Boston Scientific Neuromodulation

External Trial Stimulator Model SC-5132

EMC Test Report

Report No. BOSN0010.5

Report Prepared By

www.nwemc.com
1-888-EMI-CERT

NORTHWEST EMC

22975 NW Evergreen Parkway
Suite 400
Hillsboro, Oregon 97124

Certificate of Test

Last Date of Test: May 24, 2011
Boston Scientific Neuromodulation
Model: SC-5132

Emissions			
Test Description	**Specification**	**Test Method**	**Pass/Fail**
Field Strength of Fundamental	FCC 15.209:2011	ANSI C63.10:2009	**Pass**
Field Strength of Spurious Emissions	FCC 15.209:2011	ANSI C63.10:2009	**Pass**

Modifications made to the product
See the Modifications section of this report

Test Facility

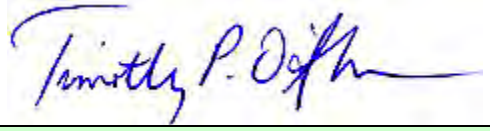
The measurement facility used to collect the data is located at:

Northwest EMC, Inc.
41 Tesla Ave.
Irvine, CA 92618

Phone: (503) 844-4066 Fax: 844-3826

This site has been fully described in a report filed with and accepted by the FCC (Federal Communications Commission) and Industry Canada (Site filing #2834B-1).

Approved By:



Tim O'Shea, Operations Manager

NVLAP Lab Code: 200676-0

This report must not be used to claim product certification, approval, or endorsement by NVLAP, NIST, or any agency of the federal government of the United States of America.

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. This Report may only be duplicated in its entirety. 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.

Revision Number	Description	Date	Page Number
00	None		

Barometric Pressure

The recorded barometric pressure has been normalized to sea level.

Accreditations and Authorizations

FCC

Accredited by NVLAP for performance of FCC radio, digital, and ISM device testing. Our Open Area Test Sites, certification chambers, and conducted measurement facilities have been fully described in reports filed with the FCC and accepted by the FCC in letters maintained in our files. Northwest EMC has been accredited by ANSI to ISO / IEC Guide 65 as a product certifier. We have been designated by the FCC as a Telecommunications Certification Body (TCB). This allows Northwest EMC to certify transmitters to FCC specifications in accordance with 47 CFR 2.960 and 2.962.

NVLAP

Northwest EMC, Inc. is accredited under the National Voluntary Laboratory Accreditation Program (NVLAP) for satisfactory compliance with the requirements of ISO/IEC 17025 for Testing Laboratories. NVLAP is administered by the National Institute of Standards and Technology (NIST), an agency of the U.S. Commerce Department. The NVLAP accreditation encompasses Electromagnetic Compatibility Testing in accordance with the European Union EMC Directive 2004/108/EC, and ANSI C63.4. Additionally, Northwest EMC is accredited by NVLAP to perform radio testing in accordance with the European Union R&TTE Directive 1999/5/EEC, the requirements of FCC, and the RSS radio standards for Industry Canada.

Industry Canada

Accredited by NVLAP for performance of Industry Canada RSS and ICES testing. Our Open Area Test Sites and certification chambers comply with RSS-Gen, Issue 2 and have been filed with Industry Canada and accepted. Northwest EMC has been accredited by ANSI to ISO / IEC Guide 65 as a product certifier. We have been designated by NIST and recognized by Industry Canada as a Certification Body (CB) per the APEC Mutual Recognition Arrangement (MRA). This allows Northwest EMC to certify transmitters to Industry Canada technical requirements. (*Site Filing Numbers - Hillsboro: 2834D-1, 2834D-2, Sultan: 2834C-1, Irvine: 2834B-1, 2834B-2, Brooklyn Park: 2834E-1)*

CAB

Designated by NIST and validated by the European Commission as a Conformity Assessment Body (CAB) to conduct tests and approve products to the EMC directive and transmitters to the R&TTE directive, as described in the U.S. - EU Mutual Recognition Agreement.

Australia/New Zealand

The National Association of Testing Authorities (NATA), Australia has been appointed by the ACA as an accreditation body to accredit test laboratories and competent bodies for EMC standards. Accredited test reports or assessments by competent bodies must carry the NATA logo. Test reports made by an overseas laboratory that has been accredited for the relevant standards by an overseas accreditation body that has a Mutual Recognition Agreement (MRA) with NATA are also accepted as technical grounds for product conformity. The report should be endorsed with the respective logo of the accreditation body (NVLAP).

Accreditations and Authorizations

VCCI

Accepted as an Associate Member to the VCCI, Acceptance No. 564. Conducted and radiated measurement facilities have been registered in accordance with Regulations for Voluntary Control Measures, Article 8. *(Registration Numbers. - Hillsboro: C-1071, R-1025, G-84, C-2687, T-1658, and R-2318, Irvine: R-1943, G-85, C-2766, and T-1659, Sultan: R-871, G-83, C-1784, and T-1511, Brooklyn Park: R-3125, G-86, G-141, C-3464, and T-1634).*

BSMI

Northwest EMC has been designated by NIST and validated by C-Taipei (BSMI) as a CAB to conduct tests as described in the APEC Mutual Recognition Agreement (US0017).

GOST

Northwest EMC, Inc. has been assessed and accredited by the Russian Certification bodies Certinform VNIINMASH, CERTINFO, SAMTES, and Federal CHEC, to perform EMC and Hygienic testing for Information Technology Products. As a result of their laboratory assessment, they will accept test results from Northwest EMC, Inc. for product certification

KCC

Northwest EMC, Inc is a CAB designated by MRA partners and recognized by Korea. (*Assigned Lab Numbers: Hillsboro: US0017, Irvine: US0158, Sultan: US0157, Brooklyn Park: US0175)*

VIETNAM

Vietnam MIC has approved Northwest EMC as an accredited test lab. Per Decision No. 194/QD-QLCL (dated December 15, 2009), Northwest EMC test reports can be used for Vietnam approval submissions.

SCOPE

For details on the Scopes of our Accreditations, please visit:
http://www.nwemc.com/accreditations/

Northwest EMC Locations

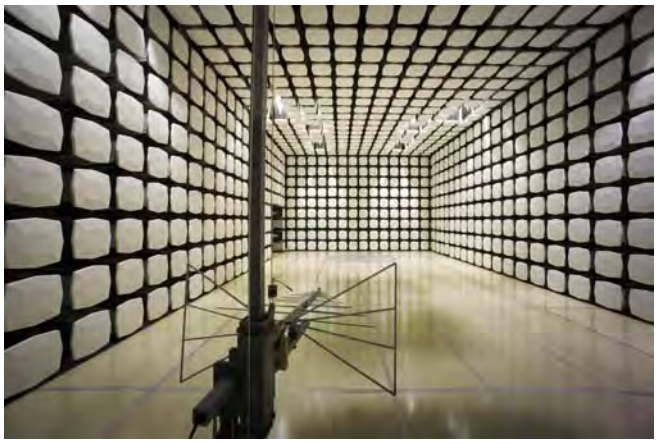
Oregon
Labs EV01-EV12
22975 NW Evergreen Pkwy
Suite 400
Hillsboro, OR 97124
(503) 844-4066

California
Labs OC01-OC13
41 Tesla
Irvine, CA 92618
(949) 861-8918

Minnesota
Labs MN01-MN08
9349 W Broadway Ave.
Brooklyn Park,
MN 55445
(763) 425-2281

Washington
Labs SU01-SU07
14128 339th Ave. SE
Sultan, WA 98294
(360) 793-8675

New York
Labs WA01-WA04
4939 Jordan Rd.
Elbridge, NY 13060
(315) 685-0796



Party Requesting the Test

Company Name:	Boston Scientific Neuromodulation
Address:	25155 Rye Canyon Loop
City, State, Zip:	Santa Clarita, CA 91355
Test Requested By:	Mizan Rahman
Model:	External Trial Stimulator, Model SC-5132
First Date of Test:	5/23/2011
Last Date of Test:	5/24/2011
Receipt Date of Samples:	5/23/2011
Equipment Design Stage:	Production
Equipment Condition:	No Damage

Information Provided by the Party Requesting the Test

Functional Description of the EUT (Equipment Under Test):
Used by the patient for trial on a temporary basis before receiving the permanent implant or IPG

Testing Objective:
To demonstrate compliance to FCC requirements.

CONFIGURATION 2 BOSN0010

EUT			
Description	**Manufacturer**	**Model/Part Number**	**Serial Number**
ETS	Boston Scientific	SC-5132/ M365SC51320/ 7096011-001	100068
Wand	Boston Scientific	NM-7190/ M365NM71900A/ 7095858-002	100233

Peripherals in test setup boundary			
Description	**Manufacturer**	**Model/Part Number**	**Serial Number**
Laptop	Toshiba	Protege	BA152613
AC/DC Power Supply	Toshiba	PA3182U-1ACA	G71C0002SB101

Cables					
Cable Type	**Shield**	**Length (m)**	**Ferrite**	**Connection 1**	**Connection 2**
OR Cable	No	1m	No	ETS	Leads
Leads (1)	No	.5m	No	OR Cable	8x365 Ohm
Leads (2)	No	.5m	No	OR Cable	8x365 Ohm
Wand Cable	Yes	1.6m	No	Laptop	Wand
DC Cable	Yes	1.2m	No	Laptop	AC/DC Power Supply
AC Cable	No	1.8m	No	AC/DC Power Supply	AC Mains
PA = Cable is permanently attached to the device. Shielding and/or presence of ferrite may be unknown.					

Equipment modifications					
Item	Date	Test	Modification	Note	Disposition of EUT
1	5/23/2011	Field Strength of Spurious Emissions	Tested as delivered to Test Station.	No EMI suppression devices were added or modified during this test.	EUT remained at Northwest EMC following the test.
2	5/24/2011	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.

FIELD STRENGTH OF FUNDAMENTAL

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.

MODES OF OPERATION

Transmitting at 125 kHz

POWER SETTINGS INVESTIGATED

120VAC/60Hz

AXIS INVESTIGATED

X-Axis
Y-Axis
Z-Axis

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
Antenna, Loop	EMCO	6502	AZB	12/6/2010	24
OC10 Cables	N/A	10kHz-1GHz RE Cables	OCH	4/1/2010	15
Spectrum Analyzer	Agilent	E4446A	AAY	1/11/2011	12

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

Measurements were made using the bandwidths and detectors specified. No video filter was used.

MEASUREMENT UNCERTAINTY

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. Our measurement data meets or exceeds the measurement uncertainty requirements of CISPR 16-4. The measurement uncertainty estimation is available upon request.

TEST DESCRIPTION

The antennas to be used with the EUT were tested. The EUT was transmitting and receiving while set at the transmitting channel available. While scanning, emissions from the EUT were maximized by rotating the EUT, adjusting the measurement antenna height and polarization, and manipulating the EUT antenna in 3 orthogonal planes (per ANSI C63.10:2009).

NORTHWEST
EMC

FIELD STRENGTH OF FUNDAMENTAL

PSA 2011.05.11
EMI 2010.9.21

EUT:	External Trial Stimulator, Model SC-5132	**Work Order:**	BOSN0010
Serial Number:	100068	**Date:**	05/24/11
Customer:	Boston Scientific Neuromodulation	**Temperature:**	20.3
Attendees:	Mizan Rahman	**Humidity:**	52%
Project:	None	**Barometric Pres.:**	1014.4
Tested by:	Jaemi Suh	**Power:** 120VAC/60Hz	**Job Site:** OC10

TEST SPECIFICATIONS	TEST METHOD
FCC 15.209:2011	ANSI C63.10:2009

TEST PARAMETERS			
Antenna Height(s) (m)	1 - 2.75	Test Distance (m)	3

COMMENTS

ETS and Wand

EUT OPERATING MODES

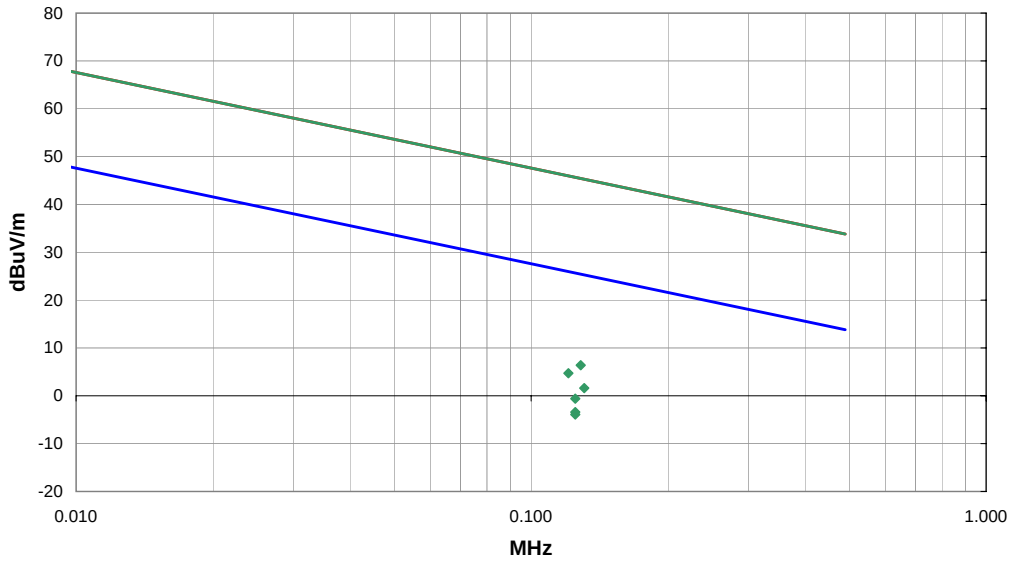
Transmitting at 125 kHz

DEVIATIONS FROM TEST STANDARD

No deviations.

Run #	4
Configuration #	2
Results	Pass

Signature



Freq (MHz)	Amplitude (dBuV)	Factor (dB)	Azimuth (degrees)	Height (meters)	Distance (meters)	External Attenuation (dB)	Polarity	Detector	Distance Adjustment (dB)	Adjusted dBuV/m	Spec. Limit dBuV/m	Compared to Spec. (dB)	Comments
0.125	68.9	10.5	296.0	1.0	3.0	0.0	Loop	AV	-80.0	-0.6	25.7	-26.3	Antenna parallel to grnd, parallel to eut.
0.125	66.1	10.5	283.0	1.0	3.0	0.0	Loop	AV	-80.0	-3.4	25.7	-29.1	Antenna parallel to grnd, perp to eut.
0.125	65.6	10.5	292.0	1.0	3.0	0.0	Loop	AV	-80.0	-3.9	25.7	-29.6	Antenna perp to ground, perp to eut
0.129	73.9	10.5	296.0	1.0	3.0	0.0	Loop	PK	-80.0	6.4	45.4	-39.0	Antenna parallel to grnd, parallel to eut.
0.121	74.2	10.5	283.0	1.0	3.0	0.0	Loop	PK	-80.0	4.7	46.0	-41.3	Antenna parallel to grnd, perp to eut.
0.131	71.1	10.5	291.0	1.0	3.0	0.0	Loop	PK	-80.0	1.6	45.3	-43.7	Antenna perp to ground, perp to eut

FIELD STRENGTH OF SPURIOUS EMISSIONS

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.

MODES OF OPERATION

Transmitting at 125 kHz

POWER SETTINGS INVESTIGATED

120VAC/60Hz

AXIS INVESTIGATED

X-Axis
Y-Axis
Z-Axis

FREQUENCY RANGE INVESTIGATED

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	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

Measurements were made using the bandwidths and detectors specified. No video filter was used.

MEASUREMENT UNCERTAINTY

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. Our measurement data meets or exceeds the measurement uncertainty requirements of CISPR 16-4. The measurement uncertainty estimation is available upon request.

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NORTHWEST EMC

FIELD STRENGTH OF SPURIOUS EMISSIONS

PSA 2011.05.11
EMI 2010.9.21

EUT:	External Trial Stimulator, Model SC-5132	Work Order:	BOSN0010
Serial Number:	100068	Date:	05/23/11
Customer:	Boston Scientific Neuromodulation	Temperature:	20.3
Attendees:	Mizan Rahman	Humidity:	52%
Project:	None	Barometric Pres.:	1014.4
Tested by:	Jaemi Suh	Power: 120VAC/60Hz	Job Site: OC10

TEST SPECIFICATIONS	TEST METHOD
FCC 15.209:2011	ANSI C63.10:2009

TEST PARAMETERS			
Antenna Height(s) (m)	1 - 2.75	Test Distance (m)	3

COMMENTS

ETS and Wand. X-Axis

EUT OPERATING MODES

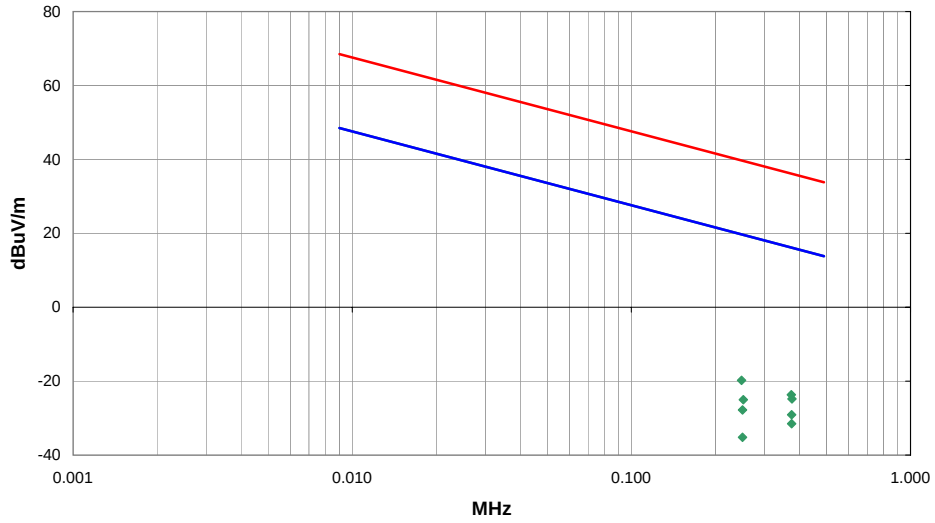
Transmitting at 125 kHz

DEVIATIONS FROM TEST STANDARD

No deviations.

Run #	3
Configuration #	2
Results	Pass

Signature



Freq (MHz)	Amplitude (dBuV)	Factor (dB)	Azimuth (degrees)	Height (meters)	Distance (meters)	External Attenuation (dB)	Polarity	Detector	Distance Adjustment (dB)	Adjusted dBuV/m	Spec. Limit dBuV/m	Compared to Spec. (dB)	Comments
0.375	40.6	10.3	358.0	1.0	3.0	0.0	Loop	AV	-80.0	-29.1	16.1	-45.2	Antenna perp to grnd, EUT parallel to grnd
0.250	41.8	10.4	339.0	1.0	3.0	0.0	Loop	AV	-80.0	-27.8	19.6	-47.4	Antenna parallel to grnd, EUT parallel to grnd
0.375	38.2	10.3	322.0	1.0	3.0	0.0	Loop	AV	-80.0	-31.5	16.1	-47.6	Antenna parallel to grnd, EUT parallel to grnd
0.250	34.4	10.4	357.0	1.0	3.0	0.0	Loop	AV	-80.0	-35.2	19.6	-54.8	Antenna perp to grnd, EUT parallel to grnd

NORTHWEST EMC

FIELD STRENGTH OF SPURIOUS EMISSIONS

PSA 2011.05.11
EMI 2010.9.21

EUT:	External Trial Stimulator, Model SC-5132	Work Order:	BOSN0010
Serial Number:	100068	Date:	05/23/11
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TEST PARAMETERS			
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COMMENTS

ETS and Wand. X-Axis

EUT OPERATING MODES

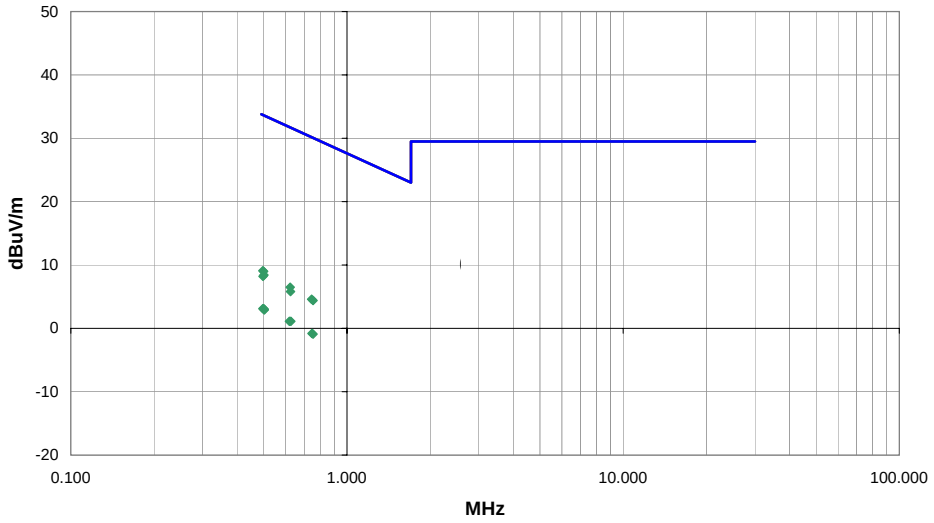
Transmitting at 125 kHz

DEVIATIONS FROM TEST STANDARD

No deviations.

Run #	3
Configuration #	2
Results	Pass

Signature



Freq (MHz)	Amplitude (dBuV)	Factor (dB)	Azimuth (degrees)	Height (meters)	Distance (meters)	External Attenuation (dB)	Polarity	Detector	Distance Adjustment (dB)	Adjusted dBuV/m	Spec. Limit dBuV/m	Compared to Spec. (dB)	Comments
0.496	38.8	10.3	194.0	1.0	3.0	0.0	Loop	PK	-40.0	9.1	33.7	-24.6	Antenna parallel to grnd, EUT parallel to grnd
0.499	38.7	10.3	359.0	2.1	3.0	0.0	Loop	PK	-40.0	9.0	33.6	-24.6	Antenna perp to grnd, EUT parallel to grnd
0.501	38.1	10.3	25.0	2.1	3.0	0.0	Loop	PK	-40.0	8.4	33.6	-25.2	Antenna parallel to grnd, EUT parallel to grnd
0.623	36.2	10.3	154.0	1.0	3.0	0.0	Loop	PK	-40.0	6.5	31.7	-25.2	Antenna parallel to grnd, EUT parallel to grnd
0.496	37.9	10.3	357.0	1.0	3.0	0.0	Loop	PK	-40.0	8.2	33.7	-25.5	Antenna perp to grnd, EUT perp to grnd
0.745	34.3	10.3	329.0	1.0	3.0	0.0	Loop	PK	-40.0	4.6	30.2	-25.6	Antenna parallel to grnd, EUT parallel to grnd
0.754	34.1	10.3	356.0	3.6	3.0	0.0	Loop	PK	-40.0	4.4	30.1	-25.7	Antenna perp to grnd, EUT parallel to grnd
0.624	35.5	10.3	356.0	1.0	3.0	0.0	Loop	PK	-40.0	5.8	31.7	-25.9	Antenna perp to grnd, EUT parallel to grnd
0.499	32.8	10.3	357.0	1.0	3.0	0.0	Loop	QP	-40.0	3.1	33.6	-30.5	Antenna parallel to grnd, EUT parallel to grnd
0.626	30.8	10.3	154.0	1.0	3.0	0.0	Loop	QP	-40.0	1.1	31.7	-30.6	Antenna parallel to grnd, EUT parallel to grnd
0.502	32.7	10.3	25.0	2.1	3.0	0.0	Loop	QP	-40.0	3.0	33.6	-30.6	Antenna parallel to grnd, EUT parallel to grnd
0.496	32.8	10.3	194.0	1.0	3.0	0.0	Loop	QP	-40.0	3.1	33.7	-30.6	Antenna parallel to grnd, EUT parallel to grnd
0.619	30.8	10.3	356.0	1.0	3.0	0.0	Loop	QP	-40.0	1.1	31.8	-30.7	Antenna perp to grnd, EUT parallel to grnd
0.502	32.6	10.3	359.0	2.1	3.0	0.0	Loop	QP	-40.0	2.9	33.6	-30.7	Antenna perp to grnd, EUT parallel to grnd
0.747	28.9	10.3	329.0	1.0	3.0	0.0	Loop	QP	-40.0	-0.8	30.1	-30.9	Antenna parallel to grnd, EUT parallel to grnd
0.754	28.8	10.3	356.0	3.6	3.0	0.0	Loop	QP	-40.0	-0.9	30.1	-31.0	Antenna perp to grnd, EUT parallel to grnd