Leva-02 Specific Absorption Rate (SAR) Analysis

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1. Introduction

This document evaluates the impact of electromagnetic radiation generated by the wireless radio in the leva-02, PDHS device on the specific absorption rate of tissue in a patient's body.

The system has three radios: one ISM radio in the Device and one ISM radio plus a BLE radio in the Case. Of these three radios, only the Device ISM radio is inside the body. The Case ISM radio transmits with the same settings, thereby presenting even less risk than the Device ISM radio since it will never reside closer to the tissue than the Device. The BLE radio presents no more SAR risk than a typical Device using BLE. The case is typically placed 2-3 feet away from the patient.

2. Definitions

Basic Restrictions (BR): Exposure restrictions that are based on established adverse health effects that incorporate appropriate safety factors and are expressed in terms of the in situ electric field (3 kHz to 5 MHz), specific absorption rate (100 kHz to 3 GHz), or incident power density (3 GHz to 300 GHz).

Maximum Permissible Exposure (MPE): The highest rms or peak electric or magnetic field
strengths, their squares, or the plane-wave equivalent power densities associated with these fields, or the induced and contact currents to which a person may be exposed without incurring an established adverse health effect and with an acceptable margin of safety. The MPEs are derived or estimated from the basic restrictions (induced electric field, SAR, or power density). If an exposure is proven to be below the basic restrictions, the MPE can be exceeded. MPEs are sometimes called reference levels, derived limits, or investigation levels.

Specific Absorption Rate (SAR): The quotient of the incremental energy (dW) absorbed by (dissipated in) an incremental mass (dm) contained in a volume (dV) of a given density (ρ).
The SI unit of specific absorption is the joule per kilogram (J/kg).

Localized Exposure: For frequencies exceeding 100 kHz, an exposure of a portion of the body wherein the incident plane-wave equivalent power density, or the squares of the field strength exceed 20 times the spatially averaged value over the projected (cross-sectional) area of the body.

3. Background

Radio frequency (RF) electromagnetic radiation in the frequency range of 100 kHz to 300 GHz, has been known to generate heat in human tissue when the radiated power is above certain thresholds. The IEEE and FCC have created guidelines for the amount of energy that can be radiated at specific frequencies and in specific contexts to protect users or patients from experiencing adverse health effects associated with this heating.

4. FCC published RF exposure KDB procedures [2]

Based on [2], Section 4.3.1 (*Standard SAR test exclusion considerations)*, the following guidelines are provided to determine if SAR testing is necessary:

> Unless specifically required by the published RF exposure KDB procedures, standalone 1-g head or body and 10-g extremity SAR evaluation for general population exposure conditions, by measurement or numerical simulation, is not required when the corresponding SAR Test Exclusion Threshold condition(s), listed below, is (are) satisfied. **These test exclusion conditions are based on source-based time-averaged maximum conducted output power of the RF channel requiring evaluation, adjusted for tune-up tolerance, and the minimum test separation distance required for the exposure conditions**. The minimum test separation distance defined in 4.1 f) is determined by the smallest distance from the antenna and radiating structures or outer surface of the device, according to the host form factor, exposure conditions and platform requirements, to any part of the body or extremity of a user or bystander. To qualify for SAR test exclusion, the test separation distances applied must be fully explained and justified, typically in the SAR measurement or SAR analysis report, by the operating configurations and exposure conditions of the transmitter and applicable host platform requirements, according to the required published RF exposure KDB procedures. When no other RF exposure testing or reporting are required, a statement of justification and compliance must be included in the equipment approval, in lieu of the SAR report, to qualify for SAR test exclusion. When required, the device specific conditions described in the other published RF exposure KDB procedures must be satisfied before applying these SAR test exclusion provisions; for example, handheld PTT two-way radios, handsets, laptops and tablets, etc.
>
> a) For 100 MHz to 6 GHz and test separation distances ≤ 50 mm, the 1-g and 10-g SAR test exclusion thresholds are determined by the following:
> [(max. power of channel, including tune-up tolerance, mW) / (min. test separation distance, mm)] · [√f(GHz)] ≤ 3.0 for 1-g SAR, and ≤ 7.5 for 10-g extremity SAR, 30 where:
>
> - f(GHz) is the RF channel transmit frequency in GHz
> - Power and distance are rounded to the nearest mW and mm before calculation31
> - The result is rounded to one decimal place for comparison
> - The values 3.0 and 7.5 are referred to as numeric thresholds in step b) below
>
> The test exclusions are applicable only when the minimum test separation distance is ≤ 50 mm, and for transmission frequencies between 100 MHz and 6 GHz. **When the minimum test separation distance is < 5 mm, a distance of 5 mm according** to 4.1 f) is applied to determine SAR test exclusion.

Since the leva-02 Device thickness is 8mm at its thinnest point in the region where the antenna lies, the minimum separation between the antenna and the tissue is 4mm. Based on the guidance above, a distance of 5mm should therefore be used in calculating the test exclusion.

In addition to the equation above, FCC provides a table in Appendix A with power thresholds based on frequency and separation.

The "Selected Frequencies" for the ISM signal transmitted by leva-02 is 915 MHz and the "Test Separation Distance" is 5mm. From the table below, the ***SAR Test Exclusion Threshold*** **is 16 mW.**

SAR Test Exclusion Thresholds **for 100 MHz – 6 GHz and ≤ 50 mm**

Approximate SAR Test Exclusion Power Thresholds at Selected Frequencies and Test Separation Distances are illustrated in the following Table. The equation and threshold in 4.3.1 must be applied to determine SAR test exclusion.

MHz	5	10	15	20	25	mm
150	39	77	116	155	194	*SAR Test Exclusion Threshold* (mW)
300	27	55	82	110	137	
450	22	45	67	89	112	
835	16	33	49	66	82	
900	16	32	47	63	79	
1500	12	24	37	49	61	
1900	11	22	33	44	54	
2450	10	19	29	38	48	
3600	8	16	24	32	40	
5200	7	13	20	26	33	
5400	6	13	19	26	32	
5800	6	12	19	25	31	

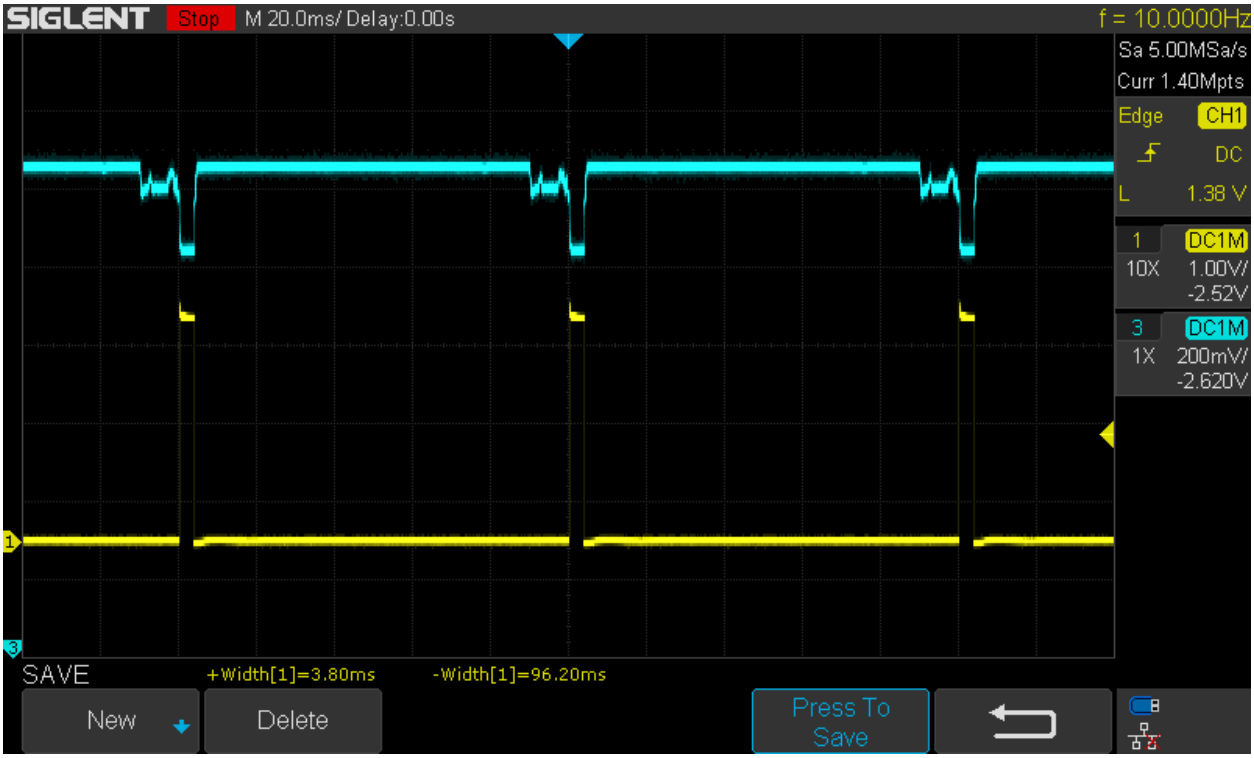
5. Leva-02 Power Calculations

The leva-02 Device uses the CC1310 radio from Texas Instruments. The chip is programmed to have a maximum peak output power of 6 dBm (3.98 mW). Furthermore, the transmission is highly duty cycle even in the worst case scenario (Device connected and transmitting data).

Based on [1], the measurement time that should be used for time averaging is 30 minutes.

5.1. Normal Worst-Case Operation

In the normal worst-case scenario, where leva-02's ISM radio is continuously connected for 30 minutes, the duty cycle of the radio is <4% (<4 ms every 100 ms). The following figure shows a trace of the TX signal from the Device captured over a period of 300ms. It shows a TX signal duty cycle of 3.8%:



The blue trace represents the Device VCC after a 15 ohm supply series resistor. The yellow trace represents the radio TX active high signal.

The average power at the antenna in the worst case is:

$$P = 4\% \times 3.98\,\text{mW} = 0.16\,\text{mW}$$

This average power is 100 times lower than the SAR Test Exclusion Power Threshold set in [2], therefore SAR testing is not necessary for the leva-02 device.

5.2. Single-Fault Failure – Duty Cycle

Under normal operation, the radio transmitter is only on for less than 4 ms every 100 ms. If a failure occurs that causes the radio to remain at 100% duty cycle (i.e. always transmitting), the average power would be as follows:

$$P = 100\% \times 3.98\,\text{mW} = 3.98\,\text{mW}$$

Under this single-fault failure scenario, the average transmit power is still below the 16 mW threshold.

5.3. Single-Fault Failure – Max Power

Under normal operation, the radio transmitter output power is set to 3.98 mW. However, the transmitter is capable of transmitting at up to 15 dBm (32 mW). If a single-fault failure occurs that causes the radio to transmit at this maximum output power, the average power would be as follows:

$$P = 4\% \times 32\,\text{mW} = 1.28\,\text{mW}$$

Under this single-fault failure scenario, the average transmit power is still below the 16 mW threshold.

6. Related Documents

[1] IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz

[2] 447498 D01 General RF Exposure Guidance v06, FCC Office of Engineering Technology Laboratory Division

7. Acronyms

CW: Continuous Wave
BR: Basic Restrictions
SAR: Specific Absorption Rate
MPE: Maximum Permissible Exposure
BLE: Bluetooth Low Energy
ISM: Industrial, Scientific and Medical radio bands

Revision History

Revision	Brief Description	Author	Date	ECO#
A	Initial Release from REC-00023	J. Bohorquez / G. Sewnath	11/19/2019	000139
B	Added trace of Device TX signal in section 5.1.	G. Sewnath	12/6/2019	000151