

Medtronic Inc. 9538/9539 Patient Assistant FCC 15:209:2012

Report #: MDTR0304.1 Rev. 1



Report Prepared By Northwest EMC Inc.

NORTHWEST EMC – (888) 364-2378 – www.nwemc.com

California – Minnesota – Oregon – New York – Washington



CERTIFICATE OF TEST

Last Date of Test: January 13, 2014 Medtronic, Inc. Model: 9538/9539 Patient Assistant

Emissions

Test Description	Specification	Test Method	Pass/Fail
Field Strength of Fundamental	FCC 15.209:2014	ANSI C63.10:2009	Pass
Spurious Radiated Emissions	FCC 15.209:2014	ANSI C63.10:2009	Pass

Deviations From Test Standards

None

Approved By:

Tim O'Shea, Operations Manager

NVLAP Lab Code: 200881-0

This report must not be used to claim product certification, approval, or endorsement by NVLAP, NIST, or any agency of the federal government of the United States of America.

Product compliance is the responsibility of the client, therefore the tests and equipment modes of operation represented in this report were agreed upon by the client, prior to testing. This Report may only be duplicated in its entirety. The results of this test pertain only to the sample(s) tested. The specific description is noted in each of the individual sections of the test report supporting this certificate of test.



REVISION HISTORY

Revision Number	Description	Date	Page Number
00	None		
01	Corrected Model Number	2/11/2014	Cover, 2, 7, 8, 11, 12, 14-17

Barometric Pressure

The recorded barometric pressure has been normalized to sea level.



ACCREDITATIONS AND AUTHORIZATIONS

United States

FCC - Designated by the FCC as a Telecommunications Certification Body (TCB). Certification chambers, Open Area Test Sites, and conducted measurement facilities are listed with the FCC.

A2LA - Accredited by A2LA to ISO / IEC Guide 65 as a product certifier. This allows Northwest EMC to certify transmitters to FCC and IC specifications.

NVLAP - Each laboratory is accredited by NVLAP to ISO 17025

Canada

IC - Recognized by Industry Canada as a Certification Body (CB). Certification chambers and Open Area Test Sites are filed with IC.

European Union

European Commission – Validated by the European Commission as a Conformity Assessment Body (CAB) under the EMC directive and as a Notified Body under the R&TTE Directive.

Australia/New Zealand

ACMA - Recognized by ACMA as a CAB for the acceptance of test data.

Korea

KCC / RRA - Recognized by KCC's RRA as a CAB for the acceptance of test data.

Japan

VCCI - Associate Member of the VCCI. Conducted and radiated measurement facilities are registered.

Taiwan

BSMI - Recognized by BSMI as a CAB for the acceptance of test data.

NCC - Recognized by NCC as a CAB for the acceptance of test data.

Singapore

IDA – Recognized by IDA as a CAB for the acceptance of test data.

Hong Kong

OFTA - Recognized by OFTA as a CAB for the acceptance of test data.

Vietnam

MIC - Recognized by MIC as a CAB for the acceptance of test data.

Russia

GOST – Accredited by Certinform VNIINMASH, CERTINFO, SAMTES, and Federal CHEC to perform EMC and Hygienic testing for Information Technology products to GOST standards.

SCOPE

For details on the Scopes of our Accreditations, please visit: http://www.nwemc.com/accreditations/



MEASUREMENT UNCERTAINTY

Measurement Uncertainty

When a measurement is made, the result will be different from the true or theoretically correct value. The difference is the result of tolerances in the measurement system that cannot be completely eliminated. To the extent that technology allows us, it has been our aim to minimize this error. Measurement uncertainty is a statistical expression of measurement error qualified by a probability distribution.

A measurement uncertainty estimation has been performed for each test per our internal quality document WP 342. The estimation is used to compare the measured result with its "true" or theoretically correct value. The expanded measurement uncertainty (K=2) for each test is listed below. Our measurement data meets or exceeds the measurement uncertainty requirements of the applicable specification; therefore, the test data can be compared directly to the specification limit to determine compliance. The calculations for estimating measurement uncertainty are based upon ETSI TR 100 028 (or CISPR 16-4-1 as applicable), and are available upon request.

The following table represents the Measurement Uncertainty (MU) budgets for each of the tests that may be contained in this report.

Test	+ MU	- MU
Frequency Accuracy (Hz)	0.12	-0.01
Amplitude Accuracy (dB)	0.49	-0.49
Conducted Power (dB)	0.41	-0.41
Radiated Power via Substitution (dB)	0.69	-0.68
Temperature (degrees C)	0.81	-0.81
Humidity (% RH)	2.89	-2.89
Field Strength (dB)	3.80	-3.80
AC Powerline Conducted Emissions (dB)	2.94	-2.94



FACILITIES





Oregon Labs EV01-12 22975 NW Evergreen Pkwy Hillsboro, OR 97124 (503) 844-4066	California Labs OC01-13 41 Tesla Irvine, CA 92618 (949) 861-8918	New York Labs NY01-04 4939 Jordan Rd. Elbridge, NY 13060 (315) 685-0796	Minnesota Labs MN01-08 9349 W Broadway Ave. Brooklyn Park, MN 55445 (763) 425-2281	Washington Labs NC01-05,SU02,SU07 19201 120 th Ave. NE Bothell, WA 98011 (425) 984-6600					
	VCCI								
A-0108	A-0029		A-0109	A-0110					
		Industry Canada							
2834D-1, 2834D-2	2834B-1, 2834B-2, 2834B-3		2834E-1	2834C-1					
NVLAP									
NVLAP Lab Code: 200630-0	NVLAP Lab Code: 200676-0	NVLAP Lab Code: 200761-0	NVLAP Lab Code: 200881-0	NVLAP Lab Code: 200629-0					









PRODUCT DESCRIPTION

Client and Equipment Under Test (EUT) Information

Company Name:	Medtronic, Inc.
Address:	8200 Coral Sea St. NE
City, State, Zip:	Mounds View, MN 55112
Test Requested By:	Girad Guillaume
Model:	9538/9539 Patient Assistant
First Date of Test:	January 13, 2014
Last Date of Test:	January 13, 2014
Receipt Date of Samples:	January 13, 2014
Equipment Design Stage:	Prototype
Equipment Condition:	No Damage

Information Provided by the Party Requesting the Test

Functional Description of the EUT (Equipment Under Test):

Hand-held, battery-operated telemetry device that enables the patient to record cardiac information via ultra low power (ULP) wireless radio telemetry.

Testing Objective:

To demonstrate compliance of the inductive portion of the device to FCC Part 15.209 specifications.



Configuration MDTR0304-1

EUT							
Description	Manufacturer	Model/Part Number	Serial Number				
Patient Assistant	Medtronic, Inc.	9538/9539	LJP125207P				



MODIFICATIONS

Equipment Modifications

Item	Date	Test	Modification	Note	Disposition of EUT
1	1/13/2014	Spurious Radiated Emissions	Tested as delivered to Test Station.	No EMI suppression devices were added or modified during this test.	EUT remained at Northwest EMC following the test.
2	1/13/2014	Field Strength of Fundamental	Tested as delivered to Test Station.	No EMI suppression devices were added or modified during this test.	Scheduled testing was completed.



FIELD STRENGTH OF FUNDAMENTAL

Testing was performed using the mode(s) of operation and configuration(s) noted within the report. The individuals and/or the organization requesting the test provided the modes, configurations and settings used to complete the evaluation. The actual test parameters are specified in the test data, this includes items such as investigated frequency range (scanned) and test levels. The testing methods and performance specifications, as well as the test site used for the evaluation are indicated in the test data. The test data represents the configuration / operating mode/ model that produced the highest emission levels as compared to the specification limit.

MODES OF OPERATION

Continuous transmit, modulated at 175 kHz

POWER SETTINGS INVESTIGATED

Battery

CONFIGURATIONS INVESTIGATED

MDTR0304 - 1

FREQUENCY RANGE INVESTIGATED

Start Frequency 9 kHz Stop Frequency 490 kHz

SAMPLE CALCULATIONS

Radiated Emissions: Field Strength = Measured Level + Antenna Factor + Cable Factor - Amplifier Gain + Distance Adjustment Factor + External Attenuation

TEST EQUIPMENT

Description	Manufacturer	Model	ID	Last Cal.	Interval
MN05 Cables	ESM Cable Corp.	Bilog Cables	MNH	5/20/2013	12 mo
Antenna, Loop	ETS Lindgren	6502	AOB	2/20/2013	24 mo
Spectrum Analyzer	Agilent	N9010A	AFI	1/27/2013	24 mo

MEASUREMENT BANDWIDTHS

Frequency Range	Peak Data	Quasi-Peak Data	Average Data
(MHz)	(kHz)	(kHz)	(kHz)
0.01 - 0.15	1.0	0.2	0.2
0.15 - 30.0	10.0	9.0	9.0
30.0 - 1000	100.0	120.0	120.0
Above 1000	1000.0	N/A	1000.0

TEST DESCRIPTION

The antennas to be used with the EUT were tested. The EUT was continuously transmitting while set to the channel specified. While scanning, emissions from the EUT were maximized by rotating the EUT, adjusting the measurement antenna height and orientation in 3 orthogonal planes, the EUT and/or associated antenna is positioned in 3 orthogonal planes (per ANSI C63.10). An active loop antenna was used for this test in order to provide sufficient measurement sensitivity.

As outlined in 15.209(e) and 15.31(f)(2), measurements may be performed at a distance closer than what is specified with the limit. The limit at the specified distance is shown on the data sheet. Measurements are made at a closer distance and the data is adjusted using a distance correction factor of 40dB/decade for comparison to the limit.

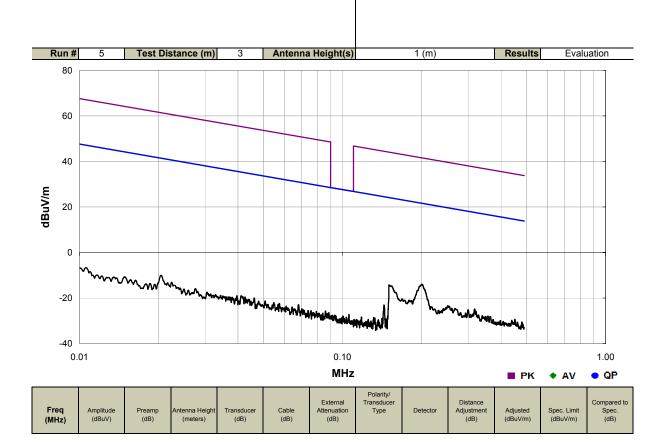
If there are no detectable emissions above the noise floor, the data included will show noise floor measurements for reference only.



FCC 15.209:2014

FIELD STRENGTH OF FUNDAMENTAL

Work Order:	MDTR0304	Date:	01/13/14						
Project:	None	Temperature:	24.5 °C						
Job Site:	MN05	Humidity:	17.3% RH						
Serial Number:	LJP125207P	Barometric Pres.:	1003.2 mbar	Tested by: Trevor Buls					
EUT:	9538/9539 Patient As	sistant							
Configuration:	1								
Customer:	Medtronic, Inc.	Medtronic, Inc.							
Attendees:	Girad Guillaume								
EUT Power:	Battery								
Operating Mode:	Continuous transmit, modulated at 175 kHz								
Deviations:	None								
Comments:	Device operates between 150-200 kHz, FSK modulated at 175 kHz								
Test Specifications			Test Meth	od					



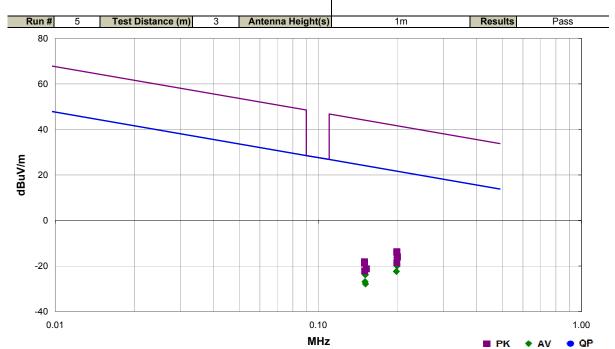


FIELD STRENGTH OF FUNDAMENTAL

Work Order:	MDTR0304	Date:	01/13/14	0 0					
Project:	None	Temperature:	24.5 °C	Trevor Buls					
Job Site:	MN05	Humidity:	17.3% RH	some contract					
Serial Number:	LJP125207P	Barometric Pres.:	1003.2 mbar	Tested by: Trevor Buls					
EUT:	9538/9539 Patient As	sistant							
Configuration:	1								
Customer:	Medtronic, Inc.	Medtronic, Inc.							
Attendees:	Girad Guillaume								
EUT Power:	Battery								
Operating Mode:	Continuous transmit,	Continuous transmit, modulated at 175 kHz							
Deviations:	None								
	Span set wide enough to encompass the entire emissions enveloupe. Device operates between 150-200 kHz, FSK nodulated at 175 kHz								

Test Specifications Test Method

FCC 15.209:2014



Freq (MHz)	Amplitude (dBuV)	Factor (dB)	Antenna Height (meters)	Azimuth (degrees)	Test Distance (meters)	External Attenuation (dB)	Polarity/ Transducer Type	Detector	Distance Adjustment (dB)	Adjusted (dBuV/m)	Spec. Limit (dBuV/m)	Compared to Spec. (dB)	Comments
0.199	52.4	11.4	1.0	159.0	3.0	0.0	Par to EUT	AV	-80.0	-16.2	21.6	-37.8	EUT Vertical
0.199	52.4	11.4	1.0	164.0	3.0	0.0	Par to EUT	AV	-80.0	-16.2	21.6	-37.8	EUT on Side
0.199	49.5	11.4	1.0	248.0	3.0	0.0	Perp to GND	AV	-80.0	-19.1	21.6	-40.7	EUT on Side
0.199	48.6	11.4	1.0	242.0	3.0	0.0	Perp to GND	AV	-80.0	-20.0	21.6	-41.6	EUT Vertical
0.198	46.2	11.4	1.0	338.0	3.0	0.0	Par to GND	AV	-80.0	-22.4	21.7	-44.1	EUT Vertical
0.151	44.8	11.4	1.0	186.0	3.0	0.0	Par to GND	AV	-80.0	-23.8	24.0	-47.8	EUT on Side
0.151	44.8	11.4	1.0	161.0	3.0	0.0	Par to GND	AV	-80.0	-23.8	24.1	-47.8	EUT Horizontal
0.151	41.7	11.4	1.0	31.0	3.0	0.0	Par to EUT	AV	-80.0	-26.9	24.1	-50.9	EUT Horizontal
0.151	40.7	11.4	1.0	338.0	3.0	0.0	Perp to GND	AV	-80.0	-27.9	24.0	-51.9	EUT Horizontal
0.199	54.9	11.4	1.0	159.0	3.0	0.0	Par to EUT	PK	-80.0	-13.7	41.6	-55.3	EUT Vertical
0.199	54.6	11.4	1.0	164.0	3.0	0.0	Par to EUT	PK	-80.0	-14.0	41.6	-55.6	EUT on Side
0.200	52.7	11.4	1.0	242.0	3.0	0.0	Perp to GND	PK	-80.0	-15.9	41.6	-57.5	EUT Vertical
0.200	52.5	11.4	1.0	248.0	3.0	0.0	Perp to GND	PK	-80.0	-16.1	41.6	-57.7	EUT on Side
0.199	50.0	11.4	1.0	161.0	3.0	0.0	Par to GND	PK	-80.0	-18.6	41.6	-60.2	EUT Horizontal
0.150	50.4	11.5	1.0	338.0	3.0	0.0	Par to GND	PK	-80.0	-18.2	44.1	-62.3	EUT Vertical
0.150	49.8	11.5	1.0	186.0	3.0	0.0	Par to GND	PK	-80.0	-18.8	44.1	-62.9	EUT on Side
0.153	47.3	11.4	1.0	31.0	3.0	0.0	Par to EUT	PK	-80.0	-21.3	44.0	-65.2	EUT Horizontal
0.150	46.4	11.4	1.0	338.0	3.0	0.0	Perp to GND	PK	-80.0	-22.2	44.1	-66.2	EUT Horizontal



Testing was performed using the mode(s) of operation and configuration(s) noted within the report. The individuals and/or the organization requesting the test provided the modes, configurations and settings used to complete the evaluation. The actual test parameters are specified in the test data, this includes items such as investigated frequency range (scanned) and test levels. The testing methods and performance specifications, as well as the test site used for the evaluation are indicated in the test data. The test data represents the configuration / operating mode/ model that produced the highest emission levels as compared to the specification limit.

MODES OF OPERATION

Continuous transmit, modulated at 175 kHz

POWER SETTINGS INVESTIGATED

Battery

CONFIGURATIONS INVESTIGATED

MDTR0304 - 1

FREQUENCY RANGE INVESTIGATED

Start Frequency 9 kHz Stop Frequency 1000 MHz

SAMPLE CALCULATIONS

Radiated Emissions: Field Strength = Measured Level + Antenna Factor + Cable Factor - Amplifier Gain + Distance Adjustment Factor + External Attenuation

TEST EQUIPMENT

Description	Manufacturer	Model	ID	Last Cal.	Interval
Pre-Amplifier	Miteq	AM-1616-1000	PAD	5/20/2013	12 mo
 Antenna, Bilog	Teseq	CBL 6141B	AYD	12/17/2013	12 mo
 MN05 Cables	ESM Cable Corp.	Bilog Cables	MNH	5/20/2013	12 mo
 Antenna, Loop	ETS Lindgren	6502	AOB	2/20/2013	24 mo
Spectrum Analyzer	Agilent	N9010A	AFI	1/27/2013	24 mo

MEASUREMENT BANDWIDTHS

Frequency Range (MHz)	Peak Data (kHz)	Quasi-Peak Data (kHz)	Average Data (kHz)
0.01 - 0.15	1.0	0.2	0.2
0.15 - 30.0	10.0	9.0	9.0
30.0 - 1000	100.0	120.0	120.0
Above 1000	1000.0	N/A	1000.0

TEST DESCRIPTION

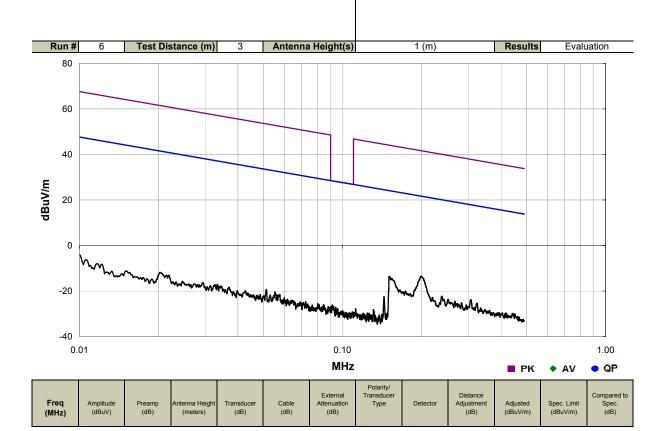
The antennas to be used with the EUT were tested. The EUT was continuously transmitting while set to the channel specified. While scanning, emissions from the EUT were maximized by rotating the EUT, adjusting the measurement antenna height and orientation in 3 orthogonal planes, the EUT and/or associated antenna is positioned in 3 orthogonal planes (per ANSI C63.10). An active loop antenna was used for this test in order to provide sufficient measurement sensitivity.

For measurements below 30 MHz, as outlined in 15.209(e) and 15.31(f)(2), measurements may be performed at a distance closer than what is specified with the limit. The limit at the specified distance is shown on the data sheet. Measurements are made at a closer distance and the data is adjusted using a distance correction factor of 40dB/decade for comparison to the limit.

If there are no detectable emissions above the noise floor, the data included will show noise floor measurements for reference only.



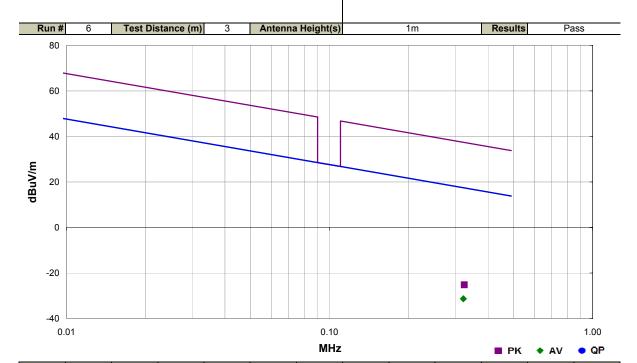
Work Order:	MDTR0304	Date:	01/13/14									
Project:	None	Temperature:	24.5 °C									
Job Site:	MN05	Humidity:	17.3% RH									
Serial Number:	LJP125207P	Barometric Pres.:	Barometric Pres.: 1003.2 mbar Tested by: Trevor Buls									
EUT:	9538/9539 Patient As	9538/9539 Patient Assistant										
Configuration:	1											
Customer:	Medtronic, Inc.											
Attendees:	Girad Guillaume											
EUT Power:	Battery											
Operating Mode:	Continuous transmit, modulated at 175 kHz											
Deviations:	None											
	Span set wide enough to encompass the entire emissions enveloupe. EUT Vertical. Device operates between 150-200 kHz, FSK modulated at 175 kHz.											
Test Specifications			Test Meth	od								
FCC 15.209:2014			ANSI C63.	10:2009								





Work Order:	MDTR0304	Date:	01/13/14	20							
Project:	None	Temperature:	24.5 °C	Trevor Buls							
Job Site:	MN05	Humidity:	17.3% RH	Drevo C o suce							
Serial Number:	LJP125207P	Barometric Pres.:	1003.2 mbar	Tested by: Trevor Buls							
EUT:	9538/9539 Patient As	sistant									
Configuration:	1										
Customer:	Medtronic, Inc.	Medtronic, Inc.									
Attendees:	Girad Guillaume										
EUT Power:	3attery										
Operating Mode:	Continuous transmit, modulated at 175 kHz										
Deviations:	None										
	Span set wide enough to encompass the entire emissions enveloupe. EUT Vertical. Device operates between 150-200 kHz, FSK modulated at 175 kHz.										
Test Specifications			Test Meth	od							

FCC 15.209:2014

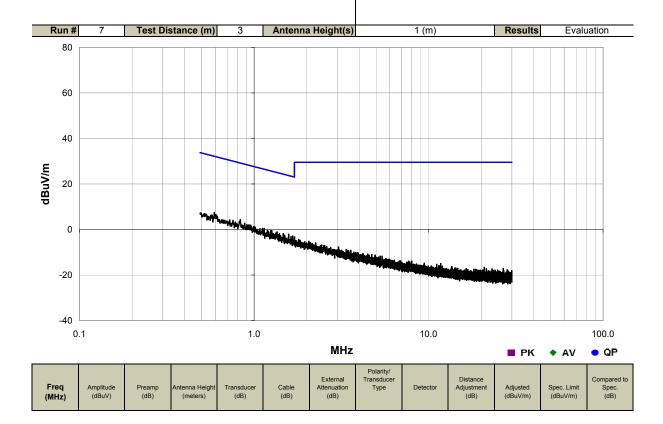


Freq (MHz)	Amplitude (dBuV)	Factor (dB)	Antenna Height (meters)	Azimuth (degrees)	Test Distance (meters)	External Attenuation (dB)	Polarity/ Transducer Type	Detector	Distance Adjustment (dB)	Adjusted (dBuV/m)	Spec. Limit (dBuV/m)	Compared to Spec. (dB)
0.323	37.3	11.4	1.0	114.0	3.0	0.0	Par to EUT	AV	-80.0	-31.3	17.4	-48.7
0.325	43.4	11.4	1.0	114.0	3.0	0.0	Par to EUT	PK	-80.0	-25.2	37.4	-62.6



Work Order:	MDTR0304	Date:	01/13/14									
Project:	None	Temperature:										
Job Site:	MN05	Humidity:	Humidity: 17.3% RH									
Serial Number:	LJP125207P	Barometric Pres.:	1003.2 mbar	Tested by: Trevor Buls								
EUT:	9538/9539 Patient As	538/9539 Patient Assistant										
Configuration:	1											
Customer:	Medtronic, Inc.	/ledtronic, Inc.										
Attendees:	Girad Guillaume											
EUT Power:	attery											
Operating Mode:	Continuous transmit, modulated at 175 kHz											
Deviations:	None											
	Span set wide enough to encompass the entire emissions enveloupe. EUT Vertical. Device operates between 150-200 kHz, FSK modulated at 175 kHz.											
Test Specifications			Test Met	thod								

FCC 15.209:2014 ANSI C63.10:2009



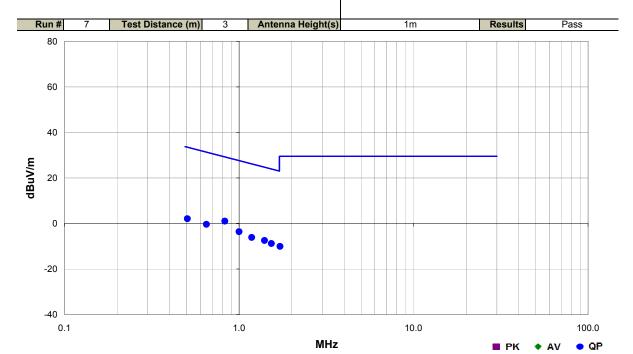


Work Order:	MDTR0304	Date:	01/13/14	0 0							
Project:	None	Temperature:	24.5 °C	Trevor Buls							
Job Site:	MN05	Humidity:	17.3% RH	spero C & siaz							
Serial Number:	LJP125207P	Barometric Pres.:	1003.2 mbar	Tested by: Trevor Buls							
EUT:	9538/9539 Patient As	sistant									
Configuration:	1										
Customer:	Medtronic, Inc.										
Attendees:	Girad Guillaume										
EUT Power:	Sattery										
Operating Mode:	Continuous transmit, modulated at 175 kHz										
Deviations:	None										
		Span set wide enough to encompass the entire emissions enveloupe. EUT Vertical. Device operates between 150-200 kHz, FSK modulated at 175 kHz.									

Test Specifications

FCC 15.209:2014

Test Method



Freq (MHz)	Amplitude (dBuV)	Factor (dB)	Antenna Height (meters)	Azimuth (degrees)	Test Distance (meters)	External Attenuation (dB)	Polarity/ Transducer Type	Detector	Distance Adjustment (dB)	Adjusted (dBuV/m)	Spec. Limit (dBuV/m)	Compared to Spec. (dB)
0.830	29.4	11.6	1.0	78.0	3.0	0.0	Par to EUT	QP	-40.0	1.0	29.2	-28.2
1.001	24.5	11.9	1.0	346.0	3.0	0.0	Par to EUT	QP	-40.0	-3.6	27.6	-31.2
0.506	30.5	11.6	1.0	115.0	3.0	0.0	Par to EUT	QP	-40.0	2.1	33.5	-31.4
0.651	28.1	11.5	1.0	349.0	3.0	0.0	Par to EUT	QP	-40.0	-0.4	31.3	-31.7
1.401	20.8	11.7	1.0	311.0	3.0	0.0	Par to EUT	QP	-40.0	-7.5	24.7	-32.2
1.183	22.0	11.8	1.0	321.0	3.0	0.0	Par to EUT	QP	-40.0	-6.2	26.2	-32.3
1.532	19.5	11.7	1.0	0.0	3.0	0.0	Par to EUT	QP	-40.0	-8.8	23.9	-32.7
1.717	18.3	11.6	1.0	216.0	3.0	0.0	Par to EUT	QP	-40.0	-10.1	29.5	-39.6