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**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.  
1601 North A.W. Grimes Blvd., Suite B  
Round Rock, Texas 78665

24 Aug 2020  
5 May 2021

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Reviewed by

A handwritten signature in black ink, appearing to read 'Larry Finn'.

Larry Finn  
Chief Technical Officer

Written by

A handwritten signature in black ink, appearing to read 'Eric Lifsey'.

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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(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.<br>Gral Paz 1363<br>Montevideo, Uruguay 11400<br>Certificate Date: 24 Aug 2020 | Model(s): Cardiac Implantable<br>Optimizer Smart Mini<br>Laboratory Project ID: 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.

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

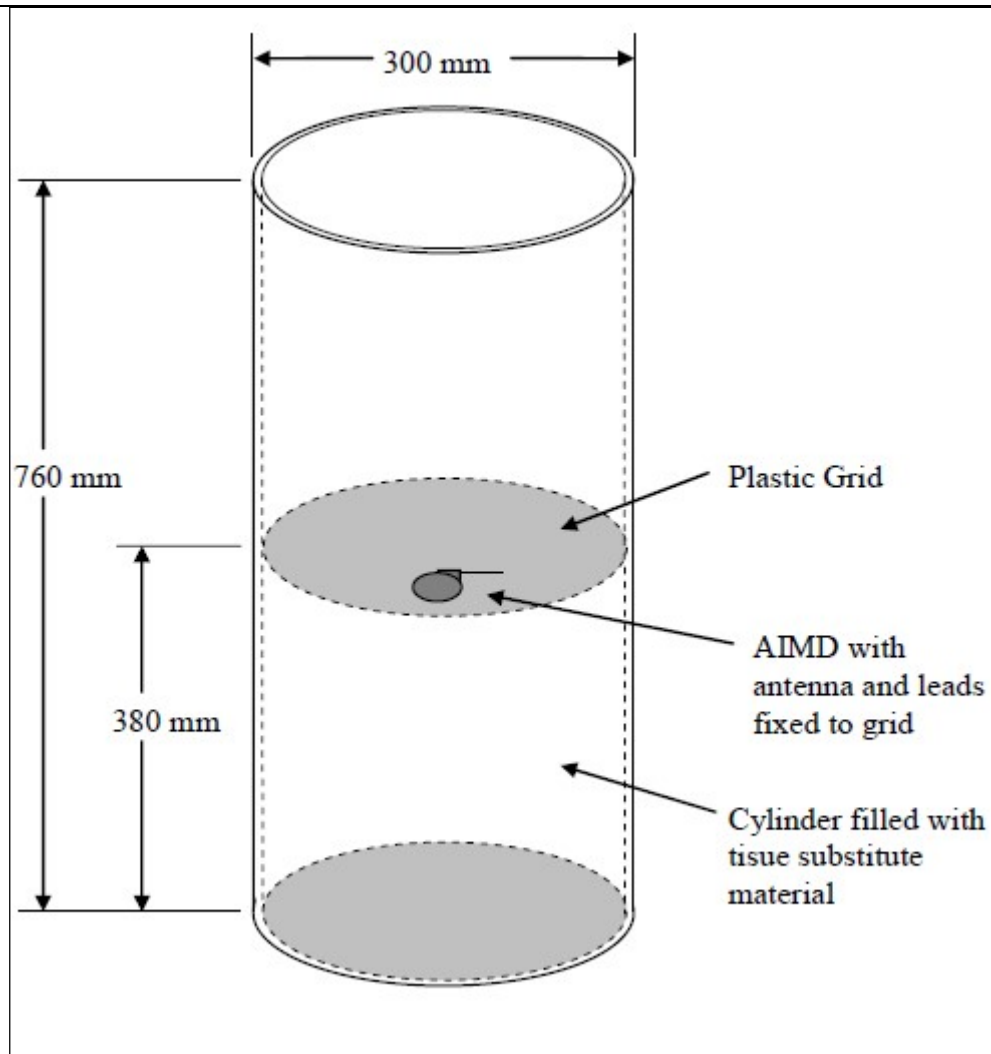
Where used, a torso simulator was assembled and filled with a solution to simulate human tissue. It was constructed as filled with solution as follows.

| <i>Ingredient</i>  | <i>% By Weight</i> | <i>For 1 liter of water</i> |
|--------------------|--------------------|-----------------------------|
| <i>Water</i>       | 52,4               | 1 liter                     |
| <i>Sugar</i>       | 45                 | 0,86 kg                     |
| <i>Salt (NaCl)</i> | 1,5                | 0,03 kg                     |
| <i>HEC(*)</i>      | 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<br>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  $P^{MT} = 10 \log B - 150 \text{ (dBm/Hz)} + G$  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).



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*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<br>Per 95.2565 | Limits<br>Frequency             |
|----------------------------|---------------------------------|
| Temperature 25 C and 45 C  | $\pm 100$ ppm or $\pm 40245$ Hz |

#### 3.3 Results

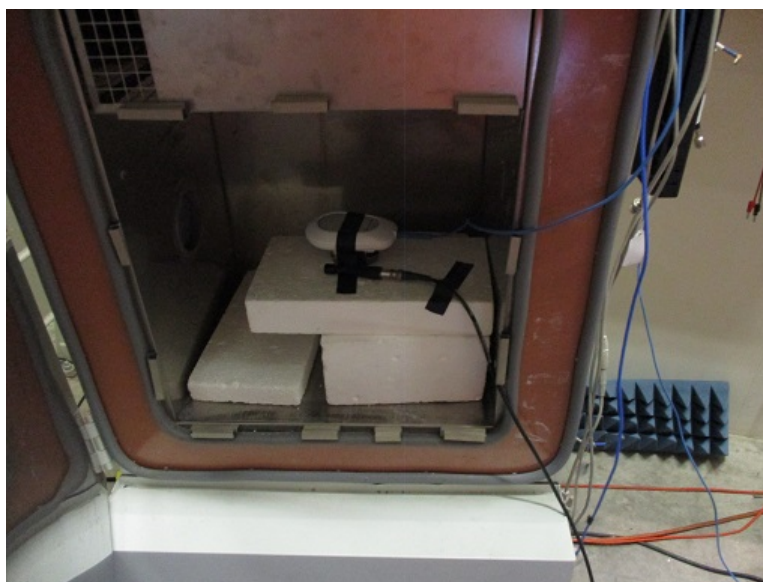
The EUT satisfied the requirement.

| 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<br>Field Strength Limit @ 3 meters | Limit<br>Restated for distance 10 meters |
|--|--|
| 25 $\mu$ W   | 74.7 dB $\mu$ V/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.

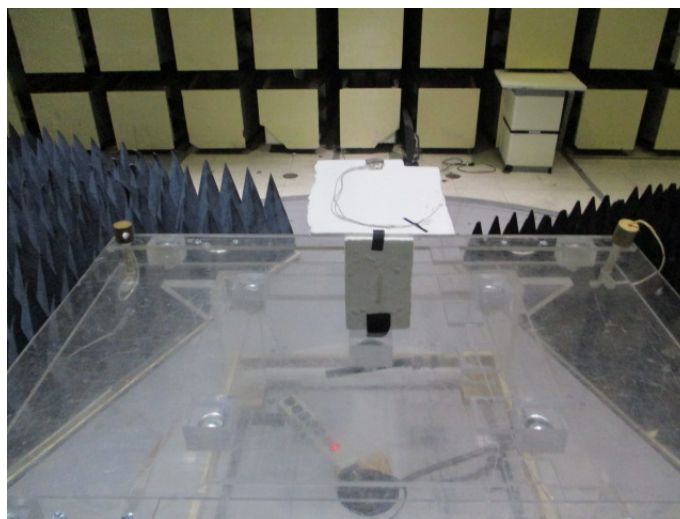
Note that EUT satisfied the requirement without a human torso simulator.

| Radiated Field Strength<br>Measured at 10 meters |                            |                        |                                    |
|--|----------------------------|------------------------|------------------------------------|
| Polarity &<br>Frequency<br>(MHz)                 | EUT Direction<br>(Degrees) | Antenna Height<br>(cm) | Quasi-peak Reading<br>(dB $\mu$ V) |
| 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                               |

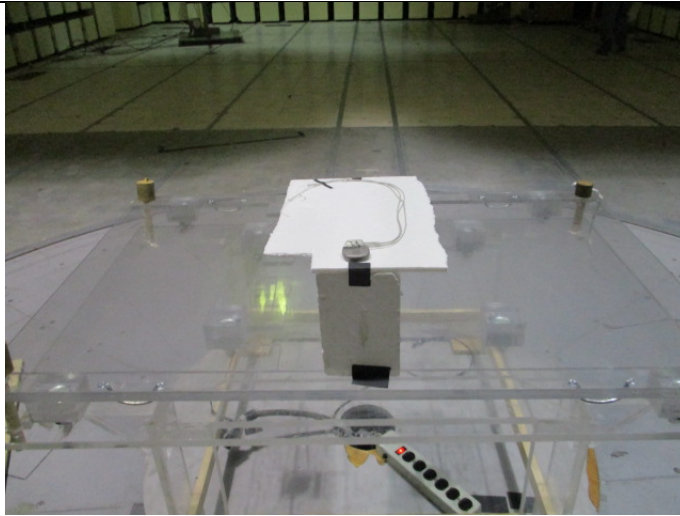
### 4.3.1 Equipment

| 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

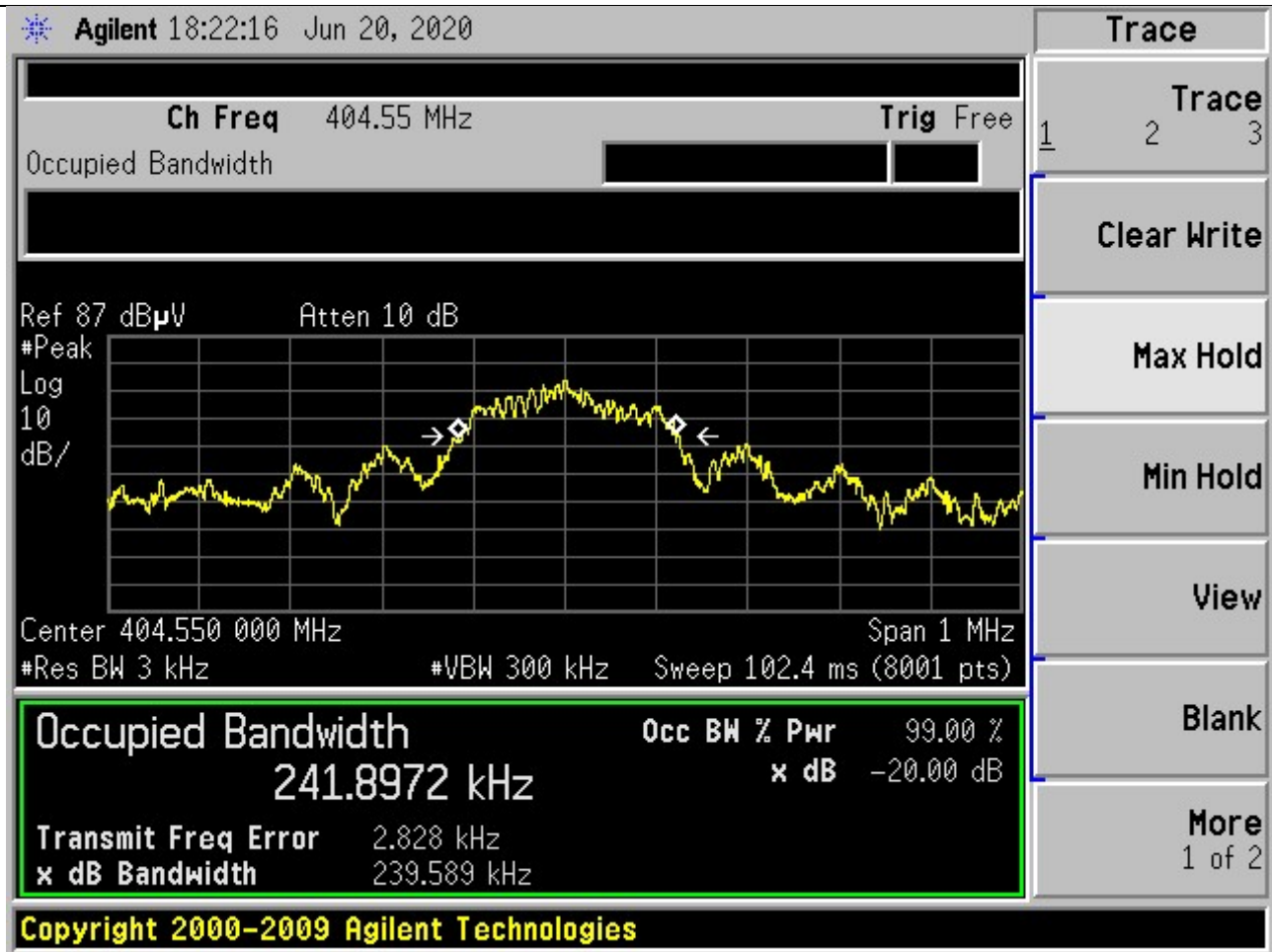
The EUT satisfied the requirement.

| 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 2<sup>nd</sup> harmonic failed but was remeasured later with the human torso simulator for a correction factor. At the 2<sup>nd</sup> harmonic frequency the correction factor measured as -19.18 dB.

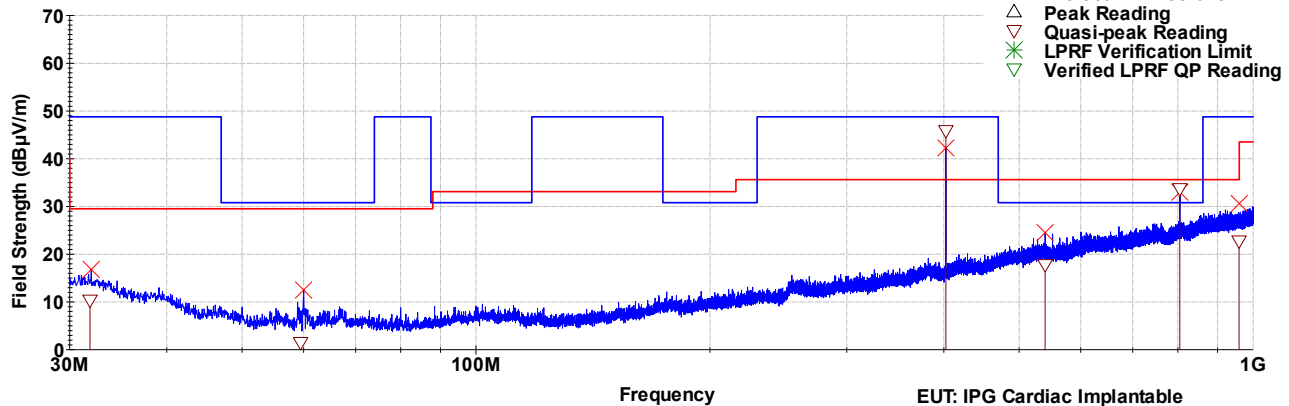
**Professional Testing, EMI, Inc****Radiated Emissions**

30MHz - 1GHz Vertical Polarity Measured Emissions

EUT Mode: Transmit 402.45

EUT Power: 3.7 Battery

Notes:



Operator: Bob Redoutey

Current Time -03:08:07 PM, Friday, June 26, 2020

EUT: IPG Cardiac Implantable

Project Number: 21613-15

Client: CCC del Uruguay S.A.

| 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       |

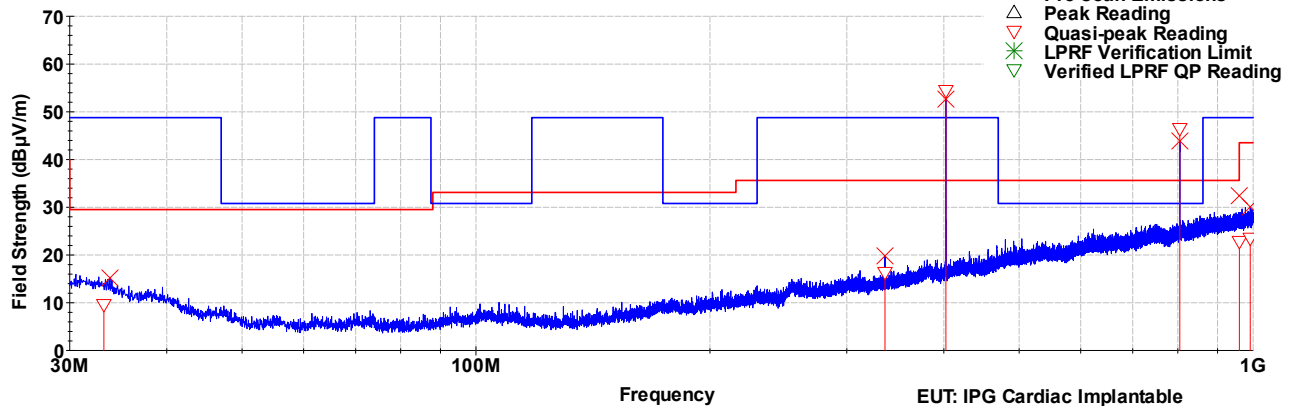
**Professional Testing, EMI, Inc****Radiated Emissions**

30MHz - 1GHz Horizontal Polarity Measured Emissions

EUT Mode: Transmit 402.45

EUT Power: 3.7 Battery

Notes:



Operator: Bob Redoutey

Current Time -03:08:07 PM, Friday, June 26, 2020

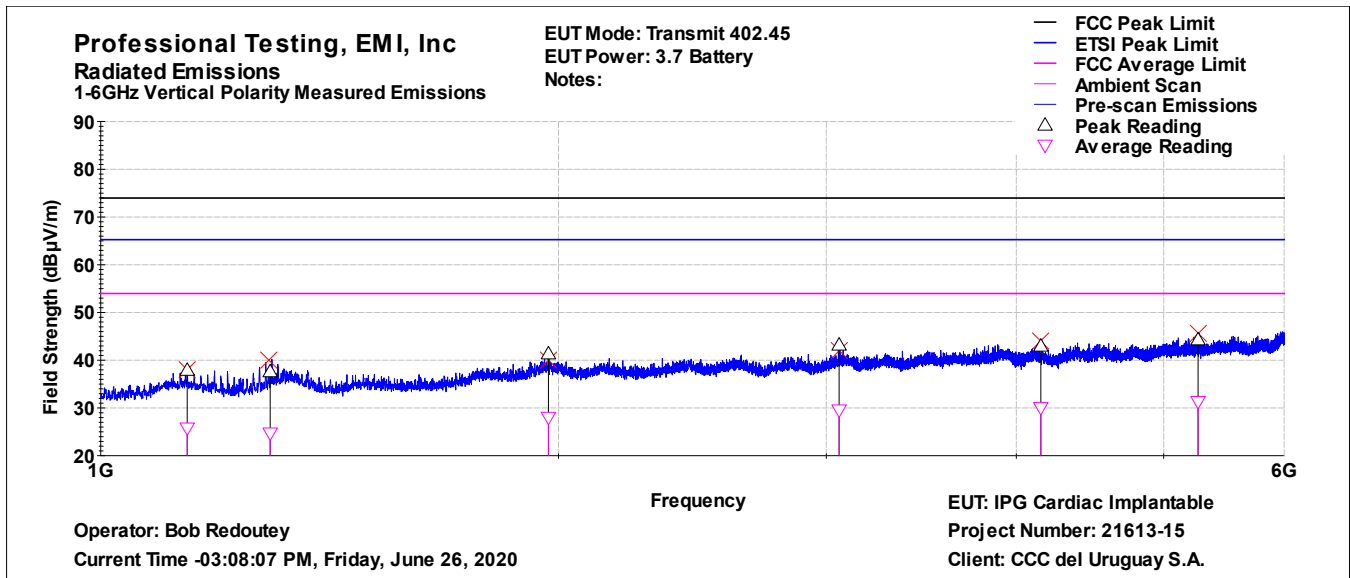
EUT: IPG Cardiac Implantable

Project Number: 21613-15

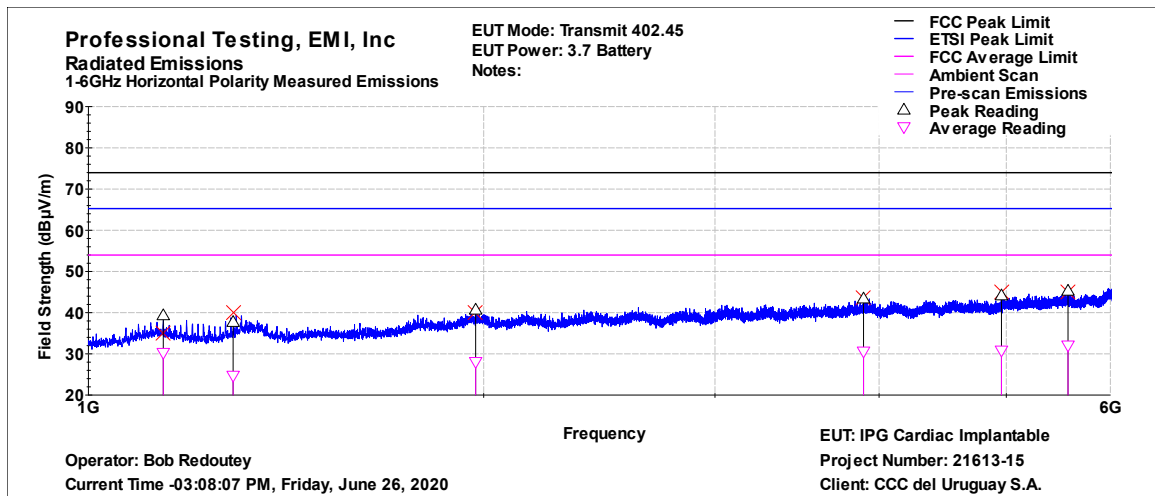
Client: CCC del Uruguay S.A.

| 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 2<sup>nd</sup> harmonic was remeasured later with the torso simulator for a correction factor. At the harmonic frequency the correction factor measured as -19.18 dB.

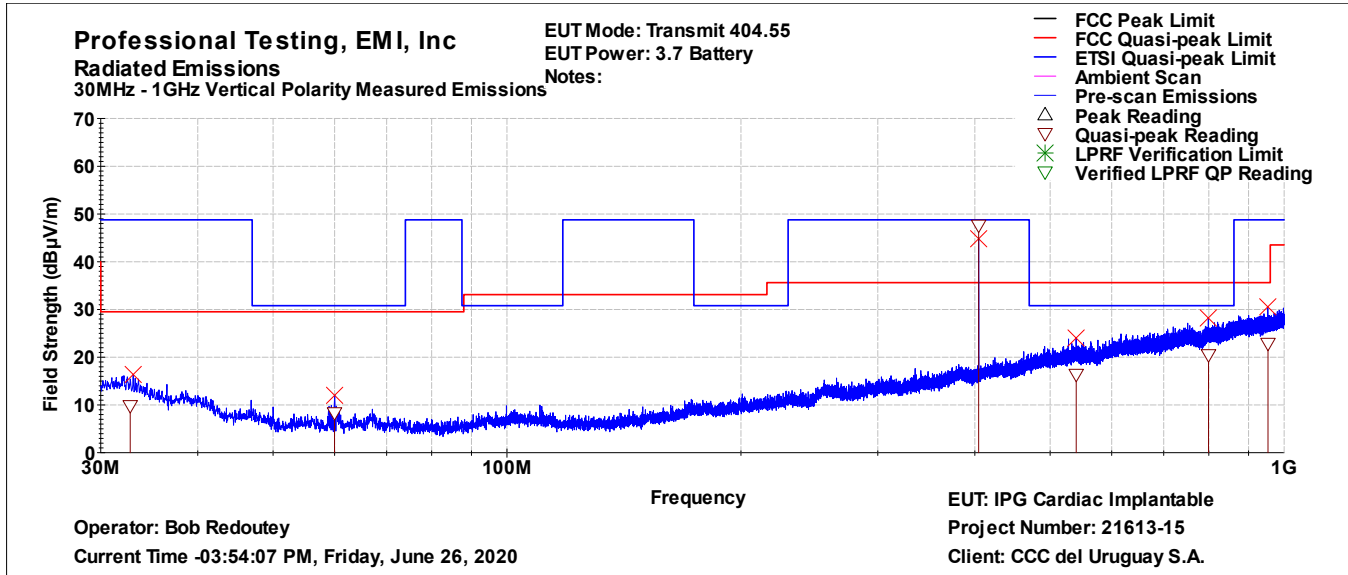


| Frequency | Azimuth | Height | Peak   | Peak Limit | Peak Margin | Peak Results | Avg    | Avg Limit | Avg Margin | Avg Results |
|-----------|---------|--------|--------|------------|-------------|--------------|--------|-----------|------------|-------------|
| (MHz)     | (deg)   | (cm)   | (dBuV) | (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        |

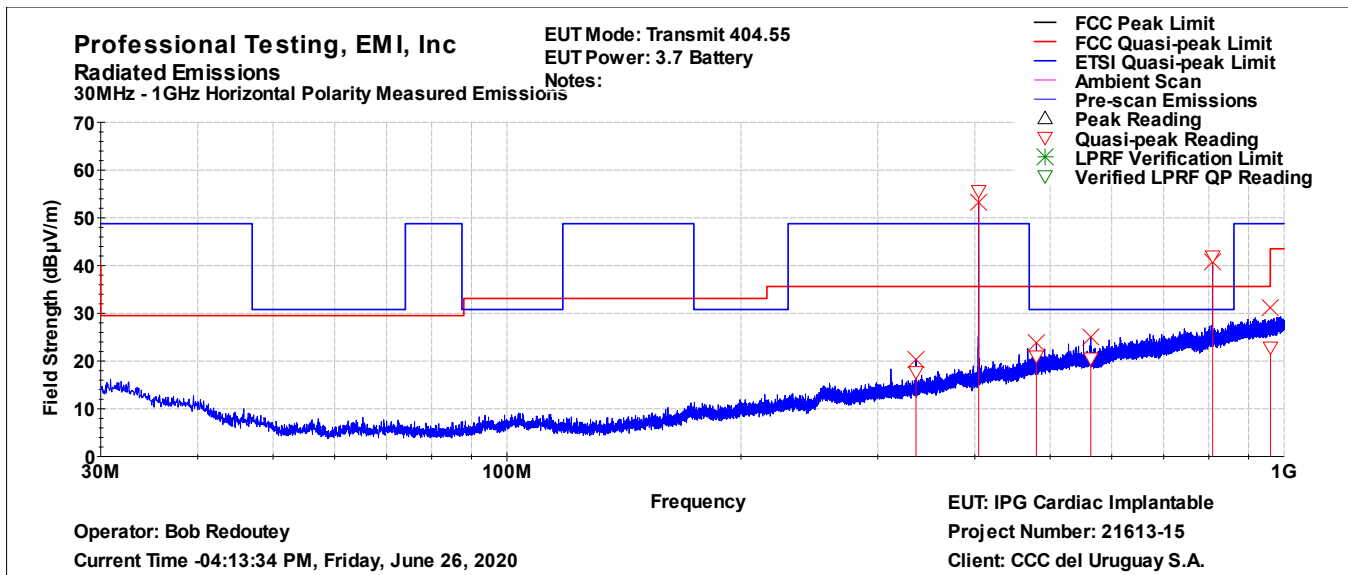


| Frequency | Azimuth | Height | Peak   | Peak Limit | Peak Margin | Peak Results | Avg    | Avg Limit | Avg Margin | Avg Results |
|-----------|---------|--------|--------|------------|-------------|--------------|--------|-----------|------------|-------------|
| (MHz)     | (deg)   | (cm)   | (dBuV) | (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       |

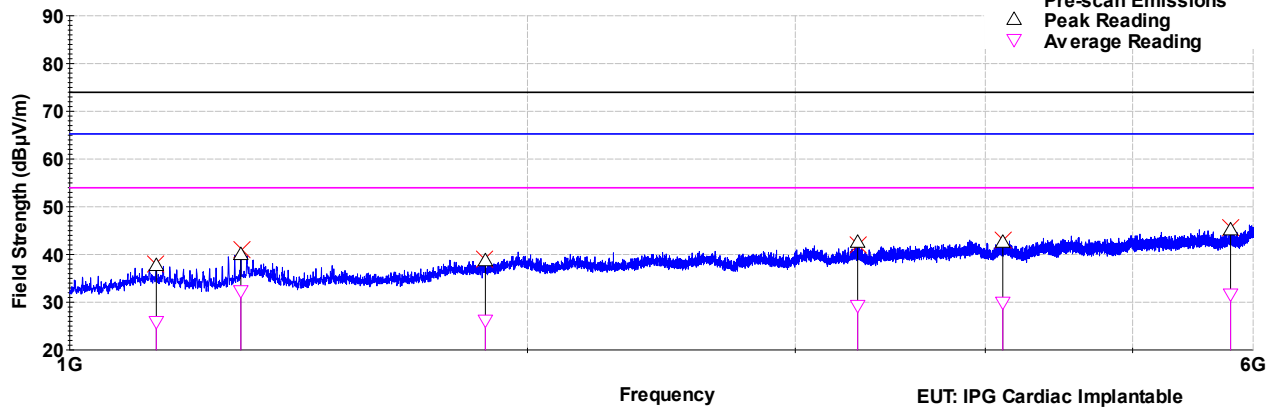
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\*The measurement was performed without using a human torso simulator. The 2<sup>nd</sup> harmonic was remeasured later with the torso simulator for a correction factor. At the harmonic frequency the correction factor measured as -19.18 dB.

**Professional Testing, EMI, Inc**  
**Radiated Emissions**  
 1-6GHz Vertical Polarity Measured Emissions

EUT Mode: Transmit 404.55  
 EUT Power: 3.7 Battery  
 Notes:

— FCC Peak Limit  
 — ETSI Peak Limit  
 — FCC Average Limit  
 — Ambient Scan  
 — Pre-scan Emissions  
 △ Peak Reading  
 ▽ Average Reading



Operator: Bob Redoutey  
 Current Time -04:44:37 PM, Friday, June 26, 2020

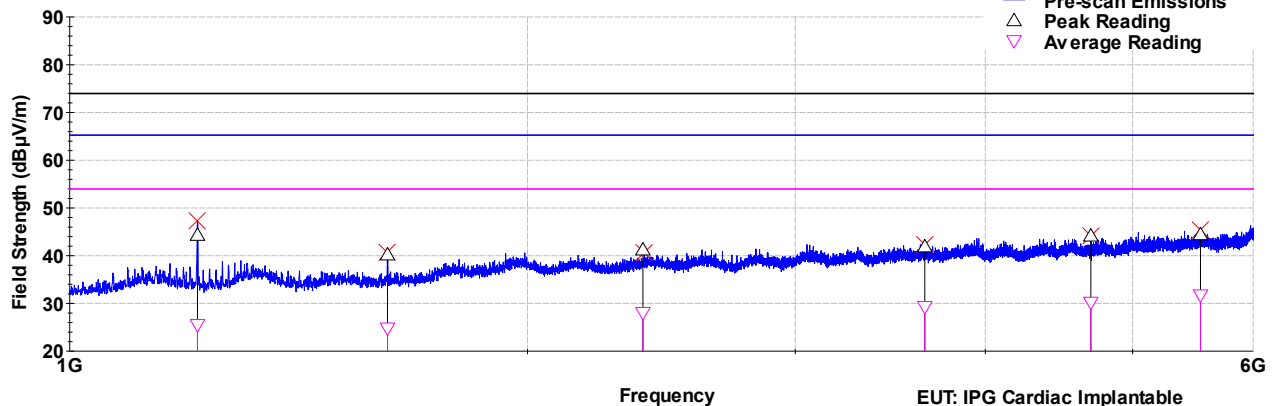
EUT: IPG Cardiac Implantable  
 Project Number: 21613-15  
 Client: CCC del Uruguay S.A.

| Frequency | Azimuth | Height | Peak   | Peak Limit | Peak Margin | Peak Results | Avg    | Avg Limit | Avg Margin | Avg Results |
|-----------|---------|--------|--------|------------|-------------|--------------|--------|-----------|------------|-------------|
| (MHz)     | (deg)   | (cm)   | (dBµV) | (dBµV)     | (dB)        | (P/F)        | (dBµV) | (dBµV)    | (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        |

**Professional Testing, EMI, Inc**  
**Radiated Emissions**  
 1-6GHz Horizontal Polarity Measured Emissions

EUT Mode: Transmit 404.55  
 EUT Power: 3.7 Battery  
 Notes:

— FCC Peak Limit  
 — ETSI Peak Limit  
 — FCC Average Limit  
 — Ambient Scan  
 — Pre-scan Emissions  
 △ Peak Reading  
 ▽ Average Reading



Operator: Bob Redoutey  
 Current Time -05:02:34 PM, Friday, June 26, 2020

EUT: IPG Cardiac Implantable  
 Project Number: 21613-15  
 Client: CCC del Uruguay S.A.

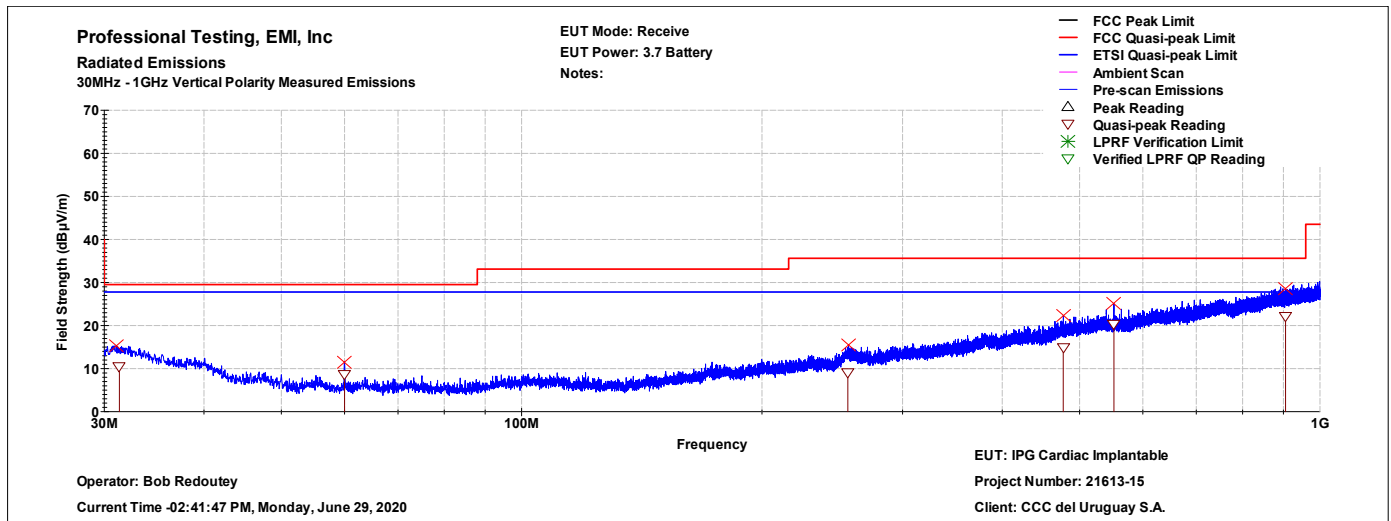
| Frequency | Azimuth | Height | Peak   | Peak Limit | Peak Margin | Peak Results | Avg    | Avg Limit | Avg Margin | Avg Results |
|-----------|---------|--------|--------|------------|-------------|--------------|--------|-----------|------------|-------------|
| (MHz)     | (deg)   | (cm)   | (dBµV) | (dBµV)     | (dB)        | (P/F)        | (dBµV) | (dBµV)    | (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        |



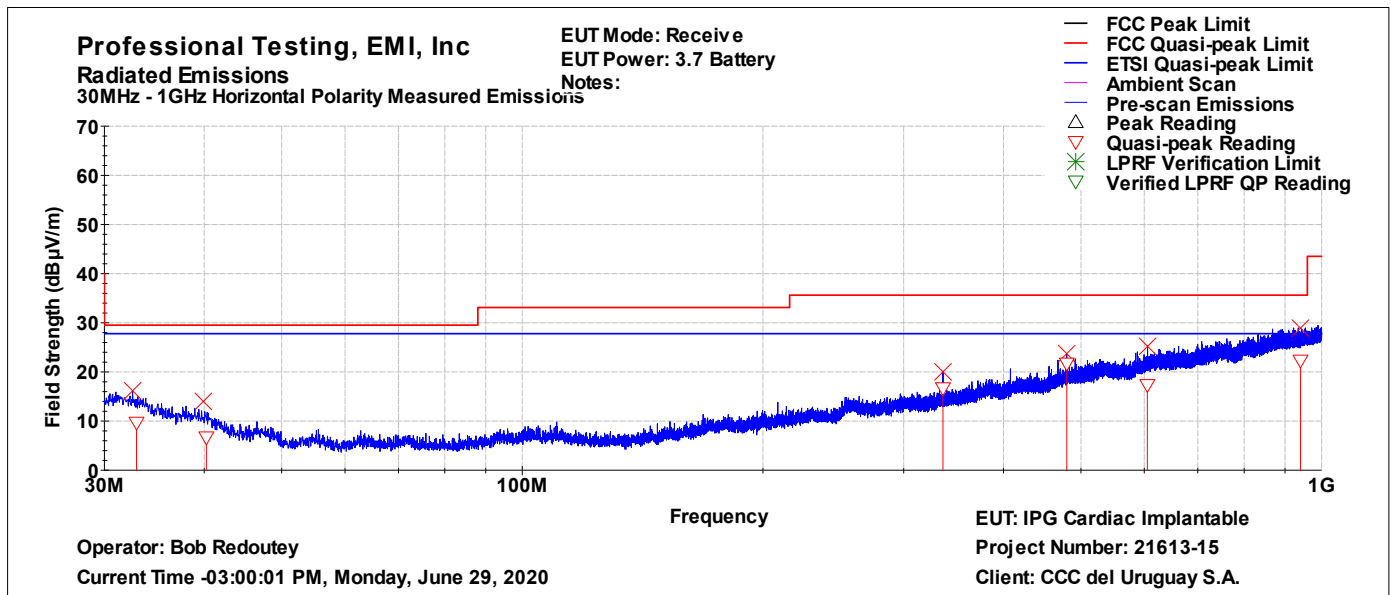
**6.3.2 Receive Mode**

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

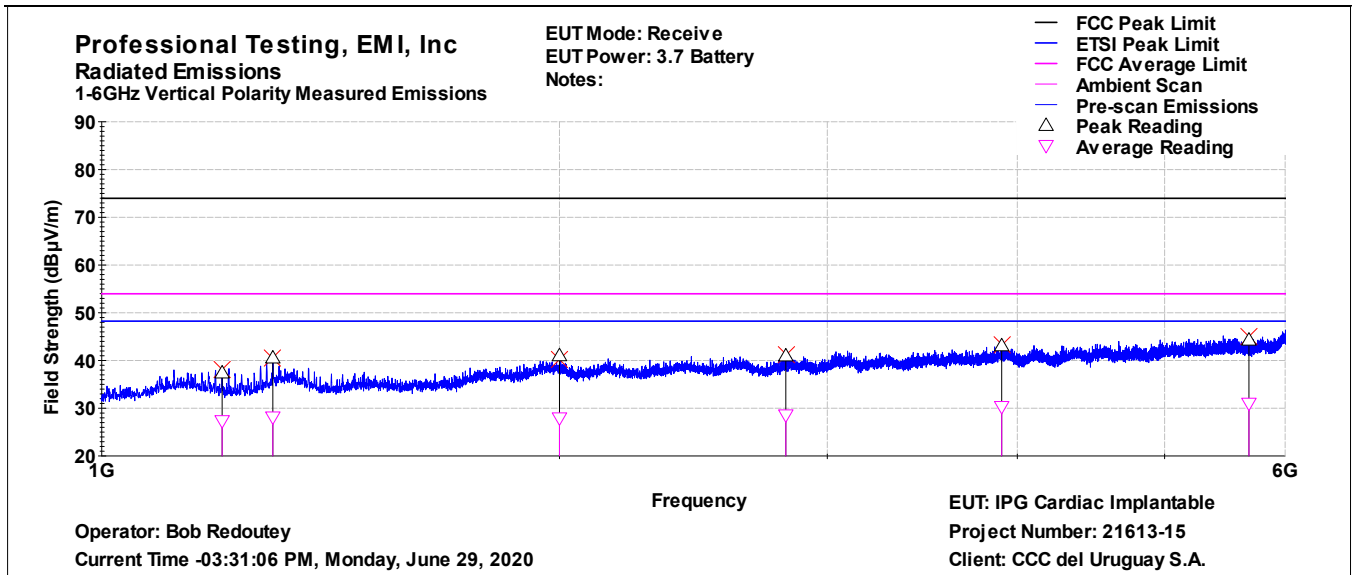
These measurements were performed without using a human torso simulator.



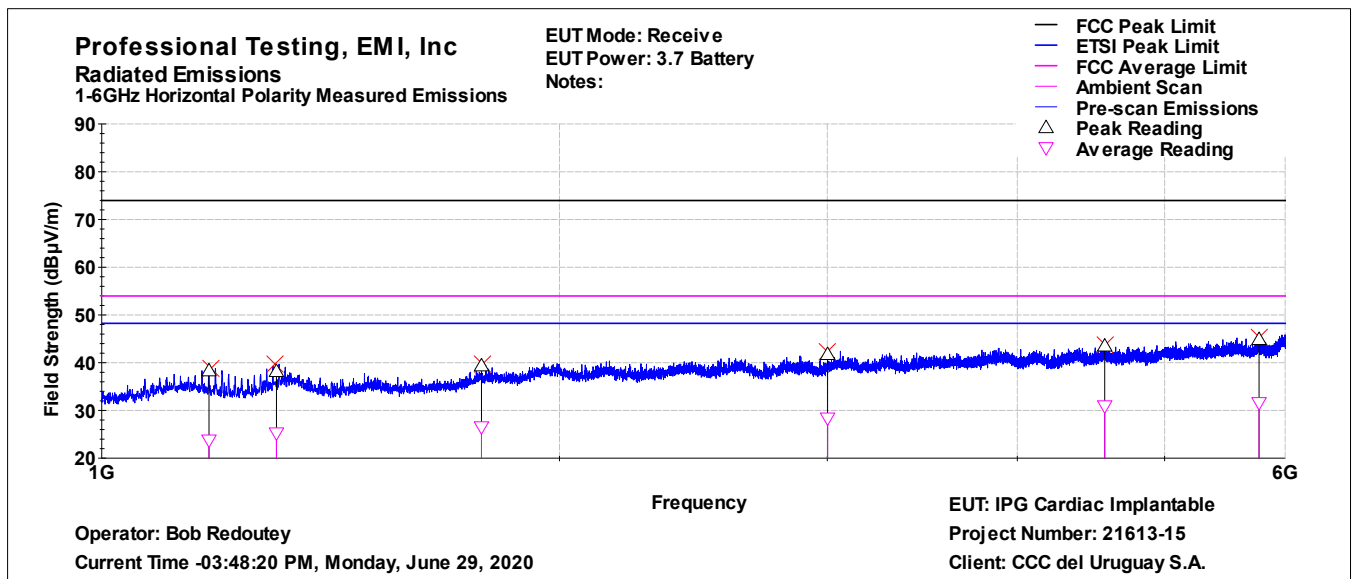
| Frequency (MHz) | EUT Direction (Degrees) | Antenna Height (cm) | Quasi-peak Reading (dB $\mu$ V) | Quasi-peak Limit (dB $\mu$ V) | Quasi-peak Margin (dB) | Quasi-peak Results |
|-----------------|-------------------------|---------------------|---------------------------------|-------------------------------|------------------------|--------------------|
| 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 (dB $\mu$ V) | Quasi-peak Limit (dB $\mu$ V) | 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        |

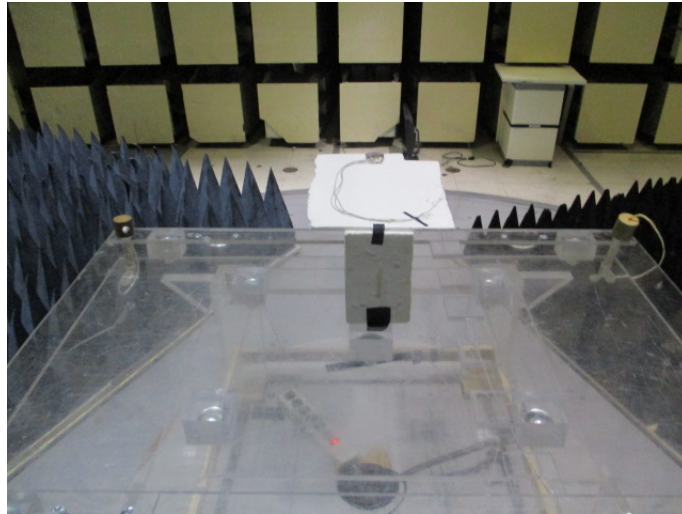


| Frequency | Azimuth | Height | Peak   | Peak Limit | Peak Margin | Peak Results | Avg    | Avg Limit | Avg Margin | Avg Results |
|-----------|---------|--------|--------|------------|-------------|--------------|--------|-----------|------------|-------------|
| (MHz)     | (deg)   | (cm)   | (dBuV) | (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        |

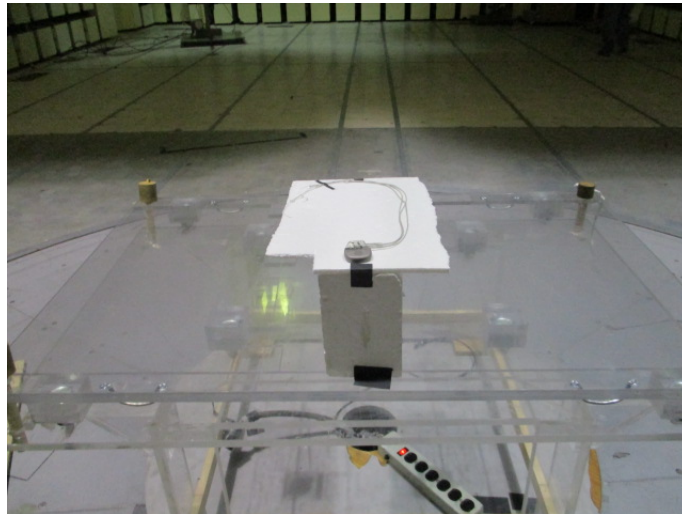
## 6.4 Equipment

| 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.  | $\leq 1.0 \text{ mW}^*$<br>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:<br>Paragraph 4.2.4. <i>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 <math>\leq 1.0 \text{ mW}</math>, 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.</i> |  |

### 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