RF Exposure Report

Report No.:	SABHSI-WTW-P21080133
FCC ID:	2AYGR-3042
Test Model:	CLS121 (Marvin IPG)
Received Date:	Aug. 04, 2021
Test Date:	Aug. 26 ~ Sep. 03, 2021
Issued Date:	Feb. 18, 2022
Applicant:	Saluda Medical Pty Ltd
Address:	Ground Floor, 407 Pacific Highway Artarmon, NSW, 2064, Australia
Issued By:	Bureau Veritas Consumer Products Services (H.K.) Ltd., Taoyuan Branch Lin Kou Laboratories
Lab Address:	No. 47-2, 14th Ling, Chia Pau Vil., Lin Kou Dist., New Taipei City, Taiwan
Test Location:	No. 19, Hwa Ya 2nd Rd., Wen Hwa Vil., Kwei Shan Dist., Taoyuan City 33383, Taiwan
FCC Registration / Designation Number:	788550 / TW0003

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Release Control Record

Issue No.	Description	Date Issued
SABHSI-WTW-P21080133	Original release	Feb. 18, 2022

1 Certificate of Conformity

Product:	Evoke™ Closed Loop Stimulator
Brand:	Saluda Medical
Test Model:	CLS121 (Marvin IPG)
Sample Status:	Engineering sample
Applicant:	Saluda Medical Pty Ltd
Test Date:	Aug. 26 ~ Sep. 03, 2021
Standards:	FCC Part 2 (Section 2.1093)
References Test Guidance:	Part 1.1307 (b)(3)(i)(A) KDB 447498 D01 General RF Exposure Guidance v06

The above equipment has been tested by **Bureau Veritas Consumer Products Services (H.K.) Ltd., Taoyuan Branch**, and found compliance with the requirement of the above standards. The test record, data evaluation & Equipment Under Test (EUT) configurations represented herein are true and accurate accounts of the measurements of the sample's RF characteristics under the conditions specified in this report.

Prepared by : Polly Chien , **Date:** Feb. 18, 2022

Polly Chien / Specialist

Approved by : Jeremy Lin , **Date:** Feb. 18, 2022

Jeremy Lin / Project Engineer

2 Evaluation Limit

According to Part 1.1307(b)(3)(i)(A) &(b)(3)(ii)(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)

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 is paragraph (b)(3)(i)(A) of this section. Medical implant devices may only use this exemption and that in paragraph (b)(3)(i)(A).

Also, according to KDB 447498 D01 General RF Exposure Guidance v06 clause 4.2.4

For Transmitters implanted in the body of a user, below requirement shall be met.

When the aggregate of the maximum power available at the antenna port and radiating structures of an implanted transmitter, under all operating circumstances, is ≤ 1.0 mW, SAR test exclusion may be applied. The maximum available output power requirement and worst case operating conditions must be supported by power measurement results, based on device design and implementation requirements, and fully justified in a SAR analysis report according to KDB Publication 865664 D02, in lieu of SAR measurement or numerical simulation.

3 SAR Test Exclusion Thresholds

Maximum tune-up transmitter power:

Frequency (MHz)	EIRP (dBm)	EIRP (mW)	Antenna Gain (dBi)	Conducted Power (dBm)	Conducted Power (mW)	Limit (mW)	Result
402 - 405	-33.5	0.0004	-30	-3.50	0.447	1	Pass

Note:

1. The above EIRP Power is Tune-up Power which client declaried.
2. Max. Power (dBm) = EIRP (dBm) – antenna gain (dBi) = -33.50 – (-30) = -3.50
3. Determining compliance based on the results of the compliance measurement, not taking into account measurement instrumentation uncertainty.

4 Conclusion

Since Source-base time average power is below maximum time-averaged power 1 mW, the SAR evaluation is not required.

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