REVISION HISTORY

Rev	Change Description	CO	Effective Date	By
A	Initial Release. SoMo Programmer AD1634 with SoMo BS PCB AD1621. (Based on VP167 Rev C.)	CO3413	11/11/13	Erik Johnson
B	Correct referenced standards covered by this test report.	CO3785	6/9/14	April Pixley

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 Trial NeuroStimulator (TNS) respond to the Programmer RF link and are not permitted to initiate an 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 95.627.a and 95.1209.d. 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 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. 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 Listen-Before-Talk FCC, FDA and CE Mark requirements and is considered suitable for human use according to its Instructions for Use.

5.4. Signatures of Test Personnel

Printed Name	Function	Signature
Erik Johnson	Firmware Engineer	See Raw Data

6. EQUIPMENT AND SUPPLIES

Log information in table below.

Equipment	Mfgr	Model Number	Serial Number	SW/FW Version	Date of Next Calibration (if required)
BS PCBA	SMI	AD1616	520066	SW1111	N/A
BS PCBA	SMI	AD1616	520042	SW1111	N/A
PC	Dell	Optiplex GX745	76487-OEM-0011903-00102	Windows XP SP3	N/A
Power Supply	Agilent	E3640A	EQ066	N/A	1/11/14
20 dB Directional coupler	Mini-ckts	ZFDC-20-4L	SF800301017	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 micro	Qualtek	3021003-03	N/A	N/A	N/A
Oscilloscope	Agilent	DSO8064A	EQ0111	N/A	4/11/14
Spectrum Analyzer	Agilent	EXA N9010A	EQ0516	N/A	5/10/14
Signal Generator	HP	8656B	EQ077	N/A	Not Calibrated (cal as part of test procedure)
BsDiag software	SMI	SW1078	N/A	2.0.5.0	N/A

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 filterwith a nominal 500 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.
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

SW1111 Basestation Compiled Executable

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.

8.3 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.

8.3.1.1 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.

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

Measured EBW is 238 kHz and Gt is -7.69 dB.

Calculated Pth:__-103.924_____dBm

Test setup:
Measure the Signal Generator output power on the spectrum analyzer:
Frequency 402.150 MHz
300 kHz steps
-103 dBm
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___dBm

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

Ch0	402.150 MHz	___402.156__MHz
Ch1	402.450 MHz	___402.456__MHz
Ch2	402.750 MHz	___403.756__MHz
Ch3	403.050 MHz	___403.056__MHz
Ch4	403.350 MHz	___403.356__MHz
Ch5	403.650 MHz	___403.656__MHz
Ch6	403.950 MHz	___403.956__MHz
Ch7	404.250 MHz	___404.256__MHz
Ch8	404.550 MHz	___404.556__MHz
Ch9	404.850 MHz	___404.856__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 #:__6_____
Lowest RSSI Ch #:__6_____

Channel	0	1	2	3	4	5	6	7	8	9
RSSI	1430	1424	1436	1449	1456	1445	1410	1412	1424	1421

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.

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	1422	1452	1448	1448	1414	1415	1429	1423

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	1458	1451	1450	1414	1409	1427	1423

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	1454	1444	1405	1414	1427	1417

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	1426	1581	1755	1464	1447	1407	1414	1422	1423

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	1423	1418	1433	1592	1756	1608	1416	1412	1423	1425

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	1427	1419	1432	1450	1596	1757	1599	1418	1419	1423

Ch 6 (-103 dBm) Highest Channel RSSI:__6____ Lowest Channel RSSI:_1/9 (tie)_ Tx Ch_1_

Channel	0	1	2	3	4	5	6	7	8	9
RSSI	1427	1419	1433	1456	1449	1444	1763	1604	1425	1419

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	1428	1418	1427	1455	1446	1438	1425	1767	1610	1423

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	1426	1416	1430	1451	1456	1437	1411	1423	1768	1611

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	1429	1427	1426	1462	1449	1447	1412	1415	1436	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_____________

8.3.1.2 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	1833	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	2392	1982	1724	1397	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	1396	1391	1399	1503	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 ≥ 300 kHz: _______PASS__________

Verify Monitor System Bandwidth ≥ Emission Bandwidth: ________PASS__________
Note: VR068 document is source of emission bandwidth. __Bandwidth per VR068 is___
____ 238 kHz. ___________

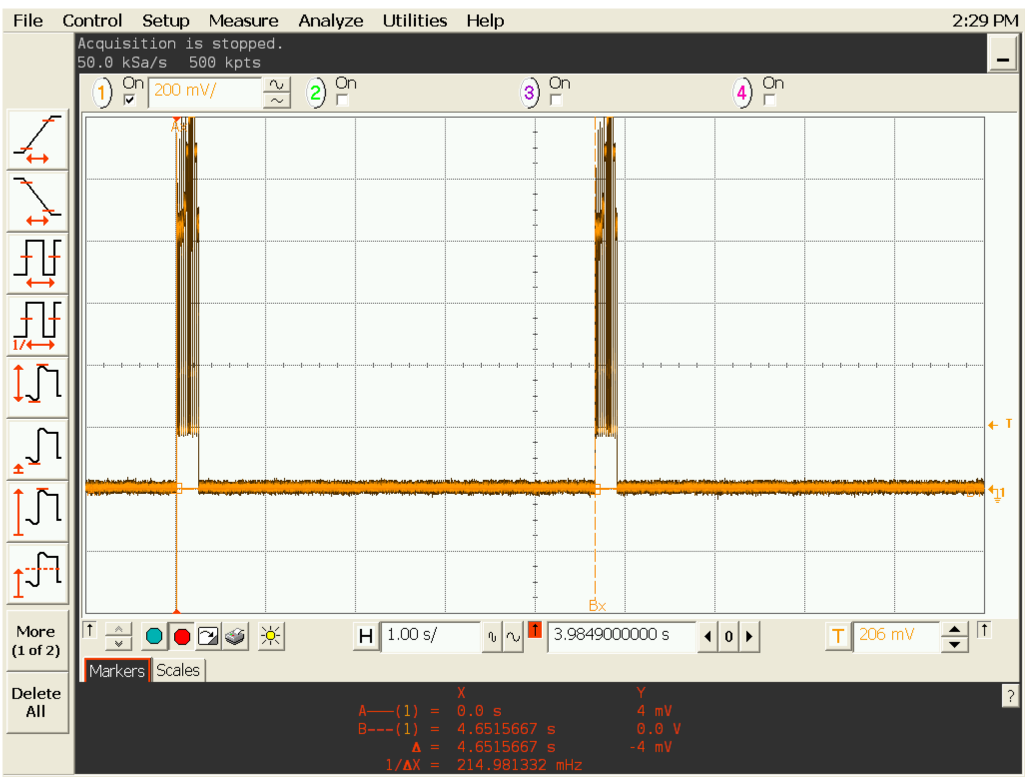
8.3.1.3 **Monitoring System Scan Cycle Time ≤ 5 seconds.**

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 ≤ 5 seconds: ___4.65_____ seconds.



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

8.3.1.4 **Minimum Channel Monitoring Period ≥ 10 msec.**

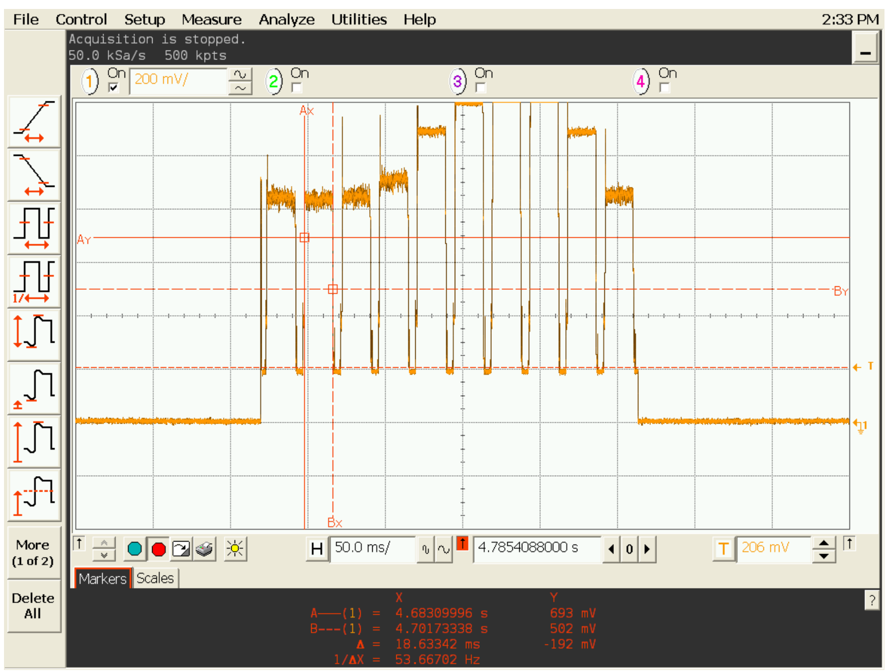
Using the setup in step 3, expand the horizontal display and measure each of the 10 channel RSSI scans and verify they are each ≥ 10 msec.

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	18.52	18.18	18.41	18.3	18.41	18.41

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



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

8.3.1.5 **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.

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

____

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: stops in 4.36 sec _______

9. ATTACHMENTS

Attachment 1 – Executed Protocol
(Note: The Revision History, Header and Footer for VP167 Rev C where updated to create the VR and then printed for data collection. There was no change to the data collection fields prior to executing the protocol.)