PCTEST ENGINEERING LABORATORY, INC.
6660-B Dobbin Road, Columbia, MD 21045 USA
Tel. 410.290.6652 / Fax 410.290.6554
http://www.pctestlab.com

Certificate of Compliance
FCC Part 95 and EN 301 839-2

Applicant Name:
Medtronic Inc.
7000 Central Ave.
Minneapolis, MN 55432

Date of Testing:
May 7-8 and May 18, 2007
Test Site/Location:
PCTEST Lab., Columbia, MD, USA
Test Report Serial No.:
0703090168.MED

TRADE NAME/MODEL:	**CONSULTA CRT-D**
U.S. RESPONSIBLE PARTY:	**MEDTRONIC INC.**
Address:	**7000 CENTRAL AVE.** **MINNEAPOLIS, MN 55432**

SUMMARY:

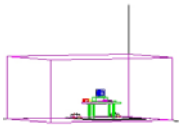
EUT Type:	Ultra Low Power Active Medical Implant Device (ULP-AMI)
Trade Name:	Medtronic
Applicable Standard(s):	EN 301 839-1 V1.1.1 (2007-04) EN 301 839-2 V1.1.1 (2007-04) FCC Part 95, Subpart I
EUT Description:	Implantable Defibrillator
Model(s):	CONSULTA CRT-D
FCC ID:	LF5MICSIMPLANT2
Tx Frequency Range:	402.15 – 404.85 MHz
Output Power:	2.04×10^{-7} Watts
Modulation:	FSK
Emission Designator:	193KF1D

This equipment has been shown to be capable of compliance with the applicable technical standards as indicated in the measurement report and was tested in accordance with the measurement procedures specified in each of the listed applicable standards.

I attest to the accuracy of data. All measurements reported herein were performed by me or were made under my supervision and are correct to the best of my knowledge and belief. I assume full responsibility for the completeness of these measurements and vouch for the qualifications of all persons taking them.

Randy Ortanez
President

TABLE OF CONTENTS



MEASUREMENT REPORT
EN 301 839-1, EN 301 839-2 and Part 95(I)

APPLICANT:	Medtronic Inc.
APPLICANT ADDRESS:	7000 Central Ave.
	Minneapolis, MN 55432
TEST SITE:	PCTEST ENGINEERING LABORATORY, INC.
TEST SITE ADDRESS:	6660-B Dobbin Road, Columbia, MD 21045 USA
Applicable Standard(s):	EN 301 839-1 V1.1.1, EN 301 839-2 V1.1.1, FCC Part 95(I)
EUT Description:	Implantable Defibrillator
FCCID:	LF5MICSIMPLANT2
Model(s):	CONSULTA CRT-D
Tx Frequency Range:	402.15 – 404.85 MHz
Test Device Serial No.:	PY2600974S ☐ Pre-production ☒ Production ☐ Engineering
DATE(S) OF TEST:	May 7-8 and May 18, 2007
TEST REPORT S/N:	

Test Facility / Accreditations

Measurements were performed at PCTEST Engineering Lab. located in Columbia, MD 21045, U.S.A.

- PCTEST facility is an FCC registered (PCTEST Reg. No. 90864) test facility with the site description report on file and has met all the requirements specified in Section 2.948 of the FCC Rules and Industry Canada (IC-2451).
- PCTEST Lab is accredited to ISO 17025 by U.S. National Institute of Standards and Technology (NIST) under the National Voluntary Laboratory Accreditation Program (NVLAP Lab code: 100431-0) in EMC, FCC and Telecommunications.
- PCTEST Lab is accredited to ISO 17025-2005 by the American Association for Laboratory Accreditation (A2LA) in Specific Absorption Rate (SAR) testing, Hearing Aid Compatibility (HAC) testing, CTIA Test Plans, and wireless testing for FCC and Industry Canada Rules.

- PCTEST Lab is a recognized U.S. Conformity Assessment Body (CAB) in EMC and R&TTE (n.b. 0982) under the U.S.-EU Mutual Recognition Agreement (MRA).
- PCTEST TCB is a Telecommunication Certification Body (TCB) accredited to ISO/IEC Guide 65 by the American National Standards Institute (ANSI) in all scopes of FCC Rules and Industry Canada Standards (RSS).
- PCTEST facility is an IC registered (IC-2451) test laboratory with the site description on file at Industry Canada.
- PCTEST is a CTIA Authorized Test Laboratory (CATL) for AMPS, CDMA, and EvDO wireless devices and for Over-the-Air (OTA) Antenna Performance testing for AMPS, CDMA, GSM, GPRS, EGPRS, UMTS (W-CDMA), CDMA 1xEVDO, and CDMA 1xRTT.

1.0 INTRODUCTION

1.1 Evaluation Procedure

Measurements of the Electromagnetic compatibility and Radio spectrum Matters (ERM) were performed in accordance with the procedures defined in EN 301 839-2 and EN 301 839-1 and in accordance with FCC Part 95, Subpart I. These measurements were performed to show conformity with the essential requirements of article 3.2 of the R&TTE Directive and FCC requirements.

1.2 Scope

The testing was performed to show conformity with the essential requirements of article 3.2 of the R&TTE Directive along with the requirements as specified in FCC Part 95, Subpart I. Testing performed included radiated emissions testing.

1.3 Testing Facility

These measurements were conducted at the PCTEST Engineering Laboratory, Inc. facility in New Concept Business Park, Guilford Industrial Park, Columbia, Maryland. The site address is 6660-B Dobbin Road, Columbia, MD 21045. The test site is one of the highest points in the Columbia area with an elevation of 390 feet above mean sea level. The site coordinates are 39° 11'15" N latitude and 76° 49'38" W longitude. The facility is 1.5 miles North of the FCC laboratory, and the ambient signal and ambient signal strength are approximately equal to those of the FCC laboratory. There are no FM or TV transmitters within 15 miles of the site. The detailed description of the measurement facility was found to be in compliance with the requirements of § 2.948 according to ANSI C63.4-2003 on January 27, 2006 and Industry Canada.

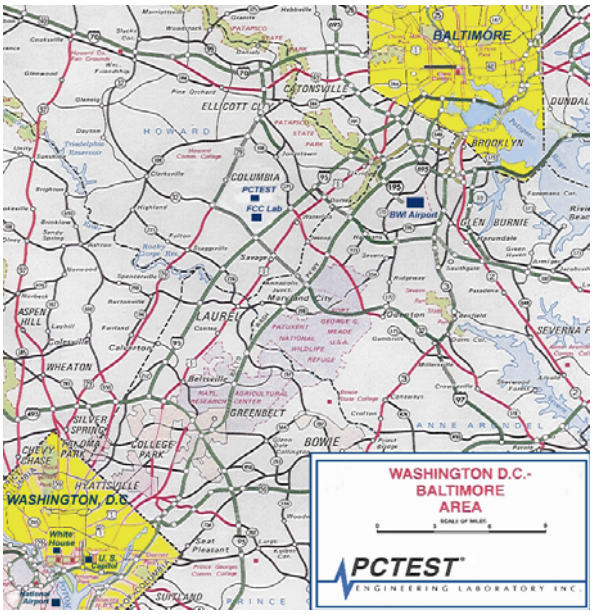


Figure 1-1. Map of the Greater Baltimore and Metropolitan Washington, D.C. area.

2.0 PRODUCT INFORMATION

2.1 Equipment Description

The Equipment Under Test (EUT) is the Medtronic Inc. Implantable Cardiac Defibrillator (ICD) Model Consulta CRT-D. The device operates on the frequency of 402.15 – 404.85 MHz. Per EN 301 839-2 the device is classified as an Ultra Low Power Active Medical Implant (ULP-AMI).

2.2 EMI Suppression Device(s)/Modifications

No EMI suppression device(s) were added and no modifications were made to the device during testing.

2.3 Operation and Test Configuration

During testing the device was setup by the programmer at the low, middle, or high channel of operation to provide continuous heart rhythm therapy. For emissions testing the device was fitted with a normal set of leads. All testing was performed with the ICD in the human torso simulator and tissue material as directed in Annex A of EN 301 839-1 and the FCC Rules.

3.0 DESCRIPTION OF TESTS

The following tests were performed in accordance with EN 301 839-2 and EN 301 839-1.

- ☑ Frequency Error, Section 4.2.2
- ☑ Emission Bandwidth, Section 4.2.3
- ☑ Effective Radiated Power of Fundamental Emission, Section 4.2.4
- ☑ Spurious Emissions (of transmitter), Section 4.2.5
- ☑ Spurious Radiation of Receivers, Section 4.2.7

Tests not listed above were not evaluated and are not reported herein. The testing performed above is also applicable to the requirements for the FCC Part 95(I).

3.1 Frequency Error

The frequency error, also known as frequency drift, is the difference between the nominal frequency as measured on the device under test and under normal test conditions and the frequency under extreme conditions.

The limit on frequency stability in the band 402 – 405 MHz shall not exceed +/- 100ppm.

3.2 Emission Bandwidth

The emission bandwidth of a ULP-AMI or ULP-AMI-P device is measured as the width of the signal between the points on either side of carrier centre frequency that are 20 dB down relative to the maximum level of the modulated carrier. Compliance is determined using instrumentation employing a peak detector function and a resolution bandwidth approximately equal to 1 % of the emission bandwidth of the EUT.

A spectrum analyzer setup per the method described in Section 8.2.1.1 of EN 301 839-1 was used to measure the 20dB bandwidth of the ULP-AMI. The maximum permissible emission bandwidth is 300kHz. All out of band emissions outside the band defined by the emission bandwidth shall be attenuated by at least 20dB.

3.3 Effective Radiated Power of the Fundamental Emissions

The effective radiated power is the power radiated within the emission bandwidth of the EUT in the direction of the maximum level under specified conditions of measurements in the presence of modulation or without modulation as appropriate and is limited to a maximum of 25 uWatts.

To measure the ERP of the device the unit was placed in the torso simulator filled with the simulated tissue as prescribed in Annex A of EN 301 839-1. The torso simulator and EUT were placed on the test site and the method of measurement as given in Section 8.3.1.1 was used in measuring the ERP level of the fundamental emission. This level is recorded for the low, mid, and high frequency of operation.

3.4 Spurious Emissions

Spurious emissions are emissions at frequencies other than those of the carrier and sidebands associated with normal test modulation.

The EUT was tested for spurious emissions while operating at the low, mid, and high frequencies of operation. Where spurious emissions were detected the substitution method described in Section 8.4.1.1 was used for measuring the emission. Emissions were scanned up to 4GHz or the tenth harmonic of the operating frequency.

The power in the reference bandwidth of any spurious emission shall not exceed the following values given in Table 3-1 or the level in Part 95 of the FCC rules whichever is lower.

State	47 MHz to 74 MHz 87,5 MHz to 118 MHz 174 MHz to 230 MHz 470 MHz to 862 MHz	Other frequencies below 1 000 MHz	Frequencies above 1 000 MHz
Operating	4 nW	250 nW	1 µW
Standby	2 nW	2 nW	20 nW

Table 3-1. Spurious Emission Limits

3.5 Spurious Radiation (Receiver)

The device was tested in accordance with the spurious radiation requirements of Section 9.1 of EN 301 839-1 and Part 15 of the FCC rules whichever was lower. Spurious radiations from the receiver are components at any frequency, generated and radiated by active receiver circuitry from the antenna and enclosure.

The spurious emissions were measured as described in Section 9.1.1.1 of EN 301 839-1. The limit on spurious emissions shall not exceed 2nW below 1 GHz and 20nW above 1 GHz or the limits in Subpart B or Part 15 of the FCC rules.

.

4.0 TEST EQUIPMENT CALIBRATION DATA

Test Equipment Calibration is traceable to the National Institute of Standards and Technology (NIST).

Manufacturer	Model / Equipment	Calibration Date	Cal Interval	Calibration Due	Serial No.
Agilent	HP 85650A Quasi-Peak Adapter	12/21/06	Annual	12/21/07	2043A00301
Agilent	HP 8449B (1-26.5GHz) Pre-Amplifier	12/12/06	Annual	12/12/07	3008A00985
Agilent	HP 11713A Attenuation/Switch Driver	12/12/06	Annual	12/12/07	N/A
Agilent	HP 85685A (20Hz-2GHz) Preselector	12/12/06	Annual	12/12/07	N/A
Agilent	HP 8566B Opt. 462 Impulse Bandwidth	12/12/06	Annual	12/12/07	3701A22204
EMCO	3115 (1-18GHz) Horn Antenna	08/25/05	Biennial	08/25/07	9205-3874
Compliance Design	A100 Roberts Dipoles	08/31/05	Biennial	08/31/07	5118
EMCO	Dipole Pair	09/21/06	Biennial	09/20/08	23951
SOLAR	8012-50 LISN (2)	11/18/05	Biennial	11/18/07	0313233, 0310234
K & L	11SH10 Band Pass Filter	N/A	Annual	N/A	1300/4000
K & L	11SH10 Band Pass Filter	N/A	Annual	N/A	4000/12000
Agilent	HP 8495A (0-70dB) DC-4GHz Attenuator	N/A		N/A	N/A
-	263-10dB (DC-18GHz) 10 dB Attenuator	N/A		N/A	N/A
Pasternack	PE2208-6 Bidirectional Coupler	N/A		N/A	N/A
-	No.165 (30MHz - 1000MHz) RG58 Coax Cable	N/A		N/A	N/A
-	No.166 (1000-26500MHz) Microwave RF Cable	N/A		N/A	N/A
-	No.167 (100kHz - 100MHz) RG58 Coax Cable	N/A		N/A	N/A
Rohde & Schwarz	NRVD Dual Channel Power Meter	12/11/06	Biennial	12/10/08	101695
Rohde & Schwarz	NRV-Z33 Peak Power Sensor (1mW-20W)	11/28/06	Biennial	11/27/08	100155
Rohde & Schwarz	NRV-Z32 Peak Power Sensor (100uW-2W)	12/21/06	Biennial	12/20/08	100004
EMCO	3116 Horn Antenna (18 - 40GHz)	09/25/05	Biennial	09/25/07	9203-2178

Table 4-1. Test Equipment

5.0 TEST RESULTS

5.1 Summary

Company Name: Medtronic Inc.

Classification: Ultra Low Power Active Medical Implant

Model: Consulta CRT-D

EN 301 839-1 Section(s)	FCC Part 95 (Rule Section)	Test Description	Test Condition	Test Result	Reference
4.2.2	§2.1055	Frequency Error	RADIATED	Pass	Section 5.2
4.2.3	§2.1049	Emission Bandwidth		Pass	Section 5.3
4.2.4	§2.1046	Effective Radiated Power of Fundamental Emission		Pass	Section 5.4
4.2.5	§2.1053	Spurious Emissions (of Transmitter)		Pass	Section 5.5
4.2.7	§15.109	Spurious Radiation of Receiver		Pass	Section 5.6

Table 5-1. Summary of Test Results

5.2 Frequency Error

As the EUT is a category IV ULP-AMI the frequency error is measured over the temperature range of +25 to +45 degree Celsius. The device was placed into a programmable environmental chamber and the method described in Section 8.1.1.2 was used to measure the frequency error. The frequency tolerance allowed for the EN 301 839-1 and FCC Part 95 is 100 ppm.

The device was measured for reference at 37 degree C and then the temperature was set to each extreme for measuring the frequency variation. At each temperature the device was kept at the temperature to allow for the components of the unit to reach the temperature.

The following table lists the measurements for the frequency stability testing.

OPERATING FREQUENCY:	403,350,000		Hz
CHANNEL:	Mid		
REFERENCE VOLTAGE:	3.2V	(100%)	VDC
DEVIATION LIMIT:	100 ppm	40335	Hz

VOLTAGE (%)	TEMP (ºC)	FREQ. (Hz)	Freq. Dev. (Hz)	Deviation (%)
100 %	+ 37 (Ref)	403,350,000	0.00	0.000000
100 %	25	403,351,080	-1,080.00	-0.000268
100 %	45	403,351,018	-1,018.00	-0.000252

Table 5-2: Frequency Stability Test Results

5.3 Emission Bandwidth

The following plot shows the emission bandwidth of the Medtronic Inc. Consulta CRT-D. The plot shows that the emission bandwidth is less than the 300 kHz limit as specified in Section 8.2.2 of the EN 301 839-1 and the FCC Part 95 Rules. The 20dB bandwidth was measured at 192.5kHz.

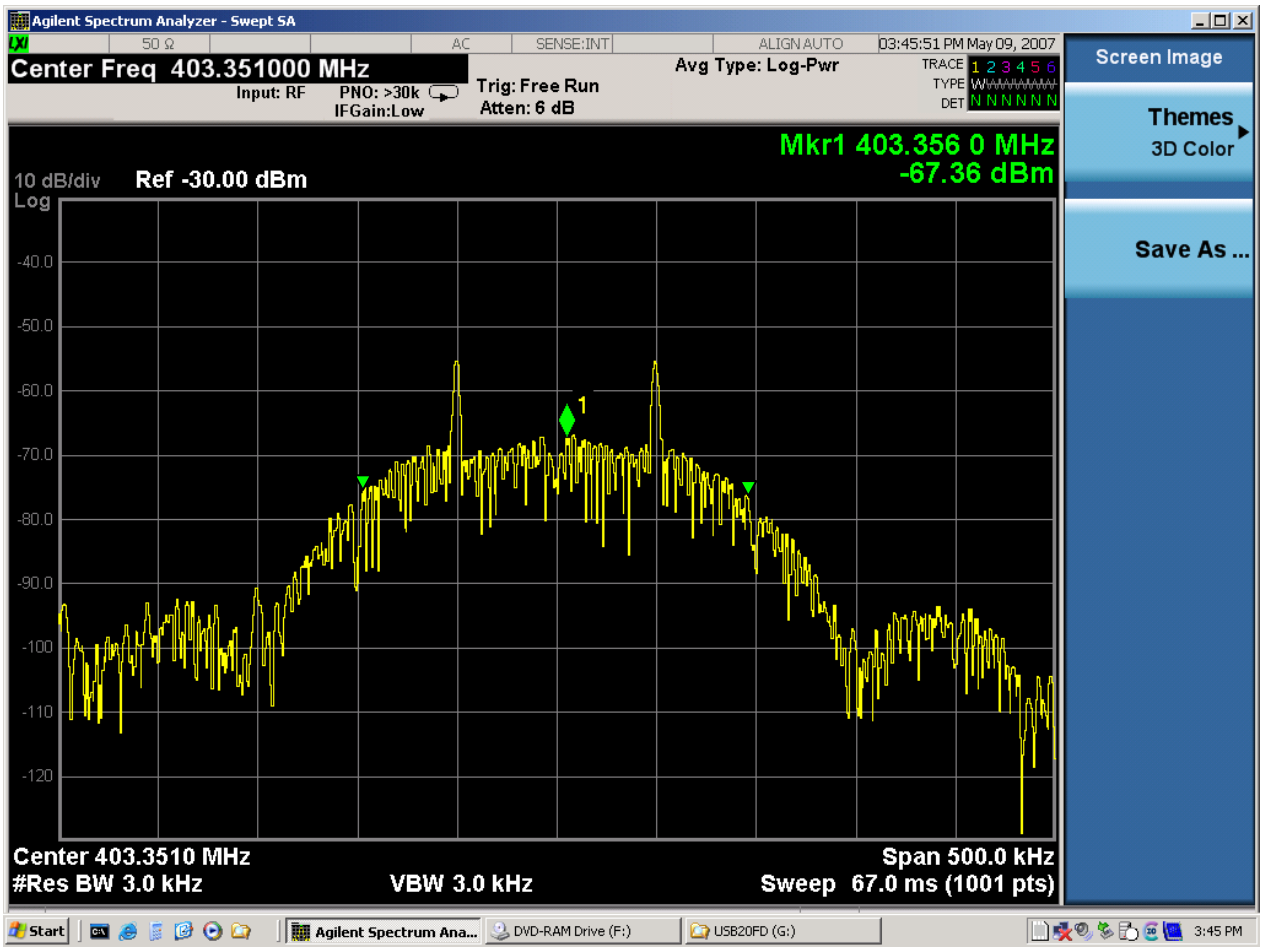


Figure 2: Occupied Bandwidth Plot

5.4 Effective Radiated Power of Fundamental Emission

Frequency [MHz]	Pol [H/V]	Azimuth [Degree]	Measured Level [dBm]	Substitute Level [dBm]	Antenna Gain [dBd]	ERP [dBm]	ERP [mWatts]
402.15	V	0.0	-65.430	-36.03	-1.65	-37.68	0.00017
403.35	V	0.0	-65.020	-35.62	-1.65	-37.27	0.00019
404.85	V	0.0	-64.650	-35.25	-1.65	-36.90	0.00020

Table 5-3. Effective Radiated Power Output Data

NOTES:

Effective Radiated Power Output Measurements by Substitution Method according to ANSI/TIA/EIA-603-C-2004, Aug. 17, 2004 and EN 301 839-1:

The EUT was placed in the torso simulator with the simulated tissue material on a wooden turn table 3-meters from the receive antenna. The receive antenna height and turntable rotation was adjusted for the highest reading on the receive spectrum analyzer. A half-wave dipole was substituted in place of the EUT. This dipole antenna was driven by a signal generator and the level of the signal generator was adjusted to obtain the same receive spectrum analyzer reading. The conducted power at the terminals of the dipole was measured. The ERP or EIRP was recorded as appropriate.

5.5 Radiated Spurious Emissions

Spurious radiated emissions testing was performed on the EUT while operating. The device was programmed to operate at 403.35MHz and placed inside the human torso simulator that was filled with simulated tissue material. Emissions were scanned up to the 10th harmonic of the fundamental emission.

Field Strength of SPURIOUS Radiation - Transmitting

Frequency (MHz)	Polarity H/V	SA Level (dBm)	Ant. Corr. (dB/m)	Cable Corr. (dB)	Corr. Level (dBµV/m)	Corr. Level (µV/m)	Power (mW)	Margin (dB)
806.700	V	-102.8	21.4	1.9	27.5	23.7	1.68E-07	-18.5
1210.000	V	-107.3	25.2	3.0	27.9	24.8	1.85E-07	-26.1
1612.000	V	-105.5	26.5	4.2	32.2	41.0	5.04E-07	-22.0
2016.880	H	-110.1	27.6	5.1	29.6	30.2	2.74E-07	-24.3

Table 5-4. Radiated Spurious Data – Mid Channel

NOTES:

1) No spurious emissions were detected.

2) All recorded levels are ambient readings.

3) Emissions testing was performed up to the 10th harmonic of the fundamental frequency.

Radiated Spurious Emission Measurements by Substitution Method according to ANSI/TIA/EIA-603-C-2004, Aug. 17, 2004:

The EUT was placed in the torso simulator with the simulated tissue material on a wooden turn table 3-meters from the receive antenna. The receive antenna height and turntable rotation was adjusted for the highest reading on the receive spectrum analyzer. A half-wave dipole was substituted in place of the EUT. This dipole antenna was driven by a signal generator and the level of the signal generator was adjusted to obtain the same receive spectrum analyzer reading. This spurious level was recorded. For readings above 1GHz, the above procedure is repeated using horn antennas and the difference between the gain of the horn and an isotropic or dipole antenna are taken into consideration.

5.6 Radiated Spurious Emissions - Receiver

Receiver spurious emissions were also measured. The device was placed into the torso simulator and the radiated spurious emissions were measured up to 4GHz.

Field Strength of SPURIOUS Radiation - Receiver

FREQ [MHz]	LEVEL [dBm]	Antenna Factor [dBm]	Cable Loss [dBm]	AFCL [dBm]	POL [H/V]	Field Strength [dBmV/m]	Field Strength [uV/m]	Limit [uV/m]	Limit [dBuV/m]	Margin [dB]
30	-104.9	10.70	0.31	11.01	V	13.1	4.53	100	40.000	-26.9
200	-104.4	10.60	0.88	11.48	V	14.1	5.06	150	43.522	-29.4
402.15	-102.9	15.10	1.30	16.40	V	20.5	10.60	200	46.021	-25.5
804.712	-104.37	21.55	1.83	23.38	V	26.0	19.97	200	46.021	-20.0
1206.16	-105	25.56	2.31	27.87	V	29.9	31.15	500	53.979	-24.1
1608.6	-104.75	29.90	2.69	32.60	V	34.8	55.24	500	53.979	-19.1

Table 5-5. Radiated Spurious Data – Receiver Mode

NOTES:

1) No spurious radiations were detected during the receiver mode testing.

2) All recorded levels are ambient readings during band scans.

3) Only field strength levels are recorded as no emissions were detected.

Radiated Spurious Emission Measurements by Substitution Method according to ANSI/TIA/EIA-603-C-2004, Aug. 17, 2004:

The EUT was placed in the torso simulator with the simulated tissue material on a wooden turn table 3-meters from the receive antenna. The receive antenna height and turntable rotation was adjusted for the highest reading on the receive spectrum analyzer. A half-wave dipole was substituted in place of the EUT. This dipole antenna was driven by a signal generator and the level of the signal generator was adjusted to obtain the same receive spectrum analyzer reading. This spurious level was recorded. For readings above 1GHz, the above procedure is repeated using horn antennas and the difference between the gain of the horn and an isotropic or dipole antenna is taken into consideration.

6.0 CONCLUSION

The data collected show that the Medtronic Inc. Consulta CRT-D Implantable Defibrillator complies with the tests evaluated for EN 301 839-1 and EN 301 839-2 and FCC Part 95, Subpart I.