Medtronic Inc.

CTM2 Model 8880T2

Report No. MDTR0042.4

Report Prepared By



www.nwemc.com 1-888-EMI-CERT

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22975 NW Evergreen Parkway Suite 400 Hillsboro, Oregon 97124

Certificate of Test

Last Date of Test: December 16, 2011 Medtronic Inc.

Model: 8880T2

Emissions					
Test Description	Specification	Test Method	Pass/Fail		
Field Strength of Fundamental	FCC 15.209:2011	ANSI C63.10:2009	Pass		
Field Strength of Fundamental	RSS-210:2010	RSS-Gen:2010	Pass		
Spurious Emissions	FCC 15.209:2011	ANSI C63.10:2009	Pass		
Spurious Emissions	RSS-210:2010	RSS-Gen:2010	Pass		
Occupied Bandwidth	RSS-210:2010	RSS-Gen:2010	Pass		

Modifications made to the product

See the Modifications section of this report

Test Facility

The measurement facility used to collect the data is located at:

Northwest EMC, Inc. 9349 W Broadway Ave., Brooklyn Park, MN 55445

Phone: (763) 425-2281 Fax: (763) 424-3469

This site has been fully described in a report (Site filing #2834E-1). filed with and accepted by the FCC (Federal Communications Commission) and Industry Canada

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 06/29/09

Revision Number	Description	Date	Page Number
00	None		



Accreditations and Authorizations

FCC

Accredited by NVLAP for performance of FCC radio, digital, and ISM device testing. Our Open Area Test Sites, certification chambers, and conducted measurement facilities have been fully described in reports filed with the FCC and accepted by the FCC in letters maintained in our files. Northwest EMC has been accredited by ANSI to ISO / IEC Guide 65 as a product certifier. We have been designated by the FCC as a Telecommunications Certification Body (TCB). This allows Northwest EMC to certify transmitters to FCC specifications in accordance with 47 CFR 2.960 and 2.962.

NVLAP

Northwest EMC, Inc. is accredited under the National Voluntary Laboratory Accreditation Program (NVLAP) for satisfactory compliance with the requirements of ISO/IEC 17025 for Testing Laboratories. NVLAP is administered by the National Institute of Standards and Technology (NIST), an agency of the U.S. Commerce Department. The NVLAP accreditation encompasses Electromagnetic Compatibility Testing in accordance with the European Union EMC Directive 2004/108/EC, and ANSI C63.4. Additionally, Northwest EMC is accredited by NVLAP to perform radio testing in accordance with the European Union R&TTE Directive 1999/5/EEC, the requirements of FCC, and the RSS radio standards for Industry Canada.

Industry Canada

Accredited by NVLAP for performance of Industry Canada RSS and ICES testing. Our Open Area Test Sites and certification chambers comply with RSS-Gen, Issue 2 and have been filed with Industry Canada and accepted. Northwest EMC has been accredited by ANSI to ISO / IEC Guide 65 as a product certifier. We have been designated by NIST and recognized by Industry Canada as a Certification Body (CB) per the APEC Mutual Recognition Arrangement (MRA). This allows Northwest EMC to certify transmitters to Industry Canada technical requirements. (Site Filing Numbers - Hillsboro: 2834D-1, 2834D-2, Sultan: 2834C-1, Irvine: 2834B-1, 2834B-2, 2834B-3, Brooklyn Park: 2834E-1)

CAB

Designated by NIST and validated by the European Commission as a Conformity Assessment Body (CAB) to conduct tests and approve products to the EMC directive and transmitters to the R&TTE directive, as described in the U.S. - EU Mutual Recognition Agreement.

Australia/New Zealand

The National Association of Testing Authorities (NATA), Australia has been appointed by the ACA as an accreditation body to accredit test laboratories and competent bodies for EMC standards. Accredited test reports or assessments by competent bodies must carry the NATA logo. Test reports made by an overseas laboratory that has been accredited for the relevant standards by an overseas accreditation body that has a Mutual Recognition Agreement (MRA) with NATA are also accepted as technical grounds for product conformity. The report should be endorsed with the respective logo of the accreditation body (NVLAP).



Accreditations and Authorizations

VCCI

Accepted as an Associate Member to the VCCI, Acceptance No. 564. Conducted and radiated measurement facilities have been registered in accordance with Regulations for Voluntary Control Measures, Article 8. (Registration Numbers. - Hillsboro: C-1071, R-1025, G-84, C-2687, T-1658, and R-2318, Irvine: R-1943, G-85, C-2766, T-1659, and G-548, Sultan: R-871, G-83, C-3265, and T-1511, Brooklyn Park: R-3125, G-86, G-141, C-3464, and T-1634).

BSMI

Northwest EMC has been designated by NIST and validated by C-Taipei (BSMI) as a CAB to conduct tests as described in the APEC Mutual Recognition Agreement (US0017).

GOST

Northwest EMC, Inc. has been assessed and accredited by the Russian Certification bodies Certinform VNIINMASH, CERTINFO, SAMTES, and Federal CHEC, to perform EMC and Hygienic testing for Information Technology Products. As a result of their laboratory assessment, they will accept test results from Northwest EMC, Inc. for product certification

KCC

Northwest EMC, Inc is a CAB designated by MRA partners and recognized by Korea. (Assigned Lab Numbers: Hillsboro: US0017, Irvine: US0158, Sultan: US0157, Brooklyn Park: US0175)

VIETNAM

Vietnam MIC has approved Northwest EMC as an accredited test lab. Per Decision No. 194/QD-QLCL (dated December 15, 2009), Northwest EMC test reports can be used for Vietnam approval submissions.

SCOPE

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



Northwest EMC Locations





Oregon Labs EV01-EV12 22975 NW Evergreen Pkwy Suite 400 Hillsboro, OR 97124 (503) 844-4066 California Labs OC01-OC13 41 Tesla Irvine, CA 92618 (949) 861-8918 Minnesota Labs MN01-MN08 9349 W Broadway Ave. Brooklyn Park, MN 55445 (763) 425-2281 Washington Labs SU01-SU07 14128 339th Ave. SE Sultan, WA 98294 (360) 793-8675 New York Labs WA01-WA04 4939 Jordan Rd. Elbridge, NY 13060 (315) 685-0796







Rev 11/17/06

Party Requesting the Test

Company Name:	Medtronic Inc.
Address:	7000 Central Avenue NE
City, State, Zip:	Minneapolis, MN 55432
Test Requested By:	Paul Wood
Model:	8880T2
First Date of Test:	December 12, 2012
Last Date of Test:	December 16, 2012
Receipt Date of Samples:	December 12, 2012
Equipment Design Stage:	Production equivalent
Equipment Condition:	No Damage

Information Provided by the Party Requesting the Test

Functional Description of the EUT (Equipment Under Test):

The Clinician Telemetry Module (CTM2) provides a communication link from the Clinician Programmer (CP) to an Implanted Medical Device (IMD). The CTM2 provides a single telemetry module solution for use with the following telemetry types: TEL-M (Medical Implant Communications Service MICS Telemetry) connection to the Intellis IMD, TEL A/N (Proximal wakeup) connection to Intellis IMD and communication with the SM3 pump, Bluetooth connection to CP, and/or USB connection to CP. The CTM2 is a Battery operated device that will be used in a hospital environment by medical professionals.

Testing Objective:

To demonstrate compliance to FCC and IC requirements for the Inductive transmitter.

Configurations

Revision 9/21/05

CONFIGURATION 1 MDTR0042

EUT			
Description	Manufacturer	Model/Part Number	Serial Number
CTM2	Medtronic Inc.	8880T2	NKW001518N

Peripherals in test setup boundary					
Description Manufacturer Model/Part Number Serial Number					
NGCP	Medtronic Inc.	MICA-101	NKR001179N		
Power Brick	SINPRO	MPU64-106	S0138633		

Remote Equipment Outside of Test Setup Boundary						
Description Manufacturer Model/Part Number Serial Number						
Pump						

Cables							
Cable Type	Shield	Length (m)	Ferrite	Connection 1	Connection 2		
USB Programmer	Yes	1.8m	Yes	CTM2	NGCP		
AC Power	No	1.8m	No	Power Brick	AC Mains		
DC Power	No	1.3m	Yes	NGCP	Power Brick		
PA = Cable is perm	nanently attac	hed to the device. SI	hielding and/o	or presence of ferrite may	be unknown.		

CONFIGURATION 3 MDTR0042

EUT			
Description	Manufacturer	Model/Part Number	Serial Number
CTM2	Medtronic Inc.	8880T2	NKW001419N

Peripherals in test setup boundary					
Description Manufacturer Model/Part Number Serial Number					
NGCP	Medtronic Inc.	MICA-101	NKR001179N		
Power Brick	SINPRO	MPU64-106	S0138633		

Remote Equipment Outside of Test Setup Boundary						
Description Manufacturer Model/Part Number Serial Number						
Pump						

Cables					
Cable Type	Shield	Length (m)	Ferrite	Connection 1	Connection 2
USB Programmer	Yes	1.8m	Yes	CTM2	NGCP
AC Power	No	1.8m	No	Power Brick	AC Mains
DC Power	No	1.3m	Yes	NGCP	Power Brick
PA = Cable is perm	nanently attac	hed to the device. SI	hielding and/o	or presence of ferrite may	y be unknown.

Revision 4/28/03

	Equipment modifications						
Item	Date	Test	Modification	Note	Disposition of EUT		
1	12/12/2011	Field Strength of Fundamental	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	12/12/2011	Spurious 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.		
3	12/16/2011	Occupied Bandwidth	Tested as delivered to Test Station.	No EMI suppression devices were added or modified during this test.	Scheduled testing was completed.		



Spurious Emissions

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

Transmitting Tel A 175 kHz

POWER SETTINGS INVESTIGATED

Battery

CONFIGURATIONS INVESTIGATED

MDTR0042 - 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	ID Last Cal.				
Pre-Amplifier	Miteq	AM-1616-1000	AVY	7/1/2011	12 mo			
Antenna, Biconilog	ETS Lindgren	3142D	AXN	12/30/2009	24 mo			
MN05 Cables	ESM Cable Corp.	Bilog Cables	MNH	2/2/2011	12 mo			
Antenna, Loop	ETS Lindgren	6502	AOB	2/9/2011	24 mo			
Spectrum Analyzer	Agilent	E4446A	AAT	2/15/2011	12 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				

Measurements were made using the IF bandwidths and detectors specified. No video filter was used, except in the case of the FCC Average Measurements above 1GHz. In that case, a peak detector with a 10Hz video bandwidth was used.

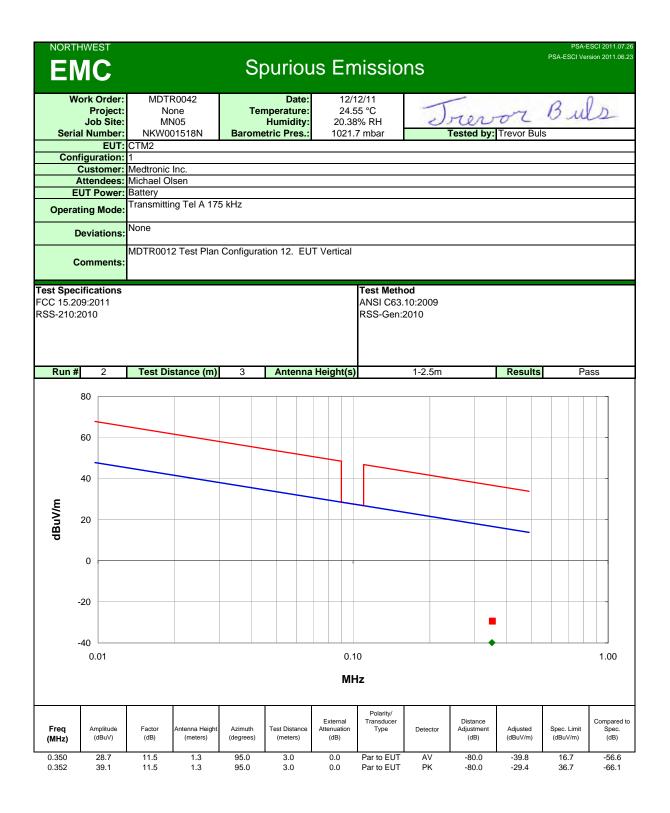
MEASUREMENT UNCERTAINTY

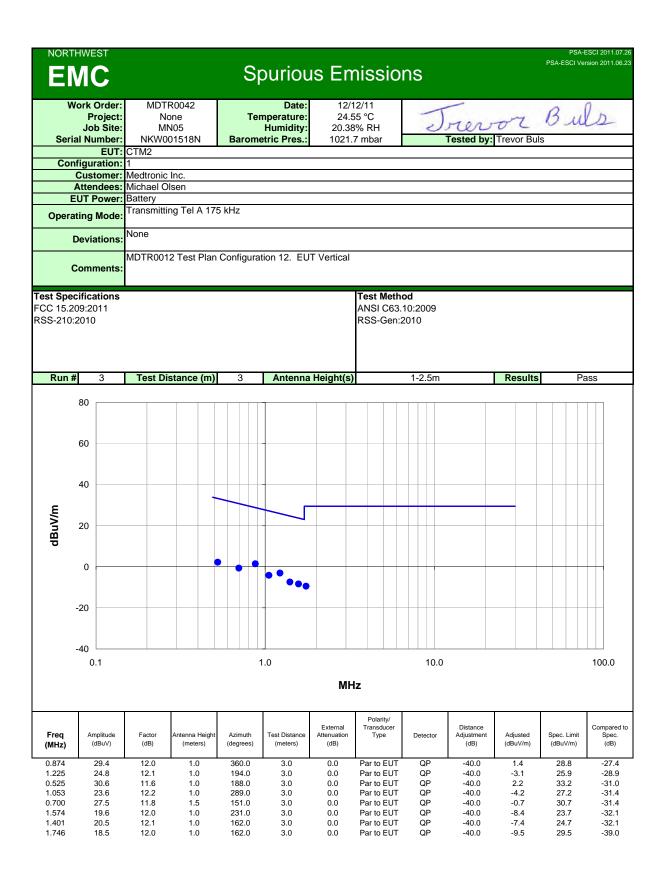
When a measurement is made, the result will be different from the true or theoretically correct value. The difference is the result of tolerances in the measurement system that cannot be completely eliminated. To the extent that technology allows us, it has been our aim to minimize this error. Measurement 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) (Frequency Strength: +/- 4.00) for each test is on each data sheet. 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.

TEST DESCRIPTION

The antennas to be used with the EUT were tested. The EUT was transmitting and receiving while set at the channel available. While scanning, emissions from the EUT were maximized by rotating the EUT, adjusting the measurement antenna height and orientation in 3 orthogonal plane, and manipulating the EUT antenna in 3 orthogonal planes (per ANSI C63.10:2009). An active loop antenna was used for this test in order to provide sufficient measurement sensitivity.







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

Transmitting Tel A 175 kHz

POWER SETTINGS INVESTIGATED

Battery

CONFIGURATIONS INVESTIGATED

MDTR0042 - 1

FREQUENCY RANGE INVESTIGATED Start Frequency 9 kHz Stop Frequency 315 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	2/2/2011	12 mo
Antenna, Loop	ETS Lindgren	6502	AOB	2/9/2011	24 mo
Spectrum Analyzer	Agilent	E4446A	AAT	2/15/2011	12 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				

Measurements were made using the IF bandwidths and detectors specified. No video filter was used, except in the case of the FCC Average Measurements above 1GHz. In that case, a peak detector with a 10Hz video bandwidth was used.

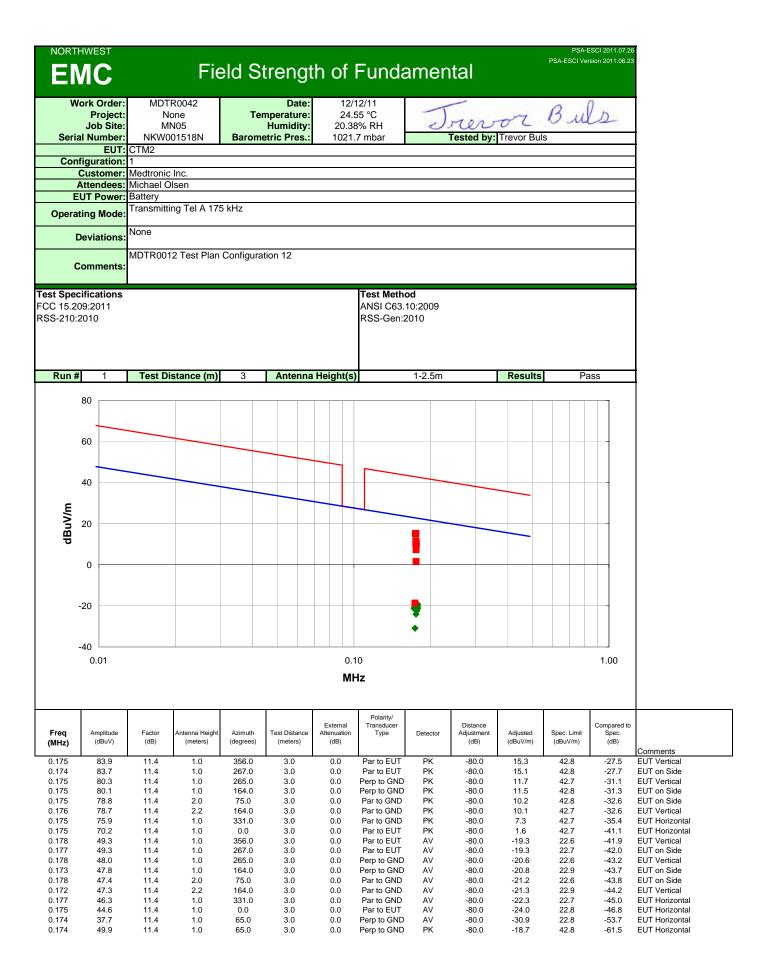
MEASUREMENT UNCERTAINTY

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) (Frequency Strength: +/- 4.00) for each test is on each data sheet. 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.

TEST DESCRIPTION

The antennas to be used with the EUT were tested. The EUT was transmitting and receiving while set at the channel available. While scanning, emissions from the EUT were maximized by rotating the EUT, adjusting the measurement antenna height and orientation in 3 orthogonal plane, and manipulating the EUT antenna in 3 orthogonal planes (per ANSI C63.4:2009). An active loop antenna was used for this test in order to provide sufficient measurement sensitivity.



Occupied Bandwidth

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.

TEST EQUIPMENT							
	Description	Manufacturer	Model	ID	Last Cal.	Interval	
	MN04 Cables	ESM Cable Corp.	MN04 Horn Cables	MNE	5/18/2011	12	
Γ	Antenna, Loop	ETS Lindgren	6502	AOB	2/9/2011	24	
	Spectrum Analyzer	Agilent	E4443A	AAS	3/17/2011	12	

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) (Frequency Accuracy: +0.12/-0.01) for each test is on each data sheet. 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.

TEST DESCRIPTION

The 99% occupied bandwidth was measured with the EUT configured for continuous modulated operation at its lowest, middle, and highest transmit frequency in a no-hop mode. The spectrum analyzer's resolution bandwidth was set to between 1% and 3% of the 20dB bandwidth and the video bandwidth was at least 3 times the resolution bandwidth. A peak detector was used to more accurately measure the emissions envelope.

NORTHWEST EMC		Occupied	Bandwidth			XMit 2011.10.26 PsaTx 2011.09.28
EUT:	CTM2			Work Order:	MDTR0042	
Serial Number:					12/16/11	
	Medtronic Inc.			Temperature:		
Attendees:				Humidity:		
Project:				Barometric Pres.:		
	Trevor Buls	Power: Batte		Job Site:	MN04	
TEST SPECIFICATI	ONS	Test I	Method			
RSS-210:2010	,	RSS-	Gen :2010			
COMMENTS						
	an Configuration 12. Transmitting Tel A at 175 kHz					
DEVIATIONS FROM	I TEST STANDARD					
None						
Configuration #	3 Signature	Trevor 1	3 uls			
Channel				Value	Limit	Result
Mid				16.3089 kHz	N/A	N/A



