Boston Scientific
Cardiac Rhythm Management

1112845

EDVT Protocol and Report

MICS LBT Compliance

Gamera Model 3140

Rev B

March 12, 2013

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EXECUTIVE SUMMARY

The ZOOM Latitude Programming System, which includes Model 3120 Programmer/Recorder/Monitor (PRM), Model 3140 ZOOM Wireless Transmitter (ZWT) and accessories, is a portable cardiac rhythm management system designed to be used with Boston Scientific implantable pulse generators.

The ZOOM Wireless Transmitter (ZWT) Model 3140 (or Gamera) device under test is powered via USB Cable Model 3141 from the PRM. The ZWT device provides RF telemetry at 402 -405 MHz (MICS band) for transferring information to and from an active implantable pulse generator (PG).

This document describes the test protocol and report for the electrical design verification testing (EDVT) performed on the ZOOM Wireless Transmitter (ZWT) Model 3140 to show compliance to the MICS LBT (Listen Before Talk) Requirements as defined in the Boston Scientific system requirements document 590630-008 entitled 3120 Zoom RF Programmer SyRS.

RESULTS

The ZWT device passed all testing required in this document.

UNEXPECTED OBSERVATIONS

There are no unexpected observations to report.

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1 ABOUT THIS DOCUMENT

1.1 Scope

The ZOOM Latitude Programming System, which includes Model 3120 Programmer/Recorder/Monitor (PRM), Model 3140 ZOOM Wireless Transmitter (ZWT) and accessories, is a portable cardiac rhythm management system designed to be used with Boston Scientific implantable pulse generators.

The ZOOM Wireless Transmitter (ZWT) Model 3140 (or Gamera) device under test is powered via USB Cable Model 3141 from the PRM. The ZWT device provides RF telemetry at 402 -405 MHz (MICS band) for transferring information to and from an active implantable pulse generator (PG).

This document describes the test protocol and report for the electrical design verification testing (EDVT) performed on the ZOOM Wireless Transmitter (ZWT) Model 3140 to show compliance to the MICS LBT (Listen Before Talk) Requirements as defined in the Boston Scientific system requirements document 590630-008 entitled 3120 Zoom RF Programmer SyRS.

1.2 Objective

This testing is intended to ensure that the Model 3140 Gamera complies with the LBT requirements outlined in the various standards. Successful completion of this EDVT will be used to support Gamera radio compliance in the MICS band.

1.3 Revision History

Table 1 Revision History

Revision	Description of change	Author
B.3	Updated with results for report	Peter Musto
A.2	New document in Windchill	Peter Musto

1.4 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	Celsius
CFR	Code of Federal Regulations
CRM	Cardiac Rhythm Management
dB	Decibel
dBm	Decibel with respect to 1 milliwatt
DUT	Device Under Test

Acronym	Definition
EDVT	Electrical Design Verification Testing
ELN	Electronic Lab Notebook
ERM	Electromagnetic compatibility and Radio spectrum Matters
ESD	Electrostatic Discharge
ETSI	European Telecommunications Standards Institute
FCC	Federal Communications Commission
FRRP	Frontier Raw Register Programmer
Gamera	Zoom Wireless Transmitter (MICS Telemetry Accessory)
HLA	High Level Assembly
Hz	Hertz
IC	Integrated Circuit
kHz	Kilohertz
LBT	Listen Before Talk
LIC	Least Interfered Channel
MAU	Multiple Application Utility
MHz	Megahertz
MIC	Ministry of Internal affairs and Communications (Japan)
MICS	Medical Implant Communications Service
ms	Milli-second
NA or N/A	Not Applicable
NG3	Next Generation Pulse Generator which includes MICS telemetry
NWEMC	Northwest EMC
PCA	Printed Circuit Assembly
PG	Pulse Generator
PN or P/N	Part Number
PRM	Programmer/Recorder/Monitor
R&TTE	Radiocommunications and Telecommunications Terminal Equipment
RF	Radio Frequency
RSS	Radio Standards Specification (Canada)
RX	Receive
s	second
SN or S/N	Serial Number
SRD	Short Range Device
SWR	Software Radio
SyRS	System Requirements Specification
TBD	To Be Determined
TX	Transmit
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
ZWT	Zoom Wireless Transmitter or Gamera (MICS Telemetry Accessory)

1.5 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
590630-008	*	SYRS PRM GAMERA	SYRS
1101209	*	PRM/GAMERA SYRS LIKELIHOOD JUSTIFICATION	-
1100936	*	GALAXY QUALITY PLAN PROCEDURE DEVIATION APPROVAL FORM	-
1108104	*	EDVT PROTOCOL AND REPORT GAMERA	EDVT
1112535	*	NG3 FCC 95I	-
400063-011	*	EXTERNAL MICS ANTENNA 3140 6X6 GAMERA	HLA
ELN 5783824	*	GAMERA MICS LBT COMPLIANCE EDVT RESULTS (WC REPORT 1112845)	ELN
ELN 5756102	*	GAMERA PILOT A ANTENNA MEASUREMENTS	ELN
Procedure 006318	*	DESIGN VERIFICATION AND VALIDATION	-
Procedure 005872	*	ESD HANDLING	-

*Current revision shall apply for reference material.

1.6 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
ETSI EN 301 839-1 V1.3.1	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	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 95:2012	Personal Radio Service
RSS-243 Issue 3	Medical Devices Operating in the 401-406 MHz Frequency Band
MIC 040527	Ordinance Regulating Radio Equipment

2 TEST APPROACH

2.1 Sample Size

Selection of the sample size is based on PRM/Gamera SyRS Likelihood Justification document 1101209 and Galaxy Device/System Development Procedure Deviation document 1100936. The sample size for this protocol is 1. The ZWT includes two antennas. For the purpose of this EDVT, all tests will be performed for each antenna circuit.

2.2 Device Under Test (DUT)

The device(s) under test for this test protocol shall be the:

- Model 3140 ZOOM® LATITUDE Wireless Transmitter (ZWT)
- Model 3141 USB Cable
- Model 3120 ZOOM® LATITUDE Programmer/Recorder/Monitor (PRM)

2.3 Test Equipment

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

- NG3 PG System Board
- ZOOM Telemetry Wand Model 6577
- RF Test Equipment (spectrum analyzer and signal generators)
- USB Keyboard
- Parallel Port Dongle Model 6807

Details of the test equipment information will be included Section 6.

2.4 Test Configuration - Standard

Testing shall be conducted with ZWT connected to PRM with USB Cable Model 3141.

The standard test configuration described below, and shown in Figure 1, is the standard configuration for system level testing using a PRM, ZWT, and an RF enabled PG.

- ZOOM® Wireless Transmitter Model 3140
- USB Cable Model 3141 (connected to PRM)
- The ZWT shall use the latest version of software available at the time of the test.
    - Bootloader – Loaded into FLASH Memory on the Control PCA
    - MICS Radio (gamera.bin) – Loaded into SDRAM on the Control PCA from the PRM
- ZOOM Programmer/Recorder/Monitor Model 3120
    - Software Radio (SWR) (swr.hex)
    - MAU (9.01)
    - 2868 Application (3.01)
- ZOOM Telemetry Wand Model 6577
- NG3 PG (In order to control signal levels accurately for the testing completed in this EDVT, an NG3 System Board will be used in place of an NG3 PG)

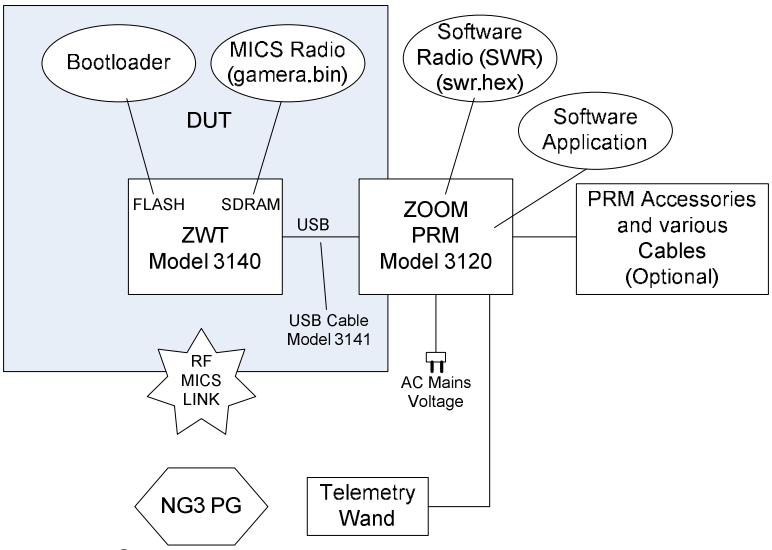


Figure 1 ZOOM® Wireless Transmitter Standard Configuration (for reference only)

2.4.1 *ZWT Test Configuration for LBT Compliance Testing*

The ZWT to PG test setup will be configured per Section 7 for this protocol.

2.4.2 *Signal Level Calibrations*

All signal levels referenced in this protocol will be calibrated to the RF inputs of the ZWT.

2.4.3 *FRRP Start Up*

Perform the following configurations steps to initiate FRRP on the 3120 PRM.

a. Connect USB Keyboard to PRM.
b. Connect Model 6807 Parallel Port Dongle to PRM.
c. Connect Model 3140 ZWT to PRM using USB Cable.
d. Turn the PRM On and wait for the unix prompt "[root@xxxxxx-ff root]#" to appear.
e. Enter "startx" <Enter> and wait for the desktop window environment to appear. Close any various "useful tip" or other window dialog boxes that might appear.
f. Click on the Shell – Konsole icon to open a shell window. Close the "tip of the day" or other windows dialog boxes that might appear.
g. Click inside the "Shell – Konsole" window.
h. Enter "cd /home/common/swr/mics" <Enter>.
i. Enter "fafrrp.sh" <Enter> and wait for the FRRP application to start.

2.5 Standard Test Conditions and Configurations

2.5.1 *Mains Voltage*

The ZWT is powered by the 3120 PRM USB bus (5VDC). The USB bus voltage is independent of mains voltage, therefore testing per this protocol will be performed at only one mains voltage combination (110 VAC/ 60 Hz).

2.5.2 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.

2.6 MICS Channelization

Refer to Table 5 for a list of channels and frequencies used in the BSC MICS telemetry system. 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 4. Several of the test protocols include using one or two "Least Interfered Channels". For this EDVT, these are chosen to be Channel 0 and Channel 9. The selection of channels for testing is arbitrary. A different set of channels will provide the same results.

Table 5 BSC MICS Band Channelization

Channel	Frequency (MHz)
0	402.15
1	402.45
2	402.75
3	403.05
4	403.35
5	403.65
6	403.95
7	404.25
8	404.55
9	404.85

2.7 PG Emissions Bandwidth

The monitoring system bandwidth test defined in Section 4.2 is required to be tested at a bandwidth that is equal to or greater than the emission bandwidth of the transmitter with the widest emission in a MICS communications session. For the BSC telemetry system, the widest bandwidth emitter is the PG. PG transmit bandwidth data is included in Windchill Report 1112535. The maximum emissions bandwidth for the PG is listed on page 21 of NWEMC report BSTN0405.1 (attachment for 1112535) as 287.171 kHz. For the purpose of this EDVT, the monitoring system bandwidth will be tested at ±150 kHz from the channel center frequency as defined in Table 5. This test condition is greater than the emission bandwidth of the widest emission in the MICS communications session.

2.8 Handling Precautions

Care should be taken in the handling of the Gamera Device under test. The signals found on the PCA are connected to Integrated Circuit (IC) devices that can be sensitive to Electro-Static Discharge (ESD). Wrist-straps should be worn whenever the Gamera PCAs are handled. The PCAs should remain on an ESD-protective work surface until test procedures require it to be removed. ESD guidelines in Boston Scientific's ESD PROCEDURE 5872 should be followed.

3 SUMMARY

3.1 Devices Under Test

A summary of the DUT serial numbers and configurations used for testing is shown in Table 6.

Table 6 Configuration of Devices used for Testing

ZOOM® Wireless Transmitter Model 3140			
Assembly Number	**Serial Number (S/N)**	**Bootloader Version**	**Software Version**
400063-011	1000035	Gamera ROM V1.00.00	SWR_MICS_v2.02.00

3.2 Results Summary

A summary of the tests to be completed is shown in Table 7.

Table 7 Test Summary

Protocol/ Report Section	Description	SyRS	Protocol/Report Specification, Method, and Acceptance Criteria	Pass / Fail
4.1	LBT Threshold Power Level	SyRS017871	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	SyRS017461	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	SyRS017461	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	SyRS017461	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	SyRS017461	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	SyRS17462	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	SyRS017461	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)	PASS

3.3 SyRS Traceability

Table 8 SyRS Traceability

SyRS	Description	Report/Protocol Section
SyRS017461	Prior to using an RF channel defined in SyRS017468, the RF MICS adapter shall identify the best available channel through the following process: • monitor each potential MICS communication channel for at least 10 milliseconds within a 5-seconds window per FCC 47 CFR 95.627(a)(2) and in accordance with FCC 47 CFR 95.627(a)(1) and (a)(3) ▪ choose any channel with no signal above the monitoring threshold power level as determined by SyRS017871, if no channel is available then use the channel with the lowest measured ambient power levels per FCC 47 CFR 95.627(a)(4) *Note: The RF MICS adapter does not use the alternate channel provision in FCC 47 CFR 95.627(a)(5). Therefore, it must always follow this channel selection process per FCC 47 CFR 95.627(a)(5)(iii) regardless of whether a new PRM/PG session is initiated, the PRM is switching from inductive to RF, or there is a need to hop from one channel to another while staying in the RF link.* *Note: In general, most geographies are aligned with international regulations for the use of the MICS band with slight variations in some geographies. This requirement is intended to define requirements using the FCC rules as reference. To determine if there are any differences, see the traceability links below for references to all the applicable standards for this requirement.*	4.2, 4.3, 4.4, 4.5, 4.7
SyRS17462	The RF MICS adapter shall transmit on the frequency channel selected under SyRS017461for no more than 5 seconds without the communication of data per FCC 47 CFR 95.1209(d) and 627(a)(4). *Note: In general, most geographies are aligned with international regulations for the use of the MICS band with slight variations in some geographies. This requirement is intended to define requirements using the FCC rules as reference. To determine if there are any differences, see the traceability links below for references to all the applicable standards for this requirement.*	4.6
SyRS017871	The monitoring threshold power level shall be no greater than: 10 log B(Hz) - 150 +G(dBi) where B is the emission bandwidth of the MICS communication session transmitter having the widest emission bandwidth and G is the system antenna gain relative to an isotropic antenna. *Note: For the RF MICS adapter, the emission bandwidth B is 300 kHz and the relative antenna gain G is -0.8. Therefore the monitoring threshold power level cannot be greater than -96 dBm.*	4.1

4 TESTS PERFORMED

The following sections describe the MICS LBT Compliance testing to be performed on the ZWT.

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.

METHOD:

1. Configure the test setup as defined in Section 7.
2. Setup the blocking band signal generator to output the signal defined in Section 8.1. 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 8.2.
4. Start FRRP on the Model 3120 PRM as defined in Section 2.4.3.
5. Use FRRP to start an RF telemetry session. Verify that the session starts on the blocking band open channel (Channel 4).
6. End the telemetry session.
7. Increase the on channel interfere signal level 1 dB from the following test and repeat Steps 5 and 6.
8. Repeat Step 7 until the session is started on a channel other than Channel 4. Record the on channel signal generator level.
9. Subtract 4 dB from the on channel signal level recorded in Step 8 to calculate the measured threshold power level.

EXPECTED RESULTS:

As specified in SyRS017871, the calculated threshold power level is -96 dBm. The threshold power level is given by:

10*log B (Hz) – 150 + G (dBi)

Where B is the emission bandwidth of the widest MICS communication session transmitter (in this case the PG), and G is the monitoring system antenna gain.

As defined in Section 2.7, the emission bandwidth is 287171 Hz. The minimum antenna gain (recorded in ELN 5756102) is -0.3 dBi. The minimum antenna gain is used for the threshold power level calculation because it will result in the minimum calculated value.

The calculated threshold power level is -95.7 dBm.

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

RESULTS: **PASS**

For detailed results see ELN 5783824.

Table 9 LBT Threshold Power Results

	Antenna A	Antenna B
Measured Threshold Power Level	-96 dBm	-96 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.

This test will be executed at BSC.

METHOD:

1. Configure the test setup as defined in Section 7.
2. Setup the blocking band signal generator to output the signal defined in Section 8.1. 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 8.2.
4. Start FRRP on the Model 3120 PRM as defined in Section 2.4.3.
5. Use FRRP to start an RF telemetry session. Verify that the session starts on one of the blocking band channels (not Channel 4).
6. End the telemetry session.
7. Decrease the on channel interfere signal level 1 dB from the following test and repeat Steps 5 and 6.
8. Repeat Step 7 until the session is started on Channel 4. Record the on channel signal generator level as P_a.
9. Set the on channel signal generator frequency 150 kHz lower than the value set in Step 3 to simulate the PG TX emissions bandwidth low frequency (Refer to Section 2.7).
10. Use FRRP to start an RF telemetry session. Verify that the session starts on the blocking band open channel (Channel 4).
11. End the telemetry session.
12. Increase the on channel interfere signal level 1 dB from the following test and repeat Steps 10 and 11.
13. Repeat Step 12 until the session is started on a channel other than Channel 4. Record the on channel signal generator level as P_b.
14. Set the on channel signal generator frequency 150 kHz higher than the value set in Step 3 to simulate the PG TX emissions bandwidth high frequency (Refer to Section 2.7) with signal level of P_a.

15. Use FRRP to start an RF telemetry session. Verify that the session starts on the blocking band open channel (Channel 4).
16. End the telemetry session.
17. Increase the on channel interfere signal level 1 dB from the following test and repeat Steps 15 and 16.
18. Repeat Step 17 until the session is started on a channel other than Channel 4. Record the on channel signal generator level as P_c.
19. Subtract P_a from P_b and record the difference as D1.
20. 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**

For detailed results see ELN 5783824.

Table 10 Monitoring System Bandwidth Results

	Antenna A	Antenna B
Low Frequency Power Delta (D1)	4 dB	4 dB
High Frequency Power Delta (D2)	4 dB	5 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.

This test will be executed at BSC.

METHOD:

1. Configure the test setup as defined in Section 7.
2. Setup the blocking band signal generator to output the signal defined in Section 8.1. 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 8.2.
4. Start FRRP on the Model 3120 PRM as defined in Section 2.4.3.
5. Use FRRP to start an RF telemetry session. Verify that the session starts on one of the blocking band channels (not Channel 4).

6. End the telemetry session.
7. Set the spectrum analyzer as follows
    a. Span: zero span
    b. Frequency: Channel 4 frequency (403.35 MHz)
    c. Sweep time: 10 seconds
    d. Sweep: Single
8. Trigger a spectrum analyzer sweep. When the sweep has hit ~ 5seconds, remove the on channel generator signal (RF off) and use FRRP to start an RF telemetry session.
9. Verify that the session starts on Channel 4 and measure the time from when the session was requested and the ZWT TX starts.
10. Repeat Steps 8 and 9 four additional times (for a total of five) to show repeatability.

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**

For detailed results see ELN 5783824.

Table 11 Monitoring Scan Cycle Time Results

	Antenna A	Antenna B
Scan Cycle time run 1 (s)	2.701	2.508
Scan Cycle time run 2 (s)	2.733	2.540
Scan Cycle time run 3 (s)	2.621	2.780
Scan Cycle time run 4 (s)	2.653	2.572
Scan Cycle time run 5 (s)	2.749	2.524

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.

METHOD:

1. Configure the test setup as defined in Section 7.
2. Setup the blocking band signal generator to output the signal defined in Section 8.1. Adjust the blocking band power level to 3 dB above the calculated threshold power level.
3. Start FRRP on the Model 3120 PRM as defined in Section 2.4.3.

4. Use FRRP to start an RF telemetry session. Verify that the session starts on the blocking band open channel (Channel 4).
5. End the telemetry session.
6. 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 8.2.
7. Remove the blocking band generator signal (RF off).
8. Use FRRP to start an RF telemetry session. Verify that the session starts on one of the blocking band channels (not Channel 4).
9. End the telemetry session.
10. 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.
11. Use FRRP to start an RF telemetry session. Verify that the session starts on the blocking band open channel (Channel 4).
12. End the telemetry session.
13. Repeat steps 11 and 12 four additional times (for a total of five).
14. Modulate the blocking band generator output so that it is on for 0.1 ms during a 10 ms period as defined in Section 8.5.
15. Use FRRP to start an RF telemetry session. Verify that the session starts on the blocking band open channel (Channel 4).
16. End the telemetry session.
17. Repeat steps 15 and 16 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 telemetry sessions only start on Channel 4 (Steps 14-16).

RESULTS: **PASS**

For detailed results see ELN 5783824.

The telemetry session started on Channel 4 for all ten runs with the modulated blocking band on.

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.

METHOD:

1. Configure the test setup as defined in Section 7.
2. Setup the blocking band signal generator to output the signal defined in Section 8.3. Adjust the blocking band power level to 10 dB above the calculated threshold power level and the LIC (Channel 0) to 3 dB above the calculated threshold power level.
3. Start FRRP on the Model 3120 PRM as defined in Section 2.4.3.
4. Use FRRP to start an RF telemetry session. Verify that the session starts on the blocking band open channel (Channel 4).
5. End the telemetry session.
6. 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 8.2.
7. Use FRRP to start an RF telemetry session. Verify that the session starts on the blocking band open channel (Channel 4).
8. End the telemetry session.
9. Increase the on channel interfere signal level 9 dB from the following test (6 dB above the calculated threshold power level).
10. Use FRRP to start an RF telemetry session. Verify that the session starts on the LIC (Channel 0).

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 telemetry session starts on the LIC (Channel 0) in Step 10.

RESULTS: **PASS**

For detailed results see ELN 5783824.

The telemetry session started on the LIC (Channel 0).

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.

METHOD:

1. Configure the test setup as defined in Section 7.

2. Setup the blocking band signal generator to output the signal defined in Section 8.3. Adjust the blocking band power level to 10 dB above the calculated threshold power level and the LIC (Channel 0) 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 8.2.Start FRRP on the Model 3120 PRM as defined in Section 2.4.3.
4. Use FRRP to start an RF telemetry session. Verify that the session starts on the LIC (Channel 0).
5. Set the spectrum analyzer as follows
    a. Span: zero span
    b. Frequency: Channel 0 frequency (402.15 MHz)
    c. Sweep time: 10 seconds
    d. Sweep: Single
6. While the telemetry session is still active, decrease the on channel interferer signal level to 3 dB below the calculated threshold power level.
7. Trigger a spectrum analyzer sweep. Adjust the attenuation in the telemetry link in order to stop communications.
8. Record the session stop time on the LIC (Channel 0). The session stop time is defined as the time period from when the external goes to the continuous TX to when it stops.
9. Reduce the link attenuation to the previous value.
10. Verify that the session starts on the blocking band open channel (Channel 4).

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 4 after the attenuation is removed.

RESULTS: **PASS**

For detailed results see ELN 5783824.

Table 12 Discontinuation of MICS Session Results

	Antenna A	Antenna B
Session Stop Time (s)	4.006	4.037

The session restarted on Channel 4 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. This test will verify that the pre-scanned alternate channel feature is not used.

This test will be executed at BSC.

METHOD:

1. Configure the test setup as defined in Section 7.
2. Setup the blocking band signal generator to output the signal defined in Section 8.3. Adjust the blocking band power level to 10 dB above the calculated threshold power level and the LIC (Channel 0) to 3 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 8.2.
4. Start FRRP on the Model 3120 PRM as defined in Section 2.4.3.
5. Use FRRP to start an RF telemetry session. Verify that the session starts on the blocking band open channel (Channel 4).
6. Adjust a second LIC channel (Channel 9) blocking band power level to 2 dB below the calculated threshold power level. The signal waveform for the blocking band with two LIC's is defined in Section 8.4.
7. Increase the on channel interfere signal level until the telemetry session changes to another channel. Record the new telemetry channel used.

EXPECTED RESULTS:

The pre-scanned alternate channel is not implemented.

This is verified if the telemetry channel recorded in Step 7 is Channel 9.

RESULTS: **PASS**

For detailed results see ELN 5783824.

The session switched channels to the second LIC, which verifies that the pre-scanned alternate channel allowance is not implemented.

5 CONCLUSION

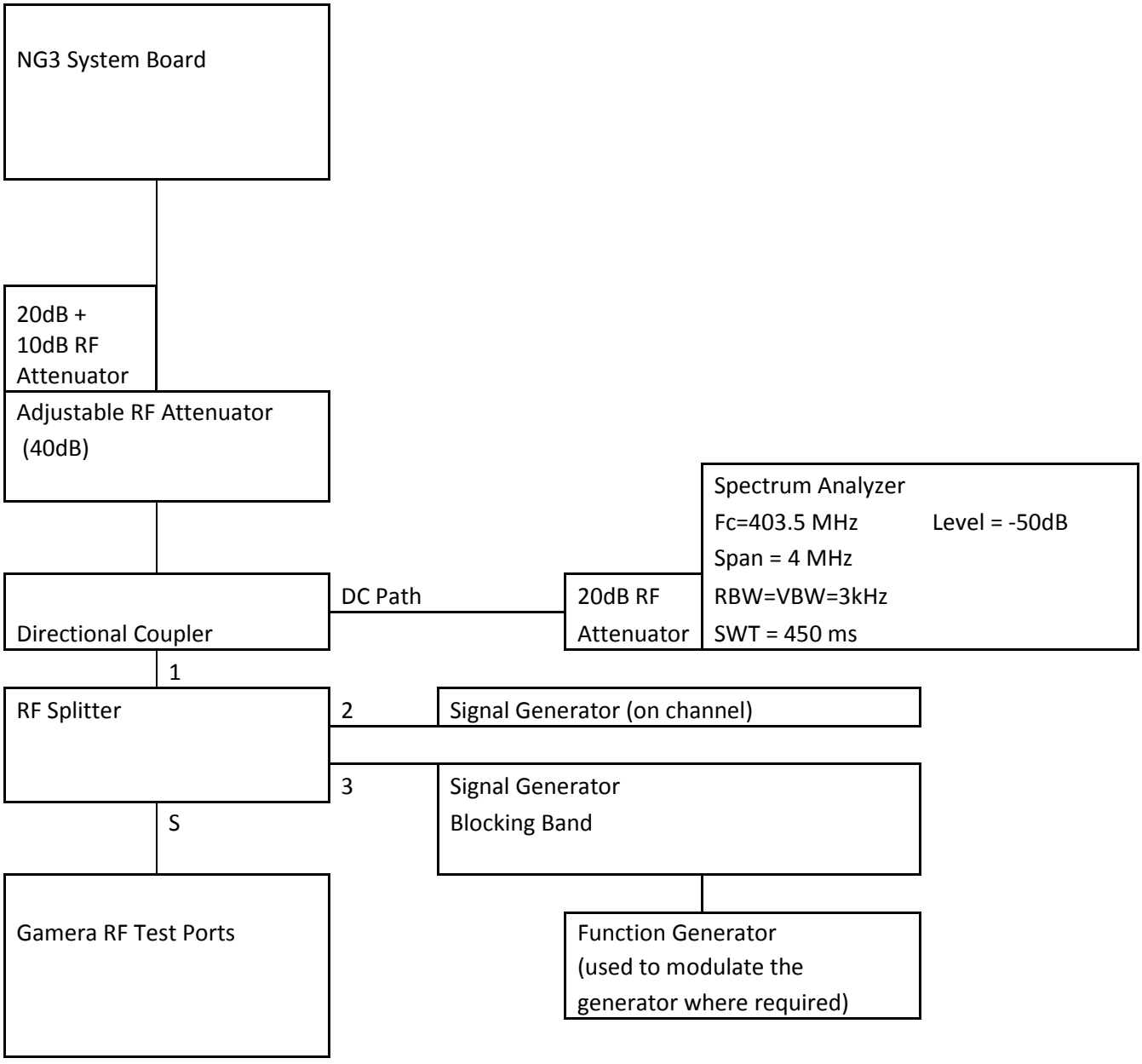
The ZWT Model 3140 **PASSED** all of the testing covered in this protocol/report.

6 APPENDIX A - MICS LBT COMPLIANCE TEST EQUIPMENT

Description	Quantity	Manufacturer	Model	ESN/SN	Cal Date	Cal Due	Notes
Gamera Pilot A (Model 3140)	1	BSC	400063-011	1000035	N/A	N/A	
PRM (Model 3120)	1	BSC	401930-222	53091	N/A	N/A	
NG3 System Board	1	BSC	E71403-105	3002160100020	N/A	N/A	
NG3 System Board Digital Daughter Card	1	BSC	E71774-201	3003353700004	N/A	N/A	
Telemetry Wand (Model 6577)	1	BSC	6577	N/A	N/A	N/A	
Parallel Port Dongle (Model 6807)	1	BSC	6807	N/A	N/A	N/A	
USB Keyboard	1	Hewlett Packard	N/A	N/A	N/A	N/A	
Blocking Band Sig Gen	1	Rohde & Schwarz	SMBV100A	25026579	1-Nov-12	1-Nov-13	
Channel Blocker Sig Gen	1	Agilent	E4421B	10060952	2-Nov-12	2-Nov-13	
Spectrum Analyzer	1	Rohde & Schwarz	FSU	10072092	28-Nov-12	28-Nov-13	
Function Generator	1	Stanford Research Systems	DS 345	10064667	9-Jan-13	9-Jan-14	
Variable Attenuator	1	JFW	50BR-008	4418820640	N/A	N/A	
Fixed Attenuator (10 dB)	1	JFW	50F-010	N/A	N/A	N/A	
Fixed Attenuator (20 dB)	2	JFW	50F-020	M/A	N/A	N/A	
RF Power Splitter (3 to 1)	1	Mini-Circuits	ZA3PD-1-S	40400640	N/A	N/A	
Directional Coupler	1	Pasternack Enterprises	PE 2213-10	N/A	N/A	N/A	
Coax Cables	As Required	N/A	N/A	N/A	N/A	N/A	

7 APPENDIX B - MICS LBT COMPLIANCE TEST SETUP

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



8 APPENDIX C - MICS LBT COMPLIANCE BLOCKING SIGNALS

8.1 Blocking band

The signal shown in Figure 2 was used as the blocking band for LBT testing. The notch is centered at 403.35 MHz (Channel 4). The figure is for reference only. Actual signal levels are set by the test method.

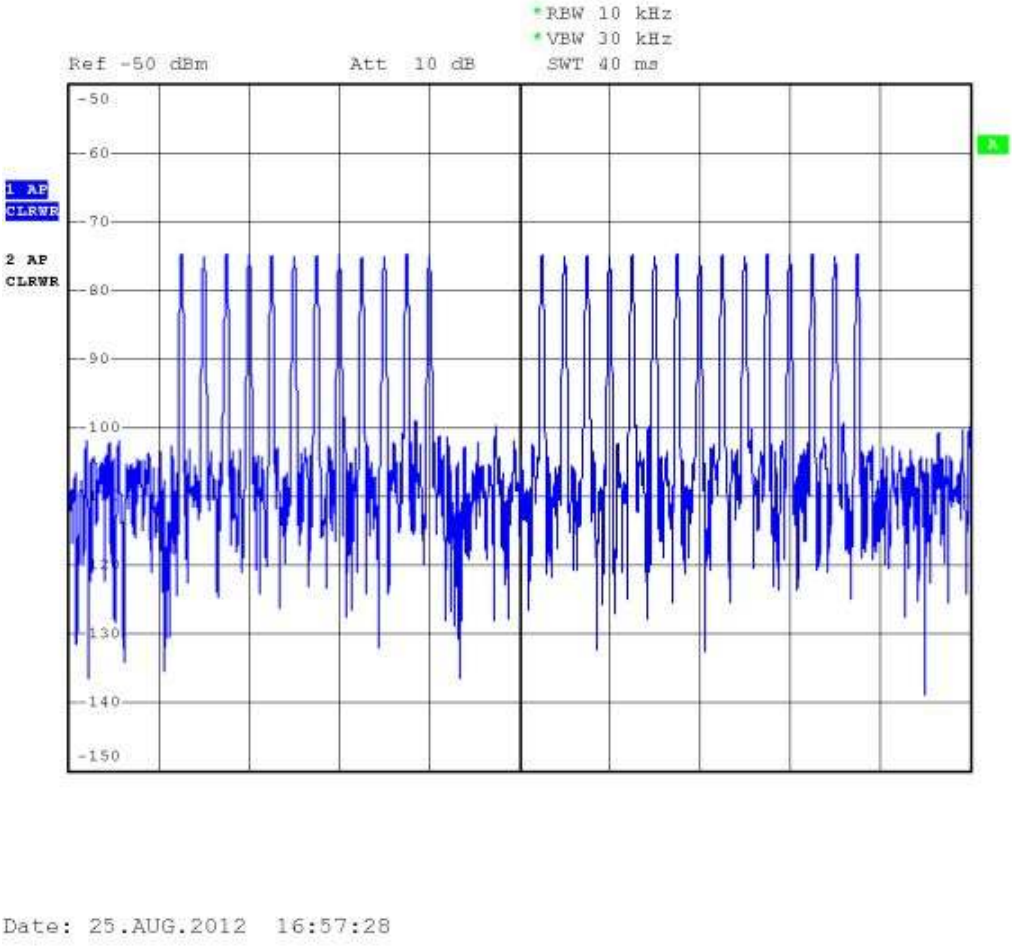


Figure 2 LBT Blocking Band Signal

8.2 Blocking band with on-channel interferer

The signal shown in Figure 3 was used as the blocking band and on-channel interferer for LBT testing. The on-channel interferer is centered at 403.35 MHz (Channel 4). The figure is for reference only. Actual signal levels are set by the test method.

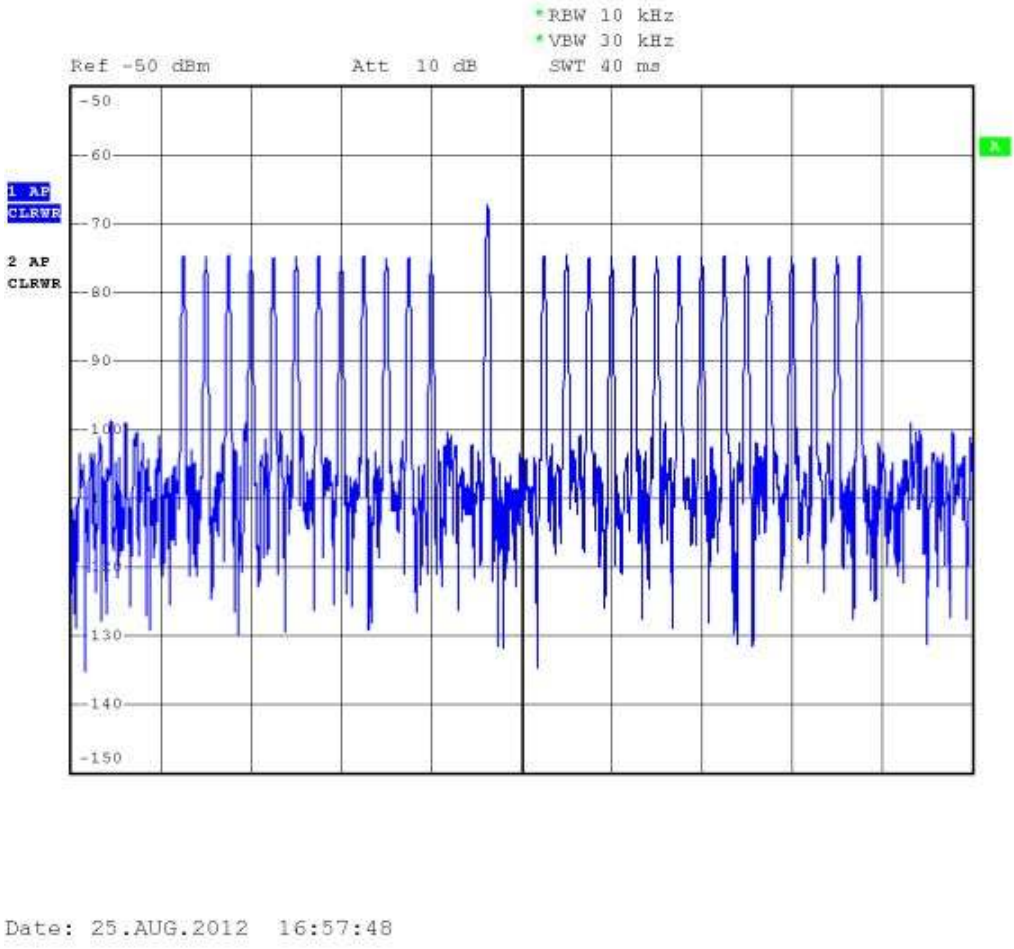


Figure 3 LBT Blocking Band with On-channel Interferer Signal

8.3 Blocking band with Least Interfered Channel

The signal shown in Figure 4 was used as the blocking band with Least Interfered Channel (LIC) for LBT testing. The notch is centered at 403.35 MHz (Channel 4). The LIC is centered at 402.15 MHz (Channel 0) and has lower amplitude that the remainder of the blocking band. The figure is for reference only. Actual signal levels are set by the test method.

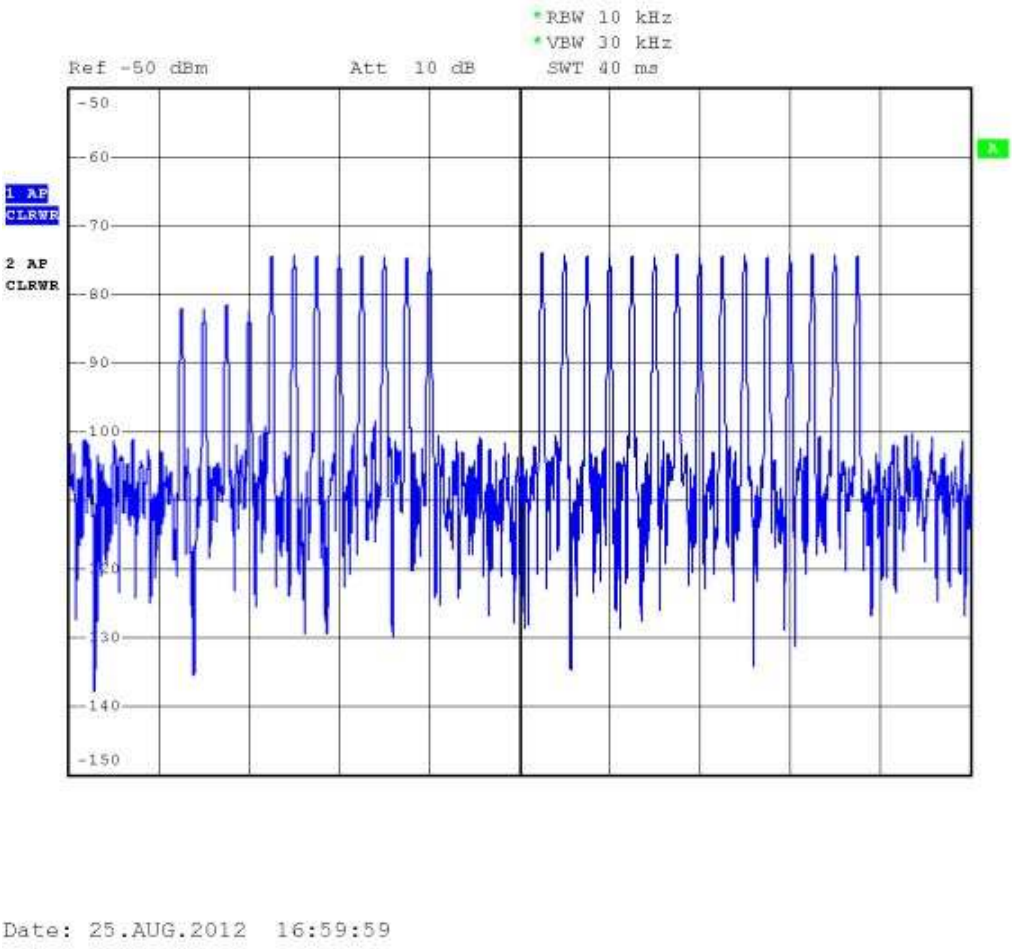


Figure 4 LBT Blocking Band with Least Interfered Channel Signal

8.4 Blocking band with Least Interfered Channel 1 and Least Interfered Channel 2

The signal shown in Figure 5 was used as the blocking band with Least Interfered Channel (LIC) for LBT testing. The notch is centered at 403.35 MHz (Channel 4). The LIC 1 is centered at 402.15 MHz (Channel 0) and has lower amplitude that the remainder of the blocking band. The LIC 2 is centered at 408.85 MHz (Channel 9) and has lowest amplitude of the blocking band. The figure is for reference only. Actual signal levels are set by the test method.

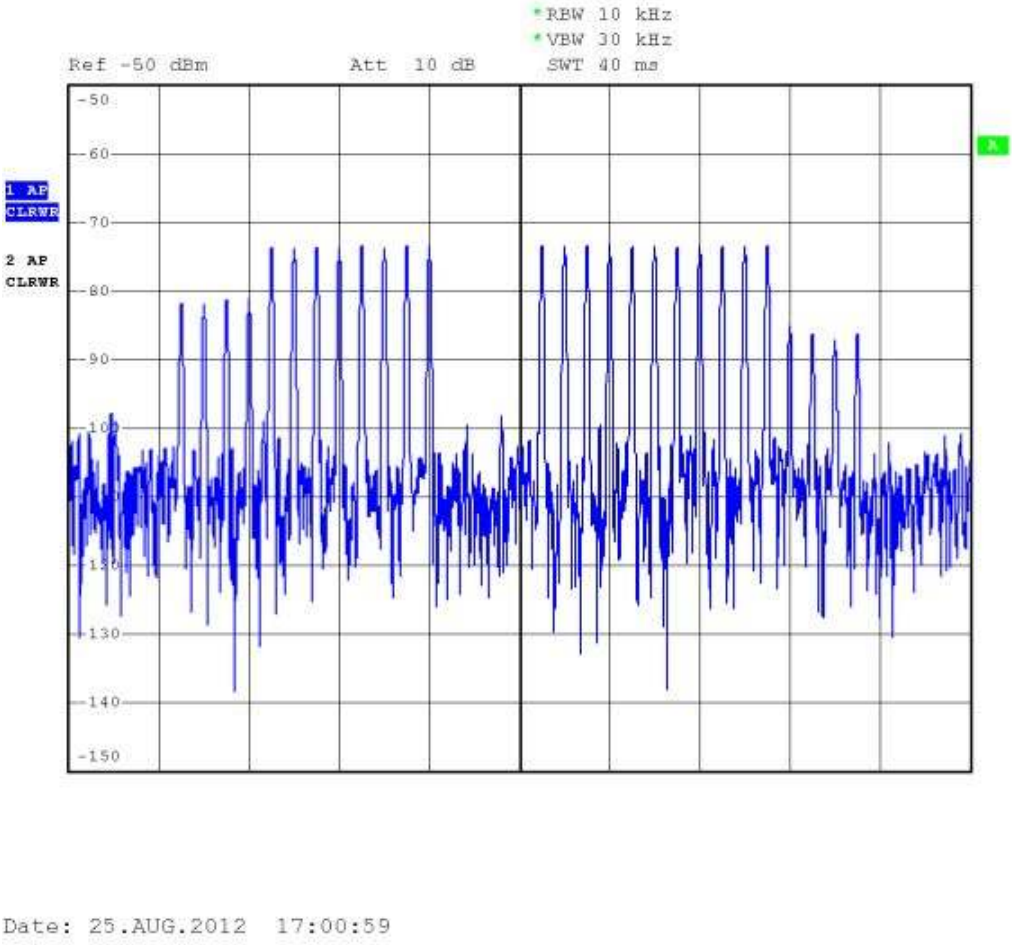


Figure 5 LBT Blocking Band with Least Interfered Channel 1 and Least Interfered Signal 2 Signal

8.5 Modulated Blocking Band for the Channel Monitoring Period Test

The signal shown in Figure 6 is the modulated blocking band waveform used for the Channel Monitoring Period test. The plot 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.

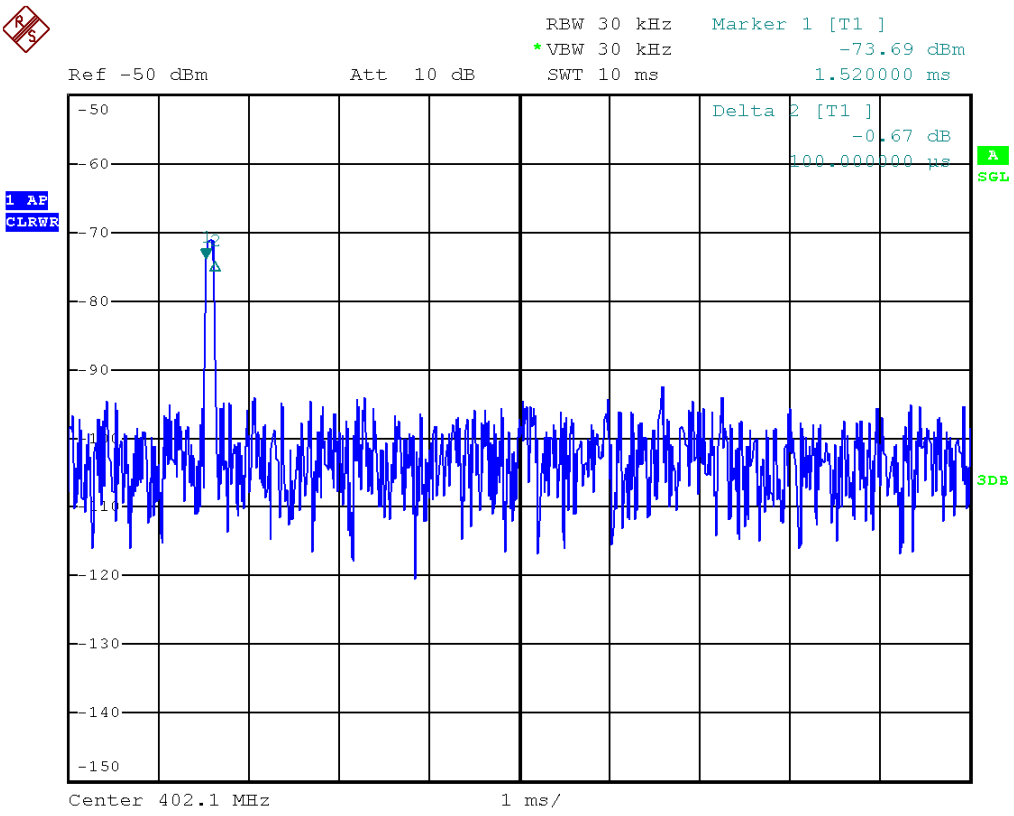


Figure 6 Modulated Blocking Band for the Channel Monitoring Period Test

9 APPENDIX D – FRRP COMMANDS

9.1 Start Telemetry Session

Perform the following FRRP sequence to start a telemetry session:

1. FRRP – Macro – Start Session
2. Verify that in the FRRP message window that macro ends with “CommSessionStarted”

9.2 End Telemetry Session

Perform the following FRRP sequence to start a telemetry session:

1. FRRP – Macro – End Session
2. Verify that in the FRRP message window that macro ends with “CommSessionEnded”

9.3 Select Antenna A

Perform the following FRRP command to select Antenna A:

1. Execute the FRRP SetSWRTmyConfig command with nominal except for the following settings:
    a. ExternalDiversityAntenna = AntennaA
    b. ExtLBTMonitoringAntenna = AntennaA
2. Verify that in the FRRP message window that Antenna A is selected in the MASRFExternal message.

9.4 Select Antenna B

Perform the following FRRP command to select Antenna B:

1. Execute the FRRP SetSWRTmyConfig command with nominal except for the following settings:
    a. ExternalDiversityAntenna = AntennaB
    b. ExtLBTMonitoringAntenna = AntennaB
2. Verify that in the FRRP message window that Antenna B is selected in the MASRFExternal message.

10 APPENDIX E – TEST PHOTOS

Figure 7 Test Setup Photos