Boston Scientific
Cardiac Rhythm Management

1122041

EDVT Protocol/Report

Listen Before Talk (LBT) MICS Compliance EMBLEM S-ICD Programmer

Model 3200

Rev B

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EXECUTIVE SUMMARY

This document describes the test results for the electrical design verification testing (EDVT) performed to demonstrate EMBLEM S-ICD Programmer, Model 3200, compliance with the relevant ETSI and FCC MICS LBT (Listen Before Talk) Requirements. This electrical design verification testing is part of a total system test plan that typically includes electromagnetic compatibility, radio compliance, electrical safety, and various functional tests. This testing is performed to ensure the Model 3200 Programmer radio meets the requirements of the EMBLEM S-ICD System Telemetry Requirements as well as the relevant portions of the FCC and ETSI MICS standards. These results along with additional radio testing completed for ETSI and FCC standards related to the 402-405 MHz MICS telemetry band will be used as part of the Model 3200 RF certifications/approvals.

RESULTS

All MICS LBT testing passed.

UNEXPECTED OBSERVATIONS

There were no unexpected observations.

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1 ABOUT THIS DOCUMENT

1.1 Scope

This document describes the test results for the electrical design verification testing (EDVT) performed to show EMBLEM S-ICD (Gen 2) Programmer, Model 3200, compliance with the MICS LBT (Listen Before Talk) Requirements.

The electrical design verification testing is part of a total system test plan that typically includes electromagnetic compatibility, modem, radio compliance, electrical safety, and various functional tests.

The electrical design verification testing is performed to ensure that the MICS LBT requirements of the Model 3200 Programmer are met as defined in the telemetry requirements specification 530467-001 entitled TELEMETRY SYSTEM REQT S-ICD GEN 2. This testing will also be used as part of the Model 3200 RF certifications/approvals.

The protocol used for the EDVT is a repeat of the protocol completed for the Cameron SMR 7.5 project (Refer to Agile Document DN-22613).

Additional radio testing is completed per 1122042 to support RF certifications/approvals.

1.2 Objective

This testing is intended to ensure that the Model 3200 Programmer complies with the LBT requirements outlined in the various radio regulatory standards. Successful completion of this EDVT will be used to support Model 3200 Programmer radio compliance in the MICS band.

1.3 Revision History

Table 1 Revision History

Revision	Description of change	Author
A	New document - Protocol	Peter Musto
B	Added Test Results - Report	Peter Musto

1.4 Device Description

The Model 3200 Programmer is an external AC/battery powered device that communicates with implantable S-ICD devices via an RF link during implant procedures and device follow-ups. The device has a programmable RF section to support telemetry with the implantable device in the global MICS RF band (402-405 MHz).

1.5 Terminology

The following are the list of acronyms used throughout this document or in the reference documents.

Table 2 List of Acronyms

Acronym	Definition
BSC	Boston Scientific Corporation
°C	Degrees Celsius
CFR	Code of Federal Regulations
CRM	Cardiac Rhythm Management
dB	Decibel
dBi	Decibels with respect to an isotropic antenna
dBm	Decibel with respect to 1 milliwatt
DUT	Device Under Test
EDVT	Electrical Design Verification Testing
EIRP	Equivalent Isotropic Radiated Power
EN	European Standard
ERM	Electromagnetic compatibility and Radio spectrum Matters
ERP	Effective Radiated Power
ESD	Electrostatic Discharge
ETSI	European Telecommunications Standards Institute
EU	Europe
FCC	Federal Communications Commission
FSK	Frequency-Shift-Keying
Hz	Hertz
IC	Industry Canada
kbps	Kilobits per second
kHz	Kilohertz
LBT	Listen Before Talk
LIC	Least Interfered Channel
MedRadio	Same as MICS
MHz	Megahertz
MIC	Ministry of Internal affairs and Communications (Japan)
MICS	Medical Implant Communications Service
ms	Milli-second
mW	Milliwatt
NA or N/A	Not Applicable
NWEMC	Northwest EMC
PG	Pulse Generator
PN or P/N	Part Number
R&TTE	Radiocommunications and Telecommunications Terminal Equipment
RF	Radio Frequency
RH	Relative Humidity
RSS	Radio Standards Specification (Canada)
RSSI	Received Signal Strength Indication
RX	Receive
s	second
S-ICD	Subcutaneous Implantable Defibrillator
SN or S/N	Serial Number
SW or S/W	Software
TBD	To Be Determined
TRP	Total Radiated Power
TX	Transmit

Acronym	Definition
ULP-AMI	Ultra Low Power Active Medical Implants
ULP-AMI-P	Ultra Low Power Active Medical Implants and Peripherals
USB	Universal Serial Bus
VAC	Volts Alternating Current
VDC	Volts Direct Current
V&V	Verification and Validation
W	Watt

1.6 BSC Reference Documents

These BSC documents are referenced directly or indirectly by this document:

Table 3 BSC Reference Documents

DOCUMENT RECORD	REV	DOCUMENT DESCRIPTION (TITLE)	ACRONYM
530467-001	*	TELEMETRY SYSTEM REQT S-ICD GEN 2	SYRS
DN-22613	*	SMR 7.5 Programmer MICS Compliance DVT Protocol	DVT
DN-22330	*	SMR 7.5 Programmer Listen Before Talk (LBT) MICS Compliance Report	DVT
DN-11691	*	Report - MICS Testing and Analysis Performed at Cameron Health Facilities	-
1122042	*	Protocol/Report EDVT Model 3200 Gen 2 MICS Compliance	DVT
1124844	*	SICD EMBLEM FCC 95I	-
1124845	*	SICD EMBLEM MIC ITEM 8 ARTICLE 2-1	-
1124891	*	SICD EMBLEM RSS-243	-
1124955	*	SICD EMBLEM EN 301 839-2	-

*Current revision shall apply for reference material.

Documents listed as “DN-XXXXX” are located in the Agile PDM system but will also be attached to the Windchill obkect for this report.

1.7 External Standards Reference Documents

These external standards and regulations are referenced directly or indirectly by this document:

Table 4 External Standards Reference Documents

DOCUMENT IDENTIFIER	DOCUMENT TITLE
AS/NZS 4268:2012	RADIO EQUIPMENT AND SYSTEMS - SHORT RANGE DEVICES - LIMITS AND METHODS OF MEASUREMENT
ETSI EN 301 839-1 V1.3.1:2009	ELECTROMAGNETIC COMPATIBILITY AND RADIO SPECTRUM MATTERS (ERM); SHORT RANGE DEVICES (SRD); ULTRA LOW POWER ACTIVE MEDICAL IMPLANTS (ULP-AMI) AND PERIPHERALS (ULP-AMI-P) OPERATING IN THE FREQUENCY RANGE 402 MHZ TO 405 MHZ; PART 1: TECHNICAL CHARACTERISTICS AND TEST METHODS
ETSI EN 301 839-2 V1.3.1:2009	ELECTROMAGNETIC COMPATIBILITY AND RADIO SPECTRUM MATTERS (ERM); SHORT RANGE DEVICES (SRD); ULTRA LOW POWER ACTIVE MEDICAL IMPLANTS (ULP-AMI) AND PERIPHERALS (ULP-AMI-P) OPERATING IN THE FREQUENCY RANGE 402 MHZ TO 405 MHZ; PART 2: HARMONIZED EN COVERING ESSENTIAL REQUIREMENTS OF ARTICLE 3.2 OF THE R&TTE DIRECTIVE
FCC CFR Title 47 Part 95:2014	PERSONAL RADIO SERVICES, PRS (218-219 MHZ FOR SUBSCRIBERS WITHIN A SPECIFIC AREA, CITIZENS BAND CB RADIO SERVICE 1-5 MILE RANGE FOR PERSONAL AND BUSINESS ACTIVITIES, FAMILY RADIO SERVICE FRS 1 MILE RANGE CITIZEN BAND SERVICE, GENERAL MOBILE RADIO SERVICE GMRS 5-25 MILE RANGE CITIZEN BAND SERVICE, LOW POWER RADIO SERVICE LPRS, MEDICAL IMPLANT COMMUNICATIONS SERVICE MICS, RADIO CONTROL RADIO SERVICE R/C, WIRELESS MEDICAL TELEMETRY SERVICE WMTS. 218-219 MHZ RADIO SERVICE THAT WAS FORMERLY IVDS.)

DOCUMENT IDENTIFIER	DOCUMENT TITLE
MIC 040527:2007	ORDINANCE REGULATING RADIO EQUIPMENT
RSS-243:2010	MEDICAL DEVICES OPERATING IN THE 401-406 MHZ FREQUENCY BAND

2 TEST APPROACH

2.1 Sample Size

The minimum sample size for testing performed within this EDVT protocol is based on the requirements of the external standards which drive the requirement.

Sample size for this entire protocol is one (1) as defined by the external standards

2.2 Device Under Test (DUT)

The device(s) under test for this test protocol were production equivalent. The Model 3200 programmer consists of an off-the-shelf tablet computer and a BSC custom designed radio board. There are two hardware versions of the Model 3200 programmer dependent on the model of tablet computer used within the device. The radio board includes the hardware and software required to perform the LBT algorithm. The radio board is the same for both versions of the Model 3200 Programmer. Since this is common to both versions of the programmer, the DVT protocol only needs to be performed for one version of the Model 3200 Programmer.

DUT					
DUT	**Description**	**Part Number**	**Rev**	**Serial #**	**Comment**
1	Assembly, Model 3200 – US PRB Application Version: 1.03	104474-2xx	A	3200-A103236	Used for protocol sections that rely on the PRB Tester Application
1	Assembly, Model 3200 – US Programmer Software Version: 3.03	104474-2xx	A	3200-A103241	Used for protocol sections that includes starting an RF telemetry session with an S-ICD.
1	Android OS for Verizon	104745-001	A	N/A	N/A
1	Power Supply, Programmer	104508-001	A	N/A	N/A
1	Wand, Telemetry, Model 3203	104781-001	A	N/A	Optional use for wireless system testing

2.3 Test Equipment

A partial list of the test equipment needed to perform this testing is listed here:

- Model A209 S-ICD
- RF Test Equipment (spectrum analyzer, signal generators, etc.)

Details of the test equipment information will be included Section 5.

2.4 Test Configuration

2.4.1 Test Configuration for LBT Compliance Testing

The DUT to PG test setup will be configured per Section 6 for this protocol.

2.4.2 Signal Level Calibrations

All signal levels referenced in this protocol will be calibrated to the RF input of the DUT.

2.5 Configuring the DUT for Test

The following is a description of how to configure the DUT for test.

2.5.1 Programmer Setup – PRB Tester Application

To configure the programmer for MICS LBT compliance testing using the PRB Tester application, complete the steps below.

NOTE: The DUT should be configured with the PRB Tester Application for this section.

1. Connect the programmer and supplied AC/DC power adapter to AC mains.
2. Power on the programmer by holding the power button until the device shows the power on splash screen.
3. From the applications menu, select the “Android PRB” application.
4. Select “PRB Tester (PRB Attached)” button.
5. Select the “Calibrate” button to get the CC1020/PRB into a known state. The application should respond with “Calibration Complete.”

2.5.2 LBT Read

To configure the programmer to perform an LBT read, complete the following steps using the PRB Tester Application:

1. Select the “Registers” Button.
2. Select the “LBT” Button.
3. Record the LBT results displayed in the device log at the bottom of the PRB Tester Application screen.

2.5.3 Programmer Setup – Programmer Software Application (Telemetry Session)

To configure the programmer to start a telemetry session with an S-ICD PG, complete the steps below.

NOTE: The DUT should be configured with the Programmer Software Application for this section.

1. Connect the programmer and supplied AC/DC power adapter to AC mains.
2. Power on the programmer by holding the power button until the device shows the power on splash screen. Wait for the device to display the S-ICD System menu.

2.6 Standard Test Conditions and Configurations

2.6.1 Model 3200 Power Source

The Model 3200 Programmer is powered by an AC/DC Power Supply or the device internal battery. The AC/DC power supply (104508-001) can be connected to AC mains voltage of 100-240 VAC and 50/60 Hz. The programmer radio board is supplied by an internal voltage regulator. The radio board voltage regulator output level is independent of the Model 3200 power source (AC Mains or battery). Therefore testing per this protocol will be performed for only one power supply combination (110 VAC/ 60 Hz).

2.6.2 Temperature and Humidity

All tests are performed at an ambient room temperature of typically 23ºC ± 5 ºC with uncontrolled humidity unless specified in the protocol sections below.

2.7 MICS Channelization

The device has a programmable RF section to support telemetry with the implanted device in the worldwide MICS RF band. The 2nd Generation MICS band telemetry system will consist of 2 channels as defined in Table 5. For the testing in this EDVT protocol, a blocking band will be set up using RF test equipment to apply RF energy in all channels except for Channel 0. The selection of the unblocked channel for testing is arbitrary. Using Channel 1 as the unblocked channel will provide similar results.

Table 5 BSC MICS Band Channelization

Channel	Frequency (MHz)
0	403.5108
1	402.818308

2.7.1 MICS LBT Algorithm Details

The Model 3200 Programmer will scan the two channels of the telemetry system and select the channel which has the lowest ambient signal level to start a telemetry session.

The LBT algorithm is included in two applications which will be used during this protocol.

- The PRB Tester Application provides a means to perform the LBT algorithm without starting a telemetry session with an S-ICD. This application performs the LBT scan on both channels, and outputs the measured signal level for both (in the form of an RSSI measurement from the RF transceiver) and the channel selected by the LBT algorithm. For protocol sections that verify the proper channel selection, the PRB Tester Application will be used.
- The Programmer Software Application provides a means to start an RF telemetry session with an S-ICD device. The LBT algorithm is integrated into this application. When a telemetry session is requested, the LBT scan is completed and the programmer initiates telemetry on the channel selected by the LBT algorithm. For protocol sections that verify timing parameters of the LBT algorithm, the Programmer Software Application will be used.

2.8 PG Emissions Bandwidth

The S-ICD PG transmit bandwidth data is included in 1124955. The maximum emissions bandwidth for the PG is listed in the NWEMC report BSTN0488.2 (attached to 1124955) as 126 kHz. The maximum emissions bandwidth is collected from the EN 301 839-2 report. This supports testing for all geographies/standards.

2.9 Programmer Emissions Bandwidth

The S-ICD programmer transmit bandwidth data is included in 1122042. The maximum emissions bandwidth for the programmer is listed in the NWEMC report BSTN0474.3 (attached to 1122042) as 101 kHz. The maximum emissions bandwidth is collected from the EN 301 839-2 report. This supports testing for all geographies/standards.

2.10 Handling Precautions

Care should be taken in the handling of the DUT. The signals found on the DUT and S-ICD PG are connected to Integrated Circuit (IC) devices that can be sensitive to Electro-Static Discharge (ESD). Wrist-straps should be worn whenever the DUT PCA is handled. The PCA should remain on an ESD-protective work surface until test procedures require it to be removed.

3 SUMMARY

3.1 Results Summary

A summary of the tests completed is shown in Table 6.

Table 6 Test Summary

Protocol/ Report Section	Description	Requirement	Protocol/Report Specification, Method, and Acceptance Criteria	Pass / Fail
4.1	LBT Threshold Power Level	530467-001: [1-010] 530467-001: [1-049]	FCC CFR Title 47 Part 95.627(a)(3) ETSI EN 301 839-1 V1.3.1 Clause 10.1 ETSI EN 301 839-2 V1.3.1 Clause 4.2.8.1 RSS-243 Clause 3.6 RSS-243 Clause 5.7.1 MIC 040527 Article 49.14.2d(1)	PASS
4.2	Monitoring System Bandwidth	530467-001: [1-009]	FCC CFR Title 47 Part 95.627(a)(1) ETSI EN 301 839-1 V1.3.1 Clause 10.2 ETSI EN 301 839-2 V1.3.1 Clause 4.2.8.1 RSS-243 Clause 3.6 RSS-243 Clause 5.7.2 MIC 040527 Article 49.14.2d(2)	PASS
4.3	Monitoring System Scan Cycle Time	530467-001: [1-041]	FCC CFR Title 47 Part 95.627(a)(2) ETSI EN 301 839-1 V1.3.1 Clause 10.3 ETSI EN 301 839-2 V1.3.1 Clause 4.2.8.1 RSS-243 Clause 3.6 RSS-243 Clause 5.7.3 MIC 040527 Article 49.14.2d(3)	PASS
4.4	Monitoring System minimum channel monitoring period	530467-001: [1-041]	FCC CFR Title 47 Part 95.627(a)(2) ETSI EN 301 839-1 V1.3.1 Clause 10.3 ETSI EN 301 839-2 V1.3.1 Clause 4.2.8.1 RSS-243 Clause 3.6 RSS-243 Clause 5.7.4 MIC 040527 Article 49.14.2d(3)	PASS
4.5	Channel access based on Least Interfered Channel	530467-001: [1-041]	FCC CFR Title 47 Part 95.627(a)(4) ETSI EN 301 839-1 V1.3.1 Clause 10.4 ETSI EN 301 839-2 V1.3.1 Clause 4.2.8.1 RSS-243 Clause 3.6 RSS-243 Clause 5.7.5 MIC 040527 Article 49.14.2d(1)	PASS
4.6	Discontinuation of MICS session	530467-001: [1-054]	FCC CFR Title 47 Part 95.627(a)(4) ETSI EN 301 839-1 V1.3.1 Clause 10.5 ETSI EN 301 839-2 V1.3.1 Clause 4.2.8.1 RSS-243 Clause 3.6 RSS-243 Clause 5.7.6 MIC 040527 Article 49.14.2e	PASS
4.7	Use of pre-scanned alternative channel	530467-001: [1-041]	FCC CFR Title 47 Part 95.627(a)(5) ETSI EN 301 839-1 V1.3.1 Clause 10.6 ETSI EN 301 839-2 V1.3.1 Clause 4.2.8.1 RSS-243 Clause 3.6 RSS-243 Clause 5.7.7 MIC 040527 Article 49.14.2d(4)	N/A The Model 3200 does not utilize the pre-scanned alternative channel option.

3.2 Requirements Traceability

Table 7 Requirements Traceability

Requirement	Description	Report/Protocol Section
530467-001: [1-009]	Before the programmer transmitter initiates a MICS communications session, the following access criteria shall be met: The programmer bandwidth measured at its 20 dB down points shall be equal to or greater than the emission bandwidth of the PG.	4.2
530467-001: [1-010]	Before the programmer transmitter initiates a MICS communications session, the following access criteria shall be met: The programmer shall monitor the signal level on the channel on which a transmission may be initiated. The programmer radio shall have calibrated receive sensitivity.	4.1
530467-001: [1-041]	Within 5 seconds prior to initiating a communications session the programmer shall monitor the channel for a minimum of 10ms for levels of MICS band activity exceeding the MICS Threshold Level as described in [1-010] and shall identify the least-interfered channel.	4.3, 4.4, 4.5, 4.7
530467-001: [1-049]	The programmer shall measure the activity and test it against the MICS threshold according to methods described in [1-010].	4.1
530467-001: [1-054]	The MICS communications session shall continue as long as any silent period between consecutive data transmission bursts does not exceed 5 seconds.	4.6

4 TESTS PERFORMED

The following sections describe the MICS LBT Compliance testing to be performed on the Model 3200 Programmer.

4.1 LBT Threshold Power Level

OBJECTIVE:

This test shows the system has sufficient sensitivity to recognize and accurately compare the ambient signals to the calculated threshold power level.

This test will be executed at BSC and uses the PRB Tester Application.

METHOD:

1. Configure the test setup as defined in Section 6.
2. Setup the blocking band signal generator to output the signal defined in Section 7.1. Adjust the blocking band power level to 3 dB above the calculated threshold power level.
3. Setup the on channel signal generator for continuous wave output, 6 dB below the calculated threshold power level, at the center frequency of the open channel in the blocking band. The signal waveform for the blocking band and on channel interferer is defined in Section 7.2.
4. Configure the device for testing per Section 2.5.1.
5. Perform an LBT Read per Section 2.5.2. Verify that the device selects Channel 0.
6. Increase the on channel interferer signal level in 1 dB steps from the previous test and repeat Step 5 until the device selects Channel 1
7. Subtract 4 dB from the on channel signal level recorded in Step 6 to calculate the measured threshold power level.

ACCEPTANCE CRITERIA:

The calculated monitoring threshold power level shall be no greater than:

10*log B (Hz) – 150 + G (dBi)

Where B is the emission bandwidth of the widest MICS communication session transmitter, and G is the monitoring system antenna gain.

As defined in Section 2.8 and Section 2.9, the S-ICD system widest emission bandwidth is 126 kHz (S-ICD PG). The programmer antenna gain is -5.0 dBi as defined in the appendix of DN-11691.

The calculated threshold power level is -104 dBm.

The requirement is met if the measured threshold power level is less than or equal to the calculated threshold power level.

RESULTS: **PASS**

Blocking band signal level = -101 dBm (3 dB above the calculated threshold)

Blocking Band Power (dBm)	CH0 Interferer Power (dBm)	LBT Result
-101	Off	CH 0
-101	-110 through -102	CH 0
-101	-101	CH 1

Table 8 LBT Threshold Power Results

Measured Threshold Power Level	-105 dBm

4.2 Monitoring System Bandwidth

OBJECTIVE:

The intent of this requirement is to ensure that the DUT measures the power in a bandwidth that is equal to or greater than the emission bandwidth of the transmitter with the widest emission that it will participate with in a MICS communications session.

For the S-ICD telemetry system, the widest bandwidth emitter is 126 kHz (maximum bandwidth as defined in Section 2.8 and Section 2.9).

This test will be executed at BSC and uses the PRB Tester Application.

METHOD:

1. Configure the test setup as defined in Section 6.
2. Setup the blocking band signal generator to output the signal defined in Section 7.1. Adjust the blocking band power level to 3 dB above the calculated threshold power level.
3. Setup the on channel signal generator for continuous wave output, 6 dB above the calculated threshold power level, at the center frequency of the open channel in the blocking band. The signal waveform for the blocking band and on channel interferer is defined in Section 7.2.
4. Configure the device for testing per Section 2.5.1.
5. Perform an LBT Read per Section 2.5.2. Verify that the device selects Channel 1.
6. Decrease the on channel interferer signal level in 1 dB steps from the previous test and repeat Step 5 until the device selects Channel 0. Record the on channel signal generator level as P_a.
7. Set the on channel signal generator frequency 63 kHz (widest bandwidth/2) lower than the value set in Step 3 to simulate the TX emissions bandwidth low frequency (Refer to Section 2.8 and 2.9).
8. Perform an LBT Read per Section 2.5.2. Verify that the device selects Channel 0.
9. Increase the on channel interferer signal level in 1 dB steps from the previous test and repeat Step 8 until the device selects Channel 1. Record the on channel signal generator level as P_b.

10. Set the on channel signal generator frequency 63 kHz (widest bandwidth/2) higher than the value set in Step 3 to simulate the PG TX emissions bandwidth high frequency (Refer to Section 2.8) with signal level of P_a.
11. Perform an LBT Read per Section 2.5.2. Verify that the device selects Channel 0.
12. Increase the on channel interferer signal level in 1 dB steps from the previous test and repeat Step 11 until the device selects Channel 1. Record the on channel signal generator level as P_c.
13. Subtract P_a from P_b and record the difference as D1.
14. Subtract P_a from P_c and record the difference as D2

EXPECTED RESULTS:

The monitoring system bandwidth measured at its 20 dB down points shall be equal to or greater than the widest emission bandwidth of the intended transmission.

This requirement is met if the calculated values D1 and D2 are less than or equal to 20 dB.

RESULTS: **PASS**

Maximum Emissions Bandwidth = 126 kHz

F_{low} = 403.4478 MHz

F_{high} = 403.5738 MHz

CH 0 Interferer Frequency = 403.5108 MHz

Blocking Band Power (dBm)	CH0 Interferer Power (dBm)	LBT Result
-101	-98 through -103	CH 1
-101	-104	CH 0

F_{low} Test: CH 0 Interferer Frequency = 403.4478 MHz

Blocking Band Power (dBm)	CH0 Interferer Power (dBm)	LBT Result
-101	-104 through -88	CH 0
-101	-87	CH 1

F_{high} Test: CH 0 Interferer Frequency = 403.5738 MHz

Blocking Band Power (dBm)	CH0 Interferer Power (dBm)	LBT Result
-101	-104 through -89	CH 0
-101	-88	CH 1

Table 9 Monitoring System Bandwidth Results

Low Frequency Power Delta (D1)	17 dB
High Frequency Power Delta (D2)	16 dB

4.3 Monitoring System Scan Cycle Time

OBJECTIVE:

The intent of this requirement is to ensure that when the monitoring system updates the detected power levels, it scans the band within 5 seconds.

The Model 3200 Programmer supports two modes of operation as defined in Section **Error! Reference source not found.**. The monitoring system scan cycle time is applicable for the device connection portion (user selects the S-ICD device for connection) of the telemetry protocol.

This test will be executed at BSC and uses the Programmer Software Application.

METHOD:

1. Configure the test setup as defined in Section 6.
2. Setup the blocking band signal generator to output the signal defined in Section 7.1. Adjust the blocking band power level to 3 dB above the calculated threshold power level.
3. Setup the on channel signal generator for continuous wave output, 6 dB above the calculated threshold power level, at the center frequency of the open channel in the blocking band. The signal waveform for the blocking band and on channel interferer is defined in Section 7.2.
4. Configure the device for testing per Section 2.5.3.
5. Set the spectrum analyzer as follows
    a. Span: zero span
    b. Frequency: Channel 0 frequency (403.5108 MHz)
    c. Sweep time: 10 seconds
    d. Sweep: Single
6. Initiate the “Scan For Device” function from the S-ICD System Menu.
7. Verify that the S-ICD device is displayed on the Model 3200 Programmer Device List page.
8. Trigger a spectrum analyzer sweep. When the sweep has hit ~ 5seconds, remove the on channel generator signal (RF off) and initiate a device connection by selecting the S-ICD device displayed in the Device List.
9. Verify that the session starts on Channel 0 and measure the time from when the connection was requested and the DUT TX starts.
10. Repeat Steps 6-9 four additional times (for a total of five) to show repeatability. In order to initiate a new connection, the telemetry session must be ended and the scan/connect sequence must be performed.

EXPECTED RESULTS:

Within 5 seconds prior to initiating a communications session, the device shall monitor all of the channels in the 402 MHz to 405 MHz band.

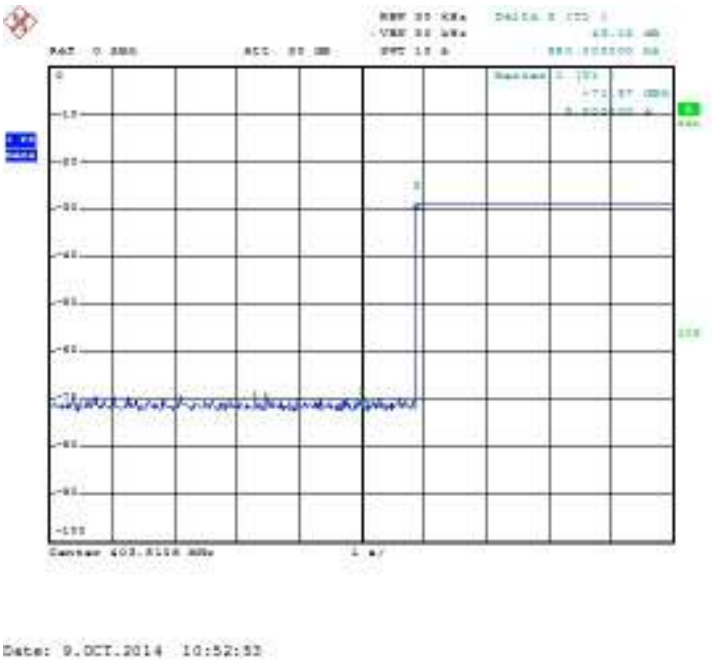
This requirement is met if each of the measured delay times is less than 5 seconds.

RESULTS: **PASS**

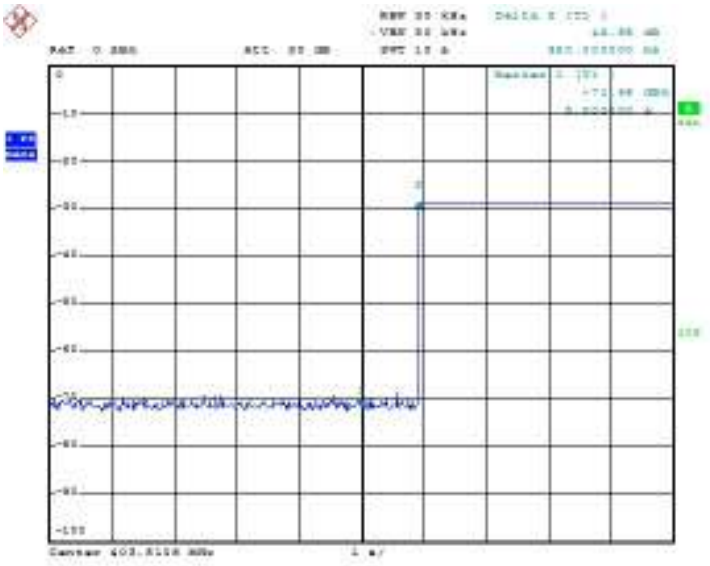
Table 10 Monitoring Scan Cycle Time Results

Test Run	Device Connect
Scan Cycle time run 1 (s)	0.880
Scan Cycle time run 2 (s)	0.920
Scan Cycle time run 3 (s)	1.040
Scan Cycle time run 4 (s)	0.860
Scan Cycle time run 5 (s)	0.920

Run 1:

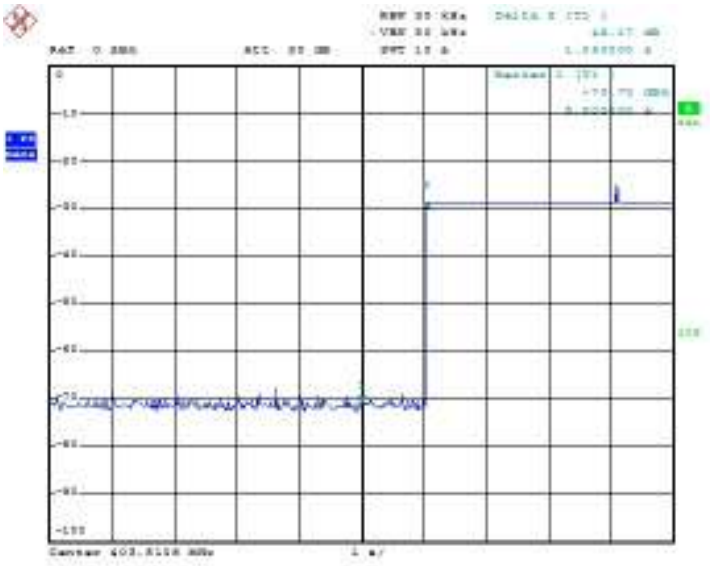


Run 2:



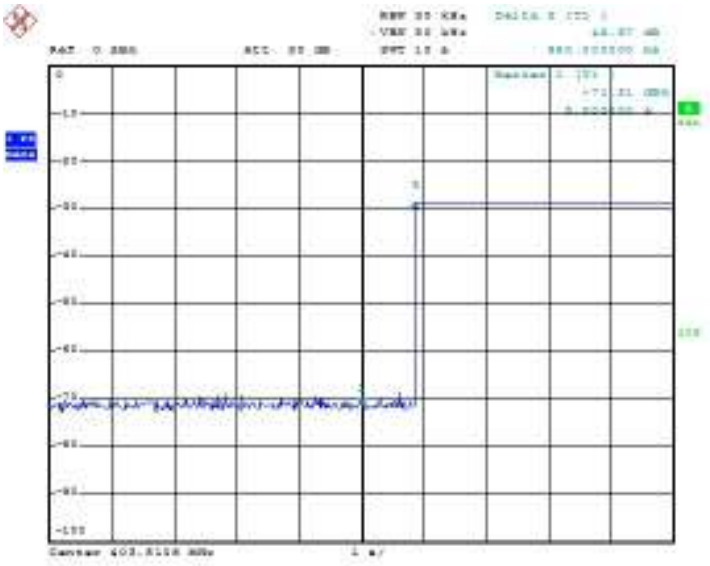
Date: 9.OCT.2014 10:54:47

Run 3:



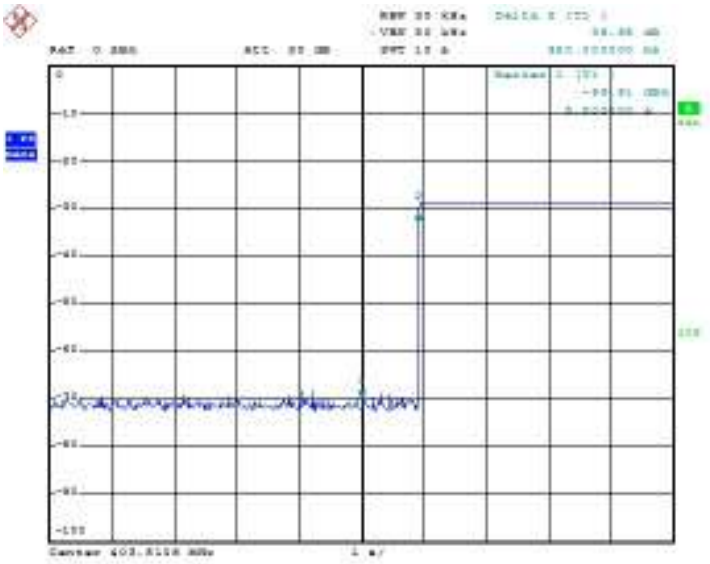
Date: 9.OCT.2014 10:57:14

Run 4:



Date: 9.OCT.2014 10:58:41

Run 5:



Date: 9.OCT.2014 11:00:08

4.4 Monitoring System Minimum Channel Monitoring Period

OBJECTIVE:

The intent of this requirement is to ensure that when the monitoring system updates the detected power levels that the monitoring period on each channel is 10 ms or longer in order to detect transmissions that may have silent periods that are less than 10 ms in duration.

This test will be executed at BSC and uses the PRB Tester Application.

METHOD:

1. Configure the test setup as defined in Section 6.
2. Setup the blocking band signal generator to output the signal defined in Section 7.1. Adjust the blocking band power level to 3 dB above the calculated threshold power level.
3. Configure the device for testing per Section 2.5.1.
4. Perform an LBT Read per Section 2.5.2. Verify that the device selects Channel 0.
5. Setup the on channel signal generator for continuous wave output, 3 dB above the calculated threshold power level, at the center frequency of the open channel in the blocking band. The signal waveform for the blocking band and on channel interferer is defined in Section 7.2.
6. Remove the blocking band generator signal (RF off).
7. Perform an LBT Read per Section 2.5.2. Verify that the device selects Channel 1.
8. Turn the blocking band generator signal on (RF on) at a power level 6 dB above the calculated threshold power level. The on channel signal generator should still be on, with signal level 3 dB above the calculated threshold power level.
9. Perform an LBT Read per Section 2.5.2. Verify that the device selects Channel 0.
10. Repeat Step 9 four additional times (for a total of five).
11. Modulate the blocking band generator output so that it is on for 0.1 ms during a 10 ms period as defined in Section 7.4.
12. Perform an LBT Read per Section 2.5.2. Verify that the device selects Channel 0.
13. Repeat Steps 12 nine additional times (for a total of ten).

EXPECTED RESULTS:

Each MICS channel shall be monitored for a minimum of 10 ms during each scan cycle of 5 seconds or less duration.

This requirement is met if the DUT selects Channel 0 in Steps 12-13.

RESULTS: **PASS**

Step 4 (Blocking Band 3 dB above threshold, on channel interferer OFF): CH 0 selected.

Step 7 (Blocking Band OFF, on channel interferer 3 dB above threshold): CH 1 selected.

Step 9/10 (Blocking Band 6 dB above threshold, on channel interferer 3 dB above threshold): CH 0 selected.

Step 12/13 (Blocking Band 6 dB above threshold modulated per Step 11, on channel interferer 3 dB above threshold): CH 0 selected.

4.5 Channel access based on Least Interfered Channel

OBJECTIVE:

MICS programmer/control transmitters are permitted to initiate a MICS communications session immediately on any channel where the ambient signal level is below the maximum permitted LBT threshold power level, P_{Th}. If no channel is available with an ambient power level at or below the maximum permitted P_{Th}, spectrum access is permitted based on the channel with the lowest ambient power level referred to as the LIC or "least interfered channel".

This test will be executed at BSC and uses the PRB Tester Application.

METHOD:

1. Configure the test setup as defined in Section 6.
2. Setup the blocking band signal generator to output the signal defined in Section 7.3. Adjust the blocking band power level to 10 dB above the calculated threshold power level and the LIC (Channel 1) to 3 dB above the calculated threshold power level.
3. Configure the device for testing per Section 2.5.1.
4. Perform an LBT Read per Section 2.5.2. Verify that the device selects Channel 0.
5. Setup the on channel signal generator for continuous wave output, 3 dB below the calculated threshold power level, at the center frequency of the open channel in the blocking band. The signal waveform for the blocking band and on channel interferer is defined in Section 7.2.
6. Perform an LBT Read per Section 2.5.2. Verify that the device selects Channel 0.
7. Increase the on channel interferer signal level 9 dB from the previous test (6 dB above the calculated threshold power level).
8. Perform an LBT Read per Section 2.5.2. Verify that the device selects the LIC (Channel 1).

EXPECTED RESULTS:

The DUT shall access and transmit on the Least Interfered Channel (LIC) when no channel is available with an ambient power level at or below the maximum permitted P_{Th}.

This requirement is met if the DUT selects the LIC (Channel 1) in Step 8.

RESULTS: **PASS**

With the blocking band configured per the test method, the DUT selected Channel 1 when it was configured as the LIC.

4.6 Discontinuation of MICS Session

OBJECTIVE:

MICS systems shall cease transmission in the event the communications session is interrupted for a period of 5 seconds or more. Once a MICS session is established, it may continue as long as the silent period in two-way communication between co-operating devices does not exceed 5 seconds.

This test will be executed at BSC and uses the Programmer Software Application.

METHOD:

1. Configure the test setup as defined in Section 6.
2. Setup the blocking band signal generator to output the signal defined in Section 7.1. Adjust the blocking band power level to 10 dB above the calculated threshold power level.
3. Setup the on channel signal generator for continuous wave output, 3 dB below the calculated threshold power level, at the center frequency of the open channel in the blocking band. The signal waveform for the blocking band and on channel interferer is defined in Section 7.2.
4. Configure the device for testing per Section 2.5.3.
5. Start an RF telemetry session with the S-ICD by performing the following:
    a. Initiate the "Scan For Device" function from the S-ICD System Menu.
    b. Initiate a device connection by selecting the S-ICD device displayed in the Device List
    c. Verify that the session starts on the blocking band open channel (Channel 0).
6. Set the spectrum analyzer as follows
    a. Span: zero span
    b. Frequency: Channel 0 frequency (403.5108 MHz)
    c. Sweep time: 10 seconds
    d. Sweep: Single
7. Trigger a spectrum analyzer sweep. Adjust the attenuation in the telemetry link in order to stop communications. This can be accomplished by disconnecting the PG RF input from the test setup.
8. Record the session stop time on Channel 0. The session stop time is defined as the time period from when the telemetry link is interrupted until transmission from the DUT stops.
9. Reduce the link attenuation to the previous value.
10. Verify that the session continues on the blocking band open channel (Channel 0).

EXPECTED RESULTS:

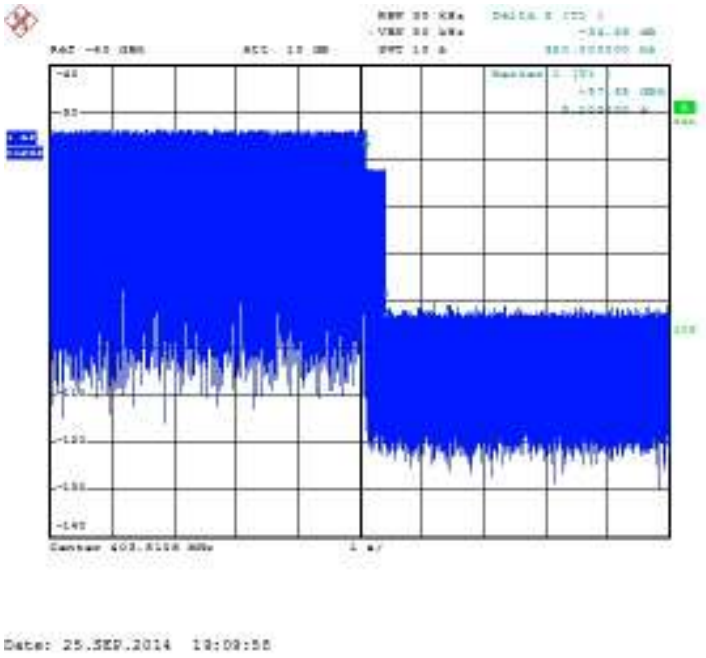
Emission from the programmer/control transmitter shall cease in an amount of time less than or equal to 5 seconds after the implanted device telemetry becomes inactive.

This requirement is met if the session stop time is less than 5 seconds after attenuation is added and if the session restarts on Channel 0 after the attenuation is removed.

RESULTS: **PASS**

Table 11 Discontinuation of MICS Session Results

Session Stop Time (s)	0.320



The session restarted on Channel 0 after the attenuation was removed.

4.7 Use of Pre-scanned Alternative Channel

OBJECTIVE:

At the time a channel for operation is initially selected and accessed, it is permissible for the monitoring system to select one additional channel for alternate operation for use if the initially selected channel becomes unavailable due to blockage of the channel from unknown disturbing ambient signals.

The feature is not implemented for this device. Since the RF telemetry system only has two possible channels, the pre-scanned alternate channel test is not applicable. Testing is not required.

RESULTS: **N/A**

CONCLUSION

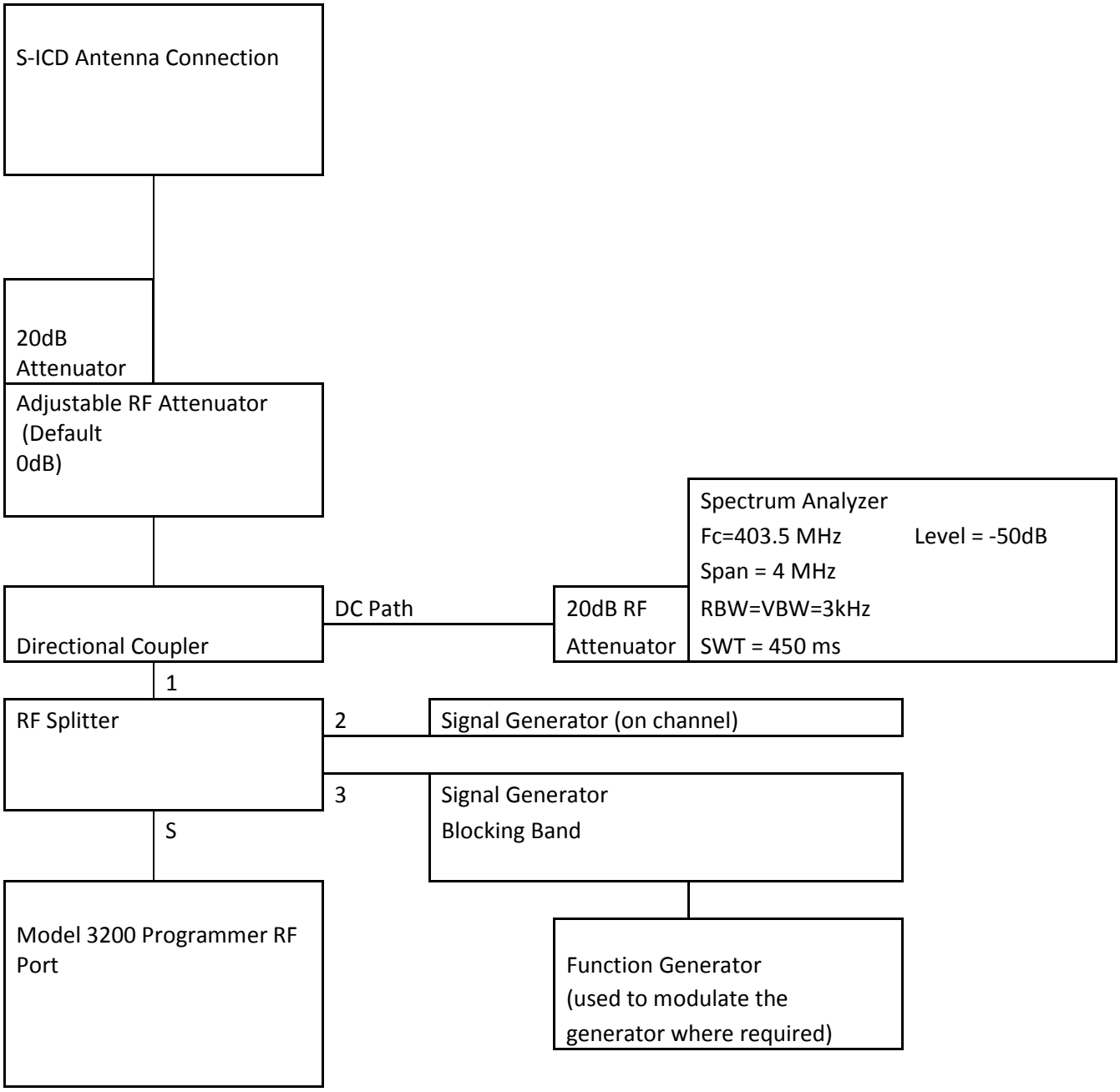
The test data and analysis summarized in this report demonstrates that the Model 3200 Programmer radio meets the Listen Before Talk requirements of the telemetry requirements as well as the relevant portions of the FCC and ETSI MICS standards.

5 APPENDIX A - MICS LBT COMPLIANCE TEST EQUIPMENT

Description	Quantity	Manufacturer	Model	ESN/SN	Cal Date	Cal Due	Notes
Assembly, Cameron PRGMR 3200 – US PRB Application Version: 1.03	1	BSC	104474-2XX	3200-A103236	N/A	N/A	Used for protocol sections that rely on the PRB Tester Application
Assembly, Cameron PRGMR 3200 – US Programmer Software Version: 3.03	1	BSC	104474-2XX	3200-A103241	N/A	N/A	Used for protocol sections that includes starting an RF telemetry session with an S-ICD
Android OS for Verizon	N/A	BSC	104745-001	N/A	N/A	N/A	
Power Supply, Programmer	1	BSC	104508-001	N/A	N/A	N/A	
S-ICD	1	BSC	A209	100619	N/A	N/A	Pilot A.3
Blocking Band Sig Gen	1	Rohde & Schwarz	SMBV100A	25026578	7-Feb-14	7-Feb-15	
Channel Blocker Sig Gen	1	Agilent	E4438C	10060926	12-Feb-14	12-Feb-15	
Spectrum Analyzer	1	Rohde & Schwarz	FSP	10074269	16-Jul-14	16-Jul-15	
Function Generator	1	Stanford Research Systems	DS345	10064666	9-Apr-14	9-Apr-15	
Variable Attenuator	1	JFW	50BR-008	4418820640	N/A	N/A	
Fixed Attenuator (20 dB)	2	JFW	50F-020	N/A	N/A	N/A	
RF Power Splitter (3 to 1)	1	Mini-Circuits	ZA3PD-1-S	040400640	N/A	N/A	
Directional Coupler	1	Pasternack	PE2213-10	N/A	N/A	N/A	
Coax Cables	As Required	N/A	N/A	N/A	N/A	N/A	

6 APPENDIX B - MICS LBT COMPLIANCE TEST SETUP

The following defines the test setup used in this protocol/report.



7 APPENDIX C - MICS LBT COMPLIANCE BLOCKING SIGNALS

7.1 Blocking band

The signal shown in Figure 1 was used as the blocking band for LBT testing. The notch is centered at 403.5108 MHz (Channel 0). The figure is for reference only. Actual signal levels and channels are set by the test method.

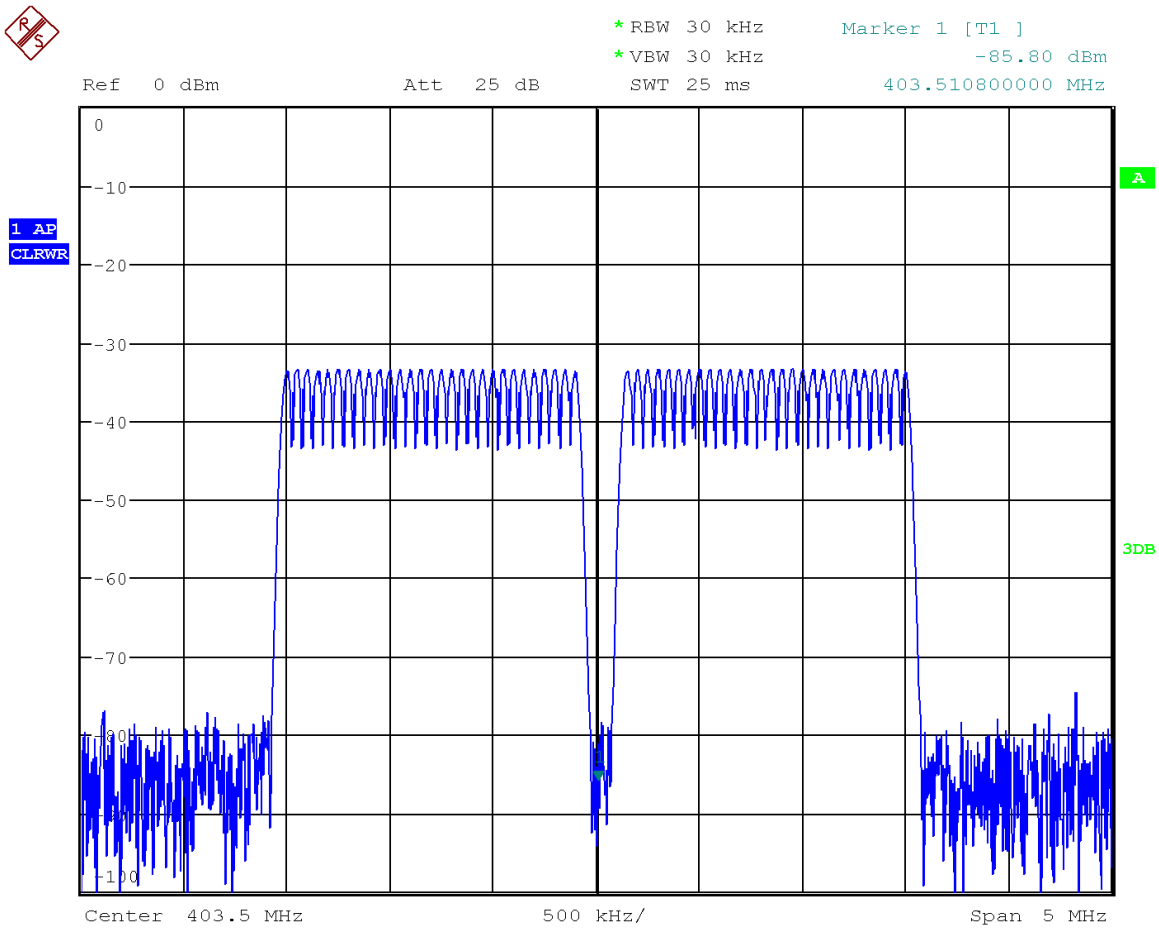


Figure 1 LBT Blocking Band Signal

7.2 Blocking band with on-channel interferer

The signal shown in Figure 2 was used as the blocking band and on-channel interferer for LBT testing. The on-channel interferer is centered at 403.5108 MHz (Channel 0). The figure is for reference only. Actual signal levels and channels are set by the test method.

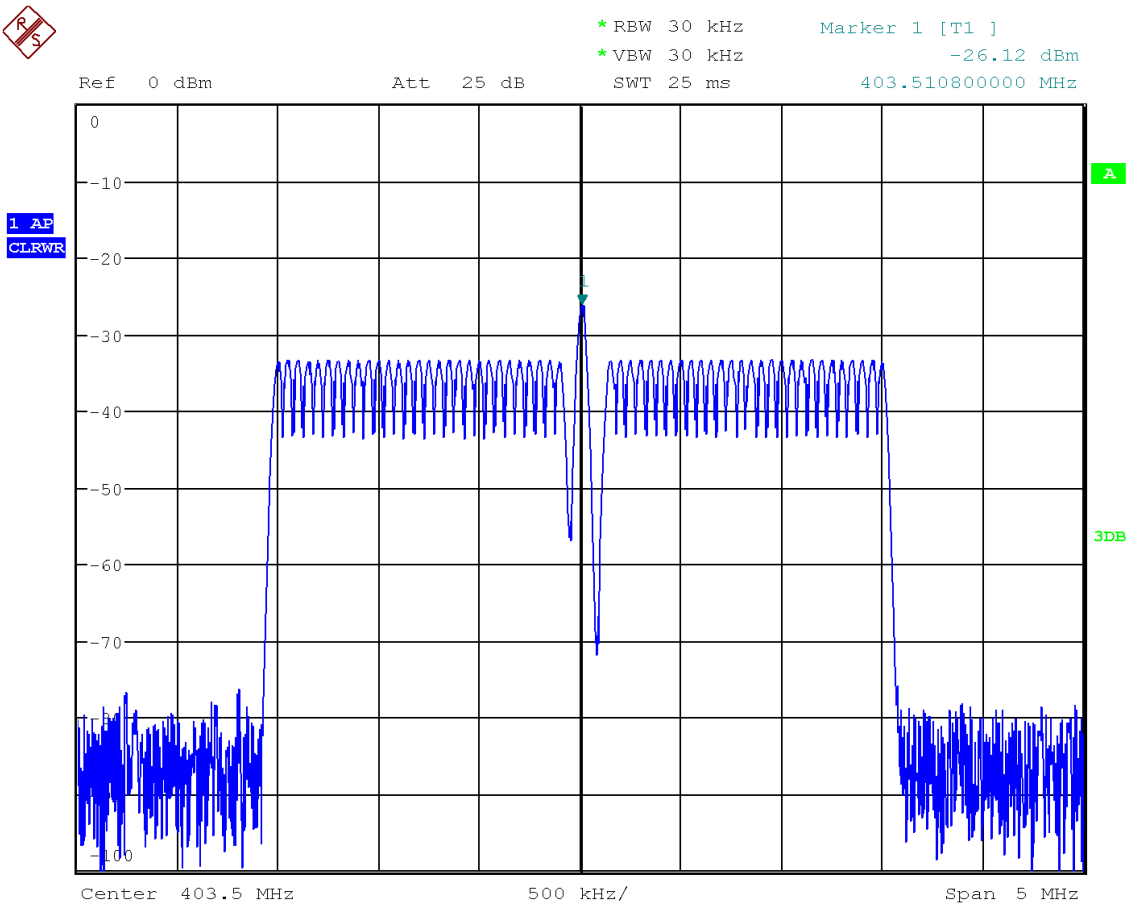


Figure 2 LBT Blocking Band with On-channel Interferer Signal

7.3 Blocking band with Least Interfered Channel

The signal shown in Figure 3 was used as the blocking band with Least Interfered Channel (LIC) for LBT testing. The notch is centered at 403.5108 MHz (Channel 0). The LIC is centered at 402.818308 MHz (Channel 1) and has lower amplitude that the remainder of the blocking band. The figure is for reference only. Actual signal levels and channels are set by the test method.

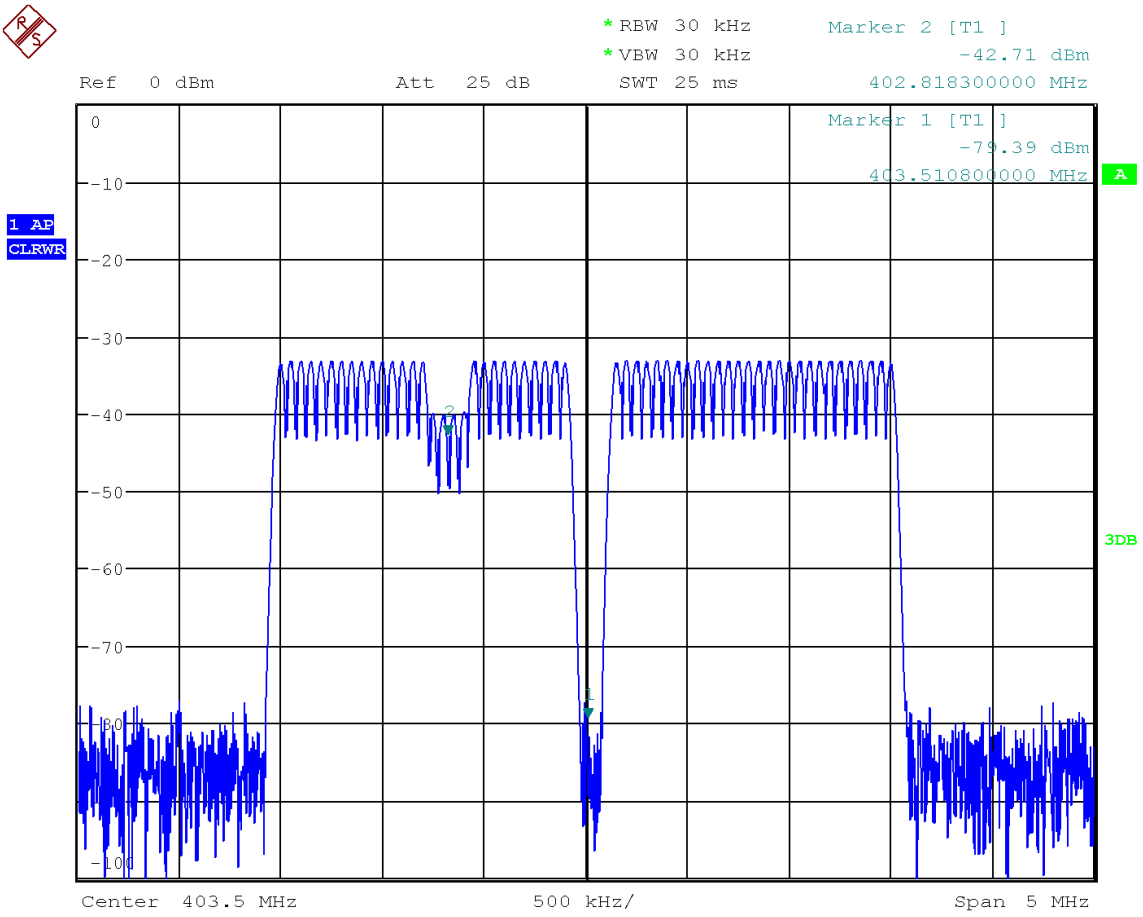


Figure 3 LBT Blocking Band with Least Interfered Channel Signal

7.4 Modulated Blocking Band for the Channel Monitoring Period Test

The signal shown in Figure 4 is the modulated blocking band waveform used for the Channel Monitoring Period test. The figure is a spectrum analyzer zero span measurement for a 10 ms period. The blocking signal is on for 100 us during the 10 ms shown.

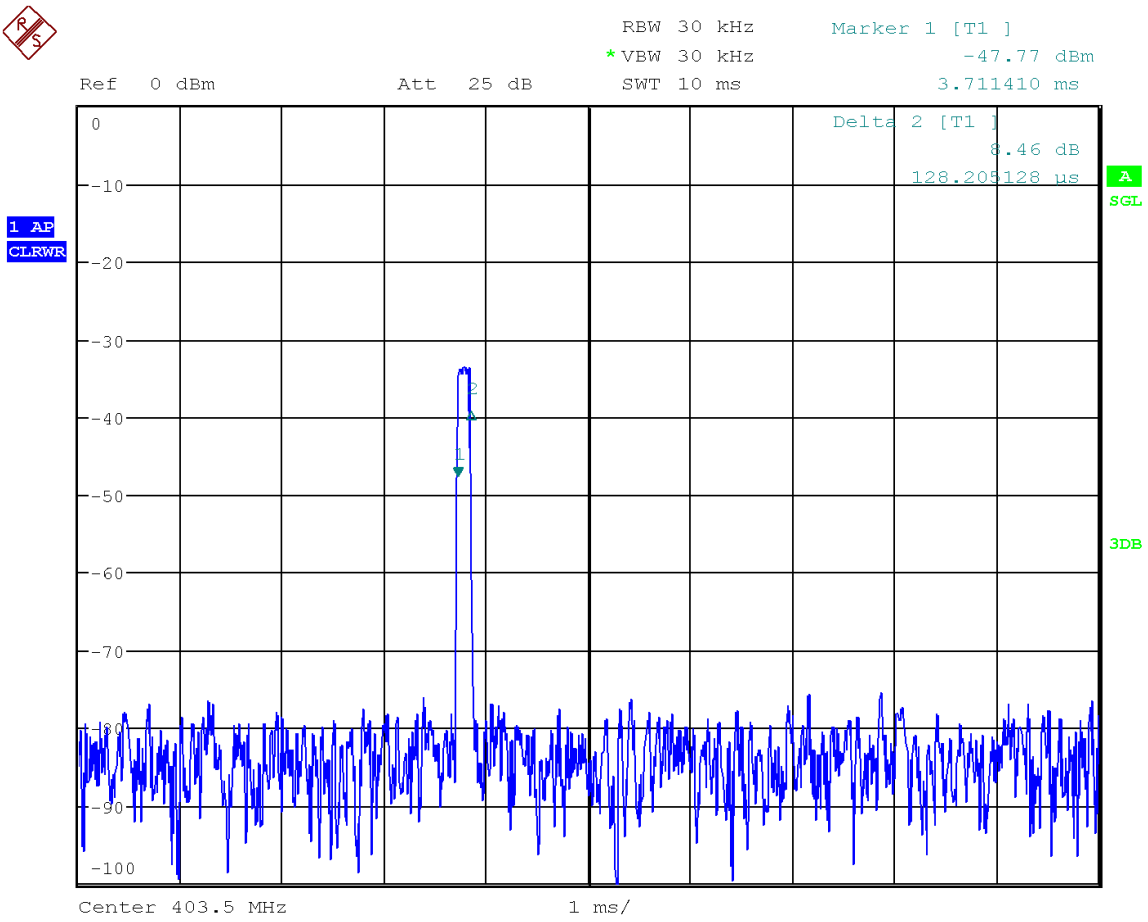


Figure 4 Modulated Blocking Band for the Channel Monitoring Period Test

8 APPENDIX D – TEST PHOTOS

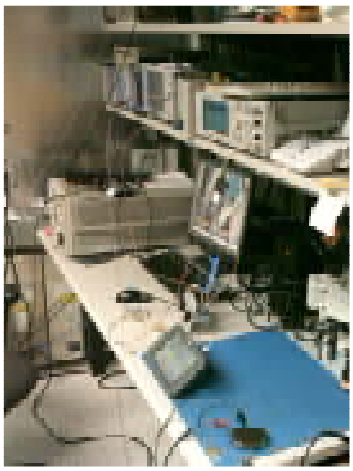


Figure 5 Test Setup Photos