RF Exposure Evaluation Report

For Theranica Bioelectronics Ltd.

Equipment Under Test:

NerivioInfinity Transceiver

Model: FGD000100
FCC ID: 2AOH8-NI

Issued by:
The Standards Institution of Israel
Industry Division
Electrical & Electronics Laboratory
EMC Branch

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1. Applicant information

Applicant:	Theranica Bioelectronics Ltd..
Address:	4 Ha-Omanut St., 4250438, P.O.B 16008, Netanya 4206001, Israel
Sample for test selected by:	The customer
The date of tests:	November & December 2022

Equipment under test information

Description of Equipment Under Test (EUT):	NerivioInfinity Transceiver
Model:	FGD000100
Software version of radio unit:	FW Version 4.0.4.70
Hardware version:	ELC-PCA-0200-1.0
Manufactured by:	Theranica Bio-Electronics Ltd.

2. Test performance

Location:	SII EMC Section
Purpose of test:	To prove the safety of radiation harmfulness to the human body for our product
Test specifications:	FCC KDB 447498 D01 General RF Exposure Guidance v06

This Test Report contains 4 pages and may be used only in full.	This Test Report applies only to the specimen tested and may not be applied to other specimens of the same product.

3. Summary of test:

Using the general SAR test exclusion guidance in Section 4.2.4 of KDB 447498 D01 v06, we show the device meeting the SAR exemption.

Electronics and
Telematics Laboratory

December 2022

Name: Eng. Yuri Rozenberg
Position: Head of EMC Branch.

Name: Alexander Konkov.
Position: Test engineer.

4. Equipment under test description.

*The applicant provided description.

4.1 General description

NerivioInfinity Transceiver(the EUT) is indicated for acute and/or preventive treatment of migraine with or without aura in patients 12 years of age or older. It is a prescription use, self-administered device for use in the home environment at the onset of migraine headache or aura for acute treatment, and/or every other day for preventive treatment.
The EUT is a wearable, battery-powered device. It is powered by a non-detachable, non-replaceable, recharge battery and is operated via a mobile application. The device is worn on a user's upper arm and delivers transcutaneous remote electrical neurostimulation ("REN") via weak electrical pulses to achieve migraine pain inhibition via conditional pain modulation (CPM). The NerivioInifinity uses standard BLE 5.0 for communication utilizing off-the-shelf Cypress controller.

EUT technical characteristics

Transmitter technical characteristics:		Note
Assigned frequency band	2400 MHz – 2483.5 MHz	-
Operating frequency range:	2402 MHz – 2480 MHz	-
DTS transmitter:	BLE 5	-
Types of modulation:	GFSK	-
Declare temperature range:	0°C - 35°C	Normal indoor use
Antenna information		
Type	Manufacturer/Model	Antenna gain, dBi
BT PCB printed antenna	Cypress. MIFA PCB printed	-1.6

5. FCC and ISEDC Exemption Limits for Routine Evaluation

FCC SAR test exclusions per KDB 447498

KDB 447498 D01 General RF Exposure Guidance v06 Section: 4.3.1.
Standalone SAR test exclusion considerations states:
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 calculation
- The result is rounded to one decimal place for comparison
- The values 3.0 and 7.5 are referred to as numeric thresholds.

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.

SAR Test Exclusion Threshold

Freq. [GHz]	d [mm]	Max. power [mW]	Calculation result	FCC Limit @ 5 mm [mW]	SAR Exclusion applicable (Yes/No)
2.402	5	0.58	0.18	3.0	Yes

Summary: SAR test exclusion threshold is < 3 for separation distance of 5 mm. Therefore, SAR test is not required.