



TEST REPORT

Report Number: 101363577MIN-001A
Project Number: G101363577

**Testing performed on the
9010 / 9011 Programmer**

FCC ID: SVHBAROSTIMPGM1
Industry Canada ID: 9464A-PGM901

to
47 CFR Part 95 Subpart I: 2013
RSS- 243, Issue 3, November 2010

CVRx Inc.

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1.0 GENERAL DESCRIPTION

Model:	9010 / 9011 Programmer
Type of EUT:	MedRadio Programmer
Serial Number:	N/A
FCC ID:	SVHBAROSTIMPGM1
Industry Canada ID:	9464A-PGM901
Related Submittal(s) Grants:	SVHBAROSTIMPG1, Implantable Device
Company:	CVRx Inc.
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Address:	9201 West Broadway Avenue, Suite 650 Minneapolis, MN 55445
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Test Standards:	<input checked="" type="checkbox"/> 47 CFR, Part 95 Subpart I: 2013 <input checked="" type="checkbox"/> RSS-243, Issue 3, November 2010 <input type="checkbox"/> RSS-Gen, Issue 3, 2010 <input type="checkbox"/> 47 CFR, Part 15:2013, §15.107 and §15.109, Class [REDACTED] <input type="checkbox"/> Other [REDACTED]
Type of radio:	<input checked="" type="checkbox"/> Stand -alone <input type="checkbox"/> Module <input type="checkbox"/> Hybrid
Date Sample Submitted:	January 5, 2011
Test Work Started:	January 10, 2011
Test Work Completed:	January 14, 2011
Test Sample Conditions:	<input type="checkbox"/> Damaged <input type="checkbox"/> Poor (Usable) <input checked="" type="checkbox"/> Good

1.1 Product Description; Test Facility

Product Description:	MedRadio Programmer
Operating Frequency	403.35MHz
Modulation:	FSK
Emission Designator:	246KF1D
Antenna(s) Info:	-2dBi Integral antenna
Antenna Installation:	<input type="checkbox"/> User <input type="checkbox"/> Professional <input checked="" type="checkbox"/> Factory
Transmitter power configuration:	<input type="checkbox"/> Internal battery <input type="checkbox"/> External power source <input type="checkbox"/> 120VAC <input type="checkbox"/> 230VAC <input type="checkbox"/> 400VAC <input type="checkbox"/>  VDC <input checked="" type="checkbox"/> Other: USB 5VDC from the Host PC <input type="checkbox"/> 50Hz <input type="checkbox"/> 60Hz
Special Test Arrangement:	None
Test Facility Accreditation:	A2LA (Certificate No. 1427.01)
Test Methodology:	Measurements performed according to the procedures in ANSI C63.4-2003 / TIA 603-C

Notes: This Report is issued to reflect updated reference to the newest editions and sections of FCC standards; to add reference to applicable sections of FCC Part 2 standard; to change technical terms from MICS Radio to MedRadio; to change the customer name, telephone and email address; to add Model 9010 Programmer to the scope of testing.

The radio equipment for the Model 9010 Programmer Interface is identical to the radio equipment used in the Model 9011 Programmer Interface. Both models use the same RF components, circuitry and antennas. The differences between the two models are the addition of a plastic hook to the mechanical enclosure and an update to the firmware for improved robustness and reliability of the communication link; therefore, testing was performed on Model 9011 Programmer and covers also the Model 9010 Programmer.

1.2 EUT Configuration

The equipment under test was operated during the measurement under the following conditions:

- Standby
- Continuous
- Continuous un-modulated
- Test program (customer specific)
- [Redacted]

Operating modes of the EUT:

No.	Description
1	The EUT was powered from host PC via USB cable, and was transmitting continuously at 403.35MHz

Cables:

No.	Type	Length	Designation	Note
1	Power and communication	6ft.	USB cable	

Support equipment/Services:

No.	Item	Description
1	Lenovo Notebook	Host PC

General notes: None

1.3 Environmental conditions

During the measurement the environmental conditions were within the listed ranges:

- Normal**

Temperature: 15-35 ° C

Humidity: 30-60 %

Atmospheric pressure: 86-106 kPa

- Extreme**

<input checked="" type="checkbox"/> Temperature:	<u>+0 to +55 ° C</u>
<input type="checkbox"/> Temperature:	<u>-20 to +55 ° C</u>
<input checked="" type="checkbox"/> DC power:	<u>± 10%</u>
<input type="checkbox"/> Battery:	<u>0.85 -1.15 times</u>

1.4 Measurement uncertainty

The expanded uncertainty ($k = 2$) for radiated emissions from 30 to 1000 MHz has been determined to be:
 ± 4 dB at 10m and ± 5.4 dB at 3m

The expanded uncertainty ($k = 2$) for conducted emissions from 150 kHz to 30 MHz has been determined to be:
 ± 2.6 dB

1.5 Field Strength Calculation

The field strength is calculated by adding the Antenna Factor and Cable Factor, and subtracting the Amplifier Gain (if any) from the measured emissions reading on the EMI Receiver.

The basic equation with a sample calculation is as follows:

$$FS = RA + AF + CF - AG$$

Where: FS = Field Strength in dB(μ V/m)

RA = Receiver Amplitude in dB(μ V)

CF = Cable Attenuation Factor in dB

AF = Antenna Factor in dB(m^{-1})

AG = Amplifier Gain in dB

Assume a receiver reading of 48.1 dB(μ V) is obtained. The antenna factor of 7.4 dB(m^{-1}) and cable factor of 1.6 dB is added and amplifier gain of 16.0 dB is subtracted giving field strength of 41.1 dB(μ V/m).

$$RA = 48.1 \text{ dB}(\mu\text{V})$$

$$AF = 7.4 \text{ dB}(m^{-1})$$

$$CF = 1.6 \text{ dB}$$

$$AG = 16.0 \text{ dB}$$

$$FS = RA + AF + CF - AG$$

$$FS = 48.1 + 7.4 + 1.6 - 16.0$$

$$FS = 41.1 \text{ dB}(\mu\text{V}/\text{m})$$

2.0 TEST SUMMARY

Referring to the performance criteria and the operating mode during the tests specified in this report, the equipment complies with the requirements according to the following standards.

TEST SPECIFICATION	TEST PARAMETERS	RESULT
FCC §2.1046 / FCC §95.639(f) / RSS-243 Section 5.4	Effective Radiated Power at Fundamental	Pass
FCC §2.1049 / FCC §95.633(e) / RSS-243 Section 5.1	Bandwidth of the emission	Pass
FCC §2.1053 / FCC §95.635 / RSS-243 Sections 5.5, 5.6	Radiated Spurious Emissions	Pass
FCC §2.1055 / FCC §95.627(e) / RSS-243 Sections 5.3	Frequency Error	Pass
FCC §95.627(a)(1-4) / RSS-243 Sections 5.7	The MedRadio Communication Sessions (Threshold Power Levels, Monitoring System Bandwidth, Scan Cycle Time, Minimum Channel Monitoring Period, Channel Access, Discontinuation of a MedRadio Session, and Use of Pre-Scanned Alternate Channel)	Pass

3.0 TEST CONDITIONS AND RESULTS

3.1 Effective Radiated Power at Fundamental

Test location: OATS Anechoic Chamber Other

Test distance: 10 meters 3 meters

Frequency range of measurements: 403.35MHz

Test result: Pass

Max. Emissions margin at fundamental: 3.7dB below the limits

Notes: The maximum effective radiated power is 25 μ W or 18.2mW/meter at 3m test distance (85.2dB μ V/m at 3m).

Date:	January 7, 2011	Result:	Pass
Standard:	FCC 95 Subpart I / RSS-243		
Tested by:	Uri Spector		
Test Point:	Enclosure with antenna		
Operation mode:	See Page 5		
Note:			

Table # 1

Frequency MHz	Antenna		Ant. CF dB1/m	Cable loss dB	Pre-amp Gain (dB)	Reading dB μ V	Total @ 3m dB μ V/m	Limit dB μ V/m	Margin dB	Comments
	Polarity	Hts(cm)								
403.30	V	103	16.7	2.3	0.0	60.9	79.9	85.2	-5.3	
403.30	H	100	16.7	2.3	0.0	62.5	81.5	85.2	-3.7	

Comments: Measurements were taken using an Peak detector at RBW 300kHz, VBW 1MHz

3.2 Bandwidth of Emissions

Center Frequency of operation MHz	Measured 20dB bandwidth kHz	Maximum bandwidth allowed kHz
403.35	246	300

Graph 3.2.1 shows bandwidth of emissions

Notes: None

Graph 3.2.1



3.3 Radiated Spurious Emissions

Test location: OATS Anechoic Chamber

Test distance: 10 meters 3 meters

Test result: **Pass**

Frequency range: 30MHz-5000MHz

Max. Emissions margin: 4.0dB below the limits

Notes: The Radiated Spurious Emissions test was performed in the Anechoic chamber at 3m measurement distance (see Tables 3.3.1, 3.3.2 and Graphs 3.3.1, 3.3.2).

Date:	January 7, 2011	Result:	Pass
Standard:	FCC Part 95 Subpart I / RSS-243		
Tested by:	Uri Spector		
Test Point:	Enclosure with antenna		
Operation mode:	See Page 5		
Note:			

Spurious emissions more than 250 kHz removed from the MedRadio band (402-405MHz) at 3 meters test distance must not exceed 40dB μ V/m in the range from 30-88 MHz, 43.5 from 88-216 MHz, 46dB μ V/m from 216-960 MHz and 54dB μ V/m above 960 MHz.

Emissions within 250kHz of the MedRadio band must be attenuated by at least 20dB below the maximum permitted output power, using an instrument resolution bandwidth approximately equal to 1% of the emissions bandwidth.

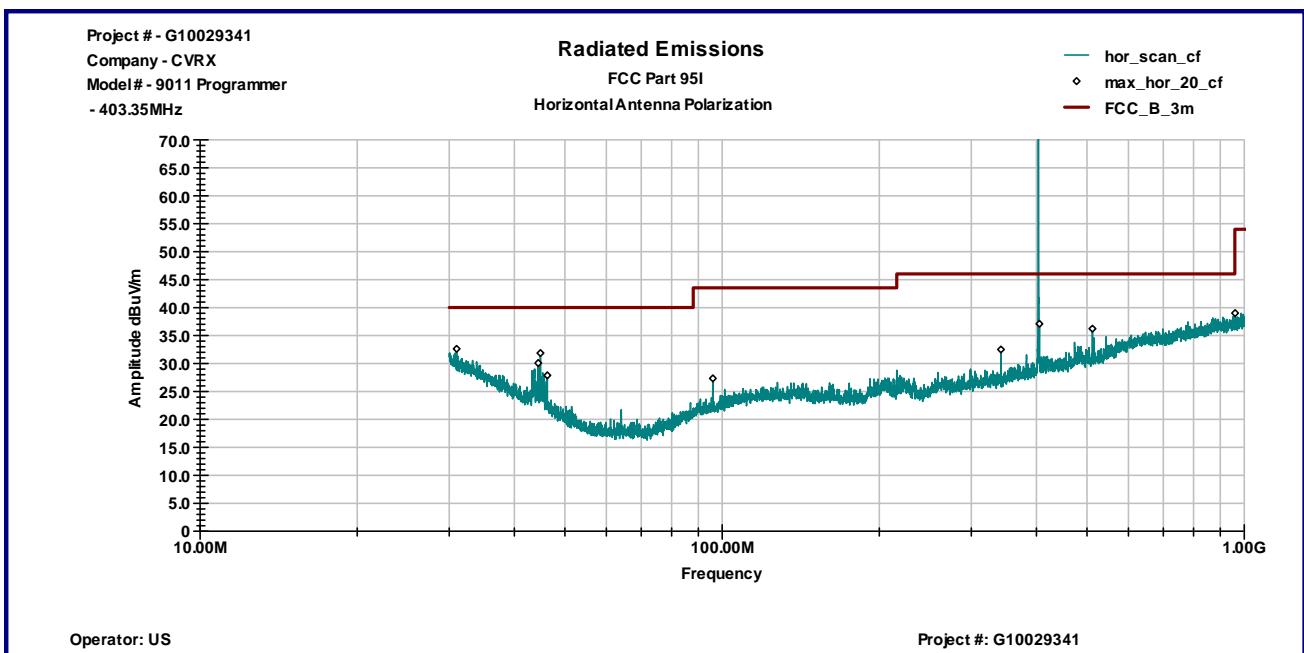
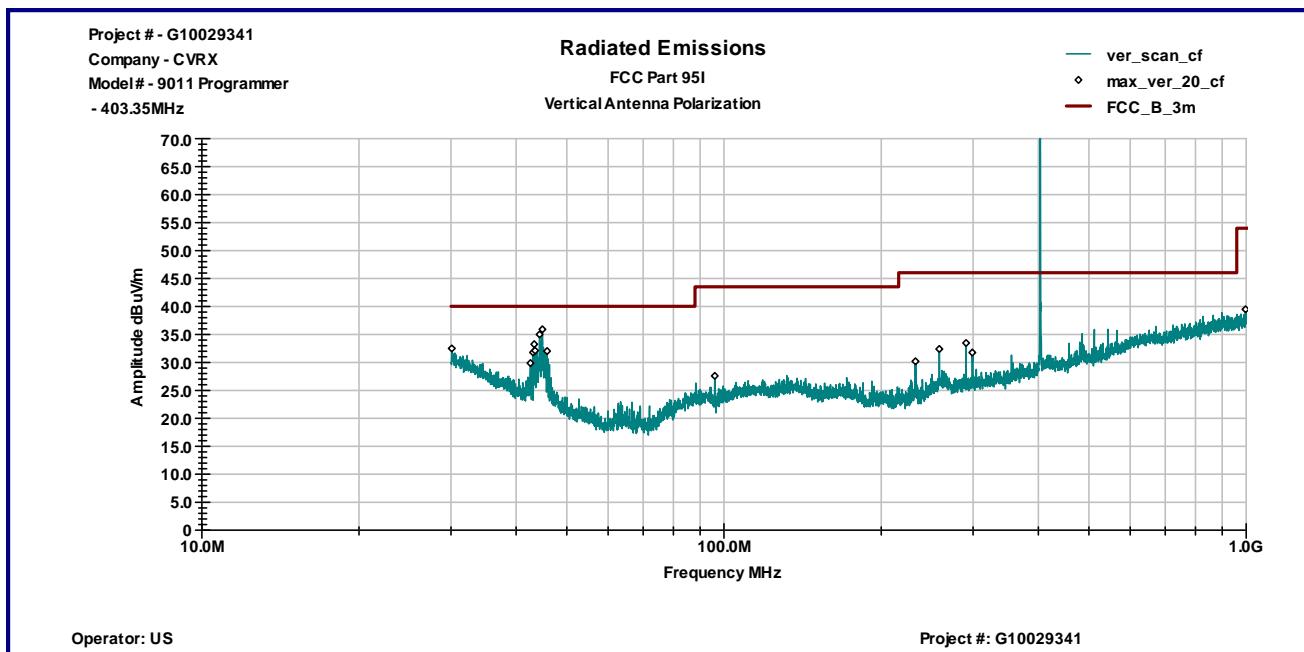
Emissions within the MedRadio band more than 150kHz away from the center frequency of the spectrum the transmission is intended to occupy, will be attenuated below the transmitter output power by at least 20dB, using an instrument resolution bandwidth approximately equal to 1% of the emissions bandwidth.

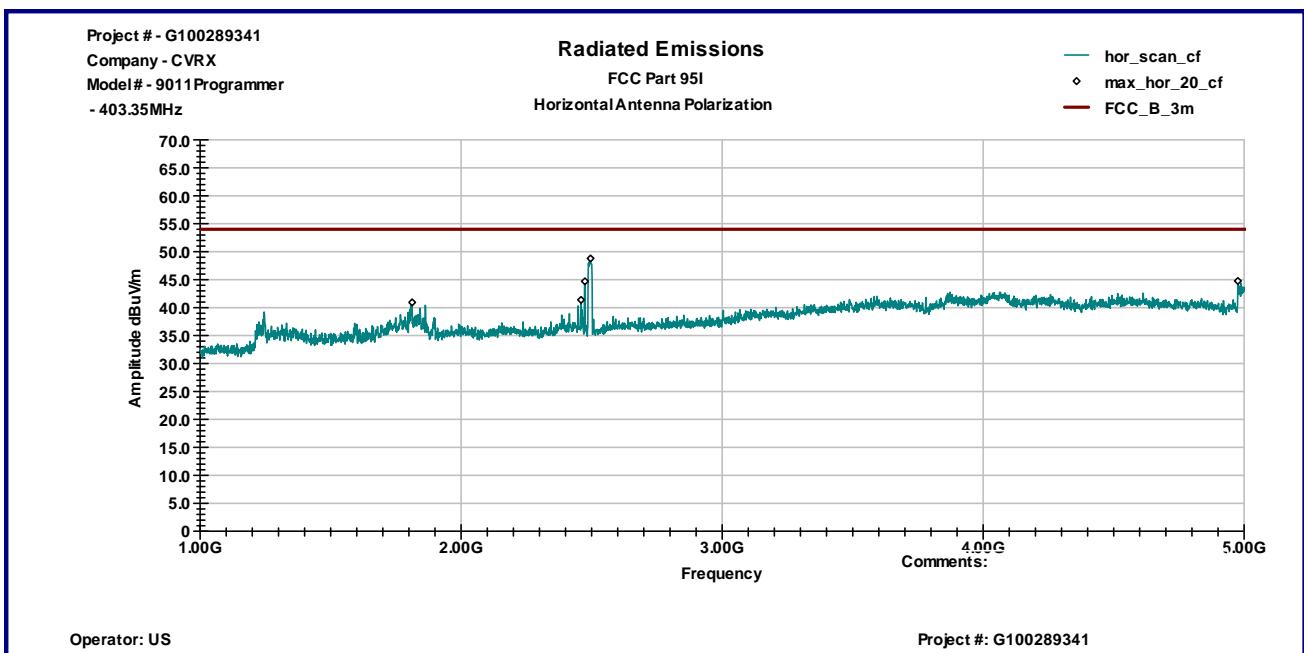
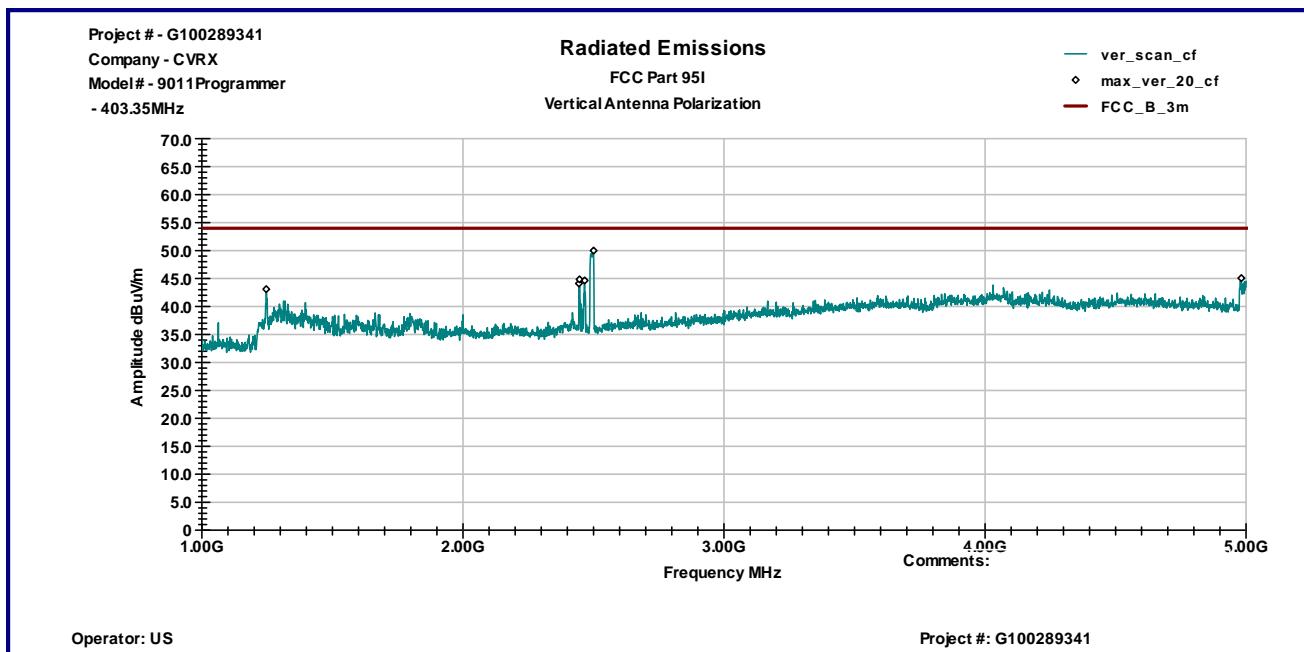
Table 3.3.1

Frequency	Ant. Polarity	Peak Reading dB μ V	Ant.Factor dB1/m	Total at 3m dB μ V/m	QP Limit dB μ V/m	Margin dB
30.117 MHz	V	12.2	20.3	32.5	40.0	-7.5
42.594 MHz	V	16.4	13.5	29.9	40.0	-10.2
44.9 MHz	V	23.5	12.4	35.9	40.0	-4.1
96.029 MHz	V	16.0	11.6	27.6	43.5	-15.9
232.72 MHz	V	17.0	13.2	30.2	46.0	-15.9
258.46 MHz	V	16.6	15.8	32.4	46.0	-13.6
290.92 MHz	V	17.8	15.7	33.5	46.0	-12.6
298.99 MHz	V	15.9	15.9	31.8	46.0	-14.3
31.005 MHz	H	12.8	19.8	32.6	40.0	-7.4
44.867 MHz	H	19.4	12.4	31.9	40.0	-8.2
46.263 MHz	H	16.1	11.7	27.9	40.0	-12.1
95.966 MHz	H	15.8	11.6	27.3	43.5	-16.2
342.07 MHz	H	15.5	17.0	32.5	46.0	-13.5
511.99 MHz	H	15.6	20.7	36.2	46.0	-9.8

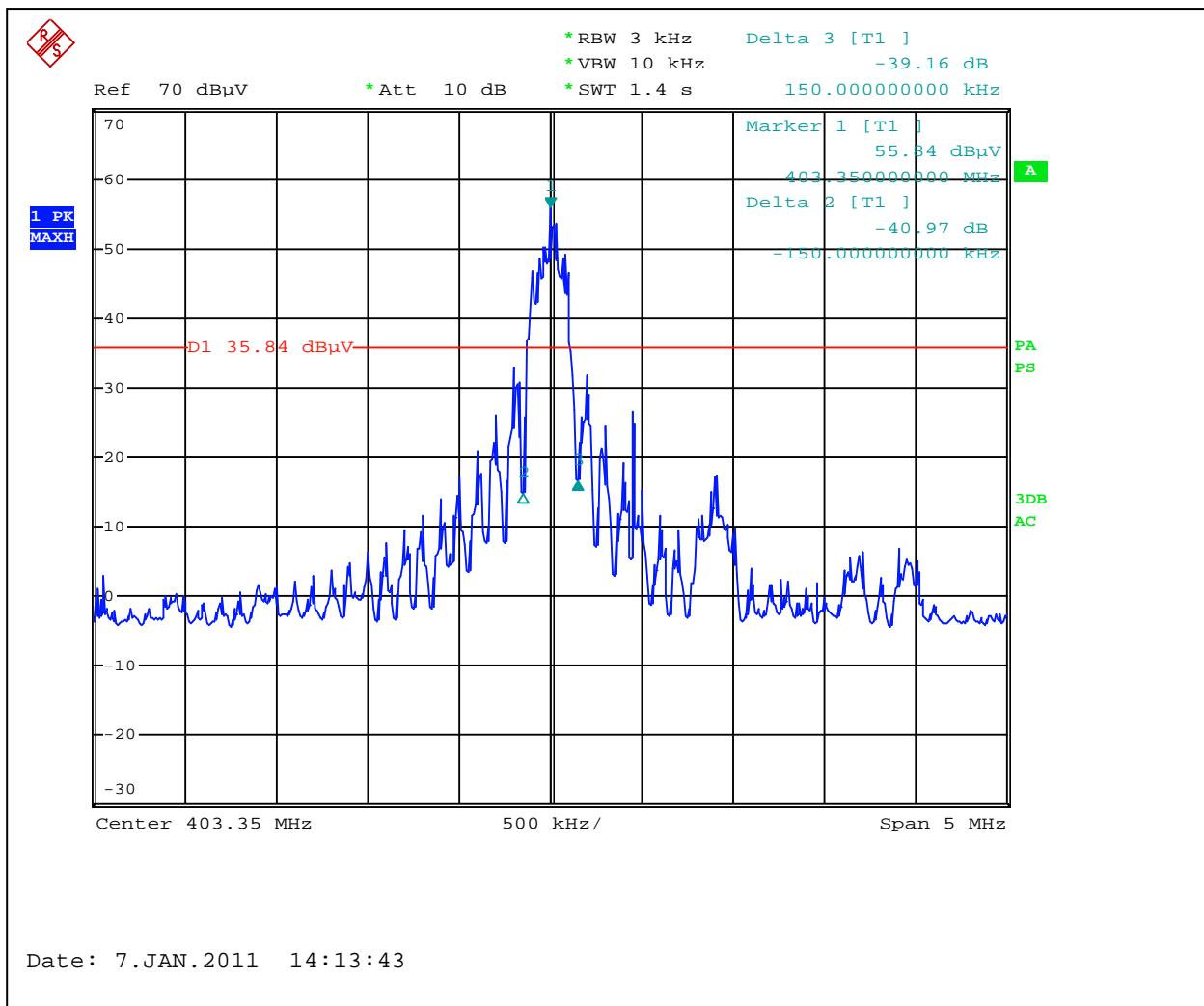
Table 3.3.2

Frequency MHz	Antenna Polarity	Reading dB μ V	Total C.F. dB1/m	Pre-Amp. Gain (dB)	Total at 3m dB μ V/m	QP Limit dB μ V/m	Margin dB
1.2469 GHz	V	54.9	27.2	38.9	43.1	54.0	-10.9
2.4469 GHz	V	50.7	31.9	37.8	44.8	54.0	-9.2
2.5006 GHz	V	55.7	32.1	37.8	50.0	54.0	-4.0
4.9817 GHz	V	43.4	38.3	36.6	45.1	54.0	-8.9
1.8126 GHz	H	49.6	29.9	38.6	40.9	54.0	-13.1
2.496 GHz	H	54.3	32.2	37.8	48.8	54.0	-5.2
4.976 GHz	H	43.1	38.2	36.6	44.7	54.0	-9.3

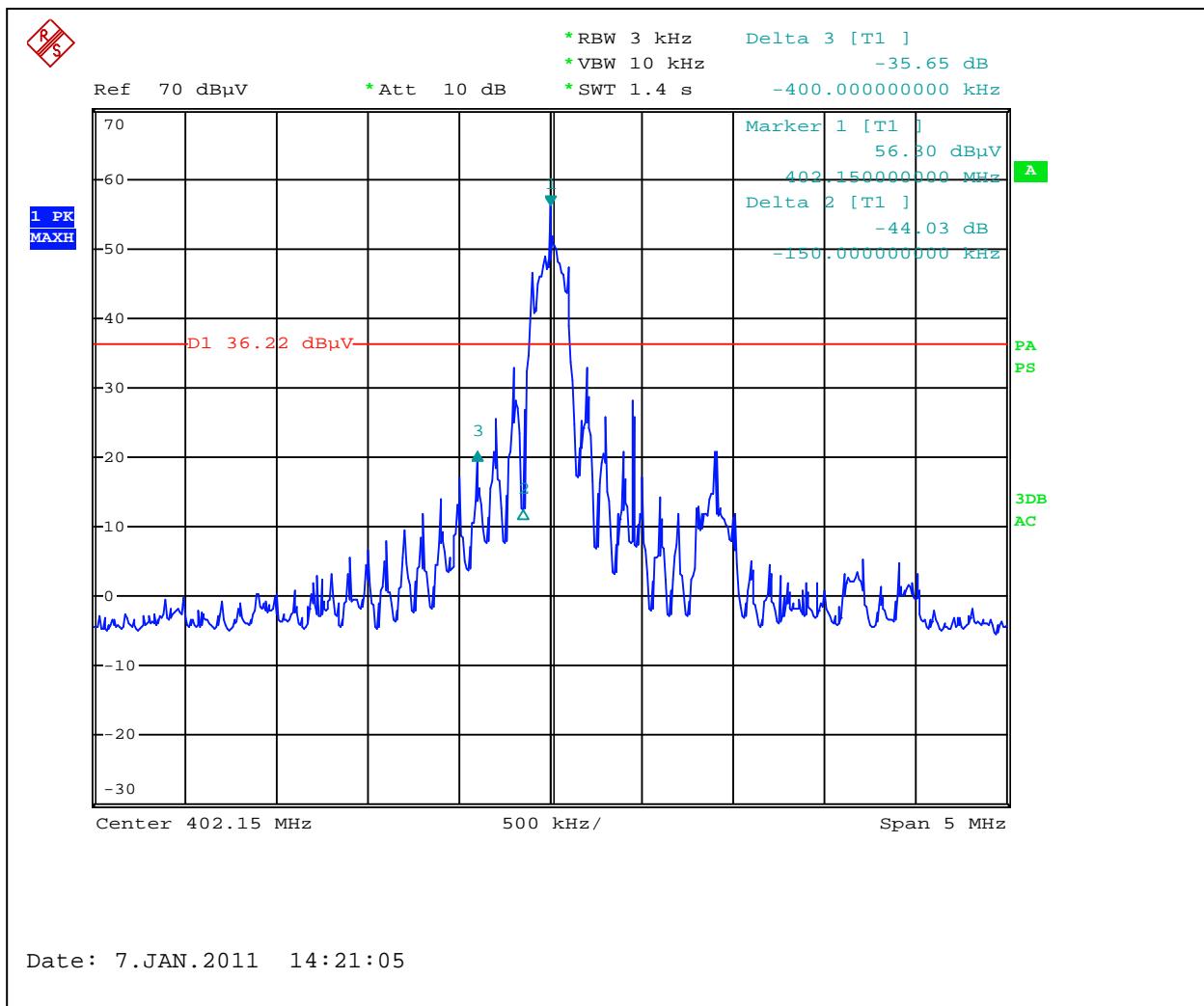
Graph 3.3.1

Graph 3.3.2

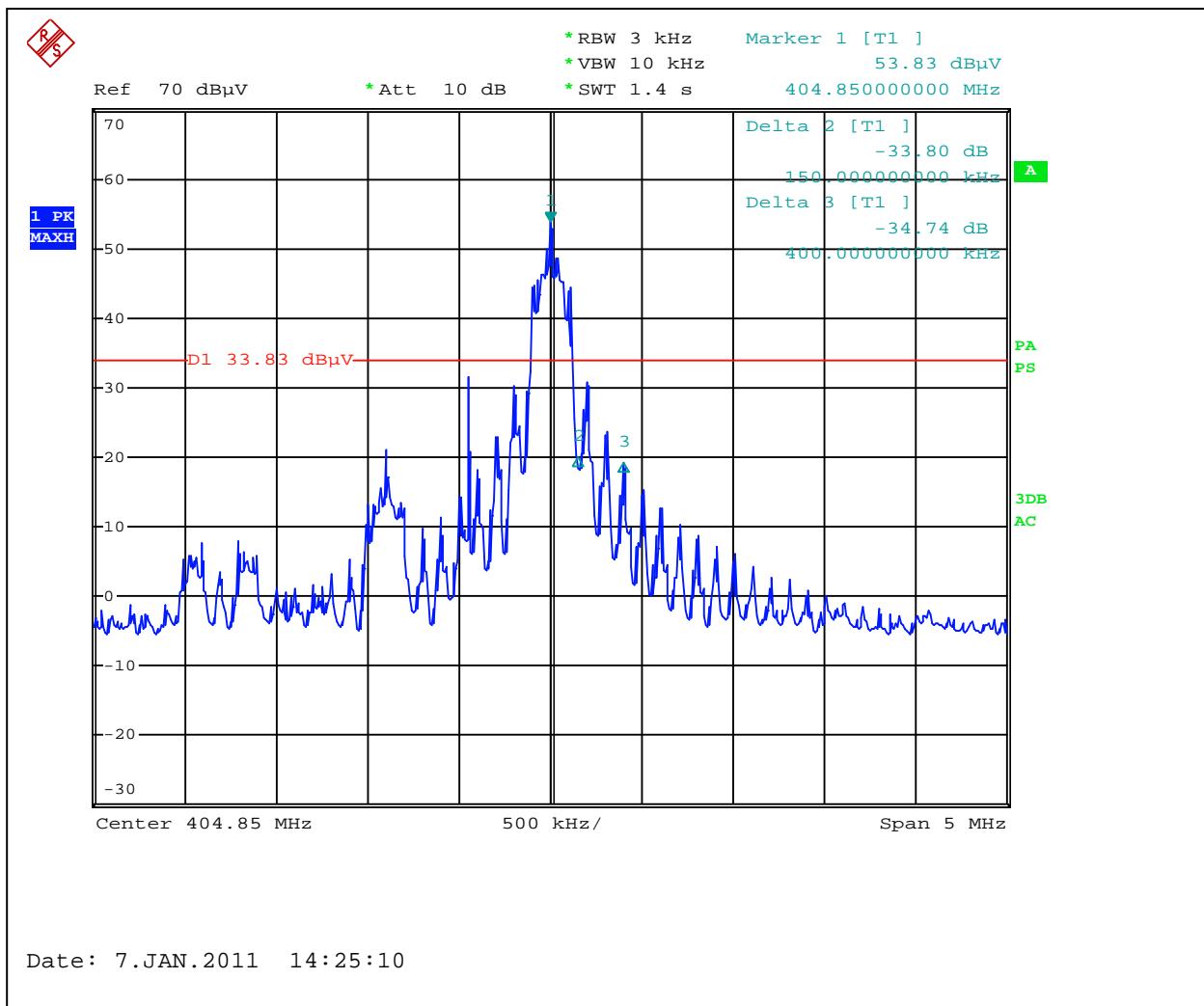
Graph 3.3.3
Emissions outside 150kHz offset from the intended frequency



Graph 3.3.4
Lower 250kHz band edge



Graph 3.3.5
Upper 250kHz band edge



3.4 Frequency Error**Table 3.4.1**

Temperature Degree C	Output Frequency MHz	Frequency Deviation kHz	Frequency Stability ppm	Frequency error limit ppm	Test Result
0	403.3498	2.3	5.7	±100	Pass
15	403.3479	0.4	1.0	±100	Pass
25	403.3475	0.0	0.0	±100	Pass
35	403.3473	0.2	0.5	±100	Pass
55	403.3502	2.7	6.7	±100	Pass

Table 3.4.2

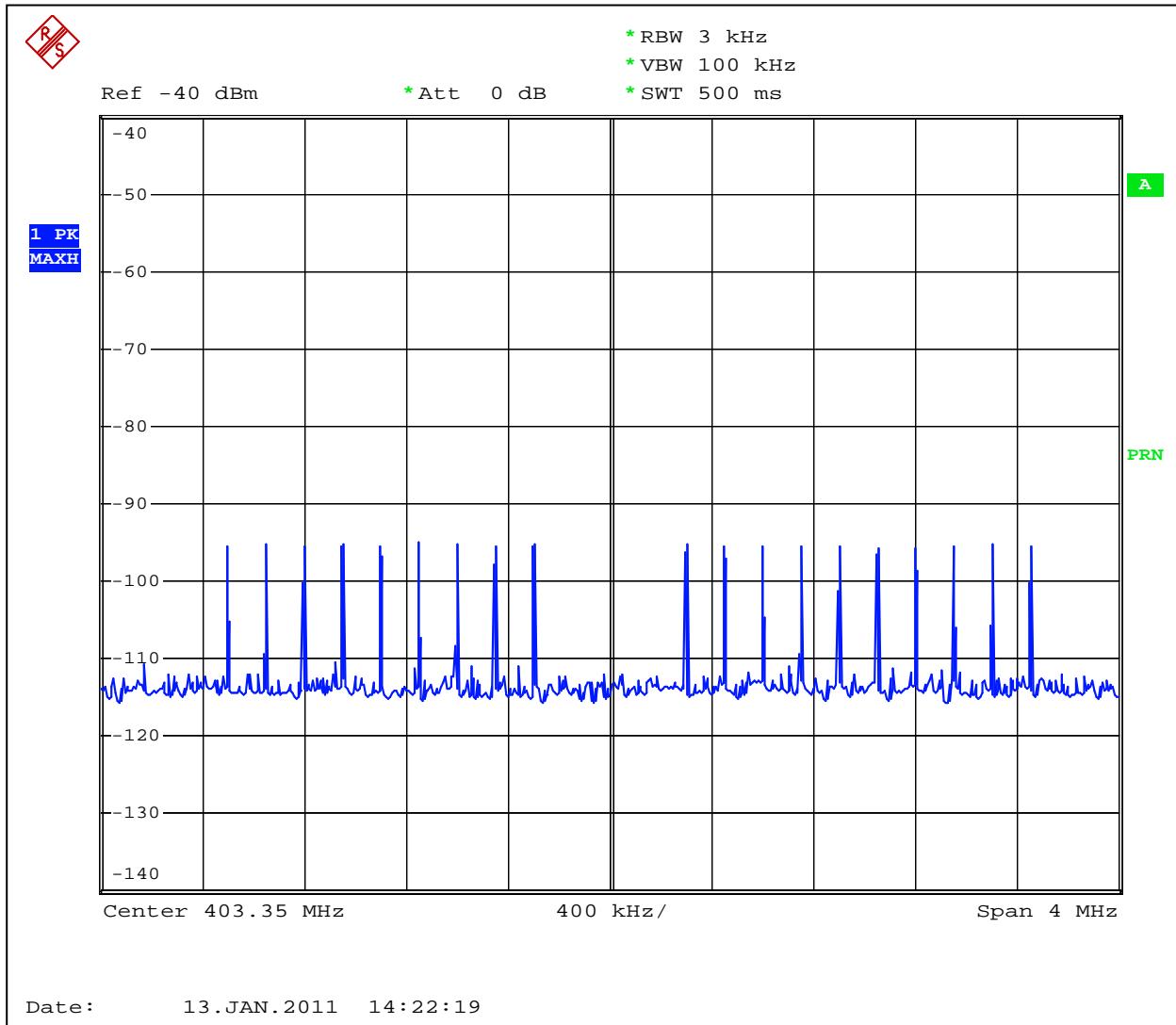
Input Voltage V	Input Voltage Description	Output Frequency MHz	Frequency Band MHz	Test Result
5.00	Rated Voltage	403.3494	402-405	Pass
5.50	+10% Rated Voltage	403.3494	402-405	Pass
4.50	-10% Rated Voltage	403.3495	402-405	Pass

3.5 MedRadio Operation

The MedRadio communication sessions must meet operating requirements for Threshold Power Levels, Monitoring System Bandwidth, Scan Cycle Time, Minimum Channel Monitoring Period, Channel Access, Discontinuation of a MedRadio Session, and Use of Pre-Scanned Alternate Channel.

For these tests, a blocking band was created using the vector signal generator. A notch was created in the blocking band by removing some of the tones, or by lowering the output power of some of the tones in relation to the other. A second signal generator was used to generate a tone on specific channel. Below is an example plot of the blocking band at the EUT, including a single notch in the center.

Graph 3.5.1



System Threshold Power Levels

The monitoring threshold power level shall not be greater than the calculated level given by the equation, $10\log B(\text{Hz}) - 150(\text{dBm}/\text{Hz}) - G(\text{dBi})$, where B is the emissions bandwidth of the MedRadio communication session transmitter having the widest emissions bandwidth and G is the antenna gain of the medical implant programmer transmitter monitoring system.

Calculated Threshold Power: $10 \log(246\text{kHz}) - 150 + (-2) = -98.1\text{dBm}$

The blocking band was set to -95.1dBm (3dB above the calculated threshold level), with a notch left open at 403.35MHz . A tone was introduced at the center of the notch at -104.1dBm , and was stepped up to the threshold level, -98.1dBm . At each step, MedRadio communications session was initiated and the selected channel was observed.

Measured Threshold Power: -100.72dBm

Monitoring System Bandwidth

The monitoring system bandwidth measured at its 20dB down points shall be equal to, or greater than the emissions bandwidth of the intended transmission.

The blocking band was set to -95.1dBm (3dB above the calculated threshold level), with a notch left open at 403.35MHz . A tone was introduced at the frequencies corresponding to the 20dB down points of the fundamental emission, and was increased until the EUT no longer transmitted on the central frequency. At each step, a MedRadio communication session was initiated and the selected channel was observed. The difference between the values at which the EUT detects the center channel emission and the channel edge emissions should be less than 20dB in order for the order for the monitoring system bandwidth to be wider than the emission bandwidth.

Flow = 403.227MHz

Fhigh = 403.473MHz

-95.9dBm Tx off channel

-96.9dBm Tx on channel

$P_a = -96.9\text{dBm}$

$P_b = -78.4\text{dBm}$

$P_c = -87.2\text{dBm}$

$D_1 = P_a - P_b = -96.9 - (-78.4) = -18.5\text{dB}$

$D_2 = P_a - P_c = -96.9 - (-87.2) = -9.7\text{dB}$

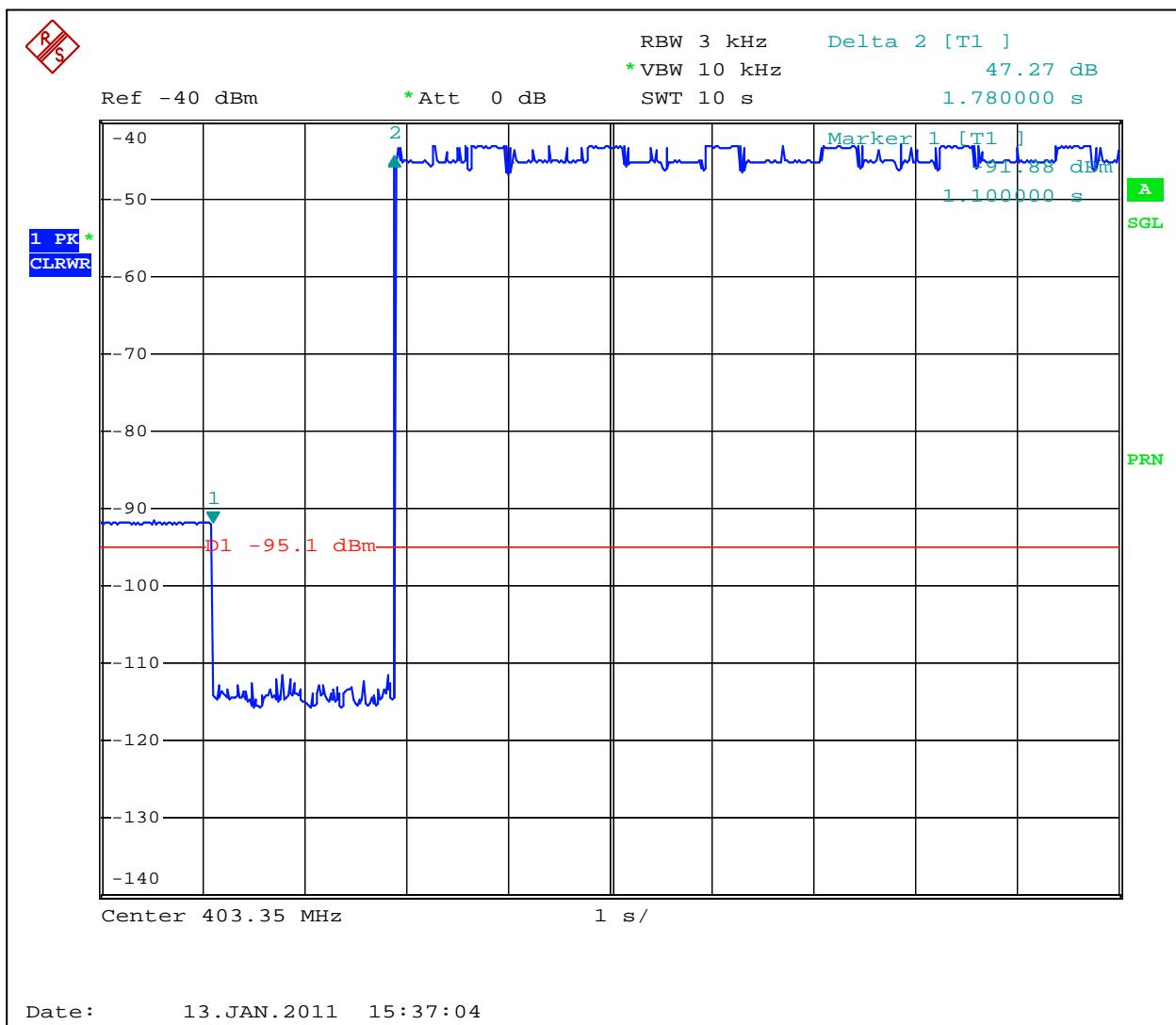
D1 and D2 are both less than 20dB

Scan Cycle Time

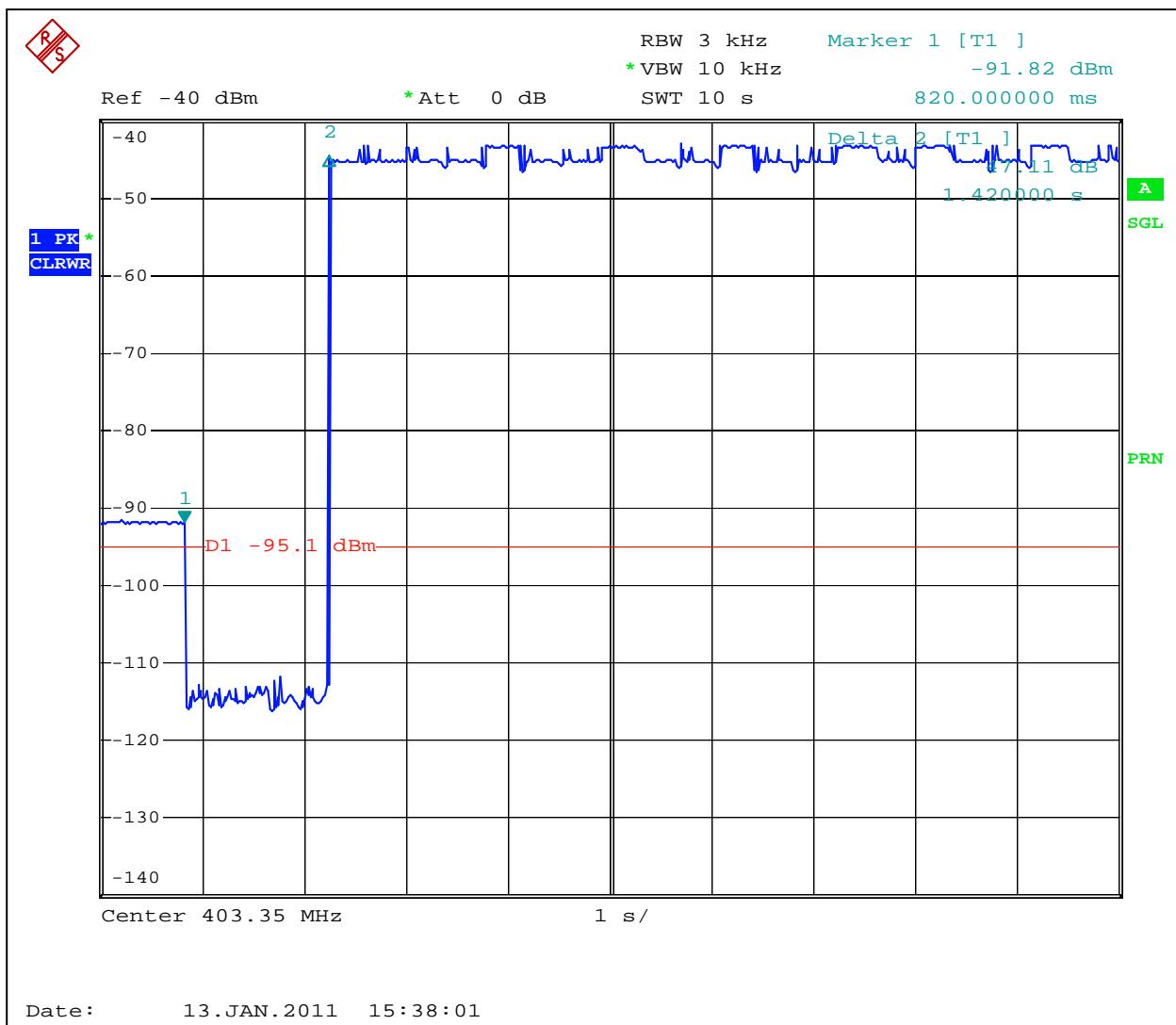
Within 5 seconds prior to initiating a communications session, circuitry associated with a medical implant programmer transmitter shall monitor all the channels in the 402-405MHz frequency band.

The blocking band was set to -95.1dBm (3dB above the calculated threshold level), with a notch left open at 403.35MHz. A tone was introduced at the center of the notch at -92.1dBm. The tone was removed and a MedRadio communications session was initiated. The time elapsed between removal of the CW tone and the start of the MedRadio session was recorded. The highest value was: **1.78 sec**

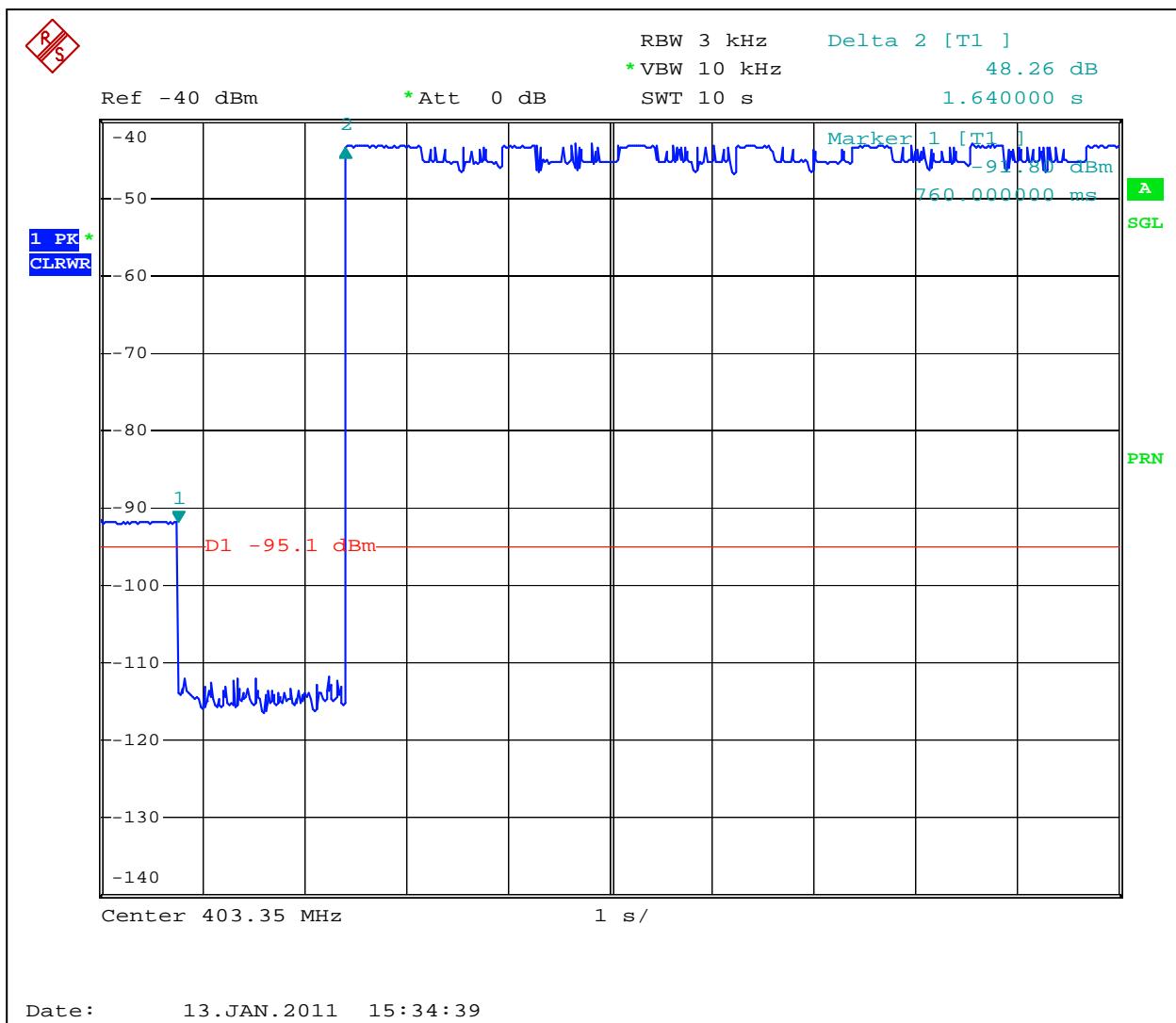
Graph 3.5.2 Scan Cycle Time 1 (1.78 sec)



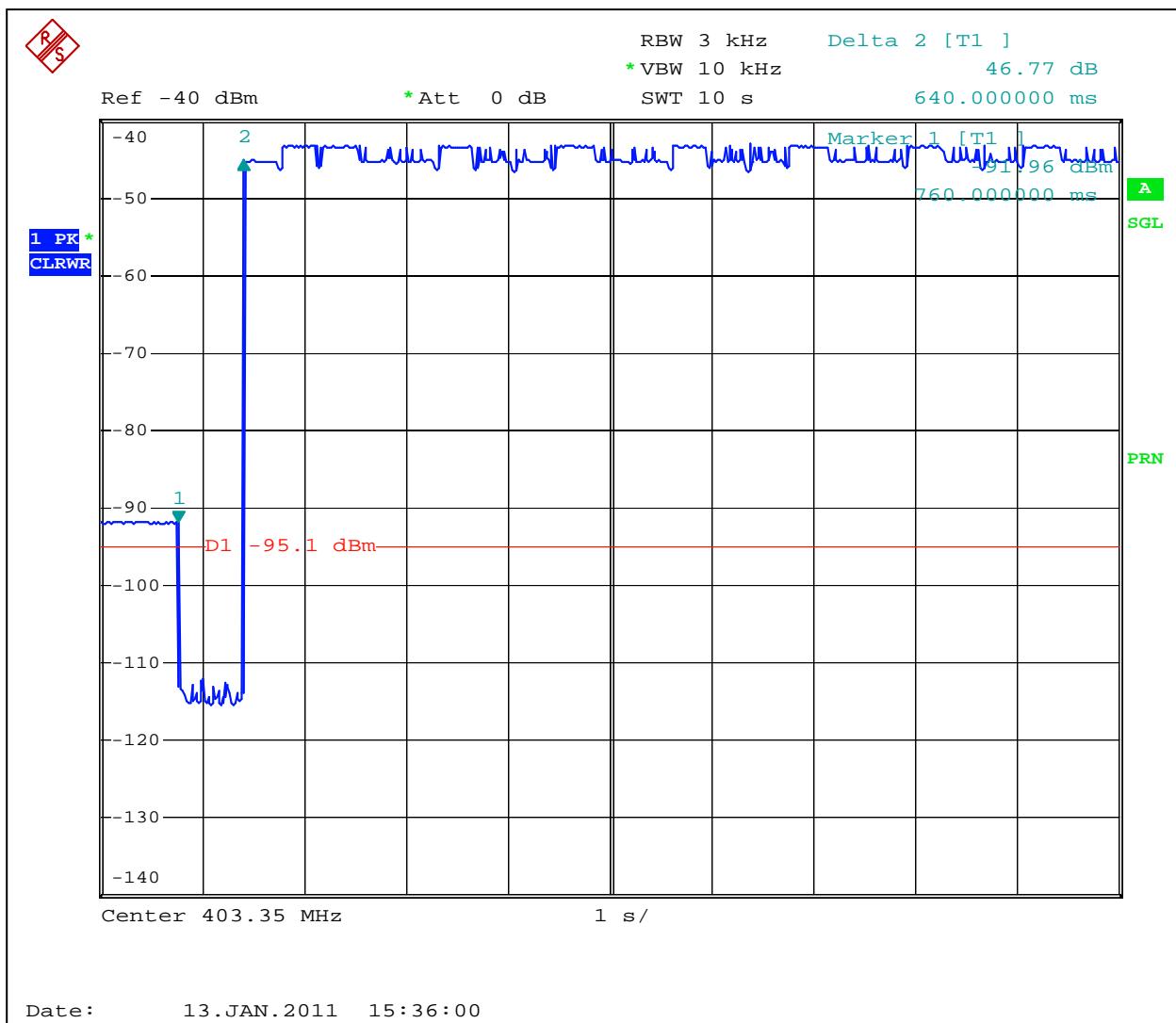
Graph 3.5.3 Scan Cycle Time 2 (820ms)



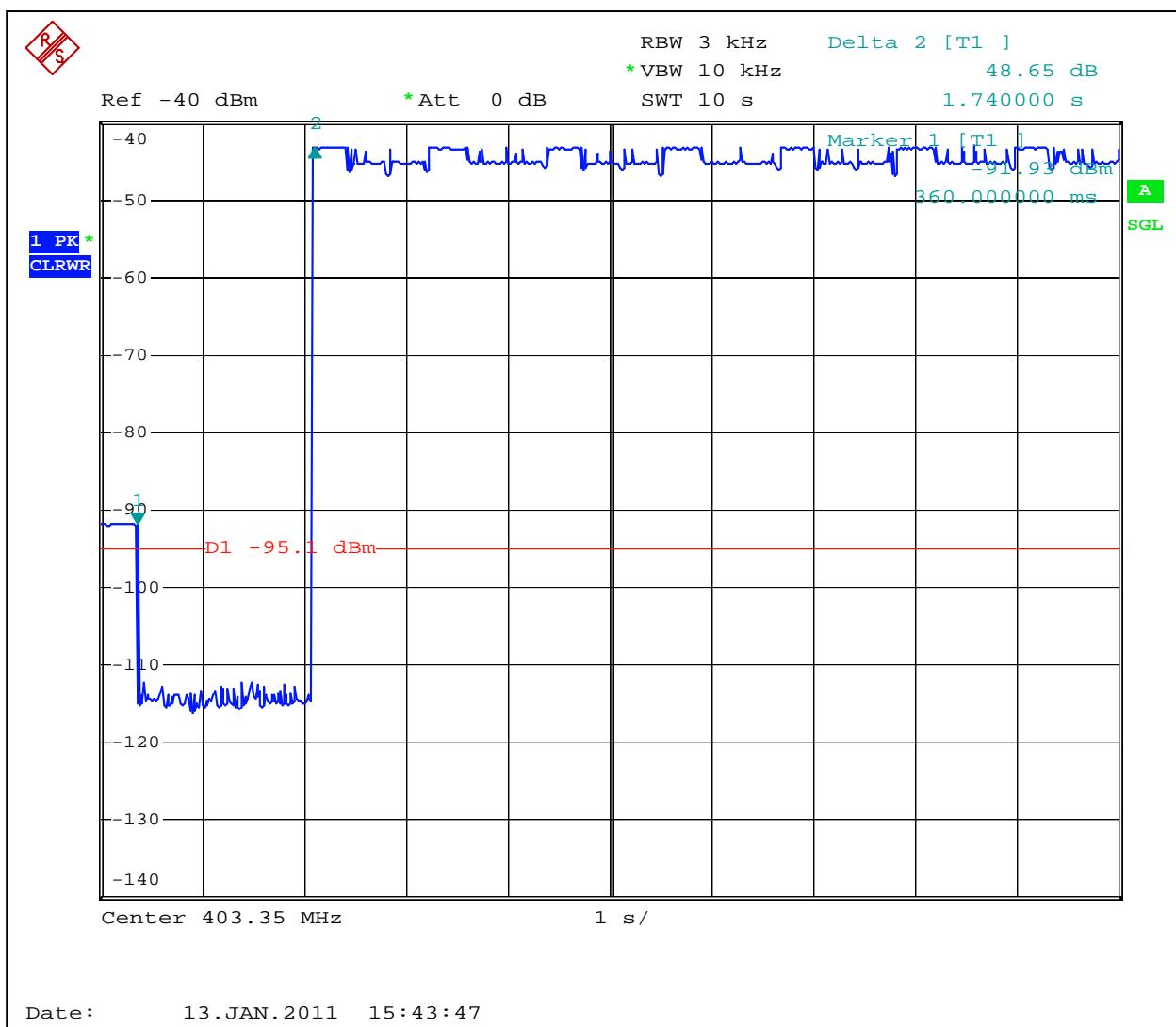
Graph 3.5.4 Scan Cycle Time 3 (1.64 sec)



Graph 3.5.5 Scan Cycle Time 4 (640ms)



Graph 3.5.6 Scan Cycle Time 5 (1.74sec)



Minimum Channel Monitoring Period

Each MedRadio channel shall be monitored for a minimum of 10 milliseconds during each scan cycle of 5 seconds or less.

The blocking band was set to -79.45dBm, with a notch left open at 403.35MHz. A tone was introduced at the center of the notch at -82.5dBm. A MedRadio communication session was initiated and it was verified that the EUT did not select a channel in the blocking band over several attempts.

The out of operating region disturbance signal was modulated with 0.1 ms pulse whose repetition frequency was adjusted to 100Hz corresponding to a silent period between pulses of 9.9 ms. This condition was monitored for several times, at least 10 attempts, and it was verified that the EUT did not select a channel in the blocking band over several attempts.

Channel Access

Immediate access is permitted on any channel having an ambient power level that is below the maximum threshold. If no channel having an ambient power below the maximum threshold is available, the equipment under test shall access and transmit on the least interfered channel.

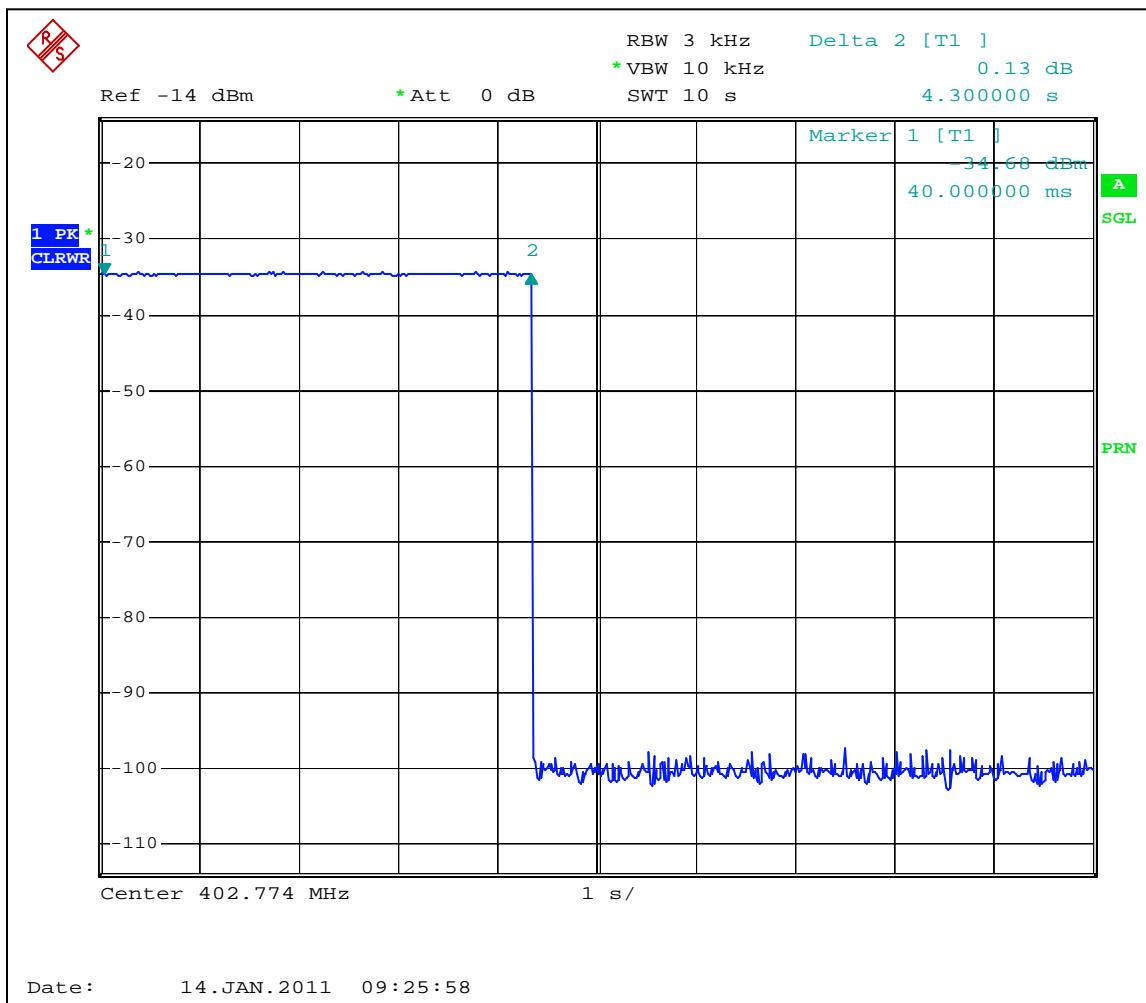
The blocking band was set to -88.1dBm (10dB above the calculated threshold level), with a notch left open at 403.35MHz. A second notch was created at channel 1(402.45MHz) by lowering the blocking tones at channel 1 by 7dB. A tone was introduced at the center of the channel at -101.1dB (3dB below the calculated threshold). A MedRadio communication session was then initiated and it was verified that the EUT transmitted only on the center frequency through several attempts. The CW tone at center frequency was then increased to -92.1dBm, and it was verified that the EUT transmitter only channel 1 over 10+ attempts.

Discontinuation of a MedRadio session

MedRadio shall cease transmission in the event the communication session is interrupted for a period of 5 seconds or more.

A MedRadio communication session was initiated, and the MedRadio implant was caused to cease transmission during the session. The time from when the implant ceased transmission until the programmer ceased communication was 4.3 seconds, as shown in the plot below. Communication was set on channel 2 (402.75MHz). Interference was introduced to block the implant transmission.

Graph 3.5.7



4.0 TEST EQUIPMENT

DESCRIPTION	MANUFACTURER	MODEL	SERIAL NO.	INTERTEK ID	CAL DUE	USED
Spectrum Analyzer	R & S	FSP 40	100024	12559	12/07/2011	<input checked="" type="checkbox"/>
Spectrum Analyzer	R & S	ESCI	100358	12909	07/12/2011	<input checked="" type="checkbox"/>
Bicono-Log Antenna	Schaffner-Chase	CBL 6112 B	2468	14459	10/18/2011	<input checked="" type="checkbox"/>
Horn Antenna	EMCO	3115	9507-4513	9936	04/13/2011	<input checked="" type="checkbox"/>
Signal Generator	HP	E4433B ESG-D series	US38080143	Rented	01/10/2012	<input checked="" type="checkbox"/>
Signal Generator	R & S	SMR20	101469	25233	08/30/2011	<input checked="" type="checkbox"/>
Power Splitter	Mini-Circuits	ZSC-2-4	F221200749		VBU	<input checked="" type="checkbox"/>
Pre-Amplifier	MITEQ	AMF-5D-00501800-28-13P	1122951	13475	10/06/2011	<input checked="" type="checkbox"/>
System	TILE! Instrument Control		Ver. 3.4.K.29	15259	VBU	<input checked="" type="checkbox"/>