

LS RESEARCH LLC

Wireless Product Development



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TEST REPORT # 311164-1 TX LSR Job #: C-1264

<u>Compliance Testing of</u>: Medtronic Neuromodulation Interstim External NeuroStimulator (ENS)

<u>Test Date(s)</u>: October 20th to November 9th 2011

Prepared For: Medtronic 7000 Central Avenue NE MS RCC270 Minneapolis, MN 55432

> In accordance with: Federal Communications Commission (FCC) Part 15, Subpart C, Section 15.247 Industry Canada (IC) RSS 210 Annex 8 Frequency Hopping Spread Spectrum (FHSS) Operating in the Frequency Band 2400 MHz – 2483.5 MHz

This Test Report is issued under the Authority of: Khairul Aidi Zainal, Senior EMC Engineer.			
Signature: Augusta Date: 12/12/2011			
Test Report Reviewed by:	Project Engineer:		
Ryan Urness, EMC-Lab Manager	Khairul Aidi Zainal, Senior EMC Engineer.		
Signature: Date: 12/5/2011	Signature: Auf Date: 12/12/2011		

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EXHIBIT 1. INTRODUCTION

<u> 1.1 - Scope</u>

References:	FCC Part 15, Subpart C, Section 15.247 RSS GEN issue 3 and RSS 210 issue 8 Annex 8
Title:	 FCC : Telecommunication – Code of Federal Regulations, CFR 47, Part 15. IC : Low-power License-exempt Radio-communication Devices (All Frequency Bands): Category I Equipment
Purpose of Test:	To gain FCC and IC Certification Authorization for Low- Power License-Exempt Transmitters.
Test Procedures:	Both conducted and radiated emissions measurements were conducted in accordance with American National Standards Institute ANSI C63.4 – 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.
Environmental Classification:	Commercial, Industrial or Business Residential

<u> 1.2 – Normative References</u>

Publication	Year	Title
47 CFR, Parts 0-15 (FCC)	2010-10	Code of Federal Regulations - Telecommunications
RSS 210 Issue 8 Annex 8	2010-12	Low-power License-exempt Radio- communication Devices (All Frequency Bands): Category I Equipment
ANSI C63.4	2003	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.
ANSI 63.10	10-2009	American National Standard For Testing Unlicensed Wireless devices.
FCC ET Docket No. 99-231	2002	Amendment to FCC Part 15 of the Commission's Rules Regarding Spread Spectrum Devices.
FCC DA 00-705	2000	Filing and Measurement Guidelines for Frequency Hopping Spread Spectrum Systems.

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<u>1.3 - LS Research, LLC Test Facility</u>

LS Research, LLC is accredited by A2LA (American Association for Laboratory Accreditation) as conforming to ISO/IEC 17025, 2005 "General Requirements for the Competence of Calibration and Testing Laboratories".

LS Research, LLC's scope of accreditation includes all test methods listed herein, unless otherwise noted. Accreditation status can be verified at A2LA's web site: <u>www.a2la.net</u>.

<u>1.4 – Location of Testing</u>

All testing was performed at the following location utilizing the facilities listed below, unless otherwise noted.

LS Research, LLC W66 N220 Commerce Court Cedarburg, Wisconsin, 53012 USA,

List of Facilities Located at LS Research, LLC:

Compact Chamber Semi-Anechoic Chamber Open Area Test Site (OATS)

<u> 1.5 – Test Equipment Utilized</u>

A complete list of equipment utilized in testing is provided in Appendix A of this test report. Calibration dates are indicated in Appendix A. All test equipment is calibrated by a calibration laboratory accredited to the requirements of ISO/IEC 17025, and traceable to the SI standard.

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EXHIBIT 2. PERFORMANCE ASSESSMENT

2.1 - Client Information

Manufacturer Name:	Medtronic
Address:	7000 Central Avenue NE MS RCC270, Minneapolis, MN
	55432
Contact Name:	Mukul Jain (mukul.jain@medtronic.com)

2.2 - Equipment Under Test (EUT) Information

The following information has been supplied by the applicant.

Product Name:	Medtronic External NeuroStimulator (ENS)	
Model Number:	3531	
Serial Number:	NLM001545N, NLM001547N, NLM001943N,	
	NLM001937N	

2.3 - Associated Antenna Description

The antenna used in the ENS is a PULSE Bluetooth/WLAN/WiFi Ceramic Chip Antenna part number W3008 with a peak gain of 2.2 dBi.

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2.4 - EUT'S Technical Specifications

EUT Frequency Range (in MHz)	2402 MHz to 2480MHz
RF Power in Watts	Conducted Measurement
Minimum:	0.00248 Watts (BT EDR2)
Maximum:	0.00409 Watts (BT GFSK)
Occupied Bandwidth (99% and 20dB)	20dB: 1408 KHz
	99%: 1205 KHz
Type of Modulation	GFSK, EDR2 and EDR3
Emission Designator	1M21FXD
Transmitter Spurious (worst case radiated) at	43.76 dBµV/m at 12010MHz
3 meters	
Stepped (Y/N)	Ν
Step Value:	N/A
Frequency Tolerance %, Hz, ppm	Better than 100 ppm
Antenna Information	
Detachable/non-detachable	Non-detacheable
Туре	Ceramic Chip Antenna
Gain	2.2 dBi
EUT will be operated under FCC Rule Part(s)	Title 47 part 15.247
EUT will be operated under RSS Rule Part(s)	RSS 210
Modular Filing	🗌 Yes 🛛 No
Portable or Mobile?	Portable

RF Technical Information:

Type of		SAR Evaluation: Device Used in the Vicinity of the Human Head
Evaluation		SAR Evaluation: Body-worn Device
(check one)	Х	RF Evaluation

If <u>RF Evaluation</u> checked above, test engineer to complete the following:

Evaluated against exposure limits: 🛛 General Public	Use Controlled Use
Duty Cycle used in evaluation: 100 %	
Standard used for evaluation: OET 65	
Measurement Distance: 20 cm	
RF Value: 0.01345 V/m A/m W/m ²	
└─ Measured ☐ Computed	

With a maximum EIRP of:

EIRP = 6.1dBm + 2.2dBi = 8.3dBm = <u>6.76mW</u>

The EUT is exempt from SAR testing.

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2.5 - Product Description

Medtronic Interstim System is a medical electronic system for the treatment of urinary retention and the symptoms of overactive bladder. Interstim therapy uses a small electronic device to send mild electrical pulses through an implanted electrode lead to a nerve located in the lower back (just above the tailbone). The electrical stimulation may eliminate or reduce certain bladder control symptoms in some people.

The device that generates the electrical pulses is surgically implanted in the patient for long-term treatment. This device is called an Internal NeuroStimulator (INS). Prior to implanting the INS in a patient, doctors test the effectiveness of the therapy using an External NeuroStimulator (ENS), also called "Test Stimulator". The ENS is carried outside the body, and is connected to electrode leads (through adapter cables) which are temporarily inserted in the patient's back.

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EXHIBIT 3. EUT OPERATING CONDITIONS & CONFIGURATIONS DURING TESTS

3.1 - Climate Test Conditions

Temperature:	70-71° F
Humidity:	34-38%
Pressure:	729-742mmHg

3.2 - Applicability & Summary Of EMC Emission Test Results

FCC and IC Paragraph	Test Requirements	Compliance (Yes/No)
FCC : 15.207 IC : RSS GEN sect. 7.2.2	Power Line Conducted Emissions Measurements	N/A
FCC : 15.247 (a)(1) IC : RSS 210 A8.1 (a)	20 dB Bandwidth	Yes
FCC : 15.247(b) & 1.1310 IC : RSS 210 A8.4	Maximum Output Power	Yes
FCC : 15.247(i), 1.1307, 1.1310, 2.1091 & 2.1093 IC : RSS 102	RF Exposure Limit	Yes
FCC :15.247(d) IC : RSS 210 A8.5	RF Conducted Spurious Emissions at the Transmitter Antenna Terminal	Yes
FCC:15.247 (a)(1)(iii) IC: RSS 210 (b)	Carrier Frequency Separation	Yes
FCC:15.247 (a)(1)(i),(ii),(iii) IC: RSS 210 (c),(d),(e)	Number of hopping channels	Yes
FCC:15.247 (a)(1)(i),(ii),(iii) IC: RSS 210 (c),(d),(e)	Time of occupancy (Dwell Time)	Yes
FCC : 15.247(b) IC : RSS 210 A8.2(b), section 2.2, 2.6 and 2.7	Transmitter Radiated Emissions in the restricted bands	Yes
The digital circuit portion of the EUT has been tested and verified to comply with FCC Part 15, Subpart B, Class B Digital Devices (RSS GEN and RSS 210 of IC) and the associated Radio Receiver has also been tested and found to comply with Part 15, Subpart B – Radio Receivers (RSS GEN and RSS 210 of IC). The Receiver Test Report is available upon request.		

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<u>3.3 - Modifications Incorporated In The EUT For Compliance Purposes</u>

🛛 None

Yes (explain below)

3.4 - Deviations & Exclusions From Test Specifications

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EXHIBIT 4. DECLARATION OF CONFORMITY

The EUT was found to MEET the requirements as described within the specification of FCC Title 47, CFR Part 15.247, and Industry Canada RSS-210, Issue 8 (2010), Annex 8 (section 8.1).

Note: If some emissions are seen to be within 3 dB of their respective limits; as these levels are within the tolerances of the test equipment and site employed, there is a possibility that this unit, or a similar unit selected out of production may not meet the required limit specification if tested by another agency.

LS Research, LLC certifies that the data contained herein was taken under conditions that meet or exceed the requirements of the test specifications. The results in this Test Report apply only to the item(s) tested on the above-specified dates. Any modifications made to the EUT subsequent to the indicated test date(s) will invalidate the data herein, and void this certification.

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EXHIBIT 5. RADIATED EMISSIONS TEST

<u>5.1 - Test Setup</u>

The test setup was assembled in accordance with Title 47, CFR FCC Part 15, RSS GEN and ANSI C63.4-2003. The EUT was placed on an 80cm high non-conductive pedestal, centered on a flush mounted 2-meter diameter turntable inside a 3 meter Semi-Anechoic, FCC listed Chamber. The EUT was operated in continuous transmit modulated mode for final testing using power as provided by 2 AAAA batteries. The unit has the capability to operate on 3 channels, controllable via a button on the EUT and via proprietary software called the "ENSTester". The modulations, modes and channels were changed via different script files.

The applicable limits apply at a 3 meter distance. The calculations to determine these limits are detailed in the following pages. Please refer to Appendix A for a complete list of test equipment. The test sample was operated on one of three (3) standard channels: low (2402MHz), middle (2440MHz) and high (2480MHz) to comply with FCC Part 15.31(m).

5.2 - Test Procedure

Radiated RF measurements were performed on the EUT in a 3 meter Semi-Anechoic, FCC listed Chamber. The frequency range from 30 MHz to 25000 MHz was scanned and investigated. The radiated RF emission levels were manually noted at the various fixed degree settings of azimuth on the turntable and antenna height. The EUT was placed on a non-conductive pedestal in the 3 meter Semi-Anechoic Chamber, with the antenna mast placed such that the antenna was 3 meters from the EUT. A Biconical Antenna was used to measure emissions from 30 MHz to 300 MHz, and a Log Periodic Antenna was used to measure emissions from 300 MHz to 1000 MHz. A Double-Ridged Waveguide Horn Antenna was used from 1 GHz to 18 GHz while a standard gain horn antenna was used in the 18 GHz to 25 GHz range. The maximum radiated RF emissions between 30MHz to 4 GHz were found by raising and lowering the sense antenna between 1 and 4 meters in height, using both horizontal and vertical antenna polarities. Between 4GHz to 25GHz, the sense antenna was raised and lowered between 1 and 1.8 meters in height.

The EUT was positioned in 3 orthogonal orientations (refer to section 5.7 of this report).

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5.3 - Test Equipment Utilized

A list of the test equipment and antennas utilized for the Radiated Emissions test can be found in Appendix A. This list includes calibration information and equipment descriptions. All equipment is calibrated and used according to the operation manuals supplied by the manufacturers. All calibrations of the antennas used were performed at a calibration laboratory accredited to ISO 17025, and are traceable to the SI standard. In addition, the Connecting Cables were measured for losses using a calibrated Signal Generator and an EMI Receiver. The resulting correction factors and the cable loss factors from these calibrations were entered into the EMI Receiver database. As a result, the data taken from the EMI Receiver accounts for the antenna correction factor as well as cable loss or other corrections, and can therefore be entered into the database as a corrected meter reading. The EMI Receiver was operated with a resolution bandwidth of 120 kHz for measurements below 1 GHz (video bandwidth of 300 kHz), and a bandwidth of 1 MHz for measurements above 1 GHz (video bandwidth of 1 MHz).

5.4 - Test Results

The EUT was found to **MEET** the Radiated Emissions requirements of Title 47 CFR, FCC Part 15.247 and Canada RSS-210, Issue 8 (2010), Annex 8 for an FHSS transmitter. The frequencies with significant RF signal strength were recorded and plotted as shown in the Data Charts and Graphs.

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5.5 - Calculation of Radiated Emissions Limits and reported data.

Reported data:

For both fundamental and spurious emissions measurement, the data reported includes all necessary correction factors. These correction factors are loaded onto the EMI receiver when measurements are performed.

Reported Measurement data = Raw receiver measurement $(dB\mu V/m)$ + Antenna correction Factor + Cable factor (dB) + Miscellaneous factors when applicable (dB) – amplification factor when applicable (dB).

Generic example of reported data at 200 MHz:

Reported Measurement data = 18.2 (raw receiver measurement) + 15.8 (antenna factor) + 1.45 (cable factor) = 35.45 (dBµV/m).

As specified in 15.247 (d) and RSS 210 A8.5, radiated emissions that fall within the restricted band described in 15.205(c) for FCC and section 2.2 of RSS 210 for IC, must comply with the general emissions limit.

The following table depicts the general radiated emission limits above 30 MHz. These limits are obtained from Title 47 CFR, Part 15.209, for radiated emissions measurements. These limits were applied to any signals found in the 15.205 restricted bands. The mentioned limits correspond to those limits listed in RSS GEN.

Frequency (MHz)	3 m Limit μV/m	3 m Limit (dBμV/m)	1 m Limit (dBµV/m)
30-88	100	40.0	-
88-216	150	43.5	-
216-960	200	46.0	-
960-24,000	500	54.0	63.5

Sample conversion of field strength (μ V/m to dB μ V/m): dB μ V/m = 20 log ₁₀ (100)= 40 dB μ V/m (from 30-88 MHz)

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5.6 - Radiated Emissions Test Data Chart

Manufacturer:	Me	Medtronic						
Date(s) of Test:	Oct	ober 25 th to November 15 ^t	^h 20)11				
Project Engineer(s):	Kha	airul Aidi Zainal						
Test Engineer(s):	Pet	er Feilen, Shane Rismeye	r, M	icha	el Hintzke and	l Kh	airul Aidi Zainal	
Voltage:	3.0	VDC						
Operation Mode:	con	tinuous transmit, modulate	ed					
Environmental	Ter	nperature: 70-71°F						
Conditions in the	Rel	Relative Humidity: 34-38%						
Lab:								
EUT Power:		Single Phase 120VAC			3 Phase	_VA	C	
LOTTOWEI.	Х	Battery			Other: Bench DC supply			
EUT Placement:	Х	80cm non-conductive pedestal			10cm Space	ers		
EUT Test Location:	Х	3 Meter Semi-Anechoic FCC Listed Chamber			3/10m OAT	S		
Measurements:		Pre-Compliance			Preliminary	Х	Final	
Detectors Used:	Х	Peak X			Quasi-Peak	Х	Average	

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RADIATED EMISSIONS DATA CHART (continued)

The following table depicts the level of significant radiated **harmonic** emissions of channel 2402 MHz in the restricted band:

Frequency	Peak reading	Peak reading	Peakreading	Peak	Peak	Avg reading	Avg reading	Avg reading	Avg	Avg	Antenna	EUT
	at 1m	at 3m	at 3m	limit at 3m	margin	at 1m	at 3m	at 3m	limit at 3m	margin	polarity	Orientation
(MHz)	(dBµV/m)	(dBµV/m)	(µV/m)	(dBµV/m)	(dB)	(dBµV/m)	(dBµV/m)	(µV/m)	(dBµV/m)	(dB)		
4804.0	53.6	44.1	159.6	74.0	29.9	46.4	36.9	69.7	54.0	17.1	Vertical	Vertical
12010.0	58.3	48.8	274.2	74.0	25.2	53.3	43.8	154.2	54.0	10.2	Horizontal	Side
19216.0	53.5	44.0	157.8	74.0	30.0	46.8	37.3	72.9	54.0	16.7	Vertical	Side

Notes:

1. Measurements above 4 GHz were made at 1 meters of separation from the EUT.

2. Refer to exhibit 5.5 on explanation of how data is reported.

The following table depicts the level of significant radiated **harmonic** emissions of channel 2440 MHz in the restricted band:

Frequency	Peakreading	Peak reading	Peakreading	Peak	Peak	Avg reading	Avgreading	Avg reading	Avg	Avg	Antenna	EUT
	at 1m	at 3m	at 3m	limit at 3m	margin	at 1m	at 3m	at 3m	limit at 3m	margin	polarity	Orientation
(MHz)	(dBµV/m)	(dBµV/m)	(µV/m)	(dBµV/m)	(dB)	(dBµV/m)	(dBµV/m)	(µV/m)	(dBµV/m)	(dB)		
4880.0	51.7	42.2	128.2	74.0	31.8	45.7	36.2	64.3	54.0	17.8	Vertical	Flat
7320.0	50.3	40.8	109.1	74.0	33.2	43.3	33.8	48.8	54.0	20.2	Vertical	Vertical
12200.0	51.8	42.3	129.7	74.0	31.7	44.8	35.3	57.9	54.0	18.7	Horizontal	Side
19520.0	53.3	43.8	154.2	74.0	30.2	46.3	36.8	68.9	54.0	17.2	Vertical	Side

Notes:

1. Measurements above 4 GHz were made at 1 meters of separation from the EUT.

2. Refer to exhibit 5.5 on explanation of how data is reported.

The following table depicts the level of significant radiated **harmonic** emissions of channel 926.4 MHz in the restricted band:

Frequency	Peakreading	Peak reading	Peakreading	Peak	Peak	Avg reading	Avg reading	Avg reading	Avg	Avg	Antenna	EUT
	at 1m	at 3m	at 3m	limit at 3m	margin	at 1m	at 3m	at 3m	limit at 3m	margin	polarity	Orientation
(MHz)	(dBµV/m)	(dBµV/m)	(µV/m)	(dBµV/m)	(dB)	(dBµV/m)	(dBµV/m)	(µV/m)	(dBµV/m)	(dB)		
4960.0	54.1	44.6	169.0	74.0	29.4	47.8	38.3	81.8	54.0	15.7	Horizontal	Vertical
7440.0	51.1	41.6	119.7	74.0	32.4	44.6	35.1	56.6	54.0	18.9	Vertical	Vertical
12400.0	52.8	43.3	145.5	74.0	30.7	44.6	35.1	56.6	54.0	18.9	Horizontal	Side

Notes:

1. Measurements above 4 GHz were made at 1 meters of separation from the EUT.

2. Refer to exhibit 5.5 on explanation of how data is reported.

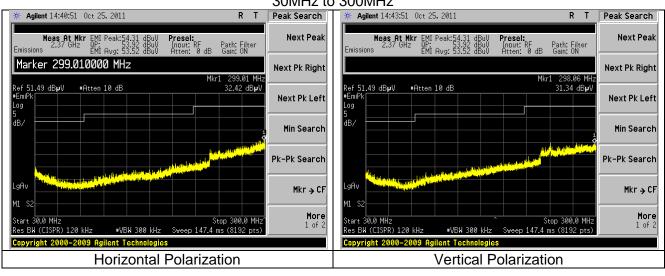
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5.7 - Test Setup Photo(s) - Radiated Emissions Test

This section is not available

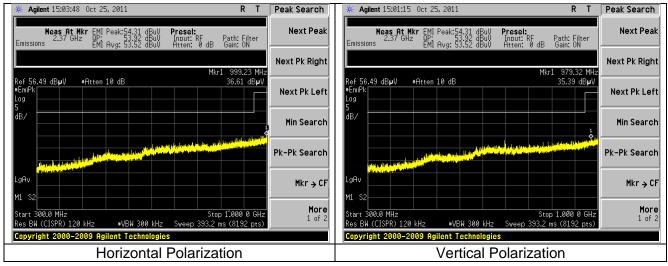
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5.8 - Screen Captures of Radiated emissions.

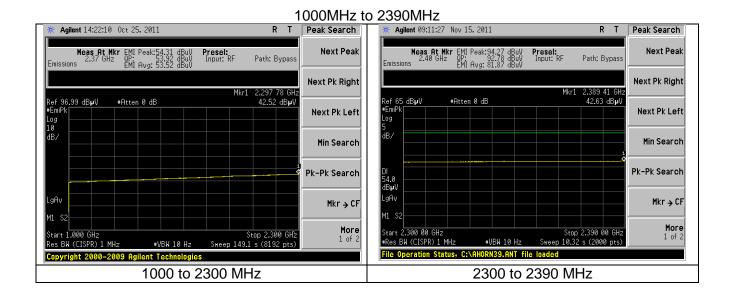


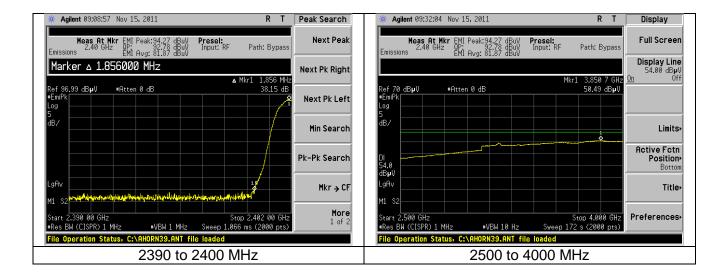
30MHz to 300MHz

300MHz to 1000MHz



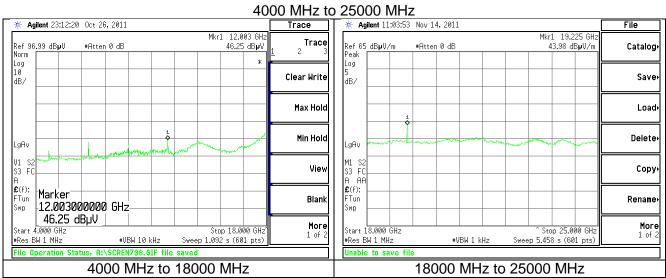
Prepared For: Medtronic	EUT: Medtronic ENS	LS Research, LLC
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Note: The range 2483.5 to 2500 MHz is in section 8 of this report (band-Edges)

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Note: The reduced bandwidth above is used solely for screen captures and not actual measurements.

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	NLM001943N, NLM001937N	

EXHIBIT 6. CONDUCTED EMISSIONS TEST, AC POWER LINE

6.1 <u>Test Setup</u>

THIS TEST WAS NOT REQUIRED; THE EUT IS BATTERY POWERED.

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EXHIBIT 7. OCCUPIED BANDWIDTH

7.1 - Limits

For an FHSS system operating in the 2400 to 2483.5 MHz band, there are no limits for 20dB bandwidth.

7.2 - Method of Measurements

Industry Canada (IC RSS GEN 4.6.1) requires the measurement of the 99% bandwidth while CFR 47 part 15.247 requires the measurement of the 20dB bandwidth. For this portion of the tests, a direct measurement of the transmitted signal was performed at the antenna port of the EUT, via a cable connection to a spectrum analyzer. An attenuator was placed in series with the cable to protect the spectrum analyzer. The loss from the cable and the attenuator were added on the analyzer as gain offset settings there by allowing direct measurements, without the need for any further corrections. The EUT was configured to run in a continuous transmit mode, while being supplied with typical data as a modulation source. A bandwidth measurement function that is built into the spectrum analyzer was used to measure the 99% bandwidths.

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	NLM001943N, NLM001937N	

7.3 <u>- Test Data</u>

A. GFSK

Occupied bandwidth (kHz)		
Channel	20dB	99%
(MHz)	(kHz)	(kHz)
2402	1108.00	839.96
2440	1108.00	1115.10
2480	1142.00	834.37

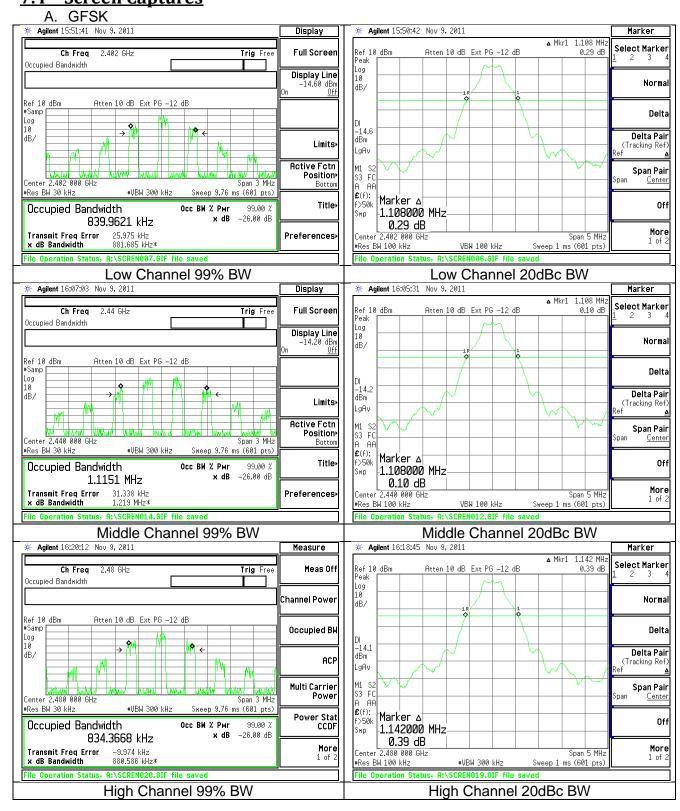
B. EDR2

Occupied bandwidth (kHz)		
CHANNEL	20dB	99%
(MHz)	(kHz)	(kHz)
2402	1408.00	1205.00
2440	1408.00	1205.40
2480	1408.00	1199.50

C. EDR3

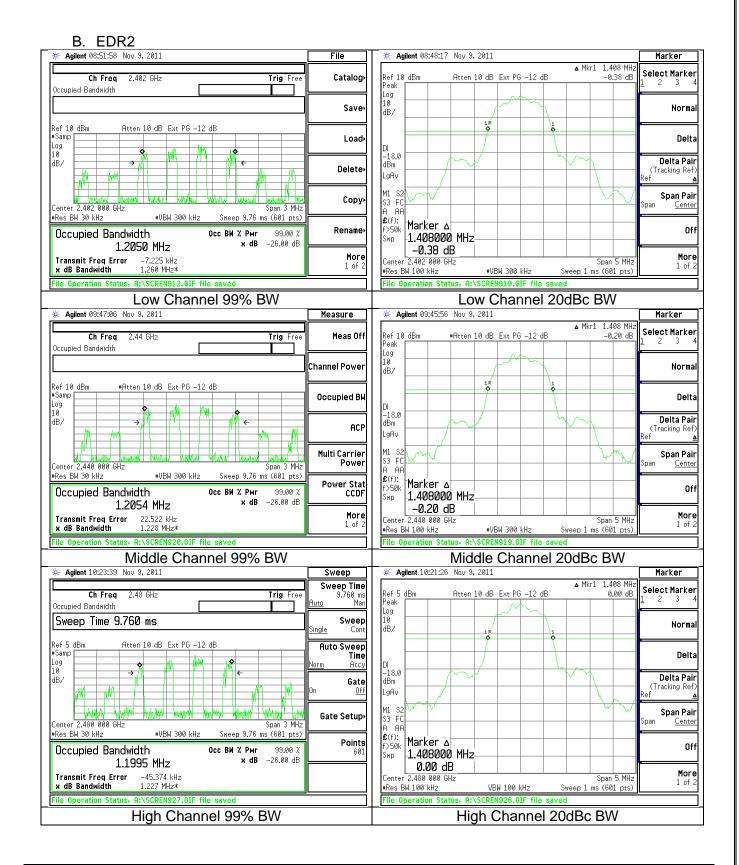
Occupied bandwidth (kHz)		
Channel	20dB	99%
(MHz)	(kHz)	(kHz)
2402	1392.00	1199.90
2440	1375.00	1184.30
2480	1375.00	1198.70

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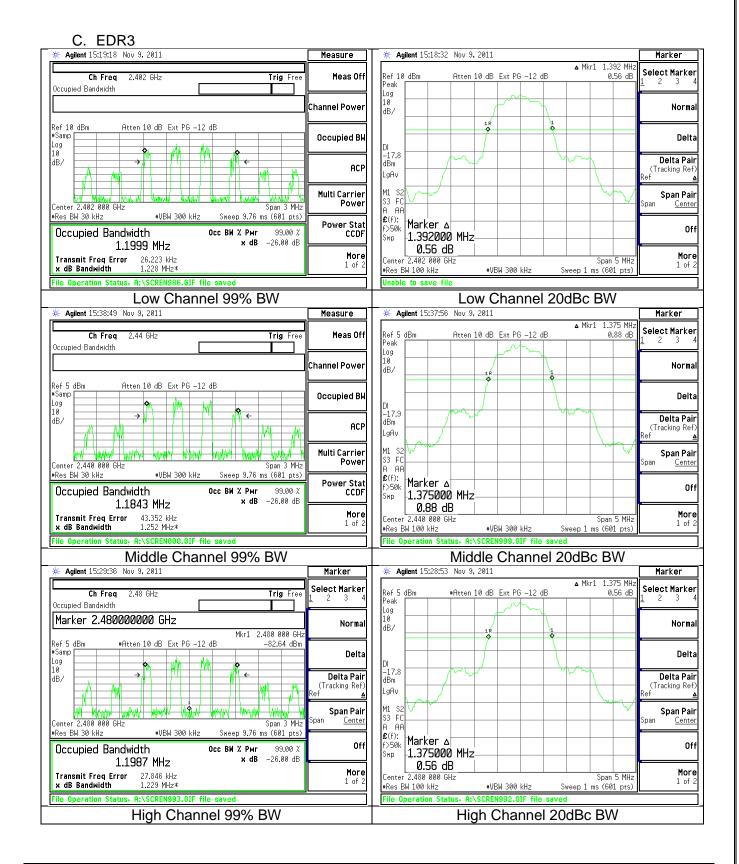


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7.4 – Screen Captures



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EXHIBIT 8. BAND EDGE MEASUREMENTS

8.1 - Method of Measurements

FCC 15.247(d) require a measurement of spurious emission levels to be at least 20 dB lower than the fundamental emission level, in particular at the Band-Edges where the intentional radiator operates. Also, RSS 210 Section 2.2 requires that unwanted emissions meet limits listed in RSS GEN and also to the limits in the applicable annex. The following screen captures demonstrate compliance of the intentional radiator at the 2400 – 2483.5 MHz Band-Edges. The EUT was operated in continuous transmit mode with continuous modulation, with internally generated data as the modulating source. The EUT was operated at the lowest channel for the investigation of the lower Band-Edge, and at the highest channel for the investigation of the higher Band-Edge.

The Band-edge measurements were performed radiated and conducted. The conducted measurement of band-edge was performed to satisfy FCC 15.247(d). The radiated measurements were performed to satisfy the conditions of 15.205 restricted bands.

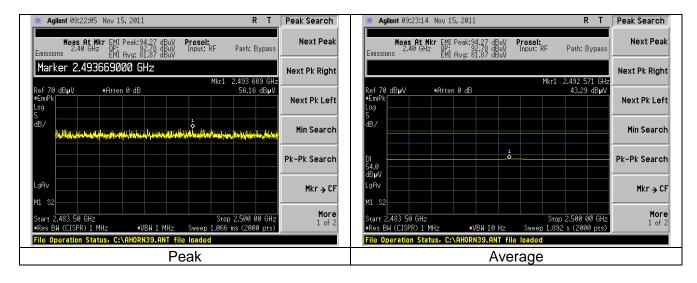
Conducted measurements of the spurious emission were performed with a measurement bandwidth of 100kHz while radiated measurements were performed with a measurement bandwidth of 1MHz.

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8.2. Band edge captures.

Radiated Band-edge:

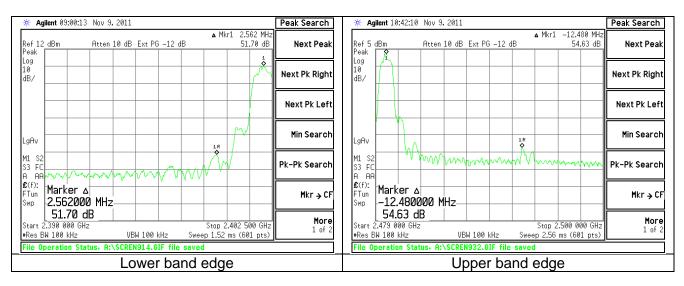
A. Continuously transmitting and modulated.



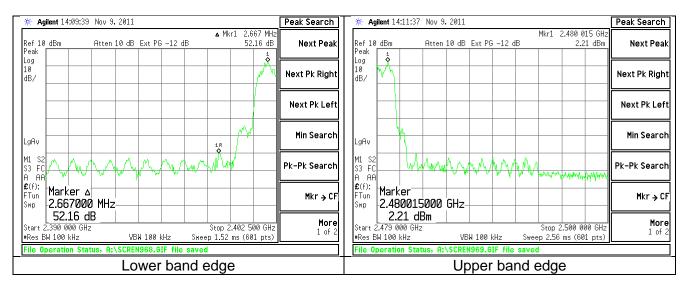
Prepared For: Medtronic	EUT: Medtronic ENS	LS Research, LLC
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Conducted Band-edge:

A. Continuously transmitting and modulated.



B. Hopping mode.



Note:

The screen captures above are those of the EUT in EDR2 mode, being used to represent all the other Bluetooth modulation.

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EXHIBIT 9. POWER OUTPUT (CONDUCTED): 15.247(b)

9.1 - Method of Measurements

The conducted RF output power of the EUT was measured at the antenna port using a short RF cable along with an attenuator as protection for the spectrum analyzer. The loss from the cable and the attenuator were added on the analyzer as gain offset settings there by allowing direct measurements without the need for any further corrections. The unit was configured to run in a continuous transmit mode, while being supplied with typical data as a modulation source. The spectrum analyzer was used with the appropriate resolution bandwidth, with measurements from a peak detector presented in the chart below.

9.2 - Test Data

Α.	GFSK

Channel	Conducted Power		Limit	Margin
(MHz)	(dBm)	(Watts)	(dBm)	(dB
2402	5.5	0.00352	30	24.5
2440	5.9	0.00391	30	24.1
2480	6.1	0.00409	30	23.9

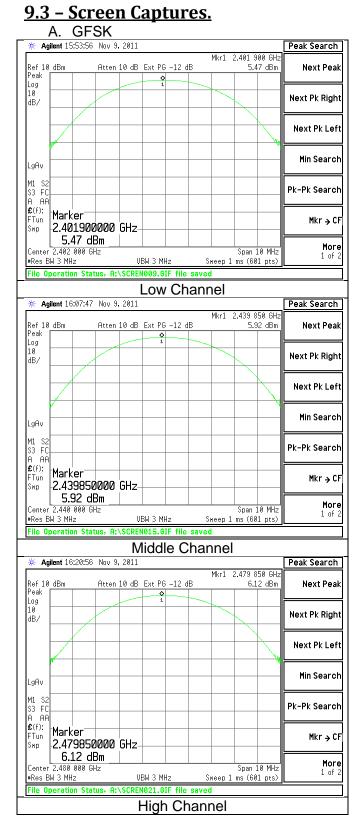
B. EDR2

Channel	Conducted Power		Limit	Margin
(MHz)	(dBm)	(Watts)	(dBm)	(dB
2402	4.0	0.00248	30	26.1
2440	4.1	0.00255	30	25.9
2480	4.2	0.00262	30	25.8

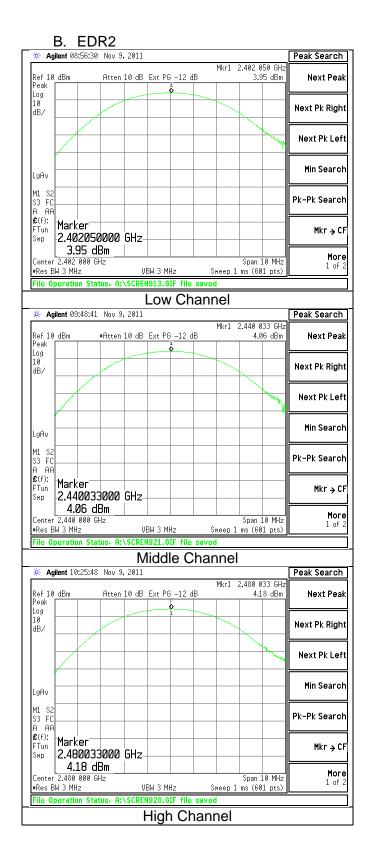
C. EDR3

Channel	Conducted Power		Limit	Margin
(MHz)	(dBm)	(Watts)	(dBm)	(dB
2402	4.4	0.00272	30	25.7
2440	4.5	0.00283	30	25.5
2480	4.7	0.00293	30	25.3

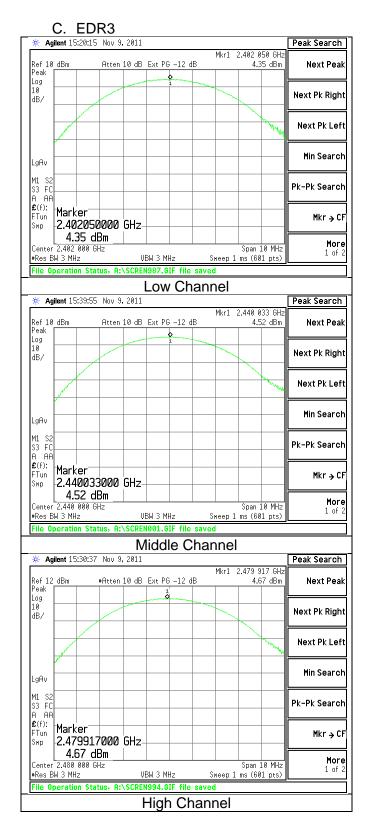
Prepared For: Medtronic	EUT: Medtronic ENS	LS Research, LLC
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EXHIBIT 10. CONDUCTED SPURIOUS EMISSIONS: 15.247(d)

<u> 10.1 - Limits</u>

In any 100 kHz bandwidth outside the frequency band in which the spread spectrum or digitally modulated intentional radiator is operating, the radio frequency power that is produced by the intentional radiator shall be at least 20 dB below that in the 100 kHz bandwidth within the band that contains the highest level of the desired power, based on either an RF conducted or a radiated measurement.

10.2 – Conducted Harmonic And Spurious RF Measurements

FCC Part 15.247(d) and IC RSS 210 A8.5 both require a measurement of conducted harmonic and spurious RF emission levels, as reference to the carrier level when measured in a 100 kHz bandwidth. For this test, the spurious and harmonic RF emissions from the EUT were measured at the EUT antenna port using a short RF cable along with an attenuator as protection for the spectrum analyzer. The loss from the cable and the attenuator were added on the analyzer as gain offset settings, thereby allowing direct readings of the measurements made without the need for any further corrections. A spectrum analyzer was used with the resolution bandwidth set to 100 kHz for this portion of the tests. The unit was configured to run in a continuous transmit mode, while being supplied with typical data as a modulation source. The spectrum analyzer was used with measurements from a peak detector presented in the chart below. Screen captures were acquired and any noticeable spurious and harmonic signals were identified and measured.

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10.3 - Test Data A. GFSK

	Channel Iow	Channel middle	Channel high
Fundamental	5.4	5.9	6.0
2 nd Harmonic	-36.7	-36.3	-36.8
3 rd Harmonic	-45.4	-48.8	-49.5
4 th Harmonic	-56.8	-59.9	-58.7
5 th Harmonic	-54.1	-56.7	-57.9
6 th Harmonic	-70.7	-71.3	-71.1
7 th Harmonic	Note 2	Note 2	Note 2
8 th Harmonic	Note 2	Note 2	Note 2
9 th Harmonic	Note 2	Note 2	Note 2
10 th Harmonic	Note 2	Note 2	Note 2

Note:

- 1. All reported data are in dBm.
- 2. Spurious emission buried within system noise floor.

B. EDR2

	Channel Iow	Channel middle	Channel high
Fundamental	2.2	2.0	2.3
2 nd Harmonic	-40.9	-40.9	-40.7
3 rd Harmonic	-61.6	-65.3	-65.2
4 th Harmonic	-61.0	-60.7	-58.9
5 th Harmonic	-67.2	-70.2	Note 2
6 th Harmonic	Note 2	Note 2	Note 2
7 th Harmonic	Note 2	Note 2	Note 2
8 th Harmonic	Note 2	Note 2	Note 2
9 th Harmonic	Note 2	Note 2	Note 2
10 th Harmonic	Note 2	Note 2	Note 2

Note:

- All reported data are in dBm.
 Spurious emission buried within system noise floor.

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C. EDR3

	Channel Iow	Channel middle	Channel high
Fundamental	2.3	2.1	2.1
2 nd Harmonic	-40.9	-40.5	-41.3
3 rd Harmonic	-60.4	-63.9	-65.2
4 th Harmonic	-62.0	-61.5	-59.0
5 th Harmonic	-68.5	-67.6	-71.2
6 th Harmonic	Note 2	Note 2	Note 2
7 th Harmonic	Note 2	Note 2	Note 2
8 th Harmonic	Note 2	Note 2	Note 2
9 th Harmonic	Note 2	Note 2	Note 2
10 th Harmonic	Note 2	Note 2	Note 2

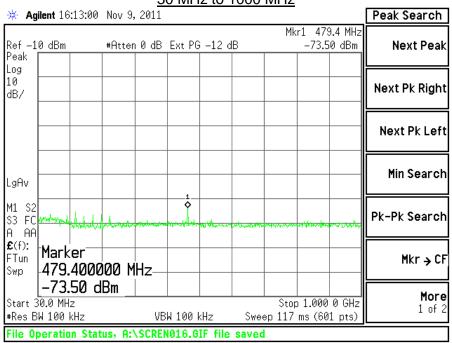
Note:

1. All reported data are in dBm.

2. Spurious emission buried within system noise floor.

10.4 – Screen Captures – Spurious Radiated Emissions

The screen captures below are those of the EUT in GFSK mode (middle channel), being used to represent all the other Bluetooth modulation and channels.



30 MHz to 1000 MHz

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K Agilent 16:15:55 Nov 9	<u>1000MHz to 100</u> , 2011	50011112	Peak Search
ef 10 dBm Atten	10 dB Ext PG -12 dB	Mkr1 4.885 GHz _36.75 dBm	Next Peak
og			Next Pk Righ
			Next Pk Lef
JAv			Min Searcl
1 S2			Pk-Pk Searcl
(f): Tun #P 4.885000000	GHz		Mkr → Cl
L -36.75 dBm tart 1.000 GHz Res BW 100 kHz	VBW 100 kHz Sv	Stop 10.000 GHz veep 1.085 s (601 pts)	More 1 of 2

10000MHz to 25000MHz

🔆 Agilent 16:14:44	Nov 9, 2 <mark>011</mark>			Peak Search
Ref -10 dBm Peak	#Atten 0 dB	Ext PG –12 dB	Mkr1 12.200 GHz -60.48 dBm	Next Peak
Log 10 dB/				Next Pk Right
				Next Pk Left
LgAv				Min Search
M1 S2 S3 FC A AA	a person and a second and	and when the second test when		Pk-Pk Search
	0000 GHz	2		Mkr → CF
-60.48 d Start 10.000 GHz #Res BW 100 kHz		 W 100 kHz Swe	Stop 25.000 GHz^ ep 1.809 s (601 pts)	More 1 of 2
File Operation Stat	tus, A:\SCREI	1017.GIF file save	d	

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EXHIBIT 11. FREQUENCY & POWER STABILITY OVER VOLTAGE VARIATIONS

The power and frequency stability of the device was examined as a function of the input voltage available to the EUT. A Spectrum Analyzer was used to measure the power and frequency at the appropriate frequency markers. Power was supplied by an external bench-type DC power supply and was varied -15% from the nominal.

2.55 VDC		3.0 VDC	
Power (dBm)	Frequency (Hz)	Power (dBm)	Frequency (Hz)
4.0	2402163854	4.0	2402163988
4.1	2440163417	4.1	2440163367
4.2	2480163083	4.2	2480163116

The power was then cycled On/Off to observe system response. No unusual response was observed, the emission characteristics were well behaved, and the system returned to the same state of operation as before the power cycle.

Transmission drops out at 1.2 VDC.

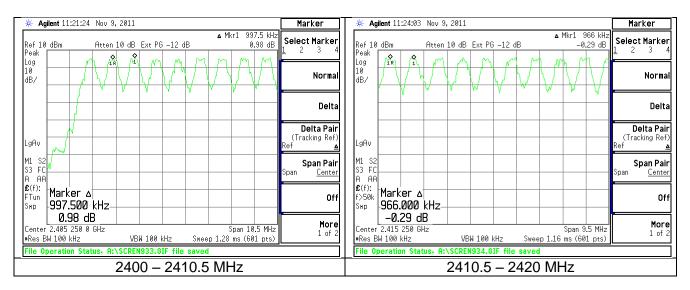
Prepared For: Medtronic	EUT: Medtronic ENS	LS Research, LLC
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EXHIBIT 12. CHANNEL PLAN AND SEPARATION

A spectrum analyzer was used with a resolution bandwidth of 100 kHz to measure the channel separation of the EUT.

The maximum and minimum channel-separations measured for this device are 1012.5 kHz and 966 kHz respectively. The maximum 20dB bandwidth of the device, as reported in the previous section is 1408 kHz. The following plots describe this spacing, and also establish the channel separation and plan.

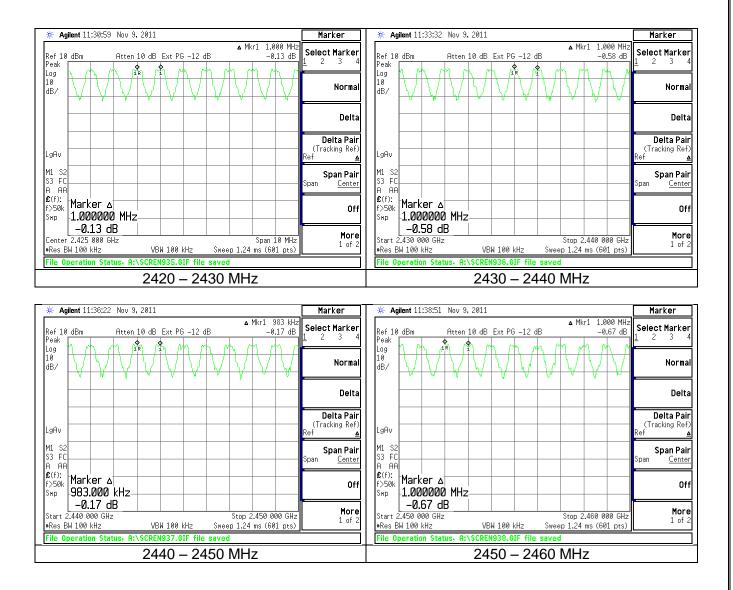
This EUT also satisfies the minimum number of hopping channels which is 15.



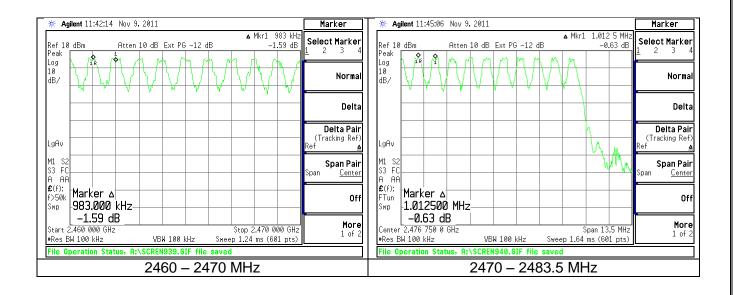
<u>12.1 - Screen Captures – Channel Separation</u>

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Screen Captures – Channel Separation (continued)



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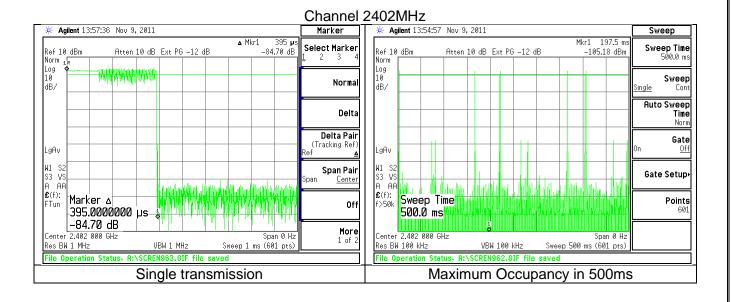
Prepared For: Medtronic	EUT: Medtronic ENS	LS Research, LLC
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EXHIBIT 13. CHANNEL OCCUPANCY.

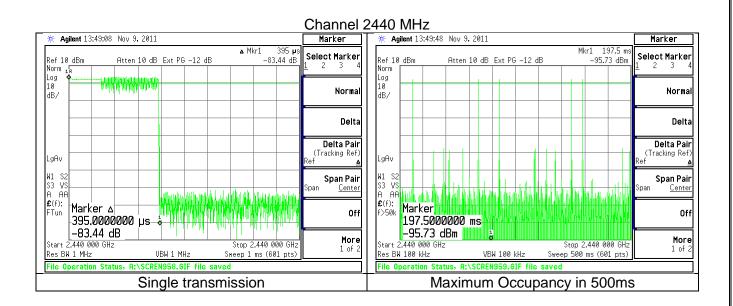
Part 15.247(a)(1)(i) requires an average channel occupancy, for this device, of no more than 400 milliseconds in a 31.6 second window .The channel occupancy for this EUT was measured using a spectrum analyzer, set to zero-span at the frequency of interest. With the analyzer in peak-hold mode, the transmission lengths can be measured by adjusting the sweep rate of the analyzer. A suitable sweep rate was used to measure the channel occupancy at the low, mid and high channels. The longest time any transmission will occur on a single channel is **395 \mus**. The maximum occupancy in a **500** millisecond window is **6**(six) transmission cycle which translates to **2370µs**. There are 63.2 500 millisecond windows in a 31.6 second time span. Therefore the total occupancy in a **31**.6 second time is

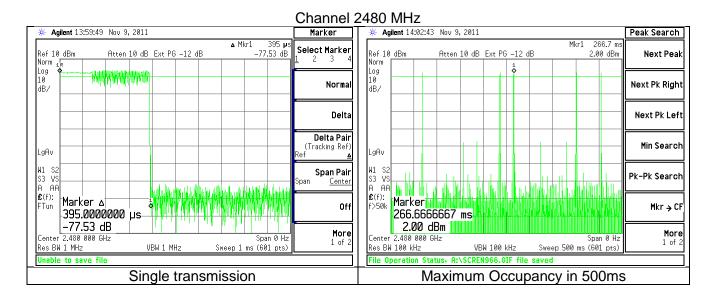
2370µs X 63.2 = <u>149.78ms</u>

<u>13.1 Time occupancy captures.</u>



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EXHIBIT 14. EQUAL CHANNEL USAGE

The transceiver implemented in the EUT is a Bluetooth core specification V2.1 + EDR hence satisfies this requirement.

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EXHIBIT 15. PSEUDORANDOM HOPPING SEQUENCE.

The transceiver implemented in the EUT is a Bluetooth core specification V2.1 + EDR hence satisfies this requirement.

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EXHIBIT 16. RECEIVER SYNCHRONIZATION AND INPUT BANDWIDTH.

The transceiver implemented in the EUT is a Bluetooth core specification V2.1 + EDR hence satisfies this requirement.

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EXHIBIT 17. MPE CALCULATIONS

The following MPE calculations are based on a maximum measured conducted RF power of +6.1 dBm as presented to the antenna. The peak gain of this antenna, based on the data sheet is 2.2 dBi.

Prediction of MPE limit at a given distance

Equation from page 18 of OET Bulletin 65, Edition 97-01

$$S = \frac{PG}{4\pi R^2}$$

where: S = power density

P = power input to the antenna

G = power gain of the antenna in the direction of interest relative to an isotropic radiator

R = distance to the center of radiation of the antenna

Maximum peak output power at antenna input terminal:	<u>6.10</u> (dBm)
Maximum peak output power at antenna input terminal: _	<u>4.074</u> (mW)
Antenna gain(typical): _	<u> </u>
Maximum antenna gain: _	<u>1.660</u> (numeric)
Prediction distance:	<u> </u>
Prediction frequency:	<u>2405</u> (MHz)
MPE limit for uncontrolled exposure at prediction frequency: _	1 (mW/cm^2)
Power density at prediction frequency:	0.001345 (mW/cm^2)
Maximum allowable antenna gain:	30.9 (dBi)

Margin of Compliance at 20 cm = 28.7 dB

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<u>APPENDIX A – Test Equipment List</u>

Date	: 24-Oct-2011	Тур	e Test : Cond	Measureme	nts		Job # :	C-1264
Prepared By	· AIDI	Qustr	omer Plexi	is Technolog	IV Group		Quote #	311164
							_	
Asset # EE 960073	Description Spectrum Analyzer	Manufactu Agilent	Irer Model E4446		Serial # US45300564	Cal Date 4/25/2011	Cal Due Date 4/25/2012	Equipment Status Active Calibration
AA 960144	Phaseflex	Gore		D010720	5800373	6/1/2011	6/1/2012	Active Calibration
		Project Engineer: Aidi				Quality Assurance	e: SDR	
LS RE	SEARCH LLC							
Equ	ipment Calibration							
Date	: 24-Oct-2011	Тур	e Test : Chan	nel Occupan	юу		Job # :	C-1264
		Oustr	mer Plevi	is Technolog	IV Group		Quote #	311164
							Quote #.	311104
Prepared By				j				
Asset #	Description	Manufactu	urer Model	#	Serial #	Cal Date	Cal Due Date	Equipment Status
			urer Model E4446	#		Cal Date 4/25/2011 6/1/2011	Cal Due Date 4/25/2012 6/1/2012	Equipment Status Active Calibration Active Calibration
Asset # EE 960073	Description Spectrum Analyzer	Manufactu Agilent	urer Model E4446	#A	Serial # US45300564	4/25/2011	4/25/2012	Active Calibration
Asset # EE 960073	Description Spectrum Analyzer	Manufactu Agilent	urer Model E4446	#A	Serial # US45300564	4/25/2011	4/25/2012 6/1/2012	Active Calibration
Asset # EE 960073	Description Spectrum Analyzer	Manufactu Agilent Gore	urer Model E4446	#A	Serial # US45300564	4/25/2011 6/1/2011	4/25/2012 6/1/2012	Active Calibration
Asset # EE 960073 AA 960144	Description Spectrum Analyzer Phaseflex	Manufactu Agilent Gore	urer Model E4446	#A	Serial # US45300564	4/25/2011 6/1/2011	4/25/2012 6/1/2012	Active Calibration
Asset # EE 960073 AA 960144	Description Spectrum Analyzer Phaseflex	Manufactu Agilent Gore	urer Model E4446	#A	Serial # US45300564	4/25/2011 6/1/2011	4/25/2012 6/1/2012	Active Calibration
Asset # EE 960073 AA 960144	Description Spectrum Analyzer Phaseflex	Manufactu Agilent Gore	urer Model E4446	#A	Serial # US45300564	4/25/2011 6/1/2011	4/25/2012 6/1/2012	Active Calibration
Asset # EE 960073 AA 960144	Description Spectrum Analyzer Phaseflex	Manufactt Agilent Gore Project Engineer: <u>Aidi</u>	Irer Model E4446 EKD01	#A	Serial # US45300564 5800373	4/25/2011 6/1/2011	4/25/2012 6/1/2012	Active Calibration
Asset # EE 960073 AA 960144 Wireles Equ Date	Description Spectrum Analyzer Phaseflex ESEARCH LLC is Product Development ipment Calibration : 24-Oct-2011	Manufactu Agilent Gore Project Engineer: Aidi	e Test : <u>Chan</u>	# A D010720 nel Plan & S	Serial # US45300564 5800373	4/25/2011 6/1/2011	4/25/2012 6/1/2012 :e: Peter 	Active Calibration Active Calibration
Asset # EE 960073 AA 960144 Wireles Equ Date Prepared By	Description Spectrum Analyzer Phaseflex ESEARCH LLC is Product Development pment Calibration : 24-Oct-2011 : ADI	Manufactu Agilent Gore Project Engineer: Aidi Typ	urer Model E4446 EKD0' e Test : <u>Chan</u> pmer : <u>Plexu</u>	# A D010720 nel Plan & S is Technolog	Serial # US45300564 5800373 eparation y Group	4/25/2011 6/1/2011 Quality Assuranc	4/25/2012 6/1/2012 :e: Peter Job # : Quote #:	Active Calibration Active Calibration
Asset # EE 960073 AA 960144 Wireles Equ Date	Description Spectrum Analyzer Phaseflex ESEARCH LLC is Product Development ipment Calibration : 24-Oct-2011	Manufactu Agilent Gore Project Engineer: Aidi	urer Model E4446 EKD0' e Test : <u>Chan</u> pmer : <u>Plexu</u>	# D010720 nel Plan & S is Technolog #	Serial # US45300564 5800373	4/25/2011 6/1/2011	4/25/2012 6/1/2012 :e: Peter 	Active Calibration Active Calibration

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	Da	ate : 24-Oct-2011	Type Test	Radiated TX sp	urs		Job #	: <u>C-1264</u>
	Prepared	By: AIDI	Customer :	Plexus Technol	ogy Group		Quote	#: <u>311164</u>
No.	Asset #	Description	Manufacturer	Model #	Serial #	Cal Date	Cal Due Date	Equipment Status
1	EE 960147	Pre-Amp	Adv. Micro	WLA612	123101	1/4/2011	1/4/2012	Active Calibration
2	AA 960081	Double Ridge Horn Antenna	EMCO	3115	6907	1/4/2011	1/4/2012	Active Calibration
3	EE 960073	Spectrum Analyzer	Agilent	E4446A	US45300564	4/25/2011	4/25/2012	Active Calibration
4	AA 960144	Phaseflex	Gore	EKD01D010720	5800373	6/1/2011	6/1/2012	Active Calibration
5	EE 960146	Std. Gain Horn Ant. w/preamp	Adv. Micro	WLA622-4	123001	11/3/2011	11/3/2012	Active Calibration
6	AA 960154	2.4GHz High Pass Filter	KWM	HPF-L-14186	7272-02	6/10/2011	6/10/2012	Active Calibration
7	AA 960007	Double Ridge Horn Antenna	EMCO	3115	9311-4138	4/27/2011	4/27/2012	Active Calibration
8	AA 960004	Log Periodic Antenna	EMCO	93146	9512-4276	9/19/2011	9/19/2012	Active Calibration
9	AA 960005	Biconical Antenna	EMCO	93110B	9601-2280	6/10/2011	6/10/2012	Active Calibration
10	EE 960160	0.8-21GHz LNA	Mini-Circuits	ZVA-213X-S+	977711030	4/27/2011	4/27/2012	Active Calibration
11	EE 960157	3Hz-13.2GHz Spectrum Analyzer	Agilent	E4445A	MY48250225	6/6/2011	6/6/2012	Active Calibration
12	EE 960158	RF Preselecter	Agilent	N9039A	MY46520110	6/11/2011	6/11/2012	Active Calibration

	Da	tte : 24-Oct-2011	Type Test	Rad Band-E	dge		Job #	: <u>C-1264</u>	
	Prepared	By: Aidi	Customer :	Plexus Tech	nology Group		Quote #	311164	
No.	Asset #	Description	Manufacturer	Model #	Serial #	Cal Date	Cal Due Date	Equipment Status	
1	EE 960157	3Hz-13.2GHz Spectrum Analyzer	Agilent	E4445A	MY 48250225	6/6/2011	6/6/2012	Active Calibration	
		RF Preselecter	Agilent	N9039A	MY 46520110	6/11/2011	6/11/2012	Active Calibration	
2	EE 960158	RF Pleselectel							

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	NLM001943N, NLM001937N	

APPENDIX B – Test Standards: CURRENT PUBLICATION DATES RADIO

STANDARD #	DATE	Am. 1	Am. 2
ANSI C63.4	2003		
ANSI C63.10	2009		
FCC 47 CFR, Parts 0-15, 18, 90, 95	2009		
FCC Public Notice DA 00- 1407	2000		
FCC ET Docket # 99-231	2002		
FCC Procedures	2007		
ICES 003	2004-02		
RSS GEN	2010		
RSS 210	2010		

Updated on 11-22-11 P=Project FD= Final Draft

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APPENDIX C - Uncertainty Statement

This uncertainty represents an expanded uncertainty expressed at approximately the 95 % confidence level, using a coverage factor of k=2.

Measurement Type	Particular Configuration	Uncertainty Values
Radiated Emissions	3 – Meter chamber, Biconical Antenna	4.24 dB
Radiated Emissions	3-Meter Chamber, Log Periodic Antenna	4.8 dB
Radiated Emissions	10-Meter OATS, Biconical Antenna	4.18 dB
Radiated Emissions	10-Meter OATS, Log Periodic Antenna	3.92 dB
Conducted Emissions	Shielded Room/EMCO LISN	1.60 dB
Radiated Immunity	3 Volts/Meter in 3-Meter Chamber	1.128 Volts/Meter
Conducted Immunity	3 Volts level	1.0 V

Table of Expanded Uncertainty Values, (K=2) for Specified Measurements

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<u>APPENDIX D – PLEXUS Instrument sheet.</u>

The equipment table below lists the peripheral attachments used in the testing of the EUT.

Equipment Description	Plexus Identification Number
Battery Pack	BFT_BP_03
	BFT_BP_02
Stimulation Board	73797-00 REV B SN006
	73797-00 REV B SN008
ENS Cable	TWIST_LOC CABLE_02
	TWIST_LOC CABLE_01
Cable Extension	PERC_EXT LEAD_02
	PERC_EXT LEAD_01
Chronic lead	3889_CHR LEAD_02
	3889_CHR LEAD_01
	3093_CHR LEAD_01
Bluetooth Dongle	BT_05
Stimulation Board Cables	BFT_SC_02
	BFT_SC_01
Conducted Measurement Cable	CM_CABLE_01

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