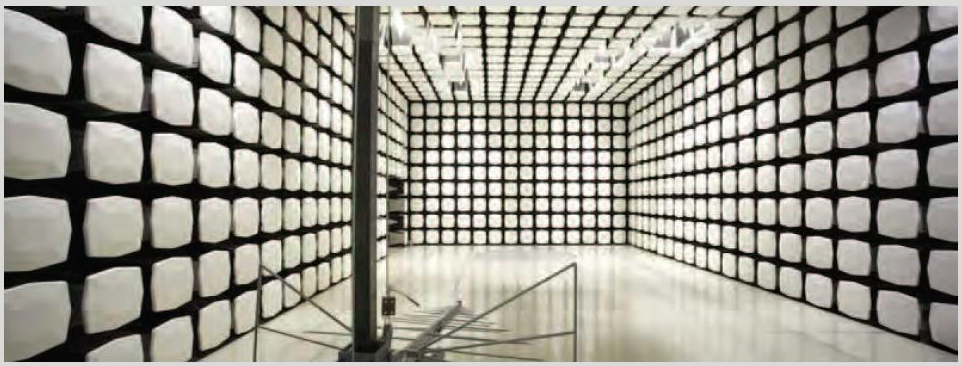
Boston Scientific Neuromodulation

Wilson-I-32 IPG (SC-1232, SC-1216, DB-1232, DB-1216)

FCC 2.1093:2019

Bluetooth Low Energy

Report # BOSN0133.4 Rev. 2



NVLAP Lab Code: 200630

CERTIFICATE OF EVALUATION

Last Date of Evaluation: Thursday, October 24, 2019
Boston Scientific Neuromodulation
EUT: Wilson-I-32 IPG (SC-1232, SC-1216, DB-1232, DB-1216)

RF Exposure Evaluation

Standards

Specification	Method
FCC 2.1093:2019	FCC 447498 D01 General RF Exposure Guidance v06

Results

Method Clause	Description	Applied	Results	Comments
4.3.1	SAR Test Exclusion	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
00	None		
01	Updated power values.	2019-10-28	8
02	Change in maximum radiated output power	2019-11-14	9

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 - Accredited by A2LA to ISO / IEC 17065 as a product certifier. This allows Element to certify transmitters to FCC and IC specifications.

NVLAP - Each laboratory is accredited by NVLAP to ISO 17025

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 – Within Element, we have a EU Notified Body validated for the EMCD and RED Directives.

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.

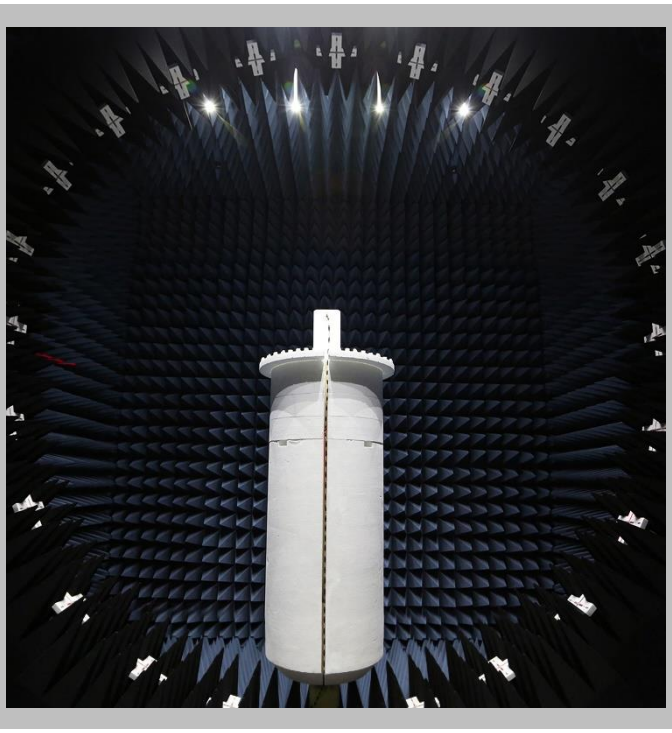
SCOPE

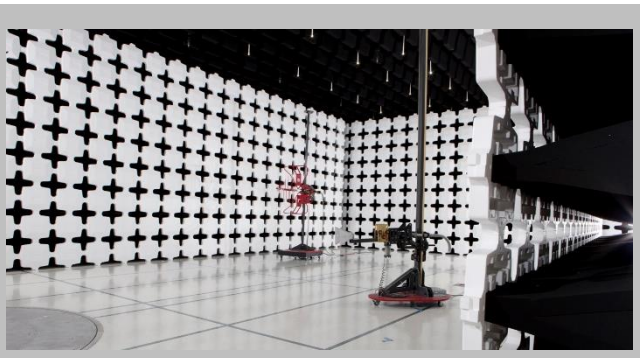
For details on the Scopes of our Accreditations, please visit:
https://www.nwemc.com/emc-testing-accreditations

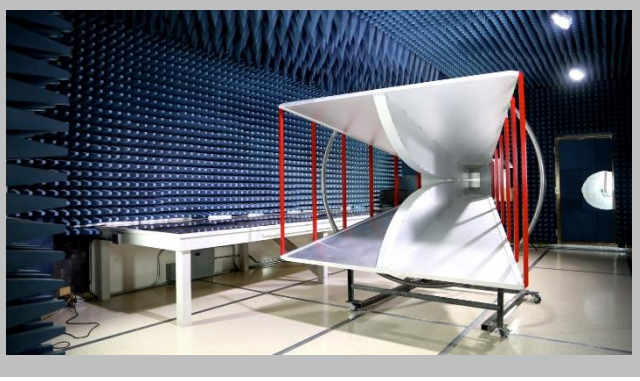
FACILITIES

element
2019.03.08

California	Minnesota	Oregon	Texas	Washington
Labs OC01-17 41 Tesla Irvine, CA 92618 (949) 861-8918	Labs MN01-10 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
NVLAP				
NVLAP Lab Code: 200676-0	NVLAP Lab Code: 200881-0	NVLAP Lab Code: 200630-0	NVLAP Lab Code:201049-0	NVLAP Lab Code: 200629-0
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







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 IPG is implanted in the body.
Radios Contained in the Same Host Device	Bluetooth Low Energy
Simultaneous Transmitting Radios	None
Body Worn Accessories	NA
Environment	General Population/Uncontrolled Exposure

PRODUCT DESCRIPTION

Client and Equipment Under Evaluation Information

Company Name:	Boston Scientific Neuromodulation
Address:	25155 Rye Canyon Loop
City, State, Zip:	Santa Clarita, CA 91355
Evaluation Requested By:	Habet Ter-Petrosyan
EUT:	Wilson-I-32 IPG (SC-1232, SC-1216, DB-1232, DB-1216)
Date of Evaluation:	Thursday, October 24, 2019

Information Provided by the Party Requesting the Evaluation

Functional Description of the Equipment:
The IPG (Implantable Pulse Generator) generates electrical pulses used to stimulate different nerve fibers depending upon the application (e.g., mitigation of chronic pain, etc.). The IPG contains a Bluetooth Low Energy Radio.

Objective:
To demonstrate compliance with FCC RF exposure requirements for 2.1093 portable devices.

SAR TEST EXCLUSION

element
EXRPT.2019.04.10

OVERVIEW

Human exposure to RF emissions from portable devices (47 CFR §2.1093) used with the radiating antenna closer than 20 cm to the user requires Specific Absorption Rate (SAR) to evaluate the environmental impact of human exposure to radiofrequency (RF) radiation.

COMPLIANCE WITH FCC 2.1093

"Portable devices that operate in the Cellular Radiotelephone Service pursuant to part 22 of this chapter; the Personal Communications Service (PCS) pursuant to part 24 of this chapter; the Satellite Communications Services pursuant to part 25 of this chapter; the Miscellaneous Wireless Communications Services pursuant to part 27 of this chapter; the Maritime Services (ship earth station devices only) pursuant to part 80 of this chapter; the Specialized Mobile Radio Service, the 4.9 GHz Band Service, and the 3650 MHz Wireless Broadband Service pursuant to part 90 of this chapter; the Wireless Medical Telemetry Service (WMTS) and the Medical Device Radiocommunication Service (MedRadio), pursuant to subparts H and I of part 95 of this chapter, respectively, unlicensed personal communication service, unlicensed NII devices and millimeter wave devices authorized under §§15.253(f), 15.255(g), 15.257(g), 15.319(i), and 15.407(f) of this chapter; and the Citizens Broadband Radio Service pursuant to part 96 of this chapter are subject to routine environmental evaluation for RF exposure prior to equipment authorization or use. All other portable transmitting devices are categorically excluded from routine environmental evaluation for RF exposure prior to equipment authorization or use, except as specified in §§1.1307(c) and 1.1307(d) of this chapter. Applications for equipment authorization of portable transmitting devices subject to routine environmental evaluation must contain a statement confirming compliance with the limits specified in paragraph (d) of this section. Technical information showing the basis for this statement must be submitted to the Commission upon request."

The EUT will be used with a separation distance of less than 20 centimeters between the radiating antenna and the body of the user or nearby persons and must therefore be considered a portable transmitter per 47 CFR 2.1093(b).

COMPLIANCE WITH FCC KDB 447498 D01 General RF Exposure Guidance v06

"KDB 447498 D01 General RF Exposure Guidance v06" provides the procedures, requirements, and authorization policies for mobile and portable devices.

Standalone radio SAR test exclusion for an implanted transmitter is covered under section 4.2.4:

> "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.[27] 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.
>
> Footnote 27: Maximum conducted and radiated power should both be taken into consideration to establish the worst case aggregate maximum output power."

General guidance regarding maximum power is found in Section 4(b),

> "As required by §§ 2.1091(d)(2) and 2.1093(d)(5), RF exposure compliance must be determined at the maximum average power level according to source-based time-averaging requirements to determine compliance for general population exposure conditions. Unless it is specified differently in the published

> RF exposure KDB procedures, these requirements also apply to test reduction and test exclusion considerations. Time-averaged maximum conducted output power applies to SAR"

ASSESSMENT

Per 2.1093(d)(2), exposure may be averaged over a time period not to exceed 30 minutes to determine compliance with general population / uncontrolled SAR limits.

Habet Ter-Petrosyan, Electrical Engineer at Boston Scientific Neuromodulation provided the following guidance about the 24% source-based duty cycle for the radio:

> "This is based upon the maximum data transfer of 240 kbps (raw PHY data including radio overhead) on a physical BLE radio signal of 1 Mbps."

The time-averaged maximum conducted output power is summarized in the following table:

Radio	Transmit Frequency (MHz)	Measured Conducted Output Power (dBm)	Duty Cycle	Time-averaged maximum conducted output power (mW)	Exclusion Threshold (mW)	Compliant
Bluetooth Low Energy	2402	2.9	0.24	0.468	≤ 1.0	Yes

The time-averaged maximum radiated output power is summarized in the following table:

Radio	Transmit Frequency (MHz)	Measured Radiated Output Power (mW)	Duty Cycle	Time-averaged maximum radiated output power (mW)	Exclusion Threshold (mW)	Compliant
Bluetooth Low Energy	2402	2.1	0.24	0.496	≤ 1.0	Yes

The aggregate (worst case) of the time averaged maximum conducted and radiated output powers are less than the exclusion threshold:

Conducted Output Power (mW)	Radiated Output Power (mW)	Exclusion Threshold (mW)	Compliant
0.468	0.496	≤ 1.0	Yes

The information in the tables above was obtained from:

From client supplied information and Element report #BOSN0134.3.