

NORTHWEST EMC

Boston Scientific Corporation

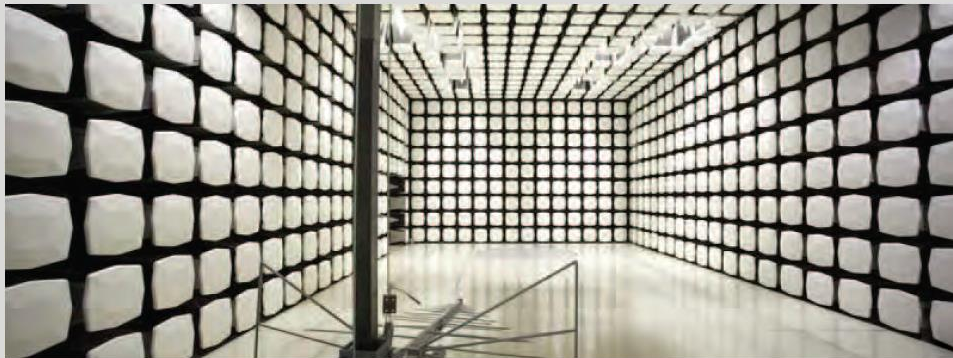
Emblem 3200 Programmer

LP0002:2018

Brand Name: Boston Scientific

**Equipment Name: Subcutaneous Implantable Cardiac Defibrillator
Programmer**

Report # BSTN0636.2 Rev. 3



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. This Report may only be duplicated in its entirety

CERTIFICATE OF TEST

Last Date of Test: May 11, 2016
Boston Scientific Corporation
Model: Emblem 3200 Programmer

Radio Equipment Testing

Standards

Specification	Method
LP0002:2018	LP0002:2018

Results

Method Clause	Test Description	Applied	Results	Comments
4.11.3.1(3)	LBT Threshold Power Level	Yes	Pass	
4.11.3.1(1)	Monitoring System Bandwidth	Yes	Pass	
4.11.3.1(2)	Monitoring System Scan Cycle Time	Yes	Pass	
4.11.3.1(4)	Discontinuation of MICS Session	Yes	Pass	
4.11.3.1(5)(A)	Minimum Channel Monitoring Period	Yes	Pass	
4.11.3.1(5)(B)	Channel Access Based on Ambient Levels	Yes	Pass	
4.11.3.1(5)(C)	Use Of Pre-Scanned Alternative Channel	No	N/A	Not required because the EUT meets section 4.11.3.1(5)(A-B)

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	Page Number
00	None		
01	Updated to LP0002:2016	7/6/2017	Various
02	Updated EUT name	12/21/2017	Cover, 2, 7, 11, 16, 22, 31, 36, 41
03	Updated Method Clause	11/28/2018	2
03	Updated standard to LP0002:2018	11/28/2018	Cover, 2, 11, 16, 22, 31, 36, 41

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 Northwest EMC to certify transmitters to FCC and IC specifications.

NVLAP - Each laboratory is accredited by NVLAP to ISO 17025

Canada

IC - Recognized by Industry Canada as a Certification Body (CB). Certification chambers and Open Area Test Sites are filed with IC.

European Union

European Commission – Validated by the European Commission as a Notified Body under the R&TTE Directive.

Australia/New Zealand

ACMA - Recognized by ACMA as a CAB for the acceptance of test data.

Korea

MSIP / 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:

<http://www.nwemc.com/accreditations/>

<http://gsi.nist.gov/global/docs/cabs/designations.html>

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 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.

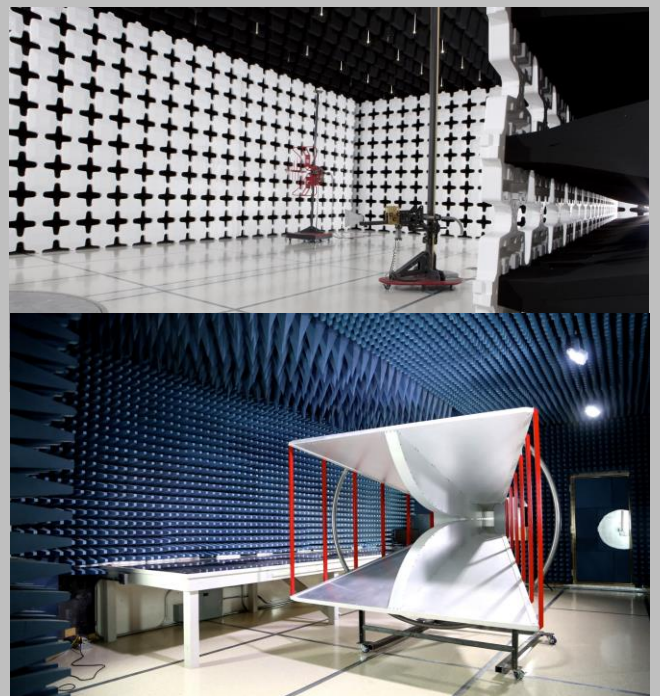
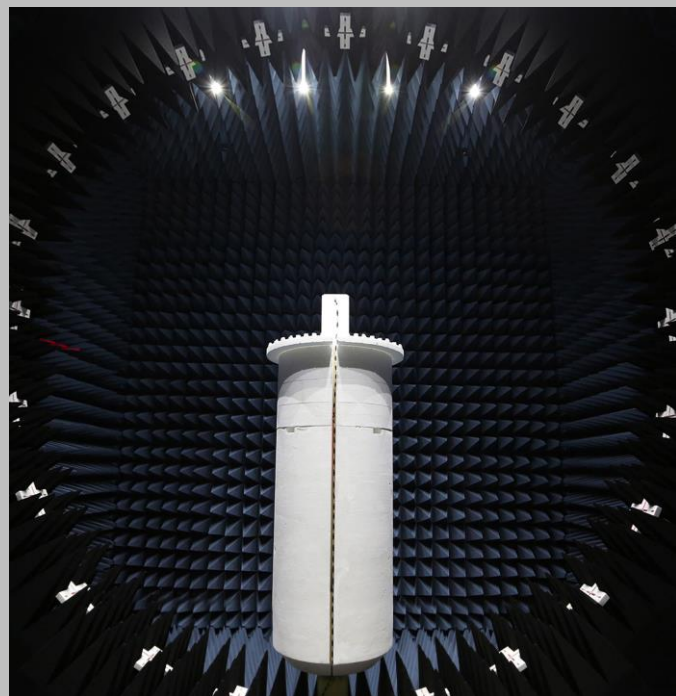
The following table represents the Measurement Uncertainty (MU) budgets for each of the tests that may be contained in this report.

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

FACILITIES



California Labs OC01-13 41 Tesla Irvine, CA 92618 (949) 861-8918	Minnesota Labs MN01-08, MN10 9349 W Broadway Ave. Brooklyn Park, MN 55445 (612)-638-5136	New York Labs NY01-04 4939 Jordan Rd. Elbridge, NY 13060 (315) 554-8214	Oregon Labs EV01-12 22975 NW Evergreen Pkwy 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
NVLAP					
NVLAP Lab Code: 200676-0	NVLAP Lab Code: 200881-0	NVLAP Lab Code: 200761-0	NVLAP Lab Code: 200630-0	NVLAP Lab Code:201049-0	NVLAP Lab Code: 200629-0
Industry Canada					
2834B-1, 2834B-3	2834E-1	N/A	2834D-1, 2834D-2	2834G-1	2834F-1
BSMI					
SL2-IN-E-1154R	SL2-IN-E-1152R	N/A	SL2-IN-E-1017	SL2-IN-E-1158R	SL2-IN-E-1153R
VCCI					
A-0029	A-0109	N/A	A-0108	A-0201	A-0110
Recognized Phase I CAB for ACMA, BSMI, IDA, KCC/RRR, MIC, MOC, NCC, OFCA					
US0158	US0175	N/A	US0017	US0191	US0157



PRODUCT DESCRIPTION

Client and Equipment Under Test (EUT) Information

Company Name:	Boston Scientific Corporation
Address:	4100 Hamline Avenue North
City, State, Zip:	St. Paul, MN 55112
Test Requested By:	Benjamin Stein
Model:	Emblem 3200 Programmer
First Date of Test:	May 11, 2016
Last Date of Test:	May 11, 2016
Receipt Date of Samples:	May 11, 2016
Equipment Design Stage:	Production
Equipment Condition:	No Damage

Information Provided by the Party Requesting the Test

Functional Description of the EUT:

A computing and radio platform which provides qualified field personnel, designated distributors, clinicians, and physicians with the capability to communicate with and program an S-ICD active medical implant. The radio platform provides bidirectional, very low power communications in the 402-405 MHz band as specified by the Medical Implant Communication Service (MICS) specifications. Only channels 402.8183 MHz and 403.5108 MHz are used.

Testing Objective:

To demonstrate compliance to LP0002 requirements.

EUT Photo



CONFIGURATIONS

Configuration BSTN0636- 1

Software/Firmware Running during test	
Description	Version
EMBLEM S-ICD APPLICATION	3.05

EUT			
Description	Manufacturer	Model/Part Number	Serial Number
3200 Programmer	Boston Scientific	Model 3200 Programmer	3200-A103225

Peripherals in test setup boundary			
Description	Manufacturer	Model/Part Number	Serial Number
AC/DC Adapter	ICCNExergy	MWA020005A	None
S-ICD Implant	Boston Scientific	A209	100588
Antenna	Boston Scientific	Model 3203	None

Cables					
Cable Type	Shield	Length (m)	Ferrite	Connection 1	Connection 2
AC Cable	Yes	2.5m	No	AC Mains	AC/DC Adapter
DC Cable	No	1m	No	AC/DC Adapter	Model 3200 Programmer

MODIFICATIONS

Equipment Modifications

Item	Date	Test	Modification	Note	Disposition of EUT
1	5/11/2016	LBT Threshold Power Level	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	5/11/2016	Monitoring System Bandwidth	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.
3	5/11/2016	Monitoring System Scan Cycle Time	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.
4	5/11/2016	Channel Access Based on Ambient Levels	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.
5	5/11/2016	Discontinuation of MICS Session	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.
6	5/11/2016	Minimum Channel Monitoring Period	Tested as delivered to Test Station.	No EMI suppression devices were added or modified during this test.	Scheduled testing was completed.

LBT THRESHOLD POWER LEVEL

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.

TEST EQUIPMENT

Description	Manufacturer	Model	ID	Last Cal.	Interval (mo)
Power Divider/Combiner	Fairview Microwave Inc (SM electronics)	MP8451-2	IAC	NCR	0
Directional Coupler	Fairview Microwave	MC2047-10	RGQ	NCR	0
Power Divider/Combiner	Fairview Microwave Inc (SM electronics)	MP8451-2	IAD	NCR	0
Cable	ESM Cable Corp.	TTBJ141 KMKM-72	MNU	9/18/2015	12
Generator - Signal	Agilent	N5182A	TIF	8/12/2014	36
Generator - Signal	Agilent	N5183A	TIK	10/17/2014	36
Attenuator	S.M. Electronics	SA26B-20	RFW	2/26/2016	12
Block - DC	Fairview Microwave	SD3379	AMI	9/18/2015	12
Analyzer - Spectrum Analyzer	Agilent	N9010A	AFI	1/27/2016	12

TEST DESCRIPTION

A spectrum analyzer was used to verify the path loss between the signal generator and The EUT per figure 1 below. The EUT was then configured according to the figure 2 below.

The signal generator was set to CW operation on the out of operation channel. The amplitude of the CW signal (out of operation region) was set to the LBT threshold of $10 \cdot \log(\text{Bandwidth}) - 150 + \text{Antenna Gain} + 3 \text{ dB}$.

The spectrum analyzer was set to measure the transmit band of 402-405 MHz. The multitone signal of the intended frequency (F_c) was set to the LBT threshold - 6 dB, and raised by 1 dB increments until the EUT choose a different channel to start a session. Screen captures were provided to show the EUT behavior at the different LBT threshold levels.

The signal generator amplitude at F_c was then measured and recorded with the spectrum analyzer.

Figure 1:

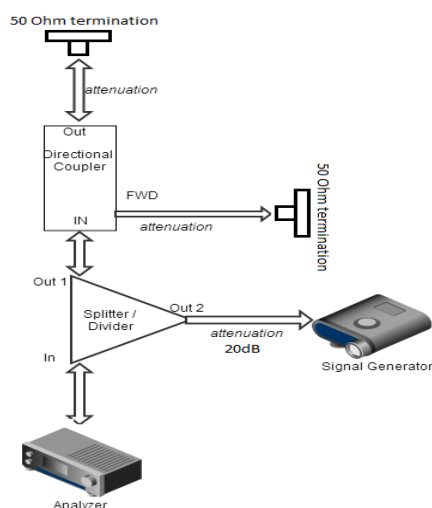
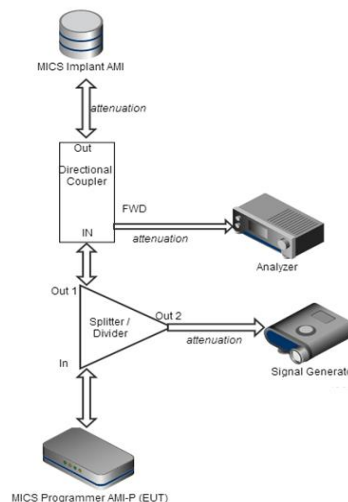


Figure 2:

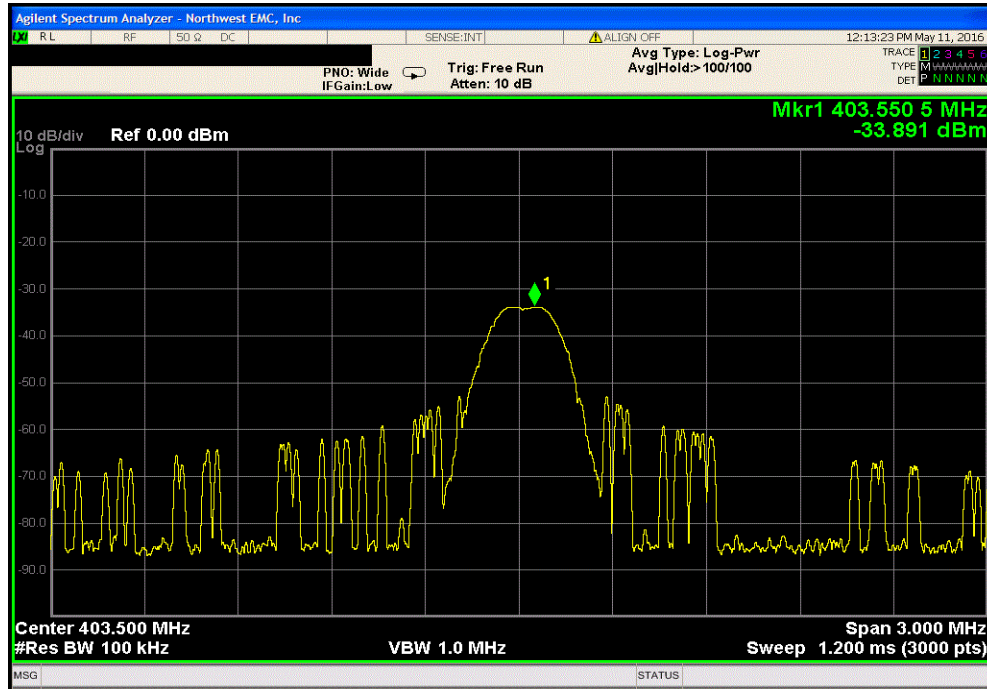


LBT THRESHOLD POWER LEVEL

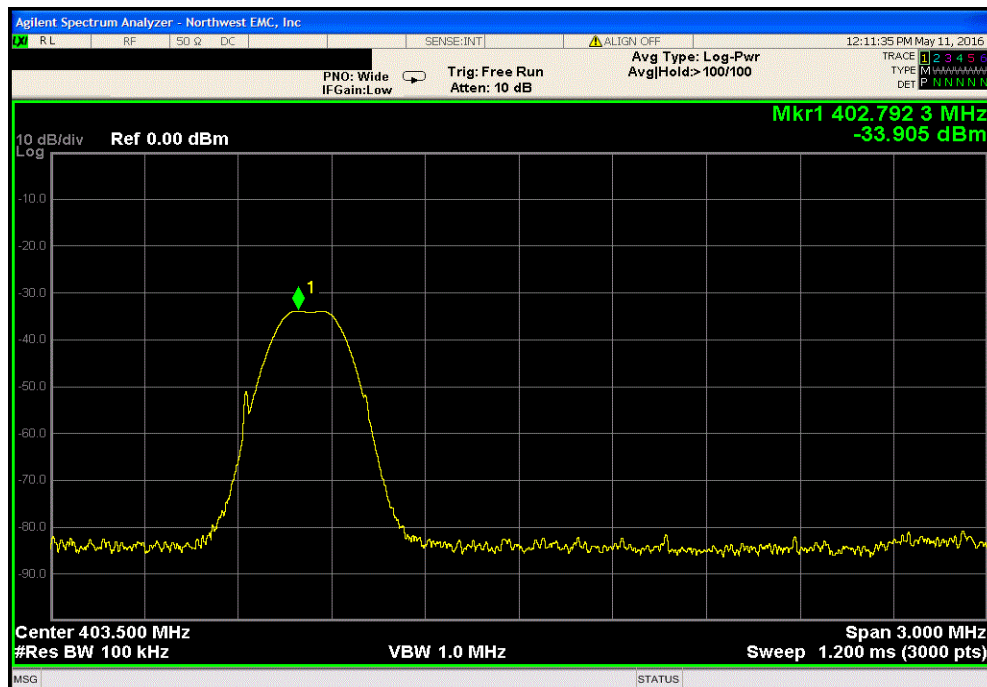
EUT: Emblem 3200 Programmer		Work Order: BSTN0636	
Serial Number: 3200-A103225		Date: 05/11/16	
Customer: Boston Scientific Coporation		Temperature: 22.4°C	
Attendees: Pete Musto		Humidity: 40%	
Project: None		Barometric Pres.: 986.8 mbar	
Tested by: Jared Ison	Power: 110VAC/60Hz	Job Site: MN08	
TEST SPECIFICATIONS			
LP0002:2018		Test Method	
LP0002:2018		LP0002:2018	
COMMENTS			
EUT Bandwidth is 126000 Hz with antenna gain of -5 dBi. EUT only has two operational channels, 402.8183 MHz and 403.5108 MHz. Path loss between the signal generator and the EUT was measured at 27.7 dB. LBT Threshold = $10 \cdot \text{LOG}(126000) - 150 + -5 = -104.0$			
DEVIATIONS FROM TEST STANDARD			
None			
Configuration #	1	Signature 	
		Signal Gen (dBm)	Path Loss (dB)
		Fc Amplitude (dBm)	Limit <(dBm)
			Result
LBT Threshold -6 dB		N/A	N/A
LBT Threshold +5 dB		-73.25	27.7
		-104.95	-104
			Pass

LBT THRESHOLD POWER LEVEL

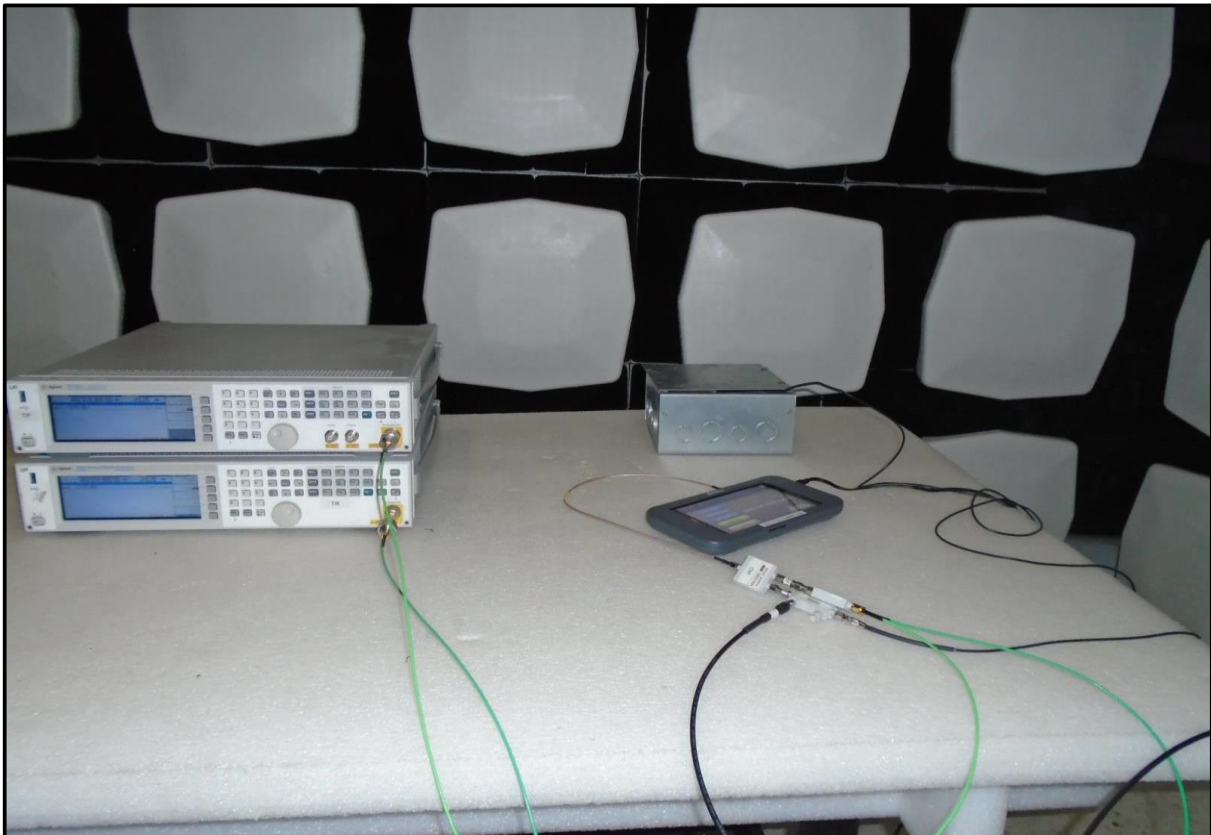
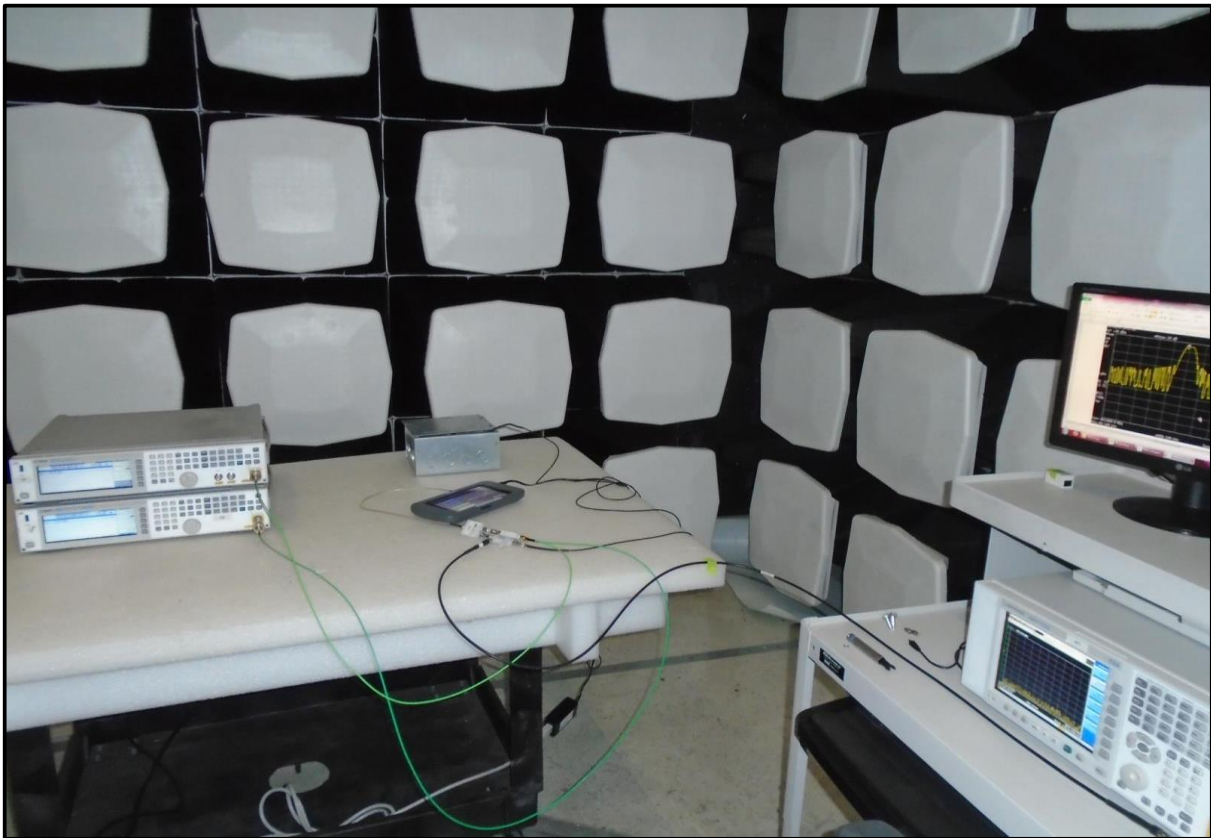
LBT Threshold -6 dB						
Signal Gen (dBm)	Path Loss (dB)	Fc Amplitude (dBm)	Limit <(dBm)	Result		
N/A	N/A	N/A	N/A	N/A		



LBT Threshold +5 dB						
Signal Gen (dBm)	Path Loss (dB)	Fc Amplitude (dBm)	Limit <(dBm)	Result		
-73.25	27.7	-105.0	-104	Pass		



LBT THRESHOLD POWER LEVEL



LBT THRESHOLD POWER LEVEL



MONITORING SYSTEM BANDWIDTH

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.

TEST EQUIPMENT

Description	Manufacturer	Model	ID	Last Cal.	Interval (mo)
Generator - Signal	Agilent	N5183A	TIK	10/17/2014	36
Generator - Signal	Agilent	N5182A	TIF	8/12/2014	36
Directional Coupler	Fairview Microwave	MC2047-10	RGQ	NCR	0
Power Divider/Combiner	Fairview Microwave Inc (SM electronics)	MP8451-2	IAC	NCR	0
Power Divider/Combiner	Fairview Microwave Inc (SM electronics)	MP8451-2	IAD	NCR	0
Cable	ESM Cable Corp.	TTBJ141 KMKM-72	MNU	9/18/2015	12
Block - DC	Fairview Microwave	SD3379	AMI	9/18/2015	12
Attenuator	S.M. Electronics	SA26B-20	RFW	2/26/2016	12
Analyzer - Spectrum Analyzer	Agilent	N9010A	AFI	1/27/2016	12

TEST DESCRIPTION

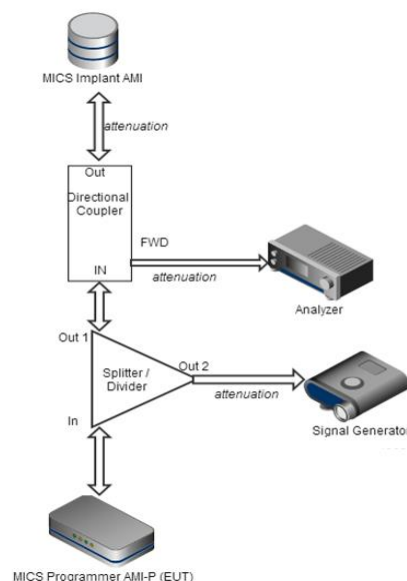
The EUT was configured according to the following block diagram:

The signal generator was set to CW signal on the out of operation channel. The amplitude of the CW signal (out of operation region) was set to the LBT threshold of $10 \cdot \log(\text{Bandwidth}) - 150 + \text{Antenna Gain} + 3 \text{ dB}$.

The spectrum analyzer was set to measure the transmit band of 402-405 MHz. The CW signal of the intended frequency (F_c) was set to a level above the LBT threshold, and lowered by 1 dB increments until the EUT chooses the intended frequency (F_c) to start a session on.

The blocking frequency at F_c was then lowered to $F_c - \text{Bandwidth} / 2$. The amplitude was then raised until the EUT chooses a channel other than F_c . This was repeated with the blocking frequency raised to $F_c + \text{Bandwidth} / 2$.

The signal generator amplitude at F_c was measured at each point.



MONITORING SYSTEM BANDWIDTH

EUT: Emblem 3200 Programmer		Work Order: BSTN0636	
Serial Number: 3200-A103225		Date: 05/11/16	
Customer: Boston Scientific Coporation		Temperature: 22.4°C	
Attendees: Pete Musto		Humidity: 40%	
Project: None		Barometric Pres.: 986.8 mbar	
Tested by: Jared Ison	Power: 110VAC/60Hz	Job Site: MN08	
TEST SPECIFICATIONS			
LP0002:2018		Test Method	
LP0002:2018		LP0002:2018	
COMMENTS			
Manufacturer's declared 20 dB EUT Bandwidth is 126000 Hz with antenna gain of -5 dBi. EUT only has two operational channels, 402.8183 MHz and 403.5108 MHz.			
DEVIATIONS FROM TEST STANDARD			
None			
Configuration #	1	Signature 	
		Measured Value(dBm)	Value (dB)
		-100.99	N/A
		-80.99	20
		-87.99	13
			Limit ≤(dB)
			20
			Result
			N/A
			Pass
			Pass

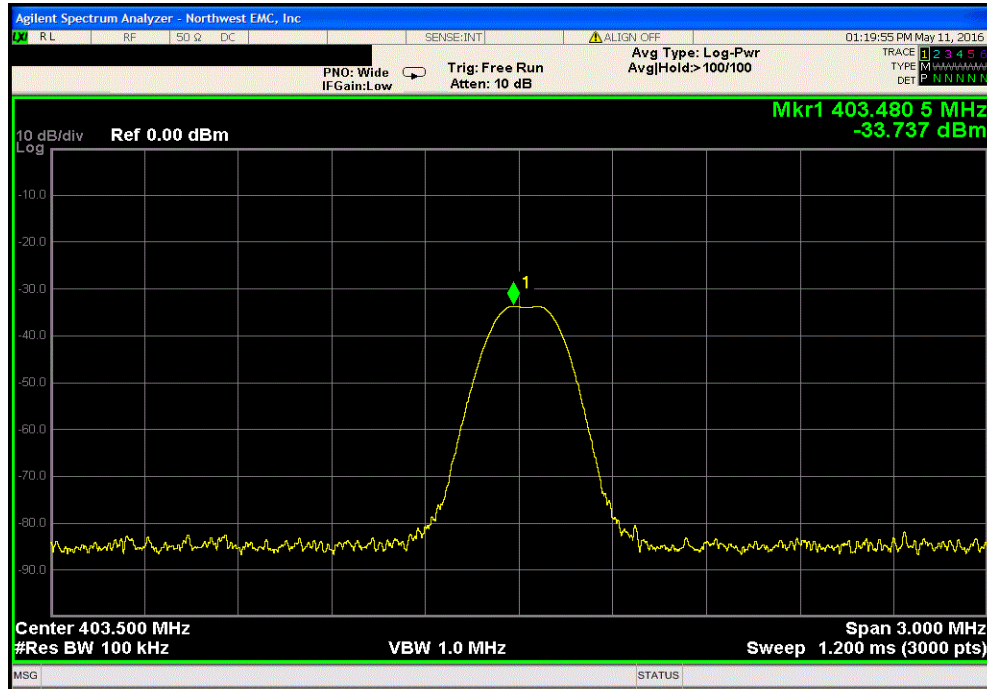
(Pa) = Fc = 403.51 MHz

(Pb) = Fc - 20 dB Emissions BW / 2 = 403.51 - 0.126 / 2 = 403.44 MHz

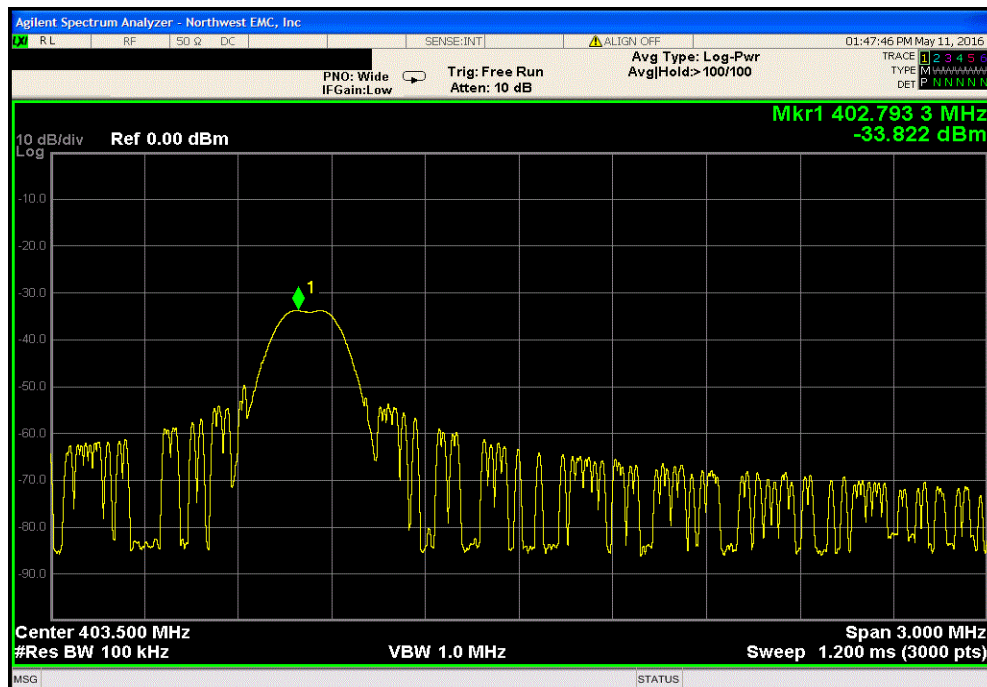
(Pc) = Fc + 20 dB Emissions BW / 2 = 403.51 + 0.126 / 2 = 403.57 MHz

MONITORING SYSTEM BANDWIDTH

(Pa) = Fc = 403.51 MHz						
	Measured Value(dBm)	Value (dB)	Limit ≤(dB)	Result		
	-100.99	N/A	N/A	N/A		

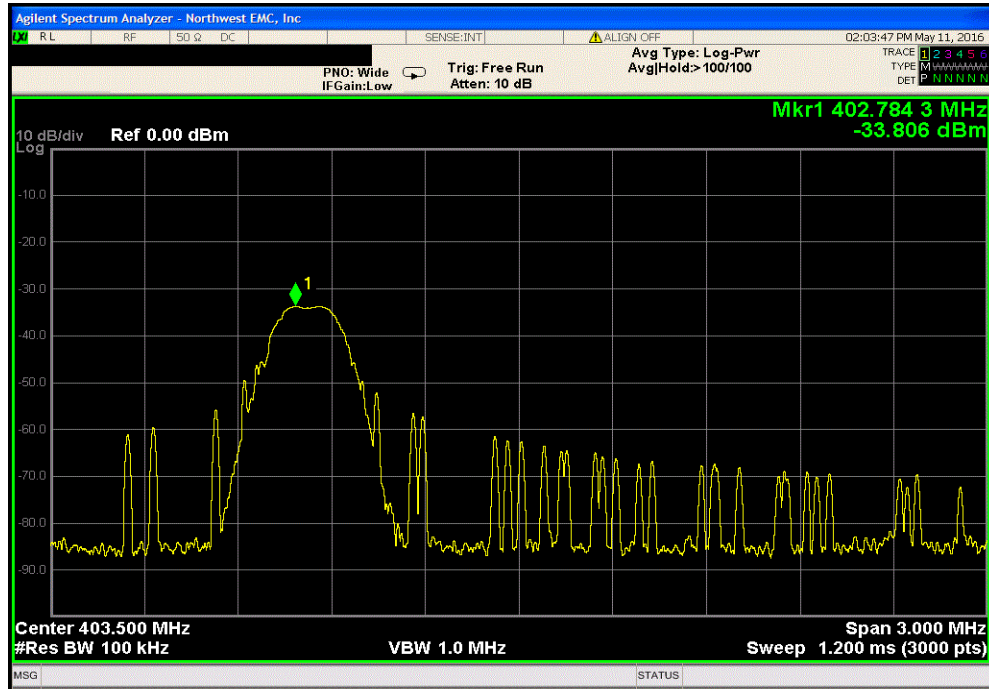


(Pb) = Fc - 20 dB Emissions BW / 2 = 403.51 - 0.126 / 2 = 403.44 MHz						
	Measured Value(dBm)	Value (dB)	Limit ≤(dB)	Result		
	-80.99	20	20	Pass		



MONITORING SYSTEM BANDWIDTH

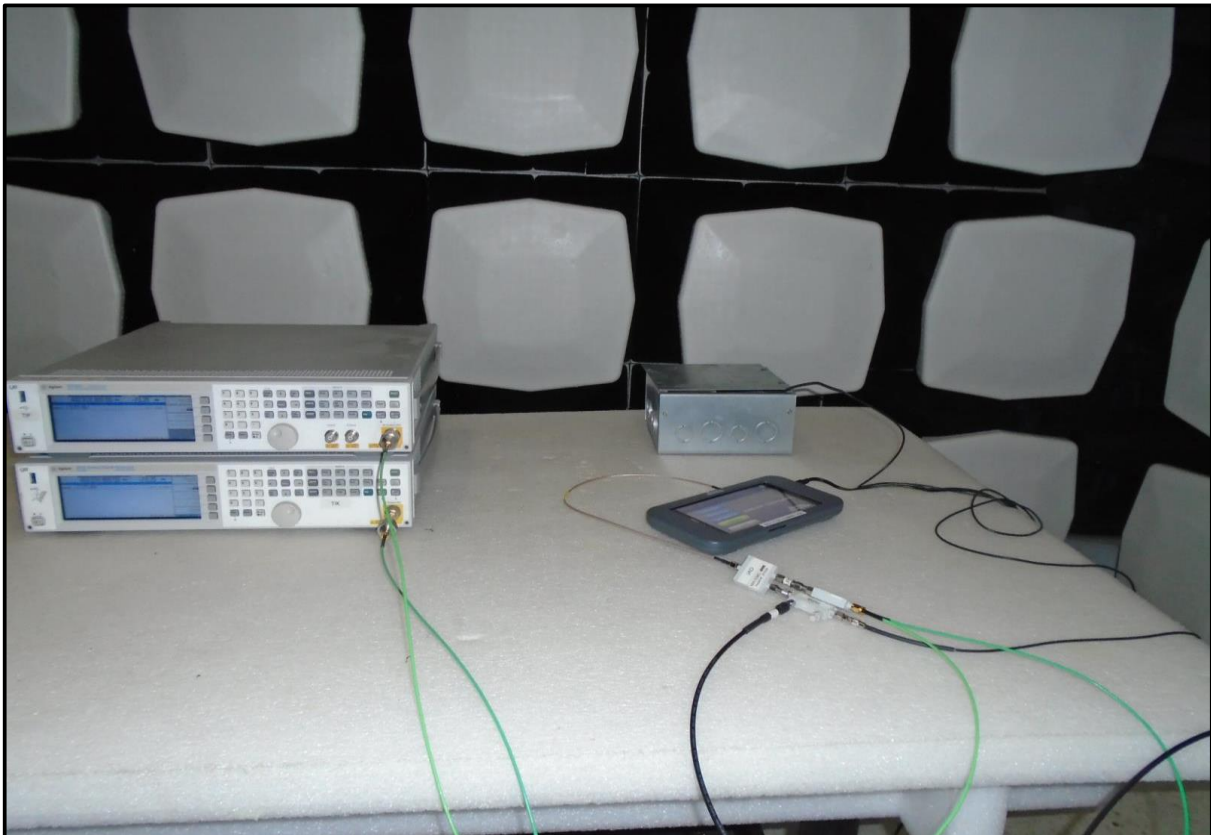
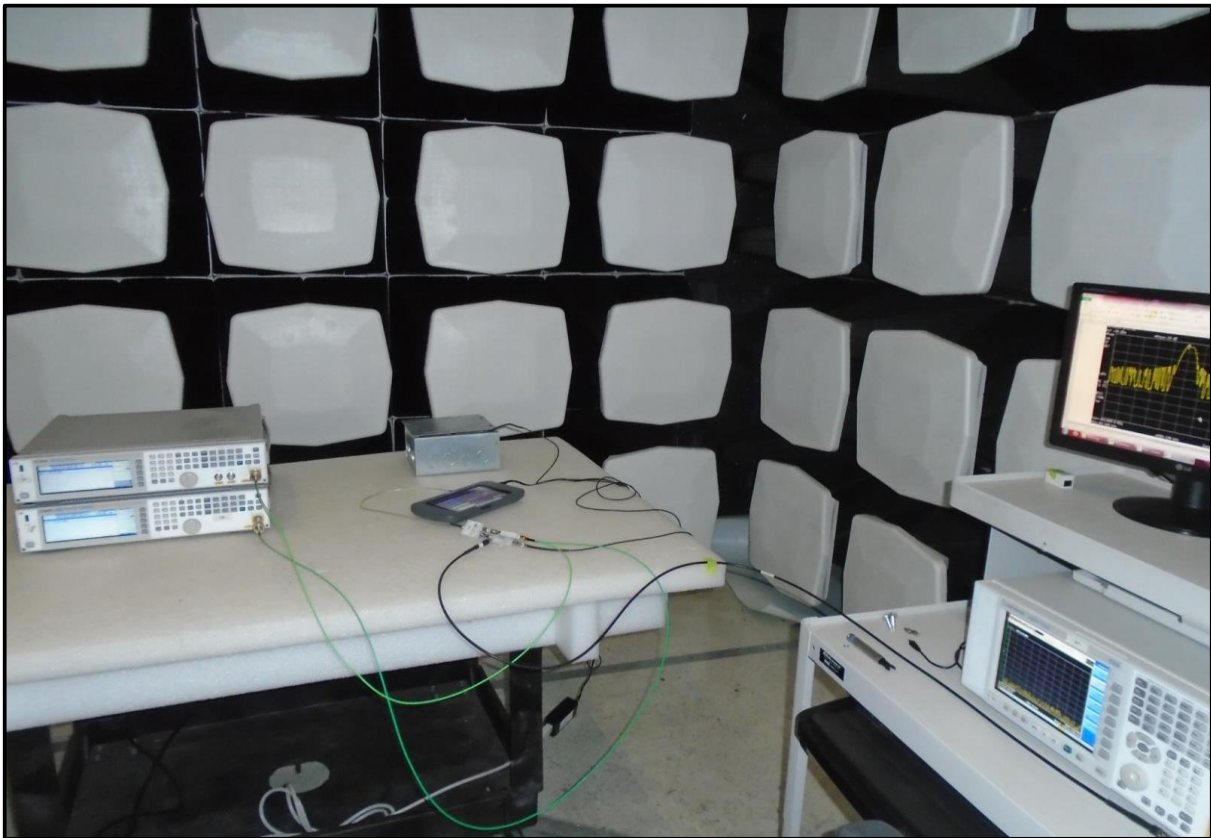
(Pc) = Fc + 20 dB Emissions BW / 2 = 403.51 + 0.126 / 2 = 403.57 MHz						
	Measured Value(dBm)	Value (dB)	Limit ≤(dB)	Result		
	-87.99	13	20	Pass		



MONITORING SYSTEM BANDWIDTH

**NORTHWEST
EMC**

XMit 2015.01.14



MONITORING SYSTEM BANDWIDTH



MONITORING SYSTEM SCAN CYCLE TIME

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.

TEST EQUIPMENT

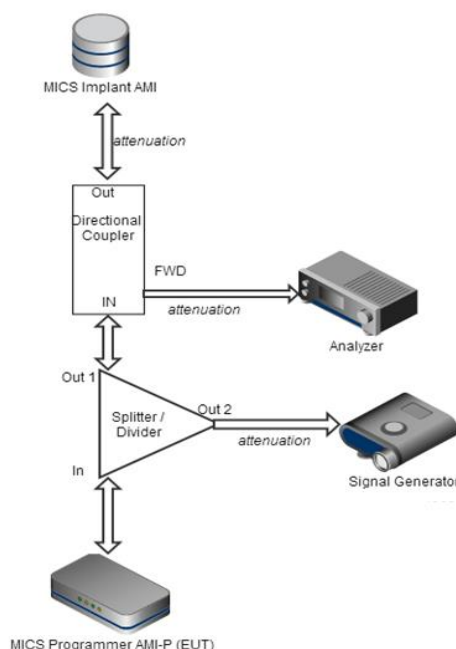
Description	Manufacturer	Model	ID	Last Cal.	Interval (mo)
Directional Coupler	Fairview Microwave	MC2047-10	RGQ	NCR	0
Power Divider/Combiner	Fairview Microwave Inc (SM electronics)	MP8451-2	IAD	NCR	0
Power Divider/Combiner	Fairview Microwave Inc (SM electronics)	MP8451-2	IAC	NCR	0
Generator - Signal	Agilent	N5182A	TIF	8/12/2014	36
Generator - Signal	Agilent	N5183A	TIK	10/17/2014	36
Block - DC	Fairview Microwave	SD3379	AMI	9/18/2015	12
Attenuator	S.M. Electronics	SA26B-20	RFW	2/26/2016	12
Cable	ESM Cable Corp.	TTBJ141 KMKM-72	MNU	9/18/2015	12
Analyzer - Spectrum Analyzer	Agilent	N9010A	AFI	1/27/2016	12

TEST DESCRIPTION

The EUT was configured according to the following block diagram:

The signal generator was set to CW operation to cause equal interference across the out of operation channel. The spectrum analyzer was set to zero span with a sweep time equal to 10 seconds.

The CW signal on the intended frequency (F_c) was removed. At the same time, the EUT was set to seek a session with the implantable device. The delay between F_c becoming available and the EUT establishing a session was measured.



MONITORING SYSTEM SCAN CYCLE TIME

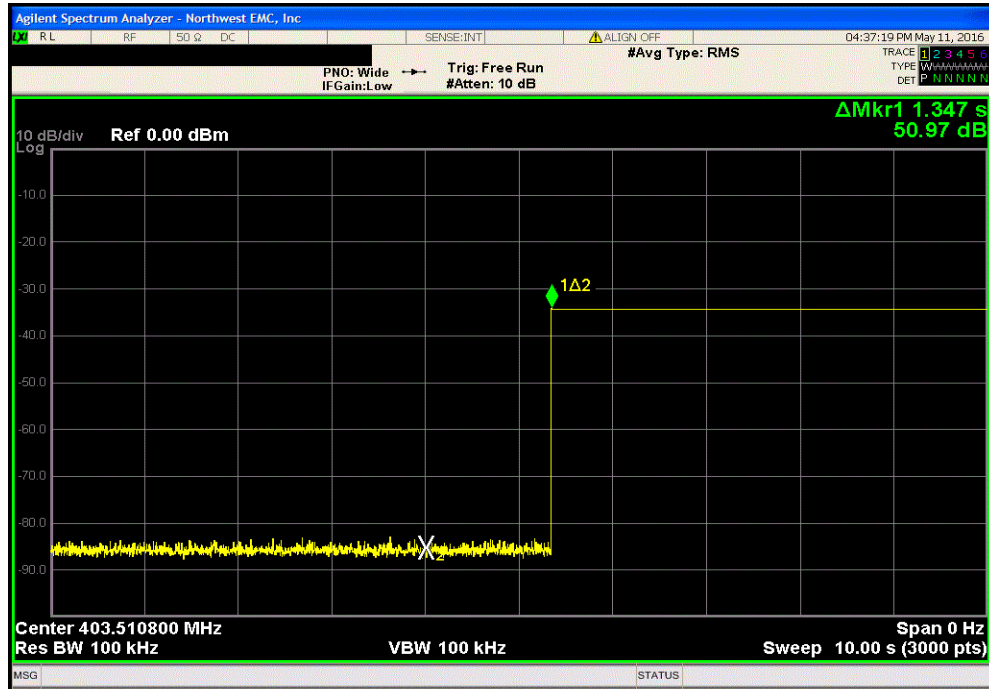


XMR 2015.01.14

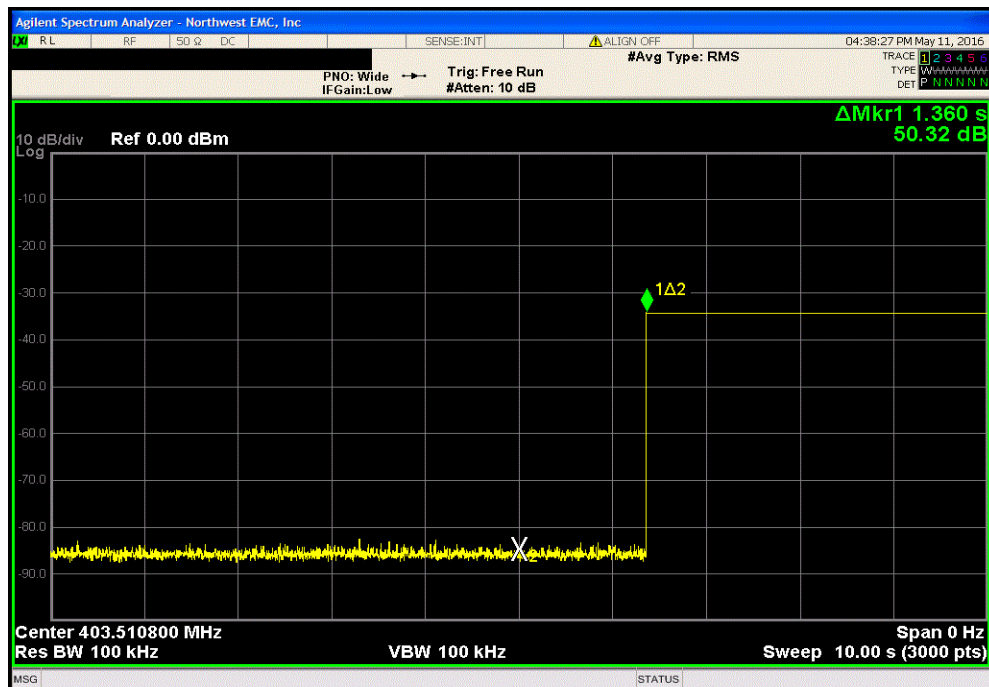
EUT: Emblem 3200 Programmer		Work Order: BSTN0636	
Serial Number: 3200-A103225		Date: 05/11/16	
Customer: Boston Scientific Coporation		Temperature: 22.4°C	
Attendees: Pete Musto		Humidity: 40%	
Project: None		Barometric Pres.: 986.8 mbar	
Tested by: Jared Ison	Power: 110VAC/60Hz	Job Site: MN08	
TEST SPECIFICATIONS			
LP0002:2018		Test Method	
LP0002:2018		LP0002:2018	
COMMENTS			
EUT Bandwidth is 126000 Hz with antenna gain of -5 dBi. EUT only has two operational channels, , 402.8183 MHz and 403.5108 MHz.			
DEVIATIONS FROM TEST STANDARD			
None			
Configuration #	1	Signature 	
		Value (Seconds)	Limit <(Seconds) Result
Sample 1		1.347	5 Pass
Sample 2		1.36	5 Pass
Sample 3		1.174	5 Pass
Sample 4		1.347	5 Pass
Sample 5		1.097	5 Pass
Sample 6		1.204	5 Pass
Sample 7		1.26	5 Pass
Sample 8		1.254	5 Pass
Sample 9		1.14	5 Pass
Sample 10		1.14	5 Pass

MONITORING SYSTEM SCAN CYCLE TIME

Sample 1						
				Value (Seconds)	Limit <(Seconds)	Result
				1.347	5	Pass

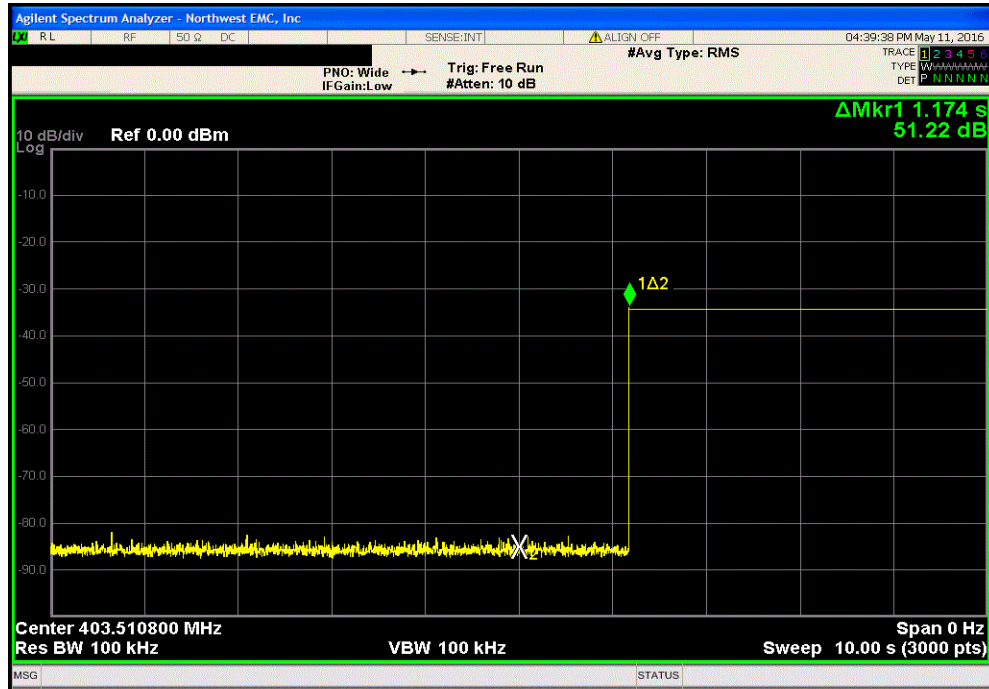


Sample 2						
				Value (Seconds)	Limit <(Seconds)	Result
				1.36	5	Pass

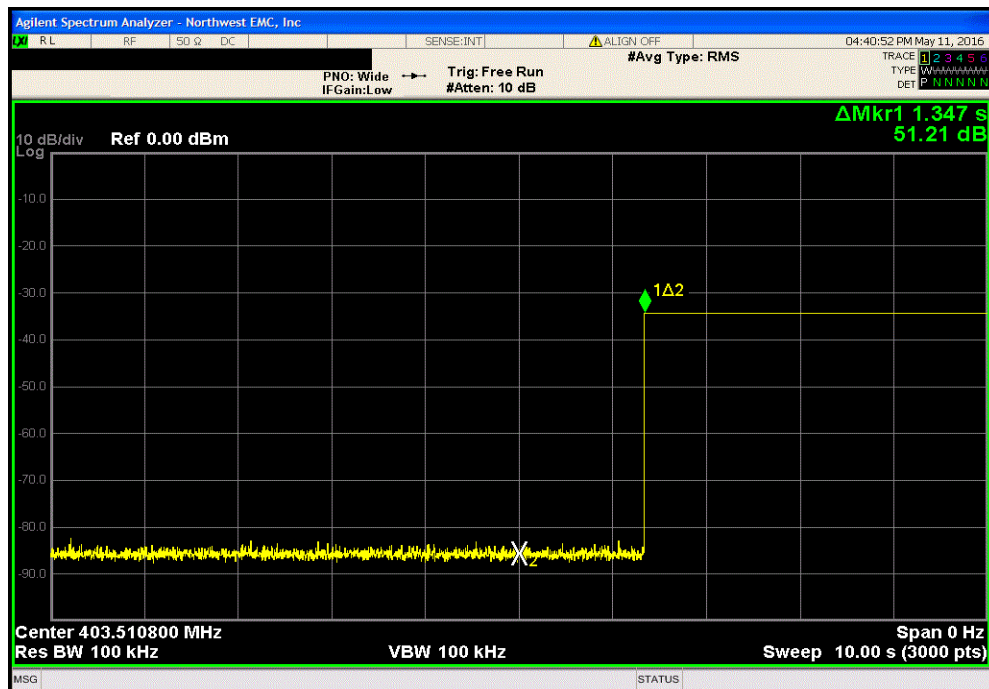


MONITORING SYSTEM SCAN CYCLE TIME

Sample 3						
				Value (Seconds)	Limit <(Seconds)	Result
				1.174	5	Pass

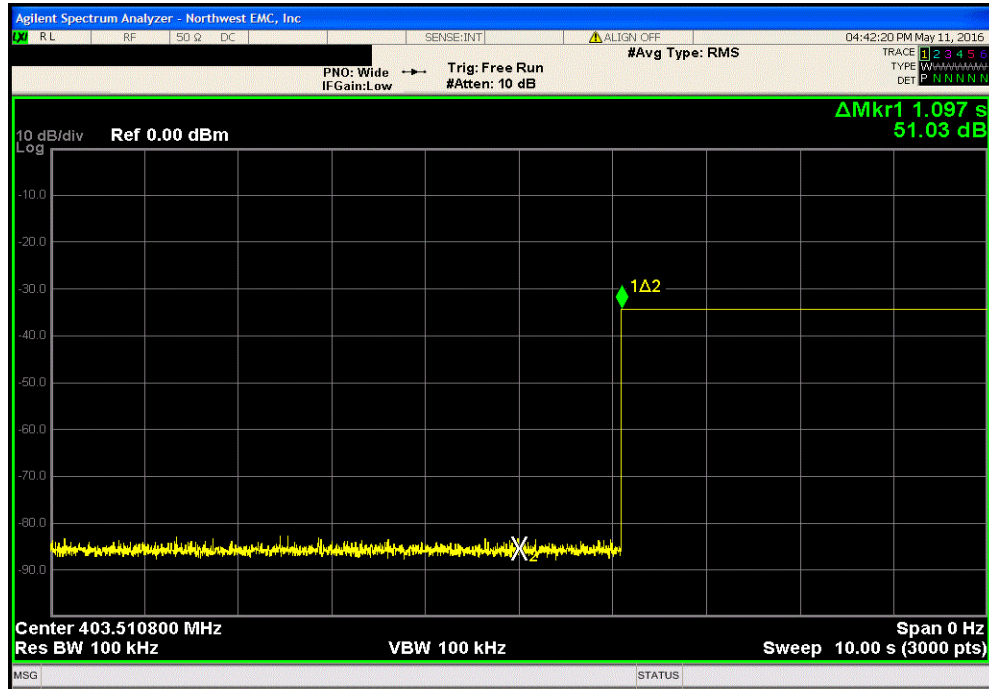


Sample 4						
				Value (Seconds)	Limit <(Seconds)	Result
				1.347	5	Pass

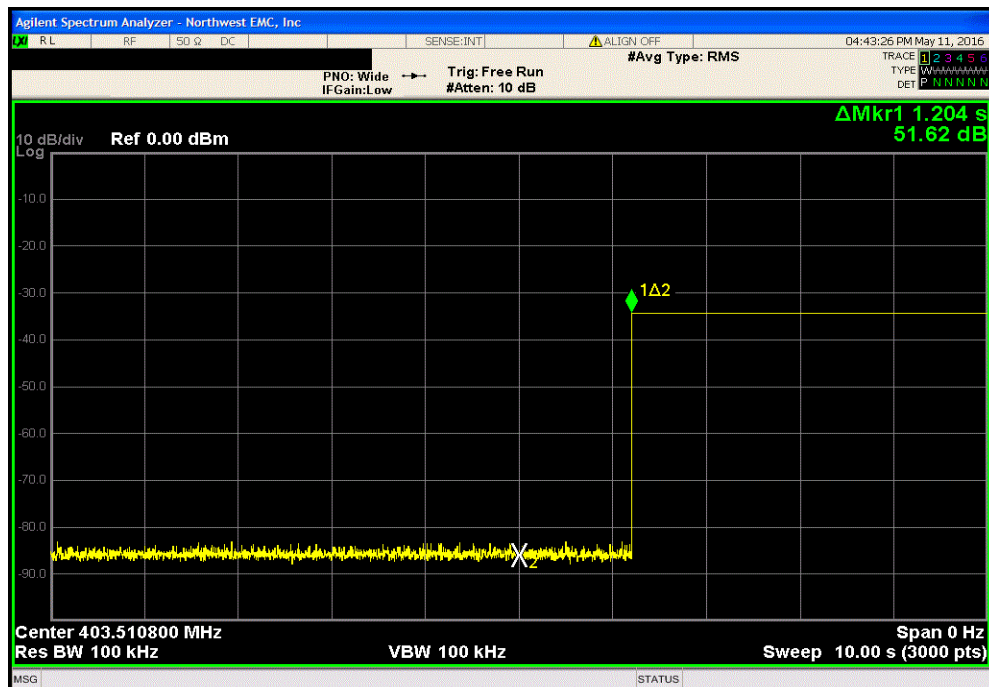


MONITORING SYSTEM SCAN CYCLE TIME

Sample 5						
				Value (Seconds)	Limit <(Seconds)	Result
				1.097	5	Pass



Sample 6						
				Value (Seconds)	Limit <(Seconds)	Result
				1.204	5	Pass



**NORTHWEST
EMC**

XMit 2015.01.14

Agilent Spectrum Analyzer - Northwest EMC, Inc.

RL RF 50 Q DC SENSE:INT ALIGN OFF 04:44:34 PM May 11, 2016

PNO: Wide Trg: Free Run #Avg Type: RMS
IFGain:Low #Atten: 10 dB

TRACE 1 2 3 4 5 6
TYPE W W W W W W
DET 2 1 1 1 1 1

10 dB/div Ref 0.00 dBm
Log

Δ Mkr1 1.260 s
51.27 dB

1A2

Center 403.510800 MHz
Res BW 100 kHz

Span 0 Hz
Sweep 10.00 s (3000 pts)

MSG STATUS

Agilent Spectrum Analyzer - Northwest EMC, Inc.

04:45:37 PM May 11, 2016

SENSE:INT

ALIGN OFF

#Avg Type: RMS

TRACE 1 2 3 4 5 6

TYPE WXXXXXXXXXX

DET P NNNNN

PNO: Wide IFGain: Low

Trig: Free Run

#Atten: 10 dB

10 dB/div

Log

Ref 0.00 dBm

ΔMkr1 1.254 s

51.21 dB

1Δ2

Center 403.510800 MHz

Res BW 100 kHz

VBW 100 kHz

Sweep 10.00 s (3000 pts)

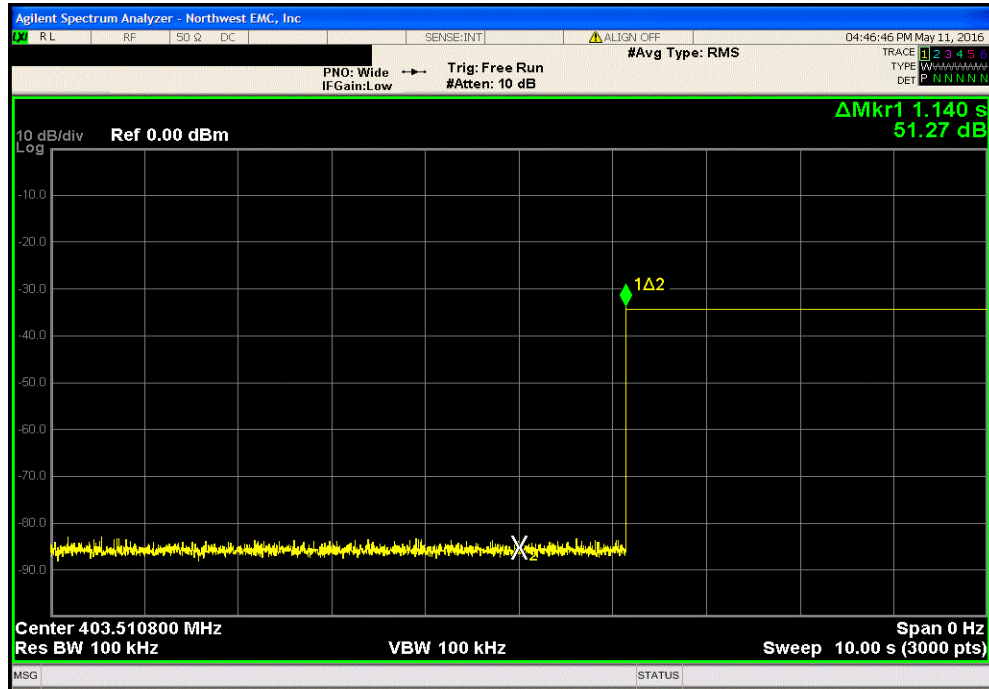
Span 0 Hz

MSG

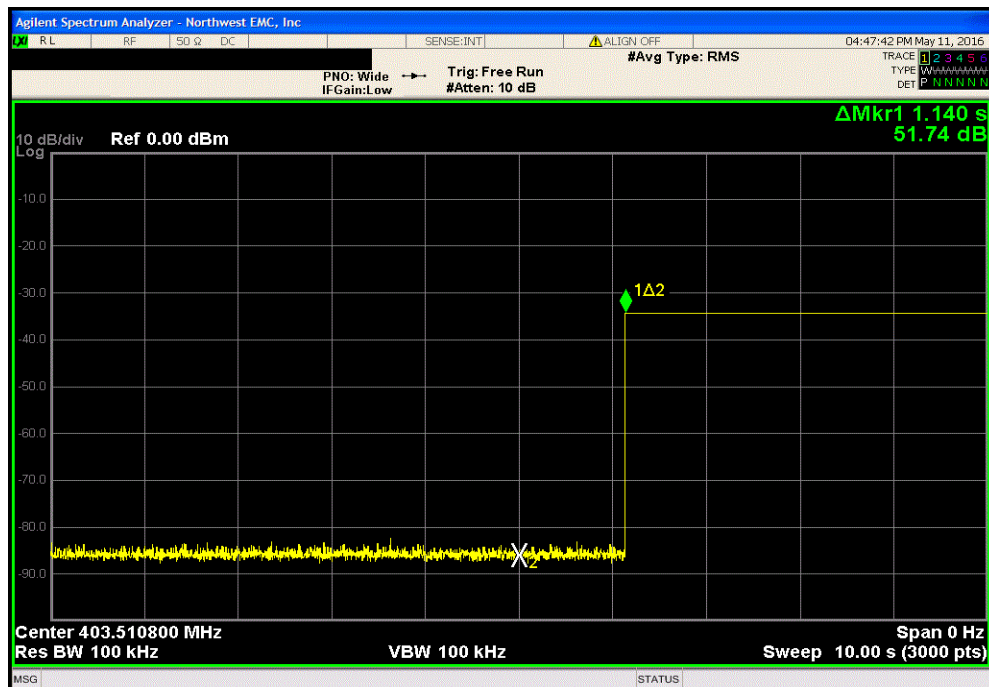
STATUS

MONITORING SYSTEM SCAN CYCLE TIME

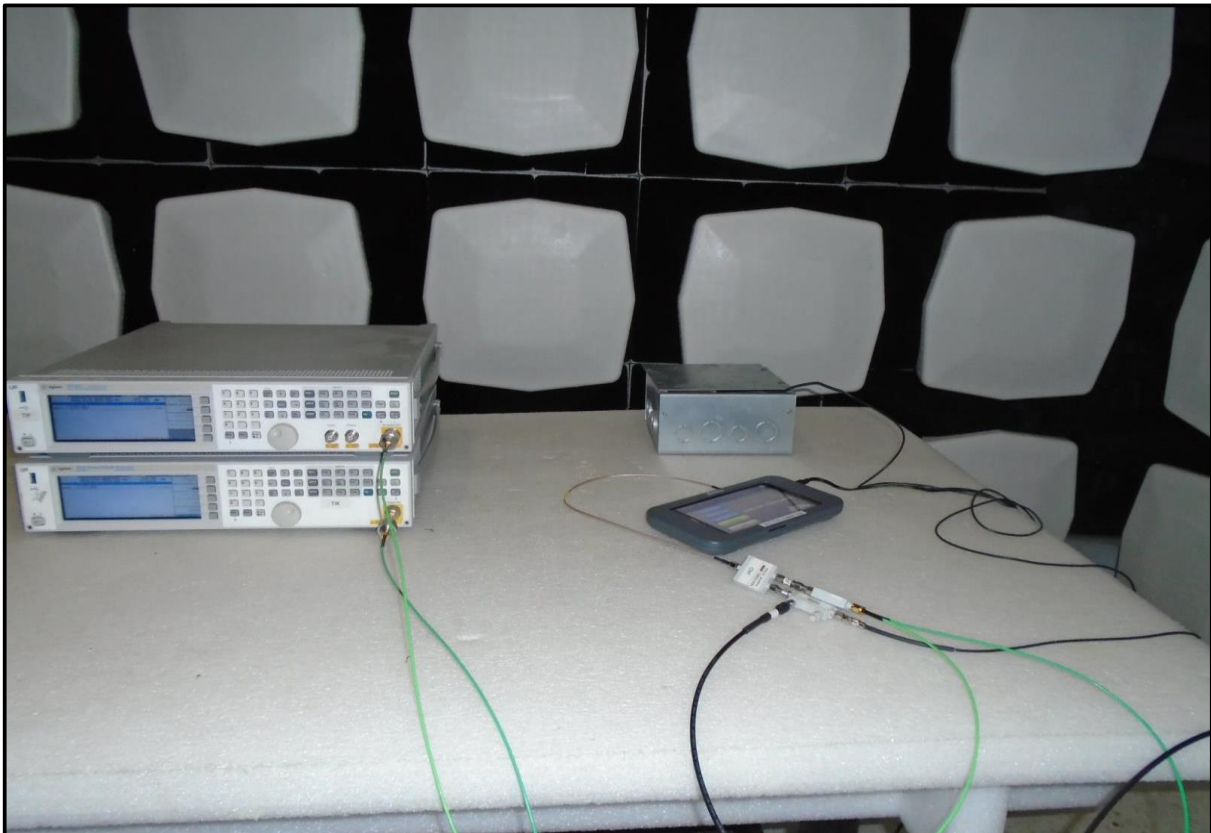
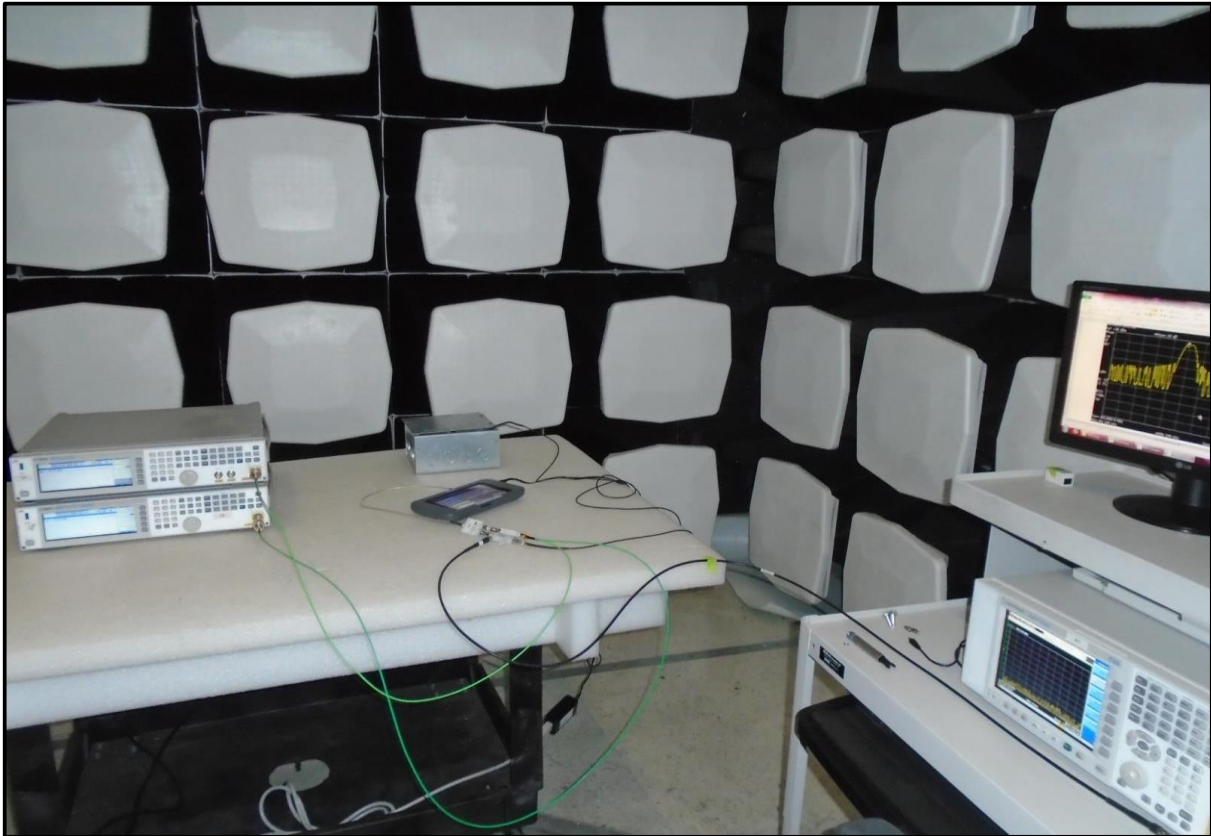
Sample 9						
				Value (Seconds)	Limit <(Seconds)	Result
				1.14	5	Pass



Sample 10						
				Value (Seconds)	Limit <(Seconds)	Result
				1.14	5	Pass



MONITORING SYSTEM SCAN CYCLE TIME



MONITORING SYSTEM SCAN CYCLE TIME



CHANNEL ACCESS BASED ON AMBIENT LEVELS

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.

TEST EQUIPMENT

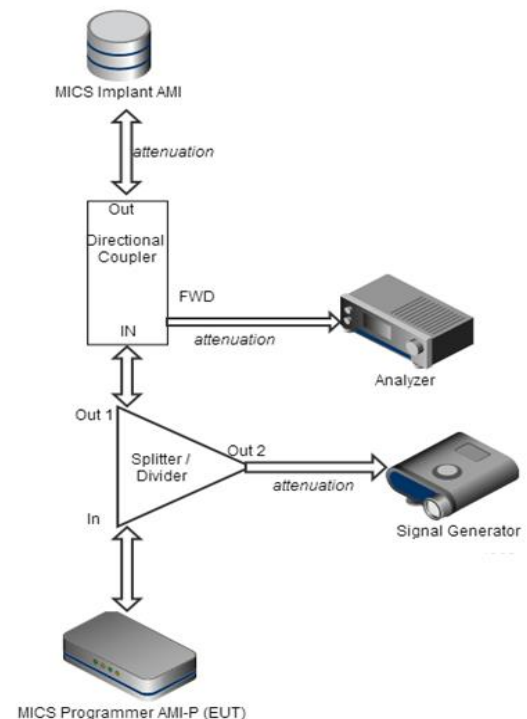
Description	Manufacturer	Model	ID	Last Cal.	Interval (mo)
Generator - Signal	Agilent	N5183A	TIK	10/17/2014	36
Generator - Signal	Agilent	N5182A	TIF	8/12/2014	36
Power Divider/Combiner	Fairview Microwave Inc (SM electronics)	MP8451-2	IAC	NCR	0
Directional Coupler	Fairview Microwave	MC2047-10	RGQ	NCR	0
Power Divider/Combiner	Fairview Microwave Inc (SM electronics)	MP8451-2	IAD	NCR	0
Attenuator	S.M. Electronics	SA26B-20	RFW	2/26/2016	12
Block - DC	Fairview Microwave	SD3379	AMI	9/18/2015	12
Cable	ESM Cable Corp.	TTBJ141 KMKM-72	MNU	9/18/2015	12
Analyzer - Spectrum Analyzer	Agilent	N9010A	AFI	1/27/2016	12

TEST DESCRIPTION

The EUT was configured according to the following block diagram:

The intended frequency (F_c) was set to the LBT threshold - 3 dB. A least interfered channel (LIC) was set to the LBT threshold + 3 dB. The EUT was verified to transmit on F_c . The amplitude of F_c was then raised to the LBT threshold + 6 dB. The EUT was verified to transmit on LIC.

The spectrum analyzer was set to measure the transmit band of 402-405 MHz. Screen captures were provided to show the EUT behavior at the different LBT threshold levels.

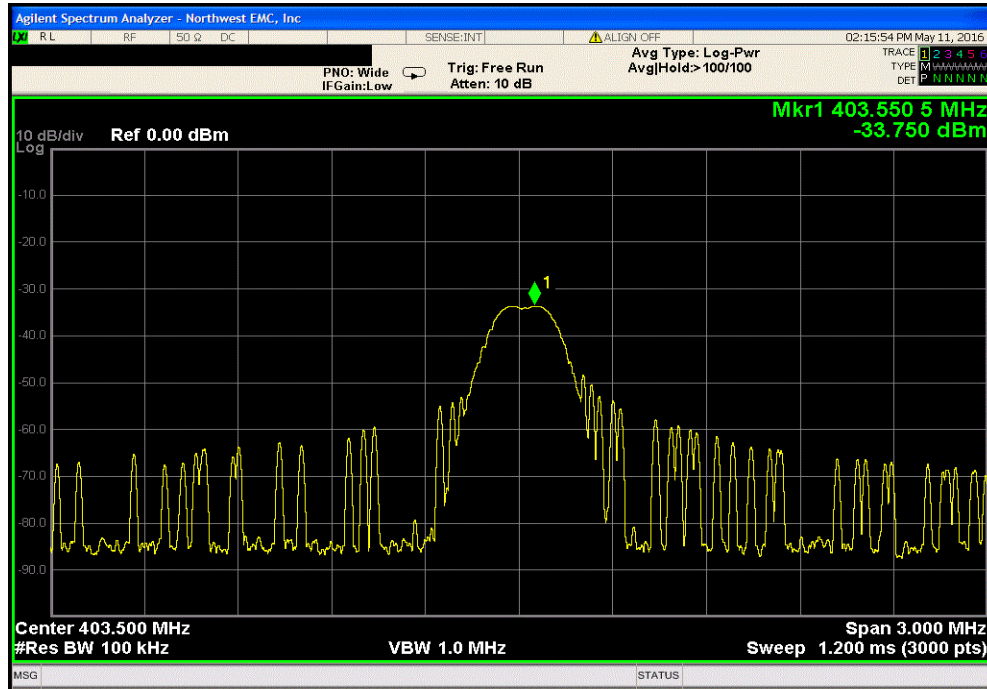


CHANNEL ACCESS BASED ON AMBIENT LEVELS

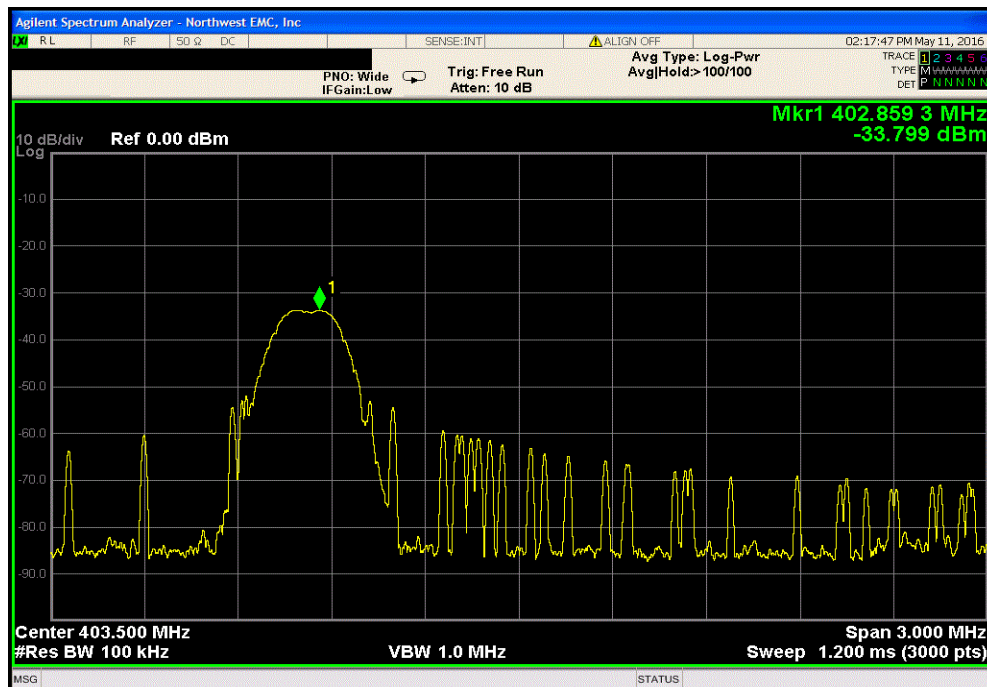
EUT: Emblem 3200 Programmer		Work Order: BSTN0636	
Serial Number: 3200-A103225		Date: 05/11/16	
Customer: Boston Scientific Coporation		Temperature: 22.4°C	
Attendees: Pete Musto		Humidity: 40%	
Project: None		Barometric Pres.: 986.8 mbar	
Tested by: Jared Ison	Power: 110VAC/60Hz	Job Site: MN08	
TEST SPECIFICATIONS		Test Method	
LP0002:2018		LP0002:2018	
COMMENTS			
EUT Bandwidth is 126000 Hz with antenna gain of -5 dBi. EUT only has two operational channels, , 402.8183 MHz and 403.5108 MHz.			
DEVIATIONS FROM TEST STANDARD			
None			
Configuration #	1	Signature 	
		Value	Limit
Fc LBT Threshold -3 dB		Yes	Yes
Fc LBT Threshold +6 dB		Yes	Yes
			Result
			Pass
			Pass

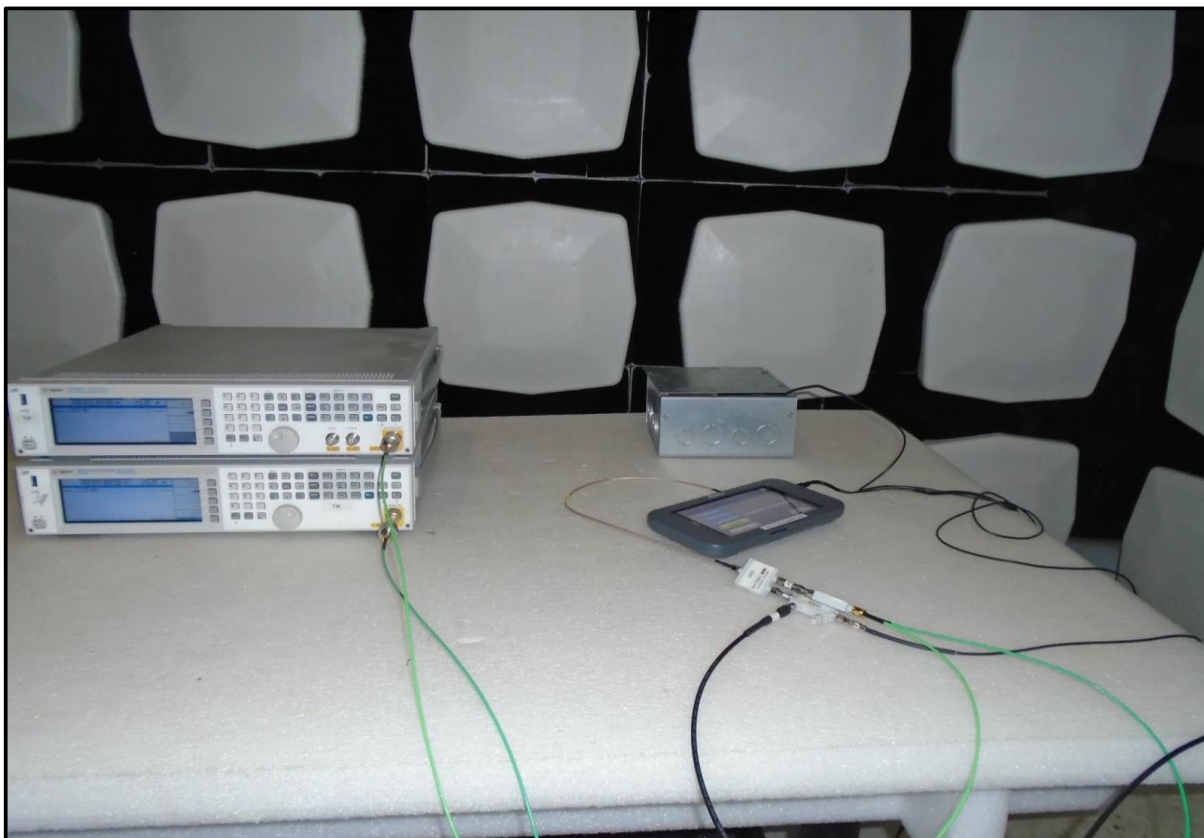
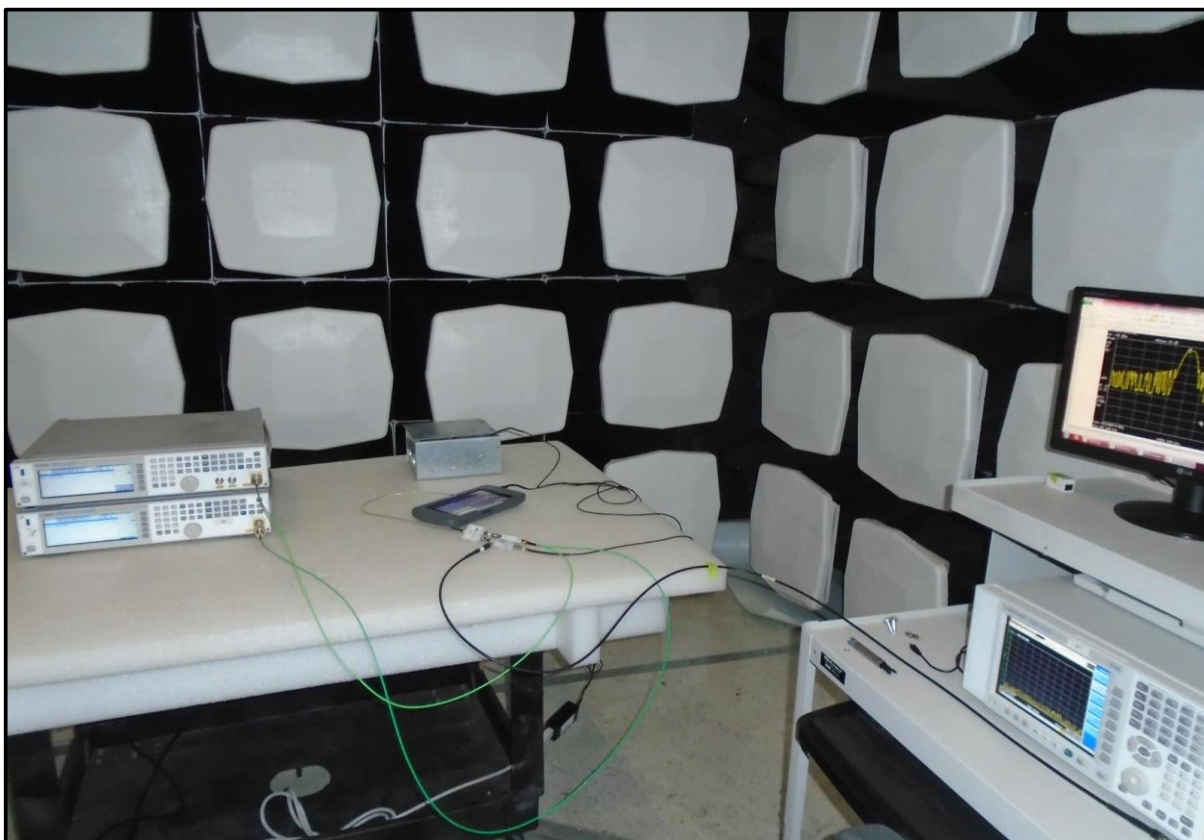
CHANNEL ACCESS BASED ON AMBIENT LEVELS

Fc LBT Threshold -3 dB						
				Value	Limit	Result
				Yes	Yes	Pass



Fc LBT Threshold +6 dB						
				Value	Limit	Result
				Yes	Yes	Pass





CHANNEL ACCESS BASED ON AMBIENT LEVELS



DISCONTINUATION OF A MICS SESSION

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.

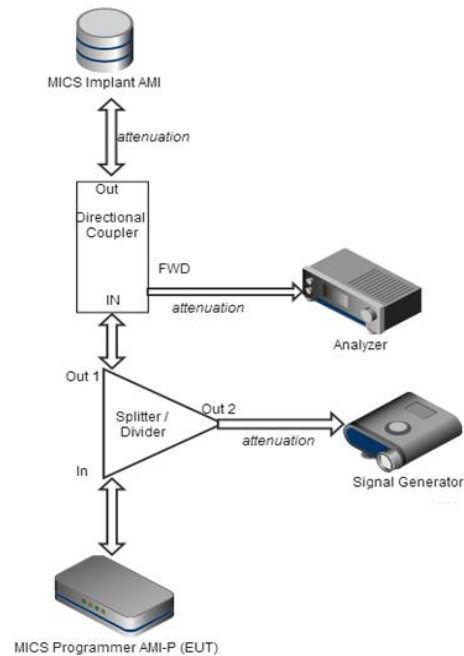
TEST EQUIPMENT

Description	Manufacturer	Model	ID	Last Cal.	Interval (mo)
Directional Coupler	Fairview Microwave	MC2047-10	RGQ	NCR	0
Power Divider/Combiner	Fairview Microwave Inc (SM electronics)	MP8451-2	IAD	NCR	0
Power Divider/Combiner	Fairview Microwave Inc (SM electronics)	MP8451-2	IAC	NCR	0
Generator - Signal	Agilent	N5182A	TIF	8/12/2014	36
Generator - Signal	Agilent	N5183A	TIK	10/17/2014	36
Block - DC	Fairview Microwave	SD3379	AMI	9/18/2015	12
Cable	ESM Cable Corp.	TTBJ141 KMKM-72	MNU	9/18/2015	12
Attenuator	S.M. Electronics	SA26B-20	RFW	2/26/2016	12
Analyzer - Spectrum Analyzer	Agilent	N9010A	AFI	1/27/2016	12

TEST DESCRIPTION

The EUT was configured according to the following block diagram:

The intended frequency (F_c) was set to the LBT threshold + 6 dB. A least interfered channel (LIC) was set to the LBT threshold + 3 dB. The spectrum analyzer was set to measure the time between the removal of the MICS Implant AMI to when the EUT does not transmit on the LIC.



DISCONTINUATION OF A MICS SESSION



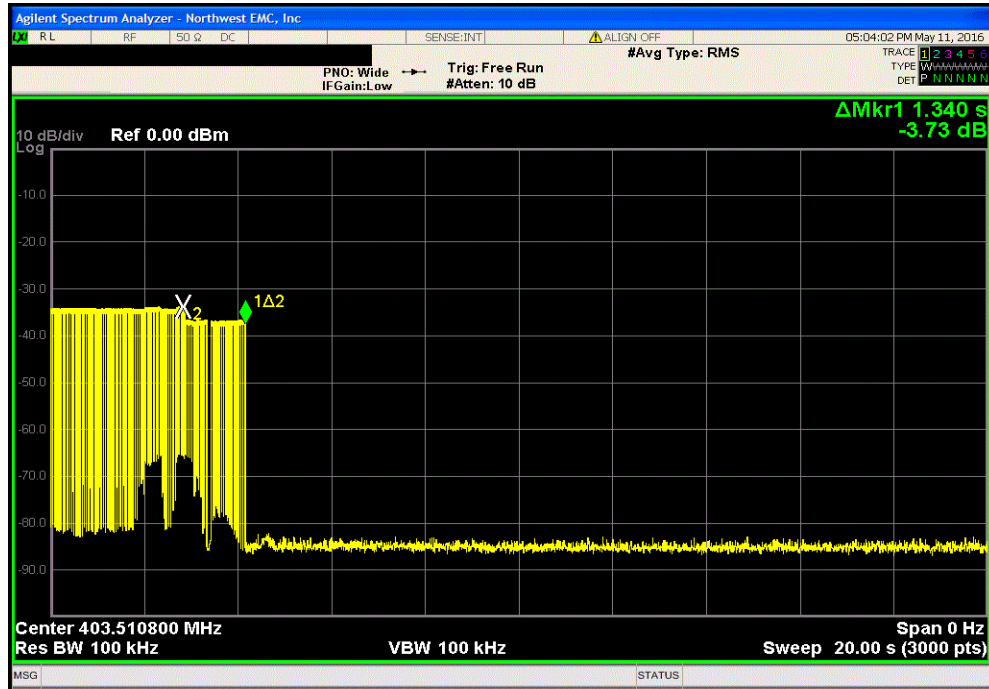
XMR 2015.01.14

EUT: Emblem 3200 Programmer		Work Order: BSTN0636	
Serial Number: 3200-A103225		Date: 05/11/16	
Customer: Boston Scientific Coporation		Temperature: 22.4°C	
Attendees: Pete Musto		Humidity: 40%	
Project: None		Barometric Pres.: 986.8 mbar	
Tested by: Jared Ison	Power: 110VAC/60Hz	Job Site: MN08	
TEST SPECIFICATIONS		Test Method	
LP0002:2018		LP0002:2018	
COMMENTS			
EUT Bandwidth is 126000 Hz with antenna gain of -5 dBi. EUT only has two operational channels, 402.8183 MHz and 403.5108 MHz.			
DEVIATIONS FROM TEST STANDARD			
None			
Configuration #	1	Signature 	
		Value (Second)	Limit <(Second) Result
		1.34	5 Pass

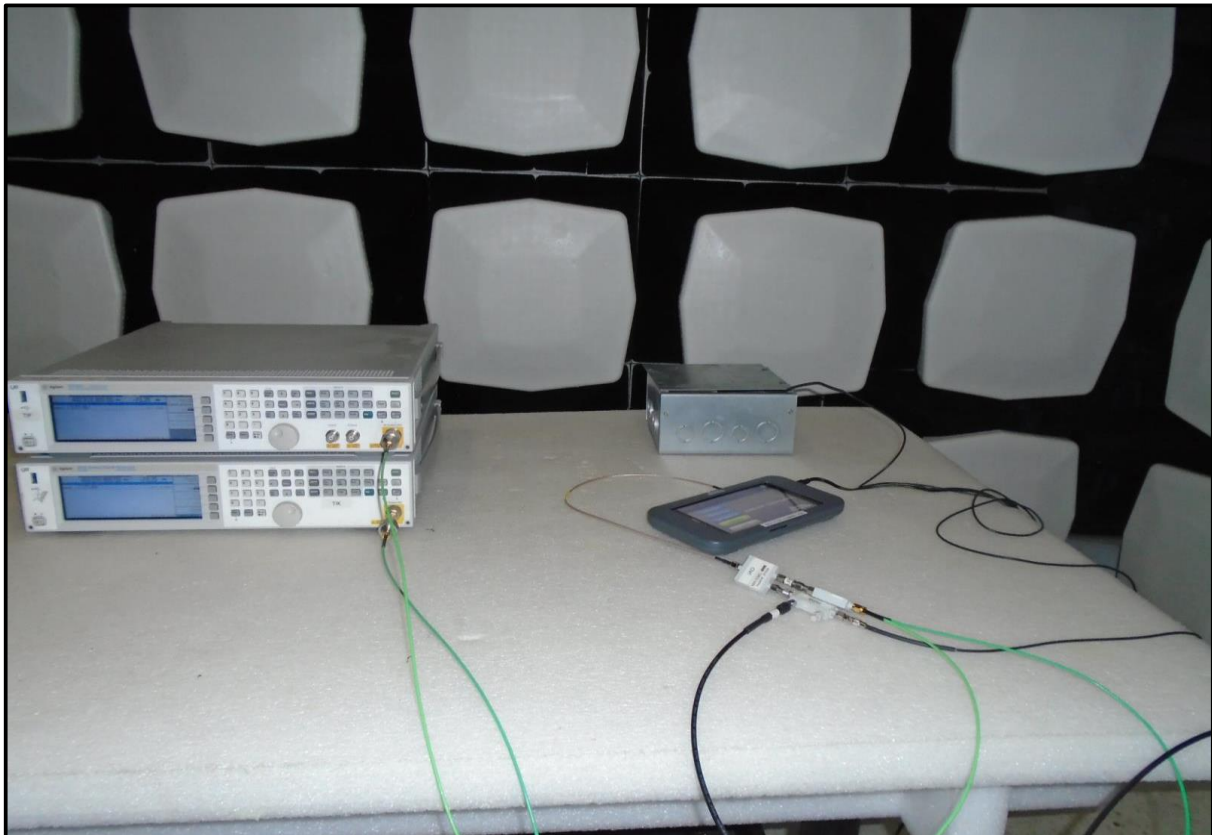
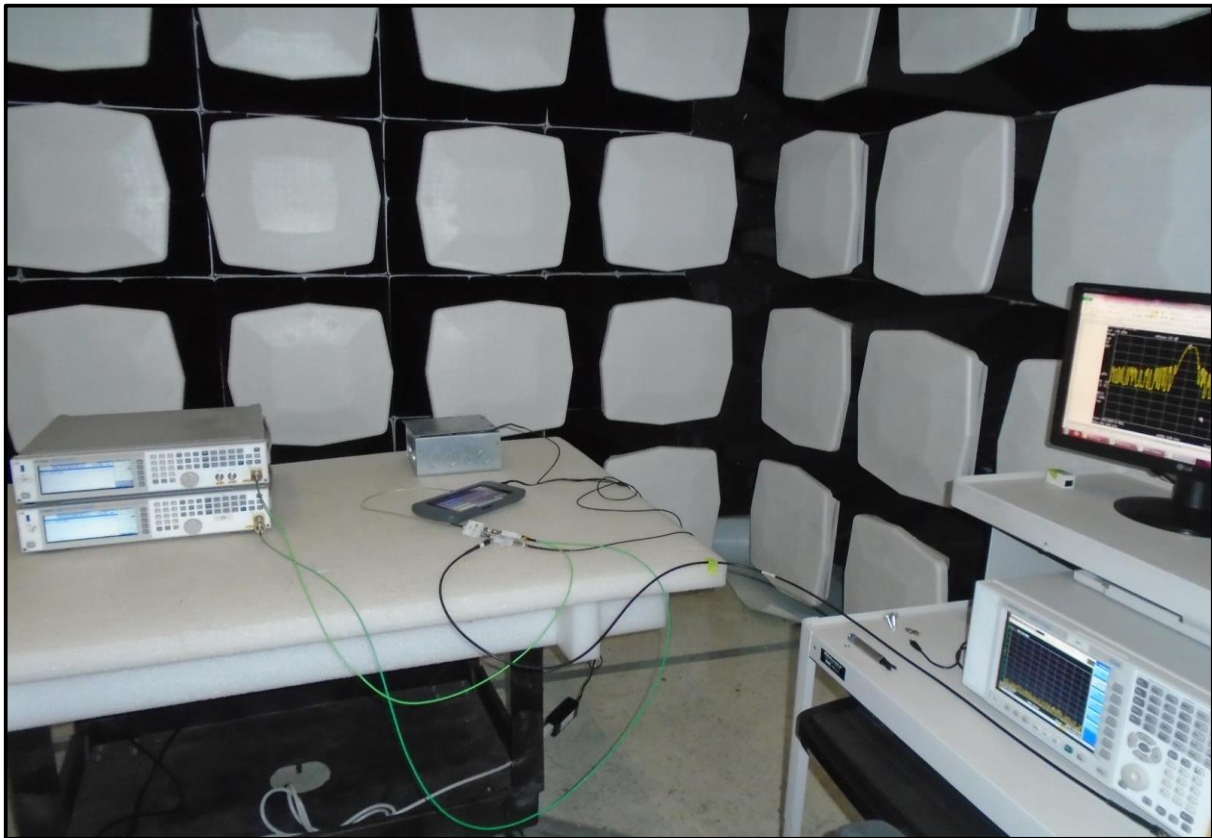
20 Second Sweep

DISCONTINUATION OF A MICS SESSION

20 Second Sweep						
				Value (Second)	Limit <(Second)	Result
				1.34	5	Pass



DISCONTINUATION OF A MICS SESSION



DISCONTINUATION OF A MICS SESSION



MINIMUM CHANNEL MONITORING PERIOD

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.

TEST EQUIPMENT

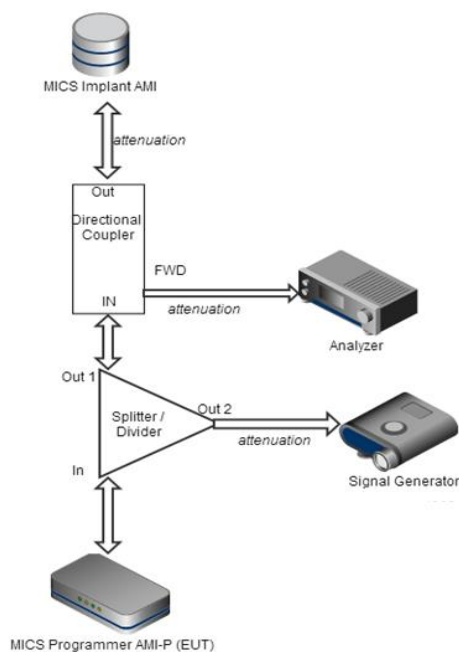
Description	Manufacturer	Model	ID	Last Cal.	Interval (mo)
Directional Coupler	Fairview Microwave	MC2047-10	RGQ	NCR	0
Generator - Signal	Agilent	N5183A	TIK	10/17/2014	36
Generator - Signal	Agilent	N5182A	TIF	8/12/2014	36
Power Divider/Combiner	Fairview Microwave Inc (SM electronics)	MP8451-2	IAD	NCR	0
Power Divider/Combiner	Fairview Microwave Inc (SM electronics)	MP8451-2	IAC	NCR	0
Attenuator	S.M. Electronics	SA26B-20	RFW	2/26/2016	12
Block - DC	Fairview Microwave	SD3379	AMI	9/18/2015	12
Cable	ESM Cable Corp.	TTBJ141 KMKM-72	MNU	9/18/2015	12
Analyzer - Spectrum Analyzer	Agilent	N9010A	AFI	1/27/2016	12

TEST DESCRIPTION

The EUT was configured according to the following block diagram:

The signal generator was set to CW operation to cause equal interference across the out of operation channel, except one channel (Fc) was left available. The CW operation (out of operation region) was also set to Pulse modulation with a Period of 10 mS, and a Pulse Width of 0.1 mS. The spectrum analyzer was set to measure the transmit band of 402-405 MHz.

The EUT was set to seek a session with the implantable device. The EUT was verified to connect on the available channel with multiple screen captures.



MINIMUM CHANNEL MONITORING PERIOD

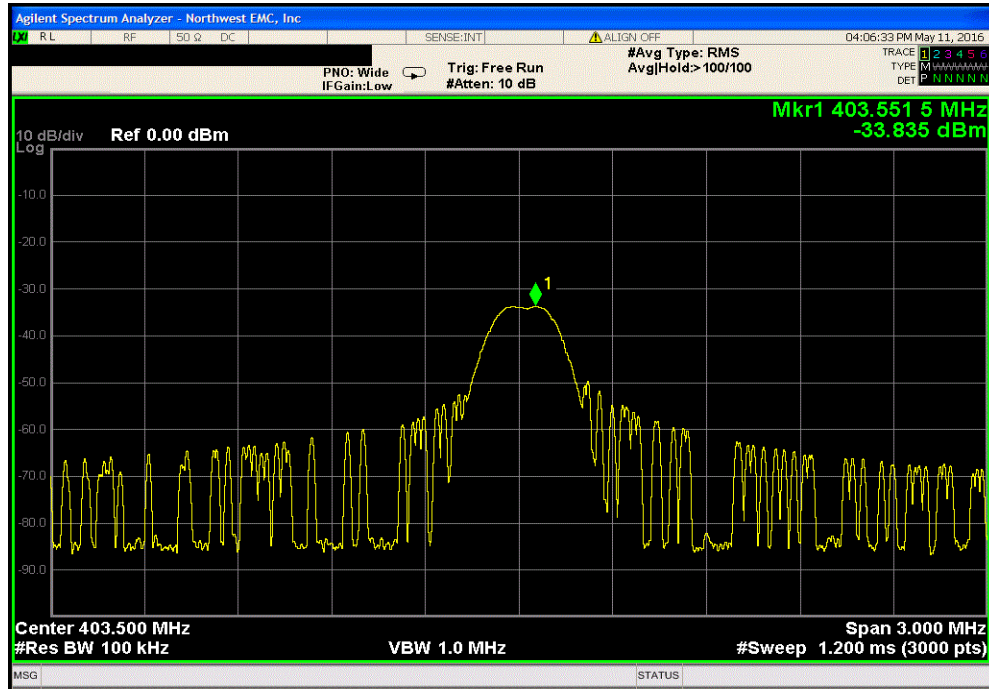


XMR 2015.01.14

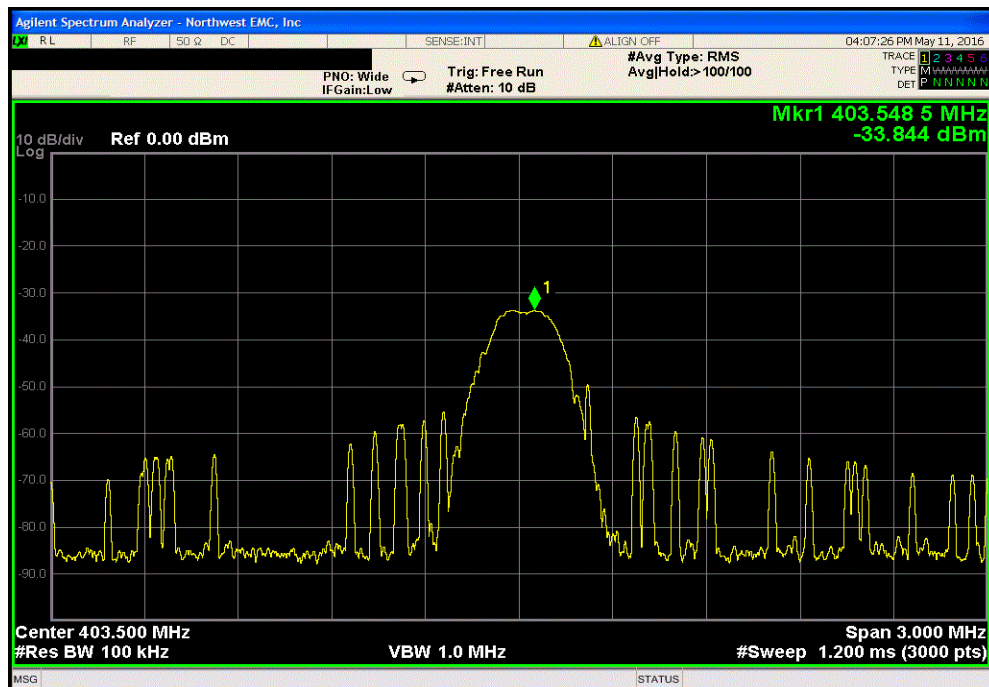
EUT: Emblem 3200 Programmer		Work Order: BSTN0636	
Serial Number: 3200-A103225		Date: 05/11/16	
Customer: Boston Scientific Coporation		Temperature: 22.4°C	
Attendees: Pete Musto		Humidity: 40%	
Project: None		Barometric Pres.: 986.8 mbar	
Tested by: Jared Ison	Power: 110VAC/60Hz	Job Site: MN08	
TEST SPECIFICATIONS			
LP0002:2018		Test Method	
LP0002:2018		LP0002:2018	
COMMENTS			
EUT Bandwidth is 126000 Hz with antenna gain of -5 dBi. EUT only has two operational channels, 402.8183 MHz and 403.5108 MHz.			
DEVIATIONS FROM TEST STANDARD			
None			
Configuration #	1	Signature 	
		Value	Limit
Sample 1		Yes	Yes
Sample 2		Yes	Yes
Sample 3		Yes	Yes
Sample 4		Yes	Yes
Sample 5		Yes	Yes
Sample 6		Yes	Yes
Sample 7		Yes	Yes
Sample 8		Yes	Yes
Sample 9		Yes	Yes
Sample 10		Yes	Yes
		Result	
		Pass	
		Pass	
		Pass	
		Pass	
		Pass	
		Pass	
		Pass	
		Pass	
		Pass	
		Pass	

MINIMUM CHANNEL MONITORING PERIOD

Sample 1						
				Value	Limit	Result
				Yes	Yes	Pass

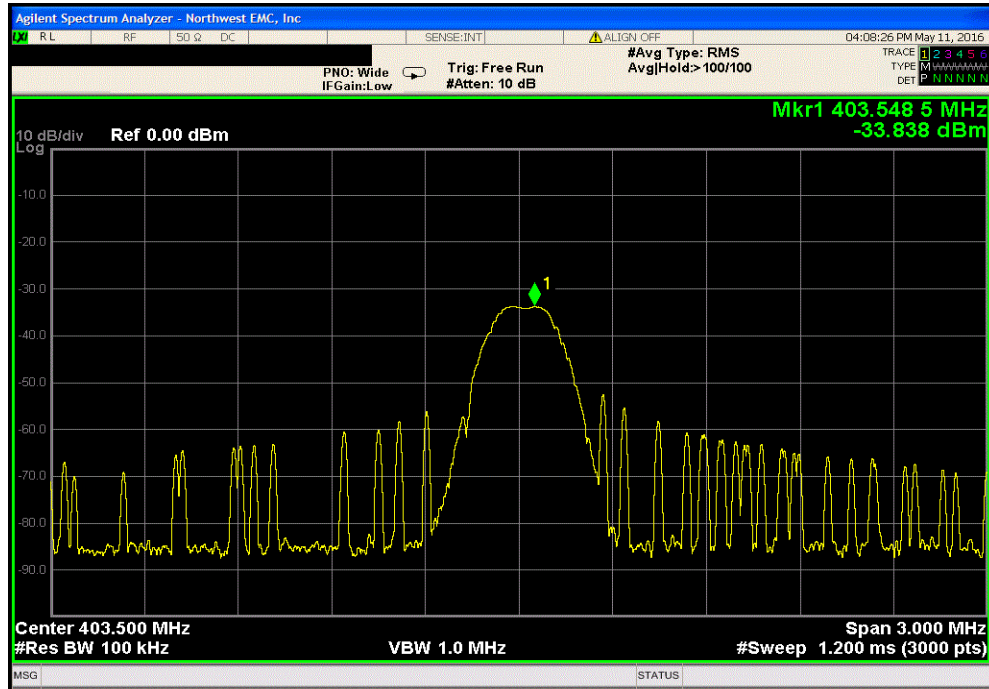


Sample 2						
				Value	Limit	Result
				Yes	Yes	Pass

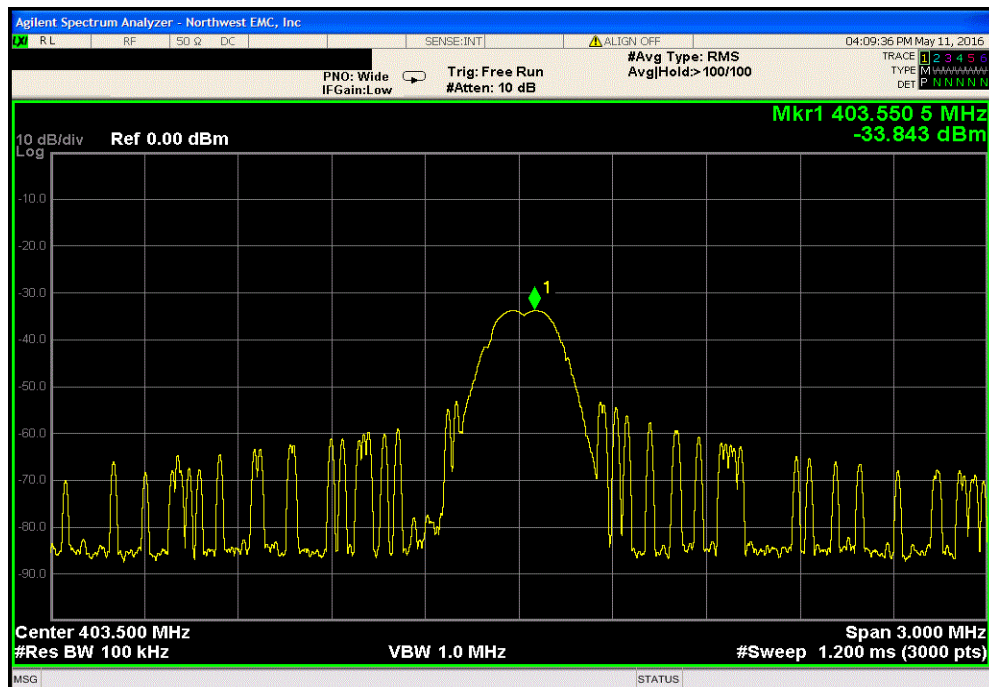


MINIMUM CHANNEL MONITORING PERIOD

Sample 3						
				Value	Limit	Result
				Yes	Yes	Pass

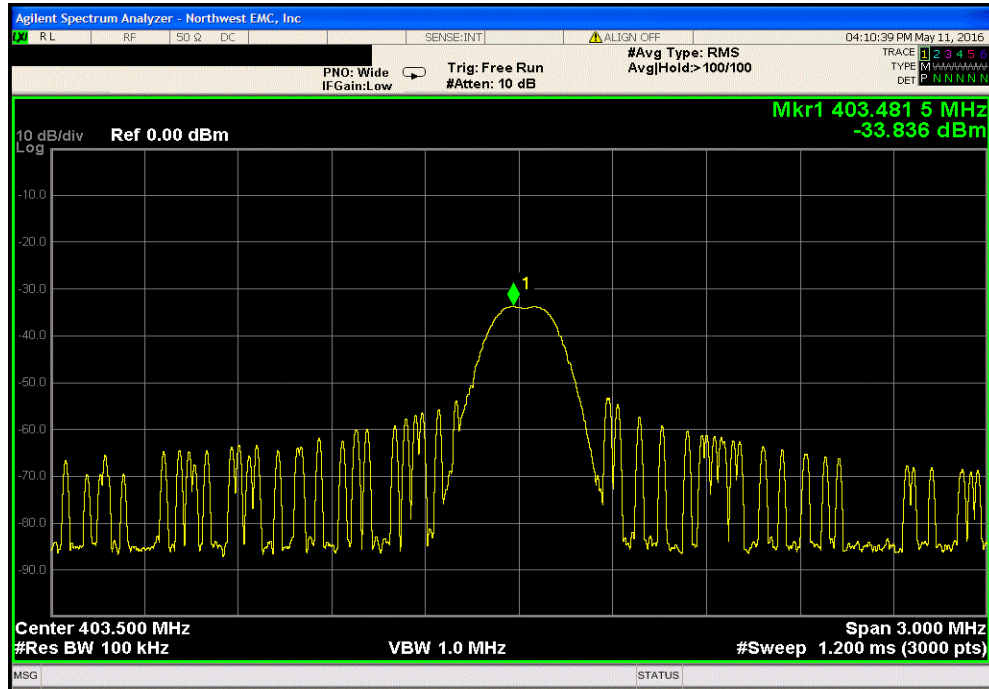


Sample 4						
				Value	Limit	Result
				Yes	Yes	Pass

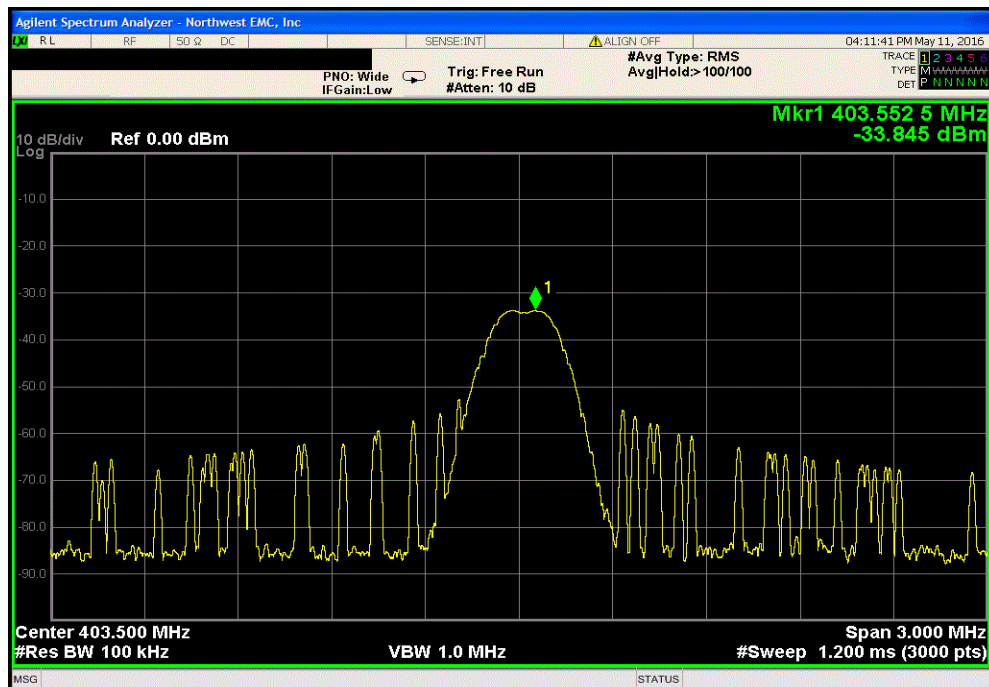


MINIMUM CHANNEL MONITORING PERIOD

Sample 5						
				Value	Limit	Result
				Yes	Yes	Pass

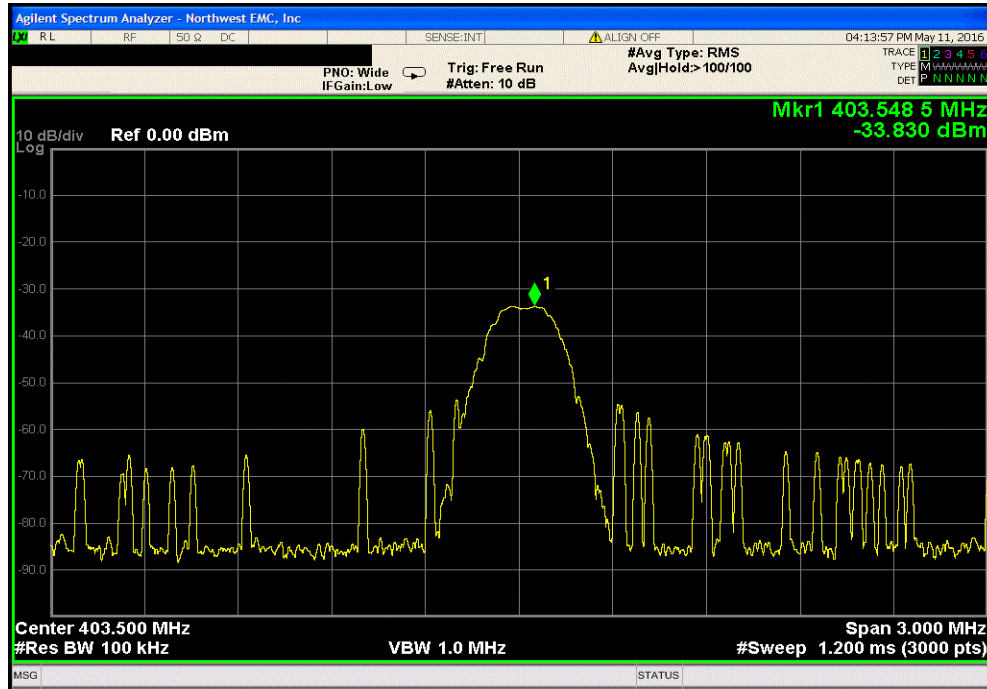


Sample 6						
				Value	Limit	Result
				Yes	Yes	Pass

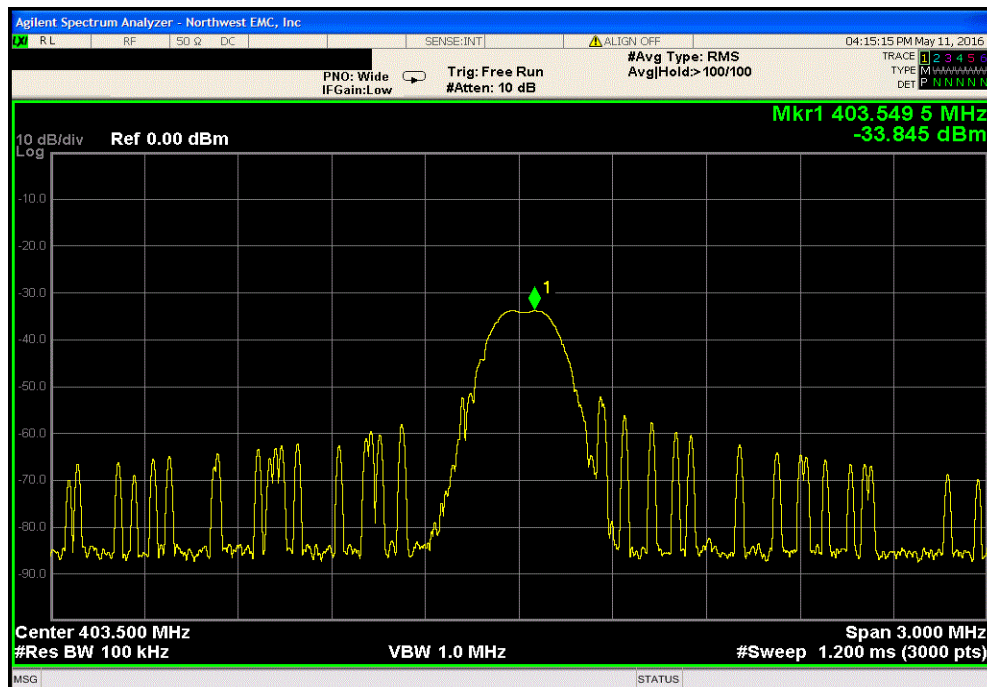


MINIMUM CHANNEL MONITORING PERIOD

Sample 7						
				Value	Limit	Result
				Yes	Yes	Pass

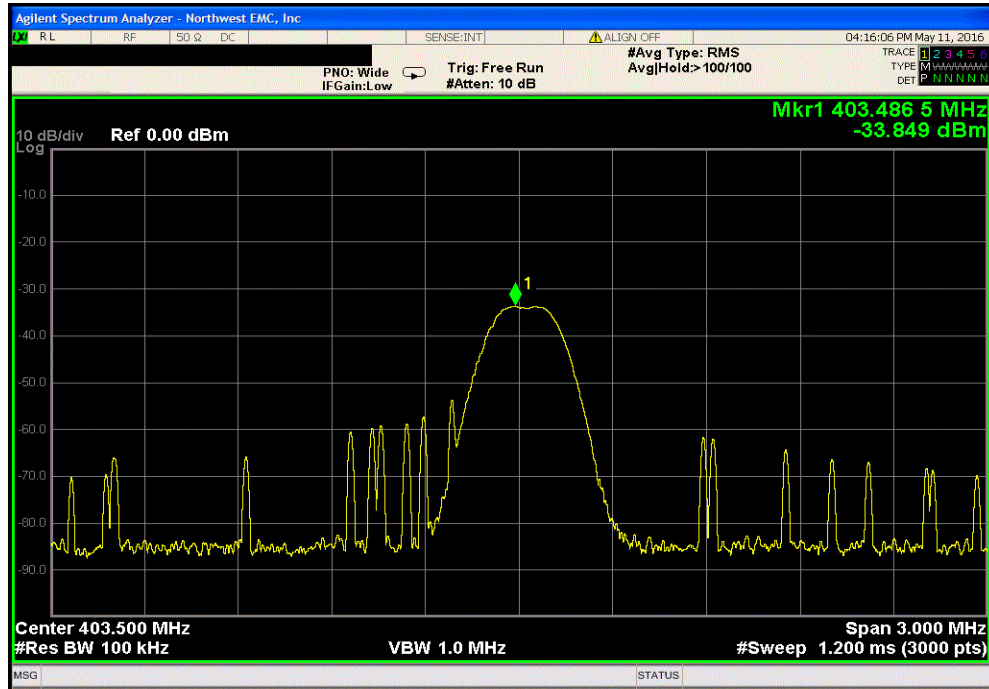


Sample 8						
				Value	Limit	Result
				Yes	Yes	Pass

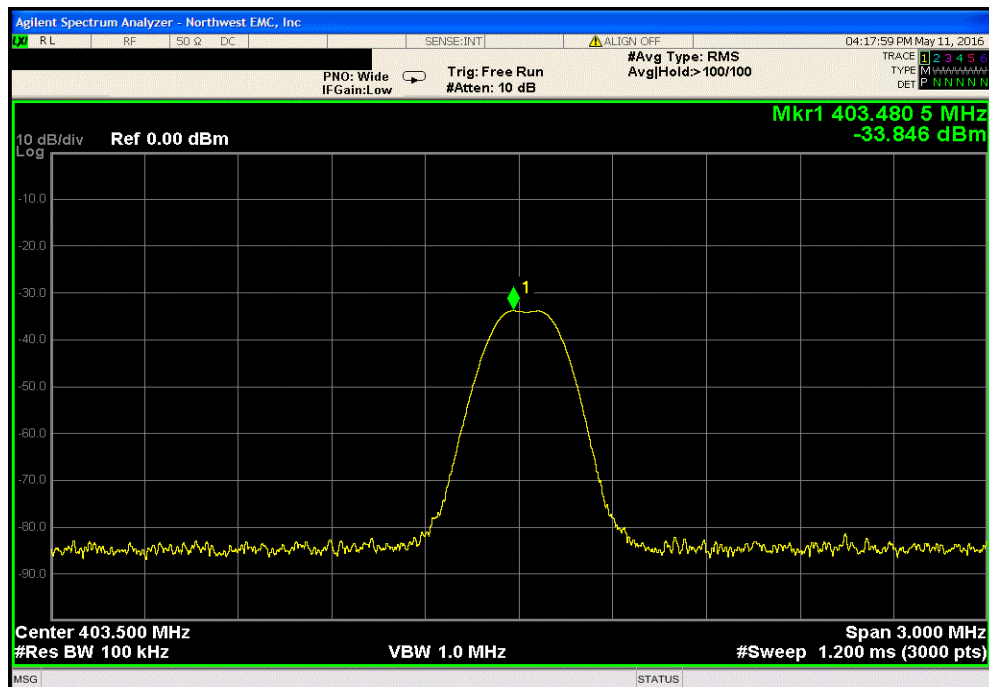


MINIMUM CHANNEL MONITORING PERIOD

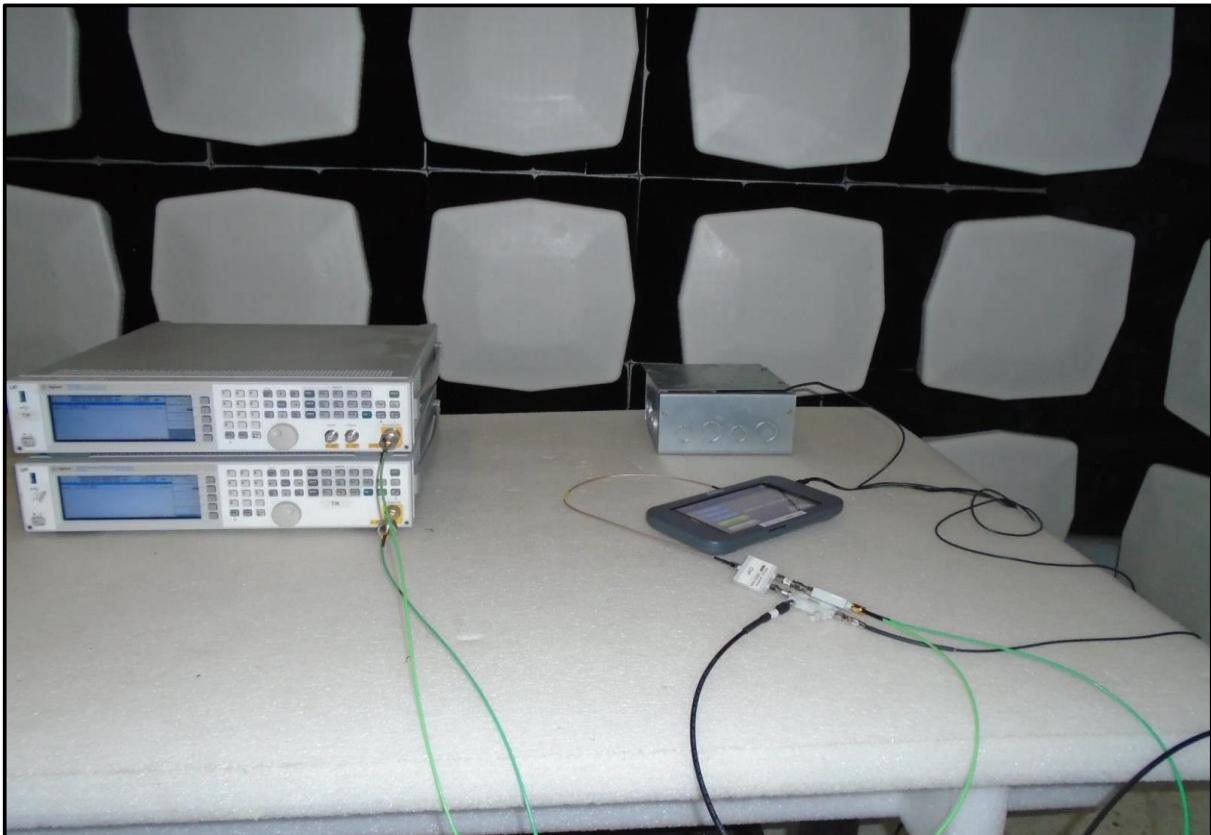
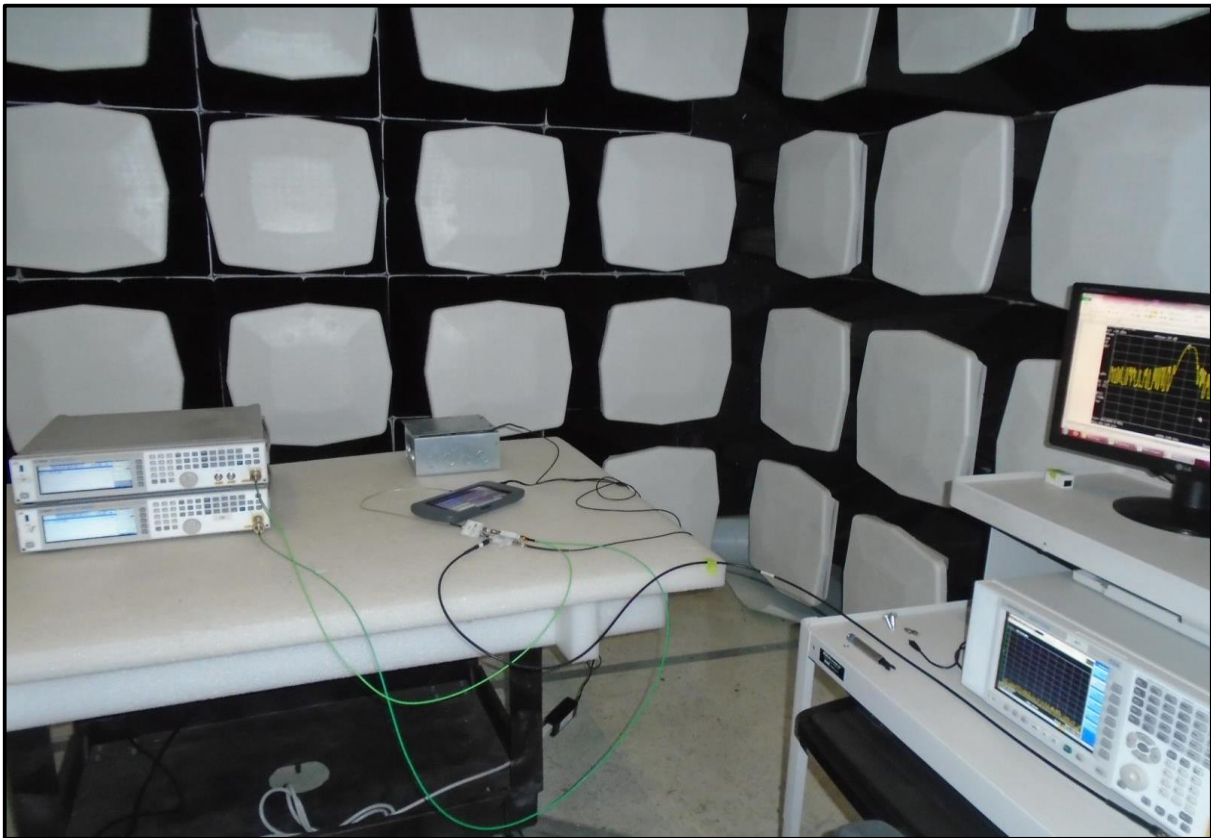
Sample 9						
				Value	Limit	Result
				Yes	Yes	Pass



Sample 10						
				Value	Limit	Result
				Yes	Yes	Pass



MINIMUM CHANNEL MONITORING PERIOD



MINIMUM CHANNEL MONITORING PERIOD

