

TEST RESULT SUMMARY

FCC PART 15 SUBPART C Section 15.209

| | |
|------------------------|--|
| MANUFACTURER'S NAME | Medtronic Incorporated |
| NAME OF EQUIPMENT | Patient Programmer |
| MODEL NUMBER | 7434A 3031A 7438 7440 External antennas: 23", 36" and 48" |
| MANUFACTURER'S ADDRESS | 800 53rd Avenue NE Columbia Heights MN 55421. |
| TEST REPORT NUMBER | W0578 |
| TEST DATE | 27 October 2000 |

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.

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.

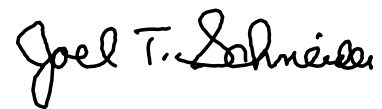
TÜV Product Service Inc, as an independent testing laboratory, declares that the equipment tested as specified above conforms to the requirements of FCC Part 15.

Date: 19 January 2001

Location: Taylors Falls MN
USA



R. M. Johnson
Test Technician



J. T. Schneider
Lead Engineer

Not Transferable

EMC EMISSION - TEST REPORT

Test Report File No. : **WC1G057801** Date of issue: 19 January 2001

Model / Serial No. : **7434A**
3031A
7438
7440 External antennas: 23", 36" and 48"

Product Type : Patient Programmer

Applicant : Medtronic Incorporated

Manufacturer : Medtronic Incorporated

License holder : Medtronic Incorporated

Address : 800 53rd Avenue NE
: Columbia Heights MN 55421

Test Result : **Positive** **Negative**

Test Project Number :
Reference(s) : **W0578**

Total pages including Appendices : **63**

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

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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 type="checkbox"/> - FCC Part 15 Subpart C Section 15.209 | | |
| <input checked="" type="checkbox"/> - FCC Part 15 Subpart B | <input type="checkbox"/> - Class A | <input checked="" 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 | : 16 °C |
| Relative Humidity | : 64 % |
| Atmospheric pressure | : 99.0 kPa |
| Power supply system | : 9 VDC |

Sign Explanations:

- not applicable
- applicable



Emissions Test Conditions: CONDUCTED EMISSIONS (Interference Voltage)

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 (150 kHz – 30 MHz)

The *RADIATED EMISSIONS* measurements were performed at the following test location:

- 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 :

- 3 meters
- 10 meters

- Test not applicable

Test equipment used :

| | Model Number | Manufacturer | Description | Serial Number | Cal Due |
|---------------------------------------|---------------------|---------------------|--------------------|----------------------|----------------|
| <input checked="" type="checkbox"/> - | HFH2-Z2 | Polarad | Loop Antenna | 879285/036 | 11-00 |
| <input checked="" type="checkbox"/> - | ESH-3 | Rohde & Schwarz | EMI Receiver | 892473/004 | 11-00 |

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

Emissions Test Conditions: RADIATED EMISSIONS (Electric Field)

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) – NSA measurements made 7-00, due 7-01
- Wild River Lab Small Test Site (Open Area Test Site) – NSA measurements made 7-00, due 7-01
- Oakwood Lab (Open Area Test Site)

at a test distance of :

- 3 meters
- 10 meters
- 30 meters

Test equipment used :

| Model Number | Manufacturer | Description | Serial Number | Cal Due |
|---|-----------------|------------------------------|---------------|---------|
| <input checked="" type="checkbox"/> - 85650A | Hewlett-Packard | Quasi-Peak Adapter | 2521A01006 | 11-01 |
| <input checked="" type="checkbox"/> - 85662A | Hewlett-Packard | Analyzer Display | 2403A08134 | 11-01 |
| <input checked="" type="checkbox"/> - 8566B | Hewlett-Packard | Spectrum Analyzer | 2430A00930 | 11-01 |
| <input checked="" type="checkbox"/> - 11867A | Hewlett-Packard | RF Limiter | 02442 | 03-01 |
| <input checked="" type="checkbox"/> - ZHL-1042J | Mini-Circuits | Pre-amplifier 1-4 GHz | H081396-16 | 03-01 |
| <input checked="" type="checkbox"/> - EM-6917B | Polarad | Biconicalog Periodic Antenna | 106 | 12-00 |

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)

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
- Refer to the Test Plan in Appendix B for details.

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 : _____
- _____ Type : _____
- _____ Type : _____
- _____ Type : _____

- unshielded power cable

- unshielded cables

- shielded cables

MPS.No.: _____

- customer specific cables

- _____

- _____

Emission Test Results:

Conducted emissions 10/150 kHz - 30 MHz

The requirements are - N/A - MET - NOT MET
 Minimum margin of compliance _____ dB at _____ MHz
 Maximum margin of non-compliance _____ dB at _____ MHz

FCC Radiated emissions 10 kHz - 30 MHz

The requirements are - N/A - MET - NOT MET
 Minimum limit margin for fundamental _____ 19 dB at _____ 175.0 kHz
 Minimum limit margin for spurious/harmonics _____ 10 dB at _____ 525.0 KHz

Remarks: The fundamental was measured to be 63 dBuV/m (1412 microvolts/meter) in quasi-peak mode at 10 meters. The 10 meter limit is extrapolated using the square of an inverse linear distance extrapolation factor (40 dB/decade) to be 82 dBuV/m (12589 microvolts/meter). The measured falloff from 3 to 10 meters on the fundamental was 21 dB – graphing this rate would yield a 30 meter reading of 42 dBuV/m compared to a limit of 62 dBuV/m. The third harmonic was measured to be 63 dBuV/m (1412 microvolts/meter) in quasi-peak mode at 3 meters. The 3 meter limit is extrapolated using the square of an inverse linear distance extrapolation factor (40 dB/decade) to be 73 dBuV/m (4668 microvolts/meter). Using the 21 dB falloff rate from 3 to 10 meters, this would graph out to 21 dBuV/m reading at 30 meters compared to a limit of 33 dBuV/m. Ambient levels prevented measurements from being made at distances further than those described.

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

The requirements are - N/A - MET - NOT MET
 Minimum margin of compliance _____ 1 dB at _____ 84.6 MHz
 Maximum margin of non-compliance _____ dB at _____ MHz

Remarks: _____

FCC Equivalent Radiated emissions 1 GHz - 4.2 GHz

The requirements are - N/A - MET - NOT MET
 Minimum margin of compliance _____ dB at _____ MHz
 Maximum margin of non-compliance _____ dB at _____ MHz

Remarks: _____

DEVIATIONS FROM STANDARD:

None.

GENERAL REMARKS:

SUMMARY:

The requirements according to the technical regulations are

- met

- **not** met.

The device under test does

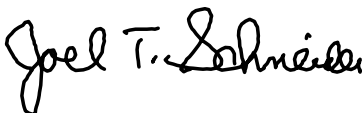
- fulfill the general approval requirements mentioned on page 3.

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

Testing Start Date: 27 October 2000

Testing End Date: 27 October 2000

- TÜV PRODUCT SERVICE INC -



J. T. Schneider
Lead Engineer



Tested By:
R. M. Johnson & J. C. Sausen

Test-setup photo(s):
Radiated emission 10 kHz - 30 MHz
And
Radiated emission 30 MHz - 1000 MHz

See Test-Setup Exhibit



Test-setup photo(s): including 36" external antenna
Radiated emission 10 kHz - 30 MHz
And
Radiated emission 30 MHz - 1000 MHz

See Test-Setup Exhibit



Test-setup photo(s): including 23", 36" and 48" external antennas
Radiated emission 10 kHz - 30 MHz
And
Radiated emission 30 MHz - 1000 MHz

See Test-Setup Exhibit



Appendix A

Test Data Sheets
and
Test Setup Drawing(s)



TEST SETUP FOR EMISSIONS TESTING

WILD RIVER LAB
Small Test Site (STS)

See Test-Setup Exhibit



FCC Pt. 15.209 Radiated Emissions on Medtronic - Model 7434A

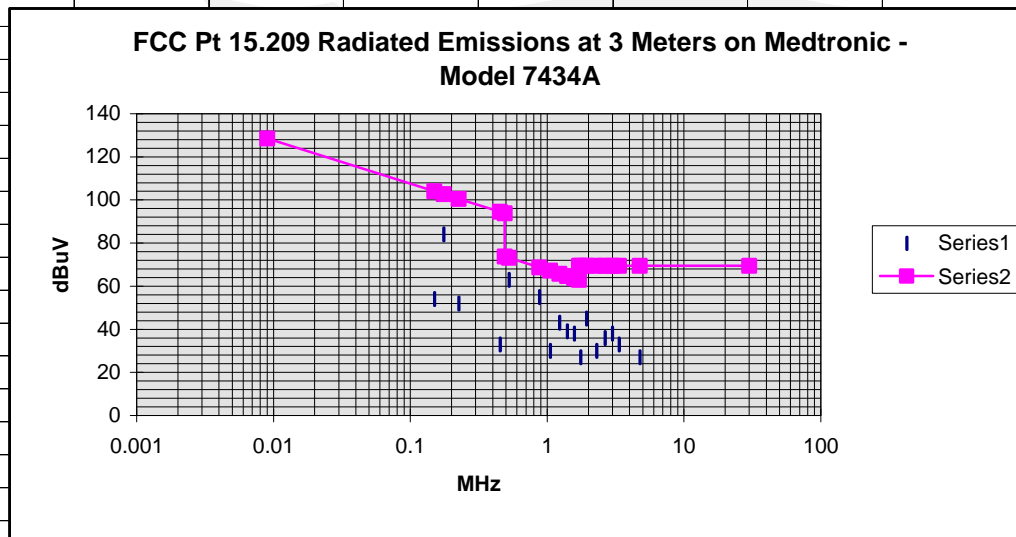
Test Report #W0578

Date: 27 October 2000

| MHz | 3 meters | | 10 meters | |
|--------|------------|-----------|-----------------|-----------|
| | dBuV/m | margin-dB | dBuV/m | margin-dB |
| | spec limit | 15.209 | spec limit | 15.209 |
| 0.009 | | 128.5194 | | 108.5194 |
| 0.15 | 54 | 104.0824 | 50.0824 | 84.0824 |
| 0.175 | 84 | 102.7435 | 18.74346 | 63 |
| 0.225 | 52 | 100.5606 | 48.56057 | 80.56057 |
| 0.45 | 33 | 94.53997 | 61.53997 | 74.53997 |
| 0.49 | | 93.8003 | | 73.8003 |
| 0.49 | | 73.8003 | | 53.8003 |
| 0.525 | 63 | 73.20104 | 10.20104 | 53.20104 |
| 0.875 | 55 | 68.76406 | 13.76406 | 48.76406 |
| 1.05 | 30 | 67.18044 | 37.18044 | 47.18044 |
| 1.2268 | 43 | 65.82875 | 22.82875 | 45.82875 |
| 1.4 | 39 | 64.68166 | 25.68166 | 44.68166 |
| 1.575 | 38 | 63.65861 | 25.65861 | 43.65861 |
| 1.705 | | 62.96974 | 62.96974 | 42.96974 |
| 1.705 | | 69.54243 | 69.54243 | 49.54243 |
| 1.75 | 27 | 69.54243 | 42.54243 | 49.54243 |
| 1.9338 | 45 | 69.54243 | 24.54243 | 49.54243 |
| 2.29 | 30 | 69.54243 | 39.54243 | 49.54243 |
| 2.6329 | 36 | 69.54243 | 33.54243 | 49.54243 |
| 2.983 | 38 | 69.54243 | 31.54243 | 49.54243 |
| 3.34 | 33 | 69.54243 | 36.54243 | 49.54243 |
| 4.75 | 27 | 69.54243 | 42.54243 | 49.54243 |
| 30 | | 69.54243 | | 49.54243 |

Quasi-Peak

Tested By: R. M. Johnson



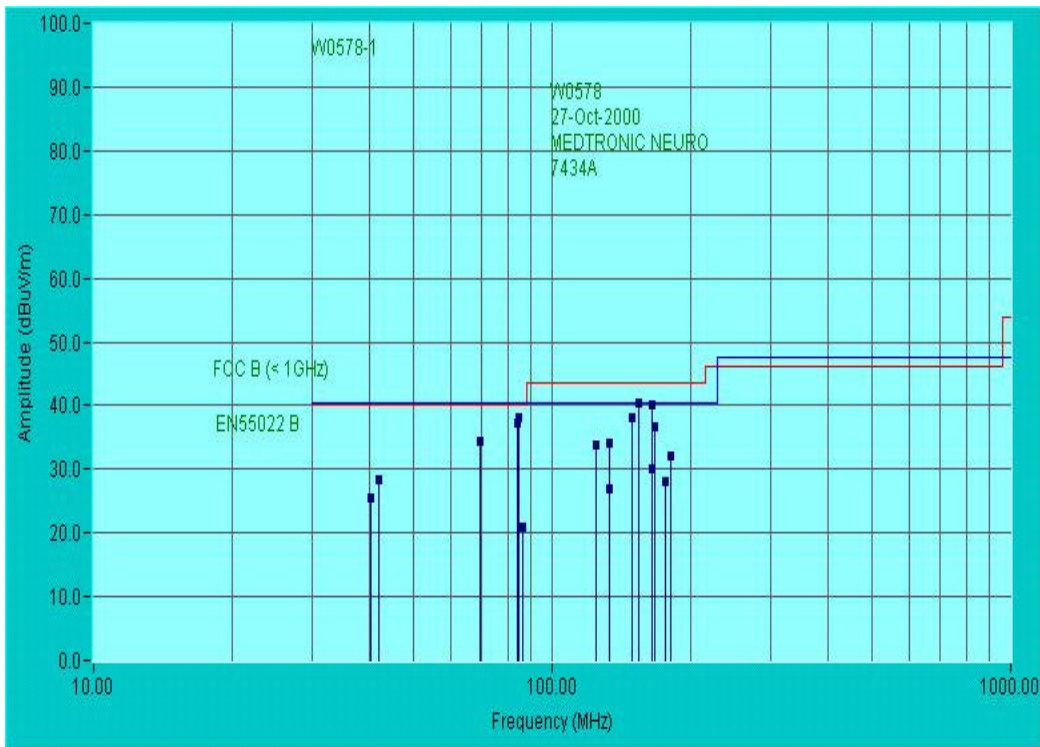
Radiated Electromagnetic Emissions



Test Report #: W0578 Run 01 Test Area: STS 3m
 Test Method: FCC Part 15 Test Date: 27-Oct-2000
 EUT Model #: 7434A EUT Power: _____
 EUT Serial #: _____
 Manufacturer: MEDTRONIC NEURO
 EUT Description: PATIENT PROGRAMMER
 Notes: _____

Temperature: 16 °C
 Relative Humidity: 64 %
 Air Pressure: 99 kPa
 Page: 1 of 7

| FREQ (MHz) | LEVEL (dBuV) | CABLE / ANT / PREAMP (dB) (dBm) (dB) | FINAL (dBuV/m) | POL / HGT / AZ (m) (DEG) | DELTA1 FCC B (< 1GHz) | DELTA2 EN55022 B |
|---------------|-----------------|---|-------------------|-----------------------------|--------------------------|---------------------|
|---------------|-----------------|---|-------------------|-----------------------------|--------------------------|---------------------|



Tested by: ROSS M. JOHNSON

Printed

Signature

Reviewed by: J. T. Schneider

Printed

Signature

Radiated Electromagnetic Emissions



Test Report #: W0578 Run 01 Test Area: STS 3m
 Test Method: FCC Part 15 Test Date: 27-Oct-2000
 EUT Model #: 7434A EUT Power: _____
 EUT Serial #: _____ Temperature: 16 °C
 Manufacturer: MEDTRONIC NEURO Relative Humidity: 64 %
 EUT Description: PATIENT PROGRAMMER Air Pressure: 99 kPa
 Notes: _____ Page: 2 of 7

| FREQ (MHz) | LEVEL (dBuV) | CABLE / ANT / PREAMP (dB) (dBm) (dB) | FINAL (dBuV/m) | POL / HGT / AZ (m) (DEG) | DELTA1 FCC B (< 1GHz) | DELTA2 EN55022 B |
|---------------|-----------------|---|-------------------|-----------------------------|--------------------------|---------------------|
|---------------|-----------------|---|-------------------|-----------------------------|--------------------------|---------------------|

| 36 INCH ANTENNA. | | | | | | |
|--|---------|-------------------|------|-----------------|-------|-------|
| 84.64 | 57.4 Qp | 1.9 / 6.6 / 28.3 | 37.7 | H / 4.0 / 0.0 | -2.3 | -2.8 |
| 83.91 | 34.4 Qp | 1.9 / 6.7 / 28.3 | 14.7 | V / 1.0 / 0.0 | -25.3 | -25.8 |
| 133.65 | 29.1 Qp | 2.4 / 8.0 / 28.2 | 11.3 | V / 1.0 / 0.0 | -32.2 | -29.2 |
| 165.15 | 37.0 Qp | 2.7 / 10.6 / 28.1 | 22.2 | V / 1.0 / 0.0 | -21.3 | -18.3 |
| 181.24 | 38.1 Qp | 2.8 / 9.4 / 28.1 | 22.2 | V / 1.0 / 0.0 | -21.3 | -18.3 |
| 83.91 | 47.6 Qp | 1.9 / 6.7 / 28.3 | 27.9 | V / 1.0 / 90.0 | -12.1 | -12.6 |
| 181.24 | 38.1 Qp | 2.8 / 9.4 / 28.1 | 22.3 | V / 1.0 / 90.0 | -21.2 | -18.2 |
| 40.20 | 36.1 Qp | 1.5 / 15.2 / 28.4 | 24.4 | V / 1.0 / 90.0 | -15.6 | -16.1 |
| 181.24 | 39.6 Qp | 2.8 / 9.4 / 28.1 | 23.7 | V / 1.0 / 180.0 | -19.8 | -16.8 |
| MAXIMIZED. | | | | | | |
| 83.91 | 50.4 Qp | 1.9 / 6.7 / 28.3 | 30.8 | V / 3.3 / 270.0 | -9.2 | -9.7 |
| 40.20 | 37.4 Qp | 1.5 / 15.2 / 28.4 | 25.6 | V / 1.0 / 96.0 | -14.4 | -14.9 |
| MAXED ANTENNA AND ROTATED EUT 360 DEGREES. | | | | | | |
| 83.93 | 56.8 Qp | 1.9 / 6.7 / 28.3 | 37.2 | H / 3.0 / 0.0 | -2.8 | -3.3 |
| 84.64 | 57.3 Qp | 1.9 / 6.6 / 28.3 | 37.6 | H / 3.0 / 0.0 | -2.4 | -2.9 |
| 133.65 | 30.3 Qp | 2.4 / 8.0 / 28.2 | 12.5 | H / 3.0 / 0.0 | -31.0 | -28.0 |
| 165.15 | 39.0 Qp | 2.7 / 10.6 / 28.1 | 24.1 | H / 3.0 / 90.0 | -19.4 | -16.4 |

Tested by: **ROSS M. JOHNSON**

Printed

Signature

Reviewed by: **J. T. Schneider**

Printed

Signature

Radiated Electromagnetic Emissions



| | | | | | |
|------------------|--------------------|--------------------|-------------|-----|--|
| Test Report #: | W0578 Run 01 | Test Area: | STS 3m | | |
| Test Method: | FCC Part 15 | Test Date: | 27-Oct-2000 | | |
| EUT Model #: | 7434A | EUT Power: | | | |
| EUT Serial #: | | Temperature: | 16 | °C | |
| Manufacturer: | MEDTRONIC NEURO | Relative Humidity: | 64 | % | |
| EUT Description: | PATIENT PROGRAMMER | Air Pressure: | 99 | kPa | |
| Notes: | | Page: | 3 of 7 | | |

| FREQ (MHz) | LEVEL (dBuV) | CABLE / ANT / PREAMP | | | FINAL (dBuV/m) | POL / HGT / AZ (m) (DEG) | DELTA1 FCC B (< 1GHz) | DELTA2 EN55022 B |
|--|-----------------|----------------------|-------|------|-------------------|-----------------------------|--------------------------|---------------------|
| | | (dB) | (dBm) | (dB) | | | | |
| 181.24 | 42.9 Qp | 2.8 / 9.4 / 28.1 | | | 27.0 | H / 3.0 / 90.0 | -16.5 | -13.5 |
| 133.65 | 34.5 Qp | 2.4 / 8.0 / 28.2 | | | 16.7 | H / 3.0 / 270.0 | -26.8 | -23.8 |
| 133.46 | 43.3 Qp | 2.4 / 8.0 / 28.2 | | | 25.5 | H / 3.0 / 270.0 | -18.0 | -15.0 |
| 165.15 | 44.6 Qp | 2.7 / 10.6 / 28.1 | | | 29.7 | H / 3.0 / 270.0 | -13.8 | -10.8 |
| 181.24 | 48.1 Qp | 2.8 / 9.4 / 28.1 | | | 32.2 | H / 3.0 / 270.0 | -11.3 | -8.3 |
| 167.53 | 52.0 Qp | 2.7 / 10.2 / 28.1 | | | 36.8 | H / 3.0 / 270.0 | -6.7 | -3.7 |
| MAXIMIZED. | | | | | | | | |
| 84.64 | 57.8 Qp | 1.9 / 6.6 / 28.3 | | | 38.1 | H / 3.8 / 0.0 | -1.9 | -2.4 |
| 83.93 | 56.9 Qp | 1.9 / 6.7 / 28.3 | | | 37.3 | H / 4.0 / 0.0 | -2.7 | -3.2 |
| MAXED ANTENNA AND ROTATED EUT 360 DEGREES. | | | | | | | | |
| CHANGED TO THE 48 INCH ANTENNA. | | | | | | | | |
| 42.00 | 32.7 Qp | 1.4 / 15.0 / 28.4 | | | 20.8 | V / 1.0 / 0.0 | -19.2 | -19.7 |
| 69.55 | 31.4 Qp | 1.7 / 9.8 / 28.3 | | | 14.6 | V / 1.0 / 0.0 | -25.4 | -25.9 |
| 86.40 | 28.7 Qp | 1.9 / 6.9 / 28.3 | | | 9.2 | V / 1.0 / 0.0 | -30.8 | -31.3 |
| 124.70 | 35.4 Qp | 2.4 / 7.9 / 28.2 | | | 17.5 | V / 1.0 / 0.0 | -26.0 | -23.0 |
| 149.65 | 44.8 Qp | 2.5 / 9.6 / 28.2 | | | 28.8 | V / 1.0 / 0.0 | -14.7 | -11.7 |
| 154.90 | 46.2 Qp | 2.6 / 10.2 / 28.1 | | | 30.9 | V / 1.0 / 0.0 | -12.6 | -9.6 |
| 176.35 | 33.6 Qp | 2.8 / 9.5 / 28.1 | | | 17.8 | V / 1.0 / 0.0 | -25.7 | -22.7 |
| 42.00 | 37.7 Pk | 1.4 / 15.0 / 28.4 | | | 25.8 | V / 1.0 / 90.0 | -14.2 | -14.7 |
| 69.55 | 35.3 Pk | 1.7 / 9.8 / 28.3 | | | 18.5 | V / 1.0 / 90.0 | -21.5 | -22.0 |
| 42.00 | 40.0 Qp | 1.4 / 15.0 / 28.4 | | | 28.0 | V / 1.0 / 90.0 | -12.0 | -12.5 |

Tested by: **ROSS M. JOHNSON**

Printed

Signature

Reviewed by: **J. T. Schneider**

Printed

Signature

Radiated Electromagnetic Emissions



Test Report #: W0578 Run 01 Test Area: STS 3m
 Test Method: FCC Part 15 Test Date: 27-Oct-2000
 EUT Model #: 7434A EUT Power: _____
 EUT Serial #: _____ Temperature: 16 °C
 Manufacturer: MEDTRONIC NEURO Relative Humidity: 64 %
 EUT Description: PATIENT PROGRAMMER Air Pressure: 99 kPa
 Notes: _____ Page: 4 of 7

| FREQ (MHz) | LEVEL (dBuV) | CABLE / ANT / PREAMP (dB) (dBm) (dB) | FINAL (dBuV/m) | POL / HGT / AZ (m) (DEG) | DELTA1 FCC B (< 1GHz) | DELTA2 EN55022 B |
|---------------|-----------------|---|-------------------|-----------------------------|--------------------------|---------------------|
| 69.55 | 41.1 Qp | 1.7 / 9.8 / 28.3 | 24.3 | V / 1.0 / 90.0 | -15.7 | -16.2 |
| 86.40 | 32.0 Qp | 1.9 / 6.9 / 28.3 | 12.6 | V / 1.0 / 90.0 | -27.4 | -27.9 |
| 176.35 | 37.2 Qp | 2.8 / 9.5 / 28.1 | 21.4 | V / 1.0 / 90.0 | -22.1 | -19.1 |
| 42.00 | 40.4 Qp | 1.4 / 15.0 / 28.4 | 28.4 | V / 1.0 / 100.0 | -11.6 | -12.1 |
| 69.55 | 42.1 Qp | 1.7 / 9.8 / 28.3 | 25.3 | V / 3.0 / 100.0 | -14.7 | -15.2 |
| 86.40 | 33.5 Qp | 1.9 / 6.9 / 28.3 | 14.1 | V / 3.0 / 100.0 | -25.9 | -26.4 |
| 86.40 | 34.1 Qp | 1.9 / 6.9 / 28.3 | 14.6 | V / 3.0 / 0.0 | -25.4 | -25.9 |
| 124.70 | 39.6 Qp | 2.4 / 7.9 / 28.2 | 21.7 | V / 3.0 / 0.0 | -21.8 | -18.8 |
| 149.65 | 46.6 Qp | 2.5 / 9.6 / 28.2 | 30.6 | V / 3.0 / 0.0 | -12.9 | -9.9 |
| 154.90 | 48.0 Qp | 2.6 / 10.2 / 28.1 | 32.7 | V / 3.0 / 0.0 | -10.8 | -7.8 |
| 69.55 | 42.8 Qp | 1.7 / 9.8 / 28.3 | 26.0 | V / 3.0 / 270.0 | -14.0 | -14.5 |
| MAXIMIZED. | | | | | | |
| 154.90 | 50.5 Qp | 2.6 / 10.2 / 28.1 | 35.1 | V / 2.3 / 25.0 | -8.4 | -5.4 |
| 69.55 | 51.1 Qp | 1.7 / 9.8 / 28.3 | 34.3 | H / 3.0 / 0.0 | -5.7 | -6.2 |
| 86.40 | 39.2 Qp | 1.9 / 6.9 / 28.3 | 19.7 | H / 3.0 / 0.0 | -20.3 | -20.8 |
| 124.70 | 47.1 Qp | 2.4 / 7.9 / 28.2 | 29.2 | H / 3.0 / 90.0 | -14.3 | -11.3 |
| 133.46 | 50.9 Qp | 2.4 / 8.0 / 28.2 | 33.1 | H / 3.0 / 90.0 | -10.4 | -7.4 |
| 133.65 | 44.4 Qp | 2.4 / 8.0 / 28.2 | 26.6 | H / 3.0 / 90.0 | -16.9 | -13.9 |

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Reviewed by: J. T. Schneider

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Radiated Electromagnetic Emissions



Test Report #: W0578 Run 01 Test Area: STS 3m
 Test Method: FCC Part 15 Test Date: 27-Oct-2000
 EUT Model #: 7434A EUT Power: _____
 EUT Serial #: _____ Temperature: 16 °C
 Manufacturer: MEDTRONIC NEURO Relative Humidity: 64 %
 EUT Description: PATIENT PROGRAMMER Air Pressure: 99 kPa
 Notes: _____ Page: 5 of 7

| FREQ (MHz) | LEVEL (dBuV) | CABLE / ANT / PREAMP (dB) (dBm) (dB) | FINAL (dBuV/m) | POL / HGT / AZ (m) (DEG) | DELTA1 FCC B (< 1GHz) | DELTA2 EN55022 B |
|--|-----------------|---|-------------------|-----------------------------|--------------------------|---------------------|
| 149.65 | 52.3 Qp | 2.5 / 9.6 / 28.2 | 36.3 | H / 3.0 / 90.0 | -7.2 | -4.2 |
| 154.90 | 53.1 Qp | 2.6 / 10.2 / 28.1 | 37.8 | H / 3.0 / 90.0 | -5.7 | -2.7 |
| 165.15 | 44.1 Qp | 2.7 / 10.6 / 28.1 | 29.3 | H / 3.0 / 90.0 | -14.2 | -11.2 |
| 176.35 | 42.8 Qp | 2.8 / 9.5 / 28.1 | 27.0 | H / 3.0 / 90.0 | -16.5 | -13.5 |
| | | | | | | |
| 86.40 | 40.5 Qp | 1.9 / 6.9 / 28.3 | 21.0 | H / 3.0 / 270.0 | -19.0 | -19.5 |
| 124.70 | 47.2 Qp | 2.4 / 7.9 / 28.2 | 29.3 | H / 3.0 / 270.0 | -14.2 | -11.2 |
| 133.46 | 51.1 Qp | 2.4 / 8.0 / 28.2 | 33.3 | H / 3.0 / 270.0 | -10.2 | -7.2 |
| 133.65 | 44.6 Qp | 2.4 / 8.0 / 28.2 | 26.8 | H / 3.0 / 270.0 | -16.7 | -13.7 |
| 149.65 | 52.5 Qp | 2.5 / 9.6 / 28.2 | 36.4 | H / 3.0 / 270.0 | -7.1 | -4.1 |
| 154.90 | 53.0 Qp | 2.6 / 10.2 / 28.1 | 37.7 | H / 3.0 / 270.0 | -5.8 | -2.8 |
| 165.15 | 44.8 Qp | 2.7 / 10.6 / 28.1 | 30.0 | H / 3.0 / 270.0 | -13.5 | -10.5 |
| 165.07 | 51.4 Qp | 2.7 / 10.6 / 28.1 | 36.6 | H / 3.0 / 270.0 | -6.9 | -3.9 |
| 176.35 | 43.8 Qp | 2.8 / 9.5 / 28.1 | 28.0 | H / 3.0 / 270.0 | -15.5 | -12.5 |
| | | | | | | |
| MAXIMIZED. | | | | | | |
| 69.55 | 51.2 Qp | 1.7 / 9.8 / 28.3 | 34.5 | H / 3.5 / 0.0 | -5.5 | -6.0 |
| 154.90 | 55.6 Qp | 2.6 / 10.2 / 28.1 | 40.3 | H / 1.6 / 291.0 | -3.2 | -0.2 |
| 165.07 | 55.0 Qp | 2.7 / 10.6 / 28.1 | 40.1 | H / 1.6 / 293.0 | -3.4 | -0.4 |
| 149.65 | 54.1 Qp | 2.5 / 9.6 / 28.2 | 38.1 | H / 2.2 / 282.0 | -5.4 | -2.4 |
| 133.46 | 52.0 Qp | 2.4 / 8.0 / 28.2 | 34.2 | H / 2.0 / 276.0 | -9.3 | -6.3 |
| | | | | | | |
| MAXED ANTENNA AND ROTATED EUT 360 DEGREES. | | | | | | |
| | | | | | | |
| CHANGED TO 23 INCH ANTENNA. | | | | | | |
| 124.70 | 51.4 Qp | 2.4 / 7.9 / 28.2 | 33.5 | H / 3.0 / 180.0 | -10.0 | -7.0 |

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Radiated Electromagnetic Emissions



Test Report #: W0578 Run 01 Test Area: STS 3m
 Test Method: FCC Part 15 Test Date: 27-Oct-2000
 EUT Model #: 7434A EUT Power: _____
 EUT Serial #: _____ Temperature: 16 °C
 Manufacturer: MEDTRONIC NEURO Relative Humidity: 64 %
 EUT Description: PATIENT PROGRAMMER Air Pressure: 99 kPa
 Notes: _____ Page: 6 of 7

| FREQ (MHz) | LEVEL (dBuV) | CABLE / ANT / PREAMP (dB) (dBm) (dB) | FINAL (dBuV/m) | POL / HGT / AZ (m) (DEG) | DELTA1 FCC B (< 1GHz) | DELTA2 EN55022 B |
|--|-----------------|---|-------------------|-----------------------------|--------------------------|---------------------|
| MAXIMIZED. | | | | | | |
| 124.70 | 51.8 Qp | 2.4 / 7.9 / 28.2 | 33.9 | H / 2.7 / 184.0 | -9.6 | -6.6 |
| MAXED ANTENNA AND ROTATED EUT 360 DEGREES. | | | | | | |
| CHANGED TO INTERNAL ANTENNA . | | | | | | |
| NO NEW OR HIGHER EMISSIONS DETECTED WITH INTERNAL ANTENNA. | | | | | | |
| END OF SCAN 30 - 1000MHZ. | | | | | | |
| | | | | | | |

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Radiated Electromagnetic Emissions



Test Report #: W0578 Run 01 Test Area: STS 3m
 Test Method: FCC Part 15 Test Date: 27-Oct-2000
 EUT Model #: 7434A EUT Power: _____
 EUT Serial #: _____ Temperature: 16 °C
 Manufacturer: MEDTRONIC NEURO Relative Humidity: 64 %
 EUT Description: PATIENT PROGRAMMER Air Pressure: 99 kPa
 Notes: _____ Page: 7 of 7

| FREQ (MHz) | LEVEL (dBuV) | CABLE / ANT / PREAMP (dB) (dBm) (dB) | FINAL (dBuV/m) | POL / HGT / AZ (m) (DEG) | DELTA1 FCC B (< 1GHz) | DELTA2 EN55022 B |
|---------------|-----------------|---|-------------------|-----------------------------|--------------------------|---------------------|
|---------------|-----------------|---|-------------------|-----------------------------|--------------------------|---------------------|

| ***** MEASUREMENT SUMMARY ***** | | | | | | |
|---------------------------------|---------|-------------------|------|-----------------|-------|-------|
| 154.90 | 55.6 Qp | 2.6 / 10.2 / 28.1 | 40.3 | H / 1.6 / 291.0 | -3.2 | -0.2 |
| 165.07 | 55.0 Qp | 2.7 / 10.6 / 28.1 | 40.1 | H / 1.6 / 293.0 | -3.4 | -0.4 |
| 84.64 | 57.8 Qp | 1.9 / 6.6 / 28.3 | 38.1 | H / 3.8 / 0.0 | -1.9 | -2.4 |
| 149.65 | 54.1 Qp | 2.5 / 9.6 / 28.2 | 38.1 | H / 2.2 / 282.0 | -5.4 | -2.4 |
| 83.93 | 56.9 Qp | 1.9 / 6.7 / 28.3 | 37.3 | H / 4.0 / 0.0 | -2.7 | -3.2 |
| 167.53 | 52.0 Qp | 2.7 / 10.2 / 28.1 | 36.8 | H / 3.0 / 270.0 | -6.7 | -3.7 |
| 69.55 | 51.2 Qp | 1.7 / 9.8 / 28.3 | 34.5 | H / 3.5 / 0.0 | -5.5 | -6.0 |
| 133.46 | 52.0 Qp | 2.4 / 8.0 / 28.2 | 34.2 | H / 2.0 / 276.0 | -9.3 | -6.3 |
| 124.70 | 51.8 Qp | 2.4 / 7.9 / 28.2 | 33.9 | H / 2.7 / 184.0 | -9.6 | -6.6 |
| 181.24 | 48.1 Qp | 2.8 / 9.4 / 28.1 | 32.2 | H / 3.0 / 270.0 | -11.3 | -8.3 |
| 165.15 | 44.8 Qp | 2.7 / 10.6 / 28.1 | 30.0 | H / 3.0 / 270.0 | -13.5 | -10.5 |
| 42.00 | 40.4 Qp | 1.4 / 15.0 / 28.4 | 28.4 | V / 1.0 / 100.0 | -11.6 | -12.1 |
| 176.35 | 43.8 Qp | 2.8 / 9.5 / 28.1 | 28.0 | H / 3.0 / 270.0 | -15.5 | -12.5 |
| 133.65 | 44.6 Qp | 2.4 / 8.0 / 28.2 | 26.8 | H / 3.0 / 270.0 | -16.7 | -13.7 |
| 40.20 | 37.4 Qp | 1.5 / 15.2 / 28.4 | 25.6 | V / 1.0 / 96.0 | -14.4 | -14.9 |
| 86.40 | 40.5 Qp | 1.9 / 6.9 / 28.3 | 21.0 | H / 3.0 / 270.0 | -19.0 | -19.5 |
| | | | | | | |

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Appendix B

Test Plan
and
Constructional Data Form





Medtronic
When Life Depends on Medical Technology

**NEUROLOGICAL
DIVISION**

**CONTROLLED
DOCUMENT/RECORD**

| | | | | |
|----------------------------|-------------------|-----------------|---|--------------------|
| MODEL OR BUCKET NO. | RECORD NO. | REV. NO. | RECORD DESCRIPTION | PROJECT NO: |
| 7434 | 60026 | 02 | Model 7434A/3031A/7438 EMC Test Plan | N1019 |

TYPE OF RECORD: **DHF** **PMR** **PHR**

AUTHOR: Debbie Gorski **SUBMITTED BY:**

ASSOCIATING RECORD:

Models Affected: 7434A, 3031A, 7438

DOCUMENT/RECORD HISTORY:

| REVISION | DESCRIPTION | AUTHOR | DATE |
|-----------------|--|---------------|-----------------|
| 01 | Initial release | Debbie Gorski | 14 August 2000 |
| 02 | Update includes modified device and model 7438 | Debbie Gorski | 23 October 2000 |
| | | | |
| | | | |

AUTHORIZATION SIGNATURES

| FUNCTION TITLE | NAME | SIGNATURE | DATE |
|-----------------------------|----------------|------------------|-------------|
| Reliability | Debbie Gorski | | |
| Mechanical Design | Dave Lee | | |
| Electrical Design | John Grevious | | |
| Project Manager 7434A/3031A | Dave Stanton | | |
| Project Manager 7438 | Toni Grabinger | | |

NOTIFICATION OF COMPLETION

| NAME | NAME |
|------------------------|-------------|
| All names listed above | |
| Steve Ahcan | |
| | |
| | |

KEY: BLUE - DOCUMENT CONTROL RED - AUTHOR GREEN - AUTHORIZATION SIGNATURES


| | | | | | |
|---|------------------------------------|---------------------------|-------------------|-------------|-----------------------------|
|  | Description | Model / Bucket No. | Record No. | Rev. | Pg 2 of 40 |
| | Model 7434A/3031A EMC Test Plan | 7434 | 60026 | 02 | |

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APPENDIX

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|---|------------------------------------|--------------------|------------|------|---------------|
| | Model 7434A/3031A EMC Test Plan | 7434 | 60026 | 02 | |

1 SCOPE

This document describes the test parameters to be applied during the EN 60601-1-2: 2000 (draft), EN45502-1 and FCC Part 15 (intentional radiator) investigations performed by TÜV Product Service. The documentation required by TÜV Product Service has been completed and is provided in the attachment of this plan labeled TÜV Product Service Forms.

The model 7434A Patient Programmer is an upgrade to the model 7435 Patient Programmer. The 7434A is to be tested in conjunction with the model 7425 IPG (Itrel 3). The 7434A can be used with the model 7440 external antenna which has three different lengths (23", 36", 48"). Test configurations incorporating the three different lengths are to be applied.

The test data for the model 3031A will be considered equivalent to the test data collected for the model 7434A. The model 3031A is mechanically and electrically equivalent to the model 7434A, except for the deletion of the parameter switch. Therefore, the model 7434A is considered to be the maximum configuration for the two devices, thus giving the worst-case test results.

1.1 FCC EMISSIONS RETESTING SUBMITTAL (REV.02 ADDITION)

A modified model 7434A is to be provided for FCC Emissions retesting. Two ferrite chips were added to reduce the emissions in the restricted bands. As noted by TÜV, no other testing will need to be redone due to this modification. The changes made relating the addition of the two ferrite chips are documented in Medtronic Document 7434-60049-01. Document 7434-60049-01 and the revised schematic and artwork submitted under ECR control have been added to this document's appendices for reference.


1.2 ADDITION OF THE MODEL 7438 TO THE MODEL 7434A PROJECT SUBMITTAL (REV.02 ADDITION)

The model 7438 is to be added to the test data and reports of the model 7434A. As like the model 3031A, the model 7438 is based on the model 7434A. There are no differences between the 7434A and the 7438 transmitter designs which would effect emissions and immunity testing. The model 7438 does not employ the use of the external antennas.

2 PURPOSE

The objective of this test plan is to specify the device parameters and requirements to be used to show compliance per the draft EN60601-1-2 (per EN45502-1) and FCC Part 15 (intentional radiator) investigations. Both internal and external antenna configurations are to be tested.

The requirements defined in the above referenced standards are to be used to show compliance to the Active Implantable Medical Device (AIMD) Directive. The RTTE Directive also applies and testing is to be performed by TÜV to show compliance to the applicable ETS requirements.


| | | | | | |
|---|------------------------------------|-------------------------------|-------------------|-------------|---------------|
|  | Description | Model / Bucket No. | Record No. | Rev. | Pg 4 of 40 |
| | Model 7434A/3031A EMC Test Plan | 7434 | 60026 | 02 | |

3 SAMPLE SIZE

The minimum device samples (Table 3-1) are to be provided to TÜV Product Service for testing. All samples are to be built per documented manufacturing procedures and marked so that each device is distinguishable and can be identified within the test documentation.

Table 3-1: Device Samples

| Sample Size | Device Description |
|--------------------|---|
| 1 | Model 7434A Patient Programmer (modified) |
| 1 | Model 7425 IPG |
| 1 | lead |
| 1 | Model 7440 external antenna (23") |
| 1 | Model 7440 external antenna (36") |
| 1 | Model 7440 external antenna (48") |


| | | | | | |
|---|------------------------------------|---------------------------|-------------------|-------------|---------------|
|  | Description | Model / Bucket No. | Record No. | Rev. | Pg 5 of 40 |
| | Model 7434A/3031A EMC Test Plan | 7434 | 60026 | 02 | |

4 APPLICABLE DOCUMENTS

The following documents are referenced to the extent listed within this plan.

Table 4-1: Reference/Applicable Documents

| TITLE | NUMBER | ISSUE/REV. |
|--|------------------------|----------------|
| 7434A, 3031A, 3032A Product Specification | 083851 | Rev. D |
| 7438 Product Specification | 083956 | Rev. A |
| Active Implantable Medical Devices – General requirements | EN 45502-1 | 1997 |
| Medical Electrical Equipment Part 1: General requirements for safety Collateral standard: Electromagnetic Compatibility - requirements and tests | EN 60601-1-2 | 2000 (draft) |
| Medical Electrical Equipment – General requirements | EN 60601-1 | +A13:1996 |
| Electromagnetic Compatibility (EMC) – Testing and measurement techniques - Electrostatic discharge immunity test and basic EMC publication | IEC 61000-4-2 | 1995 + A1:1998 |
| Electromagnetic Compatibility (EMC) – Testing and measurement techniques – Radiated-frequency, electromagnetic field immunity test | IEC 61000-4-3 | 1995 + A1:1998 |
| Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Technical characteristics and test methods for radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz | ETS 300 330 | 1995 |
| Radio Equipment and Systems (RES); Electromagnetic Compatibility (EMC) standard for Short Range Devices (SRD) operating on frequencies between 9 kHz and 25 GHz | ETS 300 683 | 1997 |
| Limits and Methods of Measurement of Radio Disturbance Characteristics of ISM Radio-Frequency Equipment | EN 55011 (CISPR11) | 1998 +A1:1999 |
| FCC Radio Frequency Devices Emissions (Intentional radiator) | FCC Part 15, Subpart C | -- |
| FCC Approval Letter for Labeling Exemption | N7434-60016 | 01 |
| FCC Identifier Memo | N1111-99-96 | -- |

|  | Description | Model / Bucket No. | Record No. | Rev. | Pg 6 of 40 |
|---|------------------------------------|--------------------|------------|------|---------------|
| | Model 7434A/3031A EMC Test Plan | 7434 | 60026 | 02 | |

5 GENERAL OVERVIEW

5.1 EMISSIONS OVERVIEW

The purpose of emissions testing is to verify that the product's spurious and unintended emissions do not exceed a level that will interfere with the operation of other electronic/electrical devices. In general, equipment is classified as Class A (commercial/industrial) or Class B (Residential). The Class A limits are relaxed by approximately 10 dB above the Class B limits.

5.1.1 CONDUCTED EMI MEASUREMENTS

Conducted EMI is usually measured in the shielded enclosure with the device configured such that all cables and peripherals are connected in a manner consistent with normal operation. Conducted EMI is measured as the RF noise voltage is injected back into the mains supply of the device. Measurements are made on both line and neutral in turn, over the frequency range 150 kHz to 30 MHz.

5.1.2 RADIATED EMI MEASUREMENTS


Radiated EMI must be measured at an open area test site (OATS) as defined in CISPR 16. This involves configuring the Equipment Under Test (EUT) for normal operation, complete with all loads and peripherals. All operating modes must be investigated and the worst-case emissions from the device must be measured. The measurements are usually performed with a calibrated electric field strength measurement antenna at a distance of 10 meters from the EUT. The EUT is continually cycled through normal operations while the Interference field strength emanating from it, is measured over the range 30 MHz to 1000 MHz. The EUT is rotated about the azimuth so that the direction of worst-case radiation is captured. Adjusting the antenna height between 1 to 4 meters to detect the maximum radiated interference field strength further maximizes the emissions.

5.2 BASIC IMMUNITY REQUIREMENTS

Compliance requires that the device has an adequate level of immunity to electromagnetic disturbances (i.e. ESD, EMF generated by radio transmitters, transceivers, cellular phones and various industrial electromagnetic sources). Compliance with immunity standards is mandatory for products to be sold in any country of the European Union (EU). The best way to achieve this is by testing to the appropriate immunity standards published in the European Journal.

5.2.1 IMMUNITY TO ELECTROSTATIC DISCHARGE (IEC 61000-4-2)

The purpose of this test is to verify the product's immunity against Electrostatic Discharge (ESD) generated by objects or persons coming into contact with, or in the vicinity of the device. Persons or objects can accumulate electrostatic charges which can reach to voltages above 15 kV. Many unexplained malfunctions and damages are likely to have been caused by ESD.

|  | Description | Model / Bucket No. | Record No. | Rev. | Pg 7 of 40 |
|---|------------------------------------|-----------------------|------------|------|---------------|
| | Model 7434A/3031A EMC Test Plan | 7434 | 60026 | 02 | |

5.2.2 RADIATED IMMUNITY (IEC 61000-4-3)


The purpose of this test is to verify the immunity of the product against electromagnetic fields generated by radio transmitters, transceivers, mobile GSM/AMPS cellular phones, and various industrial electromagnetic sources. Radiated electromagnetic fields can be coupled into the interface cables which provide a conductive path into the circuitry or they may be directly coupled onto the printed circuit wiring when the assembly is not shielded. When the amplitude of the RF field is sufficient, induced voltages and demodulated carriers can disrupt the operation of a device.

5.2.3 IMMUNITY TO CONDUCTED ELECTRICAL FAST TRANSIENTS (EFT/B) (IEC 61000-4-4)

The purpose of this test is to verify the EUT immunity to bursts of short duration fast-rise-time transients that may be generated by the switching of inductive loads or contactors. The fast rise times and repetitive nature of these test pulses results in the easy penetration of these spikes into the EUT circuitry which may disturb the EUT operation. The transients are applied directly to the power mains and capacitively to signal lines. As with other immunity tests, the EUT is to be configured for normal operation. This test is not required if cables are less than 3 meters in length.

5.2.4 IMMUNITY TO POWERLINE SURGE TRANSIENTS (IEC 61000-4-5)

The purpose of this test is to verify the EUT immunity to high-energy surges caused by over-voltage from switching, lightning and other similar transients. Many equipment specifications, in particular ITE equipment, already require compliance with this standard. This test can cause damage to the equipment under test so it is best not to perform it unless the EUT has effective transient suppression built-in. This test is not required if the EUT is battery powered.

| | | | | | |
|---|------------------------------------|---------------------------|-------------------|-------------|---------------|
|  | Description | Model / Bucket No. | Record No. | Rev. | Pg 8 of 40 |
| | Model 7434A/3031A EMC Test Plan | 7434 | 60026 | 02 | |

6 TEST PROCEDURE

The subsections identified in this section document the test parameters that are to be used during the EN60601-1-2 (EN45502-1) and FCC Part 15 investigations. The following 7434A/3031A Product Specification (083851) sections address the EN60601-1-2 (EMC) requirements:

Table 6-1: Product Specification Checklist

| Product Specification Reference | Product Specification Title | To Be Tested by TÜV Product Service | EMC Test Plan Reference | EMC Test Plan Description |
|---------------------------------|-----------------------------|-------------------------------------|-------------------------|---|
| 7.8 | ESD Susceptibility | Yes | section 6.1 | Immunity (Electrostatic Discharge) |
| 7.9 | EMC Susceptibility | Yes | section 6.2 | Immunity (Radiated Fields) |
| 7.10 | Radiated Emissions | Yes | section 6.2 | Emissions (Radiated Electric Fields: 30MHz – 1000MHz, 1GHz – 18GHz) |

Compliant TÜV Product Service Emissions and Immunity test reports must be obtained to show compliance to the Product Specification requirements listed above. These test reports are to be contained in the model 7434A/3031A EMC Test Report.

6.1 IMMUNITY (ELECTROSTATIC DISCHARGE)

Objective: The purpose of this test is to verify the 7434A/3031A's (configured with and without external antenna models) immunity against Electrostatic Discharge (ESD) generated by objects or persons coming into contact with, or in the vicinity of the device.

Standard: EN45502-1 (clause 24.1), IEC 61000-4-2 (requirement of EN60601-1-2)
Note: The EN45502-1 test requirements supercede the test requirements of IEC 61000-4-2.

Sample: One 7434A. One 7440 antenna of each length (cable length: 23", 36", 48"). One 7425 (IPG). One lead.

Procedure: The 7434A is subjected to ESD events by applying a discharge from an ESD simulator to the surfaces of the EUT and in proximity to the EUT. The 7434A is investigated for malfunction or disturbance to all its operating modes. The severity levels of the discharges are specified in EN45502-1 (refer to Table 6-2 for details). TÜV Product Service is to determine and document actual required ESD discharge sites. ESD discharges are to be performed, at a minimum, in the locations identified in Table 6-3, if determined applicable by TÜV. The 7434A is to be tested in all configurations listed in Table 6-4. After completion of all ESD discharges, a verification of the 7434A's operating modes (functionality) is to be conducted by performing a Post ESD Functional Test described below.


| | | | | | |
|---|------------------------------------|---------------------------|-------------------|-------------|-----------------------------|
|  | Description | Model / Bucket No. | Record No. | Rev. | Pg 9 of 40 |
| | Model 7434A/3031A EMC Test Plan | 7434 | 60026 | 02 | |

Table 6-2: ESD Test Voltage

| ESD Test Strengths | | | |
|---------------------------|-------------------|---------|--------------------------|
| EN45502-1 | CONTACT DISCHARGE | ±2.0 KV | minimum of 10 discharges |
| EN45502-1 | AIR DISCHARGE | ±8.0 KV | minimum of 5 discharges |


Table 6-3: Test Locations

| Insulating Test Points | |
|-------------------------------|---|
| 1 | All four pushbuttons |
| 2 | Both slide switches |
| 3 | External antenna jack area |
| 4 | External antenna (when installed) on the cable 6" from programmer |
| 5 | Programmer sides along gasket |
| Conductive Test Points | |
| 1 | BATTERY CONTACTS |

Table 6-4: Configurations

| Internal Antenna Configuration | |
|---------------------------------------|---|
| 1 | Test 7434A with external antenna jack plug cover left uncovered (most sensitive condition). |
| | |
| External Antenna Configuration | |
| 1 | Test 7434A with 23" external antenna length employed |
| 2 | Test 7434A with 36" external antenna length employed |
| 3 | Test 7434A with 48" external antenna length employed |

Note: TÜV deviations may be applied to this section, but a justification must be documented.


|  | Description | Model / Bucket No. | Record No. | Rev. | Pg 10 of 40 |
|---|------------------------------------|-----------------------|------------|------|----------------|
| | Model 7434A/3031A EMC Test Plan | 7434 | 60026 | 02 | |

POST ESD FUNCTIONAL TEST:

- a) Place the beeper switch in the right (High) position.
- b) Initiate a power-on self-test by removing the battery, pressing any key once and then replacing the battery. Verify successful completion of the Power ON Self Test (Successful self test is indicated by all four LED's turning on and then off coincident with a single beep).
- c) Remove the battery once again, press any key once, then replace the battery with the reverse polarity from Step b). Verify successful Self-Test.
- d) With the model 7425 IPG connected to a Medtronic lead, verify the 7434A functionality by monitoring the IPG output via an oscilloscope connected to the Medtronic lead. Plug in a model 7440 antenna and place its surface above the model 7425 IPG graphics surface with a separation of 5 cm. With the beeper switch in the center position (Low), press the "ON" button and confirm that the:
 - 1) programmer beeps once
 - 2) IPG ON LED turns on
 - 3) LED for IPG battery turns on
 - 4) IPG output switches on
 - 5) IPG output increases when parameter switch is set to amplitude and increase button is continually pushed
 - 6) IPG output decreases when parameter switch is set to amplitude and decrease button is continually pushed
- e) Disconnect the external antenna and set the beeper switch to the right (High) position. Place the programmer bottom surface parallel to the IPG graphics surface with a separation of 5 cm. Press the "OFF" button and confirm that the:
 - 1) programmer beeps once - louder than that of Step d) above
 - 2) IPG OFF LED turns on
 - 3) IPG output switches off
 - 4) IPG output decreases when parameter switch is set to amplitude and decrease button is continually pushed

Note: If the programmer does not provide a confirmation beep, verify the correct positioning with IPG and repeat attempt. If positioning is verified to be correct observe and record the Telemetry Diagnostic Click indication required to occur when the LED indication times out, and record results.

Pass/Fail Criteria: The 7434A is investigated for malfunction or disturbance to its operating modes via a Post ESD Functional Test. To determine if modes are functioning normally, the beeper and LED's must operate as indicated.

| | | | | | |
|---|------------------------------------|---------------------------|-------------------|-------------|----------------|
|  | Description | Model / Bucket No. | Record No. | Rev. | Pg 11 of 40 |
| | Model 7434A/3031A EMC Test Plan | 7434 | 60026 | 02 | |

6.2 IMMUNITY (RADIATED FIELDS)

- Objective:** The purpose of this test is to verify the immunity of the 7434A against various electromagnetic fields when configured with and without the external antenna lengths.
- Standard:** IEC 61000-4-3 (requirement of EN60601-1-2 per EN45502-1)
- Sample:** One 7434A. One 7440 antenna of each length (cable length: 23", 36", 48"). One 7425 (IPG).
- Procedure:** The 7434A must be arranged for normal operation and in the most sensitive mode, while subjecting it to radiated fields. Normal operation must be established within the test chamber while exposing it to the leveled disturbance field as the test frequency is stepped at 0.25% with a dwell time of 0.5 sec. over a range of 26 MHz – 80 MHz and the stepped at 1.0% with a dwell time of 3.0 sec. over a range of 80 MHz – 2.5 GHz. The test signal at 80% amplitude modulated at a modulation frequency of 1KHz. The transmitting polarity is both horizontal and vertical. The 7434A should be tested per the requirements in Table 6-5 and with all configurations listed in Table 6-6.

Table 6-5: Immunity Requirements


| Immunity (Conducted / Radiated) | | |
|---------------------------------|------------------|---------------------------------|
| EN60601-1-2: 2000 draft | Radiated E-Field | 3 or 10 V/m; 80 – 2.5 GHz. |
| EN60601-1-2: 2000 draft | Conducted RF | 3 or 10 V/m; 150 KHz. – 80 MHz. |
| EN60601-1-2: 2000 draft | Radiated H-Field | 3 A/m |

Table 6-6: Configurations

| Internal Antenna Configuration | |
|--------------------------------|---|
| 1 | Test 7434A with external antenna jack plug cover left uncovered (most sensitive condition). |
| | |
| External Antenna Configuration | |
| 1 | Test 7434A with 23" external antenna length employed |
| 2 | Test 7434A with 36" external antenna length employed |
| 3 | Test 7434A with 48" external antenna length employed |

Note: TÜV deviations may be applied to this section, but a justification must be documented.

For all test conditions, place the graphics surface of the 7425 IPG below the antenna surface (flat surface of model 7440; labeled surface of model 7434A) with a separation of 5.0 cm. Arrange the devices such that the IPG and programmer's antenna axes are coaxial within 1 cm (refer to Figure 6-1).

| | | | | | |
|---|------------------------------------|---------------------------|-------------------|-------------|----------------|
|  | Description | Model / Bucket No. | Record No. | Rev. | Pg 12 of 40 |
| | Model 7434A/3031A EMC Test Plan | 7434 | 60026 | 02 | |

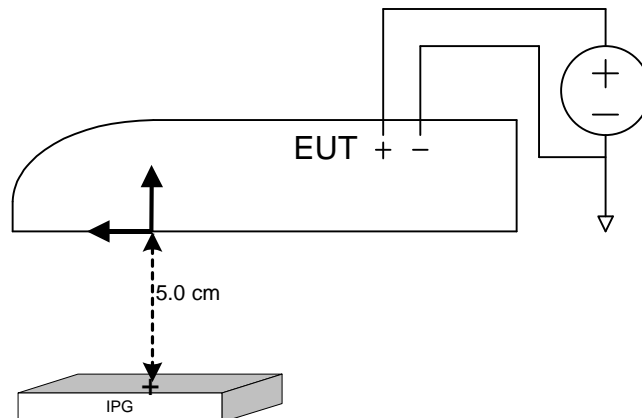


Figure 6-1: Immunity Test Setup

The orientation of the EUT/IPG system configuration to the radiation fields is determined and documented by TÜV Product Service. As the EUT is exposed to the electromagnetic radiation signals, press the ON and OFF keys (alternately) using pneumatic actuators or another non-conductive connection. With the model 7425 IPG connected to a Medtronic lead and placed in a saline bath, verify the 7434A's functionality by observing its LEDs and monitoring the IPG output via an oscilloscope connected to the submerged Medtronic lead. Record any deviation from the following EUT responses:


When the OFF button is pushed, verify the following:

- a) IPG output switches off

When the ON button is pushed, verify the following:


- a) IPG output switches on

Pass/Fail Criteria: The programmer must comply with the applicable requirements defined in IEC 61000-4-3 (requirement of EN60601-1-2 per EN45502-1) and when utilizing either antenna, the programmer must turn the IPG ON and OFF. A TÜV Immunity Test Report is to be obtained and provided in the EMC Test Report in order to show compliance.

|  | Description | Model / Bucket No. | Record No. | Rev. | Pg 13 of 40 |
|---|------------------------------------|--------------------|------------|------|----------------|
| | Model 7434A/3031A EMC Test Plan | 7434 | 60026 | 02 | |

6.3 EMISSIONS (RADIATED ELECTRIC FIELD: 30MHZ – 1000MHZ, 1GHZ – 18GHZ)

- Objective:** The purpose of emissions testing is to verify that the product's spurious and unintended emissions do not exceed a level that will interfere with the operation of other electronic/electrical devices. Conformance to this requirement will be demonstrated by testing to the standards/requirements listed below.
- Standards:** EN55011/CISPR 11 – Class A, Group 1 (external antenna)
EN55011/CISPR 11 – Class B, Group 1 (internal antenna)
- Sample:** One 7434A. One 7440 antenna of each length (cable length: 23", 36", 48").
- Procedure:** The 7434A should be tested with all configurations listed in Table 6-7. For the internal antenna configuration, operate the programmer keypad by using pneumatic actuators or another non-conductive connection. Worst-case condition for emissions is to operate the programmer in scroll mode. This is accomplished by pressing and holding any one key (i.e. ON key) on the keypad. *(Note: The device has a 30 second timeout, if no valid uplinks are received while scrolling.)* Release the key, then re-press and hold to re-establish downlink transmission.
- For the external antenna configuration(s), position the external antenna's center point 25cm \pm 1 cm from the 7434A's internal antenna's center point (refer to Figure 6-2). The antenna locations should be parallel and aligned (note: cable positioned in a U-shape). This orientation approximates the most typical orientation during usage.

| | | | | | |
|---|------------------------------------|---------------------------|-------------------|-------------|----------------|
|  | Description | Model / Bucket No. | Record No. | Rev. | Pg 14 of 40 |
| | Model 7434A/3031A EMC Test Plan | 7434 | 60026 | 02 | |

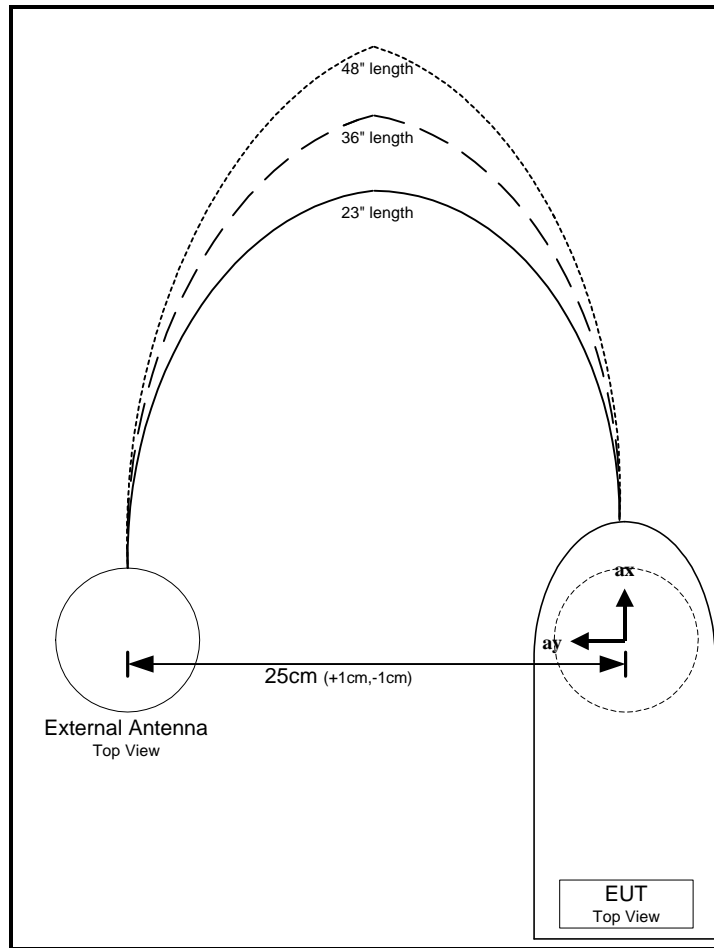



Figure 6-2: External antenna configuration
Note: Bottom surface of EUT and Antenna wire are to lie within $\pm 0.75\text{cm}$ of a common plane.

Table 6-7: Configurations

| Internal Antenna Configuration | |
|---------------------------------------|---|
| 1 | TEST 7434A WITH EXTERNAL ANTENNA JACK PLUG COVER LEFT UNCOVERED (MOST SENSITIVE CONDITION). |
| External Antenna Configuration | |
| 1 | TEST 7434A WITH 23" EXTERNAL ANTENNA LENGTH EMPLOYED |
| 2 | TEST 7434A WITH 36" EXTERNAL ANTENNA LENGTH EMPLOYED |
| 3 | TEST 7434A WITH 48" EXTERNAL ANTENNA LENGTH EMPLOYED |

Note: TÜV deviations may be applied to this section, but a justification must be documented.

|  | Description | Model / Bucket No. | Record No. | Rev. | Pg 15 of 40 |
|---|------------------------------------|--------------------|------------|------|----------------|
| | Model 7434A/3031A EMC Test Plan | 7434 | 60026 | 02 | |

Pass/Fail Criteria: The following requirements must be met when operating at the worst-case emissions condition (i.e. programming in scroll mode).

EN55011/CISPR 11 – Class A, Group 1 (external antenna)

EN55011/CISPR 11 – Class B, Group 1 (internal antenna)

A TÜV Test Report is to be obtained and provided in EMC Test Report in order to show compliance.

6.4 FCC INTENTIONAL RADIATOR TESTING AND SUBMITTAL

Objective: To contract TÜV Product Service for testing and submission per FCC requirements.

Rationale: Intentional radiators are devices specifically designed to radiate RF energy. Prior to being placed on the market, intentional radiators must comply with strict requirements for such parameters as Frequency Stability, Output Power, Harmonics, Occupied Bandwidth and Modulation Characteristics. These devices require "Certification" by the FCC.

Standards: FCC Part 15, Subpart C (intentional radiator for US) Class B

Sample: One 7434A. One 7440 antenna of each length (cable length: 23", 36", 48").


Procedure: TÜV Product Service is to perform testing to the above US standard and issue FCC approval under the Telecommunications Certification Body (TCB) Rule.

The FCC TCB Application is to be completed and submitted to the FCC for approval, on behalf of Medtronic.

The **FCC ID** number to be applied to the model 7434A and model 3031A is **LF57434A** (refer to Medtronic document N1111-99-96 for details on the assigned three digit code). It is understood that because the models 7434A and 3031A have identical transceivers, the same FCC ID (LF57434A) can be applied.

Per Medtronic document N7434-60016-01, it is acceptable to place the compliance statement in the device user's manual (only) per Section 15.19(a)(5) of the Rules when the device is too small, or it is not practical to place the compliance statement on the device.

Results: Obtain Certification to show compliance to the above standard.


|  | Description | Model / Bucket No. | Record No. | Rev. | Pg 16 of 40 |
|---|------------------------------------|-----------------------|------------|------|----------------|
| | Model 7434A/3031A EMC Test Plan | 7434 | 60026 | 02 | |

6.5 RTTED INTENTIONAL RADIATOR TESTING AND SUBMITTAL

- Objective:** To contract TÜV Product Service for testing and submission of the RTTE technical file to BABT.
- Rationale:** Intentional radiators are devices specifically designed to radiate RF energy. These devices require approval from a "Notified Body".
- Standards:** ETS 300 330 (intentional radiator for Europe)
ETS 300 683 (intentional radiator for Europe)
- Sample:** One 7434A. One 7440 antenna of each length (cable length: 23", 36", 48").
- Procedure:** TÜV Product Service is to perform testing to the above standards.
- Results:** Obtain Certification to show compliance to the above standards.

7 COMPLETION

This paragraph completes this plan.

|  | Description | Model / Bucket No. | Record No. | Rev. | Pg 17 of 40 |
|---|------------------------------------|-----------------------|------------|------|----------------|
| | Model 7434A/3031A EMC Test Plan | 7434 | 60026 | 02 | |

APPENDIX 1

TÜV Product Service Completed Forms (23 pages)

- EMC Test Plan and Constructional Data Form (7 pages)
- EMC Block Diagram Form (1 page)
- Test Plan for Electromagnetic Compatibility Testing (2 pages)
- EN55011:1991 Emissions Test Plan Details (1 page)
- Medtronic Document 7434-60049-01 (6 page)
- Revised Artwork and Schematic under ECR control (5 page)
- Model 7438 Similarity Justification (1 page)

Test Plan for Electromagnetic Compatibility Testing



| | | | |
|---|------------------------------------|-----------------------|-----------------------|
| General Information (if you need assistance completing this form contact your TÜV Product Service representative.) | | | |
| Company: | <u>Medtronic Neurological</u> | Quote Number: | <u>NM000519JP02RR</u> |
| Contact: | <u>Debbie Gorski</u> | Phone: (business hrs) | <u>763-514-7489</u> |
| Technician: | <u>Steve Ahcan</u> | | <u>763-514-5564</u> |
| E-mail Address: | <u>debbie.gorski@medtronic.com</u> | Phone: (after hrs) | <u>N/A</u> |

| | |
|----------------------------|---|
| Product Description | |
| Description: | <u>Patient Programmer</u> |
| Model Number: | <u>7434A (3031A)</u> Serial Number: <u>as noted on the device</u> |

| | |
|---|---|
| Test Objective | |
| <input type="checkbox"/> EMC Directive 89/336/EEC (EMC) <input type="checkbox"/> Machinery Directive 89/392/EEC (EMC) <input type="checkbox"/> Medical Device Directive 93/42/EEC (EMC) <input type="checkbox"/> FCC _____ Part <u>15</u> (list) | <input type="checkbox"/> Vehicle Directive 72/245/EEC (EMC) <input checked="" type="checkbox"/> Other (list) <u>RTTE and FCC submittals</u> <input checked="" type="checkbox"/> Other (list) <u>AIMD Directive 90/385/EEC (EMC)</u> |

| | |
|-------------------|--|
| Attendance | |
| Test will be: | <input checked="" type="checkbox"/> Attended by the customer (Steve Ahcan) <input type="checkbox"/> Unattended by the customer |

| |
|---|
| Failure |
| If a failure occurs, TÜV Product Service should: <ul style="list-style-type: none"> <input type="checkbox"/> Call contact listed above, if not available then stop testing. <input checked="" type="checkbox"/> Continue testing to complete test series. <input type="checkbox"/> Continue testing to define corrective action. <input type="checkbox"/> Stop testing. |

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

Test Plan for Electromagnetic Compatibility Testing



| Equipment Under Test Transportation | |
|-------------------------------------|---|
| <input checked="" type="checkbox"/> | Transportation between sites by customer. |
| <input type="checkbox"/> | Other (consult your TÜV Product Service representative) |

| Dimensions and Weight | | | |
|-----------------------|---------|--------|--------|
| Length | 13.5 cm | Width | 6.0 cm |
| Height | 3.0 cm | Weight | .17 Kg |

| Facilities | | | |
|--|---------------|--------------|---|
| Power Requirements | | | |
| <input type="checkbox"/> | 230 VAC 50 Hz | Single Phase | _____ Amps |
| <input type="checkbox"/> | 400 VAC 50 Hz | Three Phase | _____ Amps per phase |
| <input type="checkbox"/> | 120 VAC 60 Hz | Single Phase | _____ Amps |
| <input type="checkbox"/> | 208 VAC 60 Hz | Three Phase | _____ Amps per phase |
| <input type="checkbox"/> | _____ VDC | | _____ Amps |
| <input checked="" type="checkbox"/> | Battery 9.0 | VDC | Expected life _____ hours |
| <input type="checkbox"/> | Other _____ | | |
| <i>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)</i> | | | |
| Other | | | |
| <input type="checkbox"/> | Air _____ cfm | _____ psi | <input type="checkbox"/> Water _____ gpm _____ psi (describe) |
| <input type="checkbox"/> | Other _____ | | |

| Test Plan Attachments | |
|---|--|
| <input checked="" type="checkbox"/> Applicable (attached) | Constructional Data Form (CDF) * The CDF is required for all test plans. |
| <input checked="" type="checkbox"/> Applicable (attached) | Immunity Test Plan Details |
| <input type="checkbox"/> N/A | sections 6.1, 6.2 of Medtronic document 7434-60026-01 |
| <input checked="" type="checkbox"/> Applicable (attached) | Emissions Test Plan Details |
| <input type="checkbox"/> N/A | section 6.3 of Medtronic document 7434-60026-01 |
| <input type="checkbox"/> Applicable (attached) | On Site Test Plan Details |
| <input type="checkbox"/> N/A | |

EN 55011:1991 Emissions

Test Plan Details

(ATTACHMENT)



Performance Criteria

This section details the system's performance, what parameters are to be monitored, how to measure them and what limits are acceptable. It is the customers responsibility to provide all equipment necessary for verifying the system's performance, unless prior arrangements have been made with your TÜV Product Service Representative.

Standards to be Applied

IEC 60601-1-2 draft 2nd Edition
EN45502-1: 1997

Fail Safe Criteria

Compliance with the requirements given in 36.202.1 to 36.202.6 shall be checked by verifying that, under the specified conditions the EQUIPMENT and/or SYSTEM continues to perform its intended functions as specified by the manufacturer or fails without creating a SAFETY HAZARD.

Describe intended function(s) as specified, and list safe failures:

Reference the following sections within Medtronic document 7434-60026-01 (Model 7434A/3031A EMC Test Plan):

6.1 IMMUNITY (Electrostatic Discharge)

6.2 IMMUNITY (Radiated Fields)

EN 55011:1991 Emissions

Test Plan Details

(ATTACHMENT)



If testing levels or performance criteria other than those listed below are desired, then indicate the requested test levels and performance criteria in the space provided. However, to ensure compliance, the levels and criteria listed in this table must be the minimum requirements.

| Description | Basic Document | Test Level | Requirement | Customer Test Level |
|--------------------|--|--|-------------|---------------------|
| ESD Immunity | IEC 801-2: 91 | Contact | ± 3 kV | _____ |
| | | Air | ± 8 kV | _____ |
| Radiated Immunity | IEC 801-3 (1st Draft of 2nd Edition) [minimum required] ENV 50204 (TUV Recommended) | 26-1000 MHz | 3 V/m | _____ |
| | | 1 kHz (80% AM) or Bandpass Frequencies | | _____ |
| | | 900 MHz 200Hz (100% AM) | 3 V/m | _____ |
| EFT/Burst Immunity | IEC 801-4: 88 | Interconnecting (L≥3m) | ± 500 V | _____ |
| | | Mains Plug-in | ± 1 kV | _____ |
| | | Mains Permanent | ± 2 kV | _____ |
| Surge Immunity | IEC 801-5 (Draft of 1st Edition) | Mains Common Mode (L → G) | ± 2 kV | _____ |
| | | Mains Differential Mode (L → L) | ± 1kV | _____ |

EN 55011:1991 Emissions
Test Plan Details
(ATTACHMENT)



Bandpass Frequencies (list)

| |
|--|
| |
|--|

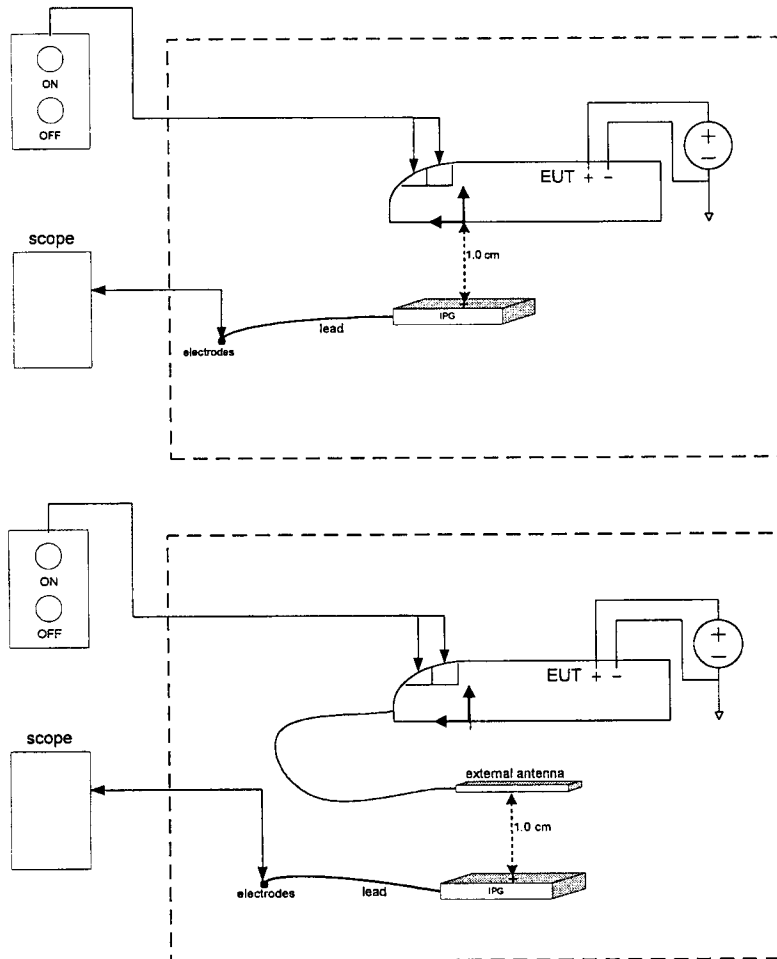
Engineering Justifications / Test Deviations

| |
|--|
| |
|--|

UEMC0918.DOC, Revision 1.0
Author: B. Dill
Revised: 20 March 1997

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.



In addition to this information, please reference the Medtronic document 7434-60026-01 for further details regarding the antenna's positioning during testing (Figure 6.1).

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

EN 55011:1991 Emissions

Test Plan Details

(ATTACHMENT)



If testing levels other than those listed below are desired, then indicate the requested levels under Engineering Justification / Test Deviations.

| Standards to be Applied | |
|-------------------------------------|--|
| <input checked="" type="checkbox"/> | IEC 60601-1-2 draft 2 nd edition |
| <input checked="" type="checkbox"/> | EN 55011: 1991 |
| <input checked="" type="checkbox"/> | Group 1 <input checked="" type="checkbox"/> Class A <input type="checkbox"/> Class B <i>(External Antenna)</i> |
| <input checked="" type="checkbox"/> | Group 1 <input type="checkbox"/> Class A <input checked="" type="checkbox"/> Class B <i>(Internal Antenna)</i> |
| <input type="checkbox"/> | Group 2 <input type="checkbox"/> Class A <input type="checkbox"/> Class B |

| Description | Basic Document | Requirement |
|--------------------------------|----------------|--------------------------|
| Radiated & Conducted Emissions | EN 55011 | Reference Basic Standard |

| Engineering Justifications / Test Deviations |
|---|
| <p><i>Reference the following section within Medtronic document 7434-60026-01 (Model 7434A/3031A EMC Test Plan):</i></p> <p><i>6.3 EMISSIONS (Radiated electric field: 30 MHz – 1000MHz, 1GHz – 18 GHz)</i></p> |

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

Address: 900 6th Ave. NE
Milaca, MN 56353

Contact: Debbie Gorski Position: Senior Product Reliability Engineer

Phone: 763-514-7489 Fax: 763-514-7285

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 patient programmer

EUT Name N/A

Model No.: 7434A Serial No.: as noted on EUT

Product Options: external detachable antenna

Configurations to be tested: refer to Medtronic document 7434-60026-01 for details

Test Objective

- | | |
|---|---|
| <input type="checkbox"/> EMC Directive 89/336/EEC (EMC) Std: _____ | <input checked="" type="checkbox"/> FCC: Class <input checked="" type="checkbox"/> A <input checked="" type="checkbox"/> B Part <u>15</u> |
| <input type="checkbox"/> Machinery Directive 89/392/EEC (EMC) Std: _____ | <input type="checkbox"/> VCCI: Class <input type="checkbox"/> A <input type="checkbox"/> B |
| <input type="checkbox"/> Medical Device Directive 93/42/EEC (EMC) Std: _____ | <input type="checkbox"/> BCIQ: Class <input type="checkbox"/> A <input type="checkbox"/> B |
| <input type="checkbox"/> Vehicle Directive 72/245/EEC (EMC) Std: _____ | <input type="checkbox"/> Canada: Class <input type="checkbox"/> A <input type="checkbox"/> B |
| <input type="checkbox"/> FDA Reviewers Guidance for Premarket Notification Submissions (EMC) | <input type="checkbox"/> Australia: Class <input type="checkbox"/> A <input type="checkbox"/> B |
| | <input checked="" type="checkbox"/> Other: <u>AIMD Directive 90/385/EEC</u> |

TÜV Product Service Certification Requested

- | | |
|---|---|
| <input type="checkbox"/> Attestation of Conformity (AoC) | <input type="checkbox"/> International EMC Mark (IEM) |
| <input checked="" type="checkbox"/> Certificate of Conformity (CoC) | <input checked="" type="checkbox"/> Compliance Document |
| Protection Class (N/A for vehicles) | <input type="checkbox"/> Class I <input type="checkbox"/> Class II <input type="checkbox"/> Class III |
- (Press F1 when field is selected to show additional information on Protection Class.)

EMC Test Plan and Constructional Data Form

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: 13.5 cm Width: 6.0 cm Height: 3.0 cm Weight: 0.17 Kg

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: 9.0 Vdc (If battery powered, make sure battery life is sufficient to complete testing.)

of Phases: N/A

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.)
Hospital / Doctor's office / residential

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 |
| EXAMPLE: 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 jack | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 1 | <input type="checkbox"/> | <input checked="" type="checkbox"/> | | inductive coupling antenna coil | 2 connector jack | | | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 23" (58.42cm) antenna cable | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 1 | <input type="checkbox"/> | <input checked="" type="checkbox"/> | | | | | 0 | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 36" (91.44cm) antenna cable | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 1 | <input type="checkbox"/> | <input checked="" type="checkbox"/> | | | | | 0 | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 48" (1.21m) antenna cable | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 1 | <input type="checkbox"/> | <input checked="" type="checkbox"/> | | | | | 1 | <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"/> |
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| | <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: 2.0

Description: Firmware; 8k bytes

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. Reference Medtronic document 7434-60026-01 for operating modes to be testing.

- 2.

- 3.

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 # |
|--------------------|---------|--------------------|----------|
| patient programmer | 7434A | as noted on device | LF57434A |

EMC Test Plan and Constructional Data Form

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 # |
|----------------------|----------|----------|----------|
| 23" external antenna | 7440-023 | as noted | |
| 36" external antenna | 7440-036 | as noted | |
| 36" external antenna | 7440-048 | as noted | |
| IPG | 7425 | as noted | |

Oscillator Frequencies

| Frequency | Derived Frequency | Component # / Location | Description of Use |
|-----------|-------------------|------------------------|-------------------------------------|
| 20 MHz | | internal | microcontroller's main oscillator |
| 32 KHz | | internal | microcontroller's second oscillator |
| | | | |
| | | | |
| | | | |

Power Supply

| Manufacturer | Model # | Serial # | Type |
|--------------|---------|----------|--|
| N/A | | | <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: _____ |

Power Line Filters

| Manufacturer | Model # | Location in EUT |
|--------------|---------|-----------------|
| N/A | | |
| | | |



EMC Test Plan and Constructional Data Form

Critical EMI Components (Capacitors, ferrites, etc.)

| <i>Description</i> | <i>Manufacturer</i> | <i>Part # or Value</i> | <i>Qty</i> | <i>Component # / Location</i> |
|--------------------|---------------------|------------------------|------------|-------------------------------|
| N/A | | | | |
| | | | | |
| | | | | |
| | | | | |

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

Reference comments for PWB layout and lower case half as described in TÜV report N301821901, page B21.

(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

**Medtronic**

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November 10, 2000

TUV Product Services
New Brighton, Minnesota

DHF File #7434-60051-01

Attn: Ron Amundson

Subject: Medtronic Models 7434A and 3031A EMI Susceptibility Testing

Dear Ron,

As you noted, the above patient Programmers have LEDs and a beeper that do not always activate after transmitting a downlink signal to the implanted Neurostimulator when subjected to certain frequencies of EMI during EMI Susceptibility testing.

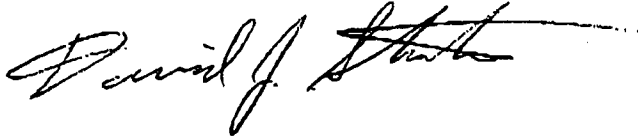
This is a normal occurrence that is inherent in the design. This phenomenon occurs because the 7434A/3031A receiver has a high sensitivity necessitated by the weak uplink signal from the implanted Neurostimulator. The signal is weak as it has to get through a titanium case, and we are limited as to signal generation to conserve the implanted battery.

This is covered in several places in our patient manual. Attached are pages 16, 23, 58, 59, and 60, which explain the occurrence to the user and guide them to move away from interfering equipment. Furthermore, the patient can feel the programmed change to his/her stimulation, with the LEDs and beeper being provided as a convenience. It is not necessary for an uplink to be successfully recognized for the patient to achieve desired programming. The patient even has the option of switching the beeper off, and many do not look at the LEDs anyway.

When Life Depends on Medical Technology

Please contact me at 763-514-9511 if you have further questions.

Regards,

A handwritten signature in black ink, appearing to read "David J. Stanton". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

David Stanton, Sr. Principle Project Engineer

Table 2. Neurostimulator Battery   lights.

| When this happens | It Means |
|---|---|
| Green Neurostimulator Battery light is on for 8 seconds after pressing any key. | Neurostimulator battery is OK. |
| Green Neurostimulator Battery light is blinking for 8 seconds after pressing any key. | The neurostimulator battery is low. Call your doctor's office. |
| Green Neurostimulator Battery light is off after pressing any key. | <p>Reposition programmer and try again. Interference from electrical equipment can cause lights to remain off. Move to another room and try again.</p> <p>If the light remains off, the neurostimulator battery may need to be replaced. The neurostimulator should be reviewed with a physician programmer. Contact your doctor immediately.</p> |

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Caution

To avoid unpleasant stimulation, always decrease the amplitude to the lowest setting after turning your neurostimulator off.

Table 3. Neurostimulator On  and Off  lights.

| When | It Means |
|---|--|
| The green Neurostimulator On light is lit for 8 seconds after pressing any key. | Neurostimulator is on. |
| The yellow Neurostimulator Off light is lit for 8 seconds after pressing any key. | Neurostimulator is off. |
| Neither Neurostimulator On nor Off light is lit after pressing any key. | The programmer does not know if the neurostimulator is on or off because it failed to communicate with the neurostimulator. Refer to "Troubleshooting," page 58. |

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Problem

Causes and Action

All the lights on your programmer are on, and it does not respond when you press a key.

Remove the battery for 3 seconds and then replace it.

The neurostimulator lights are off when you press any key.

The programmer or detachable antenna is not positioned correctly over the neurostimulator.
Reposition the programmer or antenna and try again.

The programmer was removed from the neurostimulator too soon.
Hold the programmer over the neurostimulator for at least 1 second after pressing a key.

Radio signals from appliances, computers, machinery, etc. are affecting your programmer.
Move to a different room and try again.
Remove the detachable antenna and try again.

The status lights do not flash and the beeper does not beep when a fresh battery is installed.

The programmer failed the self-test.
Remove battery, press any key, turn the beeper to low or high, and insert a second fresh battery. The status lights should flash and you should hear one beep.
If this does not occur, contact your doctor.

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Problem

The beeper does not sound. Only the Programmer Battery light is on.

Causes and Action

The beeper is not on.
Set the Beeper Volume Control switch to low or high volume and listen to be sure it is working.

The programmer or detachable antenna is not positioned correctly over the neurostimulator.
Reposition the programmer or antenna and try again.

The programmer was removed from the neurostimulator too soon.
Hold the programmer over the neurostimulator for at least 1 second.

Radio signals from appliances, computers, machinery, etc. are affecting your programmer.
Move to a different room and try again.
Remove the detachable antenna and try again.

Problem

You feel a programming change after pressing a key, but the beeper didn't beep and the Neurostimulator On or Off lights did not light.

Causes and Action

The programmer was too far away from the neurostimulator. The neurostimulator might have received the signal to change but did not tell the programmer what it did.

Hold the programmer closer to your neurostimulator and try again.

An electrical appliance blocked your neurostimulator radio signal from telling the lights and beeper to turn on.

1. Move to another room. Press any key to check the lights.
2. Move the programmer and try again.

The programmer was moved away too soon after pressing the keys.

Hold the programmer over the neurostimulator for at least 1 second after pressing a key.

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 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 dB μ 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 dB μ V and μ 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 dB μ V/m, is arrived at by taking the reading from the spectrum analyzer (Level dB μ V) and adding the antenna correction factor and cable loss factor (Factor dB) to it. 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 B. The amplifier gain is automatically accounted for by using an analyzer offset.

Example:

| Frequency (MHz) | Level (dB μ V) | + | Factor & Cable (dB) | = | Final (dB μ V/m) | - | FCC B Limit (dB μ V/m) | = | Delta FCC B (dB) |
|--------------------|-----------------------|---|------------------------|---|-------------------------|---|----------------------------------|---|------------------------|
| 32.21 | 13.9 | + | 16.3 | = | 30.2 | - | 40.0 | = | -9.8 |

DETAILS OF TEST PROCEDURES

General Standard Information

The test methods used comply with ANSI C63.4-1992 - "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 μ 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 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.