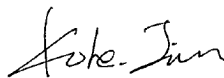


RF EXPOSURE EVALUATION REPORT

Application No.: GZCR2110021217MD
Applicant: CEFALY Technology SPRL
Address of Applicant: Rue Louis Plescia 34, 4102 Seraing, Belgium
Manufacturer: CEFALY Technology SPRL
Address of Manufacturer: Rue Louis Plescia 34, 4102 Seraing, Belgium
Factory: JDI Electronics Factory
Address of Factory: Sima Village, Chang Ping Town, Dongguan, Guangdong
Equipment Under Test (EUT):
EUT Name: Medical device for the treatment of migraine
Model No.: CEFALY DUAL Connected
Standard(s) : 47 CFR Part 2.1093
 47 CFR Part 1.1310
Date of Receipt: 2021-10-14
Date of Evaluation: 2021-12-06
Date of Issue: 2021-12-07

Evaluation Result:	Pass*
---------------------------	--------------

* In the configuration evaluated, the EUT complied with the standards specified above.



Kobe Jian
 EMC Laboratory Manager



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<i>Revision Record</i>				
<i>Version</i>	<i>Chapter</i>	<i>Date</i>	<i>Modifier</i>	<i>Remark</i>
01		2021-12-07		Original

Authorized for issue by			
			
		<hr/> Lily Kuang/Project Engineer	
			
		<hr/> Ricky Liu/Reviewer	



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2 Evaluation Summary

Radio Spectrum Technical Requirement				
Item	Standard	Method	Requirement	Result
RF Exposure	47 CFR Part 2.1093	47 CFR Part 2.1093	47 CFR Part 2.1093 47 CFR Part 1.1310	Pass

Note:

E.U.T./EUT means Equipment Under Test.

Pass means the test result passed the test standard requirement, please find the detailed decision rule in the report relative section.



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4 General Information

4.1 Details of E.U.T.

Power supply: DC 5 V powered by AC/DC adapter as below for charging:
 model: ILM-0500100M
 Input: 100~240V ~50/60Hz 0.2A
 Output: 5V===1A
 DC 3.7 V powered by built-in battery as below for normal working:
 Model: LP521540
 Rated: DC 3.7 V, 280mAh

Cable(s): DC mains (unshielded, 0.8m)

Function: Medical device for the treatment of migraine with BLE function and RFID
 For BLE

Operation Frequency: 2402MHz to 2480MHz
 Modulation Type: GFSK
 Number of Channels: 40
 Channel Spacing: 2MHz
 Antenna Type: Integral Antenna
 Antenna Gain: 0 dBi declared by manufacture
 Firmware Version: SV 01
 Hardware Version: D
 Testing Software: None

Sample NO.: GZ_SP_20211057970
 Power Setting: Default
 For RFID
 Operation Frequency: 13.56MHz
 Modulation Type: ASK
 Antenna Type: Loop Antenna

4.2 Evaluating Location

All tests were performed at:
 SGS-CSTC Standards Technical Services Co., Ltd., Guangzhou Branch EMC Laboratory,
 198 Kezhu Road, Sciencetech Park, Guangzhou Economic & Technology Development District,
 Guangzhou, China 510663
 Tel: +86 20 82155555 Fax: +86 20 82075059
 No tests were sub-contracted.



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4.3 Facility

The facility is recognized, certified, or accredited by the following organizations:

- **NVLAP (Lab Code: 200611-0)**

SGS-CSTC Standards Technical Services Co., Ltd., Guangzhou EMC Laboratory is accredited by the National Voluntary Laboratory Accreditation Program (NVLAP/NIST). NVLAP Code: 200611-0.

The report must not be used by the client to claim product certification, approval, or endorsement by NVLAP, NIST, or any agency of the Federal Government.

- **ACMA**

SGS-CSTC Standards Technical Services Co., Ltd., EMC Laboratory can also perform testing for the Australian/New Zealand Regulatory Compliance Mark (RCM).

- **SGS UK(Certificate No.: 32), SGS-TUV SAARLAND and SGS-FIMKO**

Have approved SGS-CSTC Standards Technical Services Co., Ltd., EMC Laboratory as a supplier of EMC TESTING SERVICES and SAFETY TESTING SERVICES.

- **CNAS (Lab Code: L0167)**

SGS-CSTC Standards Technical Services Co., Ltd., EMC Laboratory has been assessed and in compliance with CNAS-CL01:2018 accreditation criteria for testing laboratories (identical to ISO/IEC 17025:2017 General Requirements) for the Competence of Testing Laboratories.

- **FCC Recognized Accredited Test Firm(Registration No.: 486818)**

SGS-CSTC Standards Technical Services Co., Ltd., EMC Laboratory has been accredited and fully described in a report filed with the (FCC) Federal Communications Commission. The acceptance letter from the FCC is maintained in our files. Designation Number: CN5016, Test Firm Registration Number: 486818.

- **ISED (Registration No.: 4620B, CAB identifier: CN0052)**

SGS-CSTC Standards Technical Services Co., Ltd., has been registered by Innovation Science and Economic Development Canada for Wireless Device Testing laboratories to test to Canadian radio equipment requirements. Registration No. 4620B, CAB identifier: CN0052.

- **VCCI (Registration No.: R-12460, C-12584, G-20107 and T-11179)**

The 10m Semi-anechoic chamber, 966 Anechoic Chamber and Shielded Room of SGS-CSTC Standards Technical Services Co., Ltd. have been registered in accordance with the Regulations for Voluntary Control Measures with Registration No.: R-12460, C-12584, G-20107 and T-11179 respectively.

- **CBTL (Lab Code: TL129)**

SGS-CSTC Standards Technical Services Co., Ltd., E&E Laboratory has been assessed and fully comply with the requirements of ISO/IEC 17025:2017, the Basic Rules, IECEE 01 and Rules of procedure IECEE 02, and the relevant IECEE CB-Scheme Operational documents.

4.4 Deviation from Standards

None

4.5 Abnormalities from Standard Conditions

None



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5 Technical Requirements Specification

5.1 RF Exposure Evaluation

5.1.1 Limit & Test Method

CFR 47 Part 1.1310

Limit:

According to FCC Part1.1310: The criteria listed in the following table shall be used to evaluate the environment impact of human exposure to radio frequency (RF) radiation as specified in Part1.1307(b)

TABLE 1—LIMITS FOR MAXIMUM PERMISSIBLE EXPOSURE (MPE)

Frequency range (MHz)	Electric field strength (V/m)	Magnetic field strength (A/m)	Power density (mW/cm ²)	Averaging time (minutes)
(A) Limits for Occupational/Controlled Exposure				
0.3-3.0	614	1.63	*100	6
3.0-30	1842/f	4.89/f	*900/f ²	6
30-300	61.4	0.163	1.0	6
300-1,500			f/300	6
1,500-100,000			5	6
(B) Limits for General Population/Uncontrolled Exposure				
0.3-1.34	614	1.63	*100	30
1.34-30	824/f	2.19/f	*180/f ²	30
30-300	27.5	0.073	0.2	30
300-1,500			f/1500	30
1,500-100,000			1.0	30
f = frequency in MHz				
* = Plane-wave equivalent power density				

According to KDB447498 D01 General RF Exposure Guidance DR04-44307, the limit for Radiofrequency radiation exposure evaluation: portable devices.

$$P_{th} \text{ (mW)} = ERP_{20 \text{ cm}} \text{ (mW)} = \begin{cases} 2040f & 0.3 \text{ GHz} \leq f < 1.5 \text{ GHz} \\ 3060 & 1.5 \text{ GHz} \leq f \leq 6 \text{ GHz} \end{cases} \quad (\text{B.1})$$

$$P_{th} \text{ (mW)} = \begin{cases} ERP_{20 \text{ cm}}(d/20 \text{ cm})^x & d \leq 20 \text{ cm} \\ ERP_{20 \text{ cm}} & 20 \text{ cm} < d \leq 40 \text{ cm} \end{cases} \quad (\text{B.2})$$

where

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



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$$\sum_{i=1}^a \frac{P_i}{P_{th,i}} + \sum_{j=1}^b \frac{ERP_j}{ERP_{th,j}} + \sum_{k=1}^c \frac{Evaluated_k}{Exposure Limit_k} \leq 1 \quad (C.1)$$

Where:

f is in GHz, d is the separation distance (cm), and ERP20cm is per Formula (B.1).

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](#).

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](#).



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5.1.2 Conclusion

Normal use condition for Distance between antenna and body:	<5 mm declared by applicant
Antenna Gain(max):	0 dBi declared by applicant for 2.4G BLE antenna.

Test Mode	Frequency (MHz)	P/ E-field strength	Pi/ Ek-field strength	Pth*/ Power density _{th}
2.4G BT	2402	3.42dBm	2.20mW	2.77mW
	2440	3.15dBm	2.07mW	2.77mW
	2480	3.09dBm	2.04mW	2.67mW
RFID	13.56	26.79 dBuV/m@3m	7.87V/m @0.005m **	60.77 V/m***

: $P_{th}=3060mW(0.5/20)^{(-\log_{10}(60/3060*f^{0.5}))}$

** : E-field (dBuV/m @0.005m) = E-field (dBuV/m @3m) + 40log(3/0.005)=137.92 dBuV/m @0.005m
 E-field (V/m)= 10^[E-field (dBuV/m) /20] ×10⁻⁶=7.87V/m@0.005m

***: $E_k\text{-field strength}_{th}=824/f=824/13.56=60.77 (V/m)$

According to the formula C.1, we can calculate MPE.

$$\sum_{i=1}^a \frac{P_i}{P_{th,i}} + \sum_{j=1}^b \frac{ERP_j}{ERP_{th,j}} + \sum_{k=1}^c \frac{Evaluated_k}{Exposure Limit_k} \leq 1 \quad (C.1)$$

RFID and 2.4G BLE module can transmit simultaneously, so the maximum rate of MPE is
 Max (2.20 mW/2.77mW, 2.07mW/2.77 mW, 2.04mW/2.67mW) + 7.87 V/m /60.77 V/m =0.79+0.13 = 0.92 <1.0.

The EUT meet the Exemption Limits for Routine Evaluation – SAR Evaluation, so no SAR evaluation is required for the EUT.

Note:

Refer to report No. GZCR211002121702 for EUT test Max Conducted Peak Output Power value.

Refer to report No. GZCR211002121703 for EUT test E-field strength.



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6 EUT Constructional Details (EUT Photos)

Refer to External and Internal Photos for GZCR2110021217MD

- End of the Report -



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