TEST REPORT

FCC Part 15 Subpart C Section 15.209
IC RSS-210 Issue 8
IC RSS-Gen Issue 3

MANUFACTURER'S NAME	Medtronic Inc 710 Medtronic Parkway Minneapolis MN 55432
DESCRIPTION Patient	Reader
EUT/PRODUCT NAME	Patient Reader 25000
MODEL NUMBER TESTED	25000
SERIAL NUMBER TESTED	LJB000423A
TEST REPORT NUMBER	DM1312180.2 Rev A
TEST DATE(S)	28 March – 04 April 2014

TÜV SÜD America Inc, as an independent testing laboratory, declares that the equipment tested as specified above conforms to the applicable EMC requirements of FCC Part 15 Subpart C Section 15.209 "Radiated emission limits; general requirements" and Industry Canada RSS-210 Issue 8 "Licence-exempt Radio Apparatus (All Frequency Bands): Category I Equipment" and Industry Canada RSS-Gen Issue 3 "General Requirements and Information for the Certification of Radio Apparatus".

It is the manufacturer's responsibility to assure that additional production units of this model are manufactured with identical electrical and mechanical characteristics. Any modifications necessary for compliance made during testing on the above mentioned date(s) must be implemented in all production units for compliance to be maintained.

Issue Date: 23 April 2014

Greg S Jakubowski
EMC Test Engineer

Joel T Schneider
Senior EMC Engineer

Not Transferable

EMC TEST REPORT

Test Report No.	DM1312180.2 Rev A	Date of issue:	23 April 2014
Description	Patient Reader		
EUT/Product Name	Patient Reader 25000		
Model Number Tested	25000		
Serial Number Tested	LJB000423A		
Manufacturer	Medtronic Inc 710 Medtronic Parkway Minneapolis MN 55432		

Test Result ■ **Positive** ☐ **Negative**

TÜV SÜD America Inc reports apply only to the specific samples tested under stated test conditions. It is the manufacturer's responsibility to assure that additional production units of this model are manufactured with identical electrical and mechanical components. TÜV SÜD America Inc shall have no liability for any deductions, inferences or generalizations drawn by the client or others from TÜV SÜD America Inc issued reports.

This report is the confidential property of the client. As a mutual protection to our clients, the public and ourselves, extracts from the test report shall not be reproduced except in full without our written approval. TÜV SÜD America's Wild River Lab maintains A2LA accreditation to ISO/IEC 17025 for the specific tests listed in A2LA Certificate #2955.11 as an Electrical Testing Laboratory.

TÜV SÜD America Inc and its professional staff hold government and professional organization certifications and are members of AAMI, ACIL, AEA, ANSI, IEEE, NARTE, and VCCI.

REVISION RECORD

REVISION	TOTAL NUMBER OF PAGES	DATE	DESCRIPTION
	29	11 April 2014	Initial Release
A	29	23 April 2014	• Page 1 (and corresponding Test Result Summary): Per client request: o Added "Description: Patient Reader" o Updated "Equipment Description" to "EUT/Product Name" o Changed Model and Serial "No(s)" or "Number(s)" to "Number" • Appendix B: Updated EUT Description from "Patient Reader 25000" to "Patient Reader".

DIRECTORY

Contents

EMC TEST REGULATIONS:
The tests were performed according to the following regulations:
FCC Part 15 Subpart C §15.209
IC RSS-210 Issue 8
IC RSS-Gen Issue 3

ENVIRONMENTAL CONDITIONS IN THE LAB

Actual	
Temperature: :	19-20°C
Atmospheric pressure	: 98-99kPa
Relative Humidity	: 24%

POWER SUPPLY UTILIZED

Power supply system	:4.5 VDC

TEST EQUIPMENT
All measurement instrumentation is traceable to the National Institute of Standards and Technology and is calibrated according to internal procedure.

MEASUREMENT UNCERTAINTY
The test system for conducted emissions is defined as the LISN, tuned receiver or spectrum analyzer, and coaxial cable. The test system has a measurement uncertainty of ±1.8 dB. The test system for radiated emissions is defined as the antenna, the pre-amplifier, the spectrum analyzer and the coaxial cable. The test system has a measurement uncertainty of ±4.8 dB. All measurement instrumentation is traceable to the National Institute of Standards and Technology and is calibrated according to internal procedure.

SIGN EXPLANATIONS
☐ - not applicable
■ - applicable

General field strength limits 0.009 – 30 MHz

FCC 15.209(a), FCC 15.209(c), IC RSS-210 2.5, RSS-Gen 7.2.5

Test summary

The requirements are: ■ - MET ☐ - NOT MET
Testing was performed in accordance with the test procedure of ANSI C63.4 2009, clause 8.2.2.
No unwanted emissions exceed the level of the fundamental.

Test location

■ - Wild River Lab Large Test Site (Open Area Test Site)
☐ - Wild River Lab Small Test Site (Open Area Test Site)

Test distance

■ - 1 meters
■ - 3 meters
■ - 10 meter

Test equipment

TUV ID	Model	Manufacturer	Description	Serial	Cal Date	Cal Due
WRLE02418	6502	Electro-Mechanics (EMCO)	Loop Antenna	2215	16-Aug-13	16-Aug-14
WRLE03800	ESCS 30	Rohde & Schwarz	EMI Receiver 9kHz-6.5GHz	100312	02-Jan-14	02-Jan-15
WRLE10863	N/A	TÜV SÜD America Inc	Test Companion Software Version 3.4.71	N/A	Code Y	Code Y

Cal Code B = Calibration verification performed internally. Cal Code Y = Calibration not required when used with other calibrated equipment.

Test limit

Frequency (MHz)	Field strength μV/m	Measurement distance (m)
0.009-0.490	2400/F (kHz)	300
0.490 - 1.705	24000/F(kHz)	30
1.705 - 30	30	30

The emission limits shown in the above table are based on measurements employing a CISPR quasi-peak detector except for the frequency bands 9–90 kHz, 110–490 kHz and above 1000 MHz. Radiated emission limits in these three bands are based on measurements employing an average detector. The provisions in §§15.31, 15.33, and 15.35 for measuring emissions at distances other than the distances specified in the above table, determining the frequency range over which radiated emissions are to be measured, and limiting peak emissions apply to all devices operated under this part.

Test Data – 175 kHz fundamental

Frequency (MHz)	Field strength dBμV/m – 1m	Field strength dBμV/m – 3m	Field strength dBμV/m –10m	Field strength dBμV/m 300m	Field strength μV/m 300m	Limit μV/m 300m
0.175 (AV)	102.35	77.85	52.76 -6.32*		0.483*	13.71
0.175 (PK)	123.78	98.77	70.08	11*	3.55*	137.1
0.35 (AV)	47.66		7.66*	-51.42*	0.00269*	6.857
0.35 (PK)	72.41		32.41*	-26.67*	0.0464*	68.57
Frequency (MHz)	Field strength dBμV/m – 1m	Field strength dBμV/m – 3m	Field strength dBμV/m –10m	Field strength dBμV/m 30m	Field strength μV/m 30m	Limit μV/m 30m
0.525 (QP)	65.8			6.72*	2.17*	45.71
1.925 (QP)	50.84			-8.24*	0.387*	30
0.875 (QP)	48.03			-11.05*	0.28*	27.42
0.7 (QP)	47.16			-11.92*	0.254*	34.28

*extrapolated using 40 dB/decade falloff as indicated by measurements (59.08 dB from 10 to 300 meters)

Test Data – 150/200 kHz fundamental

Frequency (MHz)	Field strength dBμV/m – 1m	Field strength dBμV/m – 3m	Field strength dBμV/m –10m	Field strength dBμV/m 300m	Field strength μV/m 300m	Limit μV/m 300m
0.15 (AV)	99.75 74.82	49.15		-9.93*	0.319*	16
0.15 (PK)	108.07	83.94	67.19	8.11*	2.54*	160
0.2 (AV)	99.4	75.24	48.37	-10.71*	0.291*	12
0.2 (PK)	108.44	84.19	59.3	0.22*	1.03*	120
0.45 (AV)	51.08		11.08*	-48*	0.00398*	5.33
0.45 (PK)	61.08		21.08*	-38*	0.0126*	53.33
0.3 (AV)	50.32		10.32*	-48.76*	0.00365*	8
0.3 (PK)	65.61		25.61*	-33.47*	0.0212*	80
Frequency (MHz)	Field strength dBμV/m – 1m	Field strength dBμV/m – 3m	Field strength dBμV/m –10m	Field strength dBμV/m 30m	Field strength μV/m 30m	Limit μV/m 30m
0.6 (QP)	53.02			-6.06*	0.498*	40

*extrapolated using 40 dB/decade falloff as indicated by measurements (59.08 dB from 10 to 300 meters)

Data sheet

FREQ LEVEL	(dBuV)	CABLE / ANT / PREAMP / ATTEN (dB)	FINAL (dBuV / m)	POL / HGT / AZ (m)(DEG)	DELTA1	DELTA2
Telemetry A = 175 kHz, B = 150 & 200 kHz						
Determine highest fundamental field strength over 3 orthogonal axis						
Continuous telemetry A transmit mode						
3m distance						
DUT on its side edge						
DUT rotated 360 degrees						
Maximum level with the DUT's gray bottom parallel with measurement loop antenna						
175.0 kHz	67.11 Av	0.06 / 10.68 / 0.0 / 0.0	77.85	V / 1.00 / 0	n/a	n/a
175.0 kHz	88.03 Pk	0.06 / 10.68 / 0.0 / 0.0	98.77	V / 1.00 / 0	n/a	n/a
1m distance						
175.0 kHz	91.61 Av	0.06 / 10.68 / 0.0 / 0.0	102.35	V / 1.00 / 0	n/a	n/a
175.0 kHz	113.04 Pk	0.06 / 10.68 / 0.0 / 0.0	123.78	V / 1.00 / 0	n/a	n/a
10m						
175.0 kHz	42.02 Av	0.06 / 10.68 / 0.0 / 0.0	52.76	V / 1.00 / 0	n/a	n/a
175.0 kHz	59.34 Pk	0.06 / 10.68 / 0.0 / 0.0	70.08	V / 1.00 / 0	n/a	n/a
10m levels are ~9dB above the noise floor.						
Using theoretical 40dB per decade roll off (less than actual roll off of measured levels)						
Average limit = 22.7 dBuV/m @ 300m						
Peak limit = 42.7 dBuV/m @ 300m						
Telemetry B						
Maximum levels with the DUT on its side, parallel with the measurement loop antenna						
1m						
150.0 kHz	88.96 Av	0.05 / 10.75 / 0.0 / 0.0	99.75	V / 1.00 / 0	n/a	n/a
150.0 kHz	97.28 Pk	0.05 / 10.75 / 0.0 / 0.0	108.07	V / 1.00 / 0	n/a	n/a
200.0 kHz	88.72 Av	0.07 / 10.62 / 0.0 / 0.0	99.4	V / 1.00 / 0	n/a	n/a
200.0 kHz	97.76 Pk	0.07 / 10.62 / 0.0 / 0.0	108.44	V / 1.00 / 0	n/a	n/a
3m						
150.0 kHz	64.03 Av	0.05 / 10.75 / 0.0 / 0.0	74.82	V / 1.00 / 0	n/a	n/a
150.0 kHz	73.15 Pk	0.05 / 10.75 / 0.0 / 0.0	83.94	V / 1.00 / 0	n/a	n/a
200.0 kHz	64.56 Av	0.07 / 10.62 / 0.0 / 0.0	75.24	V / 1.00 / 0	n/a	n/a
200.0 kHz	73.51 Pk	0.07 / 10.62 / 0.0 / 0.0	84.19	V / 1.00 / 0	n/a	n/a
10m						
150.0 kHz	38.36 Av	0.05 / 10.75 / 0.0 / 0.0	49.15	V / 1.00 / 0	n/a	n/a
150.0 kHz	56.4 Pk	0.05 / 10.75 / 0.0 / 0.0	67.19	V / 1.00 / 0	n/a	n/a
200.0 kHz	37.69 Av	0.07 / 10.62 / 0.0 / 0.0	48.37	V / 1.00 / 0	n/a	n/a
200.0 kHz	48.62 Pk	0.07 / 10.62 / 0.0 / 0.0	59.3	V / 1.00 / 0	n/a	n/a

FREQ	LEVEL (dBuV)	CABLE / ANT / PREAMP / ATTEN (dB)	FINAL (dBuV / m)	POL / HGT / AZ (m)(DEG)	DELTA1	DELTA2
nf, DUT off						
150.0 kHz	35.34 Av	0.05 / 10.75 / 0.0 / 0.0	46.13	V / 1.00 / 0	n/a	n/a
150.0 kHz	48.06 Pk	0.05 / 10.75 / 0.0 / 0.0	58.85	V / 1.00 / 0	n/a	n/a
200.0 kHz	33.07 Av	0.07 / 10.62 / 0.0 / 0.0	43.75	V / 1.00 / 0	n/a	n/a
200.0 kHz	44.42 Pk	0.07 / 10.62 / 0.0 / 0.0	55.1	V / 1.00 / 0	n/a	n/a
150kHz fundamental						
40dB per decade roll off						
Average limit = 24.08 dBuV/m @ 300m						
Peak limit = 44.08 dBuV/m @ 300m						
200kHz fundamental						
Average limit = 21.58 dBuV/m @ 300m						
Peak limit = 41.58 dBuV/m @ 300m						
Begin spurious emissions scan, 9kHz - 30MHz						
Telemetry A						
1m distance						
harmonics						
350.0 kHz	62.08 Pk	0.1 / 10.23 / 0.0 / 0.0	72.41	V / 1.00 / 0	n/a	n/a
350.0 kHz	37.33 Av	0.1 / 10.23 / 0.0 / 0.0	47.66	V / 1.00 / 0	n/a	n/a
525.0 kHz	55.54 Qp	0.11 / 10.15 / 0.0 / 0.0	65.8	V / 1.00 / 0	n/a	n/a
700.0 kHz	36.82 Qp	0.12 / 10.21 / 0.0 / 0.0	47.16	V / 1.00 / 0	n/a	n/a
875.0 kHz	37.62 Qp	0.13 / 10.28 / 0.0 / 0.0	48.03	V / 1.00 / 0	n/a	n/a
1.925 MHz	39.97 Qp	0.2 / 10.67 / 0.0 / 0.0	50.84	V / 1.00 / 0	n/a	n/a
3m						
None of the previous emissions detected						
Telemetry B						
1m						
150kHz harmonics						
300.0 kHz	55.15 Pk	0.1 / 10.36 / 0.0 / 0.0	65.61	V / 1.00 / 0	n/a	n/a
300.0 kHz	39.86 Av	0.1 / 10.36 / 0.0 / 0.0	50.32	V / 1.00 / 0	n/a	n/a
450.0 kHz	50.85 Pk	0.11 / 10.12 / 0.0 / 0.0	61.08	V / 1.00 / 0	n/a	n/a
450.0 kHz	40.85 Av	0.11 / 10.12 / 0.0 / 0.0	51.08	V / 1.00 / 0	n/a	n/a
600.0 kHz	42.73 Qp	0.12 / 10.18 / 0.0 / 0.0	53.02	V / 1.00 / 0	n/a	n/a
200kHz harmonics						
No additional emissions detected						
3m						
None of the previous emissions detected						
Standby mode						
No significant emissions detected						

Radiated emissions in the frequency range of 10 kHz to 30 MHz, including the fundamental transmit signal, are measured using a receiver capable of quasi-peak/average/peak measurements and a magnetic loop antenna. The transmitter and loop antenna are rotated through 3 orthogonal axes in order to determine the maximum emission levels. If the signal cannot be measured at the specified limit distance, measurements are recorded at multiple distances nearer to the device and the final level mathematically extrapolated. Measurements between 150 kHz and 30 MHz are made with a 9 kHz resolution bandwidth. Measurements between 9 kHz and 150 kHz are made with a 200 Hz resolution bandwidth.

Radiated Emissions 30 - 1000 MHz

FCC 15.209(c), FCC 15.209(f), IC RSS-210 2.5, RSS-Gen 7.2.5

Test summary

The requirements are: ■ - MET ☐ - NOT MET
Testing was performed in accordance with the test procedure of ANSI C63.4 2009, clause 8.3.
No emissions were detected from the transmitter in this range.

Test location

Wild River Lab Large Test Site (Open Area Test Site)

Test distance

3 meters

Test Equipment

TUV ID	Model	Manufacturer	Description	Serial	Cal Date	Cal Due
WRLE03204	EM-6917B	Electro-Metrics	Biconicalog Periodic	102	30-May-13	30-May-14
WRLE11146	85650A	Hewlett-Packard	Quasi-Peak Adapter	2811A01299	04-Mar-14	04-Mar-15
WRLE03295	85662A	Hewlett-Packard	Analyzer Display	2349A06144	22-Apr-13	22-Apr-14
WRLE02689	8566B	Hewlett-Packard	Spectrum Analyzer	2416A00321	22-Apr-13	22-Apr-14
WRLE02670	8447D	Hewlett-Packard	Preamplifier	2443A03954	Code B 20-Jan-14	Code B 20-Jan-15
WRLE10527	SL18B4020	Phase One Microwave	Preamplifier 1 – 18 GHz	0001	Code B 23-Jan-14	Code B 23-Jan-15
WRLE10863	N/A	TÜV SÜD America Inc	Test Companion Software Version 3.4.71	N/A Cod	e Y	Code Y

Cal Code B = Calibration verification performed internally. Cal Code Y = Calibration not required when used with other calibrated equipment.

Limit

Frequency (MHz)	Field strength (μV/m)	Field strength (dBμV/m)	Measurement distance (m)
30 - 88	100	40	3
88 - 216	150	43.5	3
216 - 960	200	46	3
Above 960	500	54	3

The emission limits shown in the above tables are based on measurements employing a CISPR quasi-peak detector except for the frequency bands 9–90 kHz, 110–490 kHz and above 1000 MHz. Radiated emission limits in these three bands are based on measurements employing an average detector. When average radiated emission measurements are specified in this part, including average emission measurements below 1000 MHz, there also is a limit on the peak level of the radio frequency emissions. Unless otherwise specified, *e.g.*, see §§ 15.250, 15.252, 15.255, and 15.509–15.519, the limit on peak radio frequency emissions is 20 dB above the maximum permitted average emission limit applicable to the equipment under test. Radiated emissions from the EUT are measured in the frequency range of 30 to 1000 MHz using a spectrum analyzer and appropriate broadband linearly polarized antennas. Measurements between 30 MHz and 1000 MHz are made with a 120 kHz / 6 dB bandwidth and quasi-peak detection and measurements above 1000 MHz are made with a 1 MHz RBW/VBW / 6 dB bandwidth and peak detection, 1 MHz RBW/ 10 Hz VBW for average detection. Table top equipment is placed on a non-conductive support 80 cm above the ground plane. Interface cables that are closer than 40 centimeters to the ground plane are bundled in the center in a serpentine fashion so they are at least 40 centimeters from the ground plane. Cables to simulators/testers (if used in this test) are routed through the center of the table and to a screen room located outside the test area. The antenna is positioned 3, 10 or 30 meters horizontally from the EUT. To locate maximum emissions from the test sample the antenna is varied in height from 1 to 4 meters, measurement scans are made with both horizontal and vertical antenna polarizations and the EUT is rotated 360 degrees. When performing measurements at a distance other than that specified, the results shall be extrapolated to the specified distance using an extrapolation factor of 20 dB / decade (inverse linear-distance for field strength measurements).

Occupied bandwidth
RSS-Gen 4.6.1

Test summary
The requirements are: ■ - MET ☐ - NOT MET
Test was performed in accordance with the article “The Measurement of Occupied Bandwidth” by Industry Canada’s certification bureau.
Occupied bandwidth for 150 kHz = 25 Hz
Occupied bandwidth for 175 kHz = 4.62 kHz
Occupied bandwidth for 200 kHz = 29 Hz

Test location
■ - Wild River Lab Large Test Site (Open Area Test Site)
☐ - Wild River Lab Small Test Site (Open Area Test Site)

Test equipment

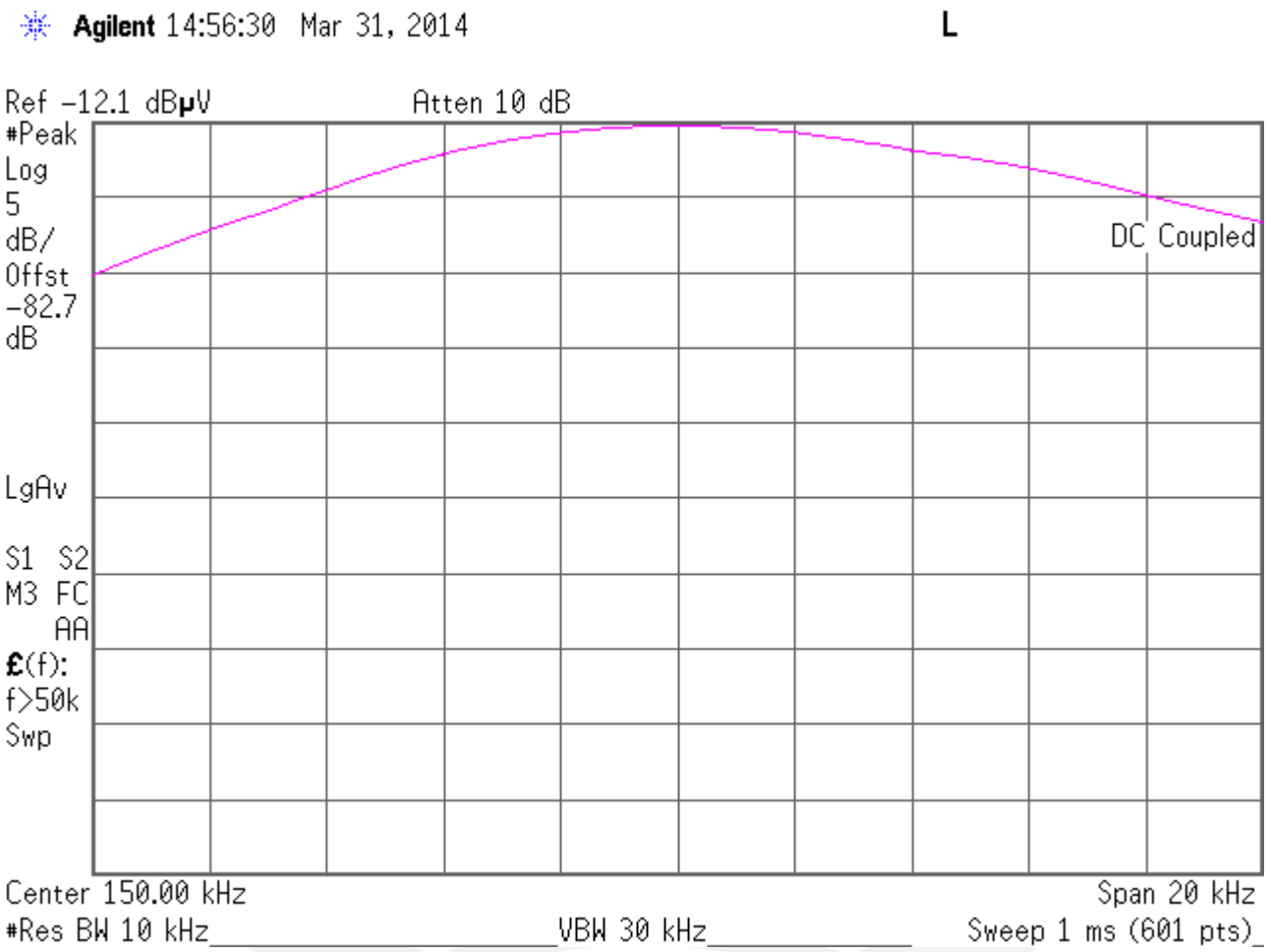
TUV ID	Model Number	Manufacturer	Description	Serial Number	Cal Date	Cal Due
WRLE02418	6502	Electro-Mechanics (EMCO)	Loop Antenna	2215	16-Aug-13	16-Aug-14
NBLE03367	E4440A	Agilent	Spectrum Analyzer	MY42510439	20-May-13	20-May-14
WRLE10863	N/A	TÜV SÜD America Inc	Test Comp anion Software Vers ion 3.4.71	N/A	Code Y	Code Y

Cal Code B = Calibration verification performed internally. Cal Code Y = Calibration not required when used with other calibrated equipment.

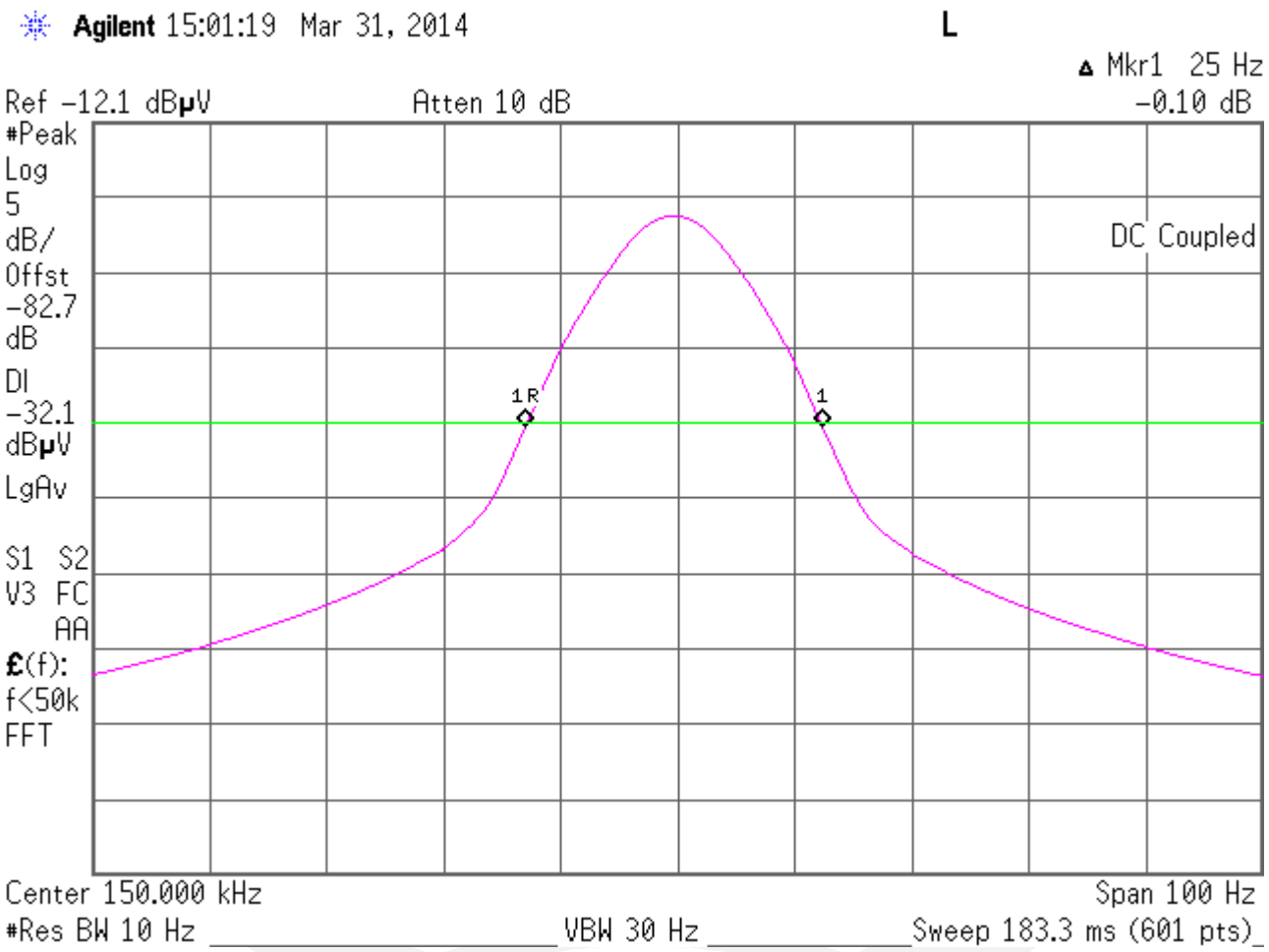
Test limit
Not specified

Test data
See following pages

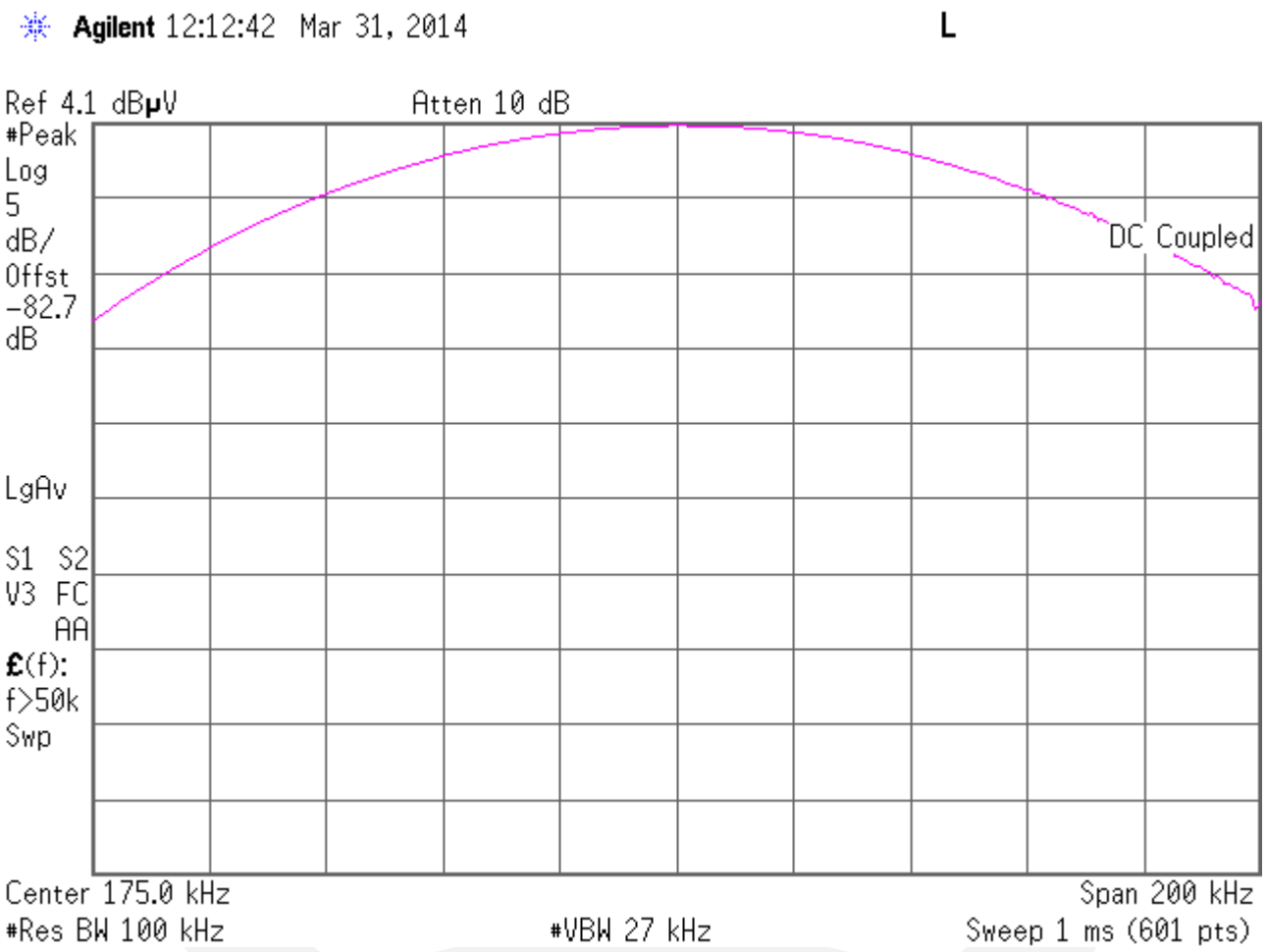
99% Occupied bandwidth
1 of 2



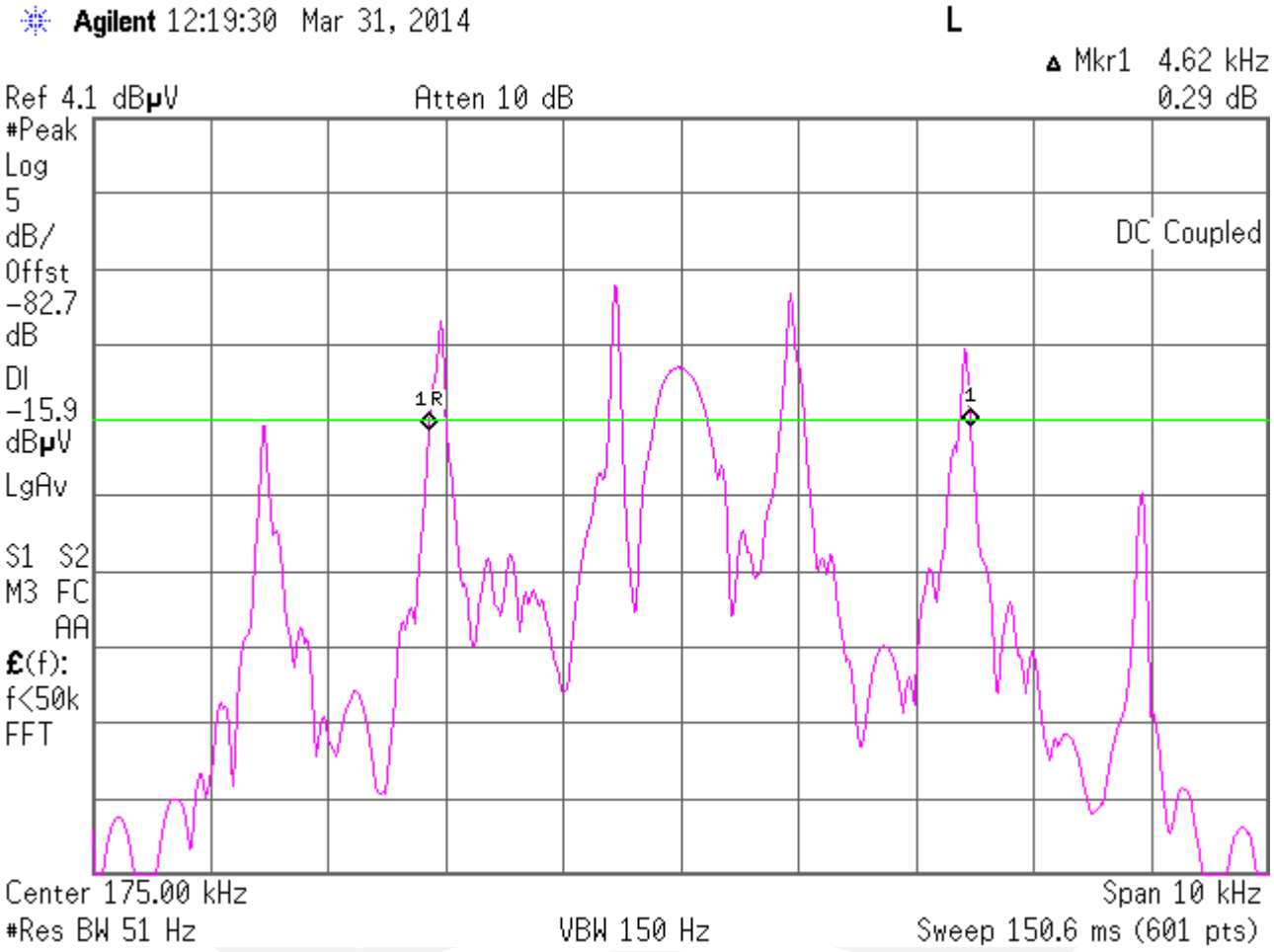
99% Occupied bandwidth
2 of 2



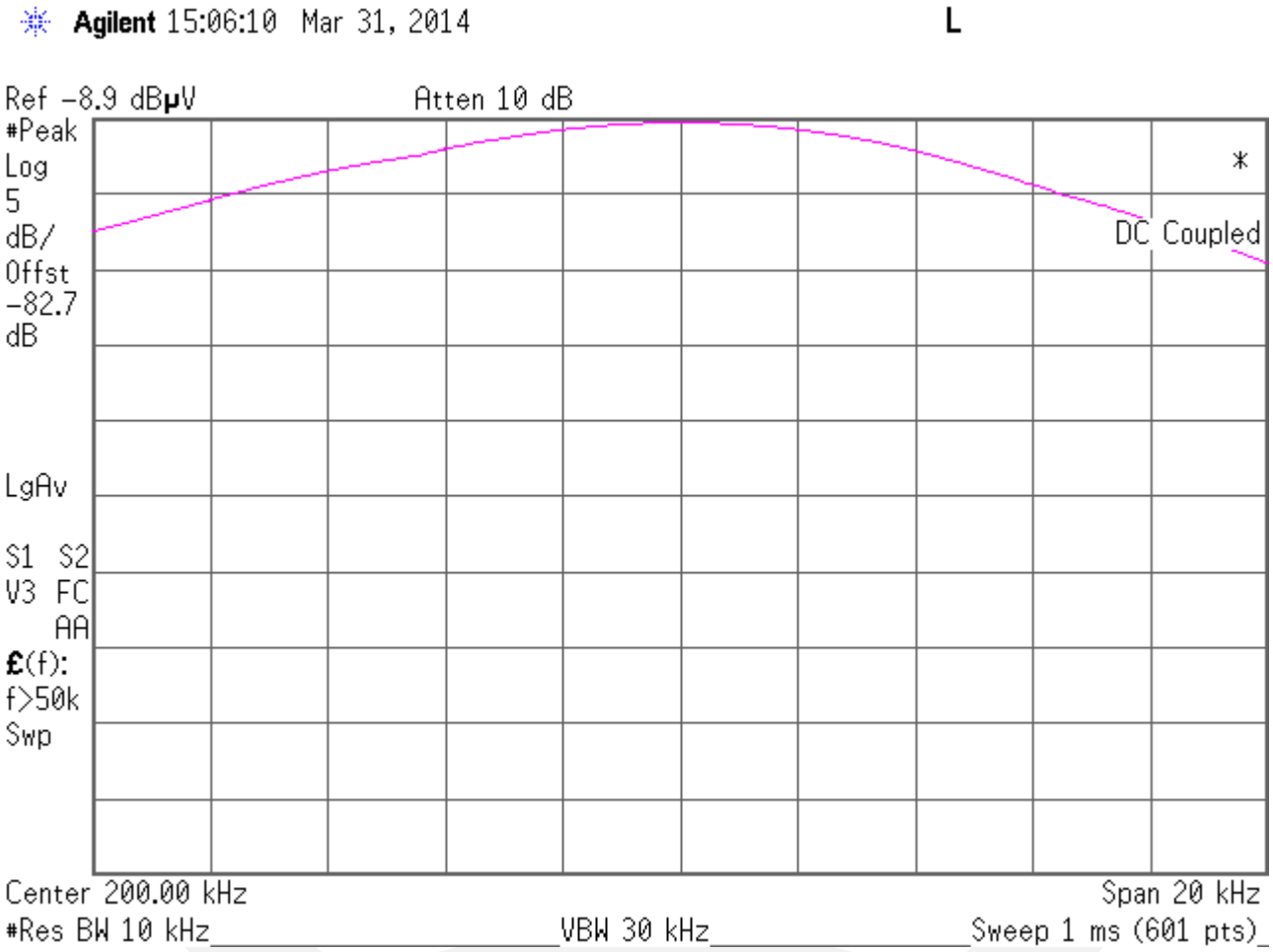
99% Occupied bandwidth
1 of 2



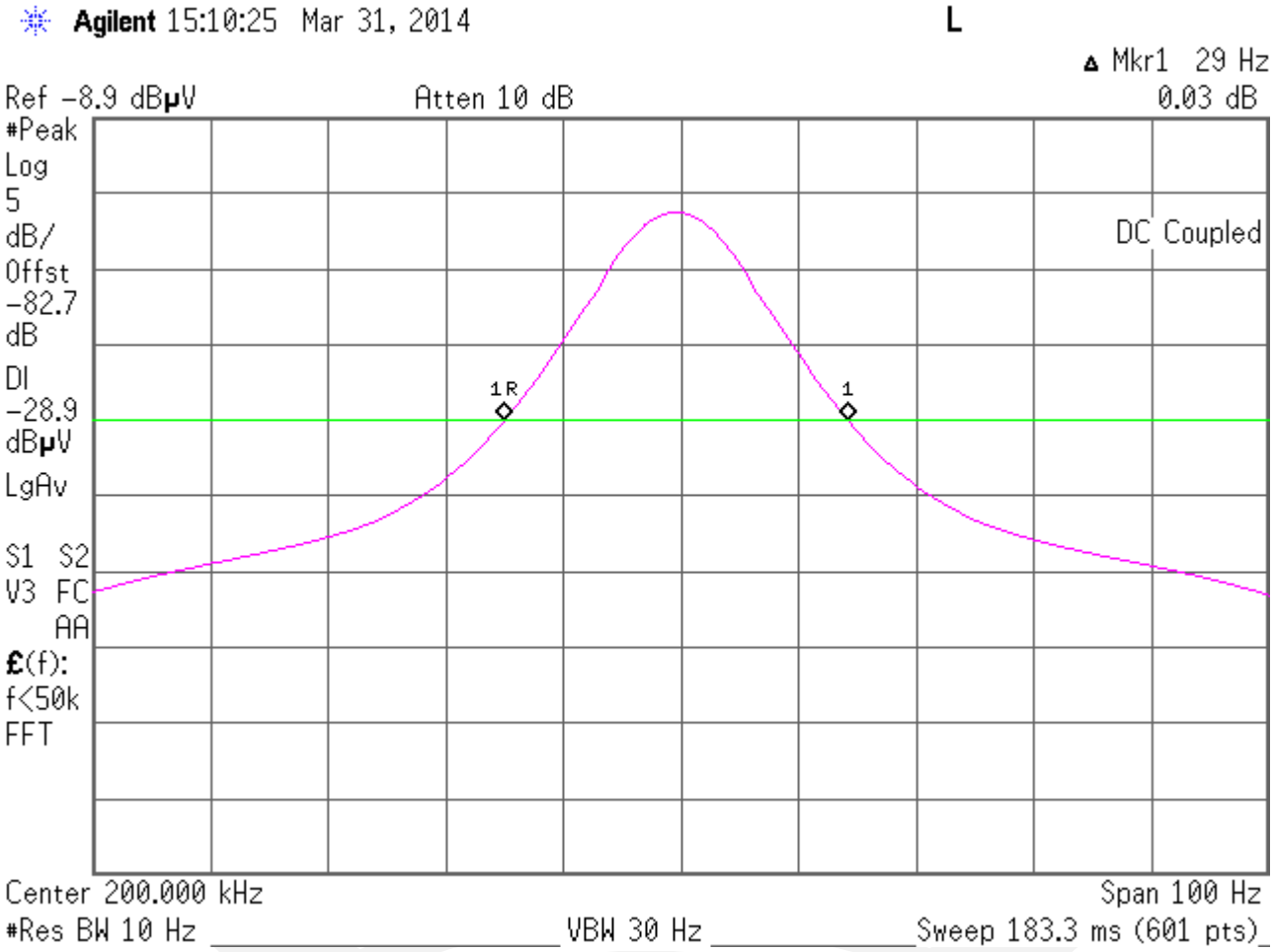
99% Occupied bandwidth
2 of 2



99% Occupied bandwidth
1 of 2



99% Occupied bandwidth
2 of 2



Conducted Emissions - AC Power Lines
FCC 15.207(a), 15.107(b), IC RSS-Gen 7.2.4

Test summary
The requirements are: ☐ - MET ■ - NOT APPLICABLE
Testing was performed in accordance with the test procedure of ANSI C63.4 2003, clause 7.2

Test location
☐ - Wild River Lab Large Test Site (Open Area Test Site)
☐ - Wild River Lab Small Test Site (Open Area Test Site)

Test limits, dBμV – Class B

Frequncy (MHz)	Quasi Peak	Average
0.15 - 0.5	66 - 56*	56 - 46*
0.5 - 5	56	46
5 - 30	60	50

*Decreases with the logarithm of the frequency

Conducted emissions on the 50 Hz and/or 60 Hz power interface of the EUT are measured in the frequency range of 150 kHz to 30 MHz. The measurements are performed using a receiver, which has CISPR characteristic bandwidth (9 kHz resolution bandwidth) and quasi-peak/average detection, and a Line Impedance Stabilization Network (LISN), with 50 Ω/50 μH (CISPR 16) characteristics. Table top equipment is placed on a non-conducting table 80 centimeters above the floor and is positioned 40 centimeters from the vertical ground plane (wall) of the screen room. In some cases, a pre-scan using a spectrum analyzer is initially performed on the units comprising the system under test to locate the highest emissions.

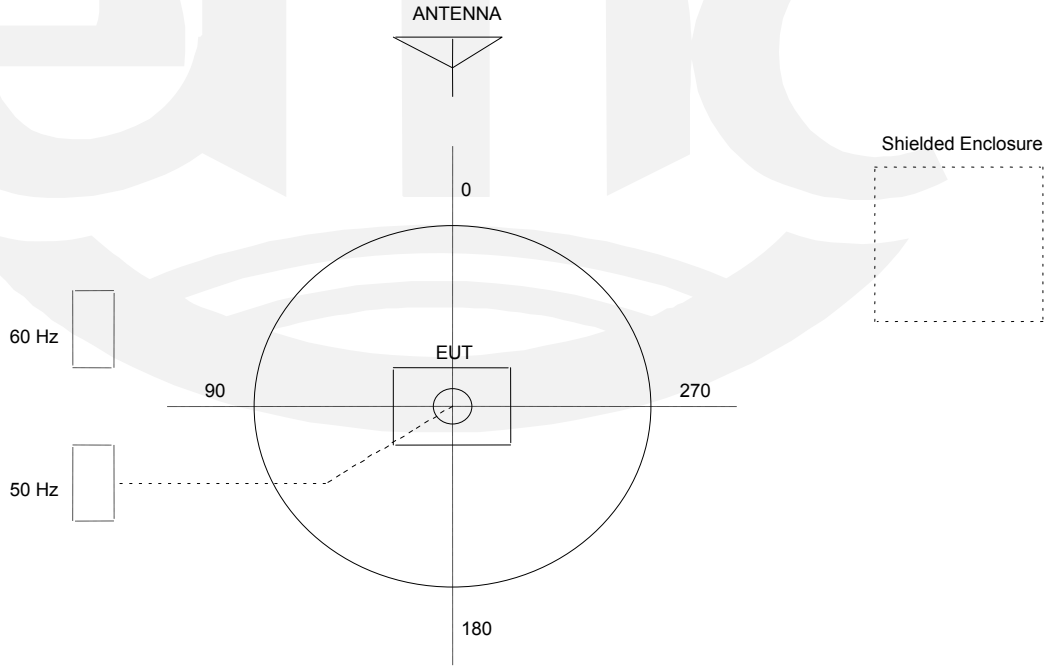
Test data
The unit under test does not connect to the AC mains.

TEST SETUP FOR EMISSIONS TESTING

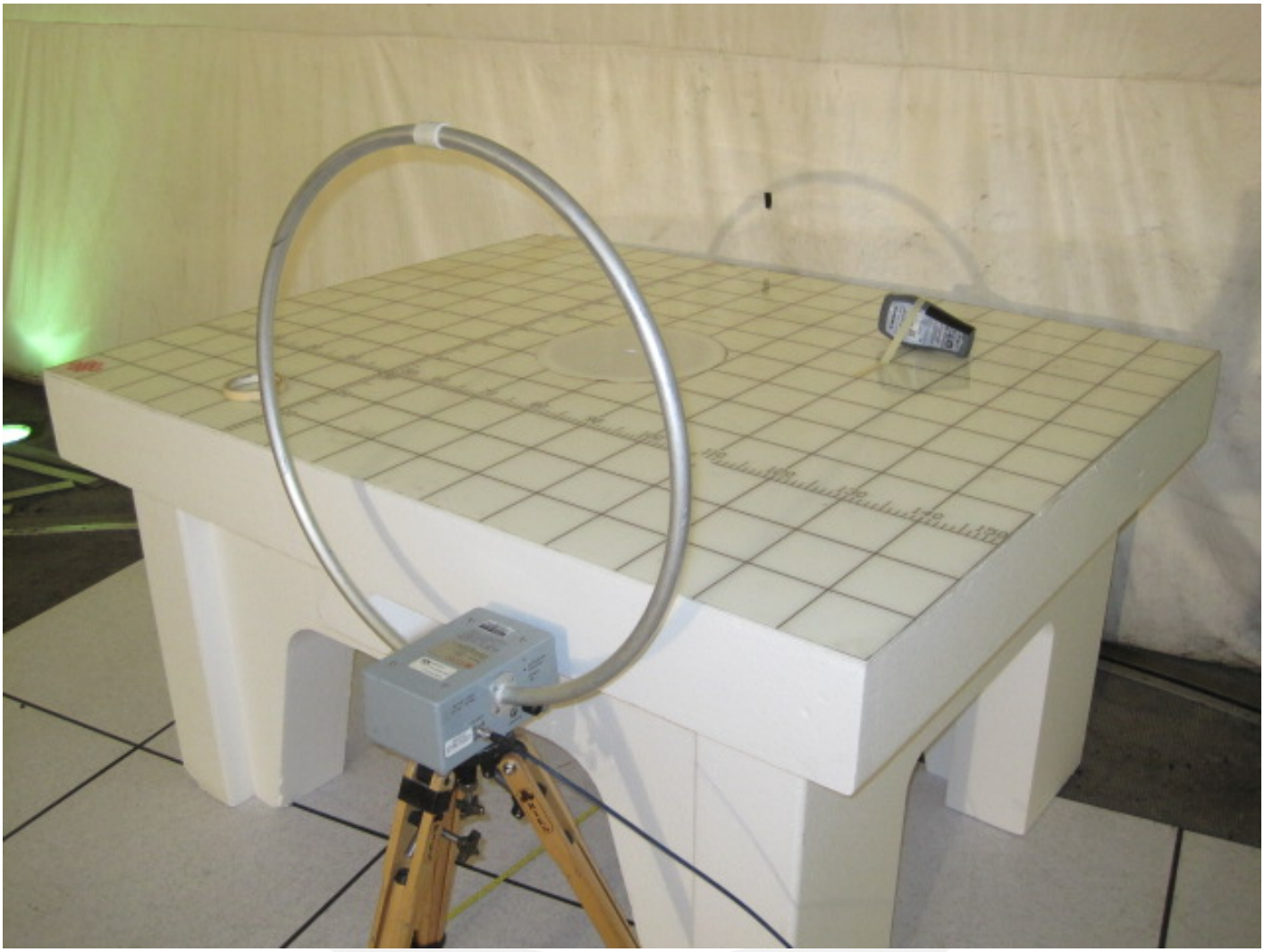
WILD RIVER LAB
Large Test Site

Notes:

1. Items shown in dotted lines are located on the floor below the test area. It is 5 meters vertically from the ground floor to the test area.
2. 50 Hz and 60 Hz are power panels for alternating current.
3. The antenna may be positioned horizontally 3 and 10 meters from the center of the turntable.
4. The circle is either a 6.7 meter or 1.2 meter diameter turntable.
5. A ground plane is in the plane of this sheet.
6. The test sample is shown in the azimuthal position representing zero degrees.



Test-setup photo(s):



Test-setup photo(s):

Equipment Under Test (EUT) Test Operation Mode:

The device under test was operated under the following conditions during immunity testing :

☐ - Standby

☐ - Test program (H - Pattern)

☐ - Test program (color bar)

☐ - Test program (customer specific)

☐ - Practice operation

■ - Normal operating mode

Configuration of the device under test:

■ - See Appendix A and test setup photos

☐ - See Product Information Form(s) in Appendix B

DEVIATIONS FROM STANDARD:
None.

GENERAL REMARKS:
None

Modifications required to pass:
■ N one
☐ As indicated on the data sheet(s)

Test Specification Deviations: Additions to or Exclusions from:
■ N one
☐ As indicated in the Test Plan

SUMMARY:
The requirements according to the technical regulations are
■ - met and the device under test does fulfill the general approval requirements.
☐ - **not** met and the device under test does **not** fulfill the general approval requirements..

EUT Received Date:	28 March 2014
Condition of EUT:	Normal
Testing Start Date:	28 March 2014
Testing End Date:	04 April 2014

TÜV SÜD AMERICA INC

Tested by:
Greg S Jakubowski
EMC Test Engineer

Approved by:
Joel T Schneider
Senior EMC Engineer

Appendix A

Constructional Data Form

Form

EMC Test Plan and Constructional Data Form

PLEASE COMPLETE THIS DOCUMENT IN FULL, ENTERING N/A IF THE FIELD IS NOT APPLICABLE. IF TESTING RESULTS IN MODIFICATIONS TO THE EQUIPMENT, PLEASE SUBMIT A REVISED TP/CDF INDICATING THOSE MODIFICATIONS.
NOTE: This information will be input into your test report as shown below. Press the F1 key at any time to get HELP for the current field selected.

Company:	Medtronic		
Address:	710 Medtronic Parkway		
	Minneapolis MN		
	55432		
Contact:	Douglas Sterlina / Jim Sponsler	Position:	Engineer
Phone:	919-807-8094 / 919-807-8043	Fax:	919-807-8190
E-mail Address:	douglas.sterlina@plexus.com / jim.sponsler@plexus.com		

General Equipment Description -- ***NOTE: This information will be input into your test report as shown below.***

EUT Description	Patient Reader		
EUT Name	Patient Reader 25000		
Model No.:	25000	Serial No.:	TBD
Product Options:	N/A		
Configurations to be tested:	Telemetry A (175kHz), Telemetry B (150/200kHz), Bluetooth (2.4 Ghz)		

Equipment Modification (***If applicable, indicate modifications since EUT was last tested. If modifications are made during this testing, submit revised TP/CDF after testing is complete.)***

Modifications since last test:	N/A
Modifications made during test:	

Test Objective(s): ***Please indicate the tests to be performed, entering the applicable standard(s) where noted.***

☒ EMC Directive 2004/108/EC (EMC)	☒ FCC:	Class ☐ A ☒ B	Part 15
Std:	☒ VCCI:	Class ☐ A ☐ B	
☐ Machinery Directive 89/392/EEC (EMC)	☐ BSMI:	Class ☐ A ☐ B	(Separate Report)
Std:	☒ Canada:	Class ☐ A ☒ B	
☒ Medical Device Directive 93/42/EEC (EMC)	☒ Australia:	Class ☐ A ☒ B	
Std:	☒ Other:	Japan/New Zealand/Europe/ARIB T66	
☐ Vehicle Directive - 2004/104/EC (EMC)	☐ Ag Directive *2009/64/EC (EMC)		
☐ Other Vehicle Std:			
☐ FDA Reviewers Guidance for Premarket Notification Submissions (EMC)			

Form

EMC Test Plan and Constructional Data Form

Third Party Certification (contact TÜV for quote), if applicable (*Signature on last page required).	
☐ Attestation of Compliance (AoC)*	☐ EMC Certification (used with Octagon Mark)*
☐ Statement of Compliance (SoC, previously CoC)* - All aspects of the essential requirements were assessed	
Protection Class (Req'd for AoC, SoC, EMC Cert. N/A for vehicles) ☐ Class I ☐ Class II ☐ Class III (Press F1 when field is selected to show additional information on Protection Class.)	
☒ FCC / TCB Certification	☐ Taiwan Certification
☒ Industry Canada / FCB Certification	☐ Korean Certification
☐ e-Mark Certification	

Attendance

Test will be: ☒ Attended by the customer ☐ Unattended by the customer

Failure - *Complete this section if testing will not be attended by the customer.*

If a failure occurs, TÜV SÜD America should:

☒ Call contact listed above, if not available then stop testing. (After hrs phone): 919-335-3313
☐ Continue testing to complete test series.
☐ Continue testing to define corrective action.
☐ Stop testing.

EUT Specifications and Requirements

Length: 16cm Width: 9cm Height: 3cm Weight: <1lb

Power Requirements

Regulations require testing to be performed at typical power ratings in the countries of intended use. (i.e., European power is typically 230 VAC 50 Hz or 400 VAC 50 Hz, single and three phase, respectively)

Voltage: 3x1.5V AA (4.5V nominal) (If battery powered, make sure battery life is sufficient to complete testing.)

# of Phases: 1 (DC)

Current (Amps/phase(max)): 1A Current (Amps/phase(nominal)): .2

Other N/A

Other Special Requirements

No essential performance for this device

Any additional testing called out in quote number: GJ24042882668
IEC 60601-1-2:2011 (4th Ed.) for the following tests only:
1) ESD: +/- 8kV contact, +/- 15kV air
2) Radiated RF EM fields: 10V/m 80 MHz - 2.7 GHz, 80% AM at 1kHz
3) Proximity fields from RF wireless communications equipment
4) Rated power frequency magnetic fields 30 A/m 50 Hz or 60 Hz

Any additional testing called out in quote number: GJ380428171604

Form

EMC Test Plan and Constructional Data Form

Typical Installation and/or Operating Environment

(ie. Hospital, Small Business, Industrial/Factory, etc.)
Home use and medical establishments

EUT Power Cable

☐ Permanent OR ☐ Removable   Length (in meters): N/A
☐ Shielded OR ☐ Unshielded
☒ Not Applicable

EUT Interface Ports and Cables

Type	Analog	Digital	During Test: Active	During Test: Passive	Qty	Shielding: Yes	Shielding: No	Shielding: Type	Termination	Connector Type	Port Termination	Length tested (in meters)	Removable	Permanent
EXAMPLE: *RS232*	☐	☒	☒	☐	*2*	☒	☐	*Foil over braid*	*Coaxial*	*Metallized 9-pin D-Sub*	*Characteristic Impedance*	*6*	☒	☐
N/A	☐	☐	☐	☐		☐	☐						☐	☐
	☐	☐	☐	☐		☐	☐						☐	☐
	☐	☐	☐	☐		☐	☐						☐	☐
	☐	☐	☐	☐		☐	☐						☐	☐
	☐	☐	☐	☐		☐	☐						☐	☐
	☐	☐	☐	☐		☐	☐						☐	☐
	☐	☐	☐	☐		☐	☐						☐	☐
	☐	☐	☐	☐		☐	☐						☐	☐
	☐	☐	☐	☐		☐	☐						☐	☐
	☐	☐	☐	☐		☐	☐						☐	☐

Form

EMC Test Plan and Constructional Data Form

America

EUT Interface Ports and Cables

Type	During Test: Analog	During Test: Digital	During Test: Active	During Test: Passive	Qty	Shielding: Yes	Shielding: No	Shielding: Type	Termination	Connector Type	Port Termination	Length tested (in meters)	Removable	Permanent
	☐	☐	☐	☐		☐	☐						☐	☐
	☐	☐	☐	☐		☐	☐						☐	☐

EUT Software.

Revision Level: SW4

Description: Basic Functional Test UUT Software

Equipment Under Test (EUT) Operating Modes to be Tested -- list the operating modes to be used during test. It is recommended the equipment be tested while operating in a typical operation mode. FCC testing of personal computers and/or peripherals requires that a simple program generate a complete line of upper case H's. Provide a general description of all software, firmware, and PLD algorithms used in the equipment. List all code modules as described above, with the revision level used during testing. Consult with your TÜV Product Service Representative if additional assistance is required.

1. Device Off/Idle

2. Device on, telemetry inactive

3. Telemetry A & B & Bluetooth Active

Form

EMC Test Plan and Constructional Data Form

Equipment Under Test (EUT) System Components -- List and describe all components which are part of the EUT. For FCC & Taiwan testing a minimum configuration is required. (ie. Mouse, Printer, Monitor, External Disk Drive, Motherboard, etc)

Description	Model #	Serial #	FCC ID #
Batteries	LR6XWA	N/A	N/A

Support Equipment -- List and describe all support equipment which is not part of the EUT. (i.e. peripherals, simulators, etc) This information is required for FCC & Taiwan testing.

Description	*Model #*	*Serial #*	*FCC ID #*
N/A			

Oscillator Frequencies

Manufacturer	*Frequency*	*Derived Frequency*	*Component # / Location*	*Description of Use*
MERCURY ELECTRONIC INDUS CO LTD-TAIPEI	8 MHz	72 MHz	Y2/Main PCB	Processor Clock
FOX ELECTRONICS	22.4 MHz	22.4 MHz	U9/Main PCB	ASIC Clock
ABRACON CORP	32.768 kHz	32.768 kHz	U4/Main PCB	Bluetooth RTC

Form

EMC Test Plan and Constructional Data Form

Power Supply

Manufacturer	Model #	Serial #	Type
N/A			☐ Switched-mode: (Frequency) _____ ☐ Linear ☐ Other: _____
			☐ Switched-mode: (Frequency) _____ ☐ Linear ☐ Other: _____

Power Line Filters

Manufacturer	Model #	Location in EUT
N/A		

Critical EMI Components (Capacitors, ferrites, etc.)

Description	Manufacturer	Part # or Value	Qty	Component # / Location
3.3V SMPS Inductor	COILCRAFT	LPS4018-103MLC	2	L1, L2
Input Ferrite	MURATA ELECTRONICS	BLM21PG121SN1D	1	FB1
Input Capacitance	AVX/KYOCERA	0805ZD106KAT2A	2	C2, C4

EMC Critical Detail -- Describe other EMC Design details used to reduce high frequency noise.

N/A

PLEASE ENTER NAMES BELOW (INSERT ELECTRONIC SIGNATURE IF POSSIBLE)

Authorization (Signature Required if a Third Party Certification is checked on pg 1)

(Jim Sponsler) — 14 April 2014

Customer authorization to perform tests according to this test plan. — Date

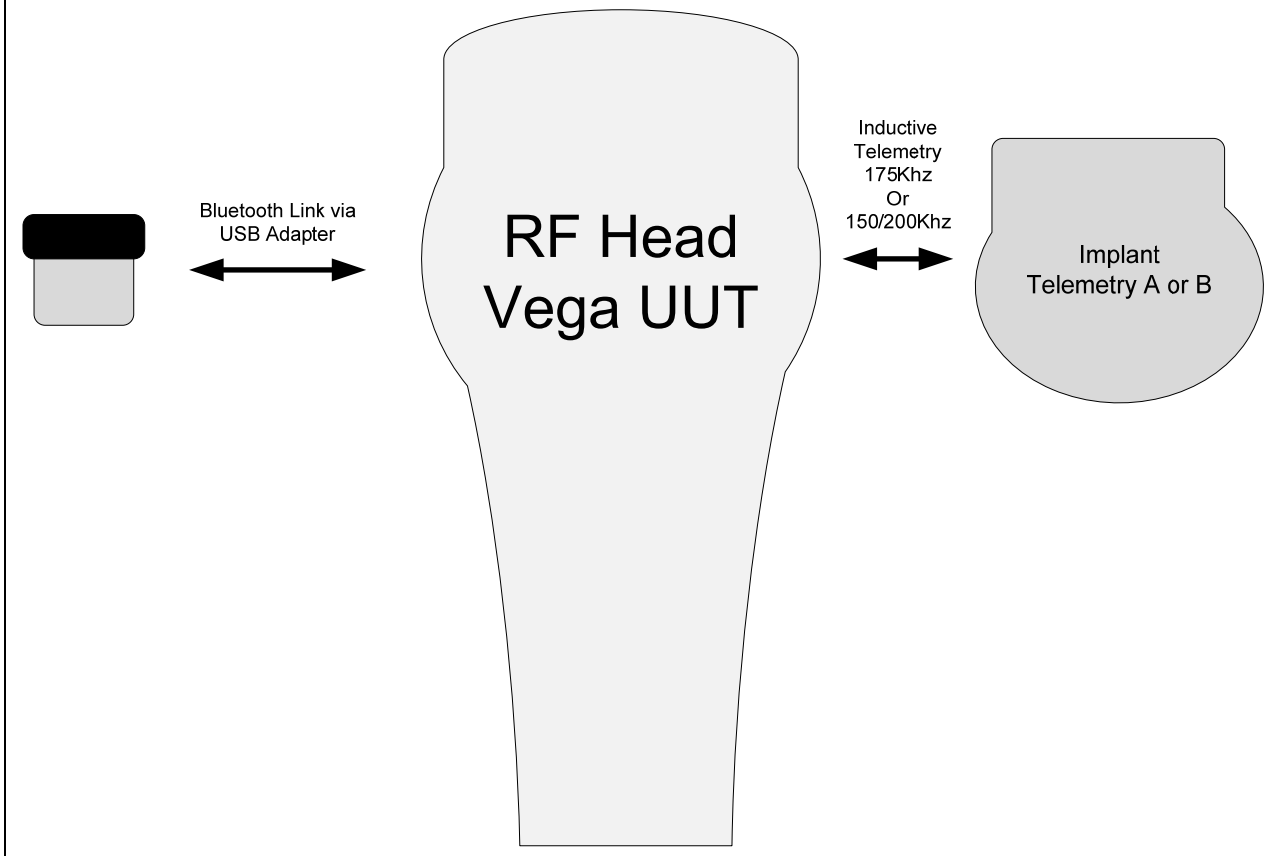
(Douglas Sterling) — 14 April 2014

Test Plan/CDF Prepared By (please print) — Date

Form

EMC Block Diagram Form

System Configuration Block Diagram -- Provide a line drawing identifying the EUT, simulators, support equipment, I/O cables, power cables, and any other pertinent components to be used during testing. Use a dashed line to separate the equipment in the testing field versus equipment outside testing field.



Authorization Signatures

Customer authorization to perform tests according to this test plan. Date

Test Plan/CDF Prepared By (please print) Date