Test Report # 317245C

Equipment Under Test:	Patient Assistant
Test Date(s):	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: 3/15/2018

Report Reviewed by: Adam Alger, Quality Systems Engineer

Signature:

Date: 1/8/2018

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:

TESTING CERT #1255.01

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

Government of Canada

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

1 TEST REPORT SUMMARY

During **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 Part 1.1307, 2.1091, 2.1093	RF Exposure and equipment authorization requirements	Reported	FCC KDB 447498	Reported
ISED Canada RSS-102	Radiofrequency Radiation Exposure Evaluation: Portable	Reported	RSS-102 Section 2.5.2	Reported

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

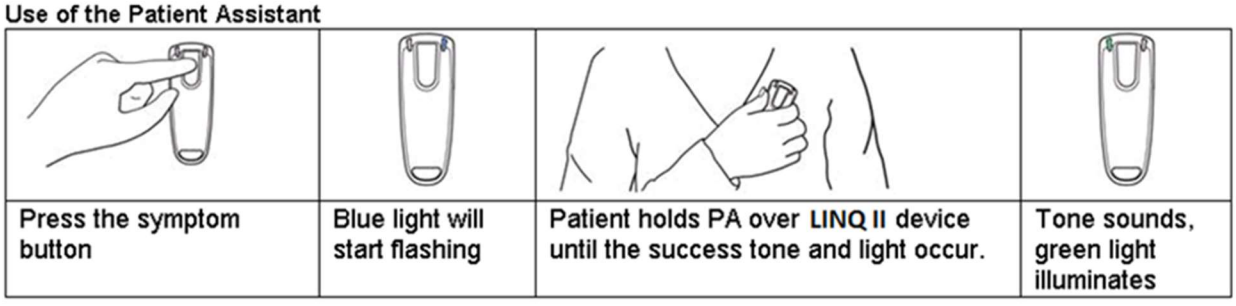
The following information has been supplied by the client

Product Name	Patient Assistant
Model Number	PA97000
Serial Number	Conducted RF Testing – MPB000027A Radiated Inductive Tx – MPB000031A
FCC/IC Number	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



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 all orientations. Unit programmed via button presses, which was configured to cycle through channels.

2.6 Channel Plan

EUT emissions tested for Low Mid and High Channel.

Low – 2402 MHz

Mid – 2442 MHz

High – 2480 MHz

3 REFERENCES

Publication	Edition	Date
CFR 47 Part 15	-	2017
ANSI C63.10	-	2013
RSS-247	2	2017
RSS GEN	4	2014
RSS-102	5	2015
CFR 47 Part 1 and 2	-	2017
FCC KDB 447498	6	2015

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 ±
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. ±	U.C. ±
Radio Frequency, from F0	$1x10^{-7}$	$0.55x10^{-7}$
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 – 2.4 GHZ BLE

Operator	Shane Dock
Test Date	11/13/17
Location	Conducted RF Measurement Area
Temp. / R.H.	71/42%
Requirement	15.247 (b) (3)
Method	FCC KDB 558074 D01 DTS Meas Guidance V04, section 9.1.1

Limits:

Maximum Conducted Output Power (watts)	Maximum Conducted Output Power (dBm)
1	30

Test Parameters

Frequency	2402, 2440, 2480 MHz
RBW	3 MHz

Table

Channel	Low	Mid	High
Pout Conducted (dBm)	-3.391	-3.242	-3.509

6 TEST DATA – INDUCTIVE TX RADIO

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(kHz) 16 = 2400/ f(kHz) Raw Data + Antenna Factor + Cable Factor = Reported Data 19.77 dBµV + 12.50 dB/m + 0.93 dB = 38.80 dBµV/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)

Table

Frequency (kHz)	Azimuth (degrees)	EUT Orientation	Antenna Polarity	Average Measure-ment at 3m (dBµV/m)	Corrected Average Measure-ment 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

7 EXCLUSION CALCULATION

7.1 FCC - 2.4 GHz BLE

Frequency = 2442 MHz
Output Power = -3.242 dBm + 3.242 dB (Tune-up Tolerance) = 0.000 dBm
=1.000 mW

[Max power (mw)/ min. separation distance] * sqrt(f(GHz)) = 1/5 * sqrt(2.442) = 0.3125

Since 0.3125 < 3.0 and 7.5, the radio is excluded from SAR testing.

7.2 FCC – Inductive Tx Radio

Worst Case Frequency = 150 kHz
Field Strength = 65.7 dBuV/m
EIRP (dBm)= Field Strength (dBuV/m) – 95.2 dB = -29.5 dBm
Tune-up tolerance = 2 dB, so EIRP (dBm) = -27.5 dBm
= 0.001778 mW.

Per KDB OET 447498, Section 4.3.1 section C:

½ * [1 + log (100/ f(MHz))] * [(power(mw)* sqrt(f(GHz))/test separation distance) + (test separation – 50 mm) * f(MHz)/150] <= 3.0

½ * [1 + log (100/.15)] * [(.001778* sqrt(.000150)/50 mm) + (5 mm – 50 mm) * 100/150] <= 3.0

Since -57.36 is less than 3.0, the radio is excluded from SAR testing.

7.3 FCC – Simultaneous Tx

Per KDB 447498 Section 4.3.2:
Power Density (Total) = Power Density (BLE) + Power Density (Ind.)
= [Output Power(BLE, mW)/ test separation distance]*(sqrt(2.442)/7.5) + [Output Power(Ind., mW)/ test separation distance]*(sqrt(.000150)/7.5)
= [1/ 5]*(sqrt(2.442)/7.5) + [0.001778/ 5]*(sqrt(.000150)/7.5) = 0.0416 + 5.81 x 10^-7 = .0416 W/kg

Since 0.0416 W/kg is less than 0.4 W/kg, the unit is excluded from SAR testing.

7.4 Industry Canada – 2.4 GHz BLE

Exemption limit at 2442 MHz (interpolated) = 4.04 mW.

Since 1 mW < 4.04 mW, the radio is therefore exempt from routine evaluation at < 5 mm.

7.5 Industry Canada – Inductive Tx Radio

Exemption limit at 300 MHz or less = 71 mW.

Since 0.001778 mW < 71 mW, the radio is therefore exempt from routine evaluation at < 5 mm.

8 REVISION HISTORY

Version	Date	Notes	Person
V0	1/3/18	First Draft	Shane Dock
V1	1/4/18	Revised Draft	Shane Dock
V2	1/9/18	Final Draft	Shane Dock
V3	2/27/18	Updated Draft	Shane Dock
V4	3/14/18	More Changes	Shane Dock

END OF REPORT