1. Change History

Version	Description of Change
2.0	Initial Release.

2. Introduction

2.1. Purpose

This document addresses compliance to the Listen Before Transmit / Frequency Monitoring requirement for the MICS Band radio internal to the 24970A CareLink SmartSync™ Device Manager Base model of the Sirius Programmer. Compliance is based on tests performed on the 24950 Home Monitor that uses the identical MICS radio and extend to include the 24970A CareLink SmartSync™ Device Manager Base.

2.2. Scope

This document lists the requirements per country and references the Test Procedure and measured results performed to verify compliance. Countries requirements:

- US: FCC CFR 47 Part 95.627 (a) Frequency Monitoring
- Canada: Industry Canada RSS-243, 2010 (5.7) Monitoring System Specifications for MICS and MEDS;
- EU: ETSI EN 301 839-1, v1.3.1 (10) Requirements and Measuring Methods for Monitoring Systems;
- Japan: Item 8 of Article 2-1, Carrier Sense Function

2.3. Required Documents

The Listen Before Transmit/Frequency Monitoring requirement for MICS band radios operating in the 402-405 MHz band has been verified and documented in the DSN009828 DHF Test Report. The tests were performed on the 24950 Home Monitor product that uses the identical MICS band radio as the Sirius programmer using the test procedures of ETSI EN 301 839-1; section 10.

Description	Document / Location	Rev
Test Procedure and Results for MICS Radio LBT requirement	DSN009828/DHF for the 24950 Home Monitor	3.0

3. End of Document

Cardiac Rhythm Disease Management

MEDTRONIC CONFIDENTIAL

Title

24950 COMPLIANCE TEST PROCEDURE

FOR ETSI EN 301 839-1 SECTION 10

Author(s): Bill Verhoef

Note: This document may be approved electronically through Documentum by the listed approvers.

Change History

Revision	Description of Change
2.0	Initial Version
3.0	Updates to add equipment accuracy analysis, measurement uncertainty and environmental conditions information. Updated the TOC for the added sections

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TABLE OF FIGURES

1.0 INTRODUCTION

1.1 PURPOSE

This document defines the method by which the ETSI monitoring requirements for the 24950 Home Monitor are tested.

1.2 SCOPE

This document defines the test method required to show compliance of the 24950 to the ETSI document EN 301 839-1 Section 10 for Listen Before Talk monitoring requirements and references all required performance parameters within.

2.0 DEFINITIONS ABREVIATIONS AND ACRONYMS

CW: Continuous Wave

dB: Abbreviation for Decibel.

dBm: An absolute measurement of power in Decibels referenced to 1 milliwatt (0 dBm == 1 milliwatt).

Decibel: A logarithmic expression of the ratio between two signal, power, voltage, or current levels.

Device: Another name for Implantable Medical Device

Deviation: Short for Frequency Deviation. The peak frequency difference between the RF carrier and the instantaneous frequency of an FM modulated RF signal.

EUT: **E**quipment **U**nder **T**est. In this case, it would be the RFIC + RFIC Carrier Board.

ETSI: **E**uropean **T**elecommunications **S**tandards **I**nstitute. The regulatory body that produces European standards for the Telecommunications industry. They are the European equivalent to the FCC.

FCC: Federal **C**ommunications **C**ommission. The federal agency charged with regulating radio frequencies in the United States of America.

In-band: A signal within the RF bandwidth of the receiver.

IMD: Implantable Medical Device

LBT: Listen Before Talk

LIC: Least Interfered Channel

MHz: Abbreviation for Megahertz, a rate of measure for Frequency.

MICS: Medical Implant Communications System. A frequency band with a fixed set of regulatory rules designed specifically for medical device RF Distance Telemetry Transceiver operation.

On Channel: A signal within the instantaneous bandwidth of the receiver.

Out-of-band: Outside the intended RF bandwidth of the receiver.

RF (**R**adio **F**requency): This term normally describes the frequency of the on the air signal and is often used to describe circuits that process signals at these frequencies.

RX: Abbreviation for Receive or Receiver.

SMA: Sub Miniature version A RF connector

Transceiver: An integrated RF transmitter and RF receiver.

TX: Abbreviation for Transmit, or Transmitter.

UHF: Ultra **H**igh **F**requency, in the range of 300 MHz to 3 GHz.

3.0 APPLICABLE REFERENCE DOCUMENTS

3.1 ETSI EN 301 839-1 SECTION 10

This document outlines the requirements governing the internationally allocated MICS frequency band. Section 10 within this document feeds directly into the Listen Before Talk (LBT) monitoring requirements tested in this document, to the end that both the capabilities and limitations comply with the rules of this standard.

This document also outlines a suggested test methodology to show compliance to the LBT requirements. This test plan was created against the guidelines outlined in version 1.3.1 dated October 2009.

4.0 TEST SETUP DESCRIPTION

4.1 EQUIPMENT UNDER TEST

4.1.1 OVERVIEW

The Equipment Under Test (hereafter referred to as the “EUT”) is a Model 24950 Home Monitor Instrument. The unit is supplied with the latest released product firmware designed to have fully spec compliant functionality.

The verification of these tests will be performed via a RF conducted method. In order to perform this testing this manner the 24950 EUT must be modified to have a test RF connection to mate up with a test RF SMA connector and removing any connection to the integrated antennas. This EUT is designed only for testing and will serve to make this testing possible via conducted RF connections.

See Figure 1 for schematic representation of the connection point (J38) of the adapter cable with the test SMA connector on the primary version of the 24950. See Figure 2 for schematic representation of the connection point (J39) of the adapter cable with the test SMA connector on the alternate version of the 24950. See Figure 3 for a visual of the EUT with the RF cable and connector.

Note that conducted measurements for the alternate version require that the digital control signal ANT_SEL at pin 2 of U3 must be set high to connect RF pin 4 through to pin 8. Also, the 0.5 dB of insertion loss of the antenna switch at 400 MHz must be considered, unlike the primary version (Figure 1) which does not have the antenna switch between the probe and the RF module.

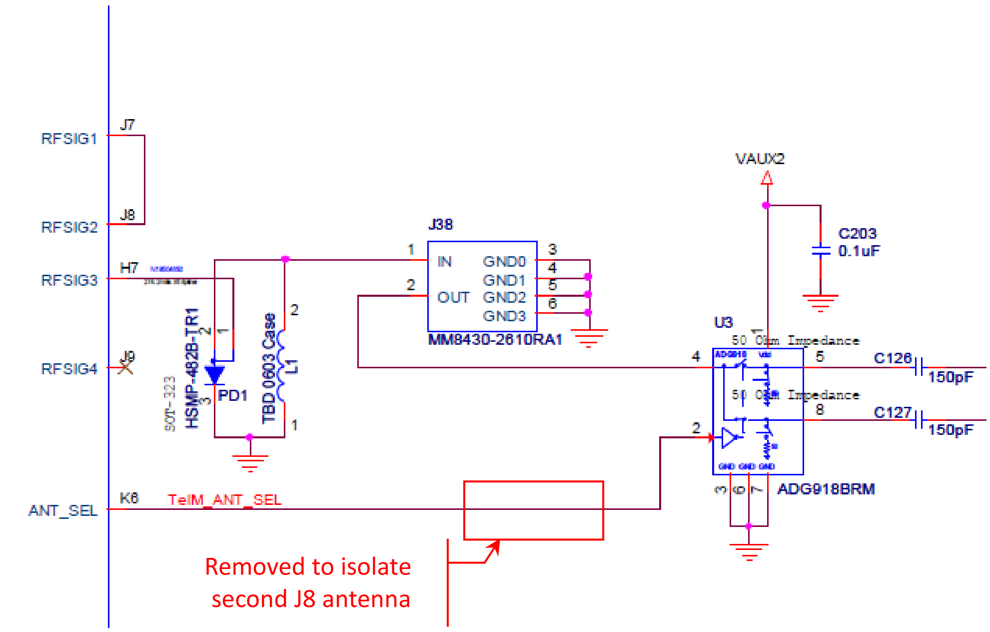


FIGURE 1: SMA TEST CONNECTOR LOCATION (J38, PRIMARY VERSION)

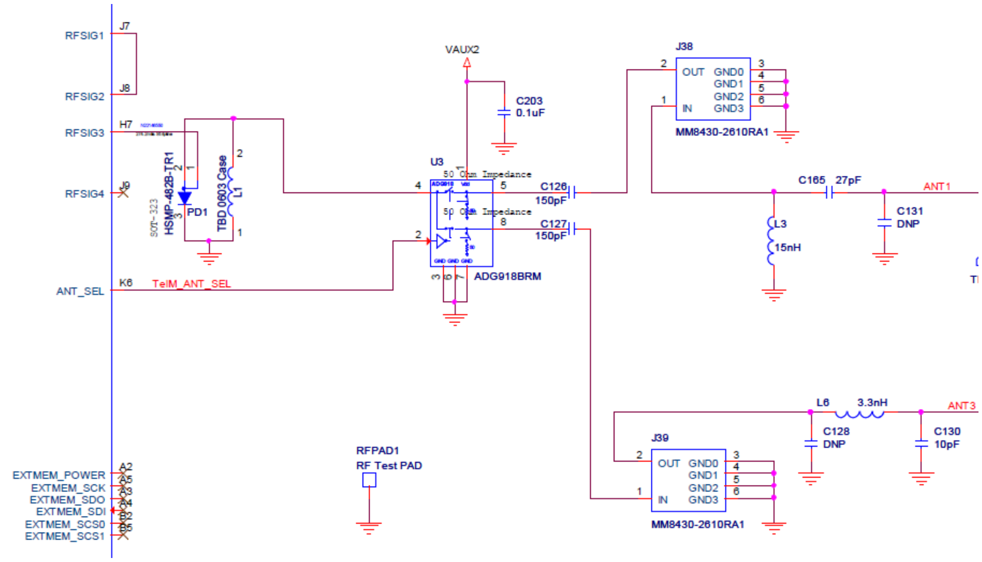


Figure 2: SMA TEST CONNECTOR LOCATION (J39, ALTERNATE VERSION)

FIGURE 3: VISUAL OF EUT WITH RF CABLE AND CONNECTOR

Included in the testing is an Implantable Medical Device (hereafter referred to as “IMD” or “device”) that will be used to create the other side of the communication link and allow us to open data transfer sessions with the EUT. It is a current product release of an IMD that utilizes the MICS band for wireless communication and is compatible with the EUT. The IMD has been modified to do conducted RF testing related to the Listen Before Talk requirements of the ETSI regulatory specification. This connects a coaxial cable with an SMA connector to point where the antenna used to be connected. Supply wires are also routed to the IMD to allow extended use of this device as a test vehicle for this testing. Without these supply wires with use the IMD battery would eventually be depleted and would be unusable.

In all other aspects the device operates without modification. As a part of the IMD’s normal operation, the RF transceiver that allows it to participate in a wireless communication is normally in a low current standby mode. This is done in order to preserve the battery life of the device. In order to communicate with the device a Conexus Activator must be used to activate the wireless transceiver. When activated, the IMD transceiver will stay active for 5 minutes. To activate the wireless transceiver hold the top rear of the Activator next to the device and press the button on the top of the Activator. The Activator indicator light should glow green indicating the transceiver is now active. If the amber indicator lights up, it was either unsuccessful or it is already in a communication session.

See Figure 4 for a visual of the IMD with the modifications for a conducted RF connector and external power capability.

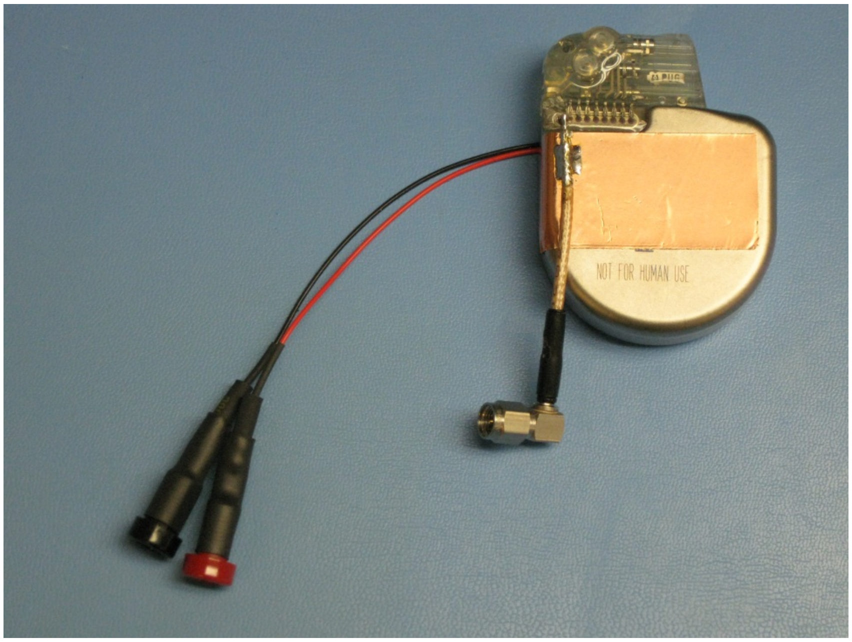


Figure 4: modified implantable medical device

4.1.2 EUT OPERATION

Upon power-up, the desktop display appears after approximately 45 seconds with an arrow pointing to the start button on the right side of the display. To begin operation, the operator presses the round start button.

Graphical images prompt the operator to lift the inductive telemetry head off the base, place the telemetry head over the IMD, and wait for device interrogation to begin.

When the progress bar graphic appears, radio Telemetry C interrogation of the IMD has begun and the inductive telemetry head can be moved away from the IMD.

If the telemetry head is placed back on the base unit while the progress bar is active, the same series of graphical images will prompt the operator to lift the head, place it over the device, and wait for a new device interrogation to begin. This is a convenient way to restart interrogation without having to disconnect and reconnect power to the unit and wait for the desktop display to appear.

If radio Telemetry C communication is lost during interrogation, the base unit will beep and the display will prompt the operator to place the telemetry head over the device to complete the interrogation using inductive telemetry (not radio Telemetry C).

When device interrogation is complete, the progress bar disappears and the only way to initiate interrogation is place the telemetry head back on the base unit, disconnect and reconnect power, wait for the desktop display, and follow the display prompts.

The operating procedure for device interrogation is outlined below.

Operating Procedure:

1) Connect the power plug to a wall outlet and to the base unit.
2) Wait approximately 45 seconds for the desktop display to appear.
3) Press the start button to the right of the arrow on the display.
4) When prompted, lift the telemetry head and place it over the IMD.
5) When the progress bar appears, wireless interrogation begins.
6) When the progress bar disappears, wireless interrogation is complete.
7) To restart interrogation, disconnect and reconnect power and go to step 2 above.

4.2 LAB ENVIRONMENTAL CONDITIONS

The lab in which the test was performed is room location N7212A on the 7th floor of the Northern most building of the Medtronic Inc. facility at 8200 Coral Sea Street NE Mounds View, MN 55112. This lab is climate controlled to 71 degrees Fahrenheit +/- 1 degree and 47.5% Relative Humidity +/- 1.5%. The test was performed on November 15, 2012. Air pressure in the lab on that day was 1022.76 millibars.

4.3 RECOMMENDED TEST EQUIPMENT

- 1 - Agilent E4438B Signal Generator with Multitone capability **(Generator 1)**
- 1 - Agilent E4430B Signal Generator **(Generator 2)**
- 1 - Agilent 4404B Spectrum Analyzer (or similar product with the same or better performance)
- 1 - Kay 839 Step Attenuator (or similar product with the same or better performance)
- 3 - Mini-Circuits ZFRSC-42 3-port Resistive Zero degree Power Splitter
- 1 - Agilent 3640A Power Supply (or similar product with the same or better performance)
- 1 - Agilent HP87405A Preamp Module (**optional** as amplification for lower power signals)
- 1 – 8542C Gigatronics Power Meter (**optional** for test setup loss calibration)
- 1 – 80601A Gigatronics Power Sensor (**optional** for test setup loss calibration)
- 1 – Model 27901 Conexus Activator
- 1 – Stopwatch

4.4 ACTUAL EQUIPMENT USED

Equipment Description	Asset Number	Calibration Due Date
Agilent E4438C Signal Generator Options: 408, 506, 601, UN7, UNJ	130692	12Oct2013
Agilent E4430C Signal Generator Options: 1E5	130591	15Oct2013
Agilent 4402B Spectrum Analyzer Options: 1DR, UKB, B72, 1DN, 1D5, A4H, BAA	130624	14Oct2013
Kay 839 Step Attenuator	ES032933	Not Calibrated

Qty. 3 - Mini-Circuits ZFRSC-42 3-port Resistive Zero degree Power Splitter	No Asset Number	Not Calibrated
Agilent 3620A Power Supply	ES015278	29Aug2013
8542C Gigatronics Power Meter	ES040887	06Nov2013
80601A Gigatronics Power Sensor	ES043683	05Jun2013
Timex Stopwatch	No Asset Number	Not Calibrated

4.5 ACCURACY ANALYSIS FOR EQUIPMENT USED

Equipment Description	Test Accuracy Needed	Equipment Resolution/Accuracy	Notes
Agilent E4438C Signal Generator (Generator 1)	Frequency Range = 100 MHz to 1 GHz Power Range = -50 dBm to -115 dBm Frequency Accuracy = 5 ppm	Frequency Range = 250 kHz to 6 GHz Power Range = +12 dBm to -136 dBm Frequency Accuracy (with option UNJ) = ±0.1ppm/yr (aging) + ±0.05ppm (temp variation) + ±0.002 ppm (Line Voltage Variation) + ±0.2ppm • Worst case typical accuracy at 10 years = ±1.252 ppm	Power accuracy is determined by calibration as a delivered power to DUT measured by a Power Meter and Sensor. Accuracy is then tied to the total uncertainty of the Gigatronics power meter setup. Relational power accuracy between the multi-tone signal powers of Generator 1 and the single tone power of Generator 2 is determined by comparative marker measurements done on the Spectrum Analyzer so then tied to the Amplitude Accuracy of the Agilent 4402B.
Agilent E4430B Signal Generator (Generator 2)	CW GENERATION Frequency Range = 100 MHz to 1 GHz Power Range = -50 dBm to -115 dBm Frequency Accuracy = 5 ppm PULSE MODULATION GENERATION Pulse Width = 0.1 ms Pulse Period = 10 ms Rise/Fall time = 1 µs	CW GENERATION Frequency Range = 250 kHz to 1 GHz Power Range = +13 dBm to -136 dBm Frequency Accuracy (with option UNJ) = ±0.1ppm/yr (aging) + ±0.05ppm (temp variation) + ±0.002 ppm (Line Voltage Variation) + ±0.2ppm • Worst case typical accuracy at 10 years = ±1.252 ppm PULSE MODULATION GENERATION Pulse Width = 8 µs to 30 sec Pulse Period = 16 µs to 30 sec Rise/Fall time = 150 ns	Power accuracy is determined by calibration as a delivered power to DUT measured by a Power Meter and Sensor.
Agilent E4402B Spectrum Analyzer	SPECTRUM ANALYSIS Frequency Range = 100 MHz to 1 GHz Frequency Readout Accuracy = ±70ppm Absolute Amplitude Accuracy = ±1.04 dB Power Measurement	SPECTRUM ANALYSIS Frequency Range = 9 kHz to 3 GHz Frequency Readout Accuracy (start, stop, center, marker) = ±((Frequency Indication x Frequency Reference Error*) + (0.5% x Span) + (span/(sweep points – 1)) + (15% of RBW) + 10 Hz + (1 Hz x 3.9214))	*Frequency Reference Error (with option 1D5) = ±0.1ppm/yr (aging) + ±0.01ppm (temp variation) + ±0.01 ppm (Set-ability Variation) Worst case typical reference error at 10 years

	Range = -40 to -125 dBm OCCUPIED BANDWIDTH Frequency Readout Accuracy = ±Span/1000	• Applied Accuracy(Hz) = (403.5 * 1.02) + (0.005*3000000) + (3000000/400) + (30000 * 0.15) + 10 + (1 * 3.9214) = 27425.5Hz /403.5=68.0ppm Absolute Amplitude Accuracy = ±1.04 dB Power Measurement Range = +30 to -150 dBm OCCUPIED BANDWIDTH Frequency Readout Accuracy = ±Span/1000	= ±1.02 ppm Frequency Accuracy of the interferer signals are determined by Generator 1 & 2 frequency accuracy
Kay 839 Step Attenuator	Frequency Range = DC to 1 GHz	Frequency Range = DC to 2 GHz	0 dB attenuation Insertion Loss and non-zero dB attenuation accuracy determined and calibrated as a part of the test setup path losses
Mini-Circuits ZFRSC-42 3-port Resistive Splitter	Frequency Range DC to 1 GHz	Frequency Range DC to 4.2 GHz	Insertion Loss determined and calibrated as part of the test setup path losses
Agilent 3620A Power Supply	±0.1 Volts DC	Resolution = 0.01 VDC ±0.5% + 2 counts at 25 ºC ±5 ºC	
8542C Gigatronics Power Meter	±0.4 dB	dB total uncertainty at 0 dBm = ±0.23 dB	
80601A Gigatronics Power Sensor	±0.2 dB	–20 to +20 dBm: ±0.05 dB/10 dB	
Timex Stopwatch	+/- 0.1 secs	Resolution = 0.01 secs	

4.6 MEASUREMENT UNCERTAINTY

Test	Frequency Range	Description	Uncertainty
Emission Bandwidth (EBW)	402 – 405 MHz	Uses the Spectrum Analyzer Occupied Bandwidth (OBW) measurement to determine Emission BW	**3000 Hz** (Based on the OBW measurement Frequency Accuracy)
LBT Threshold Power Level	402 – 405 MHz	Calculation based on measured Emission Bandwidth	**0.1 dBm** (Based on the EBW uncertainty applied to the calculation)
Monitoring System Bandwidth	402 – 405 MHz	Places the Generator 2 interference on a specific frequency and absolute power to understand the excursions of detecting interference power in the BW of the channel being observed	**506 Hz** (Frequency Error at Ch. 7 $Freq_{high}$) and **0.23 dB** (uncertainty of the calibration done on the test setup using the Power Meter)
Monitoring System Scan Cycle Time	402 – 405 MHz	Use a stopwatch to note the time from the start of a disturbance to when the DUT communication session lands on another channel	**0.015 seconds** (uncertainty from resolution of the stop watch + the sweep time of 5ms for the Spectrum Analyzer when set to 3MHz span with 30kHz RBW and 401 sweep points)
Minimum Channel Monitor Period	402 – 405 MHz	Places the Generator 2 interference on a specific frequency and running a pulse modulation of a specific on and off duration to see if the LIC algorithm dwells long enough on channel to see a periodic interference power	**506 Hz** (Frequency Error at Ch. 7 $Freq_{high}$) and **0.23 dB** (uncertainty of the calibration done on the test setup using the Power Meter) and **300 ns** (uncertainty for 0.1 µs pulse width and period on the interfering pulse modulation)
Channel Access Relative to Threshold	402 – 405 MHz	―	―
Discontinuation of Session Within 5 Second Silent Period	402 – 405 MHz	Use a stopwatch to note the time from when the communication session is interrupted to when it goes off that channel to search for another LIC channel	**0.015 seconds** (uncertainty from resolution of the stop watch + the sweep time of 5ms for the Spectrum Analyzer when set to 3MHz span with 30kHz RBW and 401 sweep points)
Use of a Pre-scanned Alternate Channel	402 – 405 MHz	―	―

4.7 TEST INNERCONNECT BLOCK DIAGRAM

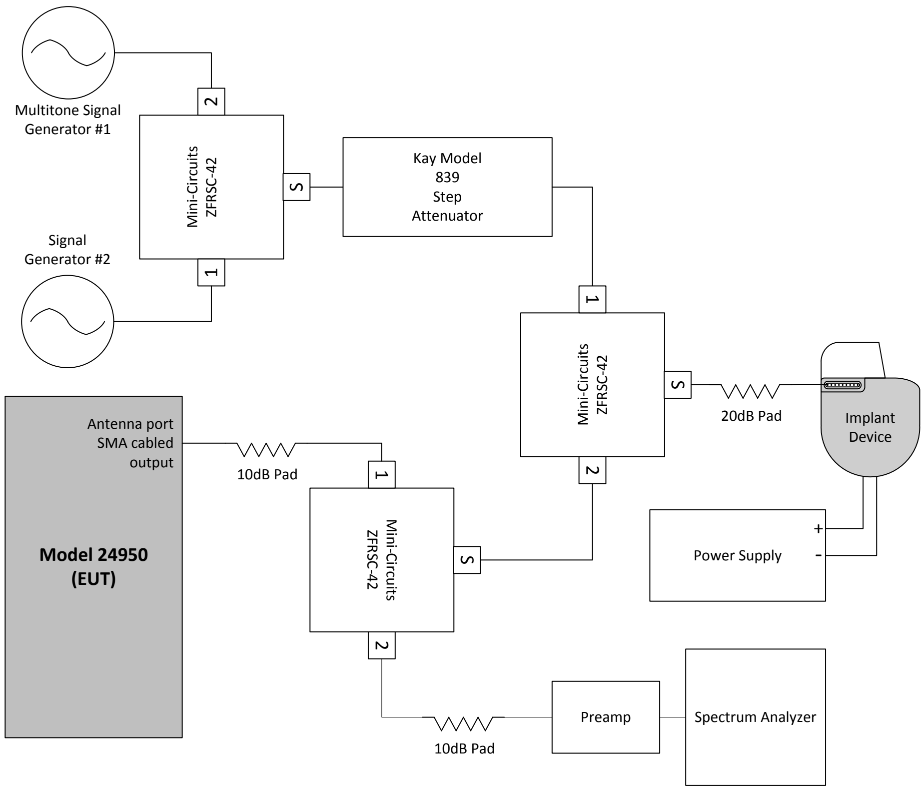


Figure 3: Equipment and EUT Interconnect Diagram

4.8 TEST SETUP CALIBRATION

All path losses and signal variances introduced by the test setup will be accounted for when measurement results are observed or recorded. This includes characterizing the preamp on the input to the Spectrum Analyzer used to monitor lower level RF activity.

4.9 CHANNELIZATION

Channel Frequency 1 = 402.15 MHz

Channel Frequency 2 = 402.45 MHz

Channel Frequency 3 = 402.75 MHz

Channel Frequency 4 = 403.05 MHz

Channel Frequency 5 = 403.35 MHz

Channel Frequency 6 = 403.65 MHz

Channel Frequency 7 = 403.95 MHz

Channel Frequency 8 = 404.25 MHz

Channel Frequency 9 = 404.55 MHz

Channel Frequency 10 = 404.85 MHz

5.0 TEST PROCEDURES

5.1 MEASURED EMISSION BANDWIDTH

The value of Emission Bandwidth (EBW) is needed in order calculate the Threshold Power Level (P_{Th}). The method that will be used to measure this value is outlined in section 8.2 of the ETSI EN 301 839-1 requirements. Record the EBW as well as f_{high} and f_{low} values. These values will also be used in LBT testing.

EMISSION BANDWIDTH RESULTS

Emission Bandwidth (kHz)	**225 kHz**
Channel 1 $Frequency_{high}$ (MHz)	**402.268000 MHz (+118 kHz)**
Channel 1 $Frequency_{low}$ (MHz)	**402.043000 MHz (-107 kHz)**
Channel 7 $Frequency_{high}$ (MHz)	**404.068000 MHz (+118 kHz)**
Channel 7 $Frequency_{low}$ (MHz)	**403.843000 MHz (-107 kHz)**

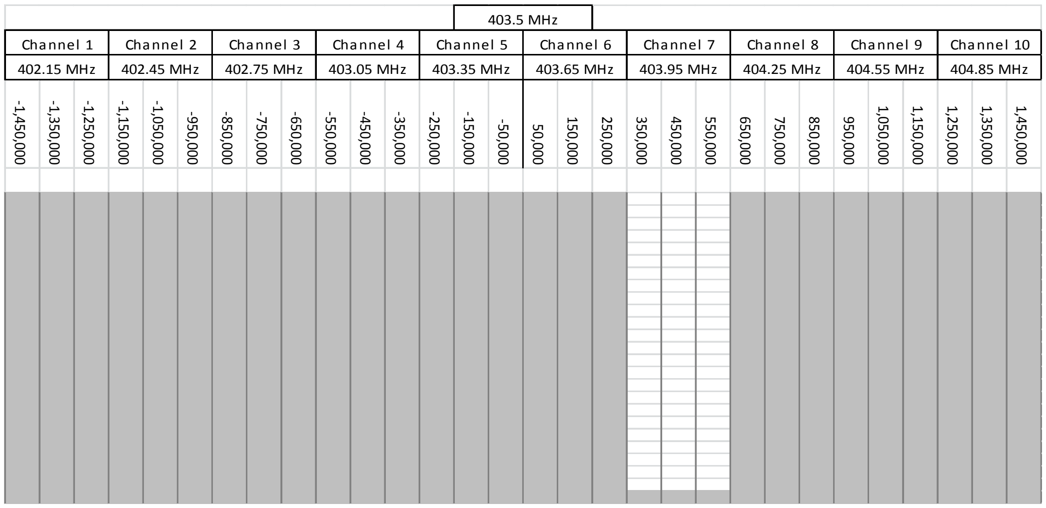
5.2 DISTURBANCE SPECTRUM PROFILES

Throughout the testing performed in this document interferer Disturbance Spectrums will be required to block channels and induce a EUT response to show the performance and compliance of the LBT requirement for transceivers using the MICS communication band. The interference profiles in this section will allow a starting point as a support for all the testing outlined in this document.

5.2.1 PROFILE #1

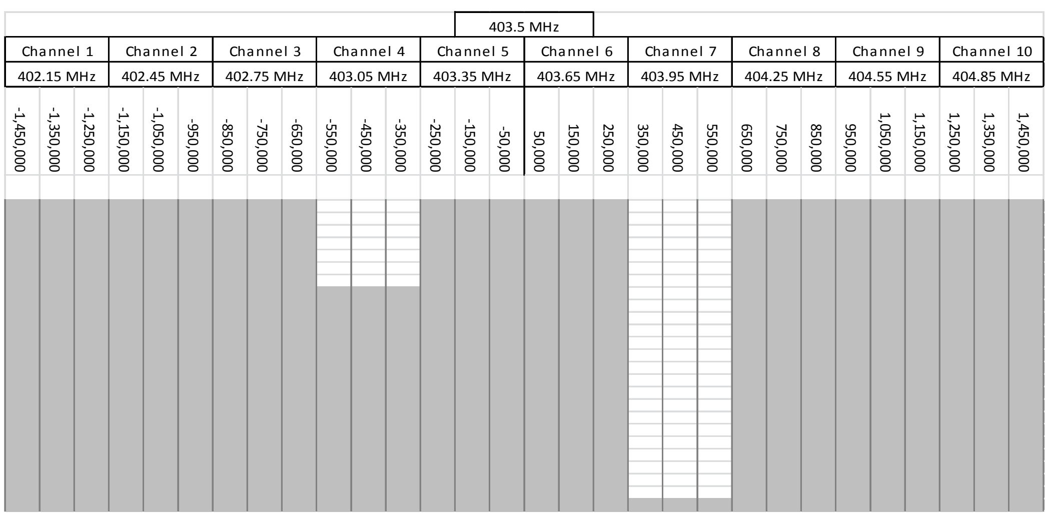
f_c will be 403.95 MHz (Channel 7). Setup the Multitone Signal Generator # 1 to create a disturbance spectrum. The power of the spectrum will be the *Calculated P_{Th}* + 3dB (see paragraph 5.3). The spectrum frequency starts at 402 MHz and stops at f_c – *Measured EBW* (see paragraph 5.1) then resumes at fc + *Measured EBW* ending at 405 MHz. This will create a spectral notch that is 2*EBW centered on f_c.

To achieve this disturbance profile, Generator #1 will need a multitone feature that is available on certain models of Signal Generators. To create this spectrum, center the multitone waveform on 403.5 MHz. Assign 100 KHz spacing and create 30 tones. Modify the list to shut off all tones between and including the tones that are 403.5 MHz + 350 KHz to 403.5 MHz + 550 KHz. After the user applies the multitone profile, observe the output on a Spectrum Analyzer connected to Generator #1. Observed will be a profile with blocked tones 2*EBW centered around 403.95 MHz (Channel 7). See a representative spectral drawing below.



5.2.2 PROFILE #2

This will be the same as profile #1 except modify the power of the spectrum will be the *Calculated* P_{Th} + 10dB (see paragraph 5.3). An additional notch in disturbance spectrum will also be created by decreasing the power 7 dB for the part of the spectrum that is 2*EBW centered around 402.75 MHz (Channel 3). This second spectral notch is referred to as “LIC channel”. To achieve this, modify the multi-tone list to offset by -7 dB all tones between and including the tones that are 403.5 MHz - 350 KHz to 403.5 MHz - 550 KHz. After the user applies the multi-tone profile, observe the output on a Spectrum Analyzer connected to Generator #1. The user should observe a profile with blocked tones 2*EBW wide centered around 403.95 MHz (Channel 7) and 7 dB lower tones 2*EBW wide centered around 402.75 MHz (Channel 3). See a representative spectral drawing below.



5.3 SECTION 10.1 LBT THRESHOLD POWER LEVEL

5.3.1 OVERVIEW

The monitoring system Threshold Power Level, P_{Th} (result units in dBm) shall not be greater than the calculated level given by the equation:

10logB (Hz) - 150 (dBm/Hz) + G (dBi),

where B is the emission bandwidth of the MICS communication session transmitter having the widest emission bandwidth and G is the medical device programmer/controlling LBT transmitter monitoring system antenna gain relative to an isotropic antenna (dBi).

LBT THRESHOLD POWER LEVEL RESULTS

Emission Bandwidth (kHz)	**225 kHz**
Antenna Gain (dBi)	**-5.2 and -5.9dBi**
Calculated P_{Th} (dBm)	**-102.4 dBm**

This test shows the system has sufficient sensitivity to recognize and accurately compare the ambient signals to the calculated Threshold Power Level.

5.3.2 REQUIREMENT

The EUT shall respond appropriately, according to the procedure below with power levels that are at, or lower than, the calculated Threshold Power Level including the recorded power level.

RESULTS

Passed the first test (procedure step 3) with profile 1 power set generator 1 at -103 dBm the DUT appropriately selected f_c channel 7 (403.95 MHz). The 2x EBW notch was maintained with no need to narrow it.

Passed the second test (procedure step 7) with profile 1 power set generator 1 at -103 dBm the DUT appropriately selected a channel other than f_c channel 7 (403.95 MHz) when generator 2 was set to -103 dBm at fc + 50 kHz. The frequency of generator 2 was offset from center +50 kHz because of the zero IF Rx channel filter design.

Passed third test (procedure step 15) with profile 1 power set generator 1 at -83 dBm the DUT appropriately selected f_c channel 7 (403.95 MHz). The 2x EBW notch was maintained with no need to narrow it.

5.3.3 PROCEDURE

1) Connect the setup as shown in Figure 5. Setup a disturbance spectrum profile #1 detailed in section 5.2.1 of this document. Verify Generator #2 CW output is off.
2) Power up the EUT, wait for the display prompt, and press the start button.
3) Allow the EUT to scan and monitor which channel the EUT settles. Verify it communicates on f_c. If it transmits on a channel other than f_c, narrow the 2*EBW notch surrounding f_c until it only transmits on f_c.
4) Cease EUT communication by placing the telemetry head on the base.
5) Turn on Generator #2. Output a CW at f_c with a power of *Calculated* P_{Th} - 6dB.
6) Lift the telemetry head and follow the screen prompts to restart communication.
7) Verify it still transmits on f_c.
8) Cease EUT communication by placing the telemetry head on the base again.

9) Raise the output of Generator #2 1 dB.

10) Monitoring the spectrum with a Spectrum Analyzer, repeat steps 6 – 9 until the EUT transmits on a channel other than f_c. Record that power level of Generator #2.

11) Cease EUT communication by placing the telemetry head on the base again.

12) If the notch was narrowed in step 3 adjust the notch to be set back to 2*Measured EBW.

13) Increase the power 20 dB for disturbance spectrum profile #1.

14) Lift the telemetry head and follow the screen prompts to restart communication.

15) Allow the EUT to scan and monitor which channel the EUT settles. Using a Spectrum Analyzer, verify it transmits on f_c. If it transmits on a channel other than f_c, narrow the 2*EBW notch surrounding f_c until it only transmits on f_c.

5.4 SECTION 10.2 MONITORING SYSTEM BANDWIDTH

5.4.1 OVERVIEW

The intent of this requirement is to insure that the EUT 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.

5.4.2 REQUIREMENT

The monitoring system bandwidth measured at its 20 dB down points shall be equal to or greater than the measured Emission Bandwidth. This is determined by verifying that the test results values of D1 and D2 are less than or equal to 20 dB.

RESULTS

Passed the first test (procedure step 3) with profile 1 power set generator 1 at -100 dBm the DUT appropriately selected f_c channel 7 (403.95 MHz). The 2x EBW notch was maintained with no need to narrow it.

Passed the second test (procedure step 5) with profile 1 power set generator 1 at -100 dBm and the generator 2 was set to -50 dBm at fc + 50 kHz. The DUT appropriately selected a channel other than f_c channel 7 (403.95 MHz). The frequency of generator 2 was offset from center +50 kHz because of the zero IF Rx channel filter design.

Passed the third test for both D1 and D2 were less than the required maximum of 20 dB.

- **(procedure step 9) Pa = -104 dBm (To get Pa, the frequency of generator 2 was offset from center +50 kHz because of the zero IF Rx channel filter design)**
- **(procedure step 13) Pb = -101 dBm**
- **(procedure step 19) Pc = -100 dBm**
- **(procedure step 20) D1 = 3 dB**
- **(procedure step 21) D2 = 4 dB**

5.4.3 PROCEDURE

1) Connect the setup as shown in Figure 5. Setup a disturbance spectrum profile #1 detailed in section 5.2.1 of this document. Verify Generator #2 CW output is off.
2) Power up the EUT and press the start button.
3) Allow the EUT to scan and monitor which channel the EUT settles. Using a Spectrum Analyzer, verify it transmits on fc. If it transmits on a channel other than fc, narrow the 2*EBW notch surrounding fc until it only transmits on fc.
4) From Generator #2, transmit a CW signal at frequency fc at a power level sufficient to block operation at the channel with a center frequency of fc. A recommended level would be -50 dBm.
5) Using a Spectrum Analyzer, verify that the EUT does not transmit on fc but does transmit on a channel frequency within the disturbance spectrum.
6) Cease EUT communication by placing the telemetry head on the base.
7) Lower the output of Generator #2 1 dB below the disturbance spectrum power level.
8) Lift the telemetry head and follow the screen prompts to restart communication.
9) Monitoring the spectrum with a Spectrum Analyzer, decrease the CW signal out of Generator #2 in 1 dB steps and restart communication each time to achieve a CW power level that just causes the EUT to transmit on the channel with a center frequency of f_c. Record that power level as Pa.
10) Cease EUT communication by placing the telemetry head on the base.
11) Adjust Generator #2 frequency to be a CW signal at frequency f_{low}.
12) Lift the telemetry head and follow the screen prompts to start communication.
13) Monitoring the spectrum with a Spectrum Analyzer, increase or decrease the CW signal out of Generator #2 in 1 dB steps and restart communication each time to a power level that just causes the EUT to transmit on a channel frequency within the disturbance spectrum. Record that power level as Pb.
14) Cease EUT communication by placing the telemetry head on the base.
15) Reduce the CW power out of Generator 2 to be the level Pa.
16) Adjust Generator #2 frequency to be a CW signal at frequency f_{high}.
17) Lift the telemetry head and follow the screen prompts to start communication.
18) Using a Spectrum Analyzer, verify that the EUT communicates on fc
19) Monitoring the spectrum with a Spectrum Analyzer, increase or decrease the CW signal out of Generator #2 in 1 dB steps and restart communication each time to a power level that just causes the EUT to transmit on a channel frequency within the disturbance spectrum. Record that power level as Pc.
20) Subtract Pb from Pa and record the difference as D1.
21) Subtract Pc from Pa and record the difference as D2.

5.5 SECTION 10.3.1.1 MONITORING SYSTEM SCAN CYCLE TIME

5.5.1 OVERVIEW

The intent of this requirement is to ensure that when the monitoring system updates the detected power levels in the ULP-AMI band, it scans the band at a rate less than or equal to 5 seconds.

5.5.2 REQUIREMENT

Within 5 seconds, circuitry associated with a medical device programmer/control transmitter shall monitor all the channels in the ULP-AMI band.

The requirement is met if all values of Tp_n are less than or equal to 5 seconds.

RESULTS

Passed the first test (procedure step 4) with profile 2 power set generator 1 at -93 dBm the DUT appropriately selected f_c channel 7 (403.95 MHz). The 2x EBW notch was maintained with no need to narrow it.

Passed the second test (procedure step 8) with profile 2 power set generator 1 at -93 dBm and the generator 2 was set to -90 dBm at fc + 50 kHz. The DUT appropriately selected the LIC Channel 4 (403.05 MHz). The frequency of generator 2 was offset from center +50 kHz because of the zero IF Rx channel filter design.

Passed the third test (procedure step 18) with a time of 1.90 seconds. The 10 different measured times were: 1.43 secs, 1.62 secs, 1.57 secs, 1.22 secs, 1.51 secs, 1.90 secs, 1.22 secs, 1.31 secs, 1.40 secs, 1.28 secs

5.5.3 PROCEDURE

1) Connect the setup as shown in Figure 5. Setup a disturbance spectrum profile #2 detailed in section 5.2.2 of this document. This disturbance spectrum creates a -7 dB notch for the part of the spectrum that is 2*EBW centered around 402.75 MHz. This second spectral notch is referred to as “LIC channel”. The power level of this disturbance spectrum is *Calculated* P_{Th} + 10dB. Verify Generator #2 CW output is off.
2) Increase the level of the disturbance spectrum to be sufficiently high to prevent operation under any circumstances on any channel other that the channel centered on f_c. A recommended power would be a power 10 dB above the power defined in profile #2.
3) Power up the EUT and press the start button.
4) Allow the EUT to scan and monitor which channel the EUT settles. Using a Spectrum Analyzer, verify it transmits on f_c. If it transmits on a channel other than f_c, narrow the 2*EBW notch surrounding fc until it only transmits on f_c.
5) Cease EUT communication by placing the telemetry head on the base.
6) From Generator #2, transmit a CW signal at frequency f_c at a power level 3 dB above the power level of the disturbance spectrum.
7) Lift the telemetry head and follow the screen prompts to restart communication.

8) Monitoring the spectrum with a Spectrum Analyzer Verify the EUT is communicating at the *LIC Channel*.

9) Cease EUT communication by placing the telemetry head on the base. Reset the stopwatch.

10) Increase the Generator #2 CW signal power to be sufficiently high to prevent communication on the channel centered on the frequency f_c. A recommended level would be -50 dBm.

11) Turn off the CW from Generator #2.

12) Lift the telemetry head and follow the screen prompts to restart communication.

13) Monitoring the spectrum with a Spectrum Analyzer Verify the EUT is communicating at the channel centered on the frequency f_c

14) Simultaneously, turn on the Generator #2 CW signal at frequency f_c and trigger a stopwatch to start.

15) Monitoring the spectrum with a Spectrum Analyzer and using the stopwatch, measure the time period from when the CW signal blocks communication on the channel centered on the frequency f_c to when the EUT starts communicating at the LIC channel. Record this value.

16) Reset the stopwatch.

17) Repeat steps 11-16 nine more times. Record all values.

18) The longest time measured, of the 10 times recorded, is the maximum scan cycle time and shall be less than 5 seconds. It should be noted that this time should be predictable and consistent based on the protocol algorithm dwelling a set amount of monitoring time per channel for a set number of channels.

5.6 SECTION 10.3.1.2 MINIMUM CHANNEL MONITOR PERIOD

5.6.1 OVERVIEW

The intent of this requirement is to insure the monitoring period on each channel is 10 ms or longer in order to detect transmissions that may have silent periods between data bursts that are less than 10 ms in duration.

5.6.2 REQUIREMENT

Each MICS channel shall be monitored for a minimum of 10 ms during each scan cycle of 5 s or less duration.

Conformity with this requirement is shown if, during testing, the EUT is unable to access the pulse modulated disturbance spectrum and only initiate a communications session on the channel centered on f_c.

RESULTS

Passed the first test (procedure step 4) with profile 1 power set generator 1 at -83 dBm the DUT appropriately selected f_c channel 7 (403.95 MHz). The 2x EBW notch was maintained with no need to narrow it.

Passed the second test (procedure step 8) with profile 1 power set generator 1 at -83 dBm and the generator 2 was set to -80 dBm at fc + 50 kHz. The DUT appropriately selected a channel

other than f_c channel 7 (403.95 MHz). The frequency of generator 2 was offset from center +50 kHz because of the zero IF Rx channel filter design.

Passed the third test (procedure step 14) 10 times with profile 1 power set generator 1 at -83 dBm and pulse modulated at a pulse width of 0.1 mS and a pulse period of 10 mS.

5.6.3 PROCEDURE

1) Connect the setup as shown in Figure 5. Setup a disturbance spectrum profile #1 detailed in section 5.2.1 of this document. Verify Generator #2 CW output is off.
2) Increase the level of the disturbance spectrum to be sufficiently high to prevent operation under any circumstances on any channel other that the channel centered on f_c. A recommended level would be 20 dB higher than the power level identified in profile #1.
3) Power up the EUT and press the start button.
4) Allow the EUT to scan and monitor which channel the EUT settles. Using a Spectrum Analyzer, verify it transmits on f_c. If it transmits on a channel other than f_c, narrow the 2*EBW notch surrounding fc until it only transmits on f_c.
5) Cease EUT communication by placing the telemetry head on the base.
6) From Generator #2, transmit a CW signal at frequency f_c at a power level 3 dB above the power level of the disturbance spectrum.
7) Lift the telemetry head and follow the screen prompts to restart communication.
8) Monitoring the spectrum with a Spectrum Analyzer Verify the EUT is not communicating at the channel centered on the frequency f_c.
9) Cease EUT communication by placing the telemetry head on the base.
10) Turn off CW signal from Generator #2.
11) Set up Generator #1 so that the disturbance spectrum is pulsed modulated with a pulse width of 0.1 msec and with an off period of 9.9 msec (total pulse period of 10 mS).
12) Lift the telemetry head and follow the screen prompts to restart communication.
13) Monitor the spectrum analyzer for the channel on which communications is established and verify that the EUT transmits on fc.
14) Repeat steps 10-11 nine more times. Each time monitor the spectrum analyzer for the channel on which communications is established and verify that the EUT always communicates on fc.

5.7 SECTION 10.4 CHANNEL ACCESS RELATIVE TO THRESHOLD

5.7.1 OVERVIEW

MICS control transmitters are permitted to initiate a MICS communications session to an IMD transmitter immediately on any channel where the ambient signal level is below the maximum permitted threshold power level. The intent of this requirement is then to insure performance of the channel access based on ambient levels relative to the calculated access threshold level, Th_p.

5.7.2 REQUIREMENT

The EUT shall access and transmit on the Least Interfered Channel (LIC) after the CW signal at frequency, fc, has been increased by 9 dB from its initial level of 3 dB below the calculated access threshold.

5.7.3 PROCEDURE

This particular EUT does not employ the threshold power provision or use a predetermined channeling plan, so this test is not necessary.

5.8 SECTION 10.5 DISCONTINUATION OF SESSION WITH 5 S SILENT PERIOD

5.8.1 OVERVIEW

MICS systems shall cease transmission in the event the communications session is interrupted for a period of 5 seconds or more.

5.8.2 REQUIREMENT

Emission from the programmer/control transmitter on the initial LIC channel shall cease in an amount of time less than or equal to 5 s after the IMD transmitter is turned off or blocked and the session should not restart on the initial LIC channel. If the time recorded is less than or equal to 5 seconds and communication does not restart on the initial LIC channel, the requirement is met.

RESULTS

Passed the first test (procedure step 3) with profile 2 power set generator 1 at -93 dBm and the generator 2 was set to -106 dBm at fc + 50 kHz. The DUT appropriately selected f_c channel 7 (403.95 MHz). The 2x EBW notch was maintained with no need to narrow it.

Passed the second test (procedure step 11) with profile 2 power set generator 1 at -93 dBm and the generator 2 was set to -97 dBm at fc + 50 kHz. The DUT appropriately selected the LIC Channel 4 (403.05 MHz). The frequency of generator 2 was offset from center +50 kHz because of the zero IF Rx channel filter design.

Passed the third test (procedure step 16) with a time of 1.98 seconds. The 10 different measured times were: 1.91 secs, 1.82 secs, 1.67 secs, 1.53 secs, 1.41 secs, 1.43 secs, 1.68 secs, 1.31 secs, 1.98 secs, 1.98 secs

5.8.3 PROCEDURE

1) Connect the setup as shown in Figure 5. Setup a disturbance spectrum profile #2 detailed in section 5.2.2 of this document. This disturbance spectrum creates a -7 dB notch for the part of the spectrum that is 2*EBW centered around 402.75 MHz. This second spectral notch is referred to as “LIC channel”. The power level of this disturbance spectrum is *Calculated* P_{Th} + 10dB. Verify Generator #2 CW output is off.
2) Power up the EUT and press the start button.
3) Allow the EUT to scan and monitor which channel the EUT settles. Verify it communicates on f_c. If it transmits on a channel other than f_c, narrow the 2*EBW notch surrounding f_c until it only transmits on f_c.

4) Cease EUT communication by placing the telemetry head on the base.
5) From Generator #2, transmit a CW signal at frequency f_c at a power level 3 dB below the power level of the *Calculated* P_{Th}.
6) Lift the telemetry head and follow the screen prompts to restart communication.
7) Monitoring the Spectrum Analyzer, verify that the EUT communicates on f_c
8) Cease EUT communication by placing the telemetry head on the base.
9) Increase the CW signal power from Generator #2 by 9 dB.
10) Lift the telemetry head and follow the screen prompts to restart communication. Reset the stopwatch.
11) Monitoring the Spectrum Analyzer, verify that the EUT communicates on center frequency of the *LIC channel*.
12) Reduce Generator #2 CW signal power back down to 3 dB below the power level of the *Calculated* $P_{Th.}$
13) Turn off the IMD power supply and at the same time trigger a stopwatch to start.
14) Monitoring the spectrum with a Spectrum Analyzer and using the stopwatch, measure the time period from when the IMD is powered down and the EUT stops communicating on the *LIC channel* and starts trying to communicate on the channel centered on f_c. Record this value.

    Note: When this occurs the EUT has realized loss of communication. It will leave that channel that is currently used and do an LBT scan for the least interfered channel (LIC). It is possible and allowed that after an LBT scan if the channel used is still the LIC, it will return to that same channel.

15) Cease EUT communication by placing the telemetry head on the base.
16) Repeat steps 9 – 15 nine more times. Record all values. All 10 measured times recorded will be less than or equal to 5 seconds.

5.9 SECTION 10.6 USE OF PRE-SCANNED ALTERNATE CHANNEL

5.9.1 OVERVIEW

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 procedures in this clause determine if the system uses this feature and, if so, if it complies with the requirements for alternate channel selection.

5.9.2 REQUIREMENT

Systems using the alternate channel provision shall monitor the alternate channel for at least 10 mS prior to transmitting on the alternate channel. The detected power level during this minimum 10 mS monitoring period shall be no higher than 6 dB above the power level detected when the channel was chosen as the alternate channel.

5.9.3 PROCEDURE

The particular EUT does not employ the provision for a pre-scanned alternate channel, so this test is not necessary.

6.0 COMPLETION

This paragraph concludes this document.