REVISION HISTORY

Rev	Change Description	CO	Effective Date	By
A	Initial Release.	CO1395	1/19/11	Jim Judkins
B	Added measurement uncertainty analysis, appendix. Changed to format FM130.	CO1598	3/21/11	Jim Judkins

TABLE OF CONTENTS

1. PURPOSE

This Report describes the MICS/MedRadio Listen Before Talk testing to be performed on the SMI Programmer Basestation Monitoring system. The Clinical Programmer MN0700 (FD0038) and Patient Programmer MN0600 (FD0039) share an identical BOM. This test will satisfy the Listen Before Talk Monitoring for both systems. This test will be 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 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) report required by applicable parts of MICS standard EN 301 839-1, EN 301 839-2 Clause 10 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. The tests were conducted using printed circuit board assemblies using coaxial cables for RF connection to the antenna test port connector for RF and a RSSI sample port .

3. REFERENCE DOCUMENTS

3.1. SMI Reference Documents

VP074	V & V Plan Neurostimulator System
PS1300	Product Requirements Specification Connector Cable
HW015	Hardware Requirements Specification Programmer
OP033	Design Verification
FM130	Report Template
ER079	SMI Standard Terminology Definitions and Acronyms

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 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
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.
BSCLI	Base Station Command Line Interface. Firmware to control Programmer Basestation
CA	Clear Channel Assessment
GUI	Graphical User Interface
LBT	Listen Before Talk
LIC	Least Interfered Channel
NS PCB	Neurostimulator printed circuit board.
PDA	Personal Digital Assistant. Device used by Programmer to control RF and remote NS.
RSSI	Receive Signal Strength Indicator
SMI	Spinal Modulation, Inc.

5. SUMMARY OF TEST RESULTS AND CONCLUSIONS

5.1. Test Results Summary

All tests in this protocol passed per the applicable test methods and Standards.

5.2. Protocol Deviations

There were no protocol deviations.

5.3. Conclusions

Since all the tests in the protocol passed, the Programmer has been determined to meet its FDA and CE Mark requirements for immunity and is considered suitable for human use according to its Instructions for Use

5.4. Signatures of Test Personnel

Printed Name	Function	Signature
Jim Judkins	Electrical Engineer	James A. Judkins

6. EQUIPMENT AND SUPPLIES

Refer to table in section 5 of attached VP167 Rev. A LISTEN BEFORE TALK TEST PROTOCOL.

Equipment	Manuf.	Model Number	Serial Number	SW/FW Version	Date of Next Calibration (if required)
BS2 PCBA	SMI	AD1480 Rev.3	201270	SW1021 Rev. 3	N/A
BS2 PCBA	SMI	AD1480	201271	SW1004 Rev. A	N/A
PC	Dell	PC	100041	N/A	N/A
Power Supply	HP	E3610A	KR7531857	N/A	N/A
20 dB Directional coupler	Mini-ckts	ZFDC-20-4L	N/A	N/A	N/A
20 dB Directional coupler	Mini-ckts	ZFDC-20-4L	N/A	N/A	N/A
30 dB attenuator	Mini-ckts	VAT-30+	N/A	N/A	N/A
30 dB attenuator	Mini-ckts	VAT-30+	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	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
Cable USB A-B mini	Qualtek	3021003-03	N/A	N/A	N/A
Oscilloscope	Agilent	DSO 8064A	MY4500254	N/A	19 OCT 2011
Spectrum Analyzer	Agilent	N9010A	MY4906023	N/A	9 Apr 2011
Signal Generator	HP	8656B	2508A0093	N/A	N/A
Neurostimulator PCB	SMI	AD1518 Rev.1	200874	SW1001 Rev.A	N/A
HP PDA	HP	IPAQ 210	3cc8220837	N/A	N/A
UCON PC GUI	Alcatel	UCON2	N/A	SVN57 Rev.7.1	N/A
Vector Network Analyzer (VNA)	Agilent	E5071C	MY4610515	N/A	28 Oct 2011
VNA Cal Kit	Agilent	85033E	MY3920400	N/A	19 Feb 2011
Attenuator Set	Agilent	11583C	61161	N/A	19 Feb 2011
Two VNA Micro-Coax cables	Micro Coax	UFA210A-0240	N/A	N/A	N/A
10 foot Coax Cable	Pasternack	PE300-120	N/A	N/A	N/A

7. SAMPLE SIZE AND JUSTIFICATION

Refer to VP074 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. TEST PROCEDURE AND RESULTS

8.1 Circuit Description

The SMI Programmer (Clinical MN0700 or Patient MN0600) uses the Zarlink ZL70101 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: 265 kHz nominal.
- +/- 25 ppm channel frequency accuracy.
- 20 dB LBT RSSI measurement bandwidth: 350 kHz nominal.
- -108 dBm LBT Rx Sensitivity.
- Antenna Gain typical: –10dB.
- LIC Threshold Power Pth = -106 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 multistage Op Amp bandpass filter (U5 to U8) with a nominal 350 kHz 20 dB bandwidth. The bandpass filter 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.

Measured Display

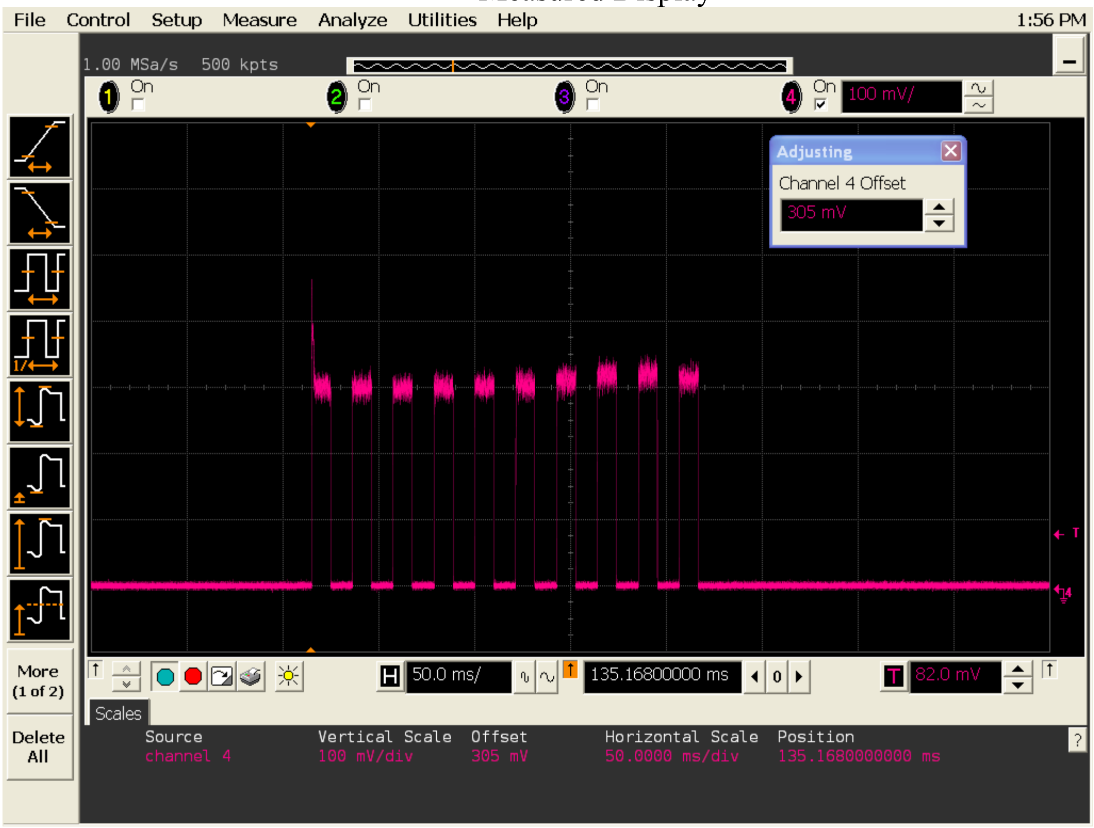


Figure 1. J20 AD8310 Output to MCU ADC. No RF Input.

There are 140 ADC measurements averaged per channel. The spike at the beginning of channel 1 RSSI has a small effect on the ADC reading; 35/1720 = 2%. It does not affect the -108 dBm sensitivity.

Figure 1 RSSI Output

Channel	RSSI ADC
0	1720
1	1659
2	1654
3	1661
4	1674
5	1688
6	1720
7	1758
8	1768
9	1734

Table 1. MCU ADC output of Figure1.

The RSSI timing of each channel scan is driven by the Zl70101 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 1800 ADC counts (see figure and table 1. The MCU ADC uses a free running mode and averages 140 measurements.

8.2 Test Firmware

SW1004 Basestation Product Code
SW1022 Executable, BSCLI
SW1039 Executable, PDA Test Comm Param
ED1335 Source Code Basestation
ED1725 Source Code BSCLI
ED1902 Source Code, PDA Test Comm Param
ED1904 User Guide, PDA Test Comm Param

The test firmware BSCLI (Base Station Command Line Interface) is controlled from a PC based GUI 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. BSCLI firmware uses the LBT same algorithm as production code.

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

Test Parameters:

8.3.1 Minimum Power Detection Threshold (< -106 dBm).
8.3.2 Monitoring System Bandwidth > Emission Bandwidth (265 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 (< -106 dBm).

Refer to attached VP167 Rev.A. LISTEN BEFORE TALK TEST PROTOCOL section 8.3.1 data.

EN 301 389-1 Section 10.1

FCC 95.68.a.3

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.

The Emission Bandwidth was measured at Nemko 1/11/011 and reported in VR068 test #4.

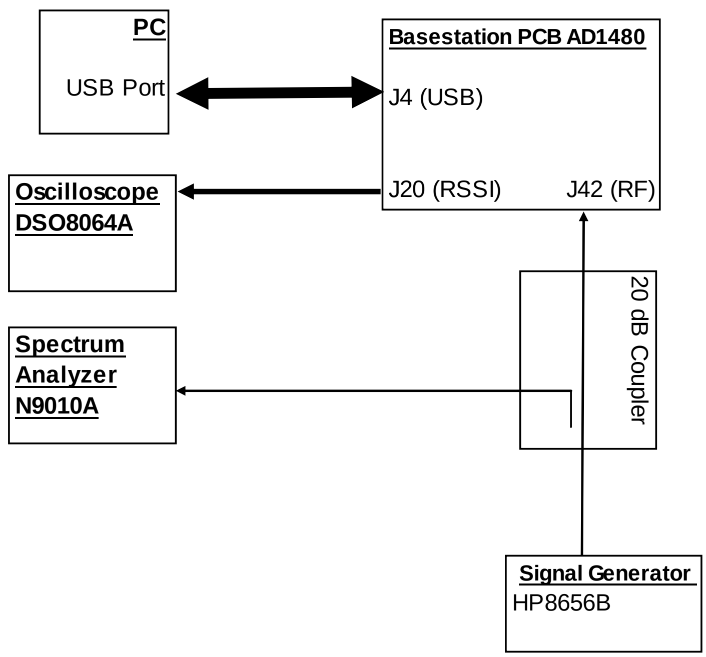
Emission BW = 242 kHz.

$$Pth\ (dBm) = 10 \log EBW\ (Hz) - 150 + Gt\ (dBi)$$

Typical EBW is 265 kHz and Gt is -10 dB.

Calculated Pth:___-106.2_____dBm

The test setup measures and calibrates the signal generator output for frequency (+/- 10 kHz) and power (+/- 0.5 dBm) for all ten channels.



8.3.1 Test Setup Diagram
Basestation PCB: AD1480 Rev.3, s/n 201270, Test Firmware BSCLI SW1021 Rev. 3

Next a baseline RSSI measurement is performed by terminating the J42 RF input and starting the Programmer connection sequence using the PC command line GUI UCON. The RSSI values are read out on the PC screen and recorded. The spectrum analyzer measures the channel the Programmer started transmitting on and compared to the lowest RSSI value. They agreed on Channel 2 and also the MAC_CHANNEL command was used to verify the transceiver channel was channel 2. See attached VP167 page table.

Verify RSSI circuit can distinguish a -108 dBm CW signal on all 10 channels.
Inject a CW signal at -108 dBm into BS2 RF port J42 on all 10 channels and read MCU RSSI measurement from UCON GUI. Verify BS2 transmits on lowest RSSI measured channel.

Using the signal generator inject a -108 dBm signal sequentially on each channel, one at a time, and record the RSSI levels for all 10 channels from the MCU. Verify the -108 dBm signal is the highest RSSI level on all 10 channels for each of the 10 tests.

The attached data tables on VP167 page 9 recorded data for each channel, one at a time, when the antenna test port connector J42 was injected with a CW signal, on each center channel frequency, at -108 dBm signal. The -108 dBm signal for each channel clearly stood out in the RSSI table with a >10% higher RSSI reading.
See appendix for oscilloscope screen images for each channel.

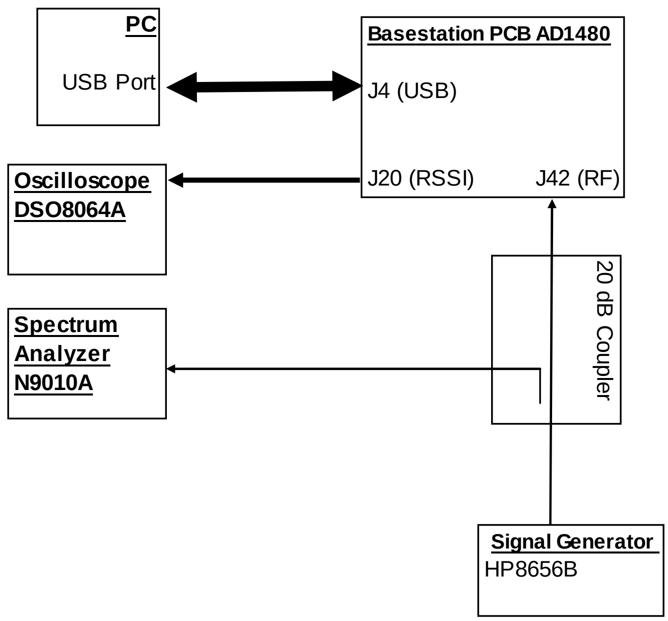
All 10 channels verified -108 dBm signal input was highest RSSI value:___PASSED_______

All 10 channels verified Tx Channel was on lowest RSSI channel:_______PASSED
Refer to attached VP167 Rev.A. LISTEN BEFORE TALK TEST PROTOCOL section 8.3.1 data.

8.3.2 Monitoring System Band width > Emission Bandwidth.
EN 301 389-1 Section 10.2
FCC 95.68.a.1

Refer to attached VP167 Rev.A. LISTEN BEFORE TALK TEST PROTOCOL section 8.3.2 data.

Inject a CW signal at -75 dBm into BS2 RF port J42 on channel 5, 403.650 MHz (+/- 10 kHz) and read MCU RSSI measurement from UCON GUI. 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.



8.3.2 Test Setup Diagram

Basestation PCB: AD1480 Rev.3, s/n 201270, Test Firmware BSCLI SW1021 Rev. 3

The test measures the -20 dB bandwidth of the monitoring system using a signal generator on channel 5 at 403,650 MHz. The RSSI value for channel 5 is measured with a -75 dBm referenced amplitude input to the antenna test port connector J42. Then the signal generator power is reduced 20 dB to -95 dBm and the RSSI value is recorded. This -95 dBm RSSI value is used to measure the RSSI on channel 5 as the signal generator frequency is increased and decreased to find the -20 dB bandwidth. The upper frequency was 403,861 kHz and the lower frequency was 403,503 KHz. The bandwidth was calculated to be 358 kHz which is > than the measured emission bandwidth of 242 kHz.

Verify Monitor System Bandwidth is ≥ 300 kHz:_____PASSED___________________

Verify Monitor System Bandwidth ≥ Emission Bandwidth:____PASSED____________

Refer to attached VP167 Rev.A. LISTEN BEFORE TALK TEST PROTOCOL section 8.3.2 data.

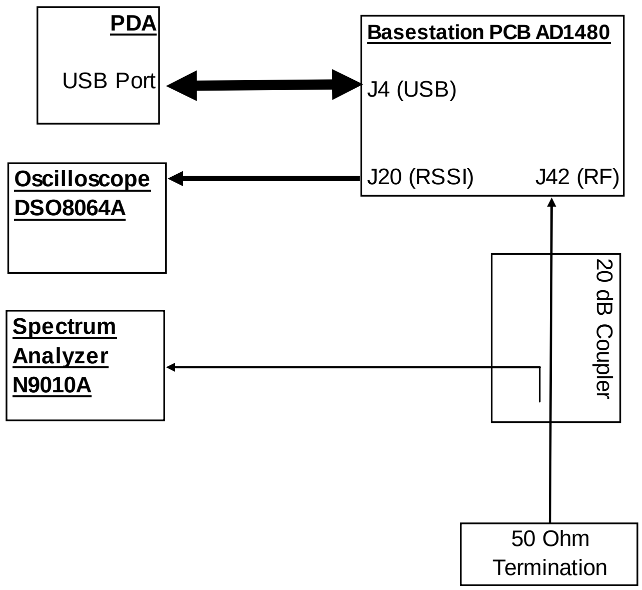
8.3.3 Monitoring System Scan Cycle Time ≤ 5 seconds.

EN 301 389-1 Section 10.3

FCC 95.68.a.2

Refer to attached VP167 Rev.A. LISTEN BEFORE TALK TEST PROTOCOL section 8.3.3 data.

Connect a coax cable to the J20 SMT connector and oscilloscope.



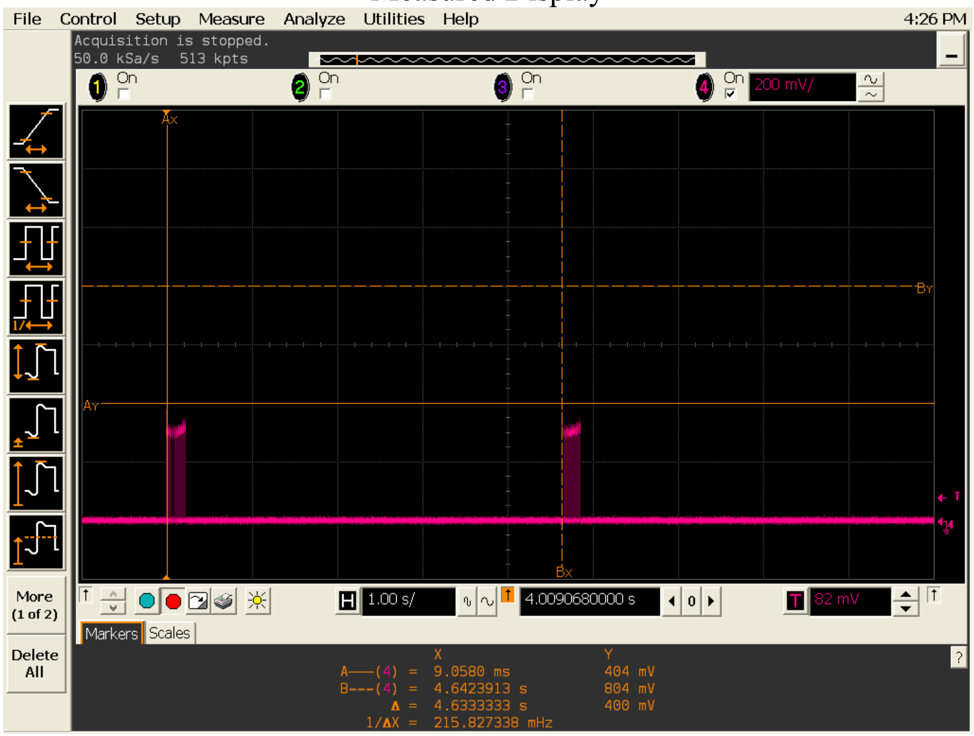
8.3.3 Test Setup Diagram
Basestation PCB: AD1480 Rev.3, s/n 201271, Product Firmware SW1004 Rev. A

Basestation and NS use Product FW for the succeeding tests.
Initiate a RF communication session by pressing Connect on the PDA.
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.

The RSSI test port J20 is attached to an oscilloscope and the Programmer connection sequence is started. There is no NS to RF link to and the Programmer will continue to transmit waiting for a NS to reply. Every 4.63 seconds, the Programmer stops transmitting and measures the RSSI on all ten channels. This sequence is repeated until a NS responds or the Programmer times out in 2 minutes. The oscilloscope measured the time for each ten channel RSSI scan to be approximately 200 milliseconds. The time between each scan was measured at 4.63 seconds. See attached VP167 section 5, page 13, for the spectrum analyzer display for the Quiet time for each RSSI scan.

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 ≤ 5 seconds:___PASSED____
Refer to attached VP167 Rev.A. LISTEN BEFORE TALK TEST PROTOCOL section 8.3.3 data

Measured Display



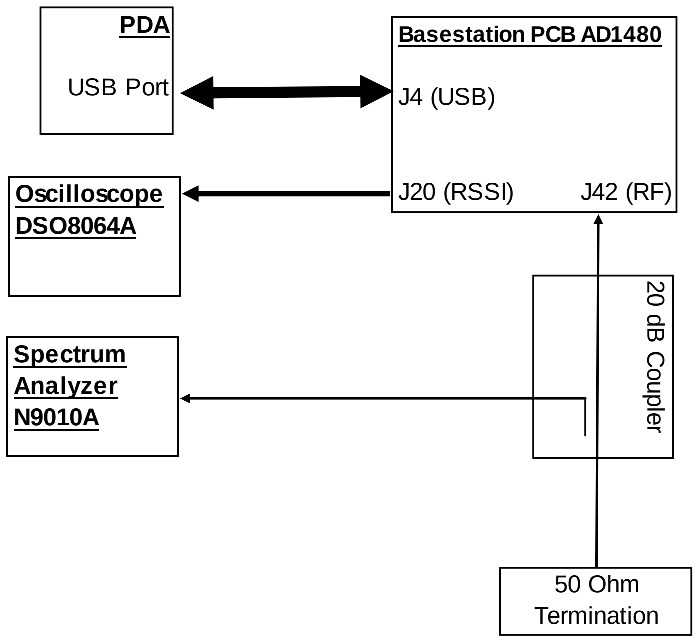
Scan Cycle Time Scope Display showing time between groupings of 10 channel scans.

8.3.4 Minimum Channel Monitoring Period ≥ 10 msec.

EN 301 389-1 Section 10.3

FCC 95.68.a.2

Refer to attached VP167 Rev.A. LISTEN BEFORE TALK TEST PROTOCOL section 8.3.4 data.



8.3.4 Test Setup Diagram

Basestation PCB: AD1480 Rev.3, s/n 201271, Product Firmware SW1004 Rev. A

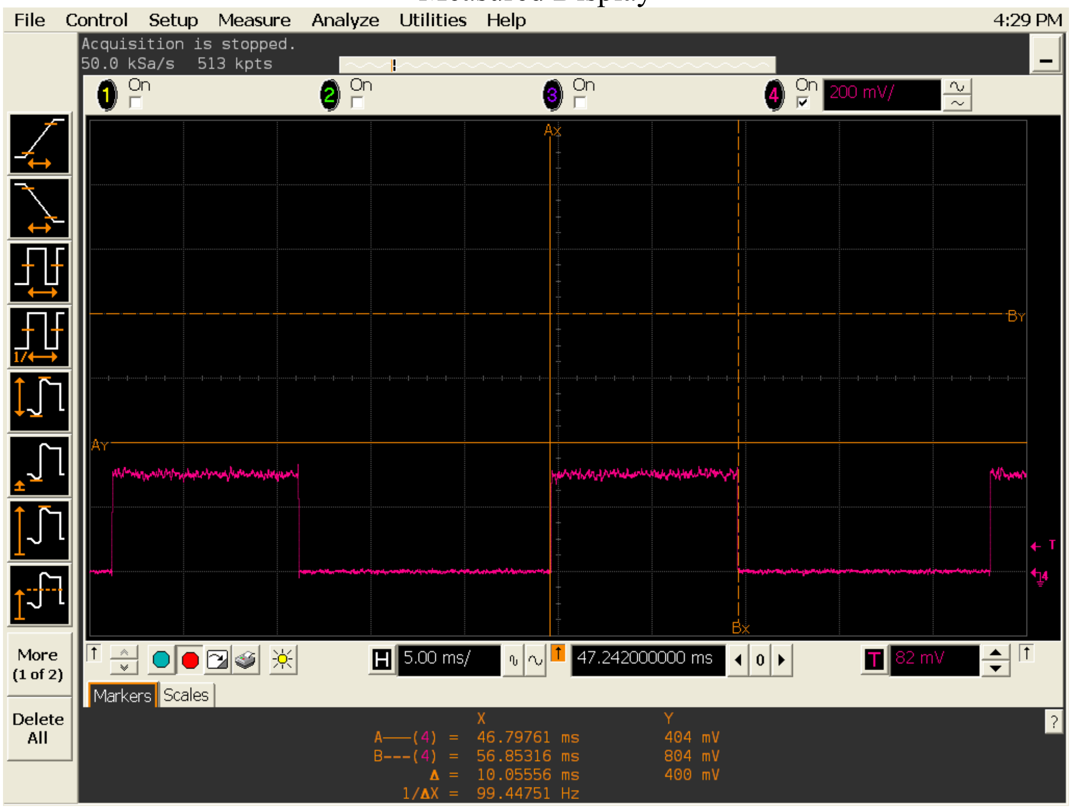
Using the setup in step 3, expand the horizontal display and measure each of the 10 channel RSSI scans and verify they are each ≥ 10 msec.

Each RSSI pulse to the MCU ADC was individually measured at 10 msec.

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

Refer to attached VP167 Rev.A. LISTEN BEFORE TALK TEST PROTOCOL section 8.3.4 data.

Measured Display



Channel Monitoring Period Scope Display

8.3.5 Discontinuation of RF Session after ≤ 5 second silent period.
EN 301 389-1 Section 10.5
FCC 95.68.a.4

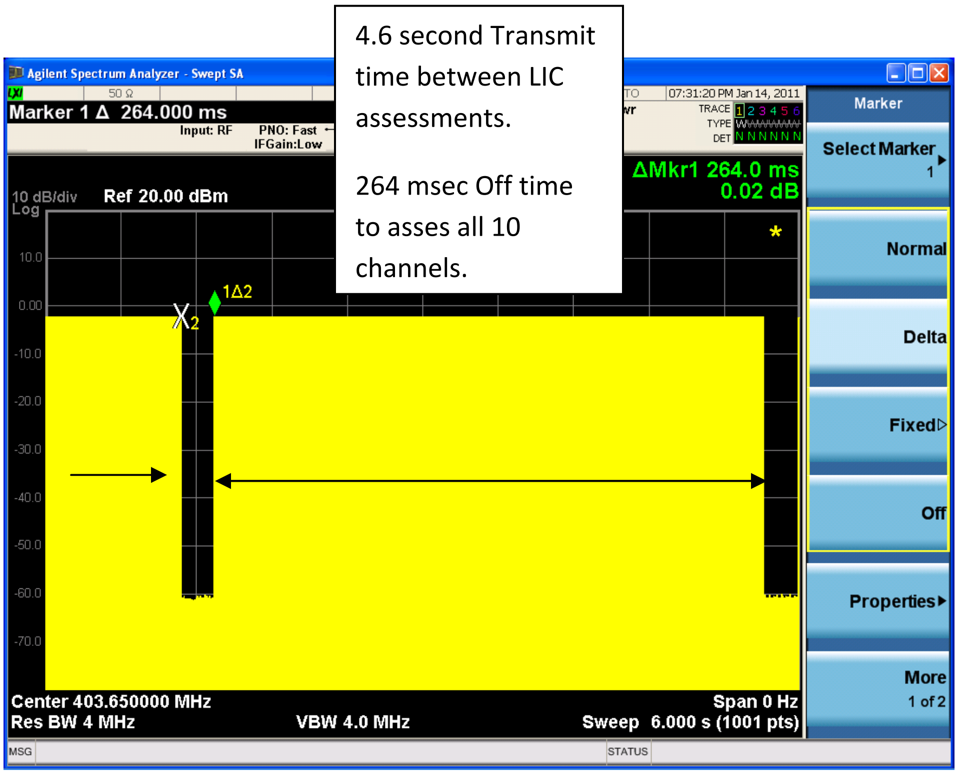
Refer to attached VP167 Rev.A. LISTEN BEFORE TALK TEST PROTOCOL section 8.3.5 data.

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.

The spectrum analyzer is used to monitor the No RF link between Programmer PCB and NS PCB. The Resolution Bandwidth is set wider than the MICS band to 4 MHz. This allows the spectrum analyzer to capture any channel transmitted in the band by the Programmer. The sweep is set slow to 6 seconds to capture the transmitter dropping out for the receiver to monitor the 10 channel RSSI. The Programmer transmit sequence is started and the spectrum analyzer displays the < 5 seconds re-evaluation of the MICS band looking for the Least Interfered Channel.

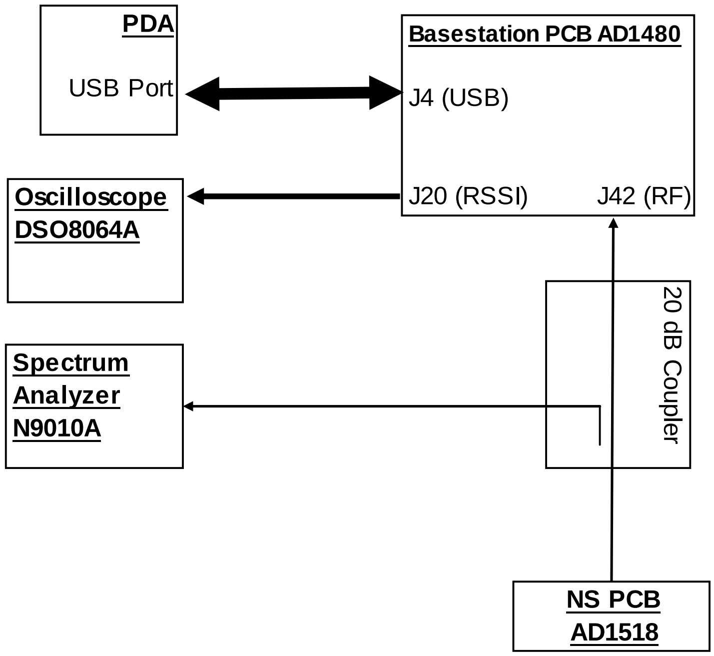
Verify the BS stops transmitting and re-evaluates the MICS band LIC in a period ≤ 5 second with No RF Link.________PASSED____

`Refer to attached VP167 Rev.A. LISTEN BEFORE TALK TEST PROTOCOL section 8.3.5 data.`



Measured Spectrum Analyzer display.

Initiate a RF communication session with a RF Link by pressing Connect on the PDA. NS PCB should be powered ON.
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.



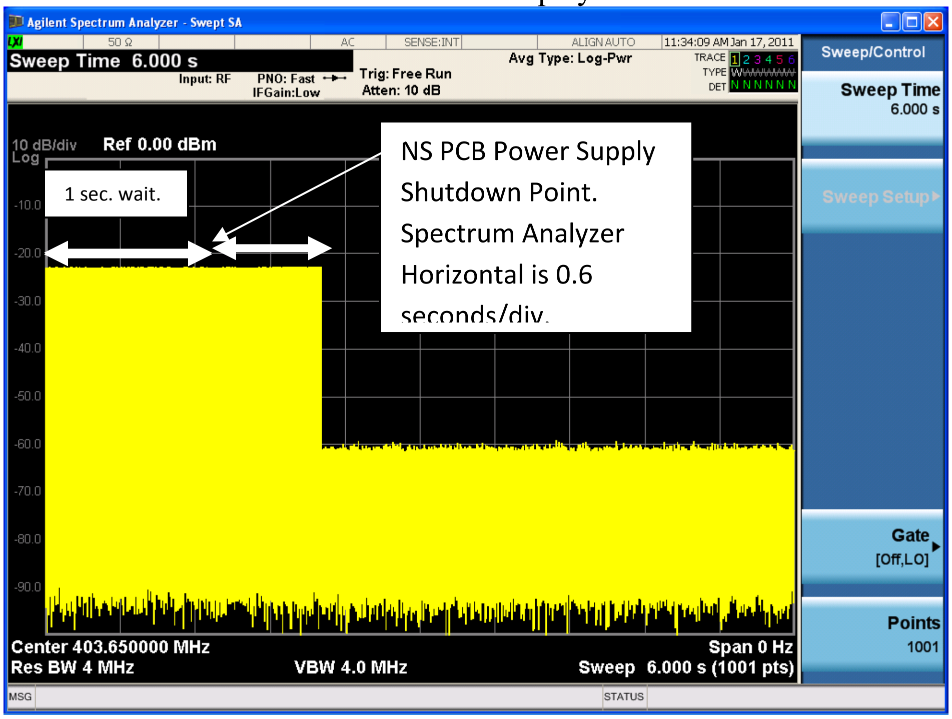
8.3.5 Test Setup Diagram

Basestation PCB: AD1480 Rev.3, s/n 201271, Product Firmware SW1004 Rev. A
Neurostimulator PCB: AD1518 Rev.1, s/n 200874, Product Firmware SW1001 Rev. A

The RF link between Programmer PCB and NS PCB is initiated and maintained. The spectrum analyzer is in the same configuration as above with a 4 MHz RBW and 6 second sweep time. The spectrum analyzer is set for single sweep, wait approximately 1 second and switch off the DC power to the NS PCB to stop it from transmitting responses. The time for the Programmer PCB to stop transmitting is recorded at approximately < 1 second. The Programmer ceases transmission and will not start until commanded to do so.

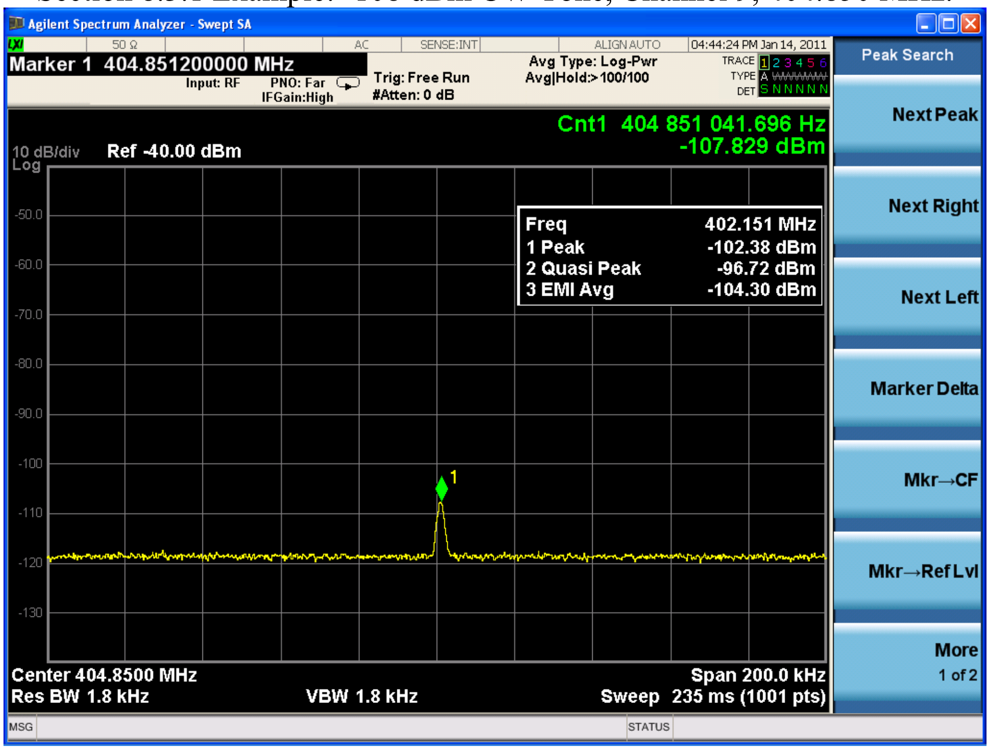
Verify BS stop transmitting in ≤ 5 seconds.______PASSED__________________
Refer to attached VP167 Rev.A. LISTEN BEFORE TALK TEST PROTOCOL section 8.3.5 data.

Measured Display

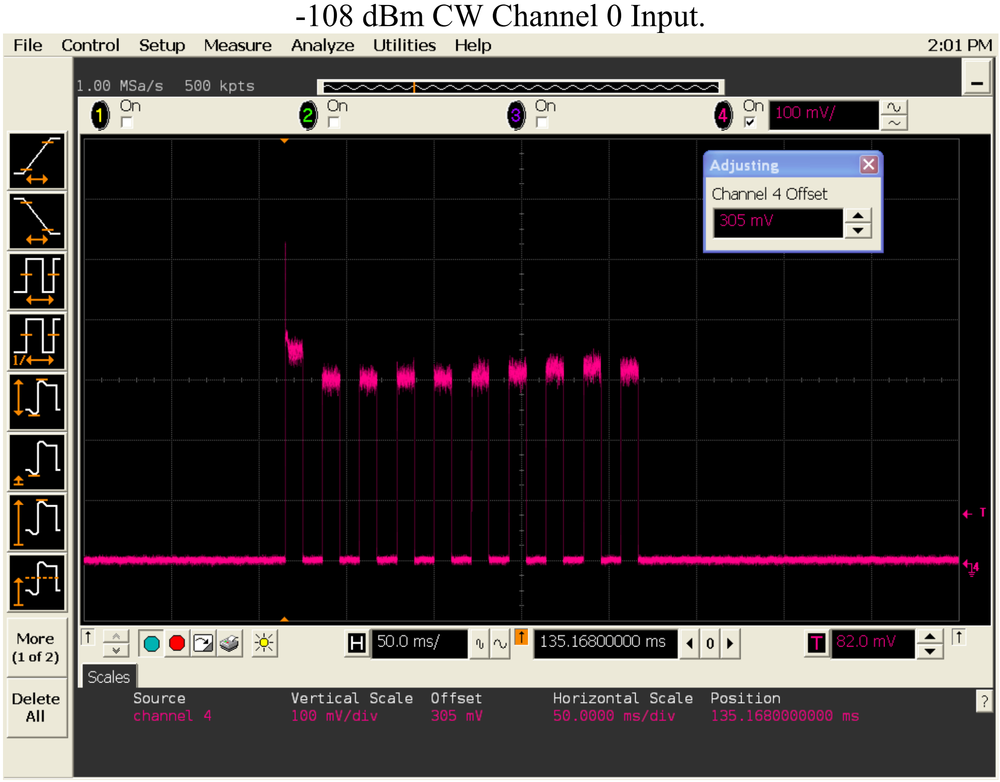


9. APPENDIX:

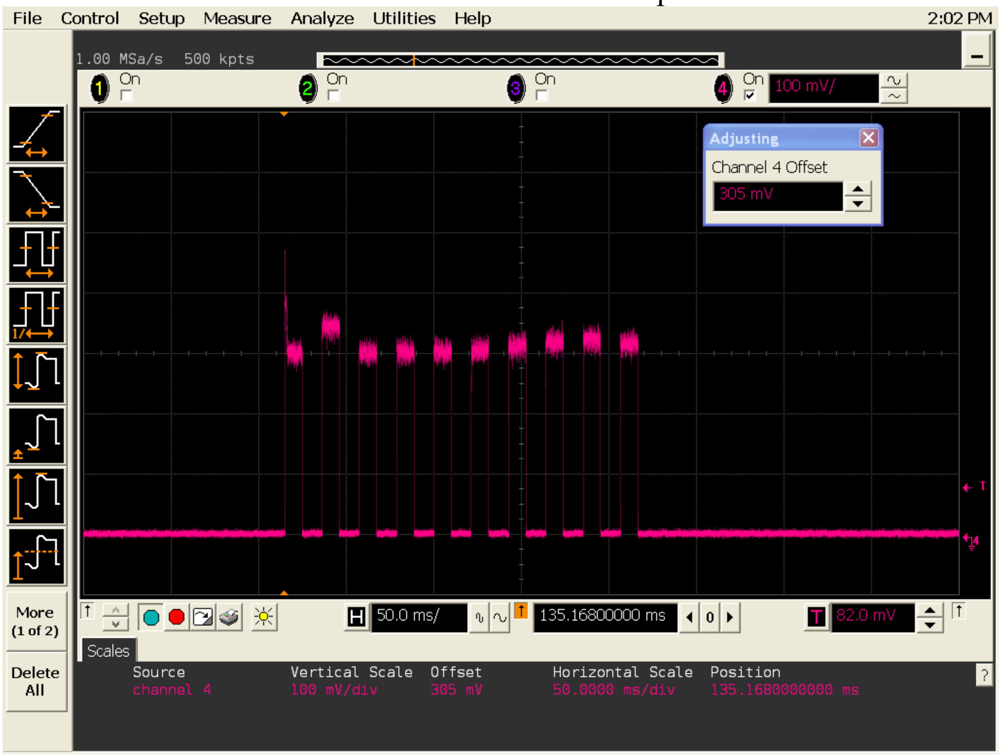
Section 8.3.1 Example: -108 dBm CW Tone, Channel 9, 404.850 MHz.



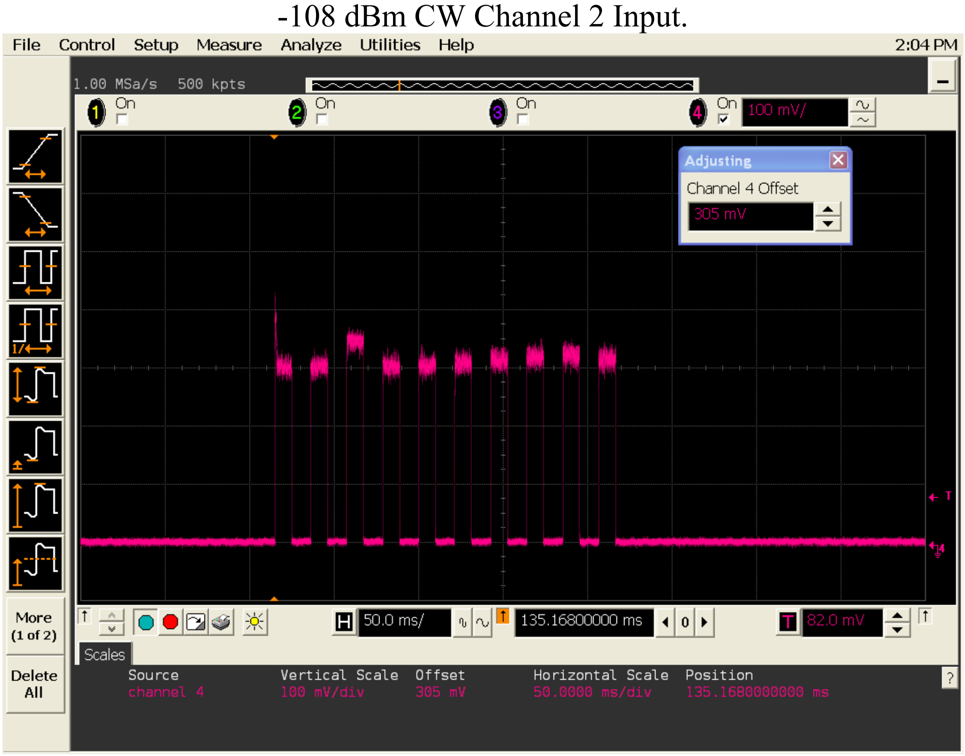
-108 dBm CW Channel 0 Input.



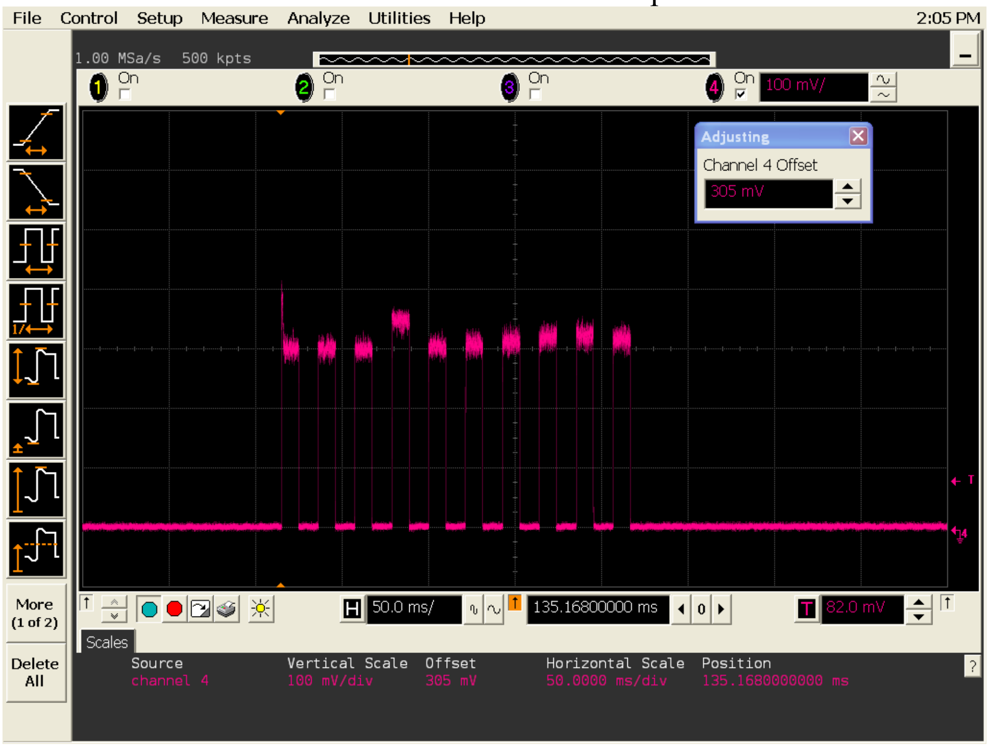
-108 dBm CW Channel 1 Input.



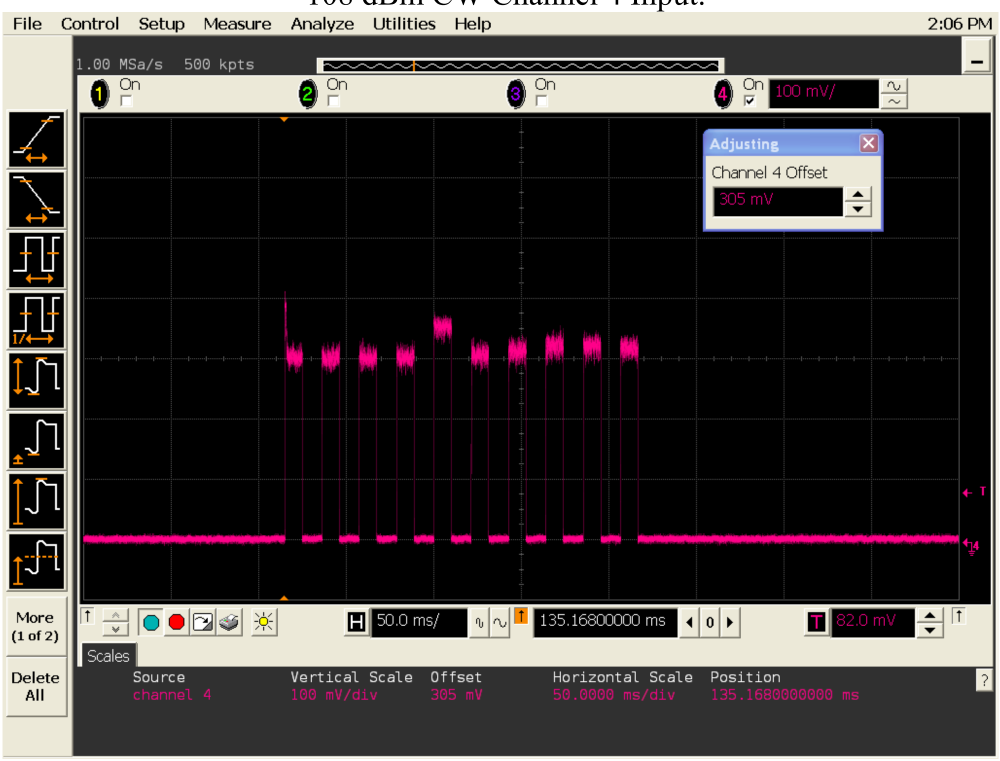
-108 dBm CW Channel 2 Input.



-108 dBm CW Channel 3 Input.



-108 dBm CW Channel 4 Input.

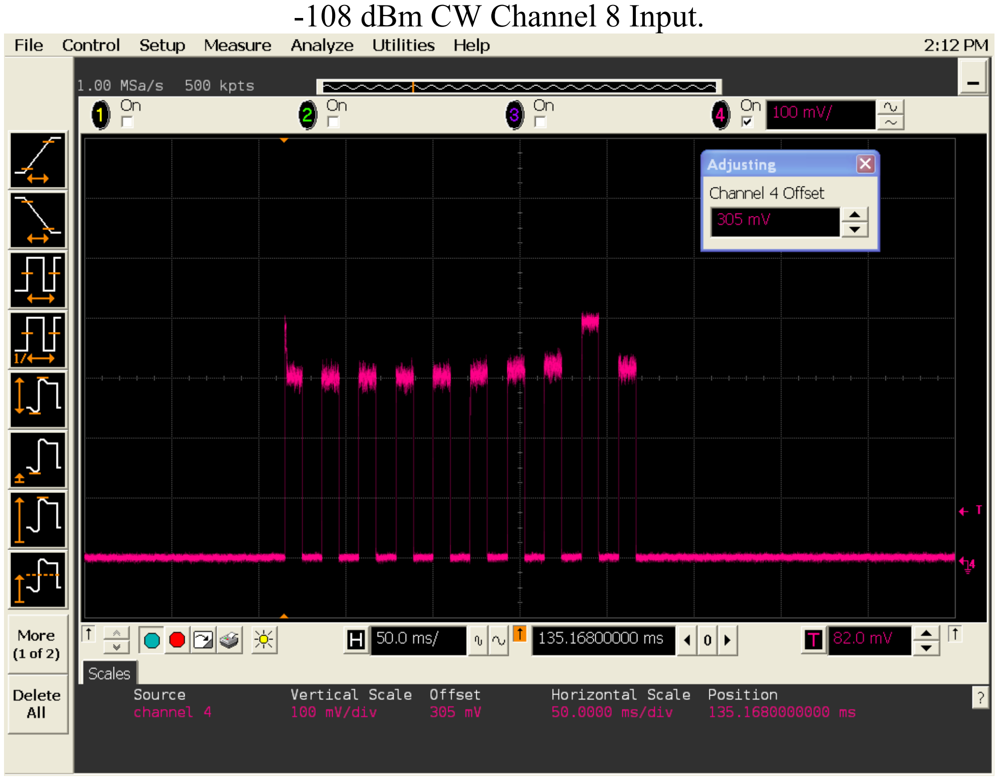


-108 dBm CW Channel 5 Input.

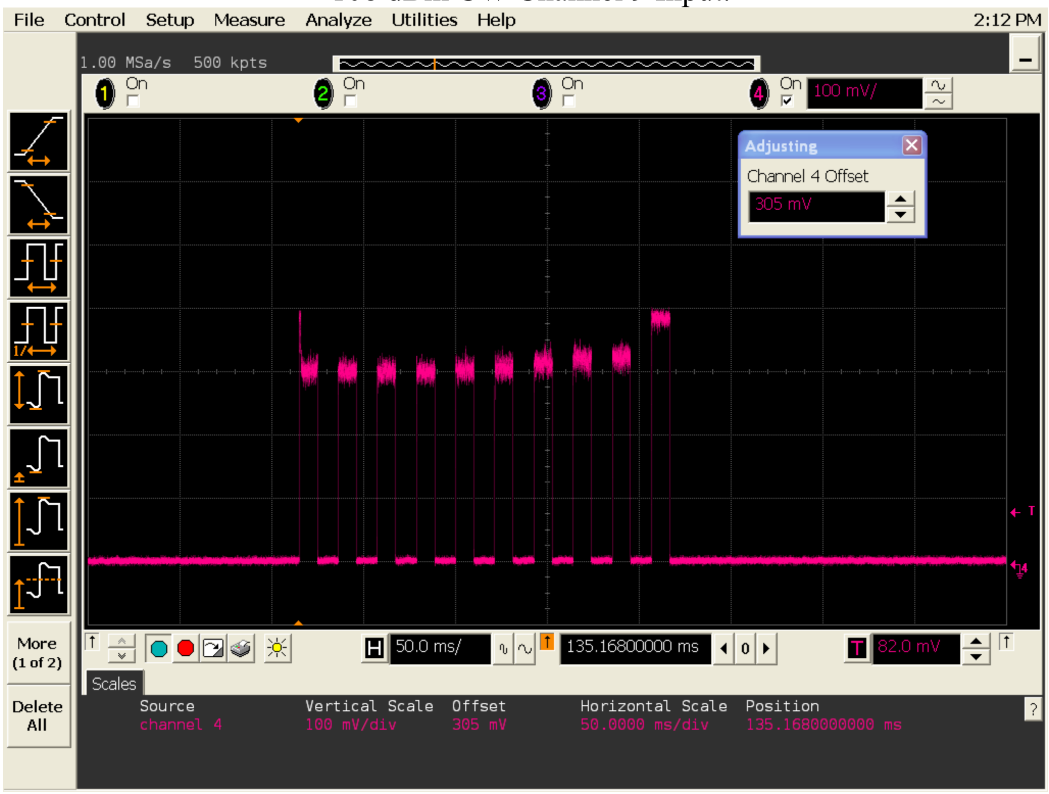
-108 dBm CW Channel 6 Input.

-108 dBm CW Channel 7 Input.

-108 dBm CW Channel 8 Input.



-108 dBm CW Channel 9 Input.



10. APPENDIX:

MEASUREMENT CALIBRATION AND UNCERTAINTY ANALYSIS

Frequency and power are measured by the Agilent N9010A spectrum analyzer.

Uncertainty data is derived from the N9010A data sheet.

- Power Measurement accuracy: +/- 0.27 dB (95th percentile) at -10 to -50 dBm input.
- Marker Frequency Counter accuracy: +/-1760 Hz at 400 MHz

The N9010A spectrum analyzer amplitude accuracy data is limited down to -50 dBm. To measure the 8656B signal generator -108 dBm output the E5071C Network Analyzer is used to calibrated 60 dB of attenuation.

Uncertainty data is derived from the E5071C Network Analyzer data sheet.

- 85033E 3.5 mm coax Full 2 Port Calibration with Isolation cal.
- Stepped Frequency
- 1601 Points

- Averaging: 16
- Transmission Uncertainty: 0.2 dB at 400 MHz and -60 dB.
- Reflection Uncertainty: 0.007 for rho = < 0.1 (Linear).
- Directivity: 44 dB
- Source Match: 40 dB
- Load Match: 44 dB
- Mismatch Loss: << 0.05 dB for attenuators measured.

Calibrate 60 db Attenuation with E5071C Network Analyzer:
Three 3.5mm and SMA attenuators are combined for 60 dB attenuation and measured:

20 dB 3.5 mm Agilent model# 11583C Attenuator Set s/n 61161
10 dB 3.5 mm Agilent model# 11583C Attenuator Set s/n 61161
30 dB SMA Mini-Circuits model #VAT-30+

Parameter	Data (dB)
S11	-46
S21	-59.9
S12	-59.9
S22	-48

Attenuation S21 Measured: -59.9 dB (+/- 0.2 dB)
Mismatch Loss Uncertainty due to Reflections S11 and S22: << 0.05 dB

Calibrate HP8656B Signal Generator Frequency and Amplitude:
Setup to figure 1 below.

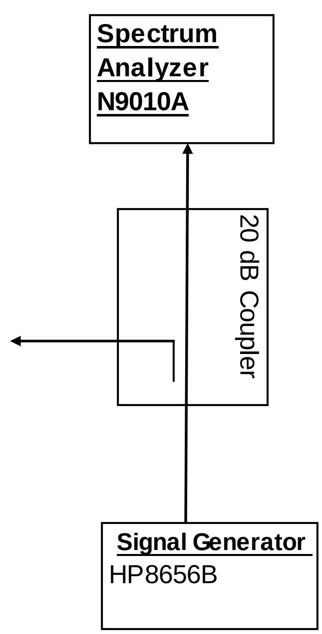


Figure 1.

Adjust signal generator amplitude for a -50 dBm +/- 0.1 dB signal on the spectrum analyzer.
Set Spectrum Analyzer Input Attenuator to 0 dB.
Measure Amplitude: -50.1 dBm
Measure Frequency: 402.151 MHz (+/- 0.00176 MHz)

Attach calibrated 60 dB Attenuation to Spectrum Analyzer Input.
Measure Amplitude: -110.4 dBm (+/- 0.2 dBm)
Measure Frequency: 402.151 MHz (+/- 0.00176 MHz)

Remove 60 dB Attenuation to Spectrum Analyzer Input and reduce HP8656B power by 60 dB and measure frequency and amplitude. Compare to previous step.
Measure Amplitude: -110.4 dBm (+/- 0.2 dBm)
Measure Frequency: 402.151 MHz (+/- 0.00176 MHz)

The HP8656B amplitude adjustment agrees with calibrated 60 dB attenuator to within 0.1 dB.

The Spectrum Analyzer Amplitude calculated measurement:
-50.1 dBm minus 59.9 dB calibrated attenuation = -110.0 dBm

The Amplitude Measurement was off by -0.4 dBm (+/- 0.2 dBm).
The Frequency Measurement agreed to < 1 kHz from -50 dBm and -110 dBm input power.

Calibrate Spectrum Analyzer, Signal Generator, cables, and coupler losses for three power levels used in VP167 sections 8.3.1 and 8.3.2.

- For Section 8.3.1 Power level -108 dBm +/-0.5 dBm: -107.7 dBm measured.
- HP8646B Signal Generator Amplitude Setting:-106.5 dBm

- For Section 8.3.2 Power level -95 dBm +/-0.5 dBm: -95.1 dBm measured.
- HP8646B Signal Generator Amplitude Setting:-93.5 dBm

- For Section 8.3.2 Power level -75 dBm +/-0.5 dBm: -75.1 dBm measured.
  HP8646B Signal Generator Amplitude Setting:-73.5 dBm

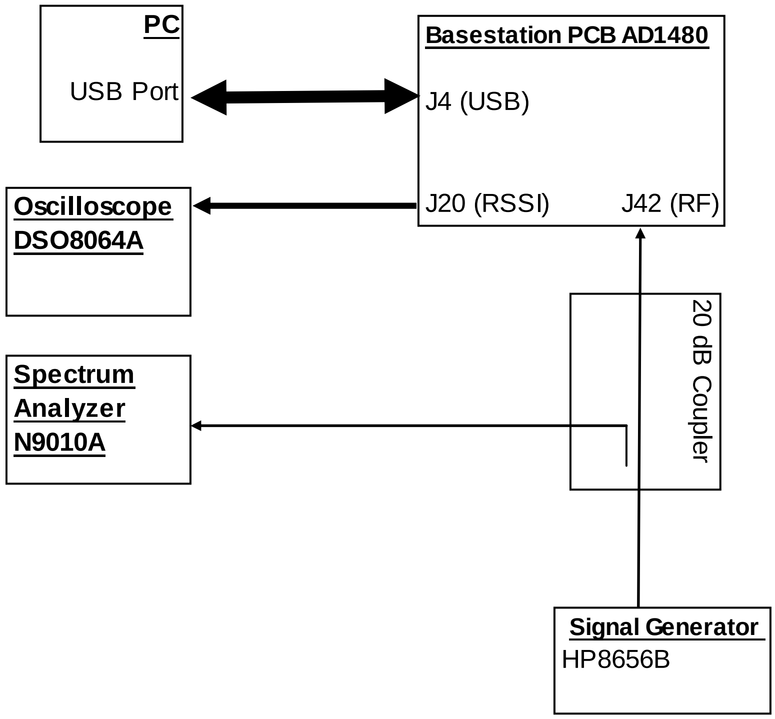


Figure 2. Final Test Configuration.