Project
21613-15

CCC del Uruguay S.A.
Cardiac Implantable Optimizer Smart Mini

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 Aug 2020
5 May 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.	3 Sep 2020
Final		5 Nov 2020
Final Rev01	Additional standards reference (1.6), setup detail (1.8), and measurement clarification (4.3) per TCB comments. Test data unchanged.	5 May 2021

Errata:

None.

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(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: 24 Aug 2020	Model(s): Laboratory Project ID:	Cardiac Implantable Optimizer Smart Mini 21613-15

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

FCC Part 95			
Subpart I Medical Device Radio Communications Service			
Test	**Class/Limits 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	25 C to 45 C	25 Jun 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	26 Jun 2020
Bandwidth 95.2573	Complies	246.8 kHz	25 Jun 2020
Unwanted Emissions 95.2579	Complies	95.2579(a) limits satisfied	26 Jun 2020
Permissible Exposure Evaluation 95.2585	Complies	1.1307(b) and 2.1093 exposure limit satisfied	26 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.

NVLAP TESTING NVLAP LAB CODE 200062-0

Larry Finn
Chief Technical Officer (CTO)

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 extent to which the equipment under test (EUT) conformed to the intentional radiator requirements of North America.

1.2 EUT Description

This device is a wireless controlled implantable pulse generator for medical applications.

Table 1.2.1: Equipment Under Test

Manufacturer	Model	Description
CCC del Uruguay S.A.	Cardiac Implantable Optimizer Smart Mini	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 C63.4:2009	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
ETSI EN 301 839 V2.1.1	Ultra Low Power Active Medical Implants (ULP-AMI) and associated Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Harmonized Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU

1.7 Deviations

The implant EUT, when tested in the torso simulator, was placed near the surface for measurement instead of the 6 cm distance allowed. Passing with this reduced loss would result in conservative measurement.

1.8 Torso Simulator

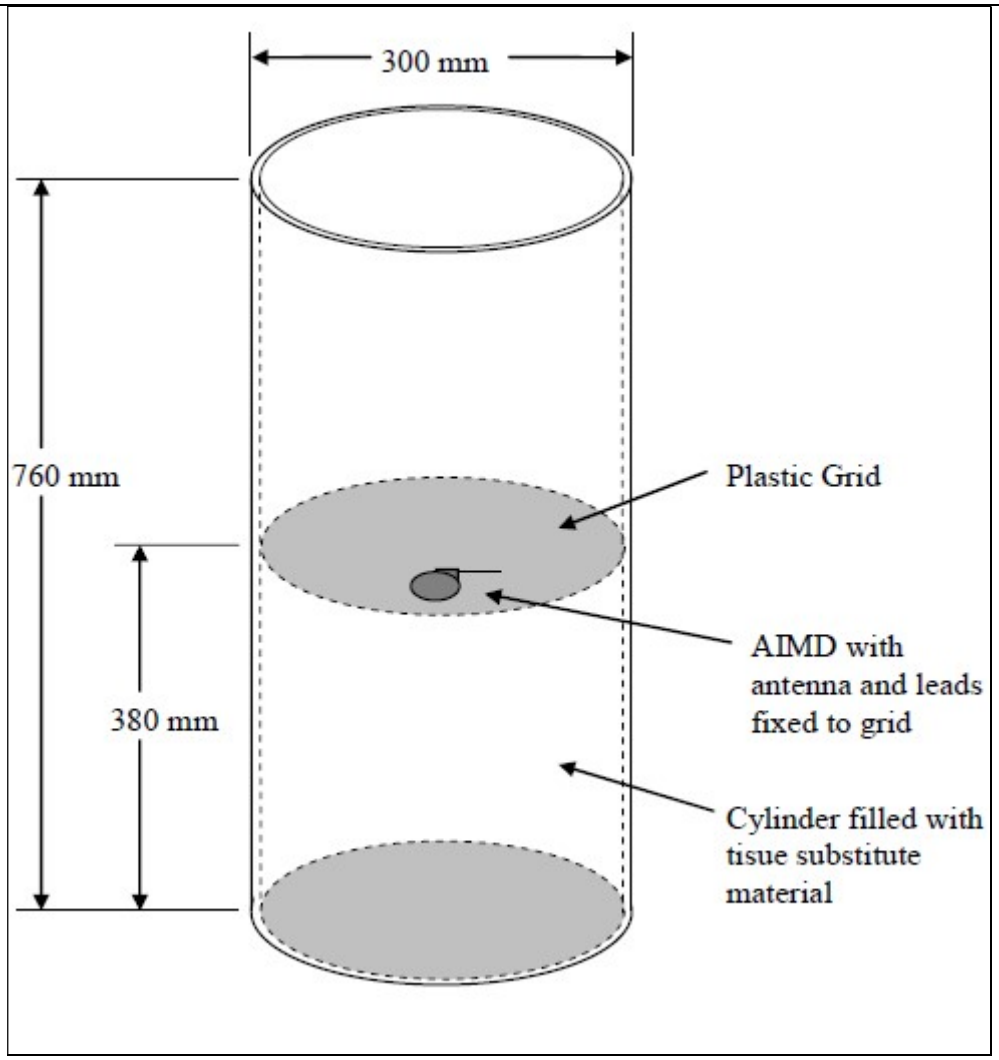
Where used, a torso simulator was assembled and filled with a solution to simulate human tissue. It was constructed as filled with solution as follows.

Ingredient	% By Weight	For 1 liter of water
Water	52,4	1 liter
Sugar	45	0,86 kg
Salt (NaCl)	1,5	0,03 kg
HEC(*)	1,1	0,02 kg

(*) Natrosol™ hydroxyethylcellulose (Natrosol 250 HHR)

These ingredients were mixed and heated to 40 C in a temperature chamber to dissolve and create a uniform solution. A fiberglass pole was used to stir the heated mixture.

The dimensions were taken from the ETSI EN 301 839 V2.1.1 and are essentially the same as called for in section 6.2.2 of ANSI C63.26-2015. Standard ANSI C63.26-2015 section 6.2.2 therefore was applied in the construction of the plexiglass torso simulator.



Construction of Torso Simulator

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 Per 95.2565	Limits Frequency
Temperature 25 C and 45 C	±100 ppm or ±40245 Hz

3.3 Results

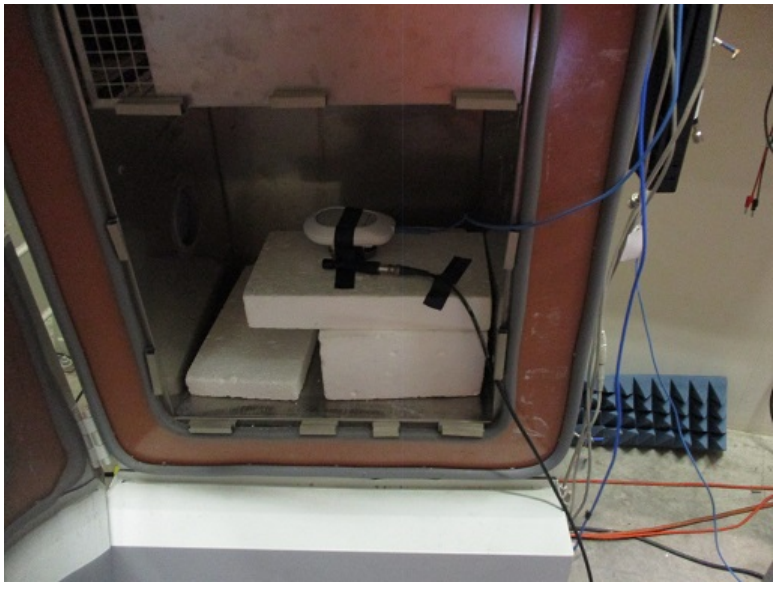
The EUT satisfied the requirement.

21613			25-Jun-2020
Condition	**Frequency**		**Deviation**
Temperature (C)	Reference Center Frequency (MHz)	Measured Frequency (MHz)	Calculated Deviation (Hz)
25	402.450000	402.444588	-5412
35	402.450000	402.446625	-3375
45	402.450000	402.447375	-2625
25	404.550000	404.550375	375
35	404.550000	404.547375	-2625
45	404.550000	404.550375	375
Max Deviation (Hz)			375
Min Deviation (Hz)			-5412

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

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.

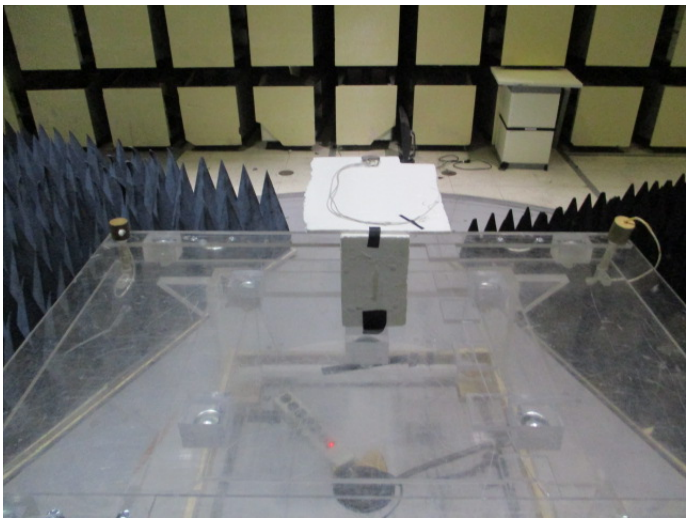
Note that EUT satisfied the requirement without a human torso simulator.

Radiated Field Strength Measured at 10 meters			
Polarity & Frequency (MHz)	EUT Direction (Degrees)	Antenna Height (cm)	Quasi-peak Reading (dBµV)
V 402.399	246	152	45.8
H 402.395	294	202	54.4
V 404.490	246	189	47.6
H 404.500	300	174	55.7

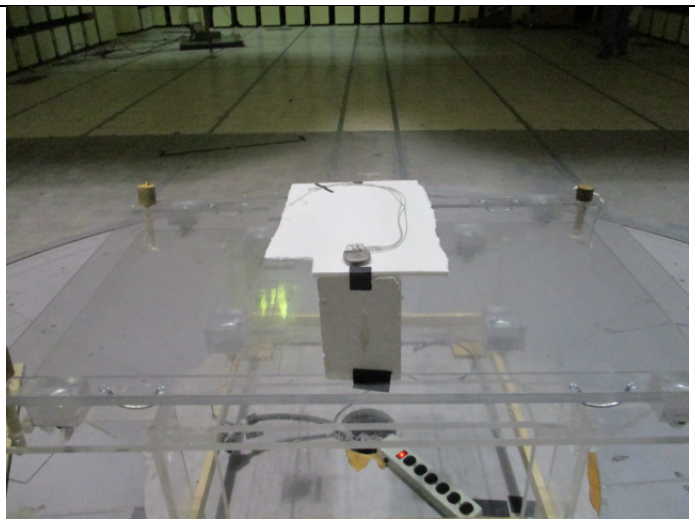
4.3.1 Equipment

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



Front



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.

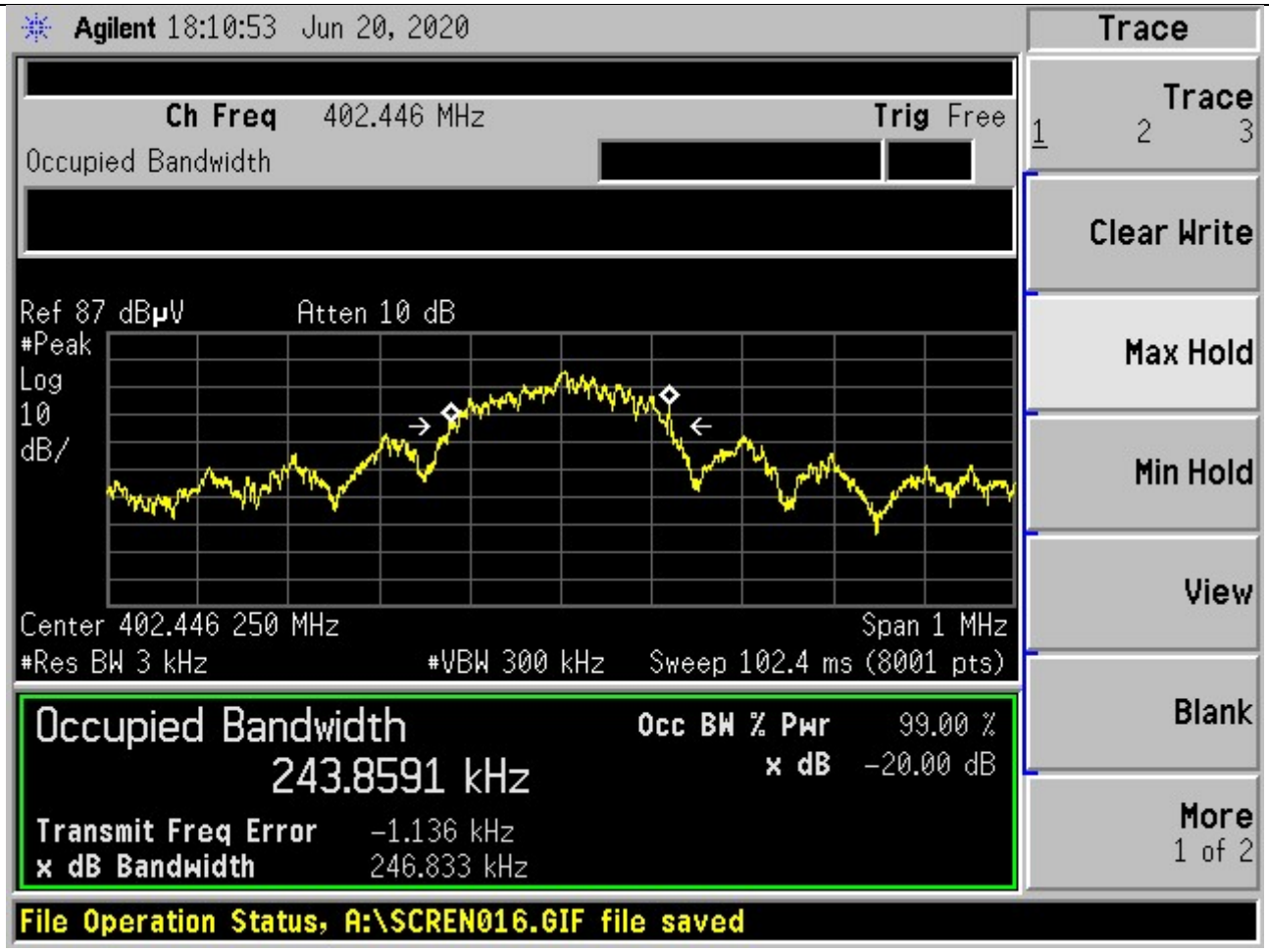
5.2 Limits

Requirement	Limit
20 dB Bandwidth	300 kHz

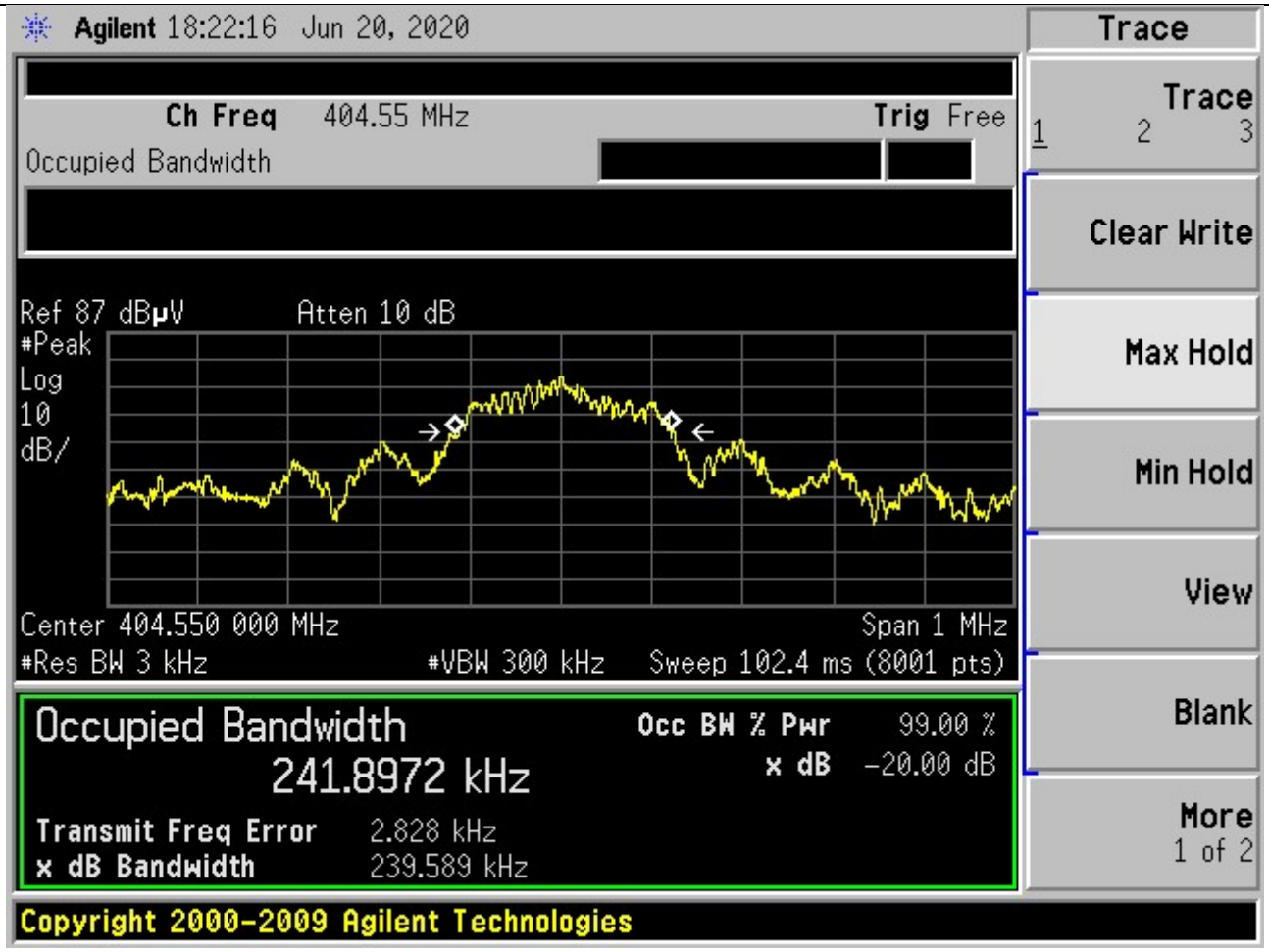
5.3 Results

The EUT satisfied the requirement.

Operating Channel	Measured 20 dB Bandwidth
Bottom	246.8 kHz
Top	239.6 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

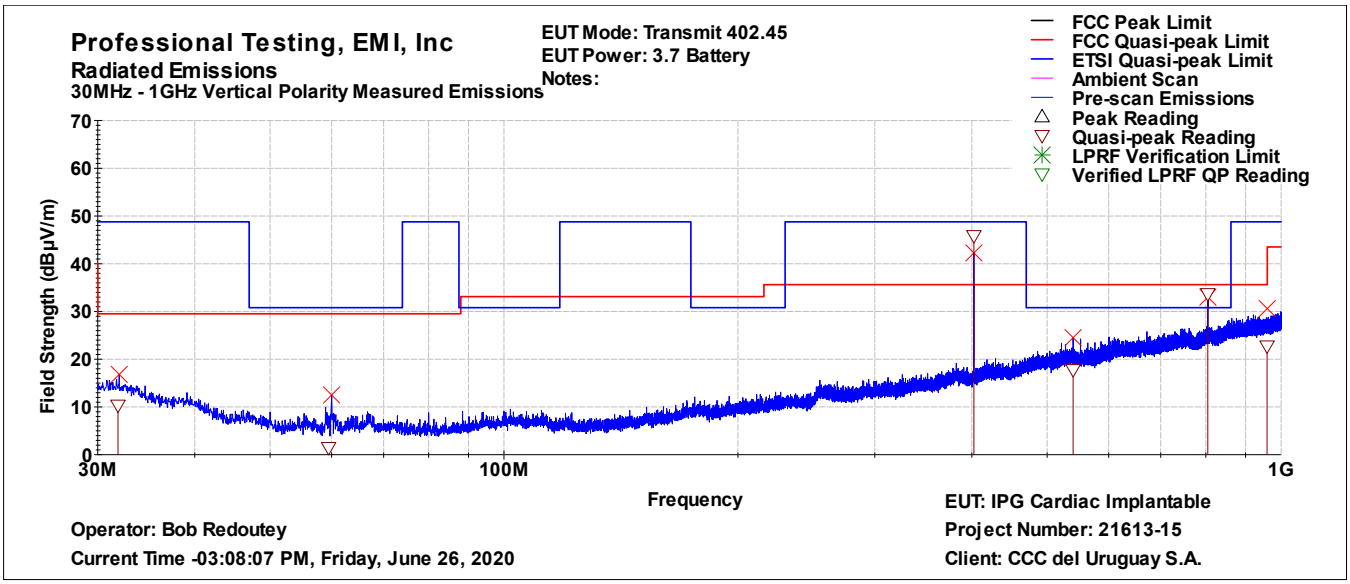
The EUT satisfied the requirement.

6.3.1 Transmit Mode

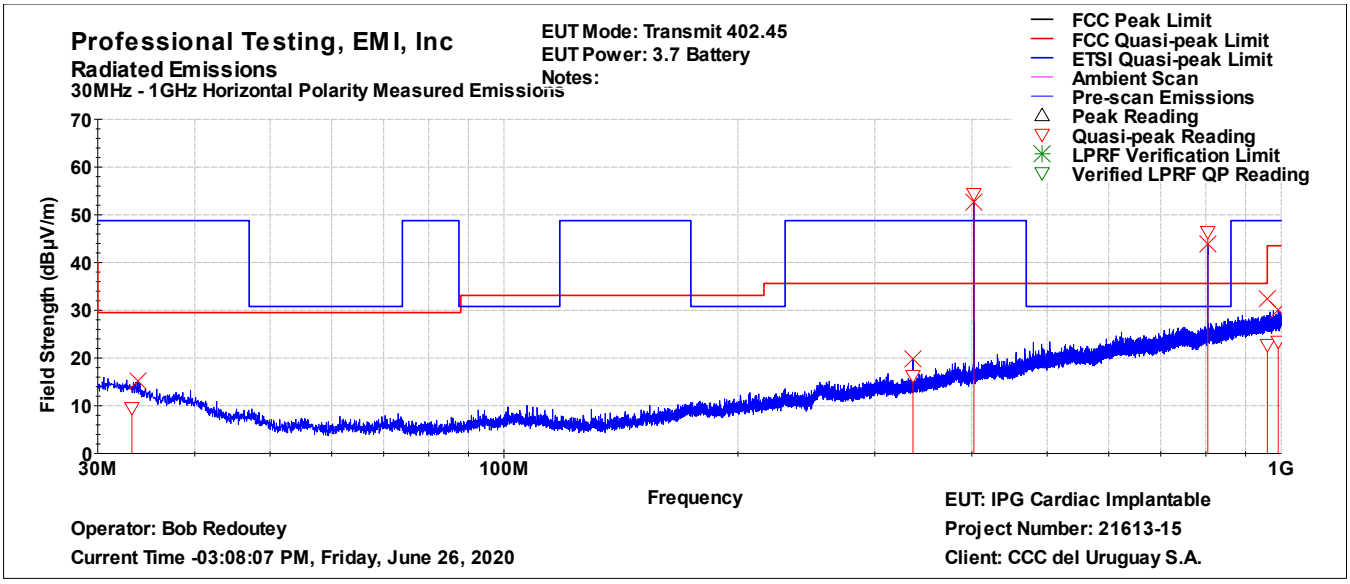
Limit is recalculated for measurement distance 10 meters. The red limit line applies.

Measured without modulation.

These measurements were performed without using a human torso simulator. The 2nd harmonic failed but was remeasured later with the human torso simulator for a correction factor. At the 2nd harmonic frequency the correction factor measured as -19.18 dB.

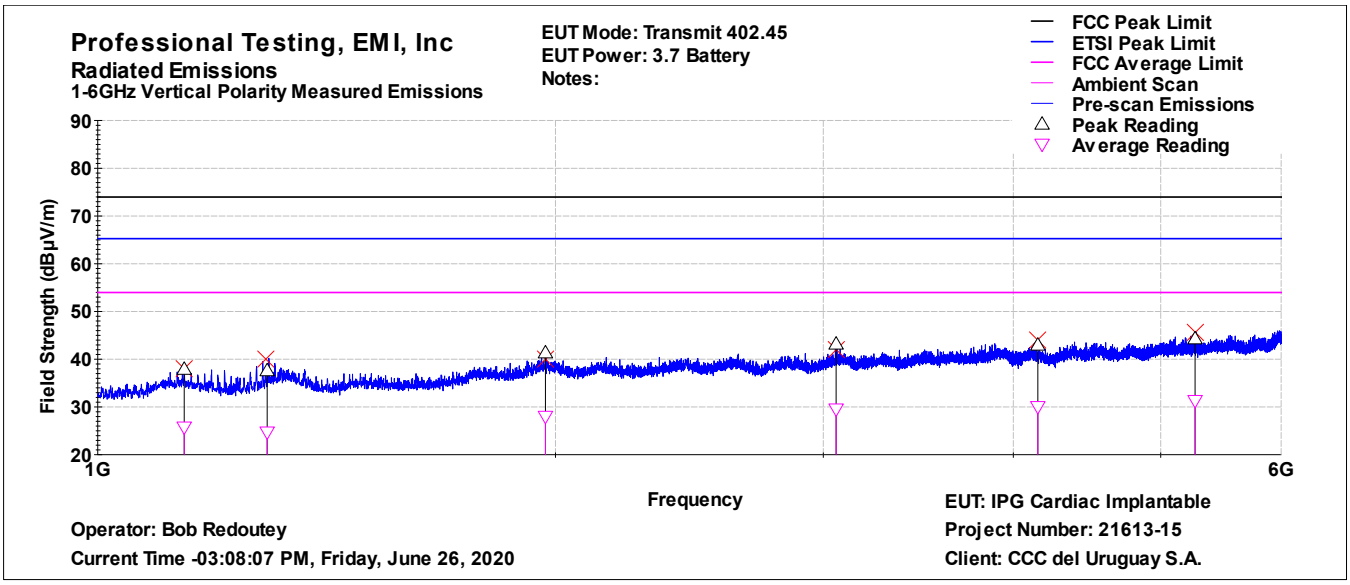


Frequency	Azimuth	Height	QP	QP Limit	QP Margin	QP Results
MHz	(deg)	(cm)	(dBµV)	(dBµV)	(dB)	(P/F)
31.867	170.000	129.000	10.308	29.500	-19.192	PASS
59.476	5.000	127.000	1.440	29.500	-28.060	PASS
540.029	74.000	128.000	17.746	35.600	-17.854	PASS
804.772	110.000	299.000	33.666	35.600	-1.934	PASS
959.372	279.000	226.000	22.707	35.600	-12.893	PASS

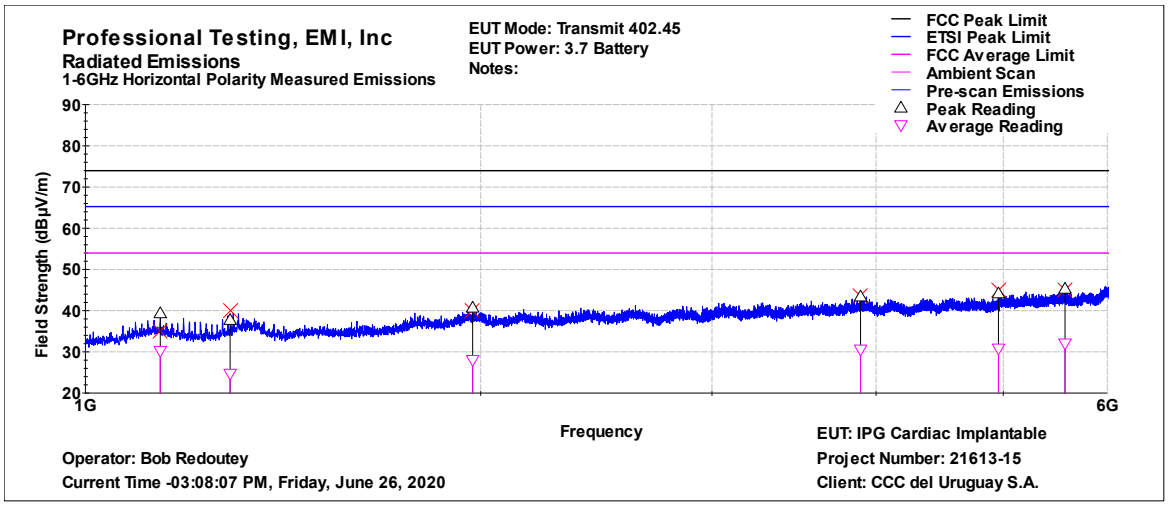


Frequency	Azimuth	Height	QP	QP Limit	QP Margin	QP Results
(MHz)	(deg)	(cm)	(dBµV)	(dBµV)	(dB)	(P/F)
33.201	34.000	126.000	9.550	29.500	-19.950	PASS
335.972	3.000	126.000	16.277	35.600	-19.323	PASS
804.777	19.000	262.000	46.422	35.600	10.822	PASS*
960.139	343.000	316.000	22.778	43.500	-20.722	PASS
991.661	223.000	364.000	23.453	43.500	-20.047	PASS

*The measurement was performed without using a human torso simulator. The 2nd harmonic was remeasured later with the torso simulator for a correction factor. At the harmonic frequency the correction factor measured as -19.18 dB.

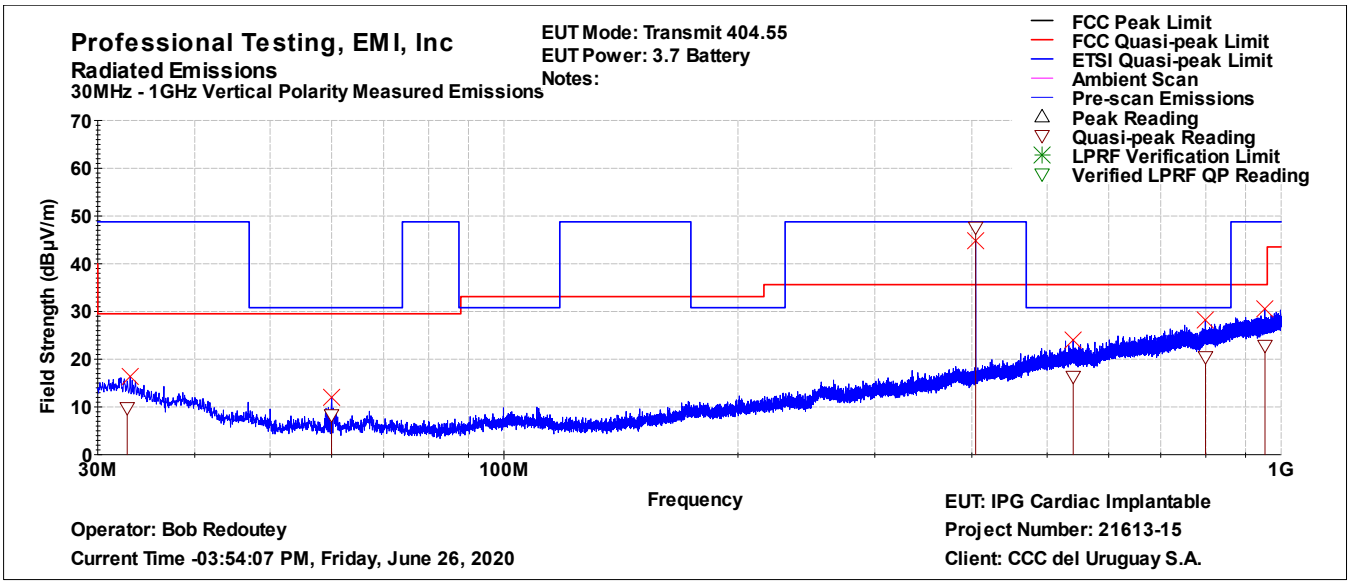


Frequency	Azimuth	Height	Peak	Peak Limit	Peak Margin	Peak Results	Avg	Avg Limit	Avg Margin	Avg Results
(MHz)	(deg)	(cm)	(dBuV)	(dBuV)	(dB)	(P/F)	(dBuV)	(dBuV)	(dB)	(P/F)
1139.93	22	327	37.929	73.958	-36.029	PASS	25.727	53.958	-28.231	PASS
1292.65	2	179	37.625	73.958	-36.333	PASS	24.678	53.958	-29.280	PASS
1969.83	235	331	41.375	73.958	-32.583	PASS	27.973	53.958	-25.985	PASS
3058.99	133	329	43.207	73.958	-30.751	PASS	29.515	53.958	-24.443	PASS
4151.18	3	193	42.994	73.958	-30.964	PASS	29.998	53.958	-23.960	PASS
5267.25	19	187	44.321	73.958	-29.637	PASS	31.274	53.958	-22.684	PASS

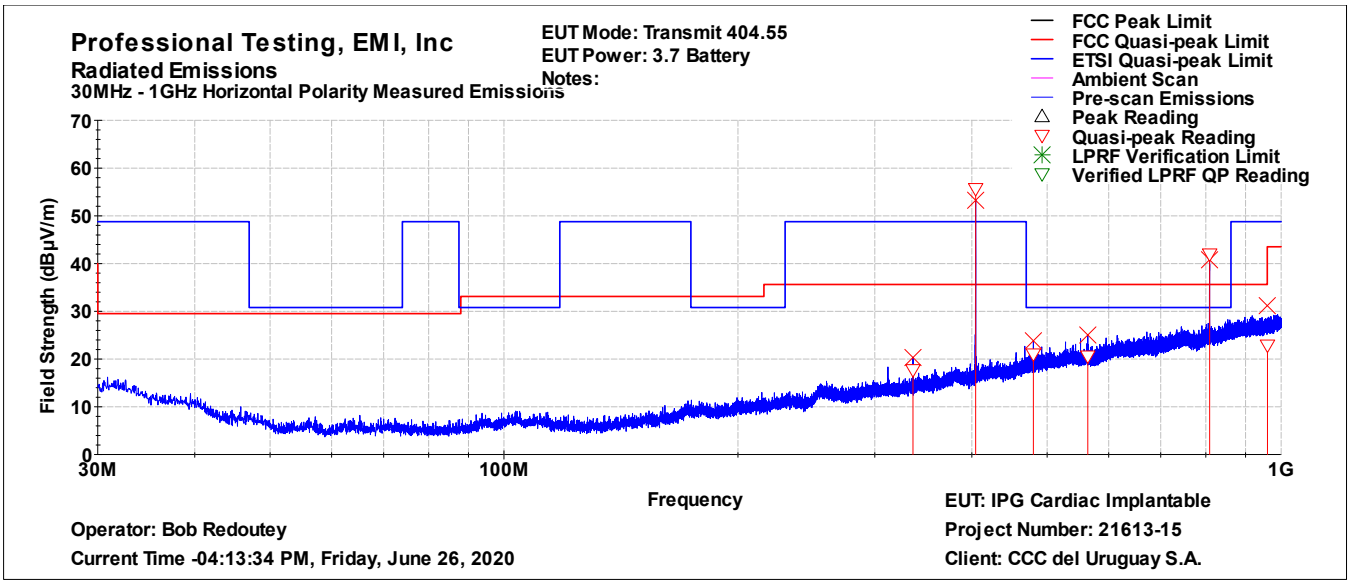


Frequency	Azimuth	Height	Peak	Peak Limit	Peak Margin	Peak Results	Avg	Avg Limit	Avg Margin	Avg Results
(MHz)	(deg)	(cm)	(dBuV)	(dBuV)	(dB)	(P/F)	(dBuV)	(dBuV)	(dB)	(P/F)
1140.30	14	329	39.384	73.958	-34.574	PASS	30.205	53.958	-23.753	PASS
1288.84	14	229	37.762	73.958	-36.196	PASS	24.653	53.958	-29.305	PASS
1971.92	16	337	40.743	73.958	-33.215	PASS	27.999	53.958	-25.959	PASS
3892.86	247	240	43.436	73.958	-30.522	PASS	30.533	53.958	-23.425	PASS
4957.68	357	357	44.204	73.958	-29.754	PASS	30.775	53.958	-23.183	PASS
5570.72	342	127	45.336	73.958	-28.622	PASS	32.003	53.958	-21.955	PASS

Top Channel

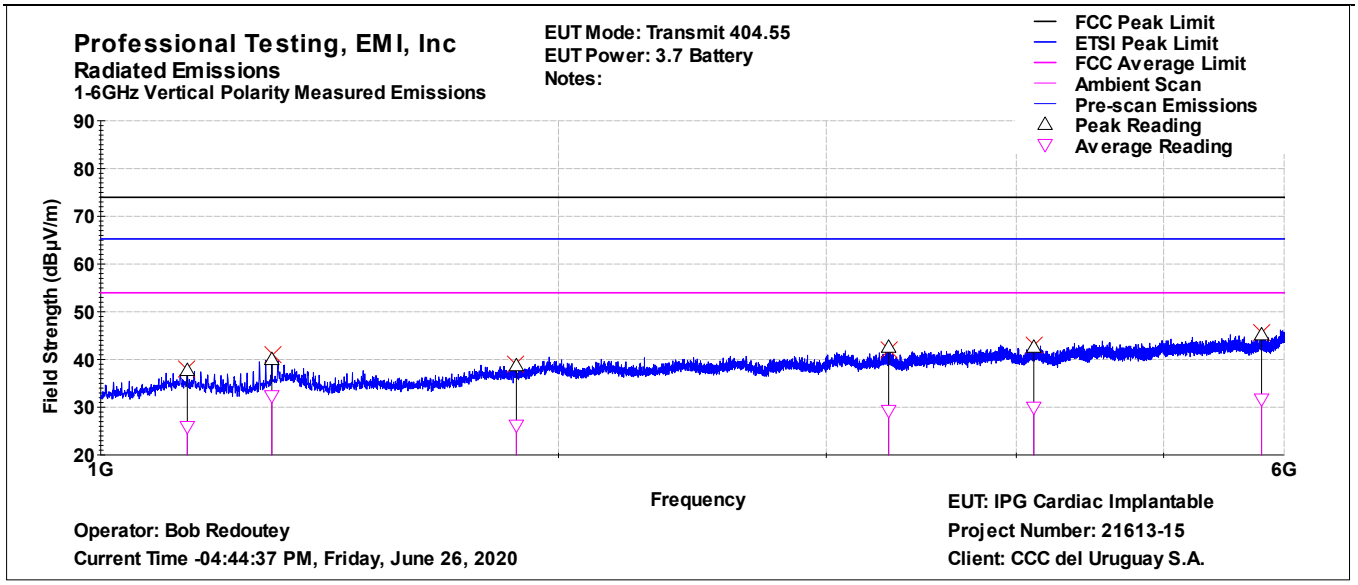


Frequency	Azimuth	Height	QP	QP Limit	QP Margin	QP Results
MHz	(deg)	(cm)	(dBµV)	(dBµV)	(dB)	(P/F)
32.745	18.000	129.000	9.786	29.500	-19.714	PASS
59.992	18.000	127.000	8.299	29.500	-21.201	PASS
540.192	205.000	128.000	16.350	35.600	-19.250	PASS
799.305	22.000	128.000	20.458	35.600	-15.142	PASS
953.338	242.000	333.000	22.834	35.600	-12.766	PASS

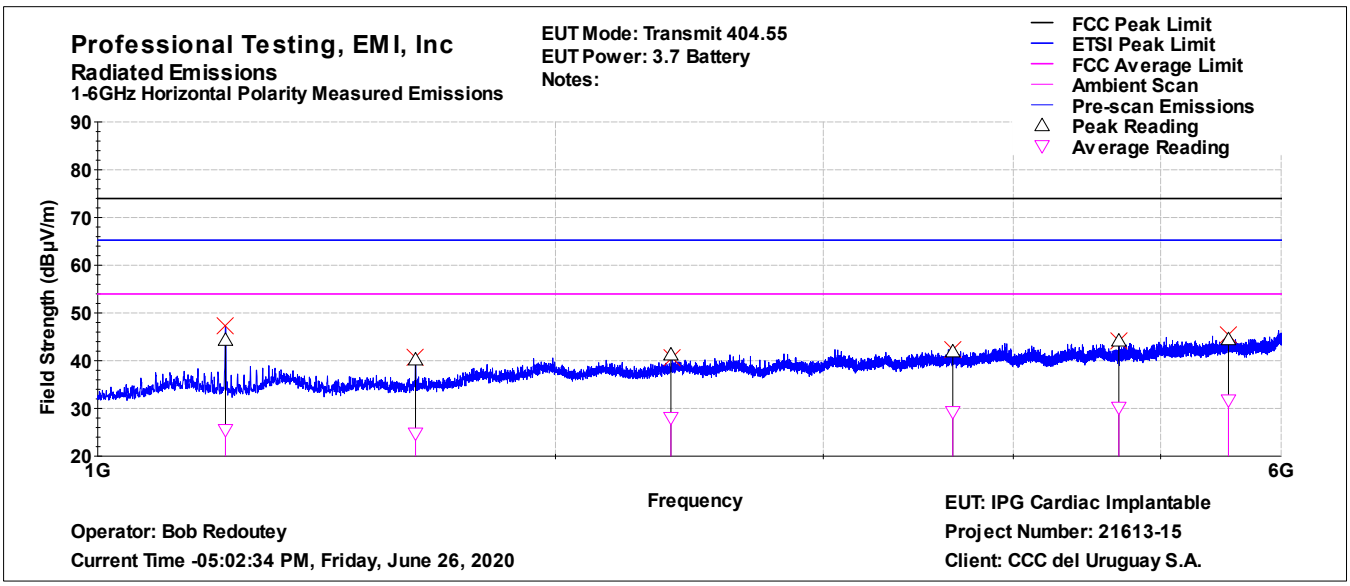


Frequency	Azimuth	Height	QP	QP Limit	QP Margin	QP Results
(MHz)	(deg)	(cm)	(dBµV)	(dBµV)	(dB)	(P/F)
336.013	357.000	126.000	17.718	35.600	-17.882	PASS
479.972	92.000	126.000	21.011	35.600	-14.589	PASS
564.012	143.000	372.000	20.571	35.600	-15.029	PASS
809.187	2.000	262.000	41.940	35.600	6.340	PASS*
960.578	2.000	203.000	22.867	43.500	-20.633	PASS

*The measurement was performed without using a human torso simulator. The 2nd harmonic was remeasured later with the torso simulator for a correction factor. At the harmonic frequency the correction factor measured as -19.18 dB.



Frequency	Azimuth	Height	Peak	Peak Limit	Peak Margin	Peak Results	Avg	Avg Limit	Avg Margin	Avg Results
(MHz)	(deg)	(cm)	(dBuV)	(dBuV)	(dB)	(P/F)	(dBuV)	(dBuV)	(dB)	(P/F)
1140.17	3	327	37.730	73.958	-36.228	PASS	25.893	53.958	-28.065	PASS
1295.83	163	179	40.017	73.958	-33.941	PASS	32.350	53.958	-21.608	PASS
1876.56	73	175	38.738	73.958	-35.220	PASS	26.187	53.958	-27.771	PASS
3297.34	344	331	42.608	73.958	-31.350	PASS	29.271	53.958	-24.687	PASS
4107.79	322	179	42.603	73.958	-31.355	PASS	29.948	53.958	-24.010	PASS
5799.50	16	102	45.192	73.958	-28.766	PASS	31.651	53.958	-22.307	PASS

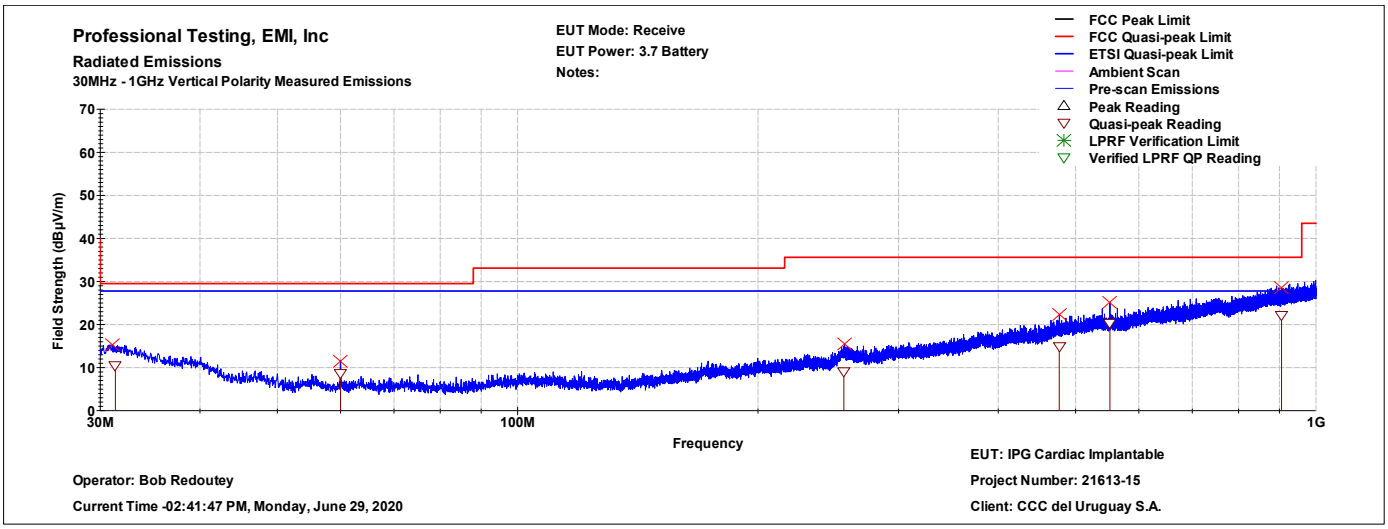


Frequency	Azimuth	Height	Peak	Peak Limit	Peak Margin	Peak Results	Avg	Avg Limit	Avg Margin	Avg Results
(MHz)	(deg)	(cm)	(dBuV)	(dBuV)	(dB)	(P/F)	(dBuV)	(dBuV)	(dB)	(P/F)
1213.55	2	329	44.314	73.958	-29.644	PASS	25.512	53.958	-28.446	PASS
1618.07	2	338	40.204	73.958	-33.754	PASS	24.772	53.958	-29.186	PASS
2382.12	112	335	41.237	73.958	-32.721	PASS	28.032	53.958	-25.926	PASS
3649.97	-4	271	41.892	73.958	-32.066	PASS	29.276	53.958	-24.682	PASS
4693.40	36	302	44.162	73.958	-29.796	PASS	30.182	53.958	-23.776	PASS
5540.26	181	146	44.438	73.958	-29.520	PASS	31.724	53.958	-22.234	PASS

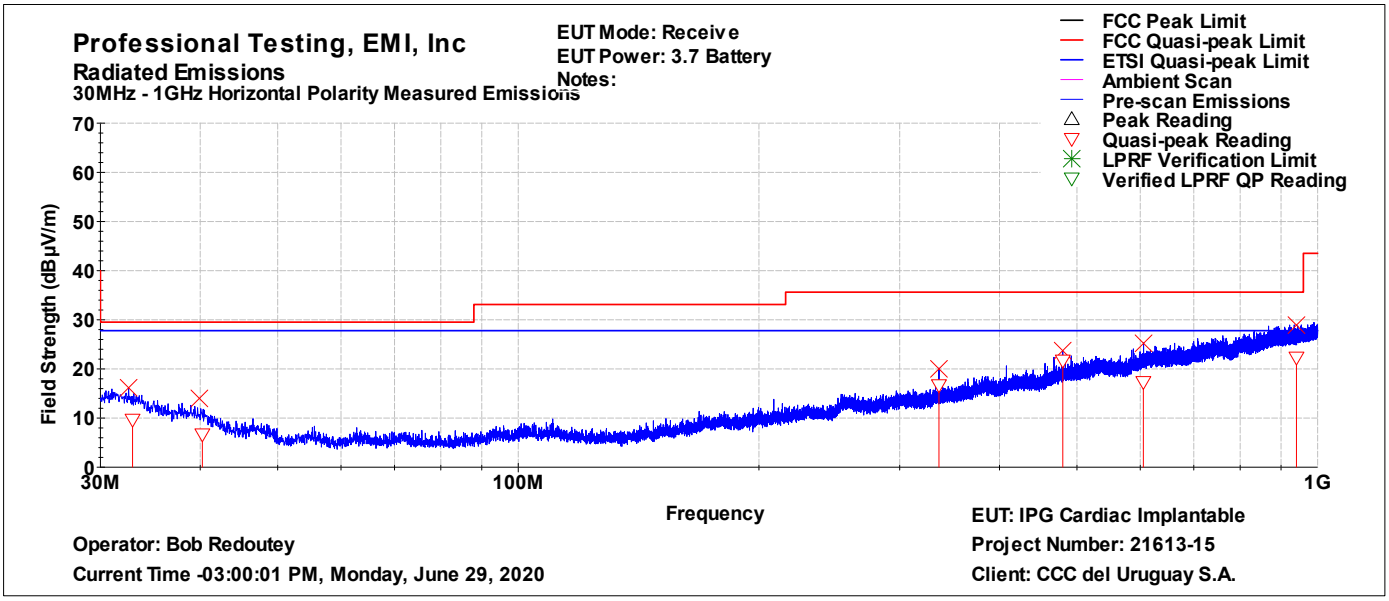
6.3.2 Receive Mode

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

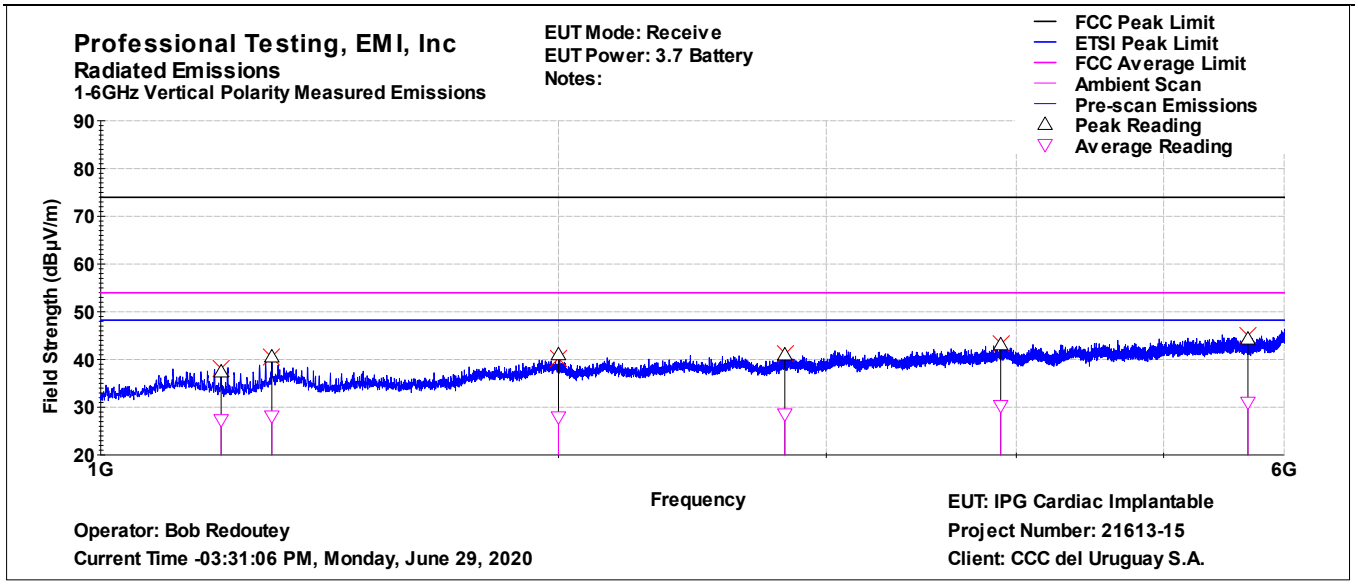
These measurements were performed without using a human torso simulator.



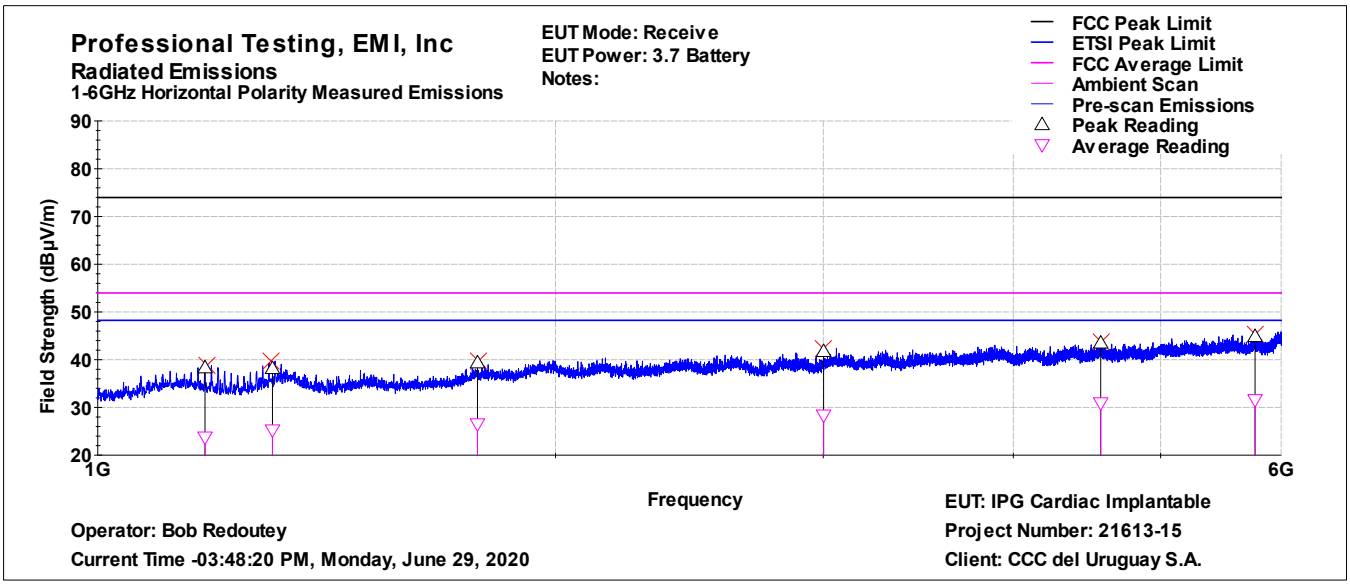
Frequency (MHz)	EUT Direction (Degrees)	Antenna Height (cm)	Quasi-peak Reading (dBµV)	Quasi-peak Limit (dBµV)	Quasi-peak Margin (dB)	Quasi-peak Results
31.340	276.000	129.000	10.516	29.500	-18.984	PASS
60.008	157.000	128.000	8.562	29.500	-20.938	PASS
256.191	295.000	128.000	9.038	35.600	-26.562	PASS
476.942	354.000	128.000	14.848	35.600	-20.752	PASS
552.011	337.000	128.000	20.283	35.600	-15.317	PASS
905.610	46.000	128.000	22.115	35.600	-13.485	PASS



Frequency (MHz)	EUT Direction (Degrees)	Antenna Height (cm)	Quasi-peak Reading (dBµV)	Quasi-peak Limit (dBµV)	Quasi-peak Margin (dB)	Quasi-peak Results
32.915	91.000	126.000	9.660	29.500	-19.840	PASS
40.249	200.000	126.000	6.674	29.500	-22.826	PASS
335.992	15.000	126.000	16.679	35.600	-18.921	PASS
479.998	50.000	153.000	21.696	35.600	-13.904	PASS
605.402	31.000	126.000	17.317	35.600	-18.283	PASS
940.869	280.000	168.000	22.307	35.600	-13.293	PASS



Frequency	Azimuth	Height	Peak	Peak Limit	Peak Margin	Peak Results	Avg	Avg Limit	Avg Margin	Avg Results
(MHz)	(deg)	(cm)	(dBuV)	(dBuV)	(dB)	(P/F)	(dBuV)	(dBuV)	(dB)	(P/F)
1200.06	79	198	37.425	73.958	-36.533	PASS	27.335	53.958	-26.623	PASS
1295.79	256	181	40.571	73.958	-33.387	PASS	28.111	53.958	-25.847	PASS
1999.99	357	292	41.039	73.958	-32.919	PASS	27.910	53.958	-26.048	PASS
2817.34	59	337	41.009	73.958	-32.949	PASS	28.537	53.958	-25.421	PASS
3906.61	172	179	43.118	73.958	-30.840	PASS	30.289	53.958	-23.669	PASS
5680.62	0	375	44.311	73.958	-29.647	PASS	30.990	53.958	-22.968	PASS

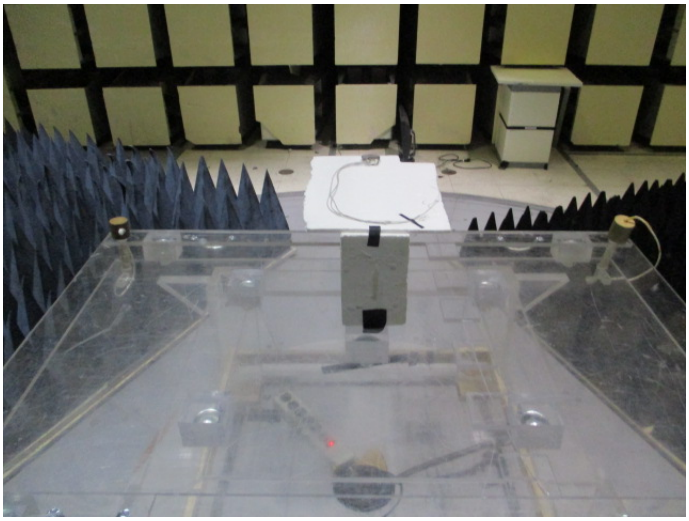


Frequency	Azimuth	Height	Peak	Peak Limit	Peak Margin	Peak Results	Avg	Avg Limit	Avg Margin	Avg Results
(MHz)	(deg)	(cm)	(dBuV)	(dBuV)	(dB)	(P/F)	(dBuV)	(dBuV)	(dB)	(P/F)
1176.45	23	334	38.331	73.958	-35.627	PASS	23.742	53.958	-30.216	PASS
1302.83	2	196	38.189	73.958	-35.769	PASS	25.215	53.958	-28.743	PASS
1777.29	84	271	39.384	73.958	-34.574	PASS	26.499	53.958	-27.459	PASS
3001.39	343	179	41.755	73.958	-32.203	PASS	28.351	53.958	-25.607	PASS
4565.97	111	346	43.529	73.958	-30.429	PASS	30.889	53.958	-23.069	PASS
5768.32	299	127	44.902	73.958	-29.056	PASS	31.558	53.958	-22.400	PASS

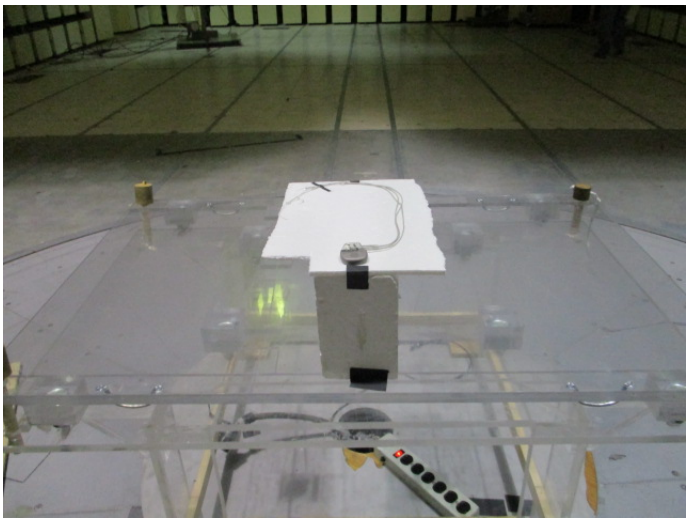
6.4 Equipment

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 55.7 dBuV/m at 10 meters as measured without phantom human torso simulator. This is conservative worst-case figure as the time-based averaging is not applied.

This calculates to EIRP of 0.0012 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.

Regarding the inductive link radio at 13.56 MHz; this is generated by the programmer wand used by the physician. The operation of the inductive link is relatively brief to read the security encryption key. Subsequently, the programming wand is removed from the patient and the Medical Radio remains active during the examination.

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