# **Boston Scientific Corporation**

100050-011

INGENIO EDVT016016
FCC and Industry Canada
Compliance for RF Link
Test Report

**Ingenio PG Family** 

Report No. BSTN0294.1

Report Prepared By



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

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22975 NW Evergreen Parkway Suite 400 Hillsboro, Oregon 97124

### **Certificate of Test**

Last Date of Test: October 14, 2010
Boston Scientific Corporation
Model: Ingenio

Emissions					
Test Description	Specification	Test Method	Pass/Fail		
Field Strength of Spurious Emissions	FCC 15.249:2010	ANSI C63.10:2009	Pass		
Field Strength of Fundamental	FCC 15.249:2010	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. 9349 W Broadway Ave. Brooklyn Park, MN 55445

Phone: (763) 425-2281 Fax: (763) 424-3469

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

Approved By:

Don Facteau, IS Manager

QAIVN

NVLAP Lab Code: 200881-0

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 History**

Revision 06/29/09

Revision Number	DASCRIPTION		Page Number
00	None		



# 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 United States Department of Commerce, National Institute of Standards and Technology, and National Voluntary Laboratory Accreditation Program for satisfactory compliance with the requirements of ISO/IEC 17025 for Testing Laboratories. 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.



NVLAP LAB CODE 200881-0

### **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.



### **NEMKO**

Assessed and accredited by NEMKO (Norwegian testing and certification body) for European emissions and immunity testing. As a result of NEMKO's laboratory assessment, they will accept test results from Northwest EMC, Inc. for product certification (Authorization No. ELA 119).





# Accreditations and Authorizations

### 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).



### **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). License No.SL2-IN-E-1017.



### **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)



### 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 339<sup>th</sup> Ave. SE Sultan, WA 98294 (360) 793-8675 New York Labs WA01-WA04 4939 Jordan Rd. Elbridge, NY 13060 (315) 685-0796







Rev 11/17/06

### Party Requesting the Test

Company Name:	Boston Scientific Corporation
Address:	4100 Hamline Avenue North
City, State, Zip:	St. Paul, MN 55112-5798
Test Requested By:	Dennis Larson
Model:	Ingenio PG Family
First Date of Test:	October 13, 2010
Last Date of Test:	October 14, 2010
Receipt Date of Samples:	October 13, 2010
Equipment Design Stage:	Pilot A
<b>Equipment Condition:</b>	No Damage

### **Information Provided by the Party Requesting the Test**

### **Functional Description of the EUT (Equipment Under Test):**

Pulse Generator with 916.5 MHz transceiver operating with a maximum output power of -1.25 dBm

### **Testing Objective:**

To demonstrate compliance to FCC 15.249 specifications

### Configurations

Revision 9/21/05

### **CONFIGURATION 1 BSTN0294**

Software/Firmware Running during test	
Description	Version
Ingenio SR IS1 Firmware (Primary Operation)	D_v0.05.30

EUT			
Description	Manufacturer	Model/Part Number	Serial Number
Ingenio SR IS1	Boston Scientific Corporation	K172	849911 (EDVT474)

Cables					
Cable Type	Shield	Length (m)	Ferrite	Connection 1	Connection 2
EZ Trak IS1 90CM Model:4538 SN:157887	No	90 cm	No	Ingenio SR IS1	Unterminated
PA = Cable is permanently attached to the device. Shielding and/or presence of ferrite may be unknown.					

### **CONFIGURATION 2 BSTN0294**

Software/Firmware Running during test			
Description	Version		
Ingenio DR STD IS1 Firmware (Primary Operation)	D_v0.05.30		

EUT			
Description	Manufacturer	Model/Part Number	Serial Number
Ingenio DR STD IS1	Boston Scientific Corporation	K173	829205 (EDVT454)

Cables					
Cable Type	Shield	Length (m)	Ferrite	Connection 1	Connection 2
EZ Trak IS1 90CM Model:4538 SN:157499	No	90 cm	No	Ingenio DR STD IS1	Unterminated
EZ Trak IS1 90CM Model:4538 SN:158122	No	90 cm	No	Ingenio DR STD IS1	Unterminated
PA = Cable is permanently attach	ed to the de	vice. Shielding	and/or pre	sence of ferrite may be ι	ınknown.



### **CONFIGURATION 3 BSTN0294**

Software/Firmware Running during test	
Description	Version
Ingenio DR LL IS1 Firmware (Primary Operation)	D_v0.05.30

EUT			
Description	Manufacturer	Model/Part Number	Serial Number
Ingenio DR LL IS1	Boston Scientific Corporation	K174	850001 (EDVT433)

Cables					
Cable Type	Shield	Length (m)	Ferrite	Connection 1	Connection 2
EZ Trak IS1 90CM Model:4538 SN:157887	No	90 cm	No	Ingenio DR LL IS1	Unterminated
EZ Trak IS1 90CM Model:4538 SN:158122	No	90 cm	No	Ingenio DR LL IS1	Unterminated
PA = Cable is permanently attach	ed to the dev	ice. Shielding	nd/or pres	ence of ferrite may be u	ınknown.

### **CONFIGURATION 4 BSTN0294**

Software/Firmware Running during test			
Description	Version		
Invive CRTP IS1 Firmware (Primary Operation)	D_v0.05.30		

EUT			
Description	Manufacturer	Model/Part Number	Serial Number
Invive CRTP IS1	Boston Scientific Corporation	V173	849702 (EDVT403)

Cables					
Cable Type	Shield	Length (m)	Ferrite	Connection 1	Connection 2
EZ Trak IS1 90CM Model:4538 SN:157499	No	90 cm	No	Invive CRTP IS1	Unterminated
EZ Trak IS1 90CM Model:4538 SN:157887	No	90 cm	No	Invive CRTP IS1	Unterminated
EZ Trak IS1 90CM Model:4538 SN:158122	No	90 cm	No	Invive CRTP IS1	Unterminated
PA = Cable is permanently attached	to the device	e Shielding ar	nd/or preser	nce of ferrite may be i	ınknown



	Equipment modifications						
Item	Date	Test	Modification	Note	Disposition of EUT		
1	10/13/2010	Field Strength of Fundamental	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	10/14/2010	Field Strength of Spurious Emission	Tested as delivered to Test Station.	No EMI suppression devices were added or modified during this test.	Scheduled testing was completed.		

### 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. 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, Psuedorandom, 916.5 MHz

#### **POWER SETTINGS INVESTIGATED**

Battery

### **CONFIGURATIONS INVESTIGATED**

4 - BSTN0294

- 3 BSTN0294
- 2 BSTN0294
- 1 BSTN0294

FREQUENCY RANGE INVESTIGATED				
Start Frequency	30 MHz	Stop Frequency	10 GHz	

#### 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
High Pass Filter 0-425 MHz	Micro-Tronics	LPM50003	HGO	7/9/2010	13 mo
High Pass Filter	Micro-Tronics	HPM50108	HGP	7/9/2010	13 mo
Attenuator, 6 dB, 'SMA'	SM Electronics	SA18H-06	REM	7/9/2010	13 mo
Attenuator, 20 dB, 'SMA'	SM Electronics	SA6-20	REO	7/9/2010	13 mo
Pre-Amplifier	Miteq	AMF-6F-08001200-30-10P	AVV	7/19/2010	13 mo
Antenna, Horn	ETS	3160-07	AXP	NCR	0 mo
MN05 Cables	ESM Cable Corp.	Standard Gain Horn Cables	MNJ	7/19/2010	13 mo
MN05 Cables	ESM Cable Corp.	Double Ridge Guide Horn Cables	MNI	7/19/2010	13 mo
Antenna, Horn (DRG)	ETS Lindgren	3115	AIP	12/22/2009	24 mo
Pre-Amplifier	Miteq	AM-1616-1000	AVY	7/19/2010	13 mo
Pre-Amplifier	Miteq	AMF-3D-00100800-32-13P	AVX	7/19/2010	13 mo
Antenna, Biconilog	ETS Lindgren	3142D	AXN	12/30/2009	13 mo
MN05 Cables	ESM Cable Corp.	Bilog Cables	MNH	1/15/2010	13 mo
Spectrum Analyzer	Agilent	E4446A	AAT	2/24/2010	12 mo

MEASUREMENT BANDWIDTHS					
	Frequency Range	Peak Data	Quasi-Peak Data	Average Data	
	(MHz)	(kHz)	(kHz)	(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	

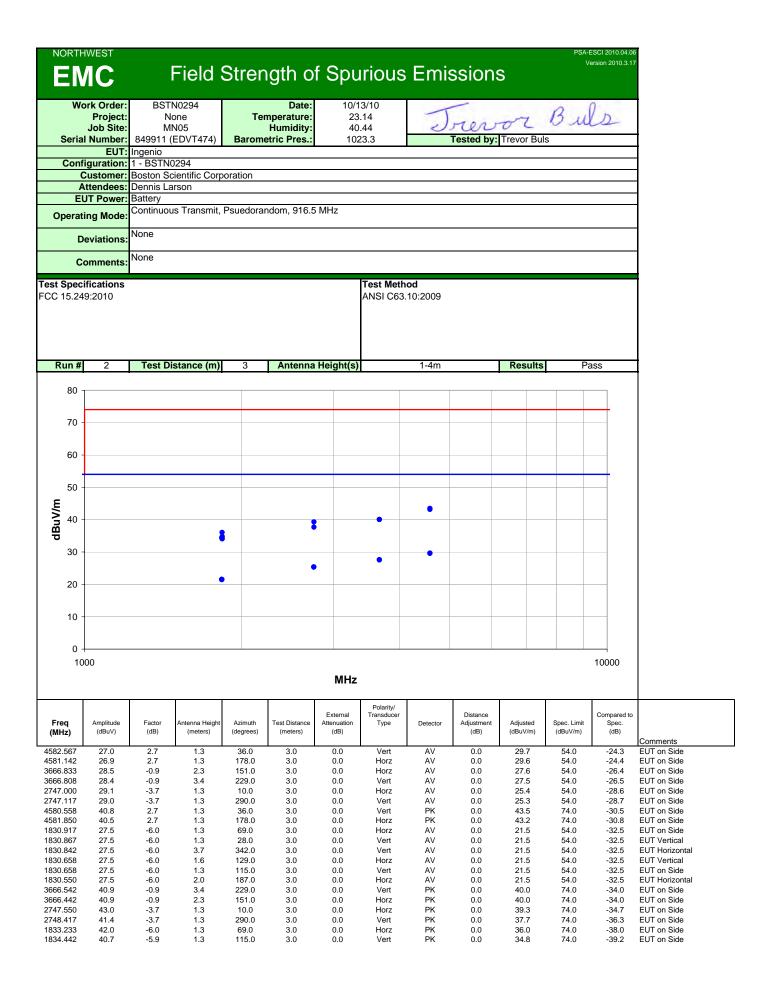
Measurements were made using the IF bandwidths and detectors specified. No video filter was used, except in the case of the FCC Average Measurements above 1GHz. In that case, a peak detector with a 10Hz video bandwidth was used.

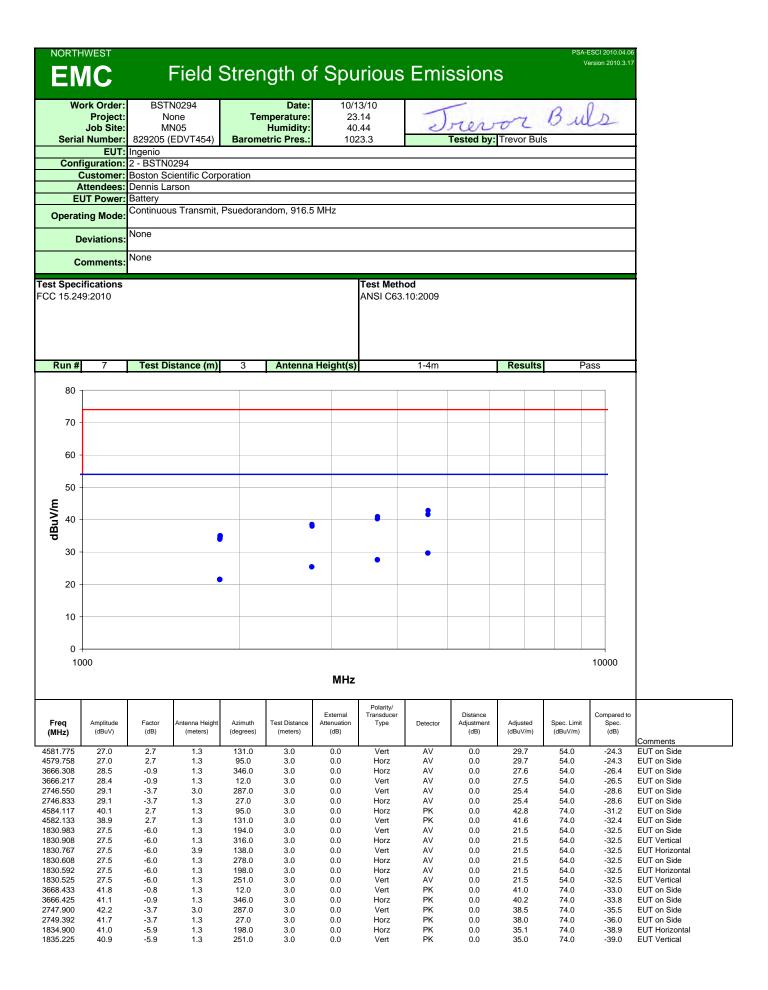
### **MEASUREMENT UNCERTAINTY**

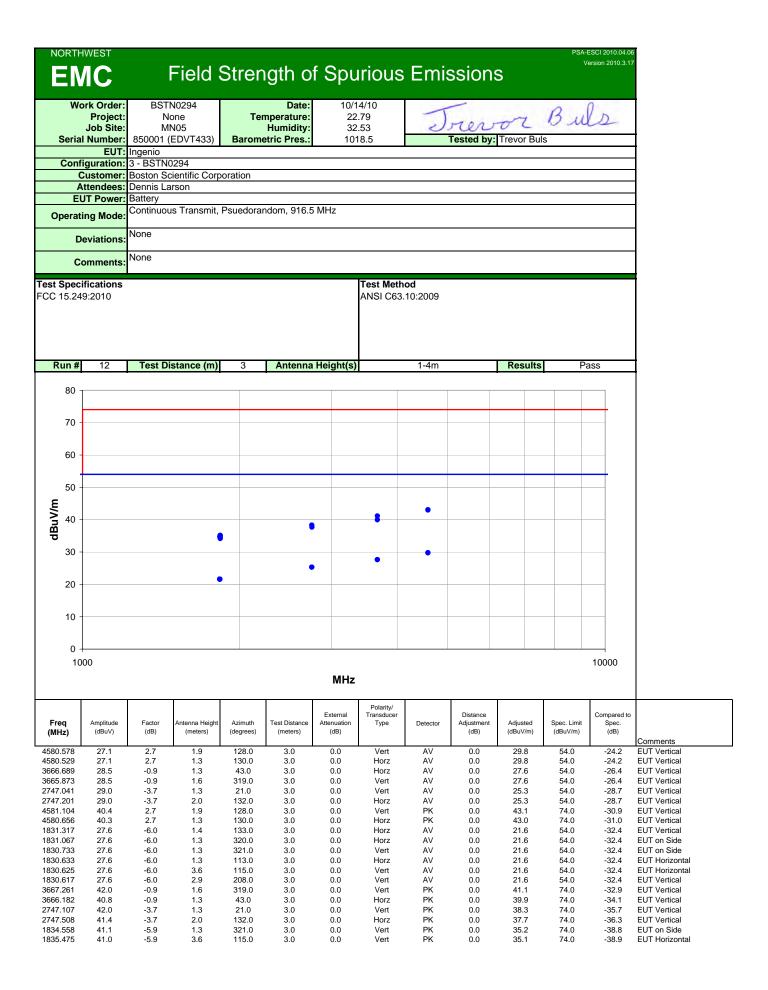
A measurement uncertainty estimation has been performed for each test per our internal quality document WP 342. The estimation is used to compare the measured result with its "true" or theoretically correct value. The expanded measurement uncertainty for radiated emissions measurements is less than +/- 4 dB, and for conducted emissions measurements is less than +/-2.7 dB. Our measurement data meets or exceeds the measurement uncertainty requirements of CISPR 16-4; therefore, the test data can be compared directly to the specification limit to determine compliance. The calculations for measurement uncertainty are available upon request.

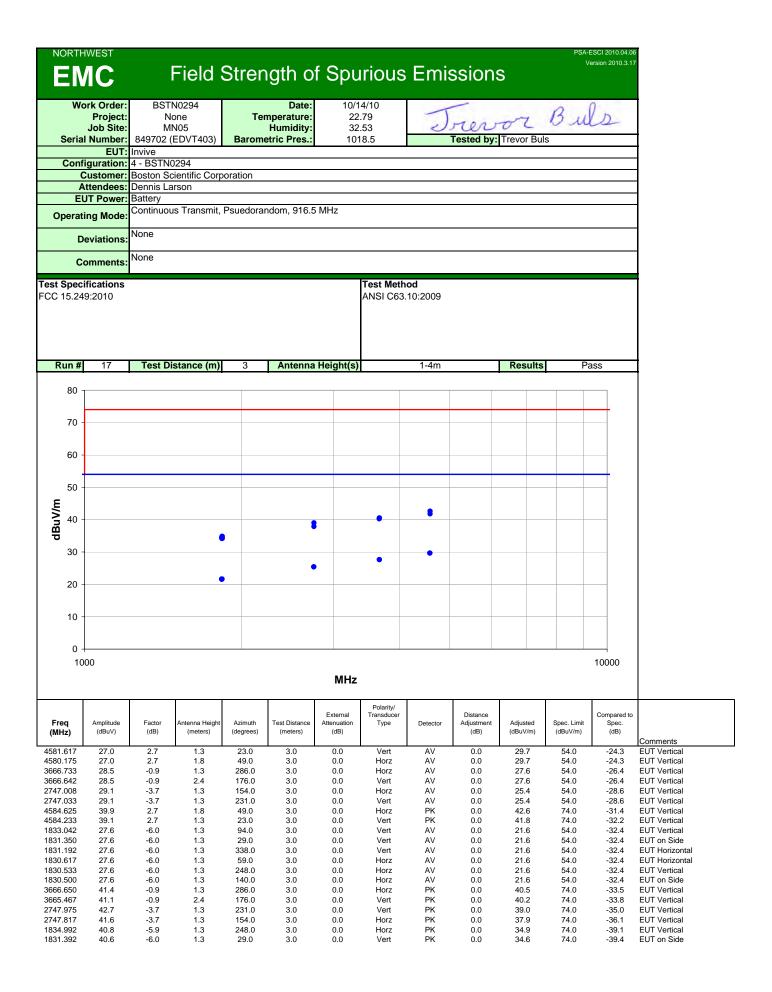
#### **TEST DESCRIPTION**

The antennas to be used with the EUT were tested. The EUT was transmitting and receiving while set at the only available channel. 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). A preamp and high pass filter were used for this test in order to provide sufficient measurement sensitivity.









### **EMC**

### 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. 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, 'All Ones' 916.5 MHz

### **POWER SETTINGS INVESTIGATED**

Battery

### **CONFIGURATIONS INVESTIGATED**

- 4 BSTN0294
- 3 BSTN0294
- 2 BSTN0294
- 1 BSTN0294

### FREQUENCY RANGE INVESTIGATED

Start Frequency 902 MHz Stop Frequency 928 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
Attenuator, 6 dB, 'SMA'	SM Electronics	SA18H-06	REM	7/9/2010	13 mo
Pre-Amplifier	Miteq	AM-1616-1000	AVY	7/19/2010	13 mo
Antenna, Biconilog	ETS Lindgren	3142D	AXN	12/30/2009	13 mo
MN05 Cables	ESM Cable Corp.	Bilog Cables	MNH	1/15/2010	13 mo
Spectrum Analyzer	Agilent	E4446A	AAT	2/24/2010	12 mo

MEASUREMENT BANDWIDTHS						
	Frequency Range	Peak Data	Quasi-Peak Data	Average Data		
	(MHz)	(kHz)	(kHz)	(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 IF bandwidths and detectors specified. No video filter was used, except in the case of the FCC Average Measurements above 1GHz. In that case, a peak detector with a 10Hz video bandwidth 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. The expanded measurement uncertainty for radiated emissions measurements is less than +/- 4 dB, and for conducted emissions measurements is less than +/- 2.7 dB. Our measurement data meets or exceeds the measurement uncertainty requirements of CISPR 16-4; therefore, the test data can be compared directly to the specification limit to determine compliance. The calculations for measurement uncertainty are available upon request.

### **TEST DESCRIPTION**

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

