



LSRESEARCH, LLC

Wireless Product Development

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ENGINEERING TEST REPORT # 312257

LSR Job #: C-1570

Compliance Testing of:

IMD

Test Date(s):

October 2012

Prepared For:

Angel Medical Systems

Attn: Tom Picciotti

1163 Shrewsbury Ave Suite E

Shrewsbury, NJ 07702

This Test Report is issued under the Authority of: Adam Alger, EMC Engineer

Signature:

Date: 11-7-12

Test Report Reviewed by:

Shane Rismeyer, EMC Engineer

Signature:

Date: 11-6-12

Report by:

Adam Alger, EMC Engineer

Signature:

Date: 10-29-12

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Prepared For: Angel Medical Systems

Report: TR 312257 FCCTX V1

LSR: C-1570

Name: IMD

Model: AMMSG3

Serial: JH3000294

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LS Research, LLC in Review

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: 2005 with Electrical (EMC) Scope of Accreditation

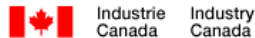
A2LA Certificate Number: 1255.01



Federal Communications Commission (FCC) – USA

Listing of 3 Meter Semi-Anechoic Chamber based on Title 47 CFR – Part 2.948

FCC Registration Number: 90756



Canada

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

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1.0 Summary of Test Report

On October 18, 2012 the IMD Model AMMSG3 was tested and MEETS the following requirements:

Rule	Description	Procedure	Compliant	Note
95.627(a)(6)(i)	Emission Bandwidth 20dB	ANSI C63.4-2003	Yes	1
95.627(g)(3)	Maximum Output Power	ANSI C63.4-2003	Yes	1
95.627(d)	Authorized Bandwidth	ANSI C63.4-2003	Yes	1
95.627(c) / 95.635	Radiated Harmonics	ANSI C63.4-2003	Yes	1
95.627(e)(1)	Frequency Stability	ANSI C63.4-2003	Yes	2
15.109	Receiver radiated Emissions	ANSI C63.4-2003	Yes	1

Note 1: Tested in three orthogonal positions on low and high channels.

Note 2: Tested in Temperature chamber.

2.0 Test Facilities

All testing was performed at:

LS Research, LLC
W66 N220 Commerce Court
Cedarburg, Wisconsin, 53012 USA

LS Research, LLC is accredited by A2LA (American Association for Laboratory Accreditation) to the requirements of ISO/IEC 17025, 2005 “General Requirements for the Competence of Calibration and Testing Laboratories”.

LS Research, LLC’s scope of accreditation includes all test methods listed herein, unless otherwise noted.

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3.0 Client Information

Manufacturer Name:	Angel Medical Systems
Address:	1163 Shrewsbury Ave Suite E Shrewsbury, NJ 07702
Contact Person:	Tom Picciotti

3.1 Equipment Under Test (EUT) Information

The following information has been supplied by the applicant.

Product Name:	IMD
Model Number:	AMSG3
Serial Number:	JH3000294
FCC ID	THL-IMDAMSG3
IC Number	N/A

3.2 Product Description

The AngelMed Guardian Implantable Medical Device (IMD) is an implantable programmable device that monitors and stores the patients' electrogram, vibrates to warn the patient of alarms and alerts, and stores electro gram 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' electrogram using baseline electrogram from the previous day for comparison.

Frequency Range (MHz)	402.5 to 404.8
RF Power In Watts (Radiated EIRP)	0.00264 mW
Field Strength at 3 meters (dBµV/m)	69.45
Occupied Bandwidth 99%	133.4 kHz
Type of Modulation	FSK (Manchester encoded)
Emission Designator	133KF7D
Transmitter Spurious (worst case) at 3 meters	37.44 QPK @ 805MHz
Frequency Tolerance %,Hz, ppm	Better than 100 ppm
Microprocessor Model #	MSP430F2410
Antenna: Detachable / Non-detachable	Non-detachable
Antenna: Type	Integral / Wire
Antenna Gain (Peak)	N/A
FCC Rule Part	Title 47 Part 95
Modular Filing	No
RF Exposure Type	Portable / Implant
Receiver Spurious (worst case) at 3 meters	51.44 PK @ 4.96 GHz (noise floor)

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3.3 Modifications Incorporated In the EUT for Compliance Purposes

None noted at time of test.

3.4 Deviations & Exclusions from Test Specifications

None noted at time of test.

4.0 Conditions of Test

Environmental:

Temperature: 20-25° C
Relative Humidity: 30-60%
Atmospheric Pressure: 86-106 kPa

Voltage:

3.6VDC from battery internal to device

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5.0 Additional Information

The EUT was programmed from a laptop computer with an Angel Medical proprietary control program and associated equipment. Unit was set to maximum power setting of FF with a continuous modulated signal for testing.

Human Torso Simulator:

The EUT was tested in the human torso simulator and tissue substitute material as specific in FCC KDB 617965 and OET Bulletin Supplement C (Ed. 01-01).

The EUT was placed in a plexi-glass container having the dimensions 30cm diameter by 76 cm height with a sidewall thickness of 0.635cm. A positioning system made of plastic and nylon hardware was used to position the EUT centered in the container at a height of 1.5m off the ground plane.

The solution consisted of (by weight) 51.16% distilled water, 46.78% sugar, 1.49% salt, 0.52% HEC, and 0.05% bactericide. With 8 gallons of water (66.8 lbs), 61.08 lbs of sugar, 1.95 lbs of salt, 0.68 lbs of HEC, 0.07 lbs bactericide the solution has a dielectric constant of 58 and a conductivity of 0.83 S/m at 400MHz.

6.0 Test Equipment

All test equipment is calibrated by a calibration laboratory accredited by A2LA to the requirements of ISO 17025. For a complete list of test equipment and calibration dates, see Appendix A. Unless otherwise noted, resolution bandwidth of measuring instrument used during testing for given frequency range, see below. For average measurements above 1000MHz the video bandwidth is set at 10Hz.

Frequency Range	Resolution Bandwidth
9 kHz – 150 kHz	200 Hz
150 kHz – 30 MHz	9 kHz
30 MHz – 1000 MHz	120 kHz
Above 1000 MHz	1 MHz

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7.0 Conformance Summary

The EUT was found to MEET the requirements as described within the specification of FCC Title 47, CFR Part 95 (2011) Subpart I and 15.109.

If some emissions are seen to be within 3 dB of their respective limits:

As these levels are within the tolerances of the test equipment and site employed, there is a possibility that this unit, or a similar unit selected out of production may not meet the required limit specification if tested by another agency.

LS Research, LLC certifies that the data contained herein was taken under conditions that meet or exceed the requirements of the test specifications. The results in this Test Report apply only to the item(s) tested on the above-specified dates. Any modifications made to the EUT subsequent to the indicated test date(s) will invalidate the data herein, and void this certification.

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Appendix A – Test Equipment



Date : 18-Oct-2012 Type Test : Radiated Emissions Job # : C-1570
Prepared By: Adam Customer : Angel Medical Systems Quote #: 312257

No.	Asset #	Description	Manufacturer	Model #	Serial #	Cal Date	Cal Due Date	Equipment Status
1	EE 960156	100kHz-1GHz Analog Signal Generator	Agilent	N5181A	MY49060062	6/30/2012	6/30/2013	Active Calibration
2	EE 960157	3Hz-13.2GHz Spectrum Analyzer	Agilent	E4445A	MY48250225	6/29/2012	6/29/2013	Active Calibration
3	EE 960158	RF Preselector	Agilent	N9039A	MY46520110	6/29/2012	6/29/2013	Active Calibration
4	AA 960078	Log Periodic Antenna	EMCO	93146	9701-4855	11/15/2011	11/15/2012	Active Calibration
5	AA 960005	Biconical Antenna	EMCO	93110B	9601-2280	6/26/2012	6/26/2013	Active Calibration
6	AA 960007	Double Ridge Horn Antenna	EMCO	3115	9311-4138	5/16/2012	5/16/2013	Active Calibration
7	EE 960147	Pre-Amp	Adv. Micro	WLA612	123101	1/6/2012	1/6/2013	Active Calibration

Project Engineer: Adam O. Meyer

Quality Assurance: [Signature]

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Appendix B – Test Data
B.1 – Radiated Emissions

Rule Part(s)	Part 95 Subpart I (MedRadio) / Part 95 Subpart E (Technical Regulations) / 15.109			
Measurement Procedure	ANSI C63.4 - 2003			
Test Location	LS Research, LLC - FCC Listed 3 meter Semi-Anechoic Chamber			
Test Distance	3 meters : 30 - 5000 MHz			
EUT Placement	150 cm height in body phantom and tissue simulation fluid			
Frequency Range of Measurement	Biconical: 30-300 MHz	Log Periodic Dipole Array: 300-1000 MHz	Double-Ridged Waveguide Horn: 1-18 GHz	Standard Gain Horn: 18-25GHz
Measurement Detectors	30-1000MHz Peak Detector Quasi-Peak Detector RBW: 120 kHz VBW: 300 kHz		1 - 25 GHz: Peak Detector RBW : 1MHz VBW: 3MHz (Peak Measurement) VBW: 10Hz (Average Measurement)	
Description of Measurement	1) The antenna, cable, pre-amp, and other necessary measurement system correction factors are loaded onto the EMI receiver / spectrum analyzer when the measurements are preformed. The data is gathered and reported as the corrected values. 2) The EUT is placed on a non-conductive pedestal centered on a turn-table in the test location with the antenna at the test distance from the EUT 3) Maximum radiated RF emissions are determined by rotation of azimuth and scanning the sense antenna between 1 and 4 meters in height using both horizontal and vertical antenna polarities. Maximized levels are manually noted at degree values of azimuth and at sense antenna height.			
Example Calculations	Reported Measurement data = Raw receiver measurement + Antenna Correction Factor + Cable factor (dB) - amplification factor (when applicable) + Additional factor (when applicable)			

FCC Part 95.635(d) (1) Limits:

Frequency (MHz)	3 m Limit ($\mu\text{V/m}$)	3 m Limit ($\text{dB}\mu\text{V/m}$)	Type
30-88	100	40.0	Quasi-Peak
88-216	150	43.5	Quasi-Peak
216-960	200	46.0	Quasi-Peak
Above 960	500	54.0	Average (>1 GHz)

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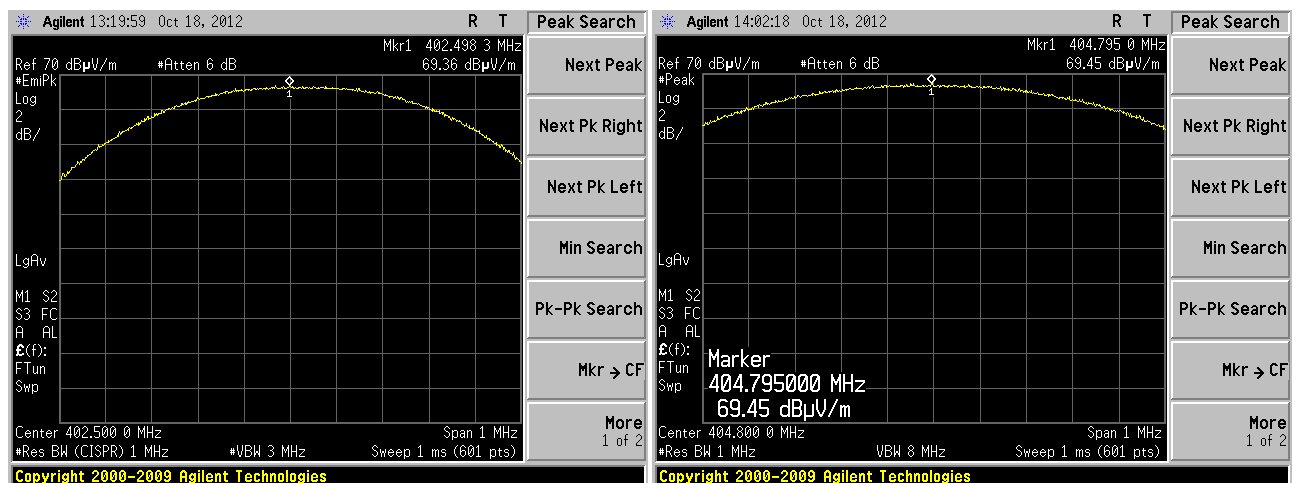
B.1.1 – Radiated Fundamental

Manufacturer	Angel Medical Systems
Date	10-18-2012
Operator	Adam A
Temp. / R.H.	20 - 25° C / 30-60% R.H.
Test Voltage	3.6 VDC battery internal to device
Test Location	LS Research, LLC - FCC Listed 3 meter Semi-Anechoic Chamber
Rule Part	95.639(f)(1) / 95.627(g)(3) / 95.627(i) / 95.627(a)(6)(i)
Measurement Procedure	ANSI C63.4 - 2003
Test Distance	3 meter (1-5 GHz)
EUT Placement	150 cm height in body phantom and tissue simulation fluid
Detectors	RBW 1MHz; Peak (VBW 3MHz); Average (VBW 10Hz)
Additional Notes	1) Tested in the worst case of continuous transmit modulated mode for radiated fundamental with low and high channels and EUT Antenna in three orthogonal positions with all channels at maximum power. 2) Worst case orientation reported. 3) EIRP limit expressed as 18.2 mV/m (95.627(g)(3)) is equivalent to 85.2 dBμV/m at 3m.

Table:

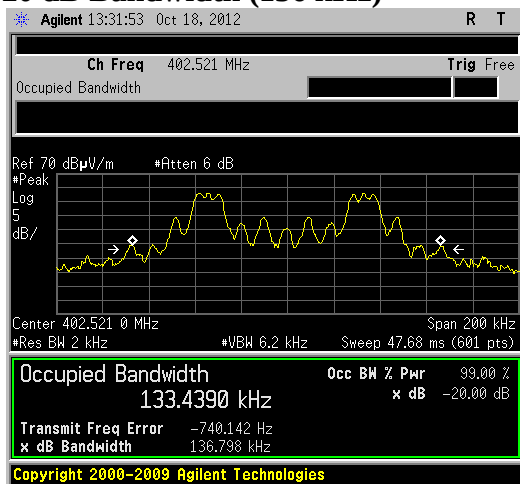
Channel	Frequency (MHz)	Antenna Polarization	EUT Position	Antenna Height (cm)	Table Azimuth (degrees)	Reading (dB μ V/m)	Limit (dB μ V/m)	Margin (dB)
0	402.5	Vertical	Horizontal	179	350	69.36	85.2	15.8
4	404.8	Vertical	Horizontal	179	350	69.45	85.2	15.8

Plot:

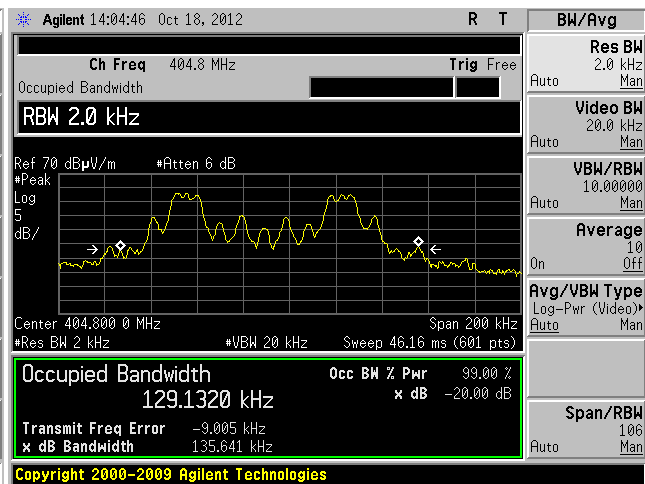


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20 dB Bandwidth (136 kHz)

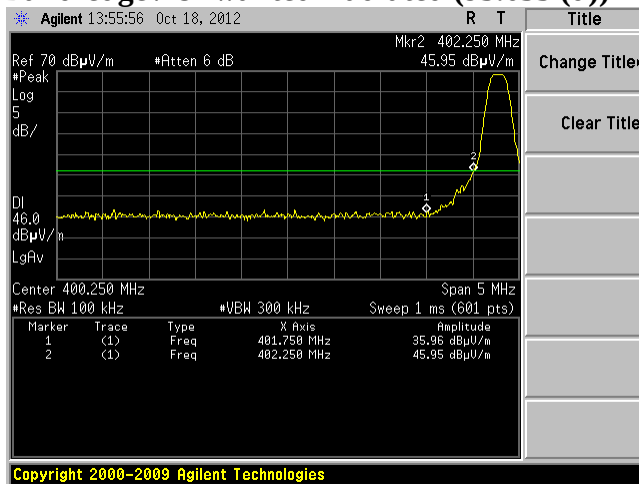


Low Channel

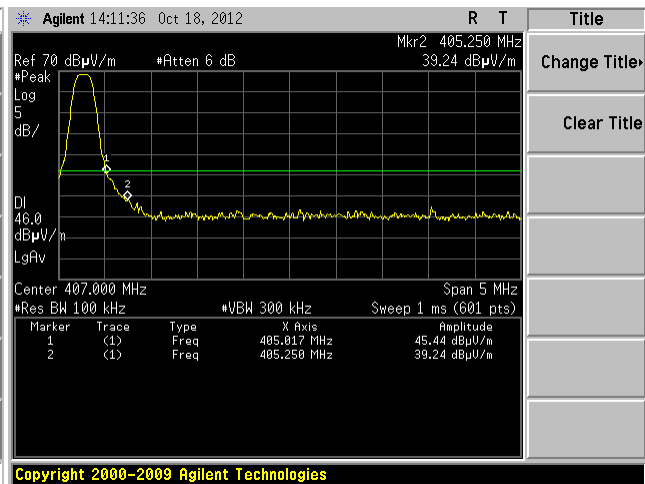


High Channel

Band-edge / Unwanted Radiated (95.635 (d))



Low Channel



High Channel

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B.1.2 – Radiated Harmonics

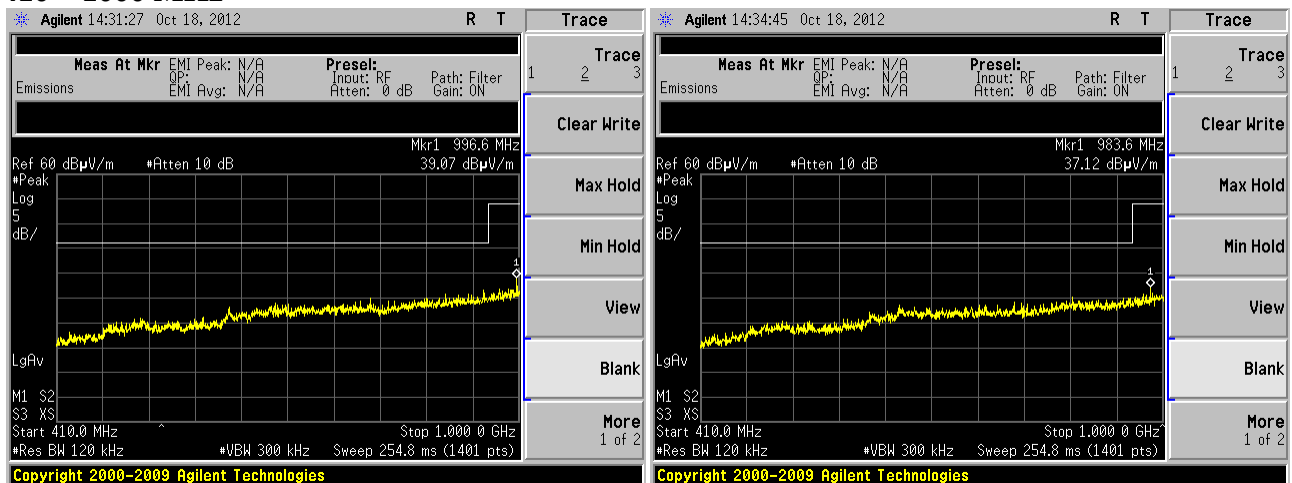
Manufacturer	Angel Medical Systems
Date	10-18-2012
Operator	Adam A
Temp. / R.H.	20 - 25° C / 30-60% R.H.
Test Voltage	3.6 VDC battery internal to device
Test Location	LS Research, LLC - FCC Listed 3 meter Semi-Anechoic Chamber
Rule Part	95.635(d)
Measurement Procedure	ANSI C63.4 - 2003
Test Distance	3 meter (30 MHz -5 GHz)
EUT Placement	150 cm height in body phantom and tissue simulation fluid
Detectors	Below 1GHz: RBW 120kHz VBW 300kHz Peak and Quasi-Peak Above 1 GHz: RBW 1MHz; Peak (VBW 3MHz); Average (VBW 10Hz)
Additional Notes	4) Tested in the worst case of continuous transmit modulated mode for radiated harmonics with low and high channels and EUT Antenna in three orthogonal positions with all channels at maximum power. 5) Worst case orientation reported. 6) All other emissions at least 20 dB below limit or below system noise floor.

Table:

Channel	Frequency (MHz)	Antenna Polarization	EUT Position	Antenna Height (cm)	Table Azimuth (degrees)	Peak Reading (dBμV/m)	QP Reading (dBμV/m)	Limit (dBμV/m)	Margin (dB)
0	805	Horizontal	Flat	109	0	40.06	37.44	46	8.6
4	809.6	Horizontal	Flat	109	0	39.71	36.68	46	9.3

Plots showing peak and average emissions:

410 – 1000 MHz

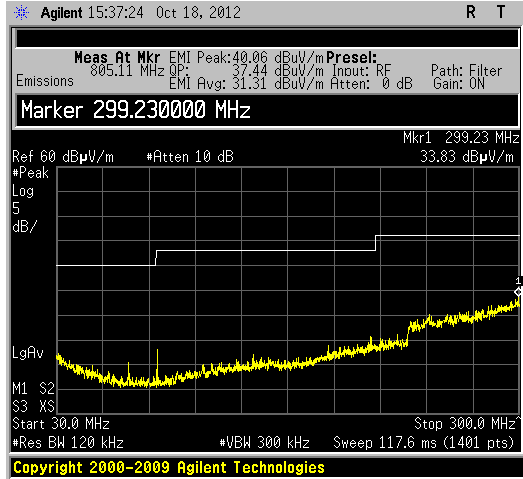


Vertical

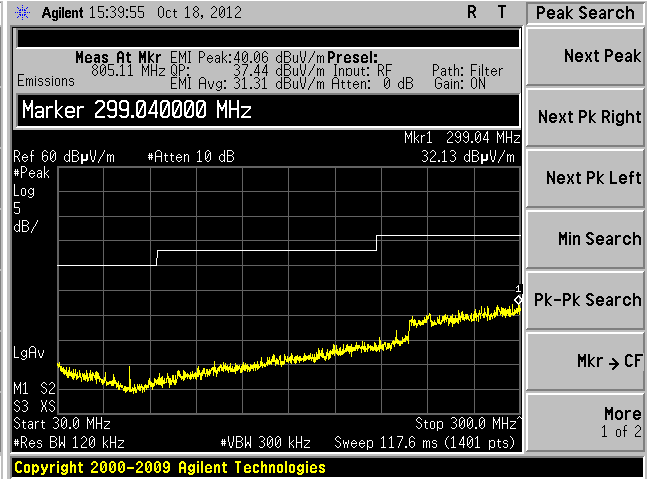
Horizontal

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30-300 MHz

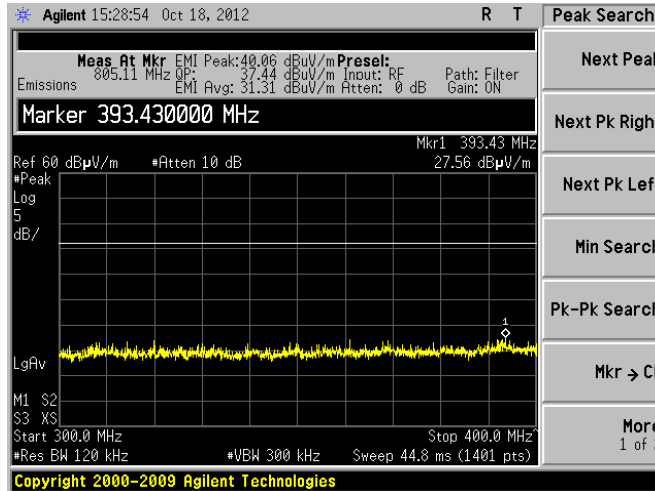


Horizontal



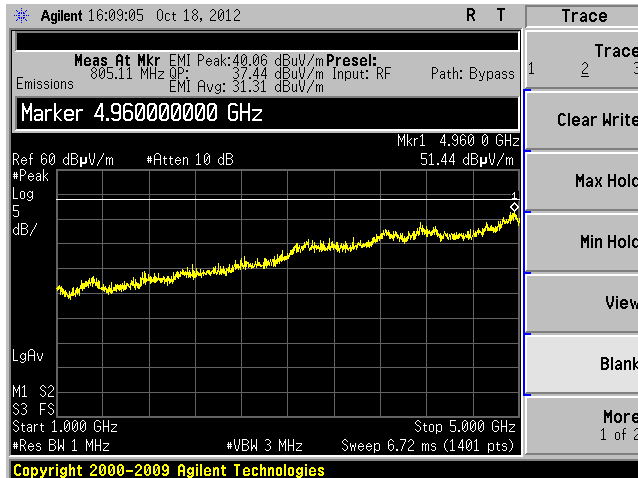
Vertical

300-400 MHz

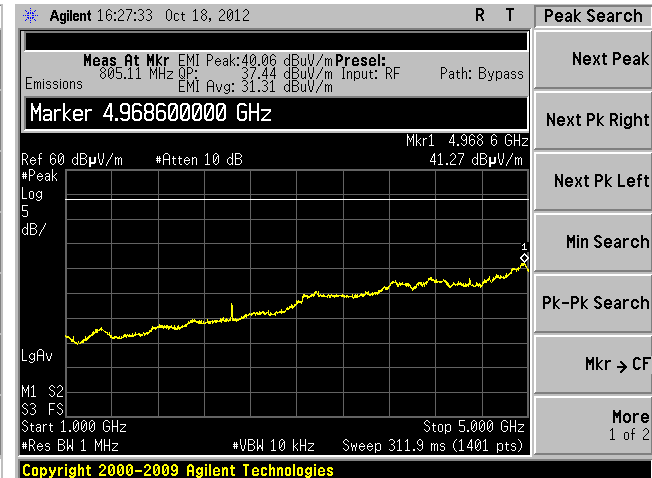


Horizontal and Vertical

1000 – 5000 MHz



Horizontal and Vertical (Peak)



Horizontal and Vertical (Average)

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B.1.3 – Frequency Stability

Manufacturer	Angel Medical Systems
Date	10-18-2012
Operator	Adam A
Temp. / R.H.	20 - 25° C / 30-60% R.H.
Test Voltage	3.6 VDC from a bench supply
Test Location	LS Research, LLC – Temperature Chamber
Rule Part	95.627(e)
Measurement Procedure	ANSI C63.4 - 2003
Test Distance	N/A
EUT Placement	Tested in temperature chamber with EUT not in tissue solution
Detectors	Below 1GHz: RBW 120kHz VBW 300kHz Peak and Quasi-Peak Above 1 GHz: RBW 1MHz; Peak (VBW 3MHz); Average (VBW 10Hz)
Additional Notes	1) Utilized a near field antenna for measurements of frequency. 2) Serial number JH3000029 with metal shell cut open to access battery terminals

	Frequency (Hz) @ 25° C	Frequency (Hz) @ 37° C	Frequency (Hz) @ 45° C	Max Delta (Hz)
VDC				
3.6	402519082	402518917	402518915	167
3.0	402519092	402518917	402518902	190

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B.2.1 – Receive Mode Radiated Emissions

Manufacturer	Angel Medical Systems
Date	10-18-12
Operator	Adam A
Temperature	20 - 25° C
Humidity	30 – 60%
Test Voltage	3.6 VDC battery internal to device
Test Location	LS Research, LLC - FCC Listed 3 meter Semi-Anechoic Chamber
Test Distance	3 meter (30 MHz to 5 GHz)
EUT Placement	150 cm height in body phantom and tissue simulation fluid
Measurements	Final
Detectors	Peak, Quasi-Peak, Average
Additional Notes	1) Emissions 30-5000MHz tested in receive mode on low and high channels in three orientations. 2) No emissions found. Noise floor reported. 3) Peak measurements compared to quasi-peak limits.

Table

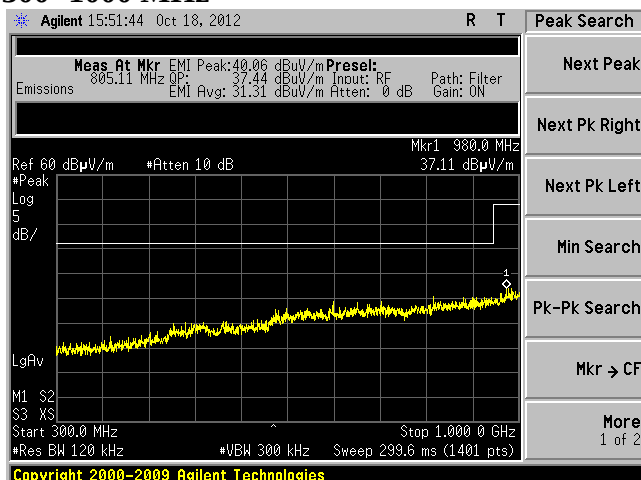
Frequency (MHz)	Height (cm)	Azimuth (degree)	Peak Reading (dBµV/m)	Quasi Peak Limit (dBµV/m)	Margin (dB)	Antenna Polarity	EUT orientation	Comment
299.0	100	0	32.13	46	13.9	Vertical	Flat	1
299.2	100	0	33.83	46	12.2	Horizontal	Flat	1
980	100	0	37.11	54	16.9	Horizontal	Vertical	1
972	100	0	36.69	54	17.3	Vertical	Vertical	1
4960	100	0	51.44	74	22.6	Vertical	Horizontal	1
4954.3	100	0	41.36	54	12.6	Horizontal	Horizontal	1,2

Note 1: No emission from EUT found. Noise floor reported.

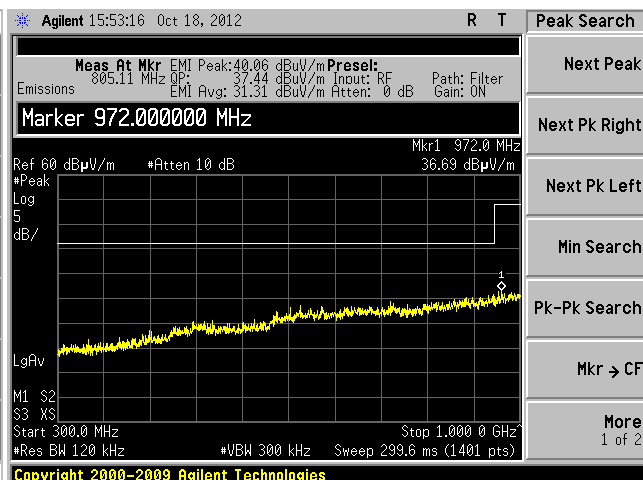
Note 2: Average reading and limit.

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300 -1000 MHz

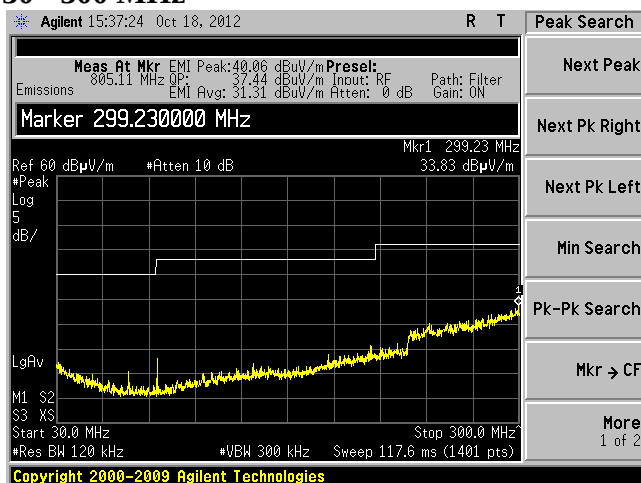


Horizontal

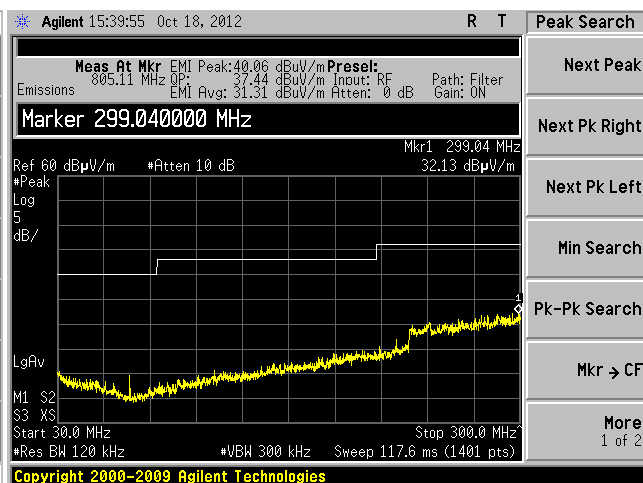


Vertical

30 - 300 MHz

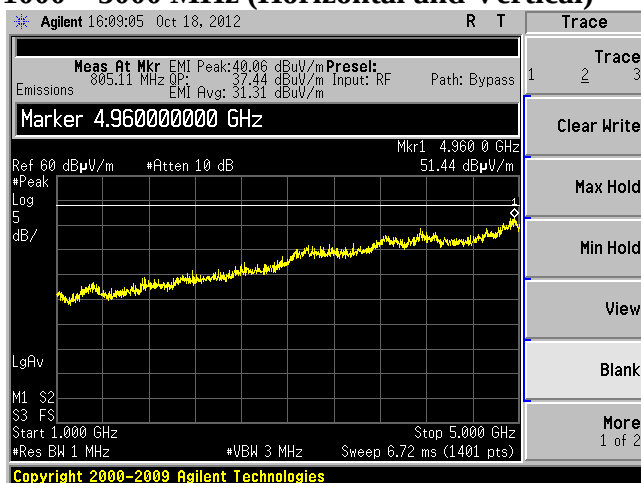


Horizontal

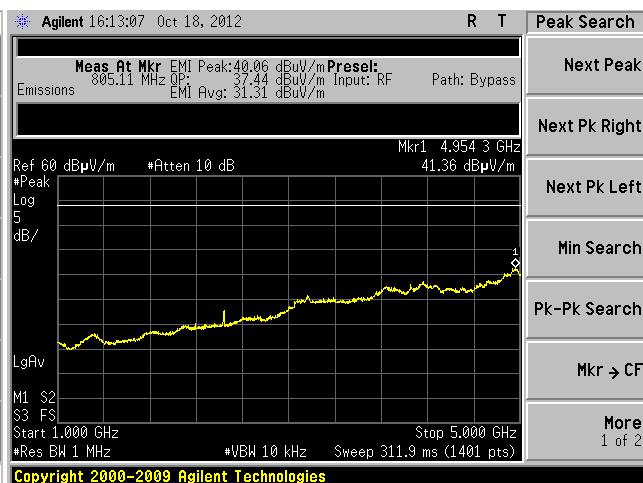


Vertical

1000 – 5000 MHz (Horizontal and Vertical)



Peak



Average

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Appendix C - Uncertainty Summary

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	4.82 dB
Radiated Emissions	3-Meter Chamber, Log Periodic Antenna	4.88 dB
Radiated Emissions	3-Meter Chamber, Horn Antenna	4.85 dB
Radiated Emissions	10-Meter OATS, Biconical Antenna	4.32 dB
Radiated Emissions	10-Meter OATS, Log Periodic Antenna	3.63 dB
Absolute Conducted Emissions	Agilent PSA/ESA Series	1.38 dB
AC Line Conducted Emissions	Shielded Room/EMCO LISN	3.20 dB
Radiated Immunity	3 Volts/Meter in 3-Meter Chamber	2.05 Volts/Meter
Conducted Immunity	3 Volts level	2.33 V
EFT Burst, Surge, VDI	230 VAC	54.4 V
ESD Immunity	Discharge at 15kV	3200 V
Temperature/Humidity	Thermo-hygrometer	0.64° / 2.88 %RH

Appendix D - References

Publication	Year	Title
FCC CFR Parts 0-15	2011	Code of Federal Regulations – Telecommunications
FCC CFR Part 95	2011	Code of Federal Regulations – Telecommunications
ANSI C63.4	2003	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.
FCC KDB 617965	2011	Part 95 MICS, Human Torso Simulator and Testing Technique, Simulator and Tissue Substitute Material
FCC OET Bulletin 65 Supplement C	Edition 01-01	Evaluating Compliance with FCC Guidelines for Human Exposure to Radiofrequency Electromagnetic Fields

END OF REPORT

Date	Version	Comments	Person
10-29-12	V0	Initial Draft Release	Adam A
11/2/12	V0	First Review	SDR
11-6-12	V1	Minor Changes	Adam A

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