

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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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

Company: Medtronic Inc.	Page 3 of 15	Name: Patient Assistant
Report: 317245B		Model: PA97000
Job: C-2837		Serial: See Section 2

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

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

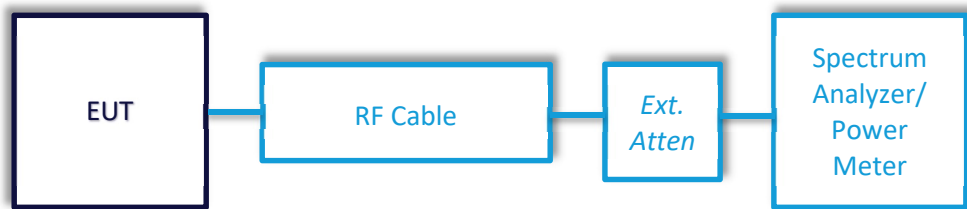
Parameter	ETSI U.C. $\pm$	U.C. $\pm$
Radio Frequency, from F0	1×10^{-7}	0.55×10^{-7}
Occupied Channel Bandwidth	5 %	2 %
RF conducted Power (Power Meter)	1.5 dB	1.2 dB
RF conducted emissions (Spectrum Analyzer)	3.0 dB	1.7 dB
All emissions, radiated	6.0 dB	5.3 dB
Temperature	1° C	0.65° C
Humidity	5 %	2.9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

5 TEST DATA

5.1 Antenna Port Conducted Emissions

Description of Measurement	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. The cable and attenuator factors are loaded into the analyzer or power meter allowing for direct measurement readings without the need for further corrections.
Example Calculations	Measurement (dBm) + Cable factor (dB) + External Attenuator (dB) = Corrected Reading (dBm) Margin (dB) = Limit (dBm) – Corrected Reading (dBm)

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
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Tables

Value	Tx Mode
99% BW (kHz)	84.1

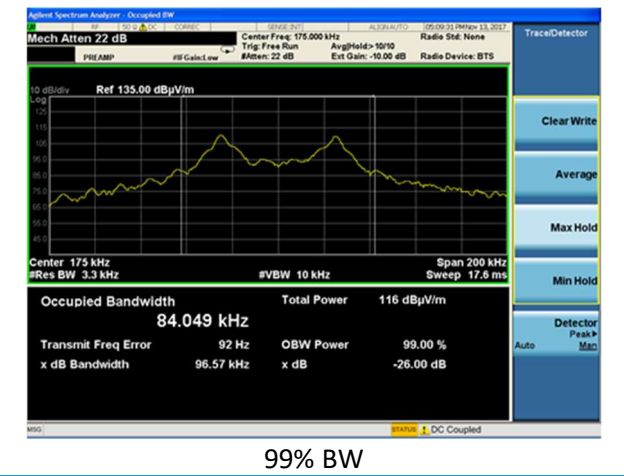
Instrumentation



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

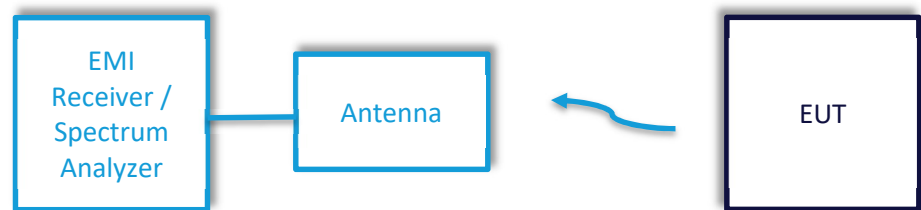


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Job: C-2837		Serial: See Section 2

5.2 Radiated Emissions

Description of Measurement	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. 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. 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.
Example Calculations	Measurement (dBμV) + Cable factor (dB) + Other (dB) + Antenna Factor (dB/m) = Corrected Reading (dBμV/m) Margin (dB) = Limit (dBμV/m) - Corrected Reading (dBμV/m) 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

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 $19.77 \text{ dB}\mu\text{V} + 12.50 \text{ dB/m} + 0.93 \text{ dB} = 33.20 \text{ dB}\mu\text{V/m}$ Corrected FS Value (150 kHz) = Measured Value – $(40 \cdot \log(\text{limit distance}/\text{measurement distance}))$ $-14.5 = 65.5 - 20 \log(300/3)$ Corrected FS Value (200 kHz) = Measured Value – $(40 \cdot \log([1/f(\text{kHz})]/\text{measurement distance})) - 20 \cdot \log(\text{limit distance}/[1/f(\text{kHz})])$ $-15.8 = 62.2 - 40 \log(238.9/3) - 20 \log(300/238.9)$

Instrumentation



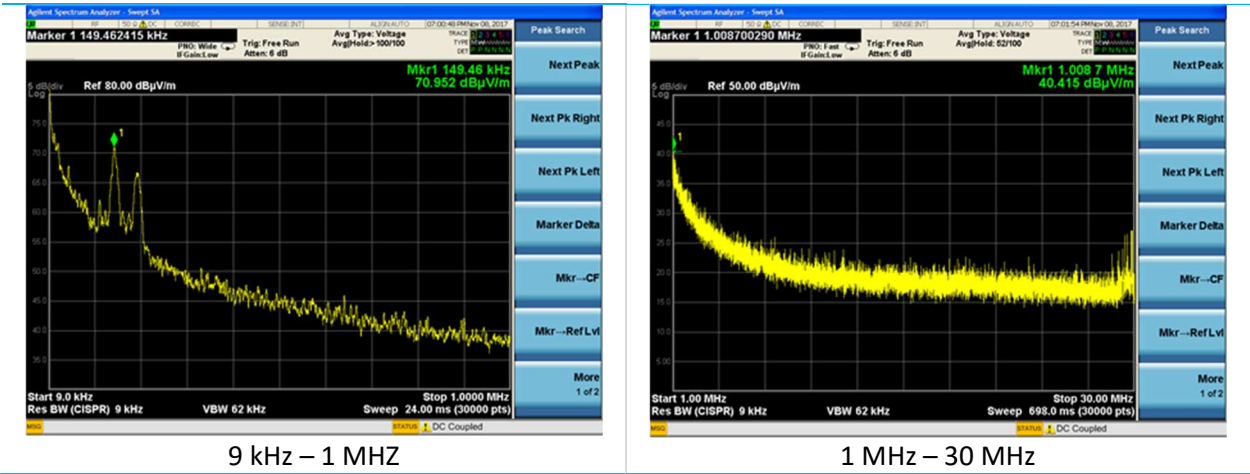
Date : 3-Nov-2017 Test : LF Tx Job : C-2837
 PE : Shane Dock Customer : Plexus Quote : 317245

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