Emissions
Test Report

EUT Name: Opel Surgical System

Model No.: O-PEL

CFR 47 Part 15.209:2015 and RSS-210:2010

Prepared for:

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Revisions

Revision No.	Date MM/DD/YYYY	Reason for Change	Author
0	11/17/2015	Original Document	N/A

Note: Latest revision report will replace all previous reports.

Statement of Compliance

Manufacturer:	Precise Light Surgical 310 W. Hamilton Ave. Suite 210. Campbell, CA 95008 U.S.A. 831-539-3323
Requester / Applicant:	Ken Arnold
Name of Equipment:	Opel Surgical System
Model No.	O-PEL
Type of Equipment:	Industrial, Scientific, or Medical (ISM)
Application of Regulations:	CFR 47 Part 15.209:2015 and RSS-210:2010
Test Dates:	November 04, 2015 to November 13, 2015

Guidance Documents:

Emissions: ANSI C63.10: 2013

Test Methods:

Emissions: ANSI C63.10: 2013

The electromagnetic compatibility test and documented data described in this report has been performed and recorded by TUV Rheinland, in accordance with the standards and procedures listed herein. As the responsible authorized agent of the EMC laboratory, I hereby declare that the equipment described above has been shown to be compliant with the EMC requirements of the stated regulations and standards based on these results. If any special accessories and/or modifications were required for compliance, they are listed in the Executive Summary of this report.

This report must not be used to claim product endorsement by A2LA or any agency of the U.S. Government. This report contains data that are not covered by A2LA accreditation. This report shall not be reproduced except in full, without the written authorization of TUV Rheinland of North America.

Suresh Kondapalli		David Spencer	
Test Engineer	Date 11/17/2015	A2LA Signatory	Date 11/17/2015

Industry Canada

Testing Cert #3331.02 **US5254** **2932M-1**

1 Executive Summary

1.1 Scope

This report is intended to document the status of conformance with the requirements of the CFR 47 Part 15.209:2015 and RSS-210:2010 based on the results of testing performed on November 04, 2015 through November 13, 2015 on the Opel Surgical System Model O-PEL manufactured by Precise Light Surgical. This report only applies to the specific samples tested under the stated test conditions. It is the responsibility of the manufacturer to assure that additional production units of this model are manufactured with identical or EMI equivalent electrical and mechanical components. This report is further intended to document changes and modifications to the EUT throughout its life cycle. All documentation will be included as a supplement.

1.2 Purpose

Testing was performed to evaluate the EMC performance of the EUT in accordance with the applicable requirements, procedures, and criteria defined in the application of regulations and application of standards listed in this report.

1.3 Summary of Test Results

Table 1: Summary of Test Results

Test	Test Method ANSI C63.4	Test Parameters (from Standard)	Result
Transmitter Spurious Emissions	CFR47 15.209, RSS-GEN Sect.8.9	Class A*	**Complied**
Restricted Bands of Operation	CFR47 15.205, RSS 210 Sect.2.2	Class B	**Complied**
AC Power Conducted Emissions	CFR47 15.207, RSS-GEN Sect.8.8	Class B	**Complied**
RF Exposure	CFR47 Part 1.1310, RSS-GEN Sec 3.2	General Population	**Complied**
Occupied Bandwidth	RSS Gen Sec 6.6	No limit	**For information only**
Frequency Stability	RSS 210 Sect. 6.11	NA/No limit	**Complied**
Voltage Variation	RSS 210 Sect. 6.11	NA/ No Limit	**Complied**

*Note: Host device is class “A” product. Please see the manufacturer’s declaration at page 48

1.4 Special Accessories

No special accessories were necessary in order to achieve compliance.

1.5 Equipment Modifications

None.

2 Laboratory Information

2.1 Accreditations & Endorsements

2.1.1 US Federal Communications Commission

TUV Rheinland of North America at 1279 Quarry Lane, Ste. A., Pleasanton, CA 94566, is accredited by the commission for performing testing services for the general public on a fee basis. These laboratory test facilities have been fully described in reports submitted to and accepted by the FCC (FRN # US5254). The laboratory scope of accreditation includes: Title 47 CFR Parts 15, 18, and 90. The accreditation is updated every 3 years.

2.1.2 ILAC / A2LA

TUV Rheinland of North America is accredited by the A2LA Accreditation Program, which is administered under the auspices of the National Institute of Standards and Technology. The laboratory has been assessed and accredited in accordance with ISO Guide 17025:2005 and ISO 9002 (Testing Cert #3331.02). The scope of laboratory accreditation includes emission and immunity testing. The accreditation is updated annually.

2.1.3 Canada – Industry Canada

INDUSTRY CANADA

TUV Rheinland of North America at the 1279 Quarry Ln, Pleasanton, CA 94566 address is accredited by Industry Canada for performing testing services for the general public on a fee basis. This laboratory test facilities have been fully described in reports submitted to and accepted by Industry Canada (File Number 2932M). This reference number is the indication to the Industry Canada Certification Officers that the site meets the requirements of RSS 212, Issue 1 (Provisional). The accreditation is updated every 3 years.

2.1.4 Japan – VCCI

The Voluntary Control Council for Interference by Information Technology Equipment (VCCI) is a group that consists of Information Technology Equipment (ITE) manufacturers and EMC test laboratories. The purpose of the Council is to take voluntary control measures against electromagnetic interference from Information Technology Equipment, and thereby contribute to the development of a socially beneficial and responsible state of affairs in the realm of Information Technology Equipment in Japan. TUV Rheinland of North America at 1279 Quarry Lane, Pleasanton, CA 94566 has been assessed and approved in accordance with the Regulations for Voluntary Control Measures. (Registration No. A-0031).

2.2 Test Facilities

All of the test facilities are located at 1279 Quarry Lane, Ste. A, Pleasanton, California 94566, USA. The 2305 Mission College, Santa Clara, 95054, USA location is considered a Pleasanton annex.

2.2.1 Emission Test Facility

The Semi-Anechoic chamber and AC Line Conducted measurement facility used to collect the radiated and conducted data has been constructed in accordance with ANSI C63.7:1992. The site has been measured in accordance with and verified to comply with the theoretical normalized site attenuation requirements of ANSI C63.4:2009, at test distances of 3 and 5 meters. The site is listed with the FCC and accredited by A2LA (Testing Cert #3331.02). The 3/5-meter semi-anechoic chamber used to collect the radiated data has been verified to comply with the theoretical normalized site attenuation requirements of ANSI C63.4:2009, at test distances of 3 meters and 5 meters. A report detailing this site can be obtained from TUV Rheinland of North America.

2.2.2 Immunity Test Facility

ESD, EFT, Surge, PQF: These tests are performed in an environmentally controlled room with a 3.7 m x 4.8 m x 3.175 mm thick aluminum floor connected to PE ground.

For ESD testing, tabletop equipment is placed on an insulated mat with a surface resistivity of 10^9 Ohms/square on a 1.6 m x 0.8 m x 0.8 m high non-conductive table with a 3.175 mm aluminum top (Horizontal Coupling Plane). The HCP is connected to the main ground plane via a low impedance ground strap through two 470-kΩ resistors. The Vertical Coupling Plane consists of an aluminum plate 50 cm x 50 cm x 3.175 mm thick. The VCP is connected to the main ground plane via a low impedance ground strap through two 470-kΩ resistors.

For EFT, Surge, PQF, the HCP and VCP are removed.

RF Field Immunity testing is performed in a 7.3m x 4.3m x 4.1m anechoic chamber.

RF Conducted and Magnetic Field Immunity testing is performed on a 4.8m x 3.7m x 3.175mm thick aluminum ground plane.

All test areas allow a minimum distance of 1 meter from the EUT to walls or conducting objects.

2.3 Measurement Uncertainty

Two types of measurement uncertainty are expressed in this report, per *ISO Guide To The Expression Of Uncertainty In Measurement*, 1st Edition, 1995.

The Combined Standard Uncertainty is the standard uncertainty of the result of a measurement when that result is obtained from the values of a number of other quantities; it is equal to the positive square root of the sum of the variances or co-variances of these other quantities, weighted according to how the measurement result varies with changes in these quantities. The term *standard uncertainty* is the result of a measurement expressed as a standard deviation.

The Expanded Uncertainty defines an interval about the result of a measurement that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the measured. The fraction may be viewed as the coverage probability or level of confidence of the interval.

2.3.1 Sample Calculation – radiated & conducted emissions

The field strength is calculated by subtracting the Amplifier Gain and adding the Cable Loss and Antenna Correction Factor to the measured reading. The basic equation is as follows:

Field Strength (dBμV/m) = RAW - AMP + CBL + ACF

Where: RAW = Measured level before correction (dBμV)

AMP = Amplifier Gain (dB)

CBL = Cable Loss (dB)

ACF = Antenna Correction Factor (dB/m)

$$\mu V/m = 10^{\frac{dB\mu V/m}{20}}$$

Sample radiated emissions calculation @ 30 MHz

Measurement +Antenna Factor–Amplifier Gain+Cable loss=Radiated Emissions (dBuV/m)

25 dBuV/m + 17.5 dB – 20 dB + 1.0 dB = 23.5 dBuV/m

2.3.2 Measurement Uncertainties

Table 2: Summary of Uncertainties

Per CISPR 16-4-2	**U_{lab}**	**U_{cispr}**
Radiated Disturbance @ 10 meters		
30 – 1,000 MHz	2.25 dB	4.51 dB
Radiated Disturbance @ 3 meters		
30 – 1,000 MHz	2.26 dB	4.52 dB
1 – 6 GHz	2.12 dB	4.25 dB
6 – 18 GHz	2.47 dB	4.93 dB

Note: U_{lab} is the calculated Combined Standard Uncertainty
U_{cispr} is the measurement uncertainty requirement per CISPR 16.

Measurement Uncertainty Immunity

The estimated combined standard uncertainty for ESD immunity measurements is ± 8.2%.
The estimated combined standard uncertainty for radiated immunity measurements is ± 4.10 dB.
The estimated combined standard uncertainty for conducted immunity measurements with CDN is ± 3.66 dB
The estimated combined standard uncertainty for power frequency magnetic field immunity is ± 11.6%.
The estimated combined standard uncertainty for harmonic current and flicker measurements is ± 5.0%.

Measurement Uncertainty – Radio Testing

The estimated combined standard uncertainty for frequency error measurements is ± 3.88 Hz
The estimated combined standard uncertainty for carrier power measurements is ± 1.59 dB.
The estimated combined standard uncertainty for adjacent channel power measurements is ± 1.47 dB.
The estimated combined standard uncertainty for modulation frequency response measurements is ± 0.46 dB.
The estimated combined standard uncertainty for transmitter conducted emission measurements is ± 4.01 dB

The expanded uncertainty at a level of 95% confidence is obtained by multiplying the combined standard uncertainty by a coverage factor of 2. Compliance criteria are not based on measurement uncertainty.

2.4 Calibration Traceability

All measurement instrumentation is traceable to the National Institute of Standards and Technology (NIST). Measurement method complies with ANSI/NCSL Z540-1-1994 and ISO Guide 17025:2005.

3 Product Information

3.1 Product Description

The Opel Surgical System is a tissue resection system utilizing light at a wavelength of approximately 2ums to cut and coagulate tissue. The system consists of a laser console, an activation switch (foot switch), a power cord and a delivery device.

3.2 Equipment Configuration

A description of the equipment configuration is given in Test Plan Section. The EUT was tested as called for in the test standard and was configured and operated in a manner consistent with its intended use. The EUT was connected to rated power and allowed to reach intended operating conditions. The placement of the EUT system components was guided by the test standard and selected to represent typical installation conditions.

In the case of an EUT that can operate in more than one configuration, preliminary testing was performed to determine the configuration that produced maximum radiation.

The final configuration was selected to produce the worst case radiation for emissions testing and to place the EUT in the most susceptible state for immunity testing.

3.3 Operating Mode

A description of the operation mode is given in Test Plan Section. In the case of an EUT that can operate in more than one state, preliminary testing was performed to determine the operating mode that produced maximum radiation.

The final operating mode was selected to produce the worst case radiation for emissions testing and to place the EUT in the most susceptible state for immunity testing.

3.4 Unique Antenna Connector

An intentional radiator shall be designed to ensure that no antenna other than that furnished by the responsible party shall be used with the device. The use of a permanently attached antenna or of an antenna that uses a unique coupling to the intentional radiator shall be considered sufficient to comply with the provisions of this section. The manufacturer may design the unit so that a broken antenna can be replaced by the user, but the use of a standard antenna jack or electrical connector is prohibited. This requirement does not apply to carrier current devices or to devices operated under the provisions of CFR47 Parts 15.211, 15.213, 15.217, 15.219, or 15.221.

3.4.1 Results

The O-PEL uses the internal antenna

- Antenna Type: Loop antenna; Diameter 1.7 inch 335uH
- Antenna Model: RFID Antenna o-pel A

4 Emissions

Testing was performed in accordance with CFR 47 Part 15.209:2015 and RSS-210 Section 2.5.1. These test methods are listed under the laboratory's A2LA Scope of Accreditation. This test measures the levels emanating from the EUT, thus evaluating the potential for the EUT to cause radio frequency interference to other electronic devices. Procedures described in ANSI C63.10: 2013 were used.

4.1 Carrier Field Strength Requirements

The RF fundamental field strength requirement is the power radiated in the direction of the maximum level under specified conditions of measurements in the presence of modulation.

The RF fundamental field strengths shall not exceed CFR47 Part 15.209 (a):2015 and RSS-Gen Section 8.9, Tables 4 & 5

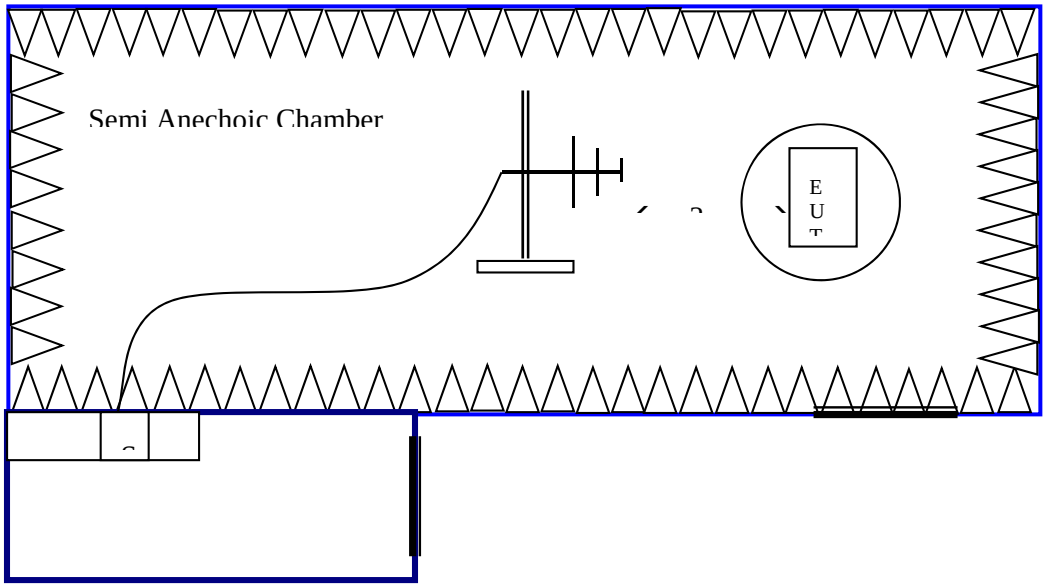
Frequency (MHz)	Field Strength (microvolts/meter)	Measurement Distance (meters)
0.009-0.490	2400/F (kHz)	300
0.490-1.705	24000/F (kHz)	30
1.705-30.0	30	30
30-88	100 **	3
88-216	150 **	3
216-960	200 **	3
Above 960	500	3

The field strength of emission at 125KHz shall be less than 17.9dBuV/m at 300 meter distance; or 105dBuV/m at 3 meter.

4.1.1 Test Method

The radiated method was used to measure the field strength of the fundamental signal according to ANSI C63.10:2009 Section 6.3. The measurement was performed with modulation. The worst result is indicated below.

Test Setup:



4.1.2 Results

As originally tested, the EUT was found to be compliant to the requirements of the test standard(s).

Table 3: RF Fundamental Field Strength – Test Results

Test Conditions: Radiated Measurement, Normal Temperature and Voltage only							
Antenna Type: Loop Antenna				**Power Setting:** Max			
Signal State: Modulated				**Duty Cycle:** 100 %			
Ambient Temp.: 22 °C				**Relative Humidity:**31 %			
Operating Frequency	**Test Results**						
	Measured Level Pk [dBuV/m]	**Measured Level Avg [dBuV/m]**	**Loop Position**	**Table [degree]**	**Antenna [cm]**	**Limit [dBuV/m]**	**Margin [dB]**
0.125	73.53	72.48	0	362	100	105.66	-34.37
0.125	68.49	68.25	90	64	144	105.66	-37.17
Note: 1. Measurements were taken at 3 meter distance, and the limit was extrapolated accordingly.							

Determination of Orientation for highest Fundamental emission

The Opel Surgical System Model O-PEL is Table top device. The device was evaluated only possible orientation i.e Table top position.

See more details in Internal Photos document and setup photos para 6.1

4.1 Occupied Bandwidth

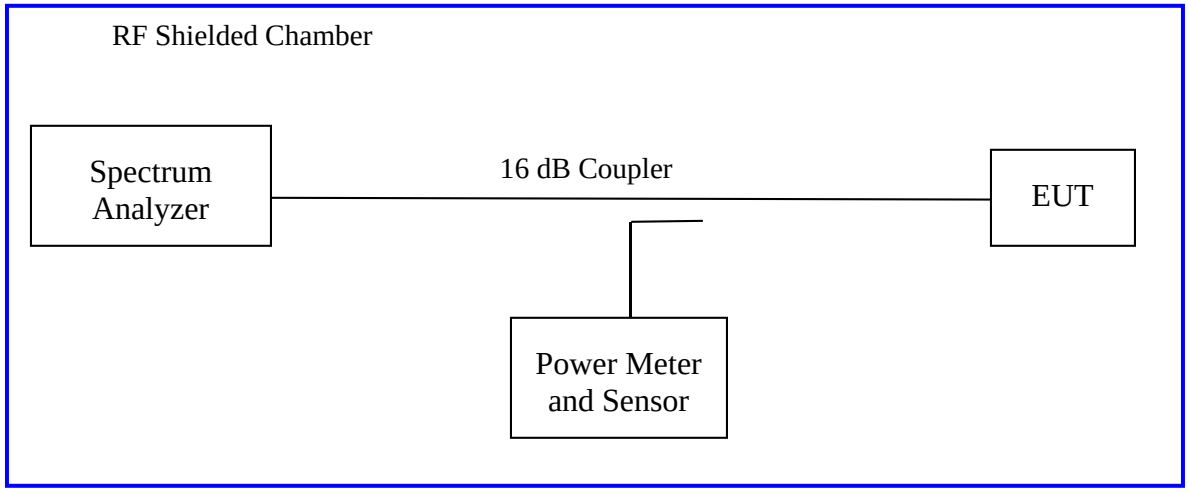
The occupied bandwidth is measured at an amplitude level reduced from the reference level by a specified ratio. The reference level is the level of the highest amplitude signal observed from the transmitter at the fundamental frequency.

Occupied bandwidth was performed by coupling the output of the EUT to the input of a spectrum Analyzer.

4.1.1 Test Method

The conducted method was used to measure the 99% Occupied bandwidth. The measurement was performed with modulation per CFR47 15.247(a) (1) 2015 and RSS Gen Sect 6.6: 2010. Initial investigation was performed at different data rates. The worst sample result indicated below.

Test Setup:



4.1.2 Results

As originally tested, the EUT was found to be compliant to the requirements of the test standard(s).

Table 4: 99% Occupied Bandwidth – Test Results

Test Conditions: Conducted Measurement, Normal Temperature and Voltage only			
Antenna Type: Internal Attached		**Power Setting:** See test plan	
Max. Antenna Gain: NA		**Signal State:** Modulated	
Ambient Temp.: 21 °C		**Relative Humidity:**33%	
Occupied Bandwidth (KHz)			
Freq. (KHz)	**20dB BW KHz**	**Occupied BW (99%) KHz**	**Results**
125	0.940	1.091	For information only
Notes: None			

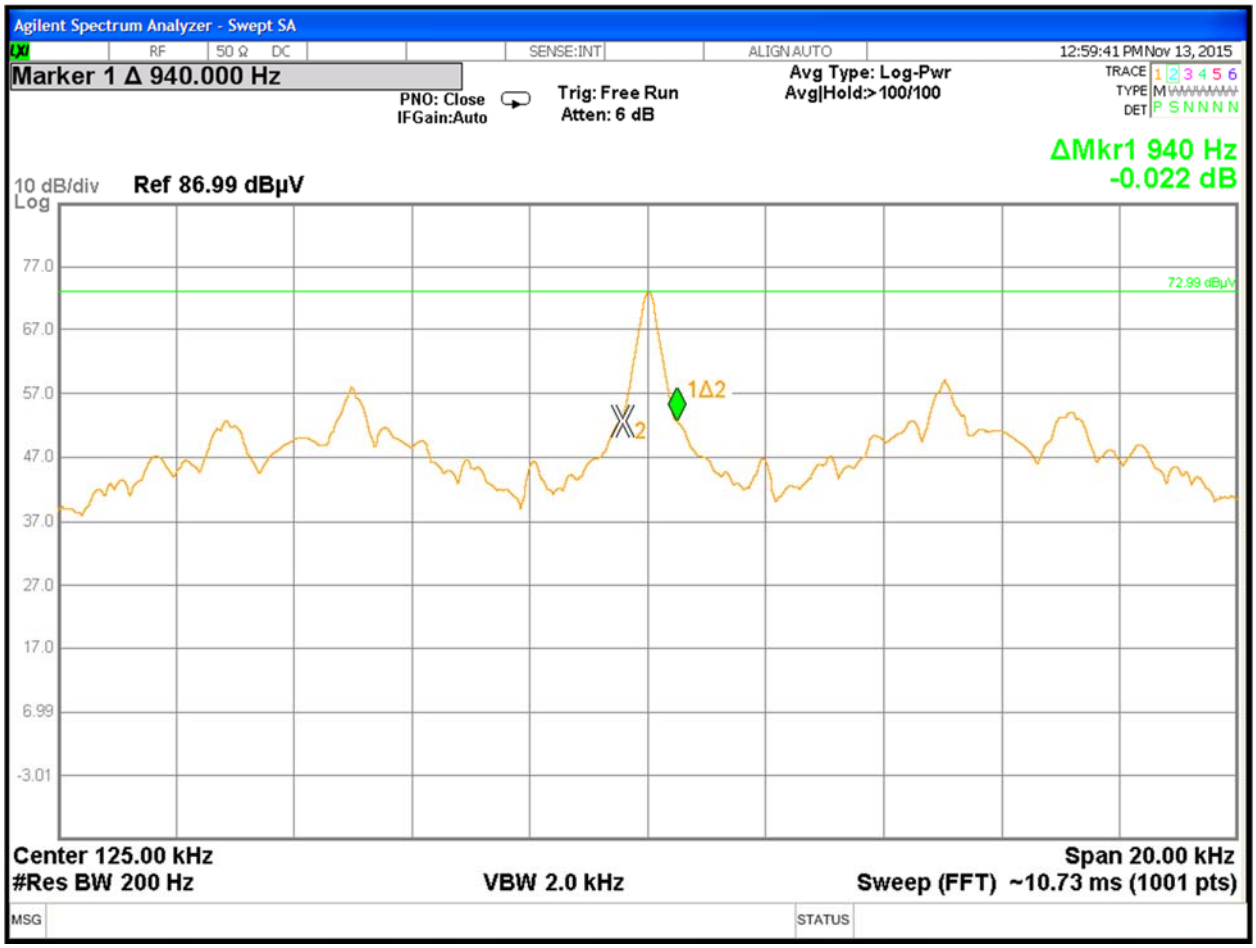


Figure 1 - 20 dB Bandwidth

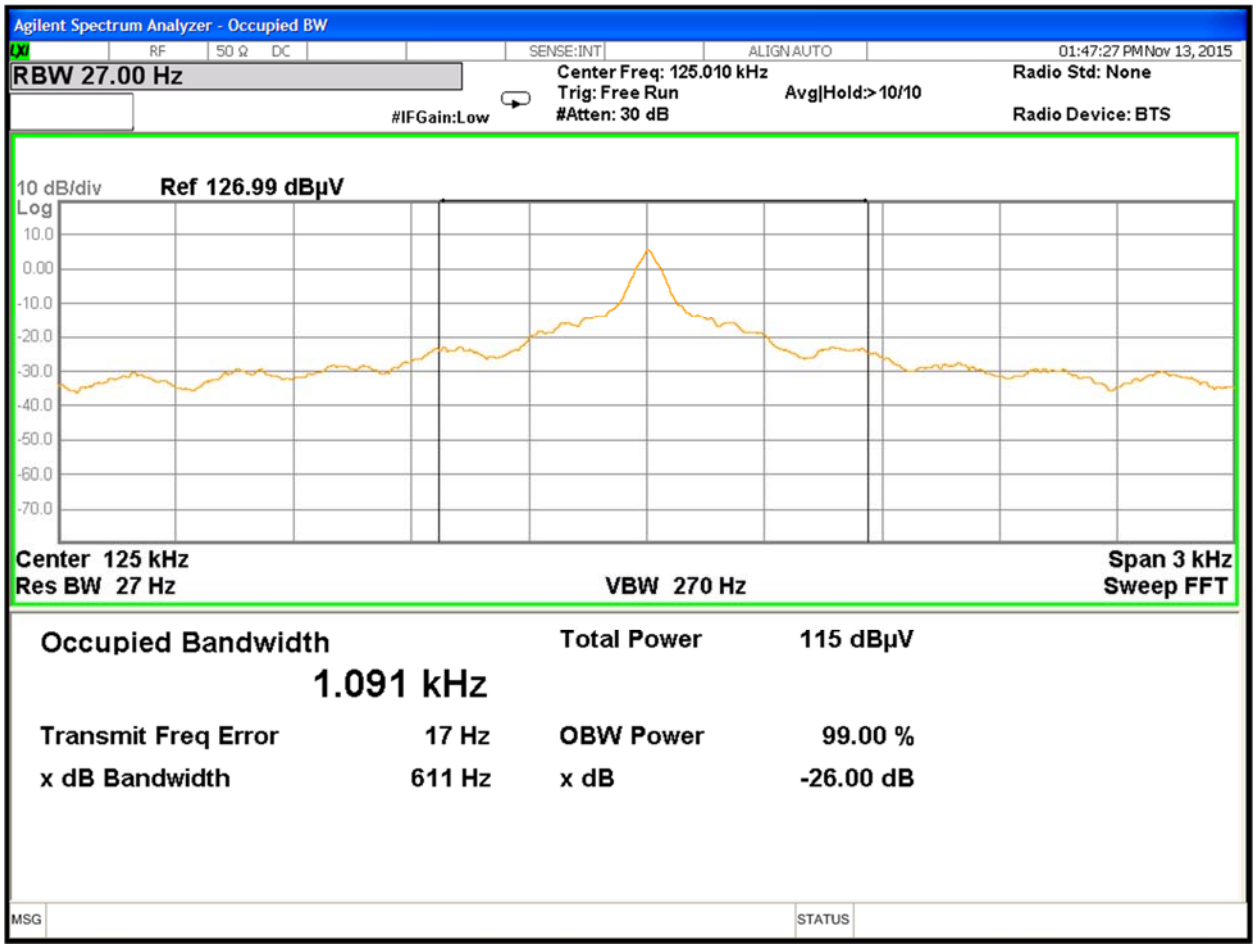


Figure 2 - 99% Occupied Bandwidth

4.2 Transmitter Spurious Emissions

Transmitter spurious emissions are emissions outside the frequency range of the equipment when the equipment is in transmit mode; per requirement of CFR47 15.205, 15.209, 15.225(d), RSS GEN Sect. 6.

4.2.1 Test Methodology

4.2.1.1 Preliminary Test

A test program that controls instrumentation and data logging was used to automate the preliminary RF emission test procedure. The frequency range of interest was divided into sub-ranges to yield a frequency resolution of approximately 120 kHz and provide a reading at each frequency for no more than 12° of turntable rotation. For each frequency sub-range the turntable was rotated 360° while peak emission data was recorded and plotted over the frequency range of interest in horizontal and vertical antenna polarization's.

Preliminary emission profile testing was performed inside the anechoic chamber. The EUT was placed on a 1.0m x 1.5m non-conductive table 80cm above the floor. The EUT was positioned as shown in the setup photographs. The receiving antenna was placed at a distance of 3m at a fixed height of 1m. Measurement equipment was located outside of the chamber. A video camera was placed inside the chamber to view the EUT.

4.2.1.2 Final Test

For each frequency measured, the peak emission was maximized by manipulating the receiving antenna from 1 to 4 meters above the ground plane and placing it at the position that produced the maximum signal strength reading. The turntable was then rotated through 360° while observing the peak signal and placing the EUT at the position that produced maximum radiation. The six highest emissions relative to the limit were measured unless such emissions were more than 20 dB below the limit. If less than six emissions are within 20 dB of the limit, than the noise level of the receiver is measured at frequencies where emissions are expected. Multiples of all oscillator and microprocessor frequencies were also checked.

Final testing was performed on an NSA compliant test site. The EUT was placed on a 1.0m x 1.5m non-conductive table 80cm above the ground plane. The placement of EUT and cables were the same as for preliminary testing and is shown in the setup photographs.

The final spurious emission scans performed on the Y-Axis.

4.2.1.3 Deviations

None.

4.2.2 Transmitter Spurious Emission Limit

The spurious emissions of the transmitter shall not exceed the values in CFR47 Part 15.205, 15.209: 2015 and RSS GEN Section 8.9: 2014.

Frequency (MHz)	Field strength (microvolts/meter)	Measurement distance (meters)
0.009-0.490	2400/F(kHz)	300
0.490-1.705	24000/F(kHz)	30
1.705-30.0	30	30
30-88	100 **	3
88-216	150 **	3
216-960	200 **	3
Above 960	500	3

4.2.3 Test Results

The final measurement data was taken under the worst case operating modes, configurations, and/or cable positions. It also reflects the results including any modifications and/or special accessories listed in Sections 1.4 and 1.5.

As originally tested, the EUT was found to be compliant to the requirements of the test standard(s).

SOP 1 Radiated Emissions

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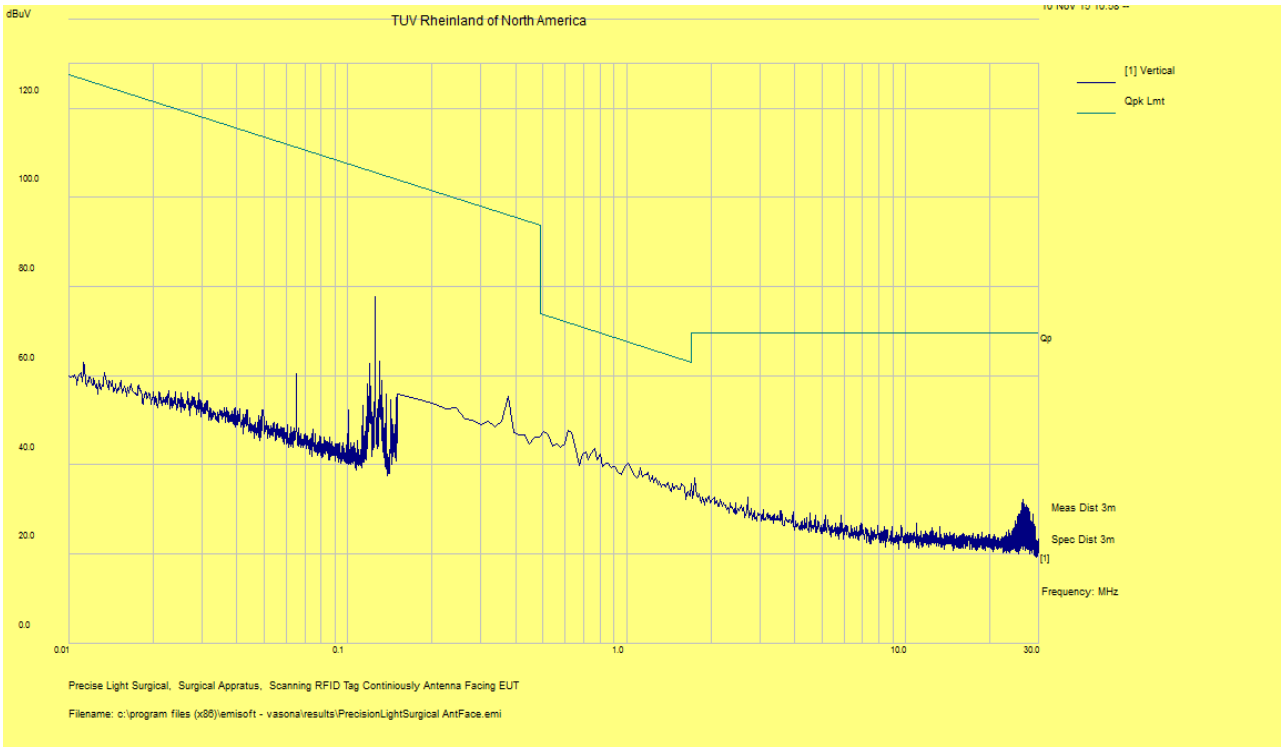
EUT Name	Opel Surgical System	**Date**	Nov 04, 2015
EUT Model	O-PEL	**Temp / Hum in**	22°C / 37%rh
EUT Serial	000002	**Temp / Hum out**	N/A
EUT Config.	On Table top scanning for RFID Tag	**Line AC**	120V/60 Hz
Standard	CFR47 Part 15 Subpart C	**RBW / VBW**	See below
Dist/Ant Used	3m / 6502	**Performed by**	Suresh Kondapalli

9 kHz to 30 MHz Plot at Loop Antenna Facing EUT (0 degree)



Notes: 9 kHz to 150 kHz; RBW = 200 Hz, VBW = 1kHz
150 kHz to 30 MHz; RBW = 9kHz, VBW = 30kHz

SOP 1 Radiated Emissions

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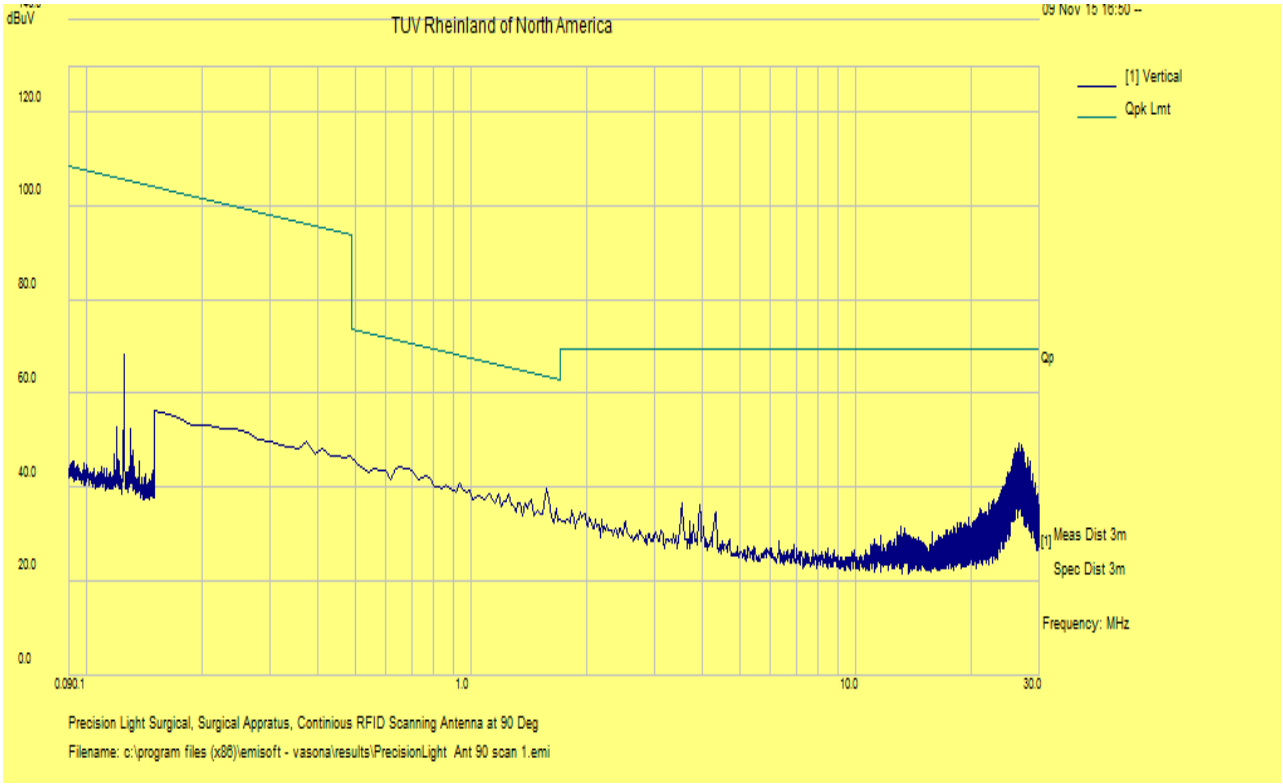
EUT Name	Opel Surgical System	**Date**	Nov 09, 2013
EUT Model	O-PEL	**Temp / Hum in**	22°C / 37%rh
EUT Serial	000002	**Temp / Hum out**	N/A
EUT Config.	On Table top scanning for RFID Tag	**Line AC**	120V/60 Hz
Standard	CFR47 Part 15 Subpart C	**RBW / VBW**	See below
Dist/Ant Used	3m / 6502	**Performed by**	Suresh Kondapalli

9 kHz to 30 MHz Plot for RFID at Loop Antenna at EUT (90 degree)



Notes: 9 kHz to 150 kHz; RBW = 200 Hz, VBW = 1kHz
150 kHz to 30 MHz; RBW = 9kHz, VBW = 30kHz

SOP 1 Radiated Emissions

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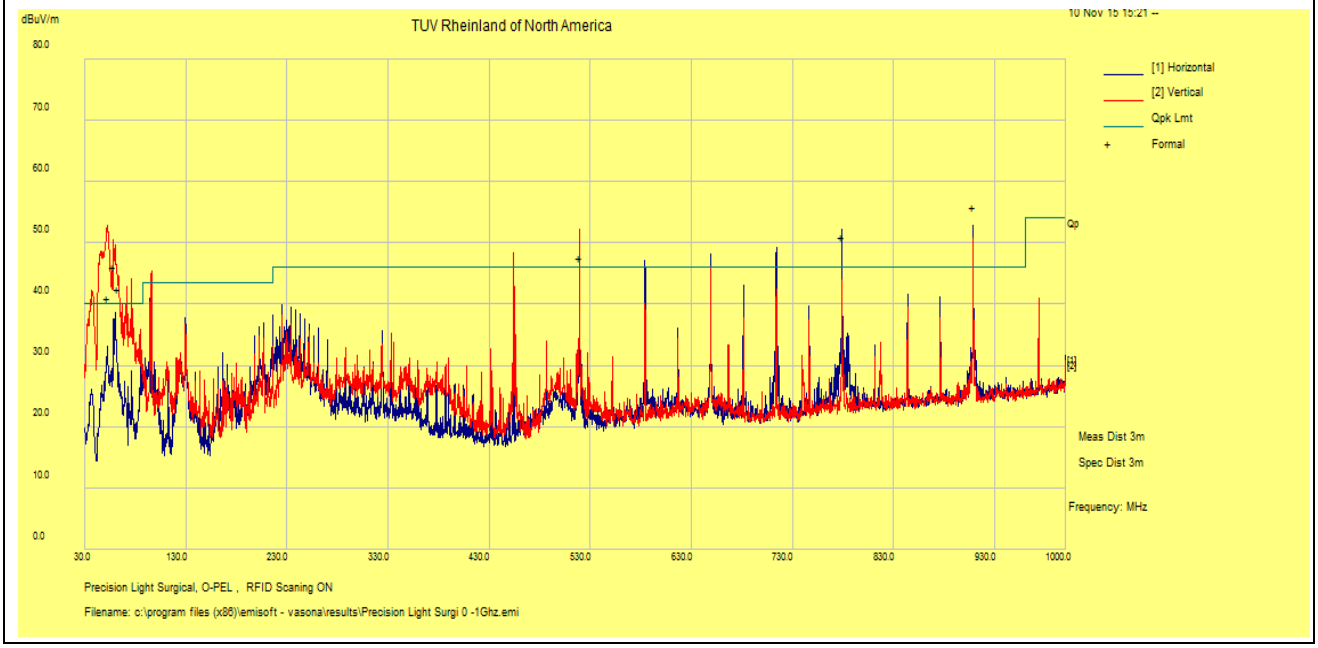
EUT Name	Opel Surgical System	**Date**	Nov 10, 2015
EUT Model	O-PEL	**Temp / Hum in**	23°C / 37%rh
EUT Serial	000002	**Temp / Hum out**	N/A
EUT Config.	On Table top scanning for RFID Tag	**Line AC**	120V/60 Hz
Standard	CFR47 Part 15 Subpart C	**RBW / VBW**	120kHz / 300kHz
Dist/Ant Used	3m / JB3	**Performed by**	Suresh Kondapalli

Pre-scan 30MHz to 1000MHz



SOP 1 Radiated Emissions

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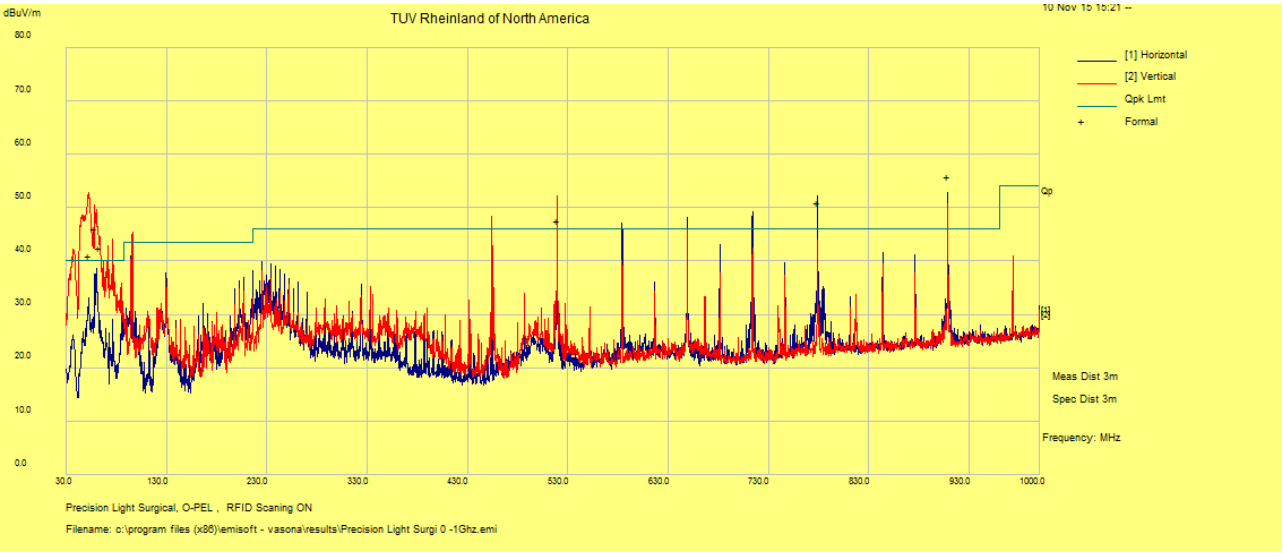
EUT Name	Opel Surgical System	**Date**	Nov 10, 2015
EUT Model	O-PEL	**Temp / Hum in**	23°C / 37%rh
EUT Serial	000002	**Temp / Hum out**	N/A
EUT Config.	On Table top scanning for RFID Tag	**Line AC**	120V/60 Hz
Standard	CFR47 Part 15 Subpart C	**RBW / VBW**	120kHz / 300kHz
Dist/Ant Used	3m / JB3	**Performed by**	Suresh Kondapalli

Final Scan 30MHz to 1000MHz



SOP 1 Radiated Emissions

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EUT Name	Opel Surgical System	**Date**	Nov 09, 2015
EUT Model	O-PEL	**Temp / Hum in**	22°C / 37%rh
EUT Serial	000002	**Temp / Hum out**	N/A
EUT Config.	On Table top scanning for RFID Tag	**Line AC / Freq**	120 Vac / 60 Hz
Standard	CFR47 Part 15 Subpart C	**RBW / VBW**	120 kHz/ 300 kHz
Dist/Ant Used	3m / JB3	**Performed by**	Suresh Kondapalli

Freq	Raw	Cable	AF	Level	Measurement	Ant Ht	Ant pol	Table Azt	Limit	Margin	comment
MHz	dBuV/m	dB	dB	dBuV/m	dB	cm	-	deg	dBuV/m	dB	
0.125	66.78	1.03	10.47	78.28	PK	V	128	361	105.66	-27.37	TX Freq
0.125	66.29	1.03	10.47	77.79	QP	V	144	10	105.66	-27.87	TX Freq
0.125	37.53	1.03	10.47	49.03	Avg	V	128	361	105.63	-56.60	TX Freq
0.63	34.93	1.07	10.40	46.41	QP	V	144	0	71.69	-25.28	Pass
0.77	27.87	1.09	10.33	39.29	QP	V	145	-2	69.87	-30.58	Pass
1.13	25.12	1.10	10.58	36.80	QP	V	145	14	66.56	-29.76	Pass
1.77	19.36	1.14	10.52	31.02	QP	V	144	8	69.50	-38.48	Pass
26.19	20.62	1.55	9.04	31.21	QP	V	145	76	69.50	-38.29	Pass

Spec Margin = E-Field QP – Limit, E-Field QP = FIM QP+ Total CF ± Uncertainty
Total CF= Amp Gain + Cable Loss + ANT Factor

Combined Standard Uncertainty $u_c(y)$ = ± 3.2 dB Expanded Uncertainty $U = ku_c(y)$ k = 2 for 95% confidence

Note: RBW/VBW Setting:
9 kHz to 150 kHz; RBW = 200 Hz, VBW = 1kHz
150 kHz to 30 MHz; RBW = 9kHz, VBW = 30kHz
30 MHz to 1000 MHz; RBW = 120kHz, VBW = 300kHz

SOP 1 Radiated Emissions

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EUT Name	Opel Surgical System	**Date**	Nov 09, 2015
EUT Model	O-PEL	**Temp / Hum in**	22°C / 37%rh
EUT Serial	000002	**Temp / Hum out**	N/A
EUT Config.	On Table top scanning for RFID Tag	**Line AC / Freq**	120 Vac / 60 Hz
Standard	CFR47 Part 15 Subpart C	**RBW / VBW**	120 kHz/ 300 kHz
Dist/Ant Used	3m / JB3	**Performed by**	Suresh Kondapalli

Freq	Raw	Cable	AF	Level	Measurement	Ant Ht	Ant pol	Table Azt	Limit	Margin	comment
MHz	dBuV/m	dB	dB	dBuV/m	dB	cm	-	deg	dBuV/m	dB	
0.125	56.99	1.03	10.47	68.49	PK	V	144	64	105.66	-37.17	TX freq
0.125	55.64	1.03	10.47	67.14	QP	V	144	56	105.66	-38.51	TX freq
0.125	55.28	1.03	10.47	66.79	Avg	V	144	64	105.66	-38.87	TX freq
1.57	20.49	1.13	10.53	32.16	QP	V	145	361	63.68	-31.52	Pass
26.58	37.57	1.56	8.93	48.05	QP	V	144	0	69.50	-21.45	Pass
26.91	36.72	1.56	8.83	47.11	QP	V	144	18	69.50	-22.39	Pass
27.11	36.77	1.56	8.78	47.11	QP	V	145	-2	69.50	-22.39	Pass
28.28	33.48	1.57	8.45	43.51	QP	V	144	-2	69.50	-25.99	Pass

Spec Margin = E-Field QP – Limit, E-Field QP = FIM QP+ Total CF ± Uncertainty
Total CF= Amp Gain + Cable Loss + ANT Factor

Combined Standard Uncertainty $u_c(y)$ = ± 3.2 dB Expanded Uncertainty $U = ku_c(y)$ k = 2 for 95% confidence

Note: RBW/VBW Setting:
9 kHz to 150 kHz; RBW = 200 Hz, VBW = 1kHz
150 kHz to 30 MHz; RBW = 9kHz, VBW = 30kHz
30 MHz to 1000 MHz; RBW = 120kHz, VBW = 300kHz

SOP 1 Radiated Emissions		Tracking #	31563434.001	Page	7	of 7
EUT Name	Opel Surgical System	**Date**	Nov 9&10, 2015			
EUT Model	O-PEL	**Temp / Hum in**	22°C / 37%rh			
EUT Serial	000002	**Temp / Hum out**	N/A			
EUT Config.	EUT on Desk top	**Line AC / Freq**	120 Vac / 60 Hz			
Standard	CFR47 Part 15 Subpart C	**RBW / VBW**	120 kHz/ 300 kHz			
Dist/Ant Used	3m /JB3	**Performed by**	Suresh Kondapalli			

Frequency	Raw	Cable Loss	AF	Level	Detector	Polarity	Height	Azimuth	Limit B	Limit A	Margin B	Margin A
MHz	dBuV/m	dB	dB	dBuV/m		H/V	cm	deg	dBuV/m	dBuV/m	dB	dB
778.99	55.67	5.45	-10.23	50.89	QP	H	111	24	46.00	56.44	4.89	-5.55
908.79	58.36	5.78	-8.27	55.88	QP	H	137	31	46.00	59.50	9.88	-3.62
52.58	62.54	2.80	-24.32	41.02	QP	V	111	302	40.00	53.54	1.02	-8.98
58.48	67.90	2.84	-24.75	45.98	QP	V	123	88	40.00	53.54	5.98	-4.02
63.48	63.96	2.88	-24.35	42.49	QP	V	139	99	40.00	53.54	2.49	-7.51
519.30	56.70	4.76	-13.91	47.54	QP	V	101	16	46.00	56.44	1.54	-8.90

Spec Margin = E-Field QP – Limit, E-Field QP = FIM QP+ Total CF ± Uncertainty
Total CF= Amp Gain + Cable Loss + ANT Factor

Combined Standard Uncertainty $u_c(y)$ = ± 3.2 dB Expanded Uncertainty $U = ku_c(y)$ k = 2 for 95% confidence

Note: RBW/VBW Setting:
9 kHz to 150 kHz; RBW = 200 Hz, VBW = 1kHz
150 kHz to 30 MHz; RBW = 9kHz, VBW = 30kHz
30 MHz to 1000 MHz; RBW = 120kHz, VBW = 300kHz

Note: EUT is class A device, see statement from manufacturer on page 48

4.2.4 Sample Calculation

The field strength is calculated by subtracting the Amplifier Gain and adding the Cable Loss and Antenna Correction Factor to the measured reading. The basic equation is as follows:

Field Strength (dBμV/m) = FIM - AMP + CBL + ACF

Where: FIM = Field Intensity Meter (dBμV)
AMP = Amplifier Gain (dB)
CBL = Cable Loss (dB)
ACF = Antenna Correction Factor (dB/m)

$$\mu V/m = 10^{\frac{dB\mu V/m}{20}}$$

4.3 AC Conducted Emissions

Testing was performed in accordance with ANSI C63.4: 2009. These test methods are listed under the laboratory's A2LA Scope of Accreditation.

This test measures the levels emanating from the EUT's AC input port, thus evaluating the potential for the EUT to cause radio frequency interference to other electronic devices.

The AC conducted emissions of equipment under test shall not exceed the values in CFR47 Part 15.207: 2010 and RSS 210: 2010.

4.3.1 Test Methodology

A test program that controls instrumentation and data logging was used to automate the AC Power Line Conducted emission test procedure. The frequency range of interest was divided into sub-ranges such as to yield a frequency resolution of 9 kHz. Each phase and neutral of the AC power line was measured with respect to ground. Measurements were performed using a set of 50μH / 50Ω LISNs.

Testing is either performed in Lab 2. The setup photographs clearly identify which site was used. The vertical ground plane used in the semi-anechoic chamber is a 2m x 2m solid aluminum frame and panel, and it is bonded to the horizontal ground plane.

In the case of tabletop equipment, the EUT is placed on a 1.0m x 1.5m non-conductive table 80cm above the ground plane and 40cm from a vertical ground reference plane. The rear of the EUT was positioned flush with the backside of the table and directly over the LISNs. The power and I/O cables were routed over the edge of the table and bundled approximately 40cm from the ground plane. Support equipment was powered from a separate LISN.

4.3.1.1 Deviations

There were no deviations from this test methodology.

4.3.2 Test Results

As originally tested, the EUT was found to be compliant to the requirements of the test standard(s).

Table 5: AC Conducted Emissions – Test Results

Test Conditions: Conducted Measurement at Normal Conditions only		
Antenna Type: Internal	**Power Level:** Fixed	
AC Power: 120 Vac/60 Hz	**Configuration:** Tabletop	
Ambient Temperature: 22° C	**Relative Humidity:** 37% RH	
Configuration	**Frequency Range**	**Test Result**
Line 1 (Hot)	0.15 to 30 MHz	Pass
Line 2 (Neutral)	0.15 to 30 MHz	Pass

SOP 2 Conducted Emissions

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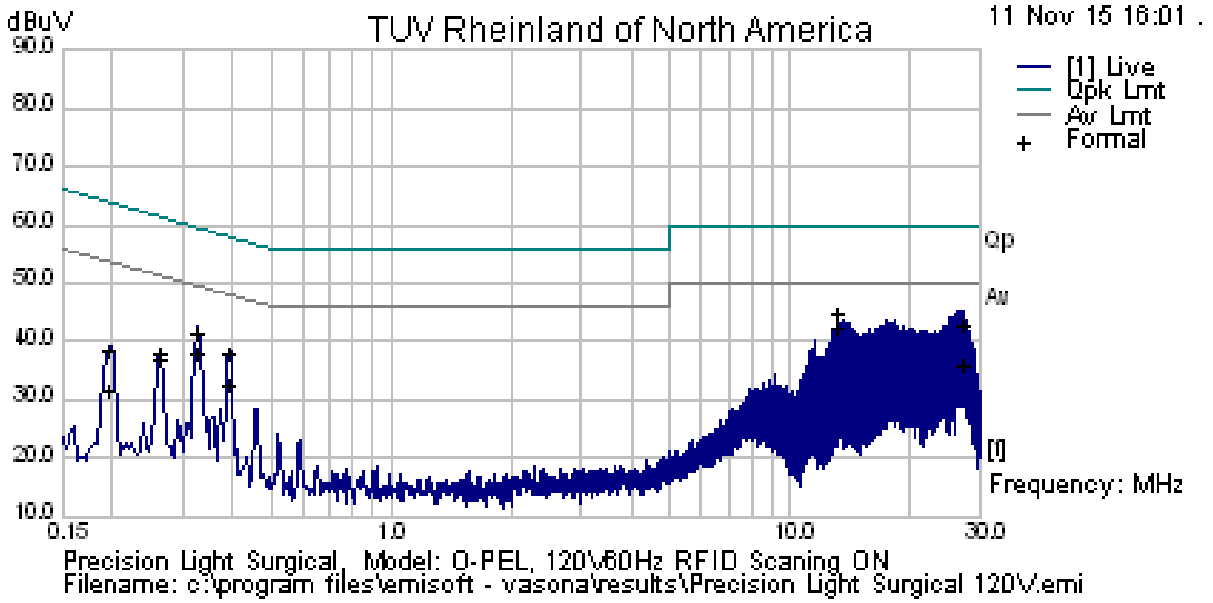
EUT Name	Opel Surgical System	**Date**	Aug 13, 2013
EUT Model	O-PEL	**Temp / Hum in**	23° C / 37% rh
EUT Serial	000002	**Temp / Hum out**	N/A
EUT Config.	Standalone Unit, Scanning for RFID	**Line AC**	120Vac/60 Hz
Standard	CFR47 Part 15.207	**RBW / VBW**	9kHz / 30 kHz
Lab/LISN	Lab 5 / ComPower, Line 1	**Performed by**	Suresh kondapalli

150 kHz to 30 MHz Plot for Line 1 (Hot)



Notes: Meet FCC Class B limit.

SOP 2 Conducted Emissions

Tracking # 31563434.001 Page 2 of 4

EUT Name	Opel Surgical System	**Date**	Nov 11, 2013
EUT Model	O-PEL	**Temp / Hum in**	23° C / 37% rh
EUT Serial	000002	**Temp / Hum out**	N/A
EUT Config.	Standalone Unit, Scanning for RFID	**Line AC / Freq**	120Vac/60 Hz
Standard	CFR47 Part 15.109	**RBW / VBW**	9kHz / 30 kHz
Lab/LISN	5m Chamber / ComPower, Line 1	**Performed by**	Suresh kondapalli

Frequency	Raw	Cable Loss	LISN Factors	Level	Measurement Type	Line	Limit	Margin	Result
MHz	dBuV	dB	dB	dBuV			dBuV	dB	
0.196	28.34	9.95	0.17	38.46	QP	Live	63.76	-25.30	Pass
0.196	21.61	9.95	0.17	31.73	Avg	Live	53.76	-22.03	Pass
0.262	27.69	9.96	0.13	37.77	QP	Live	61.37	-23.60	Pass
0.262	27.00	9.96	0.13	37.08	Avg	Live	51.37	-14.29	Pass
0.327	31.52	9.96	0.11	41.58	QP	Live	59.53	-17.94	Pass
0.327	27.94	9.96	0.11	38.01	Avg	Live	49.53	-11.52	Pass
0.393	27.78	9.96	0.09	37.83	QP	Live	58.00	-20.17	Pass
0.393	22.37	9.96	0.09	32.42	Avg	Live	48.00	-15.58	Pass
13.128	34.52	10.14	0.00	44.66	QP	Live	60.00	-15.34	Pass
13.128	32.23	10.14	0.00	42.37	Avg	Live	50.00	-7.63	Pass
26.913	32.93	10.26	-0.19	43.00	QP	Live	60.00	-17.00	Pass
26.913	26.04	10.26	-0.19	36.11	Avg	Live	50.00	-13.89	Pass

Spec Margin = QP./Ave. - Limit, ± Uncertainty

Combined Standard Uncertainty $u_c(y)$ = ± 1.2 dB Expanded Uncertainty $U = ku_c(y)$ k = 2 for 95% confidence

Note: Continuously reading RFID Tag

SOP 2 Conducted Emissions

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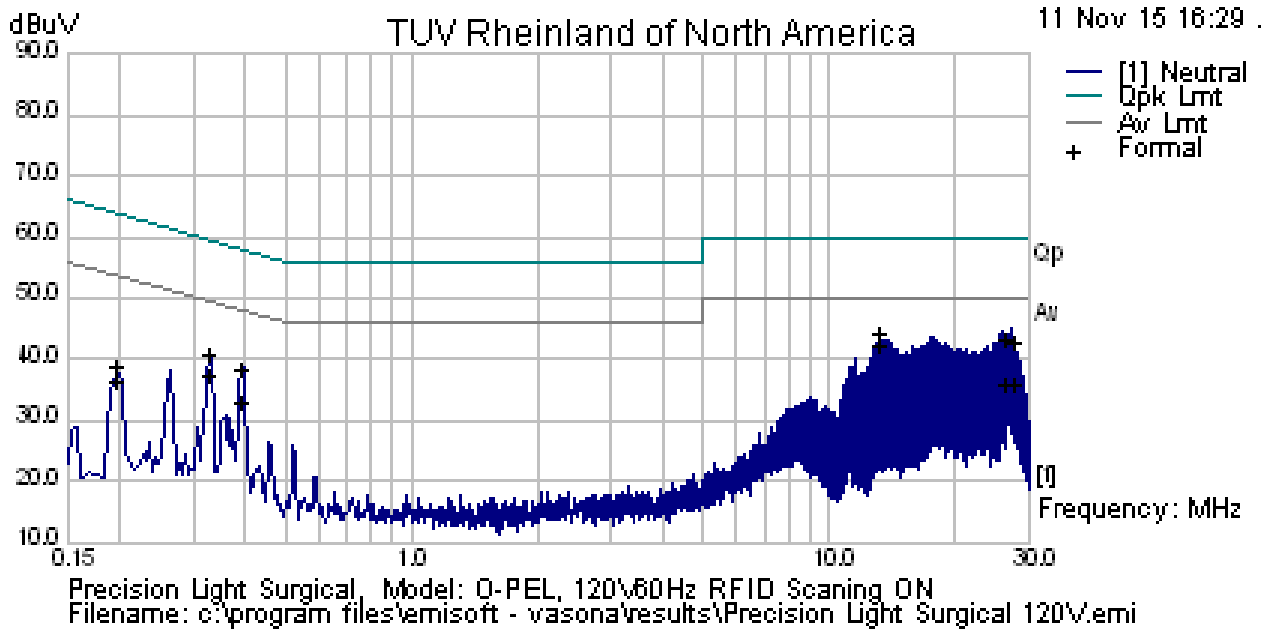
EUT Name	Opel Surgical System	**Date**	Nov 11, 2013
EUT Model	O-PEL	**Temp / Hum in**	23° C / 37% rh
EUT Serial	000002	**Temp / Hum out**	N/A
EUT Config.	Standalone Unit, Scanning for RFID	**Line AC**	120Vac/60 Hz
Standard	CFR47 Part 15.107	**RBW / VBW**	9kHz / 30 kHz
Lab/LISN	5m Chamber/ ComPower, Line 2	**Performed by**	Suresh Kondapalli

150 kHz to 30 MHz Plot for Line 2 (Neutral)



Note: Meets FCC Class B Limit.

SOP 2 Conducted Emissions

Tracking # 31563434.001 Page 4 of 4

EUT Name	Opel Surgical System	**Date**	Nov 11, 2015
EUT Model	O-PEL	**Temp / Hum in**	23° C / 37% rh
EUT Serial	000002	**Temp / Hum out**	N/A
EUT Config.	Standalone unit, Scanning for RFID	**Line AC / Freq**	120Vac/60 Hz
Standard	CFR47 Part 15.107	**RBW / VBW**	9kHz / 30 kHz
Lab/LISN	5m Chamber / ComPower, Line 2	**Performed by**	Suresh kondapalli

Frequency	Raw	Cable Loss	LISN Factors	Level	Measurement Type	Line	Limit	Margin	Result
MHz	dBuV	dB	dB	dBuV			dBuV	dB	
0.20	28.78	9.95	0.17	38.90	QP	Neutral	63.77	-24.86	Pass
0.20	26.36	9.95	0.17	36.49	Avg	Neutral	53.77	-17.28	Pass
0.33	31.05	9.96	0.11	41.12	QP	Neutral	59.57	-18.45	Pass
0.33	27.45	9.96	0.11	37.52	Avg	Neutral	49.57	-12.05	Pass
0.39	28.20	9.96	0.09	38.25	QP	Neutral	58.02	-19.77	Pass
0.39	23.08	9.96	0.09	33.13	Avg	Neutral	48.02	-14.89	Pass
13.13	34.21	10.14	0.00	44.35	QP	Neutral	60.00	-15.65	Pass
13.13	32.01	10.14	0.00	42.15	Avg	Neutral	50.00	-7.85	Pass
26.13	33.06	10.25	-0.17	43.14	QP	Neutral	60.00	-16.86	Pass
26.13	25.70	10.25	-0.17	35.78	Avg	Neutral	50.00	-14.22	Pass
27.50	32.90	10.26	-0.20	42.97	QP	Neutral	60.00	-17.03	Pass
27.50	25.88	10.26	-0.20	35.95	Avg	Neutral	50.00	-14.05	Pass

Spec Margin = QP./Ave. - Limit, ± Uncertainty

Combined Standard Uncertainty $u_c(y)$ = ± 1.2 dB Expanded Uncertainty $U = ku_c(y)$ k = 2 for 95% confidence

Continuously reading RFID Tag

4.4 Frequency Stability

In accordance with RSS General 4.7 the frequency stability of devices must be such that an emission is maintained within the band of operation under all conditions of normal operation as specified in the user's manual. The Manufacturer declares the operating temperature ranges of +0º to +50º C.

4.4.1 Test Methodology

The manufacturer of the equipment is responsible for ensuring that the frequency stability is such that emissions are always maintained within the band of operation under all conditions. This test performs according to ANSI C63.10-2009 Section 6.8

4.4.2 Limits

EUT falls under FCC 15.209 and RSS –Gen/ RSS 210 section 2.5.1. No specific band or carrier frequency stability requirements are specified for this device.

4.4.3 Test results

The EUT is compliant to the requirements

5 Setup Photos

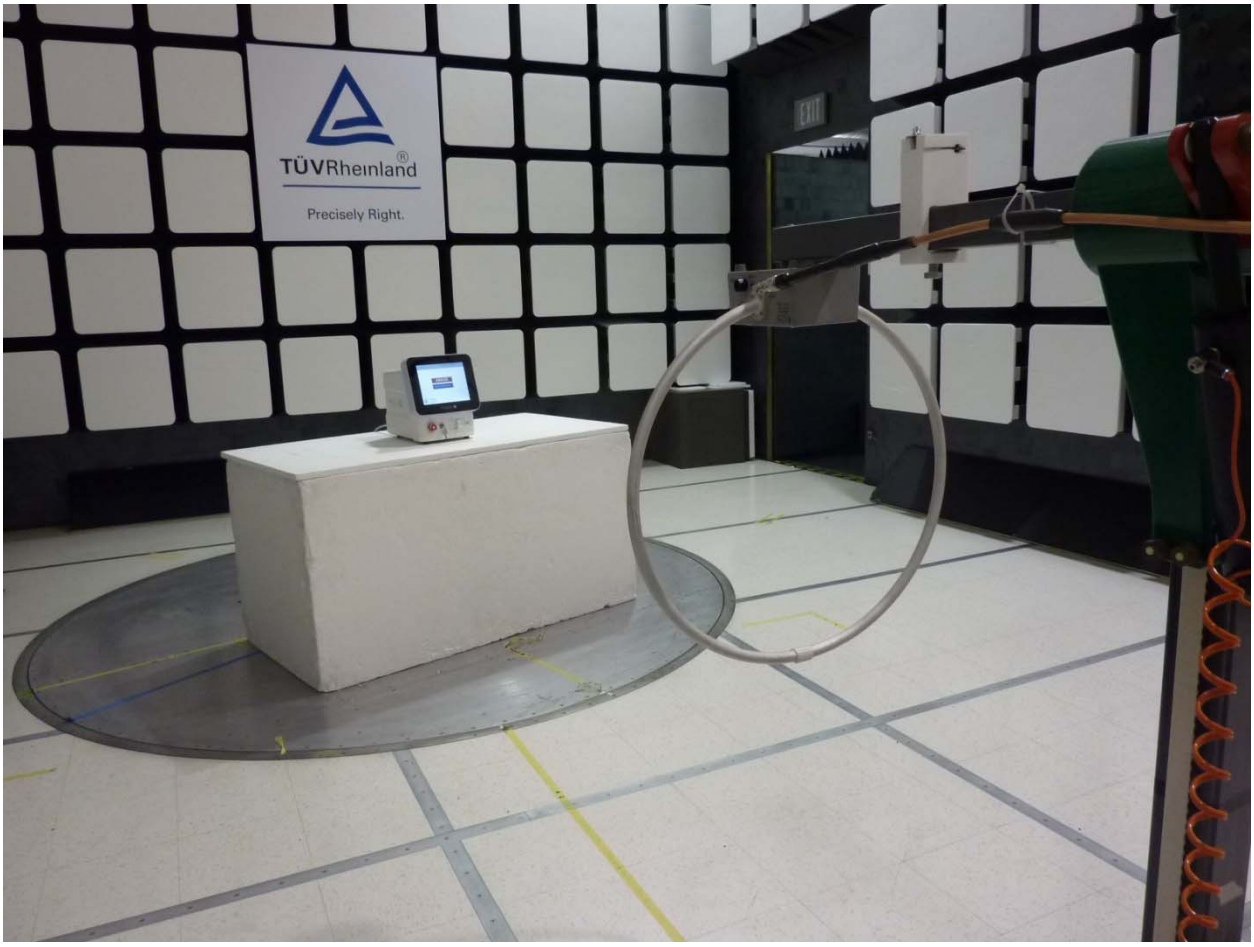


Figure 3 – Radiated Emissions 9 kHz to 30 MHz Antenna Facing EUT 0 Degrees

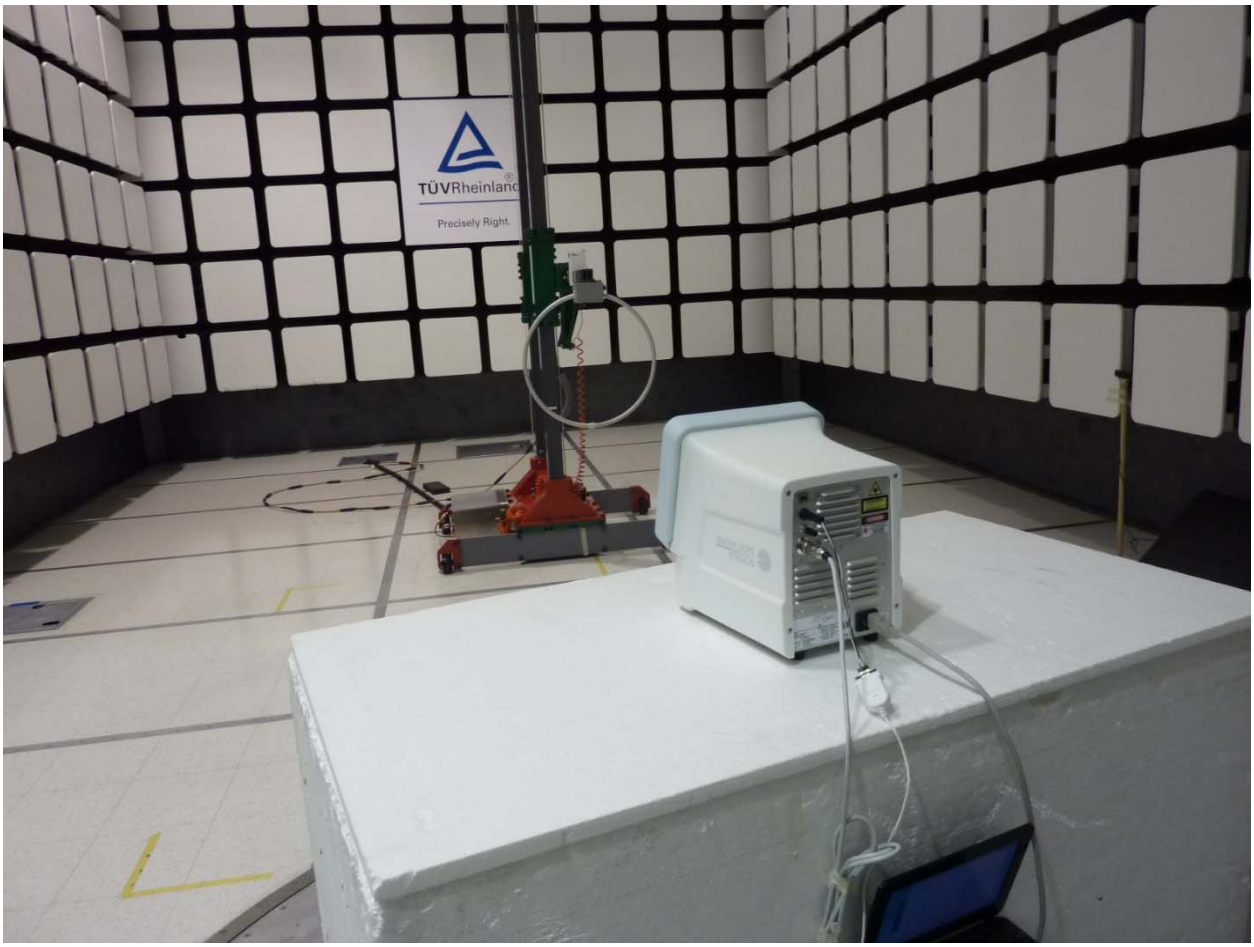


Figure 4 – Radiated Emissions 9 kHz to 30 MHz Antenna Facing EUT 0 Degrees

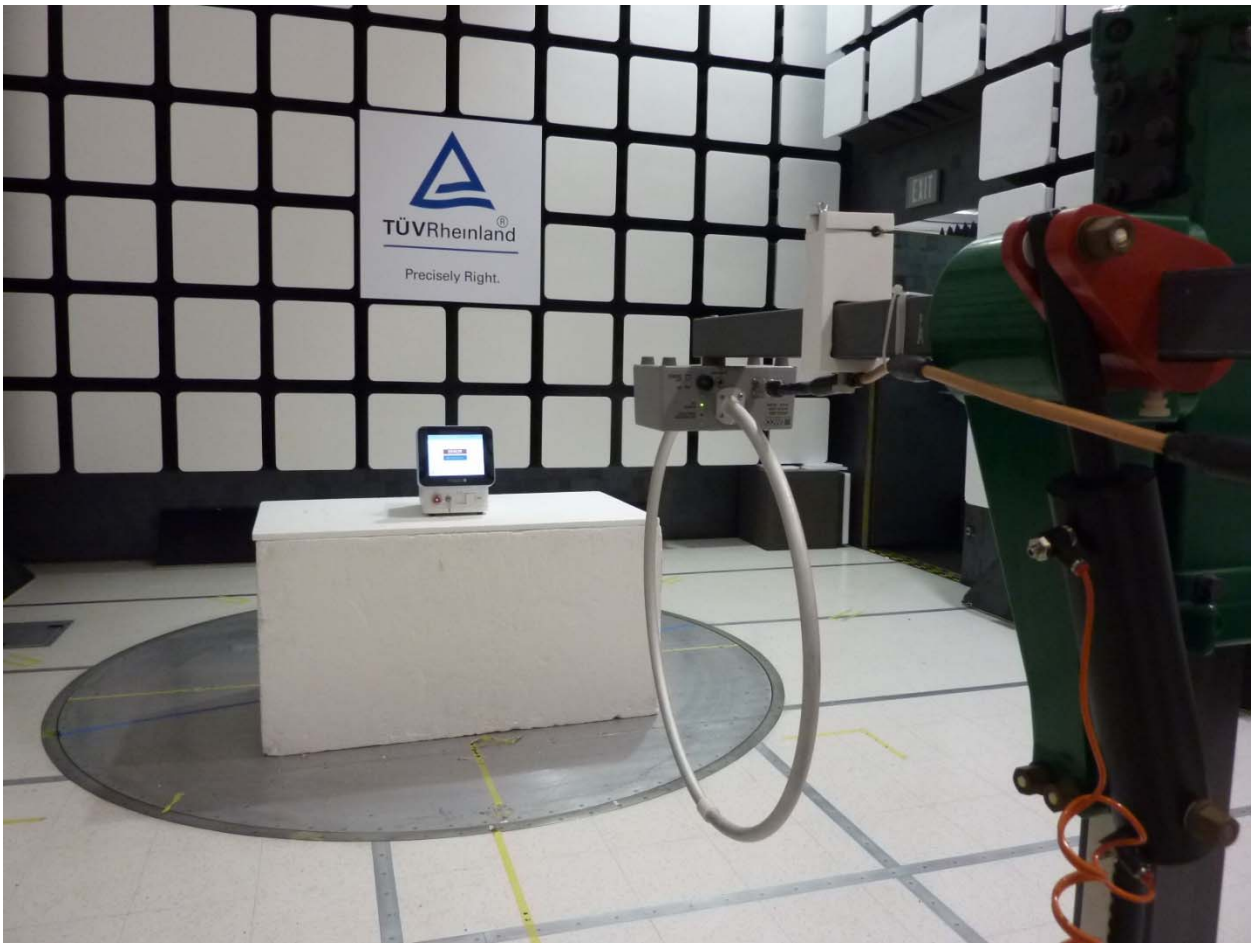


Figure 5 – Radiated Emissions 9 kHz to 30 MHz Antenna Facing EUT 90 Degrees

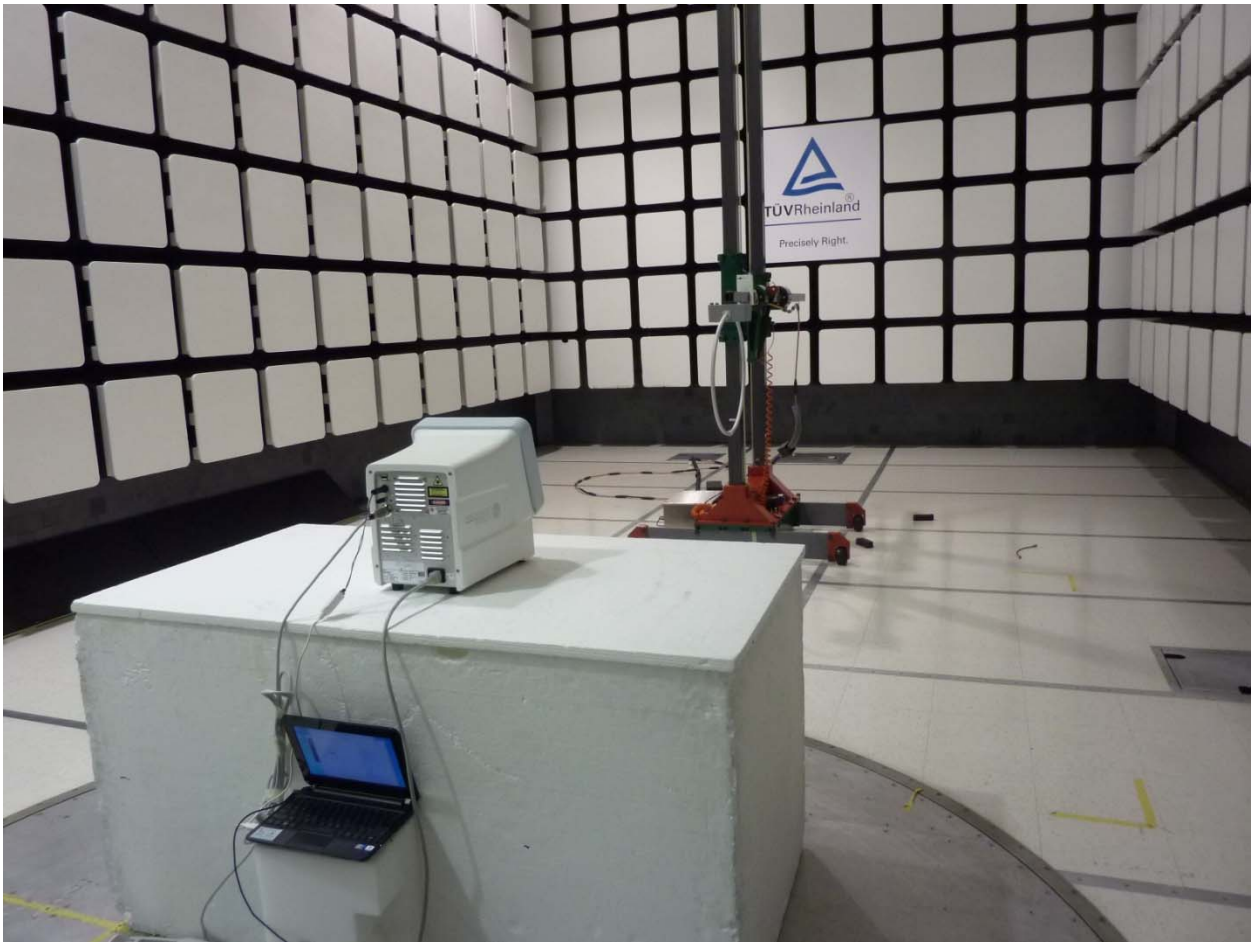


Figure 6 – Radiated emissions 9 kHz to 30 MHz Antenna Facing EUT 90 Degrees

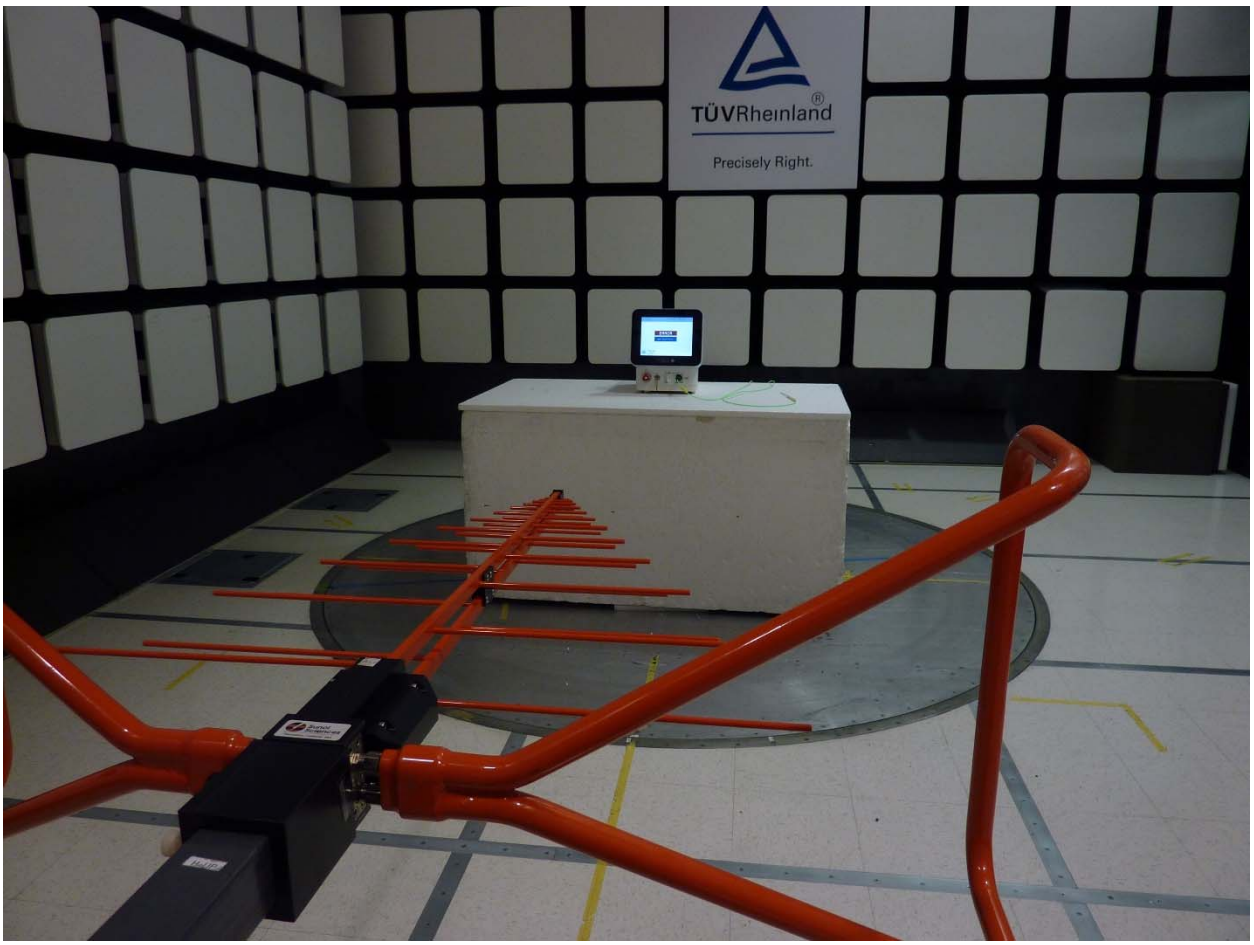


Figure 7 – Radiated emissions 30 MHz to 1000 MHz

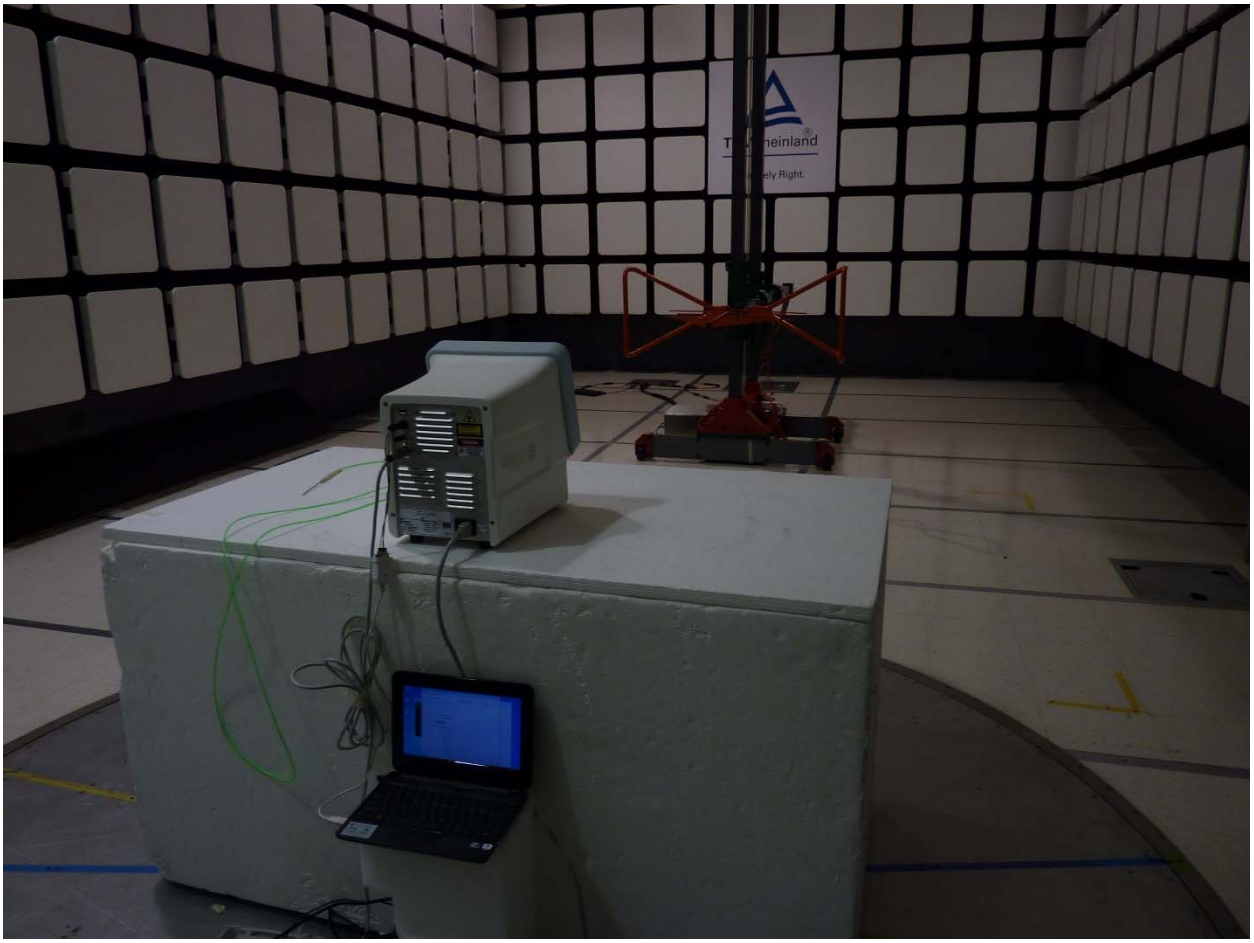


Figure 8 – Radiated emissions 30 MHz to 1000 MHz

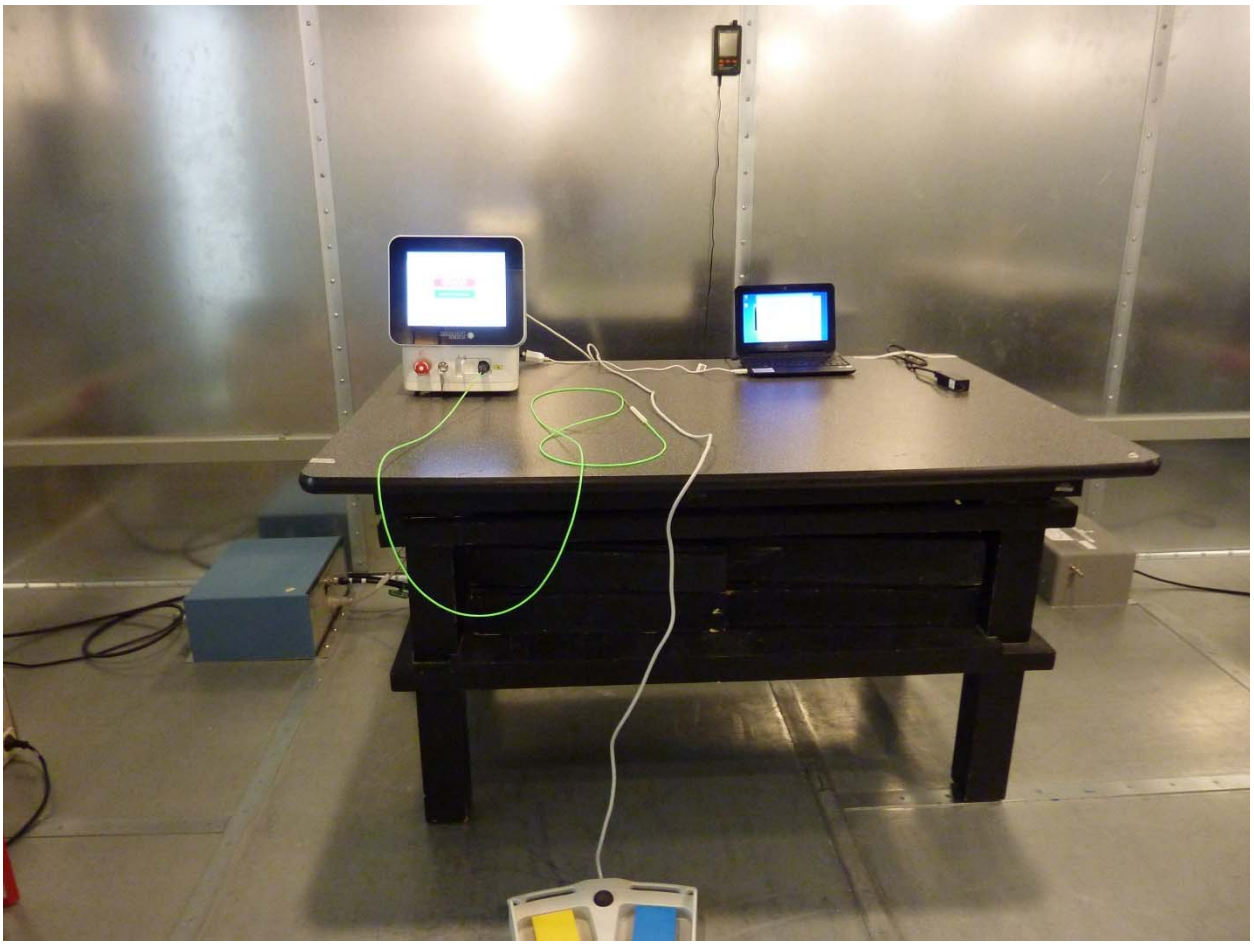


Figure 9 – AC Line Conducted Emissions

Figure 10 – AC Line Conducted Emissions

6 Test Equipment List

6.1 Equipment List

Equipment	Manufacturer	Model #	Serial/Inst #	Last Cal mm/dd/yy	Next Cal mm/dd/yy
Bilog Antenna	Sunol Sciences	JB3	A061907	07/08/2014	07/08/2016
Loop Antenna	ETS-Lindsgreen	6502	9110-2683	10/08/2015	10/08/2106
EMI Receiver	Rhode & Schwartz	ESIB40	003866	06/30/2015	06/30/2016
Pre-Amplifier	Sonoma	310N	185516	01/16/2015	01/16/2016
EMI Receiver	Agilent	N9038A	MY5210195	01/12/2015	01/12/2016
Line Impedance Network Stabilization	Com-Power	L1-215	12111	1/13/2015	1/13/2016

7 EMC Test Plan

7.1 Introduction

This section provides a description of the Equipment Under Test (EUT), configurations, operating conditions, and performance acceptance criteria. It is an overview of information provided by the manufacturer so that the test laboratory may perform the requested testing.

7.2 Customer

Table 6: Customer Information

Company Name	Precise Light Surgical
Address	310 W. Hamilton Ave. Suite 210.
City, State, Zip	Campbell, CA 95008 U.S.A.
Country	U.S.A.
Phone	831-539-3323

Table 7: Technical Contact Information

Name	Ken Arnold
E-mail	karnold@preciselightsurgical.com
Phone	831-539-3323

7.3 Equipment Under Test (EUT)

Table 8: EUT Specifications

EUT Specification	
Dimensions:	30 cm x 35 cm x 35 cm
Power Supply:	120VAC, 10A
Environment	Indoor
Operating Temperature Range:	15 to 26 degrees C EUT is used for surgical operations.
Multiple Feeds:	☐ Yes and how many ☒ No.
Hardware Version	None
RFID Software Version	V4044
Operating Mode	RFID tags backscatter modulate the carrier generated with an AM modulation
Transmitter Frequency Band	125 kHz
Chipset Rated Power Output	V=5V A= 4/10mA Typ/Max 20/50mW
Power Setting @ Operating Channel	Fixed. Power controlled by FPGA firmware.
Antenna Type	Loop antenna Diameter 1.7 inches; L = 335uH C= 0.0047uF DC resistance 1.1Ohms
Modulation Type	☒ AM ☐ FM ☐ Phase ☐ Other describe: AM PSK
Data Rate	NA
Max. Duty Cycle	100%
Type of Equipment	☒ Table Top ☐ Wall-mount ☐ Floor standing cabinet ☒ Other *describe: Controlled Environment*

Table 9: Interface Specifications

Interface Type	Cabled with what type of cable?	Is the cable shielded?	Maximum potential length of the cable?	Metallic (M), Coax (C), Fiber (F), or Not Applicable?
Power cable	4 Conductor 18 AWG	Yes	< 2.5 m	(M) Shielded and Jacketed
Foot Switch	Multi Conductor	Yes	2.5m	(M) Unshielded
Note: Only interfaces used for radio testing are shown here				

Table 10: Supported Equipment

Equipment	Manufacturer	Model	Serial	Used for
Note: None				

Table 11: Description of Sample used for Testing

Device	Serial Number	Configuration	Used For
O-PEL	000002	Radiated Sample	Max. Carrier Field Strength TX Spurious Radiated Emission AC Conducted Emission
Note:			

Table 12: Description of Test Configuration used for Radiated Measurement.

Device	Antenna	Mode	Setup Description
O-PEL	Integral	Continuously scanning RFID Tag	Table top
Note: EUT was tested normal operational orientation. EUT is not used other orientations			

PRECISE LIGHT SURGICAL

Attention: Suresh Kondapalli
TUV Rheinland of North America
(Senior Engineer)
1279 Quarry Lane, Suite A,
Pleasanton, CA 94566

Re: Opel Surgical System radio emissions test anomalies, per test (Radiated spurious Emissions test FCC 15.209 and RSS Gen 8.9)

The Opel surgical system is a Class A device and is intended for cutting tissues during surgery in an operating room or physician office environment. It is in no way intended for home use. The Opel product has a low frequency (125KHz) embedded radio system to authenticate delivery devices that are physically attached to the system console.
The radio is embedded into the Class A product and cannot be operated without other non radio components of the product being active. The testing yielded emission measurements in excess of Class B requirements when the radio was activated and when the radio was not activated, indicating the emission in excess of Class B requirements are from non radio components of the Class A system. Regardless of the source of the emissions exceeding Class B requirements, this product, including the embedded radio will only be used in a Class A environment.

Ken Arnold
President & CEO

Precise Light Surgical
310 W Hamilton Ave, Suite 210
Campbell, CA 95008
(831) 539 3323

7.4 Test Specifications

Testing requirements

Table 13: Test Specifications

Emissions	
Standard	Requirement
CFR47 Part 15.209: 2015	All
RSS-210 Issue 8, 2010	All

END OF REPORT