW. Due to the user interface of the Guardio charger, there is a minimum time between searches of 27 seconds. Time averaging this signal with the rest of the search power levels and the minimum time between searches gives a time averaged power of 165 mW or 22.2 dBm, thus SAR exclusion can be applied.

When the Charger is actively charging an ULP-AMI the 13.56 MHz antenna transmits at a different power level, for 4.3.2 considerations the reported SAR from PD_RPT_1467 Rev 00 SAR Considerations for WPT for Guardio-Vesta Chargers is used.

When multiple transmitters are active only the MICS 402-405 MHz antenna qualifies for standalone exclusion of 4.3.1. Per 4.3.2 (b) the standalone SAR must be estimated with the following equation.

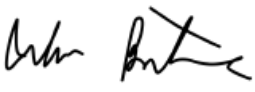
$$SAR_{estimated} = \frac{max\ power\ of\ channel}{d_{test\ separation}} * \frac{\sqrt{f_{GHz}}}{x}$$

The simultaneous transmitter configuration consists of the MICS antenna, with an estimated SAR of 0.0076 W/kg, and the 13.56 MHz antenna, with a simulated SAR of 1.21 W/kg, while charging the ULP-AMI. This combination is also below the 1.6 W/kg limit and the SAR test exclusion for simultaneous transmission applies for this mode.

All measurements were performed radiated and therefore no additional antenna information is required for FCC certification for the 402-405 MHz MICS antenna and the 13.56 MHz encryption key antenna.

9.0 REVIEW

This report and its findings were written and signed by:



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