Report No.: *Prüfbericht-Nr.:*	**US21RQHX 002 Rev.2**	**Order No.:** *Auftrags-Nr.:*	P 00310760 234175296	Page 1 of 43 *Seite 1 von 43*
Client Reference No.: *Kunden-Referenz-Nr.:*	2240690	**Order date:** *Auftragsdatum:*	6/4/2021	
Client: *Auftraggeber:*	PENTAX Medical 303 Convention Way, Suite 1 Redwood City, CA 94063			
Test item: *Prüfgegenstand:*	C2 CryoBallon Ablation System			
Identification/ Type No.: *Bezeichnung / Typ-Nr.*	C2 CryoBallon Ablation System			
Order content: *Auftrags-Inhalt:*	Radio Compliance Test Report			
Test specification: *Prüfgrundlage:*	CFR 47 Part 15.225:2021 and RSS-210: Issue 10			
Date of sample receipt: *Wareneingangsdatum:*	9/10/2021	See Test Setup Exhibit for Photos		
Test sample No: *Prüfmuster-Nr.:*	FG-1024			
Testing period: *Prüfzeitraum:*	9/30/2021- 10/5/2021			
Testing laboratory: *Prüflaboratorium:*	TUV Rheinland of North America 5015 Brandin Ct. Fremont, CA 94538			
Test result*: *Prüfergebnis*:*	Pass			

tested by:
geprüft von:

Date: 11/15/2021
Datum:

Position / Stellung: Expert

authorized by: /
genehmigt von:

Issue Date: 11/15/2021
Ausstellungsdatum:

Position / Stellung: Expert

Others /
Sonstiges:

Condition of the test item at delivery:
Zustand des Prüfgegenstandes bei Anlieferung: Test sample complete and undamaged

* Legend:	P(ass) = passed a.m. test specification(s)	F(ail) = failed a.m. test specification(s)	N/A = not applicable	N/T = not tested
** Legende:*	*P(ass) = entspricht o.g. Prüfgrundlage(n)*	*F(ail) = entspricht nicht o.g. Prüfgrundlage(n)*	*N/A = nicht anwendbar*	*N/T = nicht getestet*

Remarks
Anmerkungen

1	The equipment used during the specified testing period was calibrated according to our test laboratory calibration program. The equipment fulfils the requirements included in the relevant standards. The traceability of the test equipment used is ensured by compliance with the regulations of our management system. Detailed information regarding test conditions, equipment and measurement uncertainty is available in the test laboratory and could be provided on request. *Alle eingesetzten Prüfmittel waren zum angegebenen Prüfzeitraum gemäß eines festgelegten Kalibierungsprogramms unseres Prüfhauses kalibriert. Sie entsprechen den in den Prüfprogrammen hinterlegten Anforderungen. Die Rückverfolgbarkeit der eingesetzten Prüfmittel ist durch die Einhaltung der Regelungen unseres Managementsystems gegeben.* *Detaillierte Informationen bezüglich Prüfkonditionen, Prüfequipment und Messunsicherheiten sind im Prüflabor vorhanden und können auf Wunsch bereitgestellt werden.*
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4	The test results contained in this report refer exclusively to the product(s) presented for testing. No liability may be assumed for models or products not referred to herein. This test report may not be published or duplicated in part without permission of the testing body. This test report by itself does not constitute authorization for the use of any TÜV Rheinland test mark. The report must not be used by the client to claim product certification, approval, or endorsement by A2LA.
5	Radio Compliance Emissions Test Report. The above product was found to be Compliant to the above test standard(s).

Test report no .: US21RQHX 002 Rev.2
Prüfbericht-Nr.:

Product description
Produktbeschreibung

1	**Product details:** *Produktdetails:*	The C2 CryoBalloon Ablation System is used to destroy unwanted tissue by application of extreme cold using Nitrous Oxide as the cryogen. 13.56 MHz near field communication (NFC) interface is used to identify types of catheter and number of uses.
2	**Dimensions / Weight:** *Maße / Gewicht:*	26cm x 22cm x7cm / 1.20lb
3	**Operating elements:** *Bedienelemente:*	C2 CryoBalloon Foot Pedal Power Supply 100–240 Volts AC @50/60 Hz, Transmit band RFID 13.56MHz
4	**Equipment / Accessories:** *Ausstattung / Zubehör:*	N/A
5	**Used materials:** *Verwendete Materialien:*	None.
6	**Other:** *Sonstiges:*	Test sample(s), as well sample information, description, product details and intended usage was provided by customer.
7	**Test sample obtaining:** *Prüfmusterbereitstellung:*	☒ Sending by customer ☐ Sampling by TÜV Rheinland Group ☐ others:

Revisions

Date mm/dd/yy	Name	Page Number of Change	Describe Change
10/13/2021	Rev. 1	N/A	Original Document
11/15/2021	Rev. 2	Page Footer	IC ID updated

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1 General Information

1.1 Scope

This report is intended to document the status of conformance with the requirements of the CFR 47 Part 15.225:2021 and RSS-210: Issue 10 based on the results of testing performed on September 30, 2021 to October 05, 2021 on C2 CryoBallon Ablation System Model No. FG-1024 manufactured by Illumina, 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.

This test report documents the 13.56MHz NFC radio.

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.7.2.5	Class B	**Complied**
Restricted Bands of Operation	CFR47 15.205, RSS 210 Sect.2.6	Class B	**Complied**
AC Power Conducted Emissions	CFR47 15.207, RSS-GEN Sect.7.2.2	Class B	**Complied**
Occupied Bandwidth	CFR47 15.215 (c), RSS GEN Sect.4.4.1	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**
Frequency Stability	CFR47 15.225 (e), RSS 210 Sect. A 2.6 (d)	100 ppm / +0.01%	**Complied**
Voltage Variation	CFR47 15.31 (e),	100 ppm / +0.01%	**Complied**

1.4 Special Accessories

No special accessories were necessary in order to achieve compliance.

2 Laboratory Information

2.1 Accreditations & Endorsements

2.1.1 US Federal Communications Commission

TUV Rheinland of North America EMC test facilities located at 1279 Quarry Lane, Ste. A, Pleasanton, CA, 94566, and 5015 Brandin Ct, Fremont, CA. 94538, are recognized 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 (Pleasanton Registration No. US1131, Fremont Registration No. US1131). The laboratory Scopes of Accreditation include Title 47 CFR Parts 15, 18 and 90. The accreditations are updated every three years.

2.1.2 A2LA

TUV Rheinland of North America EMC test facilities are accredited by the American Association for Laboratory Accreditation (A2LA). The laboratories have been assessed and accredited by A2LA in accordance with ISO Standard 17025:2017 (Testing Certificate #3331.02). The Scope of Laboratory Accreditation includes emission and immunity testing. The accreditations are updated annually.

2.1.3 Industry Canada

The Pleasanton 5-meter Semi-Anechoic Chamber, Registration No. 2932M-1, has been accepted by Industry Canada to perform testing to 3 and 5 meters based on the test procedures described in ANSI C63.4-2014. The Fremont 10-meter Semi-Anechoic Chamber, Registration No. 2932D-1, has been accepted by Industry Canada to perform testing to 3 and 10 meters based on the test procedures described in ANSI C63.4-2014.

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 EMC test facilities located at 1279 Quarry Lane, Ste. A, Pleasanton, CA, 94566, and 5051 Brandin Ct, Fremont, CA. 94538, have been assessed and approved in accordance with the Regulations for Voluntary Control Measures.

VCCI Registration No. for Pleasanton: A-0326

VCCI Registration No. for Fremont: A-0327

2.1.5 Acceptance by Mutual Recognition Arrangement

The United States has an established agreement with specific countries under the Asia Pacific Laboratory Accreditation Corporation (APLAC) Mutual Recognition Arrangement. Under this agreement, all TUV Rheinland at 1279 Quarry Ln, Pleasanton, CA 94566 test results and test reports within the scope of the laboratory NIST / A2LA accreditation will be accepted by each member country.

2.2 Test Facilities & EMC Software

Test facilities are located at 1279 Quarry Lane, Ste. A, Pleasanton, California 94566, U.S.A. and 5015 Brandin Ct, Fremont, CA. 94538, U.S.A. (Fremont is the Pleasanton Annex).

2.2.1 Emission Test Facility

The Semi-Anechoic Chambers and AC Line Conducted measurement facilities used to collect radiated and conducted emissions data have been constructed in accordance with ANSI C63.7:1992. The Fremont 10 meter semi-anechoic chamber has been measured in accordance with and verified to comply with the theoretical volumetric normalized site attenuation of ANSI C63.4-2014 and SVSWR requirements of CISPR 16-1-4 Consol. Ed. 3.0 (2010-04), at test distances of 3 and 10 meters. This site has been described in reports dated November 1st, 2006, submitted to the FCC, and accepted by letter dated November 28, 2006. The site is listed with the FCC and accredited by A2LA (Testing Certificate #3331.02). The Pleasanton 5 meter semi-anechoic chamber has been verified to comply with the theoretical volumetric normalized site attenuation of ANSI C63.4-2014 and SVSWR requirements of CISPR 16-1-4 Consol. Ed. 3.0 (2010-04) at a test distance of 3 meters. This site has been described in reports dated November 1st, 2006, submitted to the FCC, and accepted by letter dated November 28, 2006. The site is listed with the FCC and accredited by A2LA (Testing Certificate #3331.02).

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 7.3 m x 4.3 m x 4.1 m anechoic chamber.

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

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

2.2.3 EMC Software – Pleasanton and Fremont

Manufacturer	Name	Version	Test Type
Rohde & Schwarz	EMC32	10.40.10	Radiated Emissions
ETS-Lindgren	TILE	3.4.K.14 @ 4.0.A.5	Radiated & Conducted Emissions
Agilent	Agilent MXE	A.11.02	Radiated & Conducted Emissions
ETS-Lindgren	TILE	3.4.K.14	Radiated & Conducted Immunity
Thermo Electron - Keytek	CEWare32	4.00	EFT/Surge/Voltage Dips & Interrupt
Voltech	IEC61000-3	1.21.07RC2	Harmonic & Flicker

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 measurement. 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 Uncertainty

Measurement Uncertainty Emissions

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 – 40 GHz	2.47 dB	4.93 dB
Conducted Disturbance @ Mains Terminals		
150 kHz – 30 MHz	1.09 dB	2.18 dB

Voltech PM6000A

The estimated combined standard uncertainty for harmonic current and flicker measurements is ± 5.0%.	Per CISPR 16-4-2 Methods

Measurement Uncertainty Immunity

The estimated combined standard uncertainty for ESD immunity measurements is ± 8.2%.	Per IEC 61000-4-2
The estimated combined standard uncertainty for radiated immunity measurements is ± 4.10 dB.	Per IEC 61000-4-3
The estimated combined standard uncertainty for conducted immunity measurements with CDN is ± 3.66 dB	Per IEC 61000-4-6
The estimated combined standard uncertainty for power frequency magnetic field immunity is ± 2.9%.	Per IEC 61000-4-8

Thermo KeyTek EMC Pro

The estimated combined standard uncertainty for EFT fast transient immunity measurements is ± 2.6%.
The estimated combined standard uncertainty for surge immunity measurements is ± 2.6%.
The estimated combined standard uncertainty for voltage variation and interruption measurements is ± 1.74%.

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 ± 0.70 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 ± 2.06 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 Standard 17025:2017. Equipment calibration records are kept on file at the test facility.

3 Product Information

3.1 Product Description

The C2 CryoBalloon™ Ablation System is used to destroy unwanted tissue by application of extreme cold using Nitrous Oxide as the cryogen. The system consists of a single-use Catheter, a reusable Controller, a reusable Foot Pedal, and small, single-use, disposable Nitrous Oxide Cartridges. The Balloon Probe at the end of the Catheter is inflated by Nitrous Oxide and contact the wall of targeted tissue. Nitrous Oxide is released into the Catheter upon activation of the Foot Pedal and directed towards the unwanted tissue, which ablates the unwanted tissue. Nitrous oxide is fully contained within the balloon and the system – the nitrous oxide gas exits through the proximal end of the Catheter and out of the Controller.

The C2 CryoBalloon™ Ablation System is comprised of the following main components:

- **C2 CryoBalloon™ Catheter**
  - C2 CryoBalloon™ Catheter connects to the Controller, which controls the operation of the Catheter such as diffuser (sprayer) positioning and ablation (nitrous oxide release). The Catheter is supplied sterile.
- **C2 CryoBalloon™ Controller**
  C2 CryoBalloon™ Controller is powered by 12VDC through the Foot Pedal and is supplied non-sterile. A LCD touch screen on the Controller communicates system status and allows the physician to input Dosimetry. The Controller performs the physician's commands via the Foot Pedal such as diffuser positioning, ablation, and balloon deflation. The Controller is supplied non-sterile.
- **C2 CryoBalloon™ Cartridge**
  C2 CryoBalloon™ Cartridge contains 36 grams of nitrous oxide. The Cartridge is easily installed into the Controller and replaced as required per procedure. The Cartridge is supplied non-sterile.
- **C2 CryoBalloon™ Foot Pedal**
  C2 CryoBalloon™ Foot Pedal communicates the physician's commands to the Controller. The Foot Pedal is powered by mains via a certified medical grade power supply. The Foot Pedal is supplied non-sterile

13.56 MHz near field communication (NFC) interface is used to identify types of catheter and number of uses. Each catheter contains a RFID tag on the catheter connector. The NFC controller and antenna are located on the Controller sensor printed circuit board (PCB) that is located near the catheter connector receptacle. The NFC circuitry is continuously turned on.

3.2 Equipment Configuration

A description and justification of the equipment configuration is given in the EMC Test Plan. The EUT was tested as described in the EMC Test Plan and was configured and operated in a manner consistent with its intended use. The EUT was connected to rated power and allowed to warm up to normal 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 a 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 worse case radiation and place the EUT in the most susceptible state. There were no deviations from the description of the Equipment Configuration given in the EMC Test Plan.

3.3 Operating Mode

A description and justification of the operation mode is given in the EMC Test Plan.

In the case of a 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 worse case radiation and place the EUT in the most susceptible state. There were no deviations from the description of the Operation Mode given in the EMC Test Plan.

The EUT was configured to operate using the manufacturer’s software to toggle the radio on/off and to applicable channels.

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 C2 CryoBallon Ablation System uses the permanently attached antenna for RF Identification. The NFC controller and 6-turn Flat PCB coil antenna are located on the Controller sensor printed circuit board (PCB). Antenna is built in and is part of the unit.

4 Emissions

Testing was performed in accordance with CFR 47 Part 15.225:2021 and RSS 210 Annex 2:2019. 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.

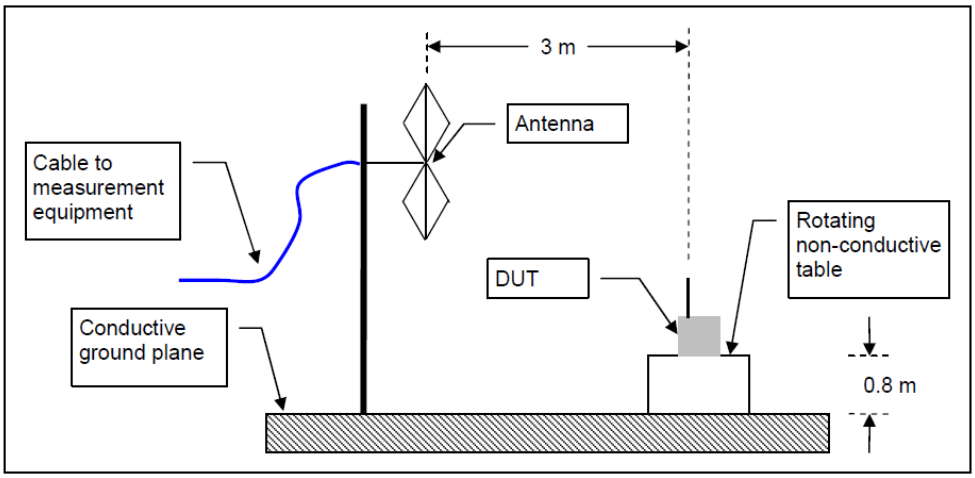
The RF fundamental field strengths shall not exceed CFR47 Part 15.225 (a):2021 and RSS 210 A2.6 (a):2010.

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 worst results indicated below.

4.1.2 Test Setup:



RBW is set to 200 Hz and VBW is set to 1 kHz for 9 kHz-150 kHz.
RBW is set to 9 kHz and VBW is set to 30 kHz for 150 kHz-30 MHz.
RBW is set to 100 kHz, VBW is set to 300 kHz for 30 MHz-1 GHz.

4.1.3 Results

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

Table 2: RF Fundamental Field Strength – Test Results

Test Conditions: Radiated Measurement, Normal Temperature and Voltage only						
Antenna Type: 6-turn Flat PCB coil			**Power Setting:** Default			
Ambient Temp.: 21 °C			**Relative Humidity:**42 %			
Test Performed by: Rachana Khanduri						
Operating Frequency	**Test Results**					
	Measured Level [dBuV/m]	**Loop Position**	**Table [degree]**	**Antenna [cm]**	**Limit [dBuV/m]**	**Margin [dB]**
13.56 MHz	51.03	0	277	100	124.00	-72.97
	48.65	90	183	100	124.00	-75.35
Note: Measurements was taken at 3-meter distance, and the limit was extrapolated accordingly. Measurement was performed on worst case EUT axis.						

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.

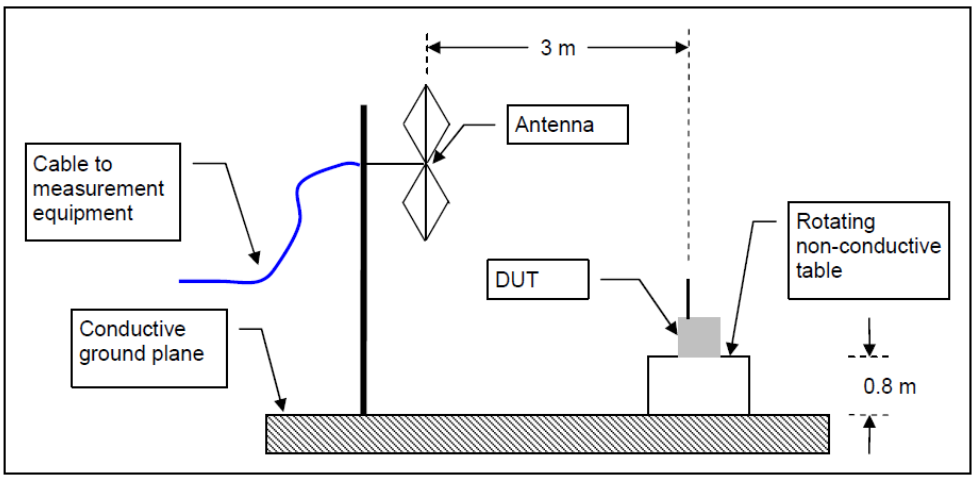
The 20dB bandwidth is defined the bandwidth of 20 dBr from highest transmitted level of the fundamental frequency.

The bandwidth shall be documented per Section CFR47 15.215(c) 2020 and RSS Gen Sect. 4.6: 2010.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. The worst result indicated below.

4.1.4 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 3: Occupied Bandwidth – Test Results

Test Conditions: Radiated Measurement, Normal Temperature and Voltage only				
Antenna Type: 6-turn Flat PCB coil			**Power Setting:** Default	
Ambient Temp.: 21 °C			**Relative Humidity:**42 %	
Test Performed by: Rachana Khanduri				
Occupied Bandwidth for 13.56 MHz				
Operating Frequency	**Limit (kHz)**	**99% BW (kHz)**	**20 dB BW (kHz)**	**Results**
13.56MHz	Note 1	2.28	2.66	Pass
Note 1: All lower and upper markers of 99% Bandwidth and 20 dB Bandwidth are within the allowable band; 13.553 MHz to 13.567MHz				

Table 4: 20 dB Bandwidth Frequency – Test Results

Test Conditions: Radiated Measurement, Normal Temperature and Voltage only				
Antenna Type: 6-turn Flat PCB coil			**Power Setting:** Default	
Ambient Temp.: 21 °C			**Relative Humidity:**42 %	
Test Performed by: Rachana Khanduri				
20 dB Bandwidth Frequencies for 13.56 MHz				
Operating Frequency	**Occupied Band Limit (MHz)**	**Lower Freq. (MHz)**	**Upper Freq. (MHz)**	**Results**
13.56MHz	13.553 < X < 13.567	13.558205128	13.560865385	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.				

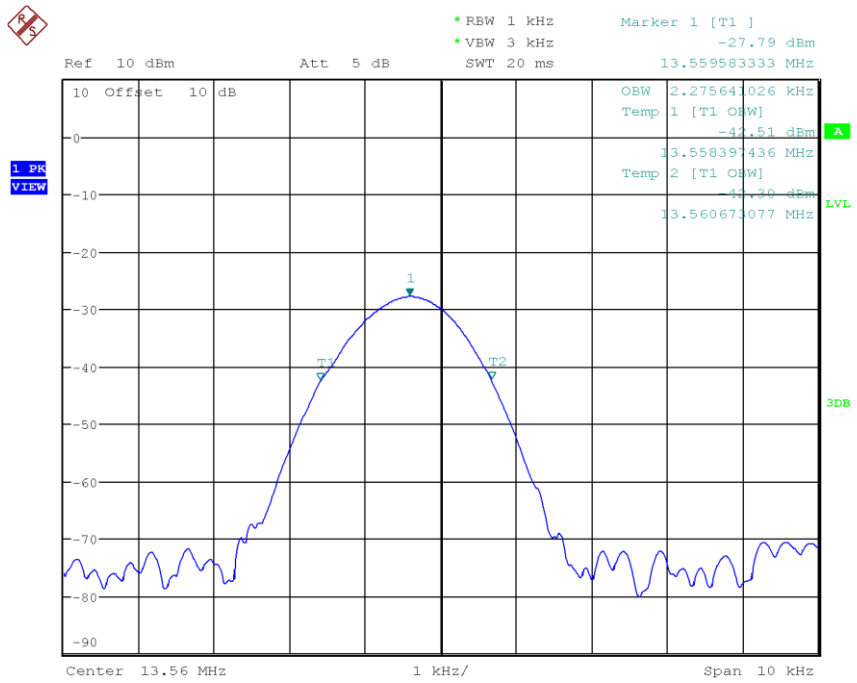


Figure 1: 99% Occupied Bandwidth

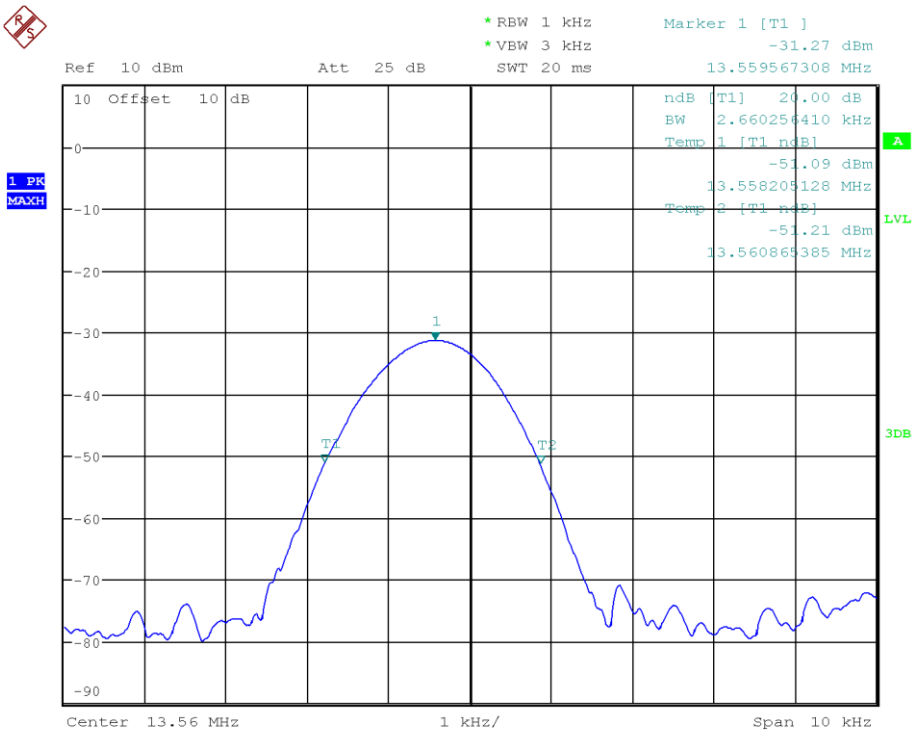


Figure 2: 20dB Occupied Bandwidth

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: 2010 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.

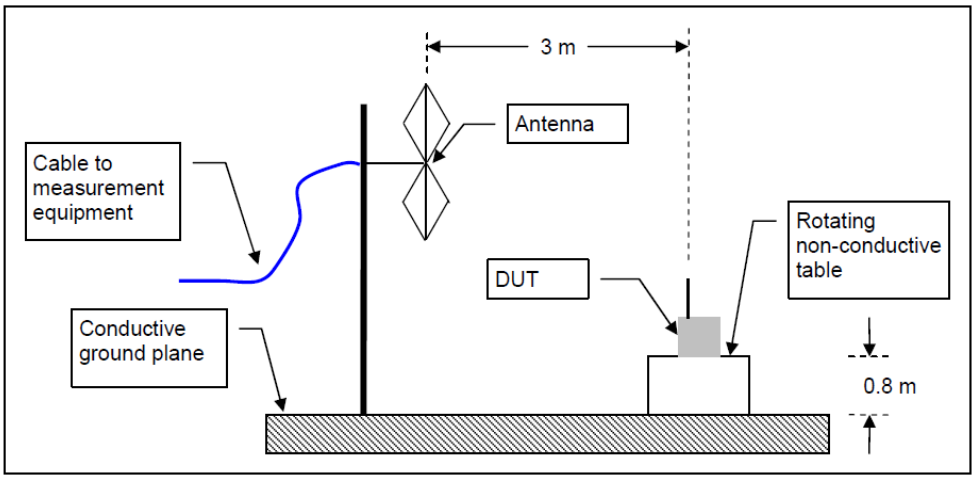
Table 5: Out of Band Emissions Limit

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) 2010 and *RSS 210 A2.6.* (b) (c)*: 2010*. The worst result indicated below.

4.1.5 Test Setup:



RBW is set to 200 Hz and VBW is set to 1 kHz for 9 kHz-150 kHz.
RBW is set to 9 kHz and VBW is set to 30 kHz for 150 kHz-30 MHz
RBW is set to 100 kHz, VBW is set to 300 kHz for 30 MHz-1 GHz.

4.3.2 Test Result

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

Table 6: Out of Band Emissions – Test Results

Test Conditions: Radiated Measurement, Normal Temperature and Voltage only				
Antenna Type: 6-turn Flat PCB coil		**Power Setting:** Default		
Ambient Temp.: 21 °C		**Relative Humidity:**42 %		
Test Performed by: Rachana Khanduri				
Operating Frequency	**Loop Antenna Position**	**Spectrum Mask (12 to 15MHz)**	**Limit**	**Result**
13.56MHz	0	Figure #3	See Table 5	Pass
	90	Figure #4		Pass
Note: All maximized emissions within 12 MHz to 15 MHz are below the spectrum mask limit.				

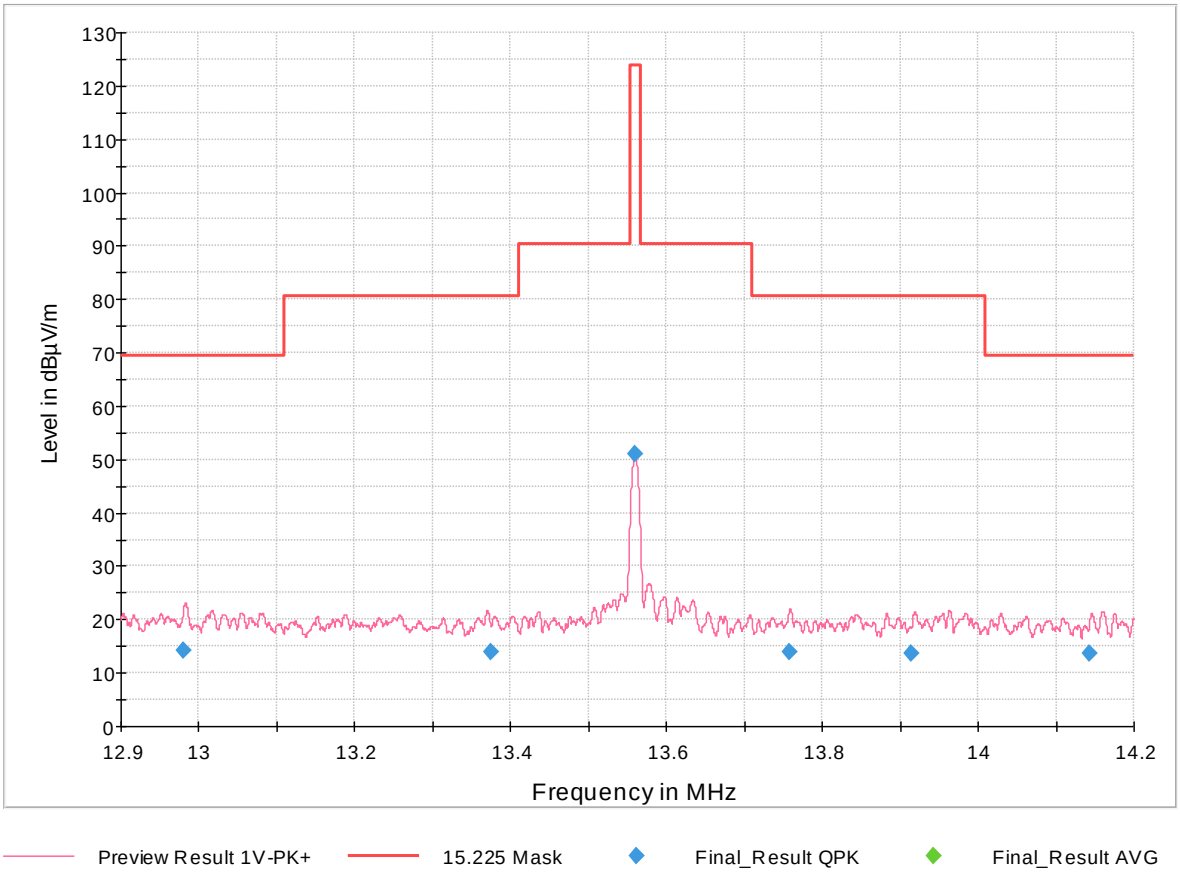


Figure 3: Out of Band Spectrum Mask– 0 Degree Loop Antenna

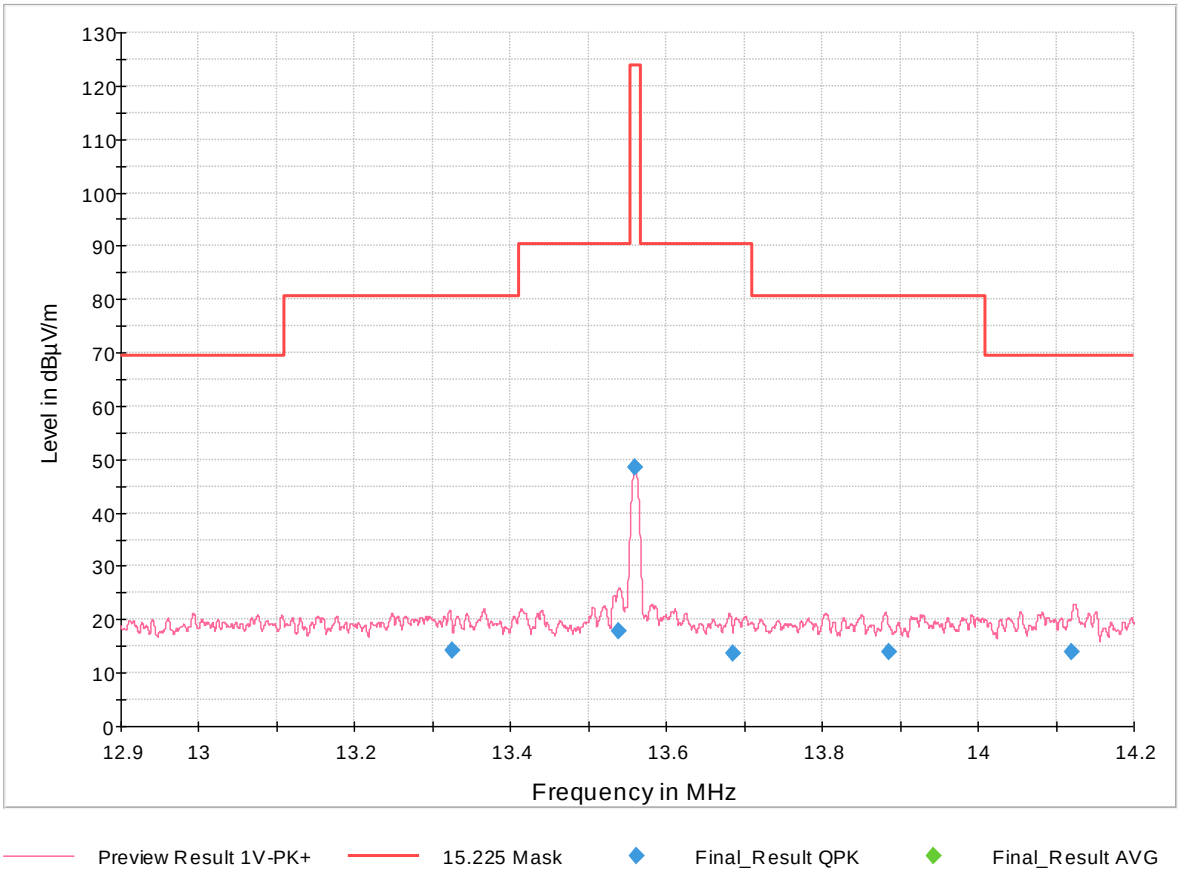


Figure 4: Out of Band Spectrum Mask for– 90 Degree Loop Antenna

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 worst case axis.

RBW is set to 200 Hz and VBW is set to 1 kHz for 9 kHz-150 kHz.
RBW is set to 9 kHz and VBW is set to 30 kHz for 150 kHz-30 MHz
RBW is set to 100 kHz, VBW is set to 300 kHz for 30 MHz-1 GHz.

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: 2020 and RSS GEN 6.1: 2010.

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 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)

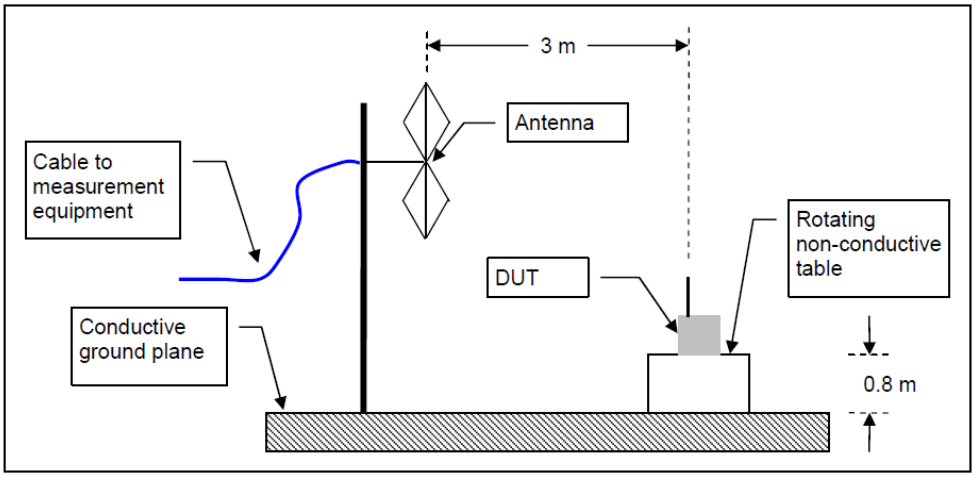
AMP = Amplifier Gain (dB)

CBL = Cable Loss (dB)

ACF = Antenna Correction Factor (dB/m)

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

Test Setup



4.4.4 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.

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

SOP 1 Radiated Emissions 9 kHz – 30 MHz			
EUT Name	C2 CryoBallon Ablation System	**Date**	October 05, 2021
EUT Model	FG-1024	**Temp / Hum in**	21°C / 44%rh
EUT Serial	N/A	**Temp / Hum out**	N/A
EUT Config.	RFID-13.56MHz	**Line AC / Freq**	120 VAC / 60Hz
Standard	CFR47 Part 15 Subpart C	**RBW / VBW**	See note 1 below
Dist/Ant Used	3m / Loop Antenna – 0 degree	**Performed by**	Rachana Khanduri

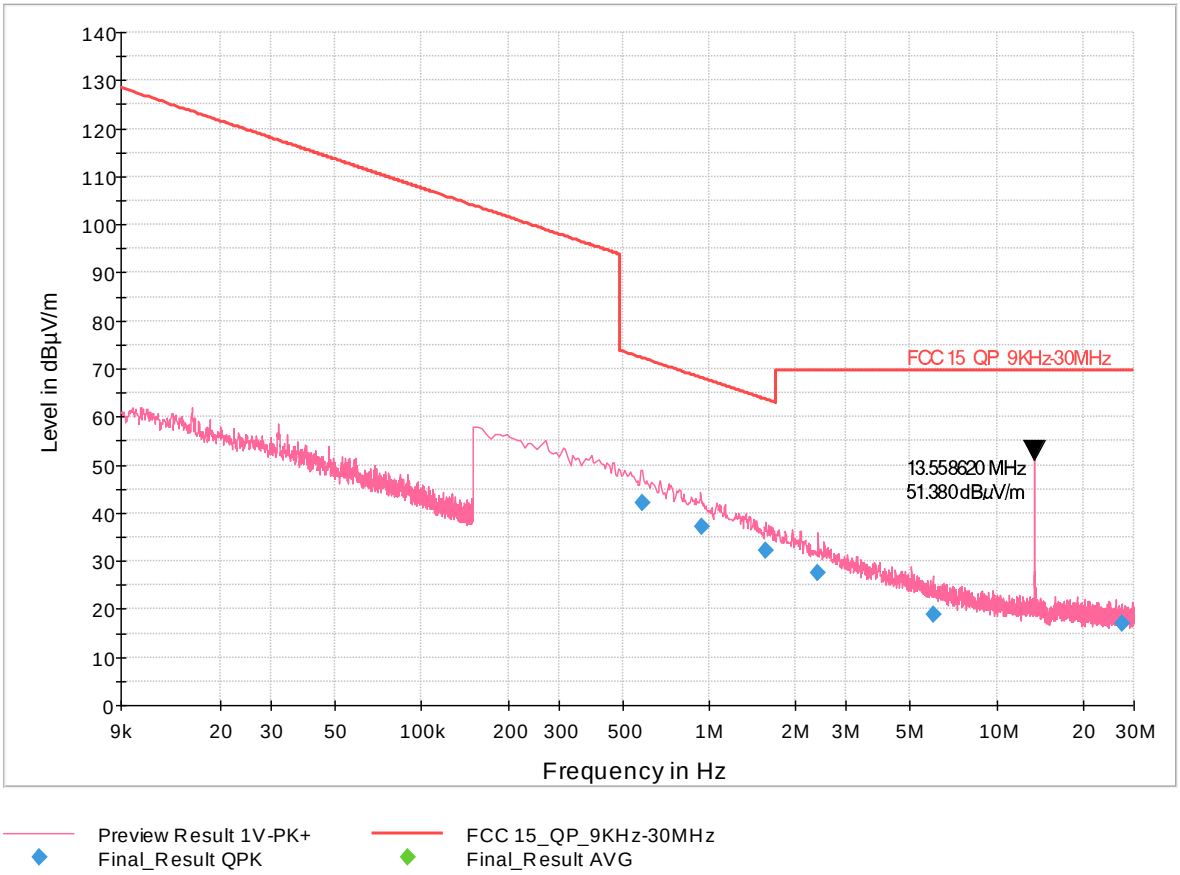


Figure 5: 9KHz-30MHz Plot – 0 Degree Loop Antenna

Final_Result

Frequency (MHz)	QuasiPeak (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol (0/90 degree)	Azimuth (deg)	Corr. (dB/m)
0.584944	**42.10**	**72.26**	**30.16**	**1000.0**	**9.000**	**100**	**0**	**246.0**	**11.8**
0.936570	**37.23**	**68.17**	**30.95**	**1000.0**	**9.000**	**100**	**0**	**54.0**	**12.0**
1.567818	**32.36**	**63.70**	**31.34**	**1000.0**	**9.000**	**100**	**0**	**252.0**	**12.1**
2.386986	**27.43**	**69.54**	**42.11**	**1000.0**	**9.000**	**100**	**0**	**141.0**	**12.0**
5.993153	**18.79**	**69.54**	**50.75**	**1000.0**	**9.000**	**100**	**0**	**298.0**	**11.6**
27.119013	**17.19**	**69.54**	**52.35**	**1000.0**	**9.000**	**100**	**0**	**145.0**	**9.6**

Note:

1. RBW/VBW Setting:
   9 kHz to 150 kHz; RBW = 200Hz, VBW = 1kHz
   150 kHz to 30 MHz; RBW = 9kHz, VBW = 30kHz
   30 MHz - 1GHz; RBW = 100 kHz, VBW = 3 x RBW

2. The highest emission on the plots is the fundamental signal at 13.56MHz.

SOP 1 Radiated Emissions 9 kHz – 30 MHz			
EUT Name	C2 CryoBallon Ablation System	**Date**	October 5, 2021
EUT Model	FG-1024	**Temp / Hum in**	21°C / 44%rh
EUT Serial	N/A	**Temp / Hum out**	N/A
EUT Config.	RFID-13.56MHz	**Line AC / Freq**	120 VAC / 60Hz
Standard	CFR47 Part 15 Subpart C	**RBW / VBW**	See note 1 below
Dist/Ant Used	3m / Loop Antenna – 90 degree	**Performed by**	Rachana Khanduri

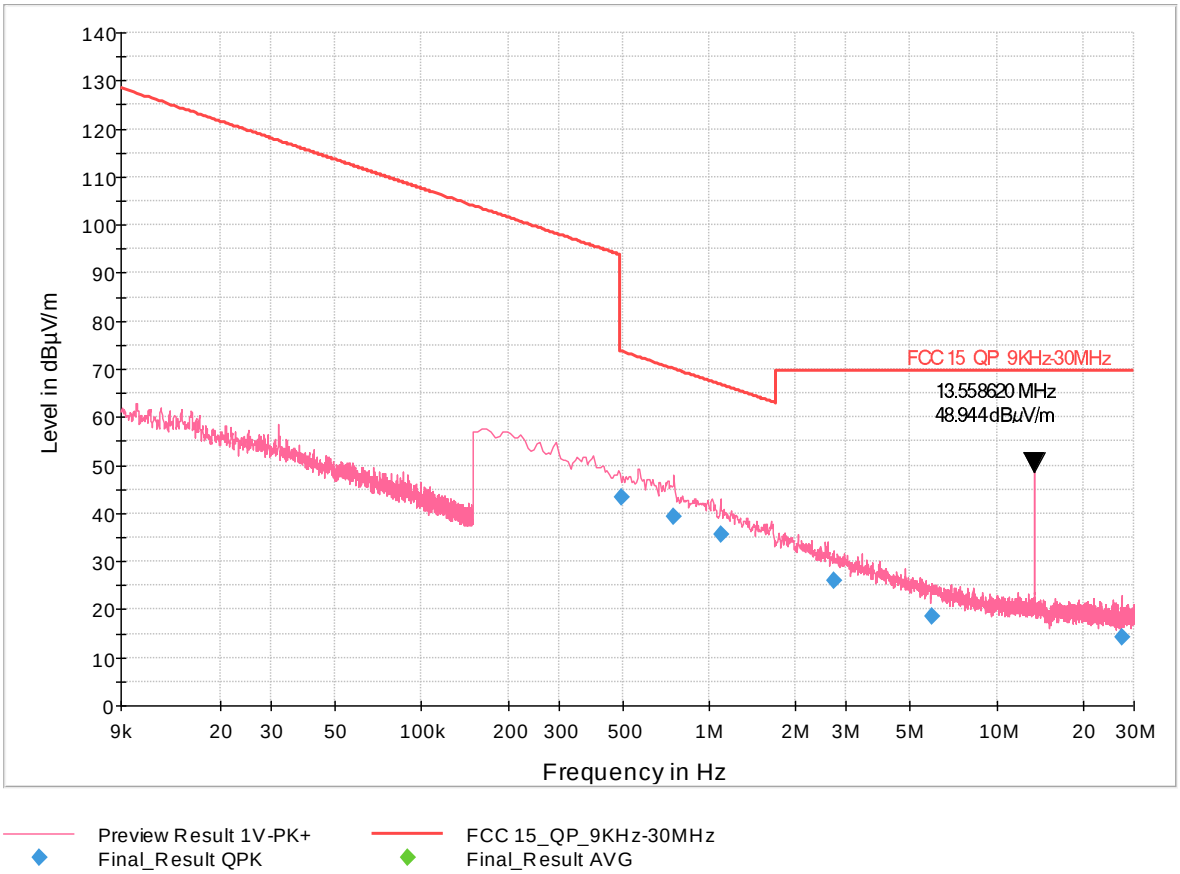


Figure 6: 9KHz-30MHz Plot– 90 Degree Loop Antenna

Final_Result

Frequency (MHz)	QuasiPeak (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol (0/90 degree)	Azimuth (deg)	Corr. (dB/m)
0.494790	**43.47**	**73.72**	**30.25**	**1000.0**	**9.000**	**100**	**90**	**225.0**	**11.8**
0.748495	**39.40**	**70.12**	**30.72**	**1000.0**	**9.000**	**100**	**90**	**175.0**	**11.8**
1.097753	**35.66**	**66.79**	**31.14**	**1000.0**	**9.000**	**100**	**90**	**248.0**	**12.1**
2.720793	**26.00**	**69.54**	**43.54**	**1000.0**	**9.000**	**100**	**90**	**260.0**	**11.9**
5.966250	**18.73**	**69.54**	**50.81**	**1000.0**	**9.000**	**100**	**90**	**32.0**	**11.6**
27.124640	**14.22**	**69.54**	**55.32**	**1000.0**	**9.000**	**100**	**90**	**178.0**	**9.6**

Note:

1. RBW/VBW Setting:
   9 kHz to 150 kHz; RBW = 200Hz, VBW = 1kHz
   150 kHz to 30 MHz; RBW = 9kHz, VBW = 30kHz
   30 MHz - 1GHz; RBW = 100 kHz, VBW = 3 x RBW

2. The highest emission on the plots is the fundamental signal at 13.56MHz.

SOP 1 Radiated Emissions			
EUT Name	C2 CryoBallon Ablation System	**Date**	October 5, 2021
EUT Model	FG-1024	**Temp / Hum in**	21°C / 42%rh
EUT Serial	N/A	**Temp / Hum out**	N/A
EUT Config.	RFID -13.56MHz	**Line AC / Freq**	120 VAC / 60Hz
Standard	CFR47 Part 15 Subpart C	**RBW / VBW**	See Note Below
Dist/Ant Used	3m / Trilog Antenna	**Performed by**	Rachana Khanduri

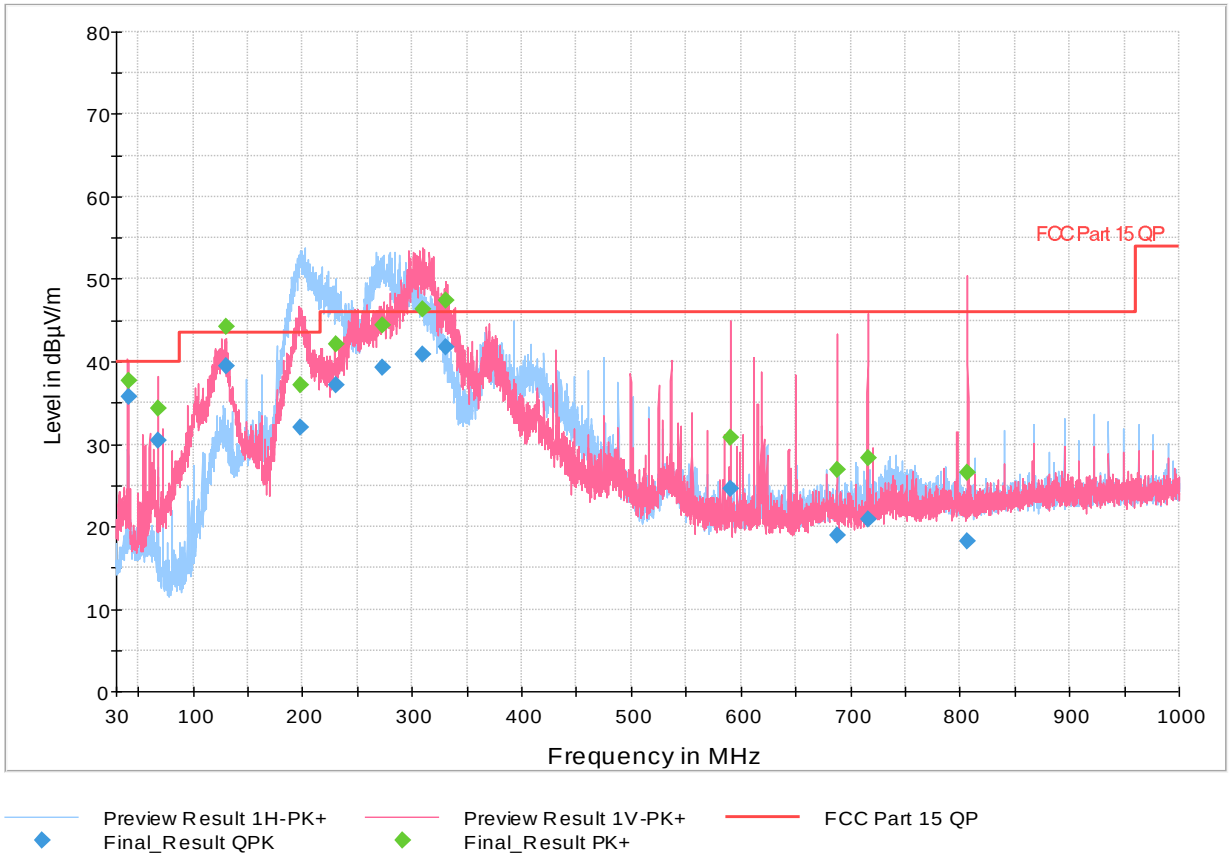


Figure 7: 30MHz – 1GHz Plot

Final_Result

Frequency (MHz)	QuasiPeak (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol	Azimuth (deg)	Corr. (dB/m)
40.682680	35.68	40.00	4.32	10000.0	120.000	100.0	V	182.0	-11.4
67.798200	30.37	40.00	9.63	10000.0	120.000	105.0	V	351.0	-14.5
130.542680	39.41	43.52	4.11	10000.0	120.000	100.0	V	196.0	-16.3
198.618680	32.05	43.52	11.47	10000.0	120.000	105.0	H	240.0	-12.9
230.299040	37.17	46.02	8.85	10000.0	120.000	106.0	H	219.0	-12.5
272.197600	39.34	46.02	6.68	10000.0	120.000	104.0	H	244.0	-11.8
310.127640	40.83	46.02	5.19	10000.0	120.000	106.0	V	151.0	-11.0
331.006960	41.85	46.02	4.17	10000.0	120.000	105.0	V	170.0	-10.1
590.494720	24.55	46.02	21.47	10000.0	120.000	100.0	V	225.0	-5.1
687.761120	18.96	46.02	27.06	10000.0	120.000	100.0	V	283.0	-3.6
715.766800	20.80	46.02	25.22	10000.0	120.000	100.0	V	249.0	-3.6
806.620560	18.18	46.02	27.84	10000.0	120.000	102.0	V	220.0	-2.2

Note: RBW/VBW Setting:

9 kHz to 150 kHz; RBW = 200Hz, VBW = 1kHz
150 kHz to 30 MHz; RBW = 9kHz, VBW = 30kHz
30 MHz - 1GHz; RBW = 100 kHz, VBW = 3 x RBW

4.5 AC Conducted Emissions

Testing was performed in accordance with ANSI C63.4: 2014. 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 and RSS-GEN. Sect. 8.8.

4.5.1 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 were measured with respect to ground. Measurements were performed using a set of 50μH / 50Ω LISNs.
Testing is performed in Lab1. 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.

4.5.1.1 Deviations

There were no deviations from this test methodology.

4.5.2 Test Results

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

Table 7: AC Conducted Emissions – Test Results

Test Conditions: Conducted Emissions at Normal Conditions only		
Antenna Type: 6-turn Flat PCB coil	**Power Level:** Default	
AC Power: 120 Vac/60 Hz	**Configuration:** Tabletop	
Configuration	**Frequency Range**	**Test Result**
Line 1 (Live)	0.15 to 30 MHz	Pass
Line 2 (Neutral)	0.15 to 30 MHz	Pass

4.5.2.1 Live Line

Frequency MHz	Raw dBuV	Cable Loss	Factors dB	Level dBuV	Measurement Type	Line	Limit dBuV	Margin dB	Pass /Fail
0.154541	36.98	10.94	0.09	48	Quasi Peak	Live	65.75	-17.75	Pass
13.55971	37.9	10.4	-0.04	48.26	Quasi Peak	Live	60	-11.74	Pass
0.212309	28.93	10.21	0.06	39.2	Quasi Peak	Live	63.11	-23.91	Pass
0.42406	20.29	10.1	0.04	30.42	Quasi Peak	Live	57.37	-26.94	Pass
9.167657	14.84	10.31	0.01	25.16	Quasi Peak	Live	60	-34.84	Pass
27.34008	0.51	10.64	-0.29	10.86	Quasi Peak	Live	60	-49.14	Pass
0.154541	20.14	10.94	0.09	31.16	Average	Live	55.75	-24.59	Pass
13.55971	37.71	10.4	-0.04	48.07	Average	Live	50	-1.93	Pass
0.212309	15.19	10.21	0.06	25.46	Average	Live	53.11	-27.65	Pass
0.42406	16.41	10.1	0.04	26.54	Average	Live	47.37	-20.83	Pass
9.167657	15.32	10.31	0.01	25.64	Average	Live	50	-24.36	Pass
27.34008	-3.24	10.64	-0.29	7.11	Average	Live	50	-42.89	Pass

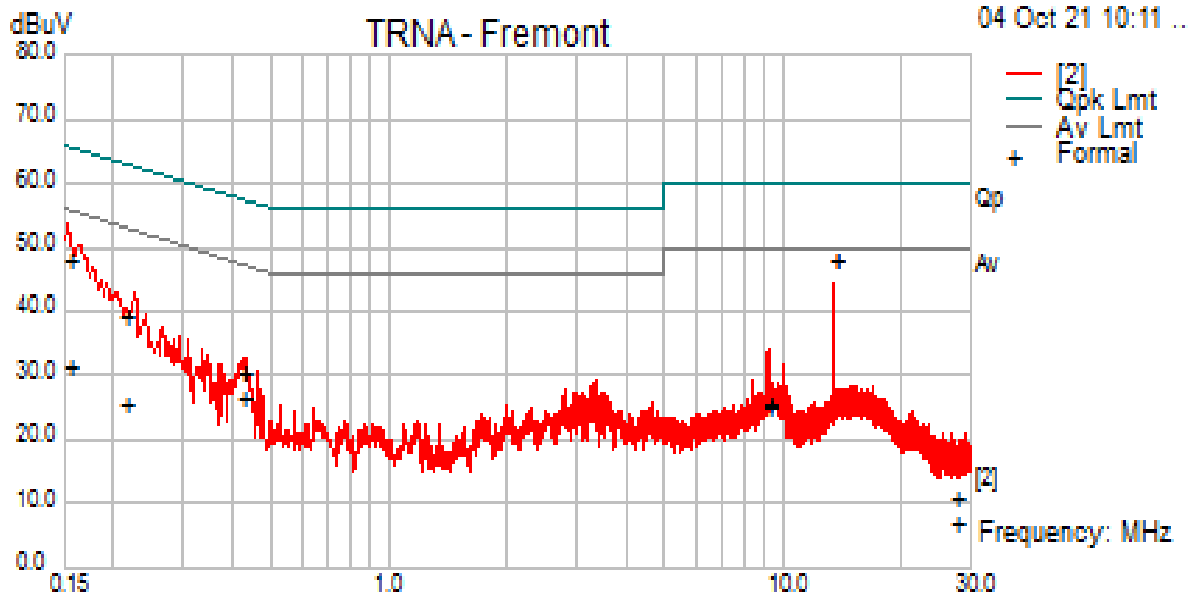


Figure 8: AC Conducted Emissions 150 kHz to 30 MHz- Live Line

Note: The highest emission on the plot is the fundamental signal at 13.56MHz.

4.5.2.2 Neutral Line

Frequency MHz	Raw dBuV	Cable Loss	Factors dB	Level dBuV	Measurement Type	Line	Limit dBuV	Margin dB	Pass /Fail
13.56002	38.77	10.4	-0.04	49.13	Quasi Peak	Neutral	60	-10.87	Pass
0.16712	36.69	10.49	0.08	47.26	Quasi Peak	Neutral	65.1	-17.84	Pass
0.273132	21.55	10.15	0.05	31.75	Quasi Peak	Neutral	61.02	-29.27	Pass
0.381232	14.13	10.1	0.04	24.27	Quasi Peak	Neutral	58.25	-33.98	Pass
3.081315	8.74	10.19	0.03	18.95	Quasi Peak	Neutral	56	-37.05	Pass
27.11845	7.55	10.63	-0.28	17.9	Quasi Peak	Neutral	60	-42.1	Pass
13.56002	38.66	10.4	-0.04	49.02	Average	Neutral	50	-0.98	Pass
0.16712	21.49	10.49	0.08	32.06	Average	Neutral	55.1	-23.04	Pass
0.273132	8.41	10.15	0.05	18.61	Average	Neutral	51.02	-32.41	Pass
0.381232	7.46	10.1	0.04	17.6	Average	Neutral	48.25	-30.65	Pass
3.081315	0.44	10.19	0.03	10.66	Average	Neutral	46	-35.34	Pass
27.11845	4.85	10.63	-0.28	15.2	Average	Neutral	50	-34.8	Pass

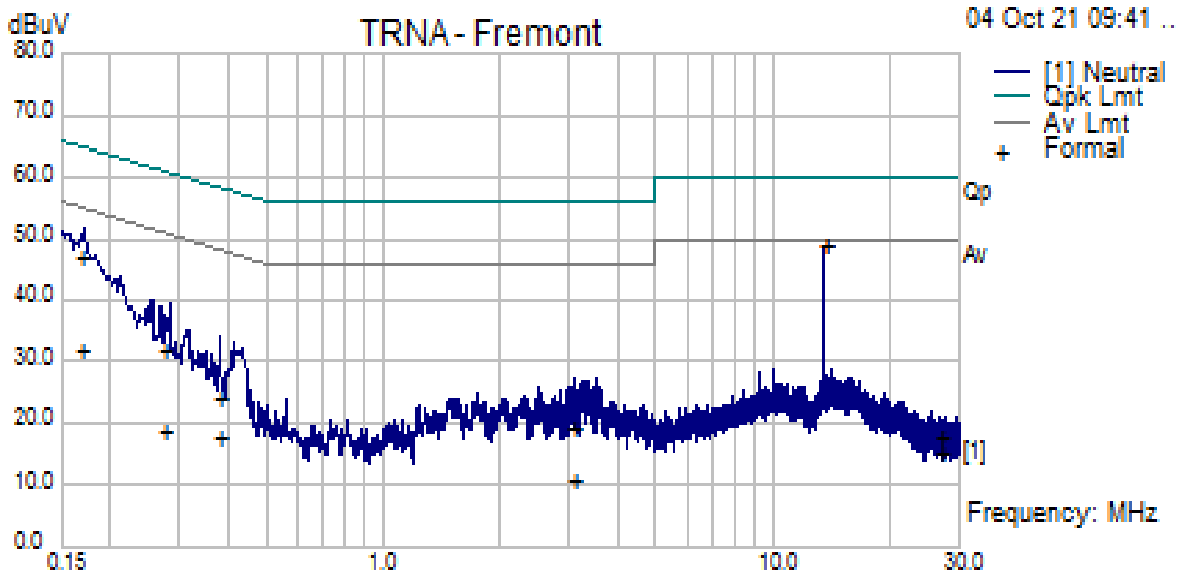


Figure 9: AC Conducted Emissions 150 kHz to 30 MHz- Neutral Line

Note: The highest emission on the plot is the fundamental signal at 13.56MHz.

4.6 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 +10º to +40º C.

4.6.1 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 C63.10-2013 Section 6.8

4.6.2 Manufacturer Declaration

The frequency stability of the reference oscillator sets the frequency stability of the RF transceiver signals. Per CFR47 Part 15.225 (e) and RSS 210 Sect. A2.6 (d), all of the RF signal should have ±0.01% or ±100 ppm stability.
This stability accounts for room temp tolerance of the crystal oscillator circuit, frequency variation across temperature, and crystal ageing.

Worst case:
±100 ppm at 13.56 MHz translates to a maximum frequency shift of ±1.356 kHz.

4.6.3 Test results

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

Table 8: Frequency Stability – Test Results

Antenna Type: 6-turn Flat PCB coil	**Power Setting:** Default
Ambient Temp.: 21 °C	**Relative Humidity:**42 %
Test Performed by: Rachana Khanduri	

Temperature (°C)	Time	Lower Frequency F_L (MHz)	Upper Frequency F_H (MHz)	PPM	Limit (PPM)
10°C	Start	13.558822115	13.560280449	-33.09	±100
	2 Min.	13.558830128	13.560280449	-32.80	
	5 Min.	13.558820513	13.560282051	-33.09	
	10 Min.	13.558822115	13.560280449	-33.09	
22°C	Start	13.558830128	13.560272436	-33.09	
	2 Min.	13.558830128	13.560288462	-32.50	
	5 Min.	13.558826923	13.560278846	-32.97	
	10 Min.	13.558820513	13.560269231	-33.56	
40°C	Start	13.558820513	13.560282051	-33.09	
	2 Min.	13.558831731	13.560288462	-32.44	
	5 Min.	13.558833333	13.560282051	-32.62	
	10 Min.	13.558822115	13.560280449	-33.09	

Note: All frequency drifts from 13.56 MHz were less than ±100 ppm.

4.7 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.

4.7.1 Test Methodology

The RFID reader was designed to operating within 102VAC to 138VAC. If the battery voltage is outside the voltage range, the reader would shut down. The fundamental frequency was observed during the variation. The RFID standalone module was powered by 120 VAC by programmable power supply. The voltage was varied from 102VAC to 138VAC mean while the fundamental frequencies were observed and recorded for the maximum drift in ppm; part per millions.

4.7.2 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 ±100 ppm.

Table 9: Voltage Variation – Test Results

Voltage Variation					
Antenna Type: 6-turn Flat PCB coil			**Power Setting:** Default		
Ambient Temp.: 21 °C			**Relative Humidity:**42 %		
Test Performed by: Rachana Khanduri					
Voltage (V_{AC})	**Lower Frequency FL (MHz)**	**Upper Frequency FH (MHz)**	**Center Frequency (Hz)**	**PPM**	**Limit PPM**
102	13.558826923	13.560285256	13559556.09	-32.74	±100
120	13.558830128	13.560288462	13559559.30	-32.50	±100
138	13.558830128	13.560272436	13559551.28	-33.09	±100
Note: All frequency drifts were less than ±100 ppm from 13.56 MHz, No frequency change was observed with time.					

6 Test Equipment Use List

6.1 Equipment List

Equipment	Manufacturer	Model #	Serial/Inst #	Last Cal mm/dd/yyyy	Next Cal mm/dd/yyyy
EMI Receiver	R&S	ESW, 2Hz-44GHz	838399	02/28/2021	02/28/2022
L.I.S.N.	Com-Power	LI-215A	192000	06/08/2020	06/08/2022
Transient Limiter	Com-Power	LIT-930	531582	02/12/2021	02/12/2022
EMI Receiver	R&S	ESIB40	839283/005	06/16/2020	06/16/2022
Preamplifier, 9 kHz – 1 GHz	Sonoma	310N	213221	06/08/2020	06/08/2022
Active Loop Antenna	EMCO	6502	00062531	08/31/2022	08/31/2023
Trilog Antenna	Rohde & Schwarz	VULB 9162	A102606	02/27/2021	02/27/2022
Preamplifier, 30MHz – 8 GHz	Rohde & Schwarz	TS-PR8	102353	02/26/2021	02/26/2022
Spectrum Analyzer	Rohde & Schwarz	FSU26.5	200050	02/24/2021	02/24/2022
Environmental Chamber	Espec	BTZ-133	0613436	N/A (See Note)	
Note: Equipment is characterized before use					

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 (information supplied by the customer and can affect the validity of results) so that the test laboratory may perform the requested testing.

7.2 Customer

The information in the following tables is required, as it should appear in the final test report.

Table 10 – Customer Information

Company Name	PENTAX Medical
Address	303 Convention Way, Suite 1
City, State, Zip	Redwood City, CA 94063
Country	U.S.A.

Table 11 – Contact Information

Name	Hecheng Hu
E-mail	hecheng.hu@pentaxmedical.com
Phone	862-202-9581

7.3 Equipment Under Test (EUT)

The information provided in the following table should be listed as it should appear in the final report. For those products that have only a model name, list the model number as *non-applicable* and vice-versa.

Table 12 – EUT Designation

Product Name	C2 CryoBallon Ablation System
Model No.	FG-1024
Product Description	The C2 CryoBalloon Ablation System is used to destroy unwanted tissue by application of extreme cold using Nitrous Oxide as the cryogen. 13.56 MHz near field communication (NFC) interface is used to identify types of catheter and number of uses.

7.3.1 Product Specifications

The information provided in the following table should be listed as it should appear in the final report.

Table 13 – EUT Specifications*

EUT Specification	
Power Supply: C2 CryoBalloon Foot Pedal RFID Reader	 110 – 240 Vac, 10-6A, 50-60Hz 12VDC
Environment	Controlled Laboratory
Operating Temperature Range:	+10 to +40 degrees C
Multiple Feeds:	☐ Yes and how many ☒ No. RFIDs receive 12VDC from C2 CryoBalloon Foot Pedal power supply
Hardware Version Identification Number (HVIN)	PRT-2363 Rev. A
Firmware Version Identification Number (FVIN)	PRT2368 Rev. B
Operating Mode	RFID Reader
Transmitter Frequency Band	13.56MHz
Chipset Rated Output Power	<55mW
Antenna Type	6-turn Flat PCB coil, 15 mm in diameter
Antenna Gain	N/A. Affected by circuit tuning.
Modulation Type	☐ AM ☐ FM ☐ DSSS ☐ OFDM ☒ Other describe: OOK
Date Rate	26 kbit/s.
Type of Equipment	☒ Table Top ☐ Wall-mount ☐ Floor standing cabinet ☐ Other:
Note: *All EUT specifications are provided by the manufacturer or the TUV direct customer. Information supplied by the customer and can affect the validity of results.	

Table 14: EUT Equipment/Cabling Information

Interface Type	Connected To	Location	Length	Shielded / Unshielded
Power Cord	Mains to Power Supply	Power Supply	3 meters	No
Power Supply to Foot Pedal Cord	From foot Pedal to Power cord at the power supply	Foot Pedal	67 inches	No
Foot Pedal to Controller Cord	From Foot Pedal to Controller	Foot Pedal	76 inches	No
Note: None				

Table 15: Supported Equipment

Equipment	Manufacturer	Model	Serial	Used for
C2 CryoBalloon ™ Cartridge	PENTAX Medical	FG-1013	NA	Store N2O, single use
C2 CryoBalloon ™ Foot Pedal	PENTAX Medical	FG - 1018	2801-0175	Provides 12VDC power to handheld controller through as interconncted cable
Note: Supporting Tags are passive devices.				

Table 16: Description of Sample used for Testing

Device	Serial Number	Configuration	Used For
C2 CryoBalloon™ Catheter	FG-1024	Radiated Sample	Max. Carrier Field Strength Occupied Bandwidth Out of Band Emission TX Spurious Radiated Emission Frequency Stability Voltage Variation AC Conducted Emission
C2 CryoBalloon™ Controller	HR0016		
Note: Catheter contains a RFID tag on the catheter connector. The NFC controller and antenna are located on the Controller sensor printed circuit board (PCB) that is located near the catheter connector receptacle. The NFC circuitry is continuously turned on.			

Table 17: Description of Test Configuration used for Radiated Measurement.

Device	Antenna	Mode	Setup Description
FG-1024	6-turn Flat PCB coil	Transmit	X-Axis
Note: Worst case position used for testing.			

7.3.2 Configuration(s)

Figure 10: Block Diagram of EUT Setup

7.4 Test Specifications

The information provided in the following table should be provided as you would like the product to be evaluated if different from the requirements of the standard.

Table 18 - Test Specifications

Emissions and Immunity	
Standard	**Requirement**
CFR 47 Part 15.225: 2021	All
RSS-210: Issue 10, December 2019	All

--- Ende des Prüfberichts / *End of Test Report* ---