TEST RESULT SUMMARY

FCC PART 15 SUBPART C
Section 15.209

MANUFACTURER'S NAME	Medtronic Neurological
NAME OF EQUIPMENT	RX1 Patient Programmer
TYPE OF EQUIPMENT	Battery-powered, hand-held programmer
MODEL NUMBER	**37742**
MANUFACTURER'S ADDRESS	800 53rd Avenue NE Columbia Heights, MN 55421
TEST REPORT NUMBER	WC402657.4 Rev B
TEST DATE	15 June 2004

According to testing performed at TÜV Product Service Inc, the above-mentioned unit is in compliance with the electromagnetic compatibility requirements defined in FCC Part 15 Subpart C, Section 15.209.

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.

TÜV Product Service Inc, as an independent testing laboratory, declares that the equipment tested as specified above conforms to the requirements of FCC Part 15 Subpart C, Section 15.209.

Date: 21 April 2005

Location: Taylors Falls MN USA

R. M. Johnson
Tested By

T. K. Swanson
Reviewed By

Not Transferable

EMC EMISSION - T E S T R E P O R T

Test Report File No.	:	**WC402657.4 Rev B**	Date of issue:	21 April 2005

Model No.	:	**37742**
Product Name	:	RX1 Patient Programmer
Product Type	:	Battery-powered, hand-held programmer
Applicant	:	Medtronic Neurological
Manufacturer	:	Medtronic Neurological
License holder	:	Medtronic Neurological
Address	:	800 53rd Avenue NE
	:	Columbia Heights, MN 55421
Test Result	:	■ **Positive** ☐ **Negative**
Test Project Number Reference(s)	:	**WC402657.4 Rev B**
Total pages including Appendices		30

TÜV Product Service Inc is a subcontractor to TÜV Product Service, GmbH according to the principles outlined in ISO/IEC Guide 25 and EN 45001.

TÜV Product Service 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 Product Service Inc shall have no liability for any deductions, inferences or generalizations drawn by the client or others from TÜV Product Service 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. This report shall not be used by the client to claim product endorsement by NVLAP or any agency of the US government.

TÜV Product Service Inc and its professional staff hold government and professional organization certifications and are members of AAMI, ACIL, AEA, ANSI, IEEE, NVLAP, and VCCI

TÜV PRODUCT SERVICE INC 19333 Wild Mountain Road Taylors Falls MN 55084-1758 Tel: 651 638 0297 Fax: 651 638 0298 Rev.No 1.0

REVISION RECORD

REVISION	TOTAL NUMBER OF PAGES	DATE	DESCRIPTION
	29	20 July 2004	Initial Release
A	30	18 April 2005	Revisions include: ▪ Changed Minimum limit margin for fundamental on page 10 to 41 dB. Also changed falloff to 52 dB/decade.
B	30	21 April 2005	Revisions include: ▪ Added peak measurement data to page A3 and added comment regarding peak measurements to page 10. ▪ Replaced photo on page 13.

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D I R E C T O R Y - EMISSIONS

TÜV PRODUCT SERVICE INC 19333 Wild Mountain Road Taylors Falls MN 55084-1758 Tel: 651 638 0297 Fax: 651 638 0298 Rev.No 1.0

EMISSIONS TEST REGULATIONS :

The emissions tests were performed according to following regulations:

☐ - EN 50081-1 / 1991

☐ - EN 55011 / 1991 ☐ - Group 1 ☐ - Group 2
☐ - Class A ☐ - Class B

☐ - EN 55013 / 1990

☐ - EN 55014 / 1987 ☐ - Household appliances and similar
☐ - Portable tools
☐ - Semiconductor devices

☐ - EN 55014 / A2:1990

☐ - EN 55014 / 1993 ☐ - Household appliances and similar
☐ - Portable tools
☐ - Semiconductor devices

☐ - EN 55015 / 1987

☐ - EN 55015 / A1:1990

☐ - EN 55015 / 1993

☐ - EN 55022 / 1987 ☐ - Class A ☐ - Class B

☐ - EN 55022 / 1994 ☐ - Class A ☐ - Class B

☐ - BS

☐ - VCCI ☐ - Class A ☐ - Class B

■ - FCC Part 15 Subpart C Section 15.209

☐ - FCC Part 15 Subpart C Section 15.207 Conducted Emission Requirements

☐ - FCC Part 15 Subpart B ☐ - Class A ☐ - Class B

☐ - CISPR 11 (1990) ☐ - Group 1 ☐ - Group 2
☐ - Class A ☐ - Class B

☐ - CISPR 22 (1993) ☐ - Class A ☐ - Class B

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Environmental conditions in the lab:

	Actual
Temperature	: 20 °C
Relative Humidity	: 40 %
Atmospheric pressure	: 97.0 kPa
Power supply system	: 3 VDC Battery

Sign Explanations:

☐ - not applicable
■ - applicable

TÜV PRODUCT SERVICE INC 19333 Wild Mountain Road Taylors Falls MN 55084-1758 Tel: 651 638 0297 Fax: 651 638 0298 Rev.No 1.0

Emissions Test Conditions: CONDUCTED EMISSIONS [FCC 15.207]

The *CONDUCTED EMISSIONS (INTERFERENCE VOLTAGE*) measurements were performed at the following test location:

■ - Test not applicable

☐ - Wild River Lab Large Test Site (Open Area Test Site)
☐ - Wild River Lab Small Test Site (Open Area Test Site)
☐ - Oakwood Lab (Open Area Test Site)
☐ - Wild River Lab Screen Room
☐ - New Brighton Lab Shielded Room

Emissions Test Conditions: RADIATED EMISSIONS (FCC 15.209 10 kHz - 30 MHz)

The *RADIATED EMISSIONS (MAGNETIC FIELD*) measurements were performed at the following test location:

☐ - Test not applicable

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

at a test distance of :

☐ - 0.3 meters
■ - 1 meter
■ - 3 meter
■ - 10 meters
■ - 30 meters

Test equipment used :

	TUV ID	Model Number	Manufacturer	Description	Serial Number	Cal Due
■ -	2534	ESHS-20	Rhode & Schwarz	EMI Receiver	837055/003	1-14-05
■ -	2517	HFH2-Z2	Polorad	Loop Antenna	879285/036	4-27-05

All measurement instrumentation is traceable to the National Institute of Standards and Technology (NIST) and is calibrated annually.

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Emissions Test Conditions: RADIATED EMISSIONS (FCC 15.209 Electric Field 30 - 1000 MHz)

The *RADIATED EMISSIONS (ELECTRIC FIELD)* measurements, in the frequency range of 30 MHz-1000 MHz, were tested in a horizontal and vertical polarization at the following test location:

☐ - Test not applicable

☐ - Wild River Lab Large Test Site (Open Area Test Site)
■ - Wild River Lab Small Test Site (Open Area Test Site) – NSA measurements made 2-03, due 2-05.
☐ - Oakwood Lab (Open Area Test Site)

at a test distance of :

■ - 3 meters
☐ - 10 meters
☐ - 30 meters

Test equipment used :

	TUV ID	Model Number	Manufacturer	Description	Serial Number	Cal Due
■ -	3203	EM-6917B	Electro-Metrics	Biconicalog Periodic	106	3-30-05
■-	2690	8566B	Hewlett-Packard	Spectrum Analyzer (Unit F)	2430A00930	1-28-05
■ -	2673	85662A	Hewlett-Packard	Analyzer Display (Unit A)	2152A03687	1-28-05
■	2681	85650A	Hewlett-Packard	Quasi-Peak Adapter	2430A00562	2-23-05
■ -	2671	8447D	Electro-Mechanics (EMCO)	Preamplifier	2648A04942	Code B

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

All measurement instrumentation is traceable to the National Institute of Standards and Technology (NIST) and is calibrated annually.

Emissions Test Conditions: INTERFERENCE POWER

The *INTERFERENCE POWER* measurements were performed by using the absorbing clamp on the mains and interface cables in the frequency range 30 MHz - 300 MHz at the following test location:

■ - Test not applicable

☐ - Wild River Lab Large Test Site (Open Area Test Site)
☐ - Wild River Lab Small Test Site (Open Area Test Site)
☐ - Oakwood Lab (Open Area Test Site)
☐ - Wild River Lab Screen Room
☐ - New Brighton Lab Shielded Room

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Emissions Test Conditions: RADIATED EMISSIONS Electric Field 1 to 100 GHz

The *EQUIVALENT RADIATED EMISSIONS* measurements in the frequency range 1 GHz - 100 GHz were performed in a horizontal and vertical polarization at the following test location:

■ - Test not applicable

☐ - Wild River Lab Large Test Site (Open Area Test Site)
☐ - Wild River Lab Small Test Site (Open Area Test Site)
☐ - Oakwood Lab (Open Area Test Site)
☐ - Wild River Lab Screen Room

at a test distance of:

☐ - 1 meters
☐ - 3 meters
☐ - 10 meters

TÜV PRODUCT SERVICE INC 19333 Wild Mountain Road Taylors Falls MN 55084-1758 Tel: 651 638 0297 Fax: 651 638 0298 Rev.No 1.0

Equipment Under Test (EUT) Test Operation Mode - Emission tests :

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

☐ - Standby

☐ - Test program (H - Pattern)

☐ - Test program (color bar)

☐ - Test program (customer specific)

☐ - Practice operation

☐ - Normal Operating Mode

■ - RF telemetry

Configuration of the device under test:

■ - See Constructional Data Form in Appendix B - Page B2

☐ - See Product Information Form in Appendix B - beginning on Page B3

The following peripheral devices and interface cables were connected during the measurement:

☐ - _____ Type : _____

☐ - _____ Type : _____

☐ - _____ Type : _____

☐ - _____ Type : _____

☐ - _____ Type : _____

☐ - unshielded power cable

☐ - unshielded cables

☐ - shielded cables MPS.No.: _____

☐ - customer specific cables

☐ - _____

☐ - _____

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Emission Test Results:

FCC 15.207 - Conducted emissions 450 kHz - 30 MHz

The requirements are ☐ - MET ☐ - NOT MET ■ - N/A

Minimum margin of compliance _____ dB at _____ kHz

Maximum margin of non-compliance _____ dB at _____ MHz

Remarks: _____

FCC 15.209 - Radiated emissions (magnetic field) 10 kHz - 30 MHz

The requirements are ■ - MET ☐ - NOT MET

Minimum limit margin for fundamental 71 dB at 175.0 kHz

Minimum limit margin for spurious/harmonics >10 dB at _____ MHz

Remarks: The fundamental was measured to be 112 dBuV/m (398107 microvolts/meter) in Average mode at 1 meter, 86 dBuV/m (19952.6 microvolts/meter) at 3 meters, and 59 dBuV/m (891.2 microvolts/meter) at 10 meters. This extrapolates to a level of -19 dBuV/m (0.11 microvolts/meter) at 300 meters using a 52 dB/decade falloff as indicated by testing. The limit is 22.7 dBuV/m (13.7 microvolts/meter) at 300 meters.

Peak level is less than 20 dB above the average limit as required.

No spurious emissions or other harmonics were detected.

FCC 15.209 - Radiated emissions (electric field) 30 MHz - 1000 MHz

The requirements are ■ - MET ☐ - NOT MET

Minimum margin of compliance 13 dB at 199.9 MHz

Minimum limit margin for spurious _____ dB at _____ MHz

Remarks: _____

Interference Power at the mains and interface cables 30 MHz - 300 MHz

The requirements are ☐ - MET ☐ - NOT MET ■ - N/A

Remarks: _____

Equivalent Radiated emissions 1 GHz - 100 GHz

The requirements are ☐ - MET ☐ - NOT MET ■ - N/A

Remarks: _____

TÜV PRODUCT SERVICE INC 19333 Wild Mountain Road Taylors Falls MN 55084-1758 Tel: 651 638 0297 Fax: 651 638 0298 Rev.No 1.0

DEVIATIONS FROM STANDARD:

None.

GENERAL REMARKS:

The radiated measurements from 10 kHz to 30 MHz are made in quasi-peak detection, except for the levels noted between 110-490 kHz, which are made in average detection.

SUMMARY:

The requirements according to the technical regulations are

■ - met

☐ - **not** met.

The device under test does

■ - fulfill the general approval requirements mentioned on page 3.

☐ - **not** fulfill the general approval requirements mentioned on page 3.

Testing Start Date: 15 June 2004

Testing End Date: 15 June 2004

- TÜV PRODUCT SERVICE INC -

T. K. Swanson
Reviewed By

Tested By:
R. M. Johnson

TÜV PRODUCT SERVICE INC 19333 Wild Mountain Road Taylors Falls MN 55084-1758 Tel: 651 638 0297 Fax: 651 638 0298 Rev.No 1.0

Test-setup photo(s):
Conducted emission 450 kHz - 30 MHz

Not Applicable

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Test-setup photo(s):
Radiated emission 10 kHz - 1000 MHz

TÜV PRODUCT SERVICE INC 19333 Wild Mountain Road Taylors Falls MN 55084-1758 Tel: 651 638 0297 Fax: 651 638 0298 Rev.No 1.0

Appendix A

Test Data Sheets

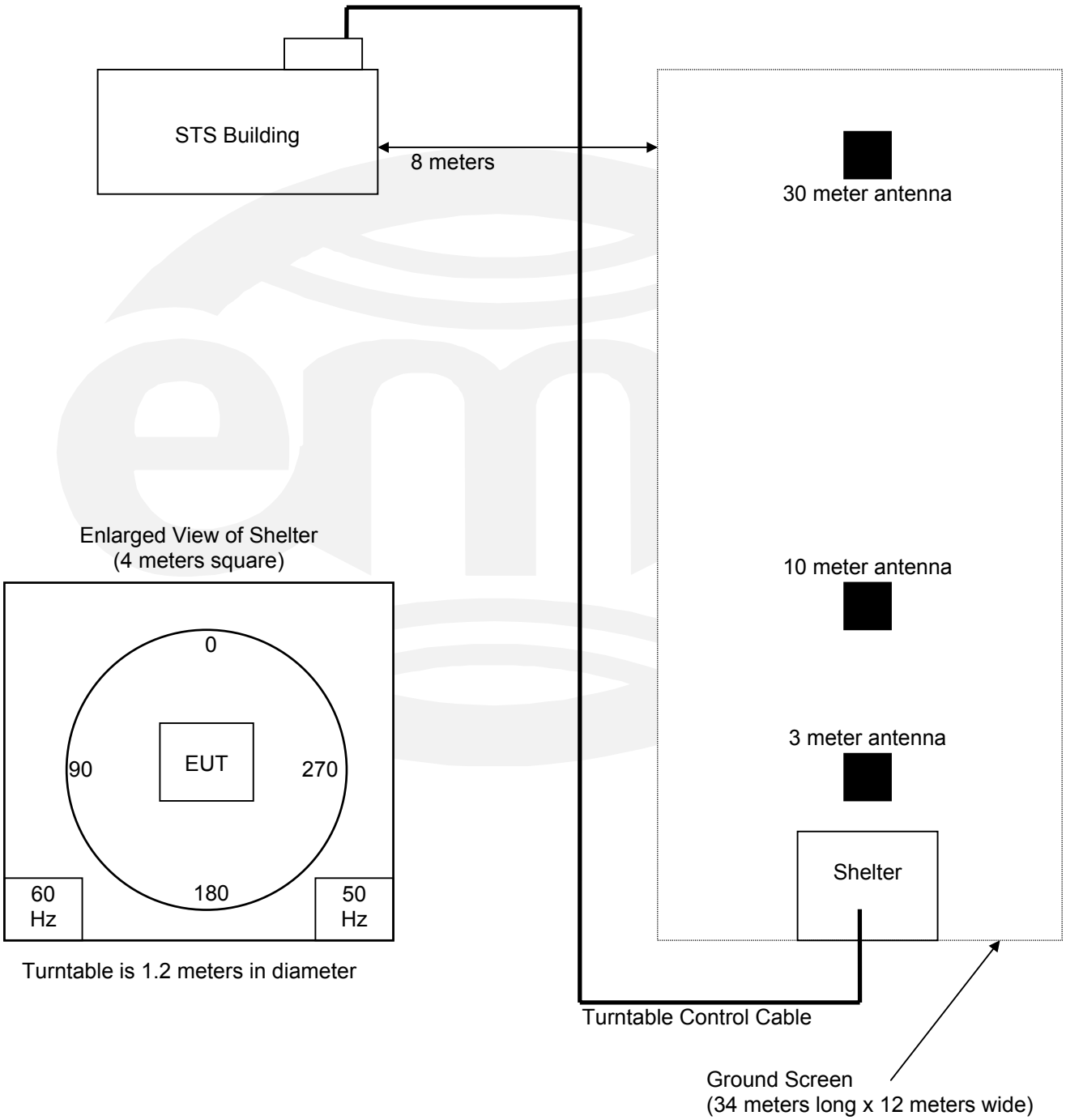
and

Test Setup Drawing(s)

TÜV PRODUCT SERVICE INC 19333 Wild Mountain Road Taylors Falls MN 55084-1758 Tel: 651 638 0297 Fax: 651 638 0298 Rev.No 1.0

TEST SETUP FOR EMISSIONS TESTING

WILD RIVER LAB
Small Test Site (STS)



TÜV PRODUCT SERVICE INC 19333 Wild Mountain Road Taylors Falls MN 55084-1758 Tel: 651 638 0297 Fax: 651 638 0298 Rev.No 1.0

FCC Part 15.209 Radiated Emissions									
Test Report # WC402657.4					**Test Date: 15 Jun-04**				
Company: Medtronic									
EUT: 37742 rx-1									
	dBuV/m	dBuV/m	dBuV/m	dBuV/m	dBuV/m	dBuV/m	dBuV/m	dBuV/m	margin
MHz	0.3 m	1 m	3 m	10 m	30 m	30 m Limit	300 m	300 m Limit	dB
0.009								48.5193746	48.51937
0.175		**112**	**86**	**59**	**33**	**N/A**	**-19**	**22.7434639**	**41.74346**
0.49						53.8003			
0.49						33.8003			
1.705						22.96974			
1.705						29.54243			
30						29.54243			
Levels at 1, 3, and 10 meters are measured - other levels are extrapolated.									
Levels at 1, 3, and 10 meters are measured AVERAGE values - other levels are extrapolated using falloff of									
52 dB per decade as indicated by 1 and 3 meter measurements.									
PEAK reading at .175 MHz is 120 dBuV/m at 1 M and 94 dBuV/m at 3 M.									
This extrapolates to -11 dBuV/m at 300 M or 33 dB under the average limit.									

RADIATED EMISSIONS

TÜV PRODUCT SERVICE

Test Report #:	WC402657 Run 3	Test Area:	STS		
EUT Model #:	37742	Date:	6/15/04		
EUT Serial #:	NJD000453P	EUT Power:	3 VDC -BATTERY	Temperature:	20.0 °C
Test Method:	FCC B			Air Pressure:	97.0 kPa
Customer:	MEDTRONIC			Rel. Humidity:	40.0 %
EUT Description:	PATIENT PROGRAMMER , RX-1 APPLICATION				
Notes:	TELEMTRY ACTIVE				
Data File Name:	2657.dat			Page:	1 of 5

List of measurements for run #: 3

FREQ	LEVEL (dBuV)	CABLE / ANT / PREAMP / ATTEN (dB)	FINAL (dBuV / m)	POL / HGT / AZ (m)(DEG)	DELTA1 FCC-B <1GHz 3m	DELTA2
109.182 MHz	38.55 Qp	1.53 / 9.58 / 26.83 / 0.0	22.83	V / 1.00 / 0	-20.67	n/a
113.627 MHz	32.5 Qp	1.58 / 9.6 / 26.88 / 0.0	16.8	V / 1.00 / 0	-26.7	n/a
125.013 MHz	33.25 Qp	1.64 / 8.81 / 26.88 / 0.0	16.83	V / 1.00 / 0	-26.67	n/a
126.704 MHz	33.8 Qp	1.68 / 8.63 / 26.86 / 0.0	17.25	V / 1.00 / 0	-26.25	n/a
128.124 MHz	36.75 Qp	1.71 / 8.51 / 26.84 / 0.0	20.13	V / 1.00 / 0	-23.37	n/a
134.803 MHz	31.95 Qp	1.77 / 8.29 / 26.8 / 0.0	15.21	V / 1.00 / 0	-28.29	n/a
219.593 MHz	35.05 Qp	2.2 / 10.75 / 26.93 / 0.0	21.07	V / 1.00 / 0	-24.93	n/a
230.127 MHz	34.45 Qp	2.2 / 10.92 / 27.0 / 0.0	20.57	V / 1.00 / 0	-25.43	n/a
128.304 MHz	35.55 Qp	1.72 / 8.49 / 26.84 / 0.0	18.92	V / 1.00 / 0	-24.58	n/a
220.295 MHz	35.55 Qp	2.2 / 10.78 / 26.94 / 0.0	21.59	V / 1.00 / 0	-24.41	n/a
108.479 MHz	39.2 Qp	1.52 / 9.55 / 26.82 / 0.0	23.45	V / 1.00 / 0	-20.05	n/a
118.303 MHz	38.6 Qp	1.6 / 9.43 / 26.9 / 0.0	22.73	V / 1.00 / 0	-20.77	n/a
127.969 MHz	30.0 Qp	1.71 / 8.52 / 26.85 / 0.0	13.38	V / 1.00 / 90	-30.12	n/a
134.803 MHz	32.5 Qp	1.77 / 8.29 / 26.8 / 0.0	15.76	V / 1.00 / 90	-27.74	n/a
219.593 MHz	37.3 Qp	2.2 / 10.75 / 26.93 / 0.0	23.32	V / 1.00 / 90	-22.68	n/a
220.295 MHz	37.65 Qp	2.2 / 10.78 / 26.94 / 0.0	23.69	V / 1.00 / 90	-22.31	n/a
230.127 MHz	35.7 Qp	2.2 / 10.92 / 27.0 / 0.0	21.82	V / 1.00 / 90	-24.18	n/a
199.935 MHz	39.15 Qp	2.1 / 10.99 / 26.9 / 0.0	25.34	V / 1.00 / 90	-18.16	n/a
125.013 MHz	34.8 Qp	1.64 / 8.81 / 26.88 / 0.0	18.38	V / 1.00 / 180	-25.12	n/a
126.704 MHz	35.8 Qp	1.68 / 8.63 / 26.86 / 0.0	19.25	V / 1.00 / 180	-24.25	n/a
128.124 MHz	38.95 Qp	1.71 / 8.51 / 26.84 / 0.0	22.33	V / 1.00 / 180	-21.17	n/a
128.304 MHz	36.6 Qp	1.72 / 8.49 / 26.84 / 0.0	19.97	V / 1.00 / 180	-23.53	n/a
134.803 MHz	33.65 Qp	1.77 / 8.29 / 26.8 / 0.0	16.91	V / 1.00 / 180	-26.59	n/a

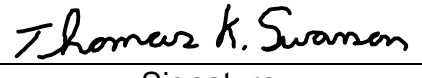
Tested by: RMJ

Printed

Signature

Reviewed by: TKS

Printed



Signature

RADIATED EMISSIONS

TÜV PRODUCT SERVICE

Test Report #:	WC402657 Run 3	Test Area:	STS		
EUT Model #:	37742	Date:	6/15/04		
EUT Serial #:	NJD000453P	EUT Power:	3 VDC -BATTERY	Temperature:	20.0 °C
Test Method:	FCC B			Air Pressure:	97.0 kPa
Customer:	MEDTRONIC			Rel. Humidity:	40.0 %
EUT Description:	PATIENT PROGRAMMER , RX-1 APPLICATION				
Notes:	TELEMTRY ACTIVE				
Data File Name:	2657.dat			Page:	2 of 5

List of measurements for run #: 3

FREQ	LEVEL (dBuV)	CABLE / ANT / PREAMP / ATTEN (dB)	FINAL (dBuV / m)	POL / HGT / AZ (m)(DEG)	DELTA1 FCC-B <1GHz 3m	DELTA2
230.127 MHz	36.25 Qp	2.2 / 10.92 / 27.0 / 0.0	22.37	V / 1.00 / 180	-23.63	n/a
108.479 MHz	40.15 Qp	1.52 / 9.55 / 26.82 / 0.0	24.4	V / 3.00 / 180	-19.1	n/a
109.182 MHz	39.1 Qp	1.53 / 9.58 / 26.83 / 0.0	23.38	V / 3.00 / 180	-20.12	n/a
113.627 MHz	33.55 Qp	1.58 / 9.6 / 26.88 / 0.0	17.85	V / 3.00 / 180	-25.65	n/a
118.303 MHz	39.6 Qp	1.6 / 9.43 / 26.9 / 0.0	23.73	V / 3.00 / 180	-19.77	n/a
127.969 MHz	31.65 Qp	1.71 / 8.52 / 26.85 / 0.0	15.03	V / 3.00 / 180	-28.47	n/a
134.803 MHz	34.9 Qp	1.77 / 8.29 / 26.8 / 0.0	18.16	V / 3.00 / 180	-25.34	n/a
MAXIMIZED.						
108.479 MHz	40.3 Qp	1.52 / 9.55 / 26.82 / 0.0	24.55	V / 2.00 / 171	-18.95	n/a
MAXED ANTENNA AND ROTATED EUT 360 DEGREES.						
108.479 MHz	40.95 Qp	1.52 / 9.55 / 26.82 / 0.0	25.2	H / 1.00 / 90	-18.3	n/a
109.182 MHz	40.7 Qp	1.53 / 9.58 / 26.83 / 0.0	24.98	H / 1.00 / 90	-18.52	n/a
113.627 MHz	37.05 Qp	1.58 / 9.6 / 26.88 / 0.0	21.35	H / 1.00 / 90	-22.15	n/a
118.303 MHz	40.75 Qp	1.6 / 9.43 / 26.9 / 0.0	24.88	H / 1.00 / 90	-18.62	n/a
125.013 MHz	35.5 Qp	1.64 / 8.81 / 26.88 / 0.0	19.08	H / 1.00 / 90	-24.42	n/a
126.704 MHz	37.2 Qp	1.68 / 8.63 / 26.86 / 0.0	20.65	H / 1.00 / 90	-22.85	n/a
128.124 MHz	40.0 Qp	1.71 / 8.51 / 26.84 / 0.0	23.38	H / 1.00 / 90	-20.12	n/a
199.935 MHz	43.45 Qp	2.1 / 10.99 / 26.9 / 0.0	29.64	H / 1.00 / 90	-13.86	n/a
219.593 MHz	42.9 Qp	2.2 / 10.75 / 26.93 / 0.0	28.92	H / 1.00 / 90	-17.08	n/a
220.295 MHz	43.45 Qp	2.2 / 10.78 / 26.94 / 0.0	29.49	H / 1.00 / 90	-16.51	n/a
230.127 MHz	43.05 Qp	2.2 / 10.92 / 27.0 / 0.0	29.17	H / 1.00 / 90	-16.83	n/a
230.823 MHz	42.75 Qp	2.21 / 10.98 / 26.99 / 0.0	28.94	H / 1.00 / 90	-17.06	n/a

Tested by: RMJ

Printed | Signature

Reviewed by: TKS

Printed | Signature

RADIATED EMISSIONS

Test Report #:	WC402657 Run 3	Test Area:	STS		
EUT Model #:	37742	Date:	6/15/04		
EUT Serial #:	NJD000453P	EUT Power:	3 VDC -BATTERY	Temperature:	20.0 °C
Test Method:	FCC B			Air Pressure:	97.0 kPa
Customer:	MEDTRONIC			Rel. Humidity:	40.0 %
EUT Description:	PATIENT PROGRAMMER , RX-1 APPLICATION				
Notes:	TELEMTRY ACTIVE				
Data File Name:	2657.dat			Page:	3 of 5

List of measurements for run #: 3

FREQ	LEVEL (dBuV)	CABLE / ANT / PREAMP / ATTEN (dB)	FINAL (dBuV / m)	POL / HGT / AZ (m)(DEG)	DELTA1 FCC-B <1GHz 3m	DELTA2
127.969 MHz	32.7 Qp	1.71 / 8.52 / 26.85 / 0.0	16.08	H / 1.00 / 270	-27.42	n/a
230.127 MHz	44.0 Qp	2.2 / 10.92 / 27.0 / 0.0	30.12	H / 1.00 / 270	-15.88	n/a
230.823 MHz	43.75 Qp	2.21 / 10.98 / 26.99 / 0.0	29.94	H / 1.00 / 270	-16.06	n/a
108.479 MHz	43.2 Qp	1.52 / 9.55 / 26.82 / 0.0	27.45	H / 3.00 / 270	-16.05	n/a
109.182 MHz	43.2 Qp	1.53 / 9.58 / 26.83 / 0.0	27.48	H / 3.00 / 270	-16.02	n/a
113.627 MHz	39.5 Qp	1.58 / 9.6 / 26.88 / 0.0	23.8	H / 3.00 / 270	-19.7	n/a
118.303 MHz	42.7 Qp	1.6 / 9.43 / 26.9 / 0.0	26.83	H / 3.00 / 270	-16.67	n/a
125.013 MHz	36.95 Qp	1.64 / 8.81 / 26.88 / 0.0	20.53	H / 3.00 / 270	-22.97	n/a
126.704 MHz	38.35 Qp	1.68 / 8.63 / 26.86 / 0.0	21.8	H / 3.00 / 270	-21.7	n/a
127.969 MHz	33.85 Qp	1.71 / 8.52 / 26.85 / 0.0	17.23	H / 3.00 / 270	-26.27	n/a
128.124 MHz	41.05 Qp	1.71 / 8.51 / 26.84 / 0.0	24.43	H / 3.00 / 270	-19.07	n/a
128.304 MHz	37.6 Qp	1.72 / 8.49 / 26.84 / 0.0	20.97	H / 3.00 / 270	-22.53	n/a
134.803 MHz	35.5 Qp	1.77 / 8.29 / 26.8 / 0.0	18.76	H / 3.00 / 270	-24.74	n/a
199.935 MHz	36.6 Qp	2.1 / 10.99 / 26.9 / 0.0	22.79	H / 3.00 / 270	-20.71	n/a
126.704 MHz	39.15 Qp	1.68 / 8.63 / 26.86 / 0.0	22.6	H / 3.00 / 90	-20.9	n/a
MAXIMIZED.						
230.127 MHz	44.7 Qp	2.2 / 10.92 / 27.0 / 0.0	30.82	H / 1.00 / 253	-15.18	n/a
MAXED ANTENNA AND ROTATED EUT 360 DEGREES.						
END OF SCAN 30 - 1000MHz.						

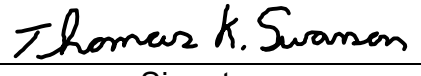
Tested by: RMJ

Printed

Signature

Reviewed by: TKS

Printed



Signature

RADIATED EMISSIONS

Test Report #:	WC402657 Run 3	Test Area:	STS		
EUT Model #:	37742	Date:	6/15/04		
EUT Serial #:	NJD000453P	EUT Power:	3 VDC -BATTERY	Temperature:	20.0 °C
Test Method:	FCC B			Air Pressure:	97.0 kPa
Customer:	MEDTRONIC			Rel. Humidity:	40.0 %
EUT Description:	PATIENT PROGRAMMER , RX-1 APPLICATION				
Notes:	TELEMTRY ACTIVE				
Data File Name:	2657.dat			Page:	4 of 5

Measurement summary for limit1: FCC-B <1GHz 3m (Qp)

FREQ	LEVEL (dBuV)	CABLE / ANT / PREAMP / ATTEN (dB)	FINAL (dBuV / m)	POL / HGT / AZ (m)(DEG)	DELTA1 FCC-B <1GHz 3m
199.935 MHz	43.45 Qp	2.1 / 10.99 / 26.9 / 0.0	29.64	H / 1.00 / 90	-13.86
230.127 MHz	44.7 Qp	2.2 / 10.92 / 27.0 / 0.0	30.82	H / 1.00 / 253	-15.18
109.182 MHz	43.2 Qp	1.53 / 9.58 / 26.83 / 0.0	27.48	H / 3.00 / 270	-16.02
108.479 MHz	43.2 Qp	1.52 / 9.55 / 26.82 / 0.0	27.45	H / 3.00 / 270	-16.05
230.823 MHz	43.75 Qp	2.21 / 10.98 / 26.99 / 0.0	29.94	H / 1.00 / 270	-16.06
220.295 MHz	43.45 Qp	2.2 / 10.78 / 26.94 / 0.0	29.49	H / 1.00 / 90	-16.51
118.303 MHz	42.7 Qp	1.6 / 9.43 / 26.9 / 0.0	26.83	H / 3.00 / 270	-16.67
219.593 MHz	42.9 Qp	2.2 / 10.75 / 26.93 / 0.0	28.92	H / 1.00 / 90	-17.08
128.124 MHz	41.05 Qp	1.71 / 8.51 / 26.84 / 0.0	24.43	H / 3.00 / 270	-19.07
113.627 MHz	39.5 Qp	1.58 / 9.6 / 26.88 / 0.0	23.8	H / 3.00 / 270	-19.7
126.704 MHz	39.15 Qp	1.68 / 8.63 / 26.86 / 0.0	22.6	H / 3.00 / 90	-20.9
128.304 MHz	37.6 Qp	1.72 / 8.49 / 26.84 / 0.0	20.97	H / 3.00 / 270	-22.53
125.013 MHz	36.95 Qp	1.64 / 8.81 / 26.88 / 0.0	20.53	H / 3.00 / 270	-22.97
134.803 MHz	35.5 Qp	1.77 / 8.29 / 26.8 / 0.0	18.76	H / 3.00 / 270	-24.74
127.969 MHz	33.85 Qp	1.71 / 8.52 / 26.85 / 0.0	17.23	H / 3.00 / 270	-26.27

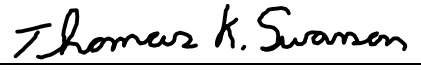
Tested by: RMJ

Printed

Signature

Reviewed by: TKS

Printed

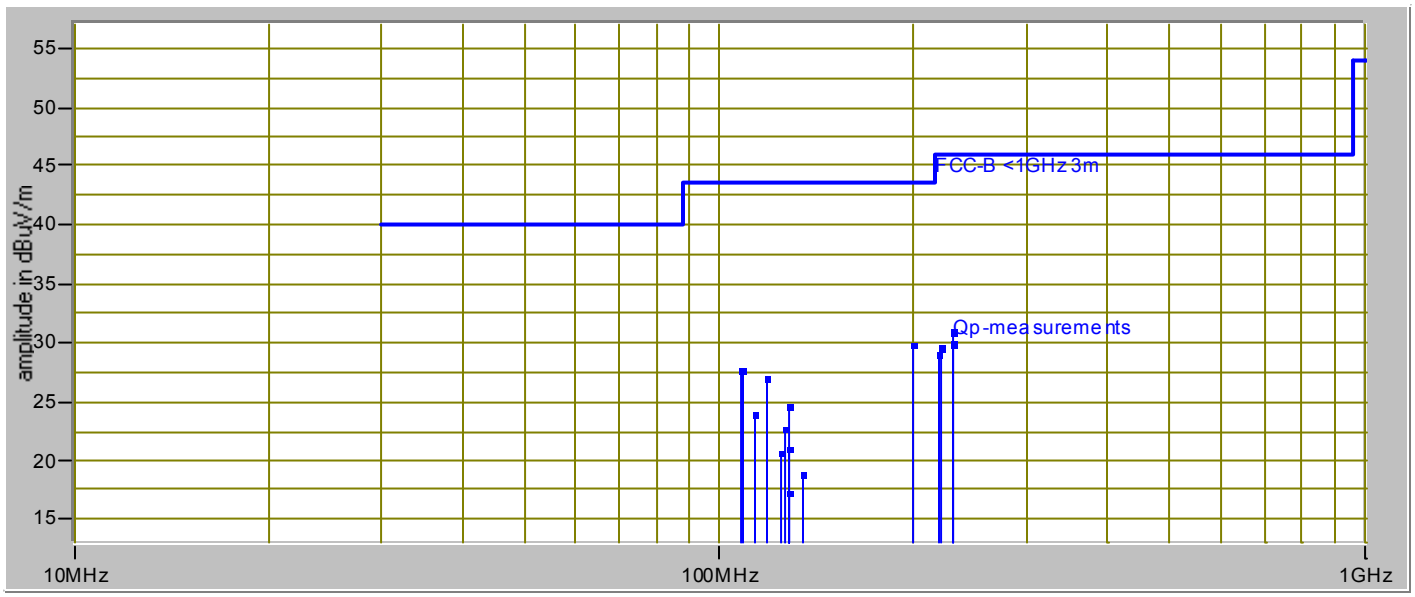


Signature

RADIATED EMISSIONS

Test Report #:	WC402657 Run 3	Test Area:	STS		
EUT Model #:	37742	Date:	6/15/04		
EUT Serial #:	NJD000453P	EUT Power:	3 VDC -BATTERY	Temperature:	20.0 °C
Test Method:	FCC B			Air Pressure:	97.0 kPa
Customer:	MEDTRONIC			Rel. Humidity:	40.0 %
EUT Description:	PATIENT PROGRAMMER , RX-1 APPLICATION				
Notes:	TELEMTRY ACTIVE				
Data File Name:	2657.dat			Page:	5 of 5

Graph:



Tested by: RMJ

Printed _____ Signature _____

Reviewed by: TKS

Printed _____ Signature _____

Appendix B

Constructional Data Form

and/or

Product Information Form(s)

TÜV PRODUCT SERVICE INC 19333 Wild Mountain Road Taylors Falls MN 55084-1758 Tel: 651 638 0297 Fax: 651 638 0298 Rev.No 1.0

Form

EMC Test Plan and Constructional Data Form

PRODUCT SERVICE

PLEASE COMPLETE THIS DOCUMENT IN FULL, ENTERING N/A IF THE FIELD IS NOT APPLICABLE.

Applicant -- ***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 Neurological
Address: 800 53rd Avenue NE
Columbia Heights, MN 55421

Contact: Debbie Gorski Position: Design Assurance Engineer
Phone: 763-514-7489 Fax: 763-514-5612
E-mail Address: debbie.gorski@medtronic.com

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

EUT Description: Battery-powered, hand-held programmer
EUT Name: RX1 Patient Programmer
Model No.: 37742 Serial No.:
Product Options: External antenna (model 37092)
Configurations to be tested: 37742 and 37092 (patient programmer and external antenna)

Test Objective

- ☐ EMC Directive 89/336/EEC (EMC)
  - Std:
- ☐ Machinery Directive 89/392/EEC (EMC)
  - Std:
- ☒ Active Implantable Medical Device Directive 90/385/EEC (EMC)
  - Std: See attachment
- ☐ Vehicle Directive 72/245/EEC (EMC)
  - Std:
- ☐ FDA Reviewers Guidance for Premarket Notification Submissions (EMC)

- ☒ FCC: Class ☐ A ☒ B Part 15,C
- ☐ VCCI: Class ☐ A ☐ B
- ☐ BCIQ: Class ☐ A ☐ B
- ☐ Canada: Class ☐ A ☐ B
- ☐ Australia: Class ☐ A ☐ B
- ☐ Other:

TÜV Product Service Certification Requested

- ☒ Attestation of Conformity (AoC)
- ☐ Certificate of Conformity (CoC)
- ☐ International EMC Mark (IEM)
- ☒ Compliance Document

Protection Class (N/A for vehicles) ☐ Class I ☐ Class II ☐

Form

EMC Test Plan and Constructional Data Form

(Press **F1** when field is selected to show additional information on Protection Class.)

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, TUV Product Service should:

☐ Call contact listed above, if not available then stop testing. (After hrs phone): _____

☐ Continue testing to complete test series.

☐ Continue testing to define corrective action.

☐ Stop testing.

EUT Specifications and Requirements

Length: 1.0" Width: 3.5" Height: 4.0" Weight: 6.0 ounces

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: 3.0Vdc (2 AAA alkaline batteries) (If battery powered, make sure battery life is sufficient to complete testing.)

# of Phases: _____

Current (Amps/phase(max)): _____ Current (Amps/phase(nominal)): _____

Other _____

Other Special Requirements

Typical Installation and/or Operating Environment

(ie. Hospital, Small Business, Industrial/Factory, etc.)

Operating environment can be residential, business and hospital/Doctor's office.

EUT Power Cable

☐ Permanent OR ☐ Removable Length (in meters): _____

☐ Shielded OR ☐ Unshielded

☒ Not Applicable

TÜV
PRODUCT SERVICE

EMC Test Plan and Constructional Data Form

EUT Interface Ports and Cables

Interface				Shielding								
Type	Analog	Digital	Qty	Yes	No	Type	Termination	Connector Type	Port Termination	Length (in meters)	Removable	Permanent
EXAMPLE: *RS232*	☐	☒	*2*	☒	☐	*Foil over braid*	*Coaxial*	*Metallized 9-pin D-Sub*	*Characteristic Impedance*	*6*	☒	☐
External antenna	☒	☐	1	☒	☐	N/A	Stranded	2.5mm, 4 position moldable plug	Solder	3	☒	☐
	☐	☐		☐	☐						☐	☐
	☐	☐		☐	☐						☐	☐
	☐	☐		☐	☐						☐	☐
	☐	☐		☐	☐						☐	☐
	☐	☐		☐	☐						☐	☐
	☐	☐		☐	☐						☐	☐
	☐	☐		☐	☐						☐	☐
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	☐	☐		☐	☐						☐	☐
	☐	☐		☐	☐						☐	☐
	☐	☐		☐	☐						☐	☐

Form

EMC Test Plan and Constructional Data Form

TÜV PRODUCT SERVICE

EUT Software.

Revision Level: Version 2.1.0

Description: **EMC Telemetry Test Menu [PEMTST-0110]**

Telemetry test menu uses the Stim On/Off keys to select the menu item.
Transmit alternating Trilogy Stim on/off commands
The Sync key on the patient programmer or the audio key on the recharger to select the highlighted item.

The telemetry test menu will provide the following:

- Transmit alternating Restore Stim on/off commands
- Transmit alternating Trilogy Stim on/off commands

Screen will display “Running” and count the number of successful transactions occurred while test is active.

Screen will display “Stopped” if telemetry is tried and failed 3 times. The success counter will display and hold the last successful transaction.

Pressing any key from the “Stopped” state will return to the telemetry test menu.

Command:
< 10 06 >< 30 01 AC 01 00 00 >< cc cc >

Responses:
[< 10 03 >< 31 01 09 >< cc cc >] = Success
[< 10 04 >< 31 02 rr ss >< cc cc >] = Failure,
rr = reason
ss = sub-reason

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. RF telemetry (see test plan attached to RFQ)

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

Description	Model #	Serial #	FCC ID #
Restore Patient programmer	37742	NJD000415P	LF537741
External antenna	37092		

Form

EMC Test Plan and Constructional Data Form

TÜV PRODUCT SERVICE

Support Equipment -- List and describe all support equipment which is not part of the EUT. (i.e. peripherals, simulators, etc)

Description	*Model #*	*Serial #*	*FCC ID #*
Neurostimulator (Restore)	37711		

Oscillator Frequencies

Frequency	*Derived Frequency*	*Component # / Location*	*Description of Use*
9.8304 MHz	N/A	Y2 (Digital Board: 602051 C)	uP Clock
32.768 kHz	N/A	Y3 (Digital Board: 602051 C)	Real Time Clock

Power Supply

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

Power Line Filters

Manufacturer	*Model #*	*Location in EUT*

Form

EMC Test Plan and Constructional Data Form

Critical EMI Components (Capacitors, ferrites, etc.)				
Description	***Manufacturer***	***Part # or Value***	***Qty***	***Component # / Location***
Ferrite Bead on External Antenna (37092)	Steward	2880268	1	External Antenna Cable

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

(PLEASE INSERT "**ELECTRONIC SIGNATURE**" BELOW IF POSSIBLE)

Authorization Signatures

Customer authorization to perform tests according to this test plan.	Date
Test Plan/CDF Prepared By (please print)	Date
Reviewed by TÜV Product Service Associate	Date

Appendix C

MEASUREMENT PROTOCOL FOR FCC

GENERAL INFORMATION

Measurement Uncertainty

The test system for conducted emissions is defined as the LISN, tuned receiver or spectrum analyzer, and coaxial cable. The test system for radiated emissions is defined as the antenna, the pre-amplifier, the spectrum analyzer and the coaxial cable. These test systems have a measurement uncertainty of ±4.5 dB. The equipment comprising the test systems are calibrated on an annual basis.

Justification

The Equipment Under Test (EUT) is configured in a typical user arrangement in accordance with the manufacturer's instructions. A cable is connected to each available port and either terminated with a peripheral into it's characteristic impedance or left unterminated. When appropriate, the cables are manually manipulated with respect to each other to obtain maximum emissions from the unit.

CONDUCTED EMISSIONS

The final level, expressed in dBμV, is arrived at by taking the reading directly from the EMI receiver. This level is compared directly to the FCC limit.

To convert between dBμV and μV, the following conversions apply:

dBμV = 20(log μV)

μV = Inverse log(dBμV/20)

RADIATED EMISSIONS

The final level, expressed in dBμV/m, is arrived at by taking the reading from the spectrum analyzer (Level dBμV), adding the antenna correction factor and cable loss factor (Factor dB) to it, then subtracting the preamp gain. This result then has the FCC limit subtracted from it to provide the Delta which gives the tabular data as shown in the data sheets in Attachment A.

Example:

FREQ (MHz)	LEVEL (dBuV)		CABLE/ANT/PREAMP (dB)			FINAL (dBuV/m)		POL/HGT/AZ	(m)	(deg)	DELTA1 FCC B
60.80	42.5Qp	+	1.2	+ 10.9	- 25.5 =	29.1		V	1.0	0.0 -	-10.9

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DETAILS OF TEST PROCEDURES

General Standard Information

The test methods used comply with ANSI C63.4-2001 - "Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz."

Conducted Emissions

Conducted emissions on the 60 Hz power interface of the EUT are measured in the frequency range of 450 kHz to 30 MHz. The measurements are performed using a receiver, which has CISPR characteristic bandwidth and quasi-peak 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. If the minimum passing margin appears to be less than 20 dB with a peak mode measurement, the emissions are re-measured using a tuned receiver or spectrum analyzer with quasi-peak and average detection and recorded on the data sheets.

Radiated Emissions

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 120 kHz/6 dB bandwidth and quasi-peak detection and measurements above 1000 MHz are made with a 1 MHz/6 dB bandwidth and peak detection. Table top equipment is placed on a 1.0 X 1.5 meter non-conducting table 80 centimeters above the ground plane. Floor standing equipment is placed directly on the turntable/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 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 are rotated 360 degrees. Intentional radiators are rotated through three orthogonal axes to determine the attitude that maximizes the emissions.

In the frequency range of 9 kHz to 30 MHz, measurements are made with quasi-peak or average detection with a loop antenna. The antenna is positioned 1 meter above the ground plane and rotated about its vertical axis for maximum response at each azimuth about the EUT. The antenna is also positioned horizontally at the specified distances.

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