Report – MICS Testing and Analysis Performed at Cameron Health Facilities

Appendix to 17 Programmer Test Report

1.0 Executive Summary

This report documents testing and analysis performed at Cameron Health facilities relating to characteristics of the telemetry devices and methods used in the S-ICD system.

2.0 Overview

This document provides supporting material for the Programmer Test Report that is submitted for FCC Review. In particular, testing is detailed herein that addresses the requirements stated in §§95.628(a)(1-4) to fill in gaps remaining after testing by the TCB. These sections are as follows:

(a)(1): The monitoring system BW is equal to or greater than the emission BW of intended transmission.
(a)(2): Within 5 seconds prior to initiating a communications session, circuitry must monitor the intended channel for at least 10 milliseconds.
(a)(3): Threshold power level of better than 10log(B)(Hz) – 150 (dBm/Hz) + G (dBi)
(a)(4), sentences 1 & 3: MICS communications may be started if channel has signal below power threshold of (a)(3) or, if no channel having that low signal is available, may use channel with lowest ambient power level.
(a)(4), sentence 2: Communication session may continue as long as any silent period does not last more than 5 seconds.

Our analysis is informed through our communications with the FCC. Copies of the email communications have been cut and pasted into the end of this document. These include a discussion regarding the use of a system with single channel operability. We address the email communication separately in association with discussion of (a)(4), sentences 1 & 3, below.

3.0 Test Equipment and Devices under Test

The following Materials and Devices under Test are not applicable for §3.6.1, which relies on activities performed offsite, as documented in the Appendix, and §3.6.2, which includes a separate listing of materials and devices under test.

Materials			
Description	**Manufacturer**	**Model/Make**	**Serial #**
PSA Series Spectrum	Agilent	E4443A	1063825

Analyzer			
Spectrum Analyzer	Agilent	E4446A	NW EMC
Signal Generator	Hewlett Packard	8648B	WDC865113

Description	**Serial #**
Q-Tech Programmer Model 2020	2020-A 100102
SQ-RX Pulse Generator	130

4.0 Definitions

PG

Pulse Generator. All references to PG herein refer to the Cameron Health SQ-RX Pulse Generator.

PRC

Programmer Radio Card. A custom-built communications card that is used with the Programmer to effect telemetry with the PG. All PRC-related data and analysis included herein is based on PRC(s) configured in a manner that conforms in relevant respects to the intended actual use.

Q-Tech

A dedicated, portable computer adapted for radio communication with the PG. The Programmer is designed to operate with the PRC installed and uses the Wand Antenna during communications with a PG.

RSSI

Received Signal Strength Indicator. The RSSI tracks the amount of power received at a selected frequency. The PRC includes an RSSI output that can be read by the Q-Tech or by a testing device such as a laptop computer.

S-ICD® System

Refers to a system developed by Cameron Health including the SQ-RX Pulse Generator and the Q-Tech Programmer. S-ICD is a registered trademark of Cameron Health.

Wand Antenna

An apparatus that is attached to and used with the Q-Tech as an antenna.

5.0 Test Activities

The Q-Tech and PG use a portion of the MICS band around a center frequency at 403.5108 MHz. Each device is configured to receive signals within a given bandwidth and transmit signals within a given bandwidth. The receiving bandwidth of the Q-Tech is measured and compared to the emission bandwidth of the PG in §5.1. This comparison shows the system meets the requirements of 95.628(a)(1).

The Q-Tech listens on the system's selected channel prior to initiating communication with a PG. This listening is performed over several intervals, each representing a minimum time period. Analysis of the Listen procedure is performed in §5.2. This analysis shows the system meets the requirements of 95.628(a)(2).

§95.628(a)(3) calls for a monitoring system threshold power level. Calculation of the required monitoring system threshold power level is performed using a formula combining the widest emission bandwidth in the S-ICD system and the gain of the Wand Antenna. Calculation of the monitoring system threshold power level is performed in §5.3.

§95.628(a)(3) does not specify how the monitoring system threshold power level is to be used. §95.628(a)(4), sentence 1 permits use of channels having lower ambient power level than the calculated threshold. Further, 95.628(a)(4) sentence 3 indicates that, if ambient power levels are above the threshold on all channels, communication may start on the channel having lowest noise. Email communications with the FCC indicate that single channel systems are allowed, and operation using a single channel can be consistent with 95.628(a) even when ambient power level is above the calculated threshold. §5.4 explains operations and analysis related to this point. The Email with the FCC indicated that Cameron Health should specifically consider §95.1211 in association with this concept and therefore §5.5 explains how Cameron Health has shown compliance with §95.1211 through internal testing.

During a communication session, the PG and Q-Tech are responsive to one another. 95.628(a)(4), second sentence limits the allowed length of silent periods during a communication session, and testing for such silent periods is documented in §5.6.

5.1 Monitoring System Bandwidth

Standard: **47 CFR 95.628 (a) (1)** *The monitoring system bandwidth measured at its 20 dB down points must be equal to or greater than the emission bandwidth of the intended transmission.*

Northwest EMC (NWEMC) is a testing certification body (TCB) that performs measurements for purposes of showing regulatory compliance. NWEMC measured the emission bandwidth for the PG, as documented in NWEMC – SQRX. A 107 kHz emission bandwidth was reported for the PG.

The Q-Tech monitoring system bandwidth was measured at Cameron Health Facilities. The following procedure measures the monitoring system bandwidth:

> Connect the HP 8648B Signal Generator RF output to the Programmer antenna connector using a coax cable. Program the Signal Generator to -70dBm continuous waveform at 403.5808MHz. Scan for devices using the Programmer. Decrease the frequency of the Signal Generator in 10 kHz increments until arriving at 403.4508 MHz (+70 kHz to -60 kHz, relative to 403.5108 kHz center frequency). Scan for devices at each 10 kHz frequency interval and capture a peak RSSI value for each interval. Convert the peak RSSI value from each scan to dBm. Plot the dBm verses frequency to find the 20 dBm down points.

By maintaining a constant RF input power level and sweeping the input power frequency, the frequency response of the receiver is determined by observing changes in the RSSI value. A graph is shown as Figure 1. The measured monitoring system bandwidth is wider than 110 kHz. Therefore the system satisfies the requirement of 47 CFR §95.628(a)(1).

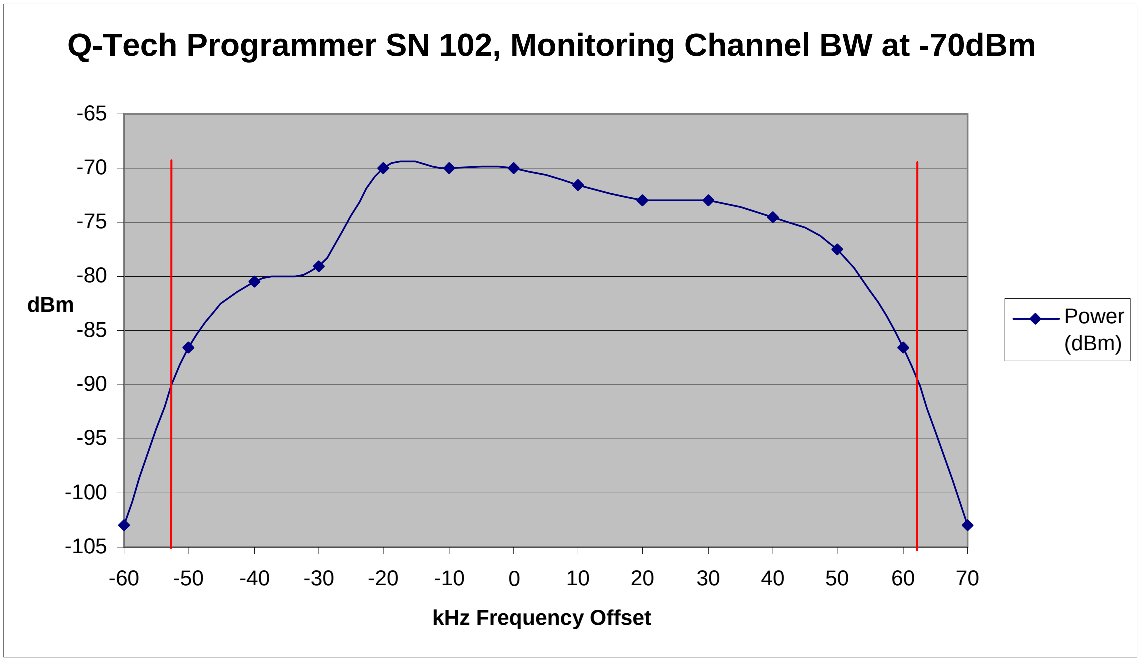

Figure 1: Monitoring System Bandwidth of the Q-Tech

5.2 Monitoring System Scan Cycle Time and Monitor Period

Standard: **47 CFR 95.628 (a) (2):** *Within 5 seconds prior to initiating a communications session, circuitry associated with a medical implant programmer/control transmitter must monitor the channel or channels the MICS system devices intend to occupy for a minimum of 10 milliseconds per channel.*

A code review was held by responsible Cameron Health Personnel. During the code review, the group determined that the Q-Tech performs a listening cycle prior to beginning a communications session as follows:

> The Q-Tech Programmer places radio board into receive mode then reads the RSSI for a period of 10ms four times with 16ms wait states between readings. The Q-Tech Programmer compares the peak RSSI value to the monitoring threshold. The Q-Tech Programmer records the monitoring activity, including the RSSI values and the monitoring threshold in the programmer log file. After the MICS channel monitoring completes, the scan and connection process continues immediately (within the processing time of the system < 1 second).

The reference to monitoring threshold refers to a calibrated value for RSSI that is set during manufacturing. The channel monitoring therefore includes well over 10 milliseconds of monitoring during the time period just prior to initiating a session. This meets the applicable standard.

5.3 Monitoring System Threshold Power Level

Standard: **47 CFR §95.628 (a) (3):** *Based on use of an isotropic monitoring system antenna, the monitoring threshold power level must not be more than:*

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

where B is the emission bandwidth of the MICS communication session transmitter having the widest emission and G is the medical implant programmer/control transmitter monitoring system antenna gain relative to an isotropic antenna. For purposes of showing compliance with the above provision, the above calculated threshold power level must be increased or decreased by an amount equal to the monitoring system antenna gain above or below the gain of an isotropic antenna, respectively.

The standard requires two inputs: the emission bandwidth of the widest emitter, and the antenna gain. The formula is then applied, and a monitoring system threshold power level is calculated. The formula result is in dBm. The system must be tested to show the monitoring system threshold power level meets the above calculated limit.

NWEMC measured the emission bandwidth for the Q-Tech and the PG as indicated in NWEMC – SQRX and NWEMC - QTECH. The reported emission bandwidths were 107 kHz for the PG and 100.8 kHz for the Q-Tech. Therefore the widest emission bandwidth in the system is 107 kHz.

The gain of the Wand Antenna, relative to an isotropic antenna, was calculated with the assistance of NWEMC and using NWEMC measurements. These are shown in the Antenna Information document attached to the present FCC submission. The analysis yields an antenna gain of -5 dBi.

Using B = 107 kHz and G = -5 dBi, the calculated monitoring system threshold power level is -104.7dBm.

5.4 Testing the Monitoring System Threshold Power Level

As indicated in §5.3, above, it is necessary to show the monitoring system has a threshold power level that reaches down to -104.7 dBm. Therefore the purpose of this test section is to show sensitivity allowing quantification of changes in signal input in the range of -104.7 dBm.

Because this test was performed separately from any of the other tests in this document, a separate section for test setup is provided here:

Materials			
Description	**Manufacturer**	**Model/Make**	**Serial #**
Laptop Computer	Dell	Inspiron 8600	n/a
Signal Generator	Hewlett Packard	8648B	3623A02036 Calibration Due 8-2009.

Devices Under Test		
Description	**Serial #**	**Configuration**
PRC, 102006-003	005	Version 26 Loaded
PRC, 102006-002	126	Version 26 Loaded, Device opened to expose PRB.

The test was a bench test as shown here:

Figure 2: Test Setup for Testing the Monitoring System Threshold Power Level

The test setup uses a laptop computer rather than the Q-Tech. The laptop allows ongoing observation of the RSSI level when no telemetry session is active, such that the laptop provided a useful interface for performing the test.

The PRC would be coupled to the Q-Tech via a PCMCIA slot in the Q-Tech. Connection to the PCMCIA slot of the laptop computer is equivalent to how the device would be connected in actual use, except that the user interface is different.

No shielding was used. Shielding or a fixture would be needed if a controlled condition, such as a low-noise environment, was necessary to show some feature of the system. In this instance, the capacity of the system to recognize an introduced noise signal was being tested, so no shielding was deemed necessary.

The test relies on the PRC showing an ability, through its RSSI monitor, to identify a signal having a power level at the system input of about -104.7 dBm. The laptop computer allows reading of an RSSI output from the PRC when no modulated signal is present. To observe the effectiveness of the RSSI output of the PRC, an unmodulated signal was applied at 403.5108 MHz to the PRC from the signal generator. The output of the signal generator was varied across a range from -114.7 dBm to -94.7 dBm in increments of 5 dBm. In this manner, the test allows an observer to monitor changes of the RSSI output that correlate to the input signal changes.

Two PRCs were tested. One (Part 102006-003, Serial No. 005) was a production device, and the other (Part 102006-002, Serial No. 126) was a testing device that had been opened to expose internal components such that additional internal connections could be made for testing purposes. Because the tested feature of these devices was unrelated to programming, the use of earlier revisions and/or non-production versions of the PRC was acceptable. Testing with multiple devices is not required by the applicable regulations, however, as multiple devices were tested, both sets of results are reported.

A coaxial cable was used to feed signal to the PRC, with the cable attached to the PRC using the port for the wand antenna, which was not attached. The results in the test table below do not account for cable loss and/or any connection losses. Any such losses are believed to be insignificant (< 1 dB). Adjusting for cable loss or connection losses would allow testing at a higher input signal power to offset such losses. As a result, adjustment for cable loss would make it easier to show increased sensitivity to lower amplitudes. Since adjustment for cable loss makes it easier to pass the test, omission of cable loss from the test results table is deemed permissible.

The output RSSI value was recorded from the reported values on the laptop computer. The output RSSI dithers during measurement within 1-2 counts, particularly at the lowest signal levels, and this variability is indicated by the ranges in the table:

Device Under Test	Input (dBm)	RSSI
PRC, 102006-003 #005	None – Ambient Noise	19-23
PRC, 102006-003 #005	-114.7	27-28
PRC, 102006-003 #005	-109.7	31-32
PRC, 102006-003 #005	**-104.7**	33-34
PRC, 102006-003 #005	-99.7	37-38
PRC, 102006-003 #005	-94.7	40-41
PRC, 102006-002 #126	None – Ambient Noise	20-23
PRC, 102006-002 #126	-114.7	24-27
PRC, 102006-002 #126	-109.7	28-30
PRC, 102006-002 #126	**-104.7**	32-34
PRC, 102006-002 #126	-99.7	36
PRC, 102006-002 #126	-94.7	39
Testing Performed on 25 September 2008	Mark Schroeder Jon Pike	

Table 1: Monitoring System Threshold Power Level Measurements

The RSSI varies in response to the input signal across a range of at least -114.7 dBm to upwards of -94.7 dBm. The monitoring system is able to identify and quantify noise across this range. As a result, the monitoring system threshold power level is at least lower than -104.7 dBm.

5.5 Channel Use Policy and Single Channel Operation

Standard: **47 CFR §95.628 (a) (4) (In relevant part):** *If no signal in a MICS channel above the monitoring threshold power level is detected, the medical implant programmer/control transmitter may initiate a MICS communications session involving transmissions to and from a medical implant device on that channel… If a channel meeting the criteria in paragraph (a)(3) of this section is unavailable, the channel with the lowest ambient power level may be accessed.*

The first sentence of §95.628(a)(4) is entirely permissive – if no signal above the calculated monitoring threshold power level is detected on a communication channel, the MICS session may begin on that channel. The third sentence is also permissive – if no channel having a signal level below the level calculated in §95.628(a)(3) is available, then communication may begin on the channel with the lowest ambient signal level.

The Q-Tech and S-ICD system are designed as a single channel system. The first and third sentences of §95.628(a)(4) do not prohibit single channel operation. Meeting both requirements in the context of the single channel system therefore follows this analysis:

- With respect to the first sentence, if the signal on the single channel is below the MICS Monitoring threshold calculated pursuant to §95.628(a)(3), then communication on the single channel is allowed.

- With respect to the third sentence, if the signal on the single channel is above the MICS Monitoring threshold, then no channel meets the criteria of ¶(a)(3). Communication can then begin on the channel having the lowest ambient power level which, in the case of the single channel system, is the single channel.

The QTech meets the language of §95.628(a)(4), first and third sentences because, if ambient signal on the single channel is below the MICS monitoring threshold, it communicates on the single channel and, if the ambient signal is above the MICS monitoring threshold, it communicates on the available channel having the least noise.

As can be seen, the above allows communication on the single channel both when ambient signal is below the monitoring threshold and when ambient signal is above the monitoring threshold. It was felt guidance from the FCC regarding the use of a single channel system should also be sought. Two questions were posed using the FCC's online resources, Generic Office of Engineering Technology, under Tracking Number 377298, and answered on Thursday, June 28, 2007:

Cameron Health Query 1:

> It is our belief that the regulations within section 95.628 do not exclude a system that would transmit on a single channel within the MICS band, so long as the system performs the Listen Before Talking (LBT) protocol specified in the section. We kindly request your confirmation that our understanding is correct. If you understand otherwise, we would greatly appreciate your referencing of the section that contradicts our belief.

FCC Response:

> Regarding item 1 of inquiry, in general part 95 rules do not preclude single-channel devices; note also 95.1211.

Cameron Health Query 2:

It is our belief under section 95.628, that if a channel meeting the criteria in paragraph (a)(3) of the section is unavailable, a system may still transmit so long as the channel with the lowest ambient power level is utilized, whether or not that system is a single channel or multi-channel system. We kindly request your confirmation that our understanding is correct. If you understand otherwise, we would greatly appreciate your referencing of the section that contradicts our belief.

FCC Response:

> Regarding item 2 of inquiry, description appears to be consistent with 95.628(a)(4).

The interaction with the FCC indicated that single channel operation is not prohibited, and our understanding that the channel with the lowest ambient power level can be utilized even in a single channel system. However, per the FCC Response, consideration should be given to the MICS Channel Use Policy:

Standard: **47 CFR §95.1211: Channel Use Policy:**

> *(a) The channels authorized for MICS operation by this part of the FCC Rules are available on a shared basis only and will not be assigned for the exclusive use of any entity.*

(b) Those using MICS transmitters must cooperate in the selection and use of channels in order to reduce interference and make the most effective use of the authorized facilities. Channels must be selected in an effort to avoid interference to other MICS transmissions. See § 95.628.

(c) Operation is subject to the condition that no harmful interference is caused to stations operating in the 400.150–406.000 MHz band in the Meteorological Aids, Meteorological Satellite, or Earth Exploration Satellite Services. MICS stations must accept any interference from stations operating in the 400.150–406.000 MHz band in the Meteorological Aids, Meteorological Satellite, or Earth Exploration Satellite Services.

We break our analysis into three sections as per the regulation:

5.5.1 95.1211, ¶(a)

(a) The channels authorized for MICS operation by this part of the FCC Rules are available on a shared basis only and will not be assigned for the exclusive use of any entity.

Paragraph (a) states that channels are to be used on a shared basis and will not be assigned for exclusive use by any entity. Cameron Health is not requesting any such assignment of the channel. The question therefore is whether certification would be tantamount to such assignment. This would be the case if, for example, the Q-Tech programmer prevents other users from using the band it uses.

Testing has shown cooperative use of the channel is readily feasible with the Q-Tech and S-ICD system. In particular, Cameron Health performed in-house testing of side-by-side Q-Tech systems which shows the S-ICD system and Q-Tech programmer will not interfere with others using the MICS communications band.

The side-by-side testing was performed in the environment shown here:

Figure 3: Test Setup for the Co-Channel Interferer Test: System Setup

The two systems are placed 15 feet apart in an open space, without any walls between them. Given that the purpose of testing was primarily functional (although a metric, the Bit Error Rate (BER) was monitored), the omission of the tissue equivalent medium was considered acceptable.

The telemetry wand position, relative to the PG is shown here:

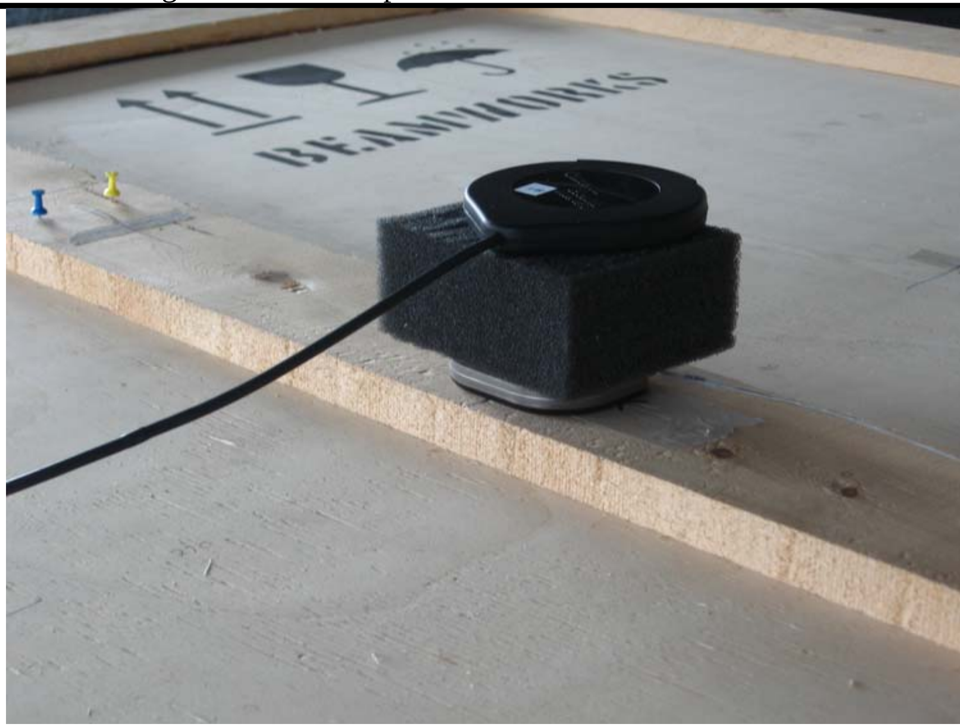

Figure 3: Test Setup for the Co-Channel Interferer Test: SQRX and Wand Spacing

The foam spacer places the telemetry wand antenna two inches above the SQRX pulse generator.

For purposes of data acquisition, non-clinical software was used on the programmers. This allowed monitoring of the BER for each system. Retries of the test were allowed to accommodate intermittent interference.

The side-by-side testing was performed with three systems in pairs (Systems 1 and 2, Systems 2 and 3, and Systems 3 and 1, operating side-by-side). All three pairs passed, with retries, with each system showing BER in the presence of another operating system of 0.001 or less.

It should be noted that the two systems were operating side-by-side using the same band that has been shown to occupy less than 150 kHz, in open space without any walls between them.

In view of this test, the QTECH does not prevent operation in the same band by a second system. As a result, certification is not tantamount to dedication of the channel to a single user. The QTECH and its use will not violate this section.

5.5.2 95.1211 ¶(b)

(b) Those using MICS transmitters must cooperate in the selection and use of channels in order to reduce interference and make the most effective use of the authorized facilities. Channels must be selected in an effort to avoid interference to other MICS transmissions. See § 95.628.

As indicated in the communications with the FCC, §95.628 does not require the use of multiple channels. As indicated above, the system design allows multiple users in close proximity using the band occupied by the QTECH programmer and S-ICD system. Therefore the QTECH meets this section as well.

5.5.3 95.1211 ¶(c)

(c) Operation is subject to the condition that no harmful interference is caused to stations operating in the 400.150–406.000 MHz band in the Meteorological Aids, Meteorological Satellite, or Earth Exploration Satellite Services. MICS stations must accept any interference from stations operating in the 400.150–406.000 MHz band in the Meteorological Aids, Meteorological Satellite, or Earth Exploration Satellite Services.

There is no reason to expect that interference of the nature noted in this section could result from use of the QTECH and/or S-ICD system. Compliance with other requirements laid out, particularly in §95.628, is believed sufficient to show this section is met.

5.6 Silent Period Duration

Standard: **47 CFR §95.628 (a) (4) (In relevant part):** *The MICS communications session may continue as long as any silent period between consecutive data transmission bursts does not exceed 5 seconds.*

This standard was tested in three iterations: first, with both a Q-Tech and a PG actively engaged in a communication session, it was determined whether there were any gaps of 5 seconds or more during the active session. Second, during an active session, using an open PG that allows power to be removed, the power to the PG was turned off, and the response of the Q-Tech was observed. Third, during another active session, the Q-Tech was turned off to observe the response of the PG. The RF activity was observed using a spectrum analyzer. Graphs of the captured data follow. It can be seen that there are no gaps of longer than 5 seconds during any of the sequences shown. Specifics for each test setup are provided after each graph.

During this test, the PG in use was an open canister device for which the power supply was externally provided, in order to enable termination as in Test 2.

Figure 3: Continuous transmission between the Programmer and the PG.

<u>Test 1 Setup – Results Shown in FIG. 3:</u>

Use the Q-Tech to initiate a session with the PG. Place the antenna of the Spectrum Analyzer within two feet of the Q-Tech wand antenna and place the PG two feet away from Spectrum Analyzer. Set the Spectrum Analyzer to zero span mode, with a 50-second sweep rate, a 150 kHz RBW and averaging. Capture a single 50- second sweep of the session.

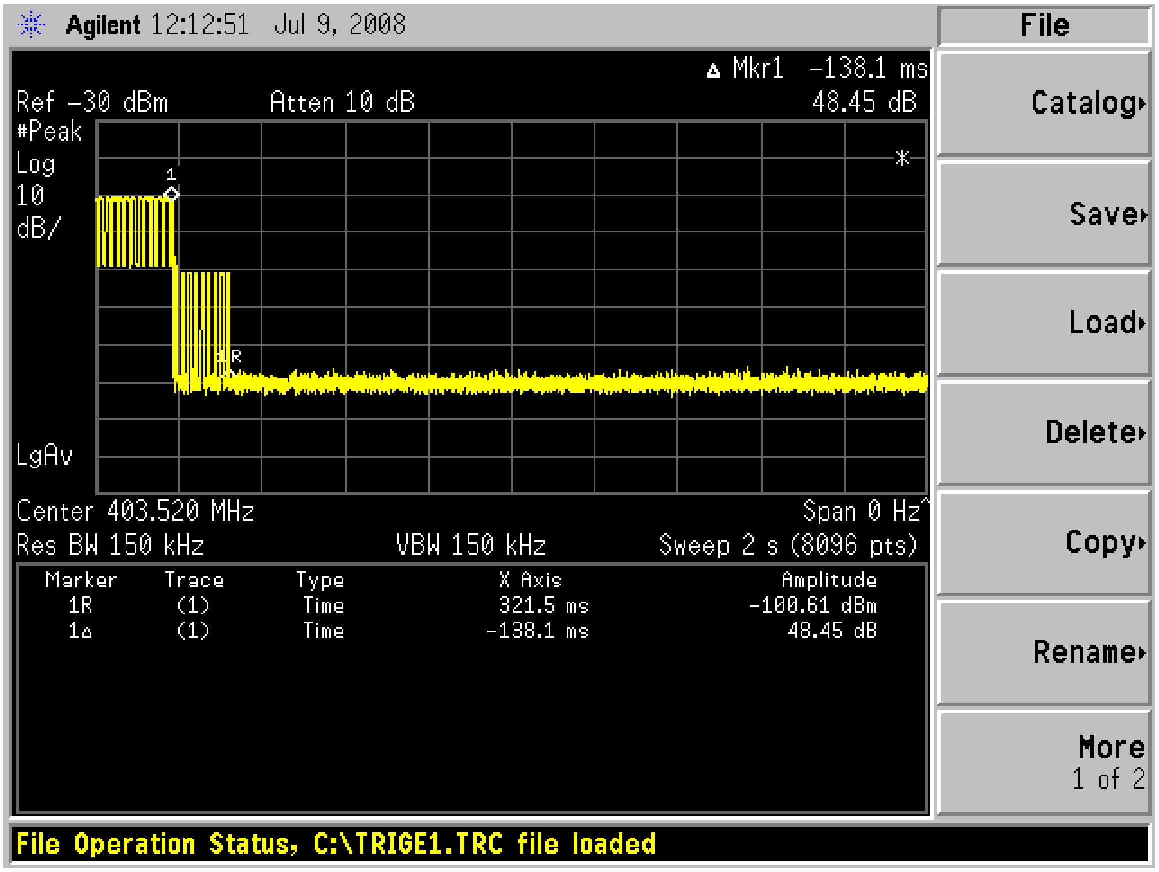

Figure 4: PG switches off during a session and ceases transmission. The left-most level shift shows the reduction in overall power of the session. Another shift follows, indicating the Q-Tech stops transmitting. Termination of transmission occurs 460ms from the time the PG ceases transmission; transmission ceases so quickly that a 5 second gap cannot occur.

Test 2 Setup – Results shown in FIG. 4:

Use the Q-Tech to initiate a session with the PG. Place the antenna of the Spectrum Analyzer within two feet of the Q-Tech wand antenna and place the PG five feet away from Spectrum Analyzer. Set the Spectrum Analyzer to zero span, with a two-second sweep rate, a 150 kHz RBW and averaging. Connect the Spectrum Analyzer external trigger through a 10:1 voltage divider to the PG power supply. Set the Spectrum Analyzer external trigger level to a power supply voltage corresponding to dropout of the PG. Switch off the PG power supply to enable the trigger of the Spectrum Analyzer and capture a single two- second sweep of the session.

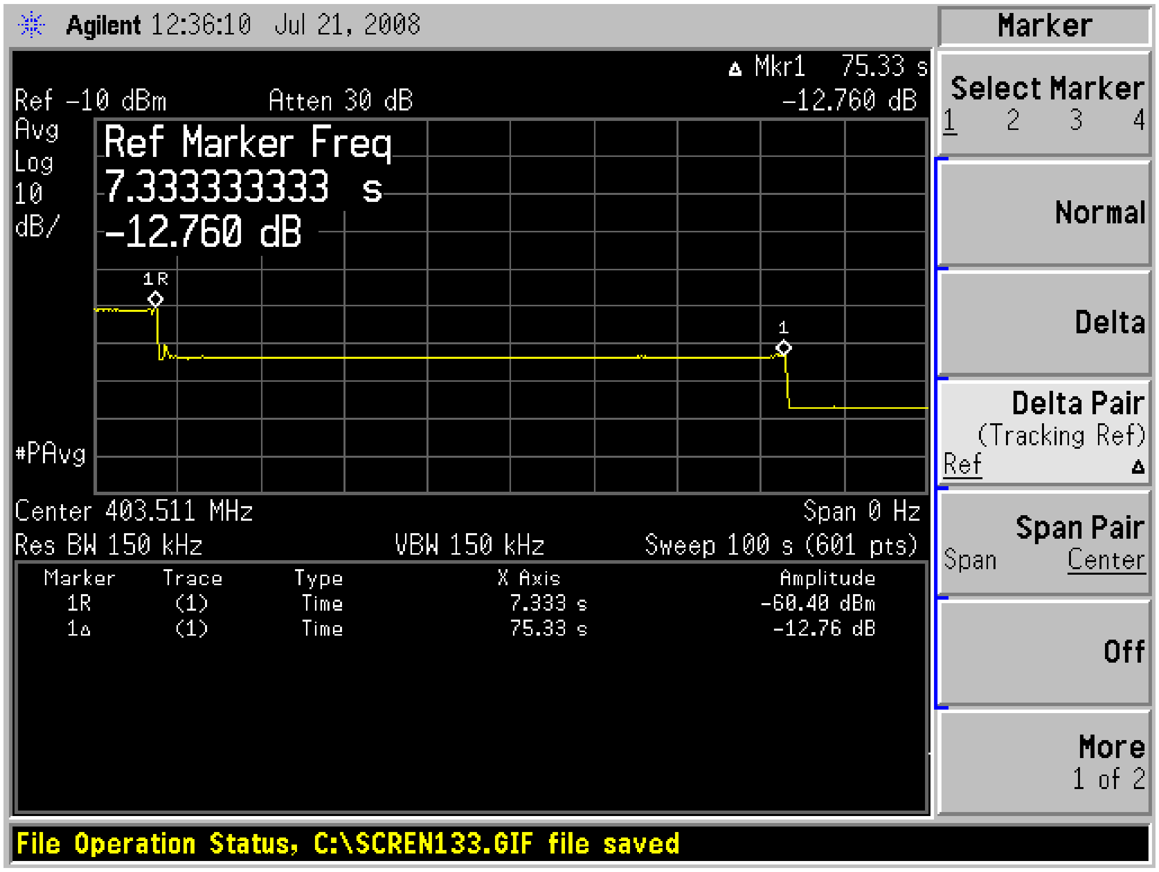

Figure 5: Q-Tech powers off during a session and ceases transmission. The left-most level shift shows the reduction in overall power of the session when the Q-Tech powers down. Another shift follows, indicating the PG stops transmitting. Termination of PG transmission occurs 68 seconds from the time the Q-Tech ceases transmission, and there are no gaps of greater than 5 seconds until transmission ends.

<u>Test 3 Setup – Results shown in FIG. 5:</u>

Use the Q-Tech to initiate a session with the PG. Place the antenna of the Spectrum Analyzer within one foot of the PG and place the Q-Tech five feet away from Spectrum Analyzer. Set the Spectrum Analyzer to zero span mode, with a 100-second sweep rate, a 150 kHz RBW and averaging. While in the session, remove the Q-Tech Wand Antenna to disrupt the session. Capture a single sweep with at least 75 seconds following the removal of the Q-Tech wand antenna.

6.0 FCC and Cameron Health Email

Sean McGeehan

From: Generic Office of Engineering Technology [oetech@fccsun27w.fcc.gov]
Sent: Thursday, June 28, 2007 12:01 PM
To: Sean McGeehan
Subject: Response to Inquiry to FCC (Tracking Number 377298)

Inquiry:

We are seeking guidance on several perceived ambiguities in the language of Section 95.628 entitled MICS transmitter.

1. It is our belief that the regulations within section 95.628 do not exclude a system that would transmit on a single channel within the MICS band, so long as the system performs the Listen Before Talking (LBT) protocol specified in the section. We kindly request your confirmation that our understanding is correct. If you understand otherwise, we would greatly appreciate your referencing of the section that contradicts our belief.

2. It is our belief under section 95.628, that if a channel meeting the criteria in paragraph (a)(3) of the section is unavailable, a system may still transmit so long as the channel with the lowest ambient power level is utilized, whether or not that system is a single channel or multi-channel system. We kindly request your confirmation that our understanding is correct. If you understand otherwise, we would greatly appreciate your referencing of the section that contradicts our belief.

Response:

Regarding item 1 of inqu! iry, in general part 95 rules do not preclude single-channel devices; note also 95.1211.

Regarding item 2 of inquiry, description appears to be consistent with 95.628(a)(4).

Please use "Reply to an Inquiry Response" if there are other related questions.
(https://gullfoss2.fcc.gov/oetcf/kdb/forms/ResponseReplyEntry.cfm)

Do not reply to this message. Please select the Reply to an Inquiry Response link from the OET Inquiry System to add any additional information pertaining to this inquiry.

7/12/2007