Emissions
Test Report

EUT Name: Coldplay CryoBalloon® Focal Ablation System

Model No.: FG1017

CFR 47 Part 15.225:2015 and RSS 210:2010

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Statement of Compliance

Manufacturer:	C2 Therapeutics, Inc. 303 Convention Way, Suite 1 Redwood City, CA 94063 (650) 521-5307
Requester / Applicant:	Pat Wu
Name of Equipment:	Coldplay CryoBalloon® Focal Ablation System
Model No.	FG1017
Type of Equipment:	Industrial, Scientific, or Medical (ISM)
Application of Regulations:	CFR 47 Part 15.225:2015 and RSS 210:2010
Test Dates:	May 09, 2016 to May 09, 2016

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.

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Bernd Jungbluth	July 25, 2017	David Spencer	July 25, 2017
Test Engineer	Date	A2LA Signatory	Date

Industry Canada

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

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1 Executive Summary

1.1 Scope

This report is intended to document the status of conformance with the requirements of the CFR 47 Part 15.225:2015 and RSS 210:2010 based on the results of testing performed on May 09, 2016 through May 09, 2016 on the Coldplay CryoBalloon® Focal Ablation System Model FG1017 manufactured by C2 Therapeutics, Inc.. 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.6.13	Class B	**Complied**
Occupied Bandwidth	CFR47 15.215 (c), RSS GEN Sect.6.6	N/A	**Complied**
Carrier Field Strength	CFR47 15.225 (a), RSS 210 Sect. A 2.6 (a)	124 dBuV/m at 3 meter	**Complied**
Out of Band Emissions	CFR47 15.225 (b), (c) RSS 210 Sect. A 2.6 (b) (c)	Per Standards.	**Complied**
Voltage Variation	CFR47 15.225 (e), RSS 210 Sect. A 2.6	100ppm / +0.01%	**Complied**
RF Exposure	CFR47 Part 1.1310, RSS-102	General Population	**Complied**

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 NIST / 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 Nos. 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 C63.4:2014, 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 C63.4:2014, 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

	U_{lab}	U_{cispr}
Radiated Disturbance		
30 MHz – 25,000 MHz	3.2 dB	5.2 dB
Conducted Disturbance @ Mains Terminals		
150 kHz – 30 MHz	2.4 dB	3.6 dB
Disturbance Power		
30 MHz – 300 MHz	3.92 dB	4.5 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 ± 4.1%.
The estimated combined standard uncertainty for radiated immunity measurements is ± 2.7dB.
The estimated combined standard uncertainty for conducted immunity measurements is ± 1.4dB.
The estimated combined standard uncertainty for damped oscillatory wave immunity measurements is ± 8.8%.
The estimated combined standard uncertainty for harmonic current and flicker measurements is ± 0.45%.

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

Coldplay CryoBalloon® Focal Ablation System, model FG1017, is an ACK RFID operating at 13.56MHz.

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

N/A - The FG1017 uses an integral antenna.

4 Emissions

Testing was performed in accordance with CFR 47 Part 15.225:2015 and RSS 210 Annex 2:2010. 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.

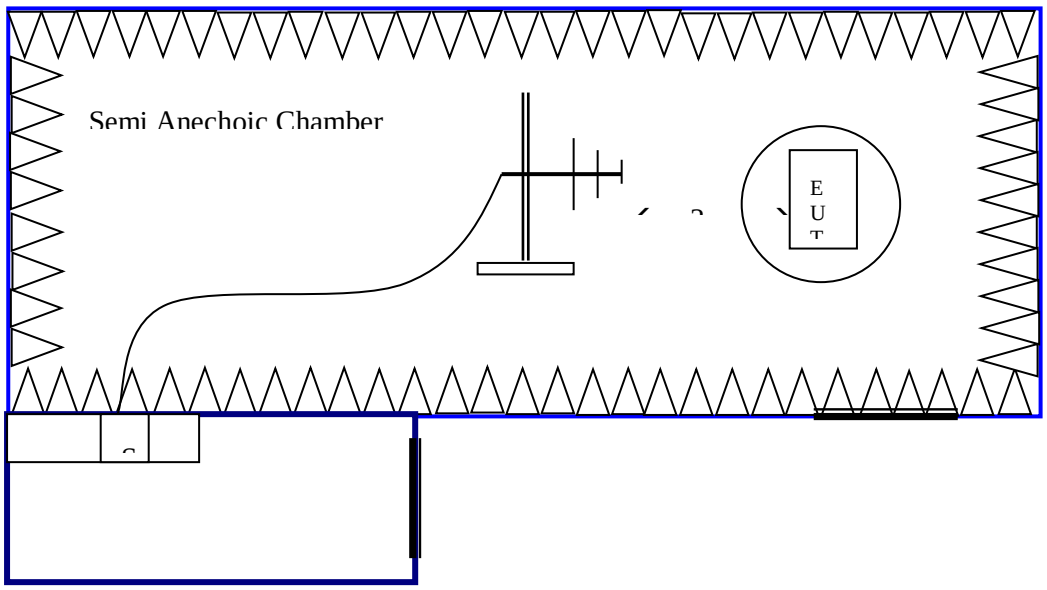
The RF fundamental field strengths shall not exceed CFR47 Part 15.225 (a):2015 and RSS 210 A2.6 (a):2010.

The field strength of any emission in the band of 13.553 and 13.567MHz shall be less than 84 dBuV/m at 30 meter distance; or 124 dBuV/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 C63.10:2013 Section 6.3. The measurement was performed with modulation. All three axis were conducted. The worst result indicated below.

Test Setup:



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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: Internal Loop			**Power Setting:** Maximum output setting			
Signal State: Modulated			**Duty Cycle:** 100 %			
Ambient Temp.: 22 °C			**Relative Humidity:**36 %			
Operating Frequency:	**Test Results**					
13.56 MHz	**Measured Level [dBuV/m]**	**Loop Position**	**Table [degree]**	**Antenna [cm]**	**Limit [dBuV/m]**	**Margin [dB]**
X-Axis	**57.47**	0	281.8	100	124.00	-66.53
X-Axis	52.67	90	199.0	100	124.00	-71.33
Y-Axis	50.26	0	237.5	100	124.00	-73.74
Y-Axis	32.95	90	131.0	100	124.00	-91.05
Z-Axis	56.90	0	13.8	100	124.00	-67.1
Z-Axis	52.49	90	278.0	100	124.00	-66.53
Note: 1. Measurements were taken at 3 meter distance, and the limit was extrapolated accordingly.						

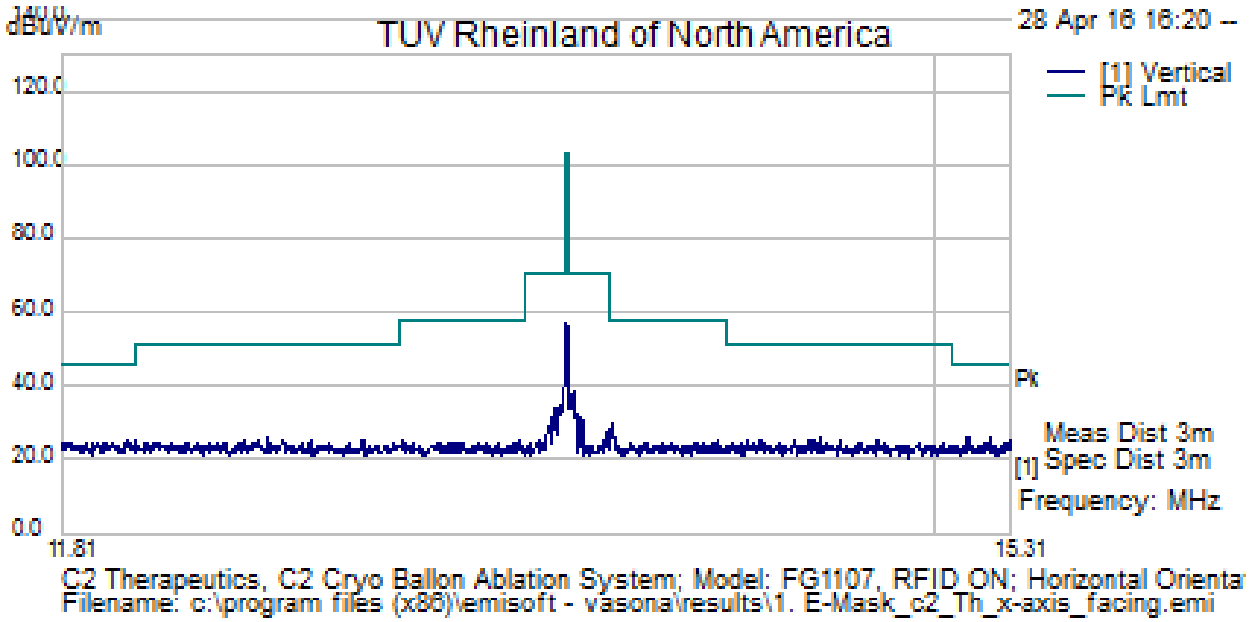


Figure 1: X-Axis Power Output – Orientation resulting in maximum field strength

4.2 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.

The 99% bandwidth is the bandwidth in which 99% of the transmitted power occupied.

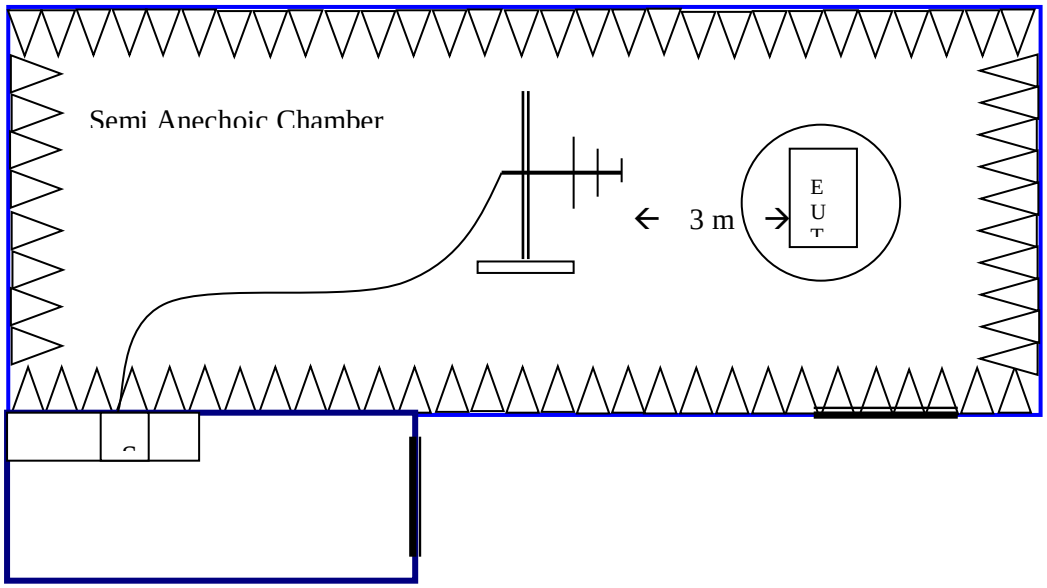
The 20dB bandwidth is defined the bandwidth of 20 dBr from highest transmitted level of the fundamental frequency.

The bandwidth shall be documented per Section CFR47 15.215(c) 2015 and RSS Gen Sect. 6.6: 2014. Intentional radiators operating under the alternative provisions to the general emission limits, must be designed to ensure that the 20 dB bandwidth of the emission, or whatever bandwidth may otherwise be specified in the specific rule section under which the equipment operates, is contained within the frequency band designated in the rule section under which the equipment is operated. The requirement to contain the designated bandwidth of the emission within the specified frequency band includes the effects from frequency sweeping, frequency hopping and other modulation techniques that may be employed as well as the frequency stability of the transmitter over expected variations in temperature and supply voltage. If the frequency stability is not specified in the regulations, it is recommended that the fundamental emission be kept within at least the central 80% of the permitted band in order to minimize the possibility of out-of-band operation.

4.2.1 Test Method

The radiated method was used to measure the occupied bandwidth according to ANSI C63.10:2013. The measurement was performed with modulation. This test was performed on all three axis of RFID. The worst sample result indicated below.

Test Setup:



4.2.2 Results

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

Table 4: Occupied Bandwidth – Test Results

Test Conditions: Radiated Measurement, Normal Temperature and Voltage only				
Antenna Type: Internal Loop		**Power Setting:** Maximum output setting		
Signal State: Modulated		**Duty Cycle:** 100 %		
Ambient Temp.: 22 °C		**Relative Humidity:**36%		
Occupied Bandwidth for 13.56 MHz RFID				
Sample	**Occupied Band Limit (MHz)**	**Lower Freq. (MHz)**	**Upper Freq. (MHz)**	**Results**
FG1017	13.553 < X < 13.567	13.559	13.561	Pass
Note: All lower and upper markers of 99% Bandwidth and 20 dB Bandwidth are within the allowable band; 13.553 MHz to 13.567MHz				

Table 5: 20 dB Bandwidth Frequency – Test Results

Test Conditions: Radiated Measurement, Normal Temperature and Voltage only				
Antenna Type: Internal Loop		**Power Setting:** Maximum output setting		
Signal State: Modulated		**Duty Cycle:** 100 %		
Ambient Temp.: 22 °C		**Relative Humidity:**36%		
20 dB Bandwidth Frequencies for 13.56 MHz RFID				
Sample	**Occupied Band Limit (MHz)**	**Lower Freq. (MHz)**	**Upper Freq. (MHz)**	**Results**
FG1017	13.553 < X < 13.567	13.559	13.561	Pass
Note: All lower and upper markers of 20 dB Bandwidth are within the allowable band; 13.553 MHz to 13.567MHz; where X is the lower frequency and upper frequency.				

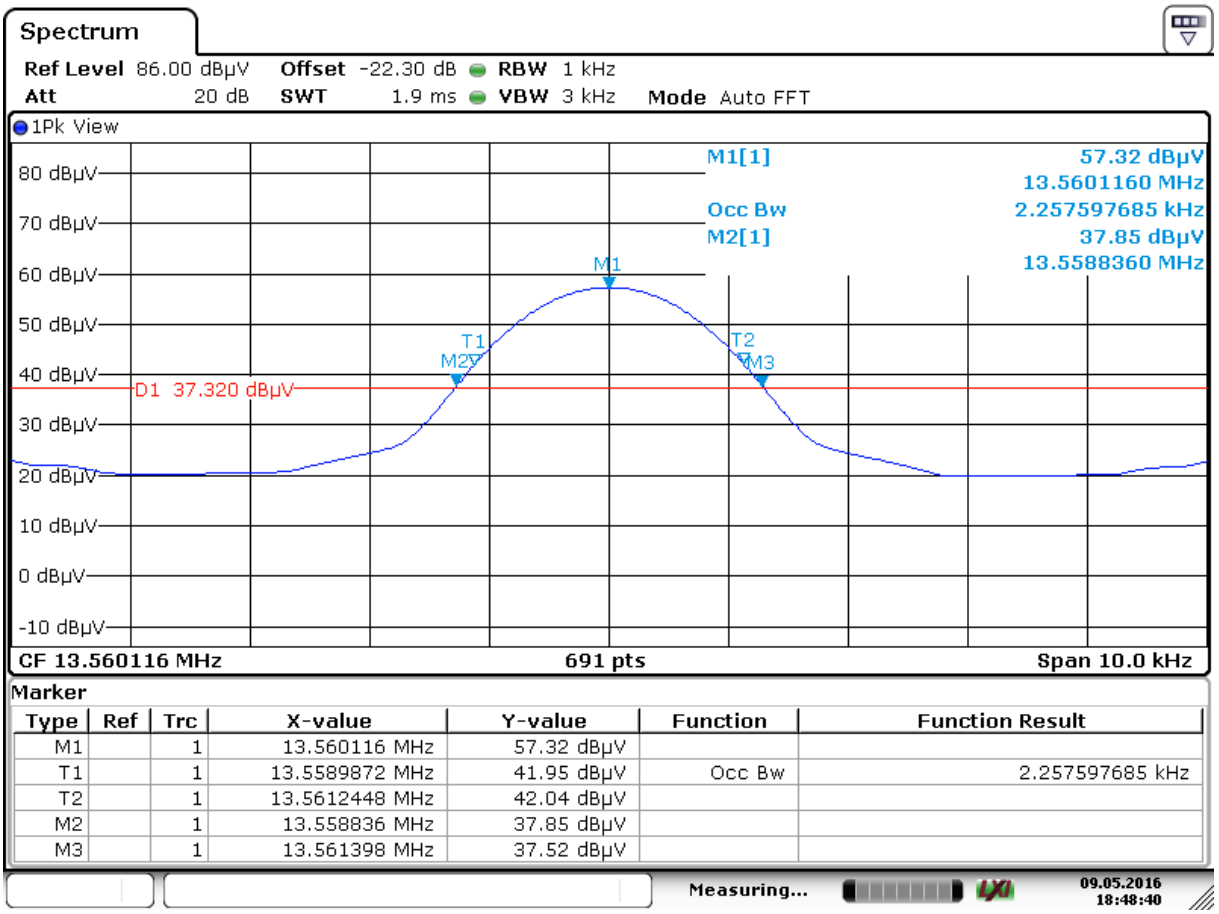


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Figure 2: 99% Bandwidth and 20 dB Bandwidth

4.3 Out-of-Band Emissions

The out of band emission is leakage measurement of the main carrier outside the allocated operating frequency band; 13.553 MHz to 13.567 MHz.
According to CFR47 Part 15.225: 2015 and RSS210 A2.6: 2010, the out of band emission shall;
-Within the bands 13.410–13.553 MHz and 13.567–13.710 MHz, the field strength of any emissions shall not exceed 334 microvolts/meter (84 dBuV/m) at 30 meters,
-Within the bands 13.110–13.410 MHz and 13.710–14.010 MHz the field strength of any emissions shall not exceed 106 microvolts/meter (40.5 dBuV/m) at 30 meters.

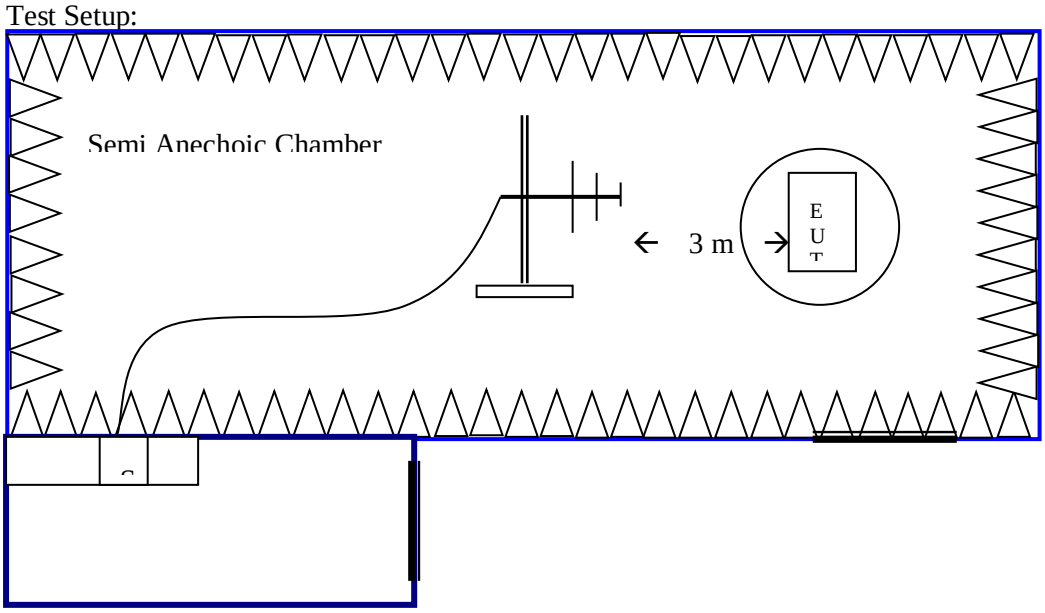
Table 6: Out of Band Emissions Limit

Frequency (MHz)	*Limit at 30m (dBuV/m)*	*Limit at 3m (dBuV/m)*	*Comment*
<13.110	*29.5*	*69.5*	*CFR47 15.225 (d), RSS210 A2.6 (d). Out of Band*
13.110-13.410	*40.5*	*80.5*	*CFR47 15.225 (c), RSS210 A2.6 (c). Out of Band*
13.410-13.533	*50.5*	*90.5*	*CFR47 15.225 (b), RSS210 A2.6 (b). Out of Band*
13.553-13.567	*84.0*	*124.0*	*CFR47 15.225 (a), RSS210 A2.6 (a), Inband (Carrier)*
13.567-13.710	*50.5*	*90.5*	*CFR47 15.225 (b), RSS210 A2.6 (b), Out of Band*
13.710-14.010	*40.5*	*80.5*	*CFR47 15.225 (c), RSS210 A2.6 (c), Out of Band*
>14.010	*29.5*	*69.5*	*CFR47 15.225 (d), RSS210 A2.6 (d), Out of Band*
Note: The limit was extrapolated 40dB/decade per CFR47 Part 15.31 (f)(3).			

4.3.1 Test Method

The radiated method was used to measure the out-of-band emission requirement. The measurement was performed with modulation per CFR47 15.225 (b) (c) 2015 and RSS 210 A2.6. (b) (c): 2010. This test was performed on three axis. The worst result indicated below.

Test Setup:



4.3.2 Test Result

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

Table 7: Out of Band Emissions – Test Results

Test Conditions: Conducted Measurement, Normal Temperature and Voltage only				
Antenna Type: Internal Loop		**Power Setting:** Maximum output setting		
Signal State: Modulated		**Duty Cycle:** 100 %		
Ambient Temp.: 21 °C		**Relative Humidity:**37%		
Sample	**Limit**	**Loop Antenna Position**	**Spectrum Mask (13.410 to 14.010MHz)**	**Result**
X-Axis	See Table 6	0	Figure 5	Pass
		90	N/A*	Pass
Y-Axis	See Table 6	0	N/A*	Pass
		90	N/A*	Pass
Z-Axis	See Table 6	0	N/A*	Pass
		90	N/A*	Pass
Note: All maximized emissions within 12 MHz to 15 MHz are below the spectrum mask limit per Table 6.				

*All EUT and Antenna orientation mask readings verified. (s. Section 4.1.2.). Worst Case orientation is represented by EUT X-Axis orientation, Antenna Position at 0 Degree.

All emission mask margins > 60 dB.

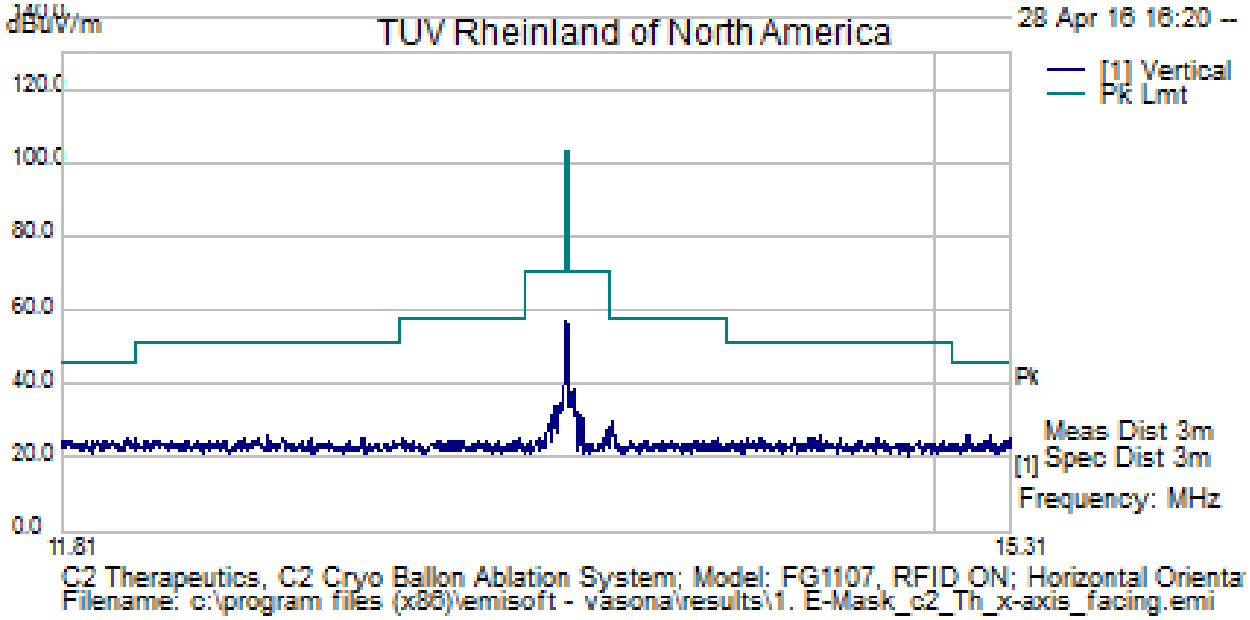


Figure 3: Out of Band Spectrum Mask for RFID Module; 0 Degree Loop Antenna – X axis – Highest identified field strength

4.4 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

4.4.1 Test Methodology

4.4.1.1 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.

4.4.1.2 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 Z-Axis.

4.4.1.3 Deviations

None.

4.4.2 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

4.4.3 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).

Table 8: Radiated Emissions – 9kHz – 30 MHz – Antenna at 0 degree

SOP 1 Radiated Emissions - worst case orientation		Tracking #	**Error! Reference source not found.**	Page 1 of 6
EUT Name	Coldplay CryoBalloon® Focal Ablation System	**Date**	April 28, 2016	
EUT Model	FG1017	**Temp / Hum in**	23°C / 34%rh	
EUT Serial	Prototype	**Temp / Hum out**	N/A	
EUT Config.	Standalone Module – Orientation X axis	**Line AC / Freq**	120 VAC	
Standard	CFR47 Part 15 Subpart C	**RBW / VBW**	See Note	
Dist/Ant Used	3m / 6502 & JB3	**Performed by**	Bernd Jungbluth	

9kHz – 30MHz

Frequency	Raw	Corrected Level	Detector	Height	Turntable	Limit	Margin	Ant	Comment
MHz	dBuV/m	dBuV/m		cm	degree	dBuV/m	dB	degree	
0.579094	33.12	44.58	Pk	146	59	72.35	-27.77	0	Spurious
1.082813	28.14	39.81	Pk	146	361	66.91	-27.10	0	Spurious
1.679813	23.86	35.49	Pk	146	0	63.10	-27.61	0	Spurious
2.407406	19.65	31.27	Pk	146	80	69.50	-38.23	0	Spurious
13.563844	44.42	56.53	Pk	146	196	69.50	-12.97	0	Carrier
0.523125	34.48	45.94	Pk	146	297	73.23	-27.30	0	Spurious
0.877594	29.95	41.41	Pk	146	335	68.74	-27.33	0	Spurious

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

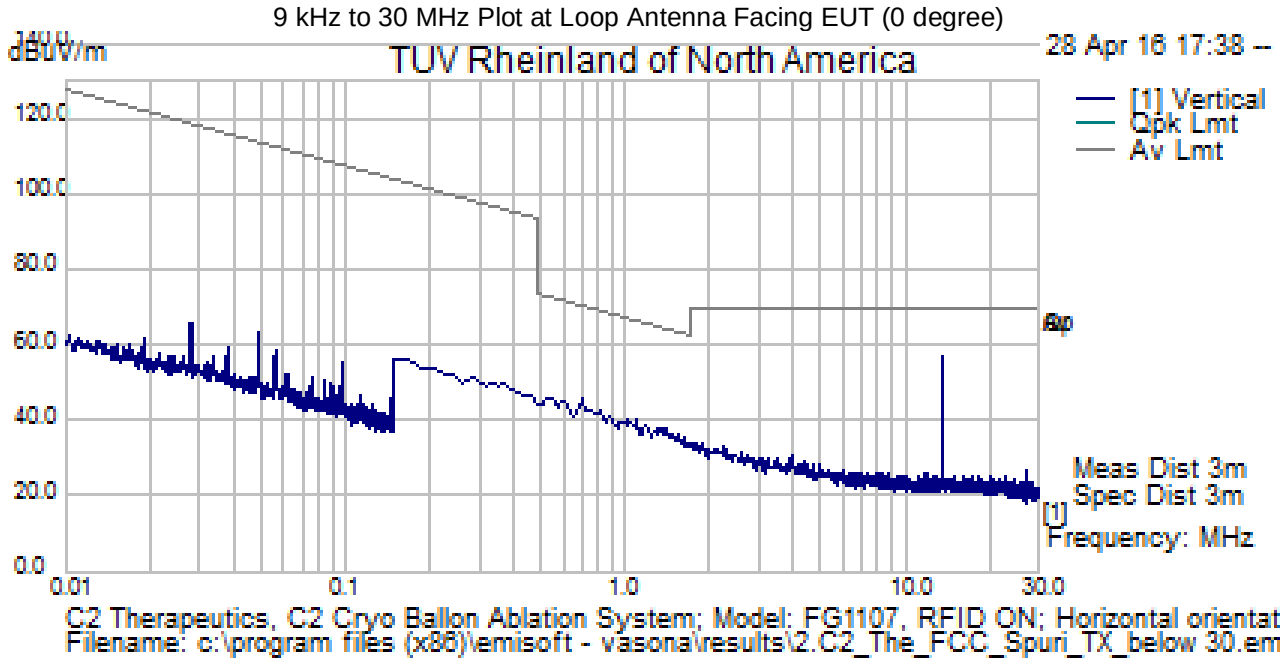
Combined Standard Uncertainty $u_c(y)$ = ± 3.2 dB Expanded Uncertainty $U = ku_c(y)$ k = 2 for 95% confidence

Note: 1. An AC PSU (TDK-Lambda, model LS25-3.3) was used to power DC voltage to EUT, Ferrite bead on DC wire.
2. RBW/VBW Setting:
9 kHz to 150 kHz; RBW = 200Hz, VBW = 1kHz
150 kHz to 30 MHz; RBW = 9kHz, VBW = 30kHz
30 MHz to 1000 MHz; RBW = 120kHz, VBW = 300kHz

Table 9: Radiated Emissions Table – 9kHz – 30 MHz – Antenna at 0 degree

SOP 1 Radiated Emissions – worst case orientation		Tracking #	**Error! Reference source not found.**	Page 2 of 6
EUT Name	Coldplay CryoBalloon® Focal Ablation System	**Date**	April 28, 2016	
EUT Model	FG1017	**Temp / Hum in**	23°C / 34%rh	
EUT Serial	Prototype	**Temp / Hum out**	N/A	
EUT Config.	Standalone Module – Orientation X axis	**Line AC / Freq**	120 VAC	
Standard	CFR47 Part 15 Subpart C	**RBW / VBW**	See Note	
Dist/Ant Used	3m / 6502 & JB3	**Performed by**	Bernd Jungbluth	

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



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

Table 10: Radiated Emissions – 9kHz – 30 MHz – Antenna at 90 degree

SOP 1 Radiated Emissions - worst case orientation		Tracking # **Error! Reference source not found.**	Page 3 of 6
EUT Name	Coldplay CryoBalloon® Focal Ablation System	**Date**	April 28, 2016
EUT Model	FG1017	**Temp / Hum in**	23°C / 34%rh
EUT Serial	Prototype	**Temp / Hum out**	N/A
EUT Config.	Standalone Module – Orientation X axis	**Line AC / Freq**	120 VAC
Standard	CFR47 Part 15 Subpart C	**RBW / VBW**	See Note
Dist/Ant Used	3m / 6502 & JB3	**Performed by**	Bernd Jungbluth

9kHz – 30MHz									
Frequency	Raw	Corrected Level	Detector	Height	Turntable	Limit	Margin	Ant	Comment
MHz	dBuV/m	dBuV/m		cm	degree	dBuV/m	dB	degree	
13.563844	39.72	51.83	Pk	146	200	69.50	-17.67	90	Carrier
1.567875	29.82	41.46	Pk	146	18	63.70	-22.24	90	Spurious
3.937219	32.53	44.38	Pk	146	114	69.50	-25.12	90	Spurious
3.545438	30.83	42.60	Pk	146	81	69.50	-26.90	90	Spurious
0.523125	33.12	44.58	Pk	146	114	73.23	-28.65	90	Spurious
4.347656	28.22	40.09	Pk	146	157	69.50	-29.41	90	Spurious
3.732	26.51	38.32	Pk	146	39	69.50	-31.18	90	Spurious
4.086469	26.24	38.10	Pk	146	60	69.50	-31.40	90	Spurious
1.978313	23.88	35.49	Pk	146	315	69.50	-34.01	90	Spurious
3.153656	23.4	35.08	Pk	146	315	69.50	-34.42	90	Spurious
27.126938	24.67	34.88	Pk	146	136	69.50	-34.62	90	Spurious
4.720781	20.26	32.13	Pk	146	304	69.50	-37.37	90	Spurious

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

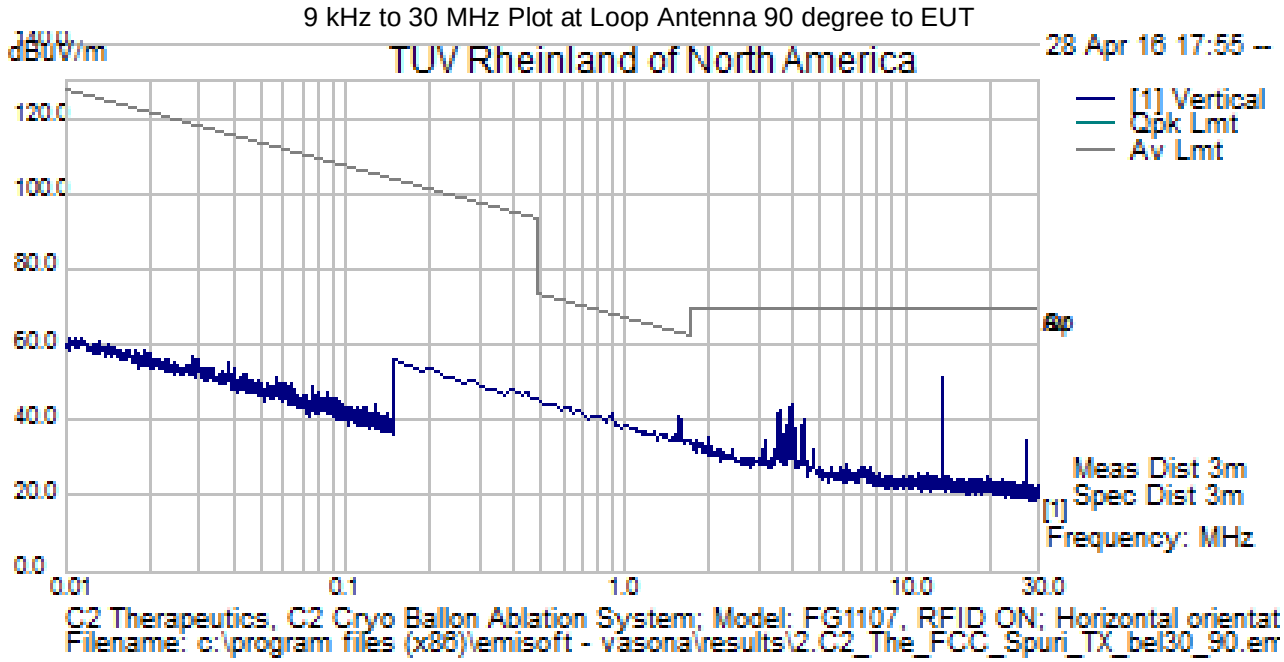
Combined Standard Uncertainty $u_c(y)$ = ± 3.2 dB Expanded Uncertainty $U = ku_c(y)$ k = 2 for 95% confidence

Note: 1. An AC PSU (TDK-Lambda, model LS25-3.3) was used to power DC voltage to EUT, Ferrite bead on DC wire.
2. RBW/VBW Setting:
9 kHz to 150 kHz; RBW = 200Hz, VBW = 1kHz
150 kHz to 30 MHz; RBW = 9kHz, VBW = 30kHz
30 MHz to 1000 MHz; RBW = 120kHz, VBW = 300kHz

Table 11: Radiated Emissions Table – 9kHz – 30 MHz – Antenna at 0 degree

SOP 1 Radiated Emissions – worst case orientation		Tracking #	**Error! Reference source not found.**	Page 4 of 6
EUT Name	Coldplay CryoBalloon® Focal Ablation System	**Date**	April 28, 2016	
EUT Model	FG1017	**Temp / Hum in**	23°C / 34%rh	
EUT Serial	Prototype	**Temp / Hum out**	N/A	
EUT Config.	Standalone Module – Orientation X axis	**Line AC / Freq**	120 VAC	
Standard	CFR47 Part 15 Subpart C	**RBW / VBW**	See Note	
Dist/Ant Used	3m / 6502 & JB3	**Performed by**	Bernd Jungbluth	

9 kHz to 30 MHz Plot at Loop Antenna 90 degree to EUT



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

Table 12: Radiated Emissions – 30MHz – 1 GHz

SOP 1 Radiated Emissions – worst case orientation		Tracking #	**Error! Reference source not found.**	Page 5 of 6
EUT Name	Coldplay CryoBalloon® Focal Ablation System	**Date**	April 25, 2016	
EUT Model	FG1017	**Temp / Hum in**	22°C / 36%rh	
EUT Serial	Prototype	**Temp / Hum out**	N/A	
EUT Config.	Standalone Module – Orientation X axis	**Line AC / Freq**	120 VAC	
Standard	CFR47 Part 15 Subpart C	**RBW / VBW**	See Note	
Dist/Ant Used	3m / 6502 & JB3	**Performed by**	Bernd Jungbluth	

30MHz – 1000MHz

Frequency	Raw	Cable Loss	AF	Level	Detector	Polarity	Height	Azimuth	Limit	Margin	Comment
MHz	dBuV/m	dB	dB	dBuV/m		H/V	cm	deg	dBuV/m	dB	
227.19	48.70	2.46	-20.34	30.81	QP	H	138	188	46.00	-15.19	Spurious
398.68	47.45	2.95	-15.87	34.53	QP	H	196	66	46.00	-11.47	Spurious
444.49	45.29	3.07	-14.85	33.50	QP	H	143	64	46.00	-12.50	Spurious
453.24	32.81	3.08	-14.77	21.12	QP	H	352	70	46.00	-24.88	Spurious
465.37	43.96	3.11	-14.23	32.84	QP	H	154	170	46.00	-13.16	Spurious
469.13	33.04	3.12	-14.07	22.09	QP	H	159	163	46.00	-23.91	Spurious
479.77	35.99	3.15	-13.95	25.20	QP	H	144	16	46.00	-20.80	Spurious
536.75	23.86	3.28	-13.30	13.83	QP	H	378	12	46.00	-32.17	Spurious
538.89	46.10	3.29	-13.28	36.11	QP	H	141	18	46.00	-9.90	Spurious
49.52	55.16	1.70	-23.31	33.55	QP	V	213	30	40.00	-6.45	Spurious
227.89	49.74	2.46	-20.31	31.89	QP	V	119	277	46.00	-14.11	Spurious
231.79	47.78	2.47	-20.16	30.09	QP	V	109	346	46.00	-15.91	Spurious
438.16	38.21	3.05	-14.90	26.36	QP	V	115	297	46.00	-19.64	Spurious
475.05	32.73	3.13	-13.85	22.01	QP	V	126	244	46.00	-23.99	Spurious
504.01	34.66	3.21	-13.91	23.96	QP	V	123	230	46.00	-22.04	Spurious
507.02	47.94	3.21	-13.85	37.30	QP	V	102	244	46.00	-8.70	Spurious
511.48	36.61	3.21	-13.84	25.98	QP	V	104	258	46.00	-20.02	Spurious
532.17	25.59	3.26	-13.34	15.52	QP	V	173	284	46.00	-30.49	Spurious

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

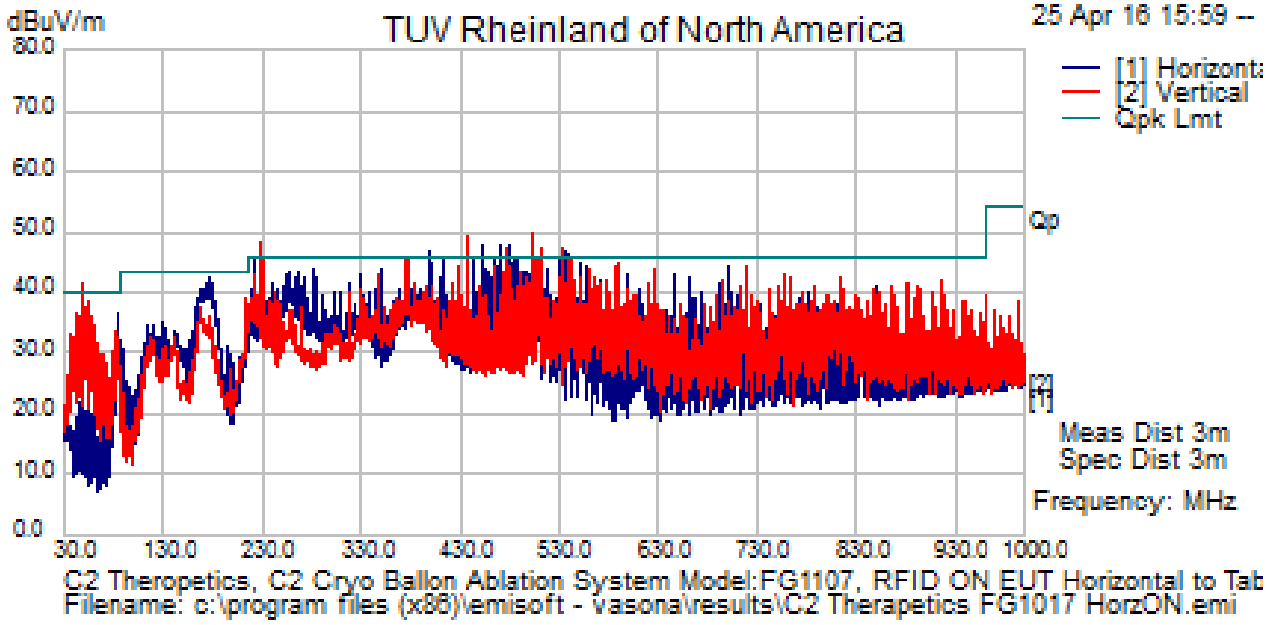
Combined Standard Uncertainty $u_c(y)$ = ± 3.2 dB Expanded Uncertainty $U = ku_c(y)$ k = 2 for 95% confidence

Note: 1. An AC PSU (TDK-Lambda, model LS25-3.3) was used to power DC voltage to EUT, Ferrite bead on DC wire.
2. RBW/VBW Setting:
9 kHz to 150 kHz; RBW = 200Hz, VBW = 1kHz
150 kHz to 30 MHz; RBW = 9kHz, VBW = 30kHz
30 MHz to 1000 MHz; RBW = 120kHz, VBW = 300kHz

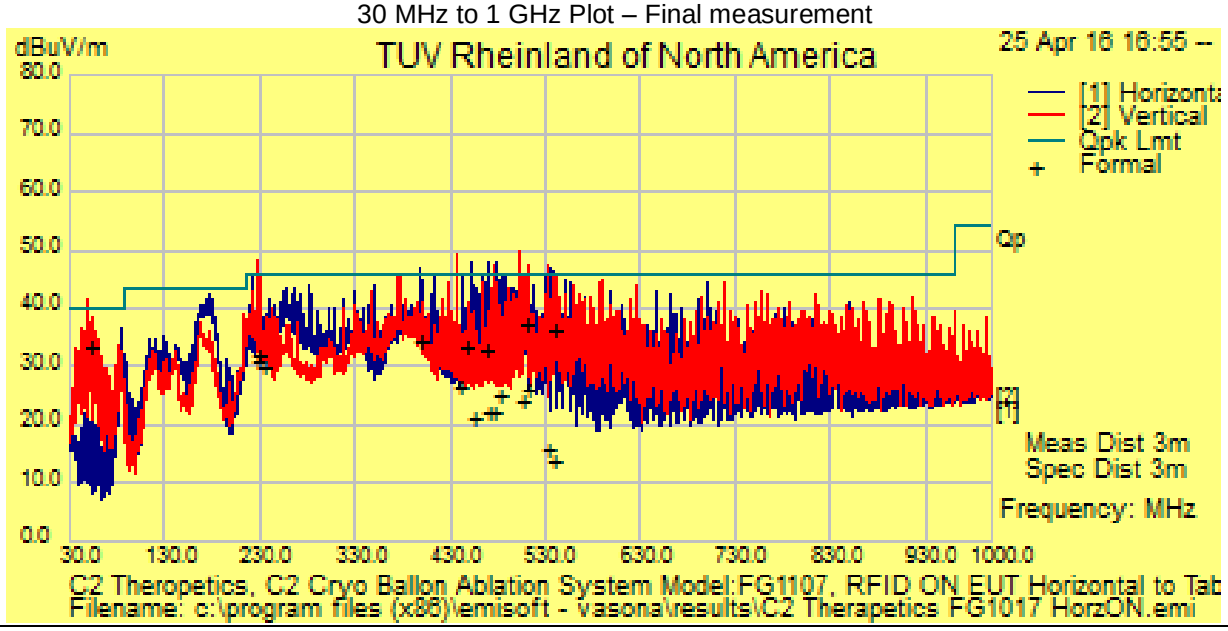
Table 13: Radiated Emissions – 30MHz – 1 GHz

SOP 1 Radiated Emissions – worst case orientation		Tracking #	**Error! Reference source not found.**	Page 6 of 6
EUT Name	Coldplay CryoBalloon® Focal Ablation System	**Date**	April 25, 2016	
EUT Model	FG1017	**Temp / Hum in**	22°C / 36%rh	
EUT Serial	Prototype	**Temp / Hum out**	N/A	
EUT Config.	Standalone Module – Orientation X axis	**Line AC / Freq**	120 VAC	
Standard	CFR47 Part 15 Subpart C	**RBW / VBW**	See Note	
Dist/Ant Used	3m / 6502 & JB3	**Performed by**	Bernd Jungbluth	

30 MHz to 1 GHz Plot – Prescan



30 MHz to 1 GHz Plot – Final measurement



Notes: 30 MHz to 1000 MHz; RBW = 120kHz, VBW = 300kHz

4.4.4 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:

$$\text{Field Strength (dB}\mu\text{V/m)} = \text{FIM} - \text{AMP} + \text{CBL} + \text{ACF}$$

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

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

5 Frequency Stability

In accordance with 47 CFR Part 15.225(e) the frequency stability of RFID 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 +35º C.

5.1 Voltage Variation

In accordance with 47 CFR Part 15.31 (e) intentional radiators, measurements of the variation of the input power or the radiated signal level of the fundamental frequency component of the emission, as appropriate, shall be performed with the supply voltage varied between 85% and 115% of the nominal rated supply voltage. For battery operated equipment, the equipment tests shall be performed using a new battery.

5.1.1 Test Methodology

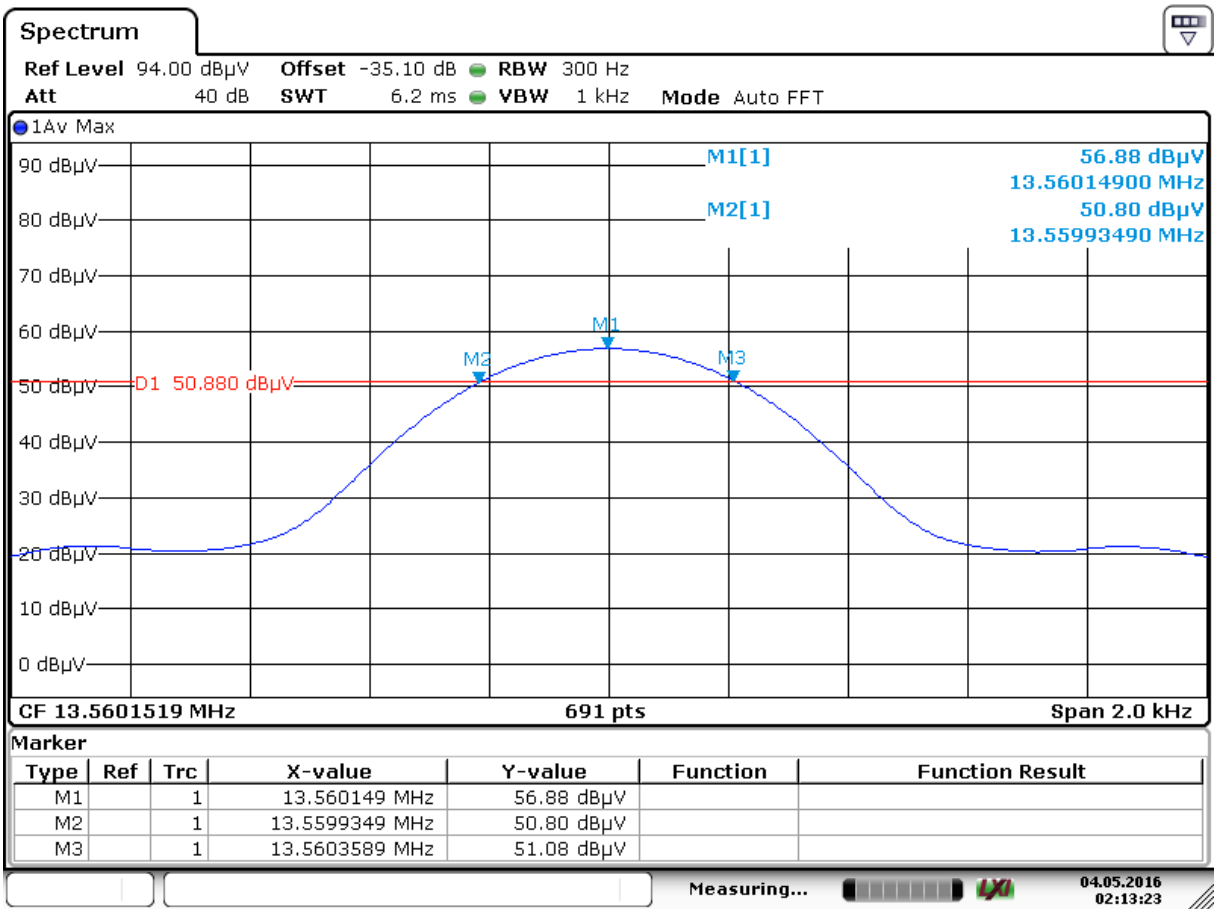
The ac supply voltage was varied between 85% and 115% of the nominal rated supply voltage. The fundamental frequency was observed during the variation. The RF ID standalone module was powered 3.3V DC by programmable power supply. The voltage was varied from 2.97VDC to 3.63VDC mean while the fundamental frequencies were observed and recorded for the maximum drift in ppm; part per millions. The operating Temperature is defined as 0

5.1.2 Test results

As originally tested, the EUT was found to be compliant to the requirements of the test standard(s). The fundamental frequencies drifted less than ±100ppm.

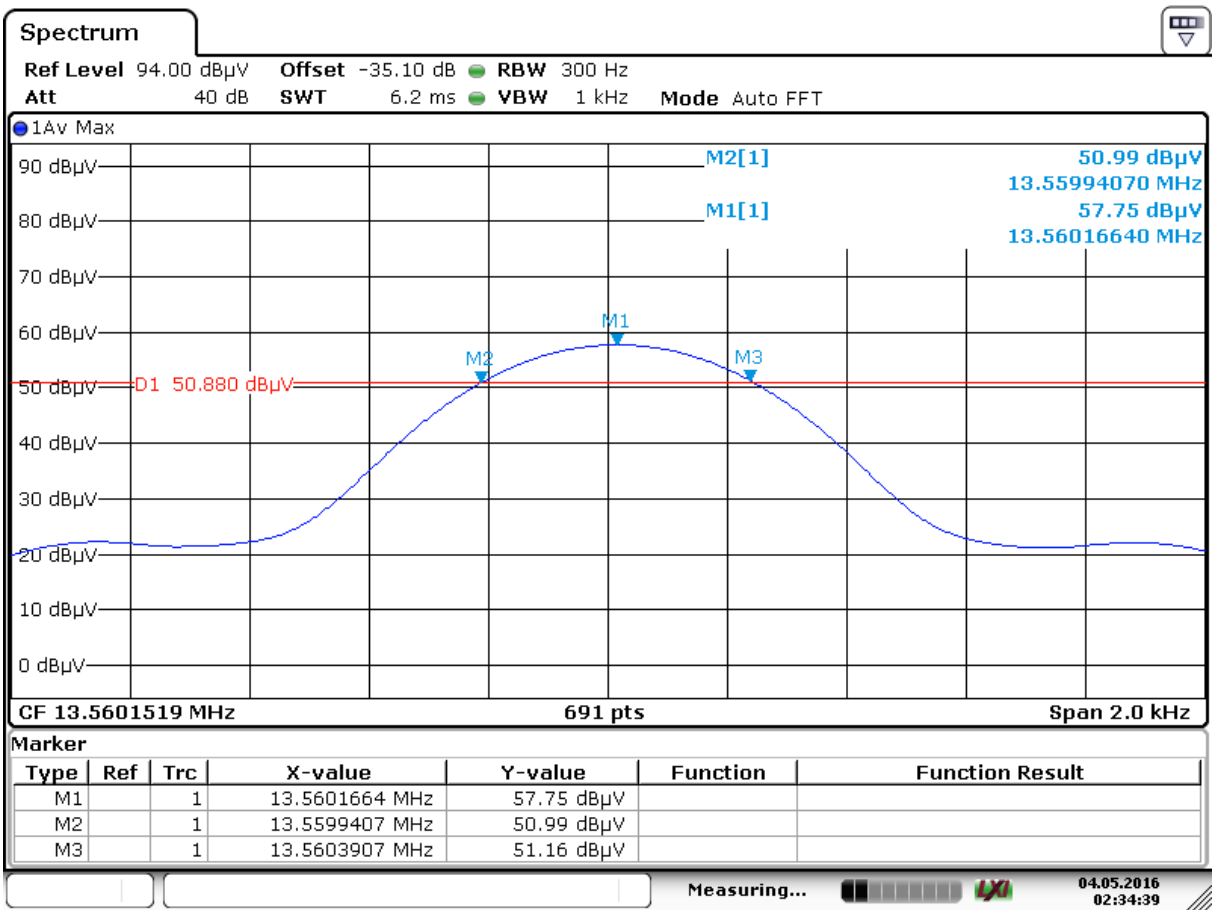
Table 14: Voltage Variation – Temperature Variation - Test Results

Temperature [°C]		Voltage [VAC]		-6 dB Lower Edge (MHz)	Center Frequency (MHz)	6 dB Upper Edge (MHz)	PPM
Tnom	20	Vnom	120	13.559935	13.560149	13.560359	nominal
Tmin	0	Vnom	120	13.559941	13.560166	13.560400	+ 1.25
Tmax	35	Vnom	120	13.560365	13.560143	13.560365	- 0.44
Tnom	20	Vmin	102	13.559941	13.560149	13.560353	0.0*
Tnom	20	Vmax	138	13.559941	13.560149	13.560356	0.0*
Note: All frequency drifts were less than ±100 ppm in relation to 13.56 MHz. *No frequency deviation observed. EUT utilizes voltage stabilized circuit.							



Date: 4 MAY 2016 02:13:23

Figure 4: Nominal Voltage at 120 VAC



Date: 4.MAY.2016 02:34:40

Figure 5: Nominal Voltage at 120 VAC - Tmin

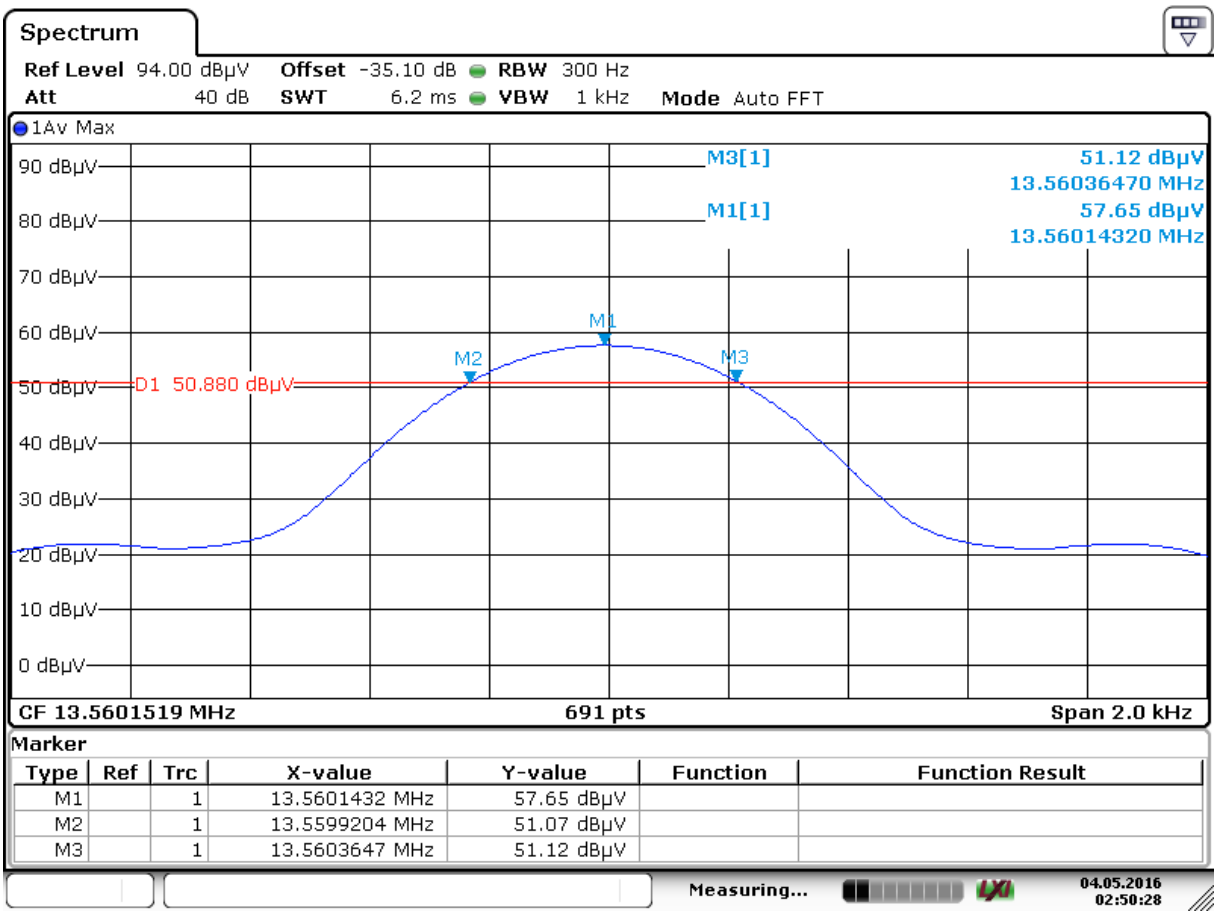


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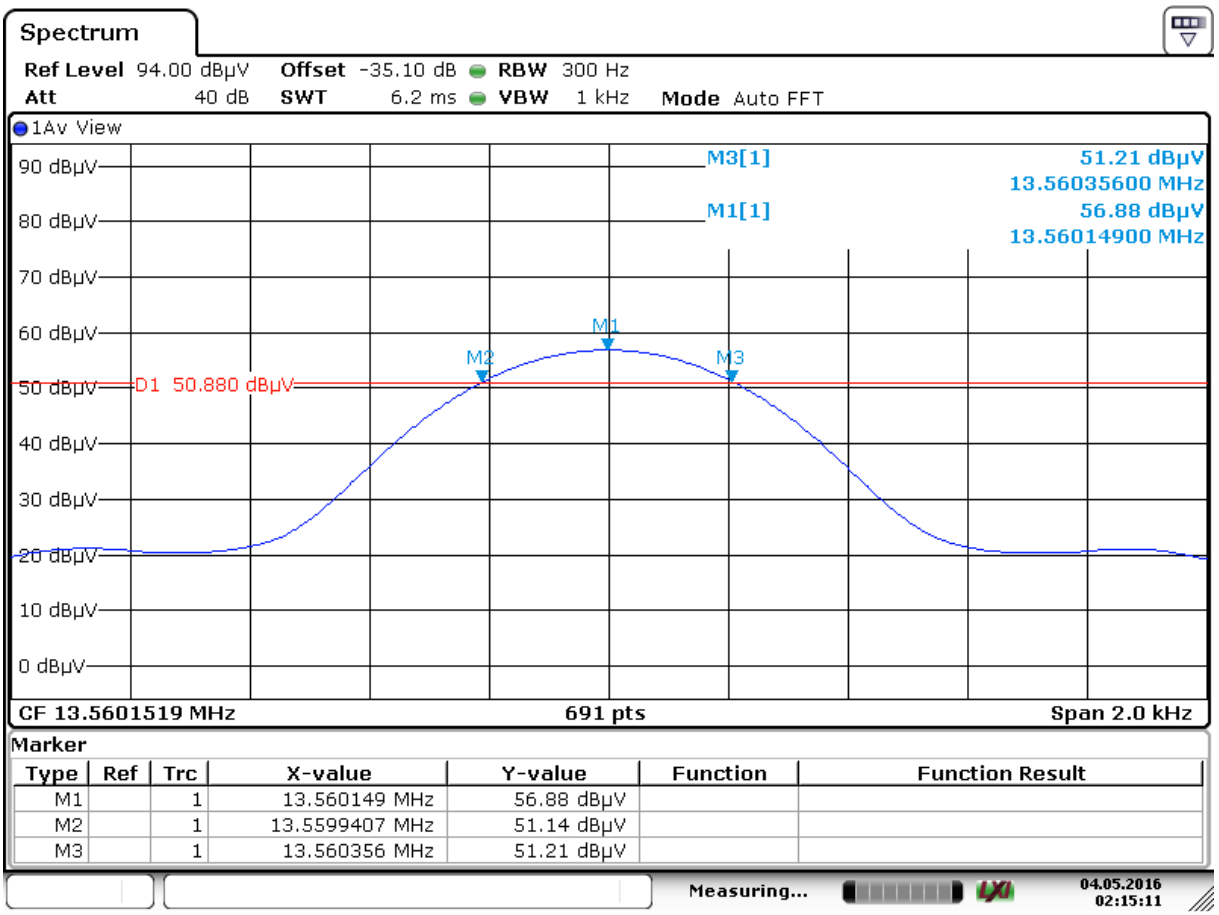
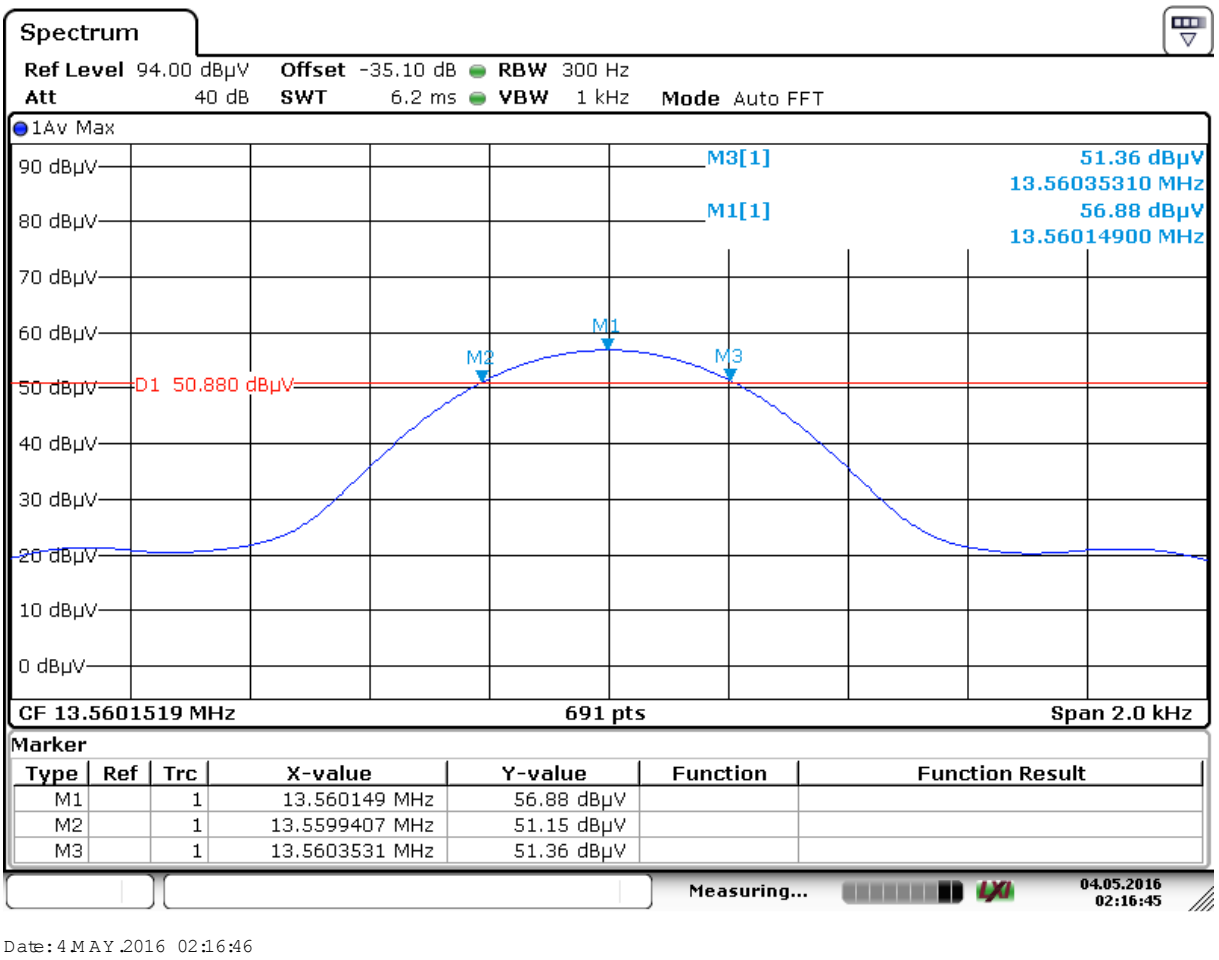
Figure 6: Nominal Voltage at 120 VAC - Tmax



Date: 4.MAY.2016 02:15:11

Figure 7: Voltage Variation at 102 VAC



Date: 4.MAY.2016 02:16:46

Figure 8: Voltage Variation at 138 VAC

5.2 Maximum Permissible Exposure

5.2.1 Test Methodology

In this document, we try to prove the safety of radiation harmfulness to the human body for our product. The limit for Maximum Permissible Exposure (MPE) specified in FCC 1.1310 is followed. The Gain of the antenna used in this product is measured in a Semi-Anechoic Chamber, and also the maximum total power input to the antenna is measured. Through the Friis transmission formula and the maximum gain of the antenna, we can calculate the distance, away from the product, where the limit of MPE is reached.

Although the Friis transmission formula is a far field assumption, the calculated result of that is an over-prediction for near field power density. We will take that as the worst case to specify the safety range.

5.2.2 RF Exposure Limit (FCC)

According to FCC 1.1310 table 1: The criteria listed in the following table shall be used to evaluate the environmental impact of human exposure to radio-frequency (RF) radiation as specified in 1.1307(b)

LIMITS FOR MAXIMUM PERMISSIBLE EXPOSURE (MPE)

Frequency Range (MHz)	Electric Field Strength (V/m)	Magnetic Field Strength (A/m)	Power Density (mW/cm2)	Average Time (minutes)
(A)Limits For Occupational / Control Exposures				
300 - 1500	…	…	F/300	6
1500 - 100,000	…	…	5	6
(B)Limits For General Population / Uncontrolled Exposure				
300 - 1500	…	…	F/1500	6
1500 - 100,000	…	…	1.0	30

F = Frequency in MHz

5.2.3 RF Exposure Limit (IC)

According to RSS-102 Issue 5 table 4: The criteria listed in the following table shall be used to evaluate the environmental impact of human exposure to radio-frequency (RF) radiation as defined in RSS-GEN

RF FIELD STRENGTH LIMITS FOR DEVICES USED BY THE GENERAL PUBLIC (UNCONTROLLED ENVIRONMENT)

Frequency Range (MHz)	**Electric Field (V/m rms)**	**Magnetic Field (A/m rms)**	**Power Density (W/m2)**	**Reference Period (minutes)**
0.003-1021	83	90	-	Instantaneous*
0.1-10	-	0.73/ f	-	6**
1.1-10	87/ $f^{0.5}$	-	-	6**
10-20	27.46	0.0728	2	6
20-48	58.07/ $f^{0.25}$	0.1540/ $f^{0.25}$	8.944/ $f^{0.5}$	6
48-300	22.06	0.05852	1.291	6
300-6000	3.142 f 0.3417	0.008335 f 0.3417	0.02619 f 0.6834	6
6000-15000	61.4	0.163	10	6
15000-150000	61.4	0.163	10	616000/ f 1.2
150000-300000	0.158 $f^{0.5}$	4.21 x 10-4 $f^{0.5}$	6.67 x 10-5 f	616000/ f 1.2
Note: f is frequency in MHz. *Based on nerve stimulation (NS). ** Based on specific absorption rate (SAR).				

5.2.4 EUT Operating Condition

The software provided by Manufacturer enabled the EUT to transmit at the regulated power for RFID;

The chipset output power was set to continuous maximum transmission.

5.2.5 Classification

The antenna of the product, under normal use condition, is at least 20cm away from the body of the user. Warning statement to the user for keeping at least 20cm or more separation distance with the antenna should be included in user's manual. So, this device is classified as a **Mobile Device**.

5.2.6 Test Results

5.2.6.1 Antenna Gain

N/A – Internal loop antenna

5.2.6.2 Output Power into Antenna & RF Exposure value at distance 20cm:

Calculations for this report are based on highest carrier field strength measurement.

The highest carrier field strength was +57.47 dBuV/m at 3 meter distance.

The calculated EIRP is -37.76 dBm or 0.00010216 mW

The Friss transmission formula: $Pd = (Pout*G) / (4*\pi*R^2)$

Using the Friss transmission formula, the EIRP is Pout*G, and R is 20cm.

$Pd = (0.00010216) / (1600\pi) = 2.03241E\text{-}08$ mW/cm^2, which is well below to the limit of 2W/m, in the range of 10 MHz to 20 MHz.

The RFID main carrier is not regulated per FCC 1.1310; furthermore, the calculated power density of the RFID Module is less than 1mW/cm^2 which meet limit stated above.

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

5.2.7 Sample Calculation

The Friss transmission formula: $Pd = (Pout*G) / (4*\pi*R^2)$

Where;

Pd = power density in mW/cm2
Pout = output power to antenna in mW
G = gain of antenna in linear scale
$\pi \approx 3.1416$
R = distance between observation point and center of the radiator in cm

Ref. : David K. Cheng, *Field and Wave Electromagnetics*, Second Edition, Page 640, Eq. (11-133).

6 Test Equipment List

6.1 Equipment List

Equipment	Manufacturer	Model #	Serial/Inst #	Last Cal dd/mm/yy	Next Cal dd/mm/yy
Bilog Antenna	Sunol Science	JB3	A020502	NCR	NCR
Passive Loop Antenna	EMCO	6502	62531	10/08/2015	10/08/2017
EMI Receiver*	Agilent	MXE N9038A	MY52260210	10/15/2015	10/15/2016
Preamplifier	Sonoma Instruments	310N	185516	01/11/2016	01/11/2017
Spectrum Analyzer	Rohde Schwarz	FSV40	1321.3008K40	11/01/2014	11/01/2016
Signal Generator	Hewlett Packard	8648C	3642U01274	01/11/2016	01/11/2017
RF Power Meter	Hewlett Packard	E4418B	MY45103859	01/15/2016	01/15/2017
Power Sensor	Hewlett Packard	8482A	1925A04647	01/11/2016	01/11/2017
Transient Limiter	Hewlett Packard	11947A	3107A03612	01/14/2016	01/14/2017
Thermo Chamber	ESPEC	BTZ-133	0613436	NCR	NCR
Thermometer	Fluke	52II	96480032	07/15/2015	07/15/2016
Digital Multimeter	Fluke	177	92780312	01/11/2016	01/11/2017

NCR = No Calibration Required

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 15: Customer Information

Company Name	C2 Therapeutics, Inc.
Address	303 Convention Way, Suite 1
City, State, Zip	Redwood City, CA 94063
Country	USA
Phone	(650) 521-5307
Fax	(650) 556-1145

Table 16: Technical Contact Information

Name	Pat Wu
E-mail	pat@c2therapeutics.com
Phone	(650) 521-5307
Fax	(650) 556-1145

7.3 Equipment Under Test (EUT)

Table 17: EUT Specifications

EUT Specification	
Dimensions: RFID Reader	245mm x 272mm x 73 mm
Power Supply: RFID Reader (via auxiliary)	110 – 240 Vac
Environment	0° C to +35° C; Category III
Declared Operating Temp.	0° C to +35° C
Multiple Feeds:	☐ Yes and how many ☒ No. RFID is powered via Host System.
Operating Mode	RFID Reader
Transmitter / Product Class	1
Receiver Category	3
Transmitter Frequency Band	13.56 MHz
Chipset Rated Power Output	200 mW
Power Setting @ Operating Channel	Fixed. Installed firmware rated as representative for maximum transmission level.
Antenna Type	Internal Loop antenna
Modulation Type	☐ AM ☐ FM ☐ Phase ☒ Other describe: OOK
Date Rate	N\A
Max. Duty Cycle	100%
Type of Equipment	☒ Table Top ☐ Wall-mount ☐ Floor standing cabinet ☐ Other *describe:*
Note: 1. The manufacturer declared the EUT operational temperature range as 0 to 35°C.	

Table 18: 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?
N/A	--	--	--	--
Note: None				

Table 19: Support Equipment

Equipment	Manufacturer	Model	Serial	Used for
RFID catheter	C2 therapeutics, Inc.	Catheter - unlabelled	None	Catheter for use with EUT
Footswitch control	C2 therapeutics, Inc.	FG - 1018	5071 - 0020	Control of EUT
PSU	IDEAL POWER	EM10681	1312610680005 C3	Power EUT auxiliary 12VDC
Note: Supporting Tag is passive device.				

Table 20: Description of Sample used for Testing

Device	Serial Number	Configuration	Used For
FG1017	Prototype	Radiated Sample	Max. Radiated Field Strength Permitted Range of Operating Freq. Range of Modulation Bandwidth Radiated Field Strength Effective Radiated Power RX Spurious Emission
FG1017	Prototype	Radiated Sample	Extreme Conditions

Table 21: Description of Test Configuration used for Radiated Measurement.

Device	Antenna	Mode	Setup Description
FG1017	Internal	Continuous Transmit & Continuous Receive	EUT 3 axis orientations
Note: EUT was tested in all 3 orthogonal axis			

7.4 Test Specifications

Testing requirements

Table 22: Test Specifications

Emissions and Immunity	
Standard	Requirement
CFR 47 Part 15.225: 2015	All
RSS 210 Iss. 8 2010	All

END OF REPORT