Medtronic

Electromagnetic Compatibility Declaration

(EN 60601-1-2)

Reference manual

! USA Rx only

CE0123

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Wireless quality of service

Proximal telemetry, also known as Telemetry N or Tel-N, is the main communication medium between Medtronic Neuromodulation external instruments and neurostimulators. Successful programming requires close proximity between the programmer and the neurostimulator. A connection is established only through direct inductive coupling with no dependence on a network. If the wireless connection is lost without warning, the user should reposition the programmer to reestablish the connection. Interrupted or partial messages are invalid and must be resent.

Wireless security

A model-specific device access code is used to initiate a programming session. The Tel-N link between a programmer and a neurostimulator is limited to a maximum distance of approximately 9 cm, and inadvertent programming, malicious programming, and eavesdropping are mitigated by close contact with the patient for any communication.

Electromagnetic compatibility declaration

Tables 1, 2, 3, and 4 apply to Medtronic Neuromodulation in-line powered and battery powered external devices.

Table 1. Electromagnetic emissions

The N'Vision Model 8840 Clinician Programmer is intended for use in the electromagnetic environment specified below. The customer or the user of this device should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
Radio-frequency (RF) emissions CISPR 11	Group 1	The Model 8840 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Model 8840 is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions EN 61000-3-2	Not applicable (Battery powered device)	The device is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions EN 61000-3-3	Not applicable (Battery powered device)	

Table 2. Electromagnetic immunity

The N'Vision Model 8840 Clinician Programmer is intended for use in the electromagnetic environment specified below. The customer or the user of this device should ensure that it is used in such an environment.			
Immunity test	**EN 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD): EN 61000-4-2	±6 kV contact ±8 kV air	±2 kV, ±4 kV, ±6 kV contact ±2 kV, ±4 kV, ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Table 2. Electromagnetic immunity (continued)

The N'Vision Model 8840 Clinician Programmer is intended for use in the electromagnetic environment specified below. The customer or the user of this device should ensure that it is used in such an environment.			
Immunity test	**EN 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrical fast transient/burst: EN 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	Not applicable (Battery powered device)	Mains power quality should be that of a typical home health care environment.
Surge: EN 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable (Battery powered device)	Mains power quality should be that of a typical home health care environment.
Voltage dips, short interruptions and voltage variations on power supply input lines: EN 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Not applicable (Battery powered device)	Mains power quality should be that of a typical home health care environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field: EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home health care environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Table 3. Electromagnetic immunity

The N'Vision Model 8840 Clinician Programmer is intended for use in the electromagnetic environment specified below. The customer or the user of this device should ensure that it is used in such an environment.			
Immunity test	**EN 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
			Recommended separation distance
Radiated RF EN 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	d=4 √P 80 MHz to 800 MHz d=7,7 √P 800 MHz to 2,5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.

Table 3. Electromagnetic immunity (continued)

The N'Vision Model 8840 Clinician Programmer is intended for use in the electromagnetic environment specified below. The customer or the user of this device should ensure that it is used in such an environment.			
Immunity test	**EN 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

Table 4. Recommended separation distances between portable and mobile radio-frequency (RF) communications equipment and the device

The N'Vision Model 8840 Clinician Programmer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device as recommended below, according to the maximum output power of the communications equipment.		
Rated maximum output power of transmitter (W)	**80 MHz to 800 MHz (m) $d=1,2\sqrt{P}$**	**800 MHz to 2,5 GHz (m) $d=2,3\sqrt{P}$**
0,01	0,12	0,23
0,1	0,38	0,73
1	1,2	2,3
10	3,8	7,3
100	12	23

Table 4. Recommended separation distances between portable and mobile radio-frequency (RF) communications equipment and the device (continued)

The N'Vision Model 8840 Clinician Programmer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	80 MHz to 800 MHz (m) $d=1,2\sqrt{P}$	800 MHz to 2,5 GHz (m) $d=2,3\sqrt{P}$

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

△**CAUTION:** Do not use non-Medtronic components with Medtronic battery-powered external devices. The use of non-Medtronic components may result in damage to Medtronic components, increased emissions, or decreased electromagnetic immunity of the Medtronic devices or systems.

△**CAUTION:** Do not use Medtronic battery-powered external devices adjacent to, or stacked with, other electronic devices. Using Medtronic devices in these configurations may result in decreased electromagnetic immunity of the Medtronic devices or systems.

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