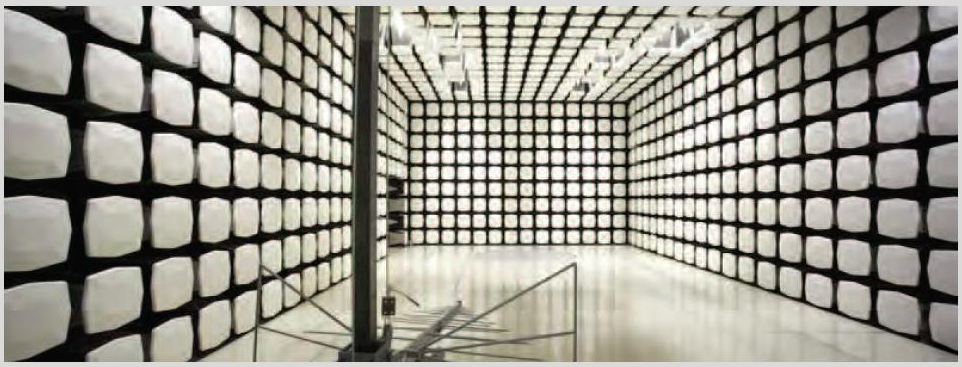
BIOTRONIK, Inc.

Neuro SCS IPG

FCC 15.209:2021
Inductive

Report: BIOT0080.1 Rev. 1, Issue Date: October 14, 2021



NVLAP LAB CODE: 200630-0

CERTIFICATE OF TEST

Last Date of Test: January 20, 2021
BIOTRONIK, Inc.
EUT: Neuro SCS IPG

Radio Equipment Testing

Standards

Specification	Method
FCC 15.209:2021	ANSI C63.10:2013

Results

Method Clause	Test Description	Applied	Results	Comments
6.2	Powerline Conducted Emissions	No	N/A	Not required for a battery powered EUT.
6.4	Field Strength of Fundamental	Yes	Pass	
6.4, 6.5	Spurious Radiated Emissions	Yes	Pass	

Deviations From Test Standards

None

Approved By:

Kyle Holgate, Operations Manager

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	Updated power settings to inductive radio.	2021-10-14	8
	Removed 10m data from Field Strength of Fundamental.	2021-10-14	14

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

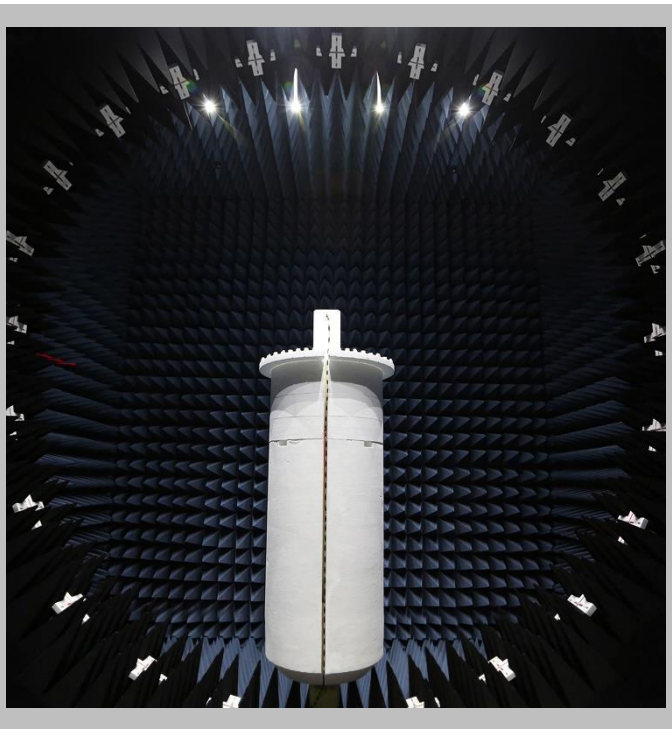
MIC – Recognized by MIC as a CAB for the acceptance of test data.

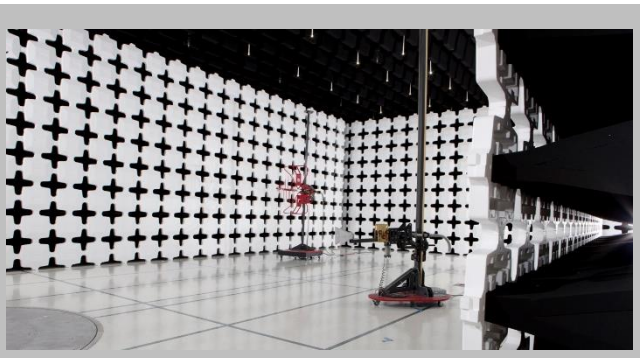
SCOPE

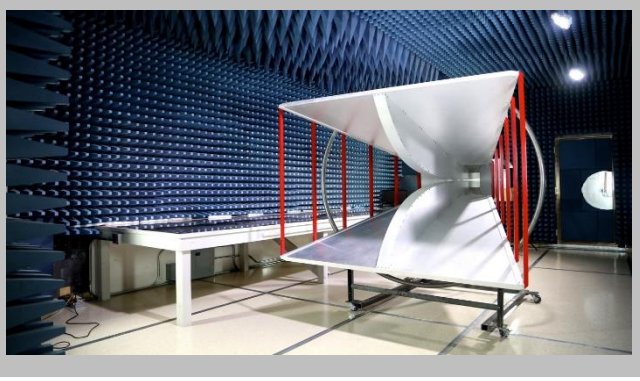
For details on the Scopes of our Accreditations, please visit:
https://www.nwemc.com/emc-testing-accreditations

FACILITIES

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
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







MEASUREMENT UNCERTAINTY

element
TMU.2015.07.10

Measurement Uncertainty

When a measurement is made, the result will be different from the true or theoretically correct value. The difference is the result of tolerances in the measurement system that cannot be completely eliminated. To the extent that technology allows us, it has been our aim to minimize this error. Measurement uncertainty is a statistical expression of measurement error qualified by a probability distribution.

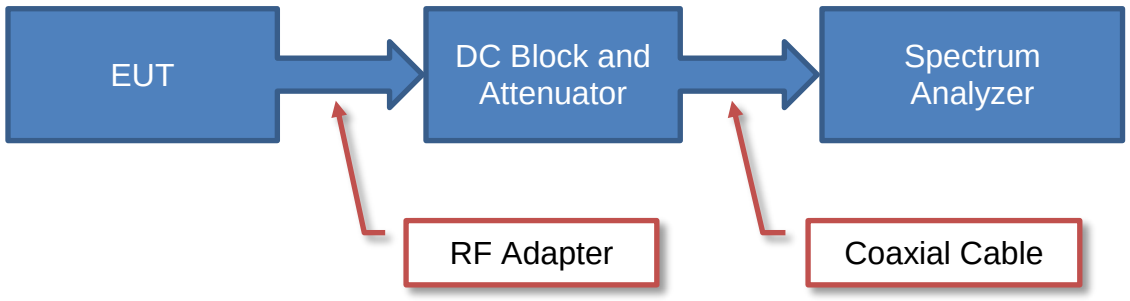
A measurement uncertainty estimation has been performed for each test per our internal quality document QM205.4.6. The estimation is used to compare the measured result with its "true" or theoretically correct value. The expanded measurement uncertainty (K=2) can be found included as part of the applicable test description page. Our measurement data meets or exceeds the measurement uncertainty requirements of the applicable specification; therefore, the test data can be compared directly to the specification limit to determine compliance. The calculations for estimating measurement uncertainty are based upon ETSI TR 100 028 (or CISPR 16-4-2 as applicable), and are available upon request.

The following table represents the Measurement Uncertainty (MU) budgets for each of the tests that may be contained in this report.

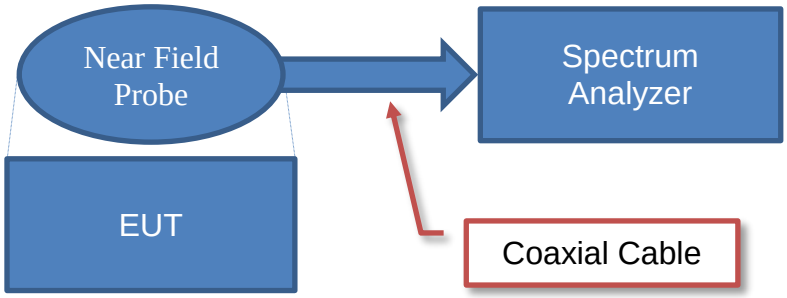
Test	+ MU	- MU
Frequency Accuracy	0.0007%	-0.0007%
Amplitude Accuracy (dB)	1.2 dB	-1.2 dB
Conducted Power (dB)	1.2 dB	-1.2 dB
Radiated Power via Substitution (dB)	0.7 dB	-0.7 dB
Temperature (degrees C)	0.7°C	-0.7°C
Humidity (% RH)	2.5% RH	-2.5% RH
Voltage (AC)	1.0%	-1.0%
Voltage (DC)	0.7%	-0.7%
Field Strength (dB)	5.2 dB	-5.2 dB
AC Powerline Conducted Emissions (dB)	2.6 dB	-2.6 dB

Test Setup Block Diagrams

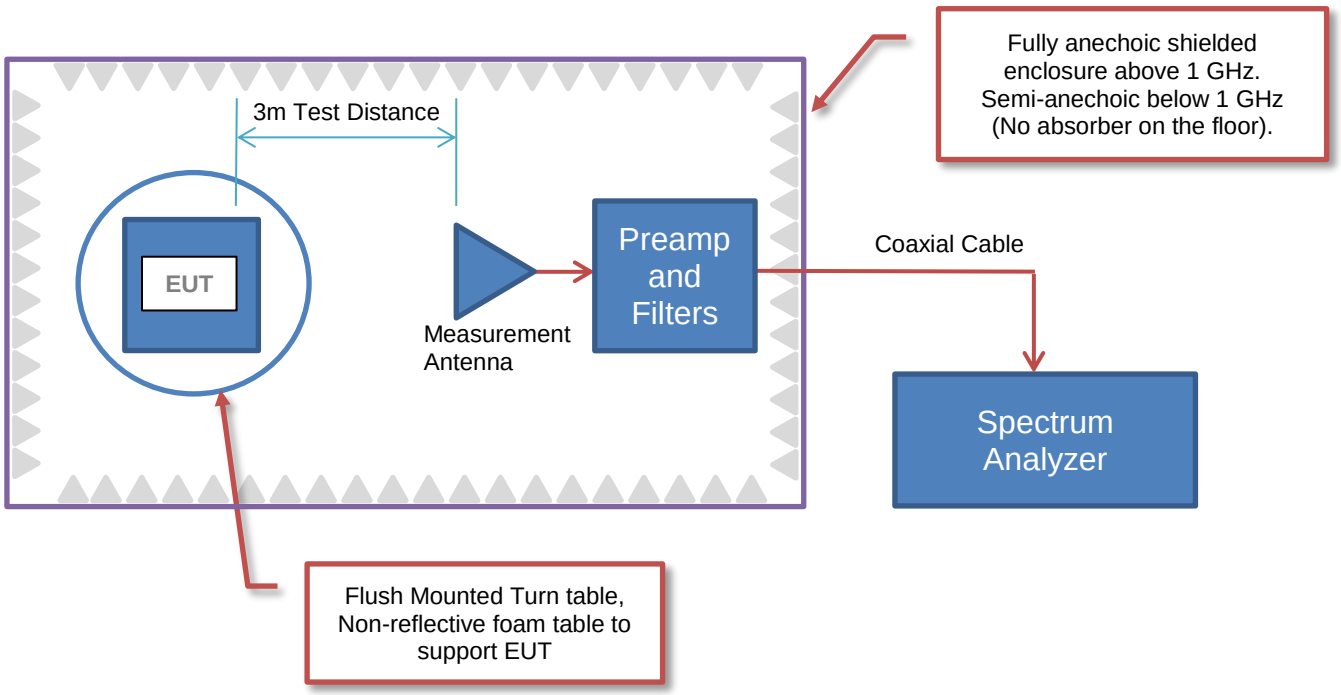
Antenna Port Conducted Measurements



Near Field Test Fixture Measurements



Spurious Radiated Emissions



POWER SETTINGS AND ANTENNAS

The power settings, antenna gain value(s) and cable loss (if applicable) used for the testing contained in this report were provided by the customer and will affect the validity of the results. Element assumes no responsibility for the accuracy of this information.

ANTENNA GAIN (dBi)

Type	Provided by:	Frequency Range (MHz)	Gain (dBi)
3mm Diameter coil, 1600 turns	Manufacturer	Inductive Radio	N/A

No adjustable power settings were provided. The EUT was tested using power settings pre-defined by the manufacturer.

PRODUCT DESCRIPTION

Client and Equipment Under Test (EUT) Information

Company Name:	BIOTRONIK, Inc.
Address:	6024 Jean Road, BLDG B
City, State, Zip:	Lake Oswego, OR 97035
Test Requested By:	Roy Wang
EUT:	Neuro SCS IPG
First Date of Test:	January 19, 2021
Last Date of Test:	January 20, 2021
Receipt Date of Samples:	January 18, 2021
Equipment Design Stage:	Production
Equipment Condition:	No Damage
Purchase Authorization:	Verified

Information Provided by the Party Requesting the Test

Functional Description of the EUT:
Implantable Neurostimulator

Testing Objective:
To demonstrate compliance of the inductive portion of the device to FCC Part 15.209 specifications.

CONFIGURATIONS

Configuration BIOT0080- 1

Software/Firmware Running during test	
Description	**Version**
SCS ROM	2.1

EUT			
Description	**Manufacturer**	**Model/Part Number**	**Serial Number**
Implantable Neurostimulator	BIOTRONIK, Inc.	Prospera	88200467

MODIFICATIONS

Equipment Modifications

Item	Date	Test	Modification	Note	Disposition of EUT
1	2021-01-19	Field Strength of Fundamental	Tested as delivered to Test Station.	No EMI suppression devices were added or modified during this test.	EUT remained at Element following the test.
2	2021-01-20	Spurious Radiated Emissions	Tested as delivered to Test Station.	No EMI suppression devices were added or modified during this test.	Scheduled testing was completed.

FIELD STRENGTH OF FUNDAMENTAL

PSA-ESCI 2020.12.30.0

Testing was performed using the mode(s) of operation and configuration(s) noted within the report. The individuals and/or the organization requesting the test provided the modes, configurations and settings used to complete the evaluation. The actual test parameters are specified in the test data, this includes items such as investigated frequency range (scanned) and test levels. The testing methods and performance specifications, as well as the test site used for the evaluation are indicated in the test data. The test data represents the configuration / operating mode/ model that produced the highest emission levels as compared to the specification limit.

MODES OF OPERATION

Continuous transmit inductive, 32kHz

POWER SETTINGS INVESTIGATED

Battery

CONFIGURATIONS INVESTIGATED

BIOT0080 - 1

FREQUENCY RANGE INVESTIGATED

Start Frequency	9 kHz	Stop Frequency	30 MHz

SAMPLE CALCULATIONS

Radiated Emissions: Field Strength = Measured Level + Antenna Factor + Cable Factor - Amplifier Gain + Distance Adjustment Factor + External Attenuation

TEST EQUIPMENT

Description	Manufacturer	Model	ID	Last Cal.	Cal. Due
Cable	None	3m Test Distance Cable	EVM	2020-02-28	2/28/2021
Antenna - Loop	EMCO	6502	AOA	2020-07-06	7/6/2022
Analyzer - Spectrum Analyzer	Agilent	E4443A	AFB	2020-06-26	6/26/2021

MEASUREMENT BANDWIDTHS

Frequency Range (MHz)	Peak Data (kHz)	Quasi-Peak Data (kHz)	Average Data (kHz)
0.01 - 0.15	1.0	0.2	0.2
0.15 - 30.0	10.0	9.0	9.0
30.0 - 1000	100.0	120.0	120.0
Above 1000	1000.0	N/A	1000.0

TEST DESCRIPTION

The antennas to be used with the EUT were tested. The EUT was continuously transmitting while set to the channel specified.

The fundamental carrier of the EUT was maximized by rotating the EUT on a turntable, adjusting the position of the EUT and EUT antenna in three orthogonal axis, and adjusting the measurement antenna polarization (per ANSI C63.10). A calibrated active loop antenna was used for this test in order to provide sufficient measurement sensitivity. The reference point of the loop antenna was maintained at 1m above the ground plane during the testing.

Measurements were made with the required detectors and annotated on the data for each individual point using the following annotation:

QP = Quasi-Peak Detector
PK = Peak Detector
AV = RMS Detector

As outlined in 15.209(e), 15.31(f)(2), and RSS-GEN, 6.5, measurements may be performed at a distance closer than what is specified with the limit. The limit at the specified distance is shown on the data sheet. Measurements are made at a closer distance and the data is adjusted using a distance correction factor of 40dB/decade for comparison to the limit.

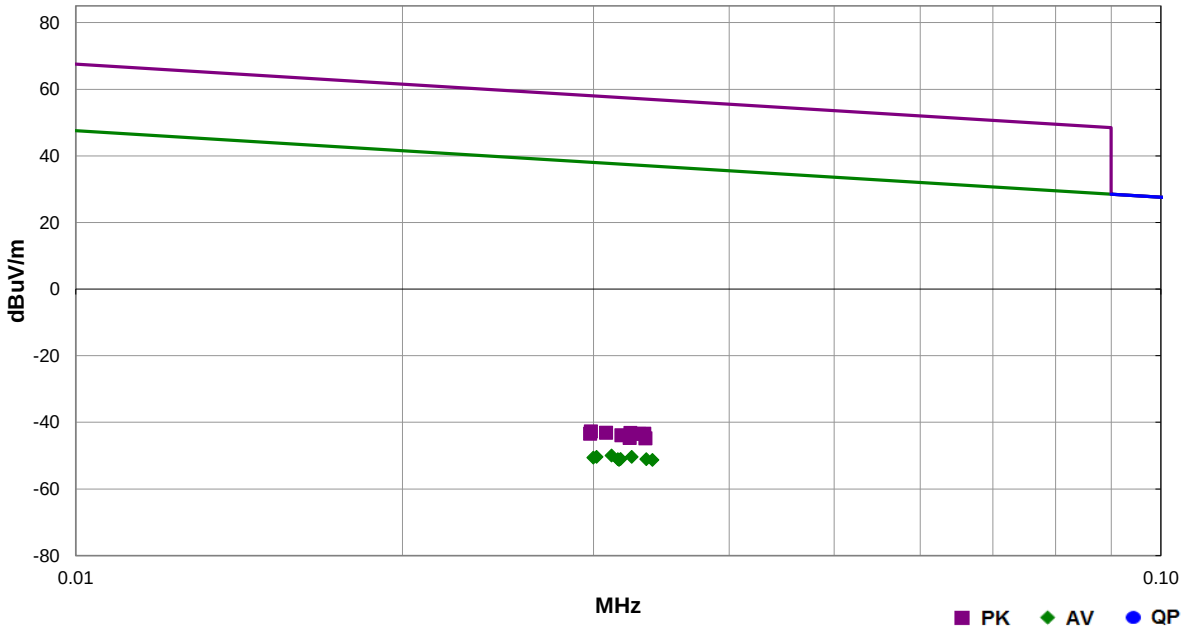
FIELD STRENGTH OF FUNDAMENTAL

EmiR5 2020.12.09.0 PSA-ESCI 2020.12.30.0

Work Order:	BIOT0080	**Date:**	2021-01-19		
Project:	None	**Temperature:**	23.9 °C		
Job Site:	EV11	**Humidity:**	30% RH		
Serial Number:	88200467	**Barometric Pres.:**	1031 mbar	**Tested by:**	Cole Ghizzone
EUT:	Neuro SCS IPG				
Configuration:	1				
Customer:	BIOTRONIK, Inc.				
Attendees:	Roy Wang				
EUT Power:	Battery				
Operating Mode:	Continuous transmit inductive, 32kHz				
Deviations:	None				
Comments:	See data comments for EUT orientation. EUT leads terminated in distilled water				

Test Specifications	**Test Method**
FCC 15.209:2021	ANSI C63.10:2013

Run #	2	**Test Distance (m)**	1	**Antenna Height(s)**	1 (m)	**Results**	Pass



Freq (MHz)	Amplitude (dBuV)	Factor (dB)	Antenna Height (meters)	Azimuth (degrees)	Test Distance (meters)	External Attenuation (dB)	Polarity/ Transducer Type	Detector	Distance Adjustment (dB)	Adjusted (dBuV/m)	Spec. Limit (dBuV/m)	Compared to Spec. (dB)	Comments
0.033	34.9	13.8	1.0	358.0	1.0	0.0	Perp EUT	AV	-99.1	-50.4	37.3	-87.7	EUT Horizontal
0.031	35.1	14.0	1.0	222.0	1.0	0.0	Para EUT	AV	-99.1	-50.0	37.7	-87.7	EUT Vertical
0.034	34.3	13.7	1.0	27.0	1.0	0.0	Para Floor	AV	-99.1	-51.1	37.1	-88.2	EUT Horizontal
0.034	34.2	13.6	1.0	197.0	1.0	0.0	Perp EUT	AV	-99.1	-51.3	37.0	-88.3	EUT On Side
0.030	34.6	14.1	1.0	350.0	1.0	0.0	Para Floor	AV	-99.1	-50.4	38.0	-88.4	EUT On Side
0.032	34.2	13.9	1.0	31.0	1.0	0.0	Para EUT	AV	-99.1	-51.0	37.5	-88.5	EUT On Side
0.030	34.4	14.1	1.0	310.0	1.0	0.0	Para Floor	AV	-99.1	-50.6	38.0	-88.6	EUT Vertical
0.032	34.1	13.9	1.0	349.0	1.0	0.0	Para EUT	AV	-99.1	-51.1	37.6	-88.7	EUT Horizontal
0.032	33.9	13.9	1.0	47.0	1.0	0.0	Perp EUT	AV	-99.1	-51.3	37.6	-88.9	EUT Vertical
0.033	42.0	13.7	1.0	47.0	1.0	0.0	Perp EUT	PK	-99.1	-43.4	57.1	-100.5	EUT Vertical
0.032	42.1	13.8	1.0	222.0	1.0	0.0	Para EUT	PK	-99.1	-43.2	57.4	-100.6	EUT Vertical
0.033	41.9	13.7	1.0	358.0	1.0	0.0	Perp EUT	PK	-99.1	-43.5	57.2	-100.7	EUT Horizontal
0.030	42.3	14.1	1.0	27.0	1.0	0.0	Para Floor	PK	-99.1	-42.7	58.1	-100.8	EUT Horizontal
0.031	42.0	14.0	1.0	349.0	1.0	0.0	Para EUT	PK	-99.1	-43.1	57.8	-100.9	EUT Horizontal
0.032	41.3	13.9	1.0	197.0	1.0	0.0	Perp EUT	PK	-99.1	-43.9	57.5	-101.4	EUT On Side
0.030	41.6	14.1	1.0	350.0	1.0	0.0	Para Floor	PK	-99.1	-43.4	58.1	-101.5	EUT On Side
0.034	40.6	13.7	1.0	310.0	1.0	0.0	Para Floor	PK	-99.1	-44.8	57.1	-101.9	EUT Vertical
0.032	40.6	13.8	1.0	31.0	1.0	0.0	Para EUT	PK	-99.1	-44.7	57.4	-102.1	EUT On Side

SPURIOUS RADIATED EMISSIONS

element

PSA-ESCI 2020.12.30.0

Testing was performed using the mode(s) of operation and configuration(s) noted within the report. The individuals and/or the organization requesting the test provided the modes, configurations and settings used to complete the evaluation. The actual test parameters are specified in the test data, this includes items such as investigated frequency range (scanned) and test levels. The testing methods and performance specifications, as well as the test site used for the evaluation are indicated in the test data. The test data represents the configuration / operating mode/ model that produced the highest emission levels as compared to the specification limit.

MODES OF OPERATION

Continuous transmit inductive, 32kHz

POWER SETTINGS INVESTIGATED

Battery

CONFIGURATIONS INVESTIGATED

BIOT0080 - 1

FREQUENCY RANGE INVESTIGATED

Start Frequency	9 kHz	Stop Frequency	30 MHz

SAMPLE CALCULATIONS

Radiated Emissions: Field Strength = Measured Level + Antenna Factor + Cable Factor - Amplifier Gain + Distance Adjustment Factor + External Attenuation

TEST EQUIPMENT

Description	Manufacturer	Model	ID	Last Cal.	Cal. Due
Cable	None	3m Test Distance Cable	EVM	2020-02-28	2/28/2021
Antenna - Loop	EMCO	6502	AOA	2020-07-06	7/6/2022
Analyzer - Spectrum Analyzer	Agilent	E4443A	AFB	2020-06-26	6/26/2021

MEASUREMENT BANDWIDTHS

Frequency Range (MHz)	Peak Data (kHz)	Quasi-Peak Data (kHz)	Average Data (kHz)
0.01 - 0.15	1.0	0.2	0.2
0.15 - 30.0	10.0	9.0	9.0
30.0 - 1000	100.0	120.0	120.0
Above 1000	1000.0	N/A	1000.0

TEST DESCRIPTION

The antennas to be used with the EUT were tested. The EUT was continuously transmitting while set to the channel specified.

For each configuration, the spectrum was scanned throughout the specified range as part of the exploratory investigation of the emissions. These “pre-scans” are not included in the report. Final measurements on individual emissions were then made and included in this test report.

The individual emissions from the EUT were maximized by rotating the EUT on a turntable, adjusting the position of the EUT and EUT antenna in three orthogonal axis, and adjusting the measurement antenna height (where applicable) and polarization (per ANSI C63.10). A calibrated active loop antenna was used for this test in order to provide sufficient measurement sensitivity. The reference point of the loop antenna was maintained at 1m above the ground plane during the testing.

Measurements were made with the required detectors and annotated on the data for each individual point using the following annotation:

QP = Quasi-Peak Detector
PK = Peak Detector
AV = CISPR Detector

If there are no detectable emissions above the noise floor, the data included may show noise floor measurements for reference only.

As outlined in 15.209(e), 15.31(f)(2), and RSS-GEN, 6.5, measurements may be performed at a distance closer than what is specified with the limit. The limit at the specified distance is shown on the data sheet. Measurements are made at a closer distance and the data is adjusted using a distance correction factor of 40dB/decade for comparison to the limit.

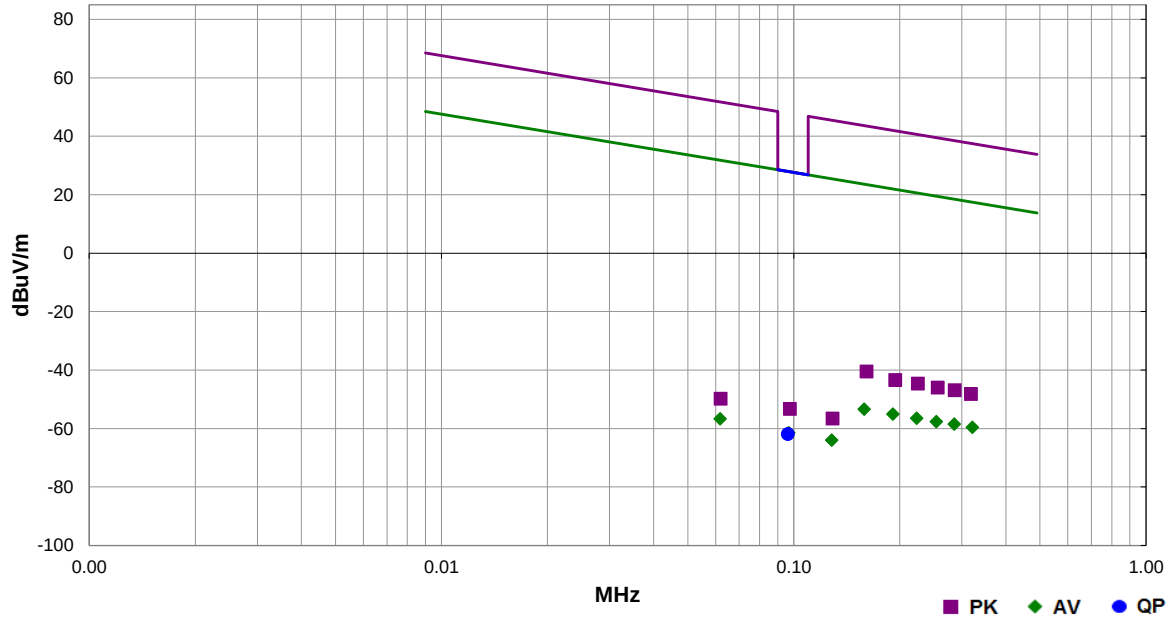
SPURIOUS RADIATED EMISSIONS

EmiR5 2020.12.09.0 PSA-ESCI 2020.12.30.0

Work Order:	BIOT0080	**Date:**	2021-01-20		
Project:	None	**Temperature:**	21.8 °C		
Job Site:	EV11	**Humidity:**	29% RH		
Serial Number:	88200467	**Barometric Pres.:**	1025 mbar	**Tested by:**	Cole Ghizzone
EUT:	Neuro SCS IPG				
Configuration:	1				
Customer:	BIOTRONIK, Inc.				
Attendees:	Roy Wang				
EUT Power:	Battery				
Operating Mode:	Continuous transmit inductive, 32kHz				
Deviations:	None				
Comments:	EUT leads terminated in distilled water				

Test Specifications	**Test Method**
FCC 15.209:2021	ANSI C63.10:2013

Run #	7	**Test Distance (m)**	1	**Antenna Height(s)**	1 to 4(m)	**Results**	Pass



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Freq (MHz)	Amplitude (dBuV)	Factor (dB)	Antenna Height (meters)	Azimuth (degrees)	Test Distance (meters)	External Attenuation (dB)	Polarity/ Transducer Type	Detector	Distance Adjustment (dB)	Adjusted (dBuV/m)	Spec. Limit (dBuV/m)	Compared to Spec. (dB)	Comments
0.158	34.7	11.0	1.0	130.0	1.0	0.0	Perp EUT	AV	-99.1	-53.4	23.6	-77.0	EUT Horizontal
0.286	29.9	10.7	1.0	100.0	1.0	0.0	Perp EUT	AV	-99.1	-58.5	18.5	-77.0	EUT Horizontal
0.191	33.2	10.8	1.0	177.0	1.0	0.0	Perp EUT	AV	-99.1	-55.1	22.0	-77.1	EUT Horizontal
0.223	31.8	10.8	1.0	366.0	1.0	0.0	Perp EUT	AV	-99.1	-56.5	20.6	-77.1	EUT Horizontal
0.321	28.7	10.8	1.0	366.0	1.0	0.0	Perp EUT	AV	-99.1	-59.6	17.5	-77.1	EUT Horizontal
0.254	30.7	10.7	1.0	306.0	1.0	0.0	Perp EUT	AV	-99.1	-57.7	19.5	-77.2	EUT Horizontal
0.097	34.6	11.2	1.0	58.0	1.0	0.0	Perp EUT	PK	-99.1	-53.3	27.8	-81.1	EUT Horizontal
0.161	47.6	11.0	1.0	130.0	1.0	0.0	Perp EUT	PK	-99.1	-40.5	43.5	-84.0	EUT Horizontal
0.225	43.7	10.8	1.0	366.0	1.0	0.0	Perp EUT	PK	-99.1	-44.6	40.6	-85.2	EUT Horizontal
0.194	44.9	10.8	1.0	177.0	1.0	0.0	Perp EUT	PK	-99.1	-43.4	41.9	-85.3	EUT Horizontal
0.256	42.4	10.7	1.0	306.0	1.0	0.0	Perp EUT	PK	-99.1	-46.0	39.4	-85.4	EUT Horizontal
0.287	41.5	10.7	1.0	100.0	1.0	0.0	Perp EUT	PK	-99.1	-46.9	38.5	-85.4	EUT Horizontal
0.318	40.1	10.8	1.0	366.0	1.0	0.0	Perp EUT	PK	-99.1	-48.2	37.5	-85.7	EUT Horizontal
0.062	30.6	11.8	1.0	303.0	1.0	0.0	Perp EUT	AV	-99.1	-56.7	31.8	-88.5	EUT Horizontal
0.097	26.4	11.2	1.0	58.0	1.0	0.0	Perp EUT	AV	-99.1	-61.5	27.9	-89.4	EUT Horizontal
0.128	24.2	10.9	1.0	193.0	1.0	0.0	Perp EUT	AV	-99.1	-64.0	25.5	-89.5	EUT Horizontal
0.096	26.0	11.2	1.0	58.0	1.0	0.0	Perp EUT	QP	-99.1	-61.9	27.9	-89.8	EUT Horizontal
0.062	37.5	11.8	1.0	303.0	1.0	0.0	Perp EUT	PK	-99.1	-49.8	51.7	-101.5	EUT Horizontal
0.129	31.6	10.9	1.0	193.0	1.0	0.0	Perp EUT	PK	-99.1	-56.6	45.4	-102.0	EUT Horizontal