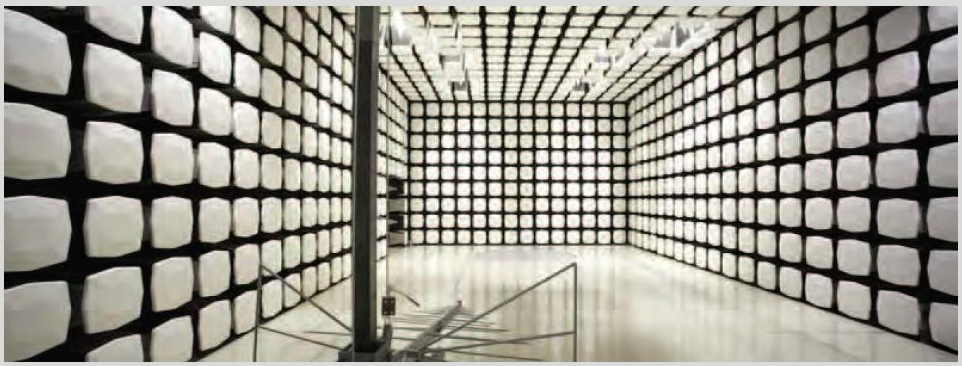
Boston Scientific Corporation

PERCIVA Models D412, D413

LP0002:2018
Inductive

Report # BSTN0901 Rev 01



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CERTIFICATE OF TEST

Last Date of Test: June 11, 2019
Boston Scientific Corporation
PERCIVA Models D412, D413

Radio Equipment Testing

Standards

Specification	Method
LP0002:2018	LP0002:2018

Results

Method Clause	Test Description	Applied	Results	Comments
Appendix I, II.(II)	Powerline Conducted Emissions	No	N/A	Not required for a battery powered EUT.
Appendix I, II.(III, IV)	Field Strength of Fundamental	Yes	Pass	
Appendix I, II.(III, IV)	Spurious Radiated Emissions	Yes	Pass	

Deviations From Test Standards

None

Approved By:

Matt Nuernberg, 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.

REVISION HISTORY

Revision Number	Description	Date (yyyy-mm-dd)	Page Number
01	Added model numbers	2019-08-28	1,2,8

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

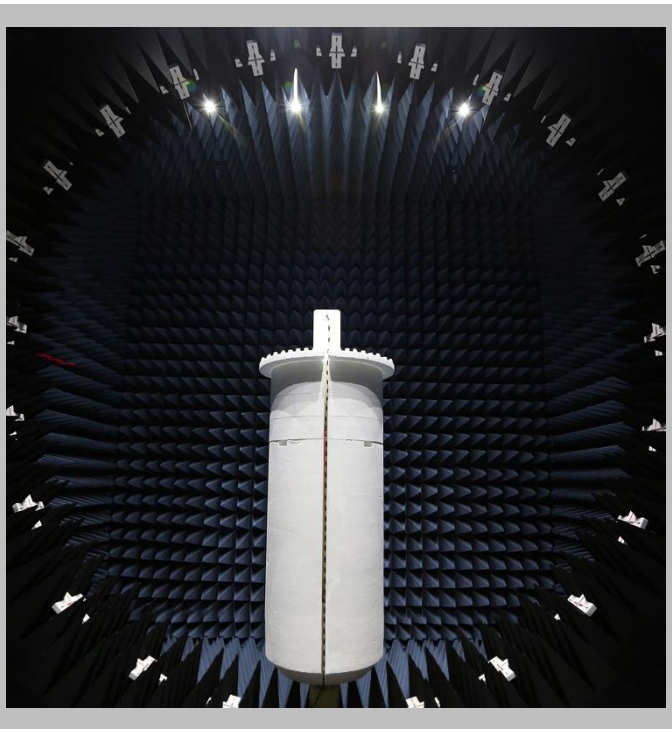
MIC – Recognized by MIC as a CAB for the acceptance of test data.

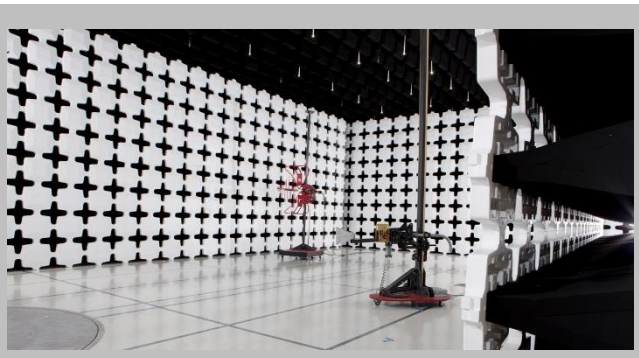
SCOPE

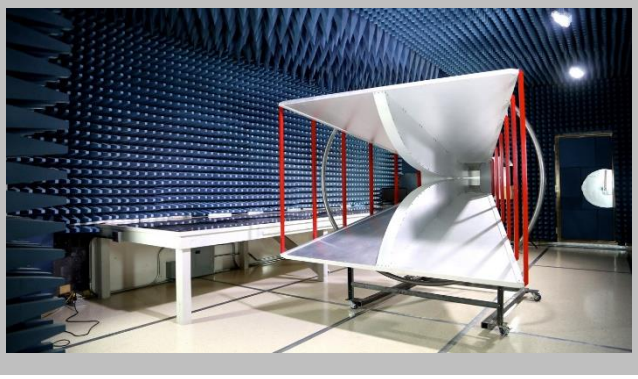
For details on the Scopes of our Accreditations, please visit:
https://www.nwemc.com/emc-testing-accreditations

FACILITIES

California	Minnesota	Oregon	Texas	Washington
Labs OC01-17 41 Tesla Irvine, CA 92618 (949) 861-8918	Labs MN01-10 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







MEASUREMENT UNCERTAINTY

WTD.2016.12.19

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.

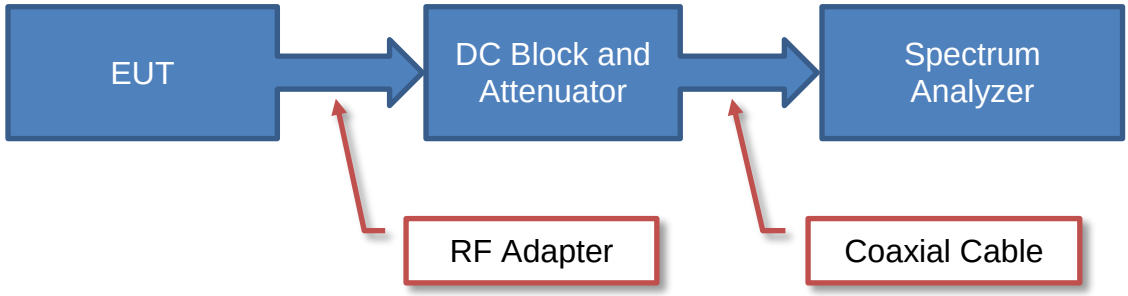
A measurement uncertainty estimation has been performed for each test per our internal quality document WP 342. The estimation is used to compare the measured result with its "true" or theoretically correct value. The expanded measurement uncertainty (K=2) for each test is on each data sheet. Our measurement 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.

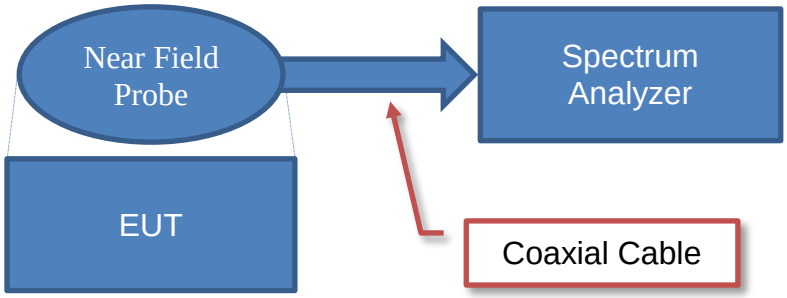
Test	+ MU	- MU
Frequency Accuracy (Hz)	0.0007%	-0.0007%
Amplitude Accuracy (dB)	1.2 dB	-1.2 dB
Conducted Power (dB)	0.3 dB	-0.3 dB
Radiated Power via Substitution (dB)	0.7 dB	-0.7 dB
Temperature (degrees C)	0.7°C	-0.7°C
Humidity (% RH)	2.5% RH	-2.5% RH
Voltage (AC)	1.0%	-1.0%
Voltage (DC)	0.7%	-0.7%
Field Strength (dB)	5.2 dB	-5.2 dB
AC Powerline Conducted Emissions (dB)	2.4 dB	-2.4 dB

Test Setup Block Diagrams

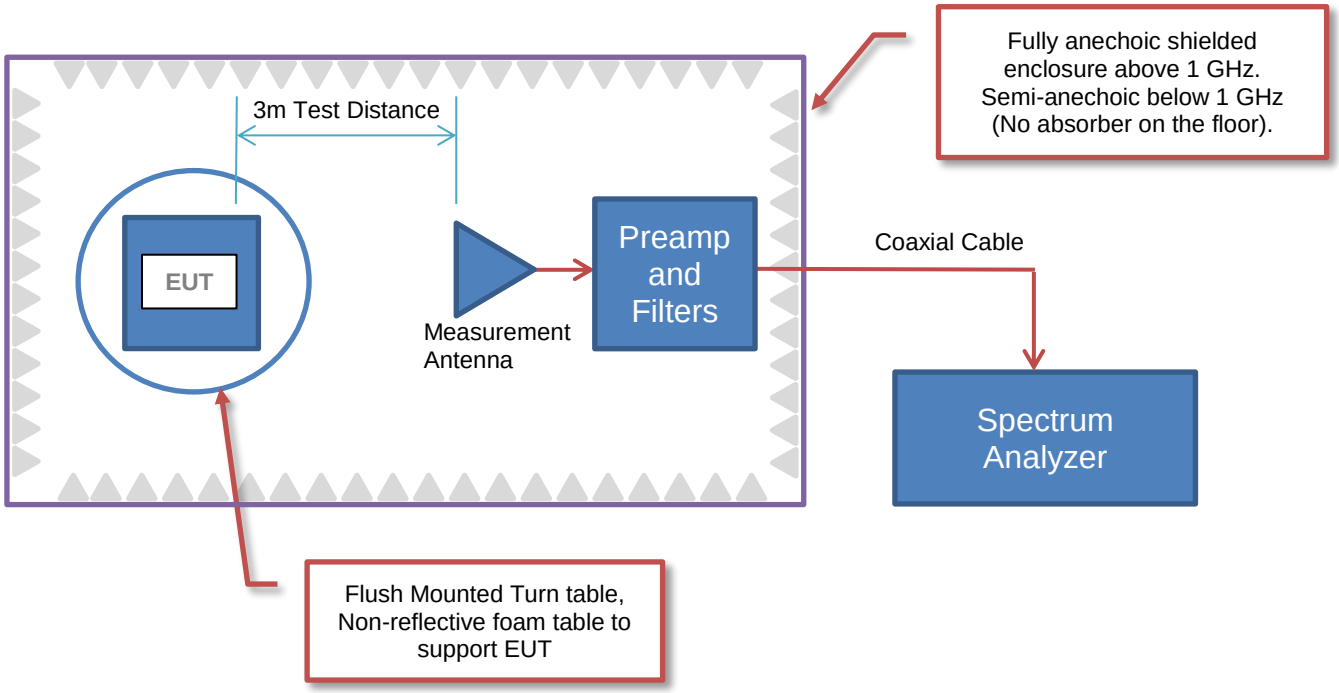
Antenna Port Conducted Measurements



Near Field Test Fixture Measurements



Spurious Radiated Emissions



PRODUCT DESCRIPTION

Client and Equipment Under Test (EUT) Information

Company Name:	Boston Scientific Corporation
Address:	4100 Hamline Ave.
City, State, Zip:	St. Paul, MN 55112
Test Requested By:	James Kippola
Model:	PERCIVA Models D412, D413
First Date of Test:	June 11, 2019
Last Date of Test:	June 11, 2019
Receipt Date of Samples:	June 11, 2019
Equipment Design Stage:	Production
Equipment Condition:	No Damage
Purchase Authorization:	Verified

Information Provided by the Party Requesting the Test

Functional Description of the EUT:

The PERCIVA models are medical devices belonging to the categories of Implantable Cardioverter Defibrillator (ICD) and Cardiac Resynchronization Therapy Defibrillator (CRT-D). They are intended to be used for detecting and treating life-threatening cardiac rhythms. These devices incorporate a radiofrequency (RF) telemetry function, and all models incorporate an electrically identical RF design. A bi-directional RF communication with the implantable device (during implant procedure and patient follow up) is enabled by the model 3120 Zoom Latitude programmer and the model 3140 Zoom Wireless Transmitter (ZWT), which connects to the model 3120 via USB connection. The model 3120 incorporates a near field inductively coupled coil (loop antenna), operating at approximately 57 kHz that is used during the initial interrogation/authentication with the implant. Following authentication the RF link is enabled for longer range communication at up to a 10 foot distance. The RF link operates in the 402-405 MHz band, implements Listen Before Talk (LBT) over ten communication channels, and conforms to the internationally recognized (U.S., Canada, Europe, Australia, Japan, etc.) radiated output power limit of 25 Î¼W. The 402-405 MHz radio uses an integrated antenna with a maximum allowed radiated output power of -16.1 dBm.

Explanation of Model Equivalency:

The PERCIVA device models share an identical electrical and mechanical radiofrequency (RF) design, concerning the inductive (57 kHz) and MICS (402 – 405 MHz) telemetry function.

The model tested (D413) represents RF performance of all models in the PERCIVA family (D413, D412), and accounts for mechanical design differences. While there are no mechanical differences in the RF design between any of the listed models, conservative consideration is given to other mechanical structures (i.e. header and lead connectors) in proximity to the antenna which could minimally impact antenna performance. These variations are fully accounted for in the test sample chosen.

Testing Objective:

To demonstrate compliance of the inductive portion of the device to Taiwan specifications.

EUT Photo

PRODUCT DESCRIPTION

CONFIGURATIONS

Configuration BSTN0901- 1

EUT			
Description	**Manufacturer**	**Model/Part Number**	**Serial Number**
Perciva	Boston Scientific Corporation	D413	119935

Peripherals in test setup boundary			
Description	**Manufacturer**	**Model/Part Number**	**Serial Number**
Lead 1	Boston Scientific Corporation	IS-1	508691
Lead 2	Boston Scientific Corporation	GDT-LLHH	019333

MODIFICATIONS

Equipment Modifications

Item	Date	Test	Modification	Note	Disposition of EUT
1	2019-06-11	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	2019-06-11	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 2019.05.10

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

Tx Inductive 57 kHz

POWER SETTINGS INVESTIGATED

Battery

CONFIGURATIONS INVESTIGATED

BSTN0901 - 1

FREQUENCY RANGE INVESTIGATED

Start Frequency	50 kHz	Stop Frequency	65 kHz

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.	Interval
Antenna - Loop	ETS Lindgren	6502	AOB	21-May-2019	24 mo
Cable	Element	Biconilog Cable	MNX	23-Feb-2019	12 mo
Analyzer - Spectrum Analyzer	Agilent	E4440A	AFG	5-Jul-2018	12 mo

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 5.5.2, 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.

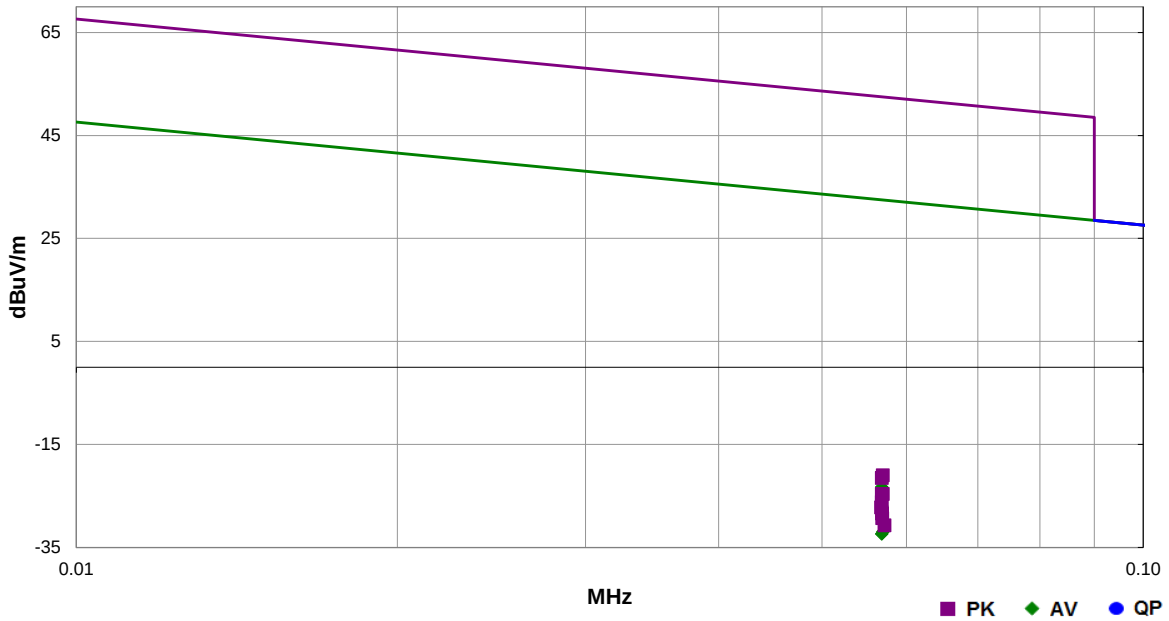
FIELD STRENGTH OF FUNDAMENTAL

EmiR5 2019.05.20 PSA-ESCI 2019.05.10

Work Order:	BSTN0901	**Date:**	11-Jun-2019		
Project:	None	**Temperature:**	21.6 °C		
Job Site:	MN09	**Humidity:**	49.7% RH		
Serial Number:	119935	**Barometric Pres.:**	1023 mbar	**Tested by:**	Kyle McMullan
EUT:	PERCIVA				
Configuration:	1				
Customer:	Boston Scientific Corporation				
Attendees:	James Kippola				
EUT Power:	Battery				
Operating Mode:	Tx Inductive 57 kHz				
Deviations:	None				
Comments:	None				

Test Specifications	**Test Method**
LP0002:2018	LP0002:2018

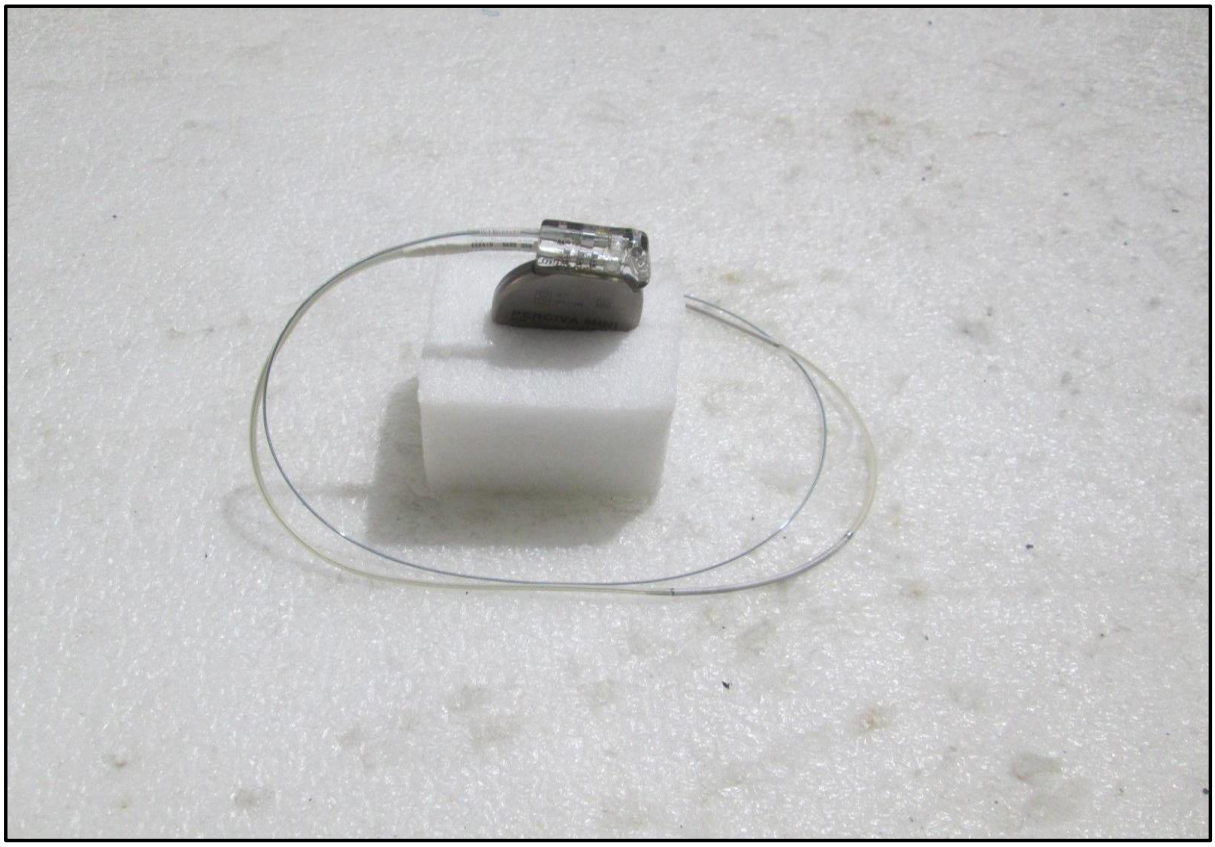
Run #	14	**Test Distance (m)**	3	**Antenna Height(s)**	1(m)	**Results**	Pass



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
0.057	44.3	12.4	1.0	360.0	3.0	0.0	Par to EUT	AV	-80.0	-23.3	32.5	-55.8	EUT On Side
0.057	44.0	12.4	1.0	13.0	3.0	0.0	Par to EUT	AV	-80.0	-23.6	32.5	-56.1	EUT Vert
0.057	40.6	12.4	1.0	89.0	3.0	0.0	Perp to EUT	AV	-80.0	-27.0	32.5	-59.5	EUT Vert
0.057	40.1	12.4	1.0	117.0	3.0	0.0	Perp to EUT	AV	-80.0	-27.5	32.5	-60.0	EUT On Side
0.057	38.6	12.4	1.0	5.0	3.0	0.0	Par to GND	AV	-80.0	-29.0	32.5	-61.5	EUT On Side
0.057	35.6	12.4	1.0	162.0	3.0	0.0	Par to GND	AV	-80.0	-32.0	32.5	-64.5	EUT Vert
0.057	35.2	12.4	1.0	205.0	3.0	0.0	Par to GND	AV	-80.0	-32.4	32.5	-64.9	EUT Horz
0.057	32.5	12.4	1.0	60.0	3.0	0.0	Par to EUT	AV	-80.0	-35.1	32.5	-67.6	EUT Horz
0.057	30.9	12.4	1.0	137.0	3.0	0.0	Perp to EUT	AV	-80.0	-36.7	32.5	-69.2	EUT Horz
0.057	46.6	12.4	1.0	13.0	3.0	0.0	Par to EUT	PK	-80.0	-21.0	52.5	-73.5	EUT Vert
0.057	46.1	12.4	1.0	360.0	3.0	0.0	Par to EUT	PK	-80.0	-21.5	52.5	-74.0	EUT On Side
0.057	43.0	12.4	1.0	89.0	3.0	0.0	Perp to EUT	PK	-80.0	-24.6	52.5	-77.1	EUT Vert
0.057	43.0	12.4	1.0	117.0	3.0	0.0	Perp to EUT	PK	-80.0	-24.6	52.5	-77.1	EUT On Side
0.057	41.4	12.4	1.0	5.0	3.0	0.0	Par to GND	PK	-80.0	-26.2	52.5	-78.7	EUT On Side
0.057	40.4	12.4	1.0	162.0	3.0	0.0	Par to GND	PK	-80.0	-27.2	52.5	-79.7	EUT Vert
0.057	39.2	12.4	1.0	205.0	3.0	0.0	Par to GND	PK	-80.0	-28.4	52.5	-80.9	EUT Horz
0.057	38.3	12.4	1.0	60.0	3.0	0.0	Par to EUT	PK	-80.0	-29.3	52.5	-81.8	EUT Horz
0.057	36.9	12.4	1.0	137.0	3.0	0.0	Perp to EUT	PK	-80.0	-30.7	52.4	-83.1	EUT Horz

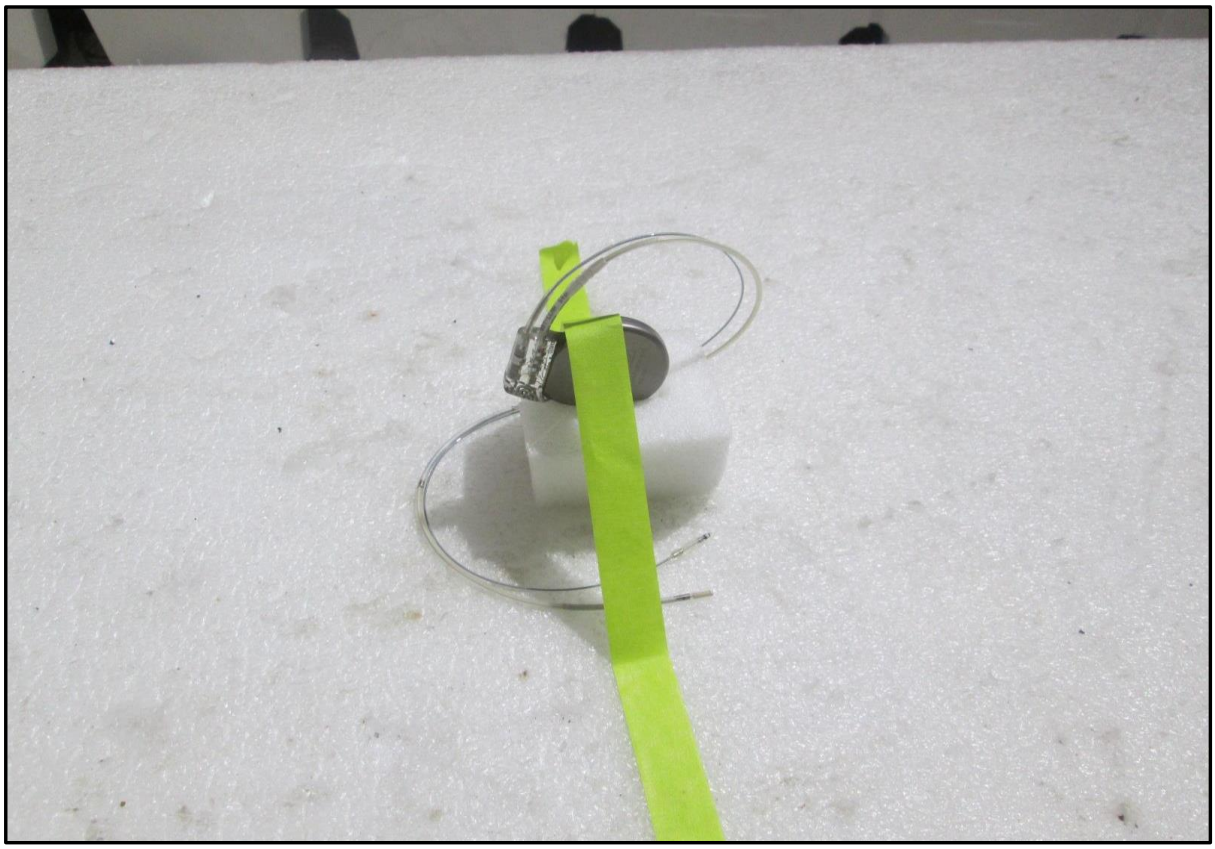
FIELD STRENGTH OF FUNDAMENTAL

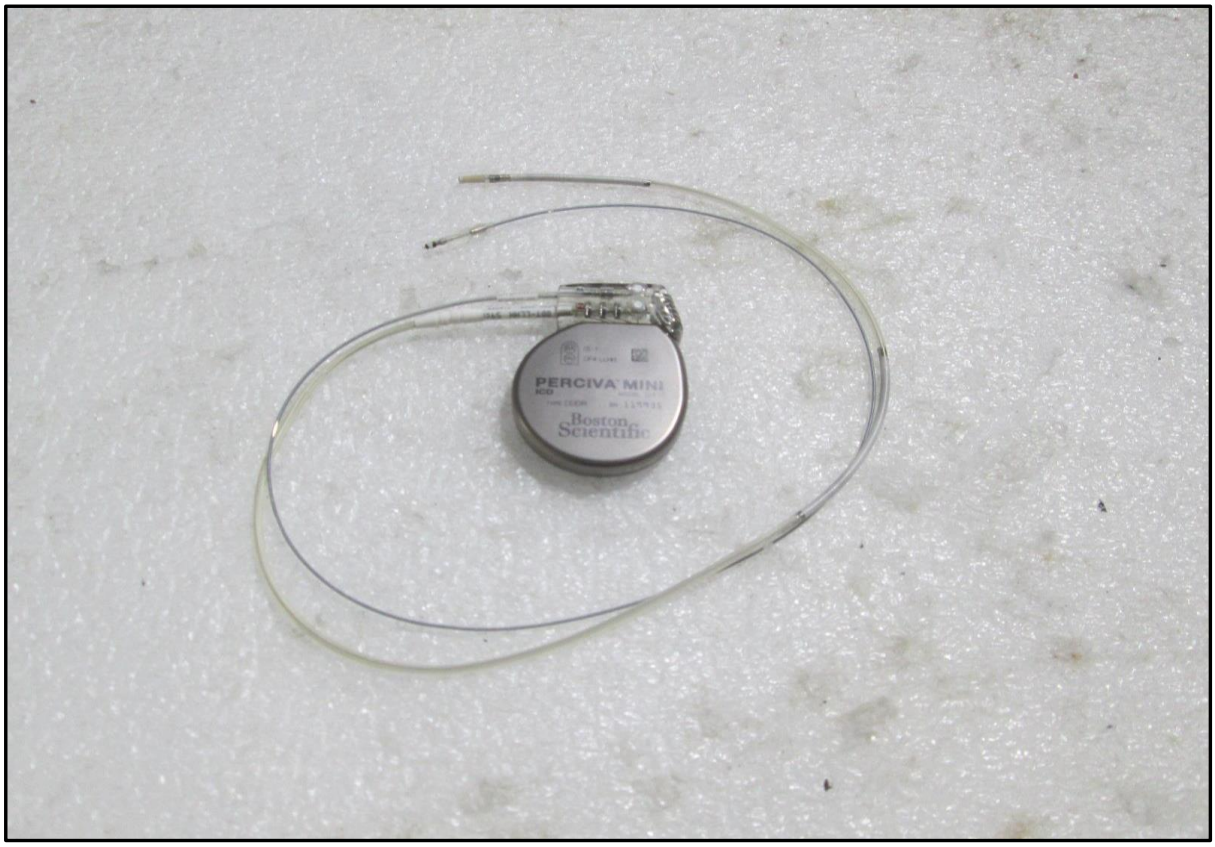
PSA-ESCI 2019.05.10



FIELD STRENGTH OF FUNDAMENTAL

PSA-ESCI 2019.05.10





SPURIOUS RADIATED EMISSIONS

PSA-ESCI 2019.05.10

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

Tx Inductive 57 kHz

POWER SETTINGS INVESTIGATED

Battery

CONFIGURATIONS INVESTIGATED

BSTN0901 - 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.	Interval
Analyzer - Spectrum Analyzer	Agilent	E4440A	AFG	5-Jul-2018	12 mo
Cable	Element	Biconilog Cable	MNX	23-Feb-2019	12 mo
Antenna - Loop	ETS Lindgren	6502	AOB	21-May-2019	24 mo

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 5.5.2, 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.

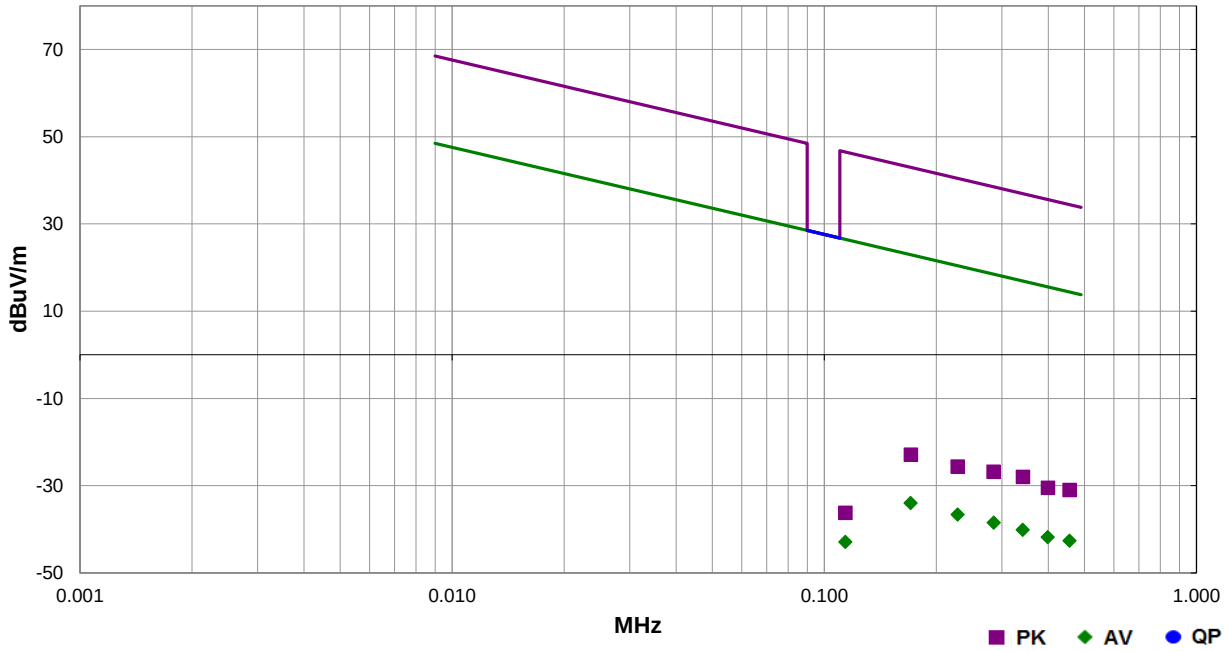
SPURIOUS RADIATED EMISSIONS

EmiR5 2019.05.20 PSA-ESCI 2019.05.10

Work Order:	BSTN0901	**Date:**	11-Jun-2019		
Project:	None	**Temperature:**	21.6 °C		
Job Site:	MN09	**Humidity:**	49.7% RH		
Serial Number:	119935	**Barometric Pres.:**	1023 mbar	**Tested by:**	Kyle McMullan
EUT:	PERCIVA				
Configuration:	1				
Customer:	Boston Scientific Corporation				
Attendees:	James Kippola				
EUT Power:	Battery				
Operating Mode:	Tx Inductive 57 kHz				
Deviations:	None				
Comments:	None				

Test Specifications	**Test Method**
LP0002:2018	LP0002:2018

Run #	15	**Test Distance (m)**	3	**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
0.171	34.4	11.6	1.0	349.0	3.0	0.0	Par to EUT	AV	-80.0	-34.0	23.0	-57.0	EUT On Side
0.228	31.8	11.6	1.0	184.0	3.0	0.0	Par to EUT	AV	-80.0	-36.6	20.4	-57.0	EUT On Side
0.285	29.9	11.6	1.0	173.0	3.0	0.0	Par to EUT	AV	-80.0	-38.5	18.5	-57.0	EUT On Side
0.342	28.3	11.6	1.0	228.0	3.0	0.0	Par to EUT	AV	-80.0	-40.1	16.9	-57.0	EUT On Side
0.456	25.7	11.7	1.0	271.0	3.0	0.0	Par to EUT	AV	-80.0	-42.6	14.4	-57.0	EUT On Side
0.399	26.7	11.5	1.0	39.0	3.0	0.0	Par to EUT	AV	-80.0	-41.8	15.6	-57.4	EUT On Side
0.342	40.4	11.6	1.0	228.0	3.0	0.0	Par to EUT	PK	-80.0	-28.0	36.9	-64.9	EUT On Side
0.285	41.6	11.6	1.0	173.0	3.0	0.0	Par to EUT	PK	-80.0	-26.8	38.5	-65.3	EUT On Side
0.456	37.3	11.7	1.0	271.0	3.0	0.0	Par to EUT	PK	-80.0	-31.0	34.4	-65.4	EUT On Side
0.171	45.5	11.6	1.0	349.0	3.0	0.0	Par to EUT	PK	-80.0	-22.9	43.0	-65.9	EUT On Side
0.228	42.8	11.6	1.0	184.0	3.0	0.0	Par to EUT	PK	-80.0	-25.6	40.5	-66.1	EUT On Side
0.399	38.0	11.5	1.0	39.0	3.0	0.0	Par to EUT	PK	-80.0	-30.5	35.6	-66.1	EUT On Side
0.114	25.4	11.7	1.0	153.0	3.0	0.0	Par to EUT	AV	-80.0	-42.9	26.5	-69.4	EUT On Side
0.114	32.1	11.7	1.0	153.0	3.0	0.0	Par to EUT	PK	-80.0	-36.2	46.5	-82.7	EUT On Side

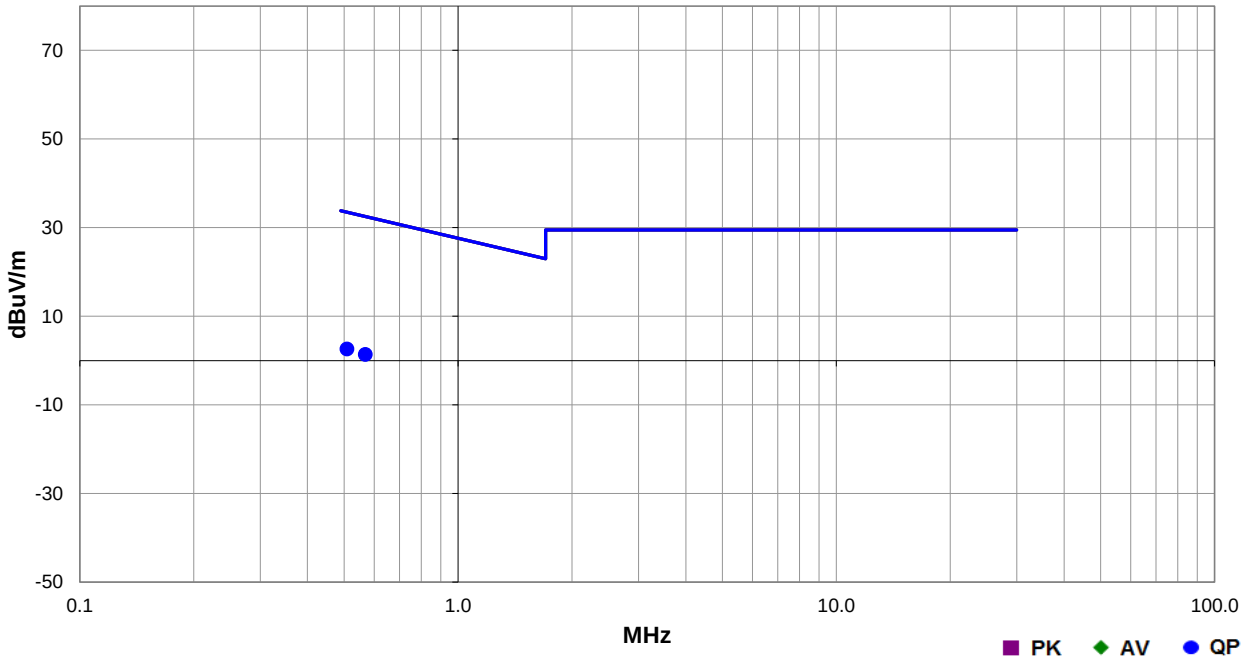
SPURIOUS RADIATED EMISSIONS

EmiR5 2019.05.20 PSA-ESCI 2019.05.10

Work Order:	BSTN0901	**Date:**	11-Jun-2019		
Project:	None	**Temperature:**	21.6 °C		
Job Site:	MN09	**Humidity:**	49.7% RH		
Serial Number:	119935	**Barometric Pres.:**	1023 mbar	**Tested by:**	Andrew Rogstad
EUT:	PERCIVA				
Configuration:	1				
Customer:	Boston Scientific Corporation				
Attendees:	James Kippola				
EUT Power:	Battery				
Operating Mode:	Tx Inductive 57 kHz				
Deviations:	None				
Comments:	None				

Test Specifications	**Test Method**
LP0002:2018	LP0002:2018

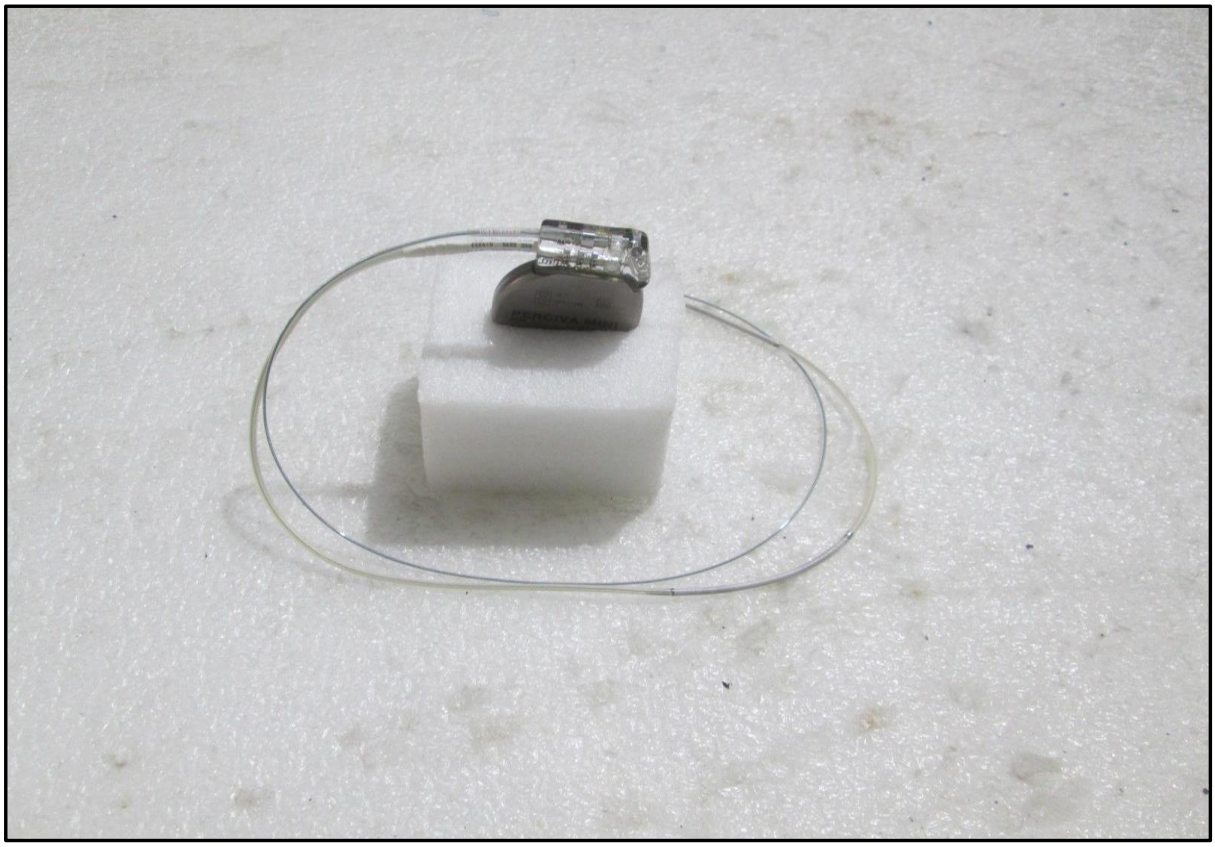
Run #	17	**Test Distance (m)**	3	**Antenna Height(s)**	1(m)	**Results**	Pass

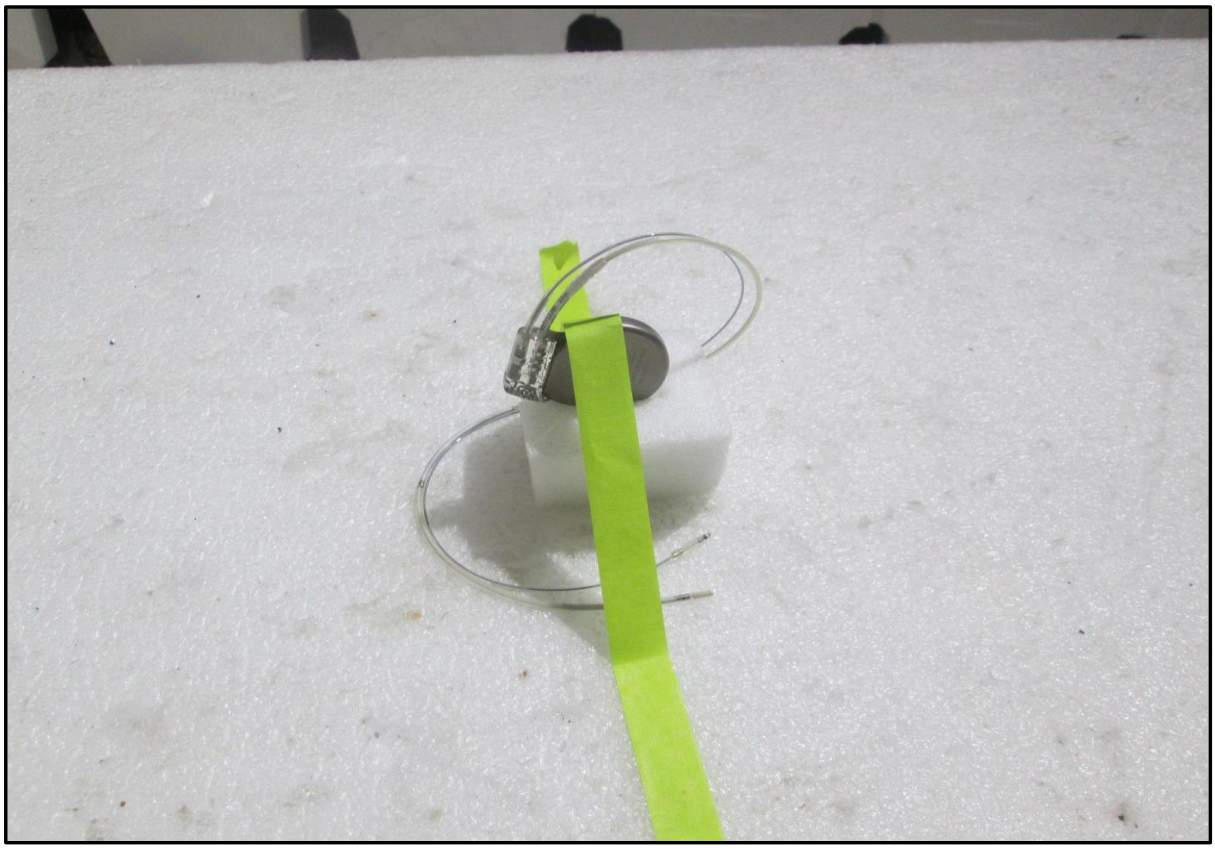
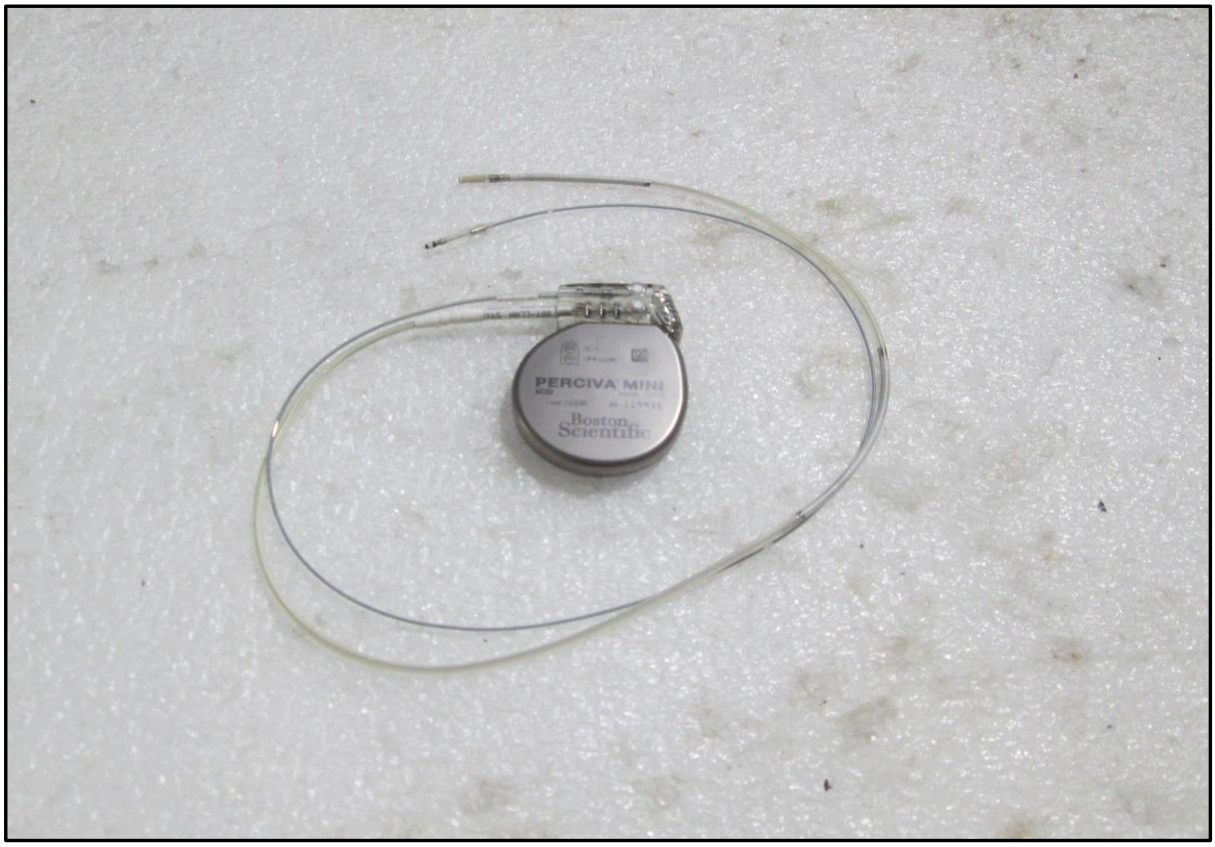


Freq (MHz)	Amplitude (dBuV)	Factor (dB)	Antenna Height (meters)	Azimuth (degrees)	Test Distance (meters)	External Attenuation (dB)	Polarity/ Transducer Type	Detector	Distance Adjustment (dB)	Adjusted (dBuV/m)	Spec. Limit (dBuV/m)	Compared to Spec. (dB)	Comments
0.508	30.8	11.8	1.0	64.0	3.0	0.0	Par to EUT	QP	-40.0	2.6	33.5	-30.9	EUT on side
0.569	29.6	11.8	1.0	176.0	3.0	0.0	Par to EUT	QP	-40.0	1.4	32.5	-31.1	EUT on side

SPURIOUS RADIATED EMISSIONS

PSA-ESCI 2019.05.10



SPURIOUS RADIATED EMISSIONS

PSA-ESCI 2019.05.10