LS Research, LLC
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ENGINEERING TEST REPORT # 312122 B
LSR Job #: C-1479

Compliance Testing of:
Medtronic PAIN External NeuroStimulator (ENS)

Test Date(s):
June 5th to 19th 2012

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

In accordance with:
RSS-GEN
&
CFR 47 15.109

This Test Report is issued under the Authority of:
Khairul Aidi Zainal, Senior EMC Engineer

Signature: Date:9/11/12

Test Report Reviewed by:
Peter Feilen, EMC Engineer

Signature: Date: 8/7/12

Project Engineer:
Khairul Aidi Zainal, Senior EMC Engineer

Signature: Date:7/29/12

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EXHIBIT 1. INTRODUCTION

1.1 SCOPE

References:	RSS-GEN Section 6 CFR 47 15.109
Title:	General Requirements and Information for the Certification of Radiocommunication Equipment
Purpose of Test:	To gain IC and FCC Certification Authorization for a Digital Device operated in Receive Mode
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

1.2 NORMATIVE REFERENCES

Publication	Title
RSS-Gen Issue 3	Spectrum Management and Telecommunications Radio Standards Specification
CFR 47 Part 15	Radio Frequency devices
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.

1.3 LS Research, LLC TEST FACILITY

LS Research, LLC is accredited by A2LA (American Association for Laboratory Accreditation) to conform 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.

1.4 LOCATION OF TESTING

All testing was performed at LS Research, LLC, W66 N220 Commerce Court, Cedarburg, Wisconsin, 53012 USA, utilizing the facilities listed below, unless otherwise noted.

List of Facilities Located at LS Research, LLC:

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

1.5 TEST EQUIPMENT UTILIZED

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 in accordance with A2LA standards.

EXHIBIT 2. PERFORMANCE ASSESSMENT

2.1 CLIENT INFORMATION

Manufacturer Name:	**Medtronics**
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:	97725
Serial Number:	NLJ002306N

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.

2.4 EUT'S TECHNICAL SPECIFICATIONS

Additional Information:

Frequency Range (in MHz)	2402MHz to 2480MHz
Operating Voltage	3.0 VDC
Receiver Sensitivity	-74.5 dBm
Highest Frequency	9912 MHz
Receiver Spurious (worst case at 3m)	27.95dBµV/m at 946MHz (Noise Floor)
EUT will be operated under FCC part(s) and IC Rule	IC: RSS-GEN FCC: CFR 47 part 15
Portable/Mobile	☒ Portable ☐ Mobile
Modular Filing	☐ Yes ☒ No

2.5 PRODUCT DESCRIPTION

Neurostimulation therapy for chronic, intractable pain consists of electrical stimulation that interferes with the perception of pain by replacing the sensation of pain with the sensation of tingling/paresthesia. The function of the neurostimulation system is accomplished with a power source (neurostimulator), lead extension (depending on neurostimulation system used), and one or more leads. Mild electrical stimulation generated from the neurostimulator is transmitted through the lead to stimulate the targeted structure through electrodes located on the distal end of the lead. The neurostimulator parameters can be non-invasively adjusted by the physician via a clinician programmer. Patients can adjust stimulation within parameters that are determined and pre-set by the physician. The External Neurostimulator (ENS) device is used for screening patients to assess efficacy in a patient without having to undergo a full system implant. The existing device that performs this screening process will be replaced by the new ENS, along with accompanying components such as a clinician programmer and patient controller. The ENS provides a means to connect up to two (2), eight-conductor (8) extensions or two (2) eight-conductor (8) leads of 0.110 in connector spacing, up to four (4), four-conductor (4) extensions or four (4), four-conductor (4) leads of 0.170 in connector spacing. Upon identifying the ideal lead location for the intraoperative screening procedure in which the ENS would be used, the patient would go home wearing the ENS for a period of time to try out the therapy. The ENS is attached to the patient via surgical tape or an optional boot accessory that is taped to the body and holds the ENS in place via a pocket. This at-home screening period typically lasts five (5) to seven (7) days and up to thirty (30) days in some markets outside the United States. The ENS has similar stimulation capabilities to the Intellis (also known as the RS2) Implantable Neurostimulator, which is being developed in parallel to the ENS. The ENS has new features compared to the existing ENS such as constant current output, wireless telemetry with the clinician and patient programmers, and field steering capability.

EXHIBIT 3. EUT OPERATING CONDITIONS & CONFIGURATIONS DURING TESTS

3.1 CLIMATE TEST CONDITIONS

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

3.2 APPLICABILITY & SUMMARY OF EMC EMISSION TEST RESULTS

RSS Paragraph	Test Requirements	Compliance (yes/no)
7.2.2	Power Line Conducted Emissions Measurements	N/A
6	Un-Intentional Radiated Emissions	Yes

CFR 47 Part 15 section	Test Requirements	Compliance (yes/no)
107	Power Line Conducted Emissions Measurements	N/A
109	Un-Intentional Radiated Emissions	Yes

3.3 MODIFICATIONS INCORPORATED IN THE EUT FOR COMPLIANCE PURPOSES

☒ **None** ☐ **Yes (explain below)**

3.4 DEVIATIONS & EXCLUSIONS FROM TEST SPECIFICATIONS

☒ **None** ☐ **Yes (explain below)**

EXHIBIT 4. DECLARATION OF CONFORMITY

The EUT was found to MEET the requirements as described within the specification of Industry Canada RSS-Gen, Issue 3 and RSS-210, Issue 8 (2010) for non-intentional radiators.

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.

EXHIBIT 5. RADIATED EMISSIONS TEST

5.1 Test Setup

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 receive 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 Setup Photo(s) – Radiated Emissions Test

This Section is not available

5.3 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.

5.4 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 an IEC/ISO 17025 accredited calibration laboratory, 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 resolution bandwidths as prescribed in ANSI C63.4.

5.5 Test Results

The EUT was found to **MEET** the Radiated Emissions requirements of Canada RSS GEN, RSS-210 and CFR 47 Part 15 sections 109. The frequencies with significant RF signal strength were recorded and plotted as shown in the Data Charts and Graphs.

5.6 CALCULATION OF RADIATED EMISSIONS LIMITS

The following table depicts the Class **B** limits for an unintentional radiator. These limits are obtained from RSS-Gen Section 6, Table 1, for radiated emissions measurements.

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 from field strength μV/m to dBμV/m:
$dB\mu V/m = 20 \log_{10} (100)$
= 40 dBμV/m (from 30-88 MHz)

For measurements made at 1.0 meter, a 9.5 dB correction has been invoked.

960 MHz to 10,000 MHz
500μV/m or 54.0 dB/μV/m at 3 meters
54.0 + 9.5 = 63.5 dB/μV/m at 1 meter

For measurements made at 0.3 meter, a 20 dB correction has been invoked.

960 MHz to 10,000 MHz
500μV/m or 54.0 dB/μV/m at 3 meters
54.0 + 20 = 74 dB/μV/m at 0.3 meters

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 (dBμV/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).

5.7 DATA CHART – RADIATED EMISSIONS TEST

Measurements of Electromagnetic Radiated Emissions
Frequency Range Inspected: 30 MHz to 25000MHz

Manufacturer:	Medtronic						
Date(s) of Test:	June 6th and 12th 2012						
Project Engineer:	Khairul Aidi Zainal						
Test Engineer(s):	Michael Hintzke						
Voltage:	3.0 VDC						
Operation Mode:	continuous receive						
Environmental Conditions in the Lab:	Temperature: 70-71° F Relative Humidity: 34-38 %						
EUT Power:		Single Phase 120 VAC		3 Phase ___VAC			
	X	Battery		Other:			
EUT Placement:	X	80cm non-conductive table		10cm Spacers			
EUT Test Location:	X	3 Meter Semi-Anechoic FCC Listed Chamber		3/10m OATS			
Measurements:		Pre-Compliance		Preliminary	X	Final	
Detectors Used:	X	Peak	X	Quasi-Peak	X	Average	

The following tables depicts the level of significant spurious radiated RF emissions found:

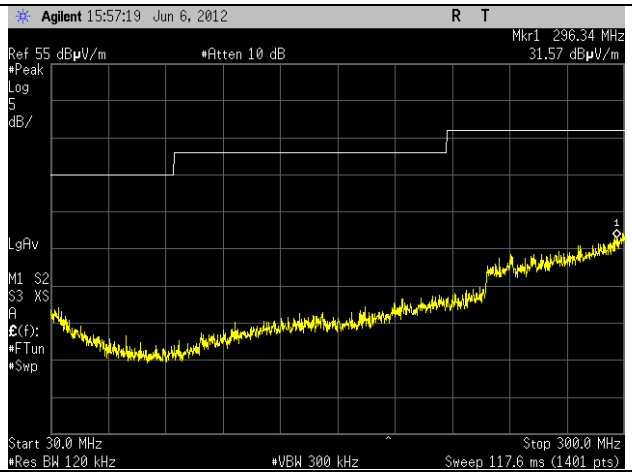
Frequency (MHz)	Height (m)	Azimuth (degree)	Reading (dBµV/m)	Reading (µV/m)	Limit (dBµV/m)	Margin (dB)	Antenna Polarity	EUT orientation
946.0	1.00	0	27.95	25.0	46.0	18.1	Vertical	Vertical
269.6	1.00	0	22.99	14.1	46.0	23.0	Horizontal	Flat
297.5	1.00	0	25.55	18.9	46.0	20.5	Vertical	Flat

Notes:
1. Measurements in the table are those of the measurement system noise floor. There were no significant emissions seen below 1000 MHz.
2. Measurements below 4000MHz were performed at 3 meters separation distance.

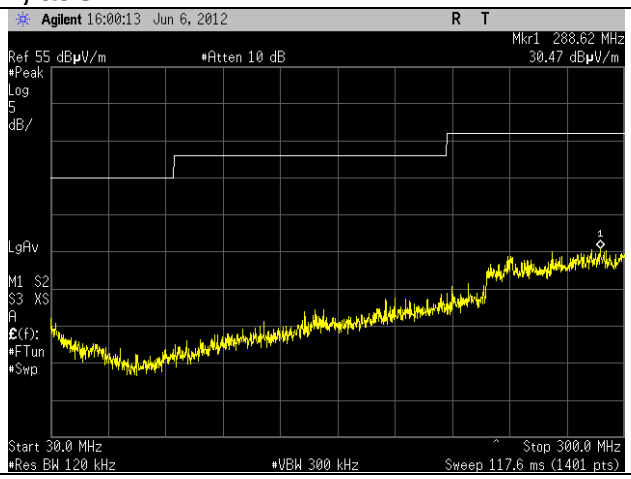
5.8 Screen Captures - Radiated Emissions Testing

These screen captures represent Peak Emissions. For radiated emission measurements, a Quasi-Peak detector function is utilized when measuring frequencies below 1 GHz, and a peak detector with video averaging is utilized when measuring frequencies above 1 GHz.

30-300 MHz, at 3m

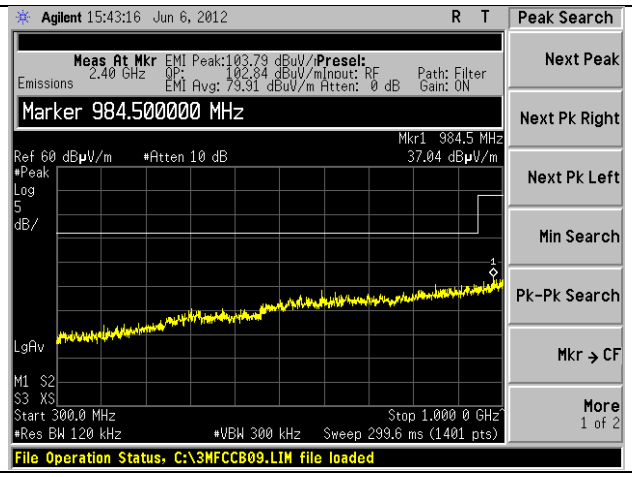


Horizontal

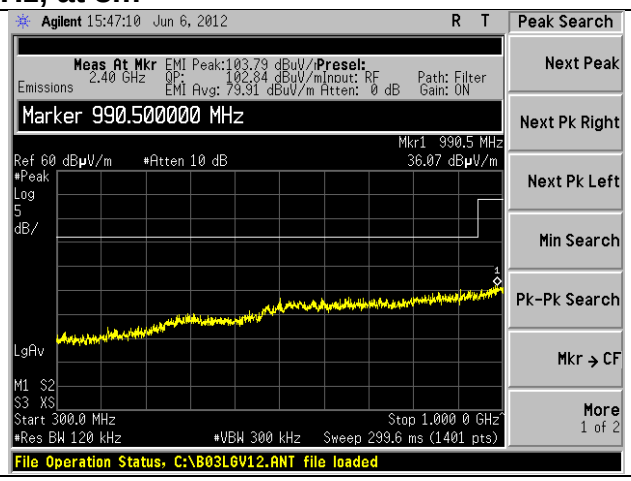


Vertical

300-1000 MHz, at 3m



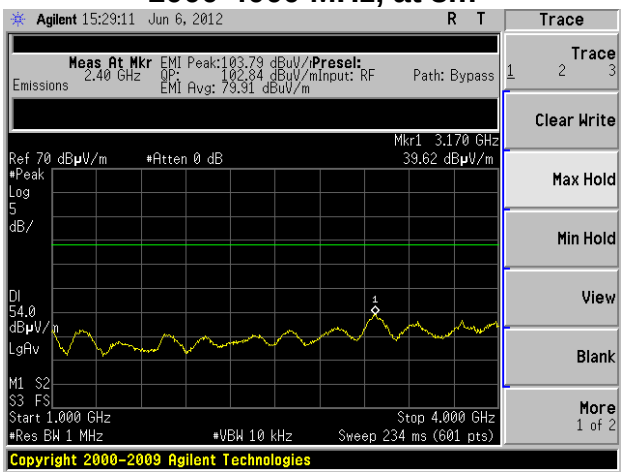
Horizontal



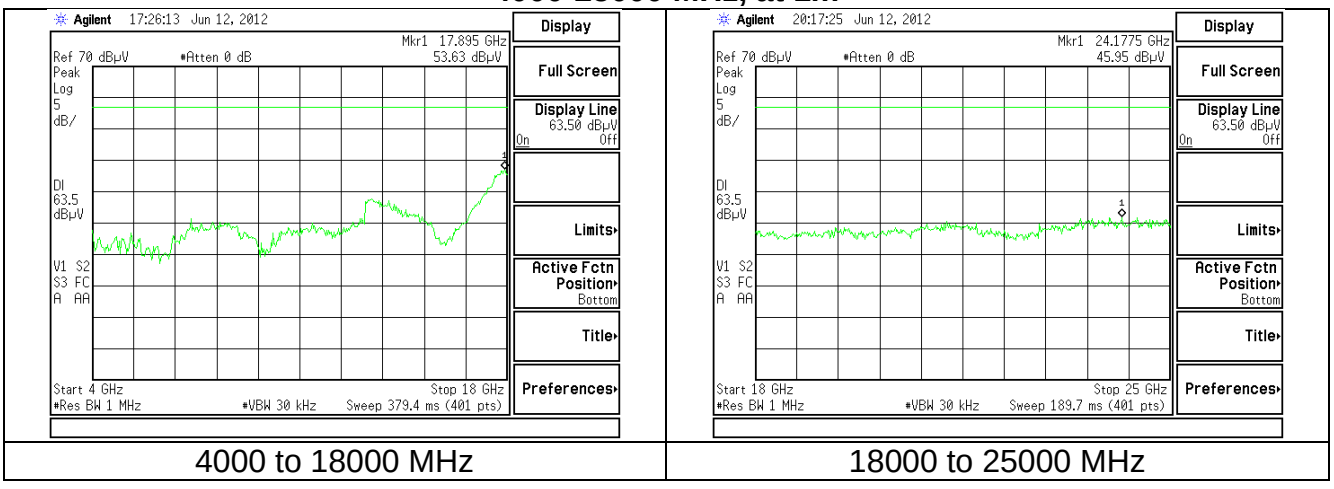
Vertical

Screen Captures - Radiated Emissions Testing *(continued)*

1000-4000 MHz, at 3m



4000-25000 MHz, at 1m



4000 to 18000 MHz	18000 to 25000 MHz

EXHIBIT 6. CONDUCTED EMISSIONS TEST, AC POWER LINE

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

APPENDIX A: Test Equipment List

LS RESEARCH LLC
Wireless Product Development
Equipment Calibration

Date : 5-Jun-2012 Type Test : Rad Measurements Job # : C-1479

Prepared By: AIDI Customer : Plexus Technology Group Quote #: 312122

No.	Asset #	Description	Manufacturer	Model #	Serial #	Cal Date	Cal Due Date	Equipment Status
1	EE 960157	3Hz-13.2GHz Spectrum Analyzer	Agilent	E4445A	MY48250225	6/11/2011	6/11/2012	Active Calibration
2	AA 960081	Double Ridge Horn Antenna	EMCO	3115	6907	1/6/2012	1/6/2013	Active Calibration
3	EE 960158	RF Preselecter	Agilent	N9039A	MY46520110	6/11/2011	6/11/2012	Active Calibration
4	EE 960073	Spectrum Analyzer	Agilent	E4446A	US45300564	5/9/2012	5/9/2013	Active Calibration
5	EE 960147	Pre-Amp	Adv. Micro	WLA612	123101	1/6/2012	1/6/2013	Active Calibration
6	AA 960081	Double Ridge Horn Antenna	EMCO	3115	6907	1/6/2012	1/6/2013	Active Calibration
7	AA 960153	2.4GHz High Pass Filter	KWM	HPF-L-14186	7272-04	3/5/2012	3/5/2013	Active Calibration
8	EE 960146	Std. Gain Horn Ant. w/preamp	Adv. Micro	WLA622-4	123001	11/3/2011	11/3/2012	Active Calibration
9	AA 960150	Bicon Antenna	ETS	3110B	0003-3346	11/15/2011	11/15/2012	Active Calibration
10	AA 960078	Log Periodic Antenna	EMCO	93146	9701-4855	11/15/2011	11/15/2012	Active Calibration
11	AA 960007	Double Ridge Horn Antenna	EMCO	3115	9311-4138	5/16/2012	5/16/2013	Active Calibration
12	EE 960013	EMI Receiver	HP	8546A System	3617A00320;3448A	11/22/2011	11/22/2012	Active Calibration
13	EE 960014	EMI Receiver-filter section	HP	85460A	3448A00296	11/22/2011	11/22/2012	Active Calibration

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

Appendix C: Uncertainty Statement

Measurement Type	Particular Configuration	Uncertainty Values
Radiated Emissions	*3 – Meter chamber, Biconical Antenna*	*4.82 dB*
Radiated Emissions	*3-Meter Chamber, Log Periodic Antenna*	*4.88 dB*
Radiated Emissions	*3-Meter Chamber, Horn Antenna*	*4.85 dB*
Radiated Emissions	*10-Meter OATS, Biconical Antenna*	*4.32 dB*
Radiated Emissions	*10-Meter OATS, Log Periodic Antenna*	*3.63 dB*
Absolute Conducted Emissions	*Agilent PSA/ESA Series*	*1.38 dB*
AC Line Conducted Emissions	*Shielded Room/EMCO LISN*	*3.20 dB*
Radiated Immunity	*3 Volts/Meter in 3-Meter Chamber*	*2.05 Volts/Meter*
Conducted Immunity	*3 Volts level*	*2.33 V*
EFT Burst, Surge, VDI	*230 VAC*	*54.4 V*
ESD Immunity	*Discharge at 15kV*	*3200 V*
Temperature/Humidity	*Thermo-hygrometer*	*0.64° / 2.88 %RH*

APPENDIX D – PLEXUS Instrument sheet.

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

Equipment Description	Plexus Identification Number
Breakout Board	BRKOUT_06
PAIN ENS	NLJ002306N
Bluetooth Dongle	BT_05
Conducted Measurement Cable	CM_CABLE_01
Quad Leads	BFT_LD_09 BFT_LD_10 BFT_LD_11 BFT_LD_12