

# 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	<b>37742</b>
MANUFACTURER'S ADDRESS	800 53 <sup>rd</sup> 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

# EMC EMISSION - TEST REPORT

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

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 53<sup>rd</sup> 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.*

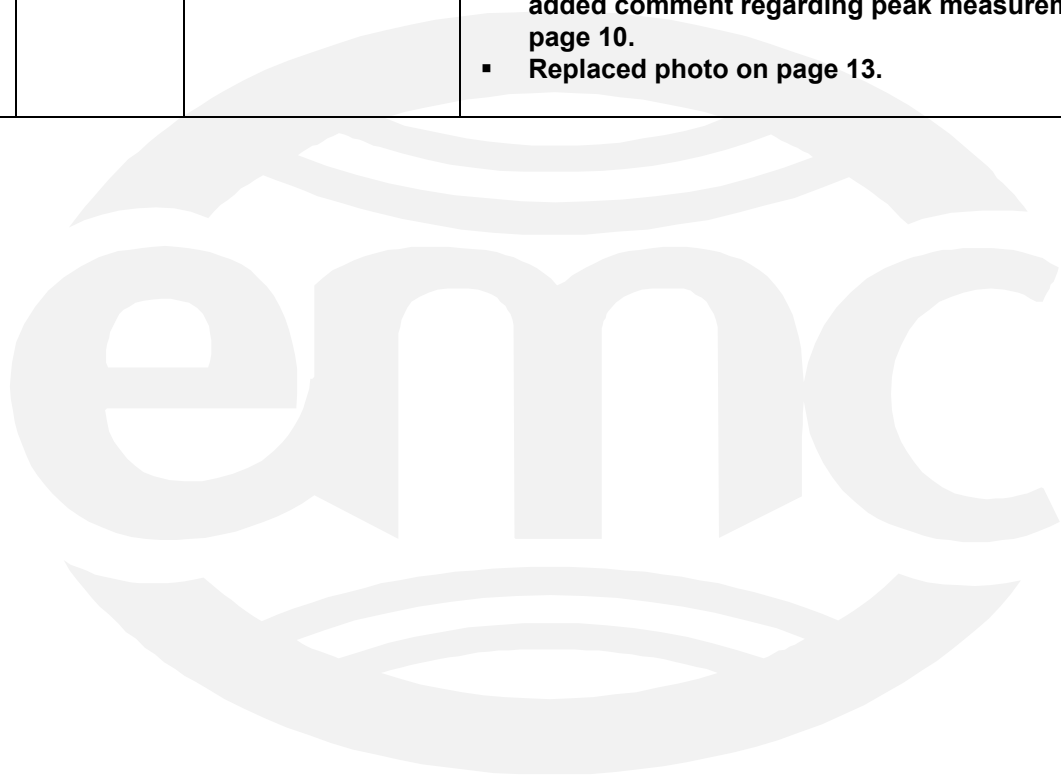
*TÜV Product Service Inc reports apply only to the specific samples tested under stated test conditions. It is the manufacturer's responsibility to assure that additional production units of this model are manufactured with identical electrical and mechanical components. TÜV Product Service Inc shall 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*

## REVISION RECORD

REVISION	TOTAL NUMBER OF PAGES	DATE	DESCRIPTION
	29	20 July 2004	Initial Release
A	30	18 April 2005	Revisions include: <ul style="list-style-type: none"> <li>▪ Changed Minimum limit margin for fundamental on page 10 to 41 dB. Also changed falloff to 52 dB/decade.</li> </ul>
B	30	21 April 2005	Revisions include: <ul style="list-style-type: none"> <li>▪ Added peak measurement data to page A3 and added comment regarding peak measurements to page 10.</li> <li>▪ Replaced photo on page 13.</li> </ul>



## D I R E C T O R Y - E M I S S I O N S

		Page(s)
<b>A)</b>	<b>Documentation</b>	
	Test report	<u>1 - 11</u>
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	Directory	<u>3</u>
	Test Regulations	<u>4</u>
	Deviation from standard / Summary	<u>11</u>
	Test-setups (Photos)	<u>12 - 13</u>
	Test-setup (drawing)	<u>Appendix A</u>
<b>B)</b>	<b>Test data</b>	
	FCC 15.207 - Conducted emissions      10/150 kHz - 30 MHz	<u>6, 10</u>
	FCC 15.209 - Radiated emissions      10 kHz - 30 MHz	<u>6, 10</u>
	FCC 15.209 - Radiated emissions      30 MHz - 1000 MHz	<u>7, 10</u>
	Interference power      30 MHz - 300 MHz	<u>N/A</u>
	Equivalent Radiated emissions      1 GHz - 18 GHz	<u>N/A</u>
<b>C)</b>	<b>Appendix A</b>	
	Test Data Sheets and Test Setup Drawing(s)	<u>A2 – A8</u>
<b>D)</b>	<b>Appendix B</b>	
	Constructional Data Form	<u>B2 – B7</u>
	Product Information Form(s)	<u>N/A</u>
<b>E)</b>	<b>Appendix C</b>	
	Measurement Protocol	<u>C1 - C2</u>

## EMISSIONS TEST REGULATIONS :

The emissions tests were performed according to following regulations:

- |   |   |                                    |
|---|---|------------------------------------|
| <input type="checkbox"/> - EN 50081-1 / 1991  | <input type="checkbox"/> - Group 1                          | <input type="checkbox"/> - Group 2 |
| <input type="checkbox"/> - EN 55011 / 1991  | <input type="checkbox"/> - Class A                          | <input type="checkbox"/> - Class B |
| <input type="checkbox"/> - EN 55013 / 1990  | <input type="checkbox"/> - Household appliances and similar |                                    |
| <input type="checkbox"/> - EN 55014 / 1987  | <input type="checkbox"/> - Portable tools                   |                                    |
|   | <input type="checkbox"/> - Semiconductor devices            |                                    |
| <input type="checkbox"/> - EN 55014 / A2:1990   | <input type="checkbox"/> - Household appliances and similar |                                    |
| <input type="checkbox"/> - EN 55014 / 1993  | <input type="checkbox"/> - Portable tools                   |                                    |
|   | <input type="checkbox"/> - Semiconductor devices            |                                    |
| <input type="checkbox"/> - EN 55015 / 1987  |   |                                    |
| <input type="checkbox"/> - EN 55015 / A1:1990   |   |                                    |
| <input type="checkbox"/> - EN 55015 / 1993  |   |                                    |
| <input type="checkbox"/> - EN 55022 / 1987  | <input type="checkbox"/> - Class A                          | <input type="checkbox"/> - Class B |
| <input type="checkbox"/> - EN 55022 / 1994  | <input type="checkbox"/> - Class A                          | <input type="checkbox"/> - Class B |
| <input type="checkbox"/> - BS   |   |                                    |
| <input type="checkbox"/> - VCCI   | <input type="checkbox"/> - Class A                          | <input type="checkbox"/> - Class B |
| <input checked="" type="checkbox"/> - FCC Part 15 Subpart C Section 15.209                      |   |                                    |
| <input type="checkbox"/> - FCC Part 15 Subpart C Section 15.207 Conducted Emission Requirements |   |                                    |
| <input type="checkbox"/> - FCC Part 15 Subpart B  | <input type="checkbox"/> - Class A                          | <input type="checkbox"/> - Class B |
| <input type="checkbox"/> - CISPR 11 (1990)  | <input type="checkbox"/> - Group 1                          | <input type="checkbox"/> - Group 2 |
|   | <input type="checkbox"/> - Class A                          | <input type="checkbox"/> - Class B |
| <input type="checkbox"/> - CISPR 22 (1993)  | <input type="checkbox"/> - Class A                          | <input type="checkbox"/> - Class B |

**Environmental conditions in the lab:**

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

**Sign Explanations:**

- not applicable
- applicable



**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
<input checked="" type="checkbox"/>	2534	ESHS-20	Rhode & Schwarz	EMI Receiver	837055/003	1-14-05
<input checked="" type="checkbox"/>	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.

**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
<input checked="" type="checkbox"/> - 3203	EM-6917B	Electro-Metrics	Biconicalog Periodic	106	3-30-05
<input checked="" type="checkbox"/> - 2690	8566B	Hewlett-Packard	Spectrum Analyzer (Unit F)	2430A00930	1-28-05
<input checked="" type="checkbox"/> - 2673	85662A	Hewlett-Packard	Analyzer Display (Unit A)	2152A03687	1-28-05
<input checked="" type="checkbox"/> - 2681	85650A	Hewlett-Packard	Quasi-Peak Adapter	2430A00562	2-23-05
<input checked="" type="checkbox"/> - 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



**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



**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
- \_\_\_\_\_
- \_\_\_\_\_

### 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: \_\_\_\_\_

**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 -

*Thomas K. Swanson*

*Russ M. Johnson*

T. K. Swanson  
Reviewed By

Tested By:  
R. M. Johnson

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

**Not Applicable**



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



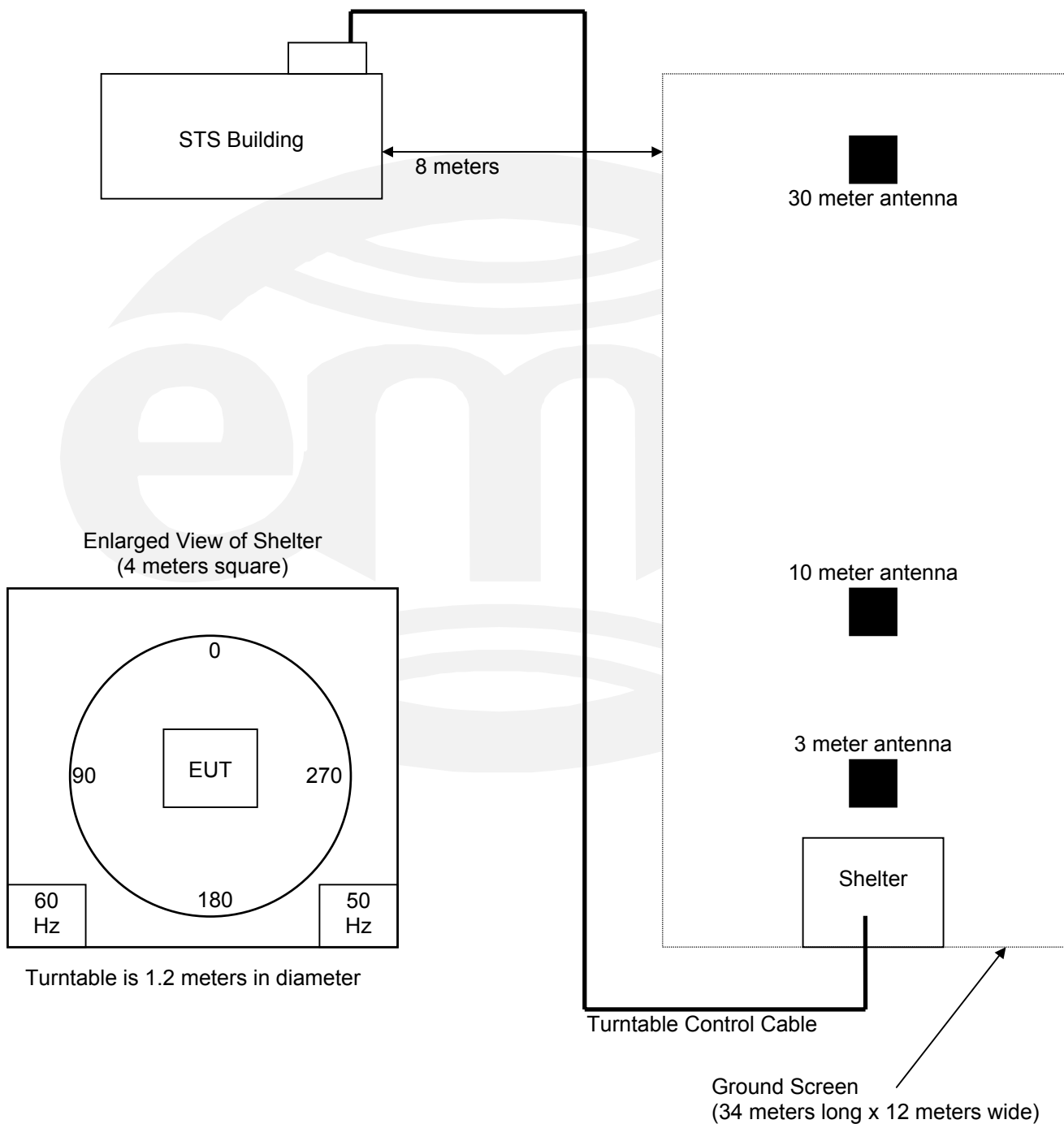
## Appendix A

Test Data Sheets  
and  
Test Setup Drawing(s)



**TEST SETUP FOR EMISSIONS TESTING**

WILD RIVER LAB  
Small Test Site (STS)





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
<b>0.175</b>		<b>112</b>	<b>86</b>	<b>59</b>	<b>33</b>	<b>N/A</b>	<b>-19</b>	<b>22.7434639</b>	<b>41.74346</b>
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



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: TELEMETRY 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



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: TELEMETRY 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

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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: TELEMETRY 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 %

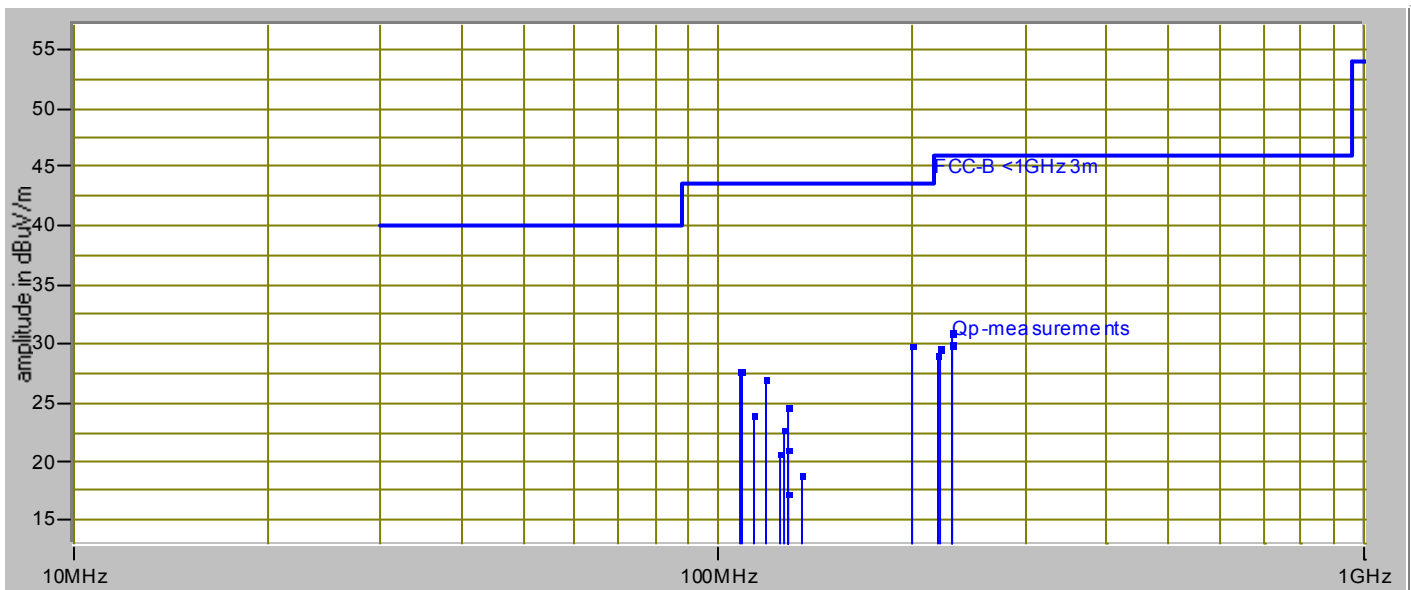
EUT Description: PATIENT PROGRAMMER , RX-1 APPLICATION

Notes: TELEMETRY 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)



# EMC Test Plan and Constructional Data Form

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 53<sup>rd</sup> 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)  FCC: Class  A  B Part 15,C  
 Std:  VCCI: Class  A  B
- Machinery Directive 89/392/EEC (EMC)  BCIQ: Class  A  B  
 Std:  Canada: Class  A  B
- Active Implantable Medical Device Directive 90/385/EEC (EMC)  Australia: Class  A  B  
 Std: See attachment  Other: \_\_\_\_\_
- Vehicle Directive 72/245/EEC (EMC)  
 Std: \_\_\_\_\_
- FDA Reviewers Guidance for Premarket Notification Submissions (EMC)

**TÜV Product Service Certification Requested**

- Attestation of Conformity (AoC)  International EMC Mark (IEM)
- Certificate of Conformity (CoC)  Compliance Document
- Protection Class (N/A for vehicles)  Class I  Class II



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

# 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

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
<b>EXAMPLE:</b> RS232	<input type="checkbox"/>	<input checked="" type="checkbox"/>	2	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Foil over braid	Coaxial	Metallized 9-pin D-Sub	Characteristic Impedance	6	<input checked="" type="checkbox"/>	<input type="checkbox"/>
External antenna	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1	<input checked="" type="checkbox"/>	<input type="checkbox"/>	N/A	Stranded	2.5mm, 4 position moldable plug	Solder	3	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>						<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>						<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>						<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>						<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>						<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>						<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>						<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>						<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>						<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>						<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>						<input type="checkbox"/>	<input type="checkbox"/>

## EMC Test Plan and Constructional Data Form

### 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		

## EMC Test Plan and Constructional Data Form

<b>Support Equipment</b> -- List and describe all support equipment which is not part of the EUT. (i.e. peripherals, simulators, etc)			
<i>Description</i>	<i>Model #</i>	<i>Serial #</i>	<i>FCC ID #</i>
Neurostimulator (Restore)	37711		

<b>Oscillator Frequencies</b>			
<i>Frequency</i>	<i>Derived Frequency</i>	<i>Component # / Location</i>	<i>Description of Use</i>
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

<b>Power Supply</b>			
<i>Manufacturer</i>	<i>Model #</i>	<i>Serial #</i>	<i>Type</i>
			<input type="checkbox"/> Switched-mode: (Frequency) _____ <input type="checkbox"/> Linear <input type="checkbox"/> Other: _____
			<input type="checkbox"/> Switched-mode: (Frequency) _____ <input type="checkbox"/> Linear <input type="checkbox"/> Other: _____

<b>Power Line Filters</b>		
<i>Manufacturer</i>	<i>Model #</i>	<i>Location in EUT</i>

Form

## EMC Test Plan and Constructional Data Form



<b>Critical EMI Components (Capacitors, ferrites, etc.)</b>				
<i>Description</i>	<i>Manufacturer</i>	<i>Part # or Value</i>	<i>Qty</i>	<i>Component # / Location</i>
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  $\pm 4.5$  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 its 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  $\text{dB}\mu\text{V}$ , is arrived at by taking the reading directly from the EMI receiver. This level is compared directly to the FCC limit.

To convert between  $\text{dB}\mu\text{V}$  and  $\mu\text{V}$ , the following conversions apply:

$$\text{dB}\mu\text{V} = 20(\log \mu\text{V})$$

$$\mu\text{V} = \text{Inverse log}(\text{dB}\mu\text{V}/20)$$

#### RADIATED EMISSIONS

The final level, expressed in  $\text{dB}\mu\text{V}/\text{m}$ , is arrived at by taking the reading from the spectrum analyzer (Level  $\text{dB}\mu\text{V}$ ), 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 ( $\text{dB}\mu\text{V}$ )	CABLE/ANT/PREAMP (dB)	FINAL ( $\text{dB}\mu\text{V}/\text{m}$ )	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

## 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  $\Omega$ /50  $\mu$ H (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.