



element

BIOTRONIK, Inc.
Neuro SCS Trial Stimulator

FCC 15.209:2021

Inductive Radio

Report: BIOT0085.3, Issue Date: August 30, 2021



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CERTIFICATE OF TEST

Last Date of Test: April 28, 2021

BIOTRONIK, Inc.

EUT: Neuro SCS Trial Stimulator

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
00	None		

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

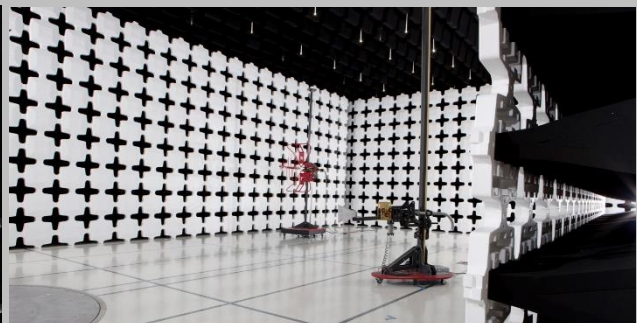
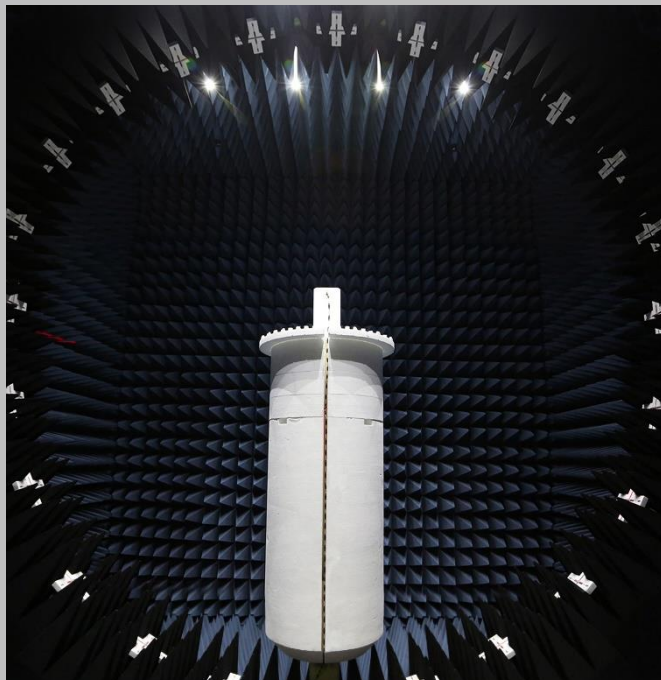
For details on the Scopes of our Accreditations, please visit:

<https://www.nwemc.com/emc-testing-accreditations>

FACILITIES



California Labs OC01-17 41 Tesla Irvine, CA 92618 (949) 861-8918	Minnesota Labs MN01-11 9349 W Broadway Ave. Brooklyn Park, MN 55445 (612)-638-5136	Oregon Labs EV01-12 6775 NE Evergreen Pkwy #400 Hillsboro, OR 97124 (503) 844-4066	Texas Labs TX01-09 3801 E Plano Pkwy Plano, TX 75074 (469) 304-5255	Washington Labs NC01-05 19201 120 th 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



MEASUREMENT UNCERTAINTY

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.

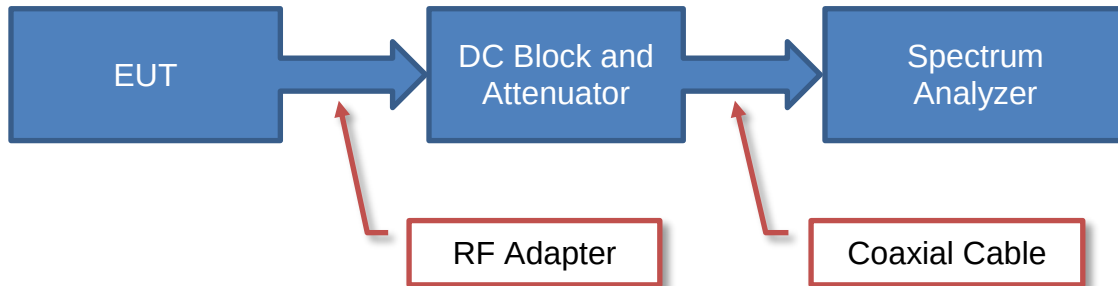
A measurement uncertainty estimation has been performed for each test per our internal quality document QM205.4.6. The estimation is used to compare the measured result with its "true" or theoretically correct value. The expanded measurement uncertainty (K=2) can be found in the table below. A lab specific value may also be found in the applicable test description section. 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.

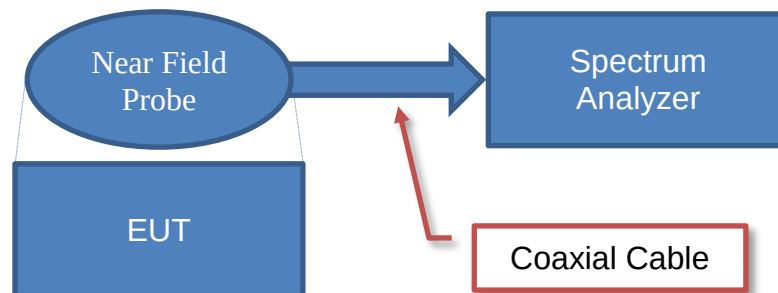
Test	+ MU	- MU
Frequency Accuracy	0.0007%	-0.0007%
Amplitude Accuracy (dB)	1.2 dB	-1.2 dB
Conducted Power (dB)	1.2 dB	-1.2 dB
Radiated Power via Substitution (dB)	0.7 dB	-0.7 dB
Temperature (degrees C)	0.7°C	-0.7°C
Humidity (% RH)	2.5% RH	-2.5% RH
Voltage (AC)	1.0%	-1.0%
Voltage (DC)	0.7%	-0.7%
Field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

Test Setup Block Diagrams

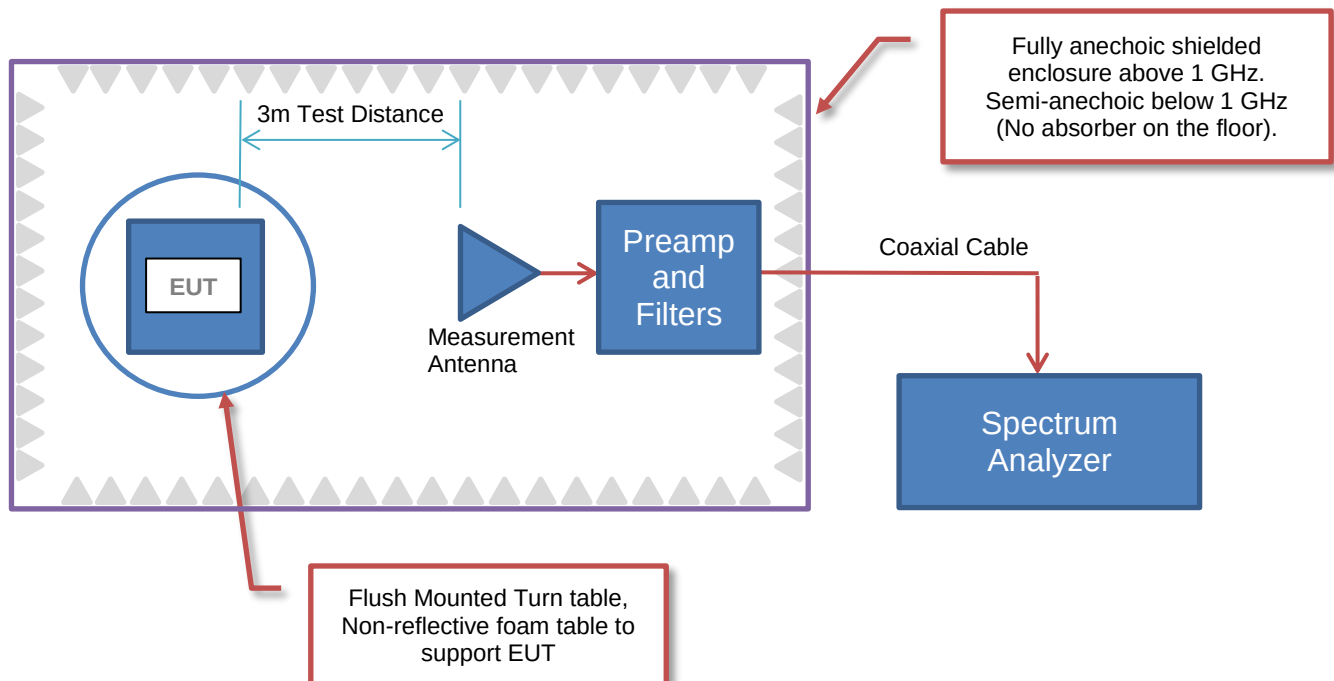
Antenna Port Conducted Measurements



Near Field Test Fixture Measurements



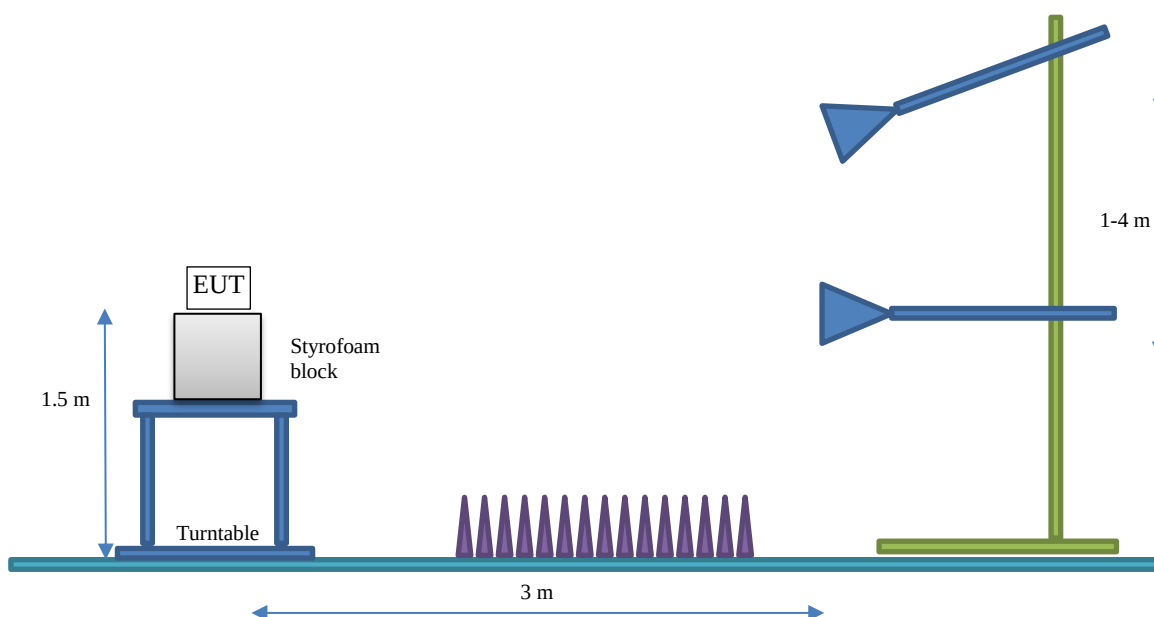
Spurious Radiated Emissions



Test Setup Block Diagrams

Bore Sighting (>1GHz)

The diameter of the illumination area is the dimension of the line tangent to the EUT formed by 3 dB beamwidth of the measurement antenna at the measurement distance. At a 3 meter test distance, the diameter of the illumination area was 3.8 meters at 1 GHz and greater than 2.1 meters up to 6 GHz. Above 1 GHz, when required by the measurement standard, the antenna is pointed for both azimuth and elevation to maintain the receive antenna within the cone of radiation from the EUT. The specified measurement detectors were used for comparison of the emissions to the peak and average specification limits.



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 Trial Stimulator
First Date of Test:	April 28, 2021
Last Date of Test:	April 28, 2021
Receipt Date of Samples:	April 26, 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:
Body-worn Neurostimulator
Testing Objective:
To demonstrate compliance of the inductive portion of the device to FCC Part 15.209 specifications.

CONFIGURATIONS



Configuration BIOT0085- 4

EUT			
Description	Manufacturer	Model/Part Number	Serial Number
Neuro SCS Trial Stimulator	BIOTRONIK, Inc.	Neuro SCS Trial Stimulator	91820147

Peripherals in test setup boundary			
Description	Manufacturer	Model/Part Number	Serial Number
Simulated Load	BIOTRONIK, Inc.	SDD-0649	003

Cables					
Cable Type	Shield	Length (m)	Ferrite	Connection 1	Connection 2
Patient Leads	No	0.4m	No	Neuro SCS Trial Stimulator	Simulated Load

MODIFICATIONS



Equipment Modifications

Item	Date	Test	Modification	Note	Disposition of EUT
1	2021-04-28	Spurious Radiated Emissions	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	2021-04-28	Field Strength of Fundamental	Tested as delivered to Test Station.	No EMI suppression devices were added or modified during this test.	Scheduled testing was completed.

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 (kHz)	Gain (dBi)
Magnetic Coil	Manufacturer	32 - 64	N/A

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

FIELD STRENGTH OF FUNDAMENTAL

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.

TEST EQUIPMENT

Description	Manufacturer	Model	ID	Last Cal.	Cal. Due
Analyzer - Spectrum Analyzer	Agilent	E4443A	AFB	2020-06-26	2021-06-26
Cable	None	3m Test Distance Cable	EVM	2021-02-16	2022-02-16
Antenna - Loop	EMCO	6502	AOA	2020-07-06	2022-07-06

MEASUREMENT UNCERTAINTY

Description		
Expanded k=2	1.7 dB	-1.7 dB

FREQUENCY RANGE INVESTIGATED

9 kHz TO 30 MHz

POWER INVESTIGATED

Battery

CONFIGURATIONS INVESTIGATED

BIOT0085-4

MODES INVESTIGATED

Inductive radio continuous Tx, ASK, 38 kHz

FIELD STRENGTH OF FUNDAMENTAL

EUT:	Neuro SCS Trial Stimulator	Work Order:	BIOT0085
Serial Number:	91820147	Date:	2021-04-28
Customer:	BIOTRONIK, Inc.	Temperature:	21.7°C
Attendees:	Roy Wang	Relative Humidity:	39%
Customer Project:	None	Bar. Pressure:	1029 mb
Tested By:	Jeff Alcock	Job Site:	EV11
Power:	Battery	Configuration:	BIOT0085-4

TEST SPECIFICATIONS

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

TEST PARAMETERS

Run #:	4	Test Distance (m):	1	Ant. Height(s) (m):	1(m)
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COMMENTS

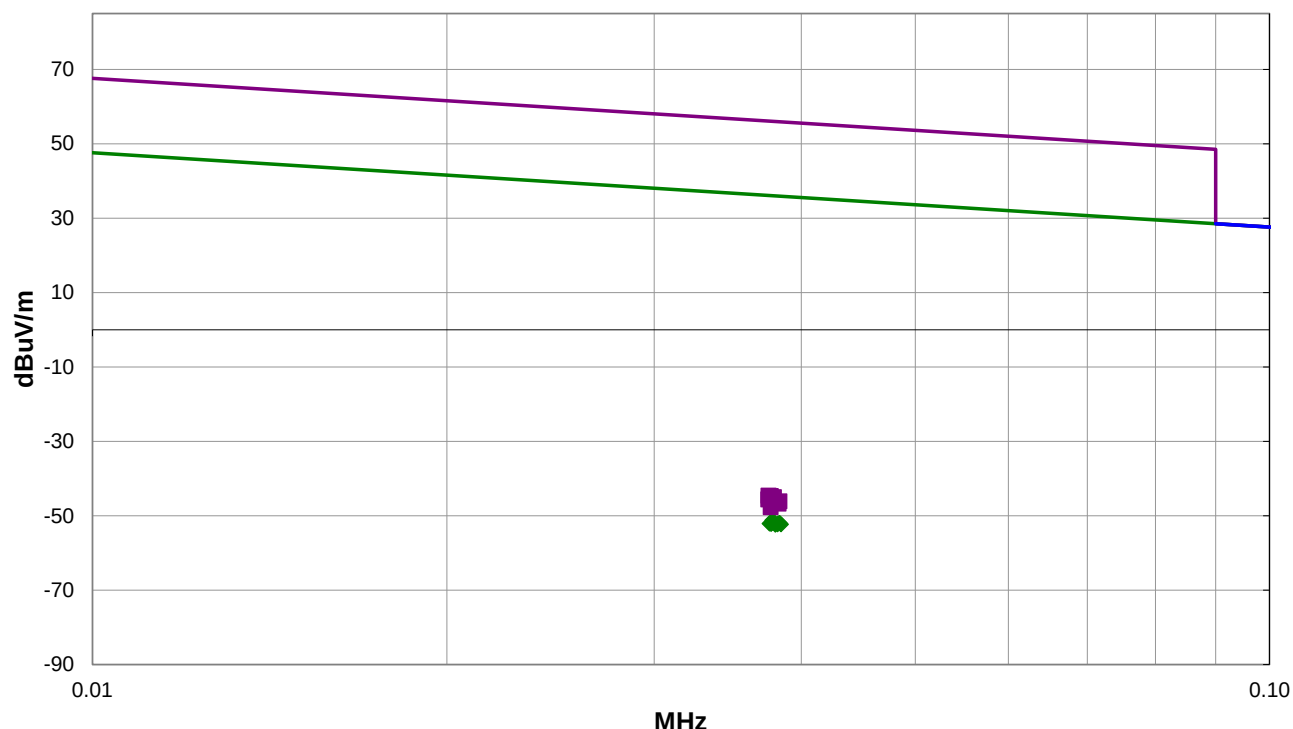
Please reference comments below for EUT orientation

EUT OPERATING MODES

Inductive radio continuous Tx, ASK, 38 kHz

DEVIATIONS FROM TEST STANDARD

None



FIELD STRENGTH OF FUNDAMENTAL

RESULTS - Run #4

Freq (MHz)	Amplitude (dBuV)	Factor (dB/m)	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
0.038	34.5	13.4	1.0	109.0	1.0	0.0	Perp EUT	AV	-99.1	-51.2	36.0	-87.2	EUT Horz
0.038	33.9	13.3	1.0	-5.0	1.0	0.0	Perp EUT	AV	-99.1	-51.9	35.9	-87.8	EUT Vert
0.038	33.8	13.4	1.0	50.0	1.0	0.0	Par EUT	AV	-99.1	-51.9	36.0	-87.9	EUT Vert
0.038	33.8	13.3	1.0	141.0	1.0	0.0	Par EUT	AV	-99.1	-52.0	35.9	-87.9	EUT on Side
0.038	33.5	13.3	1.0	201.0	1.0	0.0	Par GND	AV	-99.1	-52.3	35.9	-88.2	EUT on Side
0.038	33.5	13.3	1.0	210.0	1.0	0.0	Par EUT	AV	-99.1	-52.3	35.9	-88.2	EUT Horz
0.038	33.6	13.4	1.0	333.0	1.0	0.0	Par GND	AV	-99.1	-52.1	36.1	-88.2	EUT Vert
0.038	33.5	13.4	1.0	345.0	1.0	0.0	Par GND	AV	-99.1	-52.2	36.1	-88.3	EUT Horz
0.038	33.4	13.3	1.0	103.0	1.0	0.0	Perp EUT	AV	-99.1	-52.4	36.0	-88.4	EUT on Side
0.038	41.1	13.4	1.0	103.0	1.0	0.0	Perp EUT	PK	-99.1	-44.6	56.1	-100.7	EUT on Side
0.038	41.0	13.4	1.0	109.0	1.0	0.0	Perp EUT	PK	-99.1	-44.7	56.1	-100.8	EUT Horz
0.038	40.8	13.3	1.0	141.0	1.0	0.0	Par EUT	PK	-99.1	-45.0	56.0	-101.0	EUT on Side
0.038	40.2	13.4	1.0	201.0	1.0	0.0	Par GND	PK	-99.1	-45.5	56.0	-101.5	EUT on Side
0.038	40.1	13.4	1.0	345.0	1.0	0.0	Par GND	PK	-99.1	-45.6	56.1	-101.7	EUT Horz
0.038	39.8	13.4	1.0	333.0	1.0	0.0	Par GND	PK	-99.1	-45.9	56.0	-101.9	EUT Vert
0.038	39.7	13.3	1.0	210.0	1.0	0.0	Par EUT	PK	-99.1	-46.1	55.9	-102.0	EUT Horz
0.038	39.1	13.3	1.0	-5.0	1.0	0.0	Perp EUT	PK	-99.1	-46.7	55.9	-102.6	EUT Vert
0.038	38.0	13.4	1.0	50.0	1.0	0.0	Par EUT	PK	-99.1	-47.7	56.1	-103.8	EUT Vert

CONCLUSION

Pass



Tested By

SPURIOUS RADIATED EMISSIONS LESS THAN 30 MHz



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 = RMS 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.

TEST EQUIPMENT

Description	Manufacturer	Model	ID	Last Cal.	Cal. Due
Analyzer - Spectrum Analyzer	Agilent	E4443A	AFB	2020-06-26	2021-06-26
Cable	None	3m Test Distance Cable	EVM	2021-02-16	2022-02-16
Antenna - Loop	EMCO	6502	AOA	2020-07-06	2022-07-06

MEASUREMENT UNCERTAINTY

Description		
Expanded k=2	1.7 dB	-1.7 dB

FREQUENCY RANGE INVESTIGATED

9 kHz TO 30 MHz

POWER INVESTIGATED

Battery

CONFIGURATIONS INVESTIGATED

BIOT0085-4

MODES INVESTIGATED

Inductive radio continuous Tx, ASK, 38 kHz

SPURIOUS RADIATED EMISSIONS LESS THAN 30 MHz

EUT:	Neuro SCS Trial Stimulator	Work Order:	BIOT0085
Serial Number:	91820147	Date:	2021-04-28
Customer:	BIOTRONIK, Inc.	Temperature:	21.7°C
Attendees:	Roy Wang	Relative Humidity:	39%
Customer Project:	None	Bar. Pressure:	1029 mb
Tested By:	Jeff Alcock	Job Site:	EV11
Power:	Battery	Configuration:	BIOT0085-4

TEST SPECIFICATIONS

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

TEST PARAMETERS

Run #:	4	Test Distance (m):	1	Ant. Height(s) (m):	1(m)
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COMMENTS

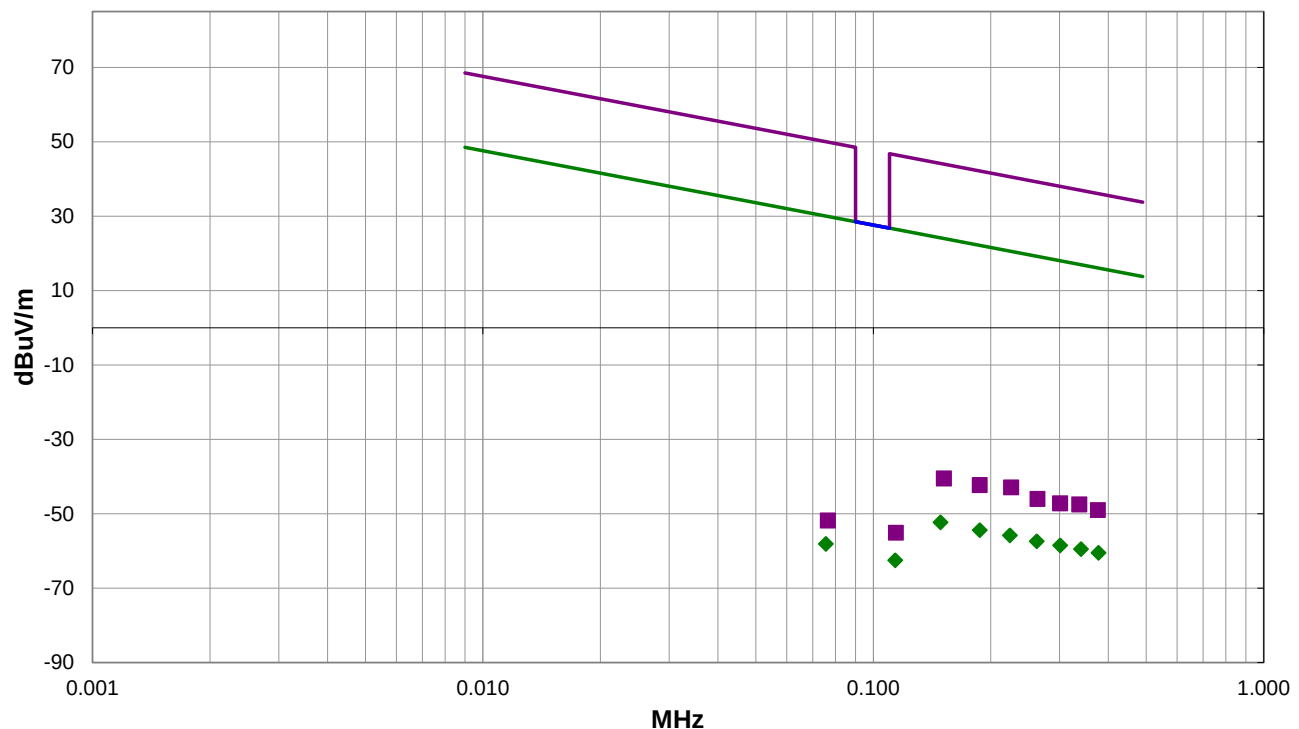
Please reference comments below for EUT orientation

EUT OPERATING MODES

Inductive radio continuous Tx, ASK, 38 kHz

DEVIATIONS FROM TEST STANDARD

None



Run #: 4

■ PK ◆ AV ● QP

SPURIOUS RADIATED EMISSIONS LESS THAN 30 MHz

RESULTS - Run #4

Freq (MHz)	Amplitude (dBuV)	Factor (dB/m)	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
0.224	32.3	11.0	1.0	59.0	1.0	0.0	Perp EUT	AV	-99.1	-55.8	20.6	-76.4	EUT Horz
0.149	35.7	11.1	1.0	133.0	1.0	0.0	Perp EUT	AV	-99.1	-52.3	24.2	-76.5	EUT Horz
0.301	29.6	11.0	1.0	186.0	1.0	0.0	Perp EUT	AV	-99.1	-58.5	18.0	-76.5	EUT Horz
0.340	28.6	11.0	1.0	115.0	1.0	0.0	Perp EUT	AV	-99.1	-59.5	17.0	-76.5	EUT Horz
0.187	33.7	11.0	1.0	103.0	1.0	0.0	Perp EUT	AV	-99.1	-54.4	22.2	-76.6	EUT Horz
0.262	30.8	10.9	1.0	149.0	1.0	0.0	Perp EUT	AV	-99.1	-57.4	19.2	-76.6	EUT Horz
0.377	27.6	11.0	1.0	185.0	1.0	0.0	Perp EUT	AV	-99.1	-60.5	16.1	-76.6	EUT Horz
0.225	45.2	11.0	1.0	59.0	1.0	0.0	Perp EUT	PK	-99.1	-42.9	40.6	-83.5	EUT Horz
0.152	47.5	11.1	1.0	133.0	1.0	0.0	Perp EUT	PK	-99.1	-40.5	44.0	-84.5	EUT Horz
0.187	45.8	11.0	1.0	103.0	1.0	0.0	Perp EUT	PK	-99.1	-42.3	42.2	-84.5	EUT Horz
0.337	40.6	11.0	1.0	115.0	1.0	0.0	Perp EUT	PK	-99.1	-47.5	37.1	-84.6	EUT Horz
0.376	39.1	11.0	1.0	185.0	1.0	0.0	Perp EUT	PK	-99.1	-49.0	36.1	-85.1	EUT Horz
0.263	42.2	10.9	1.0	149.0	1.0	0.0	Perp EUT	PK	-99.1	-46.0	39.2	-85.2	EUT Horz
0.301	40.9	11.0	1.0	186.0	1.0	0.0	Perp EUT	PK	-99.1	-47.2	38.0	-85.2	EUT Horz
0.076	29.3	11.7	1.0	154.0	1.0	0.0	Perp EUT	AV	-99.1	-58.1	30.0	-88.1	EUT Horz
0.114	25.4	11.2	1.0	276.0	1.0	0.0	Perp EUT	AV	-99.1	-62.5	26.5	-89.0	EUT Horz
0.114	32.8	11.2	1.0	276.0	1.0	0.0	Perp EUT	PK	-99.1	-55.1	46.5	-101.6	EUT Horz
0.076	35.6	11.7	1.0	154.0	1.0	0.0	Perp EUT	PK	-99.1	-51.8	49.9	-101.7	EUT Horz

CONCLUSION

Pass



Tested By