Project
21614-15

CCC del Uruguay S.A.
Guardio Charger

Test Report
FCC Part 95 Subpart I
Medical Device Radio Communications Service

Prepared for:

CCC del Uruguay S.A
General Paz 1363
Montevideo, Uruguay 11400

By

Professional Testing (EMI), Inc.
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24 Sep 2021

Reviewed by

Larry Finn
Chief Technical Officer

Written by

Eric Lifsey
EMC Engineer

Revision History

Revision Number	Description	Date
Draft 2	Draft for review.	4 Sep 2020
Final		5 Nov 2020
Final 01	Minor Corrections; Added 95.2579(c) mask plots	24 Sep 2021

Errata:

None.

Table of Contents

NOTICE:

(1) This Report must not be used to claim product endorsement, by NVLAP, NIST, the FCC or any other Agency. This report also does not warrant certification by NVLAP or NIST.

(2) This report shall not be reproduced except in full, without the written approval of Professional Testing (EMI), Inc.

(3) The significance of this report is dependent on the representative character of the test sample submitted for evaluation and the results apply only in reference to the sample tested. The manufacturer must continuously implement the changes shown herein to attain and maintain the required degree of compliance.

Certificate of Compliance

FCC MRA Designation Number: US5270
NVLAP Accreditation Number: 200062-0

Applicant	Device & Test Identification
CCC del Uruguay S.A. Gral Paz 1363 Montevideo, Uruguay 11400 Certificate Date: 25 Aug 2020	Model(s): Guardio Charger Laboratory Project ID: 21614-15 FCC ID: 2AY43-GDCH0

The EUT(s) listed above were tested utilizing the following documents and found to be in compliance with the required criteria.

FCC Part 95			
Section I Medical Device Radio Communications Service			
Test	**Class/Criteria Met**	**Test Level**	**Test Date**
Duration of Transmissions 95.2557	Complies	Declared code complies	NA
Frequency Monitoring 95.2559	Complies	Declared code complies	NA
Frequency Accuracy 95.2565	Complies	0 C to 55 C	14 Jul 2020
EIRP 95.2567	Complies using 95.2567(a)	Limit is 74.7 dBuV/m @ 10m	NA
Field Strength 95.2569	Complies	EIRP & spurious limit satisfied	17 Jul 2020
Bandwidth 95.2573	Complies	248.2 kHz	8 Jul 2020
Unwanted Emissions 95.2579	Complies	95.2579(a) limits satisfied	17 Jul 2020
Permissible Exposure Evaluation 95.2585	Complies	1.1307(b) and 2.1093 exposure limit satisfied	17 Jun 2020

Test Sites: Site 45: 11400 Burnet Rd., Austin, TX 78758

I, Larry Finn, for Professional Testing (EMI), Inc., being familiar with the electromagnetic compatibility rules and test procedures, have reviewed the test setup, measured data, and this report. I believe them to be true and accurate.

Larry Finn
Chief Technical Officer (CTO)

NVLAP TESTING
NVLAP LAB CODE 200062-0

This report has been reviewed and accepted by the Applicant. The undersigned is responsible for ensuring that this device will continue to comply with the rules listed above.

_____
Representative of Applicant

1.0 Introduction

1.1 Scope

This report describes the tests to which the equipment under test (EUT) conformed to the EMC standards as listed on the Certificate of Compliance in this report.

1.2 EUT Description

This device is a charger for implantable devices used for medical applications.

Table 1.2.1: Equipment Under Test

Manufacturer	Model	Description
CCC del Uruguay S.A.	Guardio Charger	Medical Radio Transceiver

1.3 EUT Operation

The EUT was exercised in a manner consistent with normal operations.

1.4 Modifications to Equipment

No modifications were made to the EUT during the performance of the test program.

1.5 Test Site

Measurements were made at the PTI semi-anechoic facility designated Site 45 (FCC 459644, IC 3036B-1) in Austin, Texas. The site is registered with the FCC under Section 2.948 and Industry Canada per RSS-GEN. This is subsequently confirmed by laboratory accreditation (NVLAP). The test site is located at 11400 Burnet Road, Austin, Texas 78758, while the main office is located at 1601 North A.W. Grimes Boulevard, Suite B, Round Rock, Texas, 78665.
Professional Testing (EMI), Inc., (PTI) follows the guidelines of National Institute of Standards and Technology (NIST) for all uncertainty calculations, estimates, and expressions thereof for electromagnetic compatibility testing.

1.6 Applicable Documents and Clauses

Table 1.6.1: Applicable Documents

Document	Title/Description
47 CFR Part 95 Subpart I	Medical Device Radio Communications Service
ANSI C63.26:2015	American National Standard for Compliance Testing of Transmitters Used in Licensed Radio Services
ANSI C63.4:2014	American National Standard For Methods Of Measurement Of Radio-Noise Emissions From Low-Voltage Electrical And Electronic Equipment In The Range of 9 kHz To 40 GHz

1.7 Deviations

None.

2.0 Duration of Transmissions 95.2557 and Frequency Monitoring 95.2559

2.1 Procedure

Confirm that the EUT is designed to manage transmission time to comply with limitations intended to assure sharing of the allocated spectrum.

2.2 Limits

Parameters	Limit
Duration of Transmissions Frequency Monitoring	Declared and documented.

2.3 Results

The EUT satisfied the requirement.

Declared compliance to the following:

(a)(1) The design of the receiver 20 dB bandwidth is no less than the transmit 20 dB bandwidth (we measured 243.8 kHz).
(a)(2) That the receiver monitors, within 5 seconds of use, the channels to be used for a minimum of 10 milliseconds each channel.
(a)(3) That the monitoring power level using $P^{MT} = 10 \log B - 150$ (dBm/Hz) + G is supported; again reference the measured bandwidth of 248.8 kHz.
(a)(5) through (a)(7) that the firmware supervises the use of the transmitter to comply with these transmit time limitations.
(c) that Shared Access is supported in the firmware to assure fair access to these channels for other MedRadio systems.

Hardware

The design is based on FCC and ETSI certified transceivers from Microsemi (now Microchip) https://www.microsemi.com/product-directory/ultra-low-power-wireless/1312-implantable-medical-transceivers.
I'm attaching the product brief here, more information is available on the product web https://www.microsemi.com/product-directory/implantable-medical-transceivers/3915-zl70103#resources

The Guardio Charger and Intelio Programmer Wand use the ZL70103.
The Optimizer SM Implantable device uses the ZL70323 module, based on the same transceiver.

The transceivers include all required filters to comply with transmitter and receiver bandwidth.

To perform the RSSI measure the Guardio Charger and Intelio Programmer Wand use a microcontroller's ADC and an external hardware:

The transceiver ports out the RX signal demodulated into the intermediate frequency (450 kHz). This signal is filtered with a separated analog hardware and then processed by a logarithmic amplifier. The output of this amplifier is connected to the ADC of the microcontroller.

Channel access

For channel selection we use the channel with the lowest monitored ambient power level. This guarantees we comply with either the power limit restriction (a)(3) and (a)(4) or the option in (a)(5).

As explained in the "OSM EMC Test Guide", section 1.2.1 CCA, before starting a communications session, the external device (Guardio Charger or Intelio Programmer Wand) chooses the best possible channel by selecting the one with lowest interference (the least occupied).

To select the channel, we perform a Clear Channel Assessment (CCA), which is as follows:

- *For each Channel (1..8)*
  - *Perform continuous RSSI measures for 11 ms and keep the maximum value.*
  - *Do this three times and keep the maximum.*
- *Select the channel with the lowest power level.*

The process takes close to 300ms.

The CCA is performed before every new communication regardless the time from the last transmission.
The only case where communications session is kept longer is for real-time markers, in which case data is transmitted every 100ms. If at any point communication is lost it's restarted with a new CCA.

This ensures in all cases the requirement of (a)(5) of continuous communications session not having silent periods greater than 5 seconds.

3.0 Frequency Accuracy 95.2565

3.1 Procedure

The ULP-AMI (EUT), using the associated ULP-AMI-P (support equipment) and test software, is placed into continuous transmit mode and subjected to extreme conditions while recording the operating frequency.

3.2 Limits

Requirement	Limits Frequency
Temperature 0 C and 55 C	±100 ppm or ±40245 Hz

3.3 Results

The EUT satisfied the requirement.

21614			14-Jul-2020
Condition	**Frequency**		**Deviation**
Temperature (C)	Reference Center Frequency (MHz)	Measured Frequency (MHz)	Calculated Deviation (Hz)
25	402.450000	402.447724	-2276
0	402.450000	402.453373	3373
55	402.450000	402.441871	-8129
25	404.550000	404.546173	-3827
0	404.550000	404.539926	-10074
55	404.550000	404.548993	-1007
Max Deviation (Hz)			3373
Min Deviation (Hz)			-10074

3.3.1 Equipment

Asset #	Manufacturer	Model	Description	Calibration Due
1937	Agilent	E4440A	Spectrum Analyzer	8-Nov-2020
C355	Pasternack	Unspecified	Coaxial cable, RG-223 Type	Not Required
2134	Tenny	TPC T2C	Temperature Chamber	10-Oct-2020
None	Unknown	Unknown	400 MHz short monopole antenna	CNR

3.3.2 Photographs

EUT In Chamber and Support Equipment

4.0 EIRP 95.2567 and Field Strength 95.2569

4.1 Procedure

Select the appropriate limit from the paragraph and table.

4.2 Limits

Requirement Applied Field Strength Limit @ 3 meters	Limit Restated for distance 10 meters
25 µW	74.7 dBµV/m

4.3 Results

The EUT satisfied the requirement.

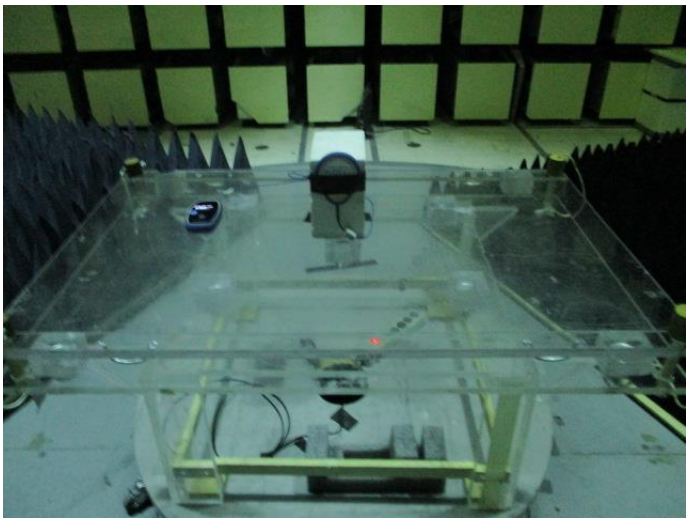
Measured without modulation. Measurement resolution bandwidth was 120 kHz with video bandwidth of 300 kHz. The transmission was continuous such that a quasi-peak detection measurement yielded the same level as would a peak detection measurement.

Radiated Field Strength Measured at 10 meters	
Polarity & Frequency (MHz)	Quasi-peak Reading (dBµV)
V 402.458	64.8
H 402.458	73.1
V 404.550	63.5
H 404.550	71.7

4.3.1 Equipment

Radiated Emissions Test Equipment List					
Tile! Software Version:			**Version: 7.1.2.17 (Jan 08, 2016 - 02:12:48 PM) or 4.1.A.0, April 14, 2009, 11:01:00PM**		
Test Profile:			**2020_RE_Unintentional_TILE7_v2.7.til**		
Asset #	**Manufacturer**	**Model**	**Equipment Nomenclature**	**Serial Number**	**Calibration Due Date**
1509A	Braden	TDK 10M	TDK 10M Chamber, NSA < 1 GHz	DAC-012915-005	9/17/2021
1890	HP	8447F-H64	Preamp/Amp, 9kHz-1300MHz, 28/25dB	3313A05298	1/9/2022
2295	Keysight	E4440A-AYZ	PSA Spectrum Analyzer	MY46186204	11/6/2020
1926	ETS-Lindgren	3142D	Antenna, Biconilog, 26 MHz - 6 GHz	135454	3/11/2021
C027	none	RG214	Cable Coax, N-N, 25m, 25MHz - 1GHz	None	9/9/2020
1327	EMCO	1050	Controller, Antenna Mast	none	N/A
0942	EMCO	11968D	Turntable, 4ft.	9510-1835	N/A
1969	HP	11713A	Attenuator/Switch Driver	3748A04113	N/A

4.3.2 Photographs



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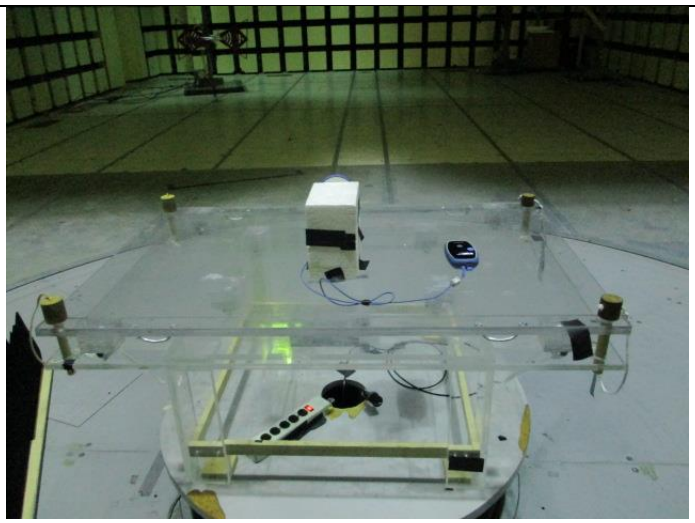


Rear

5.0 Bandwidth 95.2573

5.1 Procedure

EUT is placed into transmit mode with modulation. The signal is captured on a spectrum analyzer with its bandwidth function recording the measurement.

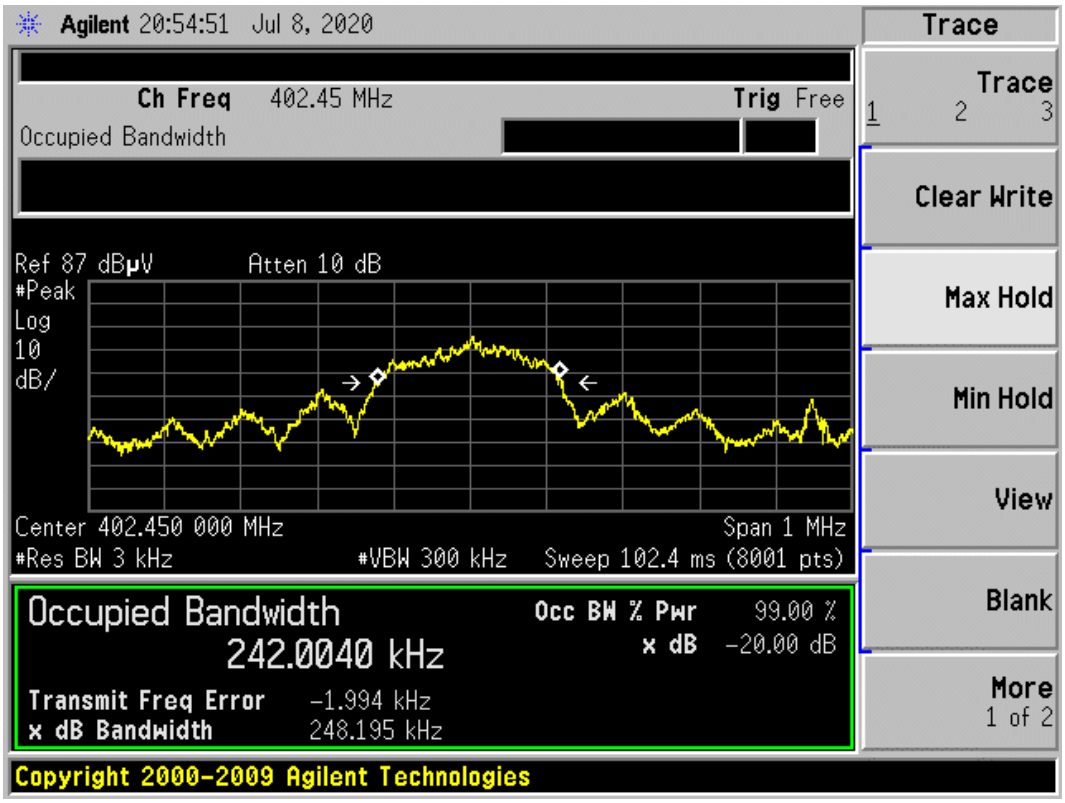
5.2 Limits

Requirement	Limit
20 dB Bandwidth	300 kHz

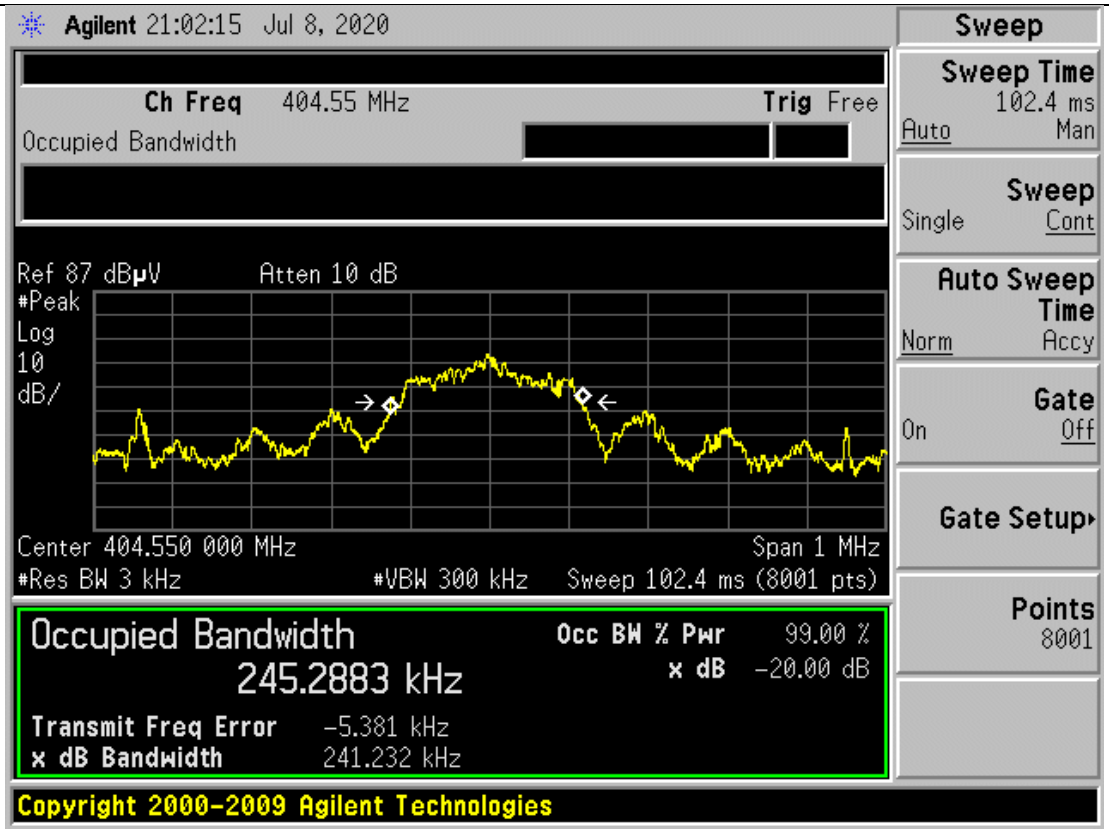
5.3 Results

The EUT satisfied the requirement.

Operating Channel	Measured 20 dB Bandwidth
Bottom	248.195 kHz
Top	241.232 kHz



Bottom Channel Bandwidth Measurement



Top Channel Bandwidth Measurement

6.0 Unwanted Emissions 95.2579

6.1 Procedure

The ULP-AMI (EUT) is placed at the specified operating distance where the field strength of the transmitted signal is measured with all required loss/gain factors applied.

6.2 Limits

Requirement	Limits
95.2579(a), (b), (c)	See below.

Frequency range (MHz)	Field strength (μV/m)
30-88	100
88-216	150
216-960	200
960 and above	500

(b) Harmonic emissions. Radiated unwanted emissions from a MedRadio transmitter type must be measured to at least the tenth harmonic of the highest fundamental frequency emitted.
(c) Attenuation requirements, 402-405 MHz. For MedRadio transmitter types designed to operate in the 402-405 MHz band, unwanted emissions must be attenuated below the maximum permitted transmitter output power by at least:

(1) 20 dB, on any frequency within the 402-405 MHz band that is more than 150 kHz away from the center frequency of the occupied bandwidth;

(2) 20 dB, on any frequency between 401.750 MHz and 402.000 MHz, and on any frequency between 405 MHz and 405.250 MHz.

6.3 Results

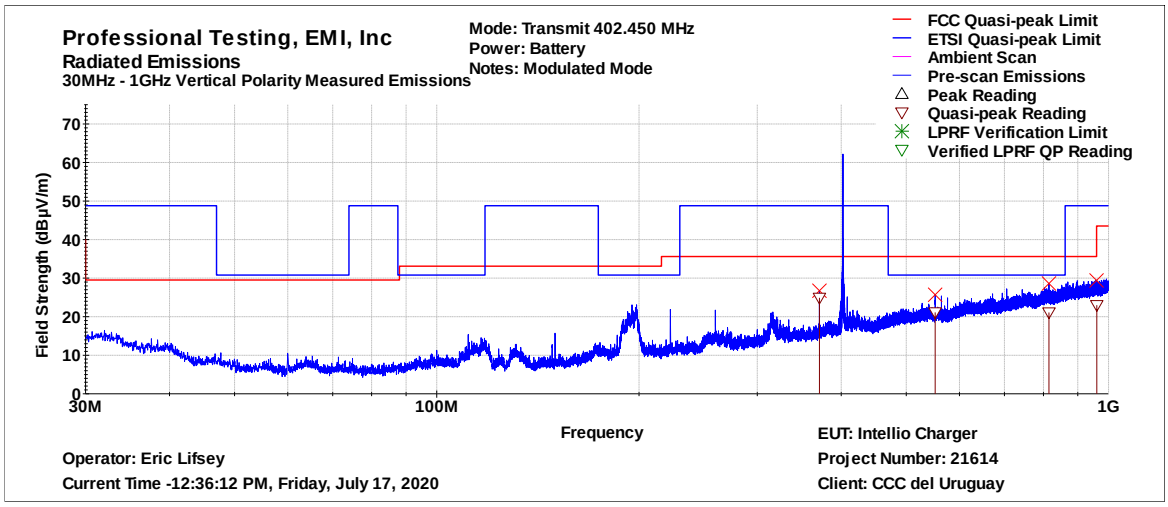
The EUT satisfied the requirement.

6.3.1 Transmit Mode

Limit is recalculated for measurement distance 10 meters. The red limit line applies.

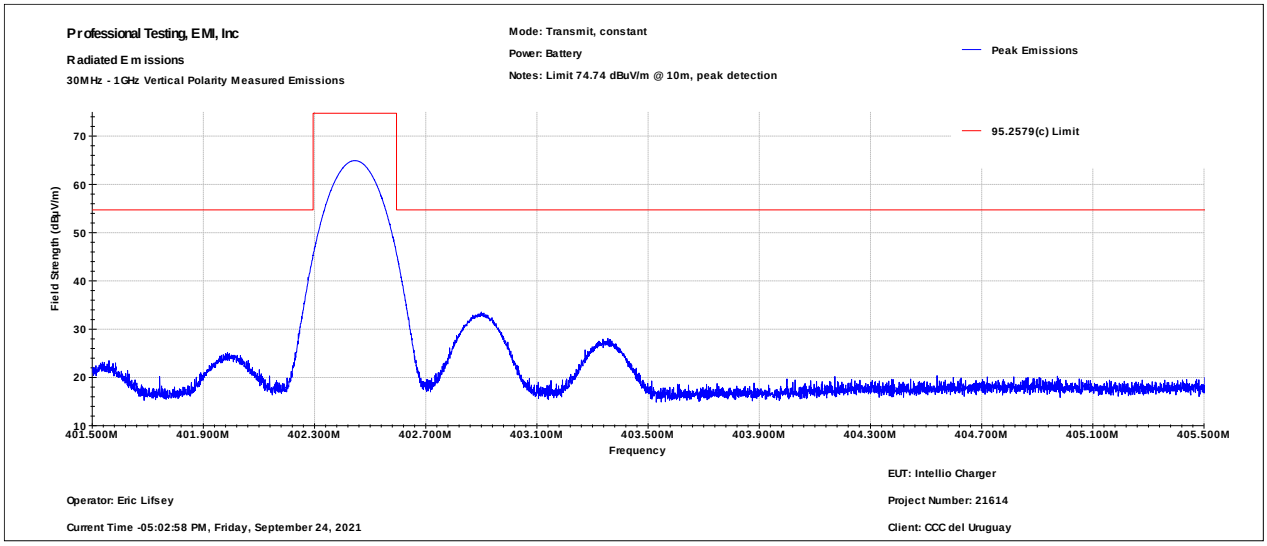
Measured without modulation.

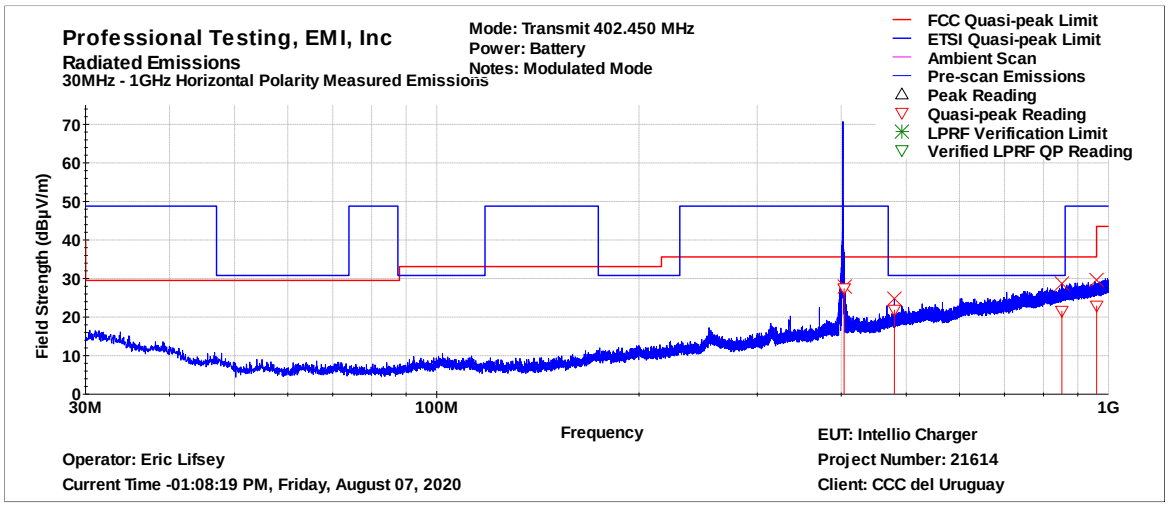
Bottom Channel



Frequency	Azimuth	Height	QP	QP Limit	QP Margin	QP Results
MHz	(deg)	(cm)	(dBµV)	(dBµV)	(dB)	(P/F)
371.236	19.000	129.000	24.9	48.8	-23.9	PASS
551.990	3.000	128.000	21.1	30.8	-9.7	PASS
815.522	95.000	128.000	21.1	30.8	-9.7	PASS
960.910	188.000	392.000	23.0	48.8	-25.8	PASS

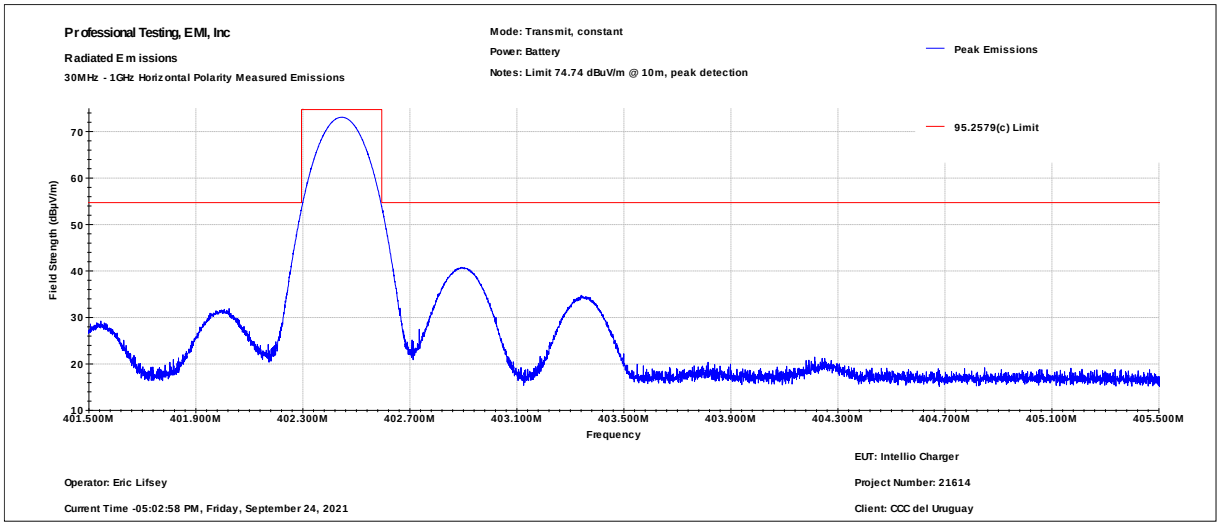
95.2579(c) Mask (120kHz RBW / 300kHz VBW, Peak Detection)

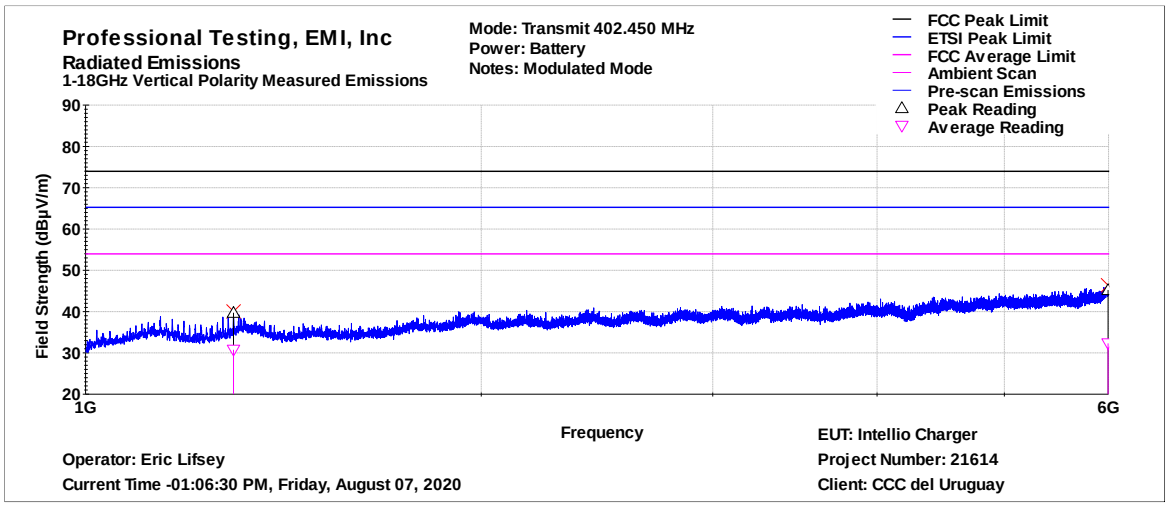




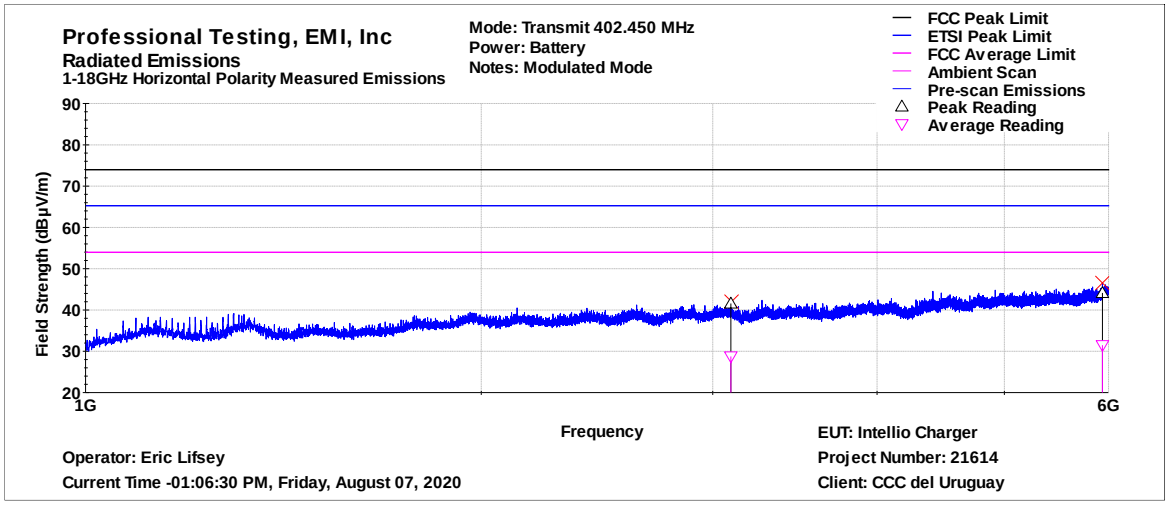
Frequency (MHz)	Azimuth (deg)	Height (cm)	QP (dBµV)	QP Limit (dBµV)	QP Margin (dB)	QP Results (P/F)
404.039	357.000	239.000	27.4	48.8	-21.4	PASS
479.997	255.000	126.000	21.9	30.8	-8.9	PASS
852.214	16.000	327.000	21.6	30.8	-9.2	PASS
960.279	130.000	102.000	23.0	48.8	-25.8	PASS

95.2579(c) Mask (120kHz RBW / 300kHz VBW, Peak Detection)



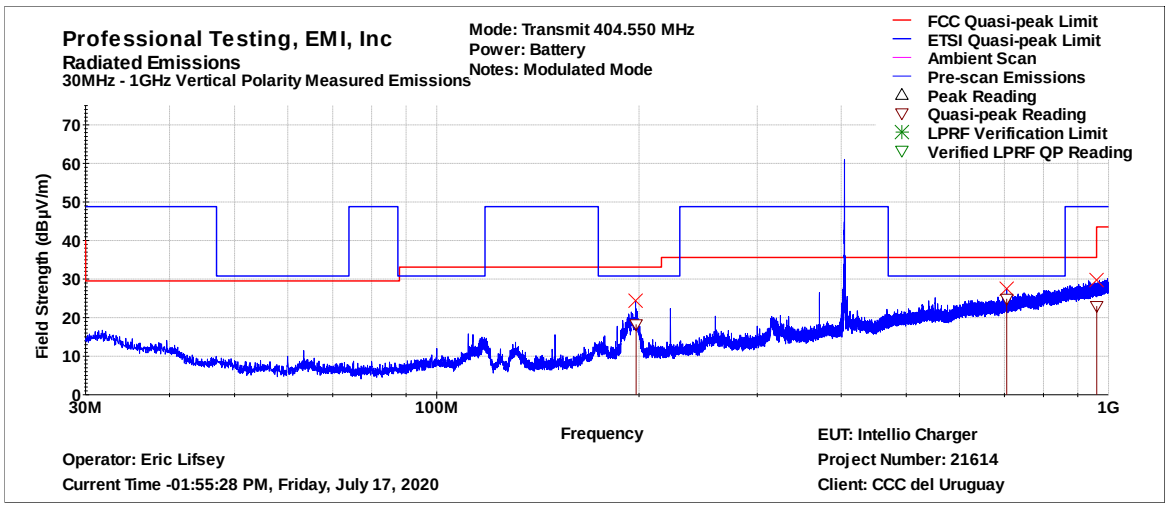


Frequency	Azimuth	Height	Peak	Peak Limit	Peak Margin	Peak Results
(MHz)	(deg)	(cm)	(dBuV)	(dBuV)	(dB)	(P/F)
1295.71	18	177	39.7	65.2	-25.5	PASS
5996.14	102	259	45.2	65.2	-20.0	PASS



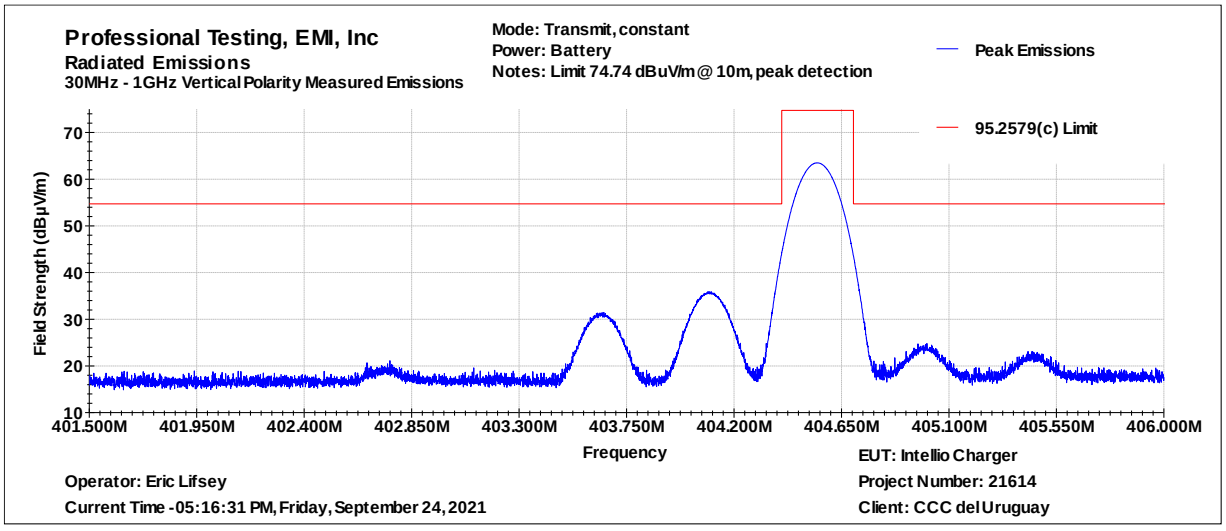
Frequency	Azimuth	Height	Peak	Peak Limit	Peak Margin	Peak Results
(MHz)	(deg)	(cm)	(dBuV)	(dBuV)	(dB)	(P/F)
3096.51	18	165	41.6	65.2	-23.6	PASS
5937.32	2	253	44.1	65.2	-21.2	PASS

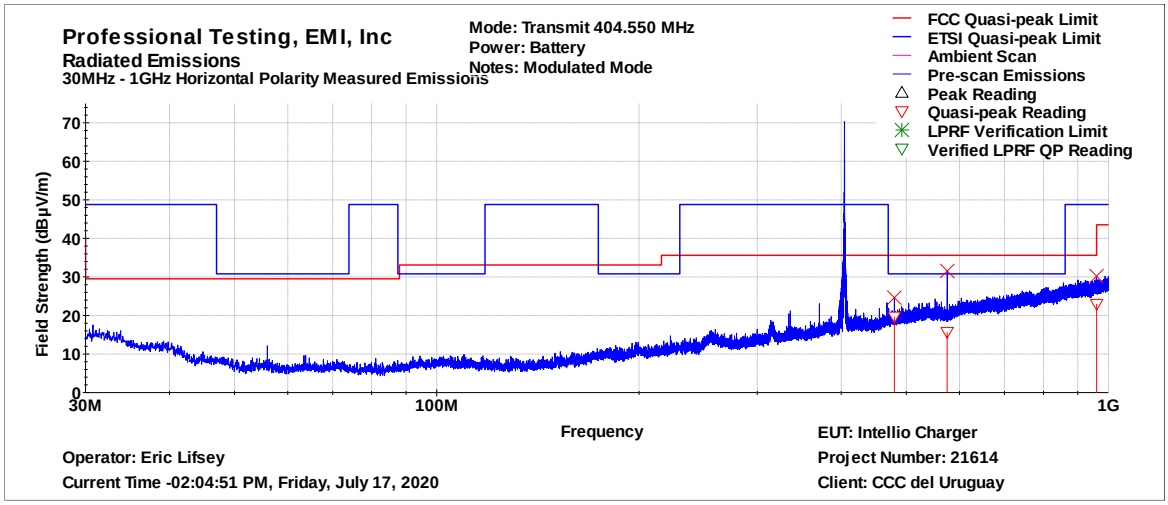
Top Channel



Frequency	Azimuth	Height	QP	QP Limit	QP Margin	QP Results
MHz	(deg)	(cm)	(dBµV)	(dBµV)	(dB)	(P/F)
198.056	118.000	128.000	18.3	30.8	-12.5	PASS
705.382	134.000	129.000	24.9	30.8	-5.9	PASS
960.507	4.000	129.000	23.0	48.8	-25.8	PASS

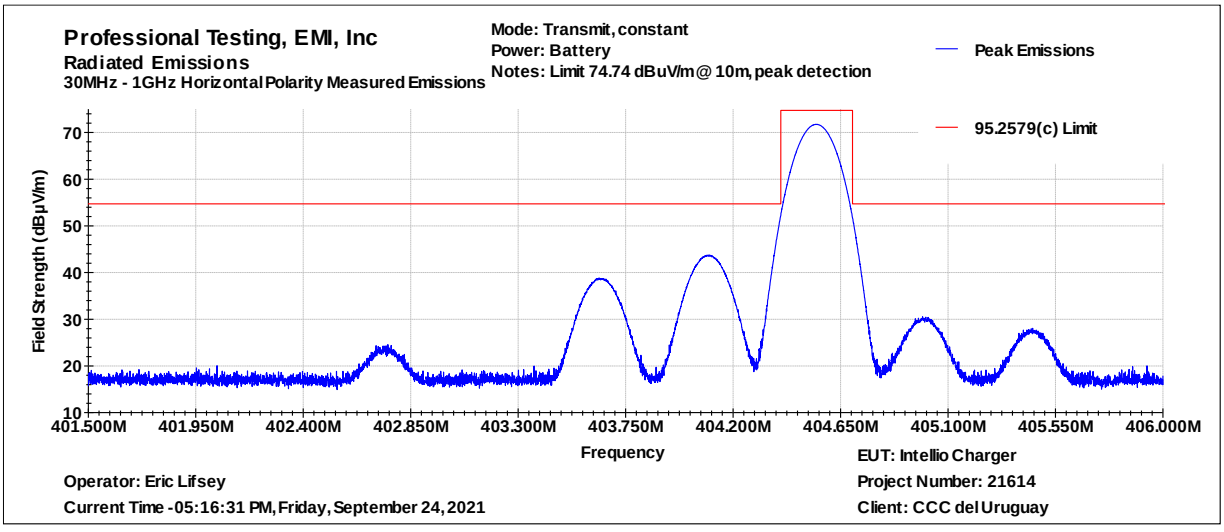
95.2579(c) Mask (120kHz RBW / 300kHz VBW, Peak Detection)

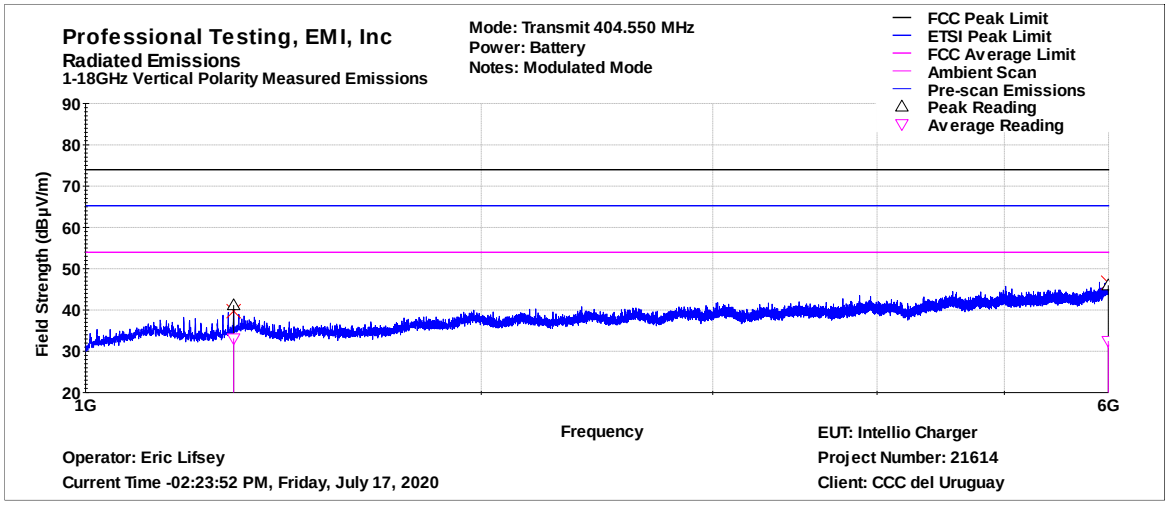




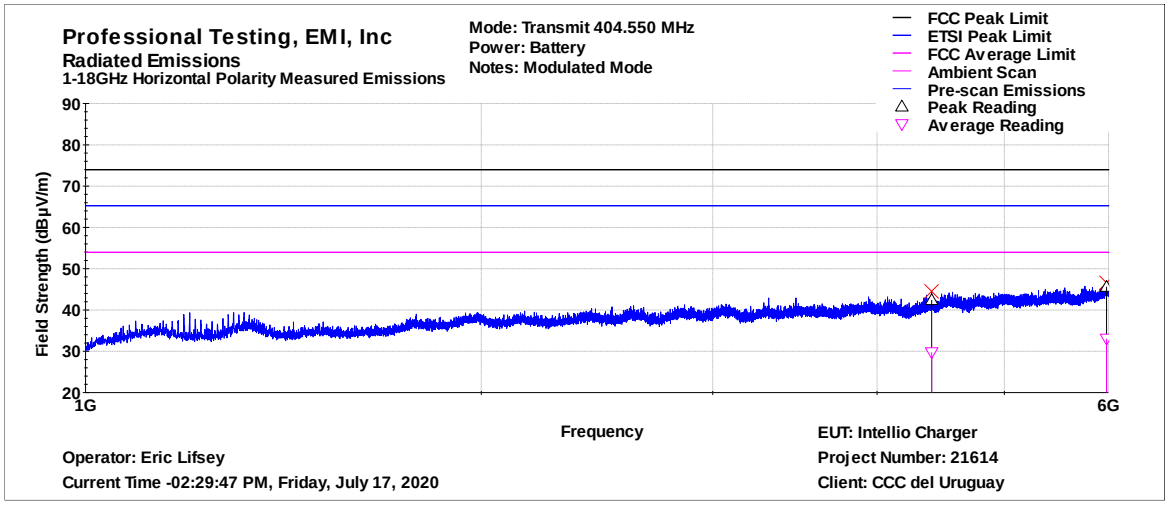
Frequency (MHz)	Azimuth (deg)	Height (cm)	QP (dBµV)	QP Limit (dBµV)	QP Margin (dB)	QP Results (P/F)
480.021	218.000	127.000	19.7	30.8	-11.1	PASS
575.236	306.000	127.000	15.7	30.8	-15.1	PASS
960.151	235.000	127.000	23.0	48.8	-25.8	PASS

95.2579(c) Mask (120kHz RBW / 300kHz VBW, Peak Detection)





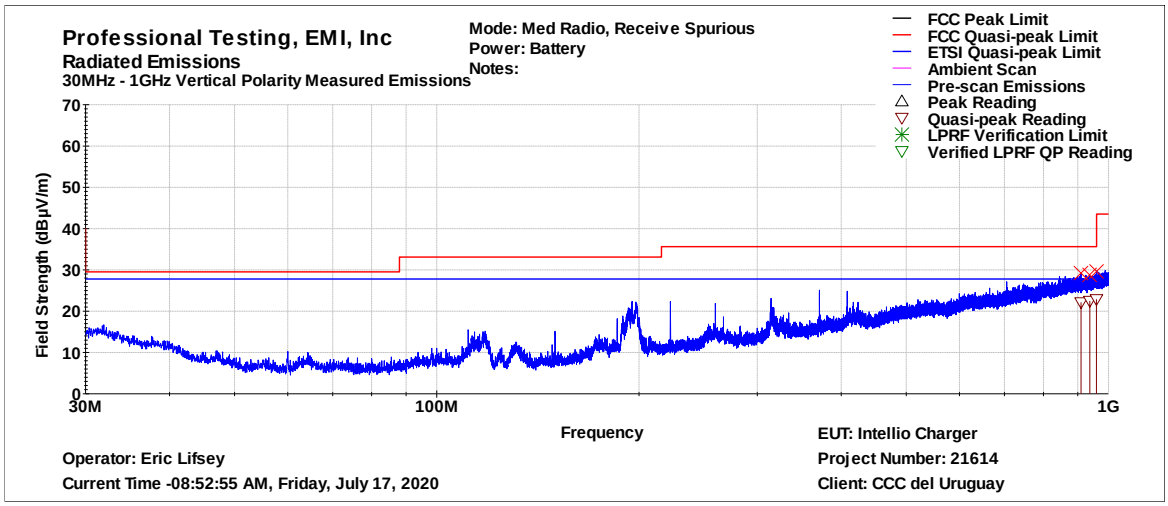
Frequency	Azimuth	Height	Peak	Peak Limit	Peak Margin	Peak Results
(MHz)	(deg)	(cm)	(dBuV)	(dBuV)	(dB)	(P/F)
1296.12	68	171	41.2	65.2	-24	PASS
5997.83	39	126	46.0	65.2	-19.2	PASS



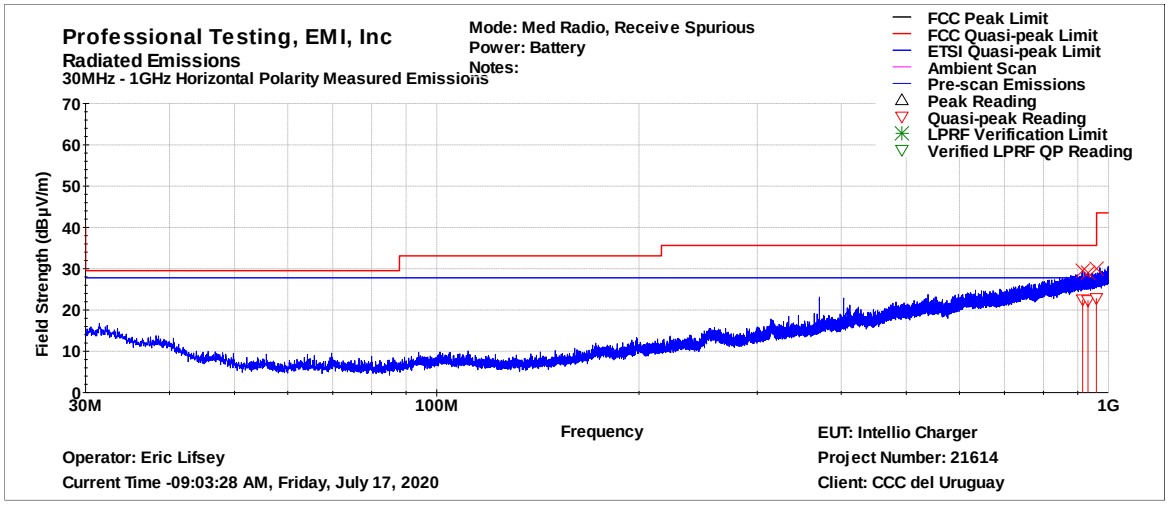
Frequency	Azimuth	Height	Peak	Peak Limit	Peak Margin	Peak Results
(MHz)	(deg)	(cm)	(dBuV)	(dBuV)	(dB)	(P/F)
4402.08	108	377	42.4	65.2	-22.8	PASS
5979.62	236	146	45.6	65.2	-19.6	PASS

6.3.2 Receive Mode

Limit is recalculated for measurement distance 10 meters. The red limit line applies.



Frequency	Azimuth	Height	QP	QP Limit	QP Margin	QP Results
MHz	(deg)	(cm)	(dBµV)	(dBµV)	(dB)	(P/F)
910.258	236.000	215.000	22.1	27.8	-5.7	PASS
938.010	88.000	128.000	22.5	27.8	-5.3	PASS
959.565	5.000	265.000	22.9	27.8	-4.9	PASS



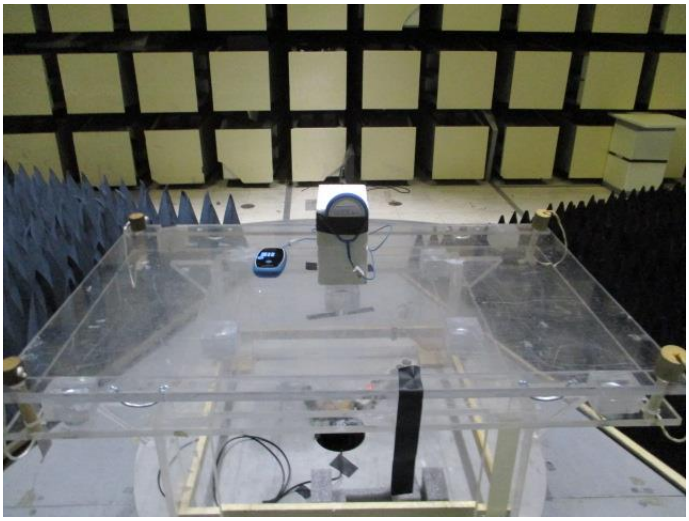
Frequency (MHz)	Azimuth (deg)	Height (cm)	QP (dBµV)	QP Limit (dBµV)	QP Margin (dB)	QP Results (P/F)
915.368	322.000	360.000	22.5	27.8	-5.3	PASS
932.064	357.000	177.000	22.3	27.8	-5.5	PASS
959.246	169.000	148.000	22.8	27.8	-5.0	PASS

As the transmit mode emissions satisfied the receive mode limit above 1 GHz the receive mode therefore passes the receive limit as well.

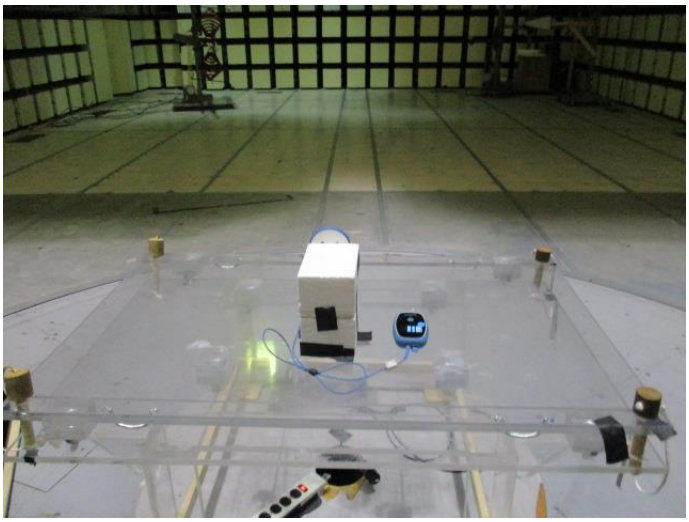
6.4 Equipment

Radiated Emissions Test Equipment List					
Tile! Software Version:		**Version: 7.1.2.17 (Jan 08, 2016 - 02:12:48 PM) or 4.1.A.0, April 14, 2009, 11:01:00PM**			
Test Profile:		**2020_RE_Unintentional_TILE7_v2.7.til**			
Asset #	**Manufacturer**	**Model**	**Equipment Nomenclature**	**Serial Number**	**Calibration Due Date**
1509A	Braden	TDK 10M	TDK 10M Chamber, NSA < 1 GHz	DAC-012915-005	9/17/2021
1890	HP	8447F-H64	Preamp/Amp, 9kHz-1300MHz, 28/25dB	3313A05298	1/9/2022
2295	Keysight	E4440A-AYZ	PSA Spectrum Analyzer	MY46186204	11/6/2020
1926	ETS-Lindgren	3142D	Antenna, Biconilog, 26 MHz - 6 GHz	135454	3/11/2021
C027	none	RG214	Cable Coax, N-N, 25m, 25MHz - 1GHz	None	9/9/2020
1327	EMCO	1050	Controller, Antenna Mast	none	N/A
0942	EMCO	11968D	Turntable, 4ft.	9510-1835	N/A
1969	HP	11713A	Attenuator/Switch Driver	3748A04113	N/A
1509B	Braden	TDK 10M	TDK 10M Chamber,sVSWR > 1 GHz	DAC-012915-005	9/21/2021
2004	Miteq	AFS44-00101800-2S-10P-44	Amplifier, 40dB, 100MHz-18GHz	None	1/9/2022
C030	none	none	Cable Coax, N-N, 30m, 1 - 18GHz	None	9/9/2020
1325	EMCO	1050	Controller, Antenna Mast	9003-1461	N/A
1780	ETS-Lindgren	3117	Antenna, Double Ridged Guide Horn, 1 - 18 GHz	110313	3/11/2021

6.5 Photographs



Front



Rear

7.0 Permissible Exposure Evaluation 95.2585

7.1 Procedure

The human exposure is determined using the transmit power as weighed per the operational transmission time required.

7.2 Limits

Requirement	Limits
Radiofrequency radiation exposure requirements specified in §§ 1.1307(b) and 2.1093.	≤1.0 mW* SAR exclusion per FCC KDB 447498.
47 CFR § 1.1307 (b)(2)(iv) Equipment authorized for use in the Medical Device Radiocommunication Service (MedRadio) as a medical implant device or body-worn transmitter (as defined in subpart I of part 95 of this chapter) is subject to routine environmental evaluation for RF exposure prior to equipment authorization, as specified in §§ 2.1093 and 95.2585 of this chapter by finite difference time domain (FDTD) computational modeling or laboratory measurement techniques. […] 47 CFR § 2.1093 (c)(1) Portable devices […] the Medical Device Radiocommunication Service (MedRadio), and […] are subject to routine environmental evaluation for RF exposure prior to equipment authorization or use.	
*FCC 447498 D01 General RF Exposure Guidance v06: Paragraph 4.2.4. *Transmitters implanted in the body of a user When the aggregate of the maximum power available at the antenna port and radiating structures of an implanted transmitter, under all operating circumstances, is ≤ 1.0 mW, SAR test exclusion may be applied. The maximum available output power requirement and worst case operating conditions must be supported by power measurement results, based on device design and implementation requirements, and fully justified in a SAR analysis report according to KDB Publication 865664 D02, in lieu of SAR measurement or numerical simulation.*	

7.3 Results

The EUT satisfied the requirement.

Highest recorded field strength of the EUT 402-405 MHz radio is 73.1 dBuV/m at 10. This is conservative worst-case figure as the time-based averaging is not applied.

This calculates to EIRP of 0.07 mW which is below the 1.0 mW limit as cited in the FCC 447498 KDB, paragraph 4.2.4, as the exclusion threshold.

Further, even if the full allowed power of 74.7 dBuV/m at 10 meters were radiated by the EUT, the EIRP would calculate to less than 0.1 mW.

It is concluded that the RF exposure is below the exclusion threshold of 1.0 mW and the SAR exclusion applies.

Appendix: Policy, Rationale, and Evaluation of EMC Measurement Uncertainty

All uncertainty calculations, estimates and expressions thereof shall be in accordance with NIST policy. Since PTI operates in accordance with NIST (NVLAP) Handbook 150-11: 2007, all instrumentation having an effect on the accuracy or validity of tests shall be periodically calibrated or verified traceable to national standards by a competent calibration laboratory. The certificates of calibration or verification on this instrumentation shall include estimates of uncertainty as required by NIST Handbook 150-11.

1. Rationale and Summary of Expanded Uncertainty.

Each piece of instrumentation at PTI that is used in making measurements for determining conformance to a standard (or limit), shall be assessed to evaluate its contribution to the overall uncertainty of the measurement in which it is used. The assessment of each item will be based on either a type A evaluation or a type B evaluation. Most of the evaluations will be type B, since they will be based on the manufacturer's statements or specifications of the calibration tolerances, or uncertainty will be stated along with a brief rationale for the type of evaluation and the resulting stated uncertainties.

The individual uncertainties included in the combined standard uncertainty for a specific test result will depend on the configuration in which the item of instrumentation is used. The combination will always be based on the law of propagation of uncertainty. Any systematic effects will be accommodated by including their uncertainties, in the calculation of the combined standard uncertainty; except that if the direction and amount of the systematic effect cannot be determined and separated from its uncertainty, the whole effect will be treated as uncertainty and combined along with the other elements of the test setup.

Type A evaluations of standard uncertainty will usually be based on calculating the standard deviation of the mean of a series of independent observations, but may be based on a least-squares curve fit or the analysis of variance for unusual situations. Type B evaluations of standard uncertainty will usually be based on manufacturer's specifications, data provided in calibration reports, and experience. The type of probability distribution used (normal, rectangular, a priori, or u-shaped) will be stated for each Type B evaluation.

In the evaluation of the uncertainty of each type of measurement, the uncertainty caused by the operator will be estimated. One notable operator contribution to measurement uncertainty is the manipulation of cables to maximize the measured values of radiated emissions. The operator contribution to measurement uncertainty is evaluated by having several operators independently repeat the same test. This results in a Type A evaluation of operator-contributed measurement uncertainty.

A summary of the expanded uncertainties of PTI measurements is shown as Table 1. These are the worst-case uncertainties considering all operative influence factors.

Table 1: Summary of Measurement Uncertainties for Site 45

Type of Measurement	Frequency Range	Meas. Dist.	Expanded Uncertainty U, dB (k=2)
Mains Conducted Emissions	150 kHz to 30 MHz	N/A	2.9
Telecom Conducted Emissions	150 kHz to 30 MHz	N/A	2.8
Radiated Emissions	30 to 1,000 MHz	10 m	4.8
	1 to 18 GHz	3 m	5.7

End of Report