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| SPINAL MODULATION, INC | |
| DOCUMENT TYPE: VERIFICATION REPORT | VR#: 167-3 |
| TITLE: LISTEN BEFORE TALK TEST REPORT | Rev: A |

REVISION HISTORY

| Rev | Change Description | CO | Effective Date | By |
|-----|--|----|----------------|--------------|
| A | Initial Release. SoMo Programmer AD1634 with SoMo BS PCB AD1621 | | | Erik Johnson |

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1. PURPOSE

This Report describes the MICS/MedRadio Listen Before Talk testing performed on the SMI Programmer Basestation. This test was performed by SMI personnel.

System Description

The Spinal Modulation (SMI) MICS/MedRadio 402 to 405 MHz system is required to scan all of its channels and select the lowest ambient noise channel prior to initiating an RF link (transmitting). The MICS/MedRadio system uses a master-slave type communication where the handheld Programmer initiates all RF communication. The Implantable NeuroStimulator (INS) or Temporary NeuroStimulator (TNS) respond to the Programmer RF link and are not permitted to initiate a RF link. SMI does not use any of the allowed special emergency transmissions from the INS or TNS. SMI uses the Least Interfered Channel (LIC) method and not the LBT threshold power level.

2. SCOPE

This document describes the testing of the Listen Before Talk (LBT) protocol required by applicable parts of MICS standard EN 301 839-1, EN 301 839-2 and MedRadio FCC Part 95.628.a. The SMI radio system uses the Least-Interfered-Channel (LIC). It does not use pre-scanned alternate channel and this test will not be performed.

3. REFERENCE DOCUMENTS

3.1. SMI Reference Documents

| | |
|--------|--|
| VP239 | Applicable V & V Plan Neurostimulator System (to be filled in report, e.g. VP239 for DP1005) |
| PS1300 | Product Requirements Specification Connector Cable |
| HW015 | Hardware Requirements Specification Programmer |
| OP033 | Design Verification |
| FM130 | Report Template |
| ER079 | SMI Standard Terminology Definitions and Acronyms |
| VR068 | Programmer Emissions Test Report |

3.2. Regulatory Agency Documents

| | |
|--------------|--|
| EN 301 839-1 | 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 |
| EN 301 839-2 | Electromagnetic Compatibility and Radio Spectrum Matters (ERM); Radio Equipment in the Frequency Range 402 MHz to 405 |

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MHz for Ultra Low Power Active Medical Implants and Accessories; Part 2: Harmonized EN Covering Essential Requirements of Article 3.2 of the R&TTE Directive

| | |
|---------------|--|
| EN 301 489-1 | Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements |
| EN 301 489-27 | Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 27: Specific conditions for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P) |
| FCC Part 95 | Federal Communications Commission PART 95 MedRadio |

4. DEFINITIONS

Refer to ER079 for the various definitions, acronyms and terminology used in this document.

Abbreviations

| | |
|--------|--|
| BS | Basestation. PCB in Programmer that has RF and RF MCU control circuitry. |
| BSDiag | Basestation API (Patch Code) allows GUI control of BS Product Code |
| CA | Clear Channel Assessment |
| GUI | Graphical User Interface |
| LBT | Listen Before Talk |
| LIC | Least Interfered Channel |
| NS PCB | Neurostimulator printed circuit board. |
| CW | Continuous Wave |
| IF | Intermediate Frequency |
| MICS | Medical Implant Communication Service |
| RSSI | Receive Signal Strength Indicator |
| SMI | Spinal Modulation, Inc. |

5. EQUIPMENT AND SUPPLIES

Log information in table below.

| | |
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| Equipment | Mfrgr | Model Number | Serial Number | SW/FW Version | Date of Next Calibration (if required) |
|---------------------------|-----------|----------------|----------------------|---------------|--|
| BS PCBA | SMI | AD1616 | 520042 ^{6C} | 5.1.1.0 | N/A |
| BS'PCBA | SMI | AD1616 | 520042 | 5.1.1.0 | N/A |
| PC | Dell | Optiplex GX745 | 7011903-00102 | winXP SP3 | N/A |
| Digital Multimeter | | | | N/A | |
| Power Supply | Agilent | E3140A | EQ066 | N/A | 1/11/14 |
| 20 dB Directional coupler | Mini-ckts | ZFDC-20-4L | SF800301017 | N/A | N/A |
| 20 dB Directional coupler | Mini-ckts | ZFDC-20-4L | | N/A | N/A |
| 30 dB attenuator | Mini-ckts | VAT-20+ | 3-0931 | N/A | N/A |
| 30 dB attenuator | Mini-ckts | VAT-20+ | 3-1008 | N/A | N/A |
| 3 ft. Coax Cable | Johnson | 415-033-036 | N/A | N/A | N/A |
| 3 ft. Coax Cable | Johnson | 415-033-036 | N/A | N/A | N/A |
| 3 ft. Coax Cable | Johnson | 415-033-036 | | N/A | N/A |
| 3 ft. Coax Cable | Johnson | 415-033-036 | | N/A | N/A |
| Cable USB A-B mini micro | Qualtek | 3021003-03 | N/A | N/A | N/A |
| Oscilloscope | Agilent | D508064A | EQ0111 | N/A | 4/11/14 |
| Spectrum Analyzer | Agilent | GXA N9010A | EQ0516 | N/A | 5/10/14 |
| Signal Generator | HP | 8656B | EQ077 | N/A | N/C |
| Bsdlory | SMC | SW-1078 | N/A | 2.05.0 | N/A |
| | | | | | |
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| | | | | | |

Crossed-out lines represent equipment not used 1/12/14

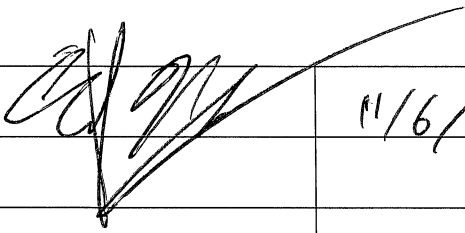
6. TEST RESULTS AND TEST SIGNATURES

Test results will be reported in VR167.

Test signatures:

| Function | Printed name | Signature | Date |
|----------|--------------|-----------|------|
| | | | |

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|----------------|--------------|--|---------|
| Firmure Gydeer | Grik Johnson |  | 11/6/13 |
| | | | |
| | | | |

7. SAMPLE SIZE AND JUSTIFICATION

Refer to OP033 for the sample size justification. In general, outside laboratory emissions testing is performed on a sample size of one. Refer to the outside laboratory reports for sample sizes used for particular tests.

8. DEVICE UNDER TEST CONFIGURATION

8.1 Circuit Description

The SMI Programmer (Clinical or Patient) uses the Zarlink ZL70102 transceiver for MICS radio communication with an INS or TNS neurostimulator.

Specifications summary:

- 10 channels equally spaced from 402 to 405 MHz
- 300 kHz channel spacing.
- Emission bandwidth 20 dB: 250 kHz nominal.
- +/- 25 ppm channel frequency accuracy.
- 20 dB LBT RSSI measurement bandwidth: 500 kHz nominal.
- -103 dBm LBT Rx Sensitivity.
- Antenna Gain typical: -7dB.
- LIC Threshold Power Pth = -103 dBm.
- Channel monitoring period 10.5 msec.
- Channel Nominal Center Frequency.
 - Ch0 402.150 MHz
 - Ch1 402.450 MHz
 - Ch2 402.750 MHz
 - Ch3 403.050 MHz
 - Ch4 403.350 MHz
 - Ch5 403.650 MHz
 - Ch6 403.950 MHz
 - Ch7 404.250 MHz
 - Ch8 404.550 MHz
 - Ch9 404.850 MHz

Prior to initiation of a RF link the Programmer scans all 10 channels in Rx mode only. The Rx 450 kHz IF is ported out of the Zarlink transceiver to the analog RSSI measurement circuit. The analog RSSI measurement circuit is comprised of a balanced passive bandpass filter with a nominal 500 kHz 20 dB bandwidth. The bandpass filter

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output goes to an AD8310 Log Detector (U10) amplifier that demodulates the 450 kHz IF Rx signal. The output is ten 10.5 msec pulsed DC signals each representing one channel RSSI amplitude in order of Ch0 to Ch9. See sample display with no RF input figure 1.



Figure 1. J6 Pin 12 RSSI. 30 msec/div. 200 mV/div AD8310 Output to MCU ADC. No RF Input.

| Channel | RSSI ADC |
|---------|-------------|
| 0 | 1100 |
| 1 | 1112 |
| 2 | 1133 |
| 3 | 1144 |
| 4 | 1170 |
| 5 | 1184 |
| 6 | 1219 |
| 7 | 1201 |
| 8 | 1145 |

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| 9 | 1119 |
|---|------|

Table 1. MCU ADC output of Figure1.

The RSSI timing of each channel scan is driven by the ZL70102 transceiver (U3) RX_EN pin to the MCU (U2). The MCU in turn outputs RSSI_EN that provides timing and scan width that controls the enable pins for all the Op Amp filters and Log Detector.

The Log Detector Output goes to the MCU 12 bit ADC with range of 4096 counts. The no-RF signal input on any channel is typically less than 2400 ADC counts (see figure and table 1). The MCU ADC uses a free running mode and averages 140 measurements.

8.2 Test Firmware

SWxxxx Basestation Compiled Executable (to be filled in report, e.g. SW1077 for DP1005)
 SW1078 BsDiag Compiled Executable
 ED1335 Source Code Basestation
 ED2040 Source Code BsDiag

The firmware is controlled from BsDiag, a PC based test interface, for most testing of the LBT circuitry. It is used to initiate a communication session and read the MCU RSSI values used to determine the LBT channel.

Circuit connections are provided by SMT coax connections to the Basestation board.

Test Parameters:

- 8.3.1 Minimum Power Detection Threshold (< -103 dBm).
- 8.3.2 Monitoring System Bandwidth $>$ Emission Bandwidth (250 kHz).
- 8.3.3 Monitoring System Scan Cycle Time ≤ 5 seconds.
- 8.3.4 Minimum Channel Monitoring Period ≥ 10 msec.
- 8.3.5 Discontinuation of RF Session after ≤ 5 second silent period.

8.3.1 Minimum Power Detection Threshold (< -103 dBm).

The minimum power detection threshold (Pth) is based on an Agency provided equation that includes Antenna Gain (Gt) and Emission bandwidth (EBW) as input parameters from the system.

Measured ²³⁸ Pth (dBm) = $10 \log \text{EBW (Hz)} - 150 + \text{Gt (dBi)}$
 Typical EBW is 250 kHz and Gt is ~~-7~~ dB.
^{-7.69}

Calculated Pth: -107.924 dBm

Test setup:

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Measure the Signal Generator output power on the spectrum analyzer:

Frequency 402.150 MHz

300 kHz steps

-103 dBm

~~72.3 dBm + 30 dB physical AT~~
~~-102.2 + 2 cables @ -1.5 + -1.57~~

off 11/6/13
 (extra physical attenuator not needed)

Spectrum analyzer settings:

RBW: 5 KHz

VBW: 5 KHz

Span: 3 MHz

Sweep: 1.17 s

Atten: 0 dB

Verify Generator output is -103 dBm +/- 0.5 dBm. Pmeasured: 103 +/- .21 dBm

Verify signal generator frequency accuracy on all 10 channel frequencies is +/- 25ppm (+/- 10 kHz):

| | | |
|-----|-------------|--------------------|
| Ch0 | 402.150 MHz | <u>402.156</u> MHz |
| Ch1 | 402.450 MHz | <u>402.456</u> MHz |
| Ch2 | 402.750 MHz | <u>402.756</u> MHz |
| Ch3 | 403.050 MHz | <u>403.056</u> MHz |
| Ch4 | 403.350 MHz | <u>403.356</u> MHz |
| Ch5 | 403.650 MHz | <u>403.656</u> MHz |
| Ch6 | 403.950 MHz | <u>403.956</u> MHz |
| Ch7 | 404.250 MHz | <u>404.256</u> MHz |
| Ch8 | 404.550 MHz | <u>404.556</u> MHz |
| Ch9 | 404.850 MHz | <u>404.856</u> MHz |

Measure RSSI baseline levels with No RF.

Terminate BS J42 output into 50 Ohms.

Start RF connection sequence.

Measure Tx frequency/channel number on spectrum analyzer.

Read RSSI and verify the Tx channel agrees with the lowest (or the 1st lowest if two channels have the same lowest reading) RSSI reading

Freq: 403.95 MHz

Ch #: 76

Lowest RSSI Ch #: 76

| Channel | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---------|-------------|-------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| RSSI | <u>1470</u> | <u>1424</u> | <u>36</u> | <u>49</u> | <u>56</u> | <u>45</u> | <u>10</u> | <u>12</u> | <u>24</u> | <u>21</u> |

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Verify RSSI circuit can distinguish a -103 dBm CW signal on all 10 channels.

Inject a CW signal at -103 dBm into BS RF port J42 on all 10 channels and read MCU RSSI measurement with the BsDiag status command. Verify BS transmits on lowest RSSI measured channel.

Using the signal generator inject a -103 dBm signal sequentially on each channel, one at a time, and record the RSSI levels for all 10 channels from the MCU. Verify the -103 dBm signal is the highest RSSI level on all 10 channels for each of the 10 tests.

Note: 2-digit values all begin w/ 14, of 22 → 1422

Ch 0 (-103 dBm) Highest Channel RSSI: 0 Lowest Channel RSSI: 6 Tx Ch 6

| Channel | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---------|------|------|----|----|----|----|----|----|----|----|
| RSSI | 1764 | 1434 | 22 | 52 | 48 | 48 | 14 | 15 | 29 | 23 |

Ch 1 (-103 dBm) Highest Channel RSSI: 1 Lowest Channel RSSI: 7 Tx Ch 7

| Channel | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---------|------|------|------|----|----|----|----|----|----|----|
| RSSI | 1592 | 1765 | 1438 | 58 | 51 | 50 | 14 | 09 | 27 | 23 |

Ch 2 (-103 dBm) Highest Channel RSSI: 2 Lowest Channel RSSI: 6 Tx Ch 6

| Channel | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---------|------|------|------|------|----|----|----|----|----|----|
| RSSI | 1434 | 1583 | 1757 | 1461 | 54 | 44 | 05 | 14 | 27 | 17 |

Ch 3 (-103 dBm) Highest Channel RSSI: 3 Lowest Channel RSSI: 6 Tx Ch 6

| Channel | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---------|------|----|------|------|------|----|----|----|----|----|
| RSSI | 1426 | 26 | 1581 | 1755 | 1464 | 47 | 07 | 14 | 22 | 23 |

Ch 4 (-103 dBm) Highest Channel RSSI: 4 Lowest Channel RSSI: 7 Tx Ch 7

| Channel | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---------|----|----|----|------|------|------|------|----|----|----|
| RSSI | 23 | 18 | 33 | 1592 | 1756 | 1608 | 1416 | 12 | 23 | 25 |

Ch 5 (-103 dBm) Highest Channel RSSI: 5 Lowest Channel RSSI: 7 Tx Ch 7

| Channel | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---------|----|----|----|----|------|------|------|------|------|----|
| RSSI | 27 | 19 | 32 | 50 | 1596 | 1758 | 1599 | 1418 | 1419 | 23 |

Ch 6 (-103 dBm) Highest Channel RSSI: 6 Lowest Channel RSSI: 19 Tx Ch 1

| Channel | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---------|----|----|----|----|----|----|------|------|------|----|
| RSSI | 27 | 19 | 33 | 56 | 49 | 44 | 1763 | 1664 | 1425 | 19 |

Ch 7 (-103 dBm) Highest Channel RSSI: 7 Lowest Channel RSSI: 1 Tx Ch 1

| Channel | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---------|----|----|----|----|----|----|----|------|------|----|
| RSSI | 28 | 18 | 27 | 55 | 46 | 38 | 25 | 1767 | 1610 | 23 |

Ch 8 (-103 dBm) Highest Channel RSSI: 8 Lowest Channel RSSI: 6 Tx Ch 6

| Channel | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---------|----|----|----|----|----|----|----|----|------|------|
| RSSI | 26 | 16 | 30 | 51 | 56 | 37 | 11 | 23 | 1768 | 1611 |

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Ch 9 (-103 dBm) Highest Channel RSSI: 9 Lowest Channel RSSI: 7 Tx Ch 7

| Channel | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---------|----|----|----|----|----|----|----|----|----|------|
| RSSI | 29 | 27 | 26 | 62 | 49 | 47 | 12 | 15 | 36 | 1769 |

All 10 channels verified -103 dBm signal input was highest RSSI value: PASS

All 10 channels verified Tx Channel was on lowest RSSI channel: PASS

8.3.2 Monitoring System Band width > Emission Bandwidth (250 kHz).

Inject a CW signal at -75 dBm into BS RF port J42 on channel 5, 403.650 MHz (+/- 10 kHz) and read MCU RSSI measurement with the BsDiag status command. Lower the signal 20 dB to -95 dBm and record the RSSI values. The channel 5 RSSI value will be used to determine the -20 dB bandwidth points.

Ch 5 (-75 dBm) RSSI: 2522

| Channel | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---------|------|------|------|------|------|------|------|------|------|------|
| RSSI | 1395 | 1394 | 1485 | 1804 | 2357 | 2522 | 2370 | 1804 | 1411 | 1395 |

Ch 5 (-95 dBm) RSSI: 1987

| Channel | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---------|------|------|------|------|------|------|------|------|------|------|
| RSSI | 1425 | 1427 | 1428 | 1465 | 1818 | 1987 | 1837 | 1430 | 1423 | 1422 |

Inject a CW signal at -75 dBm into BS RF port J42 on channel 5, 403.650 MHz (+/- 10 kHz) and read MCU RSSI measurement with the BsDiag status command.

Lower the signal generator frequency until the channel 5 RSSI value matches the -95 dBm RSSI value within 10 ADC counts and record the Minus Signal Generator Frequency.

Ch 5 (-75 dBm) RSSI: 1982 Minus Signal Generator Frequency: 403.265 kHz

| Channel | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---------|------|------|------|------|------|------|------|------|------|------|
| RSSI | 1405 | 1477 | 1725 | 2495 | 2772 | 1982 | 1724 | 1897 | 1395 | 1392 |

Raise the signal generator frequency until the channel 5 RSSI value matches the -95 dBm RSSI value within 10 ADC counts and record the Plus Signal Generator Frequency.

Ch 5 (-75 dBm) RSSI: 1988 Plus Signal Generator Frequency: 403.942 kHz

| Channel | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---------|------|------|------|------|------|------|------|------|------|------|
| RSSI | 1796 | 1351 | 1399 | 1507 | 1812 | 1988 | 2534 | 2349 | 1810 | 1402 |

Monitor system bandwidth:

Subtract the Minus Signal Generator Frequency from the Plus Signal Generator Frequency:

(fo Plus) 403.942 - (fo Minus) 403.265 = 677 kHz

Verify Monitor System Bandwidth is \geq 300 kHz: PASS

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Verify Monitor System Bandwidth \geq Emission Bandwidth: PASS
 Note: VR068 document is source of emission bandwidth. _____

8.3.3 Monitoring System Scan Cycle Time \leq 5 seconds.

Connect oscilloscope to J6, Pin12, RSSI.

Initiate an RF communication session by issuing a Start Session command from BsDiag.
 Verify the RSSI scope display that all 10 channels were scanned, 10 pulses. See figure 1.
 The RSSI scope display will update every 5 seconds.
 Verify BS is transmitting on Spectrum Analyzer. The Spectrum display will drop every 5 seconds to re-evaluate the LIC and may come up on another channel.

Scope settings:

Trigger: Positive

Horizontal: 1 second/div

Vertical: 200 mV/div

Trigger Mode: Triggered

Adjust 0V line to one graticule from bottom of screen.

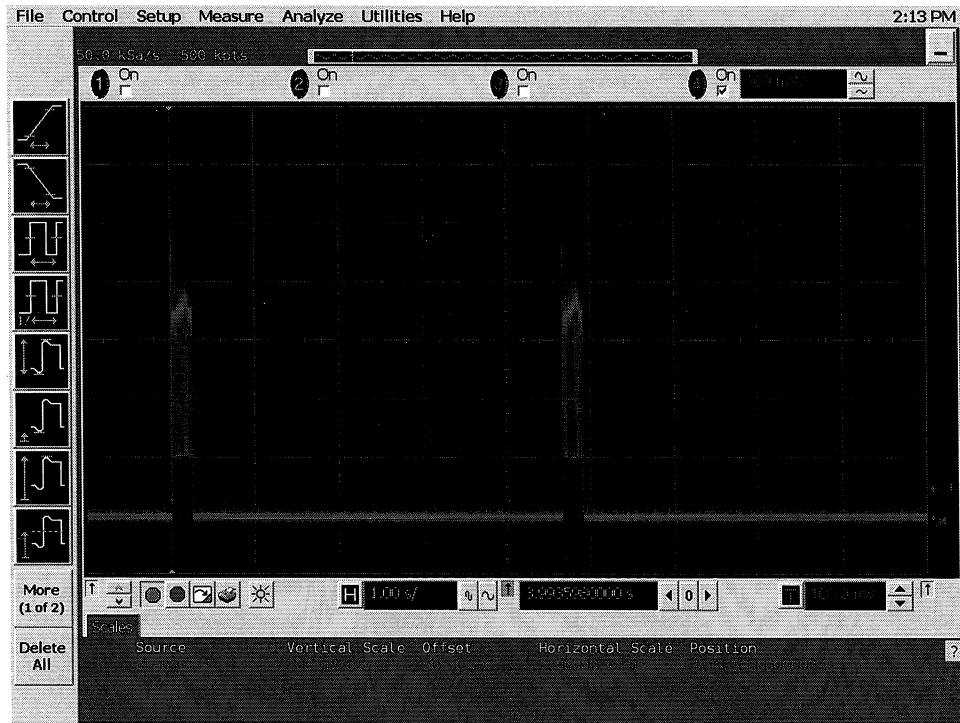
Measure the time from the beginning of one 10 channel scan to the next 10 channel scan.

Record the time and verify it is less than \leq 5 seconds: 4.65 seconds.

Sample Display



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Example of Scan Cycle Time Scope Display. 1 sec/div, 200 mV/div

8.3.4 Minimum Channel Monitoring Period ≥ 10 msec.

Using the setup in step 3, expand the horizontal display and measure each of the 10 channel RSSI scans and verify they are each ≥ 10 msec.

Scope settings:

Horizontal: 5 msec/div

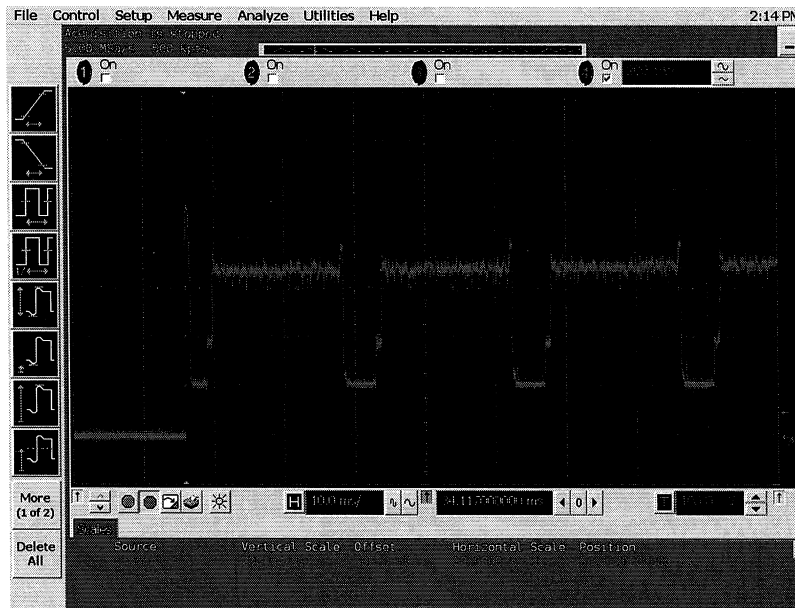
Scroll horizontally thru each channels scan pulse; measure and record each scan pulse width.

| Channel | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| Width msec | 18.63 | 18.63 | 18.63 | 18.63 | 18.97 | 18.18 | 18.41 | 18.70 | 18.41 | 18.41 |

Verify all 10 channels monitoring period is ≥ 10 msec: PASS

Sample Display

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Example of Channel Monitoring Period Scope Display. 10 msec/div, 200 mV/div

8.3.5 Discontinuation of RF Session after ≤ 5 second silent period.

Monitor BS RF output from J42 thru a 20 dB Directional Coupler to Spectrum Analyzer.
Connect J42 Thru connection to a NS PCB to establish a link.

Spectrum Analyzer settings:

Increase the RBW to 4 MHz to capture RF on any channel in the MICS band. Increase sweep time to 7.5 seconds to capture the 5 second dropouts in BS transmission.

| | |
|--------------|-------------|
| RBW | 4MHz |
| Center Freq. | 403.650 MHz |
| Span | 3 MHz |
| Sweep time | 30 msec |

Initiate a RF communication session with No RF Link by issuing a Start Session command from BsDiag. NS PCB should be powered OFF.

Verify BS RF is transmitting on the Spectrum Analyzer.

Spectrum Analyzer settings:

| | |
|----------|-----------|
| SPAN: | Zero Span |
| Trigger: | Video |

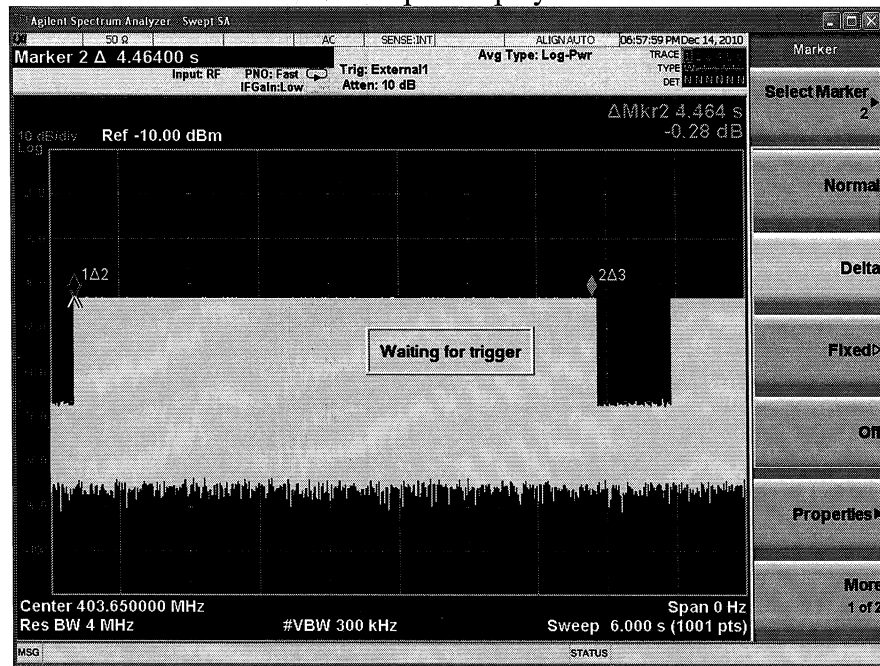
Adjust trigger level for a stable video pulse display.

Adjust Sweep time for 6 seconds.

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Verify the BS stops transmitting and re-evaluates the MICS band LIC in a period ≤ 5 second with No RF Link. PASS 4.63 sec

Sample Display



Example of Spectrum Analyzer display.

Initiate a RF communication session with a RF Link by issuing a Start Session command from BsDiag. NS PCB should be powered ON.

Verify BS RF is transmitting on the Spectrum Analyzer.

Spectrum Analyzer settings:

SPAN: Zero Span

Trigger: Video

Adjust trigger level for a stable video pulse display.

Adjust Sweep time for 6 seconds.

Verify the BS is transmitting and RF Link is continuously maintained.

Set Spectrum Analyzer Trigger to Single Sweep and wait 1 second to shutdown NS PCB power supply.

Verify BS stop transmitting in ≤ 5 seconds. PASS 4.36 sec

Sample Display

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