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

COMPLIANCE TESTING OF:

IMD medical implant

(used in the AngelMed Guardian system)

PREPARED FOR:

Hi-Tronics

TEST REPORT NUMBER:

305321-imd TX Revision 3

TEST DATE(S): August, September, 2005

Table of Contents

1. L. S. Compliance In Review

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

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 2004/108/EC (formerly 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. Testing and calibration laboratories that comply with this International Standard also operate in accordance with ISO 9001 or ISO 9002 (1994).

Presented this 26th day of March 2003.

President
For the Accreditation Council
Certificate Number 1255.01
Valid to January 31, 2005

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

3. A2LA Scope of Accreditation

American Association for Laboratory Accreditation

SCOPE OF ACCREDITATION TO ISO/IEC 17025-1999

L.S. COMPLIANCE, INC.
W66 N220 Commerce Court
Cedarburg, WI 53012
James Blaha Phone: 262 375 4400

ELECTRICAL (EMC)

Valid to: January 31, 2005 Certificate Number: 1255-01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests:

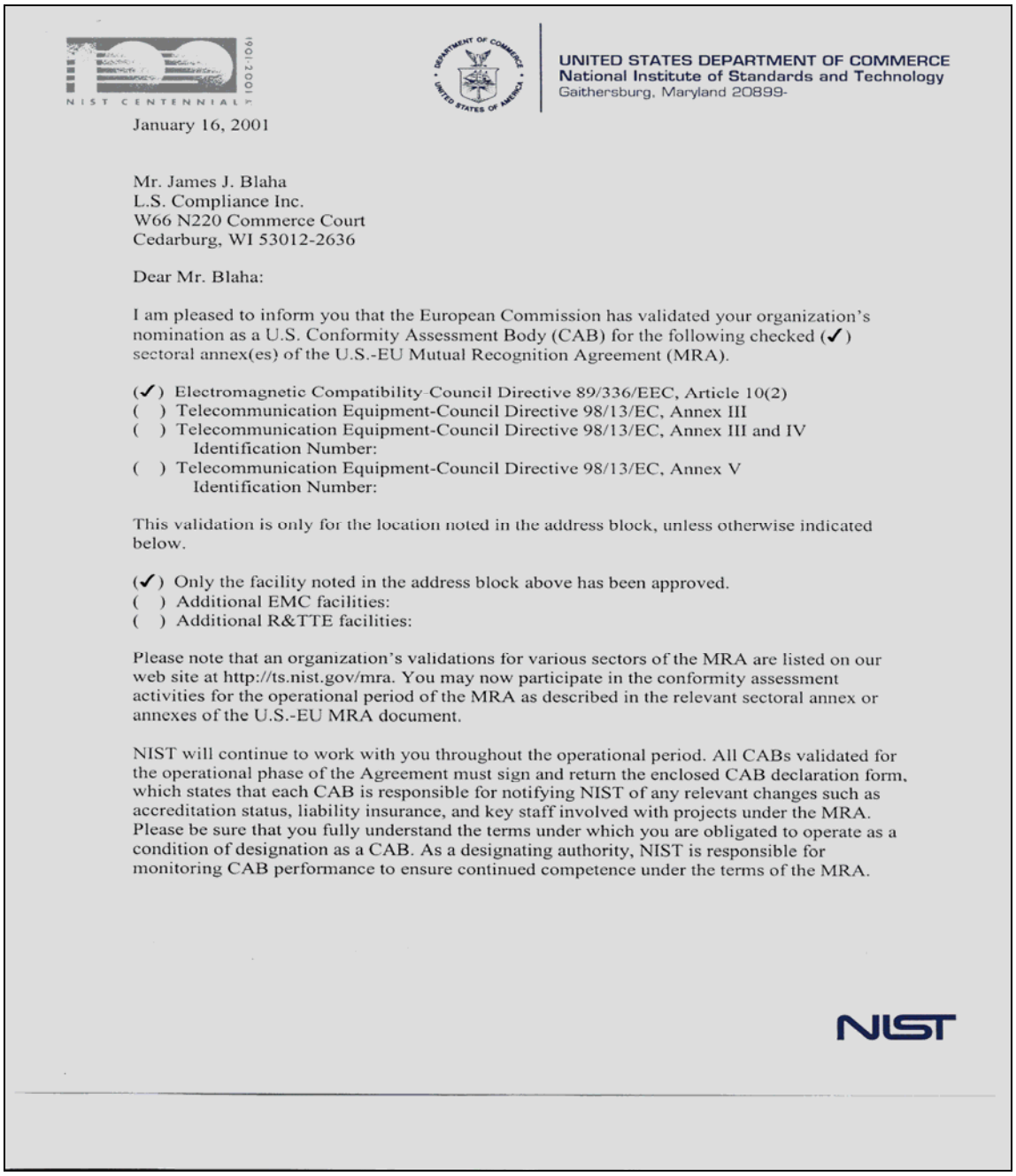
Test	Test Method(s)
Emissions	
Conducted	
Continuous/Discontinuous	Code of Federal Regulations (CFR) 47, FCC Method Parts 15, 18 using ANSI C63.4; EN: 55011, 55022, 50081-1, 50081-2; CISPR: 11, 12, 14-1, 22; CNS 13438
Radiated	Code of Federal Regulations (CFR) 47, FCC Method Parts 15, 18 using ANSI C63.4; EN: 55011, 55022, 50081-1, 50081-2; CISPR: 11, 12, 14-1, 22; CNS 13438
Current Harmonics	IEC 61000-3-2; EN 61000-3-2
Voltage Fluctuations & Flicker	IEC 61000-3-3; EN 61000-3-3
Immunity	EN: 50082-1, 50082-2 EN 61000-6-2 CISPR: 14-2, 24
Conducted Immunity	
Fast Transients/Burst	IEC 61000-4-4; EN 61000-4-4
Surge	IEC: 61000-4-5; ENV 50142; EN 61000-4-5
RF Fields	IEC: 61000-4-6; ENV 50141; EN 61000-4-6
Voltage Dips/Interruptions	IEC 61000-4-11; EN 61000-4-11

Roxanne M. Robinson

(A2LA Cert. No. 1255-01) 05/13/03 Page 1 of 2

5301 Buckeystown Pike, Suite 350 • Frederick, MD 21704-8373 • Phone: 301-644 3248 • Fax: 301-662 2974

4. 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.

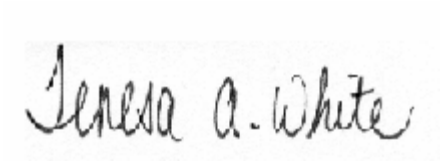
(✓) Only the facility noted in the address block above has been approved.
( ) Additional EMC facilities:
( ) Additional R&TTE facilities:

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

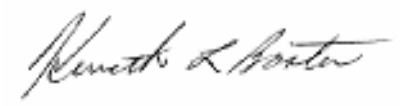
5. Signature Page



Prepared By: March 20, 2006

Teresa A. White, Document Coordinator Date

Tested and



Approved By March 20, 2006

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

6. Product and General Information

Manufacturer:	Hi-Tronics Design, Inc.
Model No.:	IMD
Serial No.:	117, 118
Description:	405 MHz MICS band transceiver

7. Product Description

The AngelMed Guardian Implantable Medical Device (IMD) is an implantable programmable device that monitors the patients' electrogram, vibrates to warn the patient of alarms and alerts, and stores electrogram signals and other data. The IMD is one of the primary components of the AngelMed Guardian System.

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

8. 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 (2002).

9. Summary of Test Report

DECLARATION OF CONFORMITY

The Hi-Tronics IMD was found to **MEET** the requirements as described within the specification of Title 47 CFR FCC, Part 95, for a MICS band transmitter.

10 Introduction

During August and September of 2005, a series of Radiated Emission tests were performed on several samples of the IMD medical device, here forth referred to as the "*Equipment Under Test*" or "*EUT*". The two models tested all use the same RF transmitter 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.

11 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, 2002

12. Radiated Emissions Test

Test Setup

The test setup was assembled in accordance with Title 47, CRF FCC Part 95 and ANSI C63.4-2001. 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.

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, 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.

Test Procedure: further details concerning the human torso simulator:

The IMD_samples were tested in a fluid filled human torso simulator which is specified for testing of Implantable medical devices. The dimensions of this cylinder are 76 CM height, 30 CM outer diameter, and .635 CM wall thickness. (30" by 12 " by 0.25" walls). Suspended in this cylinder is a plexiglass platform, with nylon hardware construction. When inserted into the cylinder this platform becomes located 36 CM up from the bottom, which is very nearly halfway up from the bottom, and centered vertically in the cylinder. The cylinder is filled with a solution (by weight) of 52.5 % distilled water; 45 % sugar; 1.37 % salt; 1 % HEC and 0.1 % bactericide. With 8.5 gallons of water (70.9 lbs), this requires 60.9 lbs of sugar, 1.86 lbs of salt, 1.38 lbs of HEC and .13 lbs of bactericide; for a total weight of fluid of 135.2 lbs. This is the formula for Body/Muscle tissue simulant as given by Hartsgrove, Kraszewski and Surowiec as given in Bioelectromagnetics, issue 8, 1987; and reprinted in Appendix C of Supplement C (2001) to OET Bulletin 65. This formula will yield a solution that gives a dielectric constant of 58 and a conductivity of 0.83 S/m at 400 MHz.

The cylinder, with solution and EUT is positioned on a pedestal that places the plexiglass platform with a nominal height of 1.5 meters from the conductive ground plane floor. The EUT is positioned on the platform, near the edge, which puts it at a 6 CM spacing from the cylinder sidewalls. The entire setup is fixed 3 meters from the antenna.

Preliminary testing of the EUT in air was used as an investigational tool, and final numbers were derived while in the fluidic cylinder. Both vertical and horizontal positions were investigated, with highest emissions seen in horizontal position, which the results which are reported.

During testing, the fluid level was somewhat lower than full (>85% of total volume) due to inaccuracies with converting weights of fluid elements to volumetric equivalents. It was found that there were at least 22 CM of fluid above the EUT as a minimum depth. It is reasonable to assume this difference would not cause any errors in the measurement results.

Additional pictures are included that show these details on pages 15 to 18.

CALCULATION OF RADIATED EMISSIONS LIMITS (for 95.635 compliance)

Frequency Range	definition	Limit (dBuV/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 uV/M; or 85.2 dBuV/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 (dBuV/m)	30 M (dBuV/m)	3 M (dBuV/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:

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

$$3\ meter.Limit|_{F=40kHz}\ (dB\mu V/m) = \{ 20Log_{10}(\underline{2400})] (dB\mu V/m) + [40Log_{10}(\underline{300})] (dB)$$
$$30 \qquad 3$$

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

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

Manufacturer:	Hi-Tronics Design, Inc
Date of Test:	August, September, 2005
Model Nos.:	IMD
Serial No.:	117, 118(highest emissions seen on this sample)

Test Requirements: 95.635/9

Distance: 3 Meters,	Frequency Range Inspected: 30 to 4050 MHz
Configuration: Continuous Transmit,	

Test Equipment Used:

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

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

The following table depicts the level of significant radiated emissions found

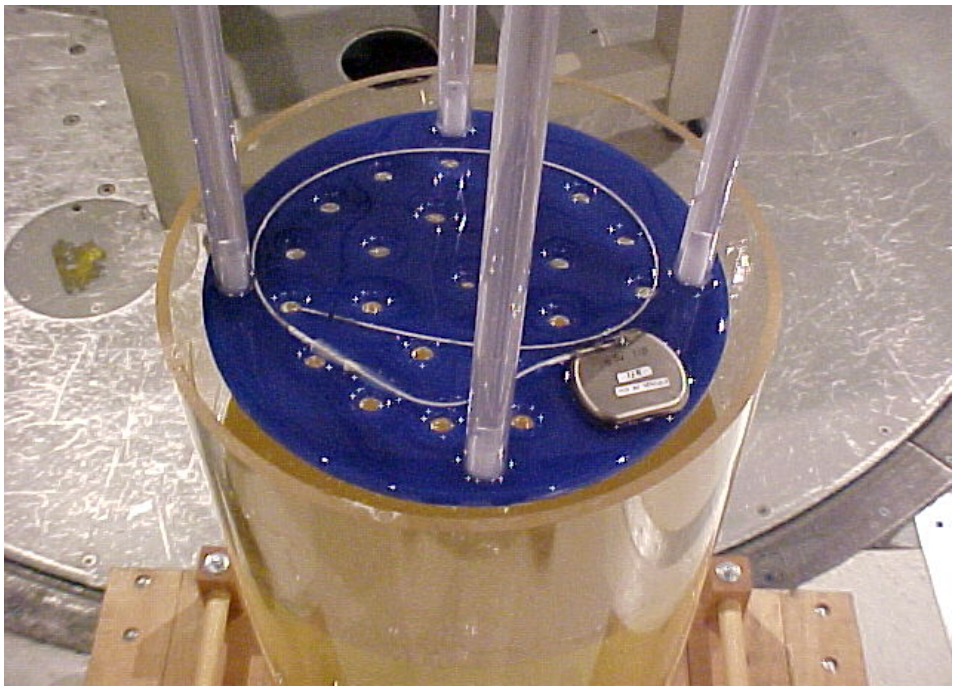
Frequency (MHz)	Antenna Polarity	Equipment Under Test	Channel #	Antenna Height (meters)	Azimuth (0° - 360°)	EMI Meter Reading (dBμV/m)	95.639 Limit (dBμV/m)	Margin (dB)
402.5	H	Flat	0	1.3	340	70.3	85.2	14.9
404.8	H	Flat	4	1.25	305	70.7	85.2	14.5
805.0	H	Flat	0	1.5	305	27.6	46.0	18.4
809.5	H	Flat	4	1.5	45	28.1	46.0	17.9

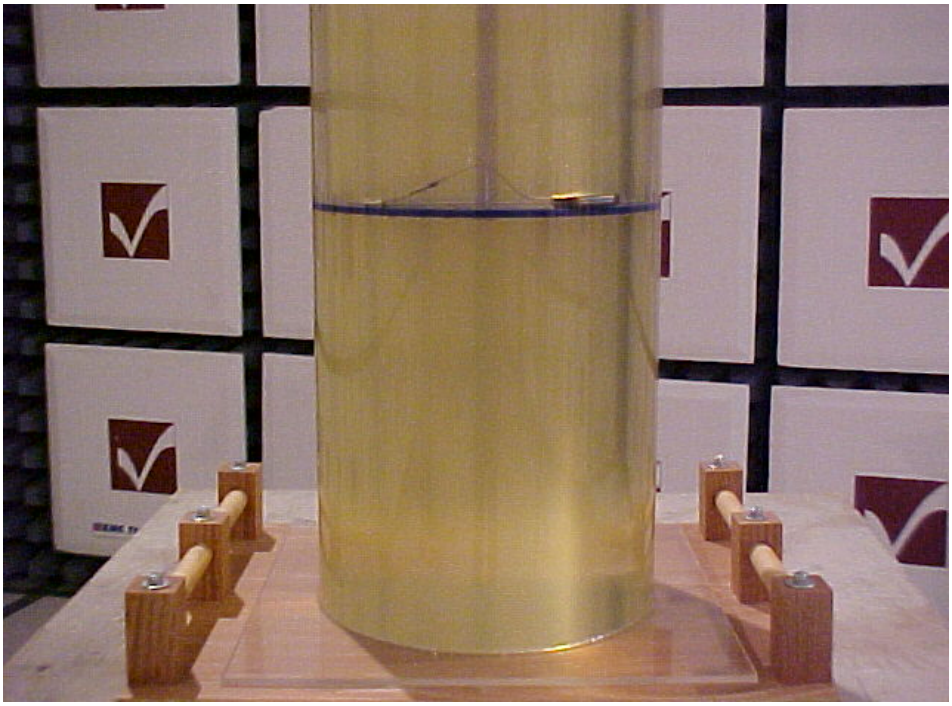
Notes: A-Peak Detector was used in measurements below 1 GHz, and both an Average and a Peak Detector were used in measurements above 1 GHz. All other Radiated Spurious Emissions seen were found to be greater than 20 dB below the limits, or below the noise floor of the instrumentation.

Power setting; PA is set to E0 via downloadable software.

Photos Taken During Radiated Emission Testing

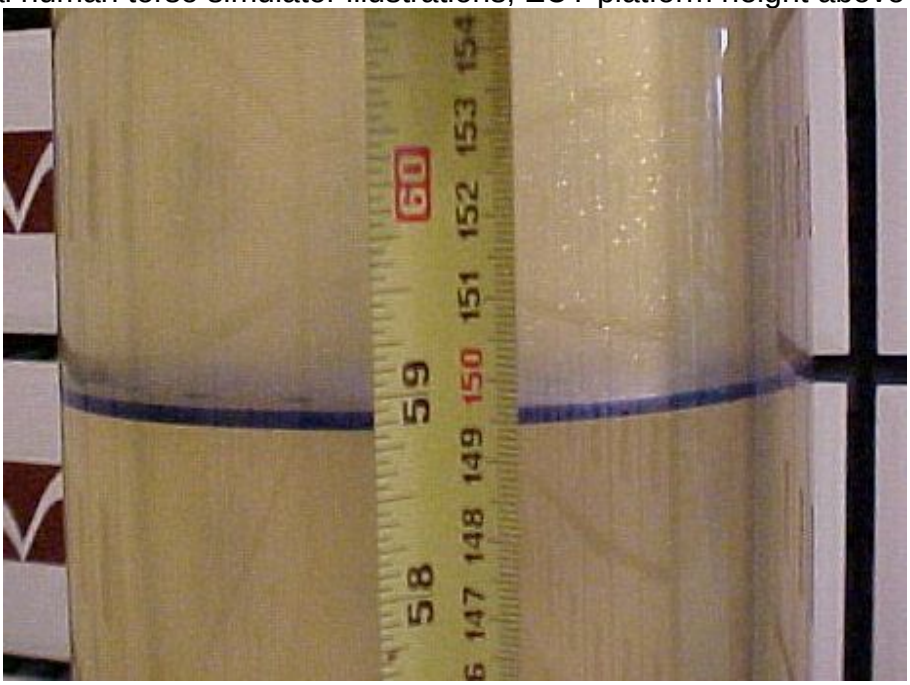
Setup for the Radiated Emissions Test



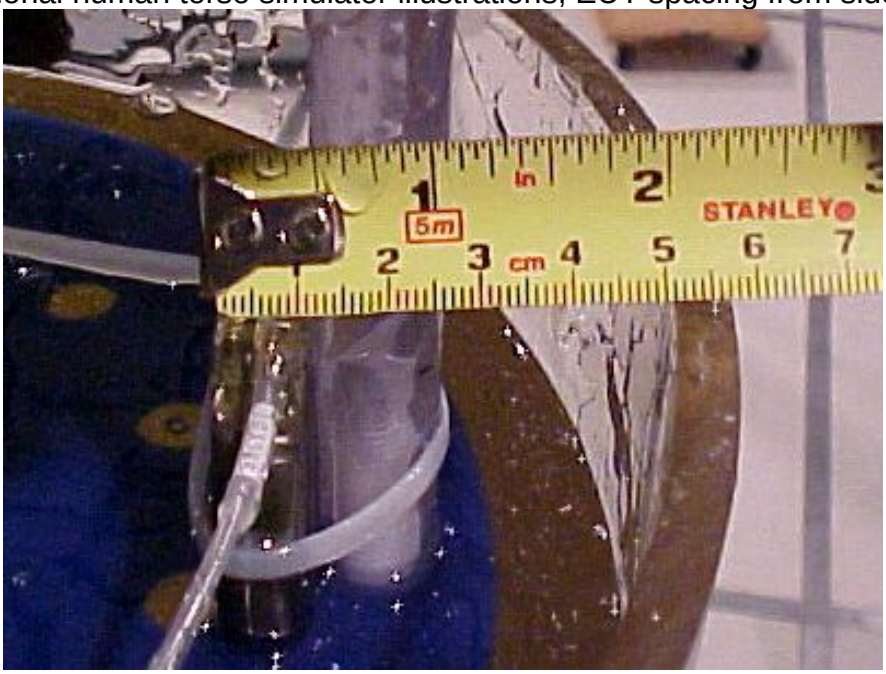


Additional human torso simulator illustrations, full view

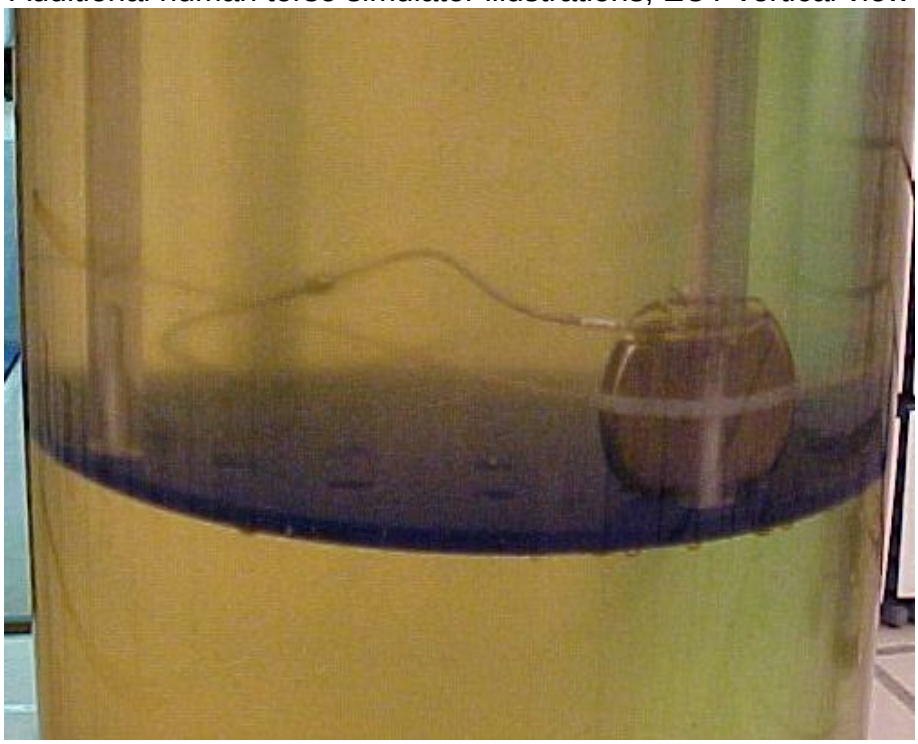
Additional human torso simulator illustrations, EUT platform height above the floor.



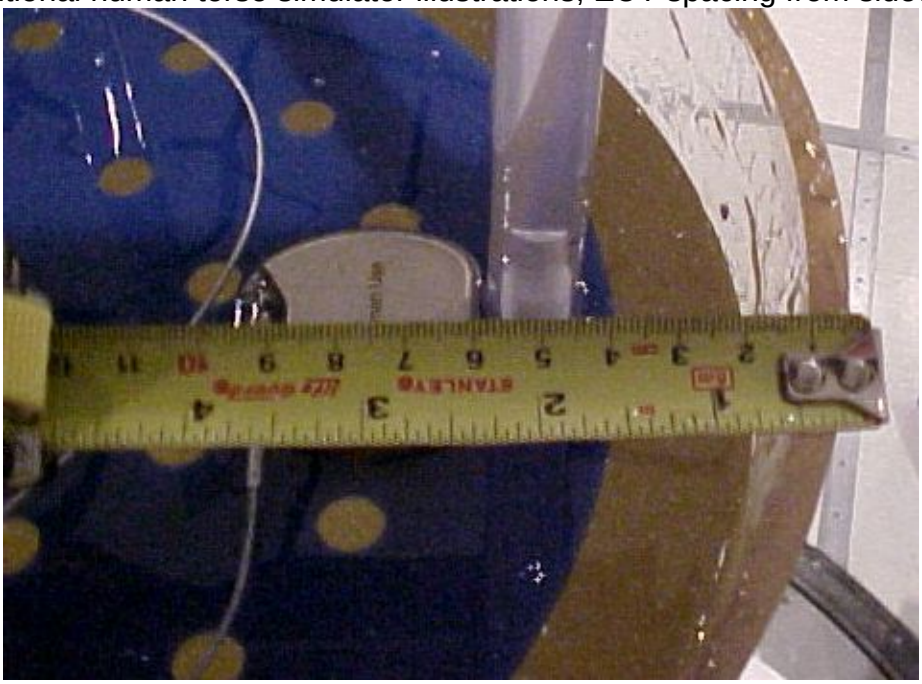
Additional human torso simulator illustrations, EUT spacing from sidewall.



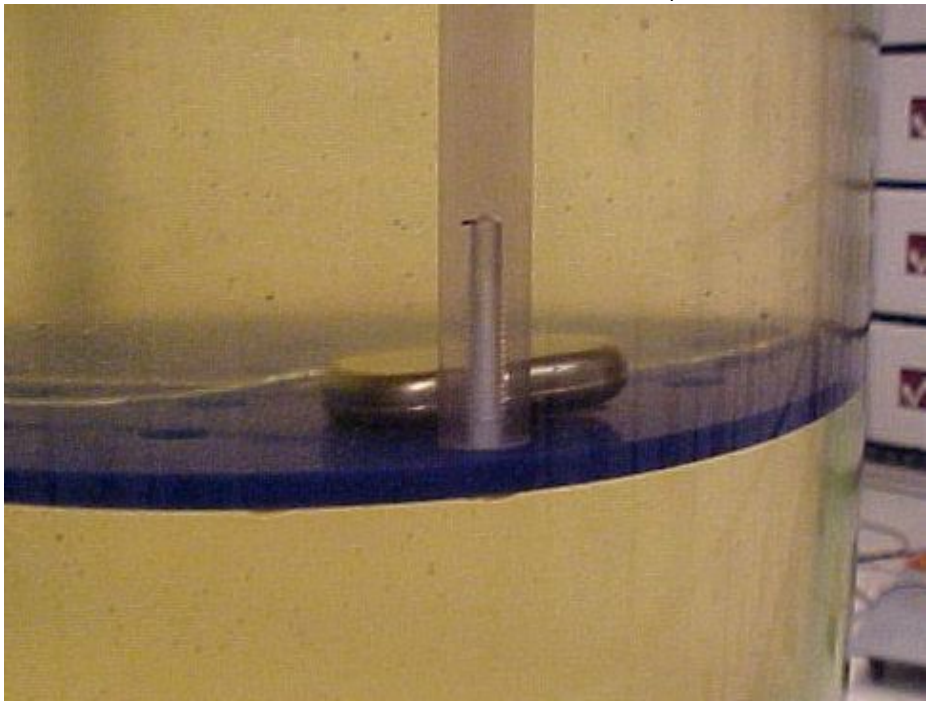
Additional human torso simulator illustrations, EUT vertical view



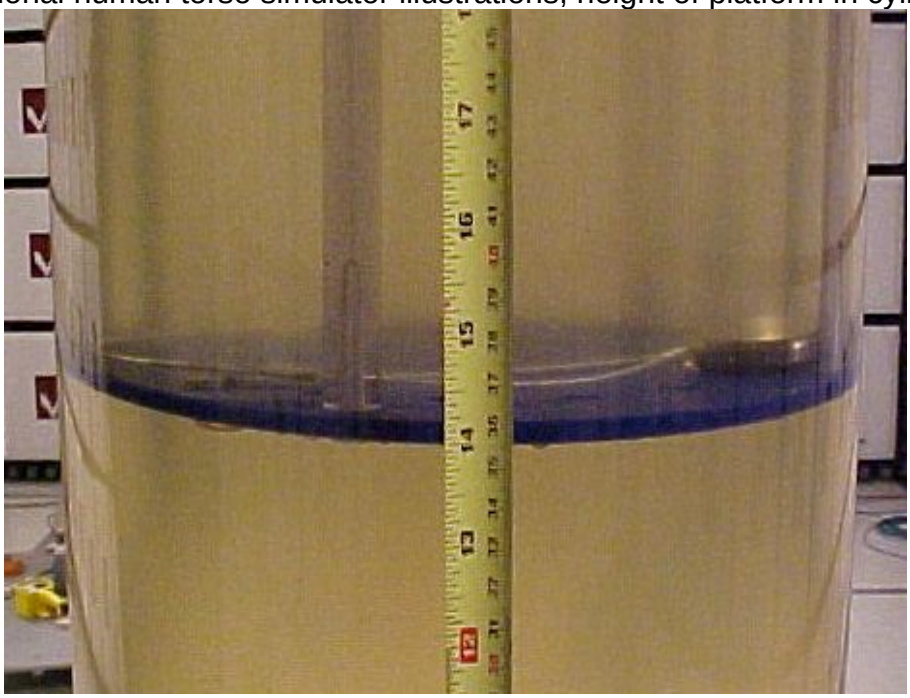
Additional human torso simulator illustrations, EUT spacing from sidewall.



Additional human torso simulator illustrations, EUT horizontal

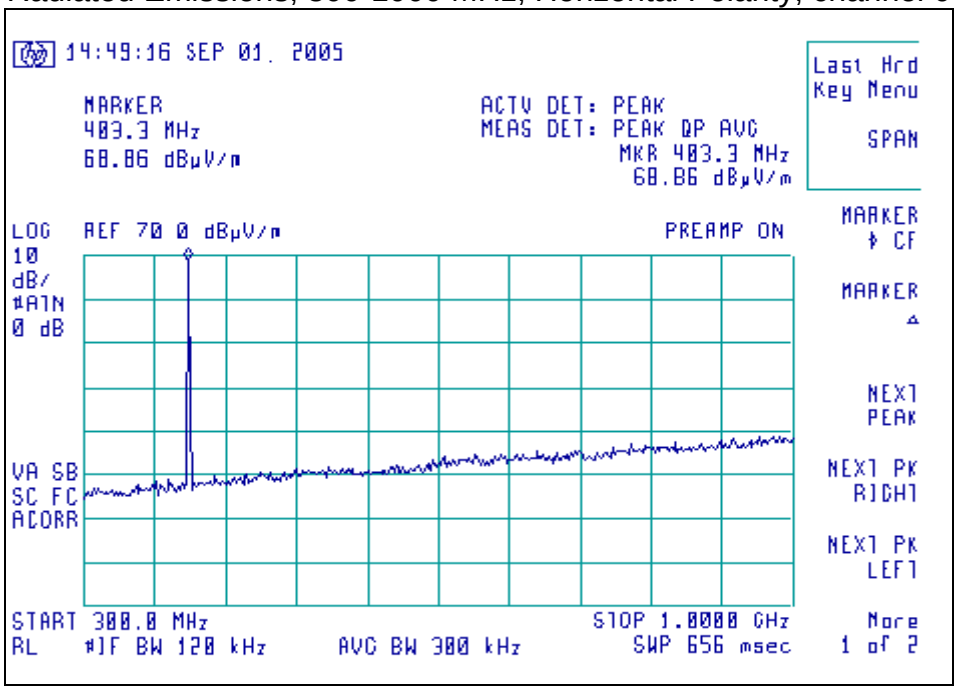


Additional human torso simulator illustrations, height of platform in cylinder.

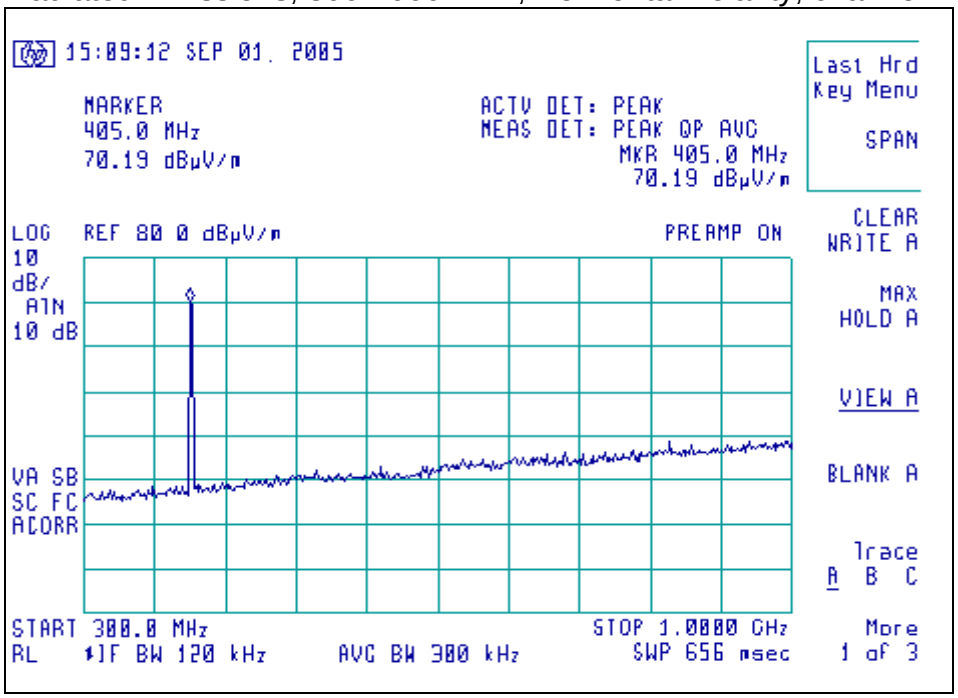


Graphs made during Radiated Emission Testing

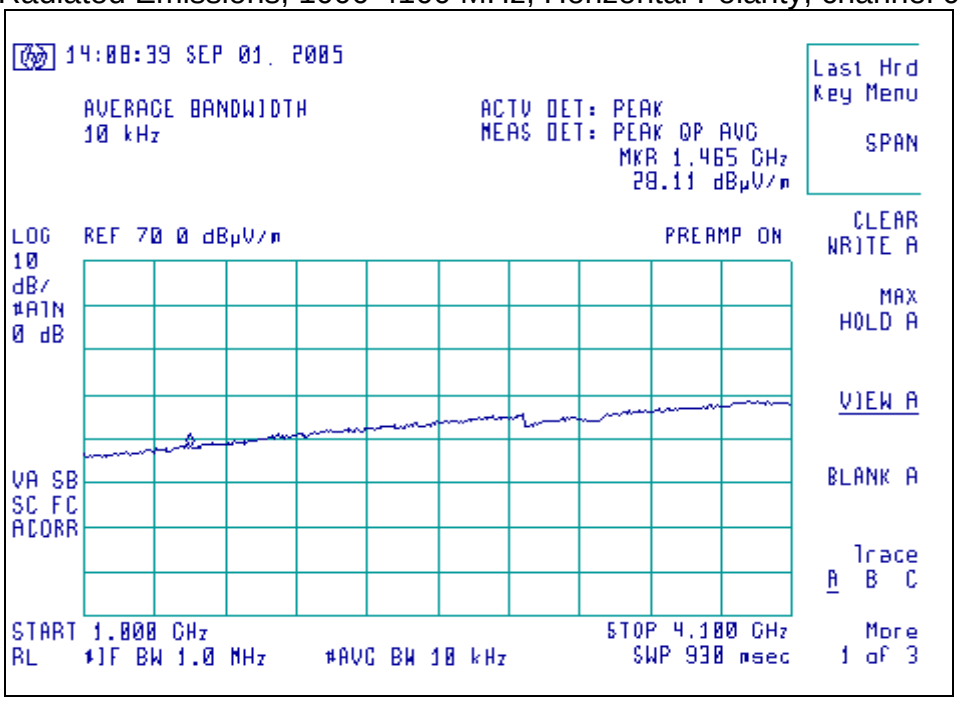
Radiated Emissions, 300-1000 MHz, Horizontal Polarity, channel 0



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



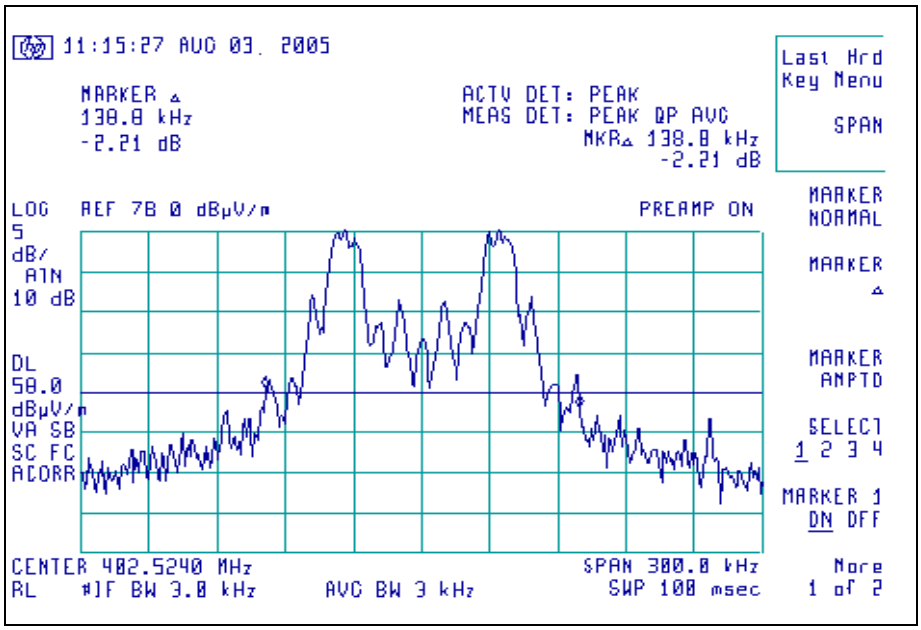
Radiated Emissions, 1000-4100 MHz, Horizontal Polarity, channel 0



16. 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 outside of the MICS band. While both the IMD and EXD devices have the same RF transmitter topology, the worst case bandwidth of the EXD test sample is repeated below. (139 kHz BW)

Signature Scan of Occupied Bandwidth measurements, Low Channel



17. Frequency Stability (47 CFR 95.628.e.)

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

Test in accordance to conditions called out in Part 95.628(e): Frequency stability must be measured from **25 to 45 degrees centigrade.** Allowing for thermal equilibrium, the measurement was performed after the desired temperature was maintained for 15 minutes.

Temperature (degree C)	Frequency (Mhz)	Frequency Delta (kHz)	Frequency Delta (PPM)
25	402.520550	0	0
35	402.519630	.92	2.3
45	402.518830	1.72	4.3

APPENDIX A

Test Equipment List

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

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