BIOTRONIK, Inc.

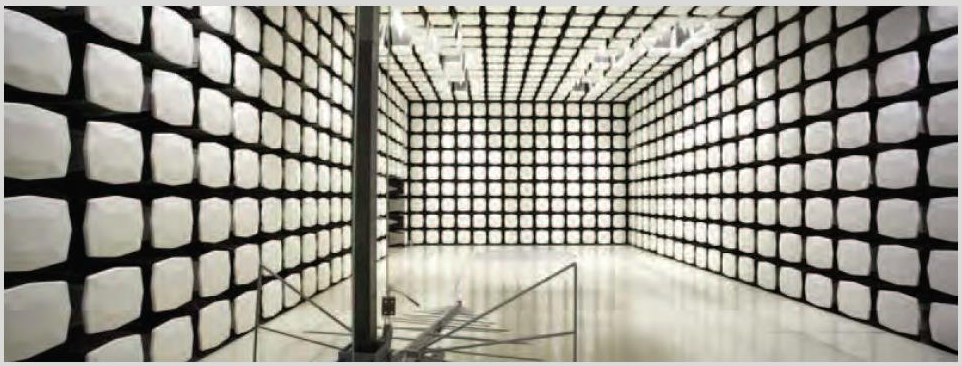
Neuro SCS Trial Stimulator

FCC 1.1307:2021

FCC 2.1093:2021

Bluetooth LE

Report: BIOT0085.4 Rev. 1, Issue Date: September 10, 2021



CERTIFICATE OF EVALUATION

Last Date of Evaluation: August 27, 2021
BIOTRONIK, Inc.
EUT: Neuro SCS Trial Stimulator

RF Exposure Evaluation

Standards

Specification	Method
FCC 1.1307:2021	FCC 1.1307:2021
FCC 2.1093:2021	FCC 447498 D01 General RF Exposure Guidance

Results

Method Clause	Description	Applied	Results	Comments
(b)(3)(i)(A)	Exemption From RF Exposure Evaluation	Yes	Pass	None

Deviations From Evaluation Standards

None

Approved By:

Donald Facteau, Process Architect

Product compliance is the responsibility of the client; therefore, the tests and equipment modes of operation represented in this report were agreed upon by the client, prior to testing. The results of this test pertain only to the sample(s) tested. The specific description is noted in each of the individual sections of the test report supporting this certificate of test. This report reflects only those tests from the referenced standards shown in the certificate of test. It does not include inspection or verification of labels, identification, marking or user information. As indicated in the Statement of Work sent with the quotation, Element's standard process is to always use the latest published version of the test methods even when earlier versions are cited in the test specification. Issuance of a purchase order was de facto acceptance of this approach. Otherwise, the client would have advised Element in writing of the specific version of the test methods they wanted applied to the subject testing

REVISION HISTORY

Revision Number	Description	Date (yyyy-mm-dd)	Page Number
01	Added FCC 2. 1093:2021	2021-09-09	1, 2

ACCREDITATIONS AND AUTHORIZATIONS

United States

FCC - Designated by the FCC as a Telecommunications Certification Body (TCB). Certification chambers, Open Area Test Sites, and conducted measurement facilities are listed with the FCC.

A2LA - Each laboratory is accredited by A2LA to ISO / IEC 17025, and as a product certifier to ISO / IEC 17065 which allows Element to certify transmitters to FCC and IC specifications.

Canada

ISED - Recognized by Innovation, Science and Economic Development Canada as a Certification Body (CB) and as a CAB for the acceptance of test data.

European Union

European Commission – Recognized as an EU Notified Body validated for the EMCD and RED Directives.

United Kingdom

BEIS – Recognized by the UK as an Approved Body under the UK Radio Equipment and UK EMC Regulations.

Australia/New Zealand

ACMA - Recognized by ACMA as a CAB for the acceptance of test data.

Korea

MSIT / RRA - Recognized by KCC's RRA as a CAB for the acceptance of test data.

Japan

VCCI - Associate Member of the VCCI. Conducted and radiated measurement facilities are registered.

Taiwan

BSMI – Recognized by BSMI as a CAB for the acceptance of test data.

NCC - Recognized by NCC as a CAB for the acceptance of test data.

Singapore

IDA – Recognized by IDA as a CAB for the acceptance of test data.

Israel

MOC – Recognized by MOC as a CAB for the acceptance of test data.

Hong Kong

OFCA – Recognized by OFCA as a CAB for the acceptance of test data.

Vietnam

MIC – Recognized by MIC as a CAB for the acceptance of test data.

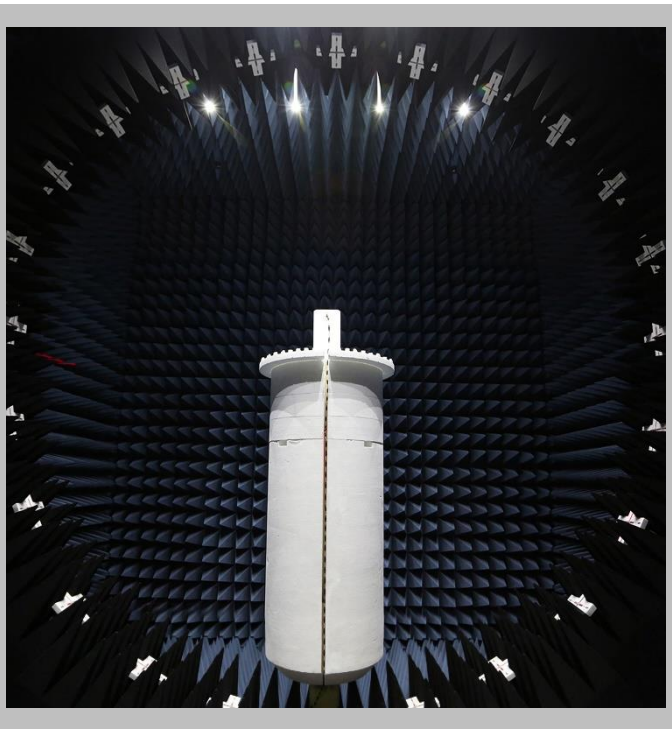
SCOPE

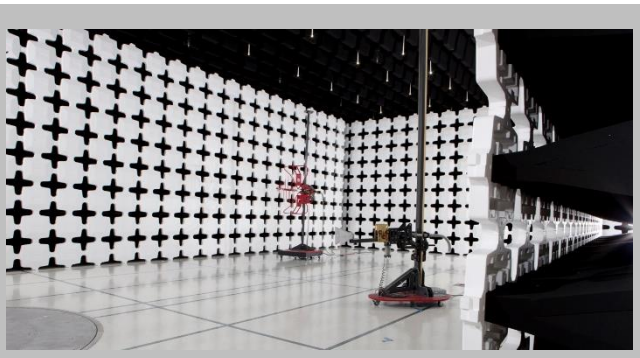
For details on the Scopes of our Accreditations, please visit:
https://www.nwemc.com/emc-testing-accreditations

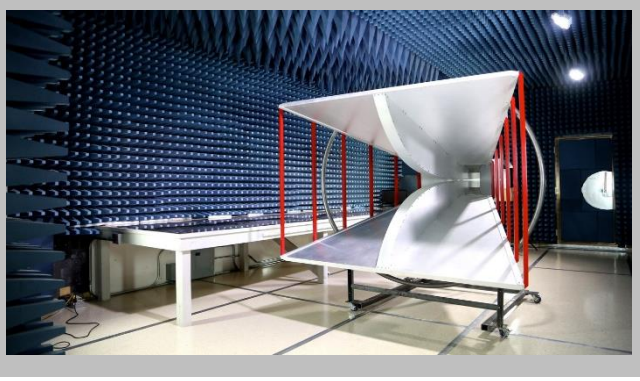
FACILITIES

element
2020.12.15

California	Minnesota	Oregon	Texas	Washington
Labs OC01-17 41 Tesla Irvine, CA 92618 (949) 861-8918	Labs MN01-11 9349 W Broadway Ave. Brooklyn Park, MN 55445 (612)-638-5136	Labs EV01-12 6775 NE Evergreen Pkwy #400 Hillsboro, OR 97124 (503) 844-4066	Labs TX01-09 3801 E Plano Pkwy Plano, TX 75074 (469) 304-5255	Labs NC01-05 19201 120th Ave NE Bothell, WA 98011 (425)984-6600
A2LA				
Lab Code: 3310.04	Lab Code: 3310.05	Lab Code: 3310.02	Lab Code: 3310.03	Lab Code: 3310.06
Innovation, Science and Economic Development Canada				
2834B-1, 2834B-3	2834E-1, 2834E-3	2834D-1	2834G-1	2834F-1
BSMI				
SL2-IN-E-1154R	SL2-IN-E-1152R	SL2-IN-E-1017	SL2-IN-E-1158R	SL2-IN-E-1153R
VCCI				
A-0029	A-0109	A-0108	A-0201	A-0110
Recognized Phase I CAB for ISED, ACMA, BSMI, IDA, KCC/RRA, MIC, MOC, NCC, OFCA				
US0158	US0175	US0017	US0191	US0157







PRODUCT DESCRIPTION

Client and Equipment Under Evaluation Information

Company Name:	BIOTRONIK, Inc.
Address:	6024 Jean Road, BLDG B
City, State, Zip:	Lake Oswego, OR 97035
Evaluation Requested By:	Roy Wang
EUT:	Neuro SCS Trial Stimulator
Date of Evaluation:	August 27, 2021

Information Provided by the Party Requesting the Evaluation

Functional Description of the Equipment:

The Neuro SCS Trial Stimulator (TS) is used in a temporary trial intended to determine if the spinal cord stimulation therapy adequately manages chronic pain symptoms.

It communicates with the Patient Remote (PR) for interaction with the patient and the Neuro Service Center. It communicates with the Clinician Programmer (CP) for communication with the clinician or sales representative.

The communication is carried out by either a Bluetooth Low Energy radio operates in 2.4GHz ISM frequency band or inductive coil communication system operates between 32kHz-64kHz.
The largest dimension of the TS is 86 mm.

Objective:

To demonstrate compliance with FCC Requirements for RF exposure for 1.1307 RF exempt devices

RF Exposure Condition

The following RF Exposure conditions were used for the assessment documented in this report:	
Intended Use	Portable
Location on Body (if applicable)	Head/Torso
How is the Device Used	The Neuro SCS Trial Stimulator (TS) is body worn.
Radios Contained in the Same Host Device	Bluetooth LE, Inductive
Simultaneous Transmitting Radios	None
Body Worn Accessories	None
Environment	General Population/Uncontrolled Exposure

EXEMPTION FROM RF EXPOSURE EVALUATION

element
EXRPT.2021.06.24.0

OVERVIEW

With respect to the limits on human exposure to RF emissions provided in 47 CFR §1.1310, if equipment can be shown to qualify for an exemption pursuant to 47 CFR §1.1307(b)(3), an evaluation is not required.

COMPLIANCE WITH FCC 1.1310

Per 1.1307(b)(3), (i) For single RF sources (*i.e.,* any single fixed RF source, mobile device, or portable device, as defined in paragraph (b)(2) of this section): A single RF source is exempt if:

(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);

(B) Or the available maximum time-averaged power or effective radiated power (ERP), whichever is greater, is less than or equal to the threshold P_{th} (mW) described in the following formula. This method shall only be used at separation distances (cm) from 0.5 cm to 40 cm and at frequencies from 0.3 GHz to 6 GHz (inclusive). P_{th} is given by:

$$P_{th}(mW) = \begin{cases} ERP_{20\ cm}(d/20\ cm) & d \leq 20\ cm \\ ERP_{20\ cm} & 20\ cm\ < d\ \leq 40\ cm \end{cases}$$

Where

$$x = -\log_{10}\left(\frac{60}{ERP_{20\ cm}\sqrt{f}}\right)\ and\ f\ is\ in\ GHz\,;$$

And

$$ERP_{20\ cm}(mW) = \begin{cases} 2040f & 0.3\ GHz\ \leq f\ < 1.5\ GHz \\ 3060 & 1.5\ GHz\ \leq f\ \leq 6\ GHz \end{cases}$$

(C) Or using Table 1 and the minimum separation distance (R in meters) from the body of a nearby person for the frequency (f in MHz) at which the source operates, the ERP (watts) is no more than the calculated value prescribed for that frequency. For the exemption in Table 1 to apply, R must be at least λ/2π, where λ is the free-space operating wavelength in meters. If the ERP of a single RF source is not easily obtained, then the available maximum time-averaged power may be used in lieu of ERP if the physical dimensions of the radiating structure(s) do not exceed the electrical length of λ/4 or if the antenna gain is less than that of a half-wave dipole (1.64 linear value).

TABLE 1 TO §1.1307(b)(3)(i)(C)—SINGLE RF SOURCES SUBJECT TO ROUTINE ENVIRONMENTAL EVALUATION

RF Source frequency (MHz)	Threshold ERP (watts)
0.3-1.34	1,920 R^2.
1.34-30	3,450 R^2/f^2.
30-300	3.83 R^2.
300-1,500	0.0128 R^2f.
1,500-100,000	19.2R^2.

EXEMPTION FROM RF EXPOSURE EVALUATION

element
EXRPT.2021.06.24.0

(ii) For multiple RF sources: Multiple RF sources are exempt if:

(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).

(B) in the case of fixed RF sources operating in the same time-averaging period, or of multiple mobile or portable RF sources within a device operating in the same time averaging period, if the sum of the fractional contributions to the applicable thresholds is less than or equal to 1 as indicated in the following equation.

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

Where:

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 λ/2π 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

ASSESSMENT

The exemption from RF exposure evaluation is summarized in the following table(s):

Radio	Transmit Frequency (MHz)	Conducted Output Power	Power Tolerance (dB)	Duty Cycle	Antenna Assembly Gain (dBi)	Minimum Separation Distance (cm)	Calculated Conducted Exposure Power (mW)	Limit (mW)	Compliant
BTLE	2480	3 dBm	3.0	10.0%	2.2	0.5	0.4	1.0	Yes

The information in the table above was obtained from:

The rated value was used in these calculations. Customer supplied information was used.

EXEMPTION FROM RF EXPOSURE EVALUATION

The Neuro SCS Trial Stimulator (TS) also contains an inductive radio which operates between 32 and 64 kHz. Because it operates below 100 kHz, it is not within the scope of 47 CFR §1.1310.

The following duty cycle information was provided by Roy Wang, RF Systems Engineer at BIOTRONIK, Inc.:

The worst case scenario for TS BLE transmitting is interrogation when all TS parameters is sent to Clinician Programmer (CP). It has been tested with production software that the TX duty cycle for that process never exceeds 10%.

End of Test Report