L.S. Compliance, Inc.
W66 N220 Commerce Court
Cedarburg, WI 53012
262-375-4400 Fax: 262-375-4248

COMPLIANCE TESTING OF:

EXD controller
(used in the AngelMed Guardian system)

PREPARED FOR:

Angel Medical Systems, Inc.
1 Sheila Drive
Tinton Falls, NJ 07724

TEST REPORT NUMBER:

305321-exd

TEST DATE(S):

August, September, October, 2005

Table of Contents

1. L. S. Compliance In Review

Brief Review of
L.S. Compliance
Accreditations and Listing's

As an EMC Testing Laboratory, our Accreditation and Assessments are recognized through the following:

A2LA – American Association for Laboratory Accreditation

Accreditation based on ISO/IEC 17025 : 1999
with Electrical (EMC) Scope of Accreditation
A2LA Certificate Number: **1255.01**

Federal Communications Commission (FCC) – USA

Listing of 3 Meter Semi-Anechoic Chamber based on Title 47 CFR – Part 2.948
FCC Registration Number: **90756**

Listing of 3 and 10 meter OATS based on Title 47CFR – Part 2.948
FCC Registration Number: **90757**

Industry Canada

On file, 3 Meter Semi-Anechoic Chamber based on RSS-212 – Issue 1
File Number: **IC 3088-A**

On file, 3 and 10 Meter OATS based on RSS-212 – Issue 1
File Number: **IC 3088**

U. S. Conformity Assessment Body (CAB) Validation

Validated by the European Commission as a **U. S. Competent Body** operating under the U. S. /EU, Mutual Recognition Agreement (MRA) operating under the European Union Electromagnetic Compatibility –Council Directive 89/336/EEC, Article 10.2.
Date of Validation: **January 16, 2001**

Validated by the European Commission as a **U.S. Notified Body** operating under the U.S./EU, Mutual Recognition Agreement (MRA) operating under the European Union Telecommunication Equipment – Council Directive 99/5/EC, Annex V.

Date of Validation: **November 20, 2002**
Notified Body Identification Number: **1243**

2. A2LA Certificate of Accreditation

THE AMERICAN
ASSOCIATION
FOR LABORATORY
ACCREDITATION

ACCREDITED LABORATORY

A2LA has accredited

L.S. COMPLIANCE, INC.
Cedarburg, WI

for technical competence in the field of

Electrical Testing

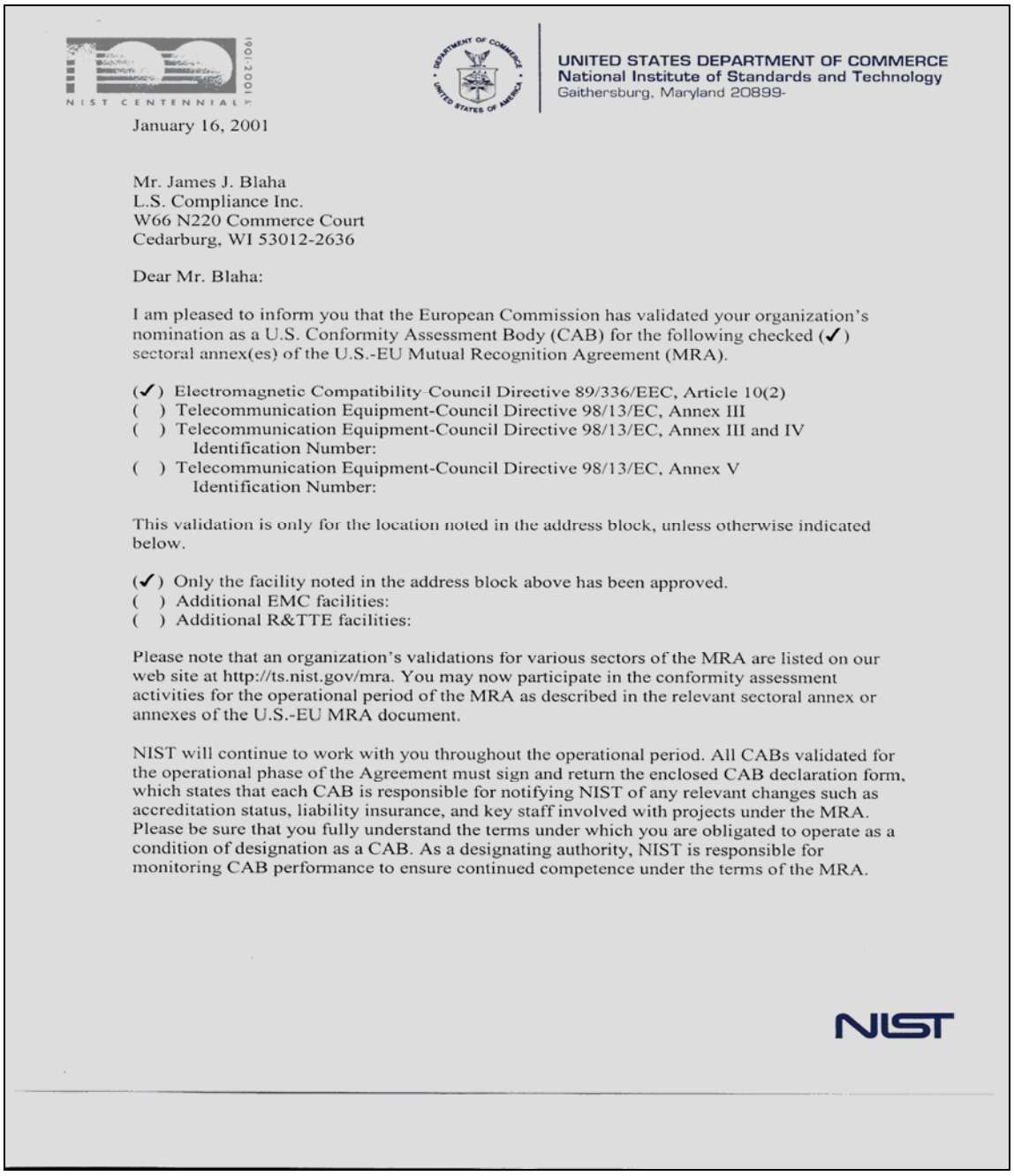
The accreditation covers the specific tests and types of tests listed on the agreed scope of accreditation. This laboratory meets the requirements of ISO/IEC 17025 - 1999 "General Requirements for the Competence of Testing and Calibration Laboratories" and any additional program requirements in the identified field of testing.

Presented this 29th day of April 2005.

President
For the Accreditation Council
Certificate Number 1255.01
Valid to January 31, 2007

For tests or types of tests to which this accreditation applies,
please refer to the laboratory's Electrical Scope of Accreditation.

3. Validation Letter – U.S. Competent Body for EMC Directive 89/336/EEC



UNITED STATES DEPARTMENT OF COMMERCE
National Institute of Standards and Technology
Gaithersburg, Maryland 20899-

January 16, 2001

Mr. James J. Blaha
L.S. Compliance Inc.
W66 N220 Commerce Court
Cedarburg, WI 53012-2636

Dear Mr. Blaha:

I am pleased to inform you that the European Commission has validated your organization's nomination as a U.S. Conformity Assessment Body (CAB) for the following checked (✓) sectoral annex(es) of the U.S.-EU Mutual Recognition Agreement (MRA).

(✓) Electromagnetic Compatibility-Council Directive 89/336/EEC, Article 10(2)
( ) Telecommunication Equipment-Council Directive 98/13/EC, Annex III
( ) Telecommunication Equipment-Council Directive 98/13/EC, Annex III and IV
Identification Number:
( ) Telecommunication Equipment-Council Directive 98/13/EC, Annex V
Identification Number:

This validation is only for the location noted in the address block, unless otherwise indicated below.

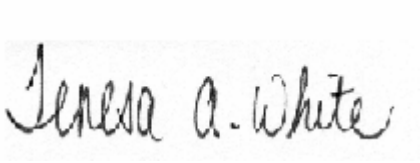
(✓) Only the facility noted in the address block above has been approved.
( ) Additional EMC facilities:
( ) Additional R&TTE facilities:

Please note that an organization's validations for various sectors of the MRA are listed on our web site at http://ts.nist.gov/mra. You may now participate in the conformity assessment activities for the operational period of the MRA as described in the relevant sectoral annex or annexes of the U.S.-EU MRA document.

NIST will continue to work with you throughout the operational period. All CABs validated for the operational phase of the Agreement must sign and return the enclosed CAB declaration form, which states that each CAB is responsible for notifying NIST of any relevant changes such as accreditation status, liability insurance, and key staff involved with projects under the MRA. Please be sure that you fully understand the terms under which you are obligated to operate as a condition of designation as a CAB. As a designating authority, NIST is responsible for monitoring CAB performance to ensure continued competence under the terms of the MRA.

NIST

4. Signature Page



Prepared By: November 1, 2005

Teresa A. White, Document Coordinator Date

Tested and Approved By November 1, 2005

Kenneth L. Boston, EMC Lab Manager Date
PE #31926 Licensed Professional Engineer
Registered in the State of Wisconsin, United States

5. Product and General Information

Manufacturer:	Angel Medical Systems, Inc.
Model No.:	EXD
Serial No.:	57, 58
Description:	405 MHz MICS band transceiver.

6. Product Description

The AngelMed Guardian External Device (EXD) is a hand held telemetry Device that warns the patient of alarms and alerts via beeps and a red or yellow flashing LED, and is used to silence alarms and alerts. The EXD is also used for communication between a laptop (serving as a programmer) and the IMD, using a low power, low frequency pulsed signal that communicates to the IMD in the near field.

The Guardian System monitors and detects changes in patients' electrograms, using baseline electrograms from the previous day for comparison.

7. Test Requirements

The above mentioned tests were performed in order to determine the compliance of the EUT system with limits contained in various provisions of Title 47 CFR, FCC Part 95, including:

95.628 95.631 95.633 95.635 95.639 plus 15.209

All radiated emissions tests were performed to measure the emissions in the frequency bands described by the above sections, and to determine whether said emissions are below the limits established by the above sections. These tests were performed in accordance with the procedure described in the American National Standard for methods of measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz (ANSI C63.4-2001). Another document used as reference for the EMI receiver specification was the International Special Committee on Radio Interference CISPR 16-1 (2003).

8. Summary of Test Report

DECLARATION OF CONFORMITY

The Angel Medical Systems EXD was found to **MEET** the requirements as described within the specification of Title 47 CFR FCC, Part 95 for a MICS band transceiver. The EXD was also found to **MEET** the 15.209 general limits for a 40 kHz transmitter.

9. Introduction

During August, September and October of 2005, a series of Radiated Emission tests were performed on two samples of the EXD medical device, here forth referred to as the "*Equipment Under Test*" or "*EUT*". The two models tested use the same RF transmitter topology (plus it is identical to the IMD topology) and are used to transmit digitized audio. These tests were performed using the procedures outlined in ANSI C63.4-2001 for intentional radiators, and in accordance with the limits set forth in FCC Part 95.635/9. These tests were performed by Kenneth Boston, EMC Lab Manager of L.S. Compliance, Inc.

10. Purpose

All Radiated and Conducted Emission tests upon the EUT were performed to measure the emissions in the frequency bands described in Title 47 CFR, FCC Part 95 to determine whether these emissions are below the limits expressed within the standards. These tests were performed in accordance with the procedure described in the American National Standard for methods of measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz (ANSI C63.4-2001). Another document used as a reference for the EMI Receiver specification was the Comite International Special Des Perturbations Radioelelectriques CISPR 16-1, 2003.

11. Radiated Emissions Test

Test Setup

The test setup was assembled in accordance with Title 47, CRF FCC Part 95 and ANSI C63.4-2003. Radiated tests were conducted on the EUT. The essential radio transceiver circuitry is identical between both the EXD and the IMD units. Each EUT was placed on an 80cm high non-conductive table, centered on a flush mounted 2-meter diameter turntable inside the 3 Meter Semi-Anechoic, FCC listed Chamber located at L. S. Compliance, Inc., Cedarburg, Wisconsin. The EUT was operated in continuous operation mode, using an internal 3.6 VDC battery as provided by the manufacturer. The applicable limits apply at a 3 meter distance. The calculations to determine the limits are detailed in the following pages. Please refer to Appendix A for a list of the test equipment. The EUT was operated on one of two (2) standard channels: Channel 0 (low): 402.5 MHz; Channel 4 (high): 404.8 MHz.

Test Procedure

Radiated Emission measurements were performed on the EUT in the 3 Meter Semi-Anechoic, FCC listed Chamber, located at L. S. Compliance, Inc. in Cedarburg, Wisconsin. The frequency range from 30 MHz to 4100 MHz was scanned, and levels were manually noted at the various fixed degree settings of azimuth on the turntable and antenna height. The EUT was placed on the non-conductive table (or pedestal) in the 3 Meter Semi-Anechoic Chamber, with the antenna mast placed such that the antenna was 3 meters from the test object. A Biconical Antenna was used to measure emissions from 30 MHz to 300 MHz, and a Log Periodic Antenna was used to measure emissions from 300 MHz to 1000 MHz. A Double Ridged Waveguide Horn Antenna was used from 1 GHz to 4 GHz. The maximum radiated emissions were found by raising and lowering the antenna between 1 and 4 meters in height, using both horizontal and vertical antenna polarities. An EMCO loop antenna was used to inspect the low frequency momentary command signal at 40 kHz used during programming.

Test Equipment Utilized

A list of the test equipment and antennas utilized for the Radiated Emissions test can be found in Appendix A. This list includes calibration information and equipment descriptions. All equipment is calibrated and used according to the operation manuals supplied by the manufacturers. All calibrations of the antennas used were performed at a N.I.S.T. traceable site. In addition, the Connecting Cables were measured for losses using a calibrated Signal Generator and a HP 8546A EMI Receiver. The resulting correction factors and the cable loss factors from these calibrations were entered into the HP 8546A EMI Receiver database. As a result, the data taken from the HP 8546A EMI Receiver accounts for the antenna correction factor as well as cable loss or other corrections, and can therefore be entered into the database as a corrected meter reading. The HP 8546A EMI Receiver was operated with a bandwidth of 120 kHz for measurements below 1 GHz (1 kHz BW for measuring 40 kHz signal), and a bandwidth of 1 MHz for measurements above 1 GHz. The Peak, Quasi-Peak and Average Detector functions were all utilized.

Test Results

The EUT was found to MEET the Radiated Emissions requirements of Title 47 CFR, FCC Part 95 for a MICS band transmitter. The frequencies with significant signals were recorded and plotted as shown in the Data Charts and Graphs.

CALCULATION OF RADIATED EMISSIONS LIMITS (for 95.635 compliance)

Frequency Range	definition	Limit (dBμV/m)
Up to 401.75 MHz	15.209 limits	See below
401.75-402.00 MHz	(-20 dB Fo limit)	65.2
402.00-405.00 MHz	Fundamental	85.2
405.00-405.25 MHz	(-20 dB Fo limit)	65.2
405.25 and above MHz	15.209 limits	See below

Fundamental signal level in the MICS band; (95.639.f.1) is 18,200 μV/M; or 85.2 dBμV/m

The following table depicts the general emissions limits for an intentional radiator. These limits are obtained from Title 47 CFR, Part 15.209(a), for radiated emissions measurements, above 30 MHz

Frequency (MHz)	3 m Limit (μV/m)	3 m Limit (dBμV/m)
30-88	100	40.0
88-216	150	43.5
216-960	200	46.0
960-10,000	500	54.0

Sample conversion from field strength μV/m to dBμV/m:

$dB\mu V/m = 20 \log_{10}$ (30m limit)

from 1.7-30 MHz for example: $dB\mu V/m = 20 \log_{10} (30)$

$29.5\ dB\mu V/m = 20 \log_{10} (30)$

Limits for radiated emissions, below 30 MHz, for 15.209(A), with a 15.31.f.2. scaling factor (40 dB/decade)

Frequency (MHz)	Measurement Distance (m)	Limit (μV/m)	300 M (dBμV/m)	30 M (dBμV/m)	3 M (dBμV/m)
0.009-0.490	300	2400/F (kHz)	35.5 **	75.5 **	115.5 **
0.490-1.705	30	24000/F (kHz)	-------	-- -- --	-- -- --
1.705-30.0	30	30	-------	29.5	69.5

3m limit (dBμV/m) = 300m limit (dBμV/m) + 40 $\log_{10}$ (300m/3m)

From 0.009 – 0.490 MHz for example: 3m limit (dBμV/m) = 20 Log [2400/F (kHz)] (dBμV/m) + 80.0 (dB)

or, for example, at 40 kHz (**):

$$3\ meter.Limit|_{F=40kHz}\ (dB\mu V/m) = 300m\ limit\ (dB\mu V/m) + 40 \log_{10}(300m/3m)$$

$$3\ meter.Limit|_{F=40kHz}\ (dB\mu V/m) = \{ 20\mathrm{Log}_{10}\left(\frac{2400}{40}\right)\ (dB\mu V/m) + \left[40 Log_{10}\left(\frac{300}{3}\right)\right] \} (dB)$$

$$3\ meter.Limit|_{F=40kHz}\ (dB\mu V/m) = 35.5\ (dB\mu V/m) + 80.0\ (dB\mu V/m) = 115.5\ (dB\mu V/m)$$

Measurement of Electromagnetic Radiated Emissions Within the 3 Meter FCC Listed Chamber

Manufacturer: Angel Medical Systems, Inc.
Date of Test: August, September October 2005
Model Nos.: EXD
Serial No.: 57, 58

Test Requirements: 95.635/9

Distance: 3 Meters,	Frequency Range Inspected: 30 to 4050 MHz, 20-400 kHz
Configuration: Continuous Transmit, momentary command mode	

Test Equipment Used:

EMI Measurement Instrument: HP 8546A and Agilent E4407B	Biconical Antenna: EMCO 93110B
Double-Ridged Wave Guide/Horn Antenna: EMCO 3115 Active Loop antenna EMCO 6502	Log Periodic Antenna: EMCO 43146A

Detector(s) Used:	X	Peak	X	Quasi-Peak	X	Average

The following table depicts the level of significant radiated emissions found

Frequency (MHz)	Antenna Polarity	Equipment Under Test	Channel #	Antenna Height (meters)	Azimuth (0° - 360°)	EMI Meter Reading (dBμV/m)	95.xxxLimit (dBμV/m)	Margin (dB)
402.5	H	Flat	0	1.0	101	75.4	85.2	9.8
404.8	H	Flat	4	1.0	100	75.5	85.2	9.7
805.0	H	Flat	0	1.05	237	38.2	46.0	7.8
809.5	H	Flat	4	1.05	239	37.8	46.0	8.2
1207.5	H	Flat	0	1.22	192	50.6	54.0	3.4
1214.4	H	Flat	4	1.22	193	52.7	54.0	1.3
1610.0	V	Vert	0	1.29	295	52.9	54.0	1.1
1619.1	V	Vert	4	1.07	67	53.2	54.0	0.8
2012.7	H	Flat	0	1.04	154	47.3	54.0	6.7
2024.0	H	Flat	4	1.05	154	46.9	54.0	7.1
2415.0	H	Flat	0	1.16	326	39.7	54.0	14.3
2429.0	H	Flat	4	1.17	335	40.0	54.0	14.0

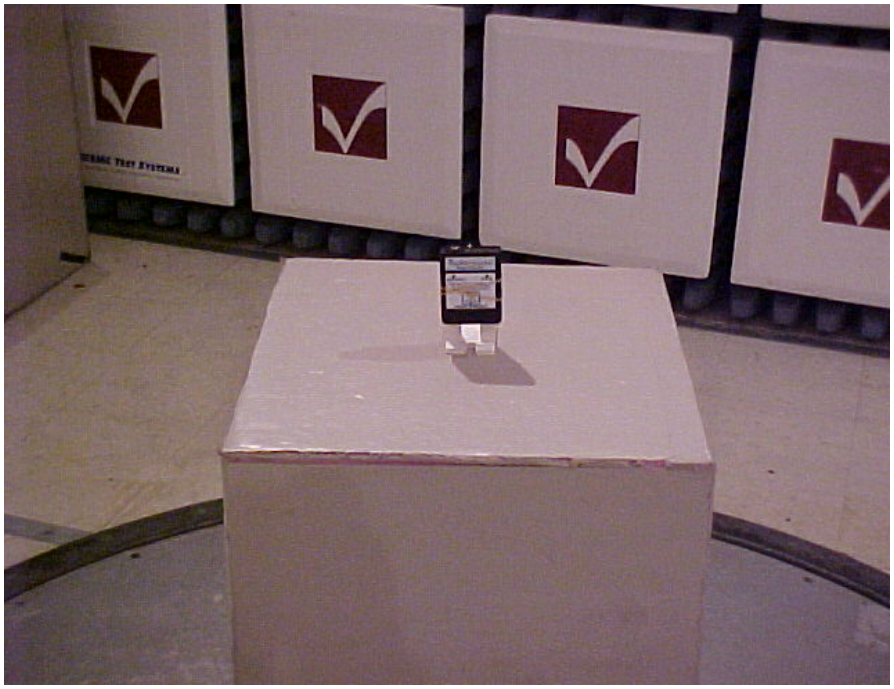
Notes: A Quasi-Peak Detector was used in measurements below 1 GHz, and both an Average and a Peak Detector were used in measurements above 1 GHz. All other Radiated Spurious Emissions seen were found to be greater than 20 dB below the limits, or below the noise floor of the instrumentation.

The 40 kHz signal used for near field activation and programming of the IMD by the EXD unit was measured at 3 meters using an EMCO 6502 loop antenna. A peak detector was used due to the short transmission on-time of the signal, which is present during the transmission of commands. CISPR 16 band A measurement bandwidth is 200 hz, or larger, and 1 kHz bandwidth was used to speed up measurement of the signal. The measured signal was found to be greater than 20 dB below the 15.209 limits, with a rapid falloff of strength at greater distances from the transmitter.

Power setting; PA is set to 07 via downloadable software.

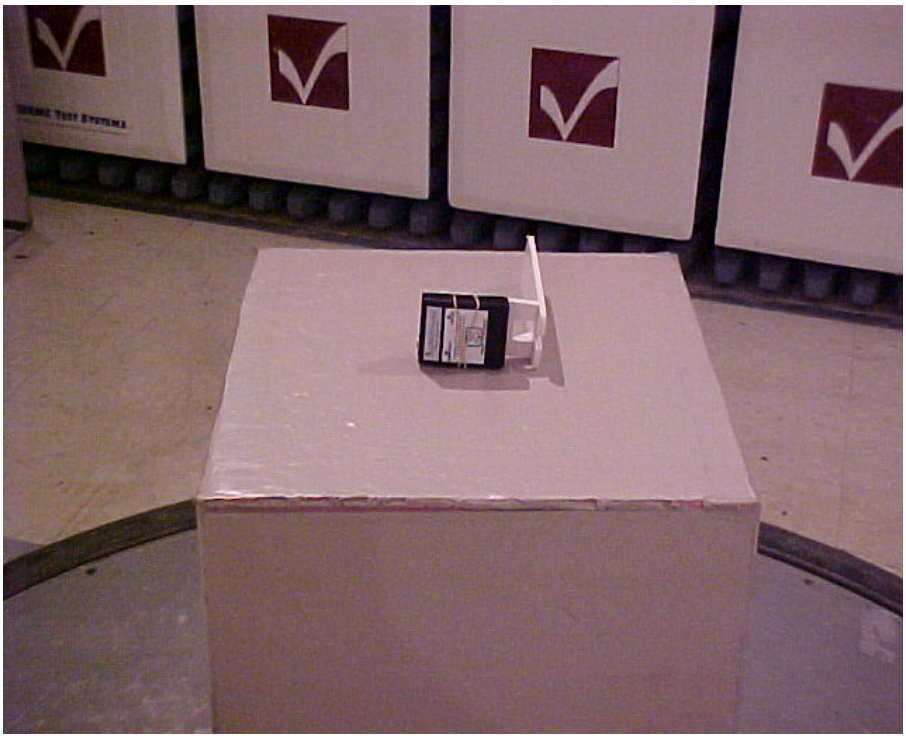
Photos Taken During Radiated Emission Testing

Setup for the Radiated Emissions Test



Vertical orientation

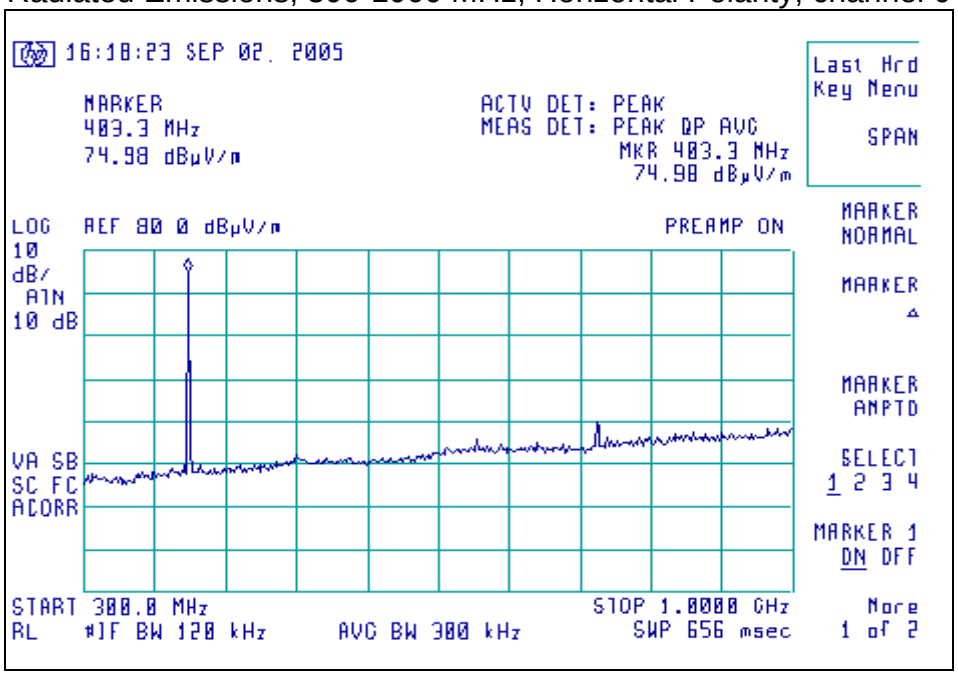
Flat orientation



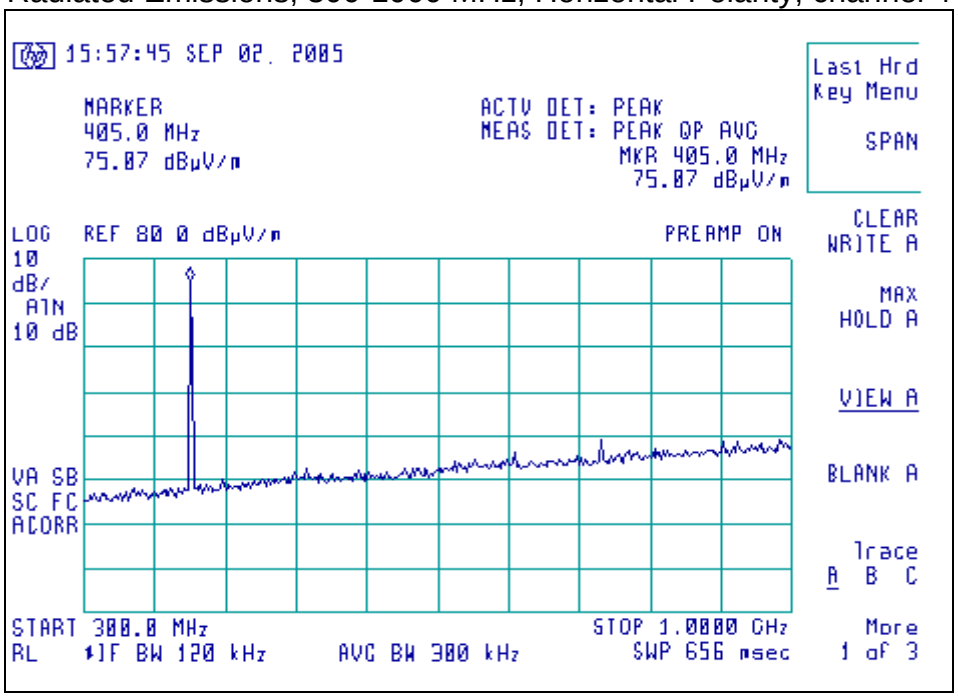
Side orientation

Graphs made during Radiated Emission Testing

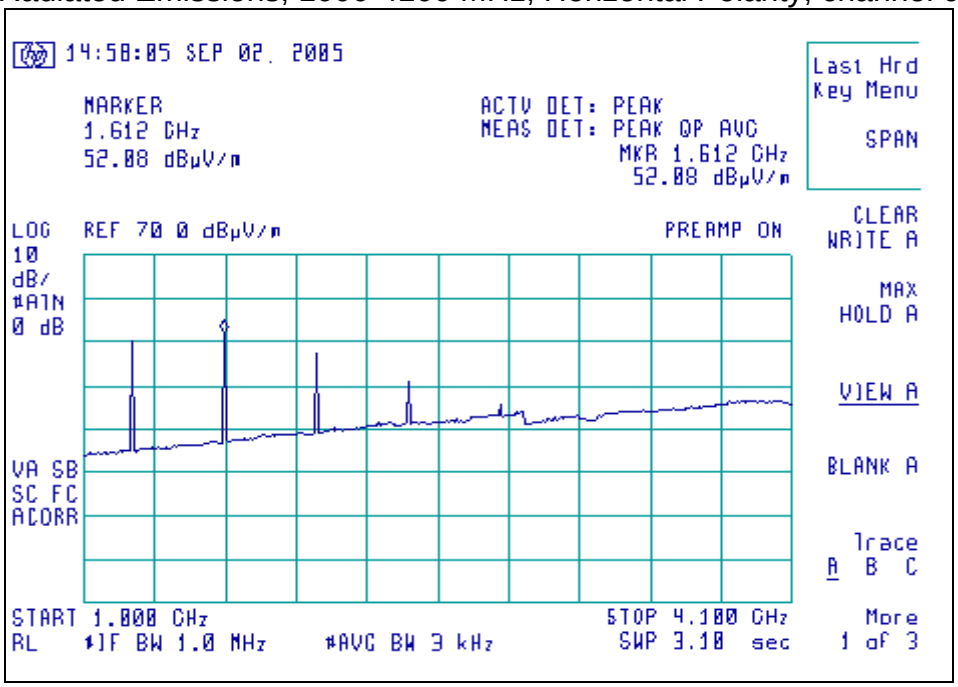
Radiated Emissions, 300-1000 MHz, Horizontal Polarity, channel 0



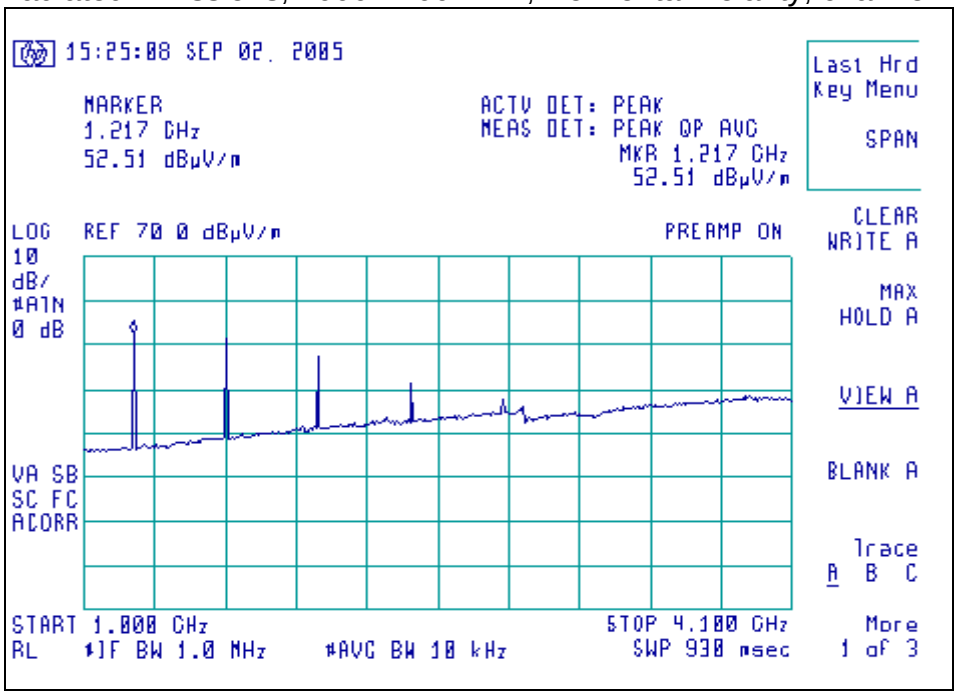
Radiated Emissions, 300-1000 MHz, Horizontal Polarity, channel 4



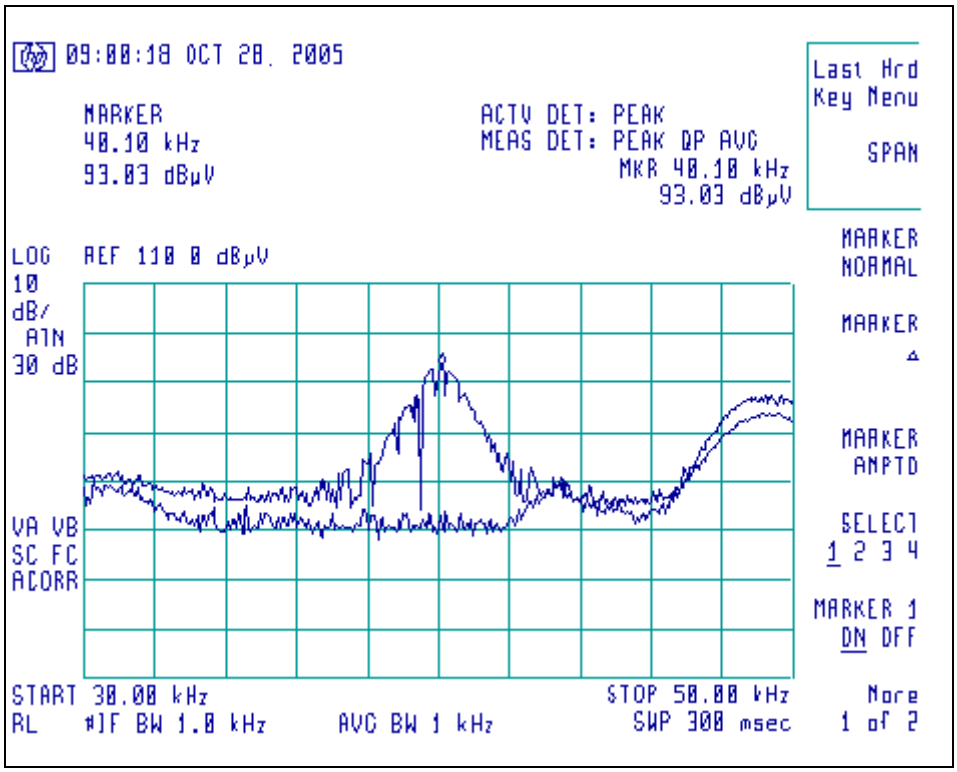
Radiated Emissions, 1000-4100 MHz, Horizontal Polarity, channel 0



Radiated Emissions, 1000-4100 MHz, Horizontal Polarity, channel 4



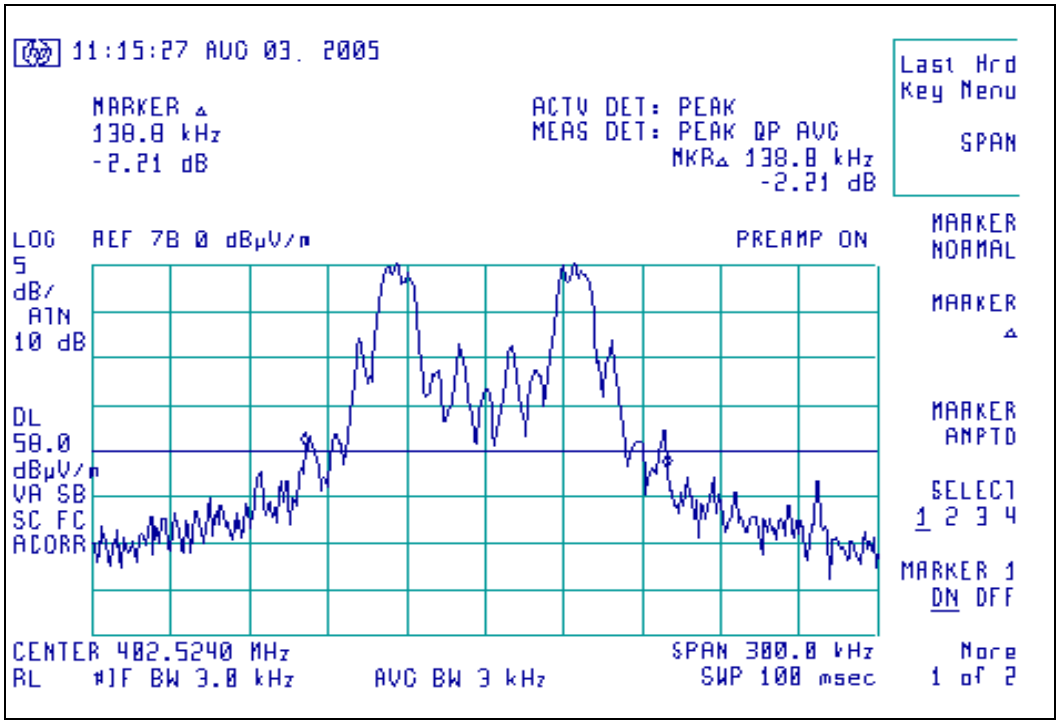
EMISSION DETAIL OF THE 40 KHZ NEAR FIELD SIGNAL at 3 meters.
(lower trace is ambient, upper shows peak hold of signal, maximum orientation)



12. Bandwidth Measurements 47 CFR 95.633

Bandwidth is defined as being 300 kHz for any modulated emissions in the MICS band assignment. Band edge compliance is defined as emissions being greater than 20 dB below the fundamental radiated EIRP. Further compliance is defined as meeting the radiated field strength limits as defined in 15.209 for emissions seen out of the MICS band. The worst case bandwidth observed was 139 kHz, which is within the allowed bandwidth of 300 kHz.

Signature Scan of Occupied Bandwidth measurements, Low Channel



13. Frequency Stability 47 CFR; 95.628e

The EUT must have an absolute frequency stability of **100 ppm** when operating in the MICS service.

Frequency stability must be measured from **0 to 55 degrees centigrade.** Allowing for thermal equilibrium, the measurement was performed after the desired temperature was maintained for 30 minutes.

Temperature (degree C)	Frequency (MHz)	Frequency Delta (kHz)	Frequency Delta (PPM)
0	402.520380	0	0
10	402.520130	.25	.62
20	402.519450	.93	2.3
30	402.518630	1.75	4.4
40	402.517530	2.85	7.1
50	402.516630	3.75	9.3
55	402.516380	4.00	9.9

APPENDIX A

Test Equipment List

Asset #	Manufacturer	Model #	Serial #	Description	Calibration Due
AA960008	EMCO	3816/2NM	9701-1057	Line Impedance Stabilization Network	9-27-06
AA960031	HP	119474A	3107A01708	Transient Limiter	Note 1
AA960077	EMCO	93110B	9702-2918	Biconical Antenna	9-27-06
AA960078	EMCO	93146	9701-4855	Log-Periodic Antenna	9-27-06
AA960081	EMCO	3115	6907	Double Ridge Horn Antenna	12-06-05
CC00221C	Agilent	E4407B	US39160256	Spectrum Analyzer	12-07-05
EE960004	EMCO	2090	9607-1164	Device Controller	N/A
EE960013	HP	8546A	3617A00320	Receiver RF Section	9-29-06
EE960014	HP	85460A	3448A00296	Receiver Pre-Selector	9-29-06
N/A	LSC	Cable	0011	3 Meter ½" Armored Cable	6-07-06
N/A	LSC	Cable	0038	1 Meter RG 214 Cable	6-07-06
N/A	LSC	Cable	0050	10 Meter RG 214 Cable	6-07-06
N/A	Pasternack	Attenuator	N/A	10 dB Attenuator	6-07-06

Note 1 - Equipment calibrated within a traceable system.*

Uncertainty Statement

This uncertainty represents an expanded uncertainty expressed
at approximately the 95% confidence level, using a coverage factor of k=2.

Table of Expanded Uncertainty Values, (K=2) for Specified Measurements

Measurement Type	Particular Configuration	Uncertainty Values
Radiated Emissions	3 – Meter chamber, Biconical Antenna	4.24 dB
Radiated Emissions	3-Meter Chamber, Log Periodic Antenna	4.8 dB
Radiated Emissions	10-Meter OATS, Biconical Antenna	4.18 dB
Radiated Emissions	10-Meter OATS, Log Periodic Antenna	3.92 dB
Conducted Emissions	Shielded Room/EMCO LISN	1.60 dB
Radiated Immunity	3 Volts/Meter in 3-Meter Chamber	1.128 Volts/Meter
Conducted Immunity	3 Volts level	1.0 V