# *Physician's Manual*

## NeuroCybernetic Prosthesis (NCP®)
## Programming Wand
## Model 201

*For Healthcare Professionals*

## June 2017

*Worldwide Version*

**Rx Only**

CE 0344

***Note:*** This manual contains information on the use of the Model 201 NCP Programming Wand. Physicians should refer to the VNS Therapy Pulse Generator physician's manuals for additional important prescribing and safety information. A copy of this VNS Therapy manual is posted at www.livanova.com.

**Caution**: U.S. federal law restricts this device to sale by or on the order of a physician.

The year of authorization to affix the CE Mark: 1999

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# 1. DESCRIPTION AND USE

**Note**: For information about VNS Therapy Programming Software, see the Programming Software physician's manual. For a description of the Pulse Generator, see the NCP or VNS Therapy Pulse Generator physician's manual.

The LivaNova® Model 201 NeuroCybernetic Prosthesis (NCP®) Programming Wand is a hand-held device that transmits programming and interrogation information between a LivaNova-supplied programming computer and the NCP or VNS Therapy® Pulse Generator. The NCP or VNS Therapy Programming Software, in conjunction with a computer and the Programming Wand, can store and retrieve telemetry data and revise programmable parameters in the Pulse Generator. The LivaNova Magnet is used with the Programming Wand when the Pulse Generator must be reset.

The Programming Software uses the Programming Wand to convert digital output from a computer to the radio frequency signal format that is required for communication with the NCP or VNS Therapy Pulse Generator, and vice versa. Powered by a single 9-Volt (V) battery, the Programming Wand sends and receives signals to and from the computer through a cable connected to a standard DB9 plug. A reset function is provided for the physician to use if the Pulse Generator must be reset.

## 1.1. Symbols and Definitions

Symbols and definitions used with the Programming Wand include the following

| | |
|---|---|
|  | Notice for reader to pay special attention to following details |
|  | Storage Temperature |
| SN | Serial Number |
| CE | CE Mark—Indicates conformity with the essential health and safety requirements set out in European Directives |
|   | Type BF Equipment—Degree of protection against electric shock |
| **IPX0** | A system of codes to indicate the degree of protection provided by an enclosure—IPX0 - not protected from liquid ingress |

Nonionizing radiation

Humidity limitations—Indicates the range of humidity to which the medical device can be safely exposed

## 1.2. Physician Training / Information

All VNS Therapy System programming should be performed by or under the supervision of a physician familiar with the use and operation of the Programming Software.

### 1.2.1. Training Materials

Physicians who implant the VNS Therapy System should be thoroughly familiar with all associated training materials, including:

- Product labeling for the Pulse Generator, Lead, and accessories, including physician and patient manuals, and directions for use
- "*Implant Guide for the VNS Therapy System*" training manual and other brochures
- Video on the proper implantation technique: "Implantation of the VNS Therapy System"
- Electrode practice fixture—a device used to practice placing the helices around the left vagus nerve

# 2. INTENDED USE

The Model 201 NCP Programming Wand is intended for use only with LivaNova' NCP or VNS Therapy Pulse Generators and NCP or VNS Therapy Programming Software.

# 3. PRECAUTIONS

The Programming Wand is *not* suitable for use **in the presence of a flammable anesthetic gas mixture**.

Never connect the Programming Wand to external equipment while the battery compartment is open. Electric shock may occur.

Use only a battery-operated computer provided by LivaNova.

Never immerse the Programming Wand in liquid.

Avoid using the Programming Wand and the Pulse Generator near sensitive electronic equipment. The low-level radio frequency signals transmitted by the two devices may interfere with the electronic equipment.

# 4. CONFORMANCE TO STANDARDS

**Caution**: Only LivaNova-supplied battery-operated computers that comply with IEC 60950 or UL 1950 should be used with the VNS Therapy Programming Wand.

The VNS Therapy Programming Wand Model 201:

- Is designed and constructed in compliance with IEC 60601-1: 2005 and IEC 60601-1-2: 2007
- Complies with EN 45502-1: 2007

The standard 9V battery conforms to IEC 60086-2 (Primary batteries), category 6 battery, 6LR61 or ANSI C18.3M battery specification 1604.

# 5. PACKAGE CONTENTS

The Programming Wand package contains the following items:

- One Model 201 NCP Programming Wand, with one standard 9V battery (IEC-6LR61) already installed
- Documentation

# 6. SYSTEM SETUP

To prepare the NCP or VNS Therapy System for programming operations, do the following:

- Check the Programming Wand Battery
- Connect the Hardware
- Access the Programming Software
- Set Up for Surgery
- Position or Reposition the Programming Wand
- Understand the Indicator Lights

## 6.1. Check the Programming Wand Battery

To check the Programming Wand's battery, briefly press down simultaneously on the two red RESET buttons, and verify that the green POWER light (battery indicator) comes on and stays on for approximately 25 seconds after the buttons are released.

If it does not, the battery needs replacing. Use one standard 9V alkaline battery.

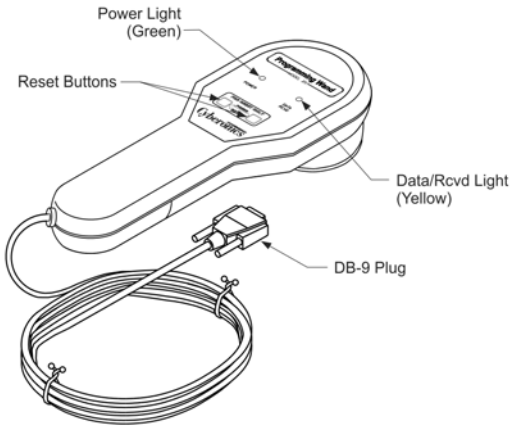
## 6.2. Connect the Hardware

**Caution**: Use only the LivaNova-supplied adapter cable for connecting the computer and the Programming Wand. The use of non-LivaNova components may result in increased emissions or decreased immunity of the Programming Wand system.

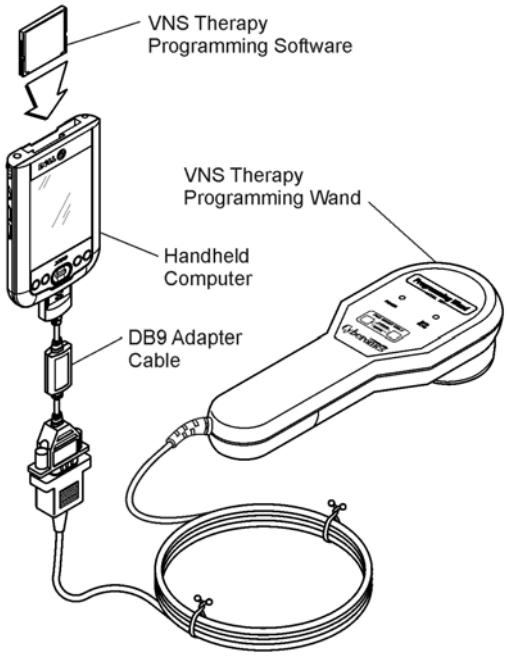
To connect the hardware follow the steps below (See Figures 1-3):

1. Connect the LivaNova-supplied adapter cable to the computer.
2. Connect the Wand cable to the adapter cable.

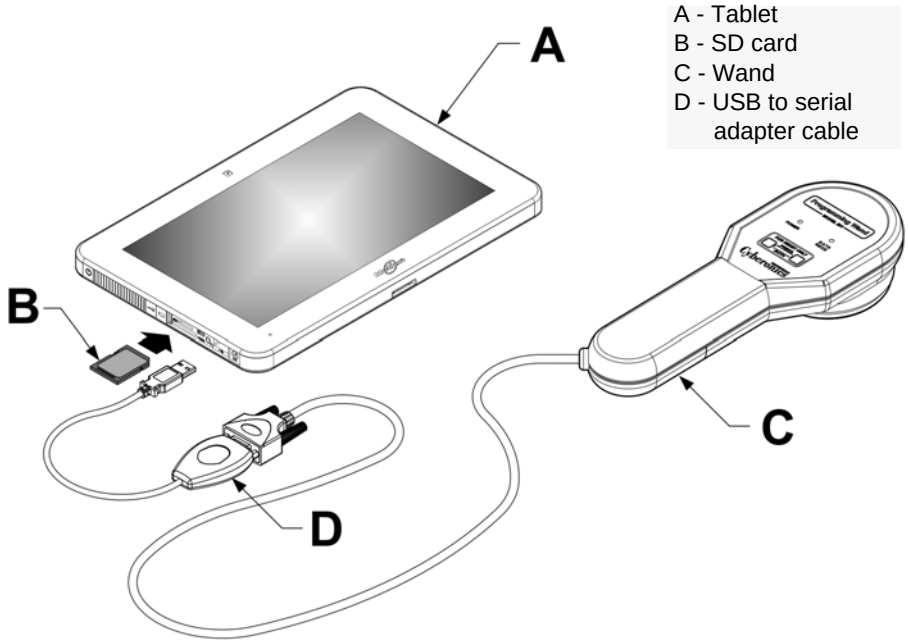
**Figure 1. Programming Wand Components**



## Figure 2. Connect the Wand and Handheld Computer




## Figure 3. Connect the Wand and Programming Computer




*Graphic does not include port covers on the left side of the programming computer

## 6.3. Access the Programming Software

For instructions on how to access the software that enables the Programming Wand and Pulse Generator to communicate, see the Programming Software physician's manual.

## 6.4. Set Up for Surgery

To set up the Programming Wand in the operating room, follow the steps below:

1. Place the battery-operated computer *outside* the sterile field.
2. Place the Programming Wand and cable in a sterile laser arm bag (7 in x 8 ft / 18 cm x 2.4 m) for insertion into the sterile field.

**Caution**: Use only a battery-operated computer provided by LivaNova.

**Caution**: The anesthesiologist and other physicians should be informed that during the brief communication interval, the Programming Wand and Pulse Generator transmit low-level radio frequency signals that may interfere with sensitive electronic equipment in the vicinity.

**Caution**: The Programming Wand is *not* suitable for use **in the presence of a flammable anesthetic gas mixture**.

## 6.5. Position or Reposition the Programming Wand

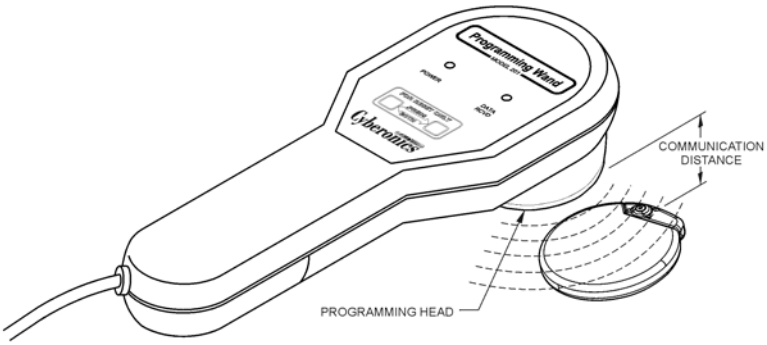
After the software has been accessed and the Programming Wand properly connected (See Figure 1 and Figure 2), the Wand must be positioned correctly before it can communicate with the NCP or VNS Therapy Pulse Generator.

The Programming Wand's programming head must be positioned directly above the center of the Pulse Generator's flat surface—either the top surface, where the NCP or VNS Therapy logo appears, or the bottom of the Pulse Generator (See Figure 4).

**Note**: Successful programming and communication are most likely if the surface of the programming head is within 2.54 cm (1 inch) of either of the Pulse Generator's flat surfaces.

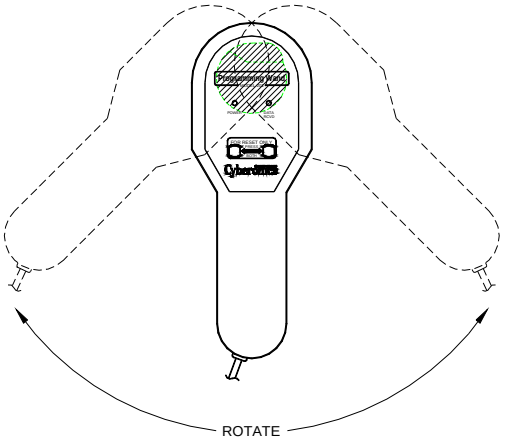
**Note**: If communication difficulties persist, see Section 7 "Troubleshooting".

**Figure 4. Position the Programming Wand**




If communication difficulties are experienced at distances of 2.54 cm (1 inch) or less, tilt the Programming Wand and/or slide the Wand left, right, up, or down (See Figure 5).

**Figure 5. Reposition the Programming Wand**




## 6.6. Understand the Indicator Lights

During normal communication with the Pulse Generator (programming and interrogation), the yellow DATA/RCVD light will come on and blink as long as the signals are being received.

When the Programming Wand is off, it can be powered briefly either to check the battery or to verify the presence of EMI. To power the Programming Wand, briefly press down simultaneously on the two

red RESET buttons. If the green POWER light does not come on, the battery needs to be replaced. If the green and yellow lights both come on, the Programming Wand has detected EMI or some other electrical noise in the area.

# 7. TROUBLESHOOTING

If the Programming Wand is not communicating properly, check the following:

- Test the battery by briefly pressing down simultaneously on the two red RESET buttons and verifying that the green POWER light comes on and stays on for approximately 25 seconds after the buttons are released. If it does not, the battery should be replaced.
- Verify that NCP or VNS Therapy System components are properly connected.
- Verify that the programming problem is not a result of electromagnetic interference (EMI) or noise from nearby electrical equipment. Examples of possible sources of EMI are computer displays, portable telephones, and fluorescent lights. Although the Programming Wand is not intended to be used for verifying that an area is free of EMI, the Programming Wand often can detect equipment that may be a source of EMI.

To check for EMI, do the following:

1. Briefly press down simultaneously on the two red RESET buttons to turn on the Programming Wand. The green POWER light will come on.
2. Move the Programming Wand closer to the equipment.

Detecting EMI is possible only while the Programming Wand is on (indicated by the green POWER light). If the green light goes off before the EMI source has been located, turn the Programming Wand on again by pressing down simultaneously on the two RESET buttons.

If EMI or other electrical noise is detected, the yellow DATA/RCVD light will come on and remain on as long as the Programming Wand is in the presence of an EMI signal.

Programming in an area with EMI will be difficult or impossible, but problems can usually be resolved by repositioning either the patient, the Programming Wand, or the EMI source.

# 8. RESET AND REPROGRAM

If the Pulse Generator malfunctions, it may not be able to communicate with the Programming Wand. However, unless the Pulse Generator battery is depleted, the Programming Wand and Magnet can still be used to reset the Pulse Generator.

## 8.1. Pulse Generator Models 100, 101, and 102/102R

**Caution**: The erased telemetry data includes the device serial number, patient code, implantation date, Magnet activation history, and operating time. Physicians should consult a LivaNova technical representative before a reset of the Pulse Generator is performed (See Section 11 "Information and Support" for LivaNova contact information).

When Model 100, 101, and 102/102R Pulse Generators are reset, all stored telemetry data are erased and programmable parameters are reset to preprogrammed settings (See Table 1).

**Table 1. Reset Parameters**

| | |
|---|---|
| Reset parameters | 0 mA; 10 Hz; 500 μsec; ON time, 30 sec; OFF time, 60 min |

## 8.2. Pulse Generator Model 103 and Subsequent Models

When Model 103 and subsequent model Pulse Generators are reset, the stimulation **output is disabled** (0.0mA) but all settings and device history are preserved. After a successful reset, the Pulse Generator stimulation output may be re-enabled to resume operation at the previously programmed settings by selecting the desired setting and pressing "Program".

## 8.3. Reset the Pulse Generator

To reset and reprogram the Pulse Generator, do the following:

1. Hold an NCP or VNS Therapy Magnet and the Programming Wand over the Pulse Generator, and press down continuously on the two red RESET buttons for at least 30 seconds.

**Figure 6. Reset the Microprocessor with the Horseshoe Magnet**

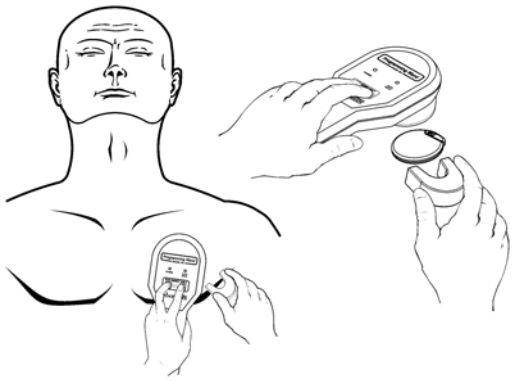
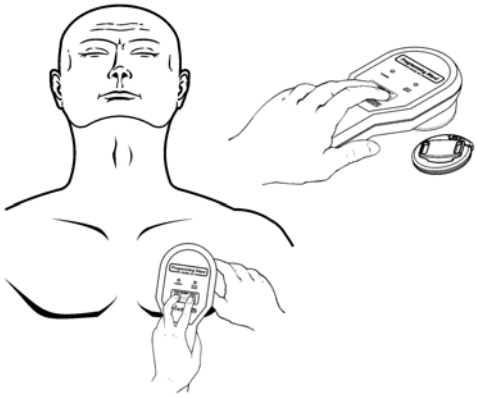


**Figure 7. Reset the Pulse Generator with the Watch-Style or Pager-Style Magnet**



**Caution**: The orientation of the Magnet on the patient's body may differ from Figure 6 and Figure 7 based on the orientation of the generator. Find the orientation that works best for your patient.

2. After the device is reset, wait 30 seconds, then interrogate the Pulse Generator to verify that it is functioning.
3. [Models 100, 101, and 102/102R only] Immediately re-enter the NCP or VNS Therapy Pulse Generator serial number, patient code, and implantation date to restore erased data after device reset. The 103 and subsequent model Pulse Generators remember this information after the device has been reset.
4. Reprogram the Pulse Generator to the desired parameters.

**Note**: See the NCP or VNS Therapy Pulse Generator physician's manual for more Pulse Generator reset or Magnet position information.

# 9. MAINTENANCE, HANDLING, AND STORAGE

Follow the guidelines below for proper maintenance, handling, and storage of the Programming Wand.

## 9.1. Maintenance

Except for the occasional 9V battery replacement, the Programming Wand requires little maintenance:

- Avoid using the Programming Wand continuously (although it is rated for continuous operation), because such use will deplete the battery more quickly.

**Note:** See Section 6.1 "Check the Programming Wand Battery" for directions.

- Test the battery periodically to verify battery status.
- Remove the battery if the Programming Wand will not be used for an extended period.
- Remove (and install) the battery only after the Programming Wand has been disconnected from all external equipment.
- If the Programming Wand needs to be cleaned, wipe it with a damp cloth.
- **Do not sterilize** the Programming Wand.
- Regularly inspect the cable, cable entry at the enclosure, connectors, and adapter cable for damage.

**Note**: See Section 11 "Information and Support" for LivaNova contact information.

- If repair or replacement is required, return the Programming Wand to LivaNova.

## 9.2. Handling

Although no component of the Programming Wand should be handled roughly or abused, no unusual handling precautions are necessary:

**Caution**: **Never immerse** the Programming Wand in liquid.

**Caution**: **Never connect** the Programming Wand to external equipment while the battery compartment is open.

**Caution**: Do not drop the Programming Wand or store it where it can be dropped.

**Caution**: Do not pull, coil tightly, bend, carry the Wand by the cord, or wrap the cord around the device.

## 9.3. Operating Environment

Operate the Programming Wand under the following conditions:

- Temperatures between +10°C (50°F) to +40°C (104°F)
- Humidity between 8% to 90% relative humidity (RH)

## 9.4. Storage Environment

Store the Programming Wand under the following conditions:

- Temperatures between -20°C (-4°F) and +55°C (+131°F).
- Humidity between 5% to 95% RH

## 9.5. Disposal

When replacing the Programming Wand 9V battery, the old battery should be disposed of in accordance with all applicable federal, state, and local regulations. Return all unused programming systems to LivaNova for examination and safe disposal.

# 10. PRODUCT SPECIFICATIONS

Product specifications for the Model 201 NCP Programming Wand are presented in Table 2:

## Table 2. Product Specifications

| | |
|---|---|
| **Power** | |
| Source | One standard 9V battery conforming to IEC 60086-2 (Primary batteries), category 6 battery, 6LR61 or ANSI C18.3M battery specification 1604 |
| **Dimensions (Nominal)** | |
| Housing | Overall length: 24.8 cm (9.76 in)<br>Width/depth at programming head: 8.9 cm x 5.1 cm (3.5 in x 2.0 in)<br>Width/depth at handle: 5.1 cm x 2.5 cm (2.0 in x .98 in) |
| Weight | 560 grams (19.75 ounces) |
| Housing material | ABS plastic |
| **Communication** | |
| Range | 2.54 cm (1 inch) |
| Cable | Standard RS-232 serial data cable (3 meters/10 feet long) that is internally connected on one end and has a DB9 serial plug on the other end for connecting to a computer. |
| Frequency (Transmitter) | The Model 201 has an internal oscillator that runs at a frequency of 97 kHz +/-10 KHz when it is active.<br><br>Effective Radiated Power (ERP): -6.92 dBm at 3m. |
| Frequency (Receiver) | The Model 201 is able to receive a nominal 40 kHz magnetically coupled signal from the Pulse Generator. |
| **Compliance** | |
| | Designed and constructed to comply with standards as specified in Section 4 "Conformance to Standards "; internally powered, Type BF; IPX0—not protected against ingress of liquids; not suitable for use in the presence of a flammable anesthetic gas mixture with air, oxygen, or nitrous oxide; suitable for continuous operation. |

## 10.1. Guidance and Manufacturer's Declarations

The Programming Wand Model 201 is intended for use in the electromagnetic environment specified below. The customer or user of the Model 201 should assure that it is used in such an environment. These declarations are presented in Table 3, Table 4, and Table 5.

### Table 3. Electromagnetic Emissions

| Emissions Test | Compliance | Electromagnetic Environment - Guidance |
|---|---|---|
| RF emissions<br>CISPR 11 | Group 2 | The Model 201 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. |
| RF emissions<br>CISPR 11 | Class B | The Model 201 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions<br>IEC 61000-3-2 | Not Applicable | |
| Voltage fluctuations/ flicker emissions<br>IEC 61000-3-3 | Not Applicable | |

## Table 4. Electromagnetic Immunity—for all Model 201 Programming Wands

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment - Guidance |
|---|---|---|---|
| Electrostatic discharge (ESD)<br><br>IEC 61000-4-2 | +/-6 kV contact<br><br>+/-8 kV air | +/-6 kV contact<br><br>+/-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%. |
| Electrical fast transient/burst<br><br>IEC 61000-4-4 | +/-2 kV for power supply lines<br><br>+/-1 kV for input/ output lines | Not Applicable | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br><br>IEC 61000-4-5 | +/-1 kV line(s) to line(s)<br><br>+/-2 kV line(s) to earth | Not Applicable | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br><br>IEC 61000-4-11 | <5% $U_T$ (>95% dip in $U_T$) for 0.5 cycle<br><br>40% $U_T$ (60% dip in $U_T$) for 5 cycles<br><br>70% $U_T$ (30% dip in $U_T$) for 25 cycles<br><br><5% $U_T$ (>95% dip in $U_T$) for 5 sec | Not Applicable | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Model 201 requires continued operation during power mains interruptions, it is recommended that the Model 201 be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field<br><br>IEC 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 commercial or hospital environment. |

**Note**: $U_T$ is the a.c. mains voltage prior to application of the test level.

## Table 5. Electromagnetic Immunity—for Model 201 Programming Wands That are not Life-Supporting

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment - Guidance |
|---|---|---|---|
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the Model 201, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of transmitter.<br><br>**Recommended separation distance** |
| Conducted RF<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz | 3 Vrms | $d=1.2\sqrt{P}$ |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80 MHz to 2.5 GHz | 3 V/m | $d=1.2\sqrt{P}$ 80 MHz to 800 MHz<br><br>$d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz<br><br>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).<br><br>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.[b]<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br><br>  |

a Field strength 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 Model 201 is used exceeds the applicable RF compliance level above, the Model 201 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Model 201.

b Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**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.

## 10.2. Recommended Separation Distances

The Model 201 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model 201 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model 201 as recommended below (See Table 6), according to the maximum output power of the communications equipment.

### Table 6. Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Model 201 Programming Wand

| | Separation Distance According to Frequency of Transmitter (m) | | |
|---|---|---|---|
| **Rated Maximum Output Power of Transmitter (W)** | **150 KHz to 80 MHz** $d=1.2\sqrt{P}$ | **80 MHz to 800 MHz** $d=1.2\sqrt{P}$ | **800 MHz to 2.5 GHz** $d=2.3\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1.0 | 1.2 | 1.2 | 2.3 |
| 10.0 | 3.8 | 3.8 | 7.3 |
| 100.0 | 12 | 12 | 23 |

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.

# 11. INFORMATION AND SUPPORT

If there are questions regarding use of the VNS Therapy System or any of its accessories, contact LivaNova:

**LivaNova USA, Inc.**

100 Cyberonics Boulevard
Houston, Texas 77058 USA

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