

TEST RESULT SUMMARY

FCC PART 15 SUBPART C, Section 15.209 Radiated Emissions

MANUFACTURER'S NAME	Medtronic, Inc.
NAME OF EQUIPMENT	N'VISION Hand Held Clinical Programme
MODEL NUMBER	8840
MANUFACTURER'S ADDRESS	710 Medtronic Parkway NE Minneapolis MN 55432-5604
TEST REPORT NUMBER	NC104316.3
TEST DATE	17 May 2001

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 electromagnetic compatibility requirements of FCC Part 15

13 September 2001 Date:

Location: Taylors Falls MN USA

T. K. Swanson Test Technician

Not Transferable

Thomas K. Swamon & C. Sausan

J. C. Sausen **Test Engineer**



EMC EMISSION - TEST REPORT

Test Report File No.	:	NC104316.3	Date of issue:	13 September 2001
Model / Serial No.	:	8840 / NHF0000	50, NHF000055	;
Product Type	:	N'VISION Hand	Held Clinical Pro	ogrammer
Applicant	:	Medtronic, Inc.		
Manufacturer	:	Medtronic, Inc.		
License holder	:	Medtronic, Inc.		
Address	<u> </u>	710 Medtronic P	arkway NE	
	:	Minneapolis MN	55432-5604	
Test Result	:	■ Positive [□ Negative	
Test Project Number Reference(s)	:	NC104316.3		
Total pages including Appendices		23		
TÜV Product Service Inc is a subcontrac EN 45001.	tor to TÜV	Product Service, GmbH acco	rding to the principles outlin	ed in ISO/IEC Guide 25 and
TÜV Product Service Inc reports apply o responsibility to assure that additional pr TÜV Product Service Inc shall have no li Product Service Inc issued reports.	oduction u	nits of this model are manufac	ctured with identical electrica	al and mechanical components.
This report is the confidential property of report shall not be reproduced except in endorsement by NVLAP or any agency c	full withou	t our written approval. This re		
	d profession	ervice Inc and its professional staff al organization certifications and a ICIL, AEA, ANSI, IEEE, NVLAP, ar	re members of	
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TÜV PRODUCT SERVICE INC 19333 Wild Mountain Road

Taylors Falls MN 55084-1758

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Tel: 651 638 0297 Fax: 651 638 0298 Rev.No 1.0



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EMISSIONS TEST REGULATIONS :

The emissions tests were performed according to for	ollowing regulations:	
□ - EN 50081-1 / 1991 □ - EN 55011 / 1991	□ - Group 1 □ - Class A	□ - Group 2 □ - Class B
□ - EN 55013 / 1990 □ - EN 55014 / 1987	 □ - Household appliances an □ - Portable tools □ - Semiconductor devices 	d similar
□ - EN 55014 / A2:1990 □ - EN 55014 / 1993	 Household appliances and Portable tools Semiconductor devices 	d similar
 □ - EN 55015 / 1987 □ - ETS 300 683 / 1997, Emission Requirements □ - EN 300 330 / 1999, Sections 7.2, 7.3, 7.4, 8.1 Class □ - EN 55022 / 1987 □ - EN 55022 / 1994, Amendment A1: 1995 & Amendment A2: 1997 		□ - Class B □ - Class B
 □ - EN 60601-1-2 / 1993, Emission Requirements □ - VCCI □ - FCC ■ - FCC Part 15 Subpart C Section 15.209 - Radiated □ - AS 3548 (1992) 	□ - Class A □ - Class A □ - Class A	□ - Class B □ - Class B □ - Class B
□ - CISPR 11 (1990) □ - CISPR 22 (1993)	□ - Group 1 □ - Class A □ - Class A	□ - Group 2 □ - Class B □ - Class B

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Environmental conditions in the lab:

Temperature
Relative Humidity
Atmospheric pressure
Power supply system

<u>Actual</u> : 24 °C : 35 % : 97.9 kPa : 6.0 VDC Battery

Sign Explanations:

- not applicableapplicable



FCC 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

FCC 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)

FCC 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



FCC Emissions Test Conditions: RADIATED EMISSIONS

The *RADIATED EMISSIONS* measurements were performed in the frequency range 9 kHz - 30 MHz 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
- 🔳	2420	ESH-3	Rhode & Schwarz	EMI Receiver	892473/004	1-24-02
- 🔳	2517	HFH2-Z2	Polorad	Loop Antenna	879285/036	2-01-02

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

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



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
- I Normal Operating Mode
- See page B5.

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:

D	Туре :
D	Туре :
D	Type :
D	Type :
unshielded power cable	
- unshielded cables	
- shielded cables	MPS.No.:
- customer specific cables	
D	
D	



Emission Test Results: FCC Conducted emissions 10/150 kHz - 30 MHz 🗆 - MET □ - NOT MET The requirements are _____ dB at MHz Minimum margin of compliance dB at MHz Maximum margin of non-compliance Remarks: FCC 15.209 Radiated emissions 10 kHz - 30 MHz - MET I - NOT MET The requirements are Minimum limit margin for fundamental 21 dB at 175.0 kHz 24 dB at 530.0 kHz Minimum limit margin for spurious/harmonics Remarks: The fundamental was measured to be 91 dBuV/m in quasi-peak mode at 3 meters, 61 dBuV/m (1122 microvolts/meter) 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 third harmonic was measured to be 49 dBuV/m in quasi-peak mode (281 microvolts/meter) 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 (4466 microvolts/meter). Radiated emissions (electric field) 30 MHz - 1000 MHz 🗆 - MET - NOT MET The requirements are Minimum margin of compliance dB at MHz Minimum limit margin for spurious dB MHz at Remarks: Interference Power at the mains and interface cables 30 MHz - 300 MHz 🗆 - MET □ - NOT MET The requirements are dB ____ MHz Minimum margin of compliance at MHz Maximum margin of non-compliance dB at Remarks: Equivalent Radiated emissions 1 GHz - 4.2 GHz □ - MET □ - NOT MET The requirements are _____dB Minimum margin of compliance at _____ MHz Maximum margin of non-compliance ____ dB at _____ MHz Remarks:

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DEVIATIONS FROM STANDARD:

None.

GENERAL REMARKS:

SUMMARY:

The requirements according to the technical regulations are

- met

□ - **not** met.

The device under test does

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

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

Testing Start Date:

17 May 2001

Testing End Date:

17 May 2001

- TÜV PRODUCT SERVICE INC -

Thomas K. Swamon

T. K. Swanson Test Technician

Clausen

Tested By: J. C. Sausen



Test-setup photo(s): Conducted emission 9 kHz - 30 MHz

Not Applicable

Test-setup photo(s): Radiated Emission 9 kHz - 30 MHz

See Test-Setup Exhibit



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

Not Applicable

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Appendix A

Test Data Sheets

and

Test Setup Drawing(s)

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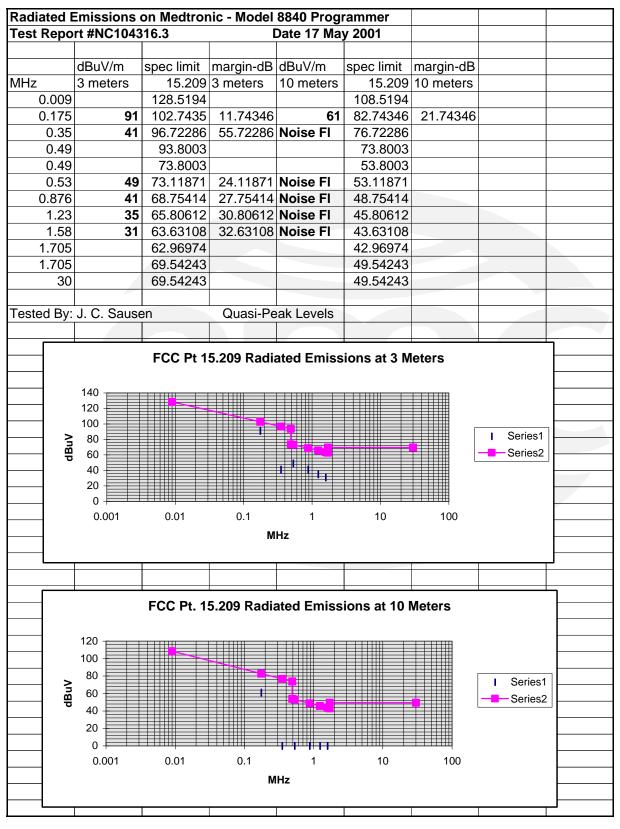
TEST SETUP FOR EMISSIONS TESTING

WILD RIVER LAB Small Test Site (STS)

See Test-Setup Exhibit

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Appendix B

Constructional Data Form

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PLEASE COMPLETE TH	IS DOCUMENT IN FULL, ENTERING	G N/A IF THE FIELD IS	NOT APPLICABLE.
Applicant NOTE: TI	his information will be input into yo time to get HELP for the current fiel	our test report as show	
Company:	Medtronic, Inc.		
Address:	710 Medtronic Parkway NE		
	Minneapolis, MN 55432-560	04	
Contact:	Roger Berg	Position:	Principal Reliability Engineer
Phone:	763-514-5052	Fax:	763-514-7285
E-mail Address:	roger.berg@medtronic.com		
General Equipment	Description NOTE: This info	rmation will be input i	nto your test report as shown below.
EUT Description	Hand held clinical programm		
EUT Name	N' VISION Clinical Programn		
Model No.:	8840	Serial No.:	NHF000050, NHF000055
Product Options:			
Configurations to be t	tested:		
Test Objective			
EMC Directive 89/	/336/EEC (EMC)		ass 🖂 A 🗌 B Part 15
Std:	(ass [] A [] B
Machinery Directiv Std:	/e 89/392/EEC (EMC [ass 🗌 A 🗌 B ass 🗍 A 🗍 B
Medical Device Di	rective 93/42/EEC (EMC)	Australia: Cl	ass 🔲 A 🗍 B
Std: EN45502 (AIMD)		TTE Directive EN300,330, S300.683
Vehicle Directive 7 Std:	72/245/EEC (EMC)		
FDA Reviewers G	uidance for Premarket		
Notification Sub	missions (EMC)		
TÜV Product Servic	e Certification Requested		
Attestation of Con	formity (AoC)	International	EMC Mark (IEM)
Certificate of Conf	formity (CoC)	Compliance I	Document
Protection Class	(N/A for vehicles)	Class I	Class II Class III
(Press F1 when field is	s selected to show additional ir	nformation on Prote	ection 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): 763-478-3027 Continue testing to complete test series. Continue testing to define corrective action. Stop testing. Stop testing.
EUT Specifications and Requirements
Length: 8.75" Height: 1.6" Weight: 24 oz.
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: <u>6 VDC</u> (If battery powered, make sure battery life is sufficient to complete testing.)
of Phases: N/A
Current Current (Amps/phase(max)): N/A (Amps/phase(nominal)): N/A
Other N/A
Other Special Requirements
N/A

Typical Installation and/or Operating Environment

(ie. Hospital, Small Business, Industrial/Factory, etc.) The Model 8840 Clinical Programmer is intended to be used by a health care professional in a hospital or clinical environment.

EUT Power Cable

- PermanentShieldedNot Applicable
- Removable Unshielded

Length (in meters):

OR

OR



EUT Interface	Po	orts	and (Cab	les							
Interface					eldi	ng						
Туре	Analog	Digital	Qty	Yes	No	Туре	Termination	Connector Type	Port Termination	Length (in meters)	Removable	Permanent
EXAMPLE:								Metallized 9-	Characteristic			
RS232		×	2	×		Foil over braid	Coaxial	pin D-Sub	Impedance	6	×	
Base module - telemetry module interface cable			1			N/A	Soldered directly to PCBs	N/A	N/A	1		
Application module port		\square	1		\boxtimes	N/A	Connector soldered directly to PCB	50 pin Compact Flash Port	N/A	0		
IR communication port			1			N/A	IR interface components soldered directly to PCB	N/A	N/A	0		
Expansion port			1			N/A	Connector soldered directly to PCB	10 pin	N/A	0		



EUT Software.	
Revision Level:	Base Module (Rev B8.0) Telemetry Module (Rev 5.6B)
Description:	Operating system software.

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. The Model 8840 Programmer will be operated in a mode that provides a continuous downlink/uplink sequence to an implantable neurostimulator (Model 7425). Valid communications link is verified by a pass/fail indication on the touchscreen display.

2.

3.

Description	Model #	Serial #	FCC ID #	
l' Vision, Model 8840 Clinical Programmer	Model 8840	NHF000050, NHF000055	LF58840	



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 #		
Itrel 3 Neurostimulator	Model 7425	CJB9GE	N/A		

Oscillator Frequencies Derived Derived Frequency Component # / Location Description of Use 11.059 MHz U1/Y1 Base Module Main time base 9.830 MHz U1/Y1 Telemetry Module Main time base 32.768 KHz Y2 Base Module Real Time Clock

Power Supply			
Manufacturer	Model #	Serial #	Туре
N/A	N/A	N/A	Switched-mode: (Frequency) Linear Other: Battery powered
N/A	N/A	N/A	Switched-mode: (Frequency) Linear Other:
Power Line Filt	ers		

Fower Line Filters			
Manufacturer	Model #	Location in EUT	
N/A	N/A	N/A	
N/A	N/A	N/A	



Critical EMI Components (Capacitors, ferrites, etc.)					
Description	Manufacturer	Part # or Value	Qty	Component # / Location	
Capacitors	AVX	100pF	41	Various #'s / I/O lines	
Ferrites	Murata	BLM21A102S	25	Various #'s / I/O lines	

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

Full ground plane and power plane

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

Roger Berg	May 17, 2001
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

GENERAL INFORMATION

Test Methodology

Testing is performed according to the procedures in EN 300 330, ETS 300 683, International Special Committee on Radio Interference (CISPR) Publication 11 (1991), European Standard EN 55011

In compliance with FCC Docket 92-152, "Harmonization of Rules for Digital Devices Incorporate International Standards", testing for FCC compliance may be done following the ANSI C63.4-1992 procedures and using the CISPR 11 Limits.

Measurement Uncertainty

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

Justification

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

CONDUCTED EMISSIONS

The final level, expressed in $dB\mu V$, is arrived at by taking the reading directly from the EMI receiver. This level is compared directly to the CISPR limit.

To convert between $dB\mu V$ and μV , the following conversions apply:

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

RADIATED EMISSIONS

The final level, expressed in $dB\mu V/m$, is arrived at by taking the reading from the spectrum analyzer (Level $dB\mu V$) and adding the antenna correction factor and cable loss factor, and subtracting the preamplifier gain, to it. This result then has the duty cycle correction factor subtracted from it to provide the final average reading.

Example: FREQ (MHz)	LEVEL (dBuV)	CABLE/ANT/PREAMP (dB) (dB/m) (dB)	FINAL (dBuV/m)	POL/HGT/AZ (m) (deg)	DELTA1 EN55022 B
79.06	40.7Qp +	1.9 + 6.6 - 28.3 =	20.9	V 1.0 0.0	-9.1

For ERP measurements, this measured level is matched by replacing the EUT with a tuned dipole antenna and applying an RF signal to the dipole. The signal generator level is adjusted until the field strength level measured from the EUT is matched.

Radiated emission levels below 30 MHz are taken directly off of the receiver and include the antenna factor and cable loss.



DETAILS OF TEST PROCEDURES

Conducted Emissions

Conducted emissions on the 50 Hz and/or 60 Hz power interface of the EUT are measured in the frequency range of 9 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 9kHz 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, 10 or 30 meters horizontally from the EUT. To locate maximum emissions from the test sample the antenna is varied in height from 1 to 4 meters, measurement scans are made with both horizontal and vertical antenna polarizations and the EUT are rotated 360 degrees.

In the frequency range of 10 kHz to 30 MHz, a shielded loop antenna is positioned with its plane vertical at 0.3 and 1 meters from the EUT and rotated about its vertical axis for maximum response at each azimuth about the EUT. The loop antenna is also positioned horizontally. The center of the loop antenna is 1 meter above the ground plane. Since the measurements were well within the requirements, the unit was not remeasured off of the ground plane.