

Test Report # 317245B

Equipment Under Test: Patient Assistant

Test Date(s): 11/8/17 – 11/13/17

Prepared for: ATTN: Ana Santos
 Medtronic Inc
 710 Medtronic Parkway NE
 Minneapolis MN 55432


Report Issued by: Shane Dock, EMC Engineer

Signature:



Date: 2/27/2018

Report Reviewed by: Adam Alger, Quality Systems Engineer

Signature: 

Date: 12/4/2017

Report Constructed by: Shane Dock, EMC Engineer

Signature:



Date: 1/9/2018

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| | | |
|-------------------------|--------------|-------------------------|
| Company: Medtronic Inc. | Page 1 of 15 | Name: Patient Assistant |
| Report: 317245B | | Model: PA97000 |
| Job: C-2837 | | Serial: See Section 2 |

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Laird Technologies Test Services in Review

The Laird Technologies, Inc. laboratory located at W66 N220 Commerce Court Cedarburg, Wisconsin, 53012 USA is recognized through the following organizations:



A2LA – American Association for Laboratory Accreditation

Accreditation based on ISO/IEC 17025: 2005 with Electrical (EMC) Scope

A2LA Certificate Number: 1255.01

Scope of accreditation includes all test methods listed herein, unless otherwise noted.



Federal Communications Commission (FCC) – USA

Accredited recognition of two 3 meter Semi-Anechoic Chambers

Accredited Test Firm Registration Number: 953492



Innovation, Science and Economic Development Canada

ISED Site listing of two 3 meter Semi-Anechoic Chambers based on RSS-GEN – Issue 4

File Number: IC 3088A-2

File Number: IC 3088A-3

| | | |
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1 TEST REPORT SUMMARY

During **11/8/17 – 11/13/17** the Equipment Under Test (EUT), **Patient Assistant**, as provided by **Medtronic Inc.** was tested to the following requirements:

| Requirement | Description | Specification | Method | Result |
|--|-----------------------------------|----------------|----------------|------------------------------------|
| FCC: 15.209 IC: ICES-003, RSS-210, RSS GEN | Radiated Emissions | 9 kHz - 30 MHz | ANSI C63.10 | Pass |
| FCC: 15.207 IC: RSS-GEN 8.8, RSS- 210 | AC Power Line Conducted Emissions | 0.150-30 MHz | ANSI C63.10 | N/A (Battery Powered EUT) |

Notice:

The results relate only to the item tested and described in this report. Any modifications made to the equipment under test after the specified test date(s) may invalidate the data herein.

If the resulting measurement margin is seen to be within the uncertainty value, as listed in this report, the possibility exists that this unit may not meet the required limit specification if subsequently tested.

2 CLIENT INFORMATION

| | |
|-----------------------|---|
| Company Name | Medtronic Inc |
| Contact Person | Keely Wagner (Plexus) |
| Address | Medtronic Inc 710 Medtronic Parkway NE Minneapolis MN 55432 |

2.1 Equipment Under Test (EUT) Information





The following information has been supplied by the client

| | |
|----------------------|--------------------------------------|
| Product Name | Patient Assistant |
| Model Number | PA97000 |
| Serial Number | MPB000031A |
| FCC / IC ID | FCC: LF5PA97000 IC: 3408D-PA97000 |

2.2 Product Description

The Activator uses a magnetic dual tone wake up signal which functions as a Tissue Conductance Communication (TCC) sting signal to initiate ICM BLE fast-advertising facilitating BLE connection. After BLE connection a symptom mark command is sent to the Device and the Device responds with an acknowledgement. A successful symptom mark is indicated by an audible tone and an illuminated green LED. The patient assistant activates the data management features in the LINQ II implanted device to initiate recording of cardiac event data in the implanted device memory.

Use of the Patient Assistant

| | | | |
|---|---|--|---|
|  |  |  |  |
| Press the symptom button | Blue light will start flashing | Patient holds PA over LINQ II device until the success tone and light occur. | Tone sounds, green light illuminates |

2.3 Modifications Incorporated for Compliance

None noted at time of test

| | | |
|-------------------------|--------------|-------------------------|
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2.4 Deviations and Exclusions from Test Specifications

None noted at time of test

2.5 Additional Information

EUT emissions peaked out in three orientations. Unit programmed via button presses.

Unit configured to run with a 3 VDC Bench Supply.

3 REFERENCES

| Publication | Edition | Date |
|----------------|---------|------|
| CFR 47 Part 15 | - | 2017 |
| ANSI C63.10 | - | 2013 |
| RSS-247 | 2 | 2017 |
| RSS GEN | 4 | 2014 |
| RSS-210 | 9 | 2016 |

4 UNCERTAINTY SUMMARY

Using the guidance of the following publications the calculated measurement uncertainty represents an expanded uncertainty expressed at approximately the 95 % confidence level, using a coverage factor of $k = 2$.

| References | Version / Date |
|-----------------|------------------|
| CISPR 16-4-1 | Ed. 2 (2009-02) |
| CISPR 16-4-2 | Ed. 2 (2011-06) |
| CISPR 32 | Ed. 1 (2012-01) |
| ANSI C63.23 | 2012 |
| A2LA P103 | February 4, 2016 |
| A2LA P103c | August 10, 2015 |
| ETSI TR 100-028 | V1.3.1 (2001-03) |

| Measurement Type | Configuration | Uncertainty \pm |
|-----------------------------|-------------------------------|-------------------|
| Radiated Emissions | Biconical Antenna | 5.0 dB |
| Radiated Emissions | Log Periodic Antenna | 5.3 dB |
| Radiated Emissions | Horn Antenna | 4.7 dB |
| AC Line Conducted Emissions | Artificial Mains Network | 3.4 dB |
| Telecom Conducted Emissions | Asymmetric Artificial Network | 4.9 dB |
| Disturbance Power Emissions | Absorbing Clamp | 4.1 dB |
| Radiated Immunity | 3 Volts/meter | 2.2 dB |
| Conducted Immunity | CDN/EM/BCI | 2.4/3.5/3.4 dB |
| EFT Burst/Surge | Peak pulse voltage | 164 volts |
| ESD Immunity | 15 kV level | 1377 Volts |

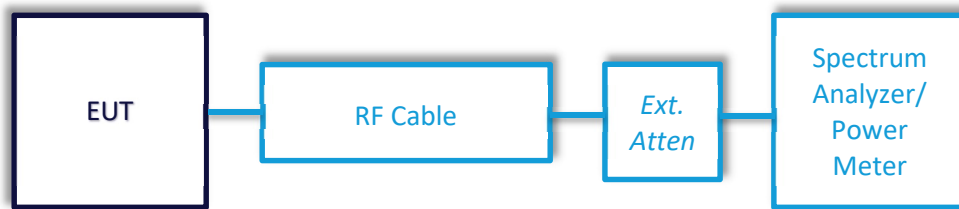
| Parameter | ETSI U.C. \pm | U.C. \pm |
|--|--------------------|-----------------------|
| Radio Frequency, from F0 | 1×10^{-7} | 0.55×10^{-7} |
| Occupied Channel Bandwidth | 5 % | 2 % |
| RF conducted Power (Power Meter) | 1.5 dB | 1.2 dB |
| RF conducted emissions (Spectrum Analyzer) | 3.0 dB | 1.7 dB |
| All emissions, radiated | 6.0 dB | 5.3 dB |
| Temperature | 1° C | 0.65° C |
| Humidity | 5 % | 2.9 % |
| Supply voltages | 3 % | 1 % |

5 TEST DATA

5.1 Antenna Port Conducted Emissions

| | |
|-----------------------------------|---|
| Description of Measurement | <p>The direct measurement of emissions at the antenna port of the EUT is achieved by use of a RF connection to a spectrum analyzer or power meter.</p> <p>The cable and attenuator factors are loaded into the analyzer or power meter allowing for direct measurement readings without the need for further corrections.</p> |
| Example Calculations | <p>Measurement (dBm) + Cable factor (dB) + External Attenuator (dB) = Corrected Reading (dBm)</p> <p>Margin (dB) = Limit (dBm) – Corrected Reading (dBm)</p> |

Block Diagram



5.1.1 Antenna Port Conducted Emissions – Bandwidth

| | |
|---------------------|--|
| Operator | Shane Dock |
| Test Date | 11/13/17 |
| Location | Conducted RF Measurement Area |
| Temp. / R.H. | 71/42% |
| Requirement | OBW: FCC: 2.1049 IC: RSS-GEN 6.6 |
| Method | ANSI C63.10 Section 6.9.2 |

Test Parameters

| | |
|------------------|---------|
| Frequency | 175 kHz |
|------------------|---------|

Tables

| Value | Tx Mode |
|-----------------|---------|
| 99% BW (kHz) | 84.1 |

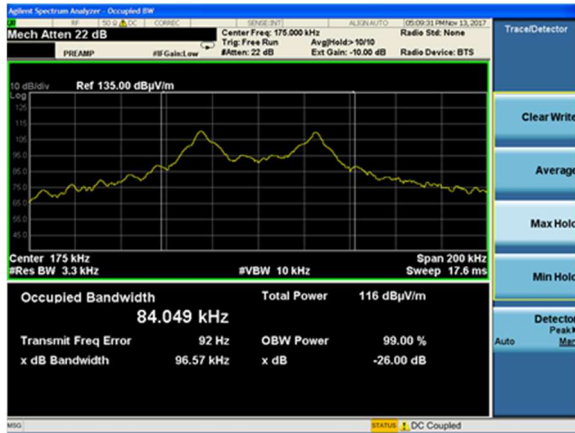
Instrumentation



Date : 3-Nov-2017 Test : LF Tx Job : C-2837
 PE : Shane Dock Customer : Plexus Quote : 317245

| No. | Asset | Description | Manufacturer | Model | Serial | Cal Date | Cal Due Date | Equipment Status |
|-----|-----------|-------------------------|--------------|--------|------------|-----------|--------------|--------------------|
| 1 | EE 960088 | Analyzer - EMI Receiver | Agilent | N9038A | MY51210138 | 3/2/2017 | 3/2/2018 | Active Calibration |
| 2 | AA 960006 | Active Loop Antenna | EMCO | 6502 | 9205-2753 | 8/28/2017 | 8/28/2019 | Active Calibration |

Plots



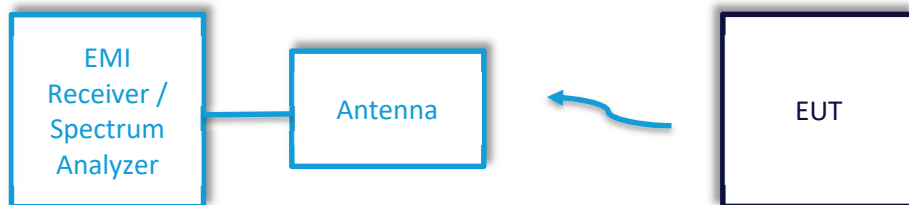
99% BW

| | | |
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5.2 Radiated Emissions

| | |
|--|---|
| <p>Description of Measurement</p> | <p>The frequency spectrum is investigated for intentional and / or unintentional signals emanating from the EUT by use of a standardized test site and measurement antenna.</p> <p>The antenna, cable, pre-amp, and other necessary measurement system correction factors are loaded onto the EMI receiver / spectrum analyzer when the measurements are performed allowing the data to be gathered and reported as corrected values.</p> <p>The maximum emissions from the EUT are determined by turn-table azimuth rotation (360°) and scanning of the measurement antenna. Maximized levels are noted at degree values of azimuth, measurement antenna height, and measurement antenna polarity.</p> |
| <p>Example Calculations</p> | <p>Measurement (dBμV) + Cable factor (dB) + Other (dB) + Antenna Factor (dB/m) = Corrected Reading (dBμV/m)</p> <p>Margin (dB) = Limit (dBμV/m) - Corrected Reading (dBμV/m)</p> <p>Example at 4000 MHz: Reading = 40 dBμV + 3.4 dB + 0.9 dB + 6.5 dB/m = 50.8 dBμV/m Average Limit = 20 log (500) = 54 dBμV/m Margin = 54 dBμV/m - 50.8 dBμV/m = 3.2 dB</p> |

Block Diagram



5.2.1 Radiated Emissions

| | |
|---------------------|--|
| Operator | Shane Dock |
| Test Date | 11/8/17 |
| Location | Chamber 5 |
| Temp. / R.H. | 70/40% |
| Requirement | FCC Part 15.209 RSS-GEN Section 7.1.2 |
| Method | ANSI C63.10 Sections 6.4 |

Limits:

| Frequency (kHz) | 150 | 200 |
|----------------------------------|------|------|
| Field Strength at 300 m (μV/m) | 16.0 | 12.0 |
| Field Strength at 300 m (dBμV/m) | 24.1 | 21.6 |

Test Parameters

| | |
|----------------------------|--|
| Frequency | 9 kHz - 30 MHz |
| Distance | 3 meters |
| EUT | Unit tested and measured in three orientations. |
| Notes | Unit tested and measured with the loop antenna in three polarizations |
| Example Calculation | Limit (dBμV/m) at 300m = $2400 / f(\text{kHz})$ $16 = 2400 / f(\text{kHz})$ Raw Data + Antenna Factor + Cable Factor = Reported Data $19.77 \text{ dB}\mu\text{V} + 12.50 \text{ dB/m} + 0.93 \text{ dB} = 38.80 \text{ dB}\mu\text{V/m}$ Corrected FS Value (150 kHz) = Measured Value – (40*log(limit distance/measurement distance) $-14.5 = 65.5 - 20 \log(300/3)$ Corrected FS Value (200 kHz) = Measured Value – (40*log([1/f(kHz)]/measurement distance)) – 20*log(limit distance/[1/f(kHz)]) $-15.8 = 62.2 - 40 \log(238.9/3) - 20 \log(300/238.9)$ |

Instrumentation



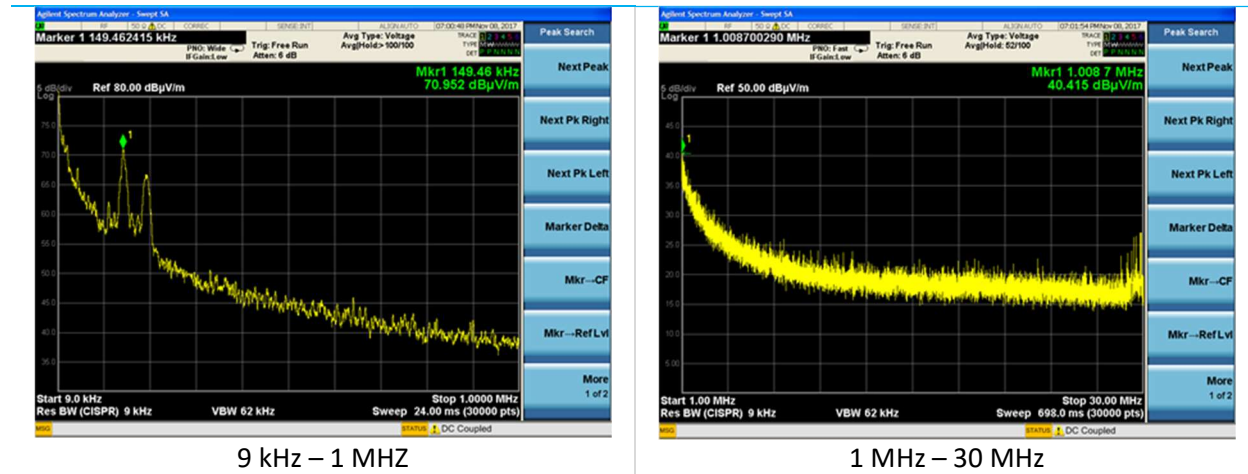
Date : 3-Nov-2017 Test : LF Tx Job : C-2837
 PE : Shane Dock Customer : Plexus Quote : 317245

| No. | Asset | Description | Manufacturer | Model | Serial | Cal Date | Cal Due Date | Equipment Status |
|-----|-----------|-------------------------|--------------|--------|-------------|-----------|--------------|--------------------|
| 1 | EE 960085 | Analyzer - EMI Receiver | Agilent | N9038A | MY 51210148 | 5/12/2017 | 5/12/2018 | Active Calibration |
| 2 | AA 960006 | Active Loop Antenna | EMCO | 6502 | 9205-2753 | 8/28/2017 | 8/28/2019 | Active Calibration |

Table

| Frequency (kHz) | Azimuth (degrees) | EUT Orientation | Antenna Polarity | Average Measurement at 3m (dBμV/m) | Corrected Average Measurement at 300m (dBμV/m) | Average Limit at 300m (dBμV/m) | Average Margin (dB) |
|-----------------|-------------------|-----------------|------------------|------------------------------------|--|--------------------------------|---------------------|
| 150 | 0 | V | V | 65.5 | -14.5 | 24.1 | 38.6 |
| 150 | 188.75 | H | V | 65.7 | -14.3 | 24.1 | 38.4 |
| 150 | 261.75 | F | V | 55.5 | -24.5 | 24.1 | 48.6 |
| 150 | 76.75 | V | S | 61.3 | -18.7 | 24.1 | 42.8 |
| 150 | 106.25 | H | S | 55.8 | -24.2 | 24.1 | 48.3 |
| 150 | 210.75 | V | F | 55.7 | -24.3 | 24.1 | 48.4 |
| 150 | 0 | H | F | 55.1 | -24.9 | 24.1 | 49.0 |
| 150 | 256.5 | F | F | 56.9 | -23.1 | 24.1 | 47.2 |
| 200 | 197.75 | V | V | 62.2 | -15.8 | 21.6 | 37.4 |
| 200 | 204.75 | H | V | 62.4 | -15.6 | 21.6 | 37.2 |
| 200 | 270.25 | F | V | 54.0 | -24.0 | 21.6 | 45.6 |
| 200 | 276.25 | V | S | 59.1 | -18.9 | 21.6 | 40.5 |
| 200 | 93.25 | H | S | 58.9 | -19.1 | 21.6 | 40.7 |
| 200 | 200 | V | F | 53.5 | -24.5 | 21.6 | 46.1 |
| 200 | 185.5 | H | F | 52.4 | -25.6 | 21.6 | 47.2 |
| 200 | 148.75 | F | F | 53.3 | -24.7 | 21.6 | 46.3 |

Plots (Worst Case Shown)



6 REVISION HISTORY

| Version | Date | Notes | Person |
|---------|----------|---------------|------------|
| V0 | 11/21/17 | Rough Draft | Shane Dock |
| V1 | 11/28/17 | Revised Draft | Shane Dock |
| V2 | 1/9/18 | Final Draft | Shane Dock |
| V3 | 2/27/18 | Updated Draft | Shane Dock |

END OF REPORT