Boston Scientific
Cardiac Rhythm Management

1115573

EDVT Protocol and Report

MICS LBT Compliance

for the Jaguar 2 MICS Communicator

Model 6290

Rev B

August 28, 2013

Responsible Department: CRM R&D Hardware Development

Author Electrical Engineer, CRM R&D Hardware Development	Peter Musto	Date
Approver Electrical Engineer, CRM R&D Hardware Development	Larry Canady	Date
Approver Design Assurance	Srividya Saptharishi	Date
Approver Systems Engineer	Par Lindh	Date
Approver Manager, CRM R&D Hardware Development	Mike Barton	Date

EXECUTIVE SUMMARY

This document describes the test protocol and report for the electrical design verification testing (EDVT) performed to show LATITUDE Jaguar 2 MICS Communicator, Model 6290 compliance with MICS LBT (Listen Before Talk) Requirements. The results will be added once testing is complete.

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 Jaguar 2 MICS Communicator are met as defined in the system requirements document 531569-120, entitled SYRS BOBCAT/JAGUAR. The SYRS includes requirements for both the Jaguar 2 MICS (Model 6290) and Jaguar 2 ISM (Model 6280) devices. Only the MICS LBT requirements applicable to Jaguar 2 MICS will be verified per this protocol/report.

RESULTS

All tests were performed with **PASSING** results.

UNEXPECTED OBSERVATIONS

There were no unexpected observations.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

1 ABOUT THIS DOCUMENT

1.1 Scope

This document describes the test protocol and report for the electrical design verification testing (EDVT) performed to show LATITUDE Jaguar 2 MICS Communicator, Model 6290 compliance with MICS LBT (Listen Before Talk) Requirements. The results will be added once testing is complete.

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 Jaguar 2 MICS Communicator are met as defined in the system requirements document 531569-120, entitled SYRS BOBCAT/JAGUAR. The SYRS includes requirements for both the Jaguar 2 MICS (Model 6290) and Jaguar 2 ISM (Model 6280) devices. Only the MICS LBT requirements applicable to Jaguar 2 MICS will be verified per this protocol/report.

1.2 Objective

This testing is intended to ensure that the Jaguar 2 MICS Model 6290 complies with the LBT requirements outlined in the various standards. Successful completion of this EDVT will be used to support Jaguar 2 radio compliance in the MICS band.

1.3 Revision History

Table 1 Revision History

Revision	Description of change	Author
A.3	New document in Windchill	Peter Musto
A.7	Updated per informal peer review.	Peter Musto
B.4	Updated with results	Peter Musto

1.4 Device Description

The Jaguar 2 MICS Communicator, Model 6290, is an externally powered device that communicates with implantable devices via an RF link and transmits information back to a central database. The device has a programmable RF section to support telemetry with the implantable device in the global MICS RF band (402-405 MHz). Connection to the central database can be either through an on-board analog phone modem or a separate USB 3G cellular device (Model 6295 or Model 6296). Connection to external Bluetooth sensors (weight scales and blood pressure monitors) is through a separate USB Bluetooth device (Model 6654). The device includes LEDs and buttons for the User Interface (UI), and two USB 2.0 device ports. These USB ports can be used in conjunction with the USB Bluetooth device or the USB 3G cellular devices for communication with external sensors or the central database.

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
2G	Second Generation Cellular Technology
3G	Third Generation Cellular Technology
AS/NZS	Australian/New Zealand Standard
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
EDAT	Electrical Design Acceptance Testing
EDVT	Electrical Design Verification Testing
EIRP	Equivalent Isotropic Radiated Power
ELN	Electronic Lab Notebook
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
FRRP	Frontier Raw Register Programmer
FSK	Frequency-Shift-Keying
FW OR F/W	Firmware
HLA	High Level Assembly
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
MTI	Manufacturing Test Interface
mW	Milliwatt
NA or N/A	Not Applicable
NG3	Next Generation Pulse Generator which includes MICS telemetry
NWEMC	Northwest EMC

Acronym	Definition
PCA	Printed Circuit Assembly
PCB	Printed Circuit Board
PG	Pulse Generator
PN or P/N	Part Number
R&TTE	Radiocommunications and Telecommunications Terminal Equipment
REA	Ripple Effects Analysis
RF	Radio Frequency
RH	Relative Humidity
RSS	Radio Standards Specification (Canada)
RX	Receive
s	second
SCHEM	Schematic
SN or S/N	Serial Number
SRD	Short Range Device
SW or S/W	Software
SWR	Software Radio
SYRS	System Requirements Specification
TBD	To Be Determined
TRP	Total Radiated Power
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
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
531569-120	*	SYRS Bobcat/Jaguar	SYRS
531570-002	*	MTI SPEC JAGUAR 2.0	MTI
6290	*	COMMUNICATOR LATITUDE JAGUAR MICS	MODEL
400374-010	*	COMM LATITUDE WAVE MICS 6290 NA	HLA
270617-003	*	PCA JAGUAR COMMUNICATOR LATITUDE MICS RF	PCA
270616-002	*	PCB JAGUAR COMM LATITUDE MICS RF	PCB
800352-006	*	SCHEM PCA JAGUAR COMMUNICATOR LATITUDE	SCHEM
850556-002	*	SCHEM JAGUAR 2.0 MICS RF COMMUNICATOR PCA LATITUDE	SCHEM
350118-001	*	ADPTR PWR 5.0VDC 3.0A TYPE A LATITUDE NA	-
1114584	*	EDVT Protocol/Report for the Jaguar 2 MICS Communicator Model 6290	EDVT
1112535	*	NG3 FCC 95I	-
1101143	*	Dragon/Jaguar 2 Stratification Likelihood Justification	-
ELN 6044658	*	JAGUAR 2 MICS - MODEL 6290 - LBT EDVT (1115573) DATA	ELN
ELN 5677919		JAGUAR 2 MICS PROTO-2 ANTENNA PERFORMANCE DATA - SATIMO	ELN
1101601	*	Jaguar2 FW 2.01.00 and Version 1.51.00 REA	REA
Procedure 005872	*	ESD HANDLING	-
Procedure 006318	*	DESIGN VERIFICATION AND VALIDATION	-

*Current revision shall apply for reference material.

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 95:2012	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

DOCUMENT IDENTIFIER	DOCUMENT TITLE
	SERVICE WMTS. 218-219 MHZ RADIO SERVICE THAT WAS FORMERLY IVDS.)
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 required for each test is based on type of the requirement to be tested (deterministic or statistical).

Deterministic requirements are binary, non-statistical or self-evident requirements; a sample size of one (1) is sufficient to verify a deterministic requirement.

For those requirements that are classified as statistical, sample size is selected to achieve required confidence and reliability levels. The level of risk and the test type (limit/stress classification) are used in combination with the data type (variable or attribute) to determine the required confidence/reliability and ultimately, an appropriate sampling plan. The level of risk is determined by assessing both the severity of potential harms and the associated occurrences, and is reported as a Product V&V Zone.

For each test performed, a summary table is provided which contains the information used to determine the sample size for the requirement under test (V&V Zone, requirement type, test type, and data type) as well as the resulting confidence and reliability and required sample plan. The minimum Ppk and/or Pp values to be demonstrated will also be included in this table if a variable sampling plan is to be used, with normal data.

The requirement type for each requirement is documented in the SYRS BOBCAT/JAGUAR. The Product V&V Zone is for each requirement is documented in 1101143.

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 shall be Pilot A or equivalent:

- Model 6290 COMMUNICATOR LATITUDE JAGUAR MICS

2.3 Test Equipment

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

- NG3 PG System Board (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)
- Communicator Power Supply 5V/3A, 350118-001 (or equivalent)
- RF Test Equipment (spectrum analyzer and signal generators)

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

2.4 Test Configuration

2.4.1 Test Configuration for LBT Compliance Testing

The DUT 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 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 Initial Setup

2.5.1.1 Serial Port Setup

1. If not already installed, download the driver for the RS-232 to serial converter from:

   If using IOGEAR GUC232A: http://www.iogear.com/support/dm/driver/GUC232A#display
   If using FTDI Custom BSC Cable:
   http://www.ftdichip.com/Products/Cables/USBTTLSerial.htm

Figure 1 FTDI BSC Custom Cable (for reference only)

2. Connect the serial (null modem) cable from the PC to the test interface board DB-9 connector (J5). Use the ribbon cable provided to connect between the interface board (J4) to the DUT serial port (J8) accessed via the cut out in the bottom of the Communicator (under the label). See Figure 2. If using the FTDI BSC Custom Cable, the interface board and ribbon cable are not needed. Connect the FTDI cable directly from the USB port of a PC to the serial port connector on the DUT (J8).

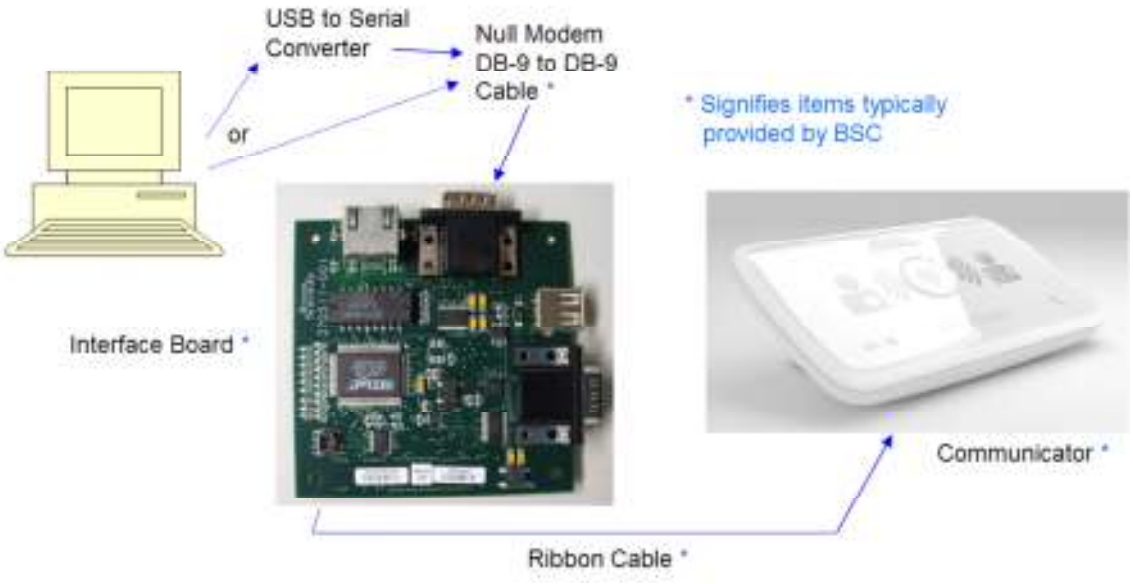


Figure 2 Jaguar Communicator Serial Connection Diagram (for reference only)

3. Determine the PC serial COM port number assigned to the serial port used for the Communicator and use Hyperterminal or TeraTerm to configure the serial port as follows:
   - Baud Rate: 115200
   - Data: 8 bit
   - Parity: none
   - Stop: 1 bit
   - Flow Control: HW

2.5.1.2 Linux Read/Write Environment

For the read/write Linux environment, perform the following actions to access the interface upon power up:

1. Log in when prompted using the following values:
   a. Login: <*login name*> where *login name* is *root*
   b. Password: <*password*> where *password* is controlled for security reasons and must be obtained directly from the appropriate personnel.

This will bring up a read-write Linux shell.

2.5.2 DUT Pre-Configuration

Prior to performing a PG interrogation with the Communicator, several PG parameters must be stored in the Communicator configuration files. Perform the following steps prior to the initial PG interrogation. The information is stored in non-volatile memory, so once a PG's parameters are loaded, this procedure does not need to be repeated unless a new PG will be used.

1. Connect the Communicator per the test set up of Section 2.5.1.1.
2. Apply power to the Communicator and boot to a Linux Read/Write environment per Section 2.5.1.2.
3. Connect the USB memory stick (provided by BSC) to either of the communicator USB ports. In the terminal program log, USB enumeration messages will be output. If failure messages are output, repeat the power on sequence. Ignore warning messages concerning toolstick and rootfs versions out of sync.

4. Setup the communicator for the PG
    a. At the Linux prompt (#) type “reconfig” <ENTER>. A configuration menu will be output. The settings for the PG used for test need to be configured: Model ID, Serial ID, and WakeUpAccessCode.
    b. At the “Enter Item Number” prompt, press 5 <ENTER>. Input the HWCID provided by BSC.
    c. At the “Enter Item Number” prompt, press 25 <ENTER>. Input the Device S/N provided by BSC.
    d. At the “Enter Item Number” prompt, press 6 <ENTER>. Input the Device Model Number provided by BSC.
    e. At the “Enter Item Number” prompt, press 0 <ENTER> then 1<ENTER> to exit and save changes.
5. Load the PG interrogation definition files
    a. At the Linux prompt (#) type “cd /mnt/usb” <ENTER> to access the USB memory stick files.
    b. Copy the BSC provided interrogation definition files using the Linux cp command format:

    cp pg-model-independent-interrogation.def Applications/data/pgif/interrogations/

    Where pg-model-independent-interrogation.def is the BSC provided file name.
6. After the “reconfig” command is run and the interrogation files are loaded. Remove the USB memory stick.

2.5.3 Communicator - PG Telemetry Session Start

Use the following to start a Communicator – PG telemetry session. The test command used is the same command implemented by the device during normal operation.

1. Perform the interrogation command from the Linux command line using the following command:

    #interrogatepg /Applications/data/pgif/interrogations/pg-model-independent-interrogation.def

    Where the “.def” file is the same file loaded onto the Communicator in Section 2.5.2.

The LBT algorithm status can be monitored in the terminal window as part of the device logging information. Included in the log is the measured signal level for each of the available wake-up channels. If all channels are above the LBT threshold the device will log a failed interrogation, and no RF signal will be output. If at least one channel is below the LBT threshold, the PG interrogation will be executed, which will be visible as data in the terminal window, as well as measured RF energy on the connected test equipment.

2.6 Standard Test Conditions and Configurations

2.6.1 Mains Voltage

The Jaguar 2 MICS Communicator is powered by an AC/DC Power Adapter. Various models of this power adapter are required to support the AC mains plug configurations for the Jaguar 2 MICS distribution plans. However, the power adapter models are equivalent with the only difference being the plug configuration. Therefore testing per this protocol will be performed at only one mains voltage combination (110 VAC/ 60 Hz) using the 350118-001 (or equivalent) power adapter.

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 BSC MICS band telemetry system will consist of 10 channels spaced 300 kHz apart between the frequencies of 402-405 MHz. 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 1 and Channel 8. The selection of channels for testing is arbitrary. A different set of channels will provide similar 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

2.7.1 MICS LBT Algorithm Details

The Jaguar 2 MICS Communicator LBT algorithm is optimized to minimize the PG battery load due to RF telemetry. The telemetry between a Communicator and a PG is initiated over the RF channel, without user interaction in almost all cases. The PG battery impact of telemetry with the Communicator is reduced by allowing the PG to wake up and listen for a Communicator session on only three (3) of the ten (10) assigned channels. Because of this implementation, the PG radio on-time is minimized.

As a result of the PG's reduced channel list for wake-up, the Communicator will only start a telemetry session on the three (3) pre-determined wake-up channels (1, 4, and 8 as defined in Table 5). Therefore at session start, the Least Interfered Channel (LIC) allowance is not implemented. The Communicator LBT algorithm is defined such that if all wake-up channels are occupied (above threshold), the device will not attempt to start a telemetry session. Instead the device will perform an LBT scan at a later time, and attempt to start a telemetry session only if at least one wake-up channel is below the device LBT threshold value. Once a telemetry session has been started between the Communicator and the PG, the system will make use of the other channels defined in Table 5.

Testing per this EDVT will be modified from that prescribed in the standards in order to account for this device behavior. Whereas the protocol would generally verify that the device chooses the LIC when all channels are above LBT threshold, for the Communicator, the modified verification is that the device does not transmit at all. Since the rescheduling of the telemetry session is a

timing item in the device FW, and not an LBT parameter, this protocol will not verify that the Communicator properly reschedules a later LBT.

2.8 PG Emissions Bandwidth

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.

2.9 Handling Precautions

Care should be taken in the handling of the DUT. 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 DUT PCA is handled. The PCA 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

Assembly Number	Serial Number (S/N)	Software Version
270617-003	JS0313260678	2.00.00

Because access to the internal RF test connector was used for this testing, the DUT was tested as a PCA. The PCA number listed in Table 6 is part of the Communicator device assembly 400374-010.

Refer to 1101601 for the Communicator FW REA.

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	SyRS017851	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	SyRS017853	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	SyRS017853	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	SyRS017853	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	SyRS017853	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	SyRS17854	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	SyRS017853	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
SyRS017853	Prior to using an RF channel defined in SyRS017848, the Communicator 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 Communicator 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 Communicator/PG session is initiated, 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
SyRS17854	The Communicator shall transmit on the frequency channel selected under SyRS017848 for 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
SyRS017851	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.	4.1

4 TESTS PERFORMED

The following sections describe the MICS LBT Compliance testing to be performed on the Jaguar 2 MICS Communicator.

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. Configure the device for testing per Section 2.5.1.1 and Section 2.5.1.2.
5. Start an RF telemetry session per Section 2.5.3. Verify that the session starts on the blocking band open channel (Channel 4).
6. Wait for the telemetry session to end.
7. Increase the on channel interferer signal level 1 dB from the following test and repeat Steps 5 and 6.
8. Repeat Step 7 until the device does not attempt to start a telemetry session due to all channels being above the LBT threshold. 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.

ACCEPTANCE CRITERIA:

As specified in SyRS017851, 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 (in this case the PG), and G is the monitoring system antenna gain.

As defined in Section 2.8, the emission bandwidth is 287171 Hz. The minimum antenna gain (recorded in ELN 5677919) is -0.45 dBi. The minimum communicator 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 -95.9 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 6044658.

Table 9 LBT Threshold Power Results

Measured Threshold Power Level	-99.0 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 BSC telemetry system, the widest bandwidth emitter is the PG (bandwidth as defined in Section 2.8). 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 PG.

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. Configure the device for testing per Section 2.5.1.1 and Section 2.5.1.2.
5. Start an RF telemetry session per Section 2.5.3.
6. Verify that the device does not attempt to start a telemetry session due to all channels being above the LBT threshold.
7. Decrease the on channel interferer 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. Wait for the telemetry session to end
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 2.8).
10. Start an RF telemetry session per Section 2.5.3. Verify that the session starts on the blocking band open channel (Channel 4).
11. Wait for the telemetry session to end.

12. Increase the on channel interferer signal level 1 dB from the following test and repeat Steps 10 and 11.
13. Repeat Step 12 until the device does not attempt to start a telemetry session due to all channels being above the LBT threshold. 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 2.8) with signal level of P_a.
15. Start an RF telemetry session per Section 2.5.3. Verify that the session starts on the blocking band open channel (Channel 4).
16. Wait for the telemetry session to end.
17. Increase the on channel interferer signal level 1 dB from the following test and repeat Steps 15 and 16.
18. Repeat Step 17 until the device does not attempt to start a telemetry session due to all channels being above the LBT threshold. 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 6044658.

Table 10 Monitoring System Bandwidth Results

Low Frequency Power Delta (D1)	6 dB
High Frequency Power Delta (D2)	6 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. Configure the device for testing per Section 2.5.1.1 and Section 2.5.1.2.
5. Start an RF telemetry session per Section 2.5.3.
6. Verify that the device does not attempt to start a telemetry session due to all channels being above the LBT threshold.
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 start an RF telemetry session per Section 2.5.3.
9. Verify that the session starts on Channel 4 and measure the time from when the session was requested and the DUT 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 6044658.

Table 11 Monitoring Scan Cycle Time Results

Scan Cycle time run 1 (s)	1.476
Scan Cycle time run 2 (s)	1.426
Scan Cycle time run 3 (s)	1.330
Scan Cycle time run 4 (s)	1.410
Scan Cycle time run 5 (s)	1.394

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. Configure the device for testing per Section 2.5.1.1 and Section 2.5.1.2.
4. Start an RF telemetry session per Section 2.5.3. Verify that the session starts on the blocking band open channel (Channel 4).
5. Wait for the telemetry session to end.
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. Start an RF telemetry session per Section 2.5.3. Verify that the session starts on one of the blocking band wake-up channels (Channel 1 or Channel 8).
9. Wait for the telemetry session to end.
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. Start an RF telemetry session per Section 2.5.3.
12. Verify that the device does not attempt to start a telemetry session due to all channels being above the LBT threshold.
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. Start an RF telemetry session per Section 2.5.3.
16. Verify that the device does not attempt to start a telemetry session due to all channels being above the LBT threshold.
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 device does not attempt to start a telemetry session due to all channels being above the LBT threshold (Steps 14-16).

RESULTS: **PASS**

For detailed results see ELN 6044658.

A telemetry session was not attempted (no RF) 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 1) to 3 dB above the calculated threshold power level.
3. Configure the device for testing per Section 2.5.1.1 and Section 2.5.1.2.
4. Start an RF telemetry session per Section 2.5.3. Verify that the session starts on the blocking band open channel (Channel 4)
5. Wait for the telemetry session to end.
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. Start an RF telemetry session per Section 2.5.3. Verify that the session starts on the blocking band open channel (Channel 4).
8. Wait for the telemetry session to end.
9. Increase the on channel interferer signal level 9 dB from the following test (6 dB above the calculated threshold power level).
10. Start an RF telemetry session per Section 2.5.3. Verify that the device does not attempt to start a telemetry session due to all channels being above the LBT threshold.

EXPECTED RESULTS:

The DUT shall not transmit if the ambient power level on all channels is above the maximum permitted $P_{Th.}$ The Communicator does not implement the Least Interfered Channel (LIC) allowance (Refer to Section 2.7.1).

This requirement is met if the device does not attempt to start a telemetry session due to all channels being above the LBT threshold in Step 10.

RESULTS: **PASS**

For detailed results see ELN 6044658.

A telemetry session was not attempted (no RF) on any channel when all channels were blocked by signal levels above the monitoring threshold.

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 8.1. 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 8.2.
4. Configure the device for testing per Section 2.5.1.1 and Section 2.5.1.2.
5. Start an RF telemetry session per Section 2.5.3. Verify that the session starts on the blocking band open channel (Channel 4).
6. 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
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 Channel 4. The session stop time is defined as the time period from when the device 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 6044658.

Table 12 Discontinuation of MICS Session Results

Session Stop Time (s)	0.181

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 1) 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. Configure the device for testing per Section 2.5.1.1 and Section 2.5.1.2.
5. Start an RF telemetry session per Section 2.5.3. Verify that the session starts on the blocking band open channel (Channel 4).
6. Adjust a second LIC channel (Channel 8) 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 interferer 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 8.

RESULTS: **PASS**

For detailed results see ELN 6044658.

The session switched channels to the second LIC (Channel 8), which verifies that the pre-scanned alternate channel allowance is not implemented.

5 CONCLUSION

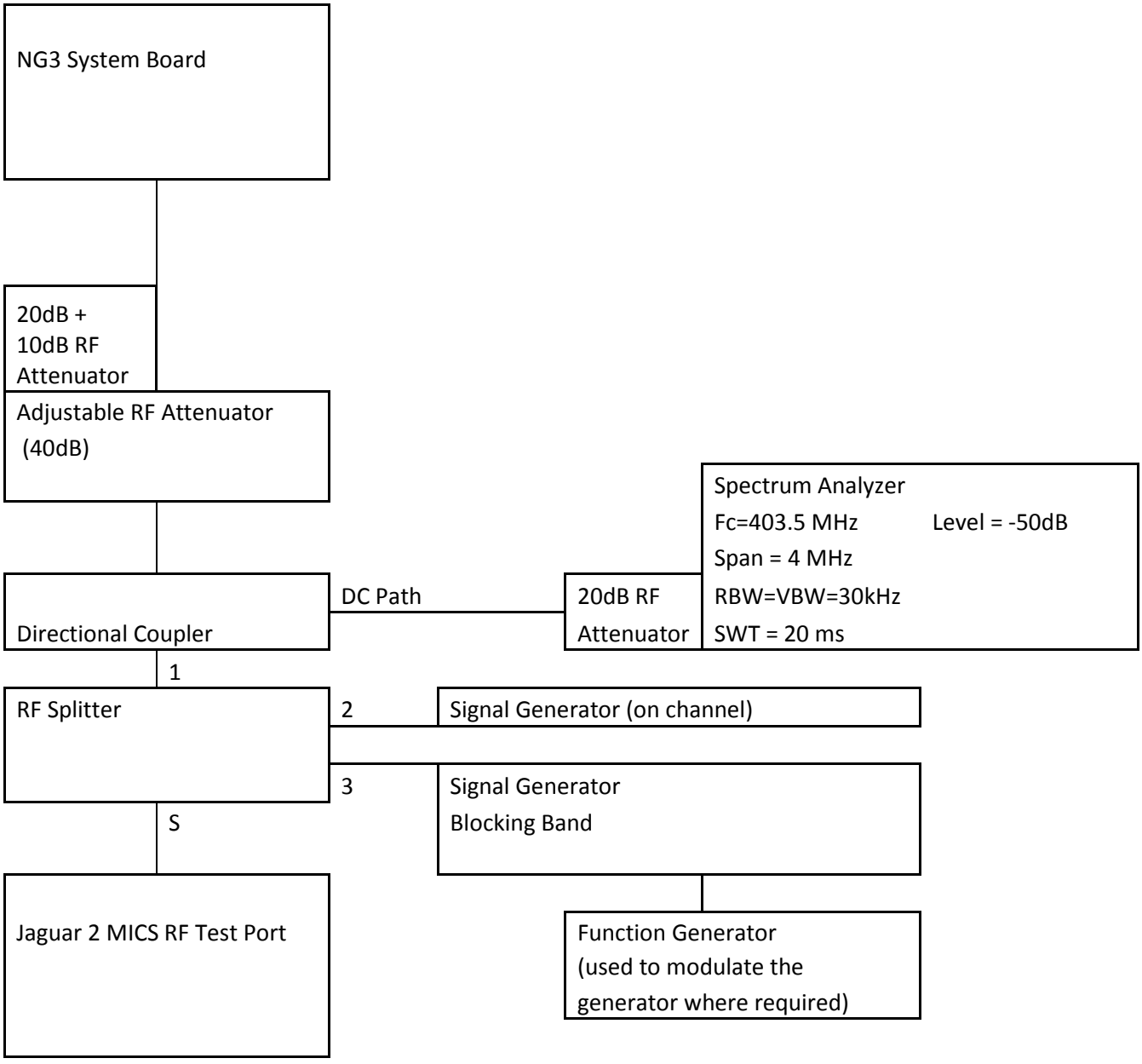
The Jaguar 2 MICS Communicator **PASSED** all of the testing in this EDVT protocol/report.

6 APPENDIX A - MICS LBT COMPLIANCE TEST EQUIPMENT

Description	Quantity	Manufacturer	Model	ESN/SN	Cal Date	Cal Due	Notes
Jaguar 2 MICS PCA	1	BSC	270617-003	JS0313260678	N/A	N/A	FW Version 2.00.00
AC/DC Power Adapter (5V/3A)	1	GlobTek	GTM41061-1512-7.0	N/A	N/A	N/A	BSC Model 350118-001
NG3 System Board	1	BSC	E71403-105	3002160100020	N/A	N/A	Programmed with FW Version E_v1.02.00 HWCID: 2453082557 Model Number: G179-200-0 S/N: 123456
NG3 System Board Digital Daughter Card	1	BSC	E71774-201	3003353700004	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	N/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	
USB to Serial Adapter Cable	1	FTDI	TTL-232RG-VSW3V3-WE	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 3 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 and channels are set by the test method.

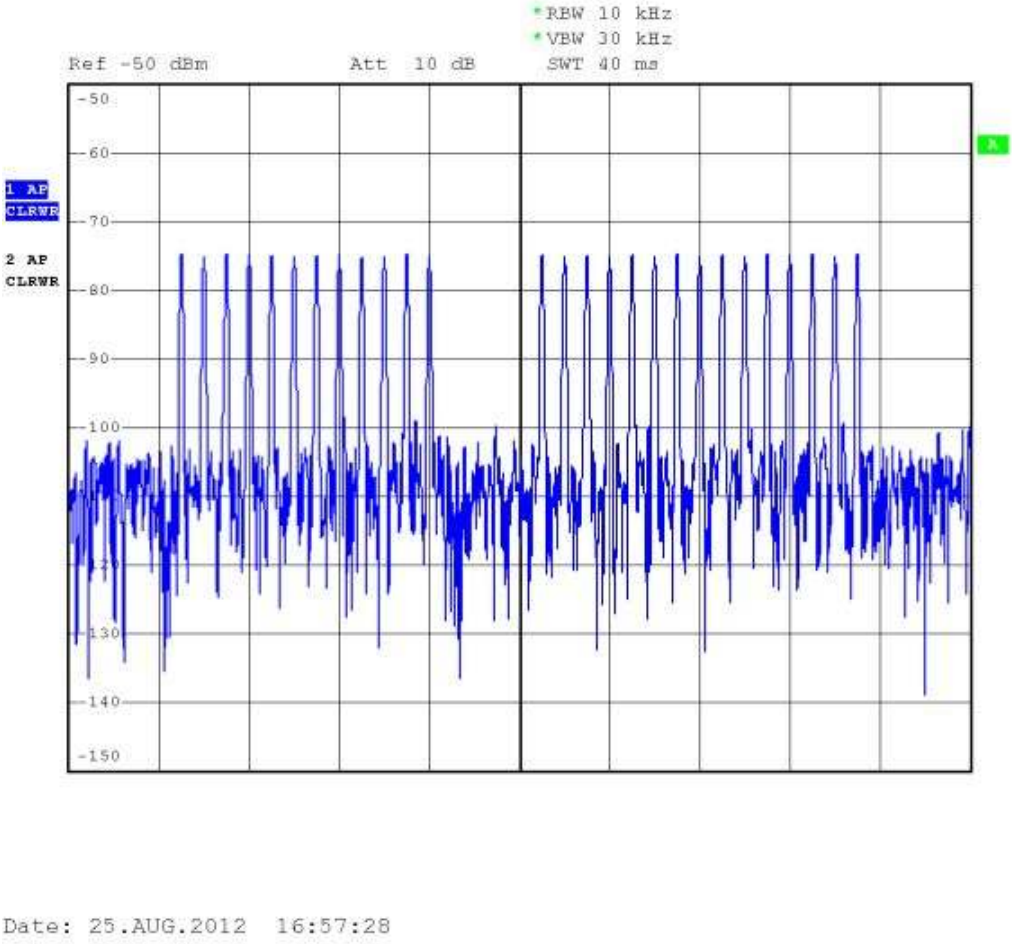


Figure 3 LBT Blocking Band Signal

8.2 Blocking band with on-channel interferer

The signal shown in Figure 4 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 and channels are set by the test method.

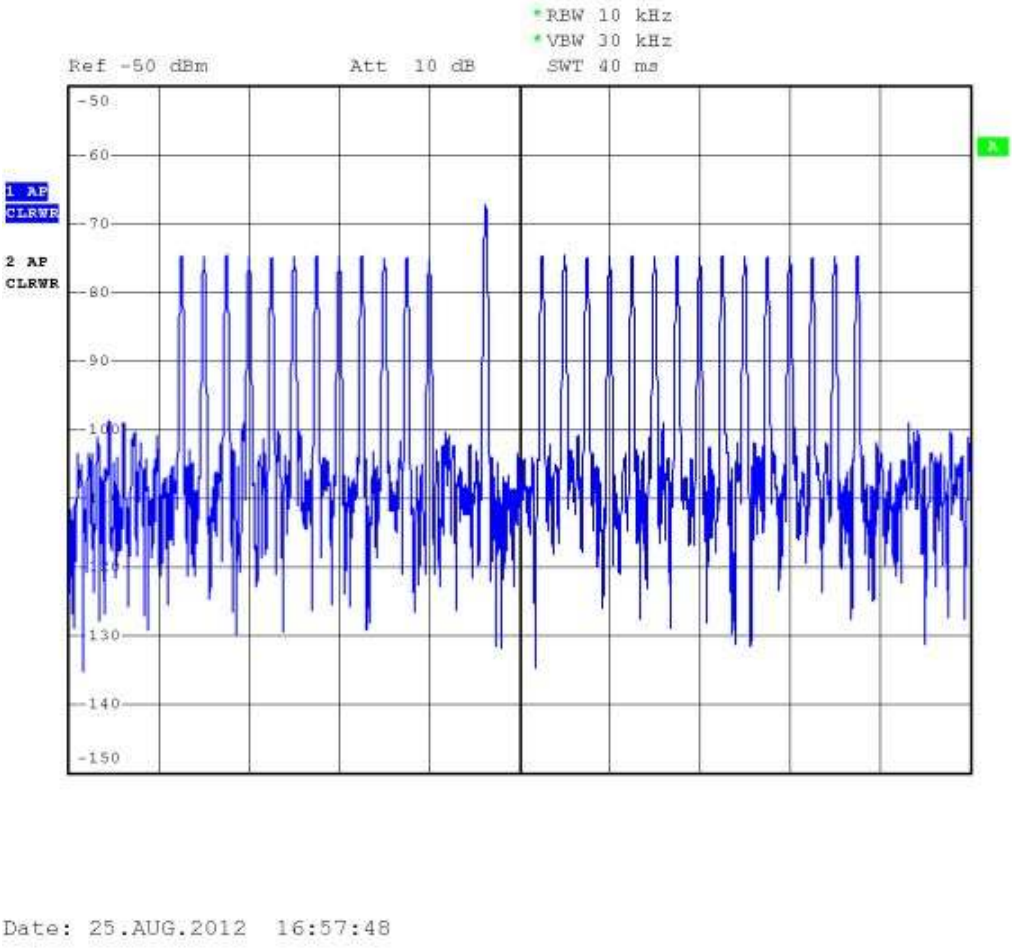


Figure 4 LBT Blocking Band with On-channel Interferer Signal

8.3 Blocking band with Least Interfered Channel

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 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 and channels are set by the test method.

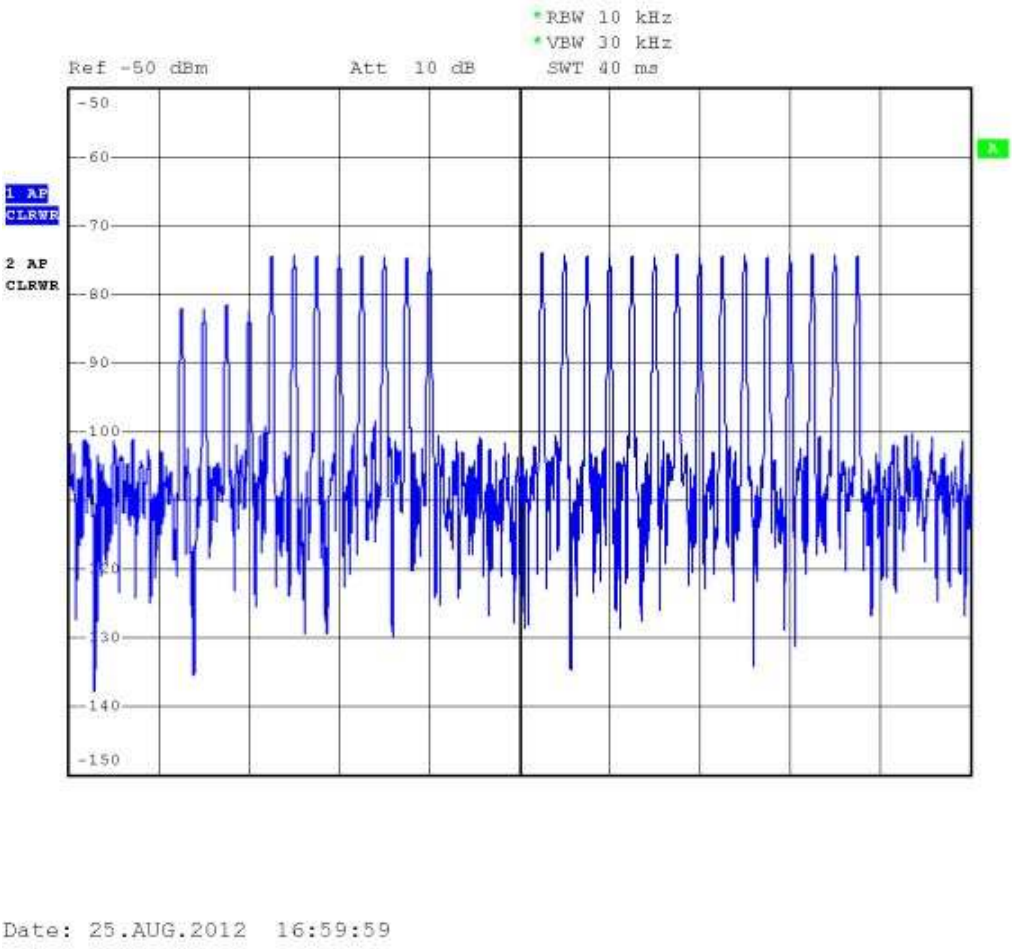


Figure 5 LBT Blocking Band with Least Interfered Channel Signal

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

The signal shown in Figure 6 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 and channels are set by the test method.

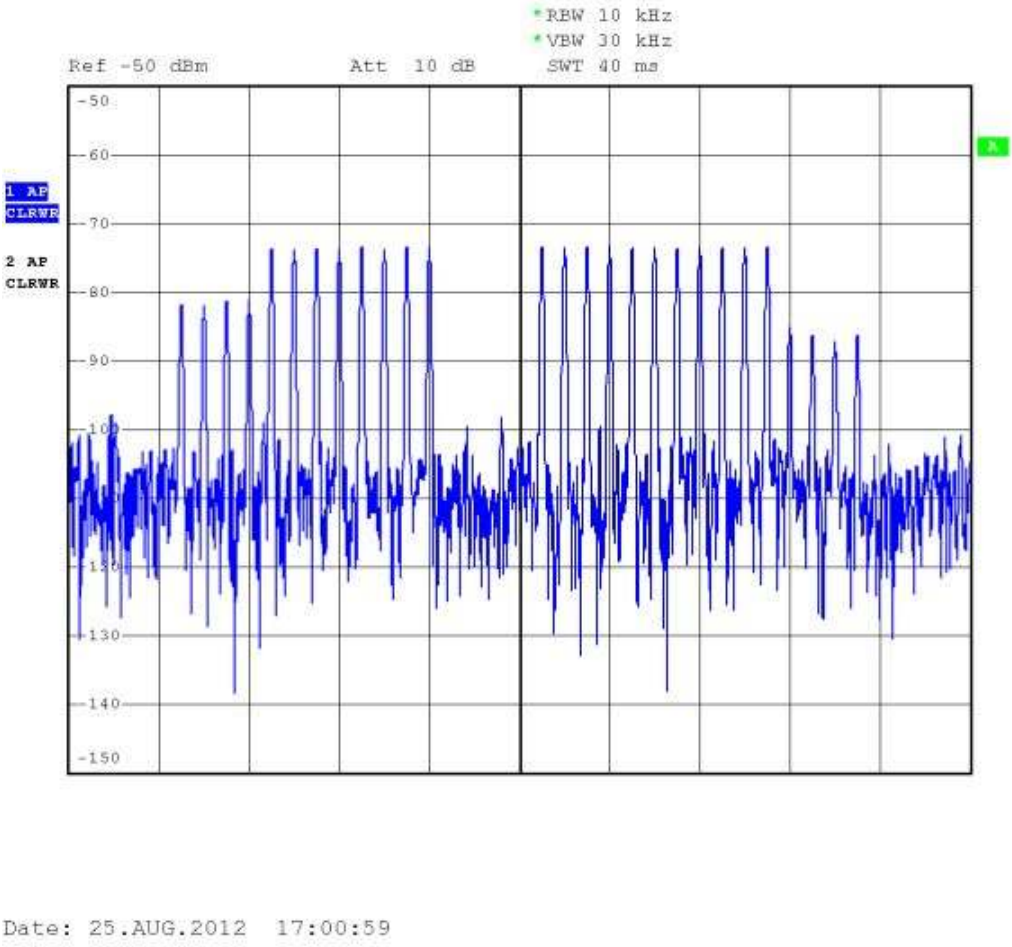


Figure 6 LBT Blocking Band with Least Interfered Channel 1 and Least Interfered Signal 2 Signal

8.5 Modulated Blocking Band for the Channel Monitoring Period Test

The signal shown in Figure 7 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.

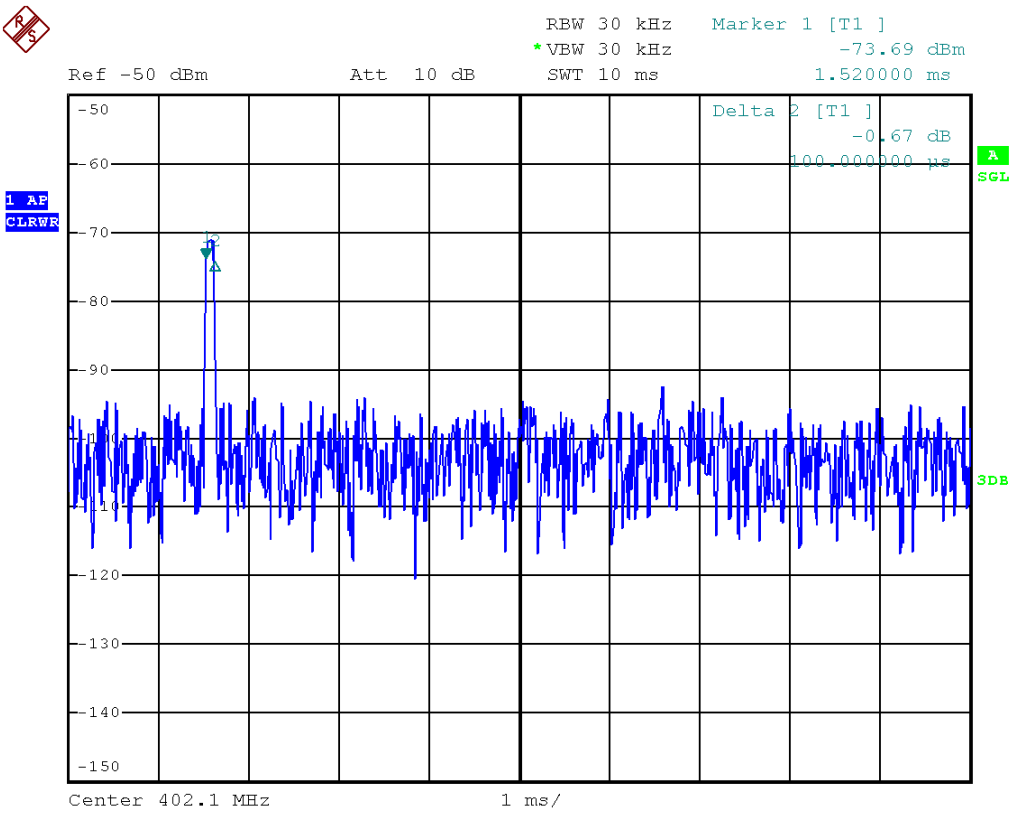


Figure 7 Modulated Blocking Band for the Channel Monitoring Period Test

9 APPENDIX D – TEST PHOTOS

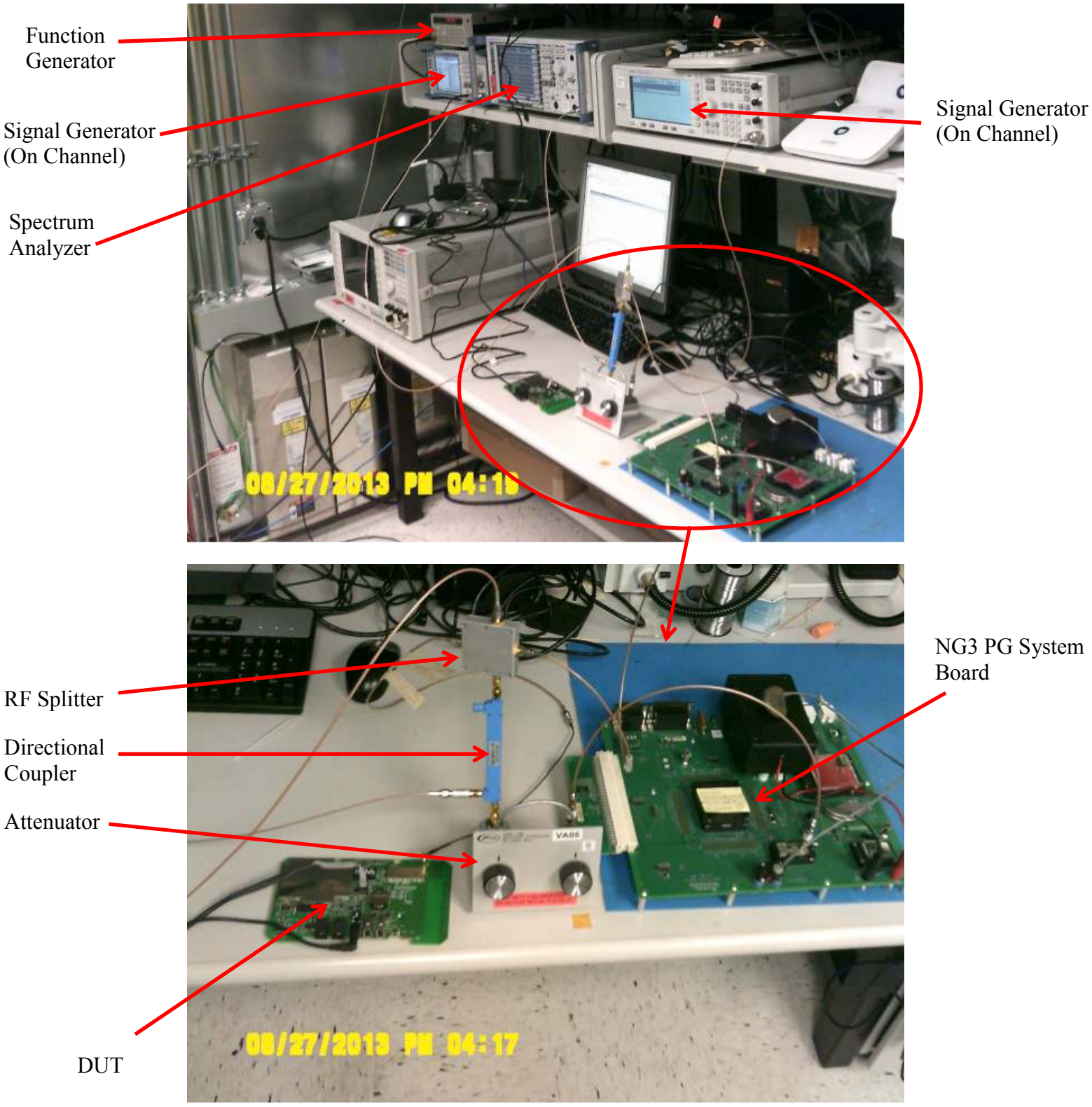


Figure 8 Test Setup Photos